National Collaborating Centre for Women's and Children's Health

Version 2

Intrapartum Care

Care of healthy women and their babies during childbirth

Clinical Guideline 190

Methods, evidence and recommendations

December 2014, updated February 2017

Version 2

Commissioned by the National Institute for Health and Care Excellence

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

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Guideline Development Group membership and acknowledgements

Guideline development group

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Guideline development group membership and acknowledgements 2014

Guideline development group

Guideline development group members

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Introduction

Giving birth is a life-changing event. The care that a woman receives during labour has the potential to affect her – both physically and emotionally, in the short and longer term – and

the health of her baby. Good communication, support and compassion from staff, and having her wishes respected, can help her feel in control of what is happening and contribute to making birth a positive experience for the woman and her birth companion(s).

This guideline covers the care of healthy women who go into labour at term (37^{+0}–41^{+6} weeks). About 700,000 women give birth in England and Wales each year, of whom about 40% are having their first baby. Most of these women are healthy and have a straightforward pregnancy. Almost 90% of women will give birth to a single baby after 37 weeks of pregnancy, with the baby presenting head first. About two-thirds of women go into labour spontaneously. Therefore most women giving birth in England and Wales are covered by this guideline.

Since the original guideline was published in 2007, the number of women giving birth in England and Wales each year has risen. In addition, there have been changes to maternity services (with some opening, closing or merging, and some reconfiguring of units), resulting in fewer obstetric units but more midwifery units. In England in 2012, 84% of births took place in designated consultant or combined consultant/midwife wards, 14% in midwife wards and 2% at home, but the way this data is collected and reported makes the figures difficult to interpret. In England in 2011, an estimated 42% of births were described as 'normal births'. The rate of intervention (instrumental births and caesarean section) has increased slightly since 2007: for example in 2011 26% were by caesarean section and 12% were instrumental births, including forceps or ventouse.

The decision to update the guideline was based on developments in the NHS and the availability of new evidence that could affect the recommendations made in 2007.

It is important that the woman is given information and advice about all available settings when she is deciding where to have her baby, so that she is able to make a fully informed decision. This includes information about outcomes for the different settings. It is also vital to recognise when transfer of care between midwifery-led care and obstetric-led care is indicated because of increased risk to the woman and/or her baby resulting from complications during labour.

Uncertainty and inconsistency of care has been identified in a number of areas, such as choosing place of birth, care during the latent first stage of labour (including pain relief), fetal assessment and monitoring during labour (particularly cardiotocography compared with intermittent auscultation) and management of the third stage of labour. These topics and others are addressed in this guideline update.

The guideline is intended to cover the care of healthy women with uncomplicated pregnancies entering labour at low risk of developing intrapartum complications. In addition, recommendations are included that address the care of women who start labour as 'low risk' but who go on to develop complications. These include the care of women with prelabour rupture of membranes at term, care of the woman and baby when meconium is present, indications for continuous cardiotocography, interpretation of cardiotocography traces, and management of retained placenta and postpartum haemorrhage. Aspects of intrapartum care for women at risk of developing intrapartum complications are covered by a range of guidelines on specific conditions (see section 1.8) and a further guideline is planned on intrapartum care of women 'at high risk' of complications during pregnancy and the intrapartum period.

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'.[4] The guideline has been developed with the aim of providing guidance on care of healthy women and their babies during childbirth.

Areas within the remit of the guideline

Care throughout labour

- Advice on communication between healthcare professionals and women during labour including decision making and consent
- Effect of support on women in labour
- Identification of women and babies who may need additional care, including recognition and referral of serious emergency maternal or fetal complications arising during labour
- Appropriate hygiene measures for vaginal birth, both in and out of water.

Care in the first and second stage of labour

- The diagnosis of the onset of labour and timing of admission or request for midwife visit at home and observations undertaken
- Assessment and management of progress in labour, including 'active management' and identification/management of delay in the first stage of labour
- Assessment of fetal wellbeing including appropriate use of electronic fetal monitoring
- Care of women in labour, including observations, nutrition, fluid balance and bladder care
- Advice on non-invasive birth techniques aimed at promoting the birthing process in the first stage of labour
- Appropriate use and effect of pharmacological and non-pharmacological pain relief
- Appropriate use of and the effects of regional analgesia, and care of women who have had regional analgesia
- Appropriate care during the birth process including the effect of positions and water birth and management of the second stage with regard to pushing techniques
- Appropriate techniques to reduce perineal trauma, including advice for women with previous third- or fourth-degree tears or genital mutilation
- Assessment and management of delay in the second stage of labour, including appropriate criteria for operative vaginal birth using either forceps or ventouse
- Identification and management of women with meconium-stained liquor
- Identification and management of women with prelabour rupture of membranes at term, with particular reference to observations and duration of 'watchful waiting' before induction, factors during prelabour rupture of membranes at term that influence maternal and neonatal outcomes following birth, use of antibiotics before birth, and criteria for antibiotics in healthy newborns.

Care in the third stage of labour

- Definition and indications for management of the third stage
- Identification of women at increased risk of postpartum haemorrhage (PPH) or with PPH, and strategies to reduce this risk
- Management of delay in the third stage and identification of retained placenta.

Immediate care after birth

- Assessment and repair of perineal trauma (vaginal tears or episiotomy)
- Assessment of neonatal wellbeing, facilitation of mother–infant bonding and basic resuscitation techniques immediately after birth
- Assessment of maternal wellbeing immediately after childbirth.

General remark on pharmacological treatments

Advice on treatment options will be based on the best evidence available to the GDG. When referring to pharmacological treatments, the guideline will normally make recommendations within the licensed indications. Exceptionally, and only where the evidence supports it, the guideline may recommend use outside the licensed indications. The guideline will assume that prescribers will use the Summary of Product Characteristics to inform their prescribing decisions for individual consumers.

Areas outside the remit of the guideline

- Women or their babies in suspected or confirmed preterm labour (before 37 weeks of gestation); women with an intrauterine fetal death; women with co-existing severe morbidities such as pre-eclampsia (high blood pressure of pregnancy) or diabetes; women who have multiple pregnancies; women with intrauterine growth restriction of the fetus.
- Women who have been covered in other guidelines, for example women who have their labour induced (inherited NICE clinical guideline D, Induction of Labour)[5], or women who have caesarean birth or with breech presentation (NICE clinical guideline 13, Caesarean Section)[6].
- Techniques for operative birth or repair of third- or fourth-degree perineal trauma; additional care for women with known or suspected infectious co-morbidities such as group B streptococcus, HIV or genital herpes virus.

Areas within the remit of the updated guideline

This guideline updates and replaces NICE guideline CG55 (published September 2007). It has not been possible to update all sections and recommendations in this update of the guideline. This means some of the recommendations that have not been reviewed may not reflect current practice. Areas for review and update were identified and agreed through the scoping process and stakeholder feedback.

Areas that have not been reviewed in this update may be addressed in 2 years' time when NICE next considers updating this guideline. NICE may undertake a more rapid update of discrete areas of the guideline if new and relevant evidence is published.

The following areas of the guideline are either new or have been updated:

- planning place of birth
- service provision for, and pain relief in, the latent first stage of labour
- service provision for one-to-one care
- initial assessment
- ongoing assessment
- transfer of care during labour
- monitoring during labour
- fetal blood sampling
- record keeping
- decision to delivery interval
- management of the third stage of labour
- management of retained placenta
- management of postpartum haemorrhage
- neonatal resuscitation
- care of babies in the presence of meconium.

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For whom is the guideline intended

This guideline is of relevance to those who work in or use the National Health Service (NHS) in England and Wales, in particular:

- midwives, obstetricians, obstetric anaesthetists, neonatologists, maternity support workers and any healthcare professional involved in care of women during labour and birth in any setting
- those responsible for commissioning and planning healthcare services, including primary care trust and local health board commissioners, Wales commissioners, and public health and trust managers
- pregnant women, their families, birth supporters and other carers.

Who has developed the guideline?

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the National Collaborating Centre for Women's and Children's Health (NCC-WCH). Membership included a senior research fellow (midwife) as the Guideline Leader, three obstetricians, a neonatologist, an obstetric anaesthetist, three midwives, and three patient/carer/consumer representatives.

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence, health economics modelling and, together with the Guideline Leader, wrote successive drafts of the guideline.

All GDG members' interests were recorded on declaration forms provided by NICE. The form covered consultancies, fee-paid work, shareholdings, fellowships, and support from the healthcare industry.

Who has developed the guideline (update)

The updated guideline was developed on the same basis as the original guideline. Membership for the updated guideline comprised an obstetrician as the Chair, two further obstetricians, two midwives, a neonatologist, an obstetric anaesthetist, a commissioner of maternity services and two lay members. For details of the guideline development group members' declarations of interests see appendix D.

Other relevant documents

Published guidance

General

- Patient experience in adult NHS services. NICE clinical guidance 138 (2012).
- Medicines adherence. NICE clinical guidance 76 (2009).

Condition-specific

- Postnatal care. NICE clinical guideline 37 (2006).
- Caesarean section. NICE clinical guideline 132 (2011).
- Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults. NICE clinical guideline 113 (2011).
- Hypertension in pregnancy. NICE clinical guideline 107 (2010).
- Neonatal jaundice. NICE clinical guideline 98 (2010).
- Therapeutic hypothermia with intracorporeal temperature monitoring for hypoxic perinatal brain injury. NICE interventional procedure guidance 347 (2010).
- Induction of labour. NICE clinical guideline 70 (2008).
- Antenatal care. NICE clinical guideline 62 (2008).

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- Antenatal and postnatal mental health. NICE clinical guideline 45 (2007).
- Intraoperative blood cell salvage in obstetrics. NICE interventional procedure guidance 144 (2005).
- Antibiotics for early-onset neonatal infection. NICE clinical guideline 149 (2012).

Under development

NICE is developing the following guidance (details available from the NICE website):

- Safe midwifery staffing for maternity settings. NICE safe staffing guideline. Publication expected January 2015.
- Preterm labour and birth. NICE clinical guideline. Publication expected June 2016.
- Cervical ripening balloon for the induction of labour in women who have previously undergone caesarean section. NICE interventional procedure guidance. Publication date to be confirmed.
- Ex utero intrapartum therapy for fetal obstruction. NICE interventional procedure guidance. Publication date to be confirmed.
- Intrapartum care for high risk women. NICE clinical guideline. Publication date to be confirmed.

Guideline development methodology

This guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in the NICE technical manual.[9]

Literature search strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the review questions was identified by systematic search strategies. Additionally, stakeholder organisations were invited to submit evidence for consideration by the GDG provided it was relevant to the review questions and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the review questions formulated and agreed by the GDG were executed using the following databases via the OVID platform: MEDLINE (1966 onwards); Embase (1980 onwards); Cumulative Index to Nursing and Allied Health Literature (1982 onwards); British Nursing Index (1985 onwards); PsycINFO (1967 onwards); Cochrane Central Register of Controlled Trials (1st quarter 2006); Cochrane Database of Systematic Reviews (1st quarter 2006); and Database of Abstracts of Reviews of Effects (1st quarter 2006). Other databases utilised were Allied and Complementary Medicine (Datastar platform, 1985 onwards) and MIDIRS (specialist midwifery database).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were not applied to searches. Both generic and specially developed methodological search filters were used appropriately.

Searches to identify economic studies were undertaken using the above databases, and the NHS Economic Evaluations Database (NHS EED) produced by the Centre for Reviews and Dissemination at the University of York.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

At the end of the guideline development process, searches were updated and re-executed, thereby including evidence published and included in the databases up to 24 April 2006. Any

evidence published after this date was not included. This date should be considered the starting point for searching for new evidence for future updates to this guideline.
Further details of the search strategies, including the methodological filters employed, can be obtained from the NCC-WCH.

Synthesis of clinical effectiveness evidence

Evidence relating to clinical effectiveness was reviewed using established guides[9–16] and classified using the established hierarchical system shown in Table 1.[16] This system reflects the susceptibility to bias that is inherent in particular study designs.

Table 1: Levels of evidence for intervention studies[15]

Level	Source of evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1−	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2−	Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example case reports, case series)
4	Expert opinion, formal consensus

The type of review question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study receives a quality rating coded as '++', '+' or '−'. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs) (EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as '−'. Usually, studies rated as '−' should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2−).
For each review question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but, where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was used.
The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting diagnostic tests of accuracy. In the absence of a validated ranking system for this type of test, NICE has developed a hierarchy for evidence of accuracy of diagnostic tests that takes into account the various factors likely to affect the validity of these studies (Table 2).[9]
For economic evaluations, no standard system of grading the quality of evidence exists. The search strategies adopted were designed to identify any relevant economic studies. Abstracts of all papers identified were reviewed by the health economists and were discarded if they did not relate to the economic question being considered in the guideline. The relevant papers were retrieved and critically appraised. Potentially relevant references in the bibliographies of

the reviewed papers were also identified and reviewed. All papers reviewed were assessed by the health economists against standard quality criteria for economic evaluation.[17]
Evidence was synthesised qualitatively by summarising the content of identified papers in evidence tables and agreeing brief statements that accurately reflected the evidence.
Quantitative synthesis (meta-analysis) was performed where appropriate.
Summary results and data are presented in the guideline text. More detailed results and data are presented in the evidence tables on the accompanying CD-ROM. Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses based on dichotomous outcomes are presented as pooled odds ratios (ORs) or pooled relative risk (RRs) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs. Forest plots for new meta- analyses carried out for the guideline are also presented on the accompanying CD-ROM.

Table 2: Levels of evidence for studies of the accuracy of diagnostics tests[18]

Level	Type of evidence
Ia	Systematic reviews (with homogeneity)a of level-1 studies[b]
Ib	Level-1 studies[b]
II	Level-2 studies[c]; systematic reviews of level-2 studies
III	Level-3 studies[d]; systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or 'first principles'

(a) Homogeneity means there are no or minor variations in the directions and degrees of results between individual studies that are included in the systematic review.
(b) Level-1 studies are studies that use a blind comparison of the test with a validated reference standard (gold standard) in a sample of patients that reflects the population to whom the test would apply.
(c) Level-2 studies are studies that have only one of the following:
- *narrow population (the sample does not reflect the population to whom the test would apply)*
- *use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')*
- *the comparison between the test and reference standard is not blind*
- *case–control studies.*

(d) Level-3 studies are studies that have at least two or three of the features listed above.

Health economics

The aim of the economic input into the guideline was to inform the GDG of potential economic issues relating to intrapartum care.
The health economist helped the GDG by identifying topics within the guideline that might benefit from economic analysis, reviewing the available economic evidence and, where necessary, conducting (or commissioning) economic analysis. Reviews of published health economic evidence are presented alongside the reviews of clinical evidence.
The primary economic focus in this guideline was on place of birth for low-risk women in England and Wales. This included a systematic review of the relevant economic literature. In addition, the health economists developed a decision-analytic cost-effectiveness model supported by the GDG who provided guidance on the data needed to populate the model and on the assumptions required to make the comparisons relevant to the scope of the analysis. A description of the model is presented in Appendix E.
A costing of ST-analysis for intrapartum fetal monitoring was also undertaken as part of this guideline. This was done to assess whether this new technology was potentially cost saving from an NHS perspective when 'downstream' resource use is considered. Further details for this analysis are presented in Appendix F.

The economic evidence resulting from these analyses was considered by the GDG members in drafting the recommendations. Summaries of the economic evidence resulting from these analyses are presented before the recommendations.

Forming and grading recommendations

For each review question, recommendations were derived using, and explicitly linked to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree evidence statements and recommendations. Additionally, in areas where important review questions were identified but no substantial evidence existed, formal consensus methods were used to identify current best practice. Shortly before the consultation period, formal consensus methods were used to agree guideline recommendations (modified Delphi technique) and to select 5–10 key priorities for implementation (nominal group technique).

External review

This guideline has been developed in accordance with the NICE guideline development process. This has included giving registered stakeholder organisations the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage.

Outcome measures used in this guideline

The GDG defined women's and babies' mortality, complications and long-term outcomes, and women's satisfaction as primary outcomes, and labour events (length of labour and interventions), birth events (mode or place of birth, complications of birth, perineal trauma), newborn events (condition at birth, birth injuries, admission to neonatal units), women's assessment of birth experience, and women's mental and psychological health as secondary outcomes. The GDG considered other outcomes when they were relevant to specific questions.

Guideline development methodology for 2014 update

Introduction

This guidance was commissioned by NICE and developed in accordance with the guideline development process outlined in the 2009 and 2012 editions of The Guidelines Manual (http://www.nice.org.uk/guidelinesmanual). Table 3 summarises the key stages of the guideline development process and which version of the process was followed for each stage.

Table 3: Stages in the NICE guideline development process and versions of The Guidelines Manual followed at each stage

Stage	2009 version	2012 version
Scoping the guideline (determining what the guideline would and would not cover)	✓	
Preparing the work plan (such as agreeing timelines, milestones, guideline development group constitution)	✓	
Forming and running the guideline development group	✓	
Developing review questions	✓	
Identifying the evidence		✓
Reviewing and grading the evidence	✓	✓
Assessing cost effectiveness	✓	✓
Making group decisions and reaching consensus		✓
Linking guidance to other NICE guidance		✓
Creating guideline recommendations		✓
Developing clinical audit criteria		✓

Stage	2009 version	2012 version
Writing the guideline		✓
Validation (stakeholder consultation on the draft guideline)		✓
Pre-publication check		✓
Internal validity check		✓
Declaration of interests		✓

In accordance with NICE's Equality Scheme, ethnic and cultural considerations and factors relating to disabilities have been considered by the guideline development group throughout the development process and specifically addressed in individual recommendations where relevant. Further information is available from: http://www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp.

Developing review questions and protocols and identifying evidence

The guideline development group formulated review questions based on the scope (see appendix B) and prepared a protocol for each review question (see appendix E). These formed the starting point for systematic reviews of relevant evidence. Published evidence was identified by applying systematic search strategies (see appendix F) to the following databases: Medline (1946 onwards), Embase (1974 onwards), the Health Technology Assessment (HTA) database and three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects). Searches to identify economic studies were undertaken using the above databases and the NHS Economic Evaluation Database (NHS EED). The Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1980 onwards) was searched for selected topics only. Where possible, searches were limited to English language only. Generic and specially developed search filters were used to identify particular study designs, such as randomised controlled trials (RCTs). There was no systematic attempt to search grey literature (conference abstracts, theses or unpublished trials), nor was hand searching of journals not indexed on the databases undertaken.

Towards the end of the guideline development process, the searches were updated and re-executed to include evidence published and indexed in the databases by 11 February 2014.

Reviewing and synthesising evidence

Evidence relating to clinical effectiveness was reviewed and synthesised according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (see http://www.gradeworkinggroup.org/index.htm). In the GRADE approach, the quality of the evidence identified for each outcome listed in the review protocol is assessed according to the factors listed below, and an overall quality rating (high, moderate, low or very low) is assigned by combining the ratings for the individual factors:

- study design (as an indicator of intrinsic bias; this determines the initial quality rating)
- limitations in the design or execution of the study (including concealment of allocation, blinding, loss to follow up; these can reduce the quality rating)
- inconsistency of effects across studies (this can reduce the quality rating)
- indirectness (the extent to which the available evidence fails to address the specific review question; this can reduce the quality rating)
- imprecision (this can reduce the quality rating)
- other considerations (including large magnitude of effect, evidence of a dose-response relationship, or confounding variables likely to have reduced the magnitude of an effect; these can increase the quality rating in observational studies, provided no downgrading for other features has occurred).

The type of review question determines the highest level of evidence that may be sought. For issues of therapy or treatment, the highest possible evidence level is a well-conducted systematic review or meta-analysis of RCTs, or an individual RCT. In GRADE, a body of evidence based entirely on such studies has an initial quality rating of high, and this may be downgraded to moderate, low or very low if factors listed above are not addressed adequately. Within GRADE it is necessary to predetermine values for minimum important differences in outcomes to assess imprecision. For categorical outcomes the GRADE default of 0.75–1.25 for risk ratios and odds ratios was used and for continuous outcomes ±0.5 times standard deviations. Where the guideline development group chose a continuous variable as a priority outcome, the minimum important difference was also decided and used when grading the evidence and in judging whether any observed differences between groups could be considered clinically significant (see section 1.10.7 for the list of minimum important differences used in this guideline). For issues of prognosis, the highest possible level of evidence is a controlled observational study (a cohort study or case–control study), and a body of evidence based on such studies would have an initial quality rating of low, which might be downgraded to very low or upgraded to moderate or high, depending on the factors listed above.

For each review question the highest available level of evidence was sought. Where appropriate, for example, if a systematic review, meta-analysis or RCT was identified to answer a question directly, studies of a weaker design were not considered. Where systematic reviews, meta-analyses and RCTs were not identified, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the accuracy of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of the condition was required, evidence from RCTs or cohort studies was optimal. For studies evaluating the accuracy of a diagnostic test, sensitivity, specificity and likelihood ratios for positive and negative test results (LR+ and LR– respectively) were calculated or quoted where possible (see table 4).

The GRADE system described above covers studies of treatment effectiveness. However, it is less well established for studies reporting accuracy of diagnostic tests. For such studies, NICE recommends using the Quality Assessment of Studies of Diagnostic Accuracy (QUADAS) methodology checklist to assess study quality (see the NICE guidelines manual, 2009).

Some studies were excluded from the guideline reviews after obtaining copies of the corresponding publications because they did not meet inclusion criteria specified by the guideline development group (see appendix E). The characteristics of each included study were summarised in evidence tables for each review question (see appendix I). Where possible, dichotomous outcomes were presented as relative risks (RRs) or odds ratios (ORs) with 95% confidence intervals (CIs), and continuous outcomes were presented as mean differences with 95% CIs or standard deviations (SDs).

The body of evidence identified for each review question (or part of a review question) was presented in the form of a GRADE evidence profile summarising the quality of the evidence and the findings (pooled relative and absolute effect sizes and associated CIs). Where possible, the body of evidence corresponding to each outcome specified in the review protocol was subjected to quantitative meta-analysis. In such cases, pooled effect sizes were presented as pooled risk ratios (RRs), pooled odds ratios (ORs) or weighted mean differences. By default, meta-analyses were conducted by fitting fixed effects models, but where statistically significant heterogeneity was identified, random effects models were used. Where quantitative meta-analysis could not be undertaken (for example because of heterogeneity in the included studies) the effect sizes reported in the included studies was presented for each individual study.

Table 4: '2 x 2' table for calculation of diagnostic accuracy parameters

	Reference standard positive	Reference standard negative	Total
Index test result positive	a (true positive)	b (false positive)	a+b
Index test result negative	c (false negative)	d (true negative)	c+d
Total	a+c	b+d	a+b+c+d=n (total number of tests in study)

Assessing cost effectiveness

The aims of the health economic input to the guideline were to inform the guideline development group of potential economic issues relating to intrapartum care, and to ensure that recommendations represented a cost-effective use of healthcare resources. Health economic evaluations aim to integrate data on benefits (ideally in terms of quality adjusted life years [QALYs]), harms and costs of different care options.

The guideline development group prioritised a number of review questions where it was thought that economic considerations would be particularly important in formulating recommendations. Systematic searches for published economic evidence were undertaken for these questions. For economic evaluations, no standard system of grading the quality of evidence exists and included papers were assessed using a quality assessment checklist based on good practice in economic evaluation. Reviews of the (very limited) relevant published health economic literature are presented alongside the clinical effectiveness reviews.

Health economic considerations were aided by original economic analysis undertaken as part of the development process. For this guideline the areas prioritised for economic analysis were as follows:

- fetal assessment and monitoring during labour:
  - cardiotocography using telemetry
  - electrocardiogram (ECG) analysis with continuous electronic fetal monitoring (EFM) compared with continuous EFM alone
- third stage of labour: management of retained placenta
- medical management of postpartum haemorrhage.

Additionally, the following areas were identified as being relevant for economic consideration:

- Intrapartum care provided in different birth settings – a recent cost-effectiveness analysis based on a large UK study has been reviewed for this question.
- Interventions during the latent (early) phase of labour – resource use issues that should be considered locally are described.
- Fetal blood sampling – a cost analysis was developed for this question.
- Appropriate staffing configuration of midwives on labour ward to support one-to-one continuous care during labour – no economic evaluation was undertaken for this question due to lack of evidence comparing staffing configurations; limitations of the evidence on appropriate staffing is discussed.

To enable assessment of cost effectiveness in the guideline, a costing survey was developed and carried out with the guideline development group in order to define costs related to intrapartum care that were unavailable from other sources (see appendix A).

Evidence to recommendations

For each review question, recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the guideline development group to agree short clinical and, where appropriate, cost effectiveness evidence statements, which were presented alongside the evidence profiles. Statements summarising the guideline development group's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared to ensure transparency in the decision-making process. The criteria used in moving from evidence to recommendations were:

- relative value placed on the outcomes considered
- consideration of the clinical benefits and harms
- consideration of net health benefits and resource use
- quality of the evidence
- other considerations (including equalities issues).

In areas where no substantial clinical research evidence was identified, the guideline development group considered other evidence-based guidelines and consensus statements or used their collective experience to identify good practice. The health economics justification in areas of the guideline where the use of NHS resources (interventions) was considered was based on guideline development group consensus in relation to the likely cost effectiveness implications of the recommendations. The guideline development group also identified areas where evidence to answer their review questions was lacking and used this information to formulate recommendations for future research.

Towards the end of the guideline development process, formal consensus methods were used to consider all the clinical care recommendations and research recommendations that had been drafted previously. The guideline development group identified 10 'key priorities for implementation' (key recommendations) and 5 high-priority research recommendations. The key priorities for implementation were those recommendations thought likely to have the biggest impact on the care of women in labour and outcomes in the NHS as a whole; they were selected using a variant of the nominal group technique (see the NICE guidelines manual). The priority research recommendations were selected in a similar way.

Stakeholder involvement

Registered stakeholder organisations were invited to comment on the draft scope and the first draft of the guideline.

Specific considerations for this guideline

Selected searches were date-limited to 2005 onwards in order to capture evidence published since the searches for the previous guideline were completed. Where searches were date-limited this is indicated in the protocol (see appendix E).

Where the guideline development group agreed that the study populations for a question could contain some degree of heterogeneity this was set at a threshold of 33%. This was used where some participants were women with complications of pregnancy rather than a healthy, uncomplicated pregnancy (as per the guideline scope) and was decided on a question by question basis. This is noted in the relevant protocol where it applies, along with any further specific considerations.

Outcomes are reported in GRADE profiles as identified as priority outcomes by the guideline development group during review protocol development. Where no evidence was found for guideline development group priority outcomes, data is reported for outcomes that received fewer guideline development group votes ('secondary' outcomes) where possible, or other proxy or similar outcomes agreed as relevant by the guideline development group chair.

Minimum important differences for continuous variables were discussed by the guideline development group and decided by consensus and were set as follows:

Table 5: Guideline development group chosen minimum important differences for continuous variables

Outcome	Minimum important difference
Length of third stage of labour	30 minutes
Woman's haemoglobin	10 g/l
Woman's blood loss	500 ml
Units of blood transfused	1
Hospital stay (woman or baby)	1 day
Intensive care unit stay (woman or baby)	0.5 days
Birthweight	50 g
Neonatal haemoglobin	20 g/l
Neonatal haematocrit	5% or 0.05
Arterial or venous pH	0.1

For reviews of diagnostic or predictive accuracy of tests the following terms and thresholds were used to define the usefulness of the test:
Sensitivity and specificity:

- high – 90% and above
- moderate – 75% to 89.9%
- low – 74.9% or below.

Positive likelihood ratio:

- very useful – more than 10
- moderately useful – 5 to 10
- not useful – less than 5

Negative likelihood ratio:

- very useful – 0 to 0.1
- moderately useful – more than 0.1 to 0.5
- not useful – more than 0.5

Correlation coefficients:

- high correlation – r-value of 0.6 to 1.0 (or −0.6 to −1.0)
- moderate correlation – r-value of 0.4 to 0.59 (or −0.4 to −0.59)
- low correlation – r-value of 0.2 to 0.39 (or −0.2 to −0.39)
- very low or no correlation – r-value of 0 to 0.19 (or 0 to −0.19)

Included in the scope for the update of this guideline was the identification and setting of thresholds for transfer into an obstetric unit for women who had planned to give birth outside an obstetric unit. The whole guideline was reviewed by the guideline development group which identified points where transfer might occur, including observations of the woman and unborn baby on initial assessment and ongoing assessment throughout labour. Informal consensus through discussion was then reached for each threshold and a recommendation made accordingly. These thresholds are also included in the updated care pathway (see chapter 2).

Schedule for updating the guideline

NICE is currently reviewing its schedule for guideline updates. For the most up-to-date information about the guideline review schedule, please see the latest version of the NICE manual available from the NICE website (http://www.nice.org.uk).

Explaining the changes in the partial update

This guideline partially updates and replaces NICE clinical guideline CG55, Intrapartum care: care of healthy women and their babies during childbirth (published 2007).
New and updated recommendations have been included on a large number of topics (see section 1.4).
Recommendations are marked to indicate the year of the last evidence review:

- [2007] if the evidence has not been updated since the original guideline
- [2007, amended 2014] if the evidence has not been updated since the original guideline, but changes have been made that alter the meaning of the recommendation
- [2014] if the evidence has been reviewed but no change has been made to the recommendation's meaning
- [new 2014] if the evidence has been reviewed and the recommendation has been added or updated.

Appendix Q contains all deleted material from the original 2007 guideline. For a list of the recommendations which have been deleted, along with reasons for their deletion, see appendix A in the NICE version.

Summary of recommendations and care pathway

Key priorities for implementation

Place of birth

- Commissioners and providers[a] should ensure that all 4 birth settings are available to all women (in the local area or in a neighbouring area). [6] [new 2014]
- Explain to both multiparous and nulliparous women that they may choose any birth setting (home, freestanding midwifery unit, alongside midwifery unit or obstetric unit), and support them in their choice of setting wherever they choose to give birth:
  - Advise low-risk multiparous women that planning to give birth at home or in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit.
  - Advise low-risk nulliparous women that planning to give birth in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. Explain that if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby. [2] [new 2014]
- Providers, senior staff and all healthcare professionals should ensure that in all birth settings there is a culture of respect for each woman as an individual undergoing a significant and emotionally intense life experience, so that the woman is in control, is listened to and is cared for with compassion, and that appropriate informed consent is sought. [14] [new 2014]
- Senior staff should demonstrate, through their own words and behaviour, appropriate ways of relating to and talking about women and their birth companion(s), and of talking about birth and the choices to be made when giving birth. [15] [new 2014]
- Maternity services should
  - provide a model of care that supports one-to-one care in labour for all women **and**
  - benchmark services and identify overstaffing or understaffing by using workforce planning models and/or woman-to-midwife ratios. [23] [new 2014]
- Commissioners and providers[b] should ensure that there are:
  - robust protocols in place for transfer of care between settings (see also recommendations 46 to 52)
  - clear local pathways for the continued care of women who are transferred from one setting to another, including:
    - when crossing provider boundaries
    - if the nearest obstetric or neonatal unit is closed to admissions or the local midwifery-led unit is full. [11] [new 2014]

Measuring fetal heart rate as part of initial assessment

- Do not perform cardiotocography on admission for low-risk women in suspected or established labour in any birth setting as part of the initial assessment. [55] [new 2014]

Update 2014

a This can also include networks of providers.
b This can also include networks of providers.

Interpretation of cardiotocograph traces

- Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone. [108] [new 2014]

First stage of labour

- Do not offer or advise clinical intervention if labour is progressing normally and the woman and baby are well. [158] [2007]

Third stage of labour

- After administering oxytocin, clamp and cut the cord:
  - Do not clamp the cord earlier than 1 minute from the birth of the baby unless there is concern about the integrity of the cord or the baby has a heartbeat below 60 beats/minute that is not getting faster.
  - Clamp the cord before 5 minutes in order to perform controlled cord traction as part of active management.
  - If the woman requests that the cord is clamped and cut later than 5 minutes, support her in her choice. [237] [new 2014]

Update 2014

Care pathway

For the care pathway, see appendix R.

Full list of recommendations

1. Explain to both multiparous and nulliparous women who are at low risk of complications that giving birth is generally very safe for both the woman and her baby. [2014]
2. Explain to both multiparous and nulliparous women that they may choose any birth setting (home, freestanding midwifery unit, alongside midwifery unit or obstetric unit), and support them in their choice of setting wherever they choose to give birth:
   - Advise low-risk multiparous women that planning to give birth at home or in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit.
   - Advise low-risk nulliparous women that planning to give birth in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. Explain that if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby. [new 2014]
3. Using tables 22 and 23, explain to low-risk multiparous women that:
   - planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit

- planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
- there are no differences in outcomes for the baby associated with planning birth in any setting. [new 2014]

Table 22: Rates of spontaneous vaginal birth, transfer to an obstetric unit and obstetric interventions for each planned place of birth: low-risk multiparous women (sources: Birthplace 2011; Blix et al. 2012)

	Number of incidences per 1000 multiparous women giving birth			
	Home	**Freestanding midwifery unit**	**Alongside midwifery unit**	**Obstetric unit**
Spontaneous vaginal birth	984*	980	967	927*
Transfer to an obstetric unit	115*	94	125	10**
Regional analgesia (epidural and/or spinal)***	28*	40	60	121*
Episiotomy	15*	23	35	56*
Caesarean birth	7*	8	10	35*
Instrumental (forceps or ventouse) birth	9*	12	23	38*
Blood transfusion	4	4	5	8

** Figures from Birthplace 2011 and Blix et al. 2012 (all other figures from Birthplace 2011)*
***Estimated transfer rate from an obstetric unit to a different obstetric unit owing to lack of capacity or expertise*
****Blix reported epidural analgesia and Birthplace reported spinal or epidural analgesia*

Table 23: Outcomes for the baby for each planned place of birth: low-risk multiparous women (source: Birthplace 2011)

	Number of babies per 1000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	997	997	998	997
Babies with serious medical problems*	3	3	2	3

** Serious medical problems were combined in the study: neonatal encephalopathy and meconium aspiration syndrome were the most common adverse events, together accounting for 75% of the total. Stillbirths after the start of care in labour and death of the baby in the first week of life accounted for 13% of the events. Fractured humerus and clavicle were uncommon outcomes (less than 4% of adverse events). For the frequency of these events (how often any of them actually occurred), see appendix K.*

4. Using tables 24 and 25, explain to low-risk nulliparous women that:
   - planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
   - planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings

- there are no differences in outcomes for the baby associated with planning birth in an alongside midwifery unit, a freestanding midwifery unit or an obstetric unit
- planning birth at home is associated with an overall small increase (about 4 more per 1000 births) in the risk of a baby having a serious medical problem compared with planning birth in other settings. [new 2014]

Table 24: Rates of spontaneous vaginal birth, transfer to an obstetric unit and obstetric interventions for each planned place of birth: low-risk nulliparous women (sources: Birthplace 2011; Blix et al. 2012)

	Number of incidences per 1000 nulliparous women giving birth			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Spontaneous vaginal birth	794*	813	765	688*
Transfer to an obstetric unit	450*	363	402	10**
Regional analgesia (epidural and/or spinal)***	218*	200	240	349
Episiotomy	165*	165	216	242*
Caesarean birth	80*	69	76	121*
Instrumental (forceps or ventouse)	126*	118	159	191*
Blood transfusion	12	8	11	16

** Figures from Birthplace 2011 and Blix et al. 2012 (all other figures from Birthplace 2011).*
***Estimated transfer rate from an obstetric unit to a different obstetric unit owing to lack of capacity or expertise.*
**** Blix reported epidural analgesia and Birthplace reported spinal or epidural analgesia*

Table 25: Outcomes for the baby for each planned place of birth: low-risk nulliparous women (source: Birthplace 2011)

	Number of babies per 1000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	991	995	995	995
Babies with serious medical problems*	9	5	5	5

** Serious medical problems were combined in the study: neonatal encephalopathy and meconium aspiration syndrome were the most common adverse events, together accounting for 75% of the total. Stillbirths after the start of care in labour and death of the baby in the first week of life accounted for 13% of the events. Fractured humerus and clavicle were uncommon outcomes – less than 4% of adverse events. For the frequency of these events (how often any of them actually occurred), see appendix K*

5. Ensure that all healthcare professionals involved in the care of pregnant women are familiar with the types and frequencies of serious medical problems that can affect babies (see appendix K), in order to be able to provide this information to women if they request it. [new 2014]
6. Commissioners and providers[c] should ensure that all 4 birth settings are available to all women (in the local area or in a neighbouring area). [new 2014]
7. Give the woman the following information, including local statistics, about all local birth settings:

c This can also include networks of providers.

- Access to midwives, including:
  - the likelihood of being cared for in labour by a familiar midwife
  - the likelihood of receiving one-to-one care throughout labour (not necessarily being cared for by the same midwife for the whole of labour)
- Access to medical staff (obstetric, anaesthetic and neonatal).
- Access to pain relief, including birthing pools, Entonox, other drugs and regional analgesia.
- The likelihood of being transferred to an obstetric unit (if this is not the woman's chosen place of birth), the reasons why this might happen and the time it may take. Refer to table 26 if no local data are available. [new 2014]

Table 26: Primary reasons for transfer to an obstetric unit (source: Birthplace 2011)

	Number of women transferred (% of total transferred from each setting)		
Primary reason for transfer to an obstetric unit*	From home (n=3529)	From a freestanding midwifery unit (n=2457)	From an alongside midwifery unit (n=4401)
Delay during first or second stage of labour	1144 (32.4%)	912 (37.1%)	1548 (35.2%)
Abnormal fetal heart rate	246 (7.0%)	259 (10.5%)	477 (10.8%)
Request for regional analgesia	180 (5.1%)	163 (6.6%)	585 (13.3%)
Meconium staining	432 (12.2%)	301 (12.2%)	538 (12.2%)
Retained placenta	250 (7.0%)	179 (7.3%)	203 (4.6%)
Repair of perineal trauma	386 (10.9%)	184 (7.5%)	369 (8.4%)
Neonatal concerns (postpartum)	180 (5.1%)	63 (2.6%)	5 (0.0%)
Other	711 (20.1%)	396 (16.2%)	676 (16.3%)
* Main reason for transfer to an obstetric unit for each woman (there may be more than 1 reason).			

8. If further discussion is wanted by either the midwife or the woman about the choice of planned place of birth, arrange this with a consultant midwife or supervisor of midwives, and/or a consultant obstetrician if there are obstetric issues. [new 2014]
9. When discussing the woman's choice of place of birth with her, do not disclose personal views or judgements about her choices. [new 2014]
10. Ensure that all women giving birth have timely access to an obstetric unit if they need transfer of care for medical reasons or because they request regional analgesia. [new 2014]
11. Commissioners and providers[d] should ensure that there are:
    - robust protocols in place for transfer of care between settings (see also recommendations 48 to 52).
    - clear local pathways for the continued care of women who are transferred from one setting to another, including:
      - when crossing provider boundaries

d This can also include networks of providers.

- if the nearest obstetric or neonatal unit is closed to admissions or the local midwifery-led unit is full. [new 2014]

12. Commissioners and providers[e] should ensure that there are multidisciplinary clinical governance structures in place to enable the oversight of all birth settings. These structures should include, as a minimum, midwifery (including a supervisor of midwives), obstetric, anaesthetic and neonatal expertise, and adequately supported user representation. [new 2014]
13. For all women giving birth in all birth settings, follow the principles in Patient experience in adult NHS services (NICE clinical guidance 138). [new 2014]
14. Providers, senior staff and all healthcare professionals should ensure that in all birth settings there is a culture of respect for each woman as an individual undergoing a significant and emotionally intense life experience, so that the woman is in control, is listened to and is cared for with compassion, and that appropriate informed consent is sought. [new 2014]
15. Senior staff should demonstrate, through their own words and behaviour, appropriate ways of relating to and talking about women and their birth companion(s), and of talking about birth and the choices to be made when giving birth. [new 2014]
16. Use tables 39, 40, 41 and 42 as part of an assessment for a woman choosing her planned place of birth:
    - Tables 39 and 40 show medical conditions or situations in which there is increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk.
    - The factors listed in tables 41 and 42 are not reasons in themselves for advising birth within an obstetric unit, but indicate that further consideration of birth setting may be required.
    - Discuss these risks and the additional care that can be provided in the obstetric unit with the woman so that she can make an informed choice about planned place of birth. [2007, amended 2014]

e This can also include networks of providers.

Table 39: Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

Disease area	Medical condition
Cardiovascular	Confirmed cardiac disease Hypertensive disorders
Respiratory	Asthma requiring an increase in treatment or hospital treatment Cystic fibrosis
Haematological	Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major History of thromboembolic disorders Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100×10^9/litre Von Willebrand's disease Bleeding disorder in the woman or unborn baby Atypical antibodies which carry a risk of haemolytic disease of the newborn
Endocrine	Hyperthyroidism Diabetes
Infective	Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended Hepatitis B/C with abnormal liver function tests Carrier of/infected with HIV Toxoplasmosis – women receiving treatment Current active infection of chicken pox/rubella/genital herpes in the woman or baby Tuberculosis under treatment
Immune	Systemic lupus erythematosus Scleroderma
Renal	Abnormal renal function Renal disease requiring supervision by a renal specialist
Neurological	Epilepsy Myasthenia gravis Previous cerebrovascular accident
Gastrointestinal	Liver disease associated with current abnormal liver function tests
Psychiatric	Psychiatric disorder requiring current inpatient care

Table 40: Other factors indicating increased risk suggesting planned birth at an obstetric unit

Factor	Additional information
Previous complications	Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty Previous baby with neonatal encephalopathy Pre-eclampsia requiring preterm birth Placental abruption with adverse outcome Eclampsia Uterine rupture Primary postpartum haemorrhage requiring additional treatment or blood transfusion Retained placenta requiring manual removal in theatre Caesarean section Shoulder dystocia
Current pregnancy	Multiple birth Placenta praevia

Factor	Additional information
	Pre-eclampsia or pregnancy-induced hypertension Preterm labour or preterm prelabour rupture of membranes Placental abruption Anaemia – haemoglobin less than 85 g/litre at onset of labour Confirmed intrauterine death Induction of labour Substance misuse Alcohol dependency requiring assessment or treatment Onset of gestational diabetes Malpresentation – breech or transverse lie BMI at booking of greater than 35 kg/m2 Recurrent antepartum haemorrhage Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound) Abnormal fetal heart rate /Doppler studies Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	Myomectomy Hysterotomy

Table 41: Medical conditions indicating individual assessment when planning place of birth

Disease area	Medical condition
Cardiovascular	Cardiac disease without intrapartum implications
Haematological	Atypical antibodies not putting the baby at risk of haemolytic disease Sickle-cell trait Thalassaemia trait Anaemia – haemoglobin 85–105 g/litre at onset of labour
Infective	Hepatitis B/C with normal liver function tests
Immune	Non-specific connective tissue disorders
Endocrine	Unstable hypothyroidism such that a change in treatment is required
Skeletal/neurological	Spinal abnormalities Previous fractured pelvis Neurological deficits
Gastrointestinal	Liver disease without current abnormal liver function Crohn's disease Ulcerative colitis

Table 42: Other factors indicating individual assessment when planning place of birth

Factor	Additional information
Previous complications	Stillbirth/neonatal death with a known non-recurrent cause Pre-eclampsia developing at term Placental abruption with good outcome History of previous baby more than 4.5 kg Extensive vaginal, cervical, or third- or fourth-degree perineal trauma Previous term baby with jaundice requiring exchange transfusion
Current pregnancy	Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation) BMI at booking of 30–35 kg/m2 Blood pressure of 140 mmHg or more systolic or 90 mmHg or more diastolic on two occasions Clinical or ultrasound suspicion of macrosomia Para 4 or more Recreational drug use Under current outpatient psychiatric care Age over 35 at booking
Fetal indications	Fetal abnormality
Previous gynaecological history	Major gynaecological surgery Cone biopsy or large loop excision of the transformation zone Fibroids

17. Treat all women in labour with respect. Ensure that the woman is in control of and involved in what is happening to her, and recognise that the way in which care is given is key to this. To facilitate this, establish a rapport with the woman, ask her about her wants and expectations for labour, and be aware of the importance of tone and demeanour, and of the actual words used. Use this information to support and guide her through her labour. [2007]
18. To establish communication with the woman:
    - Greet the woman with a smile and a personal welcome, establish her language needs, introduce yourself and explain your role in her care.
    - Maintain a calm and confident approach so that your demeanour reassures the woman that all is going well.
    - Knock and wait before entering the woman's room, respecting it as her personal space, and ask others to do the same.
    - Ask how the woman is feeling and whether there is anything in particular she is worried about.
    - If the woman has a written birth plan, read and discuss it with her.
    - Assess the woman's knowledge of strategies for coping with pain and provide balanced information to find out which available approaches are acceptable to her.
    - Encourage the woman to adapt the environment to meet her individual needs.

- Ask her permission before all procedures and observations, focusing on the woman rather than the technology or the documentation.
- Show the woman and her birth companion(s) how to summon help and reassure her that she may do so whenever and as often as she needs to. When leaving the room, let her know when you will return.
- Involve the woman in any handover of care to another professional, either when additional expertise has been brought in or at the end of a shift. [2007]

19. Encourage and help the woman to move and adopt whatever positions she finds most comfortable throughout labour. [2007]
20. Provide a woman in established labour with supportive one-to-one care. [2007]
21. Do not leave a woman in established labour on her own except for short periods or at the woman's request. [2007]
22. Encourage the woman to have support from birth companion(s) of her choice. [2007]
23. Maternity services should
    - provide a model of care that supports one-to-one care in labour for all women **and**
    - benchmark services and identify overstaffing or understaffing by using workforce planning models and/or woman-to-midwife ratios. [new 2014]
24. Team midwifery (defined as a group of midwives providing care and taking shared responsibility for a group of women from the antenatal, through intrapartum to the postnatal period) is not recommended. [2007]
25. Do not offer either H2-receptor antagonists or antacids routinely to low-risk women. [2007]
26. Either H2-receptor antagonists or antacids should be considered for women who receive opioids or who have or develop risk factors that make a general anaesthetic more likely. [2007]
27. Inform the woman that she may drink during established labour and that isotonic drinks may be more beneficial than water. [2007]
28. Inform the woman that she may eat a light diet in established labour unless she has received opioids or she develops risk factors that make a general anaesthetic more likely. [2007]
29. Tap water may be used if cleansing is required before vaginal examination. [2007]
30. Routine hygiene measures taken by staff caring for women in labour, including standard hand hygiene and single-use non-sterile gloves, are appropriate to reduce cross-contamination between women, babies and healthcare professionals. [2007]
31. Selection of protective equipment[f] must be based on an assessment of the risk of transmission of microorganisms to the woman, and the risk

f In accordance with current health and safety legislation (at the time of publication of NICE clinical guideline 139 [March 2012]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and

of contamination of the healthcare worker's clothing and skin by women's blood, body fluids, secretions or excretions.[g] [2007, amended 2014]

32. Give all nulliparous women information antenatally about:
    - what to expect in the latent first stage of labour
    - how to work with any pain they experience
    - how to contact their midwifery care team and what to do in an emergency. [new 2014]
33. Offer all nulliparous women antenatal education about the signs of labour, consisting of:
    - how to differentiate between Braxton Hicks contractions and active labour contractions
    - the expected frequency of contractions and how long they last
    - recognition of amniotic fluid ('waters breaking')
    - description of normal vaginal loss. [new 2014]
34. Consider an early assessment of labour by telephone triage provided by a dedicated triage midwife for all women. [new 2014]
35. Consider a face-to-face early assessment of labour for all low-risk nulliparous women, either:
    - at home (regardless of planned place of birth) **or**
    - in an assessment facility in her planned place of birth (midwifery-led unit or obstetric unit), comprising one-to-one midwifery care for at least 1 hour. [new 2014]
36. Include the following in any early or triage assessment of labour:
    - ask the woman how she is, and about her wishes, expectations and any concerns she has
    - ask the woman about the baby's movements, including any changes
    - give information about what the woman can expect in the latent first stage of labour and how to work with any pain she experiences
    - give information about what to expect when she accesses care
    - agree a plan of care with the woman, including guidance about who she should contact next and when.
    - provide guidance and support to the woman's birth companion(s). [new 2014]
37. The triage midwife should document the guidance that she gives to the woman. [new 2014]
38. If a woman seeks advice or attends a midwifery-led unit or obstetric unit with painful contractions, but is not in established labour:
    - recognise that a woman may experience painful contractions without cervical change, and although she is described as not

Safety Regulations 2002, Control of Substances Hazardous to Health Regulations 2002, Personal Protective Equipment Regulations 2002 and Health and Social Care Act 2008.

g This recommendation is adapted from Infection: prevention and control of healthcare-associated infections in primary and community care (NICE clinical guideline 139).

being in labour, she may well think of herself as being 'in labour' by her own definition

- offer her individualised support, and analgesia if needed
- encourage her to remain at or return home, unless doing so leads to a significant risk that she could give birth without a midwife present or become distressed. [new 2014]

39. Advise the woman and her birth companion(s) that breathing exercises, immersion in water and massage may reduce pain during the latent first stage of labour. (See also recommendation 82.) [new 2014]
40. Do not offer or advise aromatherapy, yoga or acupressure for pain relief during the latent first stage of labour. If a woman wants to use any of these techniques, respect her wishes. [new 2014]
41. When performing an initial assessment of a woman in labour, listen to her story and take into account her preferences and her emotional and psychological needs. [new 2014]
42. Carry out an initial assessment to determine if midwifery-led care in any setting is suitable for the woman, irrespective of any previous plan. The assessment should comprise the following:
    - Observations of the woman:
    - Review the antenatal notes (including all antenatal screening results) and discuss these with the woman.
    - Ask her about the length, strength and frequency of her contractions.
    - Ask her about any pain she is experiencing and discuss her options for pain relief.
    - Record her pulse, blood pressure and temperature, and carry out urinalysis.
    - Record if she has had any vaginal loss.
    - Observations of the unborn baby:
    - Ask the woman about the baby's movements in the last 24 hours.
    - Palpate the woman's abdomen to determine the fundal height, the baby's lie, presentation, position, engagement of the presenting part, and frequency and duration of contractions.
    - Auscultate the fetal heart rate for a minimum of 1 minute immediately after a contraction. Palpate the woman's pulse to differentiate between the heart rates of the woman and the baby.

    In addition (see also recommendation 45):

    - If there is uncertainty about whether the woman is in established labour, a vaginal examination may be helpful after a period of assessment, but is not always necessary.
    - If the woman appears to be in established labour, offer a vaginal examination. [new 2014]

43. Transfer the woman to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50, if any of the following are observed on initial assessment:
    - Observations of the woman:
    - pulse over 120 beats/minute on 2 occasions 30 minutes apart
    - a single reading of either raised diastolic blood pressure of 110 mmHg or more or raised systolic blood pressure of 160 mmHg or more
    - either raised diastolic blood pressure of 90 mmHg or more or raised systolic blood pressure of 140 mmHg or more on 2 consecutive readings taken 30 minutes apart
    - a reading of 2+ of protein on urinalysis and a single reading of either raised diastolic blood pressure (90 mmHg or more) or raised systolic blood pressure (140 mmHg or more)
    - temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive readings 1 hour apart
    - any vaginal blood loss other than a show
    - rupture of membranes more than 24 hours before the onset of established labour (see recommendation 278)
    - the presence of significant meconium (see recommendation 164)
    - pain reported by the woman that is differs from the pain normally associated with contractions
    - any risk factors recorded in the woman's notes that indicate the need for obstetric-led care.
    - Observations of the unborn baby:
    - any abnormal presentation, including cord presentation
    - transverse or oblique lie
    - high (4/5-5/5 palpable) or free-floating head in a nulliparous woman
    - suspected fetal growth restriction or macrosomia
    - suspected anhydramnios or polyhydramnios
    - fetal heart rate below 110 or above 160 beats/minute
    - a deceleration in fetal heart rate heard on intermittent auscultation
    - reduced fetal movements in the last 24 hours reported by the woman.

    If none of these are observed, continue with midwifery-led care unless the woman request a transfer (see also recommendation 55) [new 2014]
44. If any of the factors in recommendation 43 are observed but birth is imminent, assess whether birth in the current location is preferable to transferring the woman to an obstetric unit and discuss this with the coordinating midwife. [new 2014]
45. When conducting a vaginal examination:

- be sure that the examination is necessary and will add important information to the decision-making process
- recognise that a vaginal examination can be very distressing for a woman, especially if she is already in pain, highly anxious and in an unfamiliar environment
- explain the reason for the examination and what will be involved
- ensure the woman's informed consent, privacy, dignity and comfort
- explain sensitively the findings of the examination and any impact on the birth plan to the woman and her birth companion(s). [new 2014]

46. Base any decisions about transfer of care on clinical findings, and discuss the options with the woman and her birth companion(s). [new 2014]
47. If contemplating transfer of care:
    - talk with the woman and her birth companion(s) about the reasons for this and what they can expect, including the time needed for transfer
    - address any concerns she has and try to allay her anxiety
    - ensure that her wishes are respected and her informed consent is obtained. [new 2014]
48. When arranging transfer of care, the midwife attending the labour should contact the ambulance service (if appropriate) and the coordinating midwife in the obstetric unit. The coordinating midwife should then alert the relevant healthcare professionals (obstetric, anaesthetic and neonatal). [new 2014]
49. When arranging transfer from one location to another, ensure the following:
    - Before transfer, the woman is dressed, wrapped in a blanket or otherwise covered in a way that she feels is comfortable and appropriate.
    - The woman is made to feel as comfortable as possible before and during transfer.
    - Any ambulance staff or other personnel involved are aware that some positions may make the woman uncomfortable or afraid and could affect her labour, so she should be encouraged to choose how to move and what position to adopt if possible, in accordance with ambulance service protocols.
    - Communication and companionship are maintained. Explain the arrangements for transfer to the woman and her birth companion(s). A midwife who has been involved in her care up to that point should travel with her and carry out a handover of care that involves the woman.
    - Arrangements are in place to enable the woman's birth companion(s) to travel with her in the ambulance if that is what she wants. If this is not possible or not wanted, check that the

birth companion(s) has or can arrange their own transport. [new 2014]

50. If a woman is transferred to an obstetric unit after the birth (see recommendations 292 to 313), ensure that her baby goes with her. [new 2014]
51. Auscultate the fetal heart rate at first contact with the woman in labour, and at each further assessment. [new 2014]
52. Auscultate the fetal heart rate for a minimum of 1 minute immediately after a contraction and record it as a single rate. [new 2014]
53. Palpate the maternal pulse to differentiate between maternal heart rate and fetal heart rate. [new 2014]
54. Record accelerations and decelerations if heard. [new 2014]
55. Do not perform cardiotocography on admission for low-risk women in suspected or established labour in any birth setting as part of the initial assessment. [new 2014]
56. Offer continuous cardiotocography if any of the risk factors listed in recommendation 43 are identified on initial assessment, and explain to the woman why this is necessary. (See also recommendations 99 to 157 on fetal monitoring.) [new 2014]
57. Offer cardiotocography if intermittent auscultation indicates possible fetal heart rate abnormalities, and explain to the woman why this is necessary. Remove the cardiotocograph if the trace is normal after 20 minutes. (See also recommendations 99 to 157 on fetal monitoring). [new 2014]
58. If fetal death is suspected despite the presence of an apparently recorded fetal heart rate, offer real-time ultrasound assessment to check fetal viability. [new 2014]
59. Do not carry out a speculum examination if it is certain that the membranes have ruptured. [2007]
60. If it is uncertain whether prelabour rupture of the membranes has occurred, offer the woman a speculum examination to determine whether the membranes have ruptured. Avoid digital vaginal examination in the absence of contractions. [2007]
61. Advise women presenting with prelabour rupture of the membranes at term that:
    - the risk of serious neonatal infection is 1%, rather than 0.5% for women with intact membranes
    - 60% of women with prelabour rupture of the membranes will go into labour within 24 hours
    - induction of labour[h] is appropriate approximately 24 hours after rupture of the membranes. [2007]
62. Until the induction is started or if expectant management beyond 24 hours is chosen by the woman:
    - do not offer lower vaginal swabs and measurement of maternal C-reactive protein
    - to detect any infection that may be developing, advise the woman to record her temperature every 4 hours during waking

h The care of women who have their labour induced is covered by Induction of labour (NICE clinical guideline 70).

hours and to report immediately any change in the colour or smell of her vaginal loss

- inform the woman that bathing or showering is not associated with an increase in infection, but that having sexual intercourse may be. [2007]

63. Assess fetal movement and heart rate at initial contact and then every 24 hours after rupture of the membranes while the woman is not in labour, and advise the woman to report immediately any decrease in fetal movements. [2007]
64. If labour has not started 24 hours after rupture of the membranes, advise the woman to give birth where there is access to neonatal services and to stay in hospital for at least 12 hours after the birth. [2007]
65. Healthcare professionals should think about how their own values and beliefs inform their attitude to coping with pain in labour and ensure their care supports the woman's choice. [2007]
66. If a woman chooses to use breathing and relaxation techniques in labour, support her in this choice. [2007]
67. If a woman chooses to use massage techniques in labour that have been taught to birth companions, support her in this choice. [2007]
68. Offer the woman the opportunity to labour in water for pain relief. [2007]
69. For women labouring in water, monitor the temperature of the woman and the water hourly to ensure that the woman is comfortable and not becoming pyrexial. The temperature of the water should not be above 37.5°C. [2007]
70. Keep baths and birthing pools clean using a protocol agreed with the microbiology department and, in the case of birthing pools, in accordance with the manufacturer's guidelines. [2007]
71. Do not use injected water papules. [2007]
72. Do not offer acupuncture, acupressure or hypnosis, but do not prevent women who wish to use these techniques from doing so. [2007]
73. Support the playing of music of the woman's choice in labour. [2007]
74. Do not offer transcutaneous electrical nerve stimulation (TENS) to women in established labour. [2007]
75. Ensure that Entonox (a 50:50 mixture of oxygen and nitrous oxide) is available in all birth settings as it may reduce pain in labour, but inform the woman that it may make her feel nauseous and light-headed. [2007]
76. Ensure that pethidine, diamorphine or other opioids are available in all birth settings. Inform the woman that these will provide limited pain relief during labour and may have significant side effects for both her (drowsiness, nausea and vomiting) and her baby (short-term respiratory depression and drowsiness which may last several days). [2007]
77. Inform the woman that pethidine, diamorphine or other opioids may interfere with breastfeeding. [2007]
78. If an intravenous or intramuscular opioid is used, also administer an antiemetic. [2007]
79. Women should not enter water (a birthing pool or bath) within 2 hours of opioid administration or if they feel drowsy. [2007]

80. If a woman is contemplating regional analgesia, talk with her about the risks and benefits and the implications for her labour, including the arrangements and time involved for transfer of care to an obstetric unit if she is at home or in a midwifery unit (follow the general principles for transfer of care described in recommendations 46 to 50). [2007, amended 2014]
81. Provide information about epidural analgesia, including the following:
    - It is available only in obstetric units.
    - It provides more effective pain relief than opioids.
    - It is not associated with long-term backache.
    - It is not associated with a longer first stage of labour or an increased chance of caesarean birth.
    - It is associated with a longer second stage of labour and an increased chance of vaginal instrumental birth.
    - It will be accompanied by a more intensive level of monitoring and intravenous access, and so mobility may be reduced. [2007, amended 2014]
82. If a woman in labour asks for regional analgesia, comply with her request. This includes women in severe pain in the latent first stage of labour. [2007]
83. Always secure intravenous access before starting regional analgesia. [2007]
84. Preloading and maintenance fluid infusion need not be administered routinely before establishing low-dose epidural analgesia and combined spinal–epidural analgesia. [2007]
85. Undertake the following additional observations for women with regional analgesia:
    - During establishment of regional analgesia or after further boluses (10 ml or more of low-dose solutions), measure blood pressure every 5 minutes for 15 minutes.
    - If the woman is not pain-free 30 minutes after each administration of local anaesthetic/opioid solution, recall the anaesthetist.
    - Assess the level of the sensory block hourly. [2007]
86. Encourage women with regional analgesia to move and adopt whatever upright positions they find comfortable throughout labour. [2007]
87. Once established, continue regional analgesia until after completion of the third stage of labour and any necessary perineal repair. [2007]
88. Upon confirmation of full cervical dilatation in a woman with regional analgesia, unless the woman has an urge to push or the baby's head is visible, pushing should be delayed for at least 1 hour and longer if the woman wishes, after which actively encourage her to push during contractions. [2007]
89. After diagnosis of full dilatation in a woman with regional analgesia, agree a plan with the woman in order to ensure that birth will have occurred within 4 hours regardless of parity. [2007]
90. Do not routinely use oxytocin in the second stage of labour for women with regional analgesia. [2007]

91. Perform continuous cardiotocography for at least 30 minutes during establishment of regional analgesia and after administration of each further bolus of 10 ml or more. [2007, amended 2014]
92. Either patient-controlled epidural analgesia or intermittent bolus given by healthcare professionals are the preferred modes of administration for maintenance of epidural analgesia. [2007]
93. Use either epidural or combined spinal–epidural analgesia for establishing regional analgesia in labour. [2007]
94. If rapid analgesia is required, use combined spinal–epidural analgesia. [2007]
95. Establish combined spinal–epidural analgesia with bupivacaine and fentanyl [2007]
96. Establish epidural analgesia with a low-concentration local anaesthetic and opioid solution with, for example, 10–15 ml of 0.0625–0.1% bupivacaine with 1–2 micrograms per ml fentanyl. The initial dose of local anaesthetic plus opioid is essentially a test dose, so administer cautiously to ensure that inadvertent intrathecal injection has not occurred. [2007]
97. Use low-concentration local anaesthetic and opioid solutions (0.0625–0.1% bupivacaine or equivalent combined with 2.0 micrograms per ml fentanyl) for maintaining epidural analgesia in labour. [2007]
98. Do not use high concentrations of local anaesthetic solutions (0.25% or above of bupivacaine or equivalent) routinely for either establishing or maintaining epidural analgesia. [2007]
99. Offer intermittent auscultation of the fetal heart rate to low-risk women in established first stage of labour in all birth settings:
    - Use either a Pinard stethoscope or Doppler ultrasound.
    - Carry out intermittent auscultation immediately after a contraction for at least 1 minute, at least every 15 minutes, and record it as a single rate.
    - Record accelerations and decelerations if heard.
    - Palpate the maternal pulse if a fetal heart rate abnormality is suspected, to differentiate between the two heart rates. [new 2014]
100. Do not perform cardiotocography for low-risk women in established labour. [new 2014]
101. Advise continuous cardiotocography if any of the following risk factors are present or arise during labour:
    - suspected chorioamnionitis or sepsis, or a temperature of 38°C or above
    - severe hypertension (160/110 mmHg above [see Hypertension in pregnancy (NICE clinical guideline 107)]).
    - oxytocin use
    - the presence of significant meconium (see recommendation 164)
    - fresh vaginal bleeding that develops in labour. [new 2014]

102. If any one of the following risk factors is present or arises during labour, perform a full assessment of all factors listed in recommendation 163.

- prolonged period since rupture of membranes (24 hours or more) (see recommendations 59 to 64)
- moderate hypertension (150/100 to 159/109 mmHg [see Hypertension in pregnancy (NICE clinical guideline 107)])
- confirmed delay in the first or second stage of labour (see recommendations 175, 195 and 199)
- the presence of non-significant meconium.

Advise continuous cardiotocography if 2 or more of the above risk factors are present, or any other risk factor in recommendation 163 is present with 1 of these. [new 2014]

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

104. Address any concerns that the woman has about continuous cardiotocography, and give her the following information:

- Explain that continuous cardiotocography is used to monitor the baby's heartbeat and the labour contractions.
- Give details of the types of findings that may occur. Explain that a normal trace is reassuring and indicates that the baby is coping well with labour, but if the trace is not normal there is less certainty about the condition of the baby and further continuous monitoring will be advised.
- Explain that decisions about whether to take any further action will be based on an assessment of several factors, including the findings from cardiotocography. [new 2014]

105. If continuous cardiotocography has been used because of concerns arising from intermittent auscultation but there are no non-reassuring or abnormal features (see table 92) on the cardiotocograph trace after 20 minutes, remove the cardiotocograph and return to intermittent auscultation. [new 2014]

106. Use tables 92 and 93 to define and interpret cardiotocograph traces and to guide the management of labour for women who are having continuous cardiotocography. These tables include and summarise individual recommendations about fetal monitoring (106 to 130), fetal scalp stimulation (134 and 135), fetal blood sampling (136 to 149) and intrauterine resuscitation (132 to 134 and 185) in this guideline. [new 2014]

Table 92: Description of cardiotocograph trace features

Overall care

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

Principles for intrapartum CTG trace interpretation

- When reviewing the CTG trace, assess and document all 4 features (baseline fetal heart rate, baseline variability, presence or absence of decelerations, presence of accelerations).
- It is not possible to categorise or interpret every CTG trace. **Senior obstetric input is important in these cases.**

Accelerations

- The presence of fetal heart rate accelerations is generally a sign that the unborn baby is healthy.
- If a fetal blood sample is indicated and the sample cannot be obtained, but the associated scalp stimulation results in fetal heart rate accelerations, decide whether to continue the labour or expedite the birth in light of the clinical circumstances and in discussion with the woman.

	Feature		
Description	**Baseline (beats/ minute)**	**Baseline variability (beats/ minute)**	**Decelerations**
Normal/ reassuring	100–160	5 or more	None or early
Non-reassuring	161–180	Less than 5 for 30–90 minutes	Variable decelerations: • dropping from baseline by 60 beats/minute or less and taking 60 seconds or less to recover • present for over 90 minutes • occurring with over 50% of contractions. **OR** Variable decelerations: • dropping from baseline by more than 60 beats/minute or taking over 60 seconds to recover • present for up to 30 minutes • occurring with over 50% of contractions. **OR** Late decelerations: • present for up to 30 minutes • occurring with over 50% of contractions.
Abnormal	Above 180 **or** below 100	Less than 5 for over 90 minutes	Non-reassuring variable decelerations (see row above): • still observed 30 minutes after starting conservative measures • occurring with over 50% of contractions. **OR** Late decelerations • present for over 30 minutes • do not improve with conservative measures • occurring with over 50% of contractions. **OR** Bradycardia or a single prolonged deceleration lasting 3 minutes or more.

Abbreviation: CTG, cardiotocography.

Table 93: Management based on interpretation of cardiotocograph traces

Category	Definition	Interpretation	Management
CTG is normal/ reassuring	All 3 features are normal/ reassuring	Normal CTG, no non-reassuring or abnormal features, healthy fetus	• Continue CTG and normal care. • If CTG was started because of concerns arising from intermittent auscultation, remove CTG after 20 minutes if there are no non-reassuring or abnormal features and no ongoing risk factors.
CTG is non-reassuring and suggests need for conservative measures	1 non-reassuring feature **AND** 2 normal/ reassuring features	Combination of features that may be associated with increased risk of fetal acidosis; if accelerations are present, acidosis is unlikely	• Think about possible underlying causes. • If the baseline fetal heart rate is over 160 beats/minute, check the woman's temperature and pulse. If either are raised, offer fluids and paracetamol. • Start 1 or more conservative measures: o encourage the woman to mobilise or adopt a left-lateral position, and in particular to avoid being supine o offer oral or intravenous fluids o reduce contraction frequency by stopping oxytocin if being used and/or offering tocolysis. o Inform coordinating midwife and obstetrician.
CTG is abnormal and indicates need for conservative measures AND further testing	1 abnormal feature **OR** 2 non-reassuring features	Combination of features that is more likely to be associated with fetal acidosis	• Think about possible underlying causes. • If the baseline fetal heart rate is over 180 beats/minute, check the woman's temperature and pulse. If either are raised, offer fluids and paracetamol. • Start 1 or more conservative measures (see 'CTG is non-reassuring…' row for details). • Inform coordinating midwife and obstetrician. • Offer to take an FBS (for lactate or pH) after implementing conservative measures, or expedite birth if an FBS cannot be obtained and no accelerations are seen as a result of scalp stimulation. • Take action sooner than 30 minutes if late decelerations are accompanied by tachycardia and/or reduced baseline variability. • Inform the consultant obstetrician if any FBS result is abnormal. • Discuss with the consultant obstetrician if an FBS cannot be obtained or a third FBS is thought to be needed.
CTG is abnormal and indicates **need for urgent intervention**	Bradycardia or a single prolonged deceleration with baseline below 100 beats/minute, persisting for 3 minutes or more*	An abnormal feature that is very likely to be associated with current fetal acidosis or imminent rapid development of fetal acidosis	• Start 1 or more conservative measures (see 'CTG is non-reassuring…' row for details). • Inform coordinating midwife. • Urgently seek obstetric help. • Make preparations for urgent birth. • Expedite birth if persists for 9 minutes. • If heart rate recovers before 9 minutes, reassess decision to expedite birth in discussion with the woman.

Abbreviations: CTG, cardiotocography; FBS, fetal blood sample.
** A stable baseline value of 90–99 beats/minute with normal baseline variability (having confirmed that this is not the maternal heart rate) may be a normal variation; obtain a senior obstetric opinion if uncertain*

107. If continuous cardiotocography is needed:

- explain to the woman that it will restrict her mobility, particularly if conventional monitoring is used
- encourage and help the woman to be as mobile as possible and to change position as often as she wishes
- remain with the woman in order to continue providing one-to-one support
- monitor the condition of the woman and the baby, and take prompt action if required
- ensure that the focus of care remains on the woman rather than the cardiotocograph trace
- ensure that the cardiotocograph trace is of high quality, and think about other options if this is not the case
- bear in mind it is not possible to categorise or interpret every cardiotocograph trace: senior obstetric input is important in these cases.[new 2014]

108. Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone. [new 2014]

109. Any decision about changes to a woman's care in labour when she is on a cardiotocograph monitor should also take into account the following:

- the woman's report of how she is feeling
- the woman's report of the baby's movements
- assessment of the woman's wellbeing and behaviour
- the woman's temperature, pulse and blood pressure
- whether there is meconium or blood in the amniotic fluid
- any signs of vaginal bleeding
- any medication the woman is taking
- the frequency of contractions
- the stage and progress of labour
- the woman's parity
- the results of fetal blood sampling if undertaken (see recommendations 136 to 149)
- the fetal response to scalp stimulation if performed (see recommendations 134 and 135). [new 2014]

110. When reviewing the cardiotocograph trace, assess and document all 4 features (baseline fetal heart rate, baseline variability, presence or absence of decelerations, and presence of accelerations). [new 2014]

111. Supplement ongoing care with a documented systematic assessment of the condition of the woman and unborn baby (including any cardiotocography findings) every hour. If there are concerns about cardiotocography findings, undertake this assessment more frequently. [new 2014]

112. Be aware that if the cardiotocography parameters of baseline fetal heart rate and baseline variability are normal, the risk of fetal acidosis is low. [new 2014]

113. Take the following into account when assessing baseline fetal heart rate:

- this will usually be between 110 and 160 beats/minute
- a baseline fetal heart rate between 100 and 109 beats/minute (having confirmed that this is not the maternal heart rate) with normal baseline variability and no variable or late decelerations is normal and should not prompt further action
- a stable baseline fetal heart rate between 90 and 99 beats/minute with normal baseline variability (having confirmed that this is not the maternal heart rate) may be a normal variation; obtain a senior obstetric opinion if uncertain. [new 2014]

114. If the baseline fetal heart rate is between 161 and 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph:

- think about possible underlying causes (such as infection) and appropriate investigation
- check the woman's temperature and pulse; if either are raised, offer fluids and paracetomol
- start one or more conservative measures (see recommendation 132). [new 2014]

115. If the baseline fetal heart rate is between 161 and 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph and the woman's temperature and pulse are normal, continue cardiotocography and normal care, since the risk of fetal acidosis is low. [new 2014]

116. If the baseline fetal heart rate is between 100 and 109 beats/minute or above 160 beats/minute and there is 1 other non-reassuring feature on the cardiotocograph, start conservative measures (see recommendation 132) to improve fetal wellbeing. [new 2014]

117. If the baseline fetal heart rate is above 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph:

- think about possible underlying causes (such as infection) and appropriate investigation
- check the woman's temperature and pulse; if either are raised, offer fluids and paracetamol
- start one or more conservative measures (see recommendation 132).
- offer fetal blood sampling to measure lactate or pH (see recommendation 136 to 149) if the rate stays above 180 beats/minute despite conservative measures [new 2014]

118. If there is a bradycardia or a single prolonged deceleration with the fetal heart rate below 100 beats/minute for 3 minutes or more:

- start conservative measures (see recommendation 132)

- urgently seek obstetric help
- make preparations for urgent birth
- expedite the birth (see recommendations 220 to 223) if the bradycardia persists for 9 minutes.

If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman. [new 2014]

119. Take the following into account when assessing fetal heart rate baseline variability:
    - baseline variability will usually be 5 beats/minute or more
    - intermittent periods of reduced baseline variability are normal, especially during periods of quiescence ('sleep')
    - mild or minor pseudo-sinusoidal patterns (oscillations of amplitude 5-15 beats/minute) are of no significance. [new 2014]
120. If there is reduced baseline variability of less than 5 beats/minute with a normal baseline fetal heart rate and no variable or late decelerations:
    - start conservative measures (see recommendation 132) if this persists for over 30 minutes and
    - offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) if it persists for over 90 minutes. [new 2014]
121. If there is reduced baseline variability of less than 5 beats/minute for over 30 minutes together with 1 or more of tachycardia (baseline fetal heart rate above 160 beats/minute), a baseline fetal heart rate below 100 beats/minute or variable or late decelerations:
    - start conservative measures (see recommendation 132) **and**
    - offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149). [new 2014]
122. When describing decelerations in fetal heart rate, specify:
    - the depth and duration of the individual decelerations
    - their timing in relation to the peaks of the contractions
    - whether or not the fetal heart rate returns to baseline
    - how long they have been present for
    - whether they occur with over 50% of contractions. [new 2014]
123. Describe decelerations as 'early', 'variable' or 'late'. Do not use the terms 'typical' and 'atypical' because they can cause confusion. [new 2014]
124. Take the following into account when assessing decelerations in fetal heart rate:
    - early decelerations are uncommon, benign and usually associated with head compression
    - early decelerations with no non-reassuring or abnormal features on the cardiotocograph trace should not prompt further action. [new 2014]

125. If variable decelerations are observed that begin with the onset of a contraction:
    - be aware that these are very common, can be a normal feature in an otherwise uncomplicated labour and birth, and are usually a result of cord compression
    - think about asking the woman to change position or mobilise. [new 2014]

126. Start conservative measures (see recommendation 132) if variable decelerations are observed with a normal baseline fetal heart rate and normal baseline variability that are:
    - dropping from baseline by 60 beats/minute or less and taking 60 seconds or less to recover
    - present for over 90 minutes
    - occurring with over 50% of contractions. [new 2014]

127. Start conservative measures (see recommendation 132) if variable decelerations are observed with a normal baseline fetal heart rate and normal baseline variability that are:
    - dropping from baseline by more than 60 beats/minute or taking over 60 seconds to recover,
    - present for up to 30 minutes
    - occurring with over 50% of contractions. [new 2014]

128. Offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) if non-reassuring variable decelerations (see recommendation 125 and 126) are:
    - still observed 30 minutes after starting conservative measures or
    - accompanied by tachycardia (baseline fetal heart rate above 160 beats/minute) and/or reduced baseline variability (less than 5 beats/minute) [new 2014]

129. If late decelerations (decelerations that start after a contraction and often have a slow return to baseline) are observed:
    - start conservative measures (see recommendation 132) if the late decelerations occur with over 50% of contractions
    - offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) and/or expedite the birth (see recommendations 220 to 223) if the late decelerations persist for over 30 minutes and occur with over 50% of contractions
    - take action sooner if the late decelerations are accompanied by an abnormal baseline fetal heart rate and/or reduced baseline variability. [new 2014]

130. Take into account that the longer, the later and the deeper the individual decelerations, the more likely the presence of fetal acidosis (particularly if the decelerations are accompanied by tachycardia and/or reduced baseline variability), and take action sooner than 30 minutes if there is concern about fetal wellbeing. [new 2014]

131. Take the following into account when assessing accelerations in fetal heart rate:

- the presence of fetal heart rate accelerations is generally a sign that the baby is healthy
- the absence of accelerations in an otherwise normal cardiotocograph trace does not indicate acidosis. [new 2014]

132. If there are any concerns about the baby's wellbeing, think about the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s):
    - encourage the woman to mobilise or adopt a left-lateral position, and in particular to avoid being supine
    - offer oral or intravenous fluids
    - offer paracetamol if the woman has a raised temperature
    - reduce contraction frequency by:
        - stopping oxytocin if it is being used (the consultant obstetrician should decide whether and when to restart oxytocin) **and/or**
        - offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg). **[new 2014]**
133. Inform the coordinating midwife and an obstetrician whenever conservative measures are implemented. [new 2014]
134. Do not use maternal facial oxygen therapy for intrauterine fetal resuscitation, because it may harm the baby (but it can be used where it is administered for maternal indications such as hypoxia or as part of preoxygenation before a potential anaesthetic). [new 2014]
135. If fetal scalp stimulation leads to an acceleration in fetal heart rate, regard this as a reassuring feature. Take this into account when reviewing the whole clinical picture (see recommendation 109). [new 2014]
136. Use the fetal heart rate response after fetal scalp stimulation during a vaginal examination to elicit information about fetal wellbeing if fetal blood sampling is unsuccessful or contraindicated. [new 2014]
137. When offering fetal blood sampling, explain the following to the woman:
    - Why the test is being advised.
    - The blood sample will be used to measure the level of acid in the baby's blood, to see how well the baby is coping with labour.
    - The procedure will require her to have a vaginal examination using a small device similar to a speculum.
    - A sample of blood will be taken from the baby's head by making a small scratch on the baby's scalp. This will heal quickly after birth, but there is a small risk of infection.
    - The procedure can help to reduce the need for further, more serious interventions.
    - What the different outcomes of the test may be (normal, borderline and abnormal) and the actions that will follow each result.

- There is a small chance that it will not be possible to obtain a blood sample (especially if the cervix is less than 4 cm dilated). If a sample cannot be obtained, a caesarean section or instrumental birth (forceps or ventouse) may be needed because otherwise it is not possible to find out how well the baby is coping. [new 2014]

138. Do not carry out fetal blood sampling if any contraindications are present, including risk of maternal-to-fetal transmission of infection or risk of fetal bleeding disorders. [new 2014]
139. Take fetal blood samples with the woman in the left-lateral position. [2014]
140. Measure either lactate or pH when performing fetal blood sampling. Measure lactate if the necessary equipment and suitably trained staff are available; otherwise measure pH. [new 2014]
141. Use the classification of fetal blood sample results shown in table 110. [new 2014]

Table 110: Classification of fetal blood sample results

Lactate (mmol/l)	pH	Interpretation
≤ 4.1	≥ 7.25	Normal
4.2–4.8	7.21–7.24	Borderline
≥ 4.9	≤ 7.20	Abnormal

142. Interpret fetal blood sample results taking into account any previous lactate or pH measurement, the rate of progress in labour and the clinical features of the woman and baby. [new 2014]
143. Inform the consultant obstetrician if any fetal blood sample result is abnormal. [new 2014]
144. Discuss with the consultant obstetrician if:
    - a fetal blood sample cannot be obtained **or**
    - a third fetal blood sample is thought to be needed. [new 2014]
145. If the fetal blood sample result is normal, offer repeat sampling no more than 1 hour later if this is still indicated by the cardiotocograph trace, or sooner if additional non-reassuring or abnormal features are seen. [2014]
146. If the fetal blood sample result is borderline, offer repeat sampling no more than 30 minutes later if this is still indicated by the cardiotocograph trace, or sooner if additional non-reassuring or abnormal features are seen. [2014]
147. Take into account the time needed to take a fetal blood sample when planning repeat sampling. [2014]
148. If the cardiotocograph trace remains unchanged and the fetal blood sample result is stable (that is, lactate or pH is unchanged) after a second test, further samples may be deferred unless additional non-reassuring or abnormal features are seen. [new 2014]
149. If a fetal blood sample is indicated and the sample cannot be obtained, but the associated scalp stimulation results in fetal heart rate accelerations, decide whether to continue the labour or expedite the

birth in light of the clinical circumstances and in discussion with the consultant obstetrician and the woman. [new 2014]

150. If a fetal blood sample is indicated but a sample cannot be obtained and there is no improvement in the cardiotocograph trace, advise the woman that the birth should be expedited (see recommendations 220 to 223). [new 2014]

151. Offer telemetry to any woman who needs continuous cardiotocography during labour. [new 2014]

152. To ensure accurate record keeping for cardiotocography:

- make sure that date and time clocks on the cardiotocograph monitor are set correctly
- label traces with the woman's name, date of birth and hospital number or NHS number, the date and the woman's pulse at the start of monitoring. [new 2014]

153. Individual units should develop a system for recording relevant intrapartum events (for example, vaginal examination, fetal blood sampling and siting of an epidural) in standard notes and/or on the cardiotocograph trace. [new 2014]

154. Keep cardiotocograph traces for 25 years and, if possible, store them electronically. [2007, amended 2014]

155. In cases where there is concern that the baby may experience developmental delay, photocopy cardiotocograph traces and store them indefinitely in case of possible adverse outcomes. [2007, amended 2014]

156. Ensure that tracer systems are available for all cardiotocograph traces if stored separately from the woman's records. [2007, amended 2014]

157. Develop tracer systems to ensure that cardiotocograph traces removed for any purpose (such as risk management or for teaching purposes) can always be located. [2007, amended 2014]

158. Do not offer or advise clinical intervention if labour is progressing normally and the woman and baby are well. [2007]

159. In all stages of labour, women who have left the normal care pathway because of the development of complications can return to it if/when the complication is resolved. [2007]

160. For the purposes of this guideline, use the following definitions of labour:

- Latent first stage of labour – a period of time, not necessarily continuous, when:
  - there are painful contractions **and**
  - there is some cervical change, including cervical effacement and dilatation up to 4 cm.
- Established first stage of labour – when:
  - there are regular painful contractions **and**
  - there is progressive cervical dilatation from 4 cm. **[2007]**

161. Inform women that, while the length of established first stage of labour varies between women:

- first labours last on average 8 hours and are unlikely to last over 18 hours
- second and subsequent labours last on average 5 hours and are unlikely to last over 12 hours. [2007]

162. Record the following observations during the first stage of labour:

- half-hourly documentation of frequency of contractions
- hourly pulse
- 4-hourly temperature and blood pressure
- frequency of passing urine
- offer a vaginal examination (see recommendation 45) 4-hourly or if there is concern about progress or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss). [2007]

If any of the indications for transfer are met (see recommendation 163), transfer the woman to obstetric-led care if she is at home or in a midwifery unit. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

163. Transfer the woman to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50) if any of the following are observed at any point, unless the risks of transfer outweigh the benefits:

- Observations of the woman:
  - pulse over 120 beats/minute on 2 occasions 30 minutes apart
  - a single reading of either raised diastolic blood pressure of 110 mmHg or more or raised systolic blood pressure of 160 mmHg or more
  - either raised diastolic blood pressure of 90 mmHg or more or raised systolic blood pressure of 140 mmHg or more on 2 consecutive readings taken 30 minutes apart
  - a reading of 2+ of protein on urinalysis and a single reading of either raised diastolic blood pressure (90 mmHg or more) or raised systolic blood pressure (140 mmHg or more)
  - temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive occasions 1 hour apart
  - any vaginal blood loss other than a show
  - the presence of significant meconium (see recommendation 164)
  - pain reported by the woman that differs from the pain normally associated with contractions
  - confirmed delay in the first or second stage of labour
  - request by the woman for additional pain relief using regional analgesia

- obstetric emergency – including antepartum haemorrhage, cord prolapse, postpartum haemorrhage, maternal seizure or collapse, or a need for advanced neonatal resuscitation
- retained placenta
- third-degree or fourth-degree tear or other complicated perineal trauma that needs suturing.

- Observations of the unborn baby:
- any abnormal presentation, including cord presentation
- transverse or oblique lie
- high (4/5-5/5 palpable) or free-floating head in a nulliparous woman
- suspected fetal growth restriction or macrosomia
- suspected anhydramnios or polyhydramnios
- fetal heart rate below 110 or above 160 beats/minute
- a deceleration in fetal heart rate heard on intermittent auscultation.

If none of these are observed, continue with midwifery-led care unless the woman requests transfer (see also recommendation 55) [new 2014]

164. As part of ongoing assessment, document the presence or absence of significant meconium. This is defined as dark green or black amniotic fluid that is thick or tenacious, or any meconium-stained amniotic fluid containing lumps of meconium. [new 2014]

165. If significant meconium is present, ensure that:

- healthcare professionals trained in fetal blood sampling are available during labour **and**
- healthcare professionals trained in advanced neonatal life support are readily available for the birth. [2014]

166. If significant meconium is present, transfer the woman to obstetric-led care provided that it is safe to do so and the birth is unlikely to occur before transfer is completed. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

167. Give ongoing consideration to the woman's emotional and psychological needs, including her desire for pain relief. [2007]

168. Encourage the woman to communicate her need for analgesia at any point during labour. [2007]

169. Do not routinely use verbal assessment using a numerical pain score. [2007]

170. Use a pictorial record of labour (partogram) once labour is established. [2007]

171. Where the partogram includes an action line, use the World Health Organization recommendation of a 4-hour action line.[i] [2007]

i Anonymous (1994) World Health Organization partograph in management of labour. World Health Organization Maternal Health and Safe Motherhood Programme. Lancet 343: 1399–404. See also the WHO Multicountry Survey on Maternal and Newborn Health.

172. Do not routinely offer the package known as active management of labour (one-to-one continuous support; strict definition of established labour; early routine amniotomy; routine 2-hourly vaginal examination; oxytocin if labour becomes slow). [2007]
173. In normally progressing labour, do not perform amniotomy routinely. [2007]
174. Do not use combined early amniotomy with use of oxytocin routinely. [2007]
175. If delay in the established first stage is suspected, take the following into account:
    - parity
    - cervical dilatation and rate of change
    - uterine contractions
    - station and position of presenting part
    - the woman's emotional state
    - referral to the appropriate healthcare professional.

    Offer the woman support, hydration, and appropriate and effective pain relief. [2007]
176. If delay in the established first stage is suspected, assess all aspects of progress in labour when diagnosing delay, including:
    - cervical dilatation of less than 2 cm in 4 hours for first labours
    - cervical dilatation of less than 2 cm in 4 hours or a slowing in the progress of labour for second or subsequent labours
    - descent and rotation of the baby's head
    - changes in the strength, duration and frequency of uterine contractions. [2007]

    If delay is diagnosed, transfer the woman to obstetric-led care. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]
177. If delay in the established first stage of labour is suspected, amniotomy should be considered for all women with intact membranes, after explanation of the procedure and advice that it will shorten her labour by about an hour and may increase the strength and pain of her contractions. [2007]
178. Whether or not a woman has agreed to an amniotomy, advise all women with suspected delay in the established first stage of labour to have a vaginal examination 2 hours later, and diagnose delay if progress is less than 1 cm. [2007]
179. For women with intact membranes in whom delay in the established first stage of labour is confirmed, advise the woman to have an amniotomy, and to have a repeat vaginal examination 2 hours later whether her membranes are ruptured or intact. [2007]
180. For all women with confirmed delay in the established first stage of labour:
    - transfer the woman to obstetric-led care for an obstetric review and a decision about management options, including the use of

oxytocin (follow the general principles for transfer of care described in recommendations 46 to 50) [new 2014]

- explain to her that using oxytocin after spontaneous or artificial rupture of the membranes will bring forward the time of birth but will not influence the mode of birth or other outcomes. [2007]

181. For a multiparous woman with confirmed delay in the established first stage of labour, an obstetrician should perform a full assessment, including abdominal palpation and vaginal examination, before a decision is made about using oxytocin. [2007]

182. Offer all women with delay in the established first stage of labour support and effective pain relief. [2007]

183. Inform the woman that oxytocin will increase the frequency and strength of her contractions and that its use will mean that her baby should be monitored continuously. Offer the woman an epidural before oxytocin is started. [2007]

184. If oxytocin is used, ensure that the time between increments of the dose is no more frequent than every 30 minutes. Increase oxytocin until there are 4–5 contractions in 10 minutes. (See also recommendation 101) [2007]

185. Advise the woman to have a vaginal examination 4 hours after starting oxytocin in established labour:

- If cervical dilatation has increased by less than 2 cm after 4 hours of oxytocin, further obstetric review is required to assess the need for caesarean section.
- If cervical dilatation has increased by 2 cm or more, advise 4-hourly vaginal examinations. [2007]

186. Do not offer amnioinfusion for intrauterine fetal resuscitation. [new 2014]

187. For the purposes of this guideline, use the following definitions of labour:

- Passive second stage of labour:
  - the finding of full dilatation of the cervix before or in the absence of involuntary expulsive contractions.
- Onset of the active second stage of labour:
  - the baby is visible
  - expulsive contractions with a finding of full dilatation of the cervix or other signs of full dilatation of the cervix
  - active maternal effort following confirmation of full dilatation of the cervix in the absence of expulsive contractions. **[2007]**

188. Carry out the following observations in the second stage of labour, record all observations on the partogram and assess whether transfer of care may be needed (see recommendation 163) [2007, amended 2014]:

- half-hourly documentation of the frequency of contractions [2007]
- hourly blood pressure and pulse [2007]

- continued 4-hourly temperature [2007]
- frequency of passing urine [2007]
- offer a vaginal examination (see recommendation 45) hourly in the active second stage, or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss) [2007]

In addition:

- Continue to take the woman's emotional and psychological needs into account. [2007]
- Assess progress, which should include the woman's behaviour, the effectiveness of pushing and the baby's wellbeing, taking into account the baby's position and station at the onset of the second stage. These factors will assist in deciding the timing of further vaginal examination and any need for transfer to obstetric-led care. [2007, amended 2014]
- Perform intermittent auscultation of the fetal heart rate immediately after a contraction for at least 1 minute, at least every 5 minutes. Palpate the woman's pulse every 15 minutes to differentiate between the two heart rates. [2007, amended 2014]
- Ongoing consideration should be given to the woman's position, hydration, coping strategies and pain relief throughout the second stage. [2007]

189. Discourage the woman from lying supine or semi-supine in the second stage of labour and encourage her to adopt any other position that she finds most comfortable. [2007]

190. Inform the woman that in the second stage she should be guided by her own urge to push. [2007]

191. If pushing is ineffective or if requested by the woman, offer strategies to assist birth, such as support, change of position, emptying of the bladder and encouragement. [2007]

192. For a nulliparous woman:

- birth would be expected to take place within 3 hours of the start of the active second stage in most women
- diagnose delay in the active second stage when it has lasted 2 hours and refer the woman to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [2007]

193. For a multiparous woman:

- birth would be expected to take place within 2 hours of the start of the active second stage in most women
- diagnose delay in the active second stage when it has lasted 1 hour and refer the woman to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [2007]

194. If full dilatation of the cervix has been confirmed in a woman without regional analgesia, but she does not get an urge to push, carry out further assessment after 1 hour. [2007]
195. If there is delay in the second stage of labour, or if the woman is excessively distressed, support and sensitive encouragement and the woman's need for analgesia/anaesthesia are particularly important. [2007]
196. Consideration should be given to the use of oxytocin, with the offer of regional analgesia, for nulliparous women if contractions are inadequate at the onset of the second stage. [2007]
197. For a nulliparous woman, suspect delay if progress (in terms of rotation and/or descent of the presenting part) is inadequate after 1 hour of active second stage. Offer vaginal examination and then offer amniotomy if the membranes are intact. [2007, amended 2014]
198. For a multiparous woman, suspect delay if progress (in terms of rotation and/or descent of the presenting part) is inadequate after 30 minutes of active second stage. Offer vaginal examination and then offer amniotomy if the membranes are intact. [new 2014]
199. An obstetrician should assess a woman with confirmed delay in the second stage (after transfer to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50) before contemplating the use of oxytocin. [new 2014]
200. After initial obstetric assessment of a woman with delay in the second stage, maintain ongoing obstetric review every 15–30 minutes. [2007]
201. Think about offering instrumental birth if there is concern about the baby's wellbeing or there is a prolonged second stage. [2007]
202. Recognise that, on rare occasions, the woman's need for help in the second stage may be an indication to assist by offering instrumental birth when supportive care has not helped. [2007]
203. The choice of instrument depends on a balance of clinical circumstance and practitioner experience. [2007]
204. Because instrumental birth is an operative procedure, advise the woman to have tested effective anaesthesia. [2007]
205. If a woman declines anaesthesia, offer a pudendal block combined with local anaesthetic to the perineum during instrumental birth. [2007]
206. If there is concern about fetal compromise, offer either tested effective anaesthesia or, if time does not allow this, a pudendal block combined with local anaesthetic to the perineum during instrumental birth. [2007]
207. Advise the woman to have a caesarean section if vaginal birth is not possible.[j] [2007]
208. Do not perform perineal massage in the second stage of labour. [2007]
209. Either the 'hands on' (guarding the perineum and flexing the baby's head) or the 'hands poised' (with hands off the perineum and baby's head but in readiness) technique can be used to facilitate spontaneous birth. [2007]

j See Caesarean section (NICE clinical guideline 132).

210. Do not offer lidocaine spray to reduce pain in the second stage of labour. [2007]
211. Do not carry out a routine episiotomy during spontaneous vaginal birth. [2007]
212. If an episiotomy is performed, the recommended technique is a mediolateral episiotomy originating at the vaginal fourchette and usually directed to the right side. The angle to the vertical axis should be between 45 and 60 degrees at the time of the episiotomy. [2007]
213. Perform an episiotomy if there is a clinical need, such as instrumental birth or suspected fetal compromise. [2007]
214. Provide tested effective analgesia before carrying out an episiotomy, except in an emergency because of acute fetal compromise. [2007]
215. Inform any woman with a history of severe perineal trauma that her risk of repeat severe perineal trauma is not increased in a subsequent birth, compared with women having their first baby. [2007]
216. Do not offer episiotomy routinely at vaginal birth after previous third- or fourth-degree trauma. [2007]
217. In order for a woman who has had previous third- or fourth-degree trauma to make an informed choice, talk with her about the future mode of birth, encompassing:
    - current urgency or incontinence symptoms
    - the degree of previous trauma
    - risk of recurrence
    - the success of the repair undertaken
    - the psychological effect of the previous trauma
    - management of her labour. [2007]
218. Inform any woman with infibulated genital mutilation of the risks of difficulty with vaginal examination, catheterisation and application of fetal scalp electrodes. Inform her of the risks of delay in the second stage and spontaneous laceration together with the need for an anterior episiotomy and the possible need for defibulation in labour. [2007]
219. Inform women that there is insufficient high-quality evidence to either support or discourage giving birth in water. [2007]
220. If the birth needs to be expedited for maternal or fetal reasons, assess both the risk to the baby and the safety of the woman. Assessments should include:
    - the degree of urgency
    - clinical findings on abdominal and vaginal examination
    - choice of mode of birth (and whether to use forceps or ventouse if an instrumental birth is indicated)
    - anticipated degree of difficulty, including the likelihood of success if instrumental birth is attempted
    - location
    - any time that may be needed for transfer to obstetric-led care
    - the need for additional analgesia or anaesthesia

- the woman's preferences. [new 2014]

221. Talk with the woman and her birth companion(s) about why the birth needs to be expedited and what the options are. [new 2014]

222. Inform the team about the degree of urgency. [new 2014]

223. Record the time at which the decision to expedite the birth is made. [new 2014]

224. Recognise that the time immediately after the birth is when the woman and her birth companion(s) are meeting and getting to know the baby. Ensure that any care or interventions are sensitive to this and minimise separation or disruption of the mother and baby. [new 2014]

225. For the purposes of this guideline, use the following definitions:

- The third stage of labour is the time from the birth of the baby to the expulsion of the placenta and membranes.
- Active management of the third stage involves a package of care comprising the following components:
  - routine use of uterotonic drugs
  - deferred clamping and cutting of the cord
  - controlled cord traction after signs of separation of the placenta.
- Physiological management of the third stage involves a package of care that includes the following components:
  - no routine use of uterotonic drugs
  - no clamping of the cord until pulsation has stopped
  - delivery of the placenta by maternal effort. **[new 2014]**

226. Diagnose a prolonged third stage of labour if it is not completed within 30 minutes of the birth with active management or within 60 minutes of the birth with physiological management. Follow recommendations 244 to 251 on managing a retained placenta. [new 2014]

227. Record the following observations for a woman in the third stage of labour:

- her general physical condition, as shown by her colour, respiration and her own report of how she feels
- vaginal blood loss. [new 2014]

228. If there is postpartum haemorrhage, a retained placenta or maternal collapse, or any other concerns about the woman's wellbeing:

- transfer her to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50)
- carry out frequent observations to assess whether resuscitation is needed. [new 2014]

229. Explain to the woman antenatally about what to expect with each package of care for managing the third stage of labour and the benefits and risks associated with each. [new 2014]

230. Explain to the woman that active management:

- shortens the third stage compared with physiological management

- is associated with nausea and vomiting in about 100 in 1000 women
- is associated with an approximate risk of 13 in 1000 of a haemorrhage of more than 1 litre
- is associated with an approximate risk of 14 in 1000 of a blood transfusion. [new 2014]

231. Explain to the woman that physiological management:
    - is associated with nausea and vomiting in about 50 in 1000 women
    - is associated with an approximate risk of 29 in 1000 of a haemorrhage of more than 1 litre
    - is associated with an approximate risk of 40 in 1000 of a blood transfusion. [new 2014]
232. Discuss again with the woman at the initial assessment in labour (see recommendations 41 to 45 and 51 to 58) about the different options for managing the third stage and ways of supporting her during delivery of the placenta, and ask if she has any preferences. [new 2014]
233. Advise the woman to have active management of the third stage, because it is associated with a lower risk of a postpartum haemorrhage and/or blood transfusion. [new 2014]
234. If a woman at low risk of postpartum haemorrhage requests physiological management of the third stage, support her in her choice. [2014]
235. Document in the records the decision that is agreed with the woman about management of the third stage [new 2014].
236. For active management, administer 10 IU of oxytocin by intramuscular injection with the birth of the anterior shoulder or immediately after the birth of the baby and before the cord is clamped and cut. Use oxytocin as it is associated with fewer side effects than oxytocin plus ergometrine. [new 2014]
237. After administering oxytocin, clamp and cut the cord:
    - Do not clamp the cord earlier than 1 minute from the birth of the baby unless there is concern about the integrity of the cord or the baby has a heartbeat below 60 beats/minute that is not getting faster.
    - Clamp the cord before 5 minutes in order to perform controlled cord traction as part of active management.
    - If the woman requests that the cord is clamped and cut later than 5 minutes, support her in her choice. [new 2014]
238. After cutting the cord, use controlled cord traction. [new 2014]
239. Perform controlled cord traction as part of active management only after administration of oxytocin and signs of separation of the placenta. [new 2014]
240. Record the timing of cord clamping in both active and physiological management. [new 2014]
241. Advise a change from physiological management to active management if either of the following occur:

- haemorrhage
- the placenta is not delivered within 1 hour of the birth of the baby. [new 2014]

242. Offer a change from physiological management to active management if the woman wants to shorten the third stage. [new 2014]
243. Do not use either umbilical oxytocin infusion or prostaglandin routinely in the third stage of labour. [2014]
244. Secure intravenous access if the placenta is retained, and explain to the woman why this is needed. [new 2014]
245. Do not use umbilical vein agents if the placenta is retained. [new 2014]
246. Do not use intravenous oxytocic agents routinely to deliver a retained placenta. [new 2014]
247. Give intravenous oxytocic agents if the placenta is retained and the woman is bleeding excessively. [new 2014]
248. If the placenta is retained and there is concern about the woman's condition:
    - offer a vaginal examination to assess the need to undertake manual removal of the placenta
    - explain that this assessment can be painful and advise her to have analgesia. [new 2014]
249. If the woman reports inadequate analgesia during the assessment, stop the examination and address this immediately. [2014]
250. If uterine exploration is necessary and the woman is not already in an obstetric unit, arrange urgent transfer (following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]
251. Do not carry out uterine exploration or manual removal of the placenta without an anaesthetic. [new 2014]
252. Advise women with risk factors for postpartum haemorrhage to give birth in an obstetric unit, where more emergency treatment options are available.
    - Antenatal risk factors:
        - previous retained placenta or postpartum haemorrhage
        - maternal haemoglobin level below 85 g/litre at onset of labour
        - BMI greater than 35 kg/m^2
        - grand multiparity (parity 4 or more)
        - antepartum haemorrhage
        - overdistention of the uterus (for example, multiple pregnancy, polyhydramnios or macrosomia)
        - existing uterine abnormalities
        - low-lying placenta
        - maternal age of 35 years or older.
    - Risk factors in labour:
        - induction
        - prolonged first, second or third stage of labour

- oxytocin use
- precipitate labour
- operative birth or caesarean section. **[2007]**

253. If a woman has risk factors for postpartum haemorrhage, highlight these in her notes, and make and discuss with her a care plan covering the third stage of labour. [2007]

254. If a woman has a postpartum haemorrhage:

- call for help
- give immediate clinical treatment:
- emptying of the bladder **and**
- uterine massage **and**
- uterotonic drugs **and**
- intravenous fluids **and**
- controlled cord traction if the placenta has not yet been delivered
- continuously assess blood loss and the woman's condition, and identify the source of the bleeding
- give supplementary oxygen
- arrange for transfer of the woman to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]

255. Administer a bolus of one of the following as first-line treatment for postpartum haemorrhage:

- oxytocin (10 IU intravenous) **or**
- ergometrine (0.5 mg intramuscular) **or**
- combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular). [new 2014]

256. Offer second-line treatment for postpartum haemorrhage if needed. No particular uterotonic drug can be recommended over any other; options include:

- repeat bolus of:
- oxytocin (intravenous)
- ergometrine (intramuscular, or cautiously intravenously)
- combined oxytocin and ergometrine (intramuscular)
- misoprostol
- oxytocin infusion
- carboprost (intramuscular). [new 2014]

257. Assess the need for adjuvant options for managing significant continuing postpartum haemorrhage, including:

- tranexamic acid (intravenous)
- rarely, in the presence of otherwise normal clotting factors, rFactor VIIa, in consultation with a haematologist. [new 2014]

258. Allocate a member of the healthcare team to stay with the woman and her birth companion(s), explain what is happening, answer

any questions and offer support throughout the emergency situation. [new 2014]

259. If the haemorrhage continues:

- perform examination under anaesthetic
- ensure that the uterus is empty and repair any trauma
- consider balloon tamponade before surgical options. [new 2014]

260. Be aware that no particular surgical procedure can be recommended over any other for treating postpartum haemorrhage. [new 2014]

261. The maternity service and ambulance service should have strategies in place in order to respond quickly and appropriately if a woman has a postpartum haemorrhage in any setting. [new 2014]

262. In the first minutes after birth, evaluate the condition of the baby – specifically respiration, heart rate and tone – in order to determine whether resuscitation is needed according to nationally accredited guidelines on neonatal resuscitation. [new 2014]

263. All relevant healthcare professionals caring for women during birth should attend annually a course in neonatal resuscitation that is consistent with nationally accredited guidelines on neonatal resuscitation. [new 2014]

264. In all birth settings:

- bear in mind that it will be necessary to call for help if the baby needs resuscitation, and plan accordingly
- ensure that there are facilities for resuscitation, and for transferring the baby to another location if necessary
- develop emergency referral pathways for both the woman and the baby, and implement these if necessary. [new 2014]

265. If a newborn baby needs basic resuscitation, start with air. [2014]

266. Minimise separation of the baby and mother, taking into account the clinical circumstances. [new 2014]

267. Throughout an emergency situation in which the baby needs resuscitation, allocate a member of the healthcare team to talk with, and offer support to, the woman and any birth companion(s). [new 2014]

268. Record the time from birth to the onset of regular respirations. [new 2014]

269. If the baby is born in poor condition (on the basis of abnormal breathing, heart rate or tone):

- follow recommendations 262 to 267 on neonatal resuscitation **and**
- take paired cord-blood samples for blood gas analysis, after clamping the cord using 2 clamps.

Continue to evaluate and record the baby's condition until it is improved and stable. [new 2014]

270. Do not take paired cord blood samples (for blood gas analysis) routinely. [new 2014]

271. Ensure that a second clamp to allow double-clamping of the cord is available in all birth settings. [2014]

272. In the presence of any degree of meconium:

- do not suction the baby's upper airways (nasopharynx and oropharynx) before birth of the shoulders and trunk
- do not suction the baby's upper airways (nasopharynx and oropharynx) if the baby has normal respiration, heart rate and tone
- do not intubate if the baby has normal respiration, heart rate and tone. [new 2014]

273. If there has been significant meconium (see recommendation 164) and the baby does not have normal respiration, heart rate and tone, follow nationally accredited guidelines on neonatal resuscitation, including early laryngoscopy and suction under direct vision. [new 2014]

274. If there has been significant meconium and the baby is healthy, closely observe the baby within a unit with immediate access to a neonatologist. Perform these observations at 1 and 2 hours of age and then 2-hourly until 12 hours of age. [new 2014]

275. If there has been non-significant meconium, observe the baby at 1 and 2 hours of age in all birth settings. [new 2014]

276. If any of the following are observed after any degree of meconium, ask a neonatologist to assess the baby (transfer both the woman and baby if they are at home or in a freestanding midwifery unit, following the general principles for transfer of care described in recommendations 46 to 50):

- respiratory rate above 60 per minute
- the presence of grunting
- heart rate below 100 or above 160 beats/minute
- capillary refill time above 3 seconds
- body temperature of 38°C or above, or 37.5°C on 2 occasions 30 minutes apart
- oxygen saturation below 95% (measuring oxygen saturation is optional after non-significant meconium)
- presence of central cyanosis, confirmed by pulse oximetry if available. [new 2014]

277. Explain the findings to the woman, and inform her about what to look out for and who to talk to if she has any concerns. [new 2014]

278. Closely observe any baby born to a woman with prelabour rupture of the membranes (more than 24 hours before the onset of established labour) at term for the first 12 hours of life (at 1 hour, 2 hours, 6 hours and 12 hours) in all settings. Include assessment of:

- temperature
- heart rate
- respiratory rate
- presence of respiratory grunting

- significant subcostal recession
- presence of nasal flare
- presence of central cyanosis, confirmed by pulse oximetry if available
- skin perfusion assessed by capillary refill
- floppiness, general wellbeing and feeding.

If any of these are observed, ask a neonatologist to assess the baby (transfer both the woman and baby if they are at home or in a freestanding midwifery unit, following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]

279. If there are no signs of infection in the woman, do not give antibiotics to either the woman or the baby, even if the membranes have been ruptured for over 24 hours. [2007]
280. If there is evidence of infection in the woman, prescribe a full course of broad-spectrum intravenous antibiotics. [2007]
281. Advise women with prelabour rupture of the membranes to inform their healthcare professionals immediately of any concerns they have about their baby's wellbeing in the first 5 days after birth, particularly in the first 12 hours when the risk of infection is greatest. [2007]
282. Do not perform blood, cerebrospinal fluid and/or surface culture tests in an asymptomatic baby. [2007]
283. Refer a baby with any symptom of possible sepsis, or born to a woman who has evidence of chorioamnionitis, to a neonatal care specialist immediately. [2007]
284. Record the Apgar score routinely at 1 and 5 minutes for all births. [2007]
285. Encourage women to have skin-to-skin contact with their babies as soon as possible after the birth.[k] [2007]
286. In order to keep the baby warm, dry and cover him or her with a warm, dry blanket or towel while maintaining skin-to-skin contact with the woman. [2007]
287. Avoid separation of a woman and her baby within the first hour of the birth for routine postnatal procedures, for example, weighing, measuring and bathing, unless these measures are requested by the woman, or are necessary for the immediate care of the baby.[j] [2007]
288. Encourage initiation of breastfeeding as soon as possible after the birth, ideally within 1 hour.[j] [2007]
289. Record head circumference, body temperature and birth weight soon after the first hour following birth. [2007]
290. Undertake an initial examination to detect any major physical abnormality and to identify any problems that require referral. [2007]
291. Ensure that any examination or treatment of the baby is undertaken with the consent of the parents and either in their presence or, if this is not possible, with their knowledge. [2007]

k Recommendations relating to immediate postnatal care (within 2 hours of birth) have been adapted from Routine postnatal care of women and their babies (NICE clinical guideline 37). Please see NICE clinical guideline 37 for further guidance on care after birth.

292. Carry out the following observations of the woman after birth:

- Record her temperature, pulse and blood pressure. Transfer the woman (with her baby) to obstetric-led care if any of the relevant indications listed in recommendation 164 are met.
- Uterine contraction and lochia.
- Examine the placenta and membranes: assess their condition, structure, cord vessels and completeness. Transfer the woman (with her baby) to obstetric-led care if the placenta is incomplete.
- Early assessment of the woman's emotional and psychological condition in response to labour and birth.
- Successful voiding of the bladder. Assess whether to transfer the woman (with her baby) to obstetric-led care after 6 hours if her bladder is palpable and she is unable to pass urine.

If transferring the woman to obstetric-led care, follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

293. Define perineal or genital trauma caused by either tearing or episiotomy as follows:

- first degree – injury to skin only
- second degree – injury to the perineal muscles but not the anal sphincter
- third degree – injury to the perineum involving the anal sphincter complex:
  - 3a – less than 50% of external anal sphincter thickness torn
  - 3b – more than 50% of external anal sphincter thickness torn
  - 3c – internal anal sphincter torn.
- fourth degree – injury to the perineum involving the anal sphincter complex (external and internal anal sphincter) and anal epithelium. [2007]

294. Before assessing for genital trauma:

- explain to the woman what is planned and why
- offer inhalational analgesia
- ensure good lighting
- position the woman so that she is comfortable and so that the genital structures can be seen clearly. [2007]

295. Perform the initial examination gently and with sensitivity. It may be done in the immediate period after birth. [2007]

296. If genital trauma is identified after birth, offer further systematic assessment, including a rectal examination. [2007]

297. Include the following in a systematic assessment of genital trauma:

- further explanation of what is planned and why
- confirmation by the woman that tested effective local or regional analgesia is in place

- visual assessment of the extent of perineal trauma to include the structures involved, the apex of the injury and assessment of bleeding
- a rectal examination to assess whether there has been any damage to the external or internal anal sphincter if there is any suspicion that the perineal muscles are damaged. [2007]

298. Ensure that the timing of this systematic assessment does not interfere with mother–baby bonding unless the woman has bleeding that requires urgent attention. [2007]

299. Assist the woman to adopt a position that allows adequate visual assessment of the degree of trauma and for repair. Only maintain this position for as long as necessary for systematic assessment and repair. If it is not possible to adequately assess the trauma, transfer the woman (with her baby) to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50. [2007, amended 2014]

300. Seek advice from a more experienced midwife or obstetrician if there is uncertainty about the nature or extent of the trauma. Transfer the woman (with her baby) to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50) if the repair needs further surgical or anaesthetic expertise. [2007, amended 2014]

301. Document the systematic assessment and its results fully, possibly pictorially. [2007]

302. All relevant healthcare professionals should attend training in perineal/genital assessment and repair, and ensure that they maintain these skills. [2007]

303. Advise the woman that in the case of first-degree trauma, the wound should be sutured in order to improve healing, unless the skin edges are well opposed. [2007]

304. Advise the woman that in the case of second-degree trauma, the muscle should be sutured in order to improve healing. [2007]

305. Undertake repair of the perineum as soon as possible to minimise the risk of infection and blood loss. [2007]

306. When carrying out perineal repair:

- ensure that tested effective analgesia is in place, using infiltration with up to 20 ml of 1% lidocaine or equivalent
- top up the epidural or insert a spinal anaesthetic if necessary. [2007]

307. If the woman reports inadequate pain relief at any point, address this immediately. [2007]

308. If the skin is opposed after suturing of the muscle in second-degree trauma, there is no need to suture it. [2007]

309. If the skin does require suturing, use a continuous subcuticular technique. [2007]

310. Undertake perineal repair using a continuous non-locked suturing technique for the vaginal wall and muscle layer. [2007]

311. Use an absorbable synthetic suture material to suture the perineum. [2007]

312. Observe the following basic principles when performing perineal repairs:

- Repair perineal trauma using aseptic techniques.
- Check equipment and count swabs and needles before and after the procedure.
- Good lighting is essential to see and identify the structures involved.
- Ensure that difficult trauma is repaired by an experienced practitioner in theatre under regional or general anaesthesia.
- Insert an indwelling catheter for 24 hours to prevent urinary retention.
- Ensure that good anatomical alignment of the wound is achieved and that consideration is given to the cosmetic results.
- Carry out rectal examination after completing the repair to ensure that suture material has not been accidentally inserted through the rectal mucosa.
- After completion of the repair, document an accurate detailed account covering the extent of the trauma, the method of repair and the materials used.
- Give the woman information about the extent of the trauma, pain relief, diet, hygiene and the importance of pelvic-floor exercises. [2007]

313. Offer rectal non-steroidal anti-inflammatory drugs routinely after perineal repair of first- and second-degree trauma provided these drugs are not contraindicated. [2007]

Key research recommendations

How does the provision of accurate, evidence-based information affect women's decision-making processes and choice of place of birth? [1]

Why this is important

A report by Coxon et al. (2013) identifies in detail why women make choices about where give birth and how these choices can be influenced. Influences may include written and verbal information (both online and from midwives and doctors), previous experience, and word-of-mouth advice from friends and family. The GDG concluded from the Birthplace study that giving birth outside an obstetric unit is the optimal choice for low-risk women. This finding should be used to restructure the way in which information is provided, so that it is presented in a more accurate, less risk-based way in order to support women's choices. This change should be evaluated in a quantitative observational study and/or qualitative study that records any changes in women's choice-making about place of birth. Outcomes include understanding why and how women make choices about where to give birth and how this can influence the provision of appropriate and accessible information, a measure of informed decision-making, and fearfulness and absence of fearfulness when choosing place of birth.

What are the long term consequences for women and babies of planning birth in different settings? [2]

Why this is important

The long-term consequences of birth experiences and birth outcomes are poorly understood, particularly in relation to place of birth. A large population-based observational study would compare women's experiences and outcomes in different birth settings (with subgroup analysis by mode of birth) in relation to the wellbeing of the women and their children over different periods of time (for example, 2, 5, 10, 15, 20 and 30 years). A secondary analysis could compare different providers where birth philosophies are different. Outcomes would be compared by accessing medical records and through qualitative interviews. Primary outcomes are long-term physical morbidity, pain after birth, readmission to hospital, infection, psychological morbidity (for example, postnatal depression, bonding, relationship breakdown with partner, fear of giving birth in future) and breastfeeding rates. Secondary outcomes are impact on attachment between mother and child, obesity in children, autoimmune disease, chronic illness, educational achievement and family functioning.

Update 2014

Does enhanced education specifically about the latent first stage of labour increase the number of nulliparous women who wait until they are in established labour before attending the obstetric or midwifery unit (or calling the midwife to a home birth), compared with women who do not receive this education? [10]

Why this is important

Studies show that antenatal education about labour and birth in general makes a difference to some birth outcomes, but there is limited evidence focusing on education about the latent first stage of labour specifically. The aim of this study (randomised controlled trial or prospective observational study) would be to compare 2 groups of women experiencing their first labour and birth: a group who receive an education session in late pregnancy covering what to expect in the latent first stage of labour and how to recognise the onset of established labour, and a group who have not received this focused education. Primary outcomes would be mode of birth, satisfaction with the birth experience and the woman's physical and emotional wellbeing after birth. Secondary outcomes would be use of pharmacological pain relief, use of

oxytocin to augment labour, and time from first contact in confirmed established labour to birth.

What are the natural frequencies of the avoidable harms that cardiotocography is intended to prevent for women who are assessed as being at low risk of complications at the start of labour? Does using cardiotocography in labours where complications develop confer a net benefit compared with intermittent auscultation? [16]

Why this is important

Cardiotocography is used in current practice to monitor the fetal heart rate when there is a concern that fetal hypoxia may develop. It is regarded as unethical, in most circumstances, to conduct clinical research where women whose labour is categorised as 'high risk' are not offered cardiotocography. There is therefore no high-quality evidence about the size of the benefit or harm derived from the use of cardiotocography compared with intermittent auscultation, either in individual cases or across a whole population. Further analysis is needed to evaluate the actual (or probable) benefits and harms associated with this screening test. This would be based on analysis and modelling using data and assumptions derived from existing evidence from a range of countries, comprising data from any studies and/or historic data sets that record the natural frequencies of avoidable damage caused by intrapartum events. These data could then be used to ascertain both the natural frequencies of adverse events and whether widespread use of cardiotocography reduces these. Primary outcomes would be intrapartum fetal death, neonatal encephalopathy, cerebral palsy or other significant neurodevelopmental injury, and maternal morbidity. Other outcomes might include long-term physical and psychological outcomes (health across whole of life), health and social care costs, implications for informed decision-making, and analysis of ethical considerations.

Update 2014

What is the most effective treatment of primary postpartum haemorrhage? [27]

Why this is important

There is uncertainty about the most effective drug treatments and dosage regimes, and about which other treatments should be used, for women who develop a postpartum haemorrhage. The most effective sequencing of interventions is also uncertain. The psychological impact of postpartum haemorrhage for women can be significant, and identifying the approach that minimises this impact is important. Randomised controlled trials comparing different dosage regimes for oxytocin and misprostol, as well as comparisons with ergometrine and carboprost, are needed. Trials of mechanical measures such as intrauterine balloons or interventional radiology as early second-line treatment (rather than an alternative drug treatment) are also needed. Alternatively, a trial comparing the effectiveness of a complex intervention (for example, an educational component, sequence of interventions, immediate feedback and quality improvements) compared with standard care could be undertaken. Important outcomes include blood and blood product transfusion, need for further intervention, need for hysterectomy and psychological outcomes for the woman

Place of birth

Introduction

Before 1945, the majority of births took place at home. The Cranbrook Report of 1959 stated that hospital maternity services were to provide for 70% of births, and in the 1960s hospitalisation of birth accelerated so that by 1970 nearly 90% of births occurred within hospitals.[19,20] The Peel report in 1970 stated that facilities should be provided for all women to give birth in hospital, based largely on findings from the Reports of the Confidential Enquiry into Maternal Deaths, and this led rapidly to over 95% of women giving birth in a hospital setting.[21] This provision of care was challenged and a number of initiatives culminated in the publication of the document Changing Childbirth in 1993 which recommended that women should have more choice in their place of birth, and that more choices should be available.[22] The National Service Framework (NSF) for Children, Young People and Maternity Services in 2004 and Maternity Matters in 2007[25] both actively promoted midwife-led care for women, following appropriate assessment, and recommended that healthcare providers should develop midwife and home birth services to meet the needs of local populations.[23,24] None of these initiatives were supported by strong evidence regarding safety of place of birth.

The configuration and choice of services are evolving, but more than 90% of births still take place in designated consultant wards (obstetric units) or combined consultant/GP wards.[25] This figure is taken from the Maternity Hospital Episode Statistics but the categories used do not reflect current changes in practice. Also, local variation in the availability of different birth settings will affect women's options for choosing their preferred place of birth.

This section was prioritised for update following the publication of a large observational study conducted in England – Birthplace (2011) – which sought to answer the questions posed in a key research recommendation from the original Intrapartum care guideline. This study, plus a number of additional studies, have been incorporated into this update of the evidence, highlighting the continuing importance of women's choice in relation to this central component of intrapartum care.

Update 2014

Benefits and risks associated with each planned place of birth

Review question

What are the maternal and neonatal outcomes associated with planning birth in each of the following settings:

- home (domiciliary)
- freestanding midwifery unit
- alongside midwifery unit
- obstetric unit/hospital-based maternity unit.

For further details on the evidence review protocol, please see appendix E.

General points to note

The included studies report their outcomes in slightly different ways, so in some cases it was necessary to combine them in order to facilitate analysis. This occurs most commonly for the following outcomes:

- Instrumental vaginal birth: where ventouse and forceps have been reported as two outcomes, these have been pooled because many studies do not report them separately.
- Caesarean section: in some of the studies evaluating booked place of birth, there are a small proportion of elective caesarean sections as well as emergency caesarean sections.
- Vaginal and perineal tears: due to the variation in how this is reported, these have been classified as any tears or third/fourth degree tears.

Full details of the individual outcomes reported in the studies can be found in the evidence tables (appendix I).
One study (Birthplace in England Collaborative Group, 2011) is included in all of the systematic reviews for this question. The following details should be noted about this study:

- The above reference constitutes the main published paper for the study, but there are also further details noted in a more comprehensive report (Hollowell et al., 2011). This report was primarily used as a source of data for the outcome of maternal mortality (which was not reported elsewhere), for results of a subgroup analysis based on parity (multiparous and nulliparous) and for some details about reasons for transfer. Where it has been used as a source of data, this has been noted in the evidence tables.
- For its primary outcome, Birthplace in England Collaborative Group, 2011, reports a post-hoc sub-group analysis, planned after data collection but before full analysis, for women without complicating conditions at the onset of labour, and this is reported in the evidence profiles in this document. For the remaining outcomes, the subgroup analysis was reported in the appendices of Hollowell et al. (2011) and the authors reported that the findings for women without complicating conditions at the start of care in labour were consistent with those for the whole study population.

Home compared with freestanding midwifery unit

Description of included studies

Two studies (reported in 3 publications) were included in this review (Birthplace in England Collaborative Group, 2011; Davis et al., 2011 and 2012).
One of the included studies was a prospective cohort study from England (Birthplace in England Collaborative Group, 2011). The second was a retrospective cohort study from New Zealand (Davis et al., 2011 and 2012).
Both studies compared planned birth at home with planned birth at a freestanding midwifery unit, and analysed data on an intention-to-treat basis, so that women were analysed by their planned place of birth even if they were transferred. Both studies evaluated intended place of birth at the onset of labour.
These studies were not pooled as they were observational data.
A summary of points to note about the study populations can be found in table 6 below, and further details about the selection of the study groups are reported in the evidence tables (appendix I).

Table 6: Summary of included studies for planned birth at home compared with planned birth in a freestanding midwifery unit

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate	New to update?
Birthplace in England Collaborative Group, 2011	Prospective cohort study	Intended place of birth at start of care in labour	Home: 5.4% women had complicating conditions at start of care in labour 27.2% were nulliparous Freestanding midwifery unit: 5.5% women had complicating conditions at start of care in labour 46% were nulliparous	**Home birth group** Transfer rate: 21.0% (Before birth: 14.2% After birth: 6.2% Time of transfer missing: 0.6%) Transfer rate nulliparous – 45% (79.8% before birth) Transfer rate multiparous – 12% (55% before birth) **Freestanding midwifery unit group** Transfer rate: 21.9% (Before birth: 16.5% After birth: 4.8% Time of transfer missing: 0.5%) Transfer rate nulliparous – 36.3% (83.4% before birth) Transfer rate multiparous – 9.4% (57.4% before birth)	Yes
Davis et al., 2011 and 2012	Retrospective cohort study	Intended place of birth at onset of labour	None	Planned and actual place of birth was home: 82.7% Planned and actual place of birth was midwifery unit: 90.2%	Yes

Update 2014

Evidence profile

All risk ratios were calculated as standard using RevMan, but where the authors have reported adjusted measures of effect these have also been reported in the table. For measures of perinatal/neonatal mortality and morbidity, due to the low incidence absolute effects have been reported per 1,000,000.

Table 7: Summary GRADE profile for comparison of planned birth at home with planned birth in a freestanding midwifery unit for all women

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/16840 (0%)	0/11282 (0%)	not calculable (NC)	NC	Very low
Mode of birth: spontaneous vaginal birth[a]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	15590/16825 (92.7%)	10150/11280 (90%)	RR 1.03 (1.02 to 1.04)	27 more per 1000 (from 18 more to 36 more)	Very low
1 study (Davis et al., 2011)	observational study	1743/1826 (95.5%)	2722/2873 (94.7%)	RR 1.01 (0.99 to 1.02)	9 more per 1000 (from 9 fewer to 19 more)	Very low
Mode of birth: instrumental vaginal birth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	714/16825 (4.2%)	686/11280 (6.1%)	RR 0.7 (0.63 to 0.77)	18 fewer per 1000 (from 14 fewer to 23 fewer)	Very low
1 study (Davis et al., 2011)	observational study	36/1826 (2%)	58/2873 (2%)	RR 0.98 (0.65 to 1.47)	0 fewer per 1000	Low

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
				Adjusted RR Vacuum extraction 0.99 (0.56 to 1.74)[b] Forceps 1.11 (0.59 to 2.13)[b]	(from 7 fewer to 9 more)	
Mode of birth: caesarean section						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	458/16825 (2.7%)	405/11280 (3.6%)	RR 0.76 (0.66 to 0.86)	9 fewer per 1000 (from 5 fewer to 12 fewer)	Very low
1 study (Davis et al., 2011)	observational study	47/1826 (2.6%)	91/2873 (3.2%)	RR 0.81 (0.57 to 1.15) Adjusted RR 0.86 (0.60 to 1.24)[b]	6 fewer per 1000 (from 14 fewer to 5 more)	Low
Use of epidural						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1418/16799 (8.4%)	1251/11251 (11.1%)	RR 0.76 (0.71 to 0.82)	27 fewer per 1000 (from 20 fewer to 32 fewer)	Very low
Measures of blood loss: major postpartum haemorrhage (over 1000 ml)						
1 study (Davis et al., 2012)	observational study	19/1830 (1.0%)	32/2904 (1.1%)	RR 0.93 (0.53 to 1.65) Adjusted RR 0.93 (0.49 to 1.74)[b]	2 fewer per 1000 (from 17 fewer to 24 more)	Very low

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Measures of blood loss: need for a blood transfusion						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	101/16687 (0.61%)	67/11230 (0.6%)	RR 1.01 (0.75 to 1.38)	0 more per 1000 (from 1 fewer to 2 more)	Very low
Episiotomy						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	933/16670 (5.6%)	995/11275 (8.8%)	RR 0.63 (0.58 to 0.69)	33 fewer per 1000 (from 27 fewer to 37 fewer)	Very low
1 study (Davis et al., 2011)	observational study	NR	NR	RR 0.55 (0.39 to 0.78) Adjusted RR 0.57 (0.40 to 0.82)[b]	NC	Very low
Perineal tears						
1 study (Davis et al., 2011)	observational study	NR	NR	RR 0.77 (0.68 to 0.86) Adjusted RR 0.74 (0.65 to 0.84)[b]	NC	Very low
Third or fourth degree perineal tears						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	318/16800 (1.9%)	259/11262 (2.3%)	RR 0.82 (0.7 to 0.97)	4 fewer per 1000 (from 1 fewer to 7 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Stillbirth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	6/16839 (0.04%)	4/11282 (0.04%)	RR 1 (0.28 to 3.56)[c]	0 fewer per 1,000,000 (from 255 fewer to 908 more)	Very low
1 study (Davis et al., 2011)	observational study	0/1826 (0%)	0/2873 (0%)	NC	NC	Very low
Neonatal death						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	5/16759 (0.03%)	5/11263 (0.04%)	RR 0.67 (0.19 to 2.32)[c]	146 fewer per 1,000,000 (from 360 fewer to 586 more)	Very low
1 study (Davis et al., 2011)	observational study	2/1826 (0.11%)	0/2873 (0%)	RR 7.87 (0.38 to 163.74)	NC	Very low
Admission to neonatal intensive care unit (NICU)						
1 study (Birthplace in England Collaborative Group, 2011 study)	observational study	284/16696 (1.7%)	194/11257 (1.7%)	RR 0.99 (0.82 to 1.18)	0 fewer per 1000 (from 3 fewer to 3 more)	Very low
1 study (Davis et al., 2011)	observational study	NR	NR	RR 0.98 (0.65 to 1.47) Adjusted RR 1.00 (0.66 to 1.50)[b]	NC	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Composite perinatal mortality and morbidity[d]						
All low risk women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	70/16553 (0.42%)	41/11199 (0.37%)	RR 1.16 (0.79 to 1.7)	586 more per 1,000,000 (from 769 fewer to 2563 more)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	39/4488 (0.87%)	24/5158 (0.47%)	RR 1.87 (1.12 to 3.10)	4048 more per 1,000,000 (from 558 more to 9771 more)	Very low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	31/12050 (0.26%)	17/6035 (0.28%)	RR 0.91 (0.51 to 1.65)	254 fewer per 1,000,000 (from 1383 fewer to 1834 more)	Very low
Women without complicating conditions at the onset of labour						
1 study (Hollowell et al,, 2011)	observational study	62/15538 (0.4%)	35/10571 (0.33%)	RR 1.21 (0.8 to 1.82)	695 more per 1,000,000 (from 662 fewer to 2715 more)	Low
Nulliparous women						
1 study (Hollowell et al,, 2011)	observational study	36/4063 (0.89%)	22/4785 (0.46%)	RR 1.93 (1.14 to 3.27)	4276 more per 1,000,000 (from 644 more to 10437 more)	Low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in a freestanding midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Multiparous women						
1 study (Hollowell et al,, 2011)	observational study	26/11461 (0.23%)	13/5772 (0.23%)	RR 1.01 (0.52 to 1.96)	23 more per 1,000,000 (from 1081 fewer to 2162 more)	Low
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	34/16589 (0.2%)	17/11210 (0.15%)	RR 1.35 (0.76 to 2.42)[c]	531 more per 1,000,000 (from 364 fewer to 2153 more)	Very low
Neonatal encephalopathy (signs)[e]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/16840 (0.02%)	2/11282 (0.02%)	RR 1.34 (0.25 to 7.31)[c]	60 more per 1,000,000 (from 133 fewer to 1119 more)	Very low

CI confidence interval, NC not calculable, NR not reported, RR relative risk,

a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol; however, this was reported in the Birthplace study as 'spontaneous vertex birth'.
b. Adjusted for maternal age, parity, ethnicity and smoking
c. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components
d. Composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle
e. Defined as admission to a neonatal unit within 48 hours of birth, for at least 48 hours with evidence of feeding difficulties or respiratory distress

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Evidence statements

Only 2 studies (n=32,856) reported this comparison. The evidence around mode of birth was slightly inconsistent in terms of the magnitude of effect but the trends from both studies were that women planning birth at home had a lower rate of instrumental vaginal birth and a lower rate of caesarean section, and therefore a higher chance of a spontaneous vaginal birth, than women planning birth in a freestanding midwifery unit. Women planning birth at home also had lower rates of epidural use (n=28,050) but there was no difference in blood loss, either in terms of the risk of major postpartum haemorrhage (n=4,734) or the need for a blood transfusion (n=27,917). There was consistent evidence that women planning birth at home had lower rates of perineal trauma, either in the form of episiotomy (n=27,945), any perineal tears or third or fourth degree perineal tears (n=28,062).

In terms of neonatal outcomes, one study (n=27,752) found evidence of no difference in a composite adverse neonatal outcome between babies born to women planning birth at home and babies born to women planning birth in a freestanding midwifery unit midwifery unit. However, when sub-group analysis by parity was reported (n=9,646), the evidence from this study suggested that for nulliparous women there was a higher risk of a composite adverse neonatal outcome for babies whose mothers planned birth at home compared with those born to mothers who planned birth in a freestanding midwifery unit. There was no difference noted between groups for babies born to multiparous women. One study (n=27,799) reported neonatal encephalopathy and did not find a difference in risk for babies born to women planning birth at home and women planning birth in a freestanding midwifery unit, but this formed part of the composite outcome and the study was not powered to detect a difference in the individual components. Similarly, there was no evidence of a difference in stillbirth (n=32,820) and early neonatal death (n=32,721), but neither study was powered to detect a difference in these rare outcomes. There was no evidence of a difference in the risk of admission to a neonatal intensive care unit (NICU) (n=27,953) between the 2 groups of babies.

Within the 2 studies (n=32,856) overall the transfer rates were similar in both settings in each study. However, in 1 study only 1 in 10 women were transferred whereas in the other study about 1 in 5 women required transfer, and about three-quarters of those required transfer before birth. In that study transfers were much more common in nulliparous women in both birth settings. Just under 50% of transfers in multiparous women took place after birth. The evidence across all outcomes was of low and very low quality.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group members agreed that it was vital to consider both the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in women's decision-making process. For the baby, they felt that it was important to establish whether there was a difference in risk associated with planning birth at home compared with planning birth in a freestanding midwifery unit (given that they are both out-of-hospital settings) and therefore the outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. Similarly, for the woman, the group wanted to ascertain whether there were differences in morbidity following planned birth at home compared with planned birth in a freestanding midwifery unit, given that there may be different facilities (and potentially more staff) available in the midwifery unit but that in the case of an emergency, a transfer by vehicle would be needed in either setting. The rates of intervention, such as caesarean section and instrumental vaginal birth, were also considered priorities, as they were felt to be important to women and also associated with morbidity, such as postpartum haemorrhage. The group did

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not feel that use of epidural anaesthesia was a particularly helpful outcome, as it is a matter of personal choice for the woman and would require a transfer from either setting.
The guideline development group members also felt that the rates of transfer were important to consider and would be an important consideration for women planning where to give birth.

Consideration of clinical benefits and harms

The guideline development group discussed the fact that the evidence around mode of birth varied between the two included studies. The Birthplace study suggested that the rates of spontaneous vaginal birth were higher, and the rates of instrumental vaginal birth and caesarean section were lower, after a planned home birth. In contrast, Davis et al. (2011 and 2012) did not find a significant difference between the two settings, although the direction of the effect was the same. The group noted that Davis et al. (2011 and 2012) had adjusted for differences in confounders between the two groups of women. Birthplace similarly adjusted for confounders and noted that the main difference in outcomes was found in nulliparous women.
The group noted that the evidence from the two studies for outcomes relating to blood loss was consistent; with Davis et al. (2011 and 2012) and Birthplace both reporting no significant difference in the rates of postpartum haemorrhage and blood transfusion respectively after planned home birth and planned birth in a freestanding midwifery unit. Similarly, the evidence for rates of any perineal tears, third or fourth degree perineal tears and episiotomy consistently showed that these outcomes were less common after planned birth at home.
The group noted that no statistically significant differences were identified for the neonatal outcomes reported but they did discuss the fact that neither of the studies was powered to detect differences in rare outcomes (stillbirth, neonatal death and neonatal encephalopathy). They noted that the Birthplace study was powered to detect a difference in its composite outcome, but that this had required pooling components with very different levels of severity, from fractured clavicle to mortality. While the group agreed that this was a limitation of the data, they also conceded that conducting a study with the power to detect differences in the very severe (and hence rare) outcomes would not be feasible. Also, fractured clavicle accounted for less than 3% of events and the serious perinatal outcomes – mortality, neonatal encephalopathy and meconium aspiration – constituted just under 90% of the primary outcome events. Given this evidence, and the fact that there was no significant difference in the rate of admission to NICU, the group noted that, overall, when parity was not taken in account, there did not appear to be a difference in neonatal outcomes between planned birth at home and planned birth in a freestanding midwifery unit. However, the group did note that parity was a large confounder in the study. This, and the fact that only 27.2% of the planned home birth group were nulliparous, means the overall result is likely to be misleading.
The guideline development group noted that in the Birthplace study, the overall rates of transfer from home and freestanding units were similar. Similarly, in both settings, nulliparous women were almost four times as likely to be transferred as multiparous women. Furthermore, nearly half of the transfers in multiparous women took place after birth. In Davis et al. (2011 and 2012), rates of transfer were lower in the planned birth in a midwifery unit group, and lower overall than those in the Birthplace study.

Consideration of health benefits and resource uses

The guideline development group members discussed the relative costs associated with planning birth at home and in a freestanding midwifery unit. They agreed that a home birth was likely to be cheaper due to the overhead costs associated with running a freestanding midwifery unit, and because the transfer rates (associated with the cost of an ambulance) were similar between the two settings. However, they also noted that in a freestanding midwifery unit the midwives can be supported by auxiliary staff in providing one-to-one care, but this is not possible in a planned home birth.

Quality of evidence

Only two studies reported this comparison and both were observational studies, but they were well conducted, fairly large, and published in 2011 and 2012. The Birthplace study was the larger of the two, was prospective and was conducted in England. However, there were some demographic differences between the two study groups which could have affected birth outcomes. The authors performed adjustments for these demographic differences for other comparisons reported in the study, but not for the comparison of home and freestanding midwifery units: as a result, the evidence was graded as very low quality. Davis et al. (2011 and 2012) was based in New Zealand, was retrospective and had a smaller sample size, but it did adjust for demographic differences between the study groups for most of its reported outcomes. The guideline development group noted that New Zealand has a higher proportion of both home and midwifery unit births than the UK and that this was a consideration, but they concluded overall that the evidence was applicable to women in England and Wales.

Other considerations

The guideline development group discussed the subgroup analysis by parity that was reported in the Birthplace study and noted some examples where outcomes were slightly different to the overall analysis. Whereas overall rates of spontaneous vaginal birth, caesarean section and third or fourth degree perineal trauma were lower for women who planned birth at home compared with those who planned birth in a freestanding midwifery unit, for the subgroup of multiparous women there were no significant differences in the rates. Similarly, for the subgroup of nulliparous women, the rates of episiotomy and third or fourth degree perineal trauma were not significantly different between the two settings. In addition, for nulliparous women the subgroup analysis found that the incidence of the composite neonatal morbidity and mortality outcome was significantly higher in planned home births for all nulliparous low risk women and for the group of nulliparous women without complicating conditions at the onset of labour. Having discussed the results of the subgroup analysis, the group concluded that for multiparous women there was little difference in clinical outcomes between the two settings and therefore that it would come down to the choice of the individual woman. However, they agreed that for nulliparous women, this analysis provided evidence – for this comparison – to support the recommendation that they should be advised to plan to give birth in a freestanding midwifery unit but not at home.

Home compared with alongside midwifery unit

Description of included studies

One study was included in this review (Birthplace in England Collaborative Group, 2011). The included study was a prospective cohort study from England which evaluated outcomes for women intending to give birth at home compared with women intending to give birth in an alongside midwifery unit (Birthplace in England Collaborative Group, 2011).
A summary of points to note about the study population can be found in table 8 below, and further details about the selection of the study groups are reported in the evidence tables (appendix I).

Table 8: Summary of included studies for planned birth at home compared with planned birth in an alongside midwifery unit

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate	New to update ?
Birthplace in England	Prospective cohort study	Intended place of birth at	Home: 5.4% women had complicating	**Home birth group** Transfer rate: 21.0%	Yes

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate	New to update ?
Collaborative Group, 2011		the start of care in labour	conditions at the start of care in labour 21.2% were nulliparous Alongside midwifery unit: 6.9% women had complicating conditions at start of care in labour 50.1% were nulliparous	(Before birth: 14.2% After birth: 6.2% Time of transfer missing: 0.6%) Transfer rate nulliparous – 45% (79.8% before birth) Transfer rate multiparous – 12% (55% before birth) **Alongside midwifery unit group** Transfer rate: 26.4% (Before birth: 21.2% After birth: 4.3% Time of transfer missing: 0.9%) Transfer rate nulliparous – 40.2% (86.9% before birth) Transfer rate multiparous – 12.5% (70.8% before birth)	

Evidence profile

All risk ratios were calculated as standard using RevMan. For measures of perinatal/neonatal mortality and morbidity, due to the low incidence absolute effects have been reported per 1,000,000.

Table 9: Summary GRADE profile for comparison of planned birth at home with planned birth in an alongside midwifery unit for all women

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/16840 (0%)	0/16710 (0%)	not calculable (NC)	NC	Very low
Mode of birth: spontaneous vaginal birth[a]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	15590/16825 (92.7%)	14413/16690 (86.4%)	RR 1.07 (1.07 to 1.08)	60 more per 1000 (from 60 more to 69 more)	Very low
Mode of birth: instrumental vaginal birth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	714/16825 (4.2%)	1524/16690 (9.1%)	RR 0.46 (0.43 to 0.51)	49 fewer per 1000 (from 45 fewer to 52 fewer)	Very low
Mode of birth: caesarean section						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	458/16825 (2.7%)	727/16690 (4.4%)	RR 0.62 (0.56 to 0.7)	17 fewer per 1000 (from 13 fewer to 19 fewer)	Very low

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Use of epidural						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1418/16799 (8.4%)	2464/16661 (14.8%)	RR 0.57 (0.54 to 0.61)	64 fewer per 1000 (from 58 fewer to 68 fewer)	Very low
Measures of blood loss: need for a blood transfusion						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	101/16687 (0.61%)	136/16548 (0.82%)	RR 0.74 (0.57 to 0.95)	2 fewer per 1000 (from 0 fewer to 4 fewer)	Very low
Episiotomy						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	933/16670 (5.6%)	2098/16689 (12.6%)	RR 0.45 (0.41 to 0.48)	69 fewer per 1000 (from 65 fewer to 74 fewer)	Very low
Third or fourth degree perineal tears						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	318/16800 (1.9%)	535/16654 (3.2%)	RR 0.59 (0.51 to 0.68)	13 fewer per 1000 (from 10 fewer to 16 fewer)	Very low
Stillbirth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	6/16839 (0.04%)	1/16708 (0.006%)	RR 5.95 (0.72 to 49.44)[b]	296 more per 1,000,000 (from 17 fewer to 2899 more)	Very low
Early neonatal death						

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
1 study (Birthplace in England Collaborative Group, 2011)	observational study	5/16759 (0.03%)	3/16633 (0.02%)	RR 1.65 (0.4 to 6.92)[b]	117 more per 1,000,000 (from 108 fewer to 1068 more)	Very low
Admission to neonatal intensive care unit (NICU)						
1 study (Birthplace in England Collaborative Group, 2011 study)	observational study	284/16696 (1.7%)	307/16580 (1.9%)	RR 0.92 (0.78 to 1.08)	1 fewer per 1000 (from 4 fewer to 1 more)	Very low
Composite perinatal mortality and morbidity[c]						
All low risk women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	70/16553 (0.42%)	58/16524 (0.35%)	RR 1.2 (0.85 to 1.71)	702 more per 1,000,000 (from 527 fewer to 2492 more)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	39/4488 (0.87%)	38/8256 (0.46%)	RR 1.89 (1.21 to 2.95)	4096 more per 1,000,000 (from 967 more to 8975 more)	Very low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	31/12050 (0.26%)	20/8234 (0.24%)	RR 1.06 (0.60 to 1.86)	146 more per 1,000,000 (from 972 fewer to 2089 more)	Very low
Women without complicating conditions at the onset of labour						

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
1 study (Birthplace in England Collaborative Group, 2011)	observational study	62/15538 (0.40%)	54/15342 (0.35%)	RR 1.13 (0.79 to 1.63)	458 more per 1,000,000 (from 739 fewer to 2217 more)	Low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	36/4063 (0.89%)	35/7515 (0.47%)	RR 1.90 (1.20 to 3.03)	4190 more per 1,000,000 (from 931 more to 9451 more)	Low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	26/11461 (0.23%)	19/7792 (0.24%)	RR 0.93 (0.52 to 1.68)	195 fewer per 1,000,000 (from 1317 fewer to 2121 more)	Low
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	34/16589 (0.2%)	17/16569 (0.1%)	RR 2.00 (1.12 to 3.57)[b]	1026 more per 1,000,000 (from 123 more to 2637 more)	Very low
Neonatal encephalopathy (signs)[d]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/16840 (0.02%)	4/16710 (0.02%)	RR 0.99 (0.25 to 3.97)[b]	2 fewer per 1,000,000 from 180 fewer to 711 more)	Very low

CI confidence interval, NC not calculable, NICU neonatal intensive care unit, RR relative risk

a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol however this was reported in the Birthplace study as 'spontaneous vertex birth'.

b. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components.
c. Composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle.
d. Defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress

Evidence statements

One study (n=33,550) reported this comparison. There was evidence that women planning birth at home had a lower risk of instrumental vaginal birth and a lower risk of caesarean section, and therefore a higher rate of spontaneous vaginal birth, than women planning birth in an alongside midwifery unit. Women planning birth at home also had lower rates of epidural use, blood transfusion, episiotomy and third or fourth degree perineal tears.

In terms of neonatal outcomes, the study found evidence that there was no difference in the risk of a composite perinatal mortality and morbidity outcome between babies born to women planning birth at home and women planning birth in an alongside midwifery unit. However, when sub-group analysis by parity was undertaken, there was no difference seen between the two groups for babies born to multiparous women but there was a higher incidence of composite adverse neonatal outcome seen in babies born to nulliparous women planning birth at home compared with nulliparous women planning birth in an alongside midwifery unit. There was no evidence of a difference between the groups in terms of rates of admission to NICU and risks of stillbirth or early neonatal death, but stillbirth and early neonatal death formed part of the composite outcome and the study was not powered to detect a difference in the individual components. The study reported a higher risk of a clinical diagnosis of neonatal encephalopathy (another component of the composite outcome) among babies born to women planning birth at home, but no difference in the rates of babies with the signs of neonatal encephalopathy. The evidence across all outcomes was of low and very low quality.

Transfer rates were similar in both settings but transfers were about three times more common in nulliparous women than in multiparous women. Over one fifth of the multiparous transfers took place after birth.

3.2.4.4 Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group members agreed that it was vital to consider both the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in women's decision-making process. For the baby, they felt that it was important to establish whether there was any risk associated with planning birth at home, and therefore the outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. Similarly, the group wanted to ascertain whether there were differences in morbidity for the woman following planned birth at home compared with planned birth in an alongside midwifery unit, given that in the case of an unforeseen emergency, such as a postpartum haemorrhage, transfer from an alongside midwifery unit into an obstetric unit would be likely to be more expedient than transfer from home. The rates of intervention, such as caesarean section and instrumental vaginal birth, were also considered priorities, as they were felt to be important to women and were also associated with morbidity, such as postpartum haemorrhage. The group did not feel that use of epidural anaesthesia was a particularly helpful outcome because it is a matter of personal choice for the woman.

The guideline development group also felt that the rates of transfer were important to consider and would be an important consideration for women planning where to give birth.

Consideration of clinical benefits and harms

The evidence showed that rates of intervention were lower after planned birth at home when compared with planned birth in an alongside midwifery unit. This was consistent across the outcomes of instrumental vaginal birth, caesarean section, episiotomy and blood transfusion. In addition, it was demonstrated that the incidence of third or fourth degree perineal tears was lower after planned birth at home, although no evidence was available for less severe types of perineal trauma.

The guideline development group then considered the neonatal outcomes reported. They discussed the fact that no significant difference was identified in stillbirth or early neonatal death across the two settings, but noted that the study had not been powered to detect a difference in these rare outcomes. They noted that the Birthplace (2011) study was powered to detect a difference in its composite outcome, but that this had required pooling components with very different levels of severity, from fractured clavicle to mortality. While the group felt that this was a limitation of the data, they also conceded that conducting a study with the power to detect differences in the very severe (and hence rare) mortality outcomes would not be feasible. Also fractured clavicle accounted for less than 3% of events and the serious perinatal outcomes – mortality, neonatal encephalopathy and meconium aspiration – constituted just under 90% of the primary outcome events. No significant difference was identified between the two settings for the composite outcome (across all women) and for rates of admission to NICU, but it was found that clinical diagnosis of neonatal encephalopathy was more common in babies born after a planned home birth. The group felt that this outcome was quite difficult to interpret because it was not split by the grade of encephalopathy. Some of the babies would have had symptoms that resolved with no long term effects, whereas others might have had serious morbidity.
The group noted that the rates of transfer were fairly similar in planned home births and planned births in alongside midwifery units, and that rates of transfer were three times higher in nulliparous women. They also noted that over one-fifth of the multiparous transfers took place after birth.

Consideration of health benefits and resource uses

The guideline development group discussed the relative costs associated with planning birth at home and in an alongside unit. They noted that a planned home birth was associated with lower rates of instrumental vaginal birth, caesarean section and blood transfusion, and therefore that costs might be lower in that respect. Home birth is also free from associated 'hotel' service costs. However, they noted that transfer from home has an associated cost in terms of the ambulance whereas transfer from an alongside midwifery unit does not require a vehicle. In addition, in an alongside unit one-to-one care can be provided by midwives supported by auxiliary staff, which means that the overall staffing costs associated with providing one-to-one care can be lower than for a home birth, where one midwife is required throughout labour and then two midwives need to be present at birth. Home births also require midwives' time to be spent travelling to and from the birth. On occasion, however, in some services more midwives may be present in an alongside midwifery unit than are required to provide one-to-one care for the women in labour. Similarly, more community midwives may need to be on call to provide care than are required, in order to ensure that staffing levels are adequate for the estimated number of births.

Quality of evidence

Only one included study was available for this comparison. The study was recent, large and conducted in England, but it was an observational study and there were demographic differences between the two study groups which could have affected birth outcomes. The authors performed adjustments for these demographic differences for other comparisons reported in the study, but not for the comparison of home and alongside midwifery units and therefore the evidence was graded as very low quality.

Other considerations

The group discussed the subgroup analysis by parity that was reported and noted some cases where outcomes were slightly different to the overall analysis. For multiparous women, the main difference was that planning birth at home was no longer associated with a significantly lower rate of blood transfusion. For nulliparous women, there was no significant difference

between the two settings in terms of caesarean section rate, incidence of third or fourth degree perineal tears and rate of blood transfusion, and so some of the benefits of a planned home birth that were demonstrated in the overall analysis were not present for nulliparous women. In addition, for nulliparous women a planned home birth was associated with significantly higher rates of the composite neonatal morbidity and mortality outcome. The guideline development group felt that, with reference to this comparison, the evidence suggested that nulliparous women should be recommended to plan birth in an alongside midwifery unit.

Home compared with obstetric unit

Description of included studies

Fifteen studies (reported in 16 papers) were included in this review (Ackermann-Liebrich et al., 1996; Birthplace in England Collaborative Group, 2011; Davis et al., 2011 and 2012; de Jonge et al., 2009; de Jonge et al., 2013; Dowswell et al., 1996; Hutton et al., 2009; Janssen et al., 2002; Janssen et al., 2009; Lindgren et al., 2008; Nove et al., 2012; Pang et al., 2002; van der Kooy et al., 2011; Woodcock et al., 1994; Blix et al., 2012).

One of the studies is a pilot randomised controlled trial conducted in England (Dowswell et al., 1996). Three of the included studies are prospective cohort studies; these were conducted in England (Birthplace in England Collaborative Group, 2011), Switzerland (Ackermann-Liebrich et al., 1996) and Canada (Janssen et al., 2002). The remaining 11 studies are retrospective cohorts carried out in 8 different countries: England (Nove et al., 2012), The Netherlands (de Jonge et al., 2009 and 2013; van der Kooy et al., 2011), Sweden (Lindgren et al., 2008), USA (Pang et al., 2002), Canada (Hutton et al., 2009; Janssen et al., 2009), Australia (Woodcock et al., 1994), New Zealand (Davis et al., 2011 and 2012) and Norway (Blix et al., 2012).

All of the studies compared planned birth at home with planned birth at an obstetric unit and analysed data on an intention-to-treat basis, so that women were analysed by their planned place of birth even if they were transferred. Three of the included studies evaluated outcomes by booked place of birth during the antenatal period (Ackermann-Liebrich et al., 1996; Dowswell et al., 1996; Woodcock et al., 1994). One study (Birthplace, 2011) analysed outcomes by the intended place of birth and the start of care in labour. In the remaining studies, outcomes were analysed by the intended place of birth at the onset of labour.

The included studies aimed to restrict their populations to low risk women, but a proportion of women had complications which resulted in them being higher risk or outside the scope of the guideline. There are also systematic differences between the characteristics of the study groups in many of the studies, skewing the results in a certain direction, as the majority of included studies are cohort studies and women planning a home birth are a self-selected group of women. A summary of points to note about the study populations can be found in table 10 below. Further details about the selection of the study groups are reported in the evidence tables (appendix I).

Table 10: Summary of included studies for planned birth at home compared with planned birth in an obstetric unit for all women

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate in home birth group (or any details of transfers reported)	New to update?
Ackermann-Liebrich et al., 1996	Prospective cohort study	Booked place of birth	Home: 1.5% babies were breech; 1.4% women had hypertension; 7.9% babies were born pre- or post-term; 3.4% women had induction of labour Obstetric unit: 4.5% babies were breech; 2.4% women had hypertension; 8.9% babies were born pre- or post-term; 16.9% women had induction of labour; 1.4% women gave birth to twins	Transfer rate: 24.9% (Before birth: 10.6% During labour: 14.3%) (Note: no details are given about matched pairs; therefore, this relates to whole study population)	No
Birthplace in England Collaborative Group, 2011	Prospective cohort study	Intended place of birth at start of care in labour	Home: 5.4% women had complicating conditions at start of care in labour 27.2% were nulliparous Obstetric unit: 19.5% women had complicating conditions at start of care in labour 54% were nulliparous	Transfer rate: 21.0% (Before birth: 14.2% After birth: 6.2% Time missing: 0.6%) Transfer rate nulliparous: 45% (79.8% before birth) Transfer rate multiparous: 12% (55% before birth)	Yes

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Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate in home birth group (or any details of transfers reported)	New to update?
Blix et al., 2012	Retrospective cohort study	Intended place of birth at onset of labour	Women who planned home births were older than women who planned hospital births. More single mothers planned hospital births. Home: 12/1631 breech births Obstetric unit: 37 women >42 weeks gestation, 324/16310 breech births.	Transfer rate: 12.1%; 156 during labour; 19 after birth (maternal indication); 22 after birth (neonatal indication); 16 transfers were recorded as emergency.	
Davis et al., 2011 and 2012	Retrospective cohort study	Intended place of birth at onset of labour	The study reported two comparator groups: planned birth in a secondary hospital and planned birth in a tertiary hospital. These groups have been pooled by the technical team to provide the comparator group for this analysis.	Actual place of birth was home: 82.7%	Yes
de Jonge et al., 2009	Retrospective cohort study	Intended place of birth at onset of labour	None	No details given	Yes
de Jonge et al., 2013	Retrospective cohort study	Intended place of birth at onset of labour	Very large sample size: Comparator group included low risk births at all Dutch hospitals. Women who had had a relatively difficult previous birth may have been more likely to plan a hospital birth next time causing selection bias. Home: 41.9% nulliparous women, 9.9% aged under 25. 90.9% women Dutch ethnicity. Obstetric unit: 48.7% nulliparous women, 17.3% aged under 25, 66.9% Dutch ethnicity.	No details given	No
Dowswell et al., 1996	Randomised controlled trial (pilot)	Booked place of birth	Women reported as low risk in pregnancy but no characteristics are reported to determine risk status on admission in labour	No details given	No

Update 2014

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate in home birth group (or any details of transfers reported)	New to update?
Hutton et al., 2009	Retrospective cohort study	Intended place of birth at onset of labour	Home: 3.1% women had at least one previous caesarean section; 0.5% babies were breech or preterm; 1.7% babies were born post-term; 2.6% babies had significant congenital anomalies Obstetric unit: 3.1% women had at least one previous caesarean section; 0.8% babies were born post-term; 2.7% babies had significant congenital anomalies	Actual place of birth was home: 78.6% (Intrapartum transfer of care to physician: 12.5% Postpartum transfer of care to physician: 1.8%)	Yes
Janssen et al., 2002	Prospective cohort study	Intended place of birth at onset of labour	Home: 2.7% women had previous caesarean section; 4.3% women had induction of labour; 1.2% women had pregnancy induced hypertension; 0.6% babies had major congenital anomalies Obstetric unit: 8.1% women had previous caesarean section; 18.7% women had induction of labour; 2.5% women had pregnancy induced hypertension; 1.4% babies had major congenital anomalies. The study reported two comparator groups: planned birth in hospital with a midwife and planned birth in hospital with a physician. These groups have been pooled by the technical team to provide the comparator group for this analysis.	Transfer rate: 21.7% (It is reported that 16.5% of women planning a home birth required transfer in labour, and for 3.6% of women an emergency transport was needed)	No
Janssen et al., 2009	Retrospective cohort study	Intended place of birth at onset of labour	Home: 3% women had previous caesarean section; 0.6% babies had major congenital anomalies Obstetric unit: Previous caesarean section not included; 0.7% babies had major congenital anomalies The study reported two comparator groups: planned birth in hospital with a midwife and planned birth in hospital with a physician. These groups have been pooled by the technical team to provide the comparator group for this analysis.	Actual place of birth was home: 78.8%	Yes

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate in home birth group (or any details of transfers reported)	New to update?
Lindgren et al., 2008	Retrospective cohort study	Intended place of birth at onset of labour	Home: 11.9% pregnancies or births were complicated (0.3% diabetes; 0.9% twins; 1.2% preterm; 8.8% post-term; 0.8% breech) and 15% of women had pre-pregnancy disease* Obstetric unit: All babies were full-term and singleton; 1.3% babies were breech and 17% women had pre-pregnancy disease* * not all would be considered higher risk	No details given	Yes
Nove et al., 2012	Retrospective cohort study	Intended place of birth at end of pregnancy	Home: all "high risk" pregnancies (based on risk tables reported in NICE Intrapartum Care guideline 2007) excluded, including previous caesarean section and previous post-partum haemorrhage. Unattended births also excluded. Obstetric unit: All "high risk" pregnancies excluded as above.	No details given	Yes
Pang et al., 2002	Retrospective cohort study	Intended place of birth at onset of labour	Home: 1.3% babies were born preterm Obstetric unit: 3.7% babies were born preterm	Transfer rate: 4.5%	Yes
van der Kooy et al., 2011	Retrospective cohort study	Intended place of birth at onset of labour	Two analyses: Natural prospective approach: intention-to-treat, including preterm births (8.3% of babies born to women who planned home birth and 10.3% of babies born to women who planned hospital birth are outside scope due to prematurity, being small for gestational age, having congenital abnormalities or combination) Perfect guideline approach: subset of women who in retrospect were compliant with guidelines for home birth (6.1% of babies born to women who planned home birth and 7.7% of babies born to women who planned hospital birth are outside scope due to being small for gestational age, having congenital abnormalities or combination)	No details given	Yes
Woodcock et al., 1994	Retrospective cohort study	Booked place of birth	Home: 10.3% women had complications of pregnancy (some minor); 2.4% women had pre-existing medical conditions; 2.3% babies were breech or other non-cephalic presentation; 2.3% women had induction of labour; 0.6% women had elective caesarean section; 3.5% babies were born preterm	Transfer rate: 23.6% (Antenatal: 4.9% During labour: 15.5%	No

Update 2014

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate in home birth group (or any details of transfers reported)	New to update?
			Obstetric unit: 28.6% women had complications of pregnancy (some minor); 4.6% babies were breech or other non-cephalic presentation; 26.5% women had induction of labour; 7.5% women had elective caesarean section; 5.5% babies were born preterm	Postpartum: 1.6% Transfer of baby: 1.6%)	

Evidence profile

All risk ratios were calculated as standard using RevMan; however, where the authors have reported adjusted measures of effect, these have also been reported in the table. For measures of perinatal/neonatal mortality and morbidity, due to the low incidence absolute effects have been reported per 1,000,000.

Table 11: Summary GRADE profile for comparison of planned birth at home with planned birth in an obstetric unit

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Maternal mortality						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/16840 (0%)	0/19706 (0%)	not calculable (NC)	NC	Very low
1 study (Ackermann-Liebrich et al., 1996)	observational study	0/214 (0%)	0/214 (0%)	NC	NC	Very low
1 study (Lindgren et al., 2008)	observational study	0/897 (0%)	0/11341 (0%)	NC	NC	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Janssen et al., 2009)	observational study	0/2899 (0%)	0/10083 (0%)	NC	NC	Very low
1 study (Hutton et al., 2009)	observational study	0/6692 (0%)	0/6692 (0%)	NC	NC	Very low
Mode of birth: spontaneous vaginal birth[a]						
1 study (Dowswell et al., 1996)	randomised trials	5/5 (100%)	6/6 (100%)	RR 1 (0.73 to 1.37)	0 fewer per 1000 (from 270 fewer to 370 more)	Very low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	15590/16825 (92.7%)	14645/19688 (74.4%)	RR 1.25 (1.23 to 1.26) Adjusted OR 3.61 (99% CI 2.97 to 4.38)[b]	186 more per 1000 (from 171 more to 193 more)	Very low
1 study (Davis et al., 2011)	observational study	1743/1826 (95.5%)	9195/11448 (80.3%)	RR 1.19 (1.17 to 1.2)	153 more per 1000 (from 137 more to 161 more)	Very low
1 study (Janssen et al., 2002)	observational study	779/862 (90.4%)	941/1314 (71.6%)	RR 1.26 (1.21 to 1.31)	186 more per 1000 (from 150 more to 222 more)	Very low
1 study (Janssen et al., 2009)	observational study	2605/2899 (89.9%)	7917/10083 (78.5%)	RR 1.14 (1.13 to 1.16)	110 more per 1000 (from 102 more to 126 more)	Very low
1 study (Hutton et al., 2009)	observational study	6146/6692 (91.8%)	5852/6692 (87.4%)	RR 1.05 (1.04 to 1.06)	44 more per 1000 (from 35 more to 52 more)	Very low
1 study (Woodcock et al., 1994)	observational study	865/976 (88.6%)	1787/2928 (61%)	RR 1.45 (1.4 to 1.51)	275 more per 1000 (from 244 more to 311 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Blix et al., 2012)	observational study	1572/1631 (96.4%)	14477/16310 (88.8%)	RR 1.09 (1.07 to 1.10)	80 more per 1000 (from 62 more to 89 more)	Very Low
Mode of birth: instrumental vaginal birth						
1 study (Dowswell et al., 1996)	randomised trials	0/5 (0%)	0/6 (0%)	NC	NC	Very low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	714/16825 (4.2%)	2842/19688 (14.4%)	RR 0.29 (0.27 to 0.32) Adjusted OR Ventouse: 0.29 (99% CI 0.21 to 0.40)[b] Forceps: 0.43 (99% CI 0.32 to 0.57)[b]	102 fewer per 1000 (from 98 fewer to 105 fewer)	Very low
1 study (Davis et al., 2011)	observational study	36/1826 (2%)	1018/11448 (8.9%)	RR 0.22 (0.16 to 0.31)	69 fewer per 1000 (from 61 fewer to 75 fewer)	Very low
1 study (Ackermann-Liebrich et al., 1996)	observational study	8/207 (3.9%)	18/207 (8.7%)	RR 0.44 (0.2 to 1.00)	49 fewer per 1000 (from 70 fewer to 0 more)	Very low
1 study (Lindgren et al., 2008)	observational study	20/897 (2.2%)	1089/11341 (9.6%)	RR 0.23 (0.15 to 0.36) Adjusted RR 0.3 (0.2 to 0.5)[c]	74 fewer per 1000 (from 61 fewer to 82 fewer)	Very low
1 study (Janssen et al., 2002)	observational study	28/862 (3.2%)	170/1314 (12.9%)	RR 0.25 (0.17 to 0.37)	97 fewer per 1000 (from 82 fewer to 107 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Janssen et al., 2009)	observational study	86/2899 (3%)	1080/10083 (10.7%)	RR 0.28 (0.22 to 0.34)	77 fewer per 1000 (from 71 fewer to 84 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	195/6692 (2.9%)	293/6692 (4.4%)	RR 0.67 (0.56 to 0.8)	14 fewer per 1000 (from 9 fewer to 19 fewer)	Very low
1 study (Woodcock et al., 1994)	observational study	61/976 (6.3%)	679/2928 (23.2%)	RR 0.27 (0.21 to 0.35) Adjusted OR 0.14 (0.10 to 0.18)[d]	169 fewer per 1000 (from 151 fewer to 183 fewer)	Very low
1 study (Blix et al., 2012)	observational study	28/1631 (1.6%)	1218/16310 (7.5%)	RR 0.23 (0.16 to 0.33)	58 fewer per 1000 (50 fewer to 63 fewer)	Very Low
Mode of birth: caesarean section						
1 study (Dowswell et al., 1996)	randomised trials	0/5 (0%)	0/6 (0%)	NC	NC	Very low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	458/16825 (2.7%)	2158/19688 (11%)	RR 0.25 0.23 to 0.27) Adjusted OR 0.31 (99% CI 0.23 to 0.41)[b]	82 fewer per 1000 (from 80 fewer to 84 fewer)	Very low
1 study (Davis et al., 2011)	observational study	47/1826 (2.6%)	1232/11448 (10.8%)	RR 0.24 0.18 to 0.32)	82 fewer per 1000 (from 73 fewer to 88 fewer)	Very low
1 study (Ackermann-Liebrich et al., 1996)	observational study	12/207 (5.8%)	24/207 (11.6%)	RR 0.5 (0.26 to 0.97)	58 fewer per 1000 (from 3 fewer to 86 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Lindgren et al., 2008)	observational study	22/897 (2.5%)	776/11341 (6.8%)	RR 0.36 0.24 to 0.54) Adjusted RR 0.4 (0.2 to 0.7)[c]	44 fewer per 1000 (from 31 fewer to 52 fewer)	Very low
1 study (Janssen et al., 2002)	observational study	55/862 (6.4%)	203/1314 (15.4%)	RR 0.41 (0.31 to 0.55)	91 fewer per 1000 (from 70 fewer to 107 fewer)	Very low
1 study (Janssen et al., 2009)	observational study	208/2899 (7.2%)	1086/10083 (10.8%)	RR 0.67 (0.58 to 0.77)	36 fewer per 1000 (from 25 fewer to 45 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	348/6692 (5.2%)	544/6692 (8.1%)	RR 0.64 (0.56 to 0.73)	29 fewer per 1000 (from 22 fewer to 36 fewer)	Very low
1 study (Woodcock et al., 1994)	observational study	42/976 (4.3%)	424/2928 (14.5%)	RR 0.3 (0.22 to 0.4) Adjusted OR Emergency 0.25 (0.17 to 0.38)[d] Elective 0.06 (0.03 to 0.14)[d]	101 fewer per 1000 (from 87 fewer to 113 fewer)	Very low
1 study (Blix et al., 2012)	observational study	31/1631 (1.9%)	615/16310 (3.8%)	RR 0.50 (0.35 to 0.72)	19 fewer per 1000 (11 fewer to 30 fewer)	Very Low
Use of epidural						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1418/16799 (8.4%)	5817/19576 (29.7%)	RR 0.28 (0.27 to 0.3) Adjusted OR 0.25 (99% CI 0.20 to 0.31)[b]	214 fewer per 1000 (from 208 fewer to 217 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Janssen et al., 2002)	observational study	66/862 (7.7%)	355/1314 (27%)	RR 0.28 (0.22 to 0.36)	195 fewer per 1000 (from 173 fewer to 211 fewer)	Very low
1 study (Janssen et al., 2009)	observational study	224/2899 (7.7%)	2388/10083 (23.7%)	RR 0.33 (0.29 to 0.37)	159 fewer per 1000 (from 149 fewer to 168 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	655/6692 (9.8%)	1405/6692 (21%)	RR 0.47 0.43 to 0.51)	111 fewer per 1000 (from 103 fewer to 120 fewer)	Very low
1 study (Blix et al., 2012)	observational study	32/1631 (2.0%)	2517/16310 (15.4%)	RR 0.13 (0.09 to 0.18)	134 fewer per 1000 (127 fewer to 140 fewer)	Very Low
Measures of blood loss: postpartum haemorrhage (any)						
1 study (Lindgren et al., 2008)	observational study	not reported (NR)	NR	RR 0.4 (0.2 to 0.8) Adjusted RR 0.5 (0.2 to 1.0)[c]	NC	Very low
1 study (Janssen et al., 2009)	observational study	110/2899 (3.8%)	642/10083 (6.4%)	RR 0.6 (0.49 to 0.73)	25 fewer per 1000 (from 17 fewer to 32 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	624/6692 (9.3%)	760/6692 (11.4%)	RR 0.82 (0.74 to 0.91)	20 fewer per 1000 (from 10 fewer to 30 fewer)	Very low
1 study (Woodcock et al., 1994)	observational study	64/976 (6.6%)	46/2928 (1.6%)	RR 4.17 (2.88 to 6.05) Adjusted OR 3.83 (2.59 to 5.66)[d]	50 more per 1000 (from 30 more to 79 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Pang et al., 2002)	observational study	74/5969 (1.2%)	84/9861 (0.85%)	RR 1.46 (1.07 to 1.99) Adjusted RR 1.52 (1.12 to 2.05)[e]	4 more per 100 (from 1 more to 8 more)	Very low
1 study (Blix et al., 2012)	observational study	50/1631 (3.1%)	1361/16310 (8.3%)	RR 0.44 (0.34 to 0.57)	47 fewer (36 fewer to 55 fewer)	Very Low
Measures of blood loss: major postpartum haemorrhage (over 1000 ml)						
1 study (Janssen et al., 2002)	observational study	38/862 (4.4%)	66/1314 (5%)	RR 0.88 (0.59 to 1.3)	6 fewer per 1000 (from 21 fewer to 15 more)	Very low
1 study (Hutton et al., 2009)	observational study	56/6692 (0.84%)	82/6692 (1.2%)	RR 0.68 (0.49 to 0.96)	4 fewer per 1000 (from 0 fewer to 6 fewer)	Very low
1 study Davis et al., 2012	observational study	19/1830 (1.0%)	163/11466 (1.4%)	RR 0.73 (0.46 to 1.17)	4 fewer per 1000 (from 8 fewer to 2 more)	Very low
1 study (Nove et al., 2012)	observational study	23/5998 (0.4%)	2785/267874 (1.0%)	RR 0.37 (0.24 to 0.56)	7 fewer per 1000 (from 5 fewer to 8 fewer)	Very low
1 study (De Jonge et al., 2013)	observational study	2699/92333 (2.9%)	2172/54419 (4.0%)	RR 0.73 (0.69 to 0.77)	11 fewer per 1000 (from 15 fewer to 7 fewer)	Low
Measures of blood loss: need for a blood transfusion						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	101/16687 (0.61%)	241/19579 (1.2%)	RR 0.49 (0.39 to 0.62) Adjusted OR 0.72 (99% CI 0.47 to 1.12)[b]	6 fewer per 1000 (from 5 fewer to 8 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Janssen et al., 2002)	observational study	3/862 (0.35%)	1/1314 (0.08%)	RR 4.57 (0.48 to 43.89)	3 more per 1000 (from 0 fewer to 33 more)	Very low
1 study (Janssen et al., 2009)	observational study	2/2899 (0.07%)	25/10083 (0.25%)	RR 0.28 (0.07 to 1.17)	2 fewer per 1000 (from 2 fewer to 0 more)	Very low
1 study (De Jonge et al.' 2013)	observational study	134/92333 (0.15%)	122/54419 (0.22%)	RR 0.65 (0.51 to 0.83)	1 fewer per 1000 (from 0 fewer to 1 fewer)	Low
Episiotomy						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	933/16670 (5.6%)	3780/19678 (19.2%)	RR 0.29 (0.27 to 0.31) Adjusted OR 0.33 (99% CI 0.28 to 0.39)[b]	136 fewer per 1000 (from 133 fewer to 140 fewer)	Very low
1 study (Ackermann-Liebrich et al., 1996)	observational study	45/207 (21.7%)	128/207 (61.8%)	RR 0.35 (0.27 to 0.47)	402 fewer per 1000 (from 328 fewer to 451 fewer)	Very low
1 study (Lindgren et al., 2008)	observational study	8/897 (0.89%)	820/11341 (7.2%)	RR 0.12 (0.06 to 0.25) Adjusted RR 0.1 (0 to 0.2)[c]	64 fewer per 1000 (from 54 fewer to 68 fewer)	Very low
1 study (Janssen et al., 2002)	observational study	33/862 (3.8%)	176/1314 (13.4%)	RR 0.29 (0.2 to 0.41)	95 fewer per 1000 (from 79 fewer to 107 fewer)	Very low
1 study (Janssen et al., 2009)	observational study	84/2899 (2.9%)	1089/10083 (10.8%)	RR 0.27 (0.22 to 0.33)	79 fewer per 1000 (from 72 fewer to 84 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Hutton et al., 2009)	observational study	286/6692 (4.3%)	393/6692 (5.9%)	RR 0.73 (0.63 to 0.84)	16 fewer per 1000 (from 9 fewer to 22 fewer)	Very low
Intact perineum						
1 study (Ackermann-Liebrich et al., 1996)	observational study	63/207 (30.4%)	16/207 (7.7%)	RR 3.94 (2.36 to 6.58)	227 more per 1000 (from 105 more to 431 more)	Very low
1 study (Janssen et al., 2002)	observational study	474/862 (55%)	612/1314 (46.6%)	RR 1.18 (1.09 to 1.28)	84 more per 1000 (from 42 more to 130 more)	Very low
Vaginal/perineal tears						
1 study (Dowswell et al., 1996)	randomised trials	2/5 (40%)	3/6 (50%)	RR 0.8 (0.21 to 3.05)	100 fewer per 1000 (from 395 fewer to 1000 more)	Very low
1 study (Ackermann-Liebrich et al., 1996)	observational study	65/207 (31.4%)[g]	29/207 (14%)[g]	RR 2.24 (1.51 to 3.32)	174 more per 1000 (from 71 more to 325 more)	Very low
1 study (Lindgren et al., 2008)	observational study	Vaginal tears 161/897 (17.9%)	Vaginal tears 3577/11341 (31.5%)	RR 0.57 (0.49 to 0.66) Adjusted RR 0.7 (0.6 to 0.9)[f]	136 fewer per 1000 (from 107 fewer to 161 fewer)	Very low
		Perineal tears 178/897 (19.8%)	Perineal tears 2587/11341 (22.8%)	RR 0.87 (0.76 to 1) Adjusted RR 1.0 (0.8 to 1.3)[f]	30 fewer per 1000 (from 55 fewer to 0 more)	
1 study (Janssen et al., 2002)	observational study	388/862 (45%)	702/1314 (53.4%)	RR 0.84 (0.77 to 0.92)	85 fewer per 1000 (from 43 fewer to 123 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Janssen et al., 2009)	observational study	1321/2899 (45.6%)	5603/10083 (55.6%)	RR 0.82 (0.79 to 0.86)	100 fewer per 1000 (from 78 fewer to 117 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	3612/6692 (54%)	4081/6692 (61%)	RR 0.89 (0.86 to 0.91)	67 fewer per 1000 (from 55 fewer to 85 fewer)	Very low
Third or fourth degree vaginal/perineal tears						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	318/16800 (1.9%)	625/19638 (3.2%)	RR 0.59 (0.52 to 0.68) Adjusted OR 0.77 (99% CI 0.57 to 1.05)[b]	13 fewer per 1000 (from 10 fewer to 15 fewer)	Very low
1 study (Lindgren et al., 2008)	observational study	3/897 (0.33%)	311/11341 (2.7%)	RR 0.12 (0.04 to 0.38) Adjusted RR 0.2 (0 to 0.7)[f]	24 fewer per 1000 (from 17 fewer to 26 fewer)	Very low
1 study (Janssen et al., 2002)	observational study	19/862 (2.2%)	45/1314 (3.4%)	RR 0.64 (0.38 to 1.09)	12 fewer per 1000 (from 21 fewer to 3 more)	Very low
1 study (Hutton et al., 2009)	observational study	99/6692 (1.5%)	145/6692 (2.2%)	RR 0.68 (0.53 to 0.88)	7 fewer per 1000 (from 3 fewer to 10 fewer)	Very low
1 study (Janssen et al., 2009)	observational study	34/2899 (1.2%)	320/10083 (3.2%)	RR 0.37 (0.26 to 0.52)	20 fewer per 1000 (from 15 fewer to 23 fewer)	Very low
1 study (Woodcock et al., 1994)	observational study	2/976 (0.2%)	11/2928 (0.38%)	RR 0.55 (0.12 to 2.46) Adjusted OR 0.54 (0.12 to 2.49)[d]	2 fewer per 1000 (from 3 fewer to 5 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Perinatal death						
1 study (Lindgren et al., 2008)	observational study	2/897 (0.22%)	7/11341 (0.06%)	RR 3.61 (0.75 to 17.36)[h]	1611 more per 1,000,000 (from 154 fewer to 10098 more)	Very low
1 study (Janssen et al., 2009)	observational study	1/2882 (0.03%)	6/10017 (0.06%)	RR 0.58 (0.07 to 4.81)[i]	252 fewer per 1,000,000 (from 557 fewer to 2282 more)	Very low
1 study (Janssen et al., 2002)	observational study	3/860 (0.35%)	1/1296 (0.08%)	RR 4.52 (0.47 to 43.39)[i]	2716 more per 1,000,000 (from 409 fewer to 32708 more)	Very low
1 study (van der Kooy et al., 2011)	observational study (natural prospective approach)	594/402912 (0.15%)	403/219105 (0.18%)	RR 0.8 (0.71 to 0.91) Adjusted OR 1.05 (0.91 to 1.21)[j]	368 fewer per 1,000,000 (from 166 fewer to 533 fewer)	Very low
	observational study (perfect guideline approach)	344/363568 (0.09%)	182/190098 (0.1%)	RR 0.99 (0.83 to 1.18) Adjusted OR 1.11 (0.93 to 1.34)[j]	10 fewer per 1,000,000 (from 163 fewer to 172 more)	
1 study (de Jonge et al., 2009)	observational study	207/321307 (0.06%)	116/163261 (0.07%)	RR 0.91 (0.72 to 1.14) Adjusted RR 1.00 (0.78 to 1.27)[k]	64 fewer per 1,000,000 (from 199 fewer to 99 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Stillbirth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	6/16839 (0.04%)	3/19706 (0.02%)	RR 2.34 (0.59 to 9.36)[l]	204 more per 1,000,000 (from 62 fewer to 1273 more)	Very low
1 study (Davis et al., 2011)	observational study	0/1826 (0%)	0/11448 (0%)	NC	NC	Very low
1 study (de Jonge et al., 2009)	observational study	99/321307 (0.03%)	61/163261 (0.04%)	RR 0.82 (0.6 to 1.13) Adjusted RR 0.97 (0.69 to 1.37)[k]	67 fewer per 1,000,000 (from 149 fewer to 49 more)	Very low
1 study (Hutton et al., 2009)	observational study	3/6692 (0.04%)	4/6692 (0.06%)	RR 0.75 (0.17 to 3.35)	149 fewer per 1,000,000 (from 496 fewer to 1405 more)	Very low
1 study (Woodcock et al., 1994)	observational study	2/976 (0.2%)	11/2928 (0.38%)	RR 0.55 (0.12 to 2.46)	1691 fewer per 1,000,000 (from 3306 fewer to 5485 more)	Very low
1 study (Blix et al., 2012)	observational study	1/1631 (0.06%)	2/16310 0.01%)	RR 5.0 (0.45 to 55.11)	490 more per 1,000,000 (67 fewer to 6635 more)	Very Low
Neonatal death						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	5/16759 (0.03%)	5/19637 (0.03%)	RR 1.17 (0.34 to 4.05)[l]	43 more per 1,000,000 (from 168 fewer to 777 more)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Davis et al., 2011)	observational study	2/1826 (0.11%)	4/11448 (0.03%)	RR 3.13 (0.57 to 17.1)	744 more per 1,000,000 (from 150 fewer to 5625 more)	Very low
1 study (de Jonge et al., 2009)	observational study	108/321307 (0.03%)[m]	55/163261 (0.03%)[m]	RR 1 (0.72 to 1.38)	0 fewer per 1,000,000 (from 94 fewer to 128 more)	Very low
1 study (Hutton et al., 2009)	observational study	6/6692 (0.09%)	4/6692 (0.06%)	RR 1.5 (0.42 to 5.31)[n]	299 more per 1,000,000 (from 347 fewer to 2576 more)	Very low
1 study (Woodcock et al., 1994)	observational study	3/976 (0.31%)	1/2928 (0.03%)	RR 9 (0.94 to 86.42)	2732 more per 1,000,000 (from 20 fewer to 29174 more)	Very low
1 study (Pang et al., 2002)	observational study	20/6133 (0.33%)	18/10593 (0.17%)	RR 1.92 (1.02 to 3.63) Adjusted RR 2.09 (1.09 to 3.97)[e]	1563 more per 1,000,000 (from 34 more to 4469 more)	Very low
1 study (Blix et al., 2012)	observational study	1/1631 (0.06%)	15/16310 (0.09%)	RR 0.67 (0.09 to 5.04)	303 fewer per 1,000,000 (837 fewer to 3716 more)	Very Low
Admission to neonatal intensive care unit (NICU)						
1 study (Birthplace in England Collaborative Group, 2011 study)	observational study	284/16696 (1.7%)	543/19642 (2.8%)	RR 0.62 (0.53 to 0.71) Adjusted OR 0.73 (99% CI 0.52 to 1.01)[b]	11 fewer per 1000 (from 8 fewer to 13 fewer)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (de Jonge et al., 2009)	observational study	540/321307 (0.17%)	323/163261 (0.2%)	RR 0.85 (0.74 to 0.97) Adjusted RR 1.00 (0.86 to 1.16)[k]	0 fewer per 1000 (from 0 fewer to 1 fewer)	Very low
1 study (Hutton et al., 2009)	observational study	102/6692 (1.5%)	115/6690 (1.7%)	RR 0.89 (0.68 to 1.16)	2 fewer per 1000 (from 6 fewer to 3 more)	Very low
1 study (Woodcock et al., 1994)	observational study	13/976 (1.3%)	219/2928 (7.5%)	RR 0.18 (0.1 to 0.31)	61 fewer per 1000 (from 52 fewer to 67 fewer)	Very low
Composite perinatal mortality and morbidity[o]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	70/16553 (0.42%)	81/19551 (0.41%)	RR 1.02 (0.74 to 1.4) Adjusted OR 1.16 (0.76 to 1.77)[b]	83 more per 1,000,000 (from 1077 fewer to 1657 more)	Very low
1 study (Hutton et al., 2009)	observational study	159/6692 (2.4%)	190/6690 (2.8%)	RR 0.84 (0.68 to 1.03)	4544 fewer per 1,000,000 (from 9088 fewer to 852 more)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	39/4488 (0.87%)	52/10541 (0.49%)	RR 1.76 (1.16 to 2.66) Adjusted OR 1.75 (1.07 to 2.86)	3749 more per 1,000,000 (from 789 more to 8189 more)	Very low
1 study (Hutton et al., 2009)	observational study	NR	NR	RR 0.94 (0.70 to 1.20)	NC	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	31/12050 (0.26%)	29/8980 (0.32%)	RR 0.80 (0.48 to 1.32) Adjusted OR 0.72 (0.41 to 1.27)	646 fewer (from 1679 fewer to 1033 more)	Very low
1 study (Hutton et al., 2009)	observational study	NR	NR	RR 0.75 (0.56 to 1.00)	NC	Very low
Women without complicating conditions at the onset of labour						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	62/15538 (0.4%)	48/15676 (0.31%)	RR 1.3 (0.89 to 1.9) Adjusted OR 1.59 (1.01 to 2.52)[b]	919 more per 1,000,000 (from 337 fewer to 2756 more)	Low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	36/4063 (0.89%)	28/8018 (0.35%)	RR 2.54 (1.55 to 4.15) Adjusted OR 2.80 (1.59 to 4.92)	3538 more per 1,000,000 (from 745 more to 7728 more)	Low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	26/11461 (0.23%)	20/7637 (0.26%)	RR 0.86 (0.43 to 1.73) Adjusted OR 0.83 (0.44 to 1.58)	340 fewer per 1,000,000 (from 1362 fewer to 1440 more)	Low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth at home	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	34/16589 (0.2%)	34/19587 (0.17%)	RR 1.18 (0.73 to 1.9)[l]	312 more per 1,000,000 (from 469 fewer to 1562 more)	Very low
Neonatal encephalopathy (signs)[p]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/16840 (0.02%)	8/19706 (0.04%)	RR 0.59 (0.18 to 1.94)[l]	166 fewer per 1,000,000 (from 333 fewer to 382 more)	Very low

CI confidence interval, NC not calculable, NR not reported, OR odds ratio, RR relative risk

a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol however this was reported in the Birthplace study as 'spontaneous vertex birth'.
b. Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, body mass index, deprivation score quintile, previous pregnancies and weeks of gestation, and also weighted to reflect unit's duration of participation and probability of being sampled
c. Adjusted for parity, BMI, smoking and nationality
d. Adjusted for birth weight and gestational age. Mode of birth outcomes are reported against a reference odds ratio of 1 for spontaneous vaginal birth. Other outcomes are reported relative to the absence of the outcome.
e. Adjusted for parity and only including women whose babies were born at a gestation of at least 37 weeks
f. Adjusted for parity, BMI, smoking, nationality, use of epidural and use of oxytocin
g. Reported as "perineal lesion." 1 woman (0.6%) in the planned home birth group and 4 women (2.4%) in the planned hospital birth group had both vaginal and perineal lesions (not significantly different: p=0.38).
h. Defined as death intrapartum or during the first 28 days of life. The two deaths in the home birth group were on day 1 and day 19. The deaths in the hospital birth group were on day 0 (n=3), day 2 (n=3) and day 19 (n=1)
i. Defined as stillbirth after 20 weeks' gestation, or death either in the first 7 days of life (Janssen et al., 2009) or in the period of hospitalisation after birth (Janssen et al., 2002). It is reported only for babies without any congenital abnormalities
j. Adjusted for maternal factors (including parity, age, ethnic background and neighbourhood), gestational age, and presence of congenital abnormalities, being small for gestational age, having an Apgar score <7 at 5 minutes, or being born preterm
k. Adjusted for parity, gestational age, maternal age, ethnic background and socioeconomic status
l. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components
m. Calculated by the technical team based on the data reported for the single outcome of intrapartum death and the combined outcome of intrapartum and neonatal deaths
n. This includes 2 infants in the planned hospital group with a major congenital anomaly (1 brain tumour, 1 liver cirrhosis)

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o. For Birthplace in England Collaborative Group, 2011 the outcome was a composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle. For Hutton et al., 2009 the outcome was defined as the presence of one or more of the following: perinatal death, Apgar score <4 at 5 minutes, neonatal resuscitation requiring positive pressure ventilations and cardiac compressions, admission to NICU or paediatric intensive care for more than 4 days, birth weight <2500 g (it excludes 2 babies with a major congenital anomaly in the planned hospital birth group).
p. Defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress

Evidence statements

No incidences of maternal mortality in any setting were reported in the five studies (n=75,578) that reported this outcome. There was consistent evidence that women planning birth at home had a lower risk of caesarean section (n=112,837) and instrumental vaginal birth (n=98,158), and hence higher rates of spontaneous vaginal birth (n=100,184), than women planning birth in an obstetric unit. There was also consistent evidence that women planning birth in an obstetric unit had higher rates of epidural use (n=82,850).

The evidence around blood loss was mixed. Evidence from 4 studies (n=44,307) suggested that the risk of any postpartum haemorrhage was reduced in women planning birth at home, but conversely 2 other studies (n=19,734) reported an increased risk in women planning birth at home. In terms of major postpartum haemorrhage, 3 studies (n=434,008) reported that the risk was reduced in women planning a home birth whereas 2 other studies (n=15,472) did not find a difference between the 2 groups. Two large studies (n=183,018) found that the blood transfusion rate was lower for women planning birth at home, however 2 other studies (n=15,158) reported no difference between groups for this outcome. There was consistent evidence from 6 studies (n=77,542) that the rates of episiotomy were higher among women planning birth in an obstetric unit, and consistent evidence from 2 studies (n=2590) that the chance of an intact perineum was higher among women planning a home birth. In terms of vaginal/perineal tears, most studies (n=53,198) found that the risk was higher among women planning birth in obstetric unit. One study (n=414) found the converse and another study (n=11) did not find a difference, but the latter study had fewer than 10 women in each arm. For third or fourth degree tears, 3 studies (n=38,574) reported an increase in risk among women planning birth in an obstetric unit but 3 studies (n=42,518) reported no difference between the 2 groups.

No studies found evidence of a difference in the risk of stillbirth or perinatal death between babies of women planning birth at home and women planning birth in an obstetric unit. Five studies (n=612,134) also did not report a difference in the risk of neonatal mortality. One study did report an increased risk of neonatal mortality among babies born to women who planned birth at home, but the very serious risk of bias undermined confidence in this finding. Given the rare nature of perinatal mortality outcomes, none of the studies were powered to detect a difference in these outcomes. Similarly, 1 study (n=36,176) found no evidence of a difference in the risk of neonatal encephalopathy, but this formed a component of a composite outcome and therefore the study was not powered to detect a difference.

There was inconsistent evidence around the rate of admission to NICU, but the majority of the evidence suggested that there was no difference in risk, with only 1 study (n=3904) suggesting that the risk was reduced among babies born to women planning a home birth.

One study (n=36,104) reported a composite perinatal mortality and morbidity outcome, for which it was powered. There was evidence of no difference between the 2 groups when all low risk women were considered, but when the analysis was restricted to women without complicating conditions identified at the onset of labour, the risk of an adverse perinatal outcome was found to be increased in babies of women who planned a home birth. When sub-group analysis by parity was undertaken it was found that babies born to nulliparous women planning birth at home were more likely to have a composite adverse neonatal outcome than those born to nulliparous women planning birth in an obstetric unit. This was true for all nulliparous women and for those without complicating conditions at the onset of labour. There was no difference seen between groups for babies born to multiparous women, either for all multiparous women or for those without complicating conditions at the onset of labour. The evidence across all outcomes was of low and very low quality.

The transfer rates were fairly consistent, with most reporting rates about 20–25%. One study reported that transfer rates were nearly 4 times more common in nulliparous women.

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The quality of evidence for all of these outcomes was predominantly very low, with some studies rated as low for a few outcomes.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was vital to consider the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in a woman's decision-making process. For the baby, they felt that it was important to establish whether there was any risk associated with planning birth at home, and therefore the outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. Similarly, the group wanted to ascertain whether there were differences in morbidity for the woman following planned birth at home compared with planned birth in an obstetric unit, given that in the case of an unforeseen emergency, such as a postpartum haemorrhage, women would have to be transferred from home into hospital. The rates of intervention, such as caesarean section and instrumental vaginal birth, were also considered priorities, as they were felt to be important to women and would be associated with morbidity, such as postpartum haemorrhage. The group did not feel that epidural was a particularly helpful outcome, as it is only available in an obstetric unit and is a matter of personal choice for the woman.

The group also felt that the rates of transfer were important to consider and would be an important consideration for women planning where to give birth.

Consideration of clinical benefits and harms

The guideline development group considered the evidence around mode of birth and agreed that the data demonstrated conclusively that women planning birth at home had lower rates of instrumental vaginal birth and caesarean section, and consequently higher rates of spontaneous vaginal birth, than women planning birth in an obstetric unit.

Similarly, episiotomy was consistently more common after planning birth in an obstetric unit when compared with planning birth at home, but the evidence for other outcomes linked to perineal trauma was less consistent. For third or fourth degree tears, data from 3 studies suggested that they were more common after planned birth at an obstetric unit, while 3 studies (of which one was the Birthplace study) did not find evidence of a difference. Two studies that reported the outcome of intact perineum found that the rate was significantly higher after planned birth at home and therefore the group concluded that the chance of some trauma might be higher after planned birth in an obstetric unit, but noted the inconsistency in the evidence.

When considering the evidence around blood loss, the group noted that the Birthplace study had not reported rates of postpartum haemorrhage. However, they acknowledged the reasoning behind this decision, namely the potential bias in reporting haemorrhage rates in different birth settings, with the researchers preferring to use the more robust surrogate outcome of blood transfusion for clinically important haemorrhage. The evidence around both 'any postpartum haemorrhage' and 'major postpartum haemorrhage' was inconsistent, with studies reporting effects in both directions. The group also agreed that there was a potential for bias in the reporting of haemorrhages in different settings, particularly with smaller amounts of bleeding, and therefore that differences had to be interpreted with caution. They noted that the Birthplace study (and 2 others) did not find a difference in the rates of blood transfusion for women planning a home birth compared with women planning birth in an obstetric unit.

The group then considered neonatal outcomes and discussed the fact that there were generally no differences found in rates of perinatal death, stillbirth and neonatal death, but noted that the studies were underpowered to detect differences in such rare outcomes. The group noted that Pang et al. (2002) had found a significantly higher rate of neonatal death in babies born to

women with a planned home birth, but their reservations about the methodology of the study (discussed in more detail below) meant that they did not place much weight on this finding. The group considered the composite outcome reported by the Birthplace study and noted that achieving sufficient power in this study had required pooling components with very different levels of severity, from fractured clavicle to mortality. While the group noted that this was a limitation, it was felt to be the best available evidence about the relative risks for babies of planning birth in each setting. Also, fractured clavicle accounted for less than 3% of events, while the serious perinatal outcomes of mortality, neonatal encephalopathy and meconium aspiration constituted just under 90% of the primary outcome events. The group noted that for nulliparous women without complicating conditions at the onset of labour, the evidence suggested that there was a higher risk to babies of planning birth at home, but they concluded that the risk was very low across both settings. The evidence suggested that there was no higher risk to babies of multiparous women planning birth at home

The guideline development group discussed the rates of transfer reported in the studies, and concluded that they were generally quite consistent, at around 20–25%. They noted that in the Birthplace study, 45% of nulliparous women planning birth at home were transferred at some point during or after labour, compared to only 12% of multiparous women. The group agreed that it was important that women were given information about the likelihood that they would need to be transferred based on local figures where possible, and what the reasons for this likelihood might be.

Consideration of health benefits and resource uses

The guideline development group discussed the relative costs implicit in providing care for women planning birth at home and those planning birth in an obstetric unit. When considering women planning a home birth, they noted that these women had lower rates of interventions such as caesarean section, and that this would likely be associated with a cost saving. Also, there would be a reduction in the 'hotel' costs, both from women giving birth at home and from reduced hospital-based postnatal stays due to fewer interventions. However, they recognised that an obstetric unit always has to be available for transfer and that many such transfers have associated costs due to use of an ambulance. Given the high rate of transfer in nulliparous women, they agreed that this cost could be substantial. In terms of staffing, the group noted that more midwives would be required in the community if more women planned home births or births in a freestanding unit.

The health economic issues are complex but it is important to remember that this guideline is providing guidance on the care of low risk women in labour and not maternity services as a whole. The financial considerations may differ depending on geographical location and population density, which means that increasing community-based labour care may be cost effective for a large conurbation but not for a rural setting. In addition, the evidence demonstrates a wide variation in the configuration of both freestanding and alongside midwifery units, and this has to be factored into the health economic considerations. A consultant-led unit is always necessary to support maternity services, so reducing the number of caesarean sections or instrumental deliveries may not make a large difference to the overall cost of the service. However, there are health and cost benefits. Furthermore, reducing the number of interventions may mean that women in an obstetric unit may receive better care. For the number of non-obstetric unit deliveries to increase, midwifery staff need to be redeployed. Moving individuals from one setting to another is not always easy and some midwives prefer to work in an obstetric unit. However, working in a community setting in a team is very attractive to many midwives because they experience relative independence and the work is varied in nature (including home visits, antenatal clinics and classes as well as intrapartum care). The skills required for community practice are different and there are costs associated with re-training and maintaining skills. However, the Birthplace analysis of

established services suggested cost savings from low risk multiparous women giving birth away from obstetric units. So although there may be setup costs associated with increasing non-obstetric unit deliveries, this could offer potential savings in the future.
After consideration of all these factors, the guideline development group concluded that a shift from obstetric unit to 'non-obstetric', including community-based, deliveries could be achieved through reorganisation of the service. This would involve redeployment of midwives out of obstetric units, with provision of appropriate training and support. The group thought that moving midwives out of obstetric units and therefore increasing the number of non-obstetric unit or home births in this way would not necessarily lead to higher overall running costs.

Quality of evidence

With the exception of 1 pilot randomised controlled trial of 11 women, all of the included studies were observational studies and, as a result, the evidence was almost universally of very low quality. The guideline development group discussed the fact that women who plan a home birth are often systematically different to women who plan birth in an obstetric unit, and that these differences may be associated with differences in birth outcomes. They agreed that the results therefore had to be interpreted carefully, with this fact taken into consideration.
The group agreed that, although the studies had received the same 'grade', the quality of the studies, and their applicability to low-risk women in England and Wales, still varied considerably. The group noted that in some of the studies, adjustments had been made for the difference in characteristics between the study groups or matching had been performed, and felt that these were the more useful studies. In particular, they agreed that the Birthplace study was informative, as it was recent, conducted in England, the largest study reporting most outcomes, and performed adjustments for demographic differences. However, they also noted that although the Birthplace study was restricted to 'low risk' women, 19.5% of women planning birth in an obstetric unit had 1 or more complicating conditions identified at the start of care in labour, compared to 5.5% of the women planning a home birth.
The group noted that in some of the studies, there was a particular risk of bias due to the method of selection of the study groups. They discussed the fact that in Pang et al. (2002), large assumptions had to be made to identify the women with a planned home birth and that this could have affected results if unplanned home births had been mistakenly categorised as being planned. Similarly, in Hutton et al. (2009), a proportion of women had their planned place of birth coded as 'unknown' and therefore there was a risk that these women could have been misclassified. The group also discussed the fact that in some of the included studies, the authors had used slightly different criteria to select the 2 groups of women, in particular in Lindgren et al. (2008), where pre-term births were included in the planned home birth group only, and Janssen et al. (2009), where women with previous caesarean section were included in the planned home birth group only. They noted that this was generally a very small proportion of women and that there were demographic differences in other studies that used consistent criteria across groups, but their feeling was that there was a greater risk of bias in these studies and therefore that the results should be interpreted with more caution.

Other considerations

The guideline development group discussed the fact that the availability of home births and the rate of uptake by women varies considerably across England and Wales. They agreed that areas with higher home birth rates and a well-organised service were likely to have a better quality of midwife care for home births, which they expected would result in better outcomes for women and babies. They discussed the fact that most women do not currently choose to give birth at home, for a variety of reasons, but that it was important that women are aware of it as an option and are supported in their decision.

The group considered the subgroup analysis by parity that was reported in the Birthplace study for all outcomes and in various other studies for specific outcomes (Hutton et al., 2009; Janssen et al., 2002; Janssen et al., 2009; Pang et al., 2002). They noted that for most of the outcomes, the analysis for the individual subgroups was consistent with the overall analysis. However, the group did observe some notable differences. Firstly, they noted that for multiparous women, the risk of blood transfusion and third and fourth degree tears was lower in women planning a home birth (the analysis for all women demonstrated no significant difference). They also noted that for the babies of multiparous women, the risk of admission to NICU was lower after a planned home birth and that there was no significant difference in the risk of the composite perinatal morbidity and mortality outcome, even in the subgroup of women without complicating conditions at the onset of labour. Therefore, their conclusion was that for multiparous women and their babies, planning birth at home was as safe as planning birth in an obstetric unit and that the higher rates of intervention in obstetric units suggested that planning birth outside an obstetric unit was preferable. However, when considering outcomes for babies born to nulliparous women, they noted that there was a consistently higher risk of an adverse outcome after a planned home birth, in all low risk women and the subgroup of women without complicating conditions at the onset of labour. Although the risk was low for the babies in both settings, the group felt that the evidence was sufficient to suggest that nulliparous women should not be recommended to plan birth at home while noting that women who choose to plan birth at home should be supported in this choice.

Freestanding midwifery unit compared with alongside midwifery unit

Description of included studies

One study was included in this review (Birthplace in England Collaborative Group, 2011). The included study was a prospective cohort study from England which evaluated outcomes for women intending to give birth in a freestanding midwifery unit compared to women intending to give birth in an alongside midwifery unit.

A summary of points to note about the study population can be found in table 12 below, and further details about the selection of the study groups are reported in the evidence tables (appendix I).

Update 2014

Table 12: Summary of included studies for planned birth in a freestanding midwifery unit compared with planned birth in an alongside midwifery unit

Study	Study design	Intervention	Details of particular issues to note with study population	Transfer rate	New to update ?
Birthplace in England Collaborative Group, 2011	Prospective cohort study	Intended place of birth at start of care in labour	Freestanding midwifery unit: 5.5% women had complicating conditions at start of care in labour 46% were nulliparous Alongside midwifery unit: 6.9% women had complicating conditions at start of care in labour 54% were nulliparous	**Freestanding midwifery unit group** Transfer rate: 21.9% (Before birth: 16.5% After birth: 4.8% Time missing: 0.5%) Transfer rate nulliparous: 36.3% (83.4% before birth) Transfer rate mulliparous: 9.4% (57.4% before birth) **Alongside midwifery unit group** Transfer rate: 26.4% (Before birth: 21.2% After birth: 4.3% Time of transfer missing: 0.9%) Transfer rate nulliparous: 40.2% (86.9% before birth) Transfer rate multiparous: 12.5% (70.8% before birth)	Yes

Update 2014

Table 13: Summary GRADE profile for comparison of planned birth in a freestanding midwifery unit with planned birth in an alongside midwifery unit for all women

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/11282 (0%)	0/16710 (0%)	not calculable (NC)	NC	Very low
Mode of birth: spontaneous vaginal birth[a]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	10150/11280 (90%)	14413/16690 (86.4%)	RR 1.04 (1.03 to 1.05)	35 more per 1000 (from 26 more to 43 more)	Very low
Mode of birth: instrumental vaginal birth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	686/11280 (6.1%)	1524/16690 (9.1%)	RR 0.67 (0.61 to 0.73)	30 fewer per 1000 (from 25 fewer to 36 fewer)	Very low
Mode of birth: caesarean section						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	405/11280 (3.6%)	727/16690 (4.4%)	RR 0.82 (0.73 to 0.93)	8 fewer per 1000 (from 3 fewer to 12 fewer)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Use of epidural						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1251/11251 (11.1%)	2464/16661 (14.8%)	RR 0.75 (0.71 to 0.8)	37 fewer per 1000 (from 30 fewer to 43 fewer)	Very low
Measures of blood loss: need for a blood transfusion						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	67/11230 (0.6%)	136/16548 (0.82%)	RR 0.73 (0.54 to 0.97)	2 fewer per 1000 (from 0 fewer to 4 fewer)	Very low
Episiotomy						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	995/11275 (8.8%)	2098/16689 (12.6%)	RR 0.7 (0.65 to 0.75)	38 fewer per 1000 (from 31 fewer to 44 fewer)	Very low
Third or fourth degree perineal tears						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	259/11262 (2.3%)	535/16654 (3.2%)	RR 0.72 (0.62 to 0.83)	9 fewer per 1000 (from 5 fewer to 12 fewer)	Very low
Stillbirth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/11282 (0.04%)	1/16708 (0.006%)	RR 5.92 (0.66 to 52.99)[b]	294 more per 1,000,000 (from 20 fewer to 3112 more)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Early neonatal death						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	5/11263 (0.04%)	3/16633 (0.02%)	RR 2.46 (0.59 to 10.3)[b]	263 more per 1,000,000 (from 74 fewer to 1677 more)	Very low
Admission to neonatal intensive care unit (NICU)						
1 study (Birthplace in England Collaborative Group, 2011 study)	observational study	194/11257 (1.7%)	307/16580 (1.9%)	RR 0.93 (0.78 to 1.11)	1 fewer per 1000 (from 4 fewer to 2 more)	Very low
Composite perinatal mortality and morbidity[c]						
All low risk women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	41/11199 (0.37%)	58/16524 (0.35%)	RR 1.04 (0.7 to 1.55)	140 more per 1,000,000 (from 1053 fewer to 1931 more)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	24/5158 (0.47%)	38/8256 (0.46%)	RR 1.01 (0.61 to 1.68)	46 more per 1,000,000 (from 1795 fewer to 3130 more)	Very low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	17/6025 (0.28%)	20/8234 (0.24%)	RR 1.16 (0.61 to 2.22)	389 more per 1,000,000 (from 947 fewer to 2963 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an alongside midwifery unit	Relative (95% CI)	Absolute (95% CI)	
Women without complicating conditions at the onset of labour						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	35/10571 (0.33%)	54/15342 (0.35%)	RR 0.94 (0.62 to 1.44)	211 fewer per 1,000,000 (from 1338 fewer to 1549 more)	Low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	22/4785 (0.46%)	35/7518 (0.47%)	RR 0.99 (0.58 to 1.68)	47 fewer per 1,000,000 (from 1955 fewer to 3166 more)	Low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	13/5772 (0.23%)	19/7792 (0.24%)	RR 0.92 (0.46 to 1.87)	195 fewer per 1,000,000 (from 1317 fewer to 2121 more)	Low
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	17/11210 (0.15%)	17/16569 (0.1%)	RR 1.48 (0.75 to 2.89)[b]	492 more per 1,000,000 (from 257 fewer to 1939 more)	Very low
Neonatal encephalopathy (signs)[d]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	2/11282 (0.02%)	4/16710 (0.02%)	RR 0.74 (0.14 to 4.04)[b]	62 fewer per 1,000,000 (from 206 fewer to 728 more)	Very low

CI confidence interval, NC not calculable, RR relative risk

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a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol however this was reported in the Birthplace study as 'spontaneous vertex birth'.
b. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components.
c. Composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle.
d. Defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress

Evidence statements

Only 1 study (n=27,992) provided comparative data on planned freestanding midwifery unit and alongside midwifery unit births. The evidence suggested that women planning birth in a freestanding midwifery unit had lower rates of instrumental vaginal birth and caesarean section, and therefore higher rates of spontaneous vaginal birth, than women planning birth in an alongside midwifery unit. Women planning birth in a freestanding midwifery unit were also less likely to have an epidural, less likely to have a blood transfusion and less likely to have trauma in the form of an episiotomy or a third or fourth degree perineal tear. There were no reported incidences of maternal mortality in any setting.

In terms of neonatal outcomes, the study found evidence of no difference in a composite adverse neonatal outcome between babies born to women planning birth in a freestanding midwifery unit and babies born to women planning birth in an alongside midwifery unit. A sub-group analysis by parity also found no difference between groups for babies born to either nulliparous or multiparous women. There was also no evidence of a difference in stillbirth, early neonatal death and neonatal encephalopathy, but these outcomes formed part of the composite outcome and the study was not powered to detect a difference in the individual components. There was no evidence of a difference in the risk of admission to NICU between the two groups of babies.

Transfer rates were similar in the two settings. Transfers in nulliparous women were 3 to 4 times more common than in multiparous women. The evidence across all outcomes was of low and very low quality.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was vital to consider both the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in women's decision-making process. For the baby, they felt that it was important to establish whether there was any difference in risk between planning birth in a freestanding midwifery unit and planning birth in an alongside midwifery unit, given that the latter is based in a hospital. Therefore, the outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. Similarly, the group wanted to ascertain whether there were differences in morbidity for the woman following planned birth in a freestanding midwifery unit compared with planned birth in an alongside midwifery unit, given that in the case of an unforeseen emergency, such as a postpartum haemorrhage, transfer from an alongside midwifery unit into an obstetric unit would be more likely to be expedient than transfer from a freestanding facility. The rates of intervention, such as caesarean section and instrumental vaginal birth, were also considered priorities, as they were felt to be important to women and also associated with morbidity, such as postpartum haemorrhage. The group did not feel that using epidural anaesthesia was a particularly helpful outcome, as it is a matter of personal choice for the woman and would require a transfer from either setting.

The group also felt that the rates of transfer were important to consider and would be an important consideration for women planning where to give birth. In particular, they noted that, for many women, transfer from a freestanding unit required an ambulance and was likely to be a more stressful and negative experience for the woman than transfer from an alongside unit.

Consideration of clinical benefits and harms

The guideline development group considered the evidence around outcomes for the woman, and agreed that it universally showed a benefit of planning birth in a freestanding midwifery unit. Women planning birth in a freestanding midwifery unit had higher rates of spontaneous

vaginal birth and lower rates of instrumental vaginal birth, caesarean section, blood transfusion, episiotomy and third or fourth degree perineal tears when compared with women planning birth in an alongside midwifery unit. Although it is acknowledged that the data shown in table 13 are not adjusted for parity or other maternal characteristics, the rates of transfer from an alongside midwifery unit were slightly lower (although reasonably similar at 22% compared with 26%) from freestanding midwifery units. Also, women with planned births in alongside midwifery units were typically not transferred to the obstetric unit if the baby required admission to the neonatal unit. In both types of unit, the rates of transfer were 3 to 4 times higher for nulliparous women than for multiparous women, but the group felt that, on balance, the advantages of a freestanding unit outweighed any potential harms and nulliparous women wishing to given birth in freestanding units should be supported in this decision.

The evidence did not find a significant difference between the two settings in any of the reported perinatal outcomes, although the group noted that the study was only powered to detect a difference in the rate of the composite outcome, not the rare, serious components of stillbirth, neonatal mortality and neonatal encephalopathy. They discussed the fact that this was a limitation of the evidence available, but agreed that conducting a study large enough to detect a difference in the rare outcomes was unlikely to be feasible.

Consideration of health benefits and resource uses

The guideline development group discussed the relative costs of planning birth in the 2 types of midwifery unit. They agreed that the reduced rate of intervention (such as caesarean section and blood transfusion) among women planning birth in a freestanding unit would reduce the associated costs. However, they also noted that transfer from a freestanding unit required an ambulance and that this would increase the cost when compared to an alongside unit. They also discussed the fact that in areas with small populations, the provision of both types of midwifery unit within 1 region or trust might not be economically viable because the number of places available in midwifery units might exceed the demand. They agreed that, in principle, it was preferable that women have the choice, and felt it would be possible for all areas to provide the option of both types of midwifery-led units, either within 1 region or by working in networks or in collaboration with neighbouring healthcare providers. However, the success of this approach depends on the population density. It may be much easier to achieve in large conurbations than rural areas.

Quality of evidence

Only 1 included study was available for this comparison. The study was a recent, large prospective study that was conducted in England, but it was an observational study and there were differences between the 2 study groups which could have affected birth outcomes. For example, 6.9% of women in the alongside midwifery unit group had complicating conditions at the start of care in labour when compared with 5.5% of women in the freestanding midwifery unit group. The group also noted that the authors of the study had performed adjustments for demographic differences for other comparisons reported in the study, but not for this one. They agreed that this was a limitation, but were also aware that in fact these 2 groups were quite similar demographically and so any inherent bias caused by these differences was likely to be very small.

Other considerations

While the Birthplace study findings suggest that intervention rates are lower in planned freestanding midwifery unit births compared with planned alongside midwifery unit births, it has to be acknowledged that the data presented in table 13 are not adjusted for parity or other maternal characteristics and the confidence intervals do not take account of clustering. In the light of this, the guideline development group discussed the subgroup analysis by parity that

was reported and agreed that the trends were broadly similar to the results of the overall analysis. The main differences they noted were that when stratified by parity, the difference between freestanding and alongside midwifery units in terms of rates of caesarean section and rates of blood transfusion were no longer statistically significant.

Freestanding midwifery unit compared with obstetric unit

Description of included studies

Eight studies were included in this review (Birthplace in England Collaborative Group, 2011; David et al., 1999; Davis et al., 2011; Feldman and Hurst, 1987; Jackson et al., 2003; Overgaard et al., 20112; Scupholme et al., 1986; Stone, 1998).

Five of the included studies are prospective cohort studies, conducted in England (Birthplace in England Collaborative Group, 2011), Denmark (Overgaard et al., 2011) and the USA (Jackson et al., 2003; Scupholme et al., 1986; Stone, 1998). The remaining 3 are retrospective cohort studies, conducted in Germany (David et al., 2011), the USA (Feldman and Hurst, 1987) and New Zealand (Davis et al., 2011).

All of the studies compared planned birth in a freestanding midwifery unit or birth centre with planned birth at an obstetric unit, and analysed data on an intention-to-treat basis, so that women were analysed by their planned place of birth even if they were transferred. One of the included studies evaluated outcomes by booked place of birth during the antenatal period (Jackson et al., 2003), whereas in the remaining studies, outcomes were analysed by the intended place of birth at the onset of labour.

The included studies aimed to restrict their populations to low risk women, but some women had complications which resulted in them being higher risk or outside the scope of the guideline. In addition, there were some systematic differences in the characteristics of women planning birth in a freestanding midwifery unit and women planning birth in an obstetric unit. Three studies aimed to control for potential confounders by performing adjusted analyses (Birthplace in England Collaborative Group, 2011; Davis et al., 2011; Jackson et al., 2003) and a further 3 studies aimed to minimise the differences between the study groups by matching women on socio-demographic characteristics (Scupholme et al., 1986), risk criteria (Feldman and Hurst, 1987) or a combination of different factors (Overgaard et al., 2012).

Table 14 shows a summary of points to note about the study populations. Further details about the selection of the study groups are reported in the evidence tables (appendix I).

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Table 14: Summary of included studies for planned birth in a freestanding midwifery unit compared with planned birth in an obstetric unit

Study	Study design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit group (or any details of transfers reported)	New to update?
Birthplace in England Collaborative Group, 2011	Prospective cohort study	Intended place of birth at start of care in labour	Freestanding midwifery unit: 5.5% women had complicating conditions at onset of labour 46% were nulliparous Obstetric unit: 19.5% women had complicating conditions start of care in labour 54% were nulliparous	Transfer rate: 21.9% (Before birth: 16.5% After birth: 4.8% Time missing: 0.5%)	Yes

Study	Study design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit group (or any details of transfers reported)	New to update?
				Freestanding midwifery unit group Nulliparous – 36.3% (83.4% before birth) Multiparous – 9.4% (57.4% before birth)	
David et al., 1999	Retrospective cohort study	Intended place of birth at onset of labour	No particular issues identified, but this is likely to be a result of a lack of demographic information provided	Total: 21.8% (Intrapartum: 18.2% Postpartum: 3.6%)	No
Davis et al., 2011	Retrospective cohort study	Intended place of birth at onset of labour	No particular indirectness of population identified The authors report that continuous electronic fetal monitoring may have been available in some freestanding units, making it less comparable to UK units. The study reported outcomes for planned birth in a secondary hospital and planned birth in a tertiary hospital. These groups have been pooled by the technical team to provide the comparator group for this analysis.	Actual place of birth was freestanding midwifery unit: 90.2%	Yes
Feldman & Hurst, 1987	Retrospective cohort study	Intended place of birth at onset of labour	Freestanding midwifery unit: 4.2% women had induction of labour Obstetric unit: 1.3% women had induction of labour Women in obstetric unit group were reported as being looked after by obstetricians and obstetric nurses; therefore, this is less comparable to the UK	Transfer rate: 22% (Between 37 weeks and birth: 8% Intrapartum: 14%)	No
Jackson et al., 2003	Prospective cohort study	Booked place of birth	Freestanding midwifery unit: 16.9% women had prior medical or pregnancy risk factors; 8.4% women were induced with oxytocin/prostaglandin; 4.2% women had a previous caesarean section; 6.4% women gave birth before 37 weeks of pregnancy; 5.9% babies were small for gestational age.	Transfer rate: 54.2% (Antepartum complications: 27.2% Intrapartum complications: 18.5% Due to patient	Yes

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Study	Study design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit group (or any details of transfers reported)	New to update?
			Obstetric unit: 16.2% women had prior medical or pregnancy risk factors; 14.7% women were induced with oxytocin/prostaglandin; 10% women had a previous caesarean section; 6.5% women gave birth before 37 weeks of pregnancy; 4% babies were small for gestational age. [Note: the study aimed to evaluate low income women, and 77% of women were Hispanic] Women in obstetric unit group were reported as being looked after by obstetricians; therefore, this is less comparable to the UK mode of care	choice: 8.5%)	
Overgaard et al., 2012	Prospective cohort study (with some retrospective recruitment)	Intended place of birth at onset of labour	The following points about the population should be noted; however, they were not considered sufficiently serious to downgrade the study's quality: Healthy, multiparous women with uncomplicated previous pregnancies and births were considered low risk regardless of age and BMI Midwives in the freestanding midwifery unit could perform ventouse deliveries, which may not be comparable to all units in England and Wales The freestanding unit was based in a hospital; however, the hospital did not have an obstetric service and it is specifically stated that women had to be transferred by ambulance in the case of complications.	Transfer rate: 16.3% (Intrapartum: 11.6% Within 2 hours of birth: 3.2% More than 2 hours after birth: 1.5%)	Yes
Scupholme et al., 1986	Prospective cohort study	Intended place of birth at onset of labour	No particular indirectness of population identified Women in obstetric unit group were reported as being looked after by obstetricians and nurse midwives; therefore, this is less comparable to the UK mode of care	Transfer rate for mothers: 22.8% (Intrapartum: 21.6% Postpartum: 1.2% Babies: 12.8%)	No

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Study	Study design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit group (or any details of transfers reported)	New to update?
Stone, 1998	Prospective cohort study	Intended place of birth at onset of labour	No particular indirectness of population identified, but this is likely to be a result of a lack of demographic information provided Women in obstetric unit group were reported as being looked after by obstetricians; therefore, this is less comparable to the UK	No details given	No

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Evidence profile

All risk ratios were calculated as standard using RevMan, but where the authors have reported adjusted measures of effect these have also been reported in the table. Some of the included studies only reported percentages without raw event rate data. In order to facilitate analysis, event rate data has been calculated by the technical team where possible (studies where this has been done are designated with a footnote in the table), but in some cases this was not possible due to rounding or unclear reporting of denominators. For measures of perinatal/neonatal mortality and morbidity, due to the low incidence absolute effects have been reported per 1,000,000.

Table 15: Summary GRADE profile for comparison of planned birth in a freestanding midwifery unit and planned birth in an obstetric unit for all women

Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Maternal mortality						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/11282 (0%)	0/19706 (0%)	not calculable (NC)	NC	Very low
1 study (Feldman & Hurst, 1987)	observational study	0/77 (0%)	0/72 (0%)	NC	NC	Very low
1 study (Scupholme et al., 1986)	observational study	0/250 (0%)	0/250 (0%)	NC	NC	Very low
1 study (David et al., 1999)	observational study	0/801 (0%)	1/3271 (0.03%)	RR 1.36 (0.06 to 33.35)	110 more per 1,000,000 (from 287 fewer to 9890 more)	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Mode of birth: spontaneous vaginal birth[a]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	10150/11280 (90%)	14645/19688 (74.4%)	RR 1.21 (1.2 to 1.22) Adjusted OR 3.38 (99% CI 2.70 to 4.25)[b]	156 more per 1000 (from 149 more to 164 more)	Very low
1 study (Overgaard et al., 2012)	observational study	796/839 (94.9%)	751/839 (89.5%)	RR 1.06 (1.03 to 1.09)	54 more per 1000 (from 27 more to 81 more)	Low
1 study (Davis et al., 2011)	observational study	2722/2873 (94.7%)	9195/11448 (80.3%)	RR 1.18 (1.16 to 1.19)	145 more per 1000 (from 129 more to 153 more)	Very low
1 study (Jackson et al., 2003)	observational study	1462/1808 (80.9%)	720/1149 (62.7%)	RR 1.29 (1.23 to 1.36) Adjusted risk difference (RD) 14.9 (11.5 to 18.3)[c]	182 more per 1000 (from 144 more to 226 more)	Very low
1 study (Feldman & Hurst, 1987)	observational study	87.9%[d]	45.0%[d]	NC	Difference 42.9[d]	Very low
1 study (Scupholme et al., 1986)	observational study	92%	83%	NC	p=0.005 - 0.01 for all modes of birth	Very low
1 study (David et al., 1999)	observational study	91.4%	84.3%	NC	p<0.001	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Mode of birth: instrumental vaginal birth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	686/11280 (6.1%)	2842/19688 (14.4%)	RR 0.42 (0.39 to 0.46) Adjusted OR Ventouse: 0.32 (99% CI 0.22 to 0.47)[b] Forceps: 0.45 (99% CI 0.32 to 0.63)[b]	84 fewer per 1000 (from 78 fewer to 88 fewer)	Very low
1 study (Overgaard et al., 2012)	observational study	25/839 (3%)	61/839 (7.3%)	RR 0.41 (0.26 to 0.65)	43 fewer per 1000 (from 25 fewer to 54 fewer)	Low
1 study (Davis et al., 2011)	observational study	58/2873 (2%)	1018/11448 (8.9%)	RR 0.23 (0.17 to 0.29)[e]	68 fewer per 1000 (from 63 fewer to 74 fewer)	Low
1 study (Jackson et al., 2003)	observational study	151/1808 (8.4%)	208/1149 (18.1%)	RR 0.46 (0.38 to 0.56) Adjusted RD −9.7 (−12.5 to −6.9)[c]	98 fewer per 1000 (from 80 fewer to 112 fewer)	Very low
1 study (Feldman & Hurst, 1987)	observational study	5.6%	43.7%	NC	p<0.0001	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Scupholme et al., 1986)	observational study	2%	3%	NC	p=0.005–0.01 for all mode of birth	Very low
1 study (David et al., 1999)	observational study	5%	11%	NC	p<0.001	Very low
Mode of birth: caesarean section						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	405/11280 (3.6%)	2158/19688 (11%)	RR 0.33 (0.3 to 0.36) Adjusted OR 0.32 (99% CI 0.24 to 0.42)[b]	73 fewer per 1000 (from 70 fewer to 77 fewer)	Very low
1 study (Overgaard et al., 2012)	observational study	19/839 (2.3%)	34/839 (4.1%)	RR 0.56 (0.32 to 0.97)	18 fewer per 1000 (from 1 fewer to 28 fewer)	Low
1 study (Davis et al., 2011)	observational study	91/2873 (3.2%)	1232/11448 (10.8%)	RR 0.29 (0.24 to 0.36)[e]	76 fewer per 1000 (from 69 fewer to 82 fewer)	Low
1 study (Jackson et al., 2003)	observational study	194/1808 (10.7%)	219/1149 (19.1%)	RR 0.56 (0.47 to 0.67) Adjusted RD -4.7 (−7.3 to −2.2)[c]	84 fewer per 1000 (from 63 fewer to 101 fewer)	Very low
1 study (Feldman & Hurst, 1987)	observational study	5/77[f] (6.5%)	8/71[f] (11.3%)	RR 0.58 (0.2 to 1.68)	47 fewer per 1000 (from 90 fewer to 77 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Scupholme et al., 1986)	observational study	15/250[f] (6%)	35/250[f] (14%)	RR 0.43 (0.24 to 0.76)	80 fewer per 1000 (from 34 fewer to 106 fewer) p=0.005–0.01 for all mode of birth	Very low
1 study (David et al., 1999)	observational study	3.0%	4.6%	NC	p=0.057	Very low
Use of epidural						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1251/11251 (11.1%)	5817/19576 (29.7%)	RR 0.37 (0.35 to 0.4) Adjusted OR 0.27 (99% CI 0.22 to 0.34)[b]	187 fewer per 1000 (from 178 fewer to 193 fewer)	Very low
1 study (Overgaard et al., 2012)	observational study	35/839 (4.2%)	86/839 (10.3%)	RR 0.41 (0.28 to 0.6)	60 fewer per 1000 (from 41 fewer to 74 fewer)	Low
1 study (Jackson et al., 2003)	observational study	522/1779 (29.3%)	742/1089 (68.1%)	RR 0.43 (0.4 to 0.47) Adjusted RD -35.7 (-39.5 to -31.8)[e]	388 fewer per 1000 (from 361 fewer to 409 fewer)	Very low
1 study (Feldman & Hurst, 1987)	observational study	4/77[f] (5.2%)	40/71[f] (56.3%)	RR 0.09 (0.03 to 0.24)	513 fewer per 1000 (from 428 fewer to 546 fewer)	Very low
Measures of blood loss: postpartum haemorrhage (any)						
1 study (Overgaard et al., 2012)	observational study	29/839 (3.5%)	68/839 (8.1%)	RR 0.43 (0.28 to 0.65)	46 fewer per 1000 (from 28 fewer to 58 fewer)	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Feldman & Hurst, 1987)	observational study	2/72e (2.8%)	1/63e (1.6%)	RR 1.75 (0.16 to 18.84)	12 more per 1000 (from 13 fewer to 283 more)	Very low
1 study (Scupholme et al., 1986)	observational study	5%	1.4%	NC	p-value NR	Very low
Measures of blood loss: major postpartum haemorrhage (over 1000 ml)						
1 study (Overgaard et al., 2012)	observational study	11/839 (1.3%)	14/839 (1.7%)	RR 0.79 (0.36 to 1.72)	4 fewer per 1000 (from 11 fewer to 12 more)	Very low
1 study (Davis et al., 2011)	observational study	Event rates are not reported. RR are calculated with midwifery unit (MU) as the reference. Secondary hospital compared with MU: RR 1.20 (95% CI 0.80 to 1.79) Adjusted RR 1.20 (95% CI 0.80 to 1.81)[g] Tertiary hospital compared with MU: RR 1.47 (95% CI 0.96 to 2.24) Adjusted RR 1.39 (95% CI 0.90 to 2.16)[g]			NC	Very low
Measures of blood loss: need for a blood transfusion						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	67/11230 (0.6%)	241/19579 (1.2%)	RR 0.48 (0.37 to 0.63) Adjusted OR 0.48 (99% CI 0.32 to 0.73)[a]	6 fewer per 1000 (from 5 fewer to 8 fewer)	Very low

Update 2014

Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Episiotomy						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	995/11275 (8.8%)	3780/19678 (19.2%)	RR 0.46 (0.43 to 0.49) Adjusted OR 0.40 (99% CI 0.32 to 0.51)[b]	104 fewer per 1000 (from 98 fewer to 109 fewer)	Very low
1 study (Davis et al., 2011)	observational study	Event rates are not reported. RR are calculated with MU as the reference. Secondary hospital compared with MU: RR 2.10 (95% CI 1.72 to 2.56) Adjusted RR 1.88 (95% CI 1.54 to 2.30)[e] Tertiary hospital compared with MU: RR 3.97 (95% CI 3.25 to 4.85) Adjusted RR 2.91 (95% CI 2.37 to 3.57)[e]			NC	Low
1 study (Jackson et al., 2003)	observational study	209/1779 (11.7%)	348/1089 (32%)	RR 0.37 (0.32 to 0.43) Adjusted RD −22.5 (−26.4 to −18.5)[c]	201 fewer per 1000 (from 182 fewer to 217 fewer)	Very low
1 study (Feldman & Hurst, 1987)	observational study	47.2%	78.1%	NC	p<0.0001	Very low
1 study (David et al., 1999)	observational study	15.7%	54.8%	NC	p<0.001	Very low
1 study (Stone, 1998)	observational study	4/54 (7.4%)	29/52 (55.8%)	RR 0.13 (0.05 to 0.35)	485 fewer per 1000 (from 362 fewer to 530 fewer)	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Intact perineum or birth canal						
1 study (Overgaard et al., 2012)	observational study	514/839 (61.3%)	466/839 (55.5%)	RR 1.1 (1.02 to 1.2)	56 more per 1000 (from 11 more to 111 more)	Low
1 study (Feldman & Hurst, 1987)	observational study	18/77[f] (23.4%)	4/72[f] (5.6%)	RR 4.21 (1.50 to 11.84)	167 more per 1000 (from 28 more to 602 more)	Very low
1 study (David et al., 1999)	observational study	30%	22%	NC	p<0.001	Very low
1 study (Stone, 1998)	observational study	12/54 (22.2%)	4/52 (7.7%)	RR 2.89 (1 to 8.39)	145 more per 1000 (from 0 fewer to 568 more) p≤0.01	Very low
Any vaginal/perineal tears						
1 study (Overgaard et al., 2012)	observational study	309/839 (36.8%)	361/839 (43%)	RR 0.86 (0.76 to 0.96)	60 fewer per 1000 (from 17 fewer to 103 fewer)	Low
1 study (Davis et al., 2011)	observational study	Event rates are not reported. RR are calculated with MU as the reference. Secondary hospital compared with MU: RR 0.95 (95% CI 0.87 to 1.04) Adjusted RR 0.83 (95% CI 0.76 to 0.91)[g] Tertiary hospital compared with MU: RR 1.27 (95% CI 1.15 to 1.40) Adjusted RR 0.91 (95% CI 0.82 to 1.02)[f]			NC	Low

Update 2014

Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Feldman & Hurst, 1987)	observational study	26/77[f] (33.8%)	10/72[f] (13.9%)	RR 2.43 (1.26 to 4.68)	199 more per 1000 (from 36 more to 511 more)	Very low
1 study (Stone, 1998)	observational study	35/54 (64.8%)	18/52 (34.6%)	RR 1.87 (1.23 to 2.86)	301 more per 1000 (from 80 more to 644 more)	Very low
Third or fourth degree vaginal/perineal tears						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	259/11262 (2.3%)	625/19638 (3.2%)	RR 0.72 (0.63 to 0.83)	9 fewer per 1000 (from 5 fewer to 12 fewer)	Very low
				Adjusted OR 0.78 (99% CI 0.58 to 1.05)[b]		
1 study (Overgaard et al., 2012)	observational study	19/839 (2.3%)	24/839 (2.9%)	RR 0.79 (0.44 to 1.43)	6 fewer per 1000 (from 16 fewer to 12 more)	Low
1 study (Feldman & Hurst, 1987)	observational study	7/77[f] (9.1%)	6/72[f] (8.3%)	RR 1.09 (0.38 to 3.09)	8 more per 1000 (from 52 fewer to 174 more)	Very low
1 study (David et al., 1999)	observational study	0.9%	1.1%	NC	p=0.24	Very low
1 study (Stone, 1998)	observational study	0/54 (0%)	2/52 (3.8%)	RR 0.19 (0.01 to 3.92)	31 fewer per 1000 (from 38 fewer to 112 more)	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Maternal complications[h]						
Intrapartum						
1 study (Jackson et al., 2003)	observational study	329/1808 (18.2%)	201/1149 (17.5%)	RR 1.04 (0.89 to 1.22) Adjusted RD 0.8 (-2.4 to 4.0)[c]	7 more per 1000 (from 19 fewer to 38 more)	Very low
Postpartum						
1 study (Jackson et al., 2003)	observational study	14/1808 (0.77%)	4/1149 (0.35%)	RR 2.22 (0.73 to 6.74) Adjusted RD 0.6 (-4.2 to 5.3)[c]	4 more per 1000 (from 1 fewer to 20 more)	Very low
Maternal readmission or outpatient visit postpartum						
1 study (Overgaard et al., 2012)	observational study	24/839 (2.9%)	40/839 (4.8%)	RR 0.6 (0.37 to 0.99)	19 fewer per 1000 (from 0 fewer to 30 fewer)	Low
1 study (Jackson et al., 2003)	observational study	8/1808 (0.44%)	11/1149 (0.96%)	RR 0.46 (0.19 to 1.15) Adjusted RD -0.9 (-4.8 to 3.0)[c]	5 fewer per 1000 (from 8 fewer to 1 more)	Very low
1 study (Scupholme et al., 1986)	observational study	0/250 (0%)	0/250 (0%)	NC	NC	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Stillbirth						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/11282 (0.04%)	3/19706 (0.02%)	RR 2.33 (0.52 to 10.4)[i]	202 more per 1,000,000 (from 73 fewer to 1431 more)	Very low
1 study (Davis et al., 2011)	observational study	0/2873 (0%)	0/11448 (0%)	NC	NC	Very low
1 study (Jackson et al., 2003)	observational study	0.4%	0.4%	NC	RD 0.0 (−0.5 to 0.4)	Very low
1 study (Feldman & Hurst, 1987)	observational study	0/77 (0%)	1/72 (1.4%)	RR 0.31 (0.01 to 7.54)	9583 fewer per 1,000,000 (from 13750 fewer to 90833 more)	Very low
1 study (David et al., 1999)	observational study	0/801 (0%)	1/3271 (0.03%)	RR 1.36 (0.06 to 33.35)	110 more per 1,000,000 (from 287 fewer to 9890 more)	Very low
Neonatal death						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	5/11263 (0.04%)	5/19637 (0.03%)	RR 1.74 (0.5 to 6.02)[i]	188 more per 1,000,000 (from 127 fewer to 1278 more)	Very low
1 study (Overgaard et al., 2012)	observational study	1/839 (0.12%)	0/839 (0%)	RR 3 (0.12 to 73.54)[k]	NC	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Davis et al., 2011)	observational study	0/2873 (0%)	4/11448 (0.03%)	RR 0.44 (0.02 to 8.22)	196 fewer per 1,000,000 (from 342 fewer to 2523 more)	Very low
1 study (Jackson et al., 2003)	observational study	0.2%	0.3%	NC	RD −0.1 (−0.5 to 0.3)	Very low
1 study (Feldman & Hurst, 1987)	observational study	0/77 (0%)	0/72 (0%)	NC	NC	Very low
1 study (David et al., 1999)	observational study	0/801 (0%)	2/3271 (0.06%)	RR 0.82 (0.04 to 16.98)	110 fewer per 1,000,000 (from 587 fewer to 9771 more)	Very low
Admission to neonatal intensive care unit (NICU)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	194/11257 (1.7%)	543/19642 (2.8%)	RR 0.62 (0.53 to 0.73) Adjusted OR 0.61 (99% CI 0.40 to 0.91)[b]	11 fewer per 1000 (from 7 fewer to 13 fewer)	Very low
1 study (Overgaard et al., 2012)	observational study	28/839 (3.3%)	42/839 (5%)	RR 0.67 (0.42 to 1.07)	17 fewer per 1000 (from 29 fewer to 4 more)	Low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Davis et al., 2011)	observational study	Event rates are not reported. RR are calculated with midwifery unit (MU) as the reference. Secondary hospital compared with MU: RR 1.44 (95% CI 1.08 to 1.91) Adjusted RR 1.40 (95% CI 1.05 to 1.87)[g] Tertiary hospital compared with MU: RR 1.87 (95% CI 1.39 to 2.53) Adjusted RR 1.78 (95% CI 1.31 to 2.42)[g]			NC	Low
1 study (Jackson et al., 2003)	observational study	171/1808 (9.5%)[k]	134/1149 (11.7%)[k]	RR 0.81 (0.65 to 1) Adjusted RD -1.3 (-3.8 to 1.1)[c]	22 fewer per 1000 (from 41 fewer to 0 more)	Very low
1 study (Feldman & Hurst, 1987)	observational study	1/77[f] (1.3%)	4/72[f] (5.6%)	RR 0.23 (0.03 to 2.04)	43 fewer per 1000 (from 54 fewer to 58 more)	Very low
1 study (David et al., 1999)	observational study	2.6%	2.0%	NC	p=0.39	Very low
Composite perinatal mortality and morbidity[l]						
All low risk women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	41/11199 (0.37%)	81/19551 (0.41%)	RR 0.88 (0.61 to 1.29) Adjusted OR 0.92 (0.58 to 1.46)[b]	497 fewer per 1,000,000 (from 1616 fewer to 1201 more)	Very low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
1 study (Jackson et al., 2003)	observational study	80/1808 (4.4%)[j]	73/1149 (6.4%)[j]	RR 0.70 (0.51 to 0.95) Adjusted RD -1.8 (−3.8 to 0.1)[c]	19060 fewer per 1,000,000 (from 3177 fewer to 31131 fewer)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	24/5158 (0.47%)	52/10541 (0.49%)	RR 0.94 (0.58 to 1.53) Adjusted OR 0.91 (0.52 to 1.60)[b]	296 fewer per 1,000,000 (from 2072 fewer to 2615 more)	Very low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	17/6025 (0.28%)	29/8980 (0.32%)	RR 0.87 (0.48 to 1.59) Adjusted OR 0.91 (0.46 to 1.80)	420 fewer per 1,000,000 (from 1679 fewer to 1905 more)	Very low
Women without complicating conditions at the onset of labour						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	35/10571 (0.33%)	48/15676 (0.31%)	RR 1.08 (0.7 to 1.67) Adjusted OR 1.22 (0.76 to 1.96)[b]	245 more per 1,000,000 (from 919 fewer to 2052 more)	Low

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Number of studies	Design	Number of women/babies (or % if event rate data not reported and not calculable)		Effect		Quality
		Planned birth in a freestanding midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI) [or p-value if only % are reported]	
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	22/4785 (0.46%)	28/8018 (0.35%)	RR 1.32 (0.75 to 2.30) Adjusted OR 1.40 (0.74 to 2.65)	1117 more per 1,000,000 (from 873 fewer to 4540 more)	Low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	13/5772 (0.23%)	20/7637 (0.26%)	RR 0.86 (0.43 to 1.73) Adjusted OR 0.97 (0.46 to 2.04)	367 fewer per 1,000,000 (from 1493 fewer to 1912 more)	Low
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	17/11210 (0.15%)	34/19587 (0.17%)	RR 0.87 (0.49 to 1.56)[i]	226 fewer per 1,000,000 (from 885 fewer to 972 more)	Very low
Neonatal encephalopathy (signs)[m]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	2/11282 (0.02%)	8/19706 (0.04%)	RR 0.44 (0.09 to 2.06)[i]	227 fewer per 1,000,000 (from 369 fewer to 430 more)	Very low

CI confidence interval, MU midwifery unit, NC not calculable, OR odds ratio, RD risk difference, RR relative risk,

a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol however this was reported in the Birthplace study as 'spontaneous vertex birth'.
b. Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, body mass index, deprivation score quintile, previous pregnancies and weeks of gestation, and also weighted to reflect unit's duration of participation and probability of being sampled

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c. Adjusted for race/ethnicity, parity and history of CS, education, age, marital status, country of origin, height and smoking during pregnancy
d. Calculated by the technical team based on the outcomes reported in the study which are any vaginal birth (72/77 [93.5%] in the midwifery unit arm and 63/71 [88.7%] in the hospital arm [not significantly different]) and forceps (5.6% in the midwifery unit arm and 43.7% in the hospital arm [p<0.0001, raw event rates not calculable])
e. The authors report an analysis which adjusted for maternal age, parity, ethnicity and smoking. The adjusted risk ratios have not been reported in the GRADE table because they are reported with the midwifery unit as the reference group rather than the other way around. They do not change the significance of the effects. The adjusted RR for secondary unit compared with midwifery unit were 4.11 (95% CI 2.86 to 5.91) for vacuum extraction, 2.57 (95% CI 1.66 to 3.97) for forceps and 2.73 (95% CI 2.17 to 3.44) for emergency CS. The adjusted RR for tertiary unit compared with midwifery unit were 6.12 (95% CI 4.24 to 8.84) for vacuum extraction, 5.41 (95% CI 3.51 to 8.33) for forceps and 4.62 (95% CI 3.66 to 5.84) for emergency CS.
f. Raw event rate calculated by the technical team based on the % and denominator information reported in the study
g. Adjusted for maternal age, parity, ethnicity and smoking
h. Intrapartum complications: defined as cord prolapse, placenta praevia, placental abruption, severe pregnancy induced hypertension, pregnancy induced hypertension with eclampsia, heavy/thick meconium, premature (< 34 weeks), rupture of uterine scar, haemorrhage ≥1000 ml, shoulder dystocia, fourth degree perineal laceration, cervical laceration requiring repair, sulcus laceration requiring repair, intrauterine fetal death or other. Postpartum complications: defined as anaesthesia complications, disseminated intravascular coagulation, pulmonary embolus, haematoma, severe pregnancy induced hypertension, pregnancy induced hypertension with eclampsia, maternal death or other
i. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components
j. The death was of a baby born with a severe diaphramic hernia not detected by an ultrasound scan at 19.4 weeks. The authors specifically note that the study was not powered to detect a difference in this outcome
k. The study only includes live births in the denominator; however, for the calculation of crude relative risk, the technical team have used the entire denominator because excluding some babies does not give an accurate estimate of risk for women planning place of birth. (Note: both analyses give similar relative risks and the adjusted analysis is as reported in the study)
l. For Birthplace in England Collaborative Group, 2011 the outcome was a composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle. For Jackson et al., 2003, it is defined as seizures, asphyxia, bacterial infection other than sepsis, bronchopulmonary dysplasia, cardiac failure, hypovolemia, hypotension, shock, intraventricular haemorrhage, necrotizing enterocolitis, persistent pulmonary hypertension, pneumonia, renal failure, respiratory distress syndrome, retinopathy of prematurity, Rh disease, sepsis, gestational age<34 weeks at birth, or other including palsy or fracture.
m. Defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress

Evidence statements

There was consistent evidence from over 50,000 women that women planning birth in freestanding midwifery units had higher rates of spontaneous vaginal birth and lower rates of instrumental vaginal birth than women planning birth in an obstetric unit. The evidence around caesarean section was slightly more mixed, but most studies reported that rates were higher in women planning birth in an obstetric unit and those that did not find a difference still demonstrated the same trend. There was consistent evidence from 4 studies (n=35,521) that women planning birth in a freestanding midwifery unit had lower rates of epidural use. The evidence around blood loss was mixed. There was consistent evidence from 2 studies (n=17,888) that there was no difference in the risk of major postpartum haemorrhage between the 2 groups, but another study (n=30,809) reported that the rate of blood transfusion was higher in women planning birth in an obstetric unit.

There was consistent evidence from 6 studies (n=47,163) that rates of episiotomy were higher among women planning birth in an obstetric unit. Similarly, fewer women were found to have an intact perineum or birth canal after planning birth in an obstetric unit (n=18,037). In terms of vaginal or perineal trauma, the evidence was more mixed. There was consistent evidence of no difference in the risk of third or fourth degree trauma (n=49,038), but the evidence around the rates of any trauma was varied, with some studies (n=255) suggesting higher rates in women planning birth in freestanding unit while another large study (n=1678) suggests the converse.

One Danish observational study (n=1678; Overgaard et al., 2012) reported that women in freestanding units were less likely to sustain perineal tears or need a caesarean section than women in obstetric units. Apgar scores were very similar.

Evidence from 2 studies (n=5914) suggested that there was no difference in maternal complications between the 2 groups of women. There was further evidence from another study (n=1678) that the rate of maternal readmission or outpatient visit postpartum was reduced among women planning birth in a freestanding midwifery unit, with a further study demonstrating the same trend.

In terms of neonatal outcomes, 1 study (n=30,750) found evidence of no difference in a composite perinatal mortality and morbidity outcome among babies born to women planning birth in a freestanding midwifery unit compared with those born to women planning birth in an obstetric unit. A sub-group analysis by parity also showed evidence of no difference between groups for either nulliparous or multiparous women. Multiple studies with over 30,000 women did not find evidence of a difference in the rates of stillbirth or neonatal death, but none of the studies were powered to detect a difference in these rare outcomes. Similarly, 1 study (n=30,797) reported no evidence of a difference in the risk of neonatal encephalopathy but it was a component of the composite outcome, and therefore the sample size was insufficient to detect a difference. The evidence around the relative risks of admission to NICU was mixed: 4 studies with over 4000 women did not report a difference in the rates between the 2 groups of babies, but 2 studies with over 30,000 women reported that rates were higher among babies born to women planning birth in an obstetric unit.

Transfer rates varied from about 10–20%. One study (n=64,538) reported transfer rates for nulliparous women were 4 times those in multiparous women. The evidence across all outcomes was of low and very low quality.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was vital to consider both the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in women's decision-making process. For the baby, they felt that it was important to establish whether there was any risk associated with planning birth outside an obstetric unit and therefore the

outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. Similarly, the group wanted to ascertain whether there were differences in morbidity for the woman following planned birth in a freestanding midwifery unit compared with planned birth in an obstetric unit, given that in the case of an unforeseen emergency, such as a postpartum haemorrhage, women would have to be transferred by ambulance from a freestanding unit into hospital. The rates of intervention, such as caesarean section and instrumental vaginal birth, were also considered priorities, as they were felt to be important to women and also themselves associated with morbidity, such as postpartum haemorrhage. The group did not feel that use of epidural anaesthesia was a particularly helpful outcome, as it is only available in an obstetric unit and is a matter of personal choice for the woman.
The group also felt that the rates of transfer were important to consider and would be an important consideration for women planning where to give birth.

Consideration of clinical benefits and harms

The guideline development group first considered the outcomes for the woman. The group agreed that the evidence around mode of birth suggested that spontaneous vaginal birth was more likely, and instrumental vaginal birth and caesarean section were less common, for women planning birth in a freestanding midwifery when compared with women planning birth in an obstetric unit. They noted that 2 of the studies (David et al., 1999; Feldman & Hurst, 1987) did not find a significant difference in the rate of caesarean section, but concluded that this was likely to be a result of the small sample sizes.
The group then considered the evidence around blood loss. They noted that Overgaard et al. (2011) had found a significantly lower rate of any postpartum haemorrhage in women who had planned birth in a freestanding unit, but had not found a significant difference in the rate of postpartum haemorrhages of over 1000 ml. Furthermore, they noted that the Birthplace study (2011) had found that blood transfusions were more common for women planning birth in an obstetric unit, and concluded that this was likely to be as a result of the increased rate of operative delivery.
The group noted that evidence around outcomes linked to vaginal and perineal trauma was less consistent. Data from 3 studies suggested that vaginal/perineal tears might be more common after planned birth in a freestanding midwifery unit, but another large study (Overgaard et al., 2011) suggested the opposite. However, given that episiotomy was consistently more common in women planning birth in an obstetric unit, and that the rate of intact perineum was higher in women planning birth in a freestanding midwifery unit (reported in 4 studies, all of which found a significant difference), the group concluded that women planning birth in an obstetric unit were likely to have higher overall rates of vaginal/perineal trauma than women planning birth in a freestanding midwifery unit.
The group then considered the neonatal outcomes reported. They discussed the fact that no significant difference was identified in stillbirth or early neonatal death between the 2 settings, but that none of the studies had been powered to detect a difference in these rare outcomes. They noted that the Birthplace study (2011) was powered to detect a difference in its composite outcome and had not found a significant difference between the two settings. They discussed the fact that the composite outcome comprised outcomes with very different levels of severity (from fractured clavicle to mortality) and agreed that this was a limitation, but agreed that conducting a study with sufficient power to detect the components would probably not be feasible. Also, fractured clavicle accounted for less than 3% of events and the serious perinatal outcomes – mortality, neonatal encephalopathy and meconium aspiration – constituted just under 90% of the primary outcome events. The group noted that while 4 of the studies had not found a difference in the rate of admission to NICU, the 2 largest studies provided evidence that admission to NICU was more common after planned birth in an

obstetric unit compared with planned birth in a freestanding midwifery unit. They agreed that this might be partially a result of the difference in the proportion of women with complicating conditions at the onset of labour in the Birthplace study (2011), and could also be linked to the relative ease with which babies could be admitted to NICU from each birth setting. Alternatively, this might be a reflection of iatrogenic harm to newborn babies associated with the increased intrapartum intervention rates associated with giving birth in an obstetric unit or it could be that some obstetric units have a practice of precautionary admission to the NICU. The group discussed the rates of intrapartum transfer reported in the studies, and noted that they ranged from about 10% to over 20%. They discussed the fact that in the Birthplace study (2011), 36% of nulliparous women planning birth in a freestanding unit were transferred during labour or after birth, compared with only 9% of multiparous women. The group agreed that it was important that women were given information about the likelihood that they would need or choose to be transferred, and what the reasons for this might be. They did not believe, however, that this was a reason not to support nulliparous women in their choice of giving birth in freestanding midwifery units, with the benefits in terms of reduced intervention outweighing any potential risks.

Consideration of health benefits and resource uses

The guideline development group discussed the relative costs of planning birth in either a freestanding midwifery unit or an obstetric unit and agreed that the former was likely to be more cost effective, given the reduced rate of intervention (such as caesarean section and blood transfusion). However, they noted that transfer from a freestanding unit required an ambulance, which would have an associated cost. The group also discussed the fact that the cost effectiveness of freestanding units would depend quite a lot on the demand and the number of births taking place in the units, because if they were staffed all the time but not used, this would be a waste of resources. They agreed that this would have to be considered carefully when services were being organised. Similarly, they noted that freestanding midwifery units cannot exist in isolation and therefore that some of the cost of maintaining an obstetric unit facility had to be considered in conjunction with the direct costs of the midwifery unit. Despite this, the group concluded that there were likely to be cost savings associated with more women giving birth in a freestanding midwifery unit. The group was also aware of the possibility of some freestanding midwifery units being operated on a model whereby they could be empty when no women were in labour and opened when required, thus minimising running costs and ensuring staffing always matched demand. They felt that the service could be reorganised to move some midwives out of obstetric units into freestanding units to care for low-risk women, and that the lower rates of intervention (that is, caesarean section and instrumental vaginal birth) associated with planning birth in a freestanding midwifery unit would reduce rates overall and therefore doctors' skills in obstetric units would be focussed on caring for women who require this medical expertise because they are at high risk of developing complications and low risk women who required transfer from other settings.

Quality of evidence

The guideline development group agreed that the quality of the evidence available for this review varied considerably. In particular, the relevance of the evidence to low risk women planning place of birth in England and Wales was affected by the inclusion of some higher risk women in some of the studies and the fact that some studies were conducted in countries such as the USA, where the care of women in labour is not directly comparable to the UK. There are several possible reasons for this, including important differences in midwifery training and practice. The group noted that there were often significant differences in the characteristics of the women planning birth in freestanding midwifery units and those planning births in obstetric units. While the identified differences had been accounted for in

several of the studies, they agreed that there was a possibility that other, unknown differences could have affected outcomes. The group felt that the Birthplace study (2011) was generally a good quality observational study because it did perform adjustments for confounders, was conducted more recently and was based in England. They did note that there were more women with complicating conditions identified at the start of care in labour in the obstetric unit group, which might have affected outcomes, but overall the study was felt to be particularly helpful in informing recommendations, given its size and setting. Finally the group noted that there were low event rates for stillbirth and wide 95% confidence intervals as a result.

Other considerations

The guideline development group discussed the subgroup analysis by parity that was reported in the Birthplace study (2011) and agreed that the trends were broadly similar to the results of the overall analysis. The differences they noted were that for multiparous women, rates of third or fourth degree perineal trauma were significantly lower in women planning birth in a freestanding midwifery unit compared with women planning birth in an obstetric unit, and admissions to NICU were not significantly different between the 2 settings for babies born to multiparous women.

Alongside midwifery unit compared with obstetric unit

Description of included studies

Thirteen studies were included in this review (Begley et al., 2011; Bernitz et al., 2011; Birthplace in England Collaborative Group, 2011; Byrne et al., 2000; Campbell et al., 1999; Chapman et al., 1986; Eide et al., 2009; Gaudineau et al., 2013; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993; Waldenstrom et al., 1997; Waldenstrom and Nilsson, 1997). Nine of the studies reported the results of 8 randomised controlled trials, which were conducted in England (Chapman et al., 1986; MacVicar et al., 1993), Scotland (Hundley et al., 1994), Ireland (Begley et al., 2011), Norway (Bernitz et al., 2011), Sweden (Waldenstrom et al., 1997; Waldenstrom and Nilsson, 1997 [two reports of the same trial]), Canada (Klein et al., 1984) and Australia (Byrne et al., 2000). The remaining 4 studies were prospective observational studies, which were conducted in England (Birthplace in England Collaborative Group, 2011; Campbell et al., 1999), France (Gaudineau et al., 2013) and Norway (Eide et al., 2009).

All of the studies compared planned birth at an alongside midwifery unit with planned birth at an obstetric unit, and analysed data on an intention-to-treat basis, so that women were analysed by their planned place of birth even if they were transferred. Seven of the included studies evaluated outcomes by booked place of birth during the antenatal period (Begley et al., 2011; Byrne et al., 2000; Campbell et al., 1999; Hundley et al., 1994; MacVicar et al., 1993; Waldenstrom et al., 1997; Waldenstrom and Nilsson, 1997), whereas in the remaining studies, outcomes were analysed by the intended place of birth at the onset of labour or at the start of care at the onset of labour.

The included studies restricted their populations to low risk women, but because many of the studies allocated women during the antenatal period, a proportion of women developed complications prior to the onset of labour which resulted in them being higher risk and/or outside of the scope of the guideline (for example women whose labour was induced). Table 16 reports the main issues to note. Full details of the inclusion and exclusion criteria can be found in the evidence tables in appendix I.

Table 16: Summary of included studies for planned birth in an alongside midwifery unit compared with planned birth in an obstetric unit

Study	Study Design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit arm	New to update?
Begley et al., 2011	Randomised trial	Booked place of birth	Alongside midwifery unit: 22.5% women had induction of labour; 22.5% women had pregnancy complications (not defined) Obstetric unit: 22.5% women had induction of labour; 19.9% women had pregnancy complications	58.3% (Antenatal: 44.7% Intrapartum: 13.1% Postnatal: 0.5%)	Yes
Bernitz et al., 2011	Randomised trial	Intended place of birth at onset of labour	The study is a three arm trial, comparing a midwifery unit with a "normal unit" and a "special unit", reflecting the organisation of care in Norway. The normal unit and the special unit have been pooled to provide the comparison group (obstetric unit) for this analysis. Although it is reported that physical transfer was needed in the case of complications, the authors also report that obstetricians could be called to the midwifery unit.	28.4% (Intrapartum)	Yes
Birthplace in England Collaborative Group, 2011	Prospective observational studies	Intended place of birth at start of care in labour	Alongside midwifery unit: 6.9% women had complicating conditions at start of care in labour 50.1% were nulliparous Obstetric unit: 19.5% women had complicating conditions at start of care in labour 54% were nulliparous	26.4% (Before birth: 21.2% After birth: 4.3% Time of transfer missing: 0.9%) Transfer rate nulliparous – 40.2% (86.9% before birth) Transfer rate multiparous – 12.5% (70.8% before birth	Yes
Byrne et al., 2000	Randomised trial	Booked place of birth	Alongside midwifery unit: 20% women had induction of labour; 1% babies were breech Obstetric unit: 25% women had induction of labour The authors report that in the midwifery unit, equipment was stored behind cupboards or curtains but within easy reach, and it cannot be definitively	77% (Time of transfer not reported)	No

Study	Study Design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit arm	New to update?
			confirmed that continuous electronic fetal monitoring was unavailable in the unit; therefore, it is unclear how comparable this is to an alongside midwifery unit as defined by the GDG.		
Campbell et al., 1999	Prospective observational studies	Booked place of birth	Alongside midwifery unit: 13.4% women had induction of labour; 4.6% babies were born preterm; 3.6% babies were in non-cephalic presentation Obstetric unit: 21.7% women had induction of labour; 4.3% babies were born preterm; 4.1% babies were in non-cephalic presentation It is unclear how comparable unit is to the typical alongside midwifery unit. The alongside midwifery unit is alongside a general hospital with the obstetric labour ward located in a different hospital, and it is reported that medical staff are not present in the midwifery unit unless a midwife has requested their assistance. However, theatre facilities and access to an obstetric registrar are available on site.	36.3% (Antenatal: 27.1% Intrapartum: 9.2%)	Yes
Chapman et al., 1986	Randomised trial	Intended place of birth at onset of labour	The authors report that in the midwifery unit, equipment was available but kept out of sight; therefore, it is unclear how comparable this is to an alongside midwifery unit as defined by the GDG	28.9% (Before labour: 14.5% During labour: 14.5%)	No
Eide et al., 2009	Prospective observational studies	Intended place of birth at onset of labour	Nulliparous women only In the first stage of labour, women were transferred if there were complications or a request for epidural. In the second stage of labour women were only transferred if an emergency caesarean was needed and obstetricians could be consulted in the case of complications. Therefore, it is unclear how comparable unit is to the typical alongside midwifery unit because some instrumental vaginal births occurred in women who remained in the midwifery unit.	29.4% (Reported as 'during labour')	Yes

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Study	Study Design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit arm	New to update?
Gaudineau et al., 2013	Prospective observational studies	Intended place of birth at onset of labour	Larger control group, obstetric unit: n=890 vs n=316 for alongside midwifery unit Alongside midwifery unit known as the "home-like birth centre" created next to the obstetric unit but with many of the same features as a freestanding midwifery unit, No other details given. Women able to choose to labour in the alongside midwifery unit as long as they had no medical or obstetric risk factors, including previous caesarean section; history of feto-pelvic disproportion with difficult instrumental birth or spontaneous vaginal birth; pre-labour rupture of membranes for over 24 hours; gestation over 42 weeks or abnormal admission CTG Women were transferred from the alongside midwifery unit to the obstetric unit if there were complications but continued to be cared for by midwife from alongside midwifery unit.	Not reported	Yes
Hundley et al., 1994	Randomised trial	Booked place of birth	Alongside midwifery unit: 21% women had induction of labour; 2.8% women had pre-eclampsia; 2.6% babies were born preterm; 1.5% women had elective caesarean section Obstetric unit: 20% women had induction of labour; 1.9% women had pre-eclampsia; 3.0% babies were born preterm; 2.1% women had elective caesarean section	54.2% (Antenatal: 38.3% Intrapartum: 15.9%)	No
Klein et al., 1984	Randomised trial	Intended place of birth at onset of labour	It is unclear how much the two settings are comparable to an alongside midwifery unit as defined by the GDG and an obstetric unit in the UK, because the only details given are that a "single obstetric and nursing staff serve the two settings."	42.9% (During labour)	No
MacVicar et al., 1993	Randomised trial	Booked place of birth	Alongside midwifery unit: 9% induction of labour; 5% preterm; 4% hypertension (diastolic blood pressure >90 mmHg) Obstetric unit: 11% induction of labour; 6% preterm; 4% hypertension	45.3% (Antenatal: 23.4% Intrapartum: 20.8% Postpartum: 1.1%)	No

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Study	Study Design	Intervention	Details of particular issues to note with study population or setting	Transfer rate in midwifery unit arm	New to update?
Waldenstrom et al., 1997; Waldenstrom & Nilsson, 1997	Randomised trial	Booked place of birth	Alongside midwifery unit: 2.7% women had induction of labour; 1.9% women had elective caesarean section; 1.1% babies were premature; 2.9% babies had malformations Obstetric unit: 4.6% women had induction of labour; 2.4% women had elective caesarean section; 1.3% babies were premature; 3.4% babies had malformations An unknown proportion of women had previous caesarean sections, although they had to have had a more recent vaginal birth to be included.	34.2% (Antenatal: 13.4% Intrapartum: 19% Postpartum: 1.8%)	No

Evidence profile

A fixed effects model was used for all meta-analyses, except for 1 outcome (intact perineum) where the heterogeneity was high (I^2>60%) and so a random effects model was used. All risk ratios were calculated as standard using RevMan. However, where the authors have reported adjusted measures of effect, these have also been reported in the table. For measures of perinatal/neonatal mortality and morbidity, due to the low incidence absolute effects have been reported per 1,000,000.

Table 17: Summary GRADE profile for comparison of planned birth in an alongside midwifery unit with planned birth in an obstetric unit for all women

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Maternal mortality						
1 study (Begley et al., 2011)	randomised trial	0/1101 (0%)	0/552 (0%)	not calculable (NC)	NC	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	0/16710 (0%)	0/19706 (0%)	NC	NC	Very low
Mode of birth: spontaneous vaginal birth[a]						

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 meta-analysis of 5 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Hundley et al., 1994; MacVicar et al., 1993)	randomised trials	4449/5736 (77.6%)	2632/3472 (75.8%)	RR 1.04 (1.01 to 1.06)	30 more per 1000 (from 8 more to 45 more)	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	14413/16690 (86.4%)	14645/19688 (74.4%)	RR 1.16 (1.15 to 1.17) Adjusted OR 2.22 (99% CI 1.76 to 2.81)[b]	119 more per 1000 (from 112 more to 126 more)	Very low
1 study (Eide et al., 2009)	observational study	205/252 (81.3%)	161/201 (80.1%)	RR 1.02 (0.93 to 1.11)[b]	16 more per 1000 (from 56 fewer to 88 more)	Very low
1 study (Campbell et al., 1999)	observational study	657/782 (84%)	586/702 (83.5%)	RR 1.01 (0.96 to 1.05)	8 more per 1000 (from 33 fewer to 42 more)	Very low
1 study (Gaudineau et al., 2013)	observational study	280/316 (88.6%)	737/890 (82.8%)	RR 1.07 (1.01 to 1.12)	58 more per 1000 (from 8 more to 99 more)	Low
Mode of birth: instrumental vaginal birth						
1 meta-analysis of 7 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993;	randomised trials	661/6704 (9.9%)	477/4446 (10.7%)	RR 0.89 (0.79 to 0.99)	12 fewer per 1000 (from 1 fewer to 23 fewer)	Low

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Waldenstrom et al., 1997)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1524/16690 (9.1%)	2842/19688 (14.4%)	RR 0.63 (0.6 to 0.67) Adjusted OR Ventouse: 0.56 (99% CI 0.39 to 0.82)[b] Forceps: 0.70 (99% CI 0.46 to 1.05)[b]	53 fewer per 1000 (from 48 fewer to 58 fewer)	Very low
1 study (Eide et al., 2009)	observational study	29/252 (11.5%)	24/201 (11.9%)	RR 0.96 (0.58 to 1.6)[c]	5 fewer per 1000 (from 50 fewer to 72 more)	Very low
1 study (Campbell et al., 1999)	observational study	61/782 (7.8%)	71/702 (10.1%)	RR 0.77 (0.56 to 1.07)	23 fewer per 1000 (from 45 fewer to 7 more)	Very low
1 study (Gaudineau et al., 2013)	observational study	28/316 (8.9%)	106/890 (11.9%)	RR 0.74 (0.50 to 1.10)	31 fewer per 1000 (60 fewer to 12 more)	Very low
Mode of birth: caesarean section						
1 meta-analysis of 8 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Chapman et al., 1986; Hundley et al., 1994; Klein et	randomised trials	563/6780 (8.3%)	403/4518 (8.9%)	RR 0.89 (0.78 to 1)	10 fewer per 1000 (from 20 fewer to 0 more)	Moderate

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
al., 1984; MacVicar et al., 1993; Waldenstrom et al., 1997)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	727/16690 (4.4%)	2158/19688 (11%)	RR 0.4 (0.37 to 0.43) Adjusted OR 0.39 (99% CI 0.29 to 0.53)[b]	66 fewer per 1000 (from 62 fewer to 69 fewer)	Very low
1 study (Eide et al., 2009)	observational study	16/252 (6.3%)	14/201 (7%)	RR 0.91 (0.46 to 1.82)[c]	6 fewer per 1000 (from 38 fewer to 57 more)	Very low
1 study (Campbell et al., 1999)	observational study	63/782 (8.1%)	45/702 (6.4%)	RR 1.26 (0.87 to 1.82)	17 more per 1000 (from 8 fewer to 53 more)	Very low
1 study (Gaudineau et al., 2013)	observational study	8/316 (2.5%)	47/890 (5.3%)	RR 0.48 (0.23 to 1.00)	25 fewer per 1000 (41 fewer to 0 more)	Low
Use of epidural						
1 meta-analysis of 7 studies Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993; Waldenstrom et al., 1997)	randomised trials	998/6687 (14.9%)	847/4424 (19.1%)	RR 0.8 (0.73 to 0.87)	38 fewer per 1000 (from 25 fewer to 52 fewer)	Moderate

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Birthplace in England Collaborative Group, 2011)	observational study	2464/16661 (14.8%)	5817/19576 (29.7%)	RR 0.5 (0.48 to 0.52) Adjusted OR 0.40 (99% CI 0.32 to 0.50)[b]	149 fewer per 1000 (from 143 fewer to 155 fewer)	Very low
1 study (Eide et al., 2009)	observational study	61/252 (24.2%)	126/201 (62.7%)	RR 0.39 (0.3 to 0.49)[c]	382 fewer per 1000 (from 320 fewer to 439 fewer)	Low
1 study (Campbell et al., 1999)	observational study	107/782 (13.7%)	139/703 (19.8%)	RR 0.69 (0.55 to 0.87)	61 fewer per 1000 (from 26 fewer to 89 fewer)	Very low
Measures of blood loss: postpartum haemorrhage (any)						
1 meta-analysis of 5 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; MacVicar et al., 1993; Waldenstrom et al., 1997)	randomised trials	448/4764 (9.4%)	391/3391 (11.5%)	RR 0.92 (0.81 to 1.05)	9 fewer per 1000 (from 22 fewer to 6 more)	Very low
1 study (Campbell et al., 1999)	observational study	51/770 (6.6%)	38/695 (5.5%)	RR 1.21 (0.81 to 1.82)	11 more per 1000 (from 10 fewer to 45 more)	Very low
1 study (Gaudineau et al., 2013)	observational study	9/316 (2.9%)	46/890 (5.2%)	RR 0.55 (0.27 to 1.11	23 fewer per 1000 (38 fewer to 6 more)	Low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Measures of blood loss: major postpartum haemorrhage (over 1000 ml)						
1 study (Bernitz et al., 2011)	randomised trials	7/412 (1.7%)	18/699 (2.6%)	RR 0.66 (0.28 to 1.57)	9 fewer per 1000 (from 19 fewer to 15 more)	Low
Measures of blood loss: need for a blood transfusion						
1 meta-analysis of 2 studies (MacVicar et al., 1993; Waldenstrom et al., 1997)	randomised trials	32/3151 (1%)	22/2040 (1.1%)	RR 0.87 (0.51 to 1.49)	1 fewer per 1000 (from 5 fewer to 5 more)	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	136/16548 (0.82%)	241/19579 (1.2%)	RR 0.67 (0.54 to 0.82) Adjusted OR 0.75 (99% CI 0.55 to 1.02)[b]	4 fewer per 1000 (from 2 fewer to 6 fewer)	Very low
Episiotomy						
1 meta-analysis of 7 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993; Waldenstrom et al., 1997)	randomised trials	1239/6704 (18.5%)	951/4446 (21.4%)	RR 0.84 (0.78 to 0.91)	34 fewer per 1000 (from 19 fewer to 47 fewer)	Low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Birthplace in England Collaborative Group, 2011)	observational study	2098/16689 (12.6%)	3780/19678 (19.2%)	RR 0.65 (0.62 to 0.69) Adjusted OR 0.62 (99% CI 0.50 to 0.77)[b]	67 fewer per 1000 (from 60 fewer to 73 fewer)	Very low
1 study (Eide et al., 2009)	observational study	72/252 (28.6%)	73/201 (36.3%)	RR 0.79 (0.6 to 1.03)[c]	76 fewer per 1000 (from 145 fewer to 11 more)	Very low
1 study (Campbell et al., 1999)	observational study	131/780 (16.8%)	173/702 (24.6%)	RR 0.68 (0.56 to 0.83)	79 fewer per 1000 (from 42 fewer to 108 fewer)	Very low
1 study (Gaudineau et al., 2012)	observational study	22/316 (7.1%)	96/890 (11.4%)	RR 0.65 (0.41 to 1.00)	39 fewer per 1000 (from 64 fewer to 0 more)	Low
Intact perineum						
1 meta-analysis of 5 studies (Begley et al., 2011; Byrne et al., 2000; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993)	randomised trials	1513/5380 (28.1%)	731/2831 (25.8%)	RR 1.05 (0.89 to 1.24)	13 more per 1000 (from 28 fewer to 62 more)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Vaginal/perineal tears						
1 meta-analysis of 4 studies (Byrne et al., 2000; Hundley et al., 1994; MacVicar et al., 1993; Waldenstrom & Nilsson, 1997)	randomised trials	2456/5064 (48.5%)	1480/3036 (48.7%)	RR 1.07 (1.02 to 1.12)[d]	34 more per 1000 (from 10 more to 58 more)	Low
1 study (Campbell et al., 1999)	observational study	338/780 (43.3%)	307/702 (43.7%)	RR 0.99 (0.88 to 1.11)	4 fewer per 1000 (from 52 fewer to 48 more)	Very low
Third or fourth degree vaginal/perineal tears						
1 meta-analysis of 4 studies (Bernitz et al., 2011; Hundley et al., 1994; MacVicar et al., 1993; Waldenstrom & Nilsson, 1997)	randomised trials	50/5376 (0.93%)	36/3635 (0.99%)	RR 1.17 (0.74 to 1.84)	2 more per 1000 (from 3 fewer to 8 more)	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	535/16654 (3.2%)	625/19638 (3.2%)	RR 1.01 (0.9 to 1.13) Adjusted OR 1.04 (99% CI 0.79 to 1.38)[b]	0 more per 1000 (from 3 fewer to 4 more)	Very low
1 study (Eide et al., 2009)	observational study	34/252 (13.5%)	22/201 (10.9%)	RR 1.23 (0.75 to 2.04)[c]	25 more per 1000 (from 27 fewer to 114 more)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Maternal morbidity: seeking medical care in 2 months after birth (inpatient or outpatient)[e]						
1 study (Waldenstrom & Nilsson, 1997)	randomised trial	181/883 (20.5%)	161/853 (18.9%)	RR 1.09 (0.9 to 1.31)	17 more per 1000 (from 19 fewer to 59 more)	Low
Maternal morbidity: significant problems after giving birth (not defined further)						
1 study (Campbell et al., 1999)	observational study	83/776 (10.7%)	84/695 (12.1%)	RR 0.88 (0.67 to 1.18)	15 fewer per 1000 (from 40 fewer to 22 more)	Very low
Perinatal death (intrauterine death after 22 weeks or infant death within 7 days of birth)						
1 study (Waldenstrom et al., 1997)	randomised trial	8/912[f] (0.88%)	2/916 (0.22%)	RR 4.02 (0.86 to 18.87)	6594 more per 1,000,000 (from 306 fewer to 39017 more)	Moderate
Stillbirth						
1 meta-analysis of 3 studies (Begley et al., 2011 Hundley et al., 1994; MacVicar et al., 1993)	randomised trials	20/5225 (0.38%)	9/2676 (0.34%)	RR 1.11 (0.52 to 2.4)[g]	370 more per 1,000,000 (from 1614 fewer to 4709 more)	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	1/16708 (0.006%)	3/19706 (0.02%)	RR 0.39 (0.04 to 3.78)[h]	93 fewer per 1,000,000 (from 146 fewer to 423 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Neonatal death						
1 meta-analysis of 3 studies (Begley et al., 2011; Hundley et al., 1994; MacVicar et al., 1993)	randomised trials	16/5225 (0.31%)	4/2676 (0.15%)	RR 1.86 (0.66 to 5.27)[i]	1286 more per 1,000,000 (from 508 fewer to 6383 more)	Low
1 study (Birthplace in England Collaborative Group, 2011)	observational study	3/16633 (0.02%)	5/19637 (0.03%)	RR 0.71 (0.17 to 2.96)[h]	74 fewer per 1,000,000 (from 211 fewer to 499 more)	Very low
Admission to neonatal intensive care unit (NICU)						
1 meta-analysis of 7 studies (Begley et al., 2011; Bernitz et al., 2011; Byrne et al., 2000; Hundley et al., 1994; Klein et al., 1984; MacVicar et al., 1993; Waldenstrom et al., 1997)	randomised trials	501/6705 (7.5%)	362/4449 (8.1%)	RR 1.03 (0.91 to 1.17)	2 more per 1000 (from 7 fewer to 14 more)	Moderate
1 study (Birthplace in England Collaborative Group, 2011)	observational study	307/16580 (1.9%)	543/19642 (2.8%)	RR 0.67 (0.58 to 0.77)	9 fewer per 1000 (from 6 fewer to 12 fewer)	Very low
				Adjusted OR 0.75 (99% CI 0.50 to 1.11)[b]		

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
1 study (Campbell et al., 1999)	observational study	36/782 (4.6%)	43/702 (6.1%)	RR 0.75 (0.49 to 1.16)	15 fewer per 1000 (from 31 fewer to 10 more)	Very low
Composite perinatal mortality and morbidity[i]						
All low risk women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	58/16524 (0.35%)	81/19551 (0.41%)	RR 0.85 (0.61 to 1.19) Adjusted OR 0.92 (0.60 to 1.39)[b]	621 fewer per 1,000,000 (from 1616 fewer to 787 more)	Very low
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	38/8256 (0.46%)	52/10541 (0.49%)	RR 0.93 (0.61 to 1.42) Adjusted OR 0.96 (0.58 to 1.61)[b]	345 fewer per 1,000,000 (from 1924 fewer to 2072 more)	Very low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	20/8234 (0.24%)	29/8980 (0.32%)	RR 0.75 (0.43 to 1.33) Adjusted OR 0.81 (0.40 to 1.62)[b]	807 fewer per 1,000,000 (from 1841 fewer to 1066 more)	Very low
Women without complicating conditions at the onset of labour						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	54/15342 (0.35%)	48/15676 (0.31%)	RR 1.15 (0.78 to 1.69) Adjusted OR 1.26 (0.80 to 1.99)[b]	459 more per 1,000,000 (from 674 fewer to 2113 more)	Low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Nulliparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	35/7518	28/8018	RR 1.33 (0.81 to 2.19) Adjusted OR 1.38 (0.75 to 2.52)	196 fewer per 1,000,000 (from 664 fewer to 4156 more)	Low
Multiparous women						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	19/7792	20/7637	RR 0.93 (0.50 to 1.74) Adjusted OR 1.09 (0.50 to 2.39)	183 fewer per 1,000,000 (from 1309 fewer to 1938 more)	Low
Serious neonatal morbidity not caused by malformations or preterm birth[l]						
1 study (Waldenstrom et al., 1997)	randomised trial	6/933 (0.64%)	2/936 (0.21%)	RR 3.01 (0.61 to 14.87)	4295 more per 1,000,000 (from 833 fewer to 29637 more)	Low
1 study (Gaudineau et al., 2013)	observational	23/316 (7.3%)	64/890 (7.2%)	RR 0.94 (0.59 to 1.49)	4 fewer per 1000 (29 fewer to 35 more)	Very low
Neonatal encephalopathy (clinical diagnosis)						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	17/16569 (0.1%)	34/19587 (0.17%)	RR 0.59 (0.33 to 1.06)[h]	712 fewer per 1,000,000 from 1163 fewer to 104 more)	Very low

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Number of studies	Design	Number of women/babies		Effect		Quality
		Planned birth in an alongside midwifery unit	Planned birth in an obstetric unit	Relative (95% CI [unless otherwise stated])	Absolute (95% CI)	
Neonatal encephalopathy (signs)[k]						
1 study (Birthplace in England Collaborative Group, 2011)	observational study	4/16710 (0.02%)	8/19706 (0.04%)	RR 0.59 (0.18 to 1.96)[h]	166 fewer per 1,000,000 (from 333 fewer to 390 more)	Very low

CI confidence interval, NC not calculable, NICU neonatal intensive care unit, OR odds ratio, RR relative risk

a. It should be noted that 'spontaneous vaginal birth' was the outcome identified in the research protocol however this was reported in the Birthplace study as 'spontaneous vertex birth'.
b. Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, body mass index, deprivation score quintile, previous pregnancies and weeks of gestation, and also weighted to reflect unit's duration of participation and probability of being sampled
c. The authors report an analysis which adjusted for maternal age, smoking, education and marital status. The direction and significance of the effect were the same in all cases, except for the outcome of episiotomy, which became statistically significant once adjusted. The adjusted odds ratios have not been reported in the GRADE table because they are reported with the midwifery unit as the reference group rather than the other way around.
d. Please note that, although the % based on the raw event rate implies that the incidence of this outcome is lower in women planning birth in an alongside midwifery unit, the relative risk in the meta-analysis (weighted by study) shows that the risk is actually higher in women planning birth in a midwifery unit. This is in line with all of the relative risks of the individual studies (further details are reported in appendix J)
e. The reasons for seeking medical care are defined in more detail in the evidence table (appendix I); however, the majority of them were issues that could be related to birth and the postpartum period
f. Avoidable factors were identified in two of the deaths in women randomised to the midwifery units. Further details are reported in the evidence tables (appendix I)
g. In Begley et al., 2011, there was one fetal death at >24 weeks in the midwifery arm. In Hundley et al., 1994, in all 10 stillbirths, the baby's heartbeat was absent on admission to hospital. In MacVicar et al., 1993, possible avoidable factors were identified in 2/13 deaths in the midwifery unit group. Further details are reported in the evidence tables (appendix I)
h. It should be noted that this outcome formed part of the composite morbidity/mortality outcome in the Birthplace study and that the study was only powered to detect a difference in the composite outcome, not its individual components. Further details are reported in the evidence tables (appendix I)
i. In Hundley et al., 1994, 5/11 deaths resulted from lethal fetal abnormalities, and 4/11 were in babies of less than 37 weeks' gestation. In MacVicar et al., 1993, the authors report that no avoidable factors were identified. Further details are reported in the evidence tables (appendix I)
j. Composite of stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle
k. Defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress
l. Serious neonatal morbidity not defined further in Waldenstrom et al, 1997; defined as umbilical artery pH <7.15 and/or Apgar score at 5 min ≤6 and/or neonatal death in Gaudineau et al., 2013.

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Evidence statements

There was consistent evidence from a meta-analysis of randomised controlled trials (n=9208) and a large observational study (n=36,378) that women planning birth in an alongside midwifery unit had higher rates of spontaneous vaginal birth and lower rates of instrumental vaginal birth than women planning birth in an obstetric unit. One smaller observational study (n=1206) also found a higher rate of spontaneous vaginal birth in the alongside midwifery unit group, but no difference in rates of instrumental birth. Two other observational studies (n=1937) did not find a difference in either outcome, but they had smaller sample sizes and demonstrated similar trends. A big observational study (n=36,378) suggested a large reduction in the rate of caesarean section following planned birth in an alongside midwifery unit, and the meta-analysis of randomised controlled trials (n=11,298) demonstrated a trend in that direction, a finding mirrored in a smaller observational study. Three additional observational studies (n=3143) did not find a difference in caesarean section rates between the 2 groups.

There was consistent evidence (n=49,286) that planning birth in an alongside midwifery unit is associated with lower rates of epidural use, but no difference in outcomes of blood loss (measured either using any postpartum haemorrhage [n=10,826], major postpartum haemorrhage [n=1111] or need for a blood transfusion [n=41,318]). Women planning birth in an alongside unit had lower rates of episiotomy, but there was evidence (n=8100) from a meta-analysis of an increased risk of any vaginal/perineal tears (although one observational study [n=1482] did not find a difference in the risk of any tears). No difference was found in the proportion of women with an intact perineum or in the risk of third or fourth degree vaginal/perineal tears. There were no incidences of maternal mortality, although this outcome was only reported in 2 studies (n=38,069).

There was consistent evidence (n=30,796) that there was no difference in the rate of admission to NICU between babies born to women planning birth in an alongside midwifery unit and those born to women planning birth in an obstetric unit. In terms of other neonatal outcomes, 1 large observational study (n=36,075) and 1 smaller observational study found evidence that there was no difference in the rate of a composite perinatal mortality and morbidity outcome among babies born to women planning birth in an alongside midwifery unit and those born to women planning birth in an obstetric unit. This was true for both nulliparous and multiparous women. There was also no evidence of a difference in the risk of stillbirth (n=44,315), neonatal death (n=1828) and neonatal encephalopathy (n=36,156), but none of the studies were powered for these rare outcomes individually.

Transfer rates varied from about 20% to over 50%. Transfer rates were higher in nulliparous women than in multiparous women. The evidence across all outcomes was of low and very low quality.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was vital to consider the outcomes for the woman and the outcomes for the baby, as they felt that both would play a part in women's decision-making process. In terms of the woman, the group particularly wanted to ascertain whether the rates of intervention (namely instrumental vaginal birth, caesarean section and episiotomy) and the associated morbidities (for example perineal trauma and postpartum haemorrhage) differed in women planning birth in the 2 settings, because they are both based in hospital. For the baby, they felt that it was important to establish whether there was any risk associated with planning birth outside an obstetric unit, and therefore the outcomes relating to neonatal mortality and morbidity (including the risks of admission to NICU) were considered priorities for decision-making. The group did not feel that epidural was a particularly helpful outcome, as it is only available in an obstetric unit and is a matter of personal choice for the woman.

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The group also felt that the rates of transfer were important and would be a significant consideration for women planning where to give birth.

Consideration of clinical benefits and harms

The guidelines development group noted that for many of the outcomes, the evidence showed that there was no significant difference between planning birth in an alongside midwifery unit and planning birth in an obstetric unit. In particular, the group noted that no statistically significant differences were identified for the neonatal outcomes reported, but they did discuss the fact that the studies were not powered to detect differences in individual rare outcomes (stillbirth, neonatal death and neonatal encephalopathy). They noted that the Birthplace study (2011) was powered to detect a difference in its composite outcome, but that this had required pooling components with very different levels of severity, from fractured clavicle to mortality. While the group felt that this was a limitation of the data, they also conceded that conducting a study with the power to detect differences in the very severe (and hence rare) outcomes would not be feasible. Also, fractured clavicle accounted for less than 3% of events and the serious perinatal outcomes – mortality, neonatal encephalopathy and meconium aspiration – constituted just under 90% of the primary outcome events. Given this evidence, and the fact that there was no significant difference in the rates of admission to NICU, they concluded that planning birth in an alongside midwifery unit was as safe for the baby as planning birth in an obstetric unit.

The group then considered the outcomes around mode of birth. Overall, the evidence showed that the rates of spontaneous vaginal birth were higher, and the rates of instrumental vaginal birth and caesarean section were lower, after planning birth in alongside midwifery unit when compared with planning birth in an obstetric unit. It was felt there were several reasons why this might be the case: for example, women who wanted regional analgesia with their higher likelihood of instrumental birth would be delivered in an obstetric unit, or, if a woman was not in an obstetric unit with easy access to instrumental birth, more efforts may be made to achieve a spontaneous vaginal birth. They discussed the fact that 2 of the observational studies did not find statistically significant differences between modes of birth, but agreed that this was likely to be a function of the small size of the studies.

In terms of maternal morbidity, the group noted that there was no evidence of a difference in blood loss, in terms of either postpartum haemorrhage or blood transfusion, between women who planned birth in the 2 settings. The group then discussed the outcomes linked to vaginal and perineal trauma. They noted that rates of episiotomy were lower after planned birth in an alongside midwifery unit but that, conversely, the rates of vaginal/perineal tears were higher (although there was no significant difference found in the rates of third or fourth degree trauma). Therefore, they concluded that, on balance, there was unlikely to be a substantial difference between the two settings. This was supported by the meta-analysis of five randomised controlled trials, which showed no significant difference in the proportion of women with an intact perineum.

The group considered the rates of transfer reported in the studies. They discussed the fact that the proportion of women transferred was generally higher in the studies which evaluated outcomes by where women had booked to give birth (rather than where they intended to give birth at the onset of labour), because many of the transfers of care occurred antenatally. They also noted that the transfer rate in nulliparous women was consistently higher than the transfer rate in multiparous women. Apart from parity, the group was aware that maternal age was another confounder influencing transfer rates (Rowe et al., 2012). The group agreed that it was important that women were given information about the likelihood that they would need or choose to be transferred, and what the reasons for this might be. They were also aware of the impact that ambulance transfer in labour can have on the woman's experience and satisfaction (Rowe et al., 2012).

Consideration of health benefits and resource uses

The guideline development group felt that planning birth in an alongside midwifery unit was likely to be more cost effective than planning birth in an obstetric unit, given that the rates of intervention were lower and that there was no significant difference identified in neonatal outcomes. However, they also noted that alongside midwifery units cannot exist in isolation and therefore that some of the cost of maintaining an obstetric unit facility had to be considered in conjunction with the direct costs of the alongside unit. Despite this, the group concluded that there were likely to be cost savings associated with more women giving birth in an alongside midwifery unit. They felt that the service could be reorganised to move some midwives out of obstetric units into alongside units to care for low risk women, and that the lower rates of intervention (that is, caesarean section and instrumental vaginal birth) associated with planning birth in an alongside midwifery unit would reduce rates overall and therefore reduce costs associated with these interventions, including reduced length of postnatal stay. The care in obstetric units could be focussed on high risk women and low risk women who required transfer from other settings, ensuring that the appropriate expertise is in the right place for each woman, although it has to be acknowledged that this would have staffing and other resource implications.

Quality of evidence

The evidence available for this comparison consisted of both randomised controlled trials and prospective observational studies, and ranged from moderate to very low quality. Unlike the evidence from observational studies, the evidence from randomised trials was meta analysed. Although the evidence from randomised controlled trials is objectively considered more robust, the group noted that many of the trials had methodological issues, were conducted in the 1990s or were conducted outside the UK. In addition, they generally included a proportion of women who were not considered low risk at the start of care in labour. They agreed that these issues somewhat undermined the usefulness of the results when considering low risk women currently planning their place of birth in England and Wales. However, they also noted that in the observational studies, there were significant differences in the characteristics of the study groups. While those that were identified had been accounted for in 2 of the studies, they agreed that there was a possibility that other, unknown differences could have affected outcomes.

The group acknowledged that some of their conclusions were based on the Birthplace (2011) data alone and in some cases these were derived from re-analysis of published Birthplace data in which it has not been possible to take full account of possible confounding and relevant design effects, such as clustering. Nonetheless, the group felt that the Birthplace study was generally a good quality observational study, because it is a very large study, it did perform adjustments for confounders, it was conducted more recently and it was based in England. They noted that there were more women with complicating conditions identified at the onset of labour in the obstetric unit group, which might have affected outcomes, but this was taken into consideration by the authors in the analysis and overall the study was felt to be particularly helpful in informing recommendations, given its size and setting.

The group was disappointed to see that no evidence was available for long-term outcomes relating to place of birth. This lack of data not only impacts on the ability to make informed clinical decisions but also severely limits the usefulness of any health economic evaluation for this topic.

Other considerations

The guideline development group noted that the definition of an alongside midwifery unit varied considerably in the included studies and therefore that, in some cases, the setting might not be comparable to alongside units in England and Wales. For example, in some of the studies it was reported that an obstetrician could be called to the unit or that equipment was ‘hidden’ rather than absent. And in some cases the unit was in close proximity and in others,

although it was in the same building, it was not adjacent. They agreed that this was not optimal, but they noted that there is variation even within England and Wales and agreed that obstetricians were occasionally called to units instead of women being formally transferred. As a result, it was not possible to define the optimum alongside midwifery unit model to improve outcomes, cost effectiveness and women's experiences. Nevertheless, the group concluded that although the variation in units was a consideration, the results of the review were still valid and applicable to alongside midwifery units in England and Wales. Furthermore, the group questioned whether 'midwifery-led care' in an obstetric unit was equivalent in all respects to 'midwifery care' in an alongside unit.

The group discussed the subgroup analysis by parity that was reported in the Birthplace study (2011) and two of the randomised controlled trials. They noted that, in general, the results were consistent with those of the overall analysis. The Birthplace study (2011) showed that both nulliparous and multiparous women planning birth in an alongside midwifery unit had higher rates of spontaneous vaginal birth and lower rates of caesarean section, ventouse births and episiotomies than women planning birth in an obstetric unit, with no significant difference shown in neonatal outcomes. The group was disappointed that it was not possible to do a subgroup analysis for the outcome of 'any vaginal/perineal tears', although they noted that again no significant difference was found in the incidence of third or fourth degree trauma. The group discussed the fact that the meta-analysis of randomised controlled trials did not show a significant difference in instrumental vaginal birth or caesarean section rate in either nulliparous or multiparous women, but agreed that this was likely to be due to a loss of statistical power.

Health economics profile

Only one economic evaluation of birth place was identified for the UK (Schroeder at al., 2012). A summary of this evaluation is given here and with a full review in appendix A. The aim of the primary analysis was to estimate the cost effectiveness of births planned in different settings (home, freestanding midwifery units, alongside midwifery units and obstetric units) for women and babies at 'low risk' of complications prior to the onset of labour.

The study population was all women in the Birthplace prospective cohort study (2011) at 'low risk' of complications prior to the onset of labour where the primary outcome and potential confounders were not missing.

The time horizon of the analysis was the duration of follow-up of the Birthplace prospective cohort study (2011). Women were identified at the start of their care in labour and follow-up was complete when the intrapartum and related postnatal care for both mother and baby ended. This time horizon included higher level postnatal or neonatal care but did not include the life-long health effects due to morbidities associated with labour and birth.

The results were presented for all women considered at 'low risk', for nulliparous and multiparous women and for women without complicating conditions at the start of care in labour. The cost effectiveness of births planned at home, in freestanding midwifery units and in alongside midwifery units compared with births planned in obstetric units was presented for these separate outcomes:

- incremental cost per adverse perinatal outcome avoided
- incremental cost per maternal morbidity avoided
- incremental cost per additional 'normal birth'.

When compared with women planning to give birth in an obstetric unit, women planning a birth at home were more likely to

- be white and have a fluent understanding of English

- be older (28% were 35 years and older in the home group compared with 16% in the obstetric unit group)
- be married or living with a partner
- be living in a more socioeconomically advantaged area
- have had one or more previous pregnancies.

Each of these characteristics was associated with being cost saving.

The primary outcome was presented in the cost effectiveness analysis as increased or decreased numbers of adverse perinatal outcomes in each setting compared with the obstetric unit. It is important to note that although there is a difference in this outcome between settings, the numbers are very small. The incidence of adverse perinatal outcomes was low in all settings included in the study.

For nulliparous women, a home birth was likely to be less costly but with more adverse perinatal outcomes than birth in other settings for all women considered low risk and for women without complicating conditions at the start of care. Both freestanding midwifery units and alongside midwifery units were less costly and more effective than obstetric units: fewer adverse perinatal outcomes occurred in midwife-led units, although there is uncertainty surrounding the adverse perinatal outcomes.

Table 18: Incremental costs, clinical effects (adverse perinatal outcome avoided) per woman and cost effectiveness ratios (cost per adverse perinatal outcome avoided) for nulliparous women at low risk of complications by planned place of birth using the obstetric unit (OU) as a reference*

Setting	Incremental cost (compared to OU) (95% CI)	Incremental effect (compared to OU) (95% CI)	Incremental cost effectiveness (compared to OU)
Home	−£281 (−£343 to −£217)	−0.004 (−0.008 to −0.00001)	£69,761
FMU	−£163 (−£217 to −£108)	0.0008 (−0.002 to 0.003)	−£98,136
AMU	−£92 (−£142 to −£33)	0.0005 (−0.003 to 0.003)	−£47,995

AMU alongside midwifery unit, CI confidence interval, FMU freestanding midwifery unit, OU obstetric unit

**A negative incremental cost shows a cost saving compared to obstetric unit. A negative incremental effect shows there are more adverse perinatal outcomes compared to the obstetric unit (fewer adverse perinatal outcomes have been avoided in this setting). Where the incremental cost is negative and the incremental effect is positive then this setting is less expensive and has better perinatal outcomes than the obstetric unit, this planned place of birth will dominate the obstetric unit for this outcome.*

Table 19: Incremental costs, clinical effects (adverse perinatal outcome avoided) per woman and cost effectiveness ratios (cost per adverse perinatal outcome avoided) for multiparous women at low risk of complications by planned place of birth using obstetric unit (OU) as a reference

Setting	Incremental cost (compared to OU) (95% CI)	Incremental effect (compared to OU) (95% CI)	Incremental cost effectiveness (compared to OU)
Home	−£362 (−£390 to −£335)	0.001 (−0.0004 to 0.0025)	−£323,037
FMU	−£173 (−£208 to −£139)	0.0005 (−0.0015 to 0.0024)	−£128,134
AMU	−£151	0.0007	−£119,618

Setting	Incremental cost (compared to OU) (95% CI)	Incremental effect (compared to OU) (95% CI)	Incremental cost effectiveness (compared to OU)
	(−£184 to −£117)	(−0.001 to 0.003)	

AMU alongside midwifery unit, CI confidence interval, FMU freestanding midwifery unit, OU obstetric unit

In terms of incremental cost per maternal morbidity avoided and cost per normal birth, planned place of birth in all non-obstetric unit settings generated incremental cost savings and improved maternal outcomes.

Table 20: Incremental costs, clinical effects (maternal morbidity avoided) per woman and cost effectiveness ratios (cost per maternal morbidity avoided) for all women at low risk of complications by planned place of birth using obstetric unit (OU) as a reference*

Setting	Incremental cost (compared to OU) (95% CI)	Incremental effect (compared to OU) (95% CI)	Incremental cost effectiveness (compared to OU)
Home	−£590 (−£618 to −£563)	0.195 (0.187 to 0.204)	−£3024
FMU	−£247 (−£280 to −£211)	0.172 (0.168 to 0.182)	−£1442
AMU	−£154 (−£190 to −£118)	0.116 (0.106 to 0.126)	−£1322

AMU alongside midwifery unit, CI confidence interval, FMU freestanding midwifery unit, OU obstetric unit

** A negative incremental cost shows a cost saving compared to OU. A positive incremental effect shows there are fewer incidences of maternal morbidity compared to the OU. Where the incremental cost is negative and the incremental effect is positive then this setting is less expensive and has better maternal outcomes than the OU, this planned place of birth will dominate the OU for this outcome.*

Table 21: Incremental costs, clinical effects (normal births) per woman and cost effectiveness ratios (cost per normal birth) for all women at low risk of complications by planned place of birth using OU as a reference*

Setting	Incremental cost (compared to OU) (95% CI)	Incremental effect (compared to OU) (95% CI)	Incremental cost effectiveness (compared to OU)
Home	−£590 (−£618 to −£563)	0.300 (0.290 to 0.310)	−£1960
FMU	−£247 (−£280 to −£211)	0.256 (0.245 to 0.268)	−£956
AMU	−£154 (−£190 to −£118)	0.184 (0.173 to 0.194)	−£836

AMU alongside midwifery unit, CI confidence interval, FMU freestanding midwifery unit, OU obstetric unit

** A negative incremental cost shows a cost saving compared to OU. A positive incremental effect shows there more normal births compared to the OU.*

The authors concluded that for multiparous women at low risk of complications, planned birth at home was the most cost-effective option. For nulliparous low risk women, planned birth at home was reported to be the most cost-effective option, although they noted that home births were associated with an increase in adverse perinatal outcomes.

No long-term costs or benefits were included in the analysis. The results were not presented as an incremental cost per quality adjusted life year (QALY). Although the results were not presented in incremental costs per QALY, a willingness to pay threshold of £20,000 was used in the published analysis to make statements about the optimal birth setting by cost

effectiveness. As this composite outcome included neonatal death and encephalopathy, as well as fractured clavicle, it is difficult to interpret the results. It implies society is willing to pay £20,000 for 1 adverse perinatal event, where the adverse events vary in severity. Nearly 90% of the composite perinatal outcomes were the more serious outcomes of mortality, neonatal encephalopathy and meconium aspiration.

The same threshold has been applied where effectiveness has increased or decreased relative to the obstetric unit. So the results show home births are less expensive and there are more adverse perinatal outcomes compared with births in the obstetric unit for nulliparous women, whereas the midwifery units are both less expensive and have fewer adverse perinatal outcomes than the obstetric unit. However, if a cost effectiveness threshold of £20,000 per perinatal adverse outcome is applied, then the authors have calculated that home births would result in the highest net benefit. This implies that health decrements can be valued in the same way as health benefits. By applying the same economic value of £20,000 per adverse perinatal event, the increase in adverse perinatal events is acceptable because the cost savings and increased health benefits associated with home births outweigh the costs and health decrements resulting from this increase in adverse perinatal events.

Planned place of birth outside the obstetric unit for low risk women in labour at term (37^{+0}–41^{+6}) is likely to be cost saving. The impact on effectiveness in terms of adverse perinatal outcomes is uncertain. The impact on effectiveness in terms of maternal morbidity and normal births attained show births planned in a setting outside the hospital result in better outcomes.

The authors noted that both costs and cost effectiveness reported may change if maternity services are reconfigured. Commissioners should consider the resource use and related cost implications on the maternity service as a whole. Planning changes to a maternity service to maximise cost effectiveness should be done for a specific local area and use local data to inform decision-making.

Finally, the guideline development group acknowledged that both the contractual model implemented in practice and the providers willingness to 'absorb' the risk of lower than expected performance have a great bearing on the cost effectiveness of freestanding midwifery units.

Key conclusions (whole review)

The guideline development group noted that the evidence showed that giving birth is generally very safe for women and babies across all settings with very low incidences of mortality or severe morbidity reported.

There was consistent evidence that for women at low risk of complications in birth, giving birth in an obstetric unit is associated with a higher incidence of obstetric intervention and its associated morbidity when compared with planning birth in other settings (though some of these differences may be due to maternal choice, such as an epidural, or transfer in labour, for example because of poor progress). Furthermore, there was evidence of an increase in neonatal unit admissions for babies born in obstetric units with no difference in other neonatal outcomes between planning birth in an obstetric unit, an alongside midwifery unit or a freestanding midwifery unit. Cost effectiveness analysis based on all low risk women also indicates that planning to give birth outside an obstetric unit is more cost effective than planning to give birth in an obstetric unit owing to a reduced incidence of adverse perinatal outcomes.

There were important differences seen for neonatal outcomes when sub-group analyses by parity were undertaken. These data were drawn largely from the UK Birthplace study (2011) and thus were felt to be highly relevant. These findings indicated that for babies born to nulliparous women planning birth at home, there was an increased risk of an adverse composite neonatal outcome when compared with planning birth in all other settings, although the absolute risk of a poor outcome remains small. The guideline development group

recognised that the use of a composite outcome for perinatal morbidity could provide misleading results if planned place of birth affects different contributing outcomes in different ways. However, they did not think that was likely. Furthermore, they noted that nearly 90% of the cases with this composite perinatal outcome had conditions which were at the severe end of the spectrum (perinatal death, neonatal encephalopathy or meconium aspiration syndrome). There was no difference seen between settings for babies born to multiparous women. The group noted that this would probably impact on the cost effectiveness of each setting. Although the analysis from Schroeder et al. suggested that planning birth at home would be cost effective for both multiparous and nulliparous women, the group felt it likely that the incremental cost per QALY of giving birth at home would probably be reduced for nulliparous women, given the increased likelihood of an adverse neonatal outcome. As a result, while they recognised that offering both home and midwifery-led settings for multiparous women would be cost effective, they felt less certain about the cost effectiveness of home birth for nulliparous women.

For these reasons, coupled with the fact that planning to give birth in an obstetric unit was found to be associated with increased maternal morbidity, the guideline development group felt it appropriate to recommend that nulliparous women be advised to give birth in either a freestanding or alongside midwifery unit and multiparous women be advised to give birth either at home or in a freestanding or alongside midwifery unit. However, alongside this advice, the group felt it imperative that women be given a choice of all birth settings and be given evidence-based information, in an easily accessible format, about the key risks and benefits associated with each birth setting in order to help them decide the most appropriate place for them to plan to give birth. The group developed a 'decision aid' as an example of how this information might be presented to women in a format that facilitates discussion between the woman and the midwife and which the woman can use for future reference and as a basis for ongoing discussions (see appendix L). The group believed it important that the information given should be as relevant as possible to each woman and so recommended that local data be provided wherever possible, and that data relating to nulliparous women and multiparous women be provided separately. Because of this, although the conclusions that inform the recommendations are based on a synthesis of findings from all studies reviewed, the data included in the recommendations are drawn largely from Birthplace (2011), with data from Blix 2012 incorporated for some outcomes for home birth and birth in an obstetric unit (see appendix M for details). The group also drafted a research recommendation to investigate the impact on women's choices and decision-making of using an evidence-based decision aid and a less risk-based approach to discussions around place of birth.

When considering the evidence for each birth setting, a number of gaps in the evidence were noted by the guideline development group, which prompted the drafting of research recommendations. In particular, they drafted a research recommendation to investigate the difference in long-term outcomes associated with birth in the different settings and what components of care in midwifery-led settings contribute to lower intervention rates. They were also aware that the new recommendations would lead to a shift towards more women giving birth outside an obstetric unit than before. Research recommendations were made to look at the staff training needs associated with this shift and to develop a commissioning tool to examine the impact this would have on planning service provision.

Recommendations

1. **Explain to both multiparous and nulliparous women who are at low risk of complications that giving birth is generally very safe for both the woman and her baby. [2014]**

2. **Explain to both multiparous and nulliparous women that they may choose any birth setting (home, freestanding midwifery unit, alongside midwifery unit or obstetric unit), and support them in their choice of setting wherever they choose to give birth:**
    - Advise low-risk multiparous women that planning to give birth at home or in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit.
    - Advise low-risk nulliparous women that planning to give birth in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. Explain that if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby. [new 2014]

3. **Using tables 22 and 23, explain to low-risk multiparous women that:**
    - planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
    - planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
    - there are no differences in outcomes for the baby associated with planning birth in any setting. [new 2014]

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Table 22: Rates of spontaneous vaginal birth, transfer to an obstetric unit and obstetric interventions for each planned place of birth: low-risk multiparous women (sources: Birthplace 2011; Blix et al. 2012)

	Number of incidences per 1000 multiparous women giving birth			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Spontaneous vaginal birth	984*	980	967	927*
Transfer to an obstetric unit	115*	94	125	10**
Regional analgesia (epidural and/or spinal)***	28*	40	60	121*
Episiotomy	15*	23	35	56*
Caesarean birth	7*	8	10	35*
Instrumental (forceps or ventouse) birth	9*	12	23	38*
Blood transfusion	4	4	5	8

** Figures from Birthplace 2011 and Blix et al. 2012 (all other figures from Birthplace 2011)*
***Estimated transfer rate from an obstetric unit to a different obstetric unit owing to lack of capacity or expertise*
****Blix reported epidural analgesia and Birthplace reported spinal or epidural analgesia*

Table 23: Outcomes for the baby for each planned place of birth: low-risk multiparous women (source: Birthplace 2011)

	Number of babies per 1000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	997	997	998	997
Babies with serious medical problems*	3	3	2	3

** Serious medical problems were combined in the study: neonatal encephalopathy and meconium aspiration syndrome were the most common adverse events, together accounting for 75% of the total. Stillbirths after the start of care in labour and death of the baby in the first week of life accounted for 13% of the events. Fractured humerus and clavicle were uncommon outcomes (less than 4% of adverse events). For the frequency of these events (how often any of them actually occurred), see appendix K.*

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4. Using tables 24 and 25, explain to low-risk nulliparous women that:

- planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
- planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
- there are no differences in outcomes for the baby associated with planning birth in an alongside midwifery unit, a freestanding midwifery unit or an obstetric unit
- planning birth at home is associated with an overall small increase (about 4 more per 1000 births) in the risk of a baby having a serious medical problem compared with planning birth in other settings. [new 2014]

Table 24: Rates of spontaneous vaginal birth, transfer to an obstetric unit and obstetric interventions for each planned place of birth: low-risk nulliparous women (sources: Birthplace 2011; Blix et al. 2012)

	Number of incidences per 1000 nulliparous women giving birth			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Spontaneous vaginal birth	794*	813	765	688*
Transfer to an obstetric unit	450*	363	402	10**
Regional analgesia (epidural and/or spinal)***	218*	200	240	349
Episiotomy	165*	165	216	242*
Caesarean birth	80*	69	76	121*
Instrumental (forceps or ventouse)	126*	118	159	191*
Blood transfusion	12	8	11	16

** Figures from Birthplace 2011 and Blix et al. 2012 (all other figures from Birthplace 2011).*
***Estimated transfer rate from an obstetric unit to a different obstetric unit owing to lack of capacity or expertise.*
**** Blix reported epidural analgesia and Birthplace reported spinal or epidural analgesia*

Table 25: Outcomes for the baby for each planned place of birth: low-risk nulliparous women (source: Birthplace 2011)

	Number of babies per 1000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	991	995	995	995
Babies with serious medical problems*	9	5	5	5

** Serious medical problems were combined in the study: neonatal encephalopathy and meconium aspiration syndrome were the most common adverse events, together accounting for 75% of the total. Stillbirths after the start of care in labour and death of the baby in the first week of life accounted for 13% of the events. Fractured humerus and clavicle were uncommon outcomes – less than 4% of adverse events. For the frequency of these events (how often any of them actually occurred), see appendix K*

5. **Ensure that all healthcare professionals involved in the care of pregnant women are familiar with the types and frequencies of serious medical problems that can affect babies (see appendix K), in order to be able to provide this information to women if they request it. [new 2014]**

6. **Commissioners and providers[l] should ensure that all 4 birth settings are available to all women (in the local area or in a neighbouring area). [new 2014]**

7. **Give the woman the following information, including local statistics, about all local birth settings:**
    - Access to midwives, including:
        - the likelihood of being cared for in labour by a familiar midwife
        - the likelihood of receiving one-to-one care throughout labour (not necessarily being cared for by the same midwife for the whole of labour)
    - Access to medical staff (obstetric, anaesthetic and neonatal).
    - Access to pain relief, including birthing pools, Entonox, other drugs and regional analgesia.
    - The likelihood of being transferred to an obstetric unit (if this is not the woman's chosen place of birth), the reasons why this might happen and
    - the time it may take. Refer to table 26 if no local data are available. [new 2014]

Table 26: Primary reasons for transfer to an obstetric unit (source: Birthplace 2011)

	Number of women transferred (% of total transferred from each setting)		
Primary reason for transfer to an obstetric unit*	**From home (n=3529)**	**From a freestanding midwifery unit (n=2457)**	**From an alongside midwifery unit (n=4401)**
Delay during first or second stage of labour	1144 (32.4%)	912 (37.1%)	1548 (35.2%)
Abnormal fetal heart rate	246 (7.0%)	259 (10.5%)	477 (10.8%)
Request for regional analgesia	180 (5.1%)	163 (6.6%)	585 (13.3%)

l This can also include networks of providers.

	Number of women transferred (% of total transferred from each setting)		
Meconium staining	432 (12.2%)	301 (12.2%)	538 (12.2%)
Retained placenta	250 (7.0%)	179 (7.3%)	203 (4.6%)
Repair of perineal trauma	386 (10.9%)	184 (7.5%)	369 (8.4%)
Neonatal concerns (postpartum)	180 (5.1%)	63 (2.6%)	5 (0.0%)
Other	711 (20.1%)	396 (16.2%)	676 (16.3%)
* Main reason for transfer to an obstetric unit for each woman (there may be more than 1 reason).			

8. **If further discussion is wanted by either the midwife or the woman about the choice of planned place of birth, arrange this with a consultant midwife or supervisor of midwives, and/or a consultant obstetrician if there are obstetric issues. [new 2014]**

9. **When discussing the woman's choice of place of birth with her, do not disclose personal views or judgements about her choices. [new 2014]**

10. **Ensure that all women giving birth have timely access to an obstetric unit if they need transfer of care for medical reasons or because they request regional analgesia. [new 2014]**

11. **Commissioners and providers[m] should ensure that there are:**
    - robust protocols in place for transfer of care between settings (see also recommendations 48 to 52).
    - clear local pathways for the continued care of women who are transferred from one setting to another, including:
        - when crossing provider boundaries
        - if the nearest obstetric or neonatal unit is closed to admissions or the local midwifery-led unit is full. [new 2014]

12. **Commissioners and providers[n] should ensure that there are multidisciplinary clinical governance structures in place to enable the oversight of all birth settings. These structures should include, as a minimum, midwifery (including a supervisor of midwives), obstetric, anaesthetic and neonatal expertise, and adequately supported user representation. [new 2014]**

Research recommendations

1. **How does the provision of accurate, evidence-based information affect women's decision-making processes and choice of place of birth?**

Why this is important

A report by Coxon et al. (2013) identifies in detail why women make choices about where give birth and how these choices can be influenced. Influences may include written and verbal information (both online and from midwives and doctors), previous experience, and word-of-mouth advice from friends and family. The GDG concluded from the Birthplace study that giving birth outside an obstetric unit is the optimal choice for low-risk women. This finding

m This can also include networks of providers.
n This can also include networks of providers.

should be used to restructure the way in which information is provided, so that it is presented in a more accurate, less risk-based way in order to support women's choices. This change should be evaluated in a quantitative observational study and/or qualitative study that records any changes in women's choice-making about place of birth. Outcomes include understanding why and how women make choices about where to give birth and how this can influence the provision of appropriate and accessible information, a measure of informed decision-making, and fearfulness and absence of fearfulness when choosing place of birth.

2. **What are the long term consequences for women and babies of planning birth in different settings?**

Why this is important

The long-term consequences of birth experiences and birth outcomes are poorly understood, particularly in relation to place of birth. A large population-based observational study would compare women's experiences and outcomes for them and their babies in different birth settings (with subgroup analysis by mode of birth) in relation to the wellbeing of the women and their children over different periods of time (for example, 2, 5, 10, 15, 20 and 30 years). A secondary analysis could compare different providers where birth philosophies are different. Outcomes would be compared by accessing medical records and through qualitative interviews. Primary outcomes are mode of birth, long-term morbidity in the woman and baby, pain after birth, readmission to hospital, infection, psychological morbidity (for example, postnatal depression, bonding, relationship breakdown with partner, fear of giving birth in future) and breastfeeding rates. Secondary outcomes are impact on attachment between mother and child, obesity in children, autoimmune disease, chronic illness, educational achievement and family functioning.

3. **What are the resourcing and staff training needs associated with advising women at low risk of developing intrapartum complications to give birth outside an obstetric unit and providing a service that facilitates choice of birth setting that includes birth at home, in a freestanding midwifery unit, and alongside midwifery unit and birth in an obstetric unit. What is the impact on satisfaction for women and midwives?**

Population: Maternity services providing intrapartum care. Women at low risk of developing intrapartum complications, midwives and other health care professionals involved in providing intrapartum care.
Intervention: Advising women to give birth outside an obstetric unit and providing a choice of birth at home, in a freestanding midwifery unit, an alongside midwifery unit or an obstetric unit.
Comparison: previous model of service provision and uptake including the previous distribution of births between home, freestanding midwifery unit, alongside midwifery unit and obstetric unit.
Outcomes: Resource use, identified training needs and satisfaction for women and midwives
Study design: economic and service evaluation with a qualitative component

Why this is important

Until recently, most births have taken place in an obstetric unit. The evidence relating to safety of birth outside an obstetric unit either at home or in a midwifery-led unit has resulted in a recommendation that low risk women should give birth outside an obstetric unit. This change should lead to a change in service provision by commissioners in order to meet the altered demand. There is also likely to be a change in working practices for midwives, who are more likely to support out of hospital births, and as a result, births that take place within an obstetric unit, although reduced in number, are likely to be women at higher risk of

complications. The costs of these changes should be studied, along with satisfaction of both women and midwives. Midwives' training needs should be identified relating to offering choice of place of birth, as well as skills required to work outside a high-risk obstetric unit.

4. **Development and validation of a commissioning tool to enable the calculation of the effect of changes in the configuration of the provision of options for place of birth in an individual health economy, network or District.**

Population: a Health Economy, District or network providing maternity services for a specified population.
Intervention: a change in the provision of alternate places of birth – e.g. the opening of a freestanding and / or alongside midwifery unit or the development of a home birth team
Comparator: current service configuration/provision
Outcome: The costs of provision of maternity services (antenatal care through to postnatal care) for all women giving birth within that maternity service, taking into account alterations in service provision; number of women choosing each birth setting and actual place of birth including transfer rates; rates of normal births, and intervention rates such as emergency caesarean section; rates of maternal and neonatal morbidity and associated hospital admissions.
Study design: service evaluation based on observational data.

Why this is important

The current model of assessing costs associated with place of birth is based on the alterations in intervention rates (predominantly caesarean section) by increasing the number of births outside an obstetric unit. However, releasing those potential savings may be difficult because of the number of fixed costs associated with the obstetric unit. Developing new midwifery units is seen to add costs if corresponding savings are not made in the obstetric unit. Initial capital costs of opening a freestanding midwifery unit, as well as different staffing requirements; more senior midwives may be needed compared to alongside midwifery units or obstetric units; will have an impact on the cost-effectiveness of introducing a new service. It is also important to take into account all uses of an alternative birth setting in terms of antenatal and postnatal care and consider costs to the maternity service as a whole. Commissioners need an economic model that allows them to understand the effect of changes in service provision and how that can alter or not alter the fixed and revenue costs associated with the provision of maternity care for women at high risk of developing complications when developing the provision of services to support birth outside an obstetric unit.

5. **What are the key components in midwifery-led settings that result in lower intervention rates?**

Population: Women at low risk of developing intrapartum complications.
Intervention: Intrapartum care planned for a midwifery-led birth setting (home, freestanding midwifery unit or freestanding midwifery unit)
Comparison: Intrapartum care planned for an obstetric unit
Primary outcomes: Pain relief; coping strategies offered and used; use of water; 1 to 1 care; type of recordkeeping used; involvement of partner in birth and postnatal period. Philosophy and culture of organisation and in birth setting.
Secondary outcomes: midwives experiences of job satisfaction within midwifery-led environments. Partners experiences of care given. Women and partners' views of environment.
Study design: Observational study with qualitative component

Why this is important

The lower intervention rates observed in midwifery-led settings has been demonstrated consistently across a number of studies. Thus far, however, it has not been conclusively demonstrated what it is about care delivered in these settings that makes this difference. A number of components of care might play a part including one-to-one midwifery care, continuity of carer, intermittent rather than continuous fetal monitoring or a culture that sees labour and birth as a natural process to be worked with rather than 'treated' or 'managed'. A better understanding of what contributes to this observed difference could help improve outcomes and women's experience of care still further, hopefully across all settings.

Women's experience of planned birth in different settings

Review question

What are women's experiences associated with planning birth in each of the following settings:

- Home (domicillary)
- Freestanding midwifery units
- Alongside midwifery units
- Obstetric unit/hospital-based maternity unit

For further details on the evidence review protocol, please see appendix E.

Birth planned in an alongside midwifery unit compared with birth planned in an obstetric unit

Description of included studies

Seven studies were included in this review (Hundey et al., 2007; Waldenstrom and Nilsson, 1993; Waldenstrom and Nilsson, 1994, Byrne et al., 2000; Littlefield and Adams, 1987; Shaw, 1985; Tingstig et al., 2012). Four of these studies were randomised controlled trials (Hundey et al., 2007; Waldenstrom and Nilsson, 1993; Waldenstrom and Nilsson, 1994, Byrne et al., 2000), 1 was an observational study (Littlefield and Adams, 1987) and 2 were qualitative studies (Shaw, 1985; Tingstig et al., 2012)

One randomised controlled trial conducted in the UK compared birth planned in a 'midwife-managed unit' (from this point onwards referred to as 'alongside midwifery unit') with birth planned in a 'consultant-led labour ward' (from this point onwards referred to as 'obstetric unit') (Hundley et al., 1997). The alongside midwifery unit was 5 single rooms in a separate unit located 20 yards from the obstetric unit. The philosophy of care behind the alongside midwifery unit was to provide a safe, 'homely' environment where women can retain choice and control in the management of their labours. No further details about the 2 birth settings were reported. The mean age of women in the alongside midwifery group was 28±4.4 years and 56% were nulliparous. The mean age of women in the obstetric unit was 28±4.5 years and 57% were nulliparous. Intrapartum transfer rate was not reported. Outcomes were measured by questionnaires given to women upon discharge from the hospital. Non-responders at 3 weeks were sent the questionnaire again; non-responders at 6 weeks were reminded by telephone. The response rate was 95%.

Two reports of 1 randomised controlled trial conducted in Sweden that compared planned 'birth centre care' (from this point onwards referred to as alongside midwifery unit) with planned 'obstetric care' (from this point onwards referred to as obstetric unit) (Waldenstrom and Nilsson, 1993; Waldenstrom and Nilsson, 1994). The alongside midwifery unit was located 1 floor below the standard delivery ward but was described as being 'functionally similar to a freestanding unit with its own staff, facilities and medical guidelines, with an enrolment of 350 women per year'. The alongside midwifery unit offered integrated antenatal, intrapartum and postnatal care in the same premises. The alongside midwifery unit encouraged natural birth and pharmacological pain relief was only available in the case of

transfer to the obstetric unit. Fetal monitoring and sonography were not available in the alongside midwifery unit. Access to the alongside midwifery unit was only through participation in the trial. The mean age of women in the alongside midwifery group was 29.9 years (standard deviation not reported) and 57% were nulliparous. The mean age of women in the obstetric unit was 29.7 years (standard deviation not reported) and 53.7% were nulliparous. Intrapartum transfer rate was 17.5% (27.3% of nulliparous women were transferred and 4.5% of multiparous women). Outcomes were measured by questionnaires completed at 2 months after the expected date of birth. The response rate was 93%.

One randomised controlled trial conduced in Australia compared birth planned in a 'birth centre' (from this point onwards referred to as alongside midwifery unit) with birth planned in a 'delivery suite' (from this point onwards referred to as obstetric unit) (Byrne et al., 2000). The alongside midwifery unit consisted of 2 rooms set up close to the obstetric unit of a maternity teaching hospital. Rooms were 'homelike' and all medical equipment was stored behind curtains or in cupboards within easy reach. The mean age of women in the alongside midwifery group was 27.5±5.6 years and 47% were nulliparous. The mean age of women in the obstetric unit was 26.8±4.9 years and 46% were nulliparous. Intrapartum transfer rate was 76%, due to complications or staffing problems. Outcomes were measured by questionnaires completed at 12 hours postpartum. The response rate was 74%.

One observational study conducted in the USA compared birth planned in an 'alternative birthing unit' (from this point onwards referred to as alongside midwifery unit) with birth planned in a 'delivery suite' (from this point onwards referred to as obstetric unit) (Littlefield and Adams, 1987). The alongside midwifery unit was adjacent to the obstetric unit of a university teaching hospital. The mean age of women in the alongside midwifery unit was 29.6 years (standard deviation not reported) and 29% were nulliparous. The mean age of women in the obstetric unit was 27.1 years (standard deviation not reported) and 77% were nulliparous. Intrapartum transfer rate was 19%. It is important to note that women who transferred out of the alongside midwifery unit were excluded from the analysis. Outcomes were measured 2–3 days postpartum. The overall response rate was 95%.

The findings for these 5 studies are summarised in the GRADE profile in table 27.

One observational study, with a qualitative element, that was conducted in Australia aimed to explore the experiences of women who were transferred from an alongside midwifery unit to an obstetric unit (Shaw, 1985). A total of 189 women who had experienced transfer completed questionnaires; 82 of these women (43%) experienced intrapartum transfer. Age and parity were not reported. Questionnaires were completed either at 1 week or 3 months after delivery. Content analysis of questionnaire responses was performed. The findings of this study are summarised in table 28.

One observational study from Sweden was conducted to compare women's satisfaction with 'modified care' (in-hospital birth centre) with 'standard care' (obstetric unit) (Tingstig et al., 2012). It was a qualitative study, though some frequencies were given. The same medical low risk criteria during pregnancy applied to both groups. For the study, 661 women from the birth centre and 1,097 women from the obstetric unit were invited to take part. The difference in number reflects the researcher's assumption that a larger proportion of the birth centre group would respond than the control group. The 2 groups were each divided into 2 sub-groups (nulliparous and multiparous women). Data were elicited 2 months postpartum. The findings are summarised in table 29.

Evidence profile

When appraising the quality of the evidence where outcomes have been measured using a non-standard and simple measure, studies have been downgraded 1 level for risk of (detection) bias. Where it has not been possible to calculate relative and absolute effects, p values have been added to the absolute effect column, when reported in the studies. If a p value is not reported this suggests no significant difference.

Update 2014

Quantitative outcomes are presented under themes of: satisfaction; anxiety and psychological needs; control and decision-making; choice; and support from health professional(s).

Table 27: Summary GRADE profile for comparison of birth planned in an alongside midwifery unit with birth planned in an obstetric unit

Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Satisfaction							
Overall satisfaction with experience measured at 3-6 weeks postpartum (1 = very unsatisfactory, 7 = very satisfactory)							
1 study (Hundley et al., 2007)	RCT	Intention-to-treat analysis	Median = 8 Interquartile range 7 to 9	Median = 8 Interquartile range 7 to 9	NC	Median difference = 0	Moderate
Comprehensive assessment of satisfaction measured at 2 months postpartum (1 = very unsatisfactory, 7 = very satisfactory)							
1 study (Waldenstrom and Nilsson, 1993)	RCT	Intention-to-treat analysis	6.5 (SD not reported) N=574	5.9 (SD not reported) N=534	NC	p<0.001	Low
Satisfaction with medical supervision and/or treatment measured at 2 months postpartum (1 = very unsatisfactory, 7 = very satisfactory)							
1 study (Waldenstrom and Nilsson, 1993)	RCT	Intention-to-treat analysis	6.5 (SD not reported) N=574	6.0 (SD not reported) N=534	NC	p<0.001	Low
Experience of birth measured at 2 months postpartum – nulliparous women (1 = very negative, 7 = very positive)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	5.5 (SD not reported) N=334	5.3 (SD not reported) N=290	NC	p not reported	Low
Experience of birth measured at 2 months postpartum – multiparous women (1 = very negative, 7 = very positive)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.3 (SD not reported) N=255	6.1 (SD not reported) N=259	NC	p not reported	Low

Update 2014

Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Satisfaction with own achievement measured at 2 months postpartum – nulliparous women (1 = very negative, 7 = very positive)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.4 (SD not reported) N=334	6.1 (SD not reported) N=290	NC	p=0.01	Low
Satisfaction with own achievement measured at 2 months postpartum – multiparous women (1 = very negative, 7 = very positive)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.5 (SD not reported) N=255	6.5 (SD not reported) N=259	NC	p not reported	Low
Happy and satisfied with care measured at 12 hours postpartum							
1 study (Byrne et al., 2000)	RCT	Intention-to-treat analysis	63/73 (89%)	63/75 (86%)	1.03 (0.90 to 1.18)	25 more per 1000 (from 84 fewer to 151 more)	High
Satisfied with analgesia measured at 12 hours postpartum							
1 study (Byrne et al., 2000)	RCT	Intention-to-treat analysis	50/73 (68%)	51/75 (68%)	1.01 (0.81 to 1.25)	7 more per 1000 (from 129 fewer to 170 more)	High
Would choose allocated place of delivery for subsequent births measured at 6 months postpartum							
1 study (Byrne et al., 2000)	RCT	Intention-to-treat analysis	60% (n/N not reported)	47% (n/N not reported)	NC	p<0.007	High
Satisfaction with delivery environment measured at 2-3 days postpartum (possible score range 5 to 25)							
1 study (Littlefield and Adams, 1987)	observational study	Women transferred out of alongside midwifery unit excluded from analysis	24.40 (SD 1.0) N=21	21.10 (SD 3.68) N=78	NC	MD 3.30 higher (2.38 higher to 4.22 higher)	Very Low

Update 2014

Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Satisfaction with delivery experience measured at 2-3 days postpartum (possible score range 12 to 60)							
1 study (Littlefield and Adams, 1987)	observational study	Women transferred out of alongside midwifery unit excluded from analysis	28.03 (SD 3.7) N=21	25.82 (SD 3.24) N=78	NC	MD 2.21 higher (0.47 higher to 3.95 higher)	Very Low
Anxiety and psychological needs							
Satisfaction with professional response to women's thoughts and emotions measured at 2 months postpartum (1 = very unsatisfactory, 7 = very satisfactory)							
1 study (Waldenstrom and Nilsson, 1993)	RCT	Intention-to-treat analysis	6.3 (SD not reported) N=574	5.5 (SD not reported) N=534	NC	p<0.001	Low
Anxiety during birth measured at 2 months postpartum – nulliparous women (1 = not at all anxious, 7 = very anxious)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	2.8 (SD not reported) N=334	2.9 (SD not reported) N=290	NC	p not reported	Low
Anxiety during birth measured at 2 months postpartum – multiparous women (1 = not at all anxious, 7 = very anxious)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	2.2 (SD not reported) N=255	2.2 (SD not reported) N=259	NC	p not reported	Low
Feelings of control and involvement in decision-making							
Involvement in labour management decisions measured at 3-6 weeks postpartum							
1 study (Hundley et al., 2007)	RCT	Intention-to-treat analysis	n/N not reported (92.3%)	n/N not reported (90.6%)	NC	p=0.2	Moderate

Update 2014

Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Made own decision about type of pain relief to use measured at 3-6 weeks postpartum							
1 study (Hundley et al., 2007)	RCT	Intention-to-treat analysis	894/1616 (55.3%)	384/765 (50.2%)	1.10 (1.01 to 1.20)	50 more per 1000 (from 5 more to 100 more)	Moderate
Involvement in process of birth measured at 2 months postpartum – nulliparous women (1 = not at all involved, 7 = very involved)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.4 (SD not reported) N=334	6.2 (SD not reported) N=290	NC	p=0.03	Low
Involvement in process of birth measured at 2 months postpartum – multiparous women (1 = not at all involved, 7 = very involved)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.7 (SD not reported) N=255	6.6 (SD not reported) N=259	NC	p not reported	Low
Freedom in expression of feelings measured at 2 months postpartum – nulliparous women (1 = not at all involved, 7 = completely free)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.5 (SD not reported) N=334	6.1 (SD not reported) N=290	NC	p=0.003	Low
Freedom in expression of feelings measured at 2 months postpartum – multiparous women (1 = not at all involved, 7 = completely free)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.5 (SD not reported) N=255	6.3 (SD not reported) N=259	NC	p=0.01	Low

Update 2014

Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Choice							
Choice as to way fetal heartbeat monitored measured at 3-6 weeks postpartum							
1 study (Hundley et al., 2007)	RCT	Intention-to-treat analysis	88/1429 (6.2%)a	73/741 (9.9%)	0.63 (0.46 to 0.84)	36 fewer per 1000 (from 16 fewer to 53 fewer)	Moderate
Women who wanted to move around and were able to do so most of the time measured at 3-6 weeks postpartum							
1 study (Hundley et al., 2007)	RCT	Intention-to-treat analysis	663/937 (70.7%)	239/380 (62.8%)	1.13 (1.03 to 1.23)	82 more per 1000 (19 more to 145 more)	Moderate
Support from health professional(s)							
Support from midwife measured at 2 months postpartum – nulliparous women (1 = none at all, 7 = much support)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.1 (SD not reported) N=334	5.3 (SD not reported) N=290	NC	p<0.001	Low
Support from midwife measured at 2 months postpartum – multiparous women (1 = none at all, 7 = much support)							
1 study (Waldenstrom and Nilsson, 1994)	RCT	Intention-to-treat analysis	6.2 (SD not reported) N=255	5.5 (SD not reported) N=259	NC	p<0.001	Low
Satisfied with staff measured at 12 hours postpartum							
1 study (Byrne et al., 2000)	RCT	Intention-to-treat analysis	65/73 (90%)	70/75 (93%)	0.95 (0.86 to 1.06)	47 fewer per 1000 (from 131 fewer to 56 more)	High

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Number of studies	Design	Other considerations	Mean scores ± SD or n/N (%)		Effect		Quality
			Alongside midwifery unit	Obstetric unit	Relative (95% CI)	Absolute or reported p value	
Satisfaction with labour and birth 'nursing' care measured at 2-3 days postpartum (possible score range 18 to 90)							
1 study (Littlefield and Adams, 1987)	observational study	Women transferred out of alongside midwifery unit excluded from analysis	86.54 (SD 6.1) N=21	85.10 (SD 6.76) N=78	NC	MD 1.44 higher (1.57 lower to 4.45 higher)	Very low

CI confidence interval, MD mean difference, n number of events, N total events, NC not calculable, RCT randomised controlled trial, p probability, SD standard deviation

a. Electronic fetal monitoring (EFM) was available in the midwifery-led unit (MLU) – authors report majority of women who had EFM either intermittently or continuously were happy with it (MLU 89%, obstetric unit 91% reported being happy, n/N not reported)

Table 28: Qualitative findings for experience of transfer from an alongside unit to an obstetric unit

Women's views and experiences	
Study Total number of participants Quality rating	**Summary of findings**
Shaw 1985 Intrapartum transfer n=82 [Very low quality][1]	All results based on content analysis of description of labour Positive response to transfer = 45.1% Neutral response to transfer = 39% Negative response to transfer = 14.7% Great deal of self-criticism = 7.3% Some self-criticism = 34.2% No self-criticism = 58.5%

1. Quality assessment notes: important study details not reported, very few quotations reported which are not illustrative of positive/negative responses to transfer or degrees of self-criticism, content analysis method not adequately described, questionnaires were completed either at 1 week or 3 months after birth but results at these two time points not reported separately.

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Table 29: Qualitative findings for satisfaction with care in a modified in-hospital birth centre compared with standard care

Satisfaction with care	
Study **Total number of participants** **Quality rating**	**Summary of findings**
Tingstig et al., 2012 n=547 Very low quality[1]	It was more common in the modified hospital-based birth centre group to have a "known" midwife during labour, and the midwife was present in the birthing room "all or most of the time" in the majority of cases. The number of midwives seen during labour was almost the same for the nulliparous women of the two groups but fewer for multiparous women in the modified birth centre group compared with the standard care group. Women were more satisfied with the relationship with the caregiver in the modified birth centre group, Women in the modified birth centre group found the setting very calm, personal, pleasant, and not stressful to a greater extent than participants in the standard care group. Calmness was an important factor when giving birth. The birth centre environment was described as calmer, more personal and less stressful than the obstetric environment. Agreement with following statements: Modified birth centre (MBC): nulliparous n=247 / multiparous n=300 Standard care (SC): nulliparous n=424 / multiparous n=362 "The midwife gave me all the support I needed" MBC: 72.7% / 81.2% SC: 67.1% / 63.8% "Cared for me as a unique person" MBC: 74.4% / 80.9% SC: 69.9% / 64.0% "Understood how I perceived my situation" MBC: 68.8% / 79.0% SC: 64.6% / 61.1% "Gave me opportunity to discuss my difficulties" MBC: 70.2% / 77.2% SC: 61.7% / 57.4% "Took me seriously" MBC: 75.8% / 85.3% SC: 71% / 69.0%

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Satisfaction with care	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	Overall satisfaction with care: Very satisfied MBC: 70.2% / 84.7% SC: 60.8% / 57.2% Satisfied MBC: 24.4% / 11.6% SC: 31.6% / 34.9% In between MBC: 2.9%/ 2.7% SC: 4.5% / 3.9% Dissatisfied MBC: 2.1% / 1.0% SC: 2.6% / 2.8% Very dissatisfied MBC: 0.4% / 0.0% SC: 0.5% / 1.0%

1. The authors dichotomised some continuous outcomes and not others. This meant data were not as rich as the authors originally intended. No power calculation was performed. Copywriting and layout errors plus inconsistency of reporting meant that some interpretation of data had to be inferred by the reviewer. Inconsistency of method and reporting meant that statistical reviewing is not appropriate for this qualitative paper.

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Evidence statement

Satisfaction

Overall satisfaction with experience
One randomised controlled trial (n=2844) reported no difference in overall satisfaction with birth experience between women who planned birth in an alongside unit and women who planned birth in an obstetric unit. The evidence for this outcome was of moderate quality.
One qualitative study (n=99) reported that women receiving care in a hospital-based birth centre were more satisfied with overall care than women in an obstetric unit. Being treated as a unique person and a calm atmosphere explained some of the difference in satisfaction levels. The birth centre environment was described as calmer, more personal and less stressful than the obstetric environment.

Comprehensive assessment of satisfaction
One randomised controlled trial (n=1108) reported greater satisfaction in women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of low quality.

Satisfaction with medical supervision and/or treatment
One randomised controlled trial (n=1108) reported greater satisfaction with medical supervision and/or treatment in women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of low quality.

Experience of birth
One randomised controlled trial (n=624) reported no difference in experience of birth between nulliparous women who planned birth in an alongside unit and nulliparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.
One randomised controlled trial (n=514) reported no difference in experience of birth between multiparous women who planned birth in an alongside unit and multiparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.

Satisfaction with own achievement
One randomised controlled trial (n=624) reported greater satisfaction with own achievement in nulliparous women who planned birth in an alongside unit compared with nulliparous women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of low quality.
One randomised controlled trial (n=484) reported no difference in satisfaction with own achievement in multiparous women who planned birth in an alongside unit compared with multiparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.

Happy and satisfied with care
One randomised controlled trial (n=148) reported no difference in the number of women who were happy and satisfied with their care in an alongside unit compared with the number of women who were happy and satisfied with their care in an obstetric unit. The evidence for this outcome was of high quality.

Satisfied with analgesia
One randomised controlled trial (n=148) reported no difference in the number of women who were satisfied with their analgesia in an alongside unit compared with the number of women who were satisfied with their analgesia in an obstetric unit. The evidence for this outcome was of high quality.

Would choose allocated place of delivery for subsequent births
One randomised controlled trial (n=148) reported more women who planned birth in an alongside unit would choose the alongside unit for subsequent births compared with the number of women who planned birth in an obstetric unit who would choose the obstetric unit for subsequent births. This finding was statistically significant. The evidence for this outcome was of high quality.

Satisfaction with delivery environment
One observational study (n=99) reported greater satisfaction with delivery environment in women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Satisfaction with delivery experience
One observational study (n=99) reported greater satisfaction with delivery experience in women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Anxiety and psychological needs

Satisfaction with professionals
This considered satisfaction with professional(s) response to women's thoughts and emotions. One randomised controlled trial (n=1108) reported greater satisfaction with professional(s) response to their thoughts and emotions in women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of low quality.

Anxiety during birth
One randomised controlled trial (n=624) reported no difference in levels of anxiety during birth in nulliparous women who planned birth in an alongside unit and nulliparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.
One study (n=514) reported no difference in levels of anxiety during birth in multiparous women who planned birth in an alongside unit and multiparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.

Feelings of control and involvement in decision making

Involvement in labour management decisions
One randomised controlled trial (n=2844) reported no difference in the number of women who were involved in labour management decisions between women who planned birth in an alongside unit and women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.

Made own decision about type of pain relief
One randomised controlled trial (n=2381) reported more women who planned birth in an alongside unit made their own decision about the type of pain relief to use compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of moderate quality.

Involvement in the process of birth
One randomised controlled trial (n=624) reported greater involvement in the process of birth in nulliparous women who planned birth in an alongside unit compared with nulliparous women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of low quality.
One randomised controlled trial (n=514) reported no difference in involvement in the process of birth in multiparous women who planned birth in an alongside unit compared with multiparous women who planned birth in an obstetric unit. The evidence for this outcome was of low quality.

Freedom in expression of feelings
One randomised controlled trial (n=624) reported more freedom in expression of feelings in nulliparous women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this finding was of low quality.
One randomised controlled trial (n=514) reported more freedom in expression of feelings in multiparous women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this finding was of low quality.

Choice

Choice of the way fetal heartbeat monitored
One randomised controlled trial (n=2170) reported more women who planned birth in an obstetric unit had a choice of the way fetal heartbeat was monitored compared with women who planned birth in an alongside unit. This finding was statistically significant. The evidence for this finding was of moderate quality.

Women who wanted to move around and were able to do so most of the time
One randomised controlled trial (n=1317) reported more women who planned birth in an alongside unit who wanted to move around were able to do so compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this finding was of moderate quality.

Support from health professionals

Support from midwife
One randomised controlled trial (n=624) reported more midwife support was felt to be available by nulliparous women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this finding was of low quality.
One randomised controlled trial (n=514) reported more midwife support was felt to be available by multiparous women who planned birth in an alongside unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this finding was of low quality.

Satisfied with staff

One randomised controlled trial (n=148) reported no difference in the number of women who were satisfied with staff between women who planned birth in an alongside unit and women who planned birth in an obstetric unit. The evidence for this finding was of high quality.

Satisfaction with labour and birth 'nursing' care

One qualitative study (n=99) reported no difference in the number of women who were satisfied with labour and birth 'nursing' care between women who planned birth in an alongside unit and women who planned birth in an obstetric unit. The evidence for this finding was of very low quality.

Women's views and experiences

One qualitative study (n=82) reported that 45% of women had a positive response to intrapartum transfer from an alongside unit to an obstetric unit, 39% of women had a neutral response and 15% of women had a negative response. They also reported that 7% of women exhibited a great deal of self-criticism in response to intrapartum transfer, 34% some self-criticism and 59% no self-criticism. The evidence for these findings was of very low quality.

Birth planned in a freestanding midwifery unit compared with birth planned in an obstetric unit

Description of included studies

Three studies were included in this review (Overgaard et al., 2012; Stone, 1998; Esposito, 1999). Two of these studies were observational studies (Overgaard et al., 2012; Stone, 1998) and 1 was a qualitative study (Esposito, 1999)

One observational study conducted in Denmark compared birth planned in two freestanding midwifery units with birth planned in two 'supporting' obstetric units (Overgaard et al., 2012). The freestanding midwifery units were staffed by community midwives working in flexible shifts in a team model and generally providing one-to-one care during labour. Ambulation and use of water and music for pain relief/relaxation were encouraged. In the case of complications, women and babies were transferred to the nearest obstetric unit located 25 to 30 minutes away. In both the freestanding midwifery units and the obstetric units 60% of women were aged under 30 years. Of the women, 23% in the freestanding midwifery units and 24% in the obstetric units were nulliparous. Intrapartum transfer rate was 10%. Outcomes were measured by questionnaires distributed 28 days after birth. The response rate was 86%.

One observational study conducted in the USA compared birth planned in a 'freestanding birth centre' (from this point onwards referred to as freestanding midwifery unit) with birth planned in 'traditional physician care' (from this point onwards referred to as obstetric unit) (Stone, 1998). Details about the freestanding midwifery unit were not reported. Characteristics of the women included in the study were not clearly reported but authors report women were "generally... educated, married, in their middle to late 20s. Most women had private medical insurance and this was not their first pregnancy". The intrapartum transfer rate was not reported. The response rate was 77%.

The results of these 2 observational studies are presented in a GRADE table (table 30).

One qualitative study conducted in the USA included 29 women either receiving antenatal care or who had given birth at a 'freestanding birth centre' located in an inner city neighbourhood (Esposito, 1999). Analysis compared women's birth centre experience with their previous hospital experience. The intrapartum transfer rate was not reported. It was unclear where and when interviews were conducted. The findings of this study are summarised in table 31.

Evidence profiles

Table 30: Summary GRADE findings for comparison birth planned in a freestanding midwifery unit with birth planned in an obstetric unit

Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Freestanding midwifery unit	Obstetric unit	Relative	Absolute (or reported p value)	
Satisfaction							
Overall birth experience measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Unclear if transferred women excluded from analysis. No subgroup analysis performed	5.5 (SD not reported) N=185[a]	5.0 (SD not reported) N=190[a]	NC	p<0.0000[b]	Very low
Care satisfaction measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Unclear if transferred women excluded from analysis. No subgroup analysis performed	5.7 (SD not reported) N=185[a]	5.3 (SD not reported) N=190[a]	NC	p<0.0000[b]	Very low
Satisfaction with access measured at 6 weeks postpartum (maximum score = 24; higher score is better)							
1 study (Stone, 1998)	observational study	Transfer not reported	22.3±3.2 N=57	19.2±4.7 N=55	NC	MD 3.10 higher (1.61 higher to 4.59 higher)	Very low
Satisfaction with 'nursing care' measured at 6 weeks postpartum (maximum score = 30; higher score is better)							
1 study (Stone, 1998)	observational study	Transfer not reported	27.8±3.6 N=57	27.3±3.9 N=55	NC	MD 0.50 higher (0.89 lower to 1.89 higher)	Very low

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Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Freestanding midwifery unit	Obstetric unit	Relative	Absolute (or reported p value)	
Satisfaction with 'primary care provider' measured at 6 weeks postpartum (maximum score = 30; higher score is better)							
1 study (Stone, 1998)	observational study	Transfer not reported	28.8±2.8 N=57	25.9±4.7 N=55	NC	MD 2.9 higher (1.46 higher to 4.34 higher)	Very low
Satisfaction with environment measured at 6 weeks postpartum (maximum score = 54; higher score is better)							
1 study (Stone, 1998)	observational study	Transfer not reported	50.4±4.9 N=57	47.5±6.3 N=55	NC	MD 2.9 higher (0.8 higher to 5 higher)	Very low
Anxiety and psychological needs							
Attention to psychological needs measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Unclear if transferred women excluded from analysis. No subgroup analysis performed	5.4 (SD not reported) N=177[a]	4.9 (SD not reported) N=180[a]	NC	p<0.0000[b]	Very low
Feeling of being listened to measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Unclear if transferred women excluded from analysis. No subgroup analysis performed	5.4 (SD not reported) N=180[a]	5.0 (SD not reported) N=188[a]	NC	p<0.0000[b]	Very low

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Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Freestanding midwifery unit	Obstetric unit	Relative	Absolute (or reported p value)	
Feelings of control and involvement in decision making							
Participation in decision making measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	5.4 (SD not reported) N=176[a]	5.0 (SD not reported) N=180[a]	NC	p<0.0000[b]	Very low
Loss of external control over staff actions measured at 1 month postpartum (0 = no loss, 5 = control lost all through birth)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	0.2 (SD not reported) N=181[a]	0.5 (SD not reported) N=188[a]	NC	p=0.0061[b]	Very low
Loss of internal control over labour and own reactions measured at 1 month postpartum (0 = no loss, 5 = control lost all through birth)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	0.1 (SD not reported) N=179[a]	1.2 (SD not reported) N=190[a]	NC	p=0.031[b]	Very Low
Level of information measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	5.4 (SD not reported) N=183[a]	4.9 (SD not reported) N=187[a]	NC	p<0.0000[b]	Very Low

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Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Freestanding midwifery unit	Obstetric unit	Relative	Absolute (or reported p value)	
Support from health professional(s)							
Support from midwife measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	5.7 (SD not reported) N=182[a]	5.4 (SD not reported) N=190[a]	NC	p<0.0000[b]	Very Low
Midwife present when wanted measured at 1 month postpartum (1 = unacceptable, 6 = optimal)							
1 study (Overgaard et al., 2012)	observational study	Not stated if transfer excluded from analysis. No subgroup analysis performed	5.7 (SD not reported) N=182[a]	5.4 (SD not reported) N=189[a]	NC	p<0.0000[b]	Very Low

MD mean difference, NC not calculable, SD standard deviation

a. Between 20% and 30% of values were imputed to complete missing data for matched pair analysis
b. Authors used Bonferroni method to correct for multiple comparisons, level of significance adjusted to p<0.0025

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Table 31: Qualitative findings for freestanding midwifery unit experience compared with previous obstetric unit experience

Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
Esposito, 1999 N=29 [Very low quality][1]	Women's perceptions of accessibility (personal care and/or respect) Women repeatedly emphasised the importance of being treated like a person and feeling respected during their health care experiences at the "birth centre" (from now on referred to as freestanding midwifery unit). They contrasted this with their experiences in other hospital settings (from now on referred to as obstetric unit) [author's conclusions]: "There is something like treating you like a person. No titles, a closeness, they care about you as a person... Not like a city hospital where people are rude and obnoxious, here, they remembered my name... It was an intimate thing to share my pregnancy with the ladies here, to get to know them; they're very special". "When I first came to the [freestanding midwifery unit] I was scared [of birth]. But I found out you can be scared with friendly people or scared with people you don't know. In the clinic at the hospital, people are cold, you are there, [and], you're a number. Here [you are] a person, they know you by name. At the clinic, not caring, impersonal, they just want to get the job done. Here they make you feel at home. Now my fear is that I might get transferred during labour [to obstetric unit]". Privacy was an issue expressed by a number of women [authors' conclusion]: "People don't realize how my privacy was invaded in the hospital... A whole bunch of lights, they put your legs up. Here, [freestanding midwifery unit] it's different, there are no big spotlights, they don't strap you down. [Here], I was calm." Struggling to maintain control One participant described her obstetric unit experience: how she refused to be hooked to an intravenous drip and hated the restrictions of the fetal monitor. She felt distanced from her providers, with a sense of diminished access to the care she desired. During her freestanding midwifery unit experience she felt more connected and less intruded upon [author's conclusions]: "I wasn't nervous... because I was relaxed, the labor went faster... it was mostly me and the midwife, it was just her talking to me, just telling me what to do, just her listening to the baby's heart, it wasn't a midwife here, then a doctor, then another doctor... I didn't feel like a rat in a cage, I felt like a woman about to give birth". One woman's experience suggests that obstetric units can be responsive to the individual woman but focusing on an attractive environment does not make a humanized birth [author's conclusions]: "The obstetrician who delivered me I never saw before. The medical care was good; the nursing care was good. But I had no control. I had to go by what they said... I didn't want to be medicated [but they medicated me] and I was groggy. Then when I was fully dilated they said 'push' and made me leave the

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Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	[labor-delivery-recovery room] because the doctor had a bad back and couldn't or wouldn't deliver me in a bed. I had to make it convenient for other people... doctors do good when people are sick but when you aren't sick you need people who will support you."

1. It was unclear if all women in the study were multiparous. It was unclear where and when interviews were conducted. Derivation of themes not clearly reported and credibility of findings not discussed. All women included in the study were 'marginalised' and met low income and nutritional risk designation requirements for participation in the Special Supplemental Food Program for Women, Infants and Children.
The analysis is very poor, the 'key themes' identified by the author are "women's perceptions of accessibility" and "struggling to maintain control: searching for connections". Neither of these are well supported by the quotes the author has selected (most of which are about poor hospital experience). There is little that illustrates neatly the comparison of the two birth settings. It is very difficult to identify what the take home message is from this research.

Evidence statement

Satisfaction

Overall birth experience
One study (n=385) reported greater satisfaction with overall birth experience in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Care satisfaction
One study (n=375) reported greater care satisfaction in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Satisfaction with access
One study (n=112) reported greater satisfaction with access in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Satisfaction with 'nursing care'
One study (n=112) reported no difference in satisfaction with nursing care between women who planned birth in a freestanding midwifery unit and women who planned birth in an obstetric unit. The evidence for this outcome was of very low quality.

Satisfaction with 'primary care provider'
One study (n=112) reported greater satisfaction with 'primary care provider' in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Satisfaction with environment
One study (n=112) reported greater satisfaction with environment in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Anxiety and psychological needs

Attention to psychological needs
One study (n=357) reported greater attention to psychological needs in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Feeling of being listened to
One study (n=368) reported a greater feeling of being listened to in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric

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unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Feelings of control and involvement in decision-making

Participation in decision-making
One study (n=356) reported greater participation in decision-making in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Loss of external control over staff actions
One study (n=369) reported less loss of external control over staff actions in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Loss of internal control over labour and own reactions
One study (n=369) reported no difference in loss of internal control over labour and own reactions between women who planned birth in a freestanding midwifery unit and women who planned birth in an obstetric unit. The evidence for this outcome was of very low quality.

Level of information
One study (n=370) reported a greater level of information in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

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Support from health professionals

Support from midwife
One study (n=372) reported greater support from the midwife in women who planned birth in a freestanding midwifery unit compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Midwife present when wanted
One study (n=371) reported that more women who planned birth in a freestanding midwifery unit stated the midwife was present when wanted compared with women who planned birth in an obstetric unit. This finding was statistically significant. The evidence for this outcome was of very low quality.

Women's views and experiences
One study (n=29) found women emphasised the importance of being treated like a person, feeling respected and having their privacy respected, and feeling a connection with care providers during their healthcare experiences in the alongside unit, compared with their previous experiences in an obstetric unit. The evidence for these findings was of very low quality.

Planned home birth compared with birth planned in an obstetric unit

Description of included studies

Five studies were included in this review (Janssen et al., 2006; Geerts et al., 2014; Christiaens et al., 2007; Christiaens et al., 2008; Dahlen et al., 2010). Two of these studies were observational studies (Janssen et al., 2006; Geerts et al., 2014) and 3 were qualitative studies (Christiaens et al., 2007; Christiaens et al., 2008; Dahlen et al., 2010).

Two observational studies conducted in Canada and The Netherlands compared planned midwife-attended home births (from this point onwards referred to as home birth) and planned midwife-attended hospital births (from this point onwards referred to as obstetric unit birth) (Janssen et al., 2006 and Geerts et al., 2014). Jansen et al. examined the first 2 years of legislated midwife-attended home births in British Columbia – all women in the province planning a home birth during the study period were required by legislation to enrol in the Home Birth Demonstration Project. The mean age of women in the home birth group was 30.2±5.4 years and 48% were nulliparous. The mean age of women in the obstetric unit group was 31±5.3 years and 56% were nulliparous. The intrapartum transfer rate was 19%. Outcomes were measured by questionnaires, distributed by midwives, and were completed before 6 weeks postpartum. The response rate was 82%. The results of this study are presented in a GRADE table (table 32). Results for the comparison of planned home/actual obstetric unit birth with planned obstetric unit/actual obstetric unit are presented in a second GRADE table (table 33).

Geerts et al. measured feelings of control in women recruited over 1 year in 25 Dutch midwifery practices. Most women were aged between 25 and 35 years (76% in the home birth group and 70% in the hospital birth group). Outcomes were measured by questionnaire using the Likert scale. The results (including transfer frequency) are presented in tables 27 and 29. Hospital obstetric units were predominantly run by midwives, with medical clinicians rarely involved.

Two reports of 1 observational study conducted in Belgium and The Netherlands compared planned home birth and planned hospital birth (from this point onwards referred to as obstetric unit) (Christiaens et al., 2007; Christiaens et al., 2008). The mean age of women in the study was 31.2 years and 54.2% of women in the study were nulliparous (data not reported for home birth and obstetric unit groups separately). Outcomes were measured by questionnaires completed at 2 weeks postpartum. The response rate was estimated to range between 100% and 38% for the home birth group and 68% and 19% for the obstetric unit group. The findings of this study are summarised in table 35.

One qualitative study conducted in Australia included 8 women who had a planned home birth and 8 women who had a planned birth at a tertiary referral public hospital (from this point onwards referred to as obstetric unit) (Dahlen et al., 2010). The study also included 1 woman who gave birth in a private hospital and 2 women who gave birth in a birth centre. The mean age of women in the home birth group was 30 years (standard deviation not reported) while the mean age of women in the obstetric unit group was 25 years (standard deviation not reported). Of the study sample, 89% were nulliparous. One woman who planned a home birth was transferred to hospital (intrapartum transfer). Interviews were conducted in the women's homes between 6 and 26 weeks (mean 15 weeks) after birth. The findings of this study are summarised in table 36.

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Evidence profiles

Table 32: Summary GRADE profile for comparison planned home birth with planned birth in an obstetric unit

Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Planned home birth	Planned obstetric unit birth	Relative	Absolute (or reported p value)	
Satisfaction							
Overall, how satisfied with childbirth experience measured at 6 weeks (1 = never, 5 = always; higher score is better)							
1 study (Janssen et al., 2006)	observational study	Intention-to-treat analysis	4.87±0.42 N=550	4.80±0.49 N=108	NC	Mean difference 0.07 higher (0.03 lower to 0.17 higher)	Very low
Feelings of control and involvement in decision making							
Total Labour Agentry[a] Scale-1 mean score measured at 6 weeks post-partum (maximum score = 203; higher score is better)							
1 study (Janssen et al., 2006)	observational study	Intention-to-treat analysis	188.49±16.85 N=550	176.6±23.79 N=108	NC	Mean difference 11.89 higher (7.19 higher to 16.59 higher)	Very low
Total Labour Agentry Scale-11 score (mean) measured at approx 6 weeks post-partum (maximum score = 77; higher score is better. Only 'Control-score measured. nulliparous							
1 study (Geerts et al., 2014)	observational study	Intention-to-treat analysis	60.6 N=515	58.0 N=365	NC	Mean difference 2.6 (0.9 higher to 4.3 higher)	Low
Total Labour Agentry Scale-11 score (mean) measured at approx 6 weeks post-partum (maximum score = 77; higher score is better. Only Control measured. parous							
1 study (Geerts et al., 2014)	observational study	Intention-to-treat analysis	63.3 N=732	60.3 N=386	NC	Mean difference 3.0 (1.6 higher to 4.4 higher - 95% CI)	Low

CI confidence interval, NC not calculable, SD standard deviation

a. The Labour Agentry Scale is a standardised 29-item scale for measurement of expectancies and experiences of personal control during childbirth.

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Table 33: Summary GRADE profile for comparison planned home birth/actual obstetric unit birth with planned obstetric unit birth/ actual obstetric unit birth

Number of studies	Design	Other considerations	Mean score ± SD		Effect		Quality
			Planned home/ actual obstetric	Planned obstetric/actual obstetric	Relative	Absolute (or reported p value)	
Satisfaction							
Overall, how satisfied with childbirth experience measured at 6 weeks (1 = never, 5 = always; higher score is better)							
1 study (Janssen et al., 2006)	observational study	Analysis of women who actually gave birth in planned place of birth	4.56±0.66 N=104	4.75±0.53 N=87	Not calculable	Mean difference 0.19 lower (from 0.36 lower to 0.02 lower)	Very low
Feelings of control and involvement in decision making							
Total Labour Agentry Scale[a] score measured at 6 weeks (maximum score=203; higher score is better)							
1 study (Janssen et al., 2006)	observational study	Analysis of women who actually gave birth in planned place of birth	177.58±22.17 N=104	173.71±24.89 N=87	Not calculable	Mean difference 3.87 higher (from 2.88 lower to 10.62 higher	Very low

a. The Labour Agentry Scale is a standardised 29-item scale for measurement of expectancies and experiences of personal control during childbirth.

Table 34: Summary GRADE profile for comparison: planned home birth (transferred to OU)/planned home birth (not transferred)

Number of studies	Design	Other considerations	Mean score		Effect		Quality
			Planned home birth	Planned obstetric unit	Relative	Absolute (or reported p value)	
Total Labour Agentry Scale[a](LAS-11) score (mean) measured at approx 6 weeks post-partum (maximum score = 77; higher score is better)							
Feeling of control: nulliparous							
1 study (Geerts et al., 2014)	observational study	Intention-to-treat analysis	58.4 N=292	63.8 N=202	Not calculable	Not reported	Low
Feeling of control: parous							
1 study (Geerts et al., 2014)	observational study	Intention-to-treat analysis	58.9 N=95	44.9 N=606	Not calculable	Not reported	Low

a. The Labour Agentry Scale is a standardised 29-item scale for measurement of expectancies and experiences of personal control during childbirth.

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Table 35: Descriptive findings for home birth and obstetric unit birth

Study Total number of participants Quality rating	Summary of findings
Christiaens et al., 2007 N=592 Expected home, actual home = 163 Expected home, actual OU = 100 Expected OU, actual OU = 268 Other referrals = 61 [Very low quality][1]	When comparing women who gave birth at the place they intended to, home births were consistently more satisfying than hospital births on all dimensions of satisfaction (total and general satisfaction p<0.001). Women who had been referred from home to hospital reported lower general satisfaction scores (p=0.001) compared with women who planned a hospital birth. However, transfer to hospital was "inconsequential" in terms of other sub-dimensions of satisfaction. The "disadvantage" of being referred to the hospital when a home birth was expected was smaller in Belgium than in the Netherlands. Belgian women referred to hospital during pregnancy or labour had higher satisfaction scores than Belgian women who planned to give birth in hospital and did. The opposite was true in the Netherlands.
Christiaens et al., 2008 N=611 Home birth n = not clearly reported Hospital birth n = not clearly reported [Very low quality][1]	Women planning to give birth at home had lower W-DEQ scores compared to women planning for a hospital birth (OR=1.38 p<0.001) [lower scores are better]. Women with a home birth had more optimistic expectations and their birth experience was even more positive than expected. Women who did not give birth at the planned place had a more negative experience: they increased [made worse] the postnatal appraisal score of women planning a homebirth and decreased [made better] the postnatal appraisal score of women planning a hospital birth. Taking the actual instead of planned place of birth in to account lowers [improves] the postnatal W-DEQ score for women who actually had a home birth and heightens scores for women who had a hospital birth, resulting in a larger discrepancy between expectations and reality for home births and a smaller discrepancy for hospital births.

OR odds ratio, OU obstetric unit, W-DEQ Expectancy/Experience Questionnaire (Christiaens et al., 2008)

1. Possible selective distribution of questionnaires. Intention-to-treat analysis not performed.

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Table 36: Qualitative findings for home birth and obstetric unit birth

Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
Dahlen et al., 2010 Home birth n=8 Hospital birth n=8 [Low quality][1]	Preparation Home birth midwives prepared women for all aspects of the birth experience. This helped familiarise women in ways that better equipped them to face the unknown and reduced fear. The hospital group generally felt less empowered, less familiar and less well equipped to handle the unknown and talked about fear much more as a consequence [authors' conclusions]. Choice and control Importance of choice and control was often talked about by both groups of women [authors' conclusion]: "Without choice there's no feeling of control or participation... your personality becomes irrelevant. You're just a thing that's popping a baby out. It's all a very technical exercise... Because once your body takes over you're already losing control in one sense anyway... The last thing you need is to have everything else in your environment make you feel that way. I couldn't control anything (hospital birth)." "I suppose to put it one way, it's your turf and someone else is coming onto your ground. They respect that... At home they're just willing to do whatever you want to do as long as you and your baby are fine and well. So I think you feel a lot more confident and a lot more 'at home being in your home' (home birth)". Midwives 'honouring' the birthing woman Birth setting was not found to be the most important factor in women's birth experiences, rather it was the care received [authors' conclusion]: "She [hospital midwife] was fantastic and she was the one who gave me every opportunity and honoured me to do exactly what I wanted to do to deliver a baby. My hospital experience was very different to what I imagined and really good. When I think back to my birth, that's the part I feel good about. I felt empowered. I felt supported and I felt like I was actually in control (home/hospital birth)." [transfer from home to hospital] Information, communication and support Good information, communication and support were important to women and reduced feelings of fear, regardless of birth setting [authors' conclusion],

Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	Good communication reduced fear [authors' conclusions]: "They explained everything to me and they sort of got me through it. So I didn't feel scared during that part at all (hospital birth)". Poor communication increased fear [authors' conclusions]: "The baby's heart went down and as soon as the baby's heart went down everyone came running in and it gave me a heart attack. I thought Oh God! What has happened? The baby is going into distress (hospital birth)". Women valued quiet support more than technical expertise and the directive demeanour of some midwives [authors' conclusions]: "It's interesting when I think back of how unobtrusive the midwives were, they were definitely there. But I don't feel like I got a whole barrage of directions from her at all (home birth)". Some women discussed a lack of support: "I was just sitting there looking at this machine watching the baby's heart beat. Just laying there, not knowing what was happening. Midwives would come in and out (hospital birth)". Women who felt unsupported became fearful [authors' conclusions]: "I sort of felt lonely. I was sort of lying there and I did not have anyone to sort of say you know, 'don't worry, this is what actually happens'... I was just lying there trying to be brave. I didn't make any screaming or noises. It was just a bit sort of frightening and then if I'd had someone there with me I wouldn't have felt as sort of scared because it's more that I was on my own (hospital birth)".

1. Quality assessment notes: study included 2 women who gave birth at a birth centre and 1 woman who gave birth in a private hospital – unclear whether these women's experiences were similar/different to home and tertiary referral hospital women's experiences. Home birth women interviewed later after birth than hospital birth women. Comparative analysis insufficiently rigorous.

Evidence statements – planned home birth compared with planned obstetric unit birth

Satisfaction

Overall satisfaction with childbirth experience
One study (n=658) reported no difference in overall satisfaction with childbirth experience between women who planned a home birth and women who planned birth in an obstetric unit. The evidence was of very low quality.

Total Labour Agentry Scale score
One study (n=658) reported a higher total Labour Agentry Scale score in women who planned a home birth compared with women who planned birth in an obstetric unit (the Labour Agentry Scale is a standardised 29-item scale for measurement of expectancies and experiences of personal control during childbirth). This finding was statistically significant. The evidence was of very low quality.

Women's views and experiences
One qualitative study (n=16) found home birth women felt better equipped to deal with the unknown, which reduced fear. The hospital birth group generally felt less empowered and less well-equipped to deal with the unknown, and consequently talked about fear much more. Birth setting was not found to be the most important factor in women's birth experiences; instead, it was the care received.
The importance of choice, control and support was talked about by both home birth and hospital birth women. Regardless of birth setting, good communication reduced fear and poor communication and a lack of support increased fear. The evidence was of low quality.

Evidence statements – planned home/actual obstetric unit birth compared with planned obstetric unit/actual obstetric unit birth

Satisfaction

Overall satisfaction with childbirth experience
One study (n=191) reported lower overall satisfaction with childbirth experience in women who planned a home birth and gave birth in an obstetric unit compared with women who planned birth in an obstetric unit and gave birth in an obstetric unit. This finding was statistically significant. The evidence was of very low quality.

Feelings of control and involvement in decision making

Total Labour Agentry Scale score
One study (n=191) reported no difference in total Labour Agentry Scale score between women who planned a home birth and gave birth in an obstetric unit and women who planned birth in an obstetric unit and gave birth in an obstetric unit. The evidence was of very low quality.
A second study (n=494) reported greater feelings of control in women giving birth at home than women giving birth in hospital, though this was not a significant difference (see evidence table). Women giving birth at home had significantly greater feelings of control if they were not transferred to hospital intrapartum. The evidence was of very low quality.

Birth centre experience compared with previous hospital experience

Description of included studies

Two reports of 1 qualitative study conducted in Australia included 17 women who had given birth at 1 of 3 birth centres and had previously given birth in a hospital (Coyle et al., 2001a, Coyle et al., 2001b). It was unclear from the description of the birth centres whether these

were alongside or freestanding midwifery units. The women were aged between 22 and 34 years and none were nulliparous. Intrapartum transfer rates were not reported. Interviews were conducted in the women's homes between 2 and 4 months after birth. Analysis compared women's birth centre experience with their previous hospital experience. The findings of this study are summarised in table 37.

Evidence profile

Table 37: Qualitative findings for birth centre experience compared with previous hospital birth experience

Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
Coyle et al., 2001a Birth centre = 17 [Low quality][1]	The authors identified 2 main themes: 'care interactions' and 'beliefs about pregnancy and birth'. These were further categorised as follows: **Birth centre themes** *Non-interventionist approach* Participants' experiences revealed that birth-centre midwives did not interfere with their bodies in a physical sense, procedures were kept to a minimum and used when required rather than routinely [authors' conclusion]: "I wasn't touched when I came in and I was in labour, I wasn't examined at all which I really appreciated. They seemed to know where I was at and not interfere with me in anyway". Women also felt support of natural childbirth was enhanced by fact that technology (e.g. epidural, fetal monitoring) were not readily available. Midwives 'hands-off' approach was positively received by women and reinforced their belief that birth was a normal life event [authors' conclusion]. *Women as primary decision-makers* Women felt that they were treated as autonomous individuals at the birth centre, the midwives provided them with information that enabled them to make informed decisions [authors' conclusion]: "She [midwife] would ask me a question and say we could do it [manage labour] this way and that way and gave me suggestions, but ultimately it was my decision". **Hospital setting themes** *Interventionist approach* The use of technology was an accepted part of the process, with an assumption that women would want to use analgesia [authors' conclusion]: "When I was in the hospital, when I was actually in labour, a midwife said 'it is too late to give her an epidural' and I thought, 'well, did I ask for one?'" *Health professional superiority*

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Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	Many participants felt that medical practitioners and midwives in the hospital setting had a superior attitude because they were the experts [authors' conclusion]: "When I had a doctor it was his baby, we weren't allowed to talk and I had to do it his way." *Women as passive participants* Women did not perceive that they were encouraged to be involved in decisions affecting their care [authors' conclusion]: "And they didn't seem to take any consideration of my feelings or what I wanted or asked me what I wanted, they just went ahead and did it. They said 'this is what we have to do, this is what we are going to do'. It wasn't 'this is what we could do, we have other options'. They didn't give me any options." Failure to provide women with enough information also resulted in women sensing a lack of involvement in the decision-making process [authors' conclusion]: "…but I was never really sat down and said that when we induce this is what is going to happen"
Coyle et al., 2001b Birth centre = 17 [Low quality][1]	**Birth centre themes** *Cumulative care interactions – women comfortable with carers* Communication was facilitated as a result of being cared for by a familiar midwife (women were cared for in labour by a midwife they had met at least twice during pregnancy). Care provision by a 'known' midwife resulted in women being able to focus their energy and attention on the birth process instead of having to spend time developing a relationship with an unknown carer [authors' conclusion]: "...with the last two babies I knew the midwives and all I had to do was concentrate on myself and the labour. I think that is what causes a lot of pain during labour, your mind is elsewhere thinking about other things rather than what you are actually doing". Women were also more likely to trust and listen to familiar midwives. The closeness of their relationship with known carers had a positive impact on the woman's birth experience [authors' conclusion]: "So I just think that besides having your mum and your husband there who you can lean on, you also feel like a closeness with the midwife as well. It is a bond. You can't explain what that feels like. I really like it I think that is the way it should be comparing with other births". *Cumulative care interactions – women being known* Women felt they were known by their midwife (women were cared for in labour by a midwife they had met at least twice during pregnancy). Women found it beneficial to be cared for by someone who knew their history and past experiences [authors' conclusion]:

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Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	"She [midwife] knew what I had been going through with the first pregnancy and the birth. She knew everything, what I was scared of and all of those things. She knew exactly what I wanted, I didn't have to tell her." Known midwives were able to determine how much support individual women needed. Some required minimal physical input from the midwife, other women needed a large amount of physical and psychological support [authors' conclusion]. Being known by the midwife also facilitated participants' perception of their ability to be in control of their birth experience [authors' conclusion]: "Having met her [midwife] before and discussing what we would like to have happen and the feeling that she was putting me back in control, that really made a big difference. Rather than the doctor being in charge". For many women, control over the birth experience was directly linked to the presence of known carers [authors' conclusion]. One participant described her feelings when she was facing transfer to hospital for induction of labour after having all her pregnancy care in the birth centre: "...it was an absolutely enormous issue for me that I would be transferred out... I would lose control... [being cared for by] people I hadn't met and didn't know". *Care structures – personalised care and 'seeing me through'* Many participants described how they felt their care was adjusted to suit them individually [authors' conclusion]: "Everything went at its own pace. I didn't feel things were pushed on us... it was very very nurturing care... there was no such thing as the system taking over". When women felt their specific needs were being met they interpreted their care as being personalised [authors' conclusion]. Women had one midwife carer for the duration of labour. Women felt this had a positive effect on their experience [authors' conclusion]: "...that was what she [midwife] said to me at my visits 'whoever is with you will be with you that entire time. We are not going to leave you, there will that same person there the whole time'. Like I say, when I look at it that made all the difference in being able to concentrate..." **Hospital setting themes** *Non-cumulative care interactions – lack of rapport* Many participants received care throughout labour from unfamiliar carers. Some women described carers they did not know as strangers whose presence was a source of anxiety [authors' conclusion]:

Women's views and experiences	
Study **Total number of participants** **Quality rating**	**Summary of findings**
	"It would have been nice to have everyone around you that you knew, not just your family... rather than all these strangers around and then they change and you get more strangers coming in. It's a bit scary...". Experiencing a lack of trust was also mentioned by some participants when care was provided by unfamiliar carers [authors' conclusion]: "…with the main hospital, when I had my first baby and the people I didn't know, I was thinking to myself: 'Did I really want to listen to them?' I wanted to do my own thing but then again they were saying 'no, no, no, you have to do this' and I really didn't want to do that...". *Non-cumulative care interactions – women being unknown* Participants were often encouraged to write a birth plan, but in many cases written birth plans seemed to have minimal impact as a tool to assist women inform unfamiliar carers of their birth preferences [authors' conclusion]: "Actually, they sent out a questionnaire to your home and you filled it out and that allowed you to list all the choices and preferences you wanted. But when I actually went in it was never referred to and I remember thinking later, I can't remember specifically what happened, but I remember going home and thinking that they didn't even look at the care plan I had written". *Care structures – systemised care and fragmented labour care* Many women perceived that the organisational structure of the hospital setting dictated the type of care they received, they felt they were 'just a number' in a large system [authors' conclusion]. The hospital's inability to offer choices resulted in women perceiving care as inflexible and impersonal [authors' conclusion]: "With my first child that is what I had. This is what we've got, this is what you get. I didn't like that because I didn't have a choice. I just turned up for the experience". The hospital shift system often resulted in women being exposed to multiple carers within a short time frame [authors' conclusion]: "I liked the first lot and I was just starting to get used to them and then all of a sudden, I had an epidural, went to sleep a bit, woke up and I had different ones, and it was like, oh OK".

1. Quality assessment notes: women's previous hospital experience will likely have impacted their choice for birth centre care for subsequent deliveries, women 'acting as their own comparison'.

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Evidence statements

Women's views and experiences

Two reports of one study (n=17) identified different themes for birth centre experience and hospital experience.

Birth centre experiences: themes

The following key themes were identified for women's experience of birth at a birth centre:

- Non-interventionist approach: procedures were kept to a minimum.
- Women as primary decision-makers: midwives provided information to enable women to make informed decisions.
- Comfortable with carers: continuity of antenatal and intrapartum care facilitated a close relationship between the woman and midwife, which had a positive impact on birth experience.
- Women 'being known': facilitated women's perceptions of ability to be in control of their birth experience.
- Personalised care and 'seeing me through': women felt care was adjusted to them and there was a positive effect from having one midwife carer throughout labour.

The evidence was of low quality.

Hospital experiences: themes

The following key themes were identified for women's experience of birth in hospital:

- Interventionist approach: technology was accepted as part of the birth process.
- Health professional superiority: many women felt that medical experts had a superior attitude.
- Women as passive participants: women felt discouraged to be involved in decisions, felt a lack of information to facilitate informed decisions.
- Lack of rapport: some women described unknown carers as a source of anxiety.
- Women being unknown: carers were unfamiliar with women's birth plans and birth preferences.
- Systemised care and fragmented labour care: women felt they were 'just a number', that the hospital care system was large, inflexible and impersonal, and experienced multiple carers in a short time frame.

The evidence was of low quality.

Experiences of reactions to plans for giving birth at home

One study from Sweden (Sjoblom et al., 2011) elicited women's experiences of reactions to their plans to give birth at home. Reactions came from midwives and other health professionals. Of 1025 women invited to take part, 735 women responded. The women were asked the following question: "If you think anyone has tried to influence you not to give birth at home, would you please describe that experience or the situation you are thinking of?" Of the respondents, 34 women answered that they did not want to talk about it. Answers were analysed using thematic content analysis (Graneim and Lundman, 2008). Table 38 shows each reported category, followed by example quotations.

Table 38: Experience of reactions to plans for home birth

Experiences of reactions to plans for home birth	
Sjoblom et al., 2011	**Reported reactions to birthing plans**
N=735, Parous women giving birth at home Single sample [low][1]	**Seen as an irresponsible person** "My midwife said that she was obligated to dissuade me since a home birth involved major risks." "A selfish act" **Does not take responsibility for child as child might die** "The midwife said that the child could die (if born at home) and that I was irresponsible, and she scolded me…so I stopped going to the maternal health centre." Relatives: "You should give birth in hospital, at least for our sake." **Met with emotional arguments and ignorance** "It feels odd that people react so strongly without really knowing anything." **Exposed to persuasion** "You should definitely not give birth at home." **Intimidation and threats** "The midwife…tried everything, scare tactics, pressure, threats etc." **Alienation** "Lots of times I felt like an alien, I was just out of place in their system and didn't fit into the pigeonholes." **To be considered as different with an alternative lifestyle** "I visited a doctor who wondered if I was part of some religion that didn't allow us to use hospitals…it wasn't justified going against society like we were doing."

1. Unreported how many data analysts in research team. Little information on degree of risk of women.

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Evidence statements

One large qualitative study (n=735) found that some women were met with negative responses when telling health professionals their plans to give birth at home. They were met with ignorance and prejudice as well as feeling alienated and judged.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this question, the guideline development group wished to consider all outcomes relating to women's experience of labour and birth. The papers reported a range of outcomes under this broad heading but the group did not prioritise any in particular as they were all felt to be relevant. The group had hoped to consider long-term psychological outcomes but none were reported in the studies.

Consideration of clinical benefits and harms

For the comparison of alongside midwifery units with obstetric units, there were mixed findings. However, generally the results showed that women had a significantly better experience and were more satisfied at 2 months postpartum in the alongside midwifery unit group. For the comparison between freestanding midwifery units and obstetric units, more women felt satisfied, that they had been listened to, that they had been in control of their own decision-making and that they had been supported by a healthcare professional in a freestanding unit. However, the guideline development group recognised that these results were derived from scores on simple scales and that the absolute scores were generally high for both groups. Therefore, the significant differences reported may not be particularly meaningful in terms of women's own experience of care. The group also noted that in studies of this kind not all women will have experienced both types of care setting and this needs to be borne in mind when interpreting the findings of studies.

The group felt that some of the more valuable findings came from the qualitative studies. There were some common themes which came out from a number of the studies about the importance to women of choice, control and being given information. Women spoke positively of experiences where they were provided with sufficient information and were able to make decisions about their care, regardless of the birth setting (although generally these positive experiences were reported in the home and midwifery settings which practiced a non-interventionist model of care). Some studies also showed the importance of providing adequate support to assuage women's concerns and fears and to ensure that the women are sufficiently informed and empowered to make decisions about their care.

The group did not feel that the evidence from this specific review provided sufficient evidence alone to recommend one midwifery setting over another, although they did feel that the evidence showing greater satisfaction with care in midwifery-led settings supported their recommendations regarding place of birth. Furthermore, they agreed that the findings highlighted some extremely important principles of care which all women should be able to expect, regardless of the birth setting, and made recommendations to reflect this.

Consideration of health benefits and resource uses

As this review question focussed on women's experience of different birth settings, no health economic analysis was performed

Quality of evidence

The studies ranged in quality from high to very low, although the majority were graded as low or very low. The guideline development group considered the reasons for the studies being downgraded. They recognised that in a number of instances there were methodological flaws.

However, overall they felt that there was sufficient evidence to take into account when developing the recommendations.

Other considerations

The guideline development group recognised that although the evidence demonstrated clear themes in terms of providing supportive care to women, the evidence didn't show how best to ensure that high quality care is put into practice. They acknowledged that providing high quality, individualised care can be challenging, particularly when providing care for large numbers of women and/or when working in a highly pressurised environment. The group discussed this issue and agreed that effective leadership from senior staff can be key in ensuring that high quality care is provided within a maternity service. The group agreed that it was reasonable to recommend this despite the lack of specific evidence since it specifies a level of care that should be provided as standard.

Recommendations

13. **For all women giving birth in all birth settings, follow the principles in Patient experience in adult NHS services (NICE clinical guidance 138). [new 2014]**

14. **Providers, senior staff and all healthcare professionals should ensure that in all birth settings there is a culture of respect for each woman as an individual undergoing a significant and emotionally intense life experience, so that the woman is in control, is listened to and is cared for with compassion, and that appropriate informed consent is sought. [new 2014]**

15. **Senior staff should demonstrate, through their own words and behaviour, appropriate ways of relating to and talking about women and their birth companion(s), and of talking about birth and the choices to be made when giving birth. [new 2014]**

Assessment for choosing place of birth

Review question

What are the risk factors which should be included in assessment to determine the most appropriate place of birth for women during pregnancy and labour?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

No high quality studies were identified that directly addressed this question.

Evidence statement on choosing place of birth

There is no strong evidence on assessment for choosing place of birth and so the guideline development group discussed each condition related to place of birth.

Guideline development group interpretation of the evidence on choosing place of birth

The following criteria have been produced by consensus with the aim of providing consistency of advice for women when considering the relative risk associated with where they wish to give birth.

Recommendations on choosing place of birth

16. **Use tables 39, 40, 41 and 42 as part of an assessment for a woman choosing her planned place of birth:**

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- Tables 39 and 40 show medical conditions or situations in which there is increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk.
- The factors listed in tables 41 and 42 are not reasons in themselves for advising birth within an obstetric unit, but indicate that further consideration of birth setting may be required.
- Discuss these risks and the additional care that can be provided in the obstetric unit with the woman so that she can make an informed choice about planned place of birth. [2007, amended 2014]

Table 39: Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

Disease area	Medical condition
Cardiovascular	Confirmed cardiac disease Hypertensive disorders
Respiratory	Asthma requiring an increase in treatment or hospital treatment Cystic fibrosis
Haematological	Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major History of thromboembolic disorders Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100×10^9/litre Von Willebrand's disease Bleeding disorder in the woman or unborn baby Atypical antibodies which carry a risk of haemolytic disease of the newborn
Endocrine	Hyperthyroidism Diabetes
Infective	Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended Hepatitis B/C with abnormal liver function tests Carrier of/infected with HIV Toxoplasmosis – women receiving treatment Current active infection of chicken pox/rubella/genital herpes in the woman or baby Tuberculosis under treatment
Immune	Systemic lupus erythematosus Scleroderma
Renal	Abnormal renal function Renal disease requiring supervision by a renal specialist
Neurological	Epilepsy Myasthenia gravis Previous cerebrovascular accident
Gastrointestinal	Liver disease associated with current abnormal liver function tests
Psychiatric	Psychiatric disorder requiring current inpatient care

Table 40: Other factors indicating increased risk suggesting planned birth at an obstetric unit

Factor	Additional information
Previous complications	Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty Previous baby with neonatal encephalopathy Pre-eclampsia requiring preterm birth

Factor	Additional information
	Placental abruption with adverse outcome Eclampsia Uterine rupture Primary postpartum haemorrhage requiring additional treatment or blood transfusion Retained placenta requiring manual removal in theatre Caesarean section Shoulder dystocia
Current pregnancy	Multiple birth Placenta praevia Pre-eclampsia or pregnancy-induced hypertension Preterm labour or preterm prelabour rupture of membranes Placental abruption Anaemia – haemoglobin less than 85 g/litre at onset of labour Confirmed intrauterine death Induction of labour Substance misuse Alcohol dependency requiring assessment or treatment Onset of gestational diabetes Malpresentation – breech or transverse lie BMI at booking of greater than 35 kg/m^2 Recurrent antepartum haemorrhage Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound) Abnormal fetal heart rate /Doppler studies Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	Myomectomy Hysterotomy

Table 41: Medical conditions indicating individual assessment when planning place of birth

Disease area	Medical condition
Cardiovascular	Cardiac disease without intrapartum implications
Haematological	Atypical antibodies not putting the baby at risk of haemolytic disease Sickle-cell trait Thalassaemia trait Anaemia – haemoglobin 85–105 g/litre at onset of labour
Infective	Hepatitis B/C with normal liver function tests
Immune	Non-specific connective tissue disorders
Endocrine	Unstable hypothyroidism such that a change in treatment is required
Skeletal/neurological	Spinal abnormalities Previous fractured pelvis Neurological deficits
Gastrointestinal	Liver disease without current abnormal liver function Crohn's disease Ulcerative colitis

Table 42: Other factors indicating individual assessment when planning place of birth

Factor	Additional information
Previous complications	Stillbirth/neonatal death with a known non-recurrent cause

Factor	Additional information
	Pre-eclampsia developing at term Placental abruption with good outcome History of previous baby more than 4.5 kg Extensive vaginal, cervical, or third- or fourth-degree perineal trauma Previous term baby with jaundice requiring exchange transfusion
Current pregnancy	Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation) BMI at booking of 30–35 kg/m2 Blood pressure of 140 mmHg or more systolic or 90 mmHg or more diastolic on two occasions Clinical or ultrasound suspicion of macrosomia Para 4 or more Recreational drug use Under current outpatient psychiatric care Age over 35 at booking
Fetal indications	Fetal abnormality
Previous gynaecological history	Major gynaecological surgery Cone biopsy or large loop excision of the transformation zone Fibroids

Care throughout labour

Communication between women and healthcare professionals

Introduction

Effective communication in all its forms is a fundamental aspect of today's maternity services. The overall aim of caring for women during labour and birth is to engender a positive experience for the woman and her family, while maintaining their physical and emotional health, preventing complications and responding to emergencies. To successfully achieve this aim, good communication between all those involved in the care of women during the process of childbearing is crucial. Developing a rapport, trust and effective communication between healthcare providers and women is important to a woman's positive childbirth experience. Other factors include involvement in decision-making, informed explanations and meeting personal expectations. All these elements have a powerful impact upon women and their childbirth experience. Their influence on whether the experience of a woman and her family is good or bad cannot be overestimated.

The views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times. Women should be fully involved so that care is flexible and tailored to meet her and her baby's individual needs. Women should have the opportunity to make informed decisions about every aspect of their labour and birth. Women sometimes decline the offer of interventions for numerous reasons including previous unpleasant experiences. Individualised care should be supported by giving evidence-based information and active informed consent should be sought from women before all monitoring procedures, examinations and treatments.

Review question

What effect does communication have on a woman's perception of her birth experience?

- Interventions include the effect of control, choice and decision-making on psychosocial wellbeing in the medium and long term.
- Outcomes include postnatal depression and post-traumatic stress disorder.

For further details on the evidence review protocol, please see appendix E.

Description of included studies

The search yielded 2615 titles, 182 of which were selected for retrieval. The search did not impose geographical limits, but papers were not included if it was felt that the cultural setting of the research would be unlikely to generalise to women in the UK. Papers were also rejected if they did not have information on caregiver behaviour linked to psychosocial outcomes for women. Within the remaining papers, 19 were selected as key, either because they were methodologically sound empirical studies specifically designed to address the link between caregiver behaviour and psychosocial outcomes for women (n = 18) or because they were reviews that highlighted this link (n = 1).[67–85]

Review findings

A systematic review of 137 reports of factors influencing women's evaluation of their childbirth experiences was included.[67] [EL = 3] The review identified four factors that were seen as key in shaping women's experience of labour: personal expectations; the amount of support from caregivers; the quality of the caregiver–patient relationship; and the involvement in decision making. It is concluded that the influences of pain, pain relief, and intrapartum interventions on subsequent satisfaction are important but not as powerful as the influences of the attitudes and behaviours of the caregivers.

A Swedish longitudinal cohort study of 2541 women measured women's global experience of labour and birth and obtained information on the possible risk factors during pregnancy and 2 months after birth.68 [EL = 2+] The following categories of risk factors were identified that were associated with women's experience of labour and birth:

- factors related to unexpected medical problems
- social factors
- factors related to the woman's feelings during labour, such as pain and lack of control
- factors that may be easier for caregivers to influence, such as lack of support in labour and administration of analgesia.

A UK prospective study sent questionnaires to women 1 month before the birth to assess their preferences and expectations, and at 6 weeks after birth to discover their experiences and assess psychological outcomes.[69] [EL = 2+] Findings are based upon data from 1146 women. Parity was found to be strongly associated with feeling in control, with multiparous women feeling more in control than nulliparous women in all cases. In logistic regression analyses, the feeling of being in control associated with staff behaviour was found to relate primarily to being able to get comfortable, the feeling of being treated with respect and as an individual and perceiving staff to be considerate.

As part of a large randomised trial in the UK, which assessed the timing of intervention in prolonged labour, women's views were explored using a specifically designed questionnaire.[70] [EL = 3] Analysis of findings from 412 nulliparous women in response to an open-ended question revealed the following main themes: support, information, intervention, decision making and control, and pain relief. One hundred and eight women said they wanted to participate in decision making but the degree of involvement varied among women.

Secondary analysis of questionnaire survey data, also collected during an RCT, was carried out to explore factors relating to women's experience of birth. Data were collected from women receiving either care in an alongside midwife-led unit or standard hospital care.[71] [EL = 3] The two groups were combined for the purposes of this analysis (n = 1111). Logistic regression analysis identified five explanatory variables: involvement in the birth process (perceived control) and midwifery support were predictive of a positive experience; anxiety, pain and having a first baby were predictive of a negative experience.

Findings from a questionnaire survey (Sweden) distributed to women 1 day after giving birth (n = 295; response rate = 91%) showed that women usually experienced severe pain and

various degrees of anxiety, and most were seized with panic for a short time or for some part of their labour.[72] [EL = 3] Despite these negative feelings, most women felt greatly involved in the birth process, were satisfied with their own achievement and thought they had coped better than expected. Of the 38 variables tested in regression analysis, the six that contributed to explaining women's overall birth experience were: support from the midwife (sensitivity to needs); duration of labour; pain; expectations of the birth; involvement and participation in the birth process; and surgical procedures (emergency caesarean section, vacuum extraction, forceps, episiotomy).

Another questionnaire survey was sent to women 8–9 months after they had given birth (Australia) (n = 790; response rate = 71%).[73] [EL = 3] Findings revealed that not having an active say in decisions was associated with a six-fold increase in dissatisfaction among nulliparous women and a 15-fold increase among multiparous women. When adjusted for parity in a logistic regression model, the following factors were highly related to dissatisfaction with intrapartum care: lack of involvement in decision making ($P < 0.001$); insufficient information ($P < 0.001$); a higher score for obstetric interventions ($P < 0.015$); and the perception that caregivers were unhelpful ($P < 0.04$).

A second Australian cross-sectional questionnaire survey returned by 1336 women (response rate = 62.5%) 6–7 months after they had given birth found that, after adjusting for parity, social factors and obstetric care, caregivers perceived as unhelpful and not having an active say in decisions about their care had the greatest impact on women's experience of birth.[74] [EL = 3]

A third Australian prospective descriptive study employed telephone interviews conducted 4–6 weeks after birth to investigate women's experiences (n = 499 women).[75] [EL = 3] One in three women identified a traumatic birthing event and reported the presence of at least three trauma signs. Twenty-eight women (5.6%) met DSM-IV criteria for acute post-traumatic stress disorder. The level of obstetric intervention experienced during childbirth together with the perception of inadequate intrapartum care during labour was consistently associated with the development of acute trauma symptoms.

A questionnaire survey of first-time mothers in Finland (n = 271; response rate = 83%) investigated women's perceptions of labour and birth.[76] [EL = 3] Regression analysis showed that positive childbirth experiences were associated with the positive characteristics and professional skills of the attending midwife, the positive attitude of the child's father towards the pregnancy and a short labour.

In the USA (early 1990s), there was a convenience sample of 15 women (eight first-time mothers) who told 33 birth stories.[77] [EL = 3] From the findings, the researchers concluded that when decision making was increasingly shared between the women and the caregivers, the women expressed more positive emotions. Professional knowledge and power needs to be supportive, not directive, of the birthing processes.

A Swedish qualitative study using interviews with 18 women (six primiparous) who were 2–4 days post birth investigated women's experiences of labour and birth. The study took place in Sweden in 1994.[78] [EL = 3] Three main themes emerged: the need to be seen as an individual; to have a trusting relationship; and to be supported and guided on one's own terms. These themes were associated with a positive birth experience.

Another small-scale (n = 14) interview-based study conducted in Iceland also explored women's experience of giving birth.[79] [EL = 3] Analysis of the data showed that women have a need for a sense of control as well as a need for caring and understanding. Additionally there was a need for a good relationship with the midwife, which included the women feeling safe and secure. An explanation of events and reassurance regarding progress were also important to women.

A second Icelandic qualitative study sought views and experiences from a purposive sample of ten women who had experienced both caring and uncaring encounters during childbirth in

Iceland.[80] [EL = 3] The authors summarised three traits of the caring midwife which were defined as follows:

- competence – has the necessary knowledge and skills needed to coach a woman through the journey of labour and giving birth; is responsible, attentive, deliberate and communicates effectively
- genuine concern and respect for the woman – gives of her or himself, shows solidarity and sharing, is encouraging and supportive, respectful and benevolent
- positive mental attitude – is cheerful and positive, reliable and trustworthy, considerate and understanding.

Similarly the authors summarised three traits of the uncaring midwife:

- lack of competence – being rough when giving care to women, ineffective communication, not taking the initiative when needed and lack of understanding and flexibility
- lack of genuine concern and respect for the woman as a person – being thoughtless, strict on routines and rules, not taking notice of the woman and lacking in cooperation; being indifferent and untouched by the event as such, lack of interest and understanding in general, being non-supportive and insensitive, being hurried and in a rush
- negative character traits – being gloomy and brusque, cold, unkind or harsh.

An interesting US study showed a sample of 20 women videotapes of their births while simultaneously interviewing them.[81] [EL = 3] In separate interviews, the 25 caregivers were also shown the videotapes and interviewed. Although women and caregivers appeared to agree about what information women required and how it should be given, caregiver perceptions were more positive than those of the women. Many women wanted more information and valued detailed information to explain what was happening.

A discussion paper based on a previous paper[82] puts forward an idea that women are of less interest to the caregivers than the equipment, and that lack of information disempowers women. [EL = 3] Caregivers were seen to block women's worries or concerns by silence, changing the subject or by neutral statements such as 'let's see how we go'.

Participant observation of a convenience sample of 12 primiparous women in the second stage of labour examined communication between midwives, student midwives, labouring women and their partners, by analysing videotaped recordings.[83] [EL = 3] Communication was categorised using one of the following: innovation, encouragement, directing, educating, questioning, social and professional. Findings revealed that most communication was categorised as being directing, encouraging or educational, with the latter two categories showing a degree of overlap. Midwives were found to fall into one of two groups: those that tend to be directing or those that tend to be encouraging and educating. Women preferred the latter type of communication.

The Caring Behaviour Assessment tool has been used on a convenience sample of 31 women following normal birth (USA) to look at women's perceptions of caring behaviour from nurses during childbirth.[84] [EL = 3] Findings showed that the behaviours perceived by women to be most indicative of caring focused on professional competence and monitoring of the woman's condition. The most caring behaviours included knowing what they were doing, treating the woman with respect and as an individual, being kind and considerate and reassuring the woman.

A cross-cultural qualitative study compared responses from semi-structured interviews conducted with ten Chinese women and ten Scottish women (giving birth in Scotland).[85] [EL = 3] In addition, 45 unstructured interviews were undertaken with health workers, relatives and friends. Responses to the birth experience were partly related to the woman's culture, with Chinese women being more accepting of care given, but there were issues that were common across all the women irrespective of cultural background, notably that the feeling of

being in control was linked to a better emotional outcome. Caregivers' failure to engage with the woman as a human being was experienced as very traumatic.

Evidence statement

The studies included in this review varied in the methodology that they used as well as the method of analysis undertaken. Nevertheless, a number of strong common themes emerge and it is apparent that the way caregivers relate with the labouring women is hugely influential upon the woman's experience of birth. The first theme highlights that women value being treated as an individual, with respect and care. Secondly, most women need information and interpretation of that information in order to feel guided and supported throughout the birth. These findings are usefully summarised by the words women use to describe both the midwife and the feelings involved in a positive birth experience. These words include: caring, considerate, understanding, competent, trustworthy, empathic, tender, kind, friendly, calm, alert, peaceful, having professional expertise, unhurried.

Women want to receive information and assistance, to be involved, to feel safe and secure, to feel at ease and to be able to be themselves.

Recommendations on communication

17. **Treat all women in labour with respect. Ensure that the woman is in control of and involved in what is happening to her, and recognise that the way in which care is given is key to this. To facilitate this, establish a rapport with the woman, ask her about her wants and expectations for labour, and be aware of the importance of tone and demeanour, and of the actual words used. Use this information to support and guide her through her labour. [2007]**

18. **To establish communication with the woman:**
    - Greet the woman with a smile and a personal welcome, establish her language needs, introduce yourself and explain your role in her care.
    - Maintain a calm and confident approach so that your demeanour reassures the woman that all is going well.
    - Knock and wait before entering the woman's room, respecting it as her personal space, and ask others to do the same.
    - Ask how the woman is feeling and whether there is anything in particular she is worried about.
    - If the woman has a written birth plan, read and discuss it with her.
    - Assess the woman's knowledge of strategies for coping with pain and provide balanced information to find out which available approaches are acceptable to her.
    - Encourage the woman to adapt the environment to meet her individual needs.
    - Ask her permission before all procedures and observations, focusing on the woman rather than the technology or the documentation.
    - Show the woman and her birth companion(s) how to summon help and reassure her that she may do so whenever and as often as she needs to. When leaving the room, let her know when you will return.
    - Involve the woman in any handover of care to another professional, either when additional expertise has been brought in or at the end of a shift. [2007]

Mobilisation and position

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- mobilisation
- positions including: 'freedom to choose' option; standing; squatting; kneeling; semi-recumbent; lying on back; left lateral; birth stool, etc.

Previous guideline

Mobilisation during labour was reviewed in the Caesarean Section guideline.[6] Two RCTs were included. The guideline recommended that women should be informed that walking during labour has not been shown to influence the likelihood of CS.

Description of included studies

Evidence for the effect of different positions and mobilisation during the first stage of labour on labour outcomes is drawn from one systematic review of RCTs[86] and five RCTs.[87–91]

Review findings

A systematic review of maternal positions during the first stage of labour was identified which included 14 RCTs (seven of which used women as their own controls).[86] [EL = 1−] Most trials where women acted as their own controls were small-scale (n = 23 or fewer in six of the trials). In the other trials, sample sizes ranged from 40 to 1067, with four of the trials involving over 200 women. The trials of positioning during the first stage of labour compared mobilisation or upright positions with one or more horizontal positions in bed. Outcome measures included pain, comfort, uterine activity and labour progress. In trials where women acted as their own controls, they were requested to alternate between two different positions (e.g. standing, walking or sitting up versus side-lying or supine) during labour for equal periods (usually 30 minutes). Measures were made after each period of reported location and intensity of pain, uterine activity and labour progress. Other trials assigned women to an upright group or a recumbent group for a longer period of time e.g. active first stage, the whole of the first stage or the duration of labour. The differences in study design, the lack of detail in most papers regarding measures taken to prevent bias, difficulties of compliance and different pain assessment methods undermine the reliability of the findings and prevent pooling of data. The one consistent finding was that none of the women in any of the studies reported greater comfort in the supine position. In addition, it was found that alternating between different pairs of positions has different effects on uterine efficiency. Alternating between supine and sitting seems to reduce the efficiency of uterine activity compared with alternating between supine and standing or side-lying. It was also noted that many women had difficulty in remaining upright and/or mobilising during labour, especially towards the end of the first stage of labour and during the second stage. No conclusion could be drawn regarding the effects of position and mobilisation on reported pain or duration of labour.

A fairly large US randomised trial compared walking in the first stage of labour (n = 536) with no walking (usual care) (n = 531).[87] [EL = 1+] Women in spontaneous labour following uncomplicated pregnancies were randomised once labour had been established (cervical dilatation of 3–5 cm). Neither group underwent continuous electronic fetal monitoring (EFM) unless a fetal heart rate abnormality was detected using intermittent monitoring, epidural anaesthesia was requested or oxytocin augmentation was required. This then excluded any further ambulation. The amount of time spent walking undertaken by both groups of women was recorded by the attending nurse, and the distance walked was recorded using a pedometer (how the use of this instrument may have impacted upon the comfort of the labouring women is not discussed). Of the women assigned to the walking group, 22% chose not to walk. Of the 420 women who actually walked during labour, the mean walking time was 56 minutes (SD = 46 minutes). The degree of ambulation in the non-walking group was minimal. There were no

significant differences between the characteristics of women in the two trial groups. Analysis was on an intention-to-treat basis. No significant differences were found between the two groups in terms of labour outcomes (e.g. length, use of oxytocin for augmentation, use of analgesia), mode of giving birth, maternal or neonatal outcomes. Of those women who walked during labour, 278 were asked if they would do so in a future labour: 99% said that they would.

A prospective Australian RCT was carried out to determine whether there was any advantage or disadvantage to giving women the option to ambulate during labour compared with labouring in the recumbent position.[88] [EL = 1+] All women entering the trial (n = 196) underwent continuous EFM using a scalp electrode. This was carried out via telemetry for women in the ambulant group. The demographic and obstetric characteristics of the two trial groups were similar. Analysis was carried out on an intention-to-treat basis. No significant differences were found between the groups in terms of labour outcomes, mode of giving birth, maternal or neonatal outcome. Only 37 of the 96 women allocated to the ambulant group (39%) actually chose to ambulate for 30 minutes or longer. Of those who did ambulate, the mean time spent in an upright position was 1.5 hours (SD 0.8 hours). During the time of recruitment of women into the trial, 389 declined to participate, 46% for fear of losing the option to ambulate during labour.

In a small, older, UK prospective RCT, 68 women in spontaneous labour were allocated to either an ambulant or recumbent group for the first stage of labour.[89] [EL = 1−] Trial participants were recruited from a group of women who had expressed antenatally a desire to be ambulant. Each group comprised 17 nulliparous women and 17 parous women. Continuous EFM was performed for all women with the use of a fetal scalp electrode (via telemetry for the ambulant group) and contractions were monitored using an intrauterine pressure catheter. A number of significant differences were noted between the two groups, all in favour of the ambulant group. Ambulant women were given less analgesia, contractions were less frequent and were of greater amplitude, duration of labour was shorter, there were more normal births and babies' Apgar scores were also higher in the ambulant group. For women in the ambulant group, the mean time spent mobilising was 2.2 hours [range 0.8 to 8.3 hours]. The selection bias inherent in this study needs to be taken into consideration when interpreting these findings.

An RCT conducted in Argentina compared the pain perceptions of two groups of 50 women allocated to adopt alternately a vertical (sitting, standing or walking) or horizontal (lie on side or back) position for periods of 15 minutes throughout the first stage of labour.[90] [EL = 1+] Each woman thus acted as her own control and was asked to adopt a position of her own choosing between the assigned position periods in order to reduce 'carry-over' effects. The participants were all staff connected with the public education sector. Pain levels were measured during each 15 minutes horizontal or vertical position period using two validated pain scales (a Likert-type scale and a 10 cm visual analogue scale (VAS)). Pain scores were reported for each dilatation interval (2–3 cm, 4–5 cm, 6–7 cm and 8–9 cm). During the first half of the first stage (i.e. from 2 to 5 cm cervical dilatation) there was no difference noted in reported pain between the two positions. As labour progressed however, there was a statistically significant difference noted in measured pain levels, both abdominal contraction pain and lumbar pain, with higher levels of pain being associated with horizontal positions.

A small US trial randomly allocated nulliparous women in spontaneous labour to upright (n = 20) or recumbent (n = 20) groups.[91] [EL = 1+] The recumbent group included the options of supine, lateral or all fours. The upright group included standing, walking, kneeling, sitting or squatting. Outcome measures included the duration of the active phase of labour (defined as 4–9 cm dilatation), uterine contraction pattern and maternal comfort (as measured by a researcher using a standardised tool). Women allocated to the upright group had a significantly shorter active phase of labour (mean difference 90.25 minutes, P = 0.003) and

had contractions that were longer lasting and more frequent than women in the recumbent group. There was no significant difference in reports of women's physical comfort.

Evidence statement

Surprisingly, there are no trials examining the effect of freedom of movement throughout labour compared with restriction of movement on outcomes such as comfort, labour progress and fetal wellbeing. There is a lack of high-level evidence to suggest that either mobilisation or any particular position in the first stage of labour affects outcomes.

Recommendation on mobilisation and position

19. Encourage and help the woman to move and adopt whatever positions she finds most comfortable throughout labour. [2007]

Support in labour

1.1.1 Review question

Is there evidence that support in labour for women improves outcomes? Interventions include:

- any support from partners
- other birth supporters
- health professionals
- continuity of care

One-to-one care

Introduction

Traditionally, women have been attended and supported by other women during labour and birth. However, with the movement of the majority of births from home to hospital since the middle of the 20th century, continuous support has become the exception rather than standard care. Women's support needs in labour have been shown to have four dimensions: emotional, information support, physical support and advocacy. Women in the UK today usually labour with their partners present, providing them with physical and emotional commitment, but for some women this may be insufficient to provide them with the level and type of support that they need in the context of a modern institutional birth environment.

Previous guideline

One-to-one care is defined as continuous presence and support either by husband/partners, midwives or other birth supporters during labour and childbirth. One-to-one care was reviewed in the NICE Caesarean Section guideline.[6] The guideline reviewed one systematic review and recommended that women should be informed that continuous support during labour from women with or without training reduces the likelihood of CS.

Description of included studies

The updated systematic review was identified during the search for this guideline.[92] The systematic review examined 15 trials including 12791 women in both high income and low income countries (Australia, Belgium, Botswana, Canada, Finland, France, Greece, Guatemala, Mexico, South Africa and the USA). The impact of one-to-one care was considered different by status of caregivers, so that the review was stratified by the care providers. In eight trials, the support was provided by a member of the hospital staff, e.g. a midwife, student midwife or nurse. In the remaining seven trials, the providers were not members of the hospital staff; they were women with or without special training, a childbirth educator, a retired nurse, or a close female relative, usually the woman's mother. There is no identified trial that investigated the effectiveness of continuous support by husbands or partners. In nine of the trials, hospital policy permitted women to be accompanied by their husbands/partners or other family members during labour, while in the other six trials, no

additional support people were allowed. Presence of husbands or partners was considered as usual practice in the UK. [EL = 1+]

Review findings

Labour events

a) Stratified analysis by care-providers

Women supported by a member of the hospital staff were less likely to have analgesia than women receiving standard care (RR 0.97 [95% CI 0.95 to 0.99]). This difference was also apparent if the support was provided by birth attendants other than professionally trained staff (RR 0.83 [95% CI 0.77 to 0.89]).

b) Meta-analysis of all trials

Meta-analysis of findings from nine trials without stratification, which included 10 322 women, showed no significant difference in length of labour (WMD (random) −0.28 hours [95% CI −0.64 to 0.08 hours]).

Birth events

a) Stratified analysis by care-providers

Women supported by a hospital staff member were more likely to have a spontaneous vaginal birth (RR 1.03 [95% CI 1.01 to 1.06]), less likely to have an instrumental vaginal birth (RR 0.92 [95% CI 0.85 to 0.99]) or caesarean section (CS) birth (RR 0.92 [95% CI 0.85 to 0.99]). If support was given by non-hospital staff, the positive impact on spontaneous vaginal birth, instrumental vaginal birth and caesarean birth remained, with RR of 1.12 [95% CI 1.07 to 1.18], 0.59 [95% CI 0.42 to 0.81] and 0.74 [95% CI 0.61 to 0.90], respectively.

b) Meta-analysis of all trials

There appeared to be no difference in the rates of perineal trauma. One trial, which investigated the rate of episiotomy when support was provided from a specially trained nurse, found no significant difference between supported women versus those with standard care (RR 0.97 [95% CI 0.90 to 1.05]). Meta-analysis of two trials, both of which investigated support by a member of hospital staff, showed no significant difference in perineal trauma (RR 0.99 [95% CI 0.95 to 1.03]).

Newborn events

Meta-analysis of trials showed no significant difference in low 5 minute Apgar scores (seven trials, total RR 0.81 [95% CI 0.56 to 1.16]; with support by a member of hospital staff RR 0.83 [95% CI 0.56 to 1.22] and with support by non-hospital staff RR 0.64 [95% CI 0.22 to 1.92]); and admission to neonatal units (four trials RR 0.94 [95% CI 0.82 to 1.09]).

Women's satisfaction and experience of childbirth

Meta-analysis of eight trials showed that there was no significant difference in dissatisfaction and negative experience of childbirth between women supported by a hospital staff member (RR 0.83 [95% CI 0.67 to 1.02]) and women receiving standard care, but there was a significant difference if support was provided by a non-hospital staff member (RR 0.64 [95% CI 0.58 to 0.78]).

Women's mental and psychological health

There was one trial that investigated the incidence of postpartum depression in women given support by a specially trained nurse.[93] There were fewer supported women who reported post-partum depression than those receiving standard care, but this difference was not statistically significant (RR 0.89 [95% CI 0.75 to 1.05]). Another trial investigated the impact of postpartum self-esteem on women given support by a retired nurse.[94] There was no evidence of a difference in the number of women with low postpartum esteem, between supported care and standard care (RR 1.07 [95% CI 0.82 to 1.40]).

Long-term outcomes

One trial investigated the long-term outcomes of support by a specially trained nurse for women in labour. There were no significant differences between the trial groups for poor relationship with partner postpartum (RR 1.00 [95% CI 0.80 to 1.23]), postpartum urinary incontinence (RR 0.93 [95% CI 0.81 to 1.06]) or postpartum faecal incontinence (RR 0.89 [95% CI 0.64 to 1.24]).

Evidence statement

In general, the included studies were of good quality. A range of professionals providing one-to-one care, including obstetric nurses, was identified within the studies. There is evidence to suggest that women with one-to-one care throughout their labour are significantly less likely to have caesarean section or instrumental vaginal birth, will be more satisfied and will have a positive experience of childbirth. This impact becomes more apparent when non-professional staff members, rather than professional staff members, care for them. The non-professional person providing one-to-one care in labour within these studies varied in their level of training, background and in the context of care.

There is little evidence on perinatal mortality and the long-term wellbeing of women and their children.

There is also a lack of high-level evidence to suggest that support by partners, other family members or friends affects clinical outcomes.

GDG interpretation of evidence

Although in the UK midwives usually provide the majority of care during labour and childbirth, there were no studies identified that compared one-to-one support from a midwife with that provided by another professional. The reviewed studies are from a range of countries, some of which are not representative of the UK setting, especially in that partners/support persons were not usually allowed to accompany women during labour. This means it is not possible to extrapolate all these findings regarding support from a non-professional person to the UK. The role of maternity care support workers remains unevaluated in the UK.

Recommendations on one-to-one care

20. **Provide a woman in established labour with supportive one-to-one care. [2007]**

21. **Do not leave a woman in established labour on her own except for short periods or at the woman's request. [2007]**

22. **Encourage the woman to have support from birth companion(s) of her choice. [2007]**

Research recommendations on one-to-one care

6. **Studies should evaluate the impact of a standardised training programme for maternity care support workers in the intrapartum period. Outcomes should include: maternal and neonatal mortality, adverse outcomes, long-term outcomes, women's satisfaction and costs as outcomes.**

Appropriate staffing configuration of midwives and healthcare support staff on labour wards

Review question

What is the appropriate staffing configuration of midwives and healthcare support staff on labour wards to support one-to-one continuous care during labour?

Description of included studies

There is little evidence linking midwifery and healthcare support staffing levels to provision of one-to-one continuous care during labour. In particular, no evidence was found evaluating the staffing configuration of healthcare support staff (doulas, birth attendants, healthcare support workers, healthcare assistants, obstetric nurses and auxiliary nurses) on labour ward or in midwifery-led units. Although much work has been done to develop scoring systems for quality appraisal of a range of study designs, the NICE interim methods guide for developing service guidance (February 2013) does not contain guidance for quality assessing tool development and validation. Therefore, for the purposes of this review, a pragmatic approach was taken based on the quality assessment scoring outlined for surveys. This meant that reports of tool development were rated as very low.

Two descriptive reports (Ball, 1992; Ball and Washbrook, 1996) and two studies (Ball, 2010; Allen and Thornton, 2012) are included in this review. All included studies assessed the configuration of midwives based in UK hospitals. Two additional UK surveys of midwifery staffing levels are presented as supporting information (Ball et al., 2003; BBC Panorama survey, 2011).

Ball (1992; based on Ball, 1988) introduced a method to assess workload in the UK's maternity units known as Birthrate. Birthrate is a model for calculating midwifery staffing levels based on a retrospective assessment of events and factors arising during labour and birth. It was developed using evidence from previous nursing and midwifery workforce planning studies which used non-participant observation, qualitative methods and expert consensus to estimate the time taken to provide care to women across a range of dependency levels. Its objective was to provide a tool that could be used to calculate midwifery staffing levels needed to provide continuous one-to-one care during labour (chosen as an agreed quality standard representing high quality care). This was further developed to Birthrate Plus (Ball and Washbrook, 1996). Birthrate Plus provided a method to support workforce planning and strategic decision-making in maternity services.

Birthrate and Birthrate Plus have been approved by the Royal College of Midwives (1994, 1999) and the Royal College of Obstetricians and Gynaecologists (1994) as a planning tool to predict the number of midwives required on labour wards in order for women to receive continuous one-to-one care during labour.

Birthrate Plus has 3 main components: a scoring system; actual midwife time (based on a staff survey); and a staffing formula. The scoring system uses 5 categories of labour and birth complexity which reflect the process and outcome of birth for both the woman and the baby. The midwife time required for each category is recorded based on the provision of one-to-one care throughout labour. The amount of midwife time increases for more complicated cases (that is, those in higher categories). All staffing calculations take into consideration variability of work load, holiday, sickness and study leave. Then, using a staffing formula, this data are converted into the number of midwives required to meet the workload.

Both Birthrate and Birthrate Plus have been well described and are evidence based. However, although the tools have been developed in a robust way and have face validity, they have not been externally validated. For this reason they have been graded as very low quality in relation to the key outcome for this review, namely the provision of one-to-one midwifery care throughout labour.

Birthrate Plus methodology was further developed to prospectively measure the 'acuity' workload on a labour ward (Ball and Washbrook, 2010). Acuity is defined as "a measure of the intensity of need within a delivery suite" (Ball and Washbrook, 2010). This was developed to enable managers to assess and record fluctuating workload with midwife availability in 'real time'. The tool enables the Birthrate Plus classification system to become a predictive/prospective tool rather than the retrospective assessment of process and outcome of labour used in the standard Birthrate Plus.

Allen & Thornton (2012) examined the ability of midwifery staffing levels calculated using Birthrate Plus to enable the provision of one-to-one care during labour. Variation in workload in maternity units and how much reserve resource was needed in times of high workload was also assessed. Computer simulation of labour wards was used to investigate the expected effect of changing midwife numbers throughout the day and across the week, and also was used to see how the size of unit affects the unit's ability to cope with different levels of complexity and workload. This validation study is graded as being of low quality.

Evidence profile

Due to the descriptive nature of the evidence for appropriate staffing configuration of midwives on a labour ward to support one-to-one continuous care during labour, the findings are presented in a simple summary table below. It should be noted that although they are based on evidence, Birthrate and Birthrate Plus do not in themselves constitute evidence but rather a method of calculating midwifery staffing needs in order to provide one-to-one care in labour.

Table 43: Appropriate staffing configuration of midwives on labour ward to support one-to-one care

Birthrate programme as a basis for staffing standards	
Ball ,1992 Quality: Very low	Birthrate is a workforce planning tool for calculating midwifery staffing levels in order to provide one-to-one continuous care during labour. The calculation is based upon both the length of time midwives spend in delivering care (derived from findings from non-participant observational studies of nursing care) multiplied up to allow for differences in complexity of care (based on findings from qualitative studies of nursing care and consensus). Birthrate calculates the number of midwives needed by: 1) Identifying which category of complexity each woman should be allocated to from 5 predefined categories: Categories I and II reflect normal labour and outcome, and are predominantly midwife-led care. Category III: a woman who may have had an induction of labour, continuous fetal monitoring for known or suspected risk and instrumental birth. Category IV: might be a woman who has had a well-managed elective caesarean section or one who has had a normal delivery with a healthy infant, but has had a long labour, received an epidural, and episiotomy with sutures. Category V: usually relates to emergency operative delivery, associated medical/obstetric problem, unexpected emergency or stillbirth. Birthrate also calculates additional work that may be required in labour wards: Category X: women who self-refer, may have early signs of labour, need observation, but do not progress and either go home or are admitted. Category A1: women who are not in labour but who require some monitoring and possibly intervention Category A2: women who are not in labour but who have a more serious problem Category R: readmission

	2) Surveying and adding up the number of women in each category on the labour ward daily over a period of time. 3) Using the data: a) Multiply the time spent on the labour ward by each woman by a multiplier to allow for increased midwife time needed to care for women in complicated categories (the midwife time spent providing care to women in categories III, IV, and V increases by 20%, 30% and 40% respectively). b) The total hours of midwife time per category is then calculated. c) The total hours in each category is then divided by the total hours in category I. In this way workload ratio is produced (all calculations are based on the assumption that the mean time per category I woman is 4.9 hours). The workload ratios are calculated by using the mean time for a category I woman as the basic component of staffing. d) The Workload Index in each category is calculated by multiplying the daily mean number of cases per category by the workload ratios. Adding up the Workload Index in each category and then multiplying by category I midwife time, the number of midwife hours per day is calculated. e) To calculate the number of midwives needed the workload index is multiplied by midwife time in category I. (Note: a worked example using actual data is given below within the details of Birthrate Plus) The Birthrate planning tool is used to assess current labour ward workload and thus calculate the number of midwife whole time equivalents (wte) that would be needed to provide continuous one-to-one care during labour assuming the same workload going forward.
Ball & Washbrook, 1996 Quality: Very low	Birthrate Plus is a further development of Birthrate allowing for further complexity including variability of workload, annual leave and sickness. The basic formula is the same as Birthrate.[a] The formula is detailed here including a worked example based on actual data: 1) Identify which category of complexity each woman should be allocated to from the 5 predefined categories. (see Birthrate above for details of categories) 2) Survey and add up the number of women per category on the labour ward daily. An example (1 year's data): Category I Number cases per annum: n=324 (10.8%) Daily mean no. cases: n=0.89 Category II Number cases per annum: n=1107 (36.9%)

Daily mean no. cases: n=3.03

Category III
Number cases per annum: n=576 (19.2%)
Daily mean no. cases: n=1.58

Category IV
Number cases per annum: n=426 (14.2%)
Daily mean no. cases: n=1.17

Category V
Number cases per annum: n=567 (18.9%)
Daily mean no. cases: n=1.55

3) Using the data:

a) Multiply the time spent on the labour ward by a multiplier to allow for increased midwife time needed in complicated categories (based on the woman's category, the midwife time in care of complicated case III, IV, and V increases by 20%, 30% and 40% respectively).

Following from the above example:

Mean hours of time per category:
Category I: 4.9 hours
Midwife time needed: 100% (1 midwife)

Category II: 7.35 hours
Midwife time needed: 100% (1 midwife)

Category III: 9.42 hours
Midwife time needed: 120% (1.2 midwives)

Category IV: 12.42 hours
Midwife time needed: 130% (1.3 midwives)

Category V: 17.15 hours
Midwife time needed: 140% (1.4 midwives)

b) Based on the each woman's category the total hours needed per category will be calculated.

Following from the above example:

Total hours of time per category:
Category I: 4.9x1=4.9 hours
Category II: 7.35x1=7.35 hours
Category III: 9.42x1.2=11.3 hours
Category IV: 12.42x1.3=16.15 hours
Category V: 17.15x1.4=24.01 hours

c) The total hours in each category is divided by the total hours in category I. In this way workload ratio is produced (all calculations are based on the assumption that a mean time per category I is 4.9 hours).

Following from the above example:

Workload ratio per category
Category I: 4.9/4.9=1.0 baseline
Category II: 7.35/4.9=1.5
Category III: 11.3/4.9=2.3
Category IV: 16.15/4.9=3.3
Category V: 24.01/4.9=4.9

d) The Workload Index for each category is calculated by multiplying the daily mean number of cases per category by the workload ratios. Adding up the Workload Index in each category and then multiplying by category I midwife time, the number of midwife hours per day is calculated.

Following from the above example:

Workload Index per category
Category I: 0.89x1=0.89
Category II: 3.03x1.5=4.55
Category III: 1.58x2.3=3.63
Category IV: 1.17x3.3=3.86
Category V: 1.55x4.9=7.6

Total Workload Index = 20.53 per day

e) To calculate the number of midwives needed following the above example, the Workload Index (20.53) is multiplied by midwife time in category I.

Each category I case needs 4.9 hours of midwife time

20.53x4.9=100.6 midwife hour per day
100.6x7=704 midwife hours per week

15% is added to allow for unpredictability of workload
704x1.15=809.81 midwife hours per week

A further 5% is added to allow for ward/unit administration, staff meetings, etc.
809.81x1.05=850.30 midwife hours per week

Following on from the above example:

If midwife hours per week is divided by 37.5 (hours worked per week per midwife), the staffing figure will be produced:

850.30/37.5=22.67 whole time equivalent midwives

A further 17.3% should be added to allow for holidays, sickness/study leave to produce total establishment staffing figures (midwives only):

	22.67 whole time equivalent midwives x1.173=26.59 whole time equivalent midwives Within Birthrate Plus the amount of midwife time needed for women receiving home or caseload midwifery care is calculated on an agreed allocation of a total of 38 hours per woman for all antenatal, intrapartum, and postnatal care. The main differences in the ratios of births per whole time equivalent midwife per annum arise from differences in allowances for travel time. These range from 15% to 20%. All calculations are based on the assumption that midwives are supported by healthcare assistants/other support staff. It is suggested that the required numbers of these staff are worked out based on local experience and estimated needs. The Birthrate Plus data collection sheet has been field tested and found to be well understood and easy to use. Reliability of the time recorded and calculated for different categories has been found to be very good (89%). Note: Whilst the authors emphasise that the evidence underpinning the development of Birthrate Plus is validated no data are reported to validate the Birthrate Plus tool itself i.e. there is no evidence that staffing levels provided in accord with the calculations have enabled continuous one-to-one care to be provided to all women (or to a greater number of women than was the case with any previous or differently calculated staffing configuration).

Ball 2010 Quality: Very low	The Birthrate Plus Acuity tool was developed and tested within a Welsh trust in 2006 and 2007. The tool provides an ongoing "real time" record of workload on the labour ward and subsequently the number of midwives needed to meet the workload. Applying the tool, the number of women receiving care, their category of need (Cat I - V), the total ward acuity and the number of midwives needed to match it, can be calculated with the aim that client and staff needs can be measured and predicted and to aid in the development of policies for clinical governance. The tool consists of: a) Score sheet The same clinical indicators already used by Birthrate Plus, (see Ball, 1992; Ball, 1996) were used and a score sheet was produced based upon the same indicators. However, the scoring was changed to include category of needs on admission which could be changed if additional needs arose during labour, birth or the immediate postnatal period to indicate any increase in the level of midwifery care required. For instance, a woman admitted in category I needs one midwife for one-to-one care. As labour advances she might require an epidural and electronic fetal monitoring which would change her category from I to III needing 1.2 midwives. The woman could then have a normal birth and a healthy baby and would remain in category III. b) Assessment of the number of midwives required The same ratio applied as for the normal workforce planning system; one-to-one care for all women in labour and an additional allowance of midwife time for those in higher categories (1.2 midwives for category III, 1.3 midwives for category IV and 1.4 midwives for category V) c) Care in labour ward More categories added to normal Birthrate Plus workforce planning categories (see Ball 1992, Ball 1996): T = transfers out with midwife in attendance R = women readmitted for a procedure d) Post-operative and postnatal care PO1: women in recovery room post operation PO2: women waiting for a bed in postnatal area PN: women who remain in the delivery suite until they go home within few hours of birth e) Ward record of acuity at agreed intervals of time All women in the labour ward would have their category decided at agreed intervals (1, 2, or 4 hourly). The results are entered on an excel spread sheet. This: 1) calculated the ratio of midwife time per category to be assigned for each woman, the total acuity and number of midwives needed; and 2) compared the number of midwives present in the labour ward with the number of midwives required. This results in a regular "real time "update of acuity on the labour ward alongside the actual midwifery staffing levels and the calculated necessary staffing levels.

Update 2014

	The reliability of the Acuity Birthrate Plus tool was tested in a Welsh trust for a 2 month period and entries found to be accurate when compared with casenotes and the scoring system applied correctly for 80-90% of cases. This same high level of reliability was found when the system was piloted further across a larger number of trusts in Wales. Note: Although the Acuity tool has been field tested its validity has not been established in terms of whether the acuity score does reflect, and enable the prediction of, the need for midwifery time in order to provide one-to-one continuous care for women in labour, or whether its application aids midwifery resource allocation or policies for clinical governance.
Analysis of Birthrate Plus labour ward staffing compared with a simulation model incorporating the Birthrate Plus calculation	
Allen & Thornton, 2012 Quality: Very low	Simulation model description The simulation model was developed based on data from hospital records over 1 year and Birthrate Plus data collected over a 3 month period from the same hospital. Number of births per annum = 6000. The simulation model was designed to mimic the arrival pattern of women, separating out those in spontaneous labour from those having a planned caesarean section. Women would then be assigned to a Birthrate Plus category. Analysis of patterns in one year's data set The average births per day by month did not vary significantly: p>0.05. Number of births per day by day of the week did vary significantly: p<0.001 (average number of births was 20% higher on weekdays than on weekends) The number of births varied by hour of the day; it was significantly higher between 09.00 and 12.00 on weekdays when caesarean sections were more likely to be performed. During this 3 hour period the number of births was 60% higher than the rest of the day. When caesarean section was removed from the analysis the variation still remained significantly higher (p<0.01) but with a smaller magnitude. Analysis of staffing patterns in 3 months using the Birthrate Plus formula Mean number of women per day present on the labour ward: 5.9 (SD 2.5). Average Birthrate Plus workload index: 7.4 (SD 3.1) Mean ratio of midwives to women: 1:3 Mean ratio of midwives to work load index: 1:1 For 36% of the time there was a greater workload index than the number of midwives available. For 13% of the time there were more women than midwives present on the labour ward. The number of women exceeded the number of midwives by 5% to 10% during the day on weekends but this increased to 25% to 30% during the day on weekdays. During the period 09.00 to 13.00 on weekdays the average workload index exceeded the allocated number of midwives approx. 65% of the time. Analysis of staffing patterns in 3 months using simulation model (relationship between the staffing levels and incidence of overload) Using simulation to guarantee that there were more midwives than women, the midwife:woman ratio on the labour ward needed to be 1.8:1 (standard Birthrate Plus calculation: 1.4:1)

Update 2014

	If the workload index is taken as a guide to workload on labour ward then to guarantee that there were a sufficient number of midwives to cover the workload index 95% of the time, the ratio of midwife:women on the labour ward needed to be approx. 2.2:1 (significantly higher than BR+ guideline). Probability of labour ward overload was significantly higher during the day on weekdays. When medical records were checked to validate the model the simulated figures were found to be within 5% of actual data on all key indicators. Based on these findings, the authors concluded that the performance of the unit could be improved by: 1) Increasing resources at the time of predictable increase in load: a 25% reduction in occurrence of overload could be achieved with only 4% increase in budget. 2) Applying a no cost option with reduced staffing levels on Saturday night and all day Sundays and re-allocating these staff at peak load during the weekdays. In this no-cost option a 15% reduction in occurrence of overload could be achieved. Effect of size of unit on probability of labour ward overload Small units (approx. 2000 births per year) were forecast to have more women than midwives 16% of the time. The larger units (approx. 8000 births per year) were overloaded 10% of the time. In the small units the Workload Index was seen to rise to twice the number of allocated midwives 6% of the time. This level of severe workload was very rare in the larger units (happening only 0.1% of the time).

a. The precise link between evidence from previous studies and the values used in the Birthrate Plus calculator is not clear.

Supporting information

In Ball (2003) an outline of the Birthrate Plus programme during 2001–2002 in England and Wales was reported. The project was funded by Department of Health to help maternity units in England and Wales to implement Birthrate Plus and it required units to complete the Birthrate Plus data collection tool. Results from 44 maternity units in England and Wales were reported, representing a variety of unit sizes and locations. All units collected a minimum of 6 months of data.

Further, a Freedom of Information request by the BBC's Panorama television programme (2011) requested midwife-to-birth ratios from 171 trusts in the UK. Data were submitted by 149 trusts. The number of births in 2010 and the whole time equivalent midwives in post on 1 May 2011 was reported for each trust in this survey.

Both sources provide data for number of births per midwife ratios and are presented in the summary table below:

Table 44: Number of births per midwife ratios reported by maternity units in the UK

Number of births per midwife ratios reported by 44 maternity units during 2001–2002	
Ball et al., 2003	Survey results from 44 units (mostly District General Hospitals) in 2001 reported actual midwifery staffing levels and number of births. Data were collected for minimum of 6 months. n=68,680 hospital births, n=1520 home births. Group 1: under 2500 births per annum Mean births to midwife ratio: 28.36 births to 1 whole time equivalent (wte) midwife

Number of births per midwife ratios reported by 44 maternity units during 2001–2002	
	Range: 26.08–30.42 Group 2: 2500–3500 births per annum Mean births to midwife ratio: 27.92 births to 1 wte midwife Range: 25.04–33.20 Group 3: 3501–5800 births per annum Mean births to midwife ratio: 28.72 births to 1 wte midwife Range: 22.52–34.27 The authors concluded that the similar ratios indicate a possible framework for large-scale workforce planning and that an initial ratio of 28 hospital births to 1 wte midwife per annum might be appropriate. The ratio of home/caseload based births from 43 trusts: Mean births to midwife ratio: 35.50 births to 1 wte midwife range: 34–37.50 This suggests a ratio of 35 home/case load based births to 1 wte midwife per annum might be appropriate.
BBC Panorama national births to midwife ratio survey (UK)	
BBC Panorama survey, 2011	Average births to midwife ratio recommended by RCM: 28 births per midwife Average births to midwife ratio in England: 33 births per midwife Average births to midwife ratio in Wales: 30 births per midwife Average births to midwife ratio in Northern Ireland: 28 births per midwife (recommend level by RCM) Average births to midwife ratio in Scotland: 26 births per midwife

RCM Royal College of Midwives, wte whole time equivalent

Evidence statements

There is very little evidence to inform the staffing levels needed to provide one-to-one continuous care in labour.

Birthrate and Birthrate Plus were developed from evidence and field tested for usability and reliability, but they have not been validated in terms of whether midwifery staffing levels calculated using their formula results in midwifery staffing levels that allow provision of one-to-one continuous care during labour. The evidence was of very low quality.

The Birthrate Plus Acuity tool has been developed to allow real time assessment, prediction and planning of midwifery staffing workload on a labour ward taking into account variations in workload across time of day and days of the week. In pilot testing this tool has been found to be useable and reliable but its validity has not been established. The evidence was of very low quality. The Birthrate Plus formula for calculating number of midwives allows for 15% extra resource (above the average Workload Index) for coping with variation in workload, but 1 computer modelling study indicated that when it was applied in practice, the Workload Index exceeded planned resource 36% of the time and the number of women exceeded the number of midwives 13% of the time. The simulation model used in the study suggested that overload can be reduced by 15–25% if the resource were matched to known pattern of workload, taking into account variations between weekdays and weekends and allowing for peak hours. It also suggested smaller units are more prone to work overload than larger units. The evidence was of low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

It is recommended that all women should receive supportive one-to-one care during labour (recommendation 23). The intention of this review was to build on that recommendation and to identify whether there are particular staffing models which can be applied to enable this provision. Receipt of one-to-one care was therefore the key outcome for this review. Unfortunately, no comparative studies were identified which evaluated the effectiveness of any particular staffing model, although a computer modelling study did attempt to evaluate the ability of Birthrate Plus to provide appropriate staffing levels to allow one-to-one care for all women on the delivery suite. Three other reports that were included in the review described the development and usability of 3 tools for calculating midwifery staffing levels (Birthrate, Birthrate Plus and the Birthrate Plus Acuity Tool).

Consideration of benefits and harms

Because of the nature of the available evidence, it was not possible for the group to adequately consider the benefits and harms of the different staffing models. No outcome data were provided and so it was not possible to determine if use of the models in practice would lead to an improved level of one-to-one care. Similarly, it was not possible to determine if there were any positive or negative outcomes associated with changing midwifery staffing levels.

Consideration of health benefits and resource uses

Again, owing to the lack of data available from the studies, the guideline development group did not feel that it was possible to determine the cost effectiveness of the different staffing models. They recognised that even if the different models achieved their aim of ensuring that a greater proportion of women were able to receive one-to-one care, without proper evaluation and validation it was not possible to determine whether the models would achieve this in a cost-effective way. None of the included papers evaluated comparisons between different models for service provision. So, for example, the group noted that Birthrate and Birthrate Plus calculate midwifery staffing levels based upon the underlying assumption that support staff, such as healthcare assistants, are also available on the labour ward or midwifery-led unit. The tools do not include calculations for the number of support staff required. Potentially, staffing models using different configurations of midwives and other support staff might be more cost effective than that proposed by Birthrate or Birthrate Plus, given the difference in staff costs. The group did not necessarily believe that such a model would be more effective, but without any formal evaluation of the models, and without any comparative data available, the guideline development group did not feel that it was possible to advocate any particular staffing model or staffing calculation tool over another.

Quality of evidence

Although the data provided in the studies were clear regarding the development and usability of the tools, they did not provide good quality evidence to answer the review question, all being graded as very low. Without formal validation being conducted, it was not possible to determine if the tools are able to achieve their stated aims of calculating appropriate midwifery staffing levels for provision of one-to-one care.

Other considerations

Although the guideline development group did not feel that they could advocate a particular calculation tool or staffing model for providing one-to-one care, they agreed that this should

be an aim for all maternity services. They agreed that it was appropriate to use workforce planning tools such as Birthrate Plus as this would then allow benchmarking, so would encourage services to identify the level of care they are currently providing and then assess the difference made by adopting the new staffing model. They agreed that these data would be useful both for the individual unit in identifying the degree to which they were achieving the provision of one-to-one care during labour and their levels of under- and over-staffing, and also at a national level to determine the effectiveness of the workforce planning models used. The group also drafted a research recommendation to ensure that currently available workforce planning tools are evaluated and validated.

The group noted that the BBC Panorama findings showed a large variation in practice across the UK in terms of the ratio of births to midwives, with both England and Wales above the 28 births to 1 midwife ratio that the Royal College of Midwives recommends. However, the group was not aware of any published evidence which shows that this particular ratio allows for one-to-one care. Given this, they did not feel that it was appropriate to refer to this proposed ratio in the recommendations.

Recommendations

23. Maternity services should

- provide a model of care that supports one-to-one care in labour for all women **and**
- benchmark services and identify overstaffing or understaffing by using workforce planning models and/or woman-to-midwife ratios. [new 2014]

Continuity of care

Introduction

Continuity of care in maternity services refers to both continuity of carer and consistency of care. The former has received most attention both in terms of policy and in research where continuity of care is defined in terms of continuity of carer and describes care provided by a midwife or a small group of midwives, from early pregnancy to the postnatal period.

Continuity of carer was highlighted as a key component of good maternity care in the Health Committee Second Report: Maternity Services, vol. 1 (1992) (the Winterton Report),[95] and further endorsed by the Report of the Expert Maternity Group at the Department of Health (the Changing Childbirth Report) (1993),[96] which identified among its ten key indicators of success (page 70) that:

- every woman should know one midwife who ensures continuity of her midwifery care – the named midwife
- every woman should know the lead professional who has a key role in the planning and provision of her care
- at least 75% of women should know the person who cares for them during their birth.

Two main models of midwifery care have evolved as a way of organising services so as to provide continuity of carer in a way that is sustainable within the existing NHS structure, namely team midwifery and caseload midwifery. Team midwifery is a team of midwives looking after a group of women and caseload midwifery aims for a more personal relationship with the woman and involves a small group of midwives. Sizes of team midwifery teams vary greatly, ranging from four midwives to ten or more, with hospital-based teams tending to be larger than community-based teams. The aim of most team midwifery schemes is to increase the chance that women will be cared for in labour by a midwife they have met antenatally, with the focus on intrapartum continuity often taking precedence over antenatal and postnatal continuity. Caseload midwifery describes a system of care whereby one midwife (sometimes referred to as the 'named midwife') is responsible, and provides the majority of the care, for a

group of women backed up by a small group of associate midwives (usually two or three). When there is one midwife backing up a named midwife this system is also known as 'one-to-one' care.[97] Team midwifery schemes have usually been hospital based, or integrated across hospital and community settings. Caseload midwifery schemes tend to be community based. These two systems of care will be reviewed separately below. Some studies investigated a package of care which included both care in midwife-led units and continuity of care. This review includes schemes which provide care in a variety of settings, including traditional delivery suite, birthing rooms within a traditional midwifery suite and separate birth units. For the purposes of this review where one midwife has taken responsibility for a group of women this has been categorised as caseload midwifery. Where there has been shared responsibility between a group of midwives this has been categorised as team midwifery.

While much research confirmed that continuity of carer was highly valued by many women, concern has been raised about the effects on midwives of working in systems designed to provide continuity of care, particularly hospital-based team midwifery schemes.[98]

Previous guideline

Continuity of care was reviewed in the NICE 'Antenatal Care' clinical guideline.[99] Two systematic reviews were appraised in the guideline. It was recommended that antenatal care should be provided by a small group of carers with whom the woman feels comfortable and there should be continuity of care throughout the antenatal period. They also recommended that a system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.

Team midwifery

Description of included studies

There were two systematic reviews[100,101] and four RCTs[102–108] identified. One systematic review included two trials,[100] and another included seven trials.[101] The trials that were included in the former systematic review were all included in the latter systematic review. A new meta-analysis was conducted by using a total of ten trials.[100–108] [EL = 1+]

Among the ten trials, three were conducted in England, five in Australia, one in Canada, and one in Sweden. A total of 1229 women were involved. The ten trials were all evaluations of team midwifery, with teams ranging in size from four to ten midwives. Six of the ten studies were of community-based teams coming into the hospital or midwife-led unit to provide care during labour and the postnatal period. The review here relates to team midwifery rather than continuity of carer per se.

A cross-sectional study[98,109] with a 5% random sample of midwives in England (n = 1166) measured occupational stress, especially burnout, in midwives, comparing those in midwifery teams (hospital-based and community-based) with traditional hospital-based midwives and GP-attached midwives.

Review findings

Details of the included trials on team midwifery care are summarised in Table 45.

Table 45: Details of trials of team midwifery care

Trial	Team description	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group (%)	Restriction of medication and technology	Postnatal visits at home by team midwives	Control group
Flint et al. (1989) England Reported in Waldenstrom and Turnbull (1998)[101] and Hodnett (1999)[100]	Team of 4 midwives	At booking, 36 and 41 weeks	Traditional hospital	No	Not reported	No	Yes	Hospital antenatal, intrapartum and postnatal care provided by variety of obstetricians and midwives
MacVicar et al. (1993) England Reported in Waldenstrom and Turnbull (1998)[101]	2 midwifery sisters + 8 staff midwives	At 26, 36 and 41 weeks	3 birthing rooms	Yes	Antenatal – 23% first stage of labour – 18% second stage of labour and after birth – 4%	Yes (EFM and epidural)	No	Antenatal shared care by GPs and community midwives, birth within specialist unit by hospital staff
Kenny et al. (1994) Australia Reported in Waldenstrom and Turnbull (1998)[101]	Team of 8 (6.8 full-time midwife equivalents)	At booking, 32 and 40 weeks	Traditional hospital	No	Not reported	No	Yes	Hospital antenatal, intrapartum and postnatal care provided by a variety of doctors and midwives
Rowley et al. (1995) Australia Reported in Waldenstrom and Turnbull (1998)[101] and	Team of 6 midwives	At 12–16, 36 and 41 weeks	Traditional hospital	No	Not reported	No	No	Hospital antenatal, intrapartum and postnatal care provided by a variety of doctors and midwives

Trial	Team description	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group (%)	Restriction of medication and technology	Postnatal visits at home by team midwives	Control group
Hodnett (1999)[100]								
Rowley et al. (1995) Australia Reported in Waldenstrom and Turnbull (1998)[101] and Hodnett (1999)[100]	Team of 6 midwives	At 12–16, 36 and 41 weeks	Traditional hospital	No	Not reported	No	No	Hospital antenatal, intrapartum and postnatal care provided by a variety of doctors and midwives
Harvey et al. (1996) Canada Reported in Waldenstrom and Turnbull (1998)[101]	Team of 7 midwives	At booking and 36 weeks	1 birthing room	Yes	Antenatal – 1% Intrapartum – 26%	No	Yes	Family physician or obstetrician selected by woman, in hospital care in all city hospitals
Waldenstrom et al. (1997) Sweden Reported in Waldenstrom and Turnbull (1998)[101]	Team of 10 midwives (8.5 full-time equivalents)	On medical indication only	Birth centre	Yes	Antenatal – 13% Intrapartum – 19% Postnatal – 2%	Yes (EFM, epidural, pethidine, nitrous oxide, oxytocin)	Yes	Antenatal care provided by community midwives, 1 or 2 routine visits by doctor, hospital antenatal, intrapartum and postnatal care provided by variety of midwives in close collaboration with obstetricians

Trial	Team description	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group (%)	Restriction of medication and technology	Postnatal visits at home by team midwives	Control group
Homer et al. (2001)[103] Australia Homer et al. (2002)[104] Australia	Team of 6 midwives	An obstetrician was available at all antenatal clinic sessions. Details not given as to whether consultations with obstetrician routine or as necessary	Traditional hospital Team midwives worked 12 hour shifts on delivery suite compared with 8 hour shifts for standard care midwives	Not reported	Not reported	No	Yes	Antenatal care provided by a variety of midwives in the antenatal clinic and the woman's GP. Intrapartum and postnatal care provided by a different set of midwives in each clinical area
Biro et al. (2000)[105] Australia Biro et al. (2003)[106] Australia	Team of 7 midwives provided care for low- risk women and high- risk women alongside obstetricians (integrated team)	At 12–16, 28 and 36 weeks or as necessary	Traditional hospital Team midwives worked longer shifts on delivery suite than standard care midwives	Not reported (but not necessary for obstetric reasons as team work with obstetricians)	Not reported (but not necessary for obstetric reasons as team work with obstetricians)	No	No	Care provided by a variety of staff. Antenatally this included obstetricians, GPs, hospital-based midwives and community-based midwives. Cared for by a variety of obstetricians and midwives during labour and postnatally
Waldenstrom et al. (2000)[107] Australia	Team of 8 midwives	Not reported	Traditional hospital Team midwives worked same shift patterns	Not reported	Overall – 2.2%	No	No	Care provided by a variety of obstetricians and midwives antenatally, often also involved GP.

Trial	Team description	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group (%)	Restriction of medication and technology	Postnatal visits at home by team midwives	Control group
			as standard care midwives					Variety of midwives allocated to delivery suite and postnatal ward provided care in these areas. Comparison group also included option of care at birth centre where care was provided by a small group of midwives throughout antenatal, intrapartum and postnatal period
Hicks et al. (2003)[102] England	Team of 8 midwives	Referred as necessary to a consultant but still had care managed by midwifery team	Traditional hospital delivery suite but working to community midwifery shift patterns with on-calls	Not reported	None	No	Yes	Antenatal care provided mainly by GP and/or community midwives. Intrapartum and postnatal care undertaken by variety of midwives. Also included Domino scheme (care provided by small group of community

Trial	Team description	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group (%)	Restriction of medication and technology	Postnatal visits at home by team midwives	Control group
								midwives with care led by one midwife)

EFM = electronic fetal monitoring.

Labour events

It was not possible to conduct a meta-analysis on the length of labour owing to the different measures used. There were no consistent findings in duration of either the first, second or third stage of labour. Meta-analysis was conducted for interventions related to labour as follows. Induction (nine trials, n = 10 341): RR 0.96 [95% CI 0.88 to 1.05] (test for heterogeneity P = 0.11); augmentation (nine trials, n = 10 201): RR 0.83 [95% CI 0.78 to 0.90] (test for heterogeneity P < 0.0001); epidural (ten trials, n = 10 399): RR 0.80 [95% CI 0.74 to 0.86] (test for heterogeneity P = 0.04); opioid analgesia (nine trials, n = 10 146): RR 0.75 [95% CI 0.75 to 0.84], P < 0.00001 (test for heterogeneity P < 0.00001). Overall, women receiving care from a team of midwives were less likely to have interventions than women receiving standard maternity care, although there was a significant level of heterogeneity among these trials.

Birth events

Meta-analysis was conducted for interventions related to birth, with findings as follows. CS (ten trials, n = 10 622): RR 0.90 [95% CI 0.80 to 1.00] (test for heterogeneity P = 0.31); instrumental vaginal birth (nine trials, n = 10 449): RR 0.85 [95% CI 0.76 to 0.95] (test for heterogeneity P = 0.52); episiotomy (ten trials, n = 9810): RR 0.79 [95% CI 0.74 to 0.85] (test for heterogeneity P = 0.02). Overall, women receiving care from a team of midwives were significantly less likely to have these interventions.
Six trials reported no significant difference in postpartum haemorrhage (PPH) and five trials reported no significant difference in either manual removal of placenta or retained placenta.

Newborn outcomes

Meta-analysis was conducted for interventions related to newborn events with results as follows. Condition at birth (Apgar score less than 7 at 5 minutes) (seven trials, n = 6135): RR 1.17 [95% CI 0.81 to 1.680] (test for heterogeneity P = 0.68); admission to neonatal units (nine trials, n = 10 404): RR 0.90 [95% CI 0.79 to 1.03] (test for heterogeneity P = 0.05); perinatal mortality (nine trials, n = 10 423): RR 1.63 [95% CI 1.04 to 2.56], P = 0.03 (test for heterogeneity P = 0.69). Although there were no differences between groups regarding Apgar score at 5 minutes or admission to neonatal intensive care, there was a significantly higher perinatal mortality noted for babies born to women cared for within the team midwifery model.

Women's satisfaction and experience of childbirth

Virtually all the trials reported on women's satisfaction and their assessment of the childbirth experience. This was measured using various qualitative methods. All the trials reported that team midwifery systems of care designed to provide intrapartum care by a midwife met antenatally increased women's satisfaction and resulted in more positive experiences of childbirth compared with standard maternity care.

Women's mental and psychological health

One trial reported on the emotional wellbeing of women who were given continual support from a team of midwives. Responses to the Edinburgh Postnatal Depression Scale (EPDS) 2 months after the birth showed that 16% of women in the team midwifery care group and 12% in the standard care group were depressed (EPDS score > 12) – a non-statistically significant difference (P = 0.19).

Long-term outcomes

There were no long-term outcomes reported in the relevant articles.

Wellbeing of healthcare professionals

The cross-sectional study[98,109] (n = 1166) measured occupational stress, especially burnout, in midwives, comparing those in midwifery teams (hospital-based and community-based) with traditional hospital-based midwives and GP-attached midwives. Burnout was measured using an adaptation of the Maslach Burnout Inventory (MBI). The study found that burnout was associated with a lack of freedom to make decisions at work, longer contracted hours and low control over work pattern. Findings showed that midwives working in hospital-based teams had the highest reported levels of burnout, followed by traditional hospital-based midwives. No relationship was found between higher levels of burnout and continuity rate, number of nights worked on-call and type of caseload. It would appear, however, that this association is strongly linked with working within the constraints of a hospital-based system where midwives tend to have less autonomy over working pattern and decision making compared with community-based midwives.

Caseload midwifery

Description of included studies

One UK RCT and one UK cluster RCT were identified for inclusion in this review. The RCT compared women cared for by a named midwife with three associate midwives (n = 648) in a hospital-based midwifery development unit (MDU) with women receiving shared care (n = 651) (majority of care provided by GP with three or four visits to the obstetrician at the hospital).[110] [EL = 1+] The cluster RCT was randomised on the basis of geographical area, with three areas in each cluster.[97] [EL = 1-] In three areas caseload midwifery care was provided to all low-risk women booked for maternity care (n = 770). The caseload model involved each named midwife being allocated 35–40 women to care for, with back-up provided by one or two associate midwives. In the remaining three areas shared care was provided to women (n = 735) by the GP and community midwife in the established way, with occasional visits to the hospital to see an obstetrician. Details for each study are presented in Table 46.

Table 46: Details of included studies of caseload midwifery model

Trial	Description of caseload midwifery practice	Routine antenatal visits by doctor	Setting for intrapartum care	System for maternal transfer to obstetric team	Maternal transfer to obstetric team in midwife-managed group	Restriction of medication and technology	Postnatal visits at home by caseload midwives	Control group
Turnbull et al. (1996)[110] Scotland	Named midwife responsible for woman's care from booking until discharge to health visitor. Back-up by associate midwife if not available. Implemented within a new midwifery development unit	No. Referred to obstetrician as necessary	Birthing room in midwifery development unit (alongside)	Not described	Overall – 32.8% (permanently transferred)	No	Yes	Shared care provided by GP, a variety of midwives and obstetricians based in antenatal clinic, delivery suite and postnatal ward with community midwives providing postnatal care at home
North Staffordshire Changing Childbirth Research Team (2000)[97] England	One GP-attached community midwife with a caseload of 35–40 women. Caseload midwives worked in pairs or threes to provide 24 hour cover	Scheduled in to the shared care system	Traditional hospital setting, but caseload midwives did provide home assessment for women in early labour	Not described	Not reported	No	Yes	Community midwives part of team providing shared care to women alongside the woman's GP and hospital-based obstetricians and midwives

Review findings

It was not possible to perform a meta-analysis owing to the methodological differences between the two studies.

Labour events

Findings from the (non-cluster) RCT showed that women cared for within the caseload midwifery model had fewer inductions of labour: 199 (33.3%) versus 146 (23.9%); difference 9.4% [95% CI 4.4% to 14.5%]. There was no significant difference found for other labour events including augmentation of labour (difference −3.4%), opioid analgesia (difference 2.5%) and epidural (difference 1.4%). The lower use of epidural analgesia (10% versus 15%) and oxytocin augmentation of labour (46% versus 53%) was also evident in the cluster RCT. No differences in induction of labour were noted, however.

Birth events

Findings from the RCT showed that significantly more women in the caseload midwifery group had an intact perineum following birth: 120 (23.6%) versus 160 30.5%, while fewer had an episiotomy: 173 (34.0%) versus 147 (28.0%) or a first- or second-degree perineal tear: 216 (42.4%) versus 218 (41.5%); test for overall difference P = 0.02 (χ^2). No significant differences were found between groups for mode of birth, with the incidence of spontaneous vaginal birth being 73.7% in the shared care group compared with 73.5% in the caseload midwifery group. Findings from the cluster RCT showed no differences between groups for perineal trauma or mode of birth.

Newborn outcomes

Findings from the RCT showed no difference for newborn outcomes between groups, Apgar score 8–10 at 5 minutes: 565 (96.6%) versus 589 (97.8%), difference −1.2% [95% CI −3.1% to 0.6%]; admission to special care baby unit (SCBU) 40 (6.6%) versus 33 (5.4%), difference 1.2% [95% CI −1.4% to 3.9%]. There were nine stillbirths plus neonatal deaths in the shared care group compared with four in the caseload midwifery group (difference 0.4% [95% CI −0.4% to 1.2%]. Findings from the cluster RCT also showed no differences between the groups in newborn outcomes. There were a total of 11 stillbirths plus neonatal deaths (1.5%) in the shared care group and six (0.7%) in the caseload midwifery group (difference 0.8% [95% CI −0.2% to 1.8%]).

Women's satisfaction and experience of childbirth

In the RCT women were found to be significantly more satisfied with their maternity care; antenatal care: difference in mean scores 0.48 [95% CI 0.41 to 0.55]; intrapartum care: 0.28 [95% CI 0.18 to 0.37]; hospital-based postnatal care: 0.57 [95% CI 0.45 to 0.70]; home-based postnatal care: 0.33 [95% CI 0.25 to 0.42].

A basic cost comparison of team midwifery versus conventional midwifery

Rationale

The evidence does not suggest that team midwifery leads to significantly better outcomes. Indeed, a meta-analysis undertaken as part of this guideline suggested that team midwifery resulted in statistically significant increases in perinatal mortality compared with the standard model: RR 1.64 [95% CI 1.04 to 2.58], P = 0.03.

Anecdotally, a number of providers appear to have ceased providing a team midwifery service on the grounds of cost. Similarly, one reason team midwifery did not become more widely established was because additional funding was not made available for it. This would seem to indicate, at least from the perspective of service providers, that team midwifery is a more costly service than the conventional model. If it is both more expensive and less effective we can say unambiguously that it is not cost-effective, being 'dominated' by the conventional model.

At this stage we do not have the detailed cost data to do a full cost comparison of the two models of care. The only quantitative information we have at this stage comes from a maternity unit in the north of England currently offering a form of team midwifery care. They state that they have an annual midwife to birth ratio of 1:26 against a national average of 1:33. At this stage we do not know how representative this unit's ratio is of team midwifery models in general but it does at least seem consistent with the perception that team midwifery (TM) is a more resource-intensive service. If we assume that this service was typical then we could estimate the additional midwife staffing cost per birth as follows:

Annual cost of midwife	= £40,000 approximately
Hospital births	= n
Additional midwifery staffing in TM model	= (1/26 − 1/33) × n = 0.008 × n
Additional midwifery staffing cost	= £40,000 × 0.008 × n = £326 × n
Additional midwifery cost per birth	= £326

Clearly, a full cost comparison would also have to include 'downstream' cost differentials between the two models of care, especially as the meta-analysis undertaken for the guideline found the following intervention differences for team midwifery:

Induction:	pooled OR 0.88 [95% CI 0.80 to 0.98], P = 0.02
Augmentation:	pooled OR 0.83 [95% CI 0.76 to 0.91], P < 0.001
EFM:	pooled OR 0.30 [95% CI 0.27 to 0.33], P < 0.001
Epidural:	pooled OR 0.77 [95% CI 0.71 to 0.85], P < 0.001
Narcotics:	pooled OR 0.72 [95% CI 0.66 to 0.78], P < 0.001
Caesarean section:	pooled OR 0.91 [95% CI 0.81 to 1.02], P = 0.12; NS
Instrumental birth:	pooled OR 0.84 [95% CI 0.75 to 0.95], P = 0.005
Episiotomy:	pooled OR 0.73 [95% CI 0.67 to 0.80], P < 0.001

This meta-analysis suggests that women receiving care from team midwifery have less intervention and therefore 'downstream' costs may, to some extent, offset higher staffing costs of service provision. The most important of these 'downstream' savings is likely to relate to a lower rate of instrumental vaginal birth and the saving per birth that this might be expect to produce is calculated below.

From NHS Reference Costs (2004) finished consultant episode data:

Normal birth	= 382 669
Instrumental births	= 64 995
Caesarean sections	= 130 353
Total births	= 578 017

Odds of instrumental conventional birth	= 64 995/513 022 = 0.127
Odds of instrumental TM birth	= 0.84 OR from meta-analysis × 0.127 = 0.107
Number of instrumental TM births	= 55 870
Reduction in instrumental births due to TM	= 64 995 − 55 870 = 9125
Cost of instrumental vaginal birth	= £1,263
Cost of normal vaginal birth	= £863
Cost saving of reduction in instrumental births due to TM	= 9125 × (£1,263 - £863) = £3.65 million
Cost saving per birth	= £3,650,000/578 017 = £6.30

While this is a substantial saving it falls a long way short of what would be required to offset the additional staffing costs of providing a team midwifery service.

This analysis does not constitute a proper costing of the two alternative models of care. However, if its assumptions are accepted it would suggest that a team midwifery model is more expensive than a conventional model of midwifery care. When taken together with some

evidence of higher perinatal mortality it could not be recommended on cost-effectiveness grounds.

Evidence statement

Team midwifery

In general, the studies included were of good quality. There was heterogeneity between the studies, particularly in both the settings for intrapartum care and the size of the team, which makes interpretation difficult. There is evidence to support that women cared for by a team of midwives throughout their pregnancy, intrapartum and postnatal period are less likely to have interventions during labour, and that such care is highly valued by women. However, there is an increased perinatal mortality associated with team midwifery care. There was no indication as to which component of care, or combination of components of care, might have contributed to this.

There is some evidence that midwives working in hospital-based teams experience higher levels of burnout than those working in community-based teams.

Caseload midwifery

Findings from two trials show that women cared for in a caseload midwifery system are less likely to receive interventions during labour and that women prefer this system of care compared with traditional shared care. No evidence of difference in other maternal or neonatal outcomes was found.

There is no evidence about its cost-effectiveness.

Recommendation on continuity of care

24. Team midwifery (defined as a group of midwives providing care and taking shared responsibility for a group of women from the antenatal, through intrapartum to the postnatal period) is not recommended. [2007]

Research recommendations on continuity of care

7. Studies are needed that investigate the components affecting a woman's satisfaction with her birth experience, including her emotional and psychological wellbeing. A robust method of assessing a woman's satisfaction is also needed.

8. There should be studies carried out to investigate the effects of caseload midwifery (defined as one midwife providing care and taking responsibility for a group of women from the antenatal, through intrapartum to the postnatal period) on women, babies and healthcare professionals, including cost-effectiveness and long-term outcomes.

Eating and drinking in labour

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- restricting fluids and nutrition.

Reduction gastric aspiration in labour

Routine prophylactic drugs in normal labour for reducing gastric aspiration

Description of included studies

A systematic review identified three randomised controlled trials.[111] [EL = 1+] The intervention was any drug, with any route of administration, in any dosage. The drug categories were particulate and non-particulate antacids, H2-receptor antagonists, dopamine antagonists and proton pump inhibitors, although no trials were identified on proton pump

inhibitors. The primary outcome measure was the incidence of gastric aspiration in the woman. The review found none of the trials to be of good quality.

Review findings

There was limited evidence to suggest that antacids may reduce the chance of vomiting in labour when compared with no intervention (one trial, n = 578; RR 0.46 [95% CI 0.27 to 0.77]). When individual antacids were compared with each other, when tested in one study, there was no significant difference in incidence of vomiting (Gelusil® versus Maalox® (n = 300): RR 0.83 [95% CI 0.39 to 1.75]; Gelusil versus Mylanta II® (n = 325): RR 1.32 [95% CI 0.58 to 2.99]); Maalox versus Mylanta II (n = 285): RR 1.59 [95% CI 0.69 to 3.65]). There was no significant difference in vomiting (one trial, n = 1287; RR 0.96 [95% CI 0.73 to 1.27]); CS (one trial, n = 1287; RR 0.93 [95% CI 0.59 to 1.47]); emergency general anaesthetic (one trial, n = 1287; RR 0.92 [95% CI 0.62 to 1.35]); PPH (one trial, n = 1287; RR 0.83 [95% CI 0.08 to 9.14]) and stillbirth (one trial, n = 1287; RR 0.69 [95% CI 0.17 to 2.89]) when H2-receptor antagonists were compared with antacids. Again, the number of participants was too small for the results to be conclusive.

Dopamine antagonists given alongside pethidine may reduce vomiting in labour (one trial, n = 584; RR 0.40 [95% CI 0.23 to 0.68]) when compared with placebo or no treatment given alongside pethidine, but the subgroups from the study population were too small to make an assured comment. The trial showed no significant difference in Apgar scores < 7 at 1 minute (RR 1.02 [95% CI 0.62 to 1.69]) or perinatal deaths (RR 1.22 [95% CI 0.24 to 6.21]). When two different dopamine antagonists were compared (metoclopramide versus perphenazine; n = 393) there was no significant difference in vomiting (RR 1.45 [95% CI 0.64 to 3.32]), Apgar score < 7 at 1 minute (RR 0.83 [95% CI 0.47 to 1.47]) or perinatal death (RR 0.25 [95% CI 0.03 to 2.23]).

Evidence statement

The studies were too small to assess the incidence of gastric aspiration, Mendelson syndrome and its consequences. There is limited evidence that antacids or dopamine antagonists given alongside pethidine reduce the chance of vomiting in labour. There is also limited evidence that H2-receptor antagonists have no impact on vomiting and other outcomes when compared with antacids.

There were no trials identified on proton pump inhibitors.

Recommendations on reducing gastric aspiration

25. Do not offer either H2-receptor antagonists or antacids routinely to low-risk women. [2007]

26. Either H2-receptor antagonists or antacids should be considered for women who receive opioids or who have or develop risk factors that make a general anaesthetic more likely. [2007]

Research Recommendations on reducing gastric aspiration

9. Use of either H2-receptor antagonists or antacids in labour should be evaluated for women who have or develop risk factors, who have opioids or who may need a general anaesthetic.

Eating and drinking in labour

Description of included studies

One randomised controlled trial, published in 1999, was identified (eating group = 45; starved group = 43). The study population comprised women in labour at 37 weeks of gestation or

greater who had one baby with cephalic presentation. The intervention was a low-residue diet compared with water only.112 [EL = 1+]

Review findings

The results showed that restriction of food throughout the course of labour results in a significant increase in plasma β-hydroxybutyrate (mean difference (MD) 0.38 mmol/l [95% CI 0.21 to 0.55 mmol/l], P < 0.001) and non-esterified fatty acids (MD 0.35 mmol/l [95% CI 0.22 to 0.48 mmol/l], P < 0.001) when compared with eating a low-residue diet. There was a significant increase in plasma glucose (MD 0.62 mmol/l [95% CI 0.22 to 1.01 mmol/l], P = 0.003) and insulin (MD 15.6 mmol/l [95% CI 2.9 to 28.3 mmol/l], P = 0.017) in the eating group when compared with the starved group. Gastric antral cross-sectional areas measured within 1 hour of labour were significantly higher in the eating group (MD 1.85 cm2 [95% CI 0.81 to 2.88 cm2], P = 0.001) and these women were also twice as likely to vomit at or around giving birth (MD 19% [95% CI 0.8% to 38%], P = 0.046). The volumes vomited by the women in the eating group were significantly larger (MD 205 ml [95% CI 99 to 311 ml], P = 0.001) than the volumes vomited by women in the starved group. Lactic changes remained similar in both groups (MD −0.29 mmol/l [95% CI −0.71 to 0.12 mmol/l], P = 0.167). However, the study showed no significant differences in maternal outcomes (duration of first and second stage of labour, oxytocin requirements, mode of birth) or neonatal outcomes (Apgar scores, umbilical artery and venous blood gases) between the two groups of women (only means reported).

Evidence statement

The limited evidence suggests that a light diet significantly reduces the rise of plasma β-hydroxy-butyrate and the non-esterified fatty acids from which it is derived, while significantly increasing plasma glucose and insulin. However, the significant increase in volumes vomited must be considered, given that there were no significant differences in maternal or neonatal outcomes.

Intervention to prevent ketosis

Carbohydrate solution versus placebo

Description of included studies

Three randomised controlled trials, conducted by the same researchers at the Leyenburg Hospital in the Netherlands, were identified for review. The first study involved 201 nulliparous women randomised at 2–4 cm cervical dilatation (carbohydrate solution n = 102; placebo n = 99).115 [EL = 1+] Women were able to consume small standardised amounts of food or drink on specific demand, with total amount of intake of kilojoules calculated for each woman at the end of the study. The second trial involved 202 nulliparous women randomised at 8–10 cm cervical dilatation, (carbohydrate solution n = 100; placebo n = 102).113 [EL = 1+] Women were not allowed any other solutions. The final study involved 100 nulliparous women randomised at 8–10 cm cervical dilatation (carbohydrate solution n = 50; placebo n = 50).114 Women were only allowed water in addition to the study solutions. [EL = 1+]

Review findings

In the first study, the median intake of study solution was 300 ml [range 17 to 1600 ml] in the placebo group and 400 ml [range 0 to 1600 ml] in the carbohydrate group (P = 0.04).115 Similar proportions of women in both groups had a small additional intake (32% placebo group; 32.5% carbohydrate group). The median total calorific intake by the placebo group during the study was 0 kJ [range 0 to 1086 kJ] and 802 kJ [range 140 to 3618 kJ] for the carbohydrate group (P < 0.001). There was no statistically significant difference in the need for augmentation (RR 0.83 [95% CI 0.55 to 1.26]) or in the need for pain-relieving medication (opiates: RR 0.96 [95% CI 0.44 to 2.11]; epidural: RR 1.56 [95% CI 0.89 to 2.73]; Entonox: RR 3.64 [95% CI 0.72 to 15.8]), when women in the carbohydrate group were

compared with women in the placebo group. While there was no significant difference between the carbohydrate and placebo groups for spontaneous birth (RR 0.90 [95% CI 0.68 to 1.17]) or for instrumental birth (RR 0.78 [95% CI 0.52 to 1.17]), the number of caesarean sections was significantly higher in the carbohydrate group (RR 2.9 [95% CI 1.29 to 6.54]). There were no significant differences in Apgar scores at 1 minute (P = 0.17), Apgar scores at 5 minutes (P = 0.18) or the arterial umbilical cord pH (P = 0.07) between the carbohydrate and placebo groups.

In the second study, the median intake of study solution was 200 ml [range 15 to 200 ml] in the placebo group and 200 ml (10 ml to 200 ml) in the carbohydrate group (P = 0.42).113 There were no significant differences in spontaneous birth (RR 1.07 [95% CI 0.88 to 1.30]), instrumental birth (RR 1.05 [95% CI 0.69 to 1.60]) or CS (RR 0.15 [95% CI 0.02 to 1.16]) when the carbohydrate group was compared with the placebo group. No significant differences were observed in neonatal outcome: Apgar scores at 1 minute (P = 0.22), Apgar scores at 5 minutes (P = 0.32) or the arterial umbilical cord pH (P = 0.80), when the carbohydrate group was compared with the placebo group. In addition, when the carbohydrate and placebo groups were compared, there were no significant differences in changes in glucose (P = 1.00), lactate (P = 0.07) or plasma β-hydroxybutyrate (P = 0.21). There was a significant decrease in free fatty acid levels (P = 0.02), with the carbohydrate group tending to decrease to a higher degree.

In the third study, there were no significant differences in spontaneous birth (P = 0.30) or vaginal instrumental birth (P = 0.84) when the groups were compared.114 However, the cohort was too small to draw conclusions. There were four caesarean sections in the placebo group and none in the carbohydrate group, but no statistical calculations were made. Arterial umbilical cord pH, pCO2, pO2, HCO3 and base excess were similar in both groups, as were venous umbilical cord results. However, no statistical data were presented.

Evidence statement

There is no evidence of difference in mode of birth, or fetal and neonatal acid–base balance between taking carbohydrate solution and placebo during labour.

Isotonic sports drink versus water

Description of included studies

One randomised controlled trial conducted in the UK and published in 2002 was identified.116 The study involved 60 women at 37 weeks of gestation or greater, with a singleton fetus having cephalic presentation (sports drink group n = 30; water group n = 30). [EL = 1+]

Review findings

In the sports drink group there was a significant decrease in plasma β-hydroxybutyrate (MD −0.63 [95% CI −0.85 to −0.42]) and non-esterified fatty acids (MD −0.36 [95% CI −0.46 to −0.25]) when compared with the water-only group. Mean plasma glucose remained unchanged in the sports drink group, but decreased significantly in the water-only group (MD 0.76 mmol/l [95% CI 0.22 to 1.3 mmol/l]). The total quantity of liquid consumed was significantly higher (P = 0.001) in the sports drink group. The mean calorific intake was also higher for the sports drink group (47 kcal/hour (SD 16 kcal/hour) compared with the water-only group (0 kcal/hour). However, there was no significant difference in gastric antral cross-sectional area (MD −0.63 cm^2 [95% CI −1.12 to 0.70 cm^2]), volume vomited within 1 hour of giving birth (MD 65 ml [95% CI −141 to 271 ml]) or volume vomited throughout labour (MD 66 ml [95% CI −115 to 246 ml]), when the two groups were compared. There was no difference between the two groups with respect to duration of labour, use of oxytocin, mode of giving birth or use of epidural analgesia. The study authors only presented the data as mean (SD) or proportion (%), but noted that all results were non-significant.

Evidence statement

There is a small amount of evidence to demonstrate that ketosis is prevented by relatively small calorific intake provided by isotonic drinks and that these provide an alternative source of nutrition that is rapidly emptied from the stomach and rapidly absorbed by the gastrointestinal tract.

There is limited evidence that labour outcomes were not compromised in either the sports drink group or the water-only group.

GDG interpretation of the evidence (eating and drinking in labour)

The development of ketosis in labour may be associated with nausea, vomiting and headache and may be a feature of exhaustion. Limited evidence suggests that a light diet or fluid carbohydrate intake in labour may reduce ketone body production while maintaining or increasing glucose and insulin. However, the volume of stomach contents may increase, increasing the chances of the woman being sick. There are no differences in any measured outcomes.

Recommendations on eating and drinking labour

27. Inform the woman that she may drink during established labour and that isotonic drinks may be more beneficial than water. [2007]

28. Inform the woman that she may eat a light diet in established labour unless she has received opioids or she develops risk factors that make a general anaesthetic more likely. [2007]

Hygiene measures during labour

Introduction

Puerperal sepsis was the leading cause of maternal mortality in the UK up until the early 20th century. Deaths due to sepsis fell dramatically following the widespread availability of antibiotics in the 1940s and the passing of the Abortion Act in 1967, with no deaths from sepsis being reported in the triennium 1982–84. Unfortunately, deaths from sepsis have been reported in each of the subsequent triennial reports, with 13 maternal deaths being directly attributed to sepsis in the 2000–02 report: five women following a vaginal birth, two after giving birth at home. The continued deaths of previously healthy women by overwhelming infection following childbirth and the spread of blood-borne diseases such as HIV highlight the importance of adequate hygiene measures during labour, to protect both the woman and her caregivers. Many women are exposed to invasive procedures during labour, all of which have potential to introduce pathogens into the genital tract. While the rituals of perineal shaving and the administration of enemas, previously performed to reduce contamination of the genital tract during birth, have been discredited, well-established practices of cleansing and draping the vulva prior to vaginal examinations and birth are still commonly practised.

General points

General points in infection control were reviewed in the NICE clinical guideline Infection Control, published in June 2003.[7] The guideline reviewed 169 articles for the section relating to general principles of infection control. Twenty-six recommendations were provided for areas of hand hygiene, use of personal protective equipment, and safe use and disposal of sharps. The recommendations below are specific to women in labour; however, they do not override the recommendations in the Infection Control guideline.

Review question

Are there effective hygiene strategies for vaginal birth out of water to protect both women and babies, and healthcare professionals?

- Strategies include vaginal examination and antisepsis.

- Outcomes include infection control and rates of infection.

Chlorhexidine vaginal douching and perineal cleaning

Chlorhexidine vaginal douching

Description of included studies

There was one systematic review identified. This review included three RCTs (n = 3012) in the USA, comparing chlorhexidine vaginal douching during labour with sterile water as a placebo control.[117] [EL = 1++]

Review findings

Women's outcomes

Three trials reported the incidence of chorioamnionitis, including 1514 and 1498 women in the chlorhexidine and placebo groups, respectively. There was no statistically significant difference between the two groups (RR 1.10 [95% CI 0.86 to 1.42]). The same three trials also reported the incidence of postpartum endometritis. Although the data suggested a small reduction in the risk of postpartum endometritis with the use of the chlorhexidine vaginal wash, the difference was not statistically significant (RR 0.83 [95% CI 0.61 to 1.13]). There was no report of other maternal outcomes or side effects of chlorhexidine in these three trials.

Newborn outcomes

Three trials reported on neonatal outcomes, involving 1495 and 1492 neonates in the chlorhexidine and placebo groups, respectively. One trial (n = 910 neonates) indicated that there was no significant difference in neonatal pneumonia (RR 0.33 [95% CI 0.01 to 8.09]). For neonatal meningitis, one trial with 508 and 513 neonates in the intervention and control groups, respectively, did not show significant difference (RR 0.34 [95% CI 0.01 to 8.29]). Two trials, involving 1038 and 1039 neonates in the intervention and control groups, respectively, found neither significant difference in blood culture confirming sepsis (RR 0.75 [95% CI 0.17 to 3.35]) nor in perinatal mortality (RR 1.00 [95% CI 0.17 to 5.79]). No significant difference was found for neonatal sepsis (three trials, n = 2987; RR 0.75 [95% CI 0.17 to 3.35]). There was a trend suggesting that the use of vaginal chlorhexidine during labour might lead to a higher tendency for newborns to receive antibiotics, but this association was not statistically significant (RR 1.65 [95% CI 0.73 to 3.74]). No other neonatal outcomes or side effects of chlorhexidine were reported.

Perineal cleaning

Description of included studies

There was one UK controlled study (n = 3905) identified which compared cetrimide/chlorhexidine for perineal cleaning during labour with tap water.[118] [EL = 2+] The allocation of intervention/control was by alternate months. The study population included women who had a caesarean birth (17.2% for cetrimide/chlorhexidine and 16.3% for tap water).

Review findings

Women's outcomes

The findings (cetrimide/chlorhexidine group n = 1813; tap water group n = 2092) showed no evidence of a difference in the number of women who developed fever (temperature > 38 °C) (OR 1.2 [95% CI 0.8 to 1.9]), use of antibiotics (OR 1.02 [95% CI 0.86 to 1.9]), perineal infection (OR 1.4 [95% CI 0.77 to 2.7]), perineal infection (OR 1.4 [95% CI 0.77 to 2.7]), perineal breakdown (OR 5.8 [95% CI 0.3 to 999]) or caesarean wound infection (OR 1.3

[95% CI 0.86 to 1.9]). There was one maternal death in each arm: both were considered to be due to anticardiolipin syndrome.

Newborn outcomes

The results for babies' outcomes showed no difference in eye infection (OR 1.1 [95% CI 0.78 to 1.7]), cord infection (OR 1.3 [95% CI 0.7 to 2.1]), other infections not specified (OR 0.87 [95% CI 0.65 to 1.2]), admission to SCBU (OR 1.1 [95% CI 0.9 to 1.4]), use of antibiotics (OR 0.99 [95% CI 0.82 to 1.2]) or fever (temperature > 38 °C) (OR 1.4 [95% CI 0.66 to 3.0]). There were 27 perinatal deaths reported in the cetrimide/chlorhexidine group (total n = 1813) and 21 perinatal deaths reported in the water group (total n = 209). The causes of death were reported as one due to uterine rupture and three due to intrapartum asphyxia in the cetrimide/chlorhexidine group, and one due to necrotising enterocolitis and one due to neonatal septicaemia in the water group. Other deaths were considered to be due to either congenital abnormality or birthweight less than 1000 g.

Evidence statement

There is evidence that the use of cetrimide/chlorhexidine is no more effective than water for perineal cleaning.

No evidence exists to provide advice on the use of sterile gowns, sterile packs or vulval cleansing prior to vaginal examination or vaginal birth in reducing maternal or neonatal morbidity.

Recommendations on vaginal douching and perineal cleaning

29. Tap water may be used if cleansing is required before vaginal examination. [2007]

Double gloves during episiotomy and other procedures

Double gloves during episiotomy

Description of included studies

There were two RCTs conducted in Thailand comparing the use of double gloves with single gloves while performing an episiotomy. Outcome measures were perforation rates only. The earlier study included 2058 sets of gloves (double-gloving n = 1316; single-gloving n = 742),[119] and the later study included 300 sets of gloves (double-gloving n = 150; single-gloving n = 150).[120]

Review findings

The earlier study reported perforation rates of double inner gloves as 2.7% ($P < 0.05$), outer as 5.9%, compared with single gloves as 6.7%. The later study reported perforation rates of double inner gloves as 4.6% ($P < 0.05$), outer as 22.6%, compared with single gloves as 18.0%.

Evidence statement

Wearing two gloves appears to reduce perforation rates in inner gloves compared with single-gloving. However, caution needs to be taken in interpreting these results as there was no concealment.

Arm sleeves

Description of included studies

One case series conducted in the UK (n = 80) has evaluated the effectiveness of wearing a sterile arm sleeve on top of the gown to prevent contamination during obstetric procedures.[121] [EL = 3]

Review findings

The contamination of arms and hands was 3.8% and 5%, respectively.

Evidence statement

There is insufficient evidence on the use of a sterile arm sleeves in preventing contamination.

Recommendations on double-gloving

30. Routine hygiene measures taken by staff caring for women in labour, including standard hand hygiene and single-use non-sterile gloves, are appropriate to reduce cross-contamination between women, babies and healthcare professionals. [2007]

31. Selection of protective equipment must[o] be based on an assessment of the risk of transmission of microorganisms to the woman, and the risk of contamination of the healthcare worker's clothing and skin by women's blood, body fluids, secretions or excretions.[p] [2007, amended 2014]

Identification of women and babies who may need additional care

The GDG members decided to use the criteria below (the list is not exhaustive) to identify women and babies who may need additional care, and therefore would need referral to specialist care not covered in this guideline:

- intrapartum haemorrhage
- placental abruption
- ruptured uterus
- 'suspected' amniotic fluid embolus
- 'suspected' pulmonary embolus
- eclampsia and severe pre-eclampsia
- cord prolapse
- shoulder dystocia
- massive obstetric haemorrhage
- maternal collapse
- monitoring suggesting fetal compromise
- undiagnosed breech.

o In accordance with current health and safety legislation (at the time of publication of NICE clinical guideline 139 [March 2012]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Hazardous to Health Regulations 2002, Personal Protective Equipment Regulations 2002 and Health and Social Care Act 2008.

p This recommendation is adapted from Infection: prevention and control of healthcare-associated infections in primary and community care (NICE clinical guideline 139).

Latent phase

Effectiveness of service interventions for providing care in the latent phase

Introduction

Many women, especially those having their first baby, experience a long latent first stage of labour which is usually spent at home without the support of a healthcare professional. This can be unsettling or upsetting for some women who often express anxiety at the uncertainty associated with this phase. Women may decide to attend their chosen place of birth, or call a midwife to their home if planning a home birth, seeking advice and support for this stage of labour, uncertain as to whether labour has become established. For a proportion of women this will result in being told that labour is still in the very early stages and that it is appropriate to return home, or remain at home without a midwife in support. The questions in this chapter seek to determine what types of service provision and what forms of non-pharmacological pain relief are associated with the best birth outcomes, including women's experience of the latent first stage of labour.

Review question

What is the effectiveness of different service interventions for providing care to women in the latent first stage of labour?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

Nine studies (Weavers and Nash 2012; Green et al., 2011; Lauzon and Hodnett, 2010; Maimburg et al., 2010; Lauzon and Hodnett, 2009; Hodnett et al., 2008; Paz-Pascual et al., 2008; Janssen et al., 2006; Janssen, et al., 2003;) are included in this review. One study (Lauzon and Hodnett, 2009) was a systematic review consisting of 1 study evaluating the effectiveness of teaching pregnant women how to self-diagnose the onset of active labour in term pregnancy. Another systematic review (Lauzon and Hodnett, 2010) also comprised only 1 study and examined the effectiveness of a labour assessment programme to delay hospital admission. Two studies conducted in the UK (Weavers and Nash 2012; Green et al., 2011) evaluated women's satisfaction with early labour telephone assessment (triage line). One trial conducted in Denmark (Maimburg et al., 2010) and 1 observational study carried out in Spain (Paz-Pascual et al., 2008) compared the birth process in nulliparous women enrolled in a structured antenatal training programme, with women allocated to routine care. Two studies conducted in Canada (Janssen et al., 2006 and Janssen et al., 2003) compared the effectiveness of obstetric triage at home compared with that performed by telephone on childbirth outcomes. A further multicentre trial conducted in Canada (Hodnett et al., 2008) examined the effect of a complex nursing and midwifery intervention in hospital labour assessment units (termed 'structured care') on the likelihood of spontaneous vaginal birth and other maternal and neonatal outcomes.

Evidence profile

The findings for the effectiveness of different service interventions for providing care to women in the latent first stage of labour are reported in 4 GRADE profiles and the findings for 2 studies with qualitative elements is summarised in table 47. The following comparisons were considered based on different interventions:

- early labour assessment versus direct admission to labour ward
- 'structured care' versus usual care in latent phase
- early labour assessment and support at home versus telephone triage
- labour diagnosis education versus standard care for self-diagnosis of the onset of active labour at term

- early labour telephone assessment (triage line).

For further information on interventions please see table footnotes and the evidence table (Appendix I).

Table 47: Summary GRADE profile for comparison of early labour assessment versus direct admission to labour ward

Number of studies	Design	Number of women		Effect		Quality
		Early labour assessment[a]	Direct admission	Relative (95% CI)	Absolute (95% CI)	
Caesarean section						
1 study (Lauzon & Hodnett, 2010)	randomised trials	8/105 (7.6%)	11/104 (10.6%)	RR 0.72 (0.3 to 1.72)	30 fewer per 1000 (from 74 fewer to 76 more)	Very low
Forceps/vacuum extraction						
1 study (Lauzon & Hodnett, 2010)	randomised trials	32/105 (30.5%)	37/104 (35.6%)	RR 0.86 (0.58 to 1.26)	50 fewer per 1000 (from 149 fewer to 92 more)	Very low
Epidural analgesia						
1 study (Lauzon & Hodnett, 2010)	randomised trials	83/105 (79%)	94/104 (90.4%)	RR 0.87 (0.78 to 0.98)	117 fewer per 1000 (from 18 fewer to 199 fewer)	Moderate
Any intrapartum analgesia						
1 study (Lauzon & Hodnett, 2010)	randomised trials	84/105 (80%)	96/104 (92.3%)	RR 0.87 (0.78 to 0.97)	120 fewer per 1000 (from 28 fewer to 203 fewer)	Moderate
Intrapartum narcotic/inhalation analgesia						
1 study (Lauzon & Hodnett, 2010)	randomised trials	1/105 (0.95%)	2/104 (1.9%)	RR 0.5 (0.05 to 5.38)	10 fewer per 1000 (from 18 fewer to 84 more)	Very low
Intrapartum oxytocics						
1 study (Lauzon & Hodnett, 2010)	randomised trials	24/105 (22.9%)	42/104 (40.4%)	RR 0.57 (0.37 to 0.86)	174 fewer per 1000 (from 57 fewer to 254 fewer)	Low
Artificial rupture of membranes						
1 study (Lauzon & Hodnett, 2010)	randomised trials	49/105 (46.7%)	56/104 (53.8%)	RR 0.87 (0.66 to 1.14)	70 fewer per 1000 (from 183 fewer to 75 more)	Very low

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		Early labour assessment[a]	Direct admission	Relative (95% CI)	Absolute (95% CI)	
Discharged undelivered						
1 study (Lauzon & Hodnett, 2010)	randomised trials	19/105 (18.1%)	17/104 (16.3%)	RR 1.11 (0.61 to 2.01)	18 more per 1000 (from 64 fewer to 165 more)	Very low
Length of time from hospital admission to birth (hours)						
1 study (Lauzon & Hodnett, 2010)	randomised trials	Mean 8.3 (SD 5.6) n=105	Mean 13.5 (SD 7.9) n=104	NC	MD 5.2 shorter (7.06 shorter to 3.34 shorter) p<0.00001	Moderate
Perceived control[b]						
1 study (Lauzon & Hodnett, 2010)	randomised trials	Mean 158 (SD 27) n=99	Mean 142 (SD 34) n=102	NC	MD 16 higher (7.53 higher to 24.47 higher) p<0.0002	Moderate
5-minute Apgar <7						
1 study (Lauzon & Hodnett, 2010)	randomised trials	1/105 (0.95%)	0/104 (0%)	RR 2.97 (0.12 to 72.12)	NC	Very low
Neonatal resuscitation						
1 study (Lauzon & Hodnett, 2010)	randomised trials	4/105 (3.8%)	5/104 (4.8%)	RR 0.79 (0.22 to 2.87)	10 fewer per 1000 (from 38 fewer to 90 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation

a. Labour assessment consisted of checking: fetal heart rate, uterine test, maternal blood pressure, status of amnion membranes and presence of bloody show
b. Assessed by Labour Agency Scale; an instrument measuring expectancies and experiences of personal control during childbirth (a validated tool, no more details provided)

Update 2014

Table 48: Summary GRADE profile for comparison of 'structured care' in labour assessment unit versus usual care in latent phase

Number of studies	Design	Number of women		Effect		Quality
		'Structured care'[a]	Usual care	Relative (95% CI)	Absolute (95% CI)	
Spontaneous vaginal birth						
1 study (Hodnett et al., 2008)	randomised trials	1597/2497 (64%)	1533/2499 (61.3%)	RR 1.04 (1.0 to 1.09)	25 more per 1000 (from 0 fewer to 55 more)	Moderate
Caesarean section						
1 study (Hodnett et al., 2008)	randomised trials	559/2497 (22.4%)	604/2499 (24.2%)	RR 0.93 (0.84 to 1.02)	17 fewer per 1000 (from 39 fewer to 5 more)	Moderate
Instrumental vaginal birth						
1 study (Hodnett et al., 2008)	randomised trials	341/2497 (13.7%)	362/2499 (14.5%)	RR 0.94 (0.82 to 1.08)	9 fewer per 1000 (from 26 fewer to 12 more)	Moderate
Intramuscular or intravenous opioid						
1 study (Hodnett et al., 2008)	randomised trials	1126/2497 (45.1%)	1078/2499 (43.1%)	RR 1.05 (0.98 to 1.11)	22 more per 1000 (from 9 fewer to 47 more)	Moderate
Regional analgesia or anaesthesia						
1 study (Hodnett et al., 2008)	randomised trials	2112/2497 (84.6%)	2159/2499 (86.4%)	RR 0.98 (0.96 to 1)	17 fewer per 1000 (from 35 fewer to 0 more)	Moderate

CI confidence interval, RR relative risk

a. Participants in the 'structured care' group received one to one care by a nurse or midwife. The nurse or midwife tried to normalise the environment, palpate to assess fetal position, encourage maternal positions that promote fetal head rotation or relieve pain, assess labour pain using a visual analogue scale and asked women to describe their thoughts during the last contraction and demonstrated interventions to manage labour pain (be present continuously; encourage comfort measures, including breathing and relaxation, application of heat and cold, massage, shower or bath, movement; encourage visualisation techniques, suggesting music and rhythmic techniques)

Update 2014

Table 49: Summary GRADE profile for comparison of early labour assessment and support at home versus telephone triage

Number of studies	Design	Number of women		Effect		Quality
		Home visit[a]	Telephone triage	Relative (95% CI)	Absolute (95% CI)	
Vaginal birth						
1 study (Janssen et al., 2006)	randomised trials	336/728 (46.2%)	329/731 (45%)	RR 1.03 (0.92 to 1.15)	14 more per 1000 (from 36 fewer to 68 more)	High
Forceps/vacuum extraction						
1 study (Janssen et al., 2006)	randomised trials	184/728 (25.3%)	216/731 (29.5%)	RR 0.86 (0.72 to 1.01)	41 fewer per 1000 (from 83 fewer to 3 more)	Moderate
Caesarean section						
1 meta-analysis of 2 studies (Janssen et al., 2006; Janssen, et al., 2003)	randomised trials	229/845 (27.1%)	206/851 (24.2%)	RR 1.12 (0.95 to 1.32)	29 more per 1000 (from 12 fewer to 77 more)	Low
Number of visits to assessment room (no visits)						
1 study (Janssen et al., 2006)*	randomised trials	260/728 (35.7%)	194/731 (26.5%)	RR 1.35 (1.15 to 1.57)	93 more per 1000 (from 40 more to 151 more)	Moderate
Number of visits to assessment room (one visit)						
1 study (Janssen et al., 2006)*	randomised trials	331/728 (45.5%)	368/731 (50.3%)	RR 0.9 (0.81 to 1.01)	50 fewer per 1000 (from 96 fewer to 5 more)	High
Number of visits to assessment room (two to five visits)						
1 study (Janssen et al., 2006)	randomised trials	137/728 (18.8%)	169/731 (23.1%)	RR 0.81 (0.67 to 0.99)	44 fewer per 1000 (from 2 fewer to 76 fewer)	Moderate

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		Home visit[a]	Telephone triage	Relative (95% CI)	Absolute (95% CI)	
Use of epidural						
1 meta-analysis of 2 studies (Janssen et al., 2006; Janssen, et al., 2003)	randomised trials	516/843 (61.2%)	558/851 (65.6%)	RR 0.93 (0.87 to 1)	46 fewer per 1000 (from 85 fewer to 0 more)	Moderate
Use of narcotic analgesia IM or IV						
1 meta-analysis of 2 studies (Janssen et al., 2006; Janssen et al., 2003)	randomised trials	335/843 (39.7%)	358/851 (42.1%)	RR 0.94 (0.84 to 1.06)	25 fewer per 1000 (from 67 fewer to 25 more)	Low
Satisfied with the level of information received[b]						
1 study (Janssen et al., 2003)	randomised trials	70/98 (72.2%)	48/85 (57.1%)	RR 1.26 (1.01 to 1.58)	147 more per 1000 (from 6 more to 328 more)	Low
Number of women who believed that the nurse respected their wishes about going to hospital						
1 study (Janssen et al, 2003)	randomised trials	73/98 (78.5%)	41/85 (53.9%)	RR 1.54 (1.26 to 1.98)	260 more per 1000 (from 96 more to 473 more)	Moderate
Number of women that would recommend this type of care to a friend						
1 study (Janssen et al., 2003)	randomised trials	77/98 (78.6%)	47/85 (55.3%)	RR 1.42 (1.14 to 1.77)	232 more per 1000 (from 77 more to 426 more)	Low
Not coping with contractions on admission						
1 study (Janssen et al., 2006)	randomised trials	146/728 (20.1%)	197/731 (26.9%)	RR 0.74 (0.62 to 0.9)	70 fewer per 1000 (from 27 fewer to 102 fewer)	Moderate
Baby - Suction with endotracheal tube						
1 study (Janssen et al., 2006)*	randomised trials	56/728 (7.7%)	62/731 (8.5%)	RR 0.91 (0.64 to 1.28)	8 fewer per 1000 (from 31 fewer to 24 more)	Low

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Number of studies	Design	Number of women		Effect		Quality
		Home visit[a]	Telephone triage	Relative (95% CI)	Absolute (95% CI)	
Admission to level II nursery						
1 meta-analysis of 2 studies (Janssen et al., 2006; Janssen et al., 2003)	randomised trials	47/845 (5.6%)	62/774 (8%)	RR 0.68 (0.48 to 0.96)	26 fewer per 1000 (from 3 fewer to 42 fewer)	Low
Admit to level III nursery						
1 study (Janssen et al., 2006)	randomised trials	14/728 (1.9%)	6/731 (0.82%)	RR 2.34 (0.91 to 6.06)	11 more per 1000 (from 1 fewer to 42 more)	High
5-minute Apgar <7						
1 meta-analysis of 2 studies (Janssen et al., 2006; Janssen et al, 2003)	randomised trials	9/845 (1.1%)	7/851 (0.82%)	RR 1.28 (0.49 to 3.31)	2 more per 1000 (from 4 fewer to 19 more)	Moderate

CI confidence interval, IM intramuscular, IV intravenous, RR relative risk

a. Women randomised to the nurse visit were told that a nurse would be leaving the hospital immediately. The nursing assessment at home was the same as to that over the phone but, in addition, women were assessed for vital signs, abdominal palpation, auscultation of the fetal heart rate.
Women randomised to the telephone triage group were assessed over the phone by study nurses about their contractions, the presence of bloody show, the status of the membranes, colour of amniotic fluid (if present), the presence of vaginal bleeding , the nature of fetal movements, and their own assessment of how they were coping. Women's responses were documented on standard hospital forms. Women with coloured amniotic fluid, vaginal bleeding and decreased fetal movements were advised to come to hospital. Those who were no longer able to cope with contractions, or if the contractions were more frequent than every 5 minutes or lasting longer than 1 minute, were also advised to come to hospital. Suggestions for coping with contractions were made over the phone.
b. Number of women who replied "yes, definitely"

Update 2014

Table 50: Summary GRADE profile for comparison of labour diagnosis education versus standard care for self-diagnosis of the onset of active labour at term

Number of studies	Design	Number of women		Effect		Quality
		Labour diagnosis education[a]	Standard care	Relative (95% CI)	Absolute (95% CI)	
Visits to labour suite before active labour						
1 study (Lauzon & Hodnett, 2009)	randomised trials	Mean 0.29 (SD 0.59) n=104	Mean 0.58 (SD 0.72) n=104	NC	MD 0.29 lower (0.47 lower to 0.11 lower) p=0.001	Moderate
Cervix >3cm on arrival at the maternity ward						
1 study Maimburg et al. (2010)	randomised trials	307/ 587 (52.3)	207/57 (36%)	RR 1.45 (95% CI 1.26 to 1.65)	126 more per 1000 (from 97 more to 238 more)	Low
Use of anaesthesia in the latent phase						
1 study (Paz-Pascual et al., 2008)	prospective cohort	101/509 (20%)[b]	17/45 (39%)	RR 0.53 (95% CI 0.35 to 0.75)	178 fewer per 1000 (from 79 fewer to 246 fewer)	Very low
Visited the hospital in 'false' labour						
1 study (Paz-Pascual et al., 2008)	prospective cohort	71/509 (14%)[b]	14/45 (31%)	RR 0.45 (95% CI 0.28 to 0.73)	171 fewer per 1000 (from 84 fewer to 224 fewer)	Very low

CI confidence interval, MD mean difference, NC not calculable, SD standard deviation

a. Labour education in Lauzon & Hodnett, 2009 consisted of antenatal education regarding the palpation of uterine fundus, differentiation between Braxton- Hicks and active labour contractions, timing of contractions, recognition of amniotic fluid, and pain perception. In Maimburg et al. 2010, the training sessions consisted of antenatal lessons and discussion of labour onset, the birth process, the attending father, pain relief, birth interventions, fear of childbirth, and a film on giving birth. In Paz-Pascual et al., 2008 the education consisted of at least 8 sessions on breathing techniques, pushing, labour and birth, postpartum period, baby care, and breastfeeding.
b. 5 or more antenatal education sessions

Update 2014

Table 51: Findings for women's views and satisfaction with early labour telephone assessment

Women's views/satisfaction and birth outcomes following establishment of triage line[a]	
Weavers & Nash 2012 [Very low quality][1]	Total women served: n=88 Women's view of triage service Excellent: 69% Good: 29% Average: 2% Women's responses to the following questions: Was the information given by the midwife reassuring and helpful? Yes: 100% No: 0% Were you advised about coping strategies? (if the judgement was that the woman should remain at home) Yes: 92% No: 8% Did you feel confident with the plan of care discussed over the phone? Yes: 97% No: 3% Birth outcomes 6 months before and 6 months after introduction of the triage line in MLU (women in both groups had low risk pregnancies and first birth. Women in 'after triage' group accessed the triage line): Spontaneous vaginal birth (the percentages are an approximate measure) Before triage: 59% After triage: 70% Assisted vaginal birth Before triage: 25% After triage: 23% Caesarean section Before triage: 15% After triage: 10%
Women's views and satisfaction with early labour telephone assessment ("the Pathway")[b]	
Green et al., 2011 [Low quality][2]	Satisfaction Very satisfied: n=16 (35%) Satisfied: 17 (37%) Dissatisfied: n=13 (28%) Women aged over 30 were significantly more likely than younger women to be very satisfied (OR=25.9 [95% CI 3.0 to 223.8]) Dissatisfaction Dissatisfaction reported in relation to: - unclear and inadequate advice and information

Update 2014

Women's views/satisfaction and birth outcomes following establishment of triage line[a]	
	- unmet needs for support (ill-defined criteria for what to do next/when to call back or attend the unit) - unaddressed fears or anxieties - negative midwife manner and not being treated as an individual with respect - short length of call (more who reported call <5 min were significantly dissatisfied OR 7.0 [95% CI 1.7 to 29.1]) - being sent home from maternity unit (women who were sent home after attending maternity unit were significantly more dissatisfied compared with those who were not sent home OR 5.8 [95% CI 1.3 to 25.4]) Very satisfied Women were very satisfied by - having preparation for what to expect - the perceived adequacy of the advice given Antenatal awareness and preparation about "the Pathway" Little difference observed between satisfied and dissatisfied group, but satisfied group were more likely to have seen the leaflet, discussed the 'pathway' with the midwife and to have expected to stay at home in early labour but there was no strong relation between the preparation and high satisfaction; less than half the women who had had the antenatal preparation were very satisfied

CI confidence interval, OR odds ratio

a. A 6 month pilot labour triage telephone line was established, the line was live for 12 hours period, 7 days a week.
b. "The pathway" (The All Wales Clinical Pathway for Normal Birth) covers telephone assessment and communication with women to encourage them to remain at home until labour is established
1. Women's characteristic not reported. Unclear how data were analysed. Unclear if the questionnaire was a validated tool. Incomplete data reported.
2. Unclear selection criteria hence high risk of selection bias. Incomplete data reported.

Evidence statements

Early labour assessment versus direct admission to labour ward

Evidence from 1 study (n=4996) showed that use of 'any intrapartum analgesia', epidural analgesia specifically, and intrapartum oxytocic were lower in women who received early labour assessment compared with women who were admitted directly to the labour ward. In addition, moderate quality evidence found that the length of time from hospital admission to birth was shorter, and women's perceived control was higher, in the group who received early labour assessment compared with women who were admitted directly to the labour ward. No differences were found between the two groups for any other findings including the rate of caesarean section and the rate of instrumental birth. The evidence was of moderate to low quality.

'Structured care' in labour assessment unit versus usual care in latent phase

Evidence from one study (n=4996) showed that there was a trend towards the rate of spontaneous vaginal birth being higher and the use of regional analgesia being lower in women who received a package of care known as 'structured care' compared with women who received usual care. There was no evidence of a difference in the rate of caesarean section, instrumental vaginal birth, intramuscular or intravenous opioid use or regional analgesia or anaesthesia use between the two groups. The evidence was of moderate quality.

Early labour assessment and support at home versus telephone triage in latent phase

There was evidence that the number of visits to an assessment room (hospital) (n=1459) was lower and satisfaction (n=183) was higher in women who received a home visit in the latent phase compared with women who received telephone triage. However, no differences were

found between the 2 groups in the rate of vaginal birth (n=1459), caesarean section (n=1696), forceps/vacuum extraction (n=1459), intrapartum analgesia use (n=1694), neonatal admission to intensive care unit (n=3078) and neonatal Apgar score less than 7 at 5 minutes (n=1696). The evidence was of moderate to low quality.

Labour diagnosis education versus standard care for self-diagnosis of the onset of labour

Evidence from 1 study (n=208) showed a lower rate of visits to the labour ward before active labour in women who received antenatal and labour diagnosis education compared with women who received standard care without labour diagnosis education. A higher number of women arrived at the labour ward with their cervix dilated more than 3 cm among those who received labour diagnosis education compared with women who received standard care without labour diagnosis education (n=644). Lower use of anaesthesia was found in the latent phase in women who received antenatal and labour diagnosis education compared with women who received standard care (n=554). The evidence was of low to very low quality.

Women's views and satisfaction with early labour telephone assessment

Two studies (n=135) investigated women's views and satisfaction with early labour telephone assessment. Women were very satisfied when they were prepared for what to expect and received adequate advice in a reassuring way. Not being treated as a unique person and in a respectful manner by the midwife, not being provided with adequate information and clear criteria for what to do next, and a short length of the telephone call (less than 5 minutes) contributed to women's dissatisfaction with the early labour telephone assessment. The evidence was of low and very low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was fundamental to consider women's satisfaction with the type of service intervention they receive in the latent phase. They felt that interventions that reduce a woman's fear and anxiety might reduce the number of visits she makes to the labour ward and consequently cause less exhaustion during the labour as she will be saving her energy resources that she requires for labour. It is therefore important to identify how each intervention can best ensure women's satisfaction and improve maternal and neonatal outcomes. The group was aware that not all types of service interventions are applicable to the UK setting.

Consideration of clinical benefits and harms

The guideline development group discussed the findings from the 8 studies. They noted that although there were no statistically significant differences in any outcomes reported when the intervention was 'structured care' (which comprised one-to-one nurse or midwife care for a minimum of 1 hour in an assessment unit) compared with usual care (which did not include one-to-one care), there was a trend towards an increase in the number of spontaneous vaginal births and a decreased use of regional analgesia. The group noted that the study was only powered to detect a difference in the spontaneous vaginal birth rate. The presence of nurses providing intrapartum care on labour wards reflects the fact this study was conducted in Canada.

The group then discussed the findings from the other studies. The group noted that for the comparison between early assessments with direct admission to labour ward, there was statistically significantly less use of epidural analgesia, less intrapartum analgesia and less intrapartum oxytocics in the intervention group. In addition, these women had a lower length of time from hospital admission to birth and higher perceived control. It was also noted that the model of care in the study appeared to be different to a UK setting as there were much

higher rates of epidural use and instrumental birth in both arms of the study than would be expected in the UK.

The group discussed the comparison between early assessments at home with telephone triage. In the home assessment group, the number of women who did not require a visit to the assessment unit was significantly increased. It was also found that fewer women in the home assessment group required 2 to 5 visits to the assessment unit. More women in the home assessment group felt satisfied with the level of information they received, felt their wishes had been respected and would recommend their care to a friend. Furthermore, fewer women in the home assessment group weren't able to cope with their contractions on admission and fewer neonates from this group were admitted to a level II nursery. The group noted that in the study home visits were restricted to daylight hours.

The group also noted that women who had received focussed antenatal education to help them recognise the latent first stage and be able to 'diagnose' the onset of established labour had fewer admissions to labour ward in 'false' labour, were more likely to attend the labour ward in established labour and used less anaesthesia in the latent first stage, suggesting this was a successful programme. The group discussed the necessary components of this focussed education programme and included these in the recommendation.

It was recognised that when triaging women by telephone it can be difficult to identify those women who need to come in to the maternity unit and those who can safely be advised to wait at home. It was felt this service was better provided as a dedicated service rather than a phone on the labour ward. Also, the group felt that the service works better if one of the established models of care are used, such as caseload or team midwives or community midwives who could be on call for this component of care.

The group recognised that the findings appeared to show that a number of the interventions could be effective in improving outcomes and drafted a recommendation that healthcare professionals should consider offering them.

Overall, it was agreed that although some of the studies did not report statistically significant findings, there were studies that did provide clear demonstration of clinical benefit. The group felt confident in recommending service interventions for use in the latent first stage. It was also noted that there was no evidence of harm associated with the interventions.

Consideration of health benefits and resource uses

It was recognised that there could be a health economic benefit in reducing the number of unnecessary visits by women to the hospital in the latent first stage of labour by ensuring that midwives could focus on those women already in active labour. However, it was felt that there might not be much cost saving if this required a midwife to be available to perform home visits day and night. The resource implications of this service intervention will vary depending on each service. A small freestanding midwifery unit which is not staffed continually may benefit from the service providing home visits as the midwife would be on call anyway and less time would then be spent in the midwifery unit. Some services have a dedicated triage midwife in the unit who takes calls and sees women as they come to the unit before another midwife takes over to provide care during established labour. In this setting the triage midwife in the unit will be able to assist more women than if the midwife was doing home visits. However, a community midwife visiting a woman who the midwife already knows and knows her history may reduce the amount of time needed for the assessment compared with the time needed by a hospital-based midwife who doesn't know the woman. If the woman has been seen by a midwife she knows in her own environment this may reduce her anxiety and also increase her satisfaction with the service. It was also noted that there could be safety issues to consider for midwives being asked to attend home settings at night, particularly where the midwife has not visited that address previously.

Quality of evidence

The evidence available for this review consisted of randomised trials ranking from high to low quality. It was noted that some studies had considerable limitations and a high risk of bias in both data collection and analysis. It was unfortunate that the systematic review was only of 1 study.

Other considerations

When listening to the woman's story or giving advice to women over the telephone, midwives must be aware of the additional needs of women who are unable to speak or understand English. To ensure the advice given is appropriate and safe, interpretation services should be provided. It is also important to make sure that women understand the advice given and know what action to take should labour develop. This is of particular importance when dealing with women with mental health problems. The midwife also needs to consider potential transportation difficulties, for example for women who do not have their own means of transport or who have a physical disability preventing easy access to the service, and provide advice that takes these issues into consideration.

The importance of safety when providing early labour advice was considered paramount, especially when this advice is being offered over the telephone. This is reflected in the recommendations, which also emphasise the importance of communicating effectively with the woman and ensuring she understands the information given, what to expect and what actions to take as labour progresses.

The fact that a lengthy latent phase is more likely for nulliparous women meant that some recommendations were focussed on this group.

Finally, the guideline development group was of the view that if the assessment had to be undertaken in a midwifery unit or hospital, it was important that it takes place in a private room so that vaginal examinations can be undertaken in privacy.

Key conclusions

The guideline development group felt that all the service interventions reviewed were associated with some improved outcomes and that it was not possible to recommend one over another. Therefore they decided to recommend that all be considered and that services are provided depending upon what is appropriate based on local need and service configuration. Good communication between the midwife and the woman and ensuring the safety of the woman and her baby are essential.

Recommendations

32. Give all nulliparous women information antenatally about:

- what to expect in the latent first stage of labour
- how to work with any pain they experience
- how to contact their midwifery care team and what to do in an emergency. [new 2014]

33. Offer all nulliparous women antenatal education about the signs of labour, consisting of:

- how to differentiate between Braxton Hicks contractions and active labour contractions
- the expected frequency of contractions and how long they last
- recognition of amniotic fluid ('waters breaking')
- description of normal vaginal loss. [new 2014]

Update 2014

34. **Consider an early assessment of labour by telephone triage provided by a dedicated triage midwife for all women. [new 2014]**

35. **Consider a face-to-face early assessment of labour for all low-risk nulliparous women, either:**
    - at home (regardless of planned place of birth) **or**
    - in an assessment facility in her planned place of birth (midwifery-led unit or obstetric unit), comprising one-to-one midwifery care for at least 1 hour. [new 2014]

36. **Include the following in any early or triage assessment of labour:**
    - ask the woman how she is, and about her wishes, expectations and any concerns she has
    - ask the woman about the baby's movements, including any changes
    - give information about what the woman can expect in the latent first stage of labour and how to work with any pain she experiences
    - give information about what to expect when she accesses care
    - agree a plan of care with the woman, including guidance about who she should contact next and when.
    - provide guidance and support to the woman's birth companion(s). [new 2014]

37. **The triage midwife should document the guidance that she gives to the woman. [new 2014]**

38. **If a woman seeks advice or attends a midwifery-led unit or obstetric unit with painful contractions, but is not in established labour:**
    - recognise that a woman may experience painful contractions without cervical change, and although she is described as not being in labour, she may well think of herself as being 'in labour' by her own definition
    - offer her individualised support, and analgesia if needed
    - encourage her to remain at or return home, unless doing so leads to a significant risk that she could give birth without a midwife present or become distressed. [new 2014]

Update 2014

Research recommendations

10. **Does enhanced education specifically about the latent first stage of labour increase the number of nulliparous women who wait until they are in established labour before attending the obstetric or midwifery unit (or calling the midwife to a home birth), compared with women who do not receive this education?**

Why this is important

Studies show that antenatal education about labour and birth in general makes a difference to some birth outcomes, but there is limited evidence focusing on education about the latent first stage of labour specifically. The aim of this study (randomised controlled trial or prospective observational study) would be to compare 2 groups of women experiencing their first labour and birth: a group who receive an education session in late pregnancy covering what to expect

in the latent first stage of labour and how to recognise the onset of established labour, and a group who have not received this focused education. Primary outcomes would be mode of birth, satisfaction with the birth experience and the woman's physical and emotional wellbeing after birth. Secondary outcomes would be use of pharmacological pain relief, use of oxytocin to augment labour, and time from first contact in confirmed established labour to birth.

11. **What is the effectiveness of a care package which includes telephone triage by a midwife plus antenatal education about what to expect during the latent phase and first stage of labour and pain-relieving techniques that can be used during the latent phase before midwifery care begins. Compared to a care package of standard care, how satisfied are women with each package of care, and what is the cost effectiveness of each package of care?**

Population: nulliparous and multiparous women at low risk of intrapartum complications
Intervention: care package including telephone triage by a midwife, plus antenatal education about what to expect during the latent phase and first stage of labour and pain-relieving techniques for use in the latent phase.
Comparator: standard care
Primary outcome: child health/development outcome at 2 and 5 years
Secondary outcomes: mode of birth, transfer to obstetric care, maternal and neonatal morbidity and women's satisfaction with labour and birth experience
Study design: randomised controlled trial or prospective observational study

Why this is important
Women in the latent first stage of labour frequently attend hospital for assessment and are advised to return home because they are in the latent stage. Provision of a care package which reduces the number of women attending hospital in the early stages of labour is reported to improve satisfaction as well as outcomes for these women. An analysis is necessary in order to establish the most effective and cost-effective care package with the optimal satisfaction for women receiving the care package. A sub-group analysis to further investigate any difference in outcomes when the care is delivered by a familiar or unfamiliar midwife would also be of value.

12. **What is the effectiveness of an initial face-to-face assessment by a midwife of women who report being in labour being carried out in the woman's home, compared to the assessment being carried out in the planned place of birth (where this is not at home), and how satisfied are women with the assessment?**

Population: nulliparous and multiparous women at low risk of intrapartum complications planning birth in a midwifery unit or an obstetric unit.
Intervention: first assessment of women who report being in labour, carried out at the woman's home
Comparison: first assessment of women who report being in labour, carried out at a birth setting other than the woman's home (the woman's planned place of birth)
Outcomes: planned and actual birth location, mode of birth, transfer to obstetric care, maternal and neonatal morbidity, women's satisfaction with the experience of assessment (one month after the birth, and one year after the birth.)
Study design: Randomised controlled trial or prospective observational study

Why this is important
Women in the latent stage of labour frequently attend hospital for assessment and are advised to return home because they are in the latent stage. Provision of a care package which reduces

the number of women attending hospital in the early stages of labour is reported to improve satisfaction as well as outcomes for these women. An initial home assessment by a midwife is an important component of care provision that may contribute significantly to these improved outcomes, and thus warrants evaluation as a stand-alone intervention.

Effectiveness of non-pharmacological interventions during the latent phase

Review question

What is the effectiveness of non-pharmacological home-based interventions to help women cope with pain during the latent first stage of labour?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

Five studies are included in this review (Smith et al., 2010; Smith et al., 2011a; Smith et al., 2011b; Smith et al., 2012; Parsons et al., 2006).
The included studies consisted of 4 systematic reviews (Smith et al., 2010; Smith et al., 2011a; Smith et al., 2011b; Smith et al., 2012) with component trials from a variety of countries and 1 observational study from the USA (Parsons et al., 2006).
The 4 systematic reviews (Smith et al., 2010; Smith et al., 2011a; Smith et al., 2011b; Smith et al., 2012) included studies covering a range of pain relieving strategies and the whole duration of labour. Smith et al. (2010) evaluated the effect of complementary and alternative therapies for pain management in labour. Smith et al. (2011a) examined the effect of aromatherapy for pain management in labour on maternal and perinatal morbidity. Smith et al. (2011b) assessed the relaxation method and Smith et al. (2012) examined the efficacy of manual healing methods, including massage and reflexology, for pain management in labour on maternal and perinatal morbidity. For the purpose of this review, the only studies selected for inclusion from these reviews were those with a non-pharmacological intervention that can be used by the woman at home and were investigated during the latent first stage of labour. Parsons et al. (2006) examined the effect of eating during latent first stage of labour on the hospital-estimated labour duration and on maternal and neonatal outcomes.

Evidence profile

The included studies evaluated the following comparisons:

- aromatherapy versus no aromatherapy
- breathing exercise versus 'usual care'
- yoga versus 'usual care' for pain management in labour
- music versus 'usual care' for pain management in labour
- acupressure versus no treatment for pain management in labour
- massage versus 'usual' care for pain management in labour
- eating in latent phase versus no eating

The studies themselves often use the phrase 'usual care', so that term is used here in order to accurately reflect the evidence as reviewed. However, it should be noted that this term is not appropriate when considering interventions for women to use at home before they make contact with a healthcare professional. Each comparison is presented in the GRADE profiles below. For details of study interventions and comparisons please see the evidence tables (appendix I).

Update 2014

Table 52: Aromatherapy compared with no aromatherapy for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Aromatherapy[a]	No aromatherapy	Relative (95% CI)	Absolute (95% CI)	
Spontaneous vaginal birth						
1 study (Smith et al., 2011[a])	randomised trials	224/251 (89.2%)	234/262 (89.3%)	RR 1 (0.94 to 1.06)	0 fewer per 1000 (from 54 fewer to 54 more)	Moderate
Assisted vaginal birth						
1 study (Smith et al., 2011[a])	randomised trials	12/251 (4.8%)	12/262 (4.6%)	RR 1.04 (0.48 to 2.28)	2 more per 1000 (from 24 fewer to 59 more)	Very Low
Caesarean delivery						
1 study (Smith et al., 2011[a])	randomised trials	15/251 (6%)	16/262 (6.1%)	RR 0.98 (0.49 to 1.94)	1 fewer per 1000 (from 31 fewer to 57 more)	Very Low
Use of pharmacological analgesia during established labour						
1 study (Smith et al., 2011[a])	randomised trials	1/251 (0.4%)	3/262 (1.1%)	RR 0.35 (0.04 to 3.32)	7 fewer per 1000 (from 11 fewer to 27 more)	Moderate
Augmentation (oxytocin)						
1 study (Smith et al., 2011[a])	randomised trials	92/251 (36.7%)	84/262 (32.1%)	RR 1.14 (0.9 to 1.45)	45 more per 1000 (from 32 fewer to 144 more)	Low
Admission to NICU						
1 study (Smith et al., 2011[a])	randomised trials	0/251 (0%)	6/262 (2.3%)	RR 0.08 (0 to 1.42)	21 fewer per 1000 (from 23 fewer to 10 more)	Moderate

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

a. A decision made between women and midwife to choose one of the 5 essential oils (Roman chamomile, clay sage, frankincense, lavender and mandarin). Modes of application were acupuncture point, taper, foot-bath, massage or birthing pool.

Update 2014

Table 53: Breathing exercise and massage compared with 'usual care' for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Breathing exercise + Massage[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Pain intensity - Latent phase (Score out of 10)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 1.75 (SD 0.71) n=20	Mean 3.0 (SD 1.48) n=20	NC	MD 1.25 lower (1.97 to 0.53 lower) p=0.0006	Low
Pain intensity - Active phase(Score out of 10)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 5.8 (SD 1.15) n=20	Mean 8.35 (SD 1.08) n=20	NC	MD 2.55 lower (3.24 to 1.86 lower) p=0.00001	Low
Pain intensity - Transition (Score out of 10)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 9.15 (SD 0.93) n=20	Mean 10 (SD 0.0) n=20	NC	MD 0.75 lower (CI NC)	Low
Satisfaction with 'pain in labour'[c]						
1 study (Smith et al., 2011[b])	randomised trials	8/20 (40%)	1/20 (5%)	RR 8 (1.1 to 58.19)	350 more per 1000 (from 5 more to 1000 more)	Very low
Length of labour (minutes)						
1 study (Smith et al., 2011[b])	randomised trials	Mean 445.26 (SD 158.05) n=19	Mean 339.7 (SD 168.45) n=17	NC	MD 105.56 higher (1.5 lower to 212.62 higher) p=0.05	Low

CI confidence interval, MD mean difference, NC not calculable, RR risk ratio, SD standard deviation

a. Investigators provided information about labour, breathing techniques and massage in the latent first stage of labour, and accompanied these women during labour. The women received nurse-administered massage and were encouraged to perform breathing exercises and self-administered massage. They were also instructed to change their positions and to relax. Slow, deep inhalations were encouraged in the latent phase and rapid, shallow breathing was encouraged in the active phase. The pant-blow abdominal breathing technique was applied in the 2nd stage of labour. Plus, lower and upper back massages were administered by a nurse. Women were also instructed to give themselves a soft massage in the abdominal area.
b. The visual analogue scale (VAS) was used to assess labour pain. The scale was made of a paper ruler with numbers and a colour display over the numbers; ranging from 0 (no pain) to 10 (the most severe pain) (data extracted from the original paper; Yildirim and Sahin, 2004)
c. Obtained by postnatal interview 2 hours after birth , no further details provided (data extracted from the original paper; Yildirim and Sahin, 2004)

Update 2014

Table 54: Yoga compared with 'usual care' for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Yoga[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Pain intensity latent phase (Score out of 100)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 51.79 (SD 10.46) n=33	Mean 57.91 (SD 12.83) n=33	NC	MD 6.12 lower (11.77 lower to 0.47 lower) p=0.03	Moderate
Satisfaction with pain relief latent phase (Score out of 100)[c]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 52.88 (SD 13.57) n=33	Mean 45 (SD 12.84) n=33	NC	MD 7.88 higher (1.51 higher to 14.25 higher) p=0.02	Moderate
Satisfaction with childbirth experience 2 hours after birth (possible range from 35 to 210)[d]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 156.7 (SD 13.43) n=33	Mean 150.3 (SD 11.70) n=33	NC	MD 6.34 higher (0.26 higher to 12.42 higher) p=0.04	Moderate
Use of pharmacological pain relief during labour						
1 study (Smith et al., 2011[b])	randomised trials	14/33 (42.4%)	17/33 (51.5%)	RR 0.82 (0.49 to 1.38)	93 fewer per 1000 (from 263 fewer to 196 more)	Very Low
Length of labour 1st stage						
1 study (Smith et al., 2011[b])	randomised trials	Mean 519.88 (SD 185.68) n=33	Mean 659.79 (SD 272.79) n=33	NC	MD 139.91 lower (252.5 to 27.32 lower) p=0.01	Moderate
Augmentation with oxytocin						
1 study (Smith et al., 2011[b])	randomised trials	13/33 (39.4%)	17/33 (51.5%)	RR 0.76 (0.45 to 1.31)	124 fewer per 1000 (from 283 fewer to 160 more)	Very Low

CI confidence interval, MD mean difference, NC not calculable, SD standard deviation

Update 2014

a. The experimental group received a series of 6 60-minute yoga practice sessions at the 26th, 28th, 30th, 32nd, 34th, 36th, and 37th week of pregnancy. The yoga program was a combination of: (a) educational activities: a short explanation of basic anatomical structures related to pregnancy and birth and (b) yoga, explaining the theories linked to each session. The women were given a booklet and tape cassette, for self-study. Women were asked to retain a record, in diary format.
b. The visual analogue of pain scale (VASPS) was used to assess labour pain. The scale consisted of a 100 mm horizontal line secured by two extremes of pain; "no pain" and "worst imaginable pain". Women were asked to mark through the line to indicate the intensity of pain being experienced from uterine contractions. Internal consistency of the VASPS was found to be 0.74 (data extracted from the original paper; Chuntharapat, 2008).
c. The visual analogue scale to total comfort (VASTC) was used to assess labour comfort. The scale was a researcher modified version of visual analogue scale (VAS); consisted of a 100 mm horizontal line secured by two extremes; "strong agreement" and "strong disagreement" that comfort existed at the moment. Total scores could range from 0 to 100. Internal consistency of the VASTC during labour was 0.80 (data extracted from the original paper; Chuntharapat, 2008).
d. The maternal comfort questionnaire (MCQ) was used to assess level of comfort. The scale was a researcher modified version of general comfort questionnaire and was completed 2 hours after birth by women. The 35 item questionnaire consisted of positively and negatively stated items that were generated based on a theory of holistic comfort and had a two dimensional grid of three states: relief, ease and transcendence and four 'contexts': physical, psycho-spiritual, social and environmental. Items were scored on a 6 point Likert scale ranging from 1 = "strongly disagree "to 6 "strongly agree" (data extracted from the original paper; Chuntharapat, 2008).

Table 55: Music compared with 'usual care' for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Music[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Caesarean section						
1 study (Smith et al., 2011[b])	randomised trials	5/30 (16.7%)	4/30 (13.3%)	RR 1.25 (0.37 to 4.21)	33 more per 1000 (from 84 fewer to 428 more)	Very Low
Pain intensity - Latent phase (Score out of 10)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 6.43 (SD 2.57) n=30	Mean 6.60 (SD 2.34) n=30	NC	MD 0.17 lower (1.41 lower to 1.07 higher) p=0.79	Low
Pain intensity - Active phase (Score out of 10)[b]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 9.17 (SD 1.02) n=30	Mean 9.35 (SD 1.02) n=30	NC	MD 0.18 lower (0.7 lower to 0.34 higher) p=0.49	Low
Use of pharmacological pain relief (epidural)						
1 study (Smith et al., 2011[b])	randomised trials	15/30 (50%)	18/30 (60%)	RR 0.83 (0.53 to 1.32)	102 fewer per 1000 (from 282 fewer to 192 more)	Very Low

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		Music[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Anxiety - Latent phase (Score out of 10)[c]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 6.38 (SD 2.98) n=30	Mean 5.2 (SD 2.1) n=30	NC	MD 1.18 higher (0.13 lower to 2.49 higher) p=0.08	Low
Anxiety - Active phase (Score out of 10)[c]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 8.22 (SD 2.26) n=30	Mean 7.68 (SD 2.1) n=30	NC	MD 0.54 higher (0.56 lower to 1.64 higher) p=0.34	Low
Length of labour[d]						
1 study (Smith et al., 2011[b])	randomised trials	Mean 26.53 (SD 13.32) n=30	Mean 29.13 (SD 21.27) n=30	NC	MD 2.6 lower (11.58 lower to 6.38 higher) p=0.57	Low

CI confidence interval, MD mean difference, NC not calculable, RR risk ratio, SD standard deviation

a. Participants could choose one of the following types of relaxing, anxiety reducing music: classical, light, popular, crystal children's or Chinese religious music. In addition to receiving standard nursing care, the experimental participants listened to one of these types of music for at least 30 minutes during the latent phase (2-4 cm cervical dilation) and active phase (5-7 cm cervical dilation) of labour. Participants were allowed to choose whether or not to use headphones
b. The visual analogue scale for pain (VASP) was used to assess labour pain. The VASP scale consisted of a 10 cm horizontal line with numbers ranging from 0 (no pain) to 10 (worst possible pain) at the two extreme ends of the scale (data extracted from the original paper Liu, et.al., 2010).
c. The visual analogue scale for anxiety (VASA) was used to assess anxiety. The VASA scale consisted of a 10 cm horizontal line with numbers ranging from 0 (no anxiety) to 10 (worst possible anxiety). Women were asked to answer an open ended question about benefit of music (data extracted from the original paper Liu, et.al., 2010).
d. Data for this outcome not reported in the original paper but reported by the Cochrane review

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Table 56: Acupressure compared with no treatment for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Acupressure[a]	No treatment	Relative (95% CI)	Absolute (95% CI)	
Length of 1st stage of labour (hours)						
1 study (Smith et al., 2010)	randomised trials	Mean 6.33 (SD 2.55) n=43	Mean 8.45 (SD 4.39) n=42	NC	MD 2.12 lower (3.65 lower to 0.59 lower) p=0.007	Moderate

CI confidence interval, MD mean difference, NC not calculable, SD standard deviation

a. Trained midwives administered the acupressure to women. The intervention lasted 20 minutes, consisting of 5 minutes pressure to points LI4 and BL67. Five cycles of acupressure were completed in 5 minutes, with each cycle comprising 10 seconds of sustained pressure and 2 seconds of rest without pressure. A protocol was established to control finger pressure, accuracy of points and accuracy of technique.

Table 57: Massage compared with 'usual care' for pain management in the latent first stage of labour

Number of studies	Design	Number of women		Effect		Quality
		Massage[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Pain intensity - First stage of labour[b]						
1 meta-analysis of 2 studies (Smith et al., 2012)	randomised trials	n=62	n=60	NC	MD 1.05 lower (1.43 to 0.67 lower) p<0.00001	Moderate
Pain intensity - Second stage of labour[b]						
1 meta-analysis of 2 studies (Smith et al., 2012)	randomised trials	n=62	n=60	NC	MD 0.98 lower (2.23 lower to 0.26 higher) p=0.12	Low
Pain intensity - Third stage of labour[b]						
1 meta-analysis of 2 studies (Smith et al., 2012)	randomised trials	n=62	n=60	NC	MD 1.03 lower (2.17 lower to 0.11 higher) p=0.08	Low

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Number of studies	Design	Number of women		Effect		Quality
		Massage[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Labour pain[b]						
1 study (Smith et al., 2012)	randomised trials	Mean 3.5 (SD 0) n=14	Mean 5.0 (SD 0) n=14	NC	MD 1.5 lower (CI NC)	Moderate
Length of labour						
1 study (Smith et al., 2010)	randomised trials	Mean 10.09 (SD 4.81) n=30	Mean 9.61 (SD 4.4) n=30	NC	MD 1.35 higher (0.98 lower to 3.68 higher) p=0.26	Moderate
Satisfaction with pain relief (Score out of 5)[c]						
1 study (Smith et al., 2010)	randomised trials	Mean 4.17 (SD 1.05) n=30	Mean 3.70 (SD 1.32) n=30	NC	MD 0.47 lower (0.13 lower to 1.07 higher) p=ns	Moderate
Use of pharmacological pain relief in active phase of labour						
1 study (Smith et al., 2012)	randomised trials	2/30 (6.7%)	0/30 (0%)	RR 5 (0.25 to 99.95)	NC	Very Low
Oxytocin augmentation						
1 study (Smith et al., 2012)	randomised trials	18/30 (60%)	13/30 (43.3%)	RR 1.38 (0.84 to 2.29)	165 more per 1000 (from 69 fewer to 559 more)	Low
Length of labour (hours)						
1 study (Smith et al., 2010)	randomised trials	Mean 10.96 (4.81) n=30	Mean 9.61 (4.24) n=30	NC	MD 0.29 higher (0.22 lower to 0.8 higher) p=0.26	Moderate
Anxiety first stage of labour (Score out of 100)[d]						
1 study (Smith et al., 2012)	randomised trials	Mean 37.2 (SD 20.3) n=30	Mean 53.47 (SD 22.18) n=30	NC	MD 16.27 lower (27.03 lower to 5.51 lower) p=0.003	Moderate

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Number of studies	Design	Number of women		Effect		Quality
		Massage[a]	'Usual care'	Relative (95% CI)	Absolute (95% CI)	
Anxiety second stage of labour (Score out of 100)[d]						
1 study (Smith et al., 2012)	randomised trials	Mean 64.9 (SD 24.07) n=30	Mean 73.87 (SD 22.64) n=30	NC	MD 8.97 lower (20.79 lower to 2.85 higher) p=0.14	Moderate
Anxiety third stage of labour (Score out of 100)[d]						
1 study (Smith et al., 2012)	randomised trials	Mean 80.06 (SD 19.11) n=30	Mean 85.17 (SD 18.29) n=30	NC	MD 4.57 lower (14.04 lower to 4.9 higher) p=0.34	Moderate
Depressed mood post birth[e]						
1 study (Smith et al., 2012)	randomised trials	Mean 6.9 n=14	Mean 14.9 n=14	NC	MD 8 lower (SD NC)	Moderate

CI confidence interval, MD mean difference, NC not calculable, SD standard deviation

a. The primary researcher gave the massage during uterine contractions and taught the method to the woman's partner. Women received firm rhythmic massage lasting 30 minutes and comprised of mild, sacral pressure and shoulder and back kneading. Women were encouraged to select their preferred technique. The 30-minute massage was repeated in phase 2 and in the transitional phase 3.
b. A ten point visual analogue scale (VAS) was used to assess labour pain in one study (Abasi, 2009). The scores ranged from 0 (no pain) to 10 (worst possible pain). Women received 30 minutes massage at the start of each labour phase in Abasi, 2009. A visual analogue scale (VAS) was used to assess labour pain in the other study (Chang, 2006). The scale was a 100 mm horizontal line, ranging from 0 (no pain at all) to 100 (worse possible pain). Women received 30 minutes massage at the start of each labour phase by the investigator and women's partners repeated the massage at every stage, after the 30 minute massage by the researcher (data extracted from the abstract and the original papers Abasi, 2009, Chang, 2006 respectively).
c. This outcome in the original paper reported as women's subjective assessment of 'positive childbirth experience' and assessed with a 5 point scale. Nine experts validated the tool. Better indicated by higher values (data extracted from the original paper; Chang, 2002).
d. The visual analogue scale for anxiety (VASA) was used to assess labour pain. The VASP scale consisted of a 100 mm horizontal line with the numbers ranging from 0 (no anxiety at all) to 100 (worst possible anxiety) in the two extreme ends of the scale. VASA reported as a reliable validated tool (data extracted from the original paper; Chang, 2002).
e. The Centre for Epidemiological Studies Scale for Depression (CES-D) was used to assess depressed mood post-delivery. The CES-D scale consisted of 20 items containing questions relating to depressed mood and psychophysiological indications of depression. The ratings form a summary scale ranging from 0 to 60. A score greater than 16 indicates a high level of depression (data extracted from the original paper; Field, 1997).

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Table 58: Eating in latent phase compared with no eating

Number of studies	Design	Number of women		Effect		Quality
		Eating in latent phase[a]	No eating	Relative (95% CI)	Absolute (95% CI)	
Forceps or ventouse birth						
1 study (Parsons, 2005)	observational studies	19/82 (23.2%)	15/94 (16%)	RR 1.45 (0.79 to 2.67)	72 more per 1000 (from 34 fewer to 266 more)	Very Low
Use of epidural						
1 study (Parsons, 2005)	observational studies	10/82 (12.2%)	11/94 (11.7%)	RR 1.04 (0.47 to 2.33)	5 more per 1000 (from 62 fewer to 156 more)	Very Low
Use of pethidine						
1 study (Parsons, 2005)	observational studies	46/82 (56.1%)	49/94 (52.1%)	RR 1.08 (0.82 to 1.41)	42 more per 1000 (from 94 fewer to 214 more)	Very Low
Medical augmentation						
1 study (Parsons, 2005)	observational studies	25/82 (30.5%)	17/94 (18.1%)	RR 1.69 (0.98 to 2.89)	125 more per 1000 (from 4 fewer to 342 more)	Very Low
Duration of labour (hours)						
1 study (Parsons, 2005)	observational studies	Mean 8.52 (SD 8.31) n=82	Mean 4.05 (SD 6.79) n=94	NC	MD 4.47 longer 2.21 longer to 6.73 longer) p=0.0001	Very Low
Hospital estimated labour length (hours)						
1 study (Parsons, 2005)	observational studies	Mean 9.75 (SD 4.4) n=82	Mean 7.4 (SD 2.97) n=94	NC	MD 2.35 longer (1.22 longer to 3.48 longer) p<0.0001	Very Low

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Number of studies	Design	Number of women		Effect		Quality
		Eating in latent phase[a]	No eating	Relative (95% CI)	Absolute (95% CI)	
Admission to SCN (Special Care Nursery)						
1 study (Parsons, 2005)	observational studies	4/82 (4.9%)	7/94 (7.4%)	RR 0.66 (0.2 to 2.16)	25 fewer per 1000 (from 60 fewer to 86 more)	Very Low

CI confidence interval, MD mean difference, NC not calculable, RR risk ratio, SD standard deviation

a. The onset of labour was self-diagnosed and recorded by women and active phase was identified by midwife through women's retrospective account of her labour and not by the cervical assessment Twenty three percent (23%) of women in the eating group consumed a full meal (meat, vegetable, pasta, fish and chips) during the latent phase and 77% consumed a light meal (toast, cereal and sandwiches). Women in the non-eating group consumed fluid such water, fruit juice, tea and coffee.

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Evidence statements

Aromatherapy versus 'usual care'

One study (n=513) found no difference in mode of birth, use of pharmacological analgesia, augmentation of labour or admission of the baby to a neonatal intensive care unit (NICU) between women who received aromatherapy and those who received standard care. The evidence was of moderate to very low quality.

Breathing exercises and massage versus 'usual care'

One study (n=40) found a lower level of pain intensity in the latent phase in women who received breathing technique and massage training compared with women who received standard care. This difference continued during the active phase of labour, including the transition phase. The same study found women who received breathing technique and massage training had a higher level of satisfaction with pain relief than women who received standard care. Women who received training in breathing and massage technique were also found to have longer labours compared with those who received standard care. The evidence was of low quality.

Yoga versus 'usual care'

One study (n=66) found a lower level of pain intensity in the latent phase in women who received yoga training compared with women who received standard care. The same study also found a higher level of satisfaction with pain relief, a higher satisfaction with the childbirth experience and a shorter labour in women who received yoga training compared with women who received standard care. The evidence for these outcomes was moderate quality. No difference was found for use of pharmacological pain relief or augmentation with oxytocin between the two groups. The evidence was of very low quality.

Music versus 'usual care'

One study (n=60) did not find a statistically significant difference in the rate of caesarean section, pain intensity, use of pharmacological pain relief, anxiety or length of labour in women who listened to music compared with women who received standard care. The evidence was of low to very low quality.

Acupressure versus no treatment for pain

Length of labour

One study (n=85) found shorter length of labour in women who received acupressure compared with women who received standard care. The evidence was of low quality.

Massage versus 'usual care'

One meta-analysis of 2 studies (n=122) found lower reported pain intensity in the first stage of labour in women who received massage compared with women who received standard care. No difference was found between the 2 groups for pain intensity reported in the second and third stages of labour. The evidence was of moderate to low quality.

One study (n=60) found less anxiety during the first stage of labour in women who received massage compared with women who received standard care. No difference was found between groups for reported anxiety in the second and third stages of labour. The evidence for these outcomes was of moderate quality.

No difference was found for satisfaction with pain relief used during labour, use of pharmacological pain relief and augmentation of labour between women who received massage compared with women who received standard care. The evidence for these outcomes was of moderate to very low quality.

Eating in latent phase versus no eating

Evidence from 1 study (n=176) did not find a statistically significant difference in the rate of forceps or ventouse births, use of epidural analgesia, use of pethidine or augmentation of

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labour between women who ate during the latent phase compared with women who did not eat during the latent phase. The evidence for these outcomes was of very low quality.
One study (n=60) found longer length of labour in women who ate during the latent phase compared with women who did not eat during the latent phase. The evidence for this outcome was of very low quality.
The same study did not find a statistically significant difference in the admission rate to the special care nursery in women who ate during the latent phase compared with women who did not eat during the latent phase. The evidence for this outcome was also of very low quality.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was fundamental to consider women's satisfaction with the type of pain relief they use in the latent first stage of labour. The group felt that reducing a woman's fear and anxiety might reduce the number of visits she makes to a labour assessment setting during the latent first stage of labour if she is planning to give birth away from home and consequently cause less exhaustion during labour. Similarly, the number of calls to, and visits from, midwives to make assessments of labour in the home might be reduced. The group was aware that not all types of pain relief reduce a woman's anxieties and discomfort so it important to identify how best to ensure women's satisfaction with the pain relieving methods that they use.

Consideration of clinical benefits and harms

The guideline development group noted that for the comparison between breathing exercises and massage or yoga with 'usual care', there was statistically significantly reduced pain intensity during both the latent and active phases of labour for women in the intervention groups. The group members noted that although the studies were very small and some were poorly designed, this finding was borne out by their own experience. It was recognised that the improvement in outcomes could have been due to having the focused support of a birth companion, rather than as a direct result of the breathing exercises and/or massage.
The group noted that there were no differences in any outcomes reported when comparing music or aromatherapy with usual care.
For the comparison between acupressure and usual care, the length of the first stage of labour was reduced for women in the intervention group. The group noted that it was a small study and also noted that it did not provide compelling evidence for the efficacy of acupressure itself as there was no comparison with sham acupressure.
The group noted that for the comparison between eating in the latent first stage of labour compared with not eating, both the duration of labour and the hospital estimated labour length were longer in the intervention group. It was also noted that the onset of labour was self-diagnosed by women and that this potentially affected the findings as there is no unique way of knowing that established labour has begun – women experience and identify the onset of labour in a number of ways.
Overall, it was agreed that although some of the studies reported statistically significant findings, they were all very small studies which didn't provide any clear demonstration of clinical benefit. Furthermore, most of the studies included interventions performed during established labour as well as during the latent first stage and thus any differences observed could not be attributed purely to the intervention applied during the latent first stage.

Consideration of health benefits and resource uses

No formal health economic analysis was undertaken for this question. However, the guideline development group took into account the likely costs and benefits of each intervention when

considering the clinical evidence. Given the costs of training in providing some of the interventions as well as the additional time required to administer them, and with limited evidence of benefit from any of the interventions, the group agreed that it was very unlikely that they would be cost effective if provided by NHS staff. Some interventions required a higher level of expertise and training which would make them unlikely to be delivered by the birth companion. There was moderate evidence that massage and breathing techniques could reduce pain and anxiety and these could be delivered by the midwife or the birth companion without requiring extensive training.

Quality of evidence

The evidence available for this review consisted of randomised trials and 1 retrospective observational study. There was general agreement that the quality of the studies was quite poor. It was noted that some studies had considerable limitations and a high risk of bias in both data collection and analysis. The guideline development group recognised the difficulty in trying to determine women's levels of anxiety for different type of pain relief when there is considerable risk of bias in allocation concealment, outcome assessor and type of scale used.

Other considerations

The group noted that there was evidence elsewhere in the guideline showing that labouring in water can reduce pain and the need for analgesia (see section 8.3.4). They believed that this evidence would be directly applicable to women in the latent first stage of labour as well, and so agreed that it was appropriate to advise women about its effectiveness in reducing pain.

Key conclusions

There was moderate quality evidence to support using massage therapy to reduce perceived pain and anxiety in the first stage of labour and low quality evidence that breathing techniques and massage reduce pain in the latent first stage and first stage of labour. The group felt that these techniques could be easily taught to, and delivered by, a birth companion in any setting during the latent first stage of labour. Consequently, the group agreed that women should be advised about the potential benefits of these techniques.

However, the group did not feel that there was sufficient evidence to support the provision of pain relief such as aromatherapy and acupressure during the latent first stage of labour and, while yoga did offer some promising results, the fact that it needs to be taught by a trained yoga teacher meant the guideline development group did not feel it could be universally advised. Therefore, the group drafted a recommendation that if a woman wants to use any of these techniques, her wishes should be respected.

Recommendations

39. Advise the woman and her birth companion(s) that breathing exercises, immersion in water and massage may reduce pain during the latent first stage of labour. (See also recommendation 82.) [new 2014]

40. Do not offer or advise aromatherapy, yoga or acupressure for pain relief during the latent first stage of labour. If a woman wants to use any of these techniques, respect her wishes. [new 2014]

Initial assessment at the onset of labour

Initial assessment

Introduction

When a woman in labour, who has been previously booked for midwife-led intrapartum care, first meets a midwife they will discuss the woman's care plan. A key element of this is to perform a risk assessment to identify if it is appropriate to carry on with midwife-led care or if the woman will require obstetric-led care. This section aims to identify the key components of

this risk assessment and clarify the findings which should prompt a woman's referral to an obstetrician. This issue is particularly important as elsewhere in the guideline there are recommendations that some groups of women be encouraged to give birth in settings other than an obstetric setting. Given this potential shift to more women giving birth outside a hospital, it is particularly important to ensure that these women are assessed effectively to ensure that if any risk factors are identified, transfer can be carried out promptly and safely.

Review question

What factors should be included in an initial assessment at first contact in labour (or suspected labour) and what thresholds in these variables would prompt referral to an obstetrician?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

A broad search was conducted for this question in order to identify papers which described the validation or evaluation of risk assessment protocols, tools or scoring systems for use at the onset of labour. Despite searching for both comparative and non-comparative studies, and for a range of study designs from randomised controlled trials (RCTs) to case series, no papers were identified which addressed this question. As a result, the guideline development group members were asked to provide examples of initial assessment protocols that they were aware of from their own clinical practice. The components of these protocols were then compiled into an overarching table which split the different topics by whether they appeared in all protocols, some protocols or only once in an individual protocol. This table is produced below in the evidence profile section. Seven profiles were submitted as evidence by the guideline development group.

Evidence profile

Table 59: Components of guideline development group submitted local initial assessment protocols

Components of initial assessment shared across all protocols	Components of initial assessment shared across some protocols	Components of initial assessment which only appear in 1 protocol
Woman		
Pulse	Review of antenatal history/ identified risk factors	Recent bowel function
Blood pressure	Woman's history including psychological needs	Oedema
Temperature	Woman's behaviour	Weight on admission
Urinalysis	Regularity of contractions	Tissue viability assessment
Length, strength and frequency of contractions	Pain	Manual handling assessment
Vaginal loss (show, liquor or blood)	Respiratory rate	Assessment of external genitalia
Vaginal examination (offered if the woman appears to be in established labour)	Modified early warning score (MEWS)[a]	Membranes (assessment on vaginal examination)
	Recent bladder function/bladder care	
	Vaginal examination offered if after a period of time the woman does not appear to be in established labour	
Unborn baby		

Components of initial assessment shared across all protocols	Components of initial assessment shared across some protocols	Components of initial assessment which only appear in 1 protocol
Woman		
Abdominal palpation to measure: fundal height; lie; presentation; engagement of presenting part	Abdominal palpation to measure: position	Estimated fetal growth status
Fetal heart rate	Fetal movements	
	Estimated liquor (normal, oligohydramnios, polyhydramnios)	

a. Sometimes reported as 'modified early obstetric warning score' (MEOWS)

Evidence statements

Evaluation of initial assessment protocols submitted by guideline development group members showed that there were a number of features which were common to all. The maternal components were:

- pulse
- blood pressure
- temperature
- urinalysis
- length, strength and frequency of contractions
- vaginal loss
- the offer of a vaginal examination.

The common components relating to the baby were:

- abdominal palpation to measure fundal height, lie, presentation and engagement of the presenting part
- fetal heart rate.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The group had hoped that evidence would provide data about a number of key outcomes including mode of birth, major maternal morbidity, major neonatal morbidity and women's experience of labour and birth. However, as no studies were identified for this review, the guideline development group was unable to consider any clinical outcome findings. As a result, the guideline development group's deliberations for this topic focussed on ensuring that women who require obstetric care are identified effectively, while avoiding referring a large number of women unnecessarily to obstetric care.

Consideration of clinical benefits and harms

The guideline development group members believed that the benefits of ensuring that a woman in labour or suspected labour is fully assessed when she first meets a midwife are brought about through early recognition of any deviation from normal and early referral for obstetric care where complications have developed.

In weighing up the risks and benefits of a comprehensive risk assessment at first contact, they recognised that there are some potential harms, which are the small risk of infection from performing a vaginal examination and the potential risk of making the woman anxious if it takes too long to produce the documentation. However, the group agreed that these harms were far outweighed by the benefits of conducting the assessment and ensuring prompt

onward referral, which are that the risks of any complications should be reduced by timely identification. This, in turn, should improve both neonatal and maternal outcomes.
The group recognised that the benefits of an initial assessment depend upon it being conducted effectively by the attending midwife. Any misjudgements leading to inappropriate transfer might lead a poorer experience of labour and birth for the woman and to an increase in the risk of unnecessary intervention. However, these misjudgements are made less likely if the assessment is carried out systematically following clear guidelines with thresholds for transfer.

Consideration of health benefits and resource uses

The time taken to carry out an initial assessment following a systematic approach is integral to good midwifery care and does not require additional resources over and above the one-to-one midwife contact that is already recommended in this guideline. The potential benefits of early identification of intrapartum risks and the guideline development group's belief that this would lead to improved neonatal and maternal outcomes that far outweigh any chance of potential harm mean this would be a cost-saving component of care.

Quality of evidence

The guideline development group was disappointed that no published papers were available which specifically addressed the evaluation or validation of protocols for initial assessment. Given this lack of evidence, the group agreed that it was appropriate to consider local protocols in an attempt to identify the key elements of an initial assessment. They felt that although these tools were not necessarily validated, by drawing on the common elements of each, supported by the clinical experience of members of the guideline development group, any recommendations the group made would be likely to reflect the most appropriate clinical practice.
None of the protocols considered by the group provided thresholds for the different components regarding when referral to obstetric care should occur. As a result, the thresholds that the group identified were predominantly based on other recommendations in the guideline, along with the group members' own clinical experience.

Other considerations

While making recommendations for initial assessment, the guideline development group also discussed the process of transfer and recognised that it was important to establish principles of transfer to ensure that this potentially frightening component of care is undertaken safely and in a way that minimises any anxiety the woman may be feeling.
In order to maintain provision of one-to-one care, the guideline development group felt it important to endorse the current good practice that the woman's attending midwife should accompany her when she is transferred from one birth setting to another. Since the midwife would be with the woman anyway providing intrapartum care, regardless of the time of day, this is seen simply as an extension of that care. The guideline development group felt this would minimise anxiety caused by the need for transfer, improve safety by ensuring an expert in intrapartum care is with the woman throughout labour and improve communication with the receiving midwife by facilitating a face-to-face handover of care. It was recognised that this may on occasion involve some additional cost where the midwife needs to return to the original birth setting from the obstetric unit. However, this would not always be necessary and would usually involve quite short distances. The benefits outlined above were felt to outweigh any such costs.
Finally, to lessen the impact of the transfer, arrangements should be in place to enable the woman's birth companion to travel with her in the ambulance if this is what the woman wishes. If this is not possible, there should be some arrangement to ensure the companion has appropriate transport.

Recommendations

41. When performing an initial assessment of a woman in labour, listen to her story and take into account her preferences and her emotional and psychological needs. [new 2014]

42. Carry out an initial assessment to determine if midwifery-led care in any setting is suitable for the woman, irrespective of any previous plan. The assessment should comprise the following:

- Observations of the woman:
  - Review the antenatal notes (including all antenatal screening results) and discuss these with the woman.
  - Ask her about the length, strength and frequency of her contractions.
  - Ask her about any pain she is experiencing and discuss her options for pain relief.
  - Record her pulse, blood pressure and temperature, and carry out urinalysis.
  - Record if she has had any vaginal loss.
- Observations of the unborn baby:
  - Ask the woman about the baby's movements in the last 24 hours.
  - Palpate the woman's abdomen to determine the fundal height, the baby's lie, presentation, position, engagement of the presenting part, and frequency and duration of contractions.
  - Auscultate the fetal heart rate for a minimum of 1 minute immediately after a contraction. Palpate the woman's pulse to differentiate between the heart rates of the woman and the baby.

In addition (see also recommendation 45):

- If there is uncertainty about whether the woman is in established labour, a vaginal examination may be helpful after a period of assessment, but is not always necessary.
- If the woman appears to be in established labour, offer a vaginal examination. [new 2014]

43. Transfer the woman to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50, if any of the following are observed on initial assessment:

- Observations of the woman:
  - pulse over 120 beats/minute on 2 occasions 30 minutes apart
  - a single reading of either raised diastolic blood pressure of 110 mmHg or more or raised systolic blood pressure of 160 mmHg or more
  - either raised diastolic blood pressure of 90 mmHg or more or raised systolic blood pressure of 140 mmHg or more on 2 consecutive readings taken 30 minutes apart
  - a reading of 2+ of protein on urinalysis and a single reading of either raised diastolic blood pressure (90 mmHg or more) or raised systolic blood pressure (140 mmHg or more)

  - temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive readings 1 hour apart
  - any vaginal blood loss other than a show
  - rupture of membranes more than 24 hours before the onset of established labour (see recommendation 278)
  - the presence of significant meconium (see recommendation 164)
  - pain reported by the woman that is differs from the pain normally associated with contractions
  - any risk factors recorded in the woman's notes that indicate the need for obstetric-led care.
- Observations of the unborn baby:
  - any abnormal presentation, including cord presentation
  - transverse or oblique lie
  - high (4/5-5/5 palpable) or free-floating head in a nulliparous woman
  - suspected fetal growth restriction or macrosomia
  - suspected anhydramnios or polyhydramnios
  - fetal heart rate below 110 or above 160 beats/minute
  - a deceleration in fetal heart rate heard on intermittent auscultation
  - reduced fetal movements in the last 24 hours reported by the woman.

If none of these are observed, continue with midwifery-led care unless the woman request a transfer (see also recommendation 55) [new 2014]

44. If any of the factors in recommendation 43 are observed but birth is imminent, assess whether birth in the current location is preferable to transferring the woman to an obstetric unit and discuss this with the coordinating midwife. [new 2014]

45. When conducting a vaginal examination:

- be sure that the examination is necessary and will add important information to the decision-making process
- recognise that a vaginal examination can be very distressing for a woman, especially if she is already in pain, highly anxious and in an unfamiliar environment
- explain the reason for the examination and what will be involved
- ensure the woman's informed consent, privacy, dignity and comfort
- explain sensitively the findings of the examination and any impact on the birth plan to the woman and her birth companion(s). [new 2014]

46. Base any decisions about transfer of care on clinical findings, and discuss the options with the woman and her birth companion(s). [new 2014]

47. If contemplating transfer of care:

- talk with the woman and her birth companion(s) about the reasons for this and what they can expect, including the time needed for transfer
- address any concerns she has and try to allay her anxiety

- ensure that her wishes are respected and her informed consent is obtained. [new 2014]

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48. When arranging transfer of care, the midwife attending the labour should contact the ambulance service (if appropriate) and the coordinating midwife in the obstetric unit. The coordinating midwife should then alert the relevant healthcare professionals (obstetric, anaesthetic and neonatal). [new 2014]

49. When arranging transfer from one location to another, ensure the following:

- Before transfer, the woman is dressed, wrapped in a blanket or otherwise covered in a way that she feels is comfortable and appropriate.
- The woman is made to feel as comfortable as possible before and during transfer.
- Any ambulance staff or other personnel involved are aware that some positions may make the woman uncomfortable or afraid and could affect her labour, so she should be encouraged to choose how to move and what position to adopt if possible, in accordance with ambulance service protocols.
- Communication and companionship are maintained. Explain the arrangements for transfer to the woman and her birth companion(s). A midwife who has been involved in her care up to that point should travel with her and carry out a handover of care that involves the woman.
- Arrangements are in place to enable the woman's birth companion(s) to travel with her in the ambulance if that is what she wants. If this is not possible or not wanted, check that the birth companion(s) has or can arrange their own transport. [new 2014]

50. If a woman is transferred to an obstetric unit after the birth (see recommendations 292 to 313), ensure that her baby goes with her. [new 2014]

Continuous cardiotocography compared with intermittent auscultation on admission

Review question

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

For further details on the evidence review protocol, please see appendix E.

Description of included studies

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

One of the studies was a systematic review (Devane et al., 2012), which included 4 randomised controlled trials conducted in the UK and Ireland. This systematic review was the source for the majority of the outcome data. The other 4 included studies were reports of the same randomised controlled trials (Cheyne et al., 2003; Impey et al., 2003; Mires et al., 2001; Mitchell, 2008). These trials were incorporated in the systematic review but also had to be included as individual papers because the systematic review did not consistently report how women were monitored in labour, and there was an additional outcome reported in 1 trial which was not reported in the review.

Three of the trials only included low risk women (Cheyne et al., 2003; Impey et al., 2003; Mitchell, 2008), of which 1 specifically only included women with clear amniotic fluid following early amniotomy (Impey et al., 2003). In the fourth trial, women at low risk were randomised in the third trimester, and some women developed complications during the interval between randomisation and admission (Mires et al., 2001). However, the authors of the systematic review obtained subgroup data for the women that remained low risk on admission, and it is this data that has been reported. All of the included studies included both nulliparous and multiparous women but do not report outcomes separately.

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

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

The way that women were monitored during labour varied between the studies. In 3 trials, after the CTG admission test all women were cared for using intermittent auscultation (as described above) provided the fetal heart rate was considered normal (Cheyne et al., 2003; Impey et al. 2003; Mitchell, 2008). If the fetal heart rate was considered abnormal, then CTG was used (see evidence table for criteria). In Impey et al. (2003), 58% of the CTG arm and 42% of the auscultation arm received continuous CTG during labour. In Cheyne et al. (2003), 6% of women in each arm received continuous CTG during labour and a further 80% of the CTG arm and 34% of the auscultation arm received additional CTG. In Mitchell (2008), no detail about the proportion of women receiving continuous CTG in labour is provided. In the

fourth trial (Mires et al., 2001), the protocol for monitoring during labour is not reported but 57% of the CTG arm and 47% of the auscultation arm ended up receiving continuous CTG.

Evidence profile

Table 60: Summary GRADE profile for comparison of continuous CTG compared with intermittent auscultation on admission

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

Update 2014

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

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

Update 2014

Evidence statements

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

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

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

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

It was noted that the meta-analysis is underpowered for the rare findings of poor neonatal outcomes (mortality and HIE) and so although these are clearly the most important outcomes, the evidence relating to them is less useful for informing decision-making.

Consideration of clinical benefits and harms

The evidence did not show a statistically significant difference between the 2 groups for any of the reported outcomes, although the rate of caesarean section was on the borderline of being significantly higher in women receiving CTG on admission. The guideline development group noted that the rates of caesarean section in both groups were very low compared to current UK rates and thus it may not be possible to extrapolate the difference observed between groups to current practice.

Although not reported as an outcome in the GRADE table, some of the studies gave figures for the number of women in each group who had CTG monitoring in labour. In each study, a greater number of women who had initial continuous CTG went on to have continuous CTG throughout labour compared with women in the intermittent auscultation arm. Although not necessarily a bad outcome in its own right, taking into account the findings from the review comparing the effectiveness of continuous CTG and intermittent auscultation in labour (see section 10.1), it seemed that continuous CTG was being used unnecessarily in some cases.

The group felt that clinicians would sometimes use CTG for reassurance on admission, rather than as a result of a clear clinical indication, and this could then lead to an increase in interventions throughout labour.

From their clinical and personal experience, the group members recognised that there are advantages for women in being mobile and not being attached to a monitor. Thus, in the absence of complications, intermittent auscultation is to be preferred.

Given that the evidence showed no benefit to babies in performing CTG on admission compared with intermittent auscultation and the guideline development group's concern about wishing to avoid unnecessary interventions and wanting to enable women to be free to be mobile during labour, the group agreed that continuous CTG should not be performed on admission when a women has been confirmed to be at low risk of developing complications during labour.

The group agreed that if the findings of the intermittent auscultation are not normal, it is appropriate to further assess the woman using CTG for 20 minutes. However, if no further abnormalities are observed during this time, the monitor should be removed and intermittent auscultation recommenced. The group was concerned that in practice CTG can sometimes be used in place of one-to-one care and so felt it important to cross-reference here the recommendation on providing continuous one-to-one care.

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

Consideration of health benefits and resource uses

The guideline development group agreed that performing CTG on admission is likely to lead to an increase in unnecessary interventions for women during labour with no evidence of benefit. As a result, it was felt that there was a clear health economic benefit in continuing to recommend that admission CTG not be used.

Quality of evidence

The guideline development group recognised that the evidence was of either high or moderate quality, and thus felt confident in the strength of its recommendations.

Other considerations

The guideline development group discussed the appropriate method for conducting auscultation. It was agreed that the fetal heart rate should be recorded as a single rate rather than a range. This single rate can then be plotted on a partogram and used as a baseline figure for future measurements. The group also agreed that accelerations or decelerations should be recorded (either on the partogram or the notes) if they are heard (though it is not necessary to indicate each time if they are not heard). The group recognised that there are a number of elements which go in to determining the wellbeing of the unborn baby during labour, of which an accelerating or decelerating heart rate is just one. However, they agreed that it was essential to record any deceleration heard and that the recording of an acceleration is also good practice as it is a useful reassuring sign (see section 10.3 Interpretation of electronic fetal heart rate traces). It is also important to check that the heart sounds being detected are fetal and not maternal and thus the maternal pulse should be palpated at the same time as the fetal heart rate is listened to in order to differentiate the two. These observations, including whether fetal movements were felt during auscultation, should be documented either within the labour records or on the partogram.

The guideline development group was aware that there had been some concern in the clinical and legal community about not recording an admission CTG. They believed that there is still a view from some clinicians that continuous CTG is better at identifying unborn babies at risk than intermittent auscultation and that its use is thus justified, even in women at low risk of developing intrapartum complications. However, on reviewing the evidence from the previous guideline, as well as more recent evidence, the group was confident that there was no evidence to support this view and was happy to retain the recommendation that admission CTG should not be used for women at low risk at the onset of labour. This is also consistent with the recommendations for place of birth where the evidence supports the recommendation that women at low risk of developing intrapartum complications should be advised to give birth outside an obstetric unit as this is associated with improved maternal outcomes (fewer interventions and their associated morbidity) and the same neonatal outcomes as seen in an obstetric unit. Birth outside an obstetric unit does not involve use of an admission CTG.

The guideline development group considered the recommendations from the previous edition of the guideline addressing vaginal examination. The group agreed that where there is uncertainty about whether or not a woman is in labour, a vaginal examination can sometimes be helpful after a period of assessment. However, they also agreed that it is important to be led by the woman's wishes as to whether or not to perform one.

Recommendations

51. Auscultate the fetal heart rate at first contact with the woman in labour, and at each further assessment. [new 2014]

52. Auscultate the fetal heart rate for a minimum of 1 minute immediately after a contraction and record it as a single rate. [new 2014]

53. Palpate the maternal pulse to differentiate between maternal heart rate and fetal heart rate. [new 2014]

54. Record accelerations and decelerations if heard. [new 2014]

55. Do not perform cardiotocography on admission for low-risk women in suspected or established labour in any birth setting as part of the initial assessment. [new 2014]

56. Offer continuous cardiotocography if any of the risk factors listed in recommendation 43 are identified on initial assessment, and explain to the woman why this is necessary. (See also recommendations 99 to 157 on fetal monitoring.) [new 2014]

57. Offer cardiotocography if intermittent auscultation indicates possible fetal heart rate abnormalities, and explain to the woman why this is necessary. Remove the cardiotocograph if the trace is normal after 20 minutes. (See also recommendations 99 to 157 on fetal monitoring). [new 2014]

58. If fetal death is suspected despite the presence of an apparently recorded fetal heart rate, offer real-time ultrasound assessment to check fetal viability. [new 2014]

Prelabour rupture of membranes at term

Prelabour rupture of membranes at term

Introduction

Little guidance exists on what advice women should be given following prelabour rupture of membranes (PRoM) at term, including how long it is safe to await the onset of labour, the potential role of prophylactic antibiotics and what observations should be carried out during this period. This section seeks to determine what should happen after contact with healthcare professionals when a diagnosis of term PRoM has been made.

For guidance relating to method of induction following ProM, please refer to the NICE clinical guideline on Induction of Labour (2001).[441] (Note that the update for this guideline is expected to be published in 2008.)

Review question

Is there evidence of factors or interventions that affect outcomes in term prelabour rupture of the membranes?

- Including septic screen for mother and baby.

Is there evidence that, following prelabour rupture of the membranes at term, the length of time from prelabour rupture of membranes (before onset of labour and total), digital vaginal examination, electronic fetal heart-rate monitoring, or frequency and type of maternal surveillance influence outcomes?

Following the birth of a healthy infant where there has been prelabour rupture of the membranes, is there evidence that the length of time from prelabour rupture of membranes (before onset and total), presence of pyrexia during or before labour, routine admission to neonatal units, frequency and type of neonatal observations, or frequency and type of neonatal investigations (including invasive tests) influence outcomes?

Is there evidence that the use of antibiotics before delivery in asymptomatic or symptomatic women with prelabour rupture of membranes influences outcomes?

What are the criteria for the use of antibiotics in healthy babies born following prelabour rupture of membranes?

Previous guideline

(PRoM has been considered in the guideline Induction of Labour.[441] Four systematic reviews were included. The summary of evidence concluded that there was no difference in instrumental birth rates (no distinction is made between vaginal instrumental births and caesarean sections) between induction versus a more conservative approach in women with term or near-term PRoM. Furthermore, a policy of induction of labour is associated with a reduction in infective sequelae for woman and baby. Two practice recommendations were made:

'Women with prelabour rupture of membranes at term (over 37 weeks) should be offered a choice of immediate induction of labour or expectant management.'

'Expectant management of labour of women with prelabour rupture of membranes at term should not exceed 96 hours following membrane rupture.'

Surveillance following term PRoM

Description of included studies

No evidence was found regarding the effect of carrying out electronic fetal heart rate (FHR) monitoring, checking of maternal temperature and pulse, or carrying out infection screening on women following PRoM.

Length of waiting period following term PRoM with no additional complications

Description of included studies

One systematic review (2006) of 12 trials involving 6814 women[442] plus secondary analyses of findings from an international, multicentre trial involving 72 institutions in six countries (n = 5041 women)[300] [EL = 2++] provides the evidence for this section.

Review findings

A systematic review has compared the effects of planned early birth (immediate induction of labour or induction within 24 hours) with expectant management (no planned intervention within 24 hours).[442] [EL = 1+] All trials involved only healthy women with an uncomplicated pregnancy of at least 37 completed weeks. Meta-analysis of findings showed that women in the planned early birth groups had a significantly shorter period of time from rupture of membranes to birth compared with women in the expectant management groups (five trials): WMD −9.53 hours [95% CI −12.96 to −6.10 hours]. Women in the planned early birth groups were less likely to develop chorioamnionitis than women in the expectant management group: 226/3300 versus 327/3311; RR 0.74 [95% CI 0.56 to 0.97]. Endometritis was less common in women allocated to the planned early birth groups: 5/217 versus 19/228; RR 0.30 [95% CI 0.12 to 0.74], although there was no significant difference between groups regarding incidence of postpartum fever: 82/2747 versus 117/2774; RR 0.69 [95% CI 0.41 to 1.17]. There was no difference between groups regarding mode of birth: caesarean section (CS): 333/3401 versus 360/3413; RR 0.94 [95% CI 0.82 to 1.08]; instrumental vaginal birth: 487/2786 versus 502/2825; RR 0.98 [95% CI 0.84 to 1.16]. The largest trial in the review (n = 5041) also investigated women's satisfaction with care. Women in the planned early birth group were significantly less likely to report that there was 'nothing liked' about the management of their care: 138/2517 versus 320/2524; RR 0.43 [95% CI 0.36 to 0.52]. Women in the planned early birth group were also more likely to say there was 'nothing disliked': 821/2517 versus 688/2524; RR 1.20 [95% CI 1.10 to 1.30]. It should be noted, however, that the comparison groups here were immediate induction of labour versus expectant management up to 96 hours. Babies born to women in the planned early birth groups were less likely to be admitted to neonatal intensive care unit (NICU) or special care baby unit (SCBU): 356/2825 versus 484/2854; RR 0.73 [95% CI 0.58 to 0.91]. However, this difference in admission rate may well reflect hospital policies rather than clinical need. No significant differences were found for any other investigated neonatal outcomes, including: fetal/perinatal mortality: 3/2946 versus 7/2924; RR 0.46 [95% CI 0.13 to 1.66]; Apgar score less than 7 at 5 minutes: 335/3000 versus 366/3005; RR 0.93 [95% CI 0.81 to 1.07]; mechanical ventilation: 25/2566 versus 28/2592; RR 0.99 [95% CI 0.46 to 2.12]; neonatal infection: 74/3210 versus 93/3196; RR 0.83 [95% CI 0.61 to 1.12].

Secondary analyses of data from an international, multicentre trial were performed to identify predictors of neonatal infection following term PRoM. Findings showed that longer periods of time from rupture of membranes to active labour were associated with a higher incidence of neonatal infection: 48 hours or longer versus 12 hours: OR 2.25 [95% CI 1.21 to 4.18]; 24 to 48 hours versus 12 hours: OR 1.97 [95% CI 1.11 to 3.48].

Place of care for women with term PRoM

Description of included studies

Secondary analyses of data from a large, international trial (n = 1670 women),[443] one small UK RCT (n = 56)[444] and a Danish prospective observational study (n = 276)[445] provide the evidence for this section.

Review findings

The term ProM study data set was also analysed to determine whether adverse effects of expectant management of term PRoM and women's satisfaction were greater if women were cared for at home rather than in hospital.[443] [EL = 2+] The analysis involved 653 women

managed at home compared with 1017 managed as hospital inpatients. Multiple logistic regression analyses showed that women having their first baby were more likely to have antibiotics if they were cared for at home, compared with women having their first baby cared for in hospital: OR 1.52 [95% CI 1.04 to 2.24]. Women who were not colonised with group B streptococcus (GBS) were more likely to have CS if they were cared for at home rather than in hospital: OR 1.48 [95% CI 1.03 to 2.14]. Multiparous women were more likely to say they 'would participate in the study again' if they were cared for at home rather than in hospital: OR 1.80 [95% CI 1.27 to 2.54]. The risk of neonatal infection was higher if women were cared for at home compared with in hospital: OR 1.97 [95% CI 1.00 to 3.90].

An RCT (2002) compared expectant management at home (n = 29) with expectant management in hospital (n = 27) for women with term PRoM.[444] [EL = 1−] Women in both groups were induced if labour had not started by the time 24 hours had elapsed. There was no difference between groups regarding time from rupture of membranes to birth (home: 31.39 hours (SD 12.70 hours); hospital: 26.99 hours (SD 11.78 hours), t value = 1.34, P = 0.18). No differences were found between groups for: maternal infection on first admission (high vaginal swab on admission): 7/28 versus 9/27, $\chi^2 = 0.46$, P = 0.49; maternal infection at the onset of labour (high vaginal swab at onset of labour): 14/24 versus 11/23, $\chi^2 = 0.521$ P = 0.47, or neonatal infection (neonatal infection screen negative): 12/17 (12 not screened) versus 11/12 (15 not screened), $\chi^2 = 2.98$, P = 0.23. The authors acknowledge, however, that the trial is underpowered to detect a significant difference in these outcomes.

A prospective observational study compared outcomes for women managed at home with out-patient check-ups to await spontaneous onset of labour following term PRoM (n = 176) with a historical group of women managed as hospital inpatients with induction of labour between 6–12 hours (n = 100).[445] [EL = 2−] Women managed at home were asked to check their temperature twice daily and attend the antenatal clinic every other day for electronic FHR monitoring and to check for signs of infection. The range of time intervals from rupture of membranes to birth for women in the intervention group (10th–90th centile) was 14–85 hours. Although maternal infectious morbidity, fetal distress during labour and instrumental vaginal birth due to failure to progress were higher in the intervention group where there was longer elapsed time from rupture of membranes to birth, this did not reach statistical significance. The incidence of neonatal infectious morbidity was 2% in each study group. There were two neonatal deaths in the expectant management at home group; however, neither baby had positive cultures for infection.

Risk factors associated with maternal infection following term PRoM

Description of included studies

Evidence for this section is drawn from subgroup analyses carried out as part of the systematic review of 12 trials described above[442] [EL = 1+] plus secondary analyses of findings from the international, multicentre trial.[443,446] [EL = 2++] One small quasi-RCT,[447] [EL = 1−] one prospective observational study[449] [EL = 2+] and a retrospective case–control study[448] [EL = 2+] are also included.

Review findings

Parity

Subgroup analyses of findings from the systematic review described above investigated the effects of parity on maternal and neonatal outcome following term PRoM.[442] [EL = 1+] No significant differences were found between outcomes for nulliparous and multiparous women.

A retrospective case–control study of women with PRoM at 37 weeks of pregnancy or more has been conducted in Israel (2004) (n = 132 cases and n = 279 controls).[448] [EL = 2+] The study compared three groups of women: those who had had labour induced immediately; women who had been managed expectantly up to 24 hours and then induced; and women who had been managed expectantly for over 24 hours. The primary outcome was chosen as all

infection, no distinction being made between maternal and neonatal infection, although it is noted that the rate of neonatal infection overall was very low (less than 1%). Multivariate analysis by stepwise logistic regression revealed that nulliparity was independently associated with infections in the woman and the baby (maternal and neonatal): OR 1.92 [95% CI 1.19 to 3.00].

Unfavourable/favourable cervix

The systematic review also undertook a subgroup analysis to investigate the effects of an unfavourable versus a mixed state or unstated state of cervix.[442] [EL = 1+] No significant differences were found between outcomes when comparing these two subgroups.

A small US quasi-randomised RCT compared immediate induction of labour (n = 32) with expectant management (n = 35) for women with PRoM between 38 and 41 weeks of pregnancy.[447] [EL = 1−] All women included in the study had a cervix which was deemed unfavourable for induction of labour (2 cm or less dilated and no more than 50% effaced). The incidence of endometritis was higher in the immediate induction group: 4/35 versus 10/32, P = 0.04 (Fisher's Exact Test). This may be partly explained by the longer labours observed for women in this group: (mean) 10.44 hours (SD 5.5 hours) versus 14.1 hours (SD 6.0 hours); and the higher number of vaginal examinations performed during labour for women in this group: (mean) 3.9 versus 5.7. There were no incidents of neonatal sepsis in either group.

Vaginal examinations

The international, multicentre trial of term PRoM also investigated predictors of clinical chorioamnionitis and postpartum fever.[443,446] [EL = 2++] The predictors were calculated using secondary analysis of trial data which compared immediate with expectant management for up to 4 days following term PRoM. Clinical chorioamnionitis was defined as one or more of the following: maternal fever greater than 37.5 °C on two or more occasions 1 hour or more apart, or a single temperature greater than 38 °C before giving birth; maternal white blood cell count greater than 20,000 cells/mm^3 or foul-smelling amniotic fluid.[446] [EL = 2++] Clinical chorioamnionitis occurred in 6.7% women (n = 335). The number of vaginal examinations (VEs) was found to be the most important independent predictor, the risk of infection rising as the number of VEs increases. For example: less than 3 VEs versus 3–4 VEs: OR 2.06 [95% CI 1.07 to 3.97]; while less than 3 VEs versus 7–8 VEs: OR 3.80 [95% CI 1.92 to 7.53], and the incidence of chorioamnionitis increased from 2% to 13%.

The retrospective case–control study conducted in Israel also found number of vaginal examinations to be an independent predictor of infection (maternal and/or neonatal).[448] [EL = III] Women who had undergone seven or more vaginal examinations during labour were found to be at increased risk of infection (themselves or their baby) compared with women who had been examined vaginally less than seven times (OR 2.70 [95% CI 1.66 to 4.34]).

Duration of labour

Secondary analysis of data from the large, international multicentre trial of term PRoM also found that the effect of duration of active labour became very significant once labour duration exceeded 9 hours, with the incidence of chorioamnionitis being 12% compared with 2% where labour lasted less than 3 hours (OR 2.94 [95% CI 1.75 to 4.94]).[446] [EL = 2++] The effect of the length of the latent interval becomes statistically significant for durations over 12 hours: 12 to less than 24 hours versus less than 12 hours, incidence of infection 10% (n = 115) OR 1.77 [95% CI 1.27 to 2.47]; greater than and equal to 48 hours versus less than 12 hours, incidence of infection 10% (n = 68) OR 1.76 [95% CI 1.21 to 2.55]. Postpartum fever occurred in 3% of the study participants (n = 146).[446] [EL = 2++] The most significant independent predictor of postpartum fever was clinical chorioamnionitis (OR 5.37 [95% CI 3.60 to 8.00]). Duration of labour was also an important predictor, with the incidence rising

from 2% for labour 3 hours to less than 6 hours (OR 3.04 [95% CI 1.30 to 7.09]) to 8% for labour 12 hours or longer (OR 4.86 [95% CI 2.07 to 11.4]).

Bathing

A prospective observational study conducted in Sweden compared rates of maternal and neonatal infection between women who chose to bathe following PRoM (n = 538) and those who chose not to bathe (n = 847).[449] [EL = 2+] All women in the study had PRoM at or after 34 weeks of gestation: mean gestational age in each group 39 weeks (SD 1.5 and 1.6). Women were advised not to have a bath if there was meconium-stained liquor, fetal distress or any signs of infection (not defined). There were a significantly higher proportion of nulliparous women in the bathing group (78% versus 53%). There was a low frequency of maternal and neonatal infections. Chorioamnionitis during labour occurred in 1.1% (n = 6) women in the bath group and 0.2% (n = 2) in the no-bath group, P = 0.06. There were three incidents of endometritis in each group, 0.6% and 0.4%, respectively, P = 0.68. The frequency of neonates receiving antibiotics was 3.7% and 4.8%, respectively (P = 0.43).

Risk factors associated with neonatal infection

Secondary analyses of the findings from the international, multicentre trial of term PRoM trial were performed in order to identify independent predictors of neonatal infection.[300] [EL = 2++] Neonatal infection was defined as either definite or probable based upon clinical signs supported by at least one of an extensive range of well-recognised laboratory tests. Definite or probable infection occurred in 2.6% of neonates (n = 133). The strongest predictor of neonatal infection following term PRoM was clinical chorioamnionitis (OR 5.89 [95% CI 2.02 to 4.68]). Other independent predictors identified included positive maternal GBS status (compared with unknown or negative) (OR 3.08 [95% CI 1 2.02 to 4.68]); 7 or 8 VEs (compared with 0 to 2) (OR 2.37 [95% CI 1.03 to 5.43]); and maternal antibiotics administered before birth (OR 1.63 [95% CI 1.01 to 2.62]).

Use of intrapartum prophylactic antibiotics

Description of included studies

A systematic review of two RCTs[450] (n = 838 women) [EL = 1+] and subgroup analysis from a systematic review of 12 RCTs[442] [EL = 1+] provide the evidence for this section.

Review findings

A systematic review has been conducted to assess the effects of antibiotics administered prophylactically to women with PRoM at 36 weeks or beyond.[450] [EL = 1+] Two trials were included in the review, involving a total of 838 women. Both trials used management policies involving the administration of IV antibiotics and delayed induction of labour with oxytocin (up to 24 hours). The use of antibiotics resulted in a statistically significant reduction in: endometritis, RR 0.09 [95% CI 0.01 to 0.73]; chorioamnionitis and/or endometritis (3% versus 7%), RR 0.43 [95% CI 0.23 to 0.82]; and a reduction in the neonatal length of hospital stay (reported by one trial), mean difference −0.90 days [95% CI −1.34 to −0.46 days]. No other significant differences were found, including no significant differences in outcomes for neonatal morbidity.

Subgroup analysis from a second systematic review including 12 RCTs also examined the effects of administering prophylactic antibiotics.[442] [EL = 1+] Because of the limitations of the included trials, the comparison groups were not usefully defined, with the resultant comparison being between trials where all women had received antibiotics versus trials where some women had received antibiotics. No differences were found between the two sets of trials for incidence of maternal or neonatal infection.

Evidence statement

There is high-level evidence that shows an increase in neonatal infection when membranes rupture at term before labour starts. This risk increases with the duration of membrane rupture

and while neonatal infection is rare, it is potentially serious and can result in death or disability. Expectant management up to 24 hours shows no evidence of a significant increase in neonatal infection rates. There is absence of evidence on long-term outcomes.
For other neonatal outcomes or instrumental vaginal birth or CS rates, there are no differences between immediate induction and expectant management up to 96 hours after membrane rupture. There is significant increase in the risk of chorioamnionitis and endometritis in the mother with expectant management over 24 hours. There is no evidence for expectant management over 96 hours after membrane rupture, as the vast majority of women have given birth by then.
There is limited high-level evidence of the effect of routine maternal antibiotic prophylaxis for term PRoM on infection rates, but results are conflicting.

Recommendations

59. Do not carry out a speculum examination if it is certain that the membranes have ruptured. [2007]

60. If it is uncertain whether prelabour rupture of the membranes has occurred, offer the woman a speculum examination to determine whether the membranes have ruptured. Avoid digital vaginal examination in the absence of contractions. [2007]

61. Advise women presenting with prelabour rupture of the membranes at term that:

- the risk of serious neonatal infection is 1%, rather than 0.5% for women with intact membranes
- 60% of women with prelabour rupture of the membranes will go into labour within 24 hours
- induction of labour[q] is appropriate approximately 24 hours after rupture of the membranes. [2007]

62. Until the induction is started or if expectant management beyond 24 hours is chosen by the woman:

- do not offer lower vaginal swabs and measurement of maternal C-reactive protein
- to detect any infection that may be developing, advise the woman to record her temperature every 4 hours during waking hours and to report immediately any change in the colour or smell of her vaginal loss
- inform the woman that bathing or showering is not associated with an increase in infection, but that having sexual intercourse may be. [2007]

63. Assess fetal movement and heart rate at initial contact and then every 24 hours after rupture of the membranes while the woman is not in labour, and advise the woman to report immediately any decrease in fetal movements. [2007]

64. If labour has not started 24 hours after rupture of the membranes, advise the woman to give birth where there is access to neonatal services and to stay in hospital for at least 12 hours after the birth. [2007]

q The care of women who have their labour induced is covered by Induction of labour (NICE clinical guideline 70)

Coping with pain in labour – non-epidural

Introduction

A woman's desire for, and choice of, pain relief during labour are influenced by many factors, including her expectations, the complexity of her labour and the severity of her pain. To many women the pain of labour is significant and the majority require some form of pain relief. Flexible expectations and being prepared for labour may influence her psychological wellbeing after birth. Extreme pain can result in psychological trauma for some women, while for others undesirable side effects of analgesia can be detrimental to the birth experience. Effective forms of pain relief are not necessarily associated with greater satisfaction with the birth experience and, conversely, failure of a chosen method can lead to dissatisfaction.
There are two schools of thought around how women might cope with the pain of labour. The first suggests that in the 21st century there is no need to suffer unnecessarily during labour and that effective analgesia is available and should be offered. The second sees pain as part of the experience of birth and advocates that women should be supported and encouraged to 'work with the pain' of labour.
While individual women or carers may identify with either view, the reality for most women is probably somewhere between these two. The challenge for midwives and healthcare professionals is not only to identify where that individual woman lies on the continuum, but also, through good communication, to recognise and respond appropriately to changes in the woman's stance during labour.
Whatever the woman's viewpoint, it is fundamental that she should be treated with respect and as an individual. Women need to be in control of, and involved in, what is happening to them and the manner in which they are supported is key to this. Continuing communication between woman and midwife during the progress of labour about her desire for analgesia is also fundamental, as is the recognition of severe distress.

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- breathing and relaxation
- massage
- complementary therapies
- birth balls
- injected water papules
- water (including temperature regulation).

Women's views and experiences of pain and pain relief in childbirth

Description of included studies

This systematic review was undertaken to specifically address the outcome of women's views of pain relief and the experience of childbirth in relation to intrapartum analgesia. The included studies involve women in labour at term, entering labour without complications. Outcomes include women's views of pain relief and the overall experience of childbirth (including satisfaction with the childbirth experience).

Review findings

A systematic review of 137 reports of pain and women's satisfaction with childbirth was identified for inclusion.[67] [EL = 2++] The review includes descriptive studies, randomised controlled trials and systematic reviews of intrapartum interventions. Findings were summarised qualitatively. Thirty-five reports of 29 studies met the inclusion criteria for observational studies of childbirth satisfaction. Sample sizes ranged from 16 to 2000 and more than 14,000 women from nine countries were studied. Thirteen reports of five

systematic reviews and seven randomised controlled trials were also included. More than 27,000 women were included and the methodology of the studies was generally very good. One systematic review and 20 RCTs met the inclusion criteria for studies of intrapartum pain relief that included a measure of satisfaction as an outcome. The most common method of assessment of satisfaction was a single VAS score, usually made in the immediate postnatal period. The methodological quality of these studies was quite good with generally small sample sizes. The author illustrates the complexity of the relationship between pain, pain relief and women's experiences of childbirth with findings from two population-based surveys (one UK (n = 1150) and one Australian (n = 1336)). The UK survey found that women who were very anxious about labour pain antenatally were less satisfied after the birth. The most satisfied women postnatally were those who had used no pain-relieving drugs during labour. All effects were independent of parity or demographic variables. In the Australian survey, the odds of dissatisfaction were greater when women rated their caregivers as less than very helpful and when women felt they were not actively involved in decision making. The impact on dissatisfaction was greater than that for ratings of pain relief as unsatisfactory. It is also noted that women's views of pain and of pain relief are not the same thing. In 11 of the 21 trials reported in the review, discrepancies were noted between the ratings of pain compared with ratings of pain relief. Synthesis of evidence from all the reviewed papers led to the conclusion that four factors exist:

- personal expectations
- the amount of support from caregivers
- the quality of the caregiver–patient relationship
- the involvement in decision making.

These factors appear to be so important that they override the influence of age, socio-economic status, ethnicity, childbirth preparation, the physical birth environment, pain, immobility, medical interventions and continuity of care when women evaluate their childbirth experience. The author concluded that the influences of pain, pain relief and intrapartum interventions on subsequent satisfaction are neither as obvious, nor as powerful, as the influences of the attitudes and behaviours of the caregivers.

One RCT was identified that investigated nulliparous women's satisfaction with childbirth and intrapartum pain relief when labouring at term.[122] [EL = 1+] The study conducted in Australia compared epidural and non-epidural analgesia findings and, therefore, are from within the context of a trial. Women were 'surveyed' (presumably by questionnaire, but this is not explicit) approximately 24 hours postnatally and again 6 months postpartum by a mailed questionnaire. Women recruited into the study were randomised into one of two groups – the EPI group who were encouraged to have an epidural as their primary pain relief (n = 493), and the CMS group who received one-to-one continuous midwifery support throughout labour and were encouraged to avoid epidural analgesia but instead use Entonox, intramuscular (IM) pethidine and non-pharmacological pain relief (n = 499). There was a high crossover rate within the study: 61.3% women crossed over from the CMS group to the EPI group (n = 306) and 27.8% crossed over from the EPI group to the CMS group (n = 137). Analysis was undertaken on an intention-to-treat basis. Women allocated to the EPI group were significantly more satisfied with their intrapartum pain relief, and the reported pain intensity post-administration was significantly lower for this group. Both groups reported similar and high levels of satisfaction with a degree of midwifery support during labour (median [interquartile range],P value obtained using Wilcoxon rank sum test) (CMS 95 mm [IQR 88 to 100] versus EPI 96 mm [IQR 90 to 100], P = 0.24); participation in intrapartum decision making (CMS 5 [IQR 4 to 5] versus EPI 5 [IQR 4 to 5], P = 0.35); achievement of labour expectations (CMS 3 [IQR 2 to 4] versus EPI 3 [IQR 2 to 4], P = 0.32) and achievement of birth expectations (CMS 2 [IQR 2 to 5] versus, EPI 2 [IQR 2 to 5], P = 0.54).

Despite the difference in satisfaction with pain relief and levels of pain experienced between the two groups, reports of the overall labour experience and overall birth experience were similar for both groups (labour: CMS 4 [IQR 3 to 4] versus EPI 4 [IQR 3 to 4], P = 0.74, birth: CMS 4 [IQR 4 to 5] versus EPI 4 [IQR 3 to 5], P = 0.60). Findings obtained from the 6 month follow-up questionnaire (n = 642; response rate = 64.7%) showed that women in the CMS group were significantly less likely to plan to use an epidural in a subsequent labour (OR 0.64 [95% CI 0.47 to 0.89]). Despite the high crossover rates and intention-to-treat analysis, the findings from this study are, perhaps, as would be expected, i.e. improved pain relief associated with epidural use. This may be because women allocated to the CMS group delayed requests for an epidural. Unfortunately, this is not discussed in the paper, thus making interpretation of the findings difficult.

A prospective survey undertaken in Finland (n = 1091) sought women's expectations for intra-partum pain relief antenatally, measured pain intensity during labour and birth, and followed up women's satisfaction with pain relief on the third day postnatally.[123] [EL = 3] Antenatally, 4% of nulliparous women and 14% of multiparous women felt they would not need any analgesia during labour, with 90% of women overall expressing a wish for intrapartum analgesia. Prior to the administration of any analgesia, 89% of nulliparous women and 84% of multiparous women described their pain during labour as either 'very severe' or 'intolerable'. Twenty percent (n = 213) of women, of whom 14% were nulliparous and 86% were multiparous, received no analgesia during labour. The pain scores of these women did not differ significantly from those women who then went on to receive analgesia. After administration of pain relief, 50% of multiparous women and 19% of nulliparous women still reported pain scores of 8–10 on the BS-11. This difference reflects a higher degree of usage of epidural analgesia among the nulliparous women. Eighteen percent of women rated their pain relief as poor, 37% rated it as moderate, and 45% as good. Surprisingly, views of pain relief were not related to parity. Half of all women complained of inadequate pain relief during labour which, in multiparous women, was significantly associated with the second stage of labour. Overall, 95% of women stated that they were satisfied with their care during childbirth. Ratings of overall satisfaction were not related to parity, level of pain experienced or pain relief received. Findings reflect a lack of effective pain relief, particularly for those women who, for whatever reason, do not choose an epidural. Dissatisfaction with childbirth was very low, and was associated with instrumental births, but not with usage of analgesia. Despite an apparent low level of effectiveness of pain relief, most women expressed satisfaction with care during labour. This may reflect low expectations of pain relief in this population and again demonstrates the complexity of the relationships between reported pain, pain relief, satisfaction with pain relief and the experience of childbirth.

One European multicentre study was reviewed which examined nulliparous women's expectations and experiences of intrapartum analgesia.[124] [EL = 3] The study involved over 100 women from each of five countries (Italy, UK, Belgium, Finland and Portugal; total n = 611). All women were interviewed during the last month of pregnancy and again approximately 24 hours postnatally. Expectations of pain, pain relief and satisfaction were assessed using a 10 cm VAS. Findings showed that women who expected higher levels of pain were more likely to be satisfied with analgesia (Spearman's rho = 0.15, P = 0.001). Women who experienced higher levels of pain following administration of analgesia were less satisfied with pain relief (Spearman's rho = −0.66, P < 0.0001). Maternal satisfaction with the overall childbirth experience was positively correlated with pain expectations (Spearman's rho = 0.23, P < 0.001) and pain before analgesia (Spearman's rho = 0.16, P < 0.001), and negatively correlated with pain after analgesia (Spearman's rho = −0.30, P < 0.001). The most satisfied women were those who expected more pain, were satisfied with analgesia received and had good pain relief after analgesia. Pain did not correlate with women's educational level, age or social class. Generally, women's satisfaction with

analgesia and the birth experience was high. It should be noted that all hospitals involved in the study were tertiary centres with above average epidural rates. Other components of the birth experience, e.g. involvement in decision making, friendliness and expertise of staff, were not investigated in this study.

Evidence statement

A woman's experience of birth vary enormously and is influenced by many factors including her expectations, degree of preparation, the complexity of her labour, and the severity of the pain she experiences.

The attitude and behaviour of the caregiver is consistently seen to be the most obvious and powerful influence on women's satisfaction. Women are more satisfied with pain relief when their expectations of pain and how they choose to manage it are met.

GDG interpretation of the evidence (advice to clinicians regarding non-epidural pain relief)

It is important to remember that relatively simple things can make a difference.

Women appreciate having someone whom they know and trust with them in labour, although there is no high-level evidence on the benefits of this.

Women should be able to play music of their own choice and drink and eat a light diet if they want to during labour.

They can choose to walk, move around, find comfortable positions, sit, stand up, or lie down on their sides. However, if they lie on their backs, they are likely to feel the pain more intensely.

We have prioritised the options for analgesia on the basis of the strength of the evidence of their effectiveness:

- The evidence shows that immersion in water provides effective pain relief, so encouraging the woman to get into a warm bath or birthing pool will help reduce the pain of the first stage of labour, and mean they are less likely to need an epidural. As far as we know, this does not adversely affect maternal or neonatal outcomes. Using a bath or a birthing pool for pain relief does not mean that the woman has to remain in it for birth unless she wants to. Women can get out of the water at any time if they do not like it or want to try another method of analgesia.
- Entonox has the advantage that it acts very quickly and rapidly passes out of the system without affecting the baby and it can be used anywhere – even in the bath. It takes the edge off the pain and helps many women. Some women feel dizzy or light-headed when using it but the advantage of Entonox is that if the woman does not like it, it can be stopped and the side effects will also stop.
- Women who choose to use breathing and relaxation techniques or massage, by their birth partner, should be supported. The little evidence available shows that they may significantly reduce the pain and they do help many women in labour and do not adversely affect either maternal or neonatal outcomes.
- Women who choose to use acupuncture or hypnosis should be able to, although they are not provided by the maternity unit. The little evidence available shows that they may reduce the pain of labour and do not appear to adversely affect either maternal or neonatal outcomes.
- Opioids such as pethidine or diamorphine are widely used and the evidence available shows they provide poor analgesia and can make women feel nauseous and drowsy. As pethidine crosses the placenta, it may make the baby sleepy. This means that the baby may suffer respiratory depression at birth and is sleepy and reluctant to feed for several days after birth. Pethidine should always be administered with an anti-emetic. Women can still

use the bath or birthing pool as long as they are not drowsy and have not had pethidine in the previous 2 hours.

- There is no evidence on the effectiveness of birth balls for reducing the pain of labour. They may, however, help women find a comfortable position.
- We also know that using a transcutaneous electronic nerve stimulation (TENS) machine does not provide any pain relief once the woman is in established labour, and is therefore not recommended at this stage. There are no trials of its use in latent labour when some women choose to use it.
- All women use some kind of pain-relieving strategies during labour, and many will use several different ones. What is important is that they are able to communicate with you to ensure that as far as possible, they feel in control and confident and that both of you remain flexible about what is wanted.

Recommendation on women's views and experiences of pain and pain relief

65. Healthcare professionals should think about how their own values and beliefs inform their attitude to coping with pain in labour and ensure their care supports the woman's choice. [2007]

Pain relieving strategies

Introduction

The evidence regarding pain-relieving strategies is described below and incorporates a wide range of strategies used by many women over the centuries, to help them cope with labour, that do not require professional oversight.
See also the section on support in labour (4.3).

Breathing and relaxation

Description of included studies

One controlled trial of breathing and relaxation techniques was described in a systematic review of complementary therapies used during labour (n = 54 women, but 20 were lost to follow-up).[125] [EL = 1−] Women were randomised into an experimental group who received 'respiratory autogenic training' (progressive muscle relaxation and focused slow breathing) or a control group who attended a 'traditional psychoprophylactic course' (no details are given about the content of this course, but it may also have included a form of relaxation training).

Review findings

Although a significant reduction in reported intrapartum pain was noted for women in the experimental group, this was only found after adjusting for women who were very anxious during pregnancy. Postnatal reports of labour pain and labour experience did not differ significantly between the two groups.

Evidence statement

There is a lack of evidence that breathing and relaxation techniques reduce measured pain in labour or affect any other outcome.

Recommendation on breathing and relaxation

66. If a woman chooses to use breathing and relaxation techniques in labour, support her in this choice. [2007]

Touch and massage

Description of included studies

Two systematic reviews were identified which included evaluation of the use of massage or therapeutic touch for pain relief during labour.[85,125] [both EL = 1+] Each review included two controlled trials, with a total of three studies included overall: two RCTs and one prospective

cohort study. The two RCTs reviewed were fairly small (n = 24 and n = 60) and conducted in the USA and Taiwan, respectively.

Review findings

Differences between the trials prohibit pooling of the data. In both trials the woman's partner was shown how to carry out massage and this was then performed for set periods of time throughout the first stage of labour (20–30 minutes/hour). In the larger trial, the control group received a 'casual' contact with the researcher for the same periods of time, while in the smaller study the control group received 'usual care' including guidance on breathing and relaxation techniques. In the larger study it is not clear whether the nurse carrying out the pain assessment was blinded, while in the smaller trial, blinding of the nurse assessor was carried out. Pain was also assessed by the women themselves. Both trials showed a significant reduction in labour pain as reported by the nurse observers and the women. No mention was made of other analgesia used during labour, for women in either group.

In the smaller study, a significant reduction in intrapartum stress and anxiety was reported by both the women and the blinded observer. There was also a significant improvement in maternal mood (self-rated using a depression scale) both during labour and postnatally.

A prospective cohort study, conducted in the USA, examined the effect of therapeutic touch during labour (n = 90). Women in the experimental group received touch from the midwife (e.g. handholding) for a period of 5–10 seconds after each verbal expression of anxiety. The study was carried out during a 30 minute intervention period at the end of the first stage of labour (8–10 cm dilatation). The control group received 'usual care'. Despite the seemingly short duration of the intervention, maternal anxiety (as measured by blood pressure, verbal expressions of anxiety and anxiety scores reported by mother in the early postnatal period) were found to be reduced significantly ($P < 0.05$) in the experimental group, compared with the control group.

Evidence statement

The limited available evidence suggests that massage and reassuring touch reduces a woman's measured pain and expressed anxieties during labour. There is no high-level evidence that birth outcomes are influenced by massage.

Recommendation on touch and massage

67. If a woman chooses to use massage techniques in labour that have been taught to birth companions, support her in this choice. [2007]

Labouring in water

Introduction

The Winterton report recommended that all maternity units should provide women with the option to labour and give birth in water.[95] However, the number of women actually using water during labour is not well reported. A survey between April 1994 and March 1996 identified 0.6% of births in England and Wales occurring in water, 9% of which were home births.[126] There would appear to be a wide variation in the use of water during birth, with one birth centre reporting up to 80% of women using water during labour and up to 79% giving birth in water.[127]

Previous guideline

Water birth was reviewed in the NICE Caesarean Section guideline.[6] The guideline reviewed one systematic review, one RCT and some other observational studies and recommended that women should be informed that immersion in water during labour has not been shown to influence the likelihood of CS, although it may affect other outcomes.

Description of included studies

There was one systematic review and one RCT identified for inclusion in the review. The systematic review included eight trials.[128] [EL = 1+] Out of the eight trials, six examined

labouring in water in the first stage, one examined labouring in water in the second stage, and one investigated the timing of the use of water in the first stage of labour. An additional RCT examined effectiveness of use of water in the first stage compared with augmentation.[129] [EL = 1−]

There was no relevant study identified that addressed hygiene measures for water birth.

Review findings

Use of water versus other methods

Women's outcomes

Meta-analysis of findings from four trials reported in the systematic review[128] [EL = 1+] showed that the use of water in the first stage of labour reduces the use of epidural/spinal analgesia/anaesthesia (OR 0.84 [95% CI 0.71 to 0.99]). One trial reported significantly reduced reported pain for those women who laboured in water compared with those not labouring in water (OR 0.23 [95% CI 0.08 to 0.63]).

Meta-analysis of four trials in the review showed no evidence of differences on duration of the first and second stages of labour between women who laboured in water and those who did not. Six trials reported on instrumental birth rates and CS. Findings from a meta-analysis of these trials showed that overall there was no evidence of any difference: instrumental vaginal birth rate (OR for use of water 0.83 [95% CI 0.66 to 1.05]) and CS rate (OR for use of water 1.33 [95% CI 0.92 to 1.91]).

There was no evidence of differences on perineal trauma with labouring in water: episiotomy (OR 0.89 [95% CI 0.68 to 1.15]), second-degree tears (OR 0.90 [95% CI 0.66 to 1.23]) or third/fourth-degree tears (OR 1.38 [95% CI 0.85 to 2.24]).128 [EL = 1+]

Newborn outcomes

Five trials reported on Apgar scores at 5 minutes and there was no difference in the number of babies with a score of less than 7 at 5 minutes (OR 1.59 [95% CI 0.63 to 4.01]). Two trials reported admissions to the neonatal unit and found no evidence of difference (OR 1.05 [95% CI 0.68 to 1.61]). Infection rates were reported in four trials and were found to be very low (6/629 versus 3/633; OR 2.01 [95% CI 0.50 to 8.07]).

Timing of use of water

One trial in the systematic review compared early versus late immersion during the first stage of labour, and found significantly higher epidural analgesia rates in the early group (42/100 versus 19/100; OR 3.09 [95% CI 1.63 to 5.84]) and an increased use of augmentation of labour (57/100 versus 30/100; OR 3.09 [95% CI 1.73 to 5.54]).130

Augmentation versus use of water

One trial compared augmentation versus immersion in water during the first stage of labour.129 [EL = 1−] It showed that use of water reduced rate of augmentation (RR 0.74, P = 0.001) and increased some aspects of satisfaction (freedom of movement MD 1.46, P = 0.001; privacy MD 1.18, P = 0.03; satisfaction with the care MD 1.07, P = 0.49). There were more babies admitted to neonatal units with use of water (admission to neonatal unit 6/49 (water), 0/50 (air), P = 0.01), but there is no evidence of a difference on cord arterial pH or infection rate (cord arterial pH 7.26 (water), 7.25 (air), P = 0.97; infection 8/49 (water), 9/50 (air), P = 0.78).

Evidence statement

Labouring in water reduces pain and the use of regional analgesia. There is evidence of no significant differences regarding adverse outcomes when comparing labours with and without the use of water. There is insufficient evidence on timing of use of water in labour.

There is no good-quality evidence regarding hygiene measures for water birth.

Recommendation on labouring in water

68. Offer the woman the opportunity to labour in water for pain relief. [2007]

69. For women labouring in water, monitor the temperature of the woman and the water hourly to ensure that the woman is comfortable and not becoming pyrexial. The temperature of the water should not be above 37.5°C. [2007]

70. Keep baths and birthing pools clean using a protocol agreed with the microbiology department and, in the case of birthing pools, in accordance with the manufacturer's guidelines. [2007]

Birth balls

Overview of available evidence

No studies were identified which examined the use of birth balls during labour.

Evidence statement

There is no evidence of any effect of birth balls on birth experience or clinical outcomes.

Injected water papules

Description of included studies

Two systematic reviews were identified, both of which reviewed the same four RCTs examining the effectiveness of cutaneous water injections.[85,125] [EL = 1+]

Review findings

The four included trials were of fair to good quality, with sample sizes ranging from 35 to 272. Women in labour reporting back pain or severe back pain were entered into the trials. Three trials described adequate randomisation, three were double-blinded placebo-controlled trials, and three trials were analysed on an intention-to-treat basis. In all cases there were some missing data due to women giving birth before the end point of the trial [range 4% to 30%]. Differences between the trials mean pooling of data is not possible. In all four trials back pain was significantly reduced for 45 to 90 minutes following the intradermal injections of sterile water, as measured by a VAS. In the one trial that compared subcutaneous and intradermal water injections, both were found to be similarly effective compared with the control of subcutaneous saline injections. Despite the pain relief reported, there was no significant difference between experimental and control groups in three of the trials, regarding subsequent use of analgesia. In one trial, use of subsequent analgesia was higher in the experimental group than in the control group where women received massage, baths and were encouraged to mobilise. In this trial, women in the control group were more likely than women in the experimental group to say that they would choose the same pain relief option for a subsequent labour. In the other three trials, women who had received cutaneous water injections were more likely to say they would choose the same option for a future labour. No trial reported the effects of repeated injections.

One of the main disadvantages of this method of pain relief is the intense stinging pain that many women report during the administration of the intradermal injections. An RCT was conducted in Sweden to compare the perceived pain during administration of intradermal versus subcutaneous injections of sterile water.[131] [EL = 1+] The work involved 100 healthy women (not pregnant/in labour) in a blind, controlled trial with a crossover design. Perceived pain was measured using a VAS. The findings showed that intradermal injections were reported as being much more painful than subcutaneous injections (mean 60.8 mm versus 41.3 mm, $P < 0.001$). It is not known, however, whether this finding would apply to women in labour.

Evidence statement

There is a lack of evidence of the benefit of injected water papules on birth experience or clinical outcomes.

Recommendation on injected water papules

71. Do not use injected water papules. [2007]

Complementary and alternative therapies

Previous guideline

The Caesarean Section guideline reviewed the effectiveness and safety of complementary and alternative therapies for women during labour.[6] The guideline included a systematic review comprising seven trials and five observational studies. In the guideline, it was recommended that women should be informed that the effects of complementary therapies used during labour (such as acupuncture, aromatherapy, hypnosis, herbal products, nutritional supplements, homeopathic medicines, and Chinese medicines) on the likelihood of CS have not been properly evaluated, and further research is needed before such interventions can be recommended.

Acupressure and acupuncture

Description of included studies

Four reasonable quality RCTs were identified.[132–135] A Korean trial (intervention n = 36; control n = 39) compared SP6 acupressure to controls that received touch at the same point.[132] A second trial, conducted in Norway (intervention n = 106; control n = 92), compared a group of women who received acupuncture with a group who did not receive acupuncture or a placebo.[135] A third study, also conducted in Norway, compared acupuncture with false acupuncture (intervention n = 106; control n = 102).[134] A Swedish study involving 90 women (intervention n = 46; control n = 44) was also identified. The control did not receive any form of placebo.[133] While the trial that investigated effectiveness of acupressure in labour reported separately, a new meta-analysis was conducted using these three trials on acupuncture, as they are considered to have reasonable homogeneity. [EL = 1+]

Review findings

There was evidence of reduction in pain score after SP6 acupressure compared with SP6 touch (WMD −1.20 [95% CI −2.04 to −0.36]), but no evidence of difference in use of pharmacological pain relief (RR 0.54 [95% CI 0.20 to 1.43]).

Meta-analysis of the RCTs showed that acupuncture significantly reduced the use of pharmacological pain relief (two trials RR 0.74 [95% CI 0.63 to 0.86]), epidural analgesia (two trials RR 0.45 [95% CI 0.29 to 0.69]) and the need for augmentation of labour with oxytocin (two trials RR 0.58 [95% CI 0.40 to 0.86]). There was no evidence of differences in pain score after acupuncture (one trial MD −0.20 [95% CI −0.80 to 0.40]) or rate of spontaneous vaginal birth (three trials RR 1.03 [95% CI 0.97 to 1.09]). Outcomes such as maternal satisfaction and maternal and neonatal complications were not investigated.

Hypnosis

Description of included studies

A systematic review, published in 2004, involving five RCTs and 14 comparative studies was identified, but only the evidence from the RCTs has been included here.[136] All the RCTs were conducted in either the UK or the USA. [EL = 1+]

Review findings

Meta-analysis of the RCTs showed that hypnosis significantly reduced the use of pharmacological pain relief (three trials RR 0.51 [95% CI 0.28 to 0.98]) and of the need for

labour augmentation (two trials RR 0.31 [95% CI 0.18 to 0.52]). No other outcomes were considered.

Aromatherapy

Description of included studies

A systematic review involving one RCT in New Zealand was identified.[137] The study population comprised 22 multiparous women. Women in the intervention group received essential oil of ginger or essential oil of lemongrass in the bath, and they were required to bathe for at least 1 hour. [EL = 1+]

Review findings

There was no evidence of a difference in the use of pharmacological pain relief (RR 2.50 [95% CI 0.31 to 20.45]), rates of spontaneous vaginal birth (RR 0.93 [95% CI 0.67 to 1.28]), instrumental birth (RR 0.83 [95% CI 0.06 to 11.70]) or CS (RR 2.54 [95% CI 0.11 to 56.25]). There were no other outcomes investigated.

Music

Description of included studies

One RCT published in 2003 involving 110 women in labour (intervention n = 55; control n = 55) provides the evidence for this subsection.[138] Women in the intervention group listened to soft music without lyrics for 3 hours, whereas women in the control group did not listen to music. The trial was conducted in Thailand. [EL = 1+]

Review findings

The trial compared scores made using two VASs, and showed a significant reduction in both the sensation of, and distress from, pain (sensation of pain (pre and 3 hourly post tests undertaken three times): $F(1107) = 18.69$, $P < 0.01$, effect size = 0.15; distress of pain (undertaken as above): $F(1107) = 14.87$, $P < 0.001$, effect size = 0.12). There were no other outcomes investigated.

Audio-analgesia

Description of included studies

Again, one RCT that was included in the systematic review was included.[137] [EL = 1+] This was conducted in the UK and published in 1965. The study population comprised 25 women in labour. Women in the intervention group received audio-analgesia which consisted of 'sea noise' white sound set at 120 decibels, and the control group received sea noise at a maximum of 90 decibels.

Review findings

The trial reported maternal satisfaction about care received, which showed no evidence of a difference (RR 2.00 [95% CI 0.82 to 4.89]). There were no other outcomes available.

Evidence statement

There is some evidence from small studies regarding the use of acupuncture, acupressure and hypnosis for the management of pain in labour. There is a lack of evidence on other outcomes.

Acupuncture seems to be associated with a reduction in the use of pharmacological pain relief and augmentation, but with no reduction in pain scores.

Hypnosis seems to be associated with a reduction in the use of pharmacological pain relief and augmentation. There is a lack of evidence on pain scores.

There is a lack of high-level evidence that music, aromatherapy or audio-analgesia influence women's pain in labour or any other outcome.

Recommendations on complementary therapies

72. Do not offer acupuncture, acupressure or hypnosis, but do not prevent women who wish to use these techniques from doing so. [2007]

73. Support the playing of music of the woman's choice in labour. [2007]

Research recommendations on non-invasive techniques in labour

13. A combination of randomised trials and qualitative research should investigate the effect of a package of care, involving the use of non-invasive techniques throughout labour and birth, on women's birth experiences. This should include studies that explore which aspects of the package of care affect both women's experience and maternal and neonatal outcomes.

Non-pharmacological analgesia

Introduction

This section covers TENS, which once again does not require professional oversight.

Review question

Is there evidence that the type, frequency and mode of administration of the following pharmacological and non-pharmacological pain relief and regional analgesia influence outcomes?

- pharmacological pain relief: Entonox®, PCAs, pethidine, diamorphine and meptazinol (Meptid®)
- non-pharmacological pain relief: TENS.

Transcutaneous electrical nerve stimulation (TENS)

Description of included studies

One systematic review conducted in 1997 was identified.[139] (n = 877: TENS n = 436; controls (sham TENS or no treatment) n = 441). The systematic review included ten RCTs, among which three RCTs compared TENS with no TENS, seven RCTs compared TENS with sham TENS and one RCT compared both. Only one RCT achieved an adequate level of blinding. [EL = 1+]

Review findings

Pain outcome measures were reported in ten RCTs. There was no consistency in the method of measuring, but no study recorded any difference in pain intensity or pain relief scores between TENS and controls. The need for additional analgesic interventions was reported in eight RCTs. There was no evidence of difference for this need (combined RR 0.88 [95% CI 0.72 to 1.07]). There were no reports of adverse events in the ten RCTs.

Evidence statement

There is high-level evidence that TENS is not an effective analgesic in established labour. There is no high-level evidence on the analgesic effect of TENS in the latent phase of labour.

Recommendations on TENS

74. Do not offer transcutaneous electrical nerve stimulation (TENS) to women in established labour. [2007]

Inhalational analgesia

Introduction

This form of analgesia has been available since 1962 and approved for midwives to administer since 1970. It involves the woman inhaling through a mask or mouthpiece. It has

the advantages of rapid action, it is non-accumulative and does not pass across the placenta to affect the baby.

Nitrous oxide

Description of included studies

One systematic review published in 2002 was identified.[140] The study included eight controlled studies and eight observational studies. [EL = 2+] While most studies included use of a 50% nitrous oxide concentration, nine involved comparisons of varying concentrations ranging from 30% to 80%. Owing to the inconsistency of the included methods, the results are summarised descriptively.

Review findings

Analgesic efficacy was adequately reported in 11 studies. Although there was no clear, quantitative, objective evidence, seven studies described significant analgesia with nitrous oxide and two studies reported that women chose to continue using nitrous oxide even after the study period was over.

The effect of nitrous oxide on uterine contractions was reported in one study, and no alteration was observed. Another study found no effect on the progress of labour. Nausea and vomiting was reported as ranging from 5% to 36% with nitrous oxide but there were no proper controls in eight studies. Loss of consciousness was reported in two RCTs, but this was not statistically significant.

Apgar scores were reported in four studies, and there was no evidence of any differences. One study also showed no difference in early neurobehavioural scale.

Evidence statement

There is a moderate level of evidence to support the use of nitrous oxide in labour. Nitrous oxide seems to relieve some pain but can make women feel nauseous and light-headed. There is no evidence of harm to the baby.

Recommendation on nitrous oxide

75. Ensure that Entonox (a 50:50 mixture of oxygen and nitrous oxide) is available in all birth settings as it may reduce pain in labour, but inform the woman that it may make her feel nauseous and light-headed. [2007]

Intravenous and intramuscular use of opioids for labour

Introduction

Pethidine is widely used as an analgesic during labour. Its ease of administration and the fact that the Central Midwives' Board approved it in 1950 has probably contributed to its widespread use.

Pethidine did not undergo RCTs prior to its introduction into clinical practice in the UK, and its perceived analgesic efficacy could in part be due to its sedative effects.

Intramuscular use of opioids

Intramuscular (IM) opioids versus placebo

Pethidine versus placebo

Description of included studies

Two double-blind RCTs compared IM pethidine with an IM placebo. The first trial (n = 224) was reported in a systematic review.[141,142] [EL = 1+] A second RCT involving 50 women was conducted in Hong Kong.[143] [EL = 1+]

Review findings

An RCT, reported in a systematic review, found significantly more women were dissatisfied with pain relief in the placebo group compared with the group of women who received

pethidine when assessed during labour (83% versus 71%, P = 0.04) and after giving birth (54% versus 25%, P = 0.00004). It should be noted that the number of women dissatisfied with pain relief was high in both groups. Similarly, significantly more caregivers were dissatisfied with the placebo. No other outcomes were investigated.

Results from a second RCT conducted in Hong Kong support these findings.[143] [EL = 1+] A significant reduction in VAS pain score 30 minutes post-administration was found for women in the group who received pethidine (n = 25) compared with those who received the placebo (n = 25) (pethidine: median change −11 mm; placebo: median change +4 mm, P = 0.009). At 30 minutes the median VAS score was significantly lower in the pethidine group compared with the control group (54 versus 78 mm, P = 0.01). Eight women in the group who received pethidine required no further analgesia compared with one in the control group (P = 0.01). Thirty minutes after administration, women were also asked to rate on a 5-point Likert scale how satisfied they were with the pain relief received. Scores were significantly higher for women in the pethidine group, although neither had very high scores (median 2 for pethidine group and 1 for control group). Eight percent of women in the pethidine group were totally dissatisfied with the pain relief received compared with 60% in the control group.

IM opioids versus IM opioids: different opioids

Description of included studies and review findings

Tramadol versus pethidine

Two systematic reviews include three RCTs of tramadol 100 mg versus pethidine 50–100 mg for analgesia in labour.[141, 142] [EL = 1+] The trial sizes ranged from 40 to 60 women, and in total involved 144 women.

Two trials reported women's satisfaction with pain relief 1–2 hours post-administration and both found no significant difference between the two groups (women not satisfied with pain relief: 15/50 versus 13/49; OR 1.18 [95% CI 0.49 to 2.84]). The third trial reported VAS scores following administration of analgesia, which was significantly lower in the group of women who had received pethidine compared with those who received tramadol (mean 66.10 mm [SD 18.34 mm] versus 52.91 mm [SD 22.23 mm]; WMD 13.20 mm [95% CI 0.37 to 26.03 mm]). All trials included measures of nausea/vomiting during labour and meta-analysis of the findings showed no significant difference between the two drugs (6/74 versus 9/70; OR 0.63 [95% CI 0.21 to 1.84]). Similarly, meta-analysis of the findings showed no significant difference in drowsiness/sleepiness between tramadol and pethidine (16/74 versus 22/70; OR 0.61 [95% CI 0.29 to 1.29]). There were no significant differences found for mode of birth. Neonatal outcome was not evaluated.

A more recent RCT conducted in Turkey (n = 59) reported greater pain relief with pethidine (100 mg) compared with tramadol (100 mg), although neither provided good analgesia.[144] [EL = 1+] On a 5-point Likert scale of pain intensity, the median score at 1 hour post-administration was 4 for pethidine and 5 for tramadol (P < 0.05). Incidence of nausea and fatigue 1 hour following drug administration was also significantly higher in women who were given tramadol (nausea: 1/29 versus 9/30, P = 0.004; fatigue: 15/29 versus 23/30, P = 0.045). The findings of this study are a little difficult to interpret as it is not clear which statistical tests were applied to any given comparison. The incidence of neonatal respiratory depression was high in this study, occurring in three of the babies born in the pethidine group and seven in the tramadol group. It was reported that all recovered with 'supplementary oxygen therapy in the ICU'. No opiate antagonists were given. Mean Apgar scores at 1 minute were 7.76 (SD 1.06) and 7.13 (SD 1.38), and at 5 minutes 9.28 (SD 0.65) and 9.17 (SD 0.91) in the pethidine and tramadol groups, respectively.

Meptazinol versus pethidine

Evidence for this section is drawn from the two systematic reviews identified in the subsection above and includes the same seven trials that compare pethidine with tramadol.[141,142] [both EL = 1+] In six of the trials, 100 mg meptazinol (Meptid®) was compared with a similar dose of pethidine. In one trial the comparison was between 75 mg meptazinol and 50 mg pethidine. The trials involved a total of 1906 women, with trials ranging in size from 10 to 1035 women.

A variety of outcome measures were used to assess pain relief, e.g. lack of satisfaction with pain relief 1–2 hours post-administration, VAS (0–100), need for additional pain relief during labour and use of epidural analgesia. In these studies, analgesia was found to be similar for the two drugs, with no significant differences between the various outcome measures. Three trials investigated nausea and vomiting. In two of these trials, there were no significant differences but the largest trial (n = 1035) showed that pethidine resulted in significantly less nausea and vomiting (184/498 versus 141/507; OR 1.52 [95% CI 1.17 to 1.98]). Meta-analysis of the three trials retains this significant difference owing to the dominant effect of the large trial (OR 1.37 [95% CI 1.09 to 1.72]). The large trial was the only study to investigate drowsiness/sleepiness and found this to be significantly higher in women who had received pethidine compared with those who received meptazinol (202/522 versus 147/513; OR 0.64 [95% CI 0.49 to 0.83]). No significant differences were found regarding mode of birth, fetal distress, Apgar scores, neonatal death or admission to a neonatal unit. Only the large trial reported on naloxone administration as an outcome measure, where a tendency towards higher incidence of naloxone administration was noted for babies born to women in the pethidine group (231/496 versus 198/479; OR 0.81 [95% CI 0.63 to 1.04]). This high incidence of naloxone administration is not commented upon by the authors of the review, although it should be noted that naloxone use is much less frequent in current UK practice following recommendations made by the UK Resuscitation Council.

Diamorphine versus pethidine

One UK RCT compared IM diamorphine (n = 65) with IM pethidine (n = 68).[145] [EL = 1+] Nulliparous women were randomised to receive either IM pethidine 150 mg or diamorphine 7.5 mg. Multiparous women were randomised to receive either 100 mg pethidine IM or 5 mg diamorphine IM. All participants received the anti-emetic prochlorperazine at the same time as the trial drugs. Two measures of pain relief favoured diamorphine compared with pethidine: VAS score (0–100) 1–2 hours after administration (58 versus 67; WMD −9.00 [95% CI −10.21 to −7.79], P < 0.0001) and women not satisfied with pain relief 1–2 hours post-administration (35 versus 56; RR 0.63 [95% CI 0.43 to 0.94], P = 0.02). Vomiting during labour was also significantly reduced in the group of women who received diamorphine (11 versus 28; RR 0.39 [95% CI 0.17 to 0.86], P = 0.02). No significant difference was found for sleepiness or drowsiness during labour, mode of birth, 5 minute Apgar scores or neonatal death/admission to neonatal intensive care unit (NICU). Time from first drug dose to birth was shorter for women assigned to the pethidine group (4.5 versus 4.9 hours, WMD 0.40 hours [95% CI 0.26 to 0.54 hours]). This represents a difference of 24 minutes, which is not likely to be significant clinically.

Pentazocine versus pethidine

Six double-blind RCTs compared 40–60 mg pentazocine with 100 mg pethidine. Trial sizes ranged from 60 to 180 women, including 678 women in total, and are summarised in two systematic reviews.[141,142] [EL = 1+] Based on a meta-analysis of findings from all six studies, no significant difference was found between the two groups regarding pain relief (measured as women not satisfied with pain relief 1–2 hours after administration): OR 0.99 [95% CI 0.70 to 1.39]. Significantly more women in the pentazocine group required further analgesia (OR

1.95 [95% CI 1.31 to 2.89], data from five studies). There was a trend towards fewer women suffering nausea and vomiting during labour in the pentazocine group, although the numbers involved were small and did not reach statistical significance (OR 0.56 [95% CI 0.30 to 1.07]). No significant differences were noted for drowsiness/sleepiness in labour. Few trials reported on other outcomes and, where they did, the numbers involved were small and differences not statistically significant.

IM opioids versus IM opioids: same opioid, different doses

Description of included studies

Two trials conducted in the 1970s compared a higher and lower dose of pethidine. Both are reported in the two systematic reviews outlined above.[141,142] A total of 173 women were involved in the two studies. One trial reported in both systematic reviews compared tramadol 50 mg (n = 30) with 100 mg (n = 30).[141,142]

Review findings

Pethidine 40–50 mg versus pethidine 80–100 mg

Each study used a different outcome for the assessment of pain relief. In the larger study, women's satisfaction with pain relief 1–2 hours post-administration was recorded. A high proportion of women in both groups were not satisfied with the pain relief received; 42/55 in the lower dose group and 37/57 in the higher dose group (OR 1.73 [95% CI 0.77 to 3.88]). The smaller study (n = 20 in each group) reported numerical pain scores 2 hours after drug administration. Again there was no difference between the two groups (mean numerical pain score): lower dose 1.70 (SD 0.63); higher dose 1.35 (SD 0.45); OR 0.35 [95% CI 0.01 to 0.69]. Both studies reported the need for additional analgesia (other than epidural), which was significantly higher for women in the lower dose group (28/88 versus 10/85; OR 3.74 [95% CI 1.75 to 8.00]). The use of epidural analgesia was not reported, perhaps because these studies were carried out in the 1970s when the use of epidural analgesia was not widespread. The incidence of nausea and vomiting was also investigated by both studies and, although found to be higher for the higher dose in both, this did not reach statistical significance (9/88 versus 17/85; OR 0.46 [95% CI 0.20 to 1.06]. Drowsiness and sleepiness were also more commonly reported by women in the higher dose group, although again this increase did not reach statistical significance (11/68 versus 19/65; OR 0.48 [95% CI 0.21 to 1.07], one study). No other maternal outcomes were reported. Neonatal outcomes were only investigated by the smaller study, where one baby in the higher dose group required resuscitation and one required naloxone, compared with none in the lower dose group.

Tramadol 50 mg versus 100 mg

Findings from this trial showed that more women in the lower dose group were not satisfied with pain relief 1–2 hours after administration (27/30 versus 7/30; OR 14.44 [95% CI 5.24 to 39.74]). Side effects were rare and slightly more prevalent in the higher dose group, but these differences did not reach statistical significance (nausea or vomiting: 1/30 versus 3/30, OR 0.35 [95% CI.005 to 2.61]; drowsiness or sleepiness: 2/30 versus 3/30, OR 0.65 [95% CI 0.11 to 4.00]). There was one instrumental birth and one caesarean birth in each group. No other outcomes were considered.

Intravenous use of opioids

Intravenous (IV) opioids versus placebo

IV pethidine versus IV placebo

Description of included studies

Two RCTs were reviewed that compared IV pethidine with an IV placebo (saline). The first was a double-blind RCT undertaken primarily in order to investigate the effects of pethidine on labour dystocia, looking at analgesic efficacy as a secondary outcome.[146] [EL = 1+] A second RCT, carried out in Thailand, examined the efficacy and side effects of IV pethidine.[147] [EL = 1+]

Review findings

In an RCT involving women in delayed active labour (4–6 cm cervical dilatation, delay diagnosed by attending obstetrician), the women were randomly assigned to receive 100 mg pethidine IV (administered in 50 ml saline over 15 minutes) (n = 205) or IV placebo (n = 202).[146] [EL = 1+] Pain was assessed using a VAS 15, 30 and 60 minutes after administration. Pain scores, at all times, were significantly lower for women receiving the pethidine (severe pain score (7–10 on VAS): at 15 minutes RR 0.87 [95% CI 0.78 to 0.96]; at 30 minutes RR 0.75 [95% CI 0.66 to 0.84]; at 60 minutes RR 0.74 [95% CI 0.66 to 0.84]; during second stage: RR 0.77 [95% CI 0.69 to 0.86]). However, more than 66% of the women rated their pain scores as severe throughout the first hour following the administration of pethidine. The incidence of side effects was significantly higher in the women who received pethidine (any adverse effect: RR 1.91 [95% CI 1.44 to 2.53]; nausea: RR 1.60 [95% CI 1.05 to 2.43]; vomiting RR 1.97 [95% CI 1.09 to 3.55]; dizziness RR 4.68 [95% CI 2.59 to 8.46]). The need for augmentation with oxytocin was also significantly higher in the intervention group (RR 2.24 [95% CI 1.13 to 4.43]). Neonatal outcomes were also found to be significantly worse following the administration of pethidine, namely: Apgar < 7 at 1 minute: RR 4.11 [95% CI 1.72 to 9.80]; umbilical cord arterial pH< 7.20: RR 1.55 [95% CI 1.13 to 2.14]; umbilical cord arterial pH< 7.10: RR 3.94 [95% CI 1.76 to 8.82]. There were no significant differences in Apgar scores at 5 minutes: Apgar < 7 at 5 minutes: RR 11.82 [95% CI 0.66 to 210.25].

In a second RCT, women in established labour (3–5 cm cervical dilatation) requesting analgesia were randomly allocated to received IV pethidine (n = 42) (women < 75 kg received 50 mg, women > 75 kg received 75 mg) or IV saline (n = 42) (1.0 or 1.5 ml).[147] [EL = 1+] Women who had nausea and/or vomiting were also given 25 mg promethazine. VAS scores were reported by women 15, 30 and 60 minutes post-administration. These scores were then categorised prior to statistical analysis (0 = no pain; 1–3 = mild pain; 4–7 = moderate pain; 8–10 = severe pain). An observer recorded the woman's vital signs, the fetal heart rate (FHR) and rated level of sedation (on a 5-point Likert scale) at the same intervals. No significant differences were found between the intervention and control group regarding blood pressure (BP), pulse or respiratory rate, or the FHR (described as mean differences, no statistical analysis reported). No significant differences were found between the two groups for median pain scores at each time interval. The means of the pain increment scores for each time interval (i.e. 0–15 minutes, 15–30 minutes, etc.) were significantly higher for the control group throughout the study period. It is questionable, however, whether it is meaningful to calculate and compare means of categorical scores derived from a 0–10 scale. Side effects were more frequent in the intervention group: nausea/vomiting: n = 15 versus n = 2; dizziness: n = 11 versus n = 0. The authors reported no significant differences for mode of birth, Apgar scores or administration of naloxone, but no figures were given. Women's views of pain relief were sought within 24 hours of giving birth. While significantly more women in the intervention group gave positive reports of the effectiveness of pain relief, this figure was only 23.80% compared with 7.10% in the control group.

IV opioids: dose-finding

IV morphine

Description of included studies
A dose-finding study, conducted in Sweden, investigated the analgesic efficacy of IV morphine during the first stage of labour.[148] [EL = 3]

Review findings
IV morphine was given to 17 women (11 nulliparae) in active labour (three contractions every 10 minutes lasting at least 60 seconds and a cervical dilatation of at least 4 cm) and requesting analgesia. Amniotomy was performed if membranes had not ruptured spontaneously. All women were given repeated doses of IV morphine (0.05 mg/kg) after every third contraction, until a total dose of 0.20 mg/kg was reached. Pain intensity and level of sedation were measured using a 10 cm VAS scale. Women were also asked to indicate on a schematic diagram where the pain was located. Pain assessments were performed immediately after the first three contractions following each administration of morphine. Morphine was found to significantly reduce reported pain intensity (initial pain intensity versus pain intensity following four doses of morphine: mean = 85 mm [range 53 to 100 mm] to 70.0 mm [range 46 to 99 mm], z = 2.49, P = 0.01, Wilcoxon test). However, this decrease translates to a reduction from 'unbearable' to 'severe' pain rather than a clinically significant reduction in pain. The number of women experiencing back pain was significantly reduced from 13/14 to 4/14 (P = 0.01) but in 14/17 women there was no reduction in abdominal pain after morphine administration. Following morphine administration, 14/17 women requested and received epidural analgesia. The sedative effects of IV morphine were marked: VAS before versus after morphine administration 0 mm [range 0 to 0 mm] versus 78 mm [range 56.1 to 99.5], P < 0.05. The authors also reported that several women who received the maximum dose of morphine were asleep between contractions, and three could not be given all the dose increments of morphine owing to its severe sedative effects. No difference in neonatal outcome was reported (Apgar scores at 1 and 5 minutes).

IV opioids versus IM opioids

IV pethidine versus IM pethidine

Description of included studies
One Canadian RCT was identified that compared IV pethidine (n = 19) with IM pethidine (n = 20).[149] [EL = 1+]

Review findings
IM pethidine was administered in 50–100 mg doses every 2 hours as required, up to a maximum dose of 200 mg. The IV group of women received a 25 mg bolus then a background infusion rate of 60 mg/hour, with an additional 25 mg bolus available at hourly intervals if required. The main outcome measure was pain intensity during labour, which was measured using a 10 cm VAS when the analgesia was administered and every 30 minutes thereafter. Other outcome measures included pulse rate, BP, respiratory rate, side effects of medication, levels of sedation (5-point Likert scale), mode of birth and a second or third day postnatal assessment of satisfaction with pain relief. The baby's Apgar scores, vital signs and any required resuscitation interventions were also recorded. No significant differences were found between groups for maternal physiological measurements. The women who received IV pethidine had significantly lower pain scores from times 1.5 hours to 4.0 hours. However, women in the IM group received significantly less pethidine (mean = 82 mg) compared with the IV group (mean = 121 mg). Four women in the IV group received one additional bolus of

25 mg pethidine and one woman received two additional boluses. Eight women in the IM group also used Entonox compared with one in the IV group. Subgroup analysis of findings from women in the IV group who received 100–150 mg pethidine (mean dose 127 mg) (n = 10) still showed significantly lower pain scores when compared with women who received 100 mg pethidine IM. No other statistically significant differences were found regarding side effects, infant outcomes or women's satisfaction 2–3 days postnatally.

IV opioids versus IV opioids

Butorphanol versus pethidine versus butorphanol + pethidine

Description of included studies

A recent US RCT compared 1 mg butorphanol, 50 mg pethidine or both drugs in combination (0.5 mg butorphanol + 25 mg pethidine).150 [EL = 1−] Fifteen women were randomly allocated to each group. Unfortunately, owing to the loss of an undisclosed number of women post-randomisation (including exclusion of women who requested an epidural within seven contractions of IV drug administration), there is a potentially high level of bias within the trial.

Review findings

Level of sedation, pain intensity and nausea were assessed using a 0–10 verbal scale, just before drug administration and between the sixth and seventh contraction post-administration. Women were also asked to choose words from a pain affective magnitude check list to describe the pain of the previous two contractions. All three treatments provided significant, but only moderate, pain relief (verbal scale scores before and after administration (mean): butorphanol: 7.2 (SD 0.6) versus 5.5 (SD 0.8), $P < 0.05$; pethidine: 7.4 (SD 0.4) versus 5.2 (SD 0.5), $P < 0.05$; butorphanol + pethidine: 7.4 (SD 0.4) versus 4.7 (SD 0.8), $P < 0.05$). No significant difference was found between groups regarding degree of pain relief. Unfortunately, the study did not report on the number of women who requested or received additional pain relief (the study ended with the seventh uterine contraction after administration of the study drug). Sedation increased after all drug treatments to a similar degree. Nausea was unaffected by drug treatment. (Exact figures are not reported but the findings are represented graphically.) FHR abnormalities were not significantly different between treatment groups (n = 5, 3, 5 butorphanol, pethidine, combination, respectively). Only two babies had Apgar scores of below 8 at 1 minute (one score of 6 in the butorphanol group and one score of 7 in the pethidine group). All babies had Apgar scores of 8 or above at 5 minutes.

IV patient-controlled analgesia (PCA): different opioids

Description of included studies and review findings

IV PCA: remifentanil versus pethidine

Two small UK RCTs provided the evidence for analgesic efficacy of PCA remifentanil compared with PCA pethidine.[151] [EL = 1+] [152] [EL = 1−]

In a recent RCT women received either remifentanil 40 micrograms with a 2 minute lockout (n = 20) or pethidine 15 mg with a 10 minute lockout (n = 20).[151] [EL = 1+] Baseline assessments were carried out for pain intensity (10 cm VAS), sedation score (5-point Likert scale), vital signs, nausea and anxiety. These measurements were repeated every 30 minutes following the administration of analgesia along with assessments of women's satisfaction with analgesia (10-point VAS). Continuous pulse oximetry was also carried out, plus 1 hour of continuous FHR monitoring following the commencement of PCA. One protocol violation was noted for a woman in the pethidine group and her data removed from the analysis (i.e. not an intention-to-treat analysis). Eighteen women in the remifentanil group continued to use the

PCA up to, and during, birth compared with 14 women in the pethidine group (NS). Almost all women in both groups used Entonox as well as IV PCA. No significant differences were noted for pain intensity scores between the two groups (overall mean (SD) remifentanil: 6.4 cm (1.5 cm); pethidine: 6.9 cm (1.7 cm)). There were also no significant differences noted for levels of nausea, sedation, anxiety or time spent with oxygen saturation < 94% or < 90%. Satisfaction scores at 60 minutes were significantly higher for remifentanil than pethidine (median): 8.0 [IQR 7.5 to 9.0] versus 6.0 [IQR 4.5 to 7.5], P = 0.029). No significant differences were noted for classification of FHR tracings, Apgar scores or cord blood pH. Babies in the pethidine group had significantly lower Neurologic Adaptive Capacity Scores 30 minutes after birth, but there was no difference after 120 minutes.
An earlier small-scale double-blind RCT conducted at the same UK hospital also compared PCA remifentanil and PCA pethidine, although with slightly different doses.[152] [EL = 1−] Nine women were randomised to receive an IV bolus of remifentanil 0.5 micrograms/kg with a lockout period of 2 minutes and eight women were randomised to receive a bolus of 10 mg pethidine with a lockout period of 5 minutes. A 10 cm VAS was used to assess pain, nausea and itching immediately prior to administration of analgesia, at hourly intervals post-administration throughout labour and again 30 minutes after giving birth. Women's vital signs were also recorded along with 1 and 5 minute Apgar scores. At the start of the study, more women in the remifentanil group were receiving oxytocinon compared with women in the pethidine group (6/9 versus 2/8). Despite this, there was no significant difference in the initial baseline mean VAS score for pain (pethidine 47 mm; remifentanil 48 mm). The mean VAS score for pain throughout labour was reported as being significantly lower in the remifentanil group (actual value not given, although hourly mean scores were represented graphically). The post-birth VAS score was also reported to be significantly lower for women in the remifentanil group (again actual value not stated). No significant differences were found for nausea or itching between the two groups. No episodes of maternal hypotension, bradycardia or respiratory rate < 12 were recorded. Median Apgar scores at 1 and 5 minutes were found to be significantly lower in babies born to mothers who had received pethidine (median at 1 minute: remifentanil: 9 [range 9 to 9]; pethidine: 5.5 [range 5 to 8], P = 0.01; at 5 minutes: remifentanil: 10 [range 9 to 10]; pethidine: 7.5 [range 6 to 9], P = 0.04). One baby in the pethidine group was admitted to the neonatal unit. The trial was terminated early owing to concerns over the neonatal effects noted in the pethidine group.

IV PCA: fentanyl versus alfentanil
A small double-blind RCT conducted in Canada compared fentanyl with alfentanil, both administered as PCA.[153] [EL = 1−] Women in the fentanyl group (n = 11) received a loading dose of 50 micrograms IV. The PCA pump was then programmed to deliver a dose of 10 micrograms with a lockout of 5 minutes. A background infusion of 20 micrograms/hour was maintained. Women randomised to receive alfentanil (n = 12) were given a loading dose of 500 micrograms IV. The PCA pump was programmed to deliver a dose of 100 micrograms with a background infusion of 200 micrograms/hour. Hourly measurements were made of the drug dose received, total dose, sedation score and side effects. VAS pain scores were recorded every 30 minutes. Neonatal effects were assessed by Apgar scores, umbilical venous and arterial blood gases and neurobehavioural scores recorded at 4 and 24 hours. Two women were withdrawn from the data analysis owing to failure to observe the study protocol (these are not reported in the figures above). The two study groups were similar regarding demographic and obstetric details. No significant differences were found between the two groups for VAS pain scores from 1 to 3 cm cervical dilatation (mean [SD]: fentanyl: 61.0 mm [19.6 mm]; alfentanil: 67.3 mm [29.2 mm]) or 4 to 6 cm cervical dilatation: fentanyl: 54.9 mm [24.9 mm]; alfentanil: 67.7 mm [20.2 mm]). However, the mean VAS pain scores at 7 to 10 cm cervical dilatation were significantly higher in the alfentanil group compared with the

fentanyl group (64.6 mm [12.2 mm] versus 85.7 mm [13.9 mm], P < 0.01). No significant differences were observed for VAS scores for sedation, incidence of nausea or incidence of pruritus. Five of the 12 women receiving alfentanil described the pain relief as inadequate compared with one of the nine in the fentanyl group (NS). There were no significant differences in neonatal outcome with regard to Apgar scores, neurobehavioural scores, umbilical venous pH or naloxone requirement.

Patient-controlled administration for IV and IM use of opioids in labour

IV PCA opioids versus IM opioids

Description of included studies

One RCT was identified that compared IM diamorphine with IV PCA diamorphine for analgesia in labour.[154] [EL = 1+] A second small unblinded RCT conducted in the UK compared remifentanil via PCA (n = 18) with 100 mg pethidine IM (+ anti-emetic) (n = 18) (n = 13 primigravid women in each group).155 [EL = 1−]

Review findings

IV PCA diamorphine versus IM diamorphine

This trial, carried out in Scotland in 2000–2002, assigned women to receive either 5 mg diamorphine IM (multigravid women) or 7.5 mg diamorphine IM (primigravid women), or a loading dose of 1.2 mg diamorphine IV with a PCA pump set to deliver 0.15 mg diamorphine per dose with a 5 minute lockout period (maximum dose 1.8 mg/hour) (IM group n = 177; IV PCA group n = 179). Primary outcomes were analgesia requirements during labour and women's satisfaction with pain relief. Women's perceptions of pain in labour, side effects and clinical outcomes for the women and babies were also recorded. Pain intensity during labour was measured using a verbal descriptor with pain at four levels and a 10 cm VAS. Pain scores were repeated hourly, between contractions, throughout labour. Findings for primigravid women and multigravid women are reported separately.

In primigravid women, those in the PCA group used significantly less analgesia than those in the IM group (IM mean 3.2 mg/hour; PCA mean 1.7 mg/hour; difference 1.5 mg/hour [95% CI 1.1 to 1.9 mg/hour], P < 0.001). Women in the PCA group were more likely to opt for an epidural and less likely to remain in the trial until the baby was born, although these differences did not reach statistical significance. Most women (over 80% in both groups) used additional analgesia, e.g. Entonox or TENS). Findings for multigravid women were similar. Again women in the PCA group used significantly less diamorphine compared with women in the IM group (IM mean 3.1 mg/hour; PCA mean 1.6 mg/hour; difference 1.6 mg/hour [95% CI 1.1 to 2.0 mg/hour], P < 0.001). Significantly fewer multigravid women completed their labour using IV PCA diamorphine compared with IM diamorphine (61% versus 79%, RR 0.77 [95% CI 0.61 to 0.97] but the need for an epidural was similar between the two groups, and much lower than in primigravid women (15%). Satisfaction with intrapartum pain relief measured 6 weeks postnatally was lower for women in the PCA group. Primigravid women allocated to the PCA group were significantly more likely to state that they were very dissatisfied with their use of diamorphine compared with women in the IM group (PCA 35% versus IM 7%, RR 5.08 [95% CI 2.22 to 11.61]). Only 34 % of primigravid women in the PCA group reported that they would use diamorphine again compared with 61% of the IM group (RR 0.56 [95% CI 0.40 to 0.79]). Findings for multigravid women were similar with significantly more women saying they were very dissatisfied with PCA diamorphine and significantly fewer in the PCA group stating that they would use it again. In addition, 44% of multigravid women in the PCA group felt they had received pain relief too late in labour, compared with 19% of IM users (RR 2.32 [95% CI 1.21 to 4.49]). The mean VAS score for primigravid women in the IM group was significantly lower than that for the PCA group (6.7 versus 5.3, difference 1.4 [95% CI 0.8 to 2.0]). There was no difference in mean maximum

VAS scores. No significant differences were found for multigravid women's reported pain intensity during labour. Clinical outcomes were similar for women and babies in both groups. The authors explained the relatively poor outcomes for PCA diamorphine by stating that women and midwives appeared to lack confidence in the PCA and its ability to relieve intrapartum pain. Most women allocated to the PCA group used only a small proportion of the diamorphine potentially available to them, and quite quickly moved on to other forms of analgesia.

IV PCA remifentanil versus IM pethidine

An unblinded RCT conducted in the UK compared remifentanil via PCA (20 micrograms bolus over 20 seconds, 3 minute lockout, no background transfusion) (n = 18) with 100 mg pethidine (+ anti-emetic) (n = 18) (n = 13 primigravid women in each group).155 [EL = 1−] Pain was assessed using a 10 cm VAS. Sedation and anxiety were assessed using a similar scale. Degree of nausea and vital signs were also recorded. All measurements were made prior to administration of analgesia and every 30 minutes thereafter. All women were monitored using continuous pulse oximetry. Pain scores at 60 minutes post-administration and maximum pain score during the first 2 hours post-administration were significantly lower in the PCA remifentanil group (median scores at 1 hour: 72 versus 48, P = 0.0004; maximum scores over 2 hours: 82.5 versus 66.5, P = 0.009). Women's and midwives' assessment of 'overall effective analgesia' were both significantly higher in the remifentanil group. For two women receiving pethidine and seven receiving remifentanil, haemoglobin saturations of ≤ 94% were recorded. The minimum saturation did not differ significantly between the two groups. There was no significant difference in the minimum recorded ventilatory rates between women in the two groups. There was no significant difference in numbers of women experiencing nausea and vomiting between the two groups (pethidine n = 10, remifentanil n = 5, P = 0.06). Significantly fewer women in the remifentanil group had a spontaneous vaginal birth (11/18 versus 16/17, P = 0.04). The authors reported no difference in Apgar scores between the two groups; however, this was based on data from the subgroup of women who did not receive an epidural.

Evidence statement

Parenteral opioids have a limited effect on pain in labour irrespective of the agent, route or method of administration. Tramadol, meptazinol and pentazocine are not widely used in the UK and the evidence to date shows no advantage over pethidine. There is limited evidence that diamorphine (IM) provides more effective analgesia than the other opioids studied, with the fewest side effects for the woman.

There is a lack of evidence on the optimum dose or route of administration, as well as the effect of opioids on infant behaviour in the longer term, particularly feeding.

Recommendation on intravenous/intramuscular opioids

76. Ensure that pethidine, diamorphine or other opioids are available in all birth settings. Inform the woman that these will provide limited pain relief during labour and may have significant side effects for both her (drowsiness, nausea and vomiting) and her baby (short-term respiratory depression and drowsiness which may last several days). [2007]

77. Inform the woman that pethidine, diamorphine or other opioids may interfere with breastfeeding. [2007]

78. **If an intravenous or intramuscular opioid is used, also administer an antiemetic. [2007]**

79. **Women should not enter water (a birthing pool or bath) within 2 hours of opioid administration or if they feel drowsy. [2007]**

Research recommendation on intravenous/intramuscular opioids

14. **An RCT to compare the effect of pethidine [IM] and diamorphine [IM], and to explore optimum doses. Outcomes should encompass analgesic effect, and short- and long-term neonatal outcomes (including breastfeeding).**

Pain relief in labour: regional analgesia

Regional analgesia

Introduction

In the UK, epidural analgesia was first used during labour in the 1960s, and its use became more widespread over the following 10 years. In 1971 the Central Midwives' Board issued a statement stating that they had no objections to an experienced midwife undertaking 'top-ups'.

The advent of neuraxial opioids changed the manner in which epidural analgesia was achieved during labour. Prior to the 1980s, local anaesthetics alone were used to provide regional analgesia in labour. Subsequently, opioids, e.g. fentanyl, were added to the local anaesthetic solutions, thereby allowing a lower concentration of local anaesthetic to be used.

Review questions

Is there evidence that the type, frequency and mode of administration of the following pharmacological and non-pharmacological pain relief and regional analgesia influence outcomes?

- analgesia: spinal, combined spinal–epidural, epidural and mobile epidural.

When is use of each of these methods of regional analgesia appropriate?

What observations, above baseline care, should be undertaken on both mother and baby while using regional analgesia?

What IV fluids should be used to maintain blood pressure during labour while using regional analgesia?

What is the most effective use of regional analgesia to minimise instrumental delivery rates and optimise pain relief in the second stage of labour?

Regional analgesia versus other types of analgesia in labour

Epidural analgesia versus no analgesia

Description of included studies

One RCT (Mexico, 1999), reported in a systematic review[156] and as an English abstract of a Spanish paper,[157] has been conducted which compared epidural analgesia and no analgesia. [EL = 1+] The study involved 129 nulliparous women (epidural n = 69; no analgesia n = 63) who were recruited into the study 'at the beginning of the active first stage of labour'.

Review findings

The Mexican trial found that the first stage of labour was significantly shorter in women who had epidural analgesia compared with women with no analgesia (WMD −119.00 minutes [95% CI −154.50 to −83.50 minutes]).[156] There was no significant difference in the length of the second stage of labour (WMD −6.03 minutes [95% CI −12.61 to 0.55 minutes]).[156] Labour was described as 'very painful' by 9% of the women with epidural analgesia compared with

100% women with no analgesia.[157] There was no difference in mode of birth between the two groups.

Epidural analgesia compared with non-epidural analgesia

Description of included studies

A recent Cochrane systematic review involving 21 RCTs (n = 6664 women) compared epidural (all forms) versus non-epidural or no analgesia.[156] [EL = 1+] Only one trial compared epidural analgesia with no analgesia and is reported above. Three of the included studies were excluded from the current review as the populations involved fell outside the scope of this guideline (namely women with pregnancy-induced hypertension and severe pre-eclampsia), leaving 17 studies involving 5576 women for this meta-analysis. All trials included women in labour at ≥ 36 weeks of pregnancy. One trial included women with induced labour as well as spontaneous onset of labour. All trials compared epidural analgesia with opioid analgesia. Epidural analgesia included patient-controlled epidural analgesia (PCEA) as well as bolus top-ups with or without background infusions (continuous epidural infusion n = 6; intermittent boluses n = 5; PCEA n = 3; PCA with background infusion n = 2; intermittent boluses or continuous infusion n = 1).

Review findings

Only two of the included trials investigated women's perceptions of pain relief during the first and second stages of labour and found this was significantly better for women with epidural analgesia (first stage: WMD −15.67 [95% CI −16.98 to −14.35]; second stage: WMD −20.75 [95% CI −22.50 to −19.01], total n = 164). The need for additional pain relief was significantly lower in the groups of women who received epidural analgesia (13 trials) (RR 0.05 [95% CI 0.02 to 0.17]. The time of administration of pain relief to time pain relief was satisfactory was significantly lower for women in the epidural groups (one trial) (WMD −6.70 minutes [95% CI −8.02 to −5.38 minutes]). The second stage of labour was significantly longer for women with epidural analgesia (ten trials) (WMD 18.96 minutes [95% CI 10.87 to 27.06 minutes]) and the incidence of instrumental birth was higher for this group compared with women with non-epidural analgesia or no analgesia (15 trials) (RR 1.34 [95% CI 1.20 to 1.50]). Epidural analgesia was also found to be associated with an increased incidence of oxytocin augmentation (ten trials) (RR 1.19 [95% CI 1.02 to 1.38]), maternal hypotension (six trials) (RR 58.49 [95% CI 21.29 to 160.66]), maternal fever > 38 °C (two trials) (RR 4.37 [95% CI 2.99 to 6.38]) and urinary retention (three trials) (RR 17.05 [95% CI 4.82 to 60.39]). There was a significantly lower incidence of naloxone administration to the baby (four trials) (RR 0.15 [95% CI 0.06 to 0.40]) in the epidural groups, but no significant difference for umbilical artery pH < 7.2 (five trials) (RR 0.87 [95% CI 0.71 to 1.07]). There was no significant difference in the CS rate between the epidural and non-epidural groups (17 trials) (RR 1.08 [95% CI 0.92 to 1.26]). No significant difference was found for women's satisfaction with pain relief during labour (five trials) (RR 1.18 [95% CI 0.92 to 1.50]) or satisfaction with the childbirth experience (one trial) (RR 0.95 [95% CI 0.87 to 1.03]). There were also no differences found for: women's perceived feeling of poor control in labour, length of first stage of labour, headache, perineal trauma requiring suturing, long-term backache, Apgar score < 7 at 5 minutes and admission to NICU. No trials reported on serious potential problems such as venous thromboembolic events, respiratory failure or uterine rupture or long-term outcomes including neonatal morbidity, urinary incontinence or breastfeeding duration.

NB. The authors also conducted a sensitivity analysis excluding trials where more than 30% of women did not receive the allocated intervention. Results of this analysis did not differ significantly from the original findings.

A new meta-analysis was undertaken including only trials where low-dose epidural analgesia was used (less than, but not equal to, 0.25% bupivacaine or equivalent). Findings from this meta-analysis showed that low-dose epidural analgesia is associated with an increased risk of

instrumental birth (seven trials) (RR 1.31 [95% CI 1.14 to 1.49]), longer second stage of labour (four trials) (WMD 20.89 minutes [95% CI 10.82 to 29.57 minutes]) and an increased risk of oxytocin augmentation (four trials) (RR 1.31 [95% CI 1.03 to 1.67]).

Findings from an earlier systematic review support the findings of the Cochrane review.[158] [EL = 1+] This review included 14 RCTs involving 4324 women. Two of these trials were excluded from the Cochrane review, and one (not mentioned by Cochrane) is noted to have had trial groups that were not well matched. The review also included two prospective studies involving 397 women. The prospective cohort studies were included in order to obtain data on breastfeeding and long-term urinary incontinence, neither of which was available from RCT data. Despite the slight difference in included trials, findings were similar to those for the Cochrane, review with women in epidural groups reporting less pain in the first stage (WMD −40 mm [95% CI −42 to −38 mm], P < 0.0001) and second stage of labour (WMD −29 mm [95% CI −38 to −21 mm], P < 0.001). This meta-analysis also found women to be more satisfied with epidural pain relief than non-epidural pain relief (OR 0.27 [95% CI 0.19 to 0.38], P < 0.001). Again epidural analgesia was not found to be associated with an increase in duration of the first stage of labour but was associated with a significantly lengthened second stage, use of oxytocin post analgesia and instrumental birth. The significant increase in maternal hypotension and fever > 38 °C noted by the Cochrane review was also evident in the findings of this review. Data from one of the prospective cohort studies reviewed showed that epidural use was associated with a significantly higher rate of urinary incontinence in the immediate postpartum period, but this difference was not evident at 3 or 12 months. The other prospective cohort study found no difference between groups regarding breastfeeding 'success' (not defined) at 6 weeks.

One further systematic review has been carried out to assess the effect of epidural versus non-epidural analgesia during labour on funic acid–base status of the baby at birth.[159] [EL = 1+] The review includes eight RCTs involving 2268 women and five non-RCTs involving 185 women. Of the eight RCTs, six were included in the Cochrane review. One was excluded on methodological grounds; the other consists of unpublished data not reported by Cochrane. Based on findings from the RCTs, umbilical artery pH was found to be significantly better for babies born to women in the epidural group (WMD 0.009 [95% CI 0.002 to 0.015], P = 0.007) as was base excess (WMD 0.779 mEq/l [95% CI 0.056 to 1.502 mEq/l], P = 0.035). The authors conclude that epidural analgesia is associated with improved neonatal acid–base status, suggesting that placental exchange is well preserved during epidural analgesia.

An RCT conducted in the USA investigated the effects of epidural analgesia on maternal fever > 38 °C.[160] [EL = 1+] The study was a secondary analysis of data collected during a trial conducted at one hospital over a 9 month period (1995–96) involving 715 women comparing epidural analgesia with PCA pethidine. Thirty-two per cent (n = 115) of the women allocated to the epidural group did not receive epidural analgesia (most owing to rapid progress and birth) and 28% (n = 98) of women allocated to receive PCA pethidine did not do so, again most of these owing to rapid progress. Only five women randomised to receive PCA pethidine crossed over and were given an epidural. Tympanic temperature was measured and recorded (frequency of measurements not stated). Incidence of maternal temperature > 38 °C was significantly higher in the epidural group (54/358 (15%) versus PCA 14/357 (4%), P < 0.001). When the effects of parity were investigated, it was found that this effect was apparent in nulliparous women but not in multiparous women (nulliparous with epidural 47/197 (24%) versus nulliparous with PCA 9/189 (5%), P < 0.001; parous with epidural 7/161 (4%) versus parous with PCA 6/168 (3%), NS). Stepwise logistic regression revealed that the following factors were significantly and independently associated with women's temperature > 38 °C: prolonged labour > 12 hours, internal fetal monitoring and oxytocin augmentation. The authors conclude that nulliparity and dysfunctional labour are significant co-factors in the fever attributed to epidural analgesia. It is also described how approximately 90% of the

babies born to women with temperature > 38 °C received screening for neonatal sepsis and antibiotic therapy, even though none were found to have positive blood cultures. The proportion receiving septic screen and antibiotic therapy was the same, irrespective of whether epidural analgesia was used during labour.

A recent prospective cohort study has been undertaken in the USA to evaluate whether epidural analgesia is associated with a higher rate of abnormal fetal head positions at birth compared with non-epidural analgesia or no analgesia.[161] [EL = 2+] Women with spontaneous onset (n = 698) and induced labours (n = 864) were included in the study. The epidural group was far larger than the non-epidural group: n = 1439 and n = 123, respectively. Women were enrolled into the study 'as soon as possible' after admission to the delivery suite. Most of the women in spontaneous labour (92%) were enrolled before they had reached 4 cm cervical dilatation. An ultrasound scan was performed to ascertain the position of the fetal head at enrolment. Subsequent ultrasounds were performed at the time of administration of epidural analgesia (immediately before or within 1 hour of commencement), 4 hours after enrolment if an epidural had not been sited and when the woman was near the end of the first stage of labour (> 8 cm cervical dilatation). The position of the baby at birth was ascertained by asking the care provider immediately after the birth. Positions as recorded by ultrasound scans were determined by a single ultrasonographer some time later. For reporting of findings, ultrasound scans were divided into three categories – enrolment, epidural/4 hour and late labour. Of the study sample of 1562 women, 1208 (77%) had an interpretable epidural/4 hour ultrasound and 802 (51%) had an interpretable late ultrasound scan. The most common reason for missing data was the ultrasound scan not being performed, either because the woman declined the offer of a scan or the researcher was not available to perform it. Findings showed that changes of position by the unborn baby are common throughout labour, with final fetal position being established close to birth. Consequently, fetal position at enrolment was not a good predictor of fetal position at birth. Of women with a baby in the occiput posterior (OP) at birth, only 31% (59/190) had a baby in the OP position at enrolment in early labour. When comparing epidural with non-epidural groups, it was found that there were no significant differences in the proportion of babies in the OP position at enrolment or at the epidural/4 hour scan (enrolment: 23.4% versus 26.0%, NS; epidural/4 hours: 24.9% versus 28.3%, NS). However, women with an epidural were significantly more likely to have a baby in the OP position at birth (12.9% versus 3.3%, P = 0.002). Epidural was not associated with an occiput transverse (OT) position at any stage of labour. Further analysis also revealed that women with an unborn baby in the OP position at enrolment did not report more painful labours than those with an unborn baby in other positions, nor did these women report more severe back pain. There was also no difference in reported labour pain for different fetal positions at birth. Multinomial logistic regression examined association of epidural analgesia with the position of the baby at birth. The model incorporated maternal age, height, BMI, birthweight, gestational age, sex of baby, induction of labour, fetal position on enrolment, length of labour, and placental position. Epidural analgesia was found to be associated with an increase in the risk of OP position at birth compared with an occiput anterior (OA) position at birth (adjusted OR 3.5 [95% CI 1.2 to 9.9]). Epidurals were not associated with increased risk of OT position at birth (adjusted OR 1.3 [95% CI 0.6 to 3.0]). Mode of birth varied according to the position of the baby at birth, with spontaneous births being far more common where the baby was in an OA position (OA 76.2%; OT 13.5%; OP 17.4%, P < 0.001).

Another secondary analysis of RCT data reported above[160] was undertaken to examine the effects of epidural analgesia on the Friedman curve.[162] [EL = 1+] The analysis was performed for the subgroup of women who were admitted in labour with cervical dilatation of at least 3 cm and compared women with PCEA (n = 226) with women receiving PCA pethidine (n = 233). Progress in labour was assessed following the maternity unit's usual protocol, which included vaginal examinations performed at least 2 hourly. The absence of cervical change

over 2 hours led to augmentation of labour using oxytocin. There was a low crossover from pethidine to epidural use (n = 14). Findings for duration of labour and rate of cervical dilatation showed that epidural analgesia was associated with a significant slowing of cervical dilatation leading to a lengthened active first stage of labour (median [first and third quartiles]): 5.2 hours [3.9, 8.0] versus 4.0 hours [2.7, 7.0], P < 0.001. There was no significant difference noted for the second stage of labour. Further subgroup analysis was undertaken in order to compare women who received oxytocin augmentation with those who did not. Findings from this analysis showed that the effects of epidural analgesia were apparent where women laboured without oxytocin, with both first and second stages of labour being significantly longer for women who had epidural analgesia (active first stage of labour: 4.9 hours [3.5, 6.1] versus 3.5 hours [2.0, 5.0], P < 0.001; rate of cervical dilatation: 1.2 cm/hour [0.9, 1.6] versus 1.5 cm/hour [1.0, 2.5], P = 0.001; second stage: 0.7 hours [0.4, 1.1] versus 0.6 hours [0.3, 0.9], P = 0.046; total length of labour: 5.6 hours [4.1, 7.3] versus 4.1 hours [2.7, 5.7], P < 0.001). These effects were not evident in women whose labours were augmented with oxytocin. Epidural analgesia was associated with a significantly higher rate of oxytocin augmentation (44% versus 32%, P = 0.009), forceps birth (12% versus 3%, P = 0.003) and a significantly lower rate of spontaneous births (82% versus 92%, P = 0.004). There was no significant difference in CS rate (5% versus 6%, P = 0.94).

A recent Canadian prospective cohort study investigated whether epidural analgesia during labour is a risk factor for back pain.[163] [EL = 2+] A group of women who received epidural analgesia for pain relief during labour (n = 164) were compared with a group who did not receive epidural analgesia (n = 165). Women with back pain prior to pregnancy were excluded from the study. Multivariate logistic regression analysis was used to provide adjusted relative risk estimates for risk factors associated with back pain following birth. Adjustments were made for parity, ethnicity, mode of birth and woman's weight. The frequency of low back pain was highest on day 1 after giving birth, being about 50% for each study group. Measured using a numeric pain scale on day 1 after the birth, there was significantly higher back pain in women who had received epidural analgesia compared with those who had not (median [range]: 1 [0 to 8] versus 0 [0 to 8], P < 0.05). For the subset of women who reported no back pain during pregnancy, the incidence of new onset back pain was also higher in the epidural group (adjusted RR 2.05 [95% CI 1.07 to 3.92]). However, these differences were not apparent at 7 days or 6 weeks postpartum (day 7: adjusted RR 1.00 [95% CI 0.54 to 1.86]; 6 weeks: adjusted RR 2.22 [95% CI 0.89 to 5.53]).

One large population-based cohort study was reviewed which examined the association between epidural analgesia and mode of birth.[164] [EL = 3] The study involved all singleton births at term in Sweden during 1998–2000, excluding elective caesarean sections, giving a population sample of 94 217 women. The sample included induced and spontaneous labours. It is inferred that all women are included i.e. those with medical and/or obstetric complications, although this is not made explicit. The study population was drawn from 52 delivery units which were stratified according to epidural rate (20–29%, n = 5 units; 30–39%, n = 11 units; 40–49%, n = 20 units; 50–59%, n = 13 units and 60–64%, n = 3 units). Fewer than 6% of women gave birth in a unit with an epidural rate below 30%. Most births, 40%, took place in units where 40–49% women received an epidural analgesia for labour (n = 37985). Rates of caesarean birth and instrumental birth were then compared for each category of unit. No association was found between rate of epidural analgesia and non-elective caesarean birth. The lowest proportion of caesarean sections, 9.1%, were performed in units with the lowest epidural rate (20–29%) and the highest epidural rate (60–64%), with an OR 0.84 [95% CI 0.77 to 0.93] and OR 0.85 [95% CI 0.77 to 0.93], respectively (OR calculated to compare values with delivery units performing 40–49% epidurals as the reference group). For delivery units in other categories (30–39%, 40–49% and 50–59%) the CS rate ranged from 10.3% to 10.6%, with no statistical difference. No clear association was

seen between epidural rate and rate of instrumental birth. Instrumental births were most common in units with an epidural rate of 50–59%, OR 1.23 [95% CI 1.18 to 1.29] compared with the 40–49% group. The lowest instrumental birth rate, 14.1%, was seen in units where 30–39% women had epidural analgesia for labour, OR 0.88 [95% CI 0.84 to 0.92]. In the other groups the instrumental birth rate varied between 15.3% and 15.7%. Comparison was also made between different levels of maternity care provision (classified as levels I, IIb, IIa and III, with level III representing university hospitals). Again no clear association was found between epidural rates at different levels of maternity unit and mode of birth.

Evidence statement

There is high-level evidence that, compared with non-epidural pharmacological analgesia, epidural analgesia:

- provides more effective pain relief in labour
- is associated with a longer second stage of labour and an increase in instrumental birth, although this effect could be due to the package of care currently practised
- has no evidence of a longer first stage of labour
- has no evidence of an increase in caesarean section
- has a positive effect on neonatal acid–base status.

Recommendations on epidural analgesia versus others

80. If a woman is contemplating regional analgesia, talk with her about the risks and benefits and the implications for her labour, including the arrangements and time involved for transfer of care to an obstetric unit if she is at home or in a midwifery unit (follow the general principles for transfer of care described in recommendations 46 to 50). [2007, amended 2014]

81. Provide information about epidural analgesia, including the following:

- It is available only in obstetric units.
- It provides more effective pain relief than opioids.
- It is not associated with long-term backache.
- It is not associated with a longer first stage of labour or an increased chance of caesarean birth.
- It is associated with a longer second stage of labour and an increased chance of vaginal instrumental birth.
- It will be accompanied by a more intensive level of monitoring and intravenous access, and so mobility may be reduced. [2007, amended 2014]

Update 2014

Timing of regional analgesia

Description of included studies

Six studies which addressed this issue were identified.[165–171] The studies are heterogeneous, thus each study is summarised in a narrative manner below.

Review findings

The study, involving 60 women, was conducted in Italy.[165] [EL = 2+] This was a prospective cohort study with sequential allocation. The study attempted to quantify minimum local analgesic concentration (MLAC) of extradural bupivacaine for women in early labour (median cervical dilatation 2 cm) and for women in late labour (median cervical dilatation 5 cm). There was evidence that MLAC of bupivacaine for women in late labour was higher than that for those in early labour.

Another study, conducted in Taiwan and published in 1999, involved 120 women.[166] [EL = 1+] Women scheduled for induced labour were randomly allocated to receive either 0.0005% fentanyl for epidural analgesia in their early first stage of labour or no epidural analgesia during their early first stage of labour. The early first stage was defined as cervical dilatation equal to or less than 4 cm. Women who received fentanyl in their early first stage seemed to have less pain on the visual analogue pain scale, although there was no evidence of a difference in duration of first and second stage, mode of birth, cord arterial gas or Apgar score.

Another RCT, conducted in the USA and published in 1994, studied 149 women in whom labour was induced with oxytocin and 334 women in spontaneous labour.[167,168] [EL = 1+] The trial compared either epidural bupivacaine analgesia or intravenous nalbuphine during their early first stage of labour (defined as cervix dilated at least 3 cm but less than 5 cm) For both the induction and spontaneous labour cohorts, there was evidence that women in the early epidural group had a lower pain score between 30 and 120 minutes after the randomisation, and an increased incidence of hypotension. In comparison, women in the early IV nalbuphine group had newborns with a lower umbilical arterial and venous pH than the other group. There was no evidence of a difference in the mode of birth or duration of labour, between the cohorts. This derives from two studies (one for induced/augmented labour, the other was spontaneous labour) and therefore needs clarification.

The fourth study was an RCT, conducted in Israel, published in 1998 and involving 60 women.[169] [EL = 1+] The trial compared an early administration group, who received epidural bupivacaine with cervical dilatation less than 4 cm, and a later administration group, who received the same dose of epidural bupivacaine with cervical dilatation equal to or more than 4 cm. There was no evidence of a difference in duration of second stage, mode of birth or Apgar score at 1 and 5 minutes.

The fifth study is an RCT, conducted in the USA, published in 2005.[170] [EL = 1+] The trial compared intrathecal fentanyl and intravenous hydromorphine injection in 750 nulliparous women in spontaneous labour with cervical dilatation of less than 4 cm. Following the intrathecal fentanyl, the women received epidural analgesia (0.625 mg/ml bupivacaine with 2 micrograms/ml fentanyl by patient-controlled epidural analgesia). There is evidence that the women who received intrathecal fentanyl had a shorter duration of labour, lower pain scores and fewer newborn babies with low Apgar scores, while there was no evidence of a difference in mode of birth.

One trial, conducted in Israel involving 449 nulliparous term women in early labour (at less than 3 cm of cervical dilatation), compared either immediate initiation of epidural analgesia at first request (n = 221) with delay of epidural until at least 4 cm of cervical dilatation.[171] [EL = 1+] There was no evidence of a difference in CS rate (RR 1.18, P = 0.77), the use of oxytocin in the first stage (RR 1.07, P = 0.57) or spontaneous vaginal birth (RR 0.91, P = 0.85) between the two groups. However, in the late epidural group 78% of women stated that in their next labour they would prefer to be in the early epidural group, 7.0% preferred to be allocated to the other group and 3.2% were undetermined. The differences in preferences between the two groups were statistically significant (P < 0.001).

Evidence statement

There is a high level of evidence that intrathecal or epidural analgesia administered during the early first stage of labour does not affect the progress of labour, mode of birth or immediate neonatal condition compared with administration later in labour.

Recommendation on timing of epidural analgesia

82. If a woman in labour asks for regional analgesia, comply with her request. This includes women in severe pain in the latent first stage of labour. [2007]

Care and observations for women with regional analgesia in labour

Preloading with intravenous (IV) infusions for epidural analgesia

Description of included studies

One systematic review published in 2004 was included in this subsection.[172] [EL = 1+] The systematic review included a total of six trials involving 473 women. Among the six trials, two trials used high-dose local anaesthetic, two trials used low-dose anaesthetic with fentanyl and two trials used combined spinal–epidural (CSE), comparing preloading IV infusion with dummy or no preloading as controls.

Review findings

High-dose anaesthetic

In one trial, preloading reduced the incidence of women's hypotension (RR 0.07 [95% CI 0.01 to 0.53]; n = 102 women) and fetal heart rate abnormalities (RR 0.36 [95% CI 0.16 to 0.83]; n = 102 women), although there was no evidence of differences in other perinatal and maternal outcomes for this trial and another high-dose epidural trial.

Low-dose anaesthetic

Meta-analysis of the two trials using low-dose anaesthetic showed that there was no evidence of differences in women's hypotension (RR 0.73 [95% CI 0.36 to 1.48]; n = 260 women) and fetal heart rate abnormalities (RR 0.64 [95% CI 0.39 to 1.05]; n = 233 women). No other outcomes were reported.

Evidence statement

Preloading infusion for high-dose epidural anaesthesia may reduce the incidence of maternal hypotension and fetal heart rate abnormality. There was no evidence of differences in other outcomes.

There was no evidence that IV fluid preloads influenced maternal hypotension and fetal heart rate abnormalities, in women receiving CSE or low-dose epidural analgesia.

Recommendation on preloading for regional analgesia

83. Always secure intravenous access before starting regional analgesia. [2007]

84. Preloading and maintenance fluid infusion need not be administered routinely before establishing low-dose epidural analgesia and combined spinal–epidural analgesia. [2007]

Observations for women with epidural in labour

Description of included studies

No evidence was found for the effects upon labour outcomes of carrying out maternal observations. Two systematic reviews are summarised here that provide evidence pertaining to side effects associated with epidural analgesia. One systematic review specifically focused on side effects and co-interventions of epidural analgesia and their implications for the care of women during labour and childbirth.[173] [EL = 1+] The second is the systematic review reported above that compared epidural with non-epidural analgesia.[156] [EL = 1+]

Review findings

A systematic review of 19 RCTs published between 1990 and 2000, involving 2708 women, has been conducted to describe the side effects and co-interventions that accompany epidural analgesia in labour.[173] [EL = 1+] It is not stated whether all trials included only women with term pregnancies. A range of epidural methods was used in the included trials: CSE, traditional bolus epidural, low-dose epidural with opioid and one trial involving PCEA. Seven studies had one trial group where epinephrine was added to the epidural, and two evaluated

the use of clonidine. A narrative summary of findings is given. The most commonly investigated side effect was hypotension (16 studies). This was defined as a systolic blood pressure reading below 90–100 mmHg or a 20–30% decrease below baseline. The overall range for the incidence of maternal hypotension was 0–50%, with an average incidence of 10.5% across 44 trial groups (calculated as the mean incidence for all trial groups reporting that outcome). In 16 trial groups, covering a wide range of epidural agents, including opioids, there were no incidents of hypotension. Eight trial groups reported an incidence of hypotension above 20%. Five of these included the use of either sufentanil or clonidine (drugs not currently used in the UK).

Motor power was evaluated in eight studies using the Bromage or a modified Bromage scale to assess leg strength or the rectus abdominus muscle test (ability to rise from the supine position). Reported in terms of no impairment, the range across eight trials was 76–100%, with an overall average incidence at least 87.7% (this imprecise figure comes about owing to one trial reporting the incidence of no impairment as > 80% for all four trial groups). Eight studies also reported the ability of women to walk during labour. The incidence is given as 15.3–100%, although details are missing from the table. It is noted that even in trials where women are encouraged to walk in labour, a large proportion chose not to.

Four studies investigated voiding difficulty as a side effect of epidural analgesia. The ability to micturate 'spontaneously' (three studies) ranged from 0% to 68%, with an average incidence of 27.5%. The need for catheterisation (one study) ranged from 28% to 61% across three study groups, with an average incidence of 41.3%.

Sedation was reported by five studies. A wide range of findings was recorded: 1–56%, with an average incidence of 21%. The highest levels of sedation (32–56%) were found in women who received 5–10 micrograms sufentanil.

Pruritus was investigated by 17 studies. In comparison groups from these 17 studies, in which women were given drug combinations including opioids, the incidence of pruritus ranged from 8% to 100% with an average incidence of 62%. The highest incidences occurred in groups with the highest doses of opioid. The incidence of pruritus occurring in the eight study groups from six trials who did not receive opioids, ranged from 0% to 4%. The duration of itching was not reported by any of the studies, but most did mention that treatment was not required.

Nausea (without vomiting) was investigated by seven studies, with the incidence ranging from 0% to 30% with an average of 7.3%. Nausea and vomiting (five studies) ranged from 0% to 20% with an average of 4.6%.

Shivering as a side effect was only reported by two studies, each of which recorded one case of shivering.

The systematic review reported in the subsection above (epidural versus non-epidural) reported a number of side effects as outcomes.[156] This review is based upon meta-analysis of 18 of the included trials (n = 5705 women). All trials included women in labour at ≥ 36 weeks of pregnancy. One trial included women with induced labour as well as spontaneous onset of labour. One trial compared epidural analgesia with no analgesia and the remainder compared epidural analgesia with opioid analgesia. Epidural analgesia included PCEA as well as bolus top-ups with or without background infusions. Findings showed that epidural analgesia was associated with a significant increase in the following side effects compared with non-epidural analgesia: maternal hypotension (six trials): RR 58.49 [95% CI 21.29 to 160.66]; maternal fever > 38 °C (two trials): RR 4.37 [95% CI 2.99 to 6.38]; and urinary retention during labour (three trials): RR 17.05 [95% CI 4.82 to 60.39]. No significant differences were found between groups for nausea and vomiting (seven trials): RR 1.03 [95% CI 0.87 to 1.22] or drowsiness (three trials): RR 1.00 [95% CI 0.12 to 7.99]. Epidural analgesia was also found to be associated with a significant increase in the length of the second stage of labour (ten

trials): WMD 16.24 minutes [95% CI 6.71 to 25.78 minutes] and an increased use of oxytocin augmentation (ten trials): RR 1.19 [95% CI 1.02 to 1.38].

Evidence statement

The safety issues involved mean that there is no evidence on the effects of carrying out maternal observations upon clinical outcomes.

Evidence was found on the side effects of epidural analgesia. These were:

- hypotension (mainly derived from studies of high-dose local anaesthetic techniques)
- urinary retention
- pyrexia
- pruritus.

Recommendation on observations for women with regional analgesia

85. Undertake the following additional observations for women with regional analgesia:

- During establishment of regional analgesia or after further boluses (10 ml or more of low-dose solutions), measure blood pressure every 5 minutes for 15 minutes.
- If the woman is not pain-free 30 minutes after each administration of local anaesthetic/opioid solution, recall the anaesthetist.
- Assess the level of the sensory block hourly. [2007]

For monitoring babies' wellbeing for women with regional analgesia, refer to the section entitled 'The use of continuous EFM with regional analgesia' later in this chapter. For general observations for women in the first, second and third stages of labour, refer to Sections 11.4, 12.2 and 13.1, respectively.

Positions and mobilisation for women with regional analgesia

Description of included studies

A systematic review has been carried out to determine the effect of first-stage ambulation on mode of birth for women with epidural analgesia.[174] [EL = 1+] The review was of good quality and identified five RCTs for inclusion and meta-analysis (n = 1161 women). A second recent systematic review has been conducted in order to assess the effectiveness of maintaining an upright position versus a supine position during the second stage of labour, in order to reduce the number of instrumental births in women choosing epidural analgesia.[175] [EL = 1+] Only two studies of good methodological quality, but involving quite small samples, are included in the review (n = 281 women). Finally, a UK RCT was identified which compared lateral position with a sitting position for nulliparous women with epidural analgesia in the second stage of labour.[176] [EL = 1−] The trial is described as a pragmatic RCT, which refers to a trial that is designed to assess the outcomes of interventions as applied in practice (rather than in a trial setting, which is sometimes seen as artificial and not representative of usual practice). The drawback of this pragmatic approach is that sometimes the methodological rigour of the trial is undermined, thus not allowing generalisation of findings. In the trial, women were randomly assigned to the lateral position or upright position for second stage of labour at the first point of consent, antenatally. Women were asked to maintain their allocated trial position during the passive second stage of labour until the onset of active pushing.

Review findings

First stage

The systematic review of ambulation in the first stage of labour for women with epidural analgesia compared ambulatory with non-ambulatory groups. The ambulatory groups also included women who spent time in an upright position (standing or sitting > 45 degrees from

the horizontal) but not necessarily walking. The amount of time women were asked to spend walking also varied, ranging from at least 5 minutes in every hour to at least 20 minutes every hour (in one trial the period of time spent walking was not recorded, but all women in the ambulatory group were reported to have walked for at least some of the time). The proportion of women in the ambulatory groups who actually walked during the first stage of labour ranged from 66% to 86%. The amount of walking observed by women in the non-ambulatory groups ranged from none at all to 15% walking for at least some of the time. All included studies had similar inclusion criteria (singleton, cephalic presentation, term, uncomplicated pregnancy). Three included only nulliparous women. Four trials included induced labours as well as those with spontaneous onset. Four trials included ambulation only during the first stage, with the second stage conducted with the women in bed. There was no statistically significant difference in the mode of giving birth when women with an epidural ambulated during the first stage of labour compared with those who remained recumbent: instrumental birth (RR 0.91 [95% CI 0.93 to 1.44]) and caesarean section (RR 0.91 [95% CI 0.70 to 1.19]). There were also no significant differences between the two groups for any of the following outcomes: use of oxytocin augmentation, duration of labour, satisfaction with analgesia, hypotension, FHR abnormalities or Apgar scores. There were no apparent adverse effects associated with ambulation but the incidence of reporting adverse effects was low.

Second stage

A recent systematic review has been conducted in order to assess the effectiveness of maintaining an upright position versus a supine position during the second stage of labour.[175] [EL = 1+] Upright positions included standing, walking, kneeling, squatting or sitting > 60 degrees to the horizontal. There was no significant difference between groups regarding risk of instrumental birth (RR 0.77 [95% CI 0.46 to 1.28]) and caesarean section (RR 0.57 [95% CI 0.28 to 1.16]). Both studies reported a significant reduction in duration of labour associated with upright positions (one study reported duration of second stage and the other total labour duration). Data on other outcomes including perineal trauma, postpartum haemorrhage (PPH), maternal satisfaction and infant wellbeing were insufficient to draw any conclusions.

A UK RCT was also identified which compared lateral position in the second stage of labour with a sitting position.[176] [EL = 1−] Findings from this study showed that women allocated to the lateral position for the passive second stage (n = 49) had a lower rate of instrumental birth than women allocated to the sitting position (n = 58), although this just failed to reach statistical significance (32.7% versus 51.7%, $\chi^2 = 3.9$, degrees of freedom (df) = 1 [95% CI 0.40 to 1.01], with an associated reduction in episiotomy (44.9% versus 63.8%, $\chi^2 = 3.8$, df = 1 [95% CI 0.44 to 1.00]. However, the overall rates of perineal trauma was not significantly different (78% versus 86%, RR 0.75 [95% CI 0.47 to 1.17]). The findings from the study cannot be generalised owing to a number of methodological weaknesses, including an underpowered sample size due to difficulties in recruitment, and a significant difference between the two trial groups in body mass index and rates of induction of labour. It was also noted that the rate of instrumental birth was higher for women included in the trial than expected based on the previous year's data.

Pushing in the second stage for women with regional analgesia

Description of included studies

A recent systematic review including five RCTs, involving a total of 462 women, has been carried out to assess the impact of discontinuing epidural late in labour (> 8 cm cervical dilatation) on mode of birth, women's perceptions of analgesia and satisfaction with care.[177] [EL = 1+] The trials included spontaneous onset and induced labours. Details are not given as to the proportion of induced labours in each trial. A second recent systematic review was identified that aimed to compare the potential benefits and harms of a policy of delayed

pushing, among women who had uncomplicated pregnancies, with effective epidural analgesia established in the first stage of labour.[178] [EL = 1+] The primary outcome examined was instrumental birth. Secondary outcomes included other modes of birth, a range of maternal complications, long-term maternal outcomes and fetal outcomes. Nine trials were included in the review involving 2953 women. Most studies excluded women with medical or obstetric complications. A small, recent US RCT compared immediate (n = 22) versus delayed pushing (n = 23) in two groups of nulliparous women, in induced labour at term, with effective epidural analgesia.[179] [EL = 1+] Finally, a prospective cohort study conducted in Ireland was identified that also compared delayed pushing with early pushing, in the second stage.[180] [EL = 2+] All women were having their first baby, giving birth at term and were described as similar in terms of height and age. Infant weights were also similar between the two groups. No details were given regarding the unborn baby's position or station at the onset of the second stage.

Review findings

Findings from the meta-analysis of the systematic review carried out to assess impact of discontinuing epidural late in labour showed no difference in instrumental birth rates, i.e. discontinuing an epidural prior to the second stage of labour does not lower the incidence of instrumental births (RR 0.84 [95% CI 0.61 to 1.15]).[177] [EL = 1+] Conversely, no significant difference was found between groups regarding rates of spontaneous birth (RR 1.11 [95% CI 0.95 to 1.30]) or CS (RR 0.98 [95% CI 0.43 to 2.25]). Duration of the second stage was found to be similar between the two groups (three studies) (WMD −5.80 minutes [95% CI −12.91 to 1.30 minutes]). The two studies not included in the meta-analysis also found no significant difference in the length of the second stage. No significant differences were found for fetal outcome: low Apgar score at 1 minute (four studies) (RR 1.55 [95% CI 0.94 to 2.55]) and umbilical artery pH (three studies) (RR 3.92 [95% CI 0.45 to 34.21]). The only significant difference found between the two study groups was a significant increase in women's reports of inadequate analgesia, in groups where the epidural was discontinued late in the first stage of labour (four studies) (RR 3.68 [95% CI 1.99 to 6.80]). Unfortunately, women's views of, or satisfaction with, care during labour were not reported by any of the trials.

The second recent systematic review compared the potential benefits and harms of a policy of delayed pushing, among women with uncomplicated pregnancies and with effective epidural analgesia established in the first stage of labour.[178] [EL = 1+] Eight studies compared immediate pushing at discovery of full dilatation with delayed pushing. One study used early pushing (within 1 hour of discovery of full dilatation) as the control group. The duration of delay until pushing commenced in the experimental group varied between studies, ranging from 1 hour (or earlier if involuntary urge to push) to 3 hours. One study set no time limit on the delay. Management of the active second stage also varied between studies and included techniques for pushing (e.g. breath-holding) and use of oxytocin. The methodological quality of included studies varied, with only one reporting adequate random allocation concealment. Three studies enrolled women before full dilatation was reached, and one of these subsequently excluded 19% of enrolled women on medical grounds or owing to first-stage caesarean section. Meta-analysis of findings showed a small reduction in the incidence of instrumental births which failed to reach statistical significance (RR 0.94 [95% CI 0.84 to 1.01]). Meta-analysis of the five studies which reported mid-pelvic or rotational instrumental births showed a 31% reduction in the delayed pushing group, which was statistically significant (RR 0.69 [95% CI 0.55 to 0.87]). Total duration of the second stage of labour was significantly higher for the delayed pushing groups in seven of the eight studies where this was reported, with an overall increase of 58 minutes (calculated from findings of three trials that reported mean duration with SD) (WMD 58.2 minutes [95% CI 21.51 to 94.84 minutes]). However, duration of the active second stage varied between trials. Meta-analysis of two trials that reported the mean length of the active second stage, with SD, showed no significant

difference between the two groups (WMD 1.11 minutes [95% CI −20.19 to 22.40 minutes]). Only two studies reported intrapartum fever. One of these studies found no significant difference between the groups; the other found a significantly higher incidence of maternal fever in the delayed pushing group. None of the other secondary maternal outcomes examined showed any significant difference. Only one study reported pelvic floor morbidity at 3 months postpartum and found no significant differences between the two groups. No study reported on urinary incontinence. Few studies reported infant outcomes and no significant differences were found for any of the outcomes examined.

In the USA, an RCT compared immediate versus delayed pushing.[179] [EL = 1+] Women in the immediate pushing group commenced pushing as soon as full dilatation was reached and were coached to hold their breath and push three to four times for a count of ten, during each contraction. Women in the delayed pushing group were encouraged to wait until they felt an urge to push or until they had been in the second stage for 2 hours (whichever came first). These women were then encouraged to push without holding their breath and for no more than 6–8 seconds for each push, up to three times per contraction. The use of oxytocin enabled the researchers to control the frequency and duration of second-stage contractions. While the two groups of women were similar in terms of most demographic variables, women in the immediate pushing group were significantly younger than those in the delayed pushing group. Second stages were significantly longer in the delayed pushing group (mean duration 38 minutes longer, $P < 0.01$) but the length of active pushing was significantly longer in the immediate pushing group (mean duration 42 minutes longer, $P = 0.002$). Findings showed that while babies in both groups exhibited oxygen desaturation during the second stage, this was significantly greater in the immediate pushing group ($P = 0.001$). There were also significantly more variable fetal heart rate (FHR) decelerations and prolonged decelerations in the immediate pushing group. There were no significant differences between the two groups for other FHR patterns, umbilical cord gases or Apgar scores. There were also no significant differences in caesarean births, instrumental vaginal births, prolonged second stage (> 3 hours) and episiotomies between the two groups. There were, however, significantly more perineal tears in the immediate pushing group (n = 13 versus n = 5, $\chi^2 = 6.54$, $P = 0.01$). The findings of the study may not however, generalise to multiparous women, women without epidural analgesia or women without oxytocic infusion in the second stage.

A prospective cohort study conducted in Ireland also compared delayed pushing with early pushing in the second stage.[180] [EL = 2+] Women in the delayed group (n = 194) were discouraged from pushing until the baby's head was visible or until 3 hours had elapsed since full dilatation of the cervix. Women in the early pushing group (n = 219) were encouraged to push as soon as the second stage was diagnosed. No details are given regarding the type of pushing encouraged. Due to a labour ward policy of active management of labour, three-quarters of the women in each group had an oxytocin infusion in progress during the second stage of labour. The second stage was significantly longer for women in the delayed pushing group ($P < 0.001$), despite the fact that it appears from the figures presented that women in the early pushing group waited on average 0.7 hours before commencing pushing, compared with 0.9 hours for women in the delayed pushing group. There was no significant difference in the spontaneous birth rate between the two groups. There was, however, a significant reduction in the use of non-rotational forceps in the delayed pushing group (44.84% versus 54.79%, $P < 0.04$). Abnormal fetal heart patterns and/or the passage of meconium was more common in the delayed pushing group (27.8% versus 3.91%, $P < 0.01$). Admissions to neonatal intensive care unit (NICU) were also higher for babies from the delayed pushing group (n = 14 versus n = 5, $P = 0.017$). The authors suggest these poorer outcomes may be attributable to the extensive use of oxytocin in the second stage of labour (approximately 75% for each group). Apgar scores and number of babies requiring intubation were similar between the two

groups. No differences were reported for episiotomy rates, incidence of third-stage complications or postnatal morbidity. No further details were given.

Evidence statement

There is high-level evidence that epidural analgesia using low-dose local anaesthetic/opioid solutions allow some mobilisation compared with high-dose epidurals.

There is evidence that discontinuing epidural analgesia late in labour does not improve the rate of spontaneous birth, or any other clinical outcome, and can cause distress to the woman.

There is high-level evidence that delaying directed pushing (1 to 3 hours, or earlier if the woman has an involuntary urge to push), compared with directed pushing at diagnosis of second stage, reduces the risk of a mid-pelvic or rotational instrumental birth.

GDG interpretation of the evidence (mobilisation and pushing techniques for women with regional analgesia)

The advantage of mobilisation with low-dose local anaesthetics decreases over time. There is no effect of mobilisation following epidural analgesia on any maternal or neonatal outcomes.

Recommendations on position and pushing with regional analgesia

86. **Encourage women with regional analgesia to move and adopt whatever upright positions they find comfortable throughout labour. [2007]**

87. **Once established, continue regional analgesia until after completion of the third stage of labour and any necessary perineal repair. [2007]**

88. **Upon confirmation of full cervical dilatation in a woman with regional analgesia, unless the woman has an urge to push or the baby's head is visible, pushing should be delayed for at least 1 hour and longer if the woman wishes, after which actively encourage her to push during contractions. [2007]**

89. **After diagnosis of full dilatation in a woman with regional analgesia, agree a plan with the woman in order to ensure that birth will have occurred within 4 hours regardless of parity. [2007]**

For position and pushing for women without regional analgesia, refer to Section 12.4.

Use of oxytocin for women with regional analgesia

Description of included studies

One RCT conducted in the UK was identified.[181] [EL = 1+] The study was published in 1989, and 226 nulliparous women with an epidural were included in the study population, but the intervention was routine use of the infusion of oxytocin (initial 2 mU/minute up to 16 mU/minute) compared with a placebo targeting a normal healthy population.

Review findings

Women with an oxytocin infusion had less non-rotational forceps births than the placebo group, shorter duration of the second stage (MD −17.0 minutes [95% CI −31.4 to −3.8 minutes]), less postpartum blood loss (MD −19.0 ml [95% CI −49.0 to 1.0 ml]), and fewer episiotomies (RR 0.84, P = 0.04) compared with women in the placebo group. There is no evidence of reduction in the number of rotational forceps birth performed for the malposition of the occiput. There is no evidence of differences in Apgar scores of the babies (Apgar at 1 minute MD 0.0 [95% CI −0.31 to 0.45]; Apgar at 5 minutes MD 0.0 [95% CI −0.17 to 0.14]).

Evidence statement

There is little evidence on oxytocin infusion for management of the second stage, compared with expectant management.

Limited evidence showed a high-dose oxytocin infusion shortened the duration of the second stage and reduced the rate of non-rotational forceps births.

Recommendation on use of oxytocin with regional analgesia

90. Do not routinely use oxytocin in the second stage of labour for women with regional analgesia. [2007]

For other recommendations regarding use of oxytocin in the first and second stage of labour, refer to the sections entitled 'oxytocin administration' (section 11.6.8) and 'interventions for delay in the second stage (section 12.6.2).

The use of continuous EFM with regional analgesia

Introduction

A new review of continuous EFM and regional analgesia was undertaken considering two comparisons (low-dose and high-dose epidurals).

Epidural versus non-epidural analgesia (low dose: defined as bupivacaine less than 0.25% or equivalent)

Description of included studies

There were two studies identified.[182–184] Both studies were conducted in the USA. The epidural dose was 0.125%[184] or 0.0625%[182,183] bupivacaine with 2 micrograms/ml fentanyl following 0.25% bupivacaine, compared with meperidine 10 mg[184] or 15 mg[182,183] every 10 minutes lockup following 50 mg meperidine. The trials were of good quality. [EL = 1+]

Review findings

The first trial (n = 358 mixed parity) published in 1997 showed no difference in the incidence of non-reassuring FHR tracings (RR 1.07 [95% CI 0.27 to 4.21]). The second trial (n = 200 nulliparous) published in 2002 showed that women with epidural analgesia had less beat-to-beat variability of the FHR (RR 0.23 [95% CI 0.15 to 0.30]) and more accelerations of the FHR (RR 1.42 [95% CI 1.24 to 1.63]), although there was no evidence of difference in the incidence of decelerations of the FHR (P = 0.353).

Evidence statement

There is no overall evidence of a difference in the incidence of FHR abnormalities when comparing the use of low-dose epidural and meperidine.

Intrathecal opioid with or without local anaesthetic versus no intrathecal opioids

Description of included studies

There was one systematic review identified for intrathecal opioids including 3513 women in 24 trials.[185] [EL = 1+] Three intrathecal opioids were tested (sufentanil, fentanyl and morphine), with or without various doses of intrathecal or epidural bupivacaine. The meta-analysis included all high and low doses of intrathecal opioids.

Review findings

Meta-analyses of the included trials showed that women with intrathecal opioid had a higher incidence of fetal bradycardia within 1 hour of analgesia than the control group, although there was no evidence of an overall difference in the incidence of FHR abnormalities.[185]

Evidence statement

There is an increase in the incidence of fetal bradycardia following the administration of intrathecal opioid, compared with no use of intrathecal opioid.

GDG interpretation of the evidence (monitoring babies for women with regional analgesia)

If fetal heart rate abnormalities are to occur, this is likely to be shortly after administration of doses of analgesic in regional analgesia.

Recommendation on monitoring with regional analgesia

Update 2014

91. Perform continuous cardiotocography for at least 30 minutes during establishment of regional analgesia and after administration of each further bolus of 10 ml or more. [2007, amended 2014]

Effect of epidural fentanyl on breastfeeding

Description of included studies

Two studies were identified which investigated the effects of epidural fentanyl on breastfeeding. A US RCT (2005) assigned women who had previously breastfed a child, and who requested an epidural during labour, to one of three groups: epidural with no fentanyl (n = 60), epidural with an intermediate dose of fentanyl (1–150 micrograms) (n = 59) and epidural with a high dose of fentanyl (> 150 micrograms) (n = 58).[186] [EL = 1+] Demographic and labour characteristics were similar between the two groups. More than 95% in each group had a spontaneous vaginal birth. Differences between umbilical cord concentrations of fentanyl were significantly different in ways which reflected the group allocations. Women were asked to complete a questionnaire within 24 hours of giving birth asking for details of any breastfeeding problems encountered. They were also assessed by a lactation consultant during this period. A follow-up questionnaire survey of breastfeeding was undertaken at 6 weeks postpartum.

A UK cross-sectional study retrospectively examined the medical records of 425 nulliparous women randomly selected from the birth register (year 2000) of one hospital, to investigate the impact of intrapartum fentanyl on infant feeding at hospital discharge.[187] [EL = 3] Exclusion criteria for the study included women who were prescribed drugs for chronic conditions, preterm babies, babies admitted to NICU or babies who were unwell. Findings are reported below.

NB. These studies did not investigate analgesic effect, women's satisfaction or any other outcome other than breastfeeding.

Review findings

Newborn outcomes

Findings from the US RCT showed that within 24 hours of birth there were no significant differences between the three groups, in numbers of women reporting a breastfeeding problem (no-fentanyl group and intermediate-dose fentanyl groups n = 6 (10%) versus high-dose fentanyl group n = 12 (21%), P = 0.09).[186] The proportion of women having some difficulty breastfeeding within the first 24 hours was also assessed by a lactation consultant. Again, the proportion of women assessed as having problems was similar among the three groups. A significant difference was detected in the baby's neurological and adaptive capacity score (NACS), with median scores of 35, 34 and 32 in the no-fentanyl, intermediate-dose fentanyl and high-dose fentanyl groups, respectively, although the authors note that the clinical importance of this is not known. Among the 157 women who responded to the 6 week follow-up questionnaire, 14 (9%) were no longer breastfeeding: one in the no-fentanyl group, three in the intermediate-fentanyl group and ten in the high-dose fentanyl group (P = 0.002). If a woman reported a problem within 24 hours of birth, she was more likely to have stopped breastfeeding by 6 weeks than women who reported no problems within the first 24 hours (29% versus 6%, P = 0.004). Babies born to women in the high-dose fentanyl group with umbilical cord fentanyl concentration > 200 pg/ml were less likely to be breastfeeding at 6 weeks postpartum than babies with fentanyl concentration < 200 pg/ml (P = 0.02).

The UK retrospective cross-sectional study found that the proportion of women bottle-feeding varied with intrapartum analgesia administered: 32% women whose only analgesia was Entonox bottle-fed; 42% women who received only IM opioids plus Entonox bottle-fed; 44% women who received neuraxial analgesia containing only local anaesthetic bottle-fed; and

54% of women who received neuraxial analgesia containing an opioid (fentanyl) bottle-fed.[187] Logistic regression analysis was carried out to identify predictors of bottle-feeding at hospital discharge. The final model contained five variables as follows: caesarean section (OR 0.25 [95% CI 0.13 to 0.47]); woman's occupation (OR 0.63 [95% CI 0.40 to 0.99]); antenatal feeding intention (OR 0.12 [95% CI 0.08 to 0.19]), woman's age (OR 0.90 [95% CI 0.85 to 0.95]); and fentanyl dose (OR 1.0004 [95% CI 1.000 to 1.008] for each microgram administered). The model is predictive of 51.7% of the variation in infant feeding. Bottle-feeding is predicted for 75.3% of cases and breastfeeding for 83.3% of cases.

Evidence statement

There is a moderate level of evidence on the use of fentanyl to reduce the total dose of bupivacaine, which results in less motor block, a longer duration of analgesia but also increases the incidence of pruritus.

Evidence from small studies, of variable quality, suggests a weak association between the dose of fentanyl and the duration and success of breastfeeding.

Research recommendations on breastfeeding and regional analgesia

15. There is a need for studies:

- to optimise the management of labour in women with epidurals to reduce the excess instrumental birth rate, including the routine use of oxytocin in the second stage, in nulliparous women with a low-dose epidural
- to explore the optimum duration of the passive and active second stage of labour, for women with an epidural
- to assess the impact of low-dose epidurals with opioids (fentanyl) on neonatal outcomes, including resuscitation and breastfeeding.

Mode of administration

Continuous infusion versus intermittent bolus for epidural analgesia

Description of included studies

Eight trials were identified from the search.[188–195] All trials were compared between intermittent repeated bolus and continuous infusion for epidural analgesia during labour, except one trial that was initiated with combined spinal–epidural (CSE) analgesia and then maintained with epidural analgesia.[188] As for the medications that were used, four trials employed bupivacaine only,[190–193] three used bupivacaine plus fentanyl[189,194,195] and the rest ropivacaine plus fentanyl.[188] All the trials showed reasonable homogeneity and therefore meta-analyses were conducted to summarise the results. [EL = 1+]

Review findings

There was evidence that more local anaesthetic was required in the continuous group than the intermittent group (total dose two trials WMD −5.78 [−7.61 to −3.96]), although there was no evidence of differences in the mode of birth (spontaneous vaginal birth eight trials RR 1.23 [95% CI 0.92 to 1.65], CS eight trials OR 0.95 [95% CI 0.63 to 1.43]); adverse events (including hypotension five trials OR 1.46 [95% CI 0.80 to 2.66], pruritus one trial RR 0.73 [95% CI 0.24 to 2.21], motor block (Bromage score = 0) three trials OR 1.57 [95% CI 0.61 to 4.00], abnormal or non-reassuring FHR trace two trials OR 1.39 [95% CI 0.83 to 2.33]); or Apgar scores (Apgar score less than 7 at 1 minute two trials OR 7.79 [95% CI 0.38 to 157.97], Apgar score less than 7 at 5 minutes two trials OR 5.36 [95% CI 0.25 to 116.76]). Only two trials reported satisfaction. One reported that women with continuous infusion were more satisfied with the pain relief in both the first and second stage than those with intermittent infusion.[192] The other reported no evidence of a difference between the two arms and therefore there was a need to be careful when drawing conclusions.[190]

Evidence statement

Although continuous infusion of epidural analgesia seemed to increase the total amount of required analgesia, compared with intermittent bolus injection, it might also increase women's satisfaction. There was no evidence of differences in other outcomes including mode of birth, adverse events and neonatal outcomes.

Patient-controlled epidural analgesia (PCEA) versus continuous infusion

Description of included studies

There was one systematic review[196] [EL = 1+] and one trial[197] [EL = 1+] identified from the search. Both showed reasonable qualities. The systematic review included nine trials and 640 women, comparing patient-controlled epidural analgesia (PCEA) without background infusion with continuous infusion in labour. All the included trials used ropivacaine or bupivacaine for epidural analgesia.[197]

Review findings

Analgesia outcomes

From the meta-analysis in the systematic review, there were fewer reported anaesthetic interventions in the PCEA group than in the infusion group. The PCEA group seemed to have less local anaesthetic and experience less motor block. There was no evidence of differences in other adverse events including hypotension, high sensory block, shivering, nausea and pruritus.

The new trial showed a similar trend that hourly requirement of local anaesthetic was less in the PECA group than the infusion group, although there was no evidence of a difference in incidence of adverse events including nausea, hypotension and itching.[197]

Women's outcomes

There was no evidence of a difference in the mode of birth or duration of labour between both the two groups found in the meta-analysis and in the new trial.[196,197]

Newborn outcomes

There was no evidence of differences in the incidence of low Apgar scores at both 1 and 5 minutes reported in both the systematic review and the new trial.

Women's satisfaction

There was no evidence of a difference in women's reported satisfaction with the pain relief.

Evidence statement

PCEA seemed to reduce the need to recall the anaesthetists, the total dose of local anaesthetic and women's motor block, compared with continuous epidural infusion. There were no apparent differences in other outcomes.

PCEA versus intermittent bolus by hospital staff

Description of included studies

There were four trials identified comparing PCEA and intermittent bolus given by hospital staff for epidural analgesia during labour.[198–201] The first trial conducted in 1990 included 58 women, and used 12 ml of 0.125% bupivacaine with 1: 400,000 epinephrine on request from anaesthesiologists, compared with 4 ml increments of the same solution to a maximum 12 ml/hour by PCEA.[198] [EL = 1+] The second trial was conducted in 1991 using bupivacaine–fentanyl. It included 50 women and compared PCEA with bolus administered by midwives. PCEA was commenced with a solution of 0.125% bupivacaine plus fentanyl 2 micrograms/ml and the analgesia was maintained at either a 4 ml/hour constant infusion plus 4 ml bolus on demand (lockout interval: 15 minutes) or 8 ml/hour infusion plus 3 ml bolus.[199] [EL = 1+] The third trial was conducted in 1995, by the same author as the second trial, using bupivacaine-fentanyl (0.125% bupivacaine plus 3 micrograms/ml fentanyl). It included 167

women and compared PCEA with bolus administered by staff.[200] [EL = 1+] The latest trial using bupivacaine–fentanyl, was conducted in 2005, included 187 women, and compared PCEA with staff administration. PCEA (0.08% bupivacaine and 2 micrograms/ml fentanyl 5 ml/hour infusion with a 5 ml bolus and 15 minute lockout interval) was compared with boluses of 20 mg bupivacaine and 75 micrograms of fentanyl in a 15 ml volume.[201] [EL = 1+] All of them were of reasonable quality.

Review findings

Analgesia outcomes

In the first trial, there was no evidence of a difference in the hourly local anaesthetic required or sensory levels.[198] In the second trial, the women in the midwife-administered group showed a lower pain score 2 hours after the analgesia started, although there was no evidence of differences in the incidence of adverse events such as nausea, pruritus, shivering hypotension, or motor block.[199] In the third trial, there was borderline evidence that the women in the staff-administered group showed lower pain scores 2 and 3 hours after the initiation of the epidural analgesia, although there was no evidence of a difference in the median pain scale, incidence of hypotension, shivering, pruritus or vomiting. However, urinary retention for the women was more common in the PCEA group than in the other group.[200] The latest trial showed that women in the PCEA group experience less pain during the first and second stage of labour, but used more bupivacaine than the control group.[201]

Women's outcomes

In the first, second and latest trial, no evidence of a difference was reported in duration of labour and mode of birth.[198,199,201] In the third trial, there was a trend that the women in the PCEA group had less spontaneous vaginal birth (P = 0.08) and a longer duration of the second stage of labour (P = 0.02).[200]

Newborn outcomes

There was no evidence of a difference in Apgar scores of the newborn babies in all trials.

Women's satisfaction

The former two trials showed that women in the PCEA groups were significantly more satisfied with the pain relief than the other groups, although there was no evidence of a difference in the latter two trials.

Evidence statement

There was a moderate level of clinical evidence on PCEA versus intermittent bolus administration by hospital staff. Although there was no apparent difference in analgesic, obstetric and neonatal outcomes, PCEA might increase a woman's satisfaction.

PCEA different lockout

Description of included studies

There were four trials identified comparing different bolus doses and lockouts for PCEA.[202–205] The first trial was conducted in 1993, comparing five different doses/lockouts for PCEA (2 ml bolus/10 minutes lockout, 3 ml/15 minutes, 4 ml/20 minutes, 6 ml/30 minutes and 8 ml/hour continuous) of bupivacaine–fentanyl with epinephrine and included 68 women.[202] [EL = 1+] The second trial was conducted in 2000, comparing 12 ml bolus/25 minutes lockout and 4 ml bolus/8 minutes lockout of bupivacaine–sufentanil, PCEA and included 203 women.[203] [EL = 1+] The third trial was conducted in 2005 in Lebanon, comparing three different regimens (3 ml bolus/6 minutes lockout, 6 ml/12 minutes and 9 ml/18 minutes) and included 84 women.[204] [EL = 1+] The forth trial, conducted in the USA in 2005, compared 5 minute lockouts with 15 minutes lockouts and included 60 women.[205] [EL = 1+] All trials were of reasonable quality.

Review findings

Analgesia outcomes

In the first trial, there was no evidence of a difference in the pain score among the five different regimens except for the total amount of local anaesthetic used, which was consumed more in the continuous infusion group than in the other four groups.[202] In the second trial, the larger dose group showed a lower pain score but more total amount of anaesthetic consumed than in the smaller dose group.[206] There was no evidence of a difference in severity of hypotension shown in this trial. The third trial showed a trend that women in the largest dose group required less rescue analgesia than the other two groups, although there was no evidence of differences in pain scores, sensory and motor block or total amount of anaesthetic used among the three groups.[204] There was no evidence of differences in pain scores, motor block, sensory block or FHR changes between the 5 and 15 minute lockouts in the latest trial.[205]

Women's outcomes

All trials reported no evidence of a difference in duration of labour and mode of birth.

Newborn outcomes

All trials reported no evidence of a difference in Apgar scores of the newborn babies.

Women's satisfaction

Although the second trial showed that women in the larger dose group rated higher satisfaction with the pain relief than the smaller dose group, there was no evidence of a difference in women's satisfaction with the pain relief in the rest of the trials.[203]

Evidence statement

A larger dose for PCEA might reduce the pain score and increase women's satisfaction, but might result in a higher dose of total analgesic used.

GDG interpretation of the evidence (mode of administration – epidural analgesia)

All modes of administration of epidural analgesia were found to provide effective pain relief. PCEA, when compared with continuous epidural infusion, reduces the total dose of local anaesthetic used, resulting in less motor block. When compared with intermittent bolus injection by hospital staff, PCEA increased women's satisfaction with pain relief.
There is insufficient evidence on obstetric and neonatal outcomes for all modes of administration.

Recommendation on mode of administration (regional analgesia)

92. Either patient-controlled epidural analgesia or intermittent bolus given by healthcare professionals are the preferred modes of administration for maintenance of epidural analgesia. [2007]

Establishing regional analgesia in labour

Combined spinal–epidural versus epidural analgesia

Description of included studies

This section is informed by one systematic review plus two additional RCTs. The recent systematic review includes 14 RCTs (n = 2047 women)[207] [EL = 1+] and was undertaken to assess the relative effects of combined spinal–epidural (CSE) versus epidural analgesia. The review includes the UK COMET trial.

Review findings

The systematic review examined 25 outcomes, although many of the findings from the meta-analysis are based on data drawn from a small subset of included trials.[207] Of the outcomes examined, only three were found to differ significantly between the two trial groups. Time of

onset of effective analgesia, following first injection, was found to be significantly shorter for CSE (four trials) (WMD −5.50 minutes [95% CI −6.47 to −4.52 minutes]). The number of women satisfied with their analgesia was found to be significantly higher in the CSE group (three trials) (OR 4.69 [95% CI 1.27 to 17.29]). The only other significant difference found between groups was a higher incidence of pruritus in women with CSE (nine trials) (OR 2.79 [95% CI 1.87 to 4.18]). No significant differences were found between women in the two groups regarding outcomes relating to the clinical procedure, i.e. post-dural puncture headache (PDPH) (nine trials) (OR 1.46 [95% CI 0.37 to 5.71]); known dural tap (six trials) (OR 1.77 [95% CI 0.53 to 5.94]) or the number of women requiring a blood patch for PDPH (six trials) (OR 1.47 [95% CI 0.24 to 8.98]). In addition, no significant differences were found regarding incidence of other side effects, need for augmentation, mode of birth or neonatal outcomes.

A recently published RCT conducted in Saudi Arabia also compared CSE with epidurals.[208] [EL = 1+] Women allocated to the CSE group (n = 50) received intrathecal bupivacaine 0.25% 0.5 ml (1.25 mg) with fentanyl 25 micrograms in 0.5 ml. The epidural component consisted of 10 ml bupivacaine 0.0625% with fentanyl 1.5 micrograms/ml, followed by an infusion of 6–10 ml/hour according to the woman's height. The comparison group (n = 51) received a low-dose epidural consisting of an initial bolus (10–20 ml) of bupivacaine 0.0625% with fentanyl 1.5 micrograms/ml (volume determined by woman's height). For further analgesia, the same regimen as for CSE was used, i.e. 10 ml bupivacaine 0.0625% plus fentanyl 1.5 micrograms/ml infusion at 6–10 ml/hour. Both groups comprised healthy, nulliparous women at 36 or more weeks of gestation, in the first stage of labour, who requested epidural prior to 4 cm cervical dilatation. All women received the allocated method of analgesia. Findings showed a significantly faster onset of analgesia for women who received CSE. After 5 minutes, all of the women who received CSE reported adequate analgesia compared with 41.2% women in the epidural group ($P < 0.05$). This difference remained significant at 10 and 15 minutes, by which time the proportion of women reporting adequate analgesia in the epidural group had risen to 60.8%. By 30 minutes all women in each group reported adequate analgesia. No significant differences were found for degree of ambulation, mode of birth, duration of first stage, duration of second stage or women's satisfaction with pain relief, which was high for both groups with approximately 80% women in each group reporting their overall pain relief to be 'excellent' and the remainder reporting it as 'satisfactory'. Significantly more women in the CSE group reported pruritus as a side effect (38% versus 14%, $P < 0.05$). No other differences were noted regarding side effects or complications. The authors stated that neonatal outcomes were similar for the two groups, although figures were not reported for these.

A summary report was reviewed which gave brief details of the main findings for a UK RCT with a prospective matched cohort study for long-term outcomes, the COMET trial.[209] [EL = 2+] Short-term findings from this trial are included in the meta-analysis for the systematic review described above.[207] The primary long-term outcome was backache, for duration of over 6 weeks, occurring within 3 months of giving birth. No significant differences were found in the incidence of long-term backache between women in the three different epidural groups involved in the RCT, namely CSE, traditional (bolus injection) epidural and low-dose infusion epidural. The non-epidural group of women (recruited prospectively as a matched cohort group, n = 351) reported significantly less backache than the traditional epidural group (OR 1.46 [95% CI 1.02 to 2.09]). Women's long-term satisfaction with their overall childbirth experience did not differ between the epidural groups (findings from non-epidural group not reported). A much greater proportion of women who received a CSE would choose the same method again, compared with the proportion of women in the traditional epidural group who would choose a traditional epidural again (figures not given).

Evidence statement

There is high-level evidence that:

- CSE provides a more rapid onset of analgesia than epidural analgesia alone
- once analgesia is established, both techniques are equally effective
- CSE is associated with a higher incidence of pruritus where opioids are used.

Intrathecal opioids with or without local anaesthetic versus no intrathecal opioids

Description of included studies

There was one systematic review[185] and two relatively new trials[210,211] identified for this intervention. The systematic review included 3513 women in 24 trials.[185] [EL = 1+] Three intrathecal opioids were tested (sufentanil, fentanyl and morphine), with or without various doses of intrathecal or epidural bupivacaine. A trial conducted in the USA in 2003 included 108 women.[210] [EL = 1+] This trial compared six different doses (0, 5, 10, 15, 20, 25 microgram) of intrathecal fentanyl, combined with 2.5 mg of bupivacaine. The other trial was conducted in Singapore in 2004, and included 40 women.[211] [EL = 1+] This trial combined intrathecal 25 micrograms of fentanyl with placebo, combined with 2.5 mg of levobupivacaine, followed by a 10 ml/hour epidural infusion of 0.125% levobupivacaine and 2 micrograms/ml fentanyl.

Review findings

Analgesia outcomes

Meta-analyses of the included trials showed that women with intrathecal opioid had a higher incidence of fetal bradycardia within 1 hour of analgesia than the control group, although there was no evidence of a difference in incidence of other fetal heart abnormalities.[185,210,211] There was strong evidence that women with intrathecal opioid experienced more pruritus than the control group who had received no intrathecal opioid. The first trial showed that all women who received 15 microgram or more of fentanyl had a VAS score of less than 20 mm (on a VAS from 0 to 100 mm), while those who received less than 15 micrograms did not.[210] There was no evidence of a difference in the incidence of nausea and vomiting, or fetal heart abnormalities, although there was higher incidence of pruritus in those women who were given intrathecal fentanyl. The other trial showed a significantly longer effect of analgesia for those with 25 micrograms fentanyl than 2.5 mg levobupivacaine alone.[211] The study was underpowered to allow evaluation of adverse events.

Women's outcomes

No evidence of a difference in mode of birth or use of oxytocin was reported in the systematic review.[185] No other outcomes were reported in any study above.

Newborn outcomes

There was no evidence of a difference in incidence of a low Apgar score at 5 minutes. No other fetal outcomes were reported.

Women's satisfaction

Satisfaction was not reported in the above studies.

Evidence statement

A moderate level of evidence showed that intrathecal opioid might increase fetal bradycardia and the incidence of pruritus. Intrathecal local anaesthesia with fentanyl is more efficacious than fentanyl alone.

Intrathecal opioids versus epidural local anaesthetics

Description of included studies

There was one systematic review identified for this comparison.[212] [EL = 1+] The study included seven trials. Three opioids (morphine, sufentanil and fentanyl) were compared with bupivacaine or lidocaine.

Review findings

A meta-analysis showed comparable analgesic efficacy 15–20 minutes after intrathecal opioid administration, although there was evidence that intrathecal opioids seemed to be associated with increased incidence of pruritus. There was no evidence of a difference in nausea or mode of birth.

Evidence statement

An intrathecal opioid appeared to have comparable analgesic efficacy at 15 minutes of administration, although there is increased incidence of pruritus, compared with local anaesthetics.

Different doses for initiation of combined spinal–epidural analgesia

Description of included studies

There were six randomised controlled trials identified that compared different doses for initiation of CSE analgesia.[213–218] Due to heterogeneity in the study designs, the results are summarised by the study with the description.

Review findings

0 mg versus 1.25 mg versus 2.5 mg bupivacaine combined with 25 micrograms fentanyl

One trial conducted in the USA was published in 1999 and included 90 women.[217] [EL = 1+] The trial compared three different doses (0 mg, 1.25 mg or 2.5 mg) of bupivacaine combined with 25 micrograms fentanyl for CSE analgesia. There was evidence that women with 2.5 mg bupivacaine had analgesia of a longer duration than those without bupivacaine, and women with bupivacaine had faster onset of analgesia than those without bupivacaine. There was no evidence of differences in other outcomes.

2.5 mg/25 micrograms versus 1.25 mg/12.5 micrograms levobupivacaine/fentanyl

One trial conducted in Singapore was published in 2004 and included 40 women.[213] [EL = 1+] The trial compared 2.5 mg/25 micrograms and 1.25 mg/12.5 micrograms of intrathecal levobupivacaine/fentanyl for CSE analgesia. There was evidence that women with a lower dose experienced less motor block than the other groups, although there was no evidence of differences in onset/duration of analgesia or adverse events such as hypotension, shivering, pruritus, nausea and vomiting.

1.25 mg versus 2.5 mg bupivacaine

One trial conducted in Hong Kong was published in 1999 and included 49 women.[214] [EL = 1+] The trial compared 1.25 mg and 2.5 mg of bupivacaine combined with 25 micrograms of fentanyl for initiation of CSE analgesia. There was evidence that women with the larger dose of bupivacaine had a longer duration of analgesia but higher level of sensory block and more incidence of motor block. There was no evidence of differences in other outcomes.

5, 10, 15, 20, 25, 35 or 45 micrograms fentanyl

Another trial conducted in the USA was published in 1998 and included 84 women.[215] [EL = 1+] The trial compared seven different doses (5 to 45 micrograms) of intrathecal fentanyl for initiation of CSE analgesia. A dose–response curve indicated that the median effective dose of intrathecal fentanyl was 14 micrograms [13–15 micrograms].

0, 5, 15 or 25 micrograms fentanyl

One trial, conducted in the UK, was published in 2001 and included 124 women.[216] [EL = 1+] The trial compared three different doses (0, 5, 15 or 25 micrograms) of intrathecal fentanyl for CSE analgesia. There was evidence of dose-dependent increases in both pruritus and duration of spinal analgesia with increasing doses of fentanyl. There was no evidence of differences among different doses of fentanyl in other outcomes.

25, 37.5 or 50 micrograms fentanyl

Another trial conducted in the USA was published in 1999 and included 60 women.[218] [EL = 1+] The trial compared 25 micrograms, 37.5 micrograms or 50 micrograms of intrathecal fentanyl for initiation of CSE analgesia during labour. There was no evidence of differences in duration of analgesia or adverse events.

Evidence statement

There was limited evidence that showed starting CSE with a larger dose of local anaesthetics and/or opioid had longer analgesia effects, more incidence of motor block and higher sensory block, than a smaller dose. A dose-finding study suggested that the optimum dose of intrathecal fentanyl is approximately 15 micrograms.

Different doses for initiation of epidural analgesia

Description of included studies

Trials including opioids other than fentanyl were excluded from this review as they are regarded as not relevant to the UK setting. Three trials were identified that compared different doses for the initiation of epidural analgesia.[219–221] Owing to heterogeneity in the study designs, the results are summarised by the study with the description.

Review findings

15 mg versus 25 mg bupivacaine combined with 50 micrograms fentanyl

One trial conducted in the UK was published in 1996 and included 60 women.[221] [EL = 1+] The trial compared 15 mg and 25 mg bupivacaine (both in 15 ml) combined with 50 micrograms of fentanyl for establishing epidural analgesia. There was evidence that women who received the lower dose of bupivacaine had less motor block than the other group. There was no evidence of differences in other outcomes.

0.5% versus 0.2% versus 0.1% bupivacaine

A trial conducted in Belgium was published in 1998 and included 58 women.[220] [EL = 1+] The trial compared bupivacaine 20 mg administered as 0.5% (4 ml), 0.2% (10 ml) or 0.1% (20 ml) for establishing epidural analgesia. There was evidence that women with 0.2% or 0.1% bupivacaine experienced less pain, and women with 0.1% bupivacaine had a quicker onset of analgesia than the 0.2% group. There was no evidence of differences in other outcomes.

0.2% versus 0.15% versus 0.1% ropivacaine

A study conducted in the USA was published in 1999 and included 68 women.[219] [EL = 1+] The trial compared 13 ml of either 0.2%, 0.15% or 0.1% ropivacaine solution for establishing epidural analgesia during labour. There was evidence that women with 0.2% ropivacaine were more likely to have adequate analgesia (measured by the pain score) than the other groups. There was no evidence of differences in adverse events.

Evidence statement

There is limited evidence from one trial that establishing epidural analgesia with larger volumes of more dilute solution of local anaesthetics achieves quicker and more effective analgesia than smaller volumes of more concentrated solution. There is also limited evidence

that establishing epidural analgesia with larger doses of local anaesthetics causes a higher incidence of motor block than a smaller dose.

Maintenance of regional analgesia

Traditional versus modern regimen of epidural infusion

Introduction

Traditional epidural analgesia without opioid (e.g. bolus doses of bupivacaine 0.25%) was compared with epidural infusion with opioid (e.g. 0.0625–0.1% bupivacaine with 2 micrograms/ml fentanyl) administered as a continuous infusion).

Description of included studies

An RCT conducted in the UK compared (a) 10 ml bolus doses of bupivacaine 0.25% (traditional regimen) with (b) analgesia established with (i) 15 ml of 0.1% bupivacaine with fentanyl 2 micrograms/ml or (ii) intrathecal bupivacaine 0.25% (1 ml) and fentanyl 25 micrograms (modern regimen). Analgesia in group (a) was maintained with further boluses of bupivacaine 0.25% while in groups (i) and (ii) analgesia was maintained with a continuous infusion of bupivacaine 0.1% with fentanyl 2 micrograms/ml.[222,223] The trial comparing these methods was published in 2001 and included 703 women (traditional n = 353; modern n = 350). The trial was of reasonable quality. [EL = 1+]

Review findings

Analgesia outcomes

There was no evidence of differences in median visual analogue scores, of the severity of labour pain after the epidural was inserted (traditional n = 14; modern n = 12) or women's ability to push during labour (RR 1.04, P = 0.77). There was also no evidence of a difference in the mean amount of bupivacaine used throughout labour, excluding top-ups for operative procedures (traditional = 103.8 (SD 56.1) mg; continuous = 101.1 (SD 55.1) mg).

Obstetric outcomes

There was evidence that women in the modern regimen group had more spontaneous vaginal births (RR 1.39 [95% CI 1.02 to 1.88]) and a shorter length of second stage (≤ 60 minutes RR 1.36 [95% CI 1.01 to 1.84]) than the traditional regimen group. There was no evidence of a difference in the incidence of CS (RR 1.07 [95% CI 0.77 to 1.49]).

Newborn outcomes

There was evidence that newborn babies in the modern regimen group were more likely to have a low Apgar score at 1 minute (≤ 7 RR 1.64, P = 0.01) and require high-level resuscitation (one or more mask and bag and/or intubation (intubation or naloxone) RR 5.00, P = 0.02), although there was no evidence of a difference in the 5 minute Apgar score (RR 3.00, P = 0.09) for admission to neonatal unit (RR 0.80, P = 0.72).

Women's satisfaction

Women's long-term satisfaction with their overall childbirth experience did not differ between the two groups

Long-term outcomes

There was no evidence of a difference in long-term backache, headache or neckache or paraesthesiae between the two groups, although women in the continuous group had less stress incontinence and bowel control problems compared with the traditional group.

Evidence statement

High-level evidence from one trial showed that the modern epidural regimen (maintained with a continuous infusion of bupivacaine 0.1% with fentanyl 2 micrograms/ml) not only increased rate of spontaneous vaginal birth and shortened duration of the second stage of labour, but

also increased the number of babies who had a low Apgar score and required high-level resuscitation, than the traditional regimen (maintained with boluses of bupivacaine 0.25%).

Local anaesthetic with opioid versus local anaesthetic without opioid

Introduction

Addition of opioids to a local anaesthetic, for an epidural analgesia during labour, was tested with the comparisons between bupivacaine versus bupivacaine with fentanyl. There were two comparisons: 0.125% bupivacaine versus 0.125% bupivacaine plus 2–3 micrograms fentanyl, and 0.125% bupivacaine versus 0.0625% bupivacaine plus 2–3 micrograms fentanyl.

0.125% bupivacaine versus 0.125% bupivacaine plus 2–3 micrograms fentanyl

Description of included studies

There are two trials identified for this comparison.[224,225] The first trial included 42 women and was conducted in the UK in 1991. The second trial included 60 women and was conducted in Canada in 1991. Both showed reasonable quality and homogeneity; hence meta-analyses were conducted to summarise the results. A total of 93 women were included in this review. [EL = 1++]

Review findings

Analgesia outcomes

The analysis was underpowered, such that there was no evidence of differences in the onset of analgesia, total dose of bupivacaine or incidence of adverse events including hypotension, pruritus, urinary retention, vomiting/nausea and motor block.

Women's outcomes

There was no evidence of a difference in the mode of birth and duration of second stage. No other outcomes were reported.

Newborn outcomes

There was no evidence of a difference in the Apgar score of the newborn babies. No other neonatal outcomes were reported.

Women's satisfaction

Only the second trial reported the satisfaction of the women with their analgesia. There was borderline evidence to suggest that the women who received fentanyl were more satisfied with their pain relief in the first stage of labour, although there was no evidence of a difference in the second stage.

Evidence statement

There was no strong evidence of any differences between 0.125% bupivacaine and 0.125% bupivacaine plus 2–3 micrograms fentanyl.

0.125% bupivacaine versus 0.0625% bupivacaine plus 2–3 micrograms fentanyl

Description of included studies

Five articles studied this comparison.[226–230] These trials showed reasonable quality and homogeneity, such that meta-analyses were conducted to summarise the results. A total of 667 women were included in the analysis. The three trials[226–229] were conducted in the UK in 1995–98. Another trial was conducted in the USA in 1988.[230] [EL = 1++]

Review findings

Analgesia outcomes
The analyses showed significant evidence that the women with fentanyl had a lower total dose of bupivacaine and less motor block, with a longer duration of analgesia and more pruritus than the other group. There was no evidence of a difference in the incidence of hypotension, urinary retention and nausea/vomiting.

Women's outcomes
There was no evidence of a difference in the mode of birth and duration of second stage.

Newborn outcomes
There was no evidence of differences in the Apgar scores, cord arterial pH or neurological and adaptive capacity score (NACS) of newborn babies.

Women's satisfaction
There was no evidence of a difference in women's satisfaction with their pain relief.

Evidence statement

There is high-level evidence that the women with fentanyl had a lower total dose of bupivacaine and less motor block, with longer duration of analgesia and more pruritus than the other group. There was no strong evidence of other differences between these two groups.

Different drugs for epidural analgesia

Bupivacaine versus levobupivacaine

Description of included studies

There were six trials identified for this comparison.[231–236] Among the included trials, three were initiated with CSE analgesia,[232,234,236] and the rest with epidural analgesia. All the trials were of reasonable quality. Meta-analyses were conducted to summarise the results. [EL = 1+]

Review findings

All regional analgesia
There was evidence that women with levobupivacaine had a shorter duration of analgesia, although there was no evidence of a difference in incidence of hypotension, nausea/vomiting, motor block and abnormal fetal heart trace.
There was no evidence of differences in mode of birth, duration of second stage, in Apgar scores or NACS. Women's satisfaction was not reported in a relevant form.

Epidural analgesia only
When subgroup analysis was conducted only including trials examining epidural analgesia, there was no evidence of differences in the mode of birth (spontaneous vaginal birth one trial RR 1.39 [95% CI 0.58 to 3.37], and CS one trial RR 1.33 [95% CI 0.59 to 2.97]), duration and onset of analgesia (onset of analgesia one trial WMD −1.00 minutes [95% CI −4.93 to 2.93 minutes], and duration of analgesia WMD −1.77 minutes [95% CI −4.00 to 0.47 minutes]), adverse events (hypotension five trials RR 1.61 [95% CI 0.79 to 3.27], nausea/vomiting five trials RR 0.58 [95% CI 0.31 to 1.08], Bromage score = 0 six trials RR 0.99 [95% CI 0.89 to 1.10], abnormal or non-reassuring fetal heart trace three trials RR 0.86 [95% CI 0.30 to 2.42]) or neonatal outcome (umbilical arterial pH one trial WMD 0.01 [95% CI −0.03 to 0.05]).

Evidence statement
There is no strong evidence on differences between bupivacaine and levobupivacaine for maintenance of epidural analgesia.

Bupivacaine versus ropivacaine

Description of included studies

There were 29 trials identified for this comparison.[232,234,242–266] Among included trials, four were initiated with CSE analgesia[232,234,252,264] five were with PCEA[244,247,251,260,263] and the rest with epidural analgesia.[242,243,245,246,248–250,253–259,261,262,265,266] All the trials were of reasonable quality. Meta-analyses were conducted to summarise the results. [EL = 1+]

Review findings

All regional analgesia
There was evidence that women with ropivacaine had a shorter duration of analgesia and less motor block, although there was no evidence of a difference in the onset of analgesia, incidence of hypotension, nausea/vomiting or abnormal fetal heart trace. There was evidence that women with bupivacaine had a shorter duration of their second stage of labour, although there was no evidence of a difference in mode of birth. There was evidence that more newborn babies born with ropivacaine had more than 35 NACS at 2 hours after birth than those with bupivacaine, although there was no evidence of differences in Apgar scores at 1 and 5 minutes, cord arterial pH or NACS at 24 hours. There was no evidence of a difference in women's satisfaction with their pain relief.

Epidural only
When subgroup analysis was performed only including trials of epidural analgesia, there was no evidence of a difference in onset of analgesia (four trials WMD −0.32 minutes [95% CI −1.09 to 0.44 minutes]) or duration of analgesia (seven trials WMD 3.20 minutes [95% CI −3.03 to 9.43 minutes]). There was also no evidence of a difference in the mode of birth (spontaneous vaginal birth 22 trials RR 1.03 [95% CI 0.96 to 1.10], and CS 21 trials RR 0.95 [95% CI 0.80 to 1.12]), although prolonged duration second stage (nine trials WMD 3.22 minutes [95% CI 1.08 to 5.36 minutes]) was observed in women in the ropivacaine group, compared with the bupivacaine group. There was evidence that fewer women experienced motor block in the ropivacaine group (18 trials RR 1.21 [95% CI 1.04 to 1.39]), although there was no evidence of differences in other adverse outcomes including hypotension (12 trials RR 0.98 [95% CI 0.69 to 1.40]) and nausea and/or vomiting (eight trials RR 1.04 [95% CI 0.50 to 2.15]). There was evidence that more babies were alert at 2 hours (NACS more than 35 at 2 hours three trials RR 1.25 [95% CI 1.06 to 1.46]) in the ropivacaine group compared with the bupivacaine group, although there was no evidence of differences in other fetal and neonatal outcomes including NACS score at 24 hours (> 35 four trials RR 1.02 [95% CI 0.96 to 1.07]), abnormal/non-reassuring fetal heart trace (three trials RR 1.29 [95% CI 0.59 to 2.82]), Apgar scores (Apgar score less than 7 at 1 minute ten trials RR 0.85 [95% CI 0.63 to 1.14]; Apgar score less than 7 at 5 minutes 13 trials RR 1.39 [95% CI 0.69 to 2.82]) and umbilical arterial blood pH (five trials WMD 0.01 [95% CI −0.02 to 0.03]). There was also no evidence of a difference in women's satisfaction score (rated as excellent or good six trials RR 1.03 [95% CI 0.99 to 1.06]).

Evidence statement

The available evidence is insufficient to allow interpretable comparisons of low-dose local anaesthetic doses for regional analgesia.

Different doses/rates for maintaining epidural analgesia

Description of included studies

There were 11 trials identified that compared different doses or rates of continuous infusion/injection for epidural or CSE analgesia.[258,267–276] Owing to heterogeneity in the study designs, the results are summarised by the study with the description.

Review findings

0.125% versus 0.0625% versus 0.04% bupivacaine

The first trial was conducted in the USA, published in 2002 and included 89 women.[267] [EL = 1+] The trial compared epidural infusion of saline (n = 23), 0.125% bupivacaine (n = 22), 0.0625% bupivacaine (n = 22), and 0.04% bupivacaine plus 1:600,000 epinephrine (n = 22), after subarachnoid fentanyl 25 microgram and total 4 ml of 0.25% bupivacaine. The study was under-powered in that there were no significant findings that compared the three bupivacaine groups, in any of the results, including duration of analgesia, and adverse events.

0.08% versus 0.25% bupivacaine

The second trial was conducted in the UK, published in 1986 and included 53 women.[271] [EL = 1+] The trial compared between 0.08% (n = 25) and 0.25%(n = 28) of bupivacaine infusion with the same amount of drug dose per hour (20 mg/hour of bupivacaine) for epidural analgesia during labour, following a test dose of 3 ml of 0.5% bupivacaine plain being administered. There was evidence that the 0.08% group had longer intervention-free intervals or fewer top-ups than the other group.

0.0625% versus 0.125% bupivacaine

The third trial was conducted in the UK, published in 1985 and included 98 women.[272] [EL = 1+] The trial compared five different rates and concentrations of bupivacaine infusion for epidural analgesia: (i) no bupivacaine; (ii) 0.0625%, 6.25 mg/hour; (iii) 0.125%, 6.25 mg/hour; (iv) 0.125%, 12.5 mg/hour; and (v) 0.125%, 18.75 mg/hour. Although there were no statistically significant different results among bupivacaine groups ii–v, the 0.125%, 12.5 mg/hour (10 ml/hour) group seemed to have the smallest dose used with less motor block.

0.031% versus 0.062% versus 0.125% bupivacaine

The fourth trial was conducted in the UK, published in 1991 and included 56 women.[273] [EL = 1+] The trial compared infusion of 0.125%, 0.062% or 0.032% bupivacaine combined with 0.0002% fentanyl with the same rate (at 7.5 ml/hour) following an initial 0.5% 8 ml dose of bupivacaine. There was evidence that women with 0.032% bupivacaine had less analgesic drug than the other groups. However, there was no evidence of difference in pain scores. The study was underpowered to show any evidence of differences in other outcomes including mode of birth and neonatal outcomes.

0.0625% versus 0.125% bupivacaine

The fifth trial was conducted in the UK, published in 1994 and included 98 women.[274] [EL = 1+] The trial compared 0.0625% and 0.125% bupivacaine (both at 10 ml/hour) for epidural analgesia during labour. There was evidence that women with 0.0625% bupivacaine were more likely to have Kielland rotational forceps but less likely to have Neville–Barnes forceps than the other group.

0.5% 6–8 ml versus 0.25% 10–14 ml versus 0.25% 6–8 ml bupivacaine
The sixth trial was conducted in the UK, published in 1981 and included 517 women.[275] [EL = 1+] The trial compared three different doses (0.5% 6–8 ml, 0.25% 10–14 ml or 0.25% 6–8 ml) of bupivacaine, for initial and top-up injection for epidural analgesia. There was evidence that women with the 0.25%/6–8 ml dose had more spontaneous vaginal births but rated analgesia pain relief as lower than the other groups. Women with higher concentration or volume of bupivacaine injection were more likely to have motor block and urinary retention, although there was no evidence of differences in other outcomes.

0.25% versus 0.125%, bupivacaine versus ropivacaine
The seventh trial was conducted in Sweden, published in 2001 and included 68 women.[258] [EL = 1+] The trial compared two different doses and two different drugs (0.25% bupivacaine, 0.25% ropivacaine, 0.125% bupivacaine, 0.125% ropivacaine) for epidural analgesia during labour. There was evidence that women with 0.25% of either drug were more likely to have motor block than the other groups and, among the 0.25% groups, women with bupivacaine were more likely to have motor block than those with ropivacaine. There was no evidence of a difference in the mode of birth, Apgar score and incidence of hypotension.

4, 6, 8 and 10 ml/hour of ropivacaine
The eighth study was conducted in France, published in 1997 and included 133 women.[268] [EL = 1+] The trial compared four different rates (4, 6, 8 and 10 ml/hour) of 2 mg/ml ropivacaine for epidural analgesia during labour. There was evidence that the 4 ml/hour group required more bolus doses than the other groups and that the 10 ml/hour group had higher total dose of ropivacaine than the other groups. There was no evidence of differences in the pain score, sensory block, motor block, mode of birth or Apgar scores of the newborn babies.

4, 6, 8 and 10 ml/hour of ropivacaine
The ninth study was conducted in the USA, published in 1998 and included 127 women.[270] [EL = 1+] The trial compared different infusion rates (4, 6, 8 and 10 ml/hour) of 2 mg/ml ropivacaine for epidural analgesia during labour.[270] There was evidence that the women in the 4 ml/hour group required more additional top-up injections than the other groups, although the 4 ml/hour group had less motor block than the other group. There was no evidence of differences in Apgar scores or NACS for newborn babies.

0.2% versus 0.125% ropivacaine
The tenth trial was conducted in Singapore, published in 1999 and included 50 women.[276] [EL = 1+] The trial compared 0.2% and 0.125% ropivacaine for PCEA. There was evidence that women in the 0.125% group had less motor block, although there was no evidence of differences in other outcomes.

12, 16 and 20 ml of 0.1% ropivacaine plus 0.5 micrograms fentanyl and 4, 6 and 8 ml of 0.2% ropivacaine plus 0.5 micrograms fentanyl
The eleventh study was conducted in France, published in 2003 and included 150 women (25 for each).[269] [EL = 1+] The trial compared six different doses (0.1% ropivacaine plus 0.5 micrograms fentanyl (i) 12 ml, (ii) 16 ml and (iii) 20 ml, 0.2% ropivacaine plus 0.5 micrograms fentanyl (iv) 6 ml, (v) 8 ml and (vi) 10 ml) of ropivacaine plus fentanyl for PCEA during labour. The results showed that effectiveness of analgesia is dependent upon drug mass rather than volume or concentration.

Evidence statement

A reduced dose of local anaesthetic seems as effective as a higher dose, although there is no strong evidence to confirm appropriate dosage during epidural analgesia.

GDG interpretation of the evidence (how to maintain regional analgesia: drug and dosage)

High concentrations of local anaesthetic (0.25% or above of bupivacaine or equivalent) for epidural analgesia resulted in less mobility for women (more motor block), increased instrumental birth and increased incidence of maternal hypotension. In the longer term (12 months), women in the high-dose group appear to have more stress incontinence and bowel control problems. The addition of opioids (e.g. 2 micrograms/ml fentanyl) to low-concentration local anaesthetics (less than 0.125% bupivacaine or equivalent) provides effective analgesia with less motor block and less instrumental birth. In terms of analgesic efficacy and obstetric outcomes, there is little to separate the various low-concentration (0.0625% to 0.1% bupivacaine or equivalent) local anaesthetic/opioid solutions.

There is limited evidence to suggest that the addition of opioids may result in increased requirement for high-level neonatal resuscitation.

Recommendations on establishing and maintaining regional analgesia

93. Use either epidural or combined spinal–epidural analgesia for establishing regional analgesia in labour. [2007]

94. If rapid analgesia is required, use combined spinal–epidural analgesia. [2007]

95. Establish combined spinal–epidural analgesia with bupivacaine and fentanyl [2007]

96. Establish epidural analgesia with a low-concentration local anaesthetic and opioid solution with, for example, 10–15 ml of 0.0625–0.1% bupivacaine with 1–2 micrograms per ml fentanyl. The initial dose of local anaesthetic plus opioid is essentially a test dose, so administer cautiously to ensure that inadvertent intrathecal injection has not occurred. [2007]

97. Use low-concentration local anaesthetic and opioid solutions (0.0625–0.1% bupivacaine or equivalent combined with 2.0 micrograms per ml fentanyl) for maintaining epidural analgesia in labour. [2007]

98. Do not use high concentrations of local anaesthetic solutions (0.25% or above of bupivacaine or equivalent) routinely for either establishing or maintaining epidural analgesia. [2007]

Monitoring during labour

Cardiotocography compared with intermittent auscultation during established labour

Review question

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

For further details on the evidence review protocol, please see appendix E.

Description of included studies

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

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

Two of the included studies only included women with low risk pregnancies (Wood et al., 1981) or reported data separately for women with low risk pregnancies (Leveno et al., 1986). In the other 4 studies, the majority of women had low risk pregnancies, but 20–30% of women were giving birth before term, underwent induction of labour or had antepartum risk factors (more details of specific inclusion and exclusion criteria can be found in the evidence tables in appendix I).

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

Evidence profile

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

Update 2014

Table 61: Summary GRADE profile for comparison of electronic fetal monitoring using CTG compared with intermittent auscultation during established labour

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

Update 2014

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

Update 2014

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
Neonatal morbidity: hypoxic ischaemic encephalopathy						
1 study (Vintzileos et al., 1993)	randomised trial	1/746 (0.13%)	2/682 (0.29%)	RR 0.46 (0.04 to 5.03)	2 fewer per 1000 (from 3 fewer to 12 more)	Low
Neonatal morbidity: seizures						
1 meta-analysis of 3 studies (Leveno et al., 1986; MacDonald et al., 1985; Vintzileos et al., 1993)	randomised trials	8/13072 (0.06%)	24/13027 (0.18%)	RR 0.34 (0.16 to 0.75)	1 fewer per 1000 (from 0 fewer to 2 fewer)[a]	High
Neonatal morbidity: intraventricular haemorrhage						
1 study (Vintzileos et al., 1993)	randomised trial	0/746 (0%)	1/682 (0.15%)	RR 0.3 (0.01 to 7.47)	1 fewer per 1000 (from 1 fewer to 9 more)	Low
Neonatal morbidity: respiratory distress						
1 study (Vintzileos et al., 1993)	randomised trial	55/746 (7.4%)	40/682 (5.9%)	RR 1.26 (0.85 to 1.86)	15 more per 1000 (from 9 fewer to 50 more)	Very low
Neonatal morbidity: abnormal neurologic symptoms or signs						
1 meta-analysis of 3 studies (Kelso et al., 1978; MacDonald et al., 1985; Wood et al., 1981)	randomised trials	19/5767 (0.33%)	31/5804 (0.53%)	RR 0.62 (0.35 to 1.09)	2 fewer per 1000 (from 3 fewer to 0 more)	Low

Update 2014

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
Admission to neonatal intensive care unit (NICU) or nursery						
1 meta-analysis of 5 studies (Kelso et al., 1978; Leveno et al., 1986; MacDonald et al., 1985; Vintzileos et al., 1993; Wood et al., 1981)	randomised trials	780/15200 (5.1%)	753/15291 (4.9%)	RR 1.03 (0.94 to 1.13)	1 more per 1000 (from 3 fewer to 6 more)	Moderate
Cord blood gas values at birth: arterial or venous pH<7.10						
1 meta-analysis of 2 studies (MacDonald et al., 1985; Vintzileos et al., 1993)	randomised trials	36/1279 (2.8%)	29/1215 (2.4%)	RR 0.92 (0.27 to 3.11)	2 fewer per 1000 (from 17 fewer to 50 more)	Very low

CI confidence interval, RR relative risk

Update 2014

Evidence statements

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

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

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

Consideration of clinical benefits and harms

The evidence showed that there were significantly more spontaneous vaginal births in the group that received intermittent auscultation compared with the group that received continuous CTG. There was also a significantly greater number of instrumental vaginal births (both for any indication and specifically for fetal distress) in the CTG group. CTG was also associated with a statistically significant increase in the number of caesarean sections for fetal distress (5 more per 1000 births). These findings seemed to suggest that the use of CTG in labour results in an increase in interventions. However, for the majority of neonatal morbidities, there were no statistically significant findings between the 2 groups. The only statistically significant difference in neonatal morbidity was in seizures, with a lower incidence in the CTG group than the auscultation group, but although this was a significant finding, the absolute reduction was very low, with a rate of 1 fewer per 1000 babies.

The guideline development group concluded that the evidence seemed to suggest that the use of CTG in labour leads to an increase in the number of interventions without a concomitant increase in improved neonatal outcomes. The group noted that in a low risk population, major adverse outcomes are going to be very rare, and thus a large number of women would have to undergo CTG in order to prevent these outcomes. The group did not feel that this was a proven and clinically beneficial trade-off, so they endorsed the recommendation from the previous edition of the guideline that CTG should not be used in established labour unless there was a specific indication suggesting increased risk for the wellbeing of the unborn baby which would justify switching from intermittent auscultation.

The group discussed the appropriate method for conducting auscultation. They noted that the previous version of the guideline had indicated that the fetal heart rate heard should be recorded as an average. It was felt that this wording was not clear about whether this should be written as a range or a single figure. The group agreed that the fetal heart rate should be counted for 1 minute and the result should be written as a single figure, and the wording of the recommendation was changed accordingly. The need to auscultate the fetal heart for 1 minute immediately after a contraction in order to detect any late decelerations was also noted as important and included in the recommendations. The group also noted that if any fetal heart

rate abnormality is suspected during labour when conducting intermittent auscultation, or if there is any uncertainty about the origin of the heart sounds being heard, then the maternal pulse should be palpated to differentiate between the woman's and the unborn baby's heart rates.

Consideration of health benefits and resource uses

The clinical evidence showed that the use of CTG rather than intermittent auscultation in established labour would lead to an increase in the number of interventions such as caesarean section and instrumental vaginal birth (as well as their associated morbidities both for the woman and the baby, including the potential interruption of physiological maturation). The perceived benefits from CTG monitoring are that there will be fewer babies born with severe fetal acidosis or, at least, its impact may be ameliorated. However, the increase in caesarean sections and instrumental births did not appear to be associated with the reduction in poor outcomes required to ensure that using continuous CTG could be considered cost effective. As a result, the guideline development group felt that not recommending the use of continuous CTG could lead to potential health benefits from fewer unnecessary birth interventions. Reducing the use of continuous CTG could lead to cost savings if less CTG equipment is required in the labour ward, with its associated maintenance costs, and also reduced use of ancillary resources such as pH monitoring.

Quality of evidence

The previous version of this guideline included a Cochrane systematic review as evidence for this review question. However, for this updated review, due to the variability in the study populations among the included studies, the guideline development group agreed that it would be more appropriate to appraise them for inclusion as individual trials. This meant that it was possible to remove some papers because they were not applicable to the population of the guideline, for example if the study population only included women at higher risk. This ensured that the evidence for the updated review was more directly applicable to a low risk population than was the case for the original version of the guideline.

The quality of the evidence ranged from high to very low for different outcomes. In general though, despite the reasons for downgrading the evidence, the group felt sufficiently confident in the findings to make its recommendations

Other considerations

The guideline development group was aware that there was some concern among clinicians about not using CTG in established labour (this is similar to the concern about monitoring on admission). The group felt that too often clinicians were using CTG and the resultant fetal heart tracings for reassurance, rather than for clearly defined reasons. As a result, the group was confident in recommending that continuous CTG not be used in established labour for women at low risk of complications.

As with monitoring on admission to labour, the group agreed that accelerations or decelerations should be recorded if they are heard on intermittent auscultation.

The group agreed that it would be helpful to be more specific about the potential reasons why clinicians should consider changing from intermittent auscultation to continuous CTG. After considering the list of reasons presented in the original guideline, the group added some additional reasons based on their clinical experience. The group acknowledged that for most of these factors there is no evidence of improved outcomes with the use of CTG compared with intermittent auscultation, but they believed that the continuous surveillance afforded by CTG, along with its ability to pick up variability in the fetal heart rate, suggested it may be of benefit in circumstances where the unborn baby is at increased risk of developing acidosis. They felt it appropriate to divide indications for CTG into those where CTG should be considered and those where CTG should be advised; this was done based on the degree of risk of fetal acidosis thought to be associated with each factor and is reflected in the recommendations. Findings from the evidence for continuous CTG when there is significant

meconium show an increase in intrapartum interventions but fewer admissions to neonatal intensive care (see section 10.2). This led the group to continue to recommend that CTG should be offered where there is significant meconium present. From their clinical experience, the group members felt it appropriate to differentiate between non-significant meconium and significant meconium. The group agreed that non-significant meconium alone was not a reason to advise continuous CTG, but that instead it should prompt a full risk assessment and continuous CTG should be advised if other risk factors were then found to be present.

The group also discussed a woman's request for CTG as it was included in the original guideline. They felt that it was unusual for a woman to request switching to CTG without any other clinical indication. In addition, there is evidence that use of CTG in low risk women is associated with increased intrapartum interventions and therefore also their associated morbidities, with no evidence of improved outcomes for the baby. Consequently, the group felt it inappropriate to include women's choice as a standard intrapartum indication for switching to CTG, with the understanding that intrapartum care is always underpinned by the principles of choice and control as outlined in chapter 4 (Care throughout labour).

Finally, the group acknowledged that CTG does not measure the fetal pulse itself but an electrical signal (generated by either a Doppler recording of the fetal heart movements or an electrical signal from the fetal ECG with a fetal scalp electrode). They noted that there are limitations to the extent to which fetal heart rate is a surrogate for fetal hypoxia and acidosis. Fetal heart rate can be affected by factors other than fetal hypoxia, such as fetal behavioural state, maternal analgesia and pyrexia.

Recommendations

99. Offer intermittent auscultation of the fetal heart rate to low-risk women in established first stage of labour in all birth settings:

- Use either a Pinard stethoscope or Doppler ultrasound.
- Carry out intermittent auscultation immediately after a contraction for at least 1 minute, at least every 15 minutes, and record it as a single rate.
- Record accelerations and decelerations if heard.
- Palpate the maternal pulse if a fetal heart rate abnormality is suspected, to differentiate between the two heart rates. [new 2014]

100. Do not perform cardiotocography for low-risk women in established labour. [new 2014]

101. Advise continuous cardiotocography if any of the following risk factors are present or arise during labour:

- suspected chorioamnionitis or sepsis, or a temperature of 38°C or above
- severe hypertension (160/110 mmHg above [see Hypertension in pregnancy (NICE clinical guideline 107)]).
- oxytocin use
- the presence of significant meconium (see recommendation 164)
- fresh vaginal bleeding that develops in labour. [new 2014]

102. If any one of the following risk factors is present or arises during labour, perform a full assessment of all factors listed in recommendation 163.

- prolonged period since rupture of membranes (24 hours or more) (see recommendations 59 to 64)

- moderate hypertension (150/100 to 159/109 mmHg [see Hypertension in pregnancy (NICE clinical guideline 107)])
- confirmed delay in the first or second stage of labour (see recommendations 175, 195 and 199)
- the presence of non-significant meconium.

Advise continuous cardiotocography if 2 or more of the above risk factors are present, or any other risk factor in recommendation 163 is present with 1 of these. [new 2014]

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

104. Address any concerns that the woman has about continuous cardiotocography, and give her the following information:

- Explain that continuous cardiotocography is used to monitor the baby's heartbeat and the labour contractions.
- Give details of the types of findings that may occur. Explain that a normal trace is reassuring and indicates that the baby is coping well with labour, but if the trace is not normal there is less certainty about the condition of the baby and further continuous monitoring will be advised.
- Explain that decisions about whether to take any further action will be based on an assessment of several factors, including the findings from cardiotocography. [new 2014]

105. If continuous cardiotocography has been used because of concerns arising from intermittent auscultation but there are no non-reassuring or abnormal features (see table 92) on the cardiotocograph trace after 20 minutes, remove the cardiotocograph and return to intermittent auscultation. [new 2014]

Research recommendations

16. What are the natural frequencies of the avoidable harms that cardiotocography is intended to prevent for women who are assessed as being at low risk of complications at the start of labour? Does using cardiotocography in labours where complications develop confer a net benefit compared with intermittent auscultation?

Why this is important

Cardiotocography is used in current practice to monitor the fetal heart rate when there is a concern that fetal hypoxia may develop. It is regarded as unethical, in most circumstances, to conduct clinical research where women whose labour is categorised as ‘high risk’ are not offered cardiotocography. There is therefore no high-quality evidence about the size of the benefit or harm derived from the use of cardiotocography compared with intermittent auscultation, either in individual cases or across a whole population. Further analysis is needed to evaluate the actual (or probable) benefits and harms associated with this screening test. This would be based on analysis and modelling using data and assumptions derived from existing evidence from a range of countries, comprising data from any studies and/or historic data sets that record the natural frequencies of avoidable damage caused by intrapartum events. These data could then be used to ascertain both the natural frequencies of adverse events and whether widespread use of cardiotocography reduces these. Primary outcomes would be intrapartum fetal death, neonatal encephalopathy, cerebral palsy or other significant

neurodevelopmental injury, and maternal morbidity. Other outcomes might include long-term physical and psychological outcomes (health across whole of life), health and social care costs, implications for informed decision-making, and analysis of ethical considerations.

17. A randomised controlled trial of intermittent auscultation vs. continuous cardiotocography in otherwise low risk pregnancies complicated by meconium stained liquor

Population: women assessed at the onset of labour as being at low risk of developing intrapartum complications who go on to have meconium stained liquor
Intervention: continuous cardiotocography
Comparator: intermittent auscultation
Primary outcome: neonatal mortality or developmental delay at 2 years
Secondary outcomes: caesarean section, woman's experience of labour; neonatal unit admission, requirement for respiratory ventilation, neonatal encephalopathy
Study design: Randomised controlled trial

Why this is important

Women at low risk of intrapartum complications have lower rates of intervention (e.g. caesarean section) and no difference in neonatal outcomes when the fetus is monitored using intermittent auscultation rather than continuous cardiotocography. The studies that demonstrated this involved conversion from intermittent auscultation to cardiotocography if a fetal heart rate abnormality was detected on intermittent auscultation or if risk factors developed such as meconium stained liquor. However, it may be that in the presence of meconium-stained liquor with no other concerns intermittent auscultation would have been as effective from the fetal point of view but with the benefit of a reduced risk of intervention. A randomised controlled trial with sufficient power to consider long term neonatal outcomes is required to determine whether intermittent auscultation could be used to reduce intervention in labour whilst maintaining the safety for the fetus where there is meconium-stained liquor.

Fetal heart rate monitoring for meconium-stained liquor

Review question

What is the effectiveness of continuous electronic fetal monitoring compared with intermittent auscultation when there is meconium-stained liquor?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

One study was included in this review (Alfirevic et al., 2008). The included study is a systematic review of randomised control trials with 12 component trials from a variety of countries. Two of these trials were considered for this review.
All included trials within the systematic review evaluated the effectiveness of continuous electronic fetal monitoring (EFM) using cardiotocography (CTG) compared with intermittent auscultation of the fetal heart rate. Ten of the included studies within the systematic review had a small proportion of women with meconium stained liquor included but no subgroup analysis performed for that group, and so therefore could not be used to contribute to this review. The 2 remaining studies included a higher percentage of women with meconium stained liquor and are reported for this review. The studies were conducted in Pakistan and Melbourne. All women in the trial in Pakistan had meconium-stained liquor, but this was true for only 40% women in the Melbourne trial. Both studies were carried out more than 23 years ago and have substantial limitations. The effectiveness of continuous CTG monitoring compared with intermittent auscultation was not reported in the original intrapartum care guideline.

Evidence profile

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

Table 62: Summary GRADE profile for comparison of continuous CTG with intermittent auscultation

Number of studies	Design	Number of women		Effect		Quality
		Continuous CTG	Intermittent auscultation (IA)	Relative (95% CI)	Absolute (95% CI)	
Caesarean section						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	74/275 (26.9%)	36/275 (13.1%)	RR 2.11 (1.19 to 3.74)	145 more per 1000 (from 25 more to 359 more)	Very Low
Caesarean section for abnormal FHR pattern and/or acidosis						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	47/275 (17.1%)	21/275 (7.6%)	RR 2.24 (1.38 to 3.64)	95 more per 1000 (from 29 more to 202 more)	Low
Caesarean section for other reason						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	27/275 (9.8%)	15/275 (5.5%)	RR 1.80 (0.98 to 3.31)	43 more per 1000 (from 1 fewer to 125 more)	Very Low
Instrumental vaginal birth						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	108/275 (39.3%)	94/275 (34.2%)	RR 1.16 (0.88 to 1.54)	55 more per 1000 (from 41 fewer to 185 more)	Very Low
Spontaneous vaginal birth not achieved						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	182/275 (66.2%)	130/275 (47.3%)	RR 1.4 (1.2 to 1.63)	189 more per 1000 (from 95 more to 298 more)	Very Low

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Number of studies	Design	Number of women		Effect		Quality
		Continuous CTG	Intermittent auscultation (IA)	Relative (95% CI)	Absolute (95% CI)	
Perinatal death						
1 meta-analysis of 2 studies (Alfirevic et al., 2008)	randomised trials	5/275 (1.8%)[a]	6/275 (2.2%)[a]	RR 0.83 (0.26 to 2.67)	4 fewer per 1000 (from 16 fewer to 36 more)	Very Low
NICU admissions						
1 study (Alfirevic et al., 2008)	randomised trials	11/175 (6.3%)	30/175 (17.1%)	RR 0.37 (0.19 to 0.71)	108 fewer per 1000 (from 50 fewer to 139 fewer)	Moderate
Neonatal seizures						
1 study (Alfirevic et al., 2008)	randomised trials	0/175 (0%)	4/175 (2.3%)	RR 0.11 (0.01 to 2.05)	20 fewer per 1000 (from 23 fewer to 24 more)	Low
Damage/infection from scalp electrode or scalp sampling						
1 study (Alfirevic et al., 2008)	randomised trials	1/100 (1%)	0/100 (0%)	RR 3 (0.12 to 72.77)	NC	Low

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

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

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Evidence statements

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

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

See section 10.1.6.

Interpretation of an electronic fetal heart rate trace

Review question

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

For further details on the evidence review protocol, please see appendix E.

Introduction

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

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

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

- baseline heart rate
- baseline variability
- presence or absence of decelerations
- presence of accelerations

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

Description of included studies

This review includes 38 studies (Cahill et al., 2013; Maso et al., 2012; Salim et al., 2010; Roy et al., 2008; Larma et al., 2007 ; Giannubilo et al., 2007; Menihan et al., 2006; Sameshima et al., 2005; Williams and Galerneau 2004; Williams and Galerneau 2003; Williams and Galerneau, 2002; Hadar et al., 2001; Low et al., 2001; Sheiner et al., 2001; Dellinger et al., 2000; Heinrich, 1982; Honjo and Yamaguchi, 2001; Low et al., 1999; Berkus et al., 1999; Ozden and Demirci, 1999; Spencer et al., 1997; Nelson et al., 1996; Cardoso et al., 1995; Gaffney et al., 1994; Cibils, 1993; Samueloff et al., 1994; Ellison et al., 1991; Murphy et al.,

1991; Gilstrap et al., 1987; Spencer et al., 1986; Gilstrap et al., 1984; Krebs et al., 1982; Cibils, 1980; Low et al., 1980; Powell et al.1979; Cibils, 1978; Low et al., 1977; Cibils, 1975).

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

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

The predictive value and association of tachycardia and bradycardia for neonatal adverse outcomes were assessed in 13 studies (Maso et al., 2012; Salim et al., 2010; Roy et al., 2008; Giannubilo et al., 2007; Williams and Galerneau 2004; Sheiner et al., 2001; Honjo and Yamaguchi, 2001; Berkus et al., 1999; Ozden and Demirci, 1999; Nelson et al., 1996; Gilstrap et al., 1984; Ellison et al., 1991; Gilstrap et al., 1987).

The relation between FHR baseline variability and neonatal encephalopathy, sudden infant death and/or metabolic acidosis was evaluated in 9 studies (Roy et al., 2008; Larma et al., 2007; Menihan et al., 2006; Sheiner et al., 2001; Berkus et al., 1999; Spencer et al., 1997; Nelson et al., 1996; Samueloff et al., 1994; Ellison et al., 1991).

The predictive value of accelerations and decelerations for neonatal adverse outcomes was assessed in 18 studies (Cahill et al., 2013; Roy et al., 2008; Giannubilo et al., 2007; Sameshima et al., 2005; Williams and Galerneau, 2002; Williams and Galerneau 2004; Williams and Galerneau 2003; Hadar et al., 2001; Sheiner et al., 2001; Berkus et al., 1999; Ozden and Demirci, 1999; Spencer et al., 1997; Nelson et al., 1996; Samueloff et al., 1994; Cibils, 1993; Ellison et al., 1991; Krebs et al., 1982; Powell et al.1979; Low et al. 1977).

The ability of defined FHR classification systems to predict early adverse neonatal outcomes was assessed in 13 studies (Williams and Galerneau, 2004; Hadar et al., 2001; Sheiner et al., 2001; Dellinger et al., 2000; Heinrich, 1982; Low et al., 2001; Low et al., 1999; Ozden and Demirci, 1999; Spencer et al., 1997; Cardoso et al., 1995; Gaffney et al., 1994; Murphy et al., 1991; Gilstrap et al., 1987).

All included studies consisted of predominantly low risk or mixed populations apart from 5 (Cibils, 1993; Cibils, 1980; Low et al., 1980; Cibils, 1978; Cibils, 1975). The findings for the 5 studies with high risk populations are reported in separate GRADE profiles.

Evidence profile

Data is reported in GRADE profiles for the following FHR parameters:

- fetal heart rate (bradycardia, tachycardia)
- baseline variability
- accelerations
- decelerations
  - early decelerations

  - late decelerations
  - variable decelerations
- categorisation/classification of FHR patterns and traces.

The grading of evidence from prospective comparative observational studies or prospective consecutive case series started at high quality and was then downgraded if there were any issues identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies or retrospective consecutive case series started at moderate quality and was then downgraded if there were any issues. Evidence from non-consecutive case series started at low quality and was then downgraded if there were any issues.

Published classifications of FHR traces are detailed in appendix N.

Predictive accuracy and correlation data

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

Low risk and mixed populations of women

Fetal heart rate (bradycardia and tachycardia)

Table 63: Predictive value of bradycardia and tachycardia for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Tachycardia (> 160 bpm) (duration not reported)									
1 study (Nelson et al., 1996)	Case control	cerebral palsy	NR	378	28.2% (19.4 to 39)[a]	71.7% (66.3 to 76.5)[a]	0.99 (0.66 to 1.48)[a]	1.0 (0.85 to 1.17)[a]	Low
1 study (Gilstrap, 1984)	Cohort	umbilical cord arterial pH<7.20	NR	583	47.2% (30.9 to 63.5)[a]	80.4% (76.9 to 83.87)[a]	2.41 (1.63 to 3.55)[a]	0.65 (0.48 to 0.89)[a]	Moderate
Tachycardia (> 180 bpm) (duration not reported)									
1 study (Nelson et al., 1996)	Case control	cerebral palsy	NR	378	6.4% (2.8 to 14.1)[a]	94.7% (91.5 to 96.7)[a]	1.20 (0.45 to 3.17)[a]	0.98 (0.92 to 1.05)[a]	Low
Bradycardia (< 110 bpm) (NICHD classification) (duration not reported)									
1 study (Williams & Galerneau 2004)	Case series	seizure	1 hour before birth	50	46.7% (30.2 to 63.9)[a]	19.2% (8.5 to 37.9)[a]	0.57 (0.37 to 0.88)[a]	2.77 (1.17 to 6.52)[a]	Low
FHR baseline (< 110 bpm) (NICHD classification) (duration not reported)									
1 study (Larma et al., 2007)	Case control	moderate hypoxic ischemic encephalopathy (HIE)	last hour of tracing	214	15.4 %	98.9%	7.50	0.86	Very low
Bradycardia ('terminal deceleration')[b]									
1 study (Cahill et al., 2013)	Case control	umbilical cord arterial pH<7.10	30 min before birth	5388	21.0% (11.3 to 33.9)[a]	82.3% (81.3 to 93.4)[a]	1.20 (0.72 to 1.98)[a]	0.96 (0.84 to 1.10)[a]	Low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Bradycardia ('terminal deceleration')[b]									
1 study (Cahill et al., 2013)	Case control	umbilical cord arterial pH<7.10 and base excess < −8.0	30 min before birth	5388	22.0% (11.5 to 36.0)[a]	82.3% (81.3 to 83.4)[a]	1.25 (0.47 to 2.11)[a]	0.95 (0.82 to 1.10)[a]	Low
Bradycardia ('terminal deceleration')[b]									
1 study (Cahill et al., 2013)	Case control	NICU admission	30 min before birth	5388	06.67% (1.11 to 32.0)[a]	82.3% (81.2 to 83.3)[a]	0.38 (0.06 to 2.51)[a]	1.13 (0.99 to 1.30)	Low
Prolonged bradycardia (<110 bpm) (≥10 min)[c]									
1 study (Cahill et al., 2013)	Case control	umbilical cord arterial pH<7.10	30 min before birth	951	33.3% (10.13 to 65.5)[a]	97.12%(95.84 to 98.1)[a]	11.6 (4.80 to 28.0)[a]	0.69 (0.46 to 1.02)[a]	Low
Bradycardia (<100 bpm) (duration not reported)									
1 study (Nelson et al., 1996)	Case control	cerebral palsy	NR	378	34.6% (25 to 45.7)[a]	75% (69.8 to 79.6)[a]	1.38 (0.96 to 1.99)[a]	0.87 (0.73 to 1.03)[a]	Low
Mild bradycardia (90–119 bpm) (duration not reported)									
1 study (Gilstrap, 1984)	Cohort	umbilical cord arterial pH<7.20	10 min before birth	595	61.2% (47.5 to 74.87)[a]	75.2% (71.6 to 78.8)[a]	2.47 (1.89 to 3.23)a	0.51 (0.36 to 0.73)[a]	Very low
Bradycardia (<80 bpm) (duration not reported)									
1 study (Nelson et al., 1996)	Case control	cerebral palsy	NR	378	16.7% (10 to 26.5)[a]	88.3% (84.2 to 91.5)[a]	1.42 (0.79 to 2.56)[a]	0.94 (0.84 to 1.05)[a]	Low
Moderate/marked bradycardia (60–89 bpm) (duration not reported)									
1 study (Gilstrap, 1984)	Cohort	umbilical cord arterial pH<7.20	NR	551	63.4% (50.3 to 76.5)[a]	82.3% (79 to 85.7)[a]	3.59 (2.71 to 4.76)[a]	0.44 (0.30 to 0.63)[a]	Moderate

BPM beats per minute, CI Confidence interval, NICHD National Institute of Child Health and Human Development, NR not reported

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

Table 64: Umbilical arterial pH and base excess in babies with intrapartum tachycardia or bradycardia

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

a. Baseline tachycardia and bradycardia were defined as:
- *Mild bradycardia: baseline FHR between 90 - 109 bpm for ≥10 minutes*
- *Moderate to severe bradycardia: baseline FHR<90 bpm for ≥10 minutes*
- *Tachycardia: baseline FHR of 160 bpm for ≥10 minutes*

b. p value when compared with normal FHR tracing

Table 65: Association between FHR (bradycardia and tachycardia) and umbilical artery blood gas values or adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
'Mild' bradycardia (90–119 bpm) (compared with normal FHR tracing)[a] (duration not reported)						

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

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

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

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Sheiner et al., 2001)	Case series	pH<7.2	2nd stage	57	OR 2.3 (95% CI 0.3 to 17.1) p=0.390	Low
1 study (Sheiner et al., 2001)	Case series	BD≥12 mmol/l	1st stage	28	OR 5.2 (95% CI 0.8 to 31.9) p=0.007	Low
1 study (Sheiner et al., 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 3.8 95% CI 0.3 to 44.2) p=0.282	Low
Bradycardia ('terminal deceleration')[e]						
1 study (Cahill et al., 2013)	Cohort	cord pH <7.10	30 min before birth	951	OR[d] 1.2 (95% CI 0.6 to 2.3) p=0.49	Low
1 study (Cahill et al., 2013)	Cohort	cord pH <7.05	30 min before birth	951	OR[d] 1.4 (95% CI 0.5 to 4.4) p=0.52	Low
1 study (Cahill et al., 2013)	Cohort	cord pH <7.10 and base excess < −8.0	30 min before birth	951	OR[d] 1.3 (95% CI 0.6 to 2.5) p=0.49	Low
1 study (Cahill et al., 2013)	Cohort	NICU admission	30 min before birth	951	OR[d] 0.3 (95% CI 0.1 to 2.5) p=0.49	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Tachycardia (>160 bpm) (duration not reported)						
1 study (Berkus et al., 1999)	Cohort	immediate adverse neonatal outcome[b]	1st stage	126	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus et al., 1999)	Cohort	immediate adverse neonatal outcome[b]	2nd stage	126	OR 1.9 (95% CI 1.2 to 2.8)	Very low
1 study (Gilstrap et al., 1987)	Cohort	umbilical cord arterial pH <7.2 Mean (± SD)	2nd stage before head expulsion	32	7.25±0.05	Very low

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

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

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Table 66: Baseline fetal heart rate in babies born with umbilical cord blood acidemia compared with those born without academia

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

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

a. pH<7.2, base deficit ≥12mmol/l

Table 67: Correlation of marked tachycardia to neonatal convulsions

Number of studies	Design	Stage of labour	Number of women & baby pairs[a]	Correlation coefficient (p-value)	Quality
'Marked' tachycardia a (not defined)					
1 study (Ellison et al., 1991)	Cohort	1st stage	n=135	r=-0.02 (p=NS)	Low

NS not significant, r correlation coefficient

a. Original cohort from Dublin RCT (MacDonald et al., 1985), no definition of 'marke' tachycardia provided

Baseline variability

Table 68: Predictive value of fetal heart rate baseline variability for neonatal adverse outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
FHR reduced variability (FIGO classification)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	first 30 minutes of tracing	73	10.53% (0.77 to 20.28)[a]	94.29% (86.60 to 100)[a]	1.84 (0.35 to 9.44)[a]	0.94 (0.82 to 1.08)[a]	Very Low

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Spencer et al., 1997)	Case control	encephalopathy	last 30 minutes of tracing	73	38.89% (22.96 to 54.81)[a]	87.10% (75.30 to 98.90)[a]	3.01 (1.10 to 8.20)[a]	0.70 (0.52 to 0.94)[a]	Very Low
Baseline variability <5 bpm (NICHD classification)									
1 study (Larma et al., 2007)	Case control	moderate hypoxic ischemic encephalopathy (HIE)	last hour of tracing	214	53.8%	79.8%	2.50	0.50	Very low
Non-reactive trace (NICHD classification)									
1 study (Larma et al., 2007)	Case control	moderate hypoxic ischemic encephalopathy (HIE)	last hour of tracing	214	92.3%	61.7%	2.30	0.13	Very low
Baseline variability <5 bpm (NICHD classification)									
1 study (Nelson et al., 1996)	Case control	cerebral palsy in low and high risk population[b]	NR	378	26.9% (18.3 to 37.7)[a]	90.7% (86.8 to 93.5)[a]	2.88 (1.73 to 4.79)[a]	0.80 (0.70 to 0.92)[a]	Very low
FHR variability amplitude <3 bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	2nd stage	1814	10.99%	93.80%	1.40	0.96	Very low
FHR variability amplitude <5 bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	2nd stage	1814	26.24%	78.93%	1.18	0.94	Very low

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
FHR variability oscillation <3 bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	2nd stage	1810	6.78%	95.18%	1.36	0.98	Very low
FHR variability oscillation <5 bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	2nd stage	1810	25.23%	80.52%	1.25	0.93	Very low
FHR variability ([amplitude[d] + oscillation[e]] ÷ 2) <3 bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	2nd stage	1913	7.44%	96.30%	1.75	0.96	Very low
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	1st stage (following admission)	1913	2.1%	98.6%	1.50	0.99	Very low
FHR variability oscillation[e] <3bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	1st stage (following admission)	1810	3.16%	98.2%	1.72	0.98	Very low
FHR variability amplitude[d] <3bpm[c]									
1 study (Samueloff et al., 1994)	Cohort	umbilical cord artery pH<7.2	1st stage (following admission)	1814	3.86%	97.13%	1.31	0.99	Very low

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

a. Calculated by NCC-WCH technical team
b. High risk of cerebral palsy was defined as incidence of bleeding during pregnancy, breech presentation, gestational age of less than 37 weeks at delivery, maternal infection, and the presence of meconium in the amniotic fluid. Low risk was defined as the absence of the five risk factors and high risk as the presence of one or more of them. Positive predictive values were obtained by projection onto the entire population of children born during the three-year study period in four counties. 31% of the population were classified as being 'high risk'
c. Scored using 5 variables:

- *FHR amplitude ≥3 bpm - high variability, <3 bpm - low variability*

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- *FHR amplitude ≥5 bpm - high variability, <5 bpm - low variability*
- *FHR frequency of oscillations ≥3/min - high variability, <3/min - low variability*
- *FHR frequency of oscillations ≥5/min - high variability, <5/min - low variability*
- *Combination of (amplitude + frequency) ÷ 2. Value <3 low variability, ≥3 high variability*

d. The amplitude was measured as the highest elevation of FHR from the baseline
e. Frequency of oscillations was counted from the number of intersections of oscillations from FHR baseline

Table 69: Association between fetal heart rate variability and neonatal adverse outcomes or umbilical artery blood gas values

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

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Decreased variability (not defined)						
1 study (Roy et al., 2008)	Cohort	umbilical cord pH <7.10	NR	17	0%	Low
1 study (Roy et al., 2008)	Cohort	immediate NICU admission	NR	17	0%	Low
Reduced variability (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Cohort	pH<7.2	2nd stage	57	OR 2.2 (95% CI 0.3 to 17.1) p=0.728	Low
1 study (Sheiner et al., 2001)	Cohort	BD≥12 mmol/l	2nd stage	28	OR 5.1 (95% CI 0.6 to 46.1) p=0.098	Low

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

a. Composite neonatal outcomes: umbilical artery pH<7 and/or APGAR score <7 at 5 min and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth
b. Neonates were considered to have immediate adverse outcomes if they were admitted to level III neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)

Table 70: Association between variability (with or without accelerations or decelerations) and umbilical artery blood gas values

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
Normal variability (NICHD classification)						

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

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

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low
Decreased variability with late decelerations + no accelerations (NICHD classification)						
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	19	n=6 (31.5%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	19	n=10 (52.6%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	19	n=8 (42.1%)	Very low
Decreased variability with variable decelerations + no accelerations (NICHD classification)						
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	8	n=2 (25%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	8	n=3 (37.5%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	8	n=2 (25%)	Very low
Normal variability and recovery from bradycardia (NICHD classification)						

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	128	n=2 (2%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	128	n=28 (22%)	Very low
1 study (Williams & Galerneau, 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	128	n=6 (5%)	Very low
Normal variability and no recovery from bradycardia (NICHD classification)						
1 study (Williams & Galerneau, 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	40	n=7 (18%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	40	n=13 (33%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	40	n=5 (13%)	Very low
Decreased variability and recovery from bradycardia (NICHD classification)						
1 study (Williams & Galerneau 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	9	n=4 (44%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	9	n=5 (56%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	9	n=2 (22%)	Very low
Decreased variability and no recovery from bradycardia (NICHD classification)						

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
1 study (Williams & Galerneau 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	9	n=7 (78%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	9	n=8 (89%)	Very low
1 study (Williams & Galerneau 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	9	n=8 (89%)	Very low

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

a. Does not include the last 30 mins before birth

Accelerations

Table 71: Predictive value of lack of fetal heart rate accelerations for adverse neonatal outcomes

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

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

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

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Table 72: Association of sporadic accelerations[a] and perinatal mortality

Number of studies	Design	Stage of labour	Number of babies with defined FHR patterns	Number (percentage) of babies who died	Quality
Sporadic accelerations[a] (3 or more accelerations per 30 min tracing) (women with no identified risk factors for adverse outcome)					
1 study (Krebs et al., 1982)	Cohort	first 30 minutes of tracing	811	n=2 (0.2%)	Low
Sporadic accelerations[a] (fewer than 3 accelerations per 30 min tracing) (women with identified risk factors for adverse outcome)					
1 study (Krebs et al., 1982)	Cohort	first 30 minutes of tracing	122	n=12 (9.8%)	Very low
Sporadic accelerations[a] (3 or more accelerations per 30 min tracing) (women with identified risk factors for adverse outcome)					
1 study (Krebs et al., 1982)	Cohort	first 30 minutes of tracing	955	n=4 (0.4%)	Very low
Sporadic accelerations[a] (fewer than 3 accelerations per 30 min tracing) (women with no identified risk factors for adverse outcome)					
1 study (Krebs et al., 1982)	Cohort	first 30 minutes of tracing	108	n=3 (2.8%)	Very low

FHR fetal heart rate

a. Sporadic accelerations occur independently from uterine contractions

Early decelerations

Table 73: Correlation of fetal heart rate early decelerations with neonatal convulsions

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

NS not significant

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

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Late decelerations

Table 74: Predictive value of fetal heart rate late decelerations for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Late decelerations (Krebs classification)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	first 30 minutes of tracing	73	5.26% (1.48 to 12.36)[a]	100% (100 to 100)[a]	NC	0.95 (0.87 to 1.02)[a]	Low
1 study (Spencer et al., 1997)	Case control	encephalopathy	last 30 minutes of tracing	73	47.2% (30.91 to 63.53)[a]	74.19% (58.79 to 89.60)[a]	1.82 (0.91 to 3.64)[a]	0.71 (0.49 to 1.03)[a]	Low
Multiple late decelerations, decreased variability or both									
1 study (Nelson et al., 1996)	Cohort	cerebral palsy in low risk population	NR	378	13.8%	91.3%	1.40	0.95	Very low
'Recurrent' late decelerations with no acceleration (NICHD classification)									
1 study (Sameshima et al., 2005)	Cohort	umbilical artery pH<7.1	2 hours before birth	301	68.7% (46 to 91.4)[a]	74.7% (65.3 to 84)[a]	2.71 (1.65 to 4.46)[a]	0.41 (0.20 to 0.87)[a]	Very low
'Recurrent' late decelerations with decreased variability (NICHD classification)									
1 study (Sameshima et al., 2005)	Cohort	umbilical artery pH<7.1	2 hours before birth	301	62.5% (38.7 to 86.2)[a]	89.1% (82.4 to 95.8)[a]	5.76 (2.79 to 11.8)[a]	0.42 (0.22 to 0.79)[a]	Very low
Late decelerations (NICHD classification)									
1 study (Williams & Galerneau 2004)	Case series	seizure	1 hour before birth	50	32% (17.2 to 51.5)[a]	48% (30 to 56.5)[a]	0.61 (0.31 to 1.22)[a]	1.41 (0.86 to 2.30)[a]	Very low

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

a. Calculated by NCC-WCH technical team

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Table 75: Association between fetal heart rate late decelerations and adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Recurrent late decelerations						
1 study (Roy et al., 2008)	Cohort	umbilical cord artery pH<7.10	NR	56	n=5 (9%)	Low
1 study (Roy et al., 2008)	Cohort	admission to NICU	NR	56	n=10 (19%)	Low
Late decelerations (compared with normal tracing - NICHD classification)						
1 study (Hadar et al., 2001)	Cohort	umbilical cord artery pH<7.2 and BD≥12	1st stage	45	OR 17.5 (95% CI 1.6 to 185.7) p=0.01	Moderate
1 study (Sheiner et al., 2001)	Case series	pH< 7.2 and BD≥12	2nd stage	28	OR 3.9 (95% CI 1.1 to 13.1) p=0.02	Low
1 study (Sheiner et al., 2001)	Case series	pH<7.2	2nd stage	57	OR 15.2 (95% CI 2.8 to 91.4) p<0.001	Low
1 study (Sheiner et al., 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 17.3 (95% CI 2.9 to 101.9) p=0.002	Low
Late decelerations						
1 study (Berkus et al., 1999)	case series	immediate adverse neonatal outcome[a]	1st stage	90	No statistically significant association (numerical data not reported)	Very low

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

a. Neonates were considered to have immediate adverse outcomes if they were admitted to level III, neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)

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Table 76: Correlation of fetal heart rate late decelerations with neonatal convulsions

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

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

Variable decelerations

Table 77: Predictive value of variable fetal heart rate decelerations for adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Variable decelerations (NICHD classification)									
1 study (Williams & Galerneau 2004)	Case series	seizure	1 hour before birth	50	36% (20.2 to 55.5)[a]	40% (23.4 to 59.3)[a]	0.6 (0.32 to 1.10)[a]	1.6 (0.91 to 2.80)[a]	Low
Loss of variability during decelerations									
1 study (Ozden & Demirci, 1999	Cohort	umbilical cord arterial pH<7.20	NR	37	63.9%	65%	1.80	0.56	Moderate
Slow return to baseline from decelerations									
1 study (Ozden & Demirci, 1999	Cohort	umbilical cord arterial pH<7.20	NR	17	27.8%	82.5%	1.50	0.89	Moderate

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Loss of primary accelerations[b]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	24	47.2%	82.5%	2.60	0.64	Moderate
Loss of secondary accelerations[c]									
1 study (Ozden & Demirci, 1999	Cohort	umbilical cord arterial pH<7.20	NR	23	38.9%	77.5%	1.60	0.80	Moderate

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

a. Calculated by NCC-WCH technical team
b. Loss of primary accelerations: an initial acceleration followed by a W deceleration component.
c. Loss of secondary accelerations: acceleration after a W deceleration component

Table 78: Association between variable fetal heart rate decelerations and adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Mild or moderate' variable decelerations (Krebs classification)						
1 study (Berkus et al., 1999)	case series	immediate adverse neonatal outcome[a]	1st stage	1098	No statistically significant association (numerical data not reported)	Very low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Berkus et al., 1999)	case series	immediate adverse neonatal outcome[a]	2nd stage	1098	No statistically significant association (numerical data not reported)	Very low
Variable decelerations						
1 study (Roy et al., 2008)	Cohort	cord pH<7.10	NR	38	n=4 (10.5%)	Low
1 study (Roy et al., 2008)	Cohort	admission to NICU	NR	38	n=7 (18.4%)	Low
Variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Hadar et al., 2001)	Cohort	umbilical cord artery pH<7.2 and BD≥12	1st stage	301	OR 3.9 (95% CI 1.3 to 11.7) p=0.01	Moderate
Variable decelerations (nadir <70 bpm)[b] (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Case series	pH<7.2	1st stage	57	OR 16.3 (95% CI 3.8 to 80.5) p<0.001	Low
Variable decelerations (nadir <70 bpm)b (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 10.5 (95% CI 1.9 to 56.4) p=0.06	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations (nadir ≥70 bpm)[c] (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Case series	pH<7.2	1st stage	57	OR 5.1 (95% CI 1.4 to 21.4) p=0.08	Low
Typical variable decelerations[d]						
1 study (Maso et al., 2012)	Case series	pH<7.2	2 hour before birth	63	n=18 (28.6%)	Low
1 study (Maso et al., 2012)	Case series	pH<7.1	2 hour before birth	63	n=6 (9.5%)	Low
1 study (Maso et al., 2012)	Case series	pH<7.0	2 hour before birth	63	n=1 (1.6%)	Low
1 study (Maso et al., 2012)	Case series	BD≥12 mmol/l	2 hour before birth	63	n=5 (7.9%)	Low
1 study (Maso et al., 2012)	Case series	adverse composite neonatal outcome[e]	2 hour before birth	63	n=6 (9.5%)	Low
Atypical variable decelerations[f]						
1 study (Maso et al., 2012)	Case series	pH<7.2	2 hour before birth	27	n=13 (48.2%)	Low
1 study (Maso et al., 2012)	Case series	pH<7.1	2 hour before birth	27	n=2 (7.4%)	Low
1 study (Maso et al., 2012)	Case series	pH<7.0	2 hour before birth	27	n=0 (0%)	Low
1 study (Maso et al., 2012)	Case series	BD≥12 mmol/l	2 hour before birth	27	n=0 (0%)	Low
1 study (Maso et al., 2012)	Case series	adverse composite neonatal outcome[e]	2 hour before birth	27	n=3 (11.1%)	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations (nadir ≥70 bpm)b (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 3.5 (95% CI 0.8 to 15.8) p=0.101	Low
'Severe' variable decelerations (Krebs classification)						
1 study (Berkus et al., 1999)	case series	immediate adverse neonatal outcome[a]	1st stage	148	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus et al., 1999)	case series	immediate adverse neonatal outcome[a]	2nd stage	148	No statistically significant association (numerical data not reported)	Very low

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

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

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Table 79: Association between variable fetal heart rate decelerations and maternal outcome

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

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

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Table 80: Number of fetal heart rate decelerations (>15 bpm/15 seconds) and association with fetal academia

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

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

a. Acidemia defined as umbilical artery cord pH<7.2

Table 81: Correlation of fetal heart rate decelerations and neonatal convulsions

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

NS not significant

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

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Categorisation of fetal heart rate traces

Table 82: Predictive value of published categorisation of fetal heart rate traces for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Krebs score (abnormal vs. normal)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	First 30 mins of tracing	73	5.71% (1.98 to 13.40)[a]	96.97% (96.97 to 100)[a]	1.80 (0.11 to 7.74)[a]	0.97 (0.90 to 1.17)[a]	Very low
FIGO classification (abnormal vs. normal)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	First 30 mins of tracing	73	50% (34.10 to 65.90)[a]	74.29% (59.81 to 88.77)[a]	1.94 (1.01 to 3.71)[a]	0.67 (0.46 to 0.97)[a]	Very low
Krebs score (abnormal vs. normal)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	Last 30 mins of tracing	54	41.38% (23.45 to 59.30)	84% (69.63 to 98.37)	2.58 (0.95 to 7.01)[a]	0.69 (0.49 to 0.99)[a]	Very low
FIGO classification (abnormal vs. normal)									
1 study (Spencer et al., 1997)	Case control	encephalopathy	Last 30 mins of tracing	67	88.89% (78.2 to 99.16)[a]	48.39% (30.79 to 65.98)[a]	1.72 (1.20 to 2.46)[a]	0.22 (0.08 to 0.61)[a]	Very low
'Ominous' first stage CTG (No definition provided)									
1 study (Gaffney et al., 1994)	Cohort	encephalopathy	1st stage	96	32.50% (17.98 to 47.02)[a]	92.31% (85.06 to 99.55)[a]	4.22 (1.49 to 11.91)[a]	0.73 (0.58 to 0.9)[a]	Low
'Ominous' second stage CTG (No definition provided)									
1 study (Gaffney et al., 1994)	Cohort	encephalopathy	2nd stage	96	45.65% (31.26 to 60.05)[a]	70.31% (59.12 to 81.51)[a]	1.53 (0.94 to 2.51)[a]	0.77 (0.56 to 1.05)[a]	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Pattern 1 (absent baseline variability [≥ 1 cycle] usually with late and/or prolonged deceleration)[b]									
1 study (Low et al., 1999)	Case control	asphyxia	NR	142	17%	98%	8.50	0.84	Very low
Pattern 2 (minimal baseline variability [≥ 2 cycles] and late and/or prolonged deceleration [≥ 2 cycles])[b]									
1 study (Low et al., 1999)	Case control	asphyxia	NR	142	46%	89%	4.18	0.60	Very low
Pattern 3 (minimal baseline variability [≥ 2 cycles] or late and/or prolonged deceleration [≥ 2 cycles])[b]									
1 study (Low et al., 1999)	Case control	asphyxia	NR	142	75%	57%	1.70	0.43	Very low
Pattern 4 (minimal baseline variability [1 cycles] and/or late and/or prolonged deceleration [1 cycle])[b]									
1 study (Low et al., 1999)	Case control	asphyxia	NR	142	93%	29%	1.30	0.29	Very low
Fetal sleep pattern ≥50% of the tracing (NICHD classification) (fetal sleep pattern not defined)									
1 study (Menihan et al., 2006)	Case control	sudden infant death	NR	142	40% (21.9 to 61.3)[a]	45.7% (34.6 to 57.3)[a]	0.70 (0.41 to 1.31)[a]	1.31 (0.84 to 2.03)[a]	Very low
Mild pseudo-sinusoidal pattern[c]									
1 study (Murphy et al., 1991)	Cohort	umbilical artery pH<7.12	1st stage & 2nd stage	319	80.0% (64.3 to 95.6)[a]	32.3% (26.9 to 37.6)[a]	1.18 (0.95 to 1.46)[a]	0.61 (0.27 to 1.37)[a]	Low
1 study (Murphy et al., 1991)	Cohort	admission to NICU	1st stage & 2nd stage	319	82.6% (67.1 to 98.1)[a]	32.4% (27.1 to 37.7)[a]	1.22 (0.99 to 1.49)[a]	0.53 (0.21 to 1.32)[a]	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
'Abnormal' FHR pattern (NICHD classification)									
1 study (Hadar et al., 2001)	Cohort	umbilical artery pH 7.1, 7.2 + Base deficit > 12	1st stage	601	78.3% (70.4 to 86.1)[a]	55.9% (51.5 to 60.3)[a]	1.77 (1.54 to 2.04)[a]	0.38 (0.26 to 0.56)[a]	Moderate
'Stressed' or 'distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger et al., 2000)	Cohort	NICU admission	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	46%	72%	1.64	0.75	Low
1 study (Dellinger et al., 2000)	Cohort	umbilical artery pH<7	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	100%	66%	2.9	0	Low
1 study (Dellinger et al., 2000)	Cohort	BE< −11	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	100%	66%	2.9	0	Low
'Distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger et al., 2000)	Cohort	NICU admission	1 hour before birth	635 (normal=627, distressed n=8)	9%	99%	9.0	0.91	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Dellinger et al., 2000)	Cohort	umbilical artery pH<7	1 hour before birth	635 (normal=627, distressed n=8)	100%	98%	50	0	Low
1 study (Dellinger et al., 2000)	Cohort	BE< −11	1 hour before birth	635 (normal=627, distressed n=8)	100%	98%	50	0	Low
'Minimal absent' variability (NICHD classification)									
1 study (Williams & Galerneau 2004)	Case series	seizure	1 hour before birth	50	53% (36.2 to 69.5)[a]	64% (44.4 to 79.8)[a]	1.48 (0.79 to 2.75)[a]	0.72 (0.45 to 1.18)[a]	Moderate
Presence of 1 poor prognostic feature[d]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	13	75%	55%	1.60	0.45	Moderate
Presence of 2 poor prognostic features)[d]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	12	55.6%	70.0%	1.83	0.64	Moderate
Presence of 3 poor prognostic features)[d]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	8	36.1%	82.5%	2.06	0.77	Moderate

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Presence of 4 poor prognostic features[d]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	12	22.2%	90%	2.22	0.86	Moderate
Biphasic decelerations[d]									
1 study (Ozden & Demirci, 1999)	Cohort	umbilical cord arterial pH<7.20	NR	13	22.2%	90.0%	2.22	0.86	Moderate
FHR baseline <110 bpm, baseline variability <5 bpm and non-reactive trace (NICHD classification)									
1 study (Larma et al., 2007)	Case control	moderate hypoxic ischemic encephalopathy (HIE)	last hour of tracing	214	7.7%	98.9%	6.36	0.94	Very low

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

a. Calculated by NCC-WCH technical team
b. Fetal asphyxia was classified as mild, moderate, or severe on the basis of umbilical artery base deficit (cut off >12 mmol/l) and neonatal encephalopathy and other organ system complications
FHR criteria predictive of fetal asphyxia:

- *Absent or minimal baseline variability and late or prolong decelerations*
- *The FHR patterns are based on the findings in six 10 minute cycles of FHR recording*
- *Absent baseline variability, usually with repeat cycles (≥ 2) of the late or prolonged decelerations*
- *Repeat cycles (≥ 2) of both minimal baseline variability and late or prolonged decelerations*
- *Repeat cycles (≥ 2) of either minimal baseline variability or late or prolonged decelerations*
- *One cycle of either minimal baseline variability or late or prolong decelerations*
- *No cycle of either minimal baseline variability or late or prolonged decelerations*

c. Pseudo-sinusoidal pattern classification based on amplitude of oscillations and frequency of cycles: Minor when the amplitude of the oscillations was 5 –15 bpm & 2-5 cycles/min; intermediate when amplitude was 16 – 24 bpm & 2-5 cycles/min; major when the amplitude was ≥25 bpm& 1-2 cycles/min
d. Variable deceleration classified into 7 subtypes according to poor prognostic features (PPFs):

- *Loss of primary acceleration*
- *Loss of secondary acceleration*

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- *Loss of variability during deceleration*
- *Slow return to baseline*
- *Biphasic deceleration*
- *Prolonged secondary acceleration*
- *Prolonged deceleration*

Table 83: Predictive value of published categorisations of fetal heart rate traces for mode of birth

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Mild pseudo-sinusoidal pattern[b]									
1 study (Murphy et al., 1991)	Cohort	caesarean section	1st stage & 2nd stage	319	64.7% (48.6 to 80.7)[a]	30.8% (25.1 to 36.2)[a]	0.93 (0.72 to 1.21)[a]	1.14 (0.70 to 1.86)[a]	Low
Mild pseudo-sinusoidal pattern[b]									
1 study (Murphy et al., 1991)	Cohort	instrumental vaginal birth	1st stage & 2nd stage	319	71.43% (62.1 to 80.7)[a]	32.4% (26.3 to 38.5)[a]	1.05 (0.90 to 1.23)[a]	0.88 (0.60 to 1.28)[a]	Low
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar et al., 2001)	Cohort	spontaneous vaginal birth	2nd stage	301	45.31% (40.9 to 49.7)[a]	28.8% (20.4 to 37.26)[a]	0.63 (0.54 to 0.74)[a]	1.89 (1.40 to 2.56)[a]	Moderate
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar et al., 2001)	Cohort	vacuum birth	2nd stage	301	73.33% (60.41 to 86.25)[a]	51.8% (47.6 to 55.9)[a]	1.52 (1.25 to 1.85)[a]	0.51 (0.31 to 0.84)[a]	Moderate
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar et al., 2001)	Cohort	caesarean birth	2nd stage	301	69.70% (58.61 to 80.78)[a]	52.34% (48.10 to 56.57)[a]	1.46 (1.21 to 1.75)[a]	0.57 (0.39 to 0.84)[a]	Moderate

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Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
'Stressed' or 'distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger et al., 2000)	Cohort	caesarean birth	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	35%	71%	1.20	0.91	Low
'Distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger et al., 2000)	Cohort	caesarean birth	1 hour before birth	635 (normal=627, distressed n=8)	5%	99%	5.0	0.95	Low

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

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

Table 84: Association between categorisation of fetal heart rate traces and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Pathological' FHR pattern (NICHD classification)						
1 study (Hadar et al., 2001)	Cohort	umbilical cord artery pH<7.2 and BD≥12	2nd stage	301	OR 2.86 (95% CI 0.3 to 24.4) p=0.33	Moderate

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Predictive' FHR pattern[a]						
1 study (Low et al., 2001)	Case series	moderate or severe asphyxia (BD>12 at birth, encephalopathy and cardiovascular, respiratory and renal complications)	NR	23	n=13 (56%)	Low
'Suspect' FHR pattern[a]						
1 study (Low et al., 2001)	Case series	moderate or severe asphyxia (BD>12 at birth, encephalopathy and cardiovascular, respiratory and renal complications)	NR	23	n=7 (30%)	Low
'Non-predictive' FHR pattern[a]						
1 study (Low et al., 2001)	Case series	moderate or severe asphyxia (BD>12 at birth, encephalopathy and cardiovascular, respiratory and renal complications)	NR	26	n=3 (11.5%)	Low
'Abnormal' FHR tracing (compared with normal tracing - NICHD classification)						
1 study (Sheiner et al., 2001)	Case series	pH< 7.2 and BD≥12	1st stage	28	OR 3.4 (95% CI 1.3 to 8.7) p=0.01	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Type 0 FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	103	7.24±0.06	Low
Type 1a FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	93	7.24±0.07 p=ns	Very low
Type 1b FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	19	7.15±0.07 p=0.0001	Low
Type 2a FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	34	7.19±0.06 p=0.0001	Low
Type 2b FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	13	7.06±0.07 p=0.0001	Low
Type 3 FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	14	7.09±0.06 p=0.0001	Low
Type 4 FHR tracing[b]						
1 study (Cardoso et al., 1995)	Case series	umbilical cord arterial pH (mean ± SD)	2nd stage	15	7.19±0.07 p=0.01	Low

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Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Normal' FHR tracing[b]						
1 study (Gilstrap et al., 1987)	Cohort	umbilical cord arterial pH (mean ± SD)	1st stage	129	7.29±0.6	Very low

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

- *Mild bradycardia (FHR 90 – 119 bpm)*
- *Moderate bradycardia (FHR 60 – 89 bpm)*
- *Marked or severe bradycardia (FHR below 60 bpm)*
- *Tachycardia (FHR ≥160 bpm)*

Table 85: Umbilical cord arterial pH in women with 'normal' and 'abnormal' fetal heart rate tracing

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

Update 2014

Number of studies	Design	Stage of labour	Percentage and number of babies in each FHR tracing category				Quality
			'Normal'[a]	'Warning symptoms'[a]	'Severe functional hemodynamic'[a]	'Hypoxia'[a]	
Umbilical cord artery pH <7.20							
1 study (Heinrich, 1982)	cohort	2nd stage (30 mins prior to birth)	0.9% n=10	0.9% n=11	6.0% n=26	18% n=9	Low

FHR fetal heart rate

a. Categorisation:

- *Normal: Baseline 120 – 160 bpm, variability 10 – 25 bpm, sporadic variable accelerations, no variable or late decelerations*
- *Warning: Tachycardia, variability <10 bpm or >25 bpm, periodic accelerations, moderate variable decelerations, early decelerations*
- *Severe: Transient bradycardia, severe variable decelerations, prolonged decelerations*
- *Hypoxia: Final bradycardia, variability 0 – 5 bpm, typical late decelerations*

High risk population

Accelerations

Table 86: Association between absence of, or decreased, fetal heart rate accelerations and fetal metabolic acidosis

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Absence or decreased FHR accelerations						
1 study (Low et al., 1980)	Cohort	Fetal metabolic acidosis[a]	Last 4 hours prior to birth	280	Absence of, or decreased, FHR accelerations was not associated with fetal acidosis[b]	Moderate

FHR fetal heart rate

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

Update 2014

Decelerations

Table 87: Association between no decelerations/early decelerations and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Early decelerations[a]						
1 study (Cibils, 1980)	Cohort	Fetal distress[b]	1st stage	247	Early decelerations group: 5% with fetal distress No decelerations groups: 4% with fetal distress	Low
Early decelerations[a]						
1 study (Cibils, 1980)	Cohort	Neonatal death[c]	1st stage	247	Early deceleration group: n=1[d] No decelerations groups: n=1[d]	Low

FHR fetal heart rate

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

Update 2014

Table 88: Association between no decelerations /variable decelerations[a] and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations						
1 study (Cibils, 1978)	Cohort	Fetal distress[b]	1st stage	312	No deceleration: 4% with fetal distress Variable decelerations: 23% with fetal distress p<0.0005	Low
Variable decelerations						
1 study (Cibils, 1978)	Cohort	Neonatal death	1st stage	312	No deceleration: 0.2% Variable decelerations: 2.2% p<0.0005	Low
Variable decelerations with late component						
1 study (Cibils, 1978)	Cohort	Fetal distress[b]	1st stage	312	Variable deceleration with late component: 78% with fetal distress Variable decelerations without late component: 23% with fetal distress p<0.0005	Low

Update 2014

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations with late component						
1 study (Cibils, 1978)	Cohort	Neonatal death	1st stage	312	Variable deceleration with late component: 11% Variable decelerations without late component: 2.2% p=NS	Low
Variable decelerations						
(Low et al., 1980)	Cohort	Fetal metabolic acidosis[c]	Last 20 minutes prior to birth	68	Variable decelerations were significantly associated with fetal metabolic acidosis[d]	Moderate

NS not significant

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

Table 89: Association between no decelerations/late decelerations[a] and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Late decelerations						

Update 2014

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Cibils, 1975)	Cohort	Neonatal morbidity or death[b]	60 minutes recording prior to 2nd stage or caesarean section	147	Late deceleration group: 7% No deceleration group: 0.5% p<0.0001	Low
Late decelerations						
1 study (Cibils, 1975)	Cohort	Neonatal morbidity or death in low birthweight babies <2500 g	60 minutes recording prior to 2nd stage or caesarean section	147	Late deceleration group: 15% No deceleration group: 5% p=NS	Low
Late decelerations						
1 study (Cibils, 1975)	Cohort	Fetal distress during labour and after birth[c]	60 minutes recordings prior to 2nd stage or caesarean section	147	Distressed during labour: 50% Born 'depressed': 33%	Low
Late decelerations						
(Low et al., 1980)	Cohort	Fetal metabolic acidosis[d]	Last hour prior to birth	101	Late decelerations were significantly associated with acidosis[e]	Moderate

FHR fetal heart rate, NS not significant

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

Table 90: Association between marked patterns of total decelerations[a], moderate/marked pattern of late decelerations[b] and fetal asphyxia.

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

FHR fetal heart rate

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

Update 2014

Table 91: Predictive value of fetal heart rate decelerations for adverse neonatal outcomes in prolonged pregnancy (>42 gestational weeks)

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

CI confidence interval

Update 2014

Evidence statements

It is intended that the evidence statements are read in conjunction with the evidence profiles, providing a synthesis of the key points from the evidence.

Studies with low risk or mixed population

Neonatal outcomes

Fetal heart rate, bradycardia, tachycardia

Fetal baseline tachycardia or bradycardia has moderately useful to not useful positive and negative likelihood ratios for poor neonatal outcome or neonatal acidosis at birth, with most studies showing a moderate or high specificity and low sensitivity. Evidence from five studies (n=15,500 approximately) showed a varied association between bradycardia and neonatal acidosis at birth and no association with poor neonatal outcome unless the bradycardia is described as moderate or severe in either the first or second stage of labour, in which case there is evidence of some association with poor neonatal outcomes. There is a low degree of association between tachycardia and poor neonatal outcome or neonatal acidosis. The evidence was of moderate to very low quality.

Baseline variability

Evidence from 9 studies (n=6685) showed that reduced baseline variability has moderate or high specificity for poor neonatal outcome and neonatal acidosis. It also has not useful positive and negative likelihood ratios for neonatal acidosis. Other diagnostic parameters are low for both poor neonatal outcome and neonatal acidosis. A non-reactive trace has high sensitivity, not useful positive likelihood ratio and moderately useful negative likelihood ratio for poor neonatal outcome. There is a low or moderate association between reduced variability with other specific features (no accelerations; late decelerations; late or variable decelerations and no accelerations; or bradycardia with recovery) with neonatal acidosis. There is a high degree of association between decreased variability and no recovery from bradycardia and neonatal acidosis. There is no evidence of an association between reduced variability and poor neonatal outcome. There are no studies investigating the association between reduced variability plus other FHR trace features and poor neonatal outcome. The evidence was of moderate to very low quality.

Accelerations

Evidence from 5 studies (n=6314) showed that the diagnostic value of absence of accelerations is low for poor neonatal outcomes (across all diagnostic parameters). Fewer than 3 sporadic accelerations in the first 30 minutes of electronic fetal monitoring may be associated with neonatal mortality in women at high risk of adverse neonatal outcomes. The evidence was of very low quality.

Late decelerations

Findings for the diagnostic value of late decelerations (n=8636) are conflicting for specificity for poor neonatal outcomes (ranging from high to low). Moderately useful positive and negative likelihood ratios are reported in 1 study, but all other diagnostic values are low for both neonatal outcomes and neonatal acidosis. There is a moderate or low degree of association between late decelerations and neonatal acidosis, but a low degree of association with poor neonatal outcome. The evidence was of moderate to very low quality.

Variable decelerations

Evidence from 10 studies (n=7100) showed that variable decelerations have mostly low diagnostic value for neonatal acidosis (3 types of variable deceleration have moderate

specificity but all other diagnostic parameters are low). Variable decelerations classified as severe or with a minimum below 70 bpm have varied association with neonatal acidosis (ranging from no association to moderate association) but there is no association with poor neonatal outcome. Variable decelerations not defined as severe or with a minimum of 70 bpm or higher are not associated with neonatal acidosis or poor neonatal outcome. The evidence was of moderate to very low quality.

Categorisation/classification of fetal heart rate traces
Findings from 14 studies (n=4030) for the diagnostic value of a range of different categorisations of fetal heart rate tracings are conflicting (ranging from high to low across all diagnostic parameters). Different classification systems have different strengths, with 10 reporting high specificity for poor neonatal outcome, but only 4 classification systems have high sensitivity and very useful negative likelihood ratios for poor neonatal outcome. Fetal heart rate patterns categorised as 'stressed' or 'distressed' using the Dellinger classification have high sensitivity and specificity and also a very useful positive and negative likelihood ratios for neonatal acidosis and high specificity for NICU admission. There is a high or moderate degree of association between tracings categorised as abnormal (however defined) and neonatal acidosis and a low association with poor neonatal outcomes. The evidence was of moderate to very low quality.

Maternal outcomes

Only 3 studies (n=1829) reported maternal outcomes, reporting the association between variable decelerations and classification of FHR traces and mode of birth.

Variable decelerations
Severe variable decelerations have a high degree of association with caesarean section and a moderate degree of association with ventouse birth. Variable decelerations classified as non-significant are not associated with caesarean section and ventouse birth. The evidence was of moderate quality.

Categorisation/classification of fetal heart rate traces
The association between classification of FHR traces and caesarean section varies from low to high, with one classification system having a moderate specificity and negative predictive value. All other diagnostic parameters have a low degree of association with caesarean section. The evidence was of moderate to very low quality.

Studies with high risk population

Neonatal outcomes

Accelerations
Findings from 1 study (n=400) indicated that the absence of, or a decrease in, FHR accelerations was not associated with fetal acidosis at birth. The evidence was of moderate quality.

Late decelerations

Evidence from one study (n=400) showed a moderate to low degree of association between late decelerations in the last hour before to birth and neonatal acidosis. The evidence was of moderate and low quality.

Variable decelerations

Variable decelerations have mostly low diagnostic values for neonatal acidosis. Findings from 1 study (n=400) indicated that variable decelerations in first stage of labour and in the last 20 minutes prior to birth had a high degree of association with neonatal acidosis. The evidence was of moderate and low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

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

Consideration of clinical benefits and harms

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

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

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

CTG only records 2 parameters: the fetal heart rate and contractions. Continuous monitoring of both allows a number of features to be considered. In addition, CTG produces an automated continuous record that can show trends over a period of time. These are the purported advantages CTG has over intermittent auscultation of the fetal heart rate. Intermittent auscultation is used to record the fetal heart rate over a period of 1 minute immediately after a contraction once every 15 minutes during the first stage of labour, and after every contraction in the second stage. It can be used to detect decelerations that occur in that minute but it does not identify decelerations at other times or baseline variability. For this reason, CTG is used when there are risk factors for fetal hypoxia, including abnormalities detected with intermittent auscultation.

Disadvantages of CTG use include the increased likelihood that women may be left alone, mobility may be reduced and women may be more frightened as they hear changes in the fetal heart rate. Clinical staff may focus on the recording rather than the woman. This may translate into a lack of support for the woman. Staff may also derive a sense of false reassurance and fail to act promptly in the face of abnormality, or over-react in the face of normal

physiological fetal heart rate changes which may in turn lead to increase in the rate of interventions. CTG is sometimes incorrectly used in place of continuous supportive one-to-one care.

CTG is used in current practice to monitor the fetal heart rate when there is a concern that fetal hypoxia leading to acidosis may develop, although there is no high quality evidence about the size of the risks and benefits derived from its use. There are no other forms of alternative monitoring available that could replace CTG, although there are adjuncts to CTG that have either been considered or are being assessed (and are reviewed elsewhere in this guideline).

It is important to remember that a cardiotocograph is a screening tool, not a diagnostic test or a treatment. It is common to see abnormalities in cardiotocographs in labour and interventions based on such abnormalities occur in 10–20% of monitored labours. In contrast, severe perinatal asphyxia (causing death or severe neurological impairment) is very rare (see 10.3.2 Introduction). It is difficult to identify what proportion of perinatal asphyxia is 'avoidable'. The incidence of avoidable death or brain damage that is caused, or exacerbated by, aspects of labour and birth in higher risk labours is not known, neither is the number of interventions (operative births) required to avoid one poor outcome, though it could be high. Nevertheless, the guideline develoment group argued that, because the incidence of avoidable death or brain damage is higher in higher risk labours than in the whole population, CTG should be a more effective screening test than intermittent auscultation in such labours for 2 reasons: first, it records the fetal heart rate continuously rather than intermittently; and second, it provides more information about the fetal heart rate than is possible to determine with intermittent auscultation. However, there is also the argument that CTG can cause more harm in terms of unnecessary intervention due to the high false positive rate without the purported benefit.

CTG has a good negative likelihood ratio; that is, when it is normal there is a very low chance of hypoxia (and therefore acidosis). However, evidence from this review showed that the use of CTG is only moderately useful at best in predicting poor fetal/neonatal outcomes, with the majority of studies showing it to be not useful (not useful positive likelihood ratios). In addition, there are randomised studies (see section 10.1), albeit underpowered, which fail to show that the use of CTG in practice improves neonatal outcomes in a clinically significant way. There is some evidence supporting the usefulness of these features of CTG in predicting neonatal outcome or the surrogate measure of low umbilical cord blood pH:

- prolonged or severe bradycardia – some evidence of association with poor outcomes/low pH
- normal variability more than 5 bpm – associated with absence of poor outcomes/low pH
- decreased variability (NICHD) – some evidence of association with low pH
- decreased variability (NICHD) with no accelerations – associated with low pH
- decreased variability (NICHD) – associated with variable or late decelerations and no accelerations - some evidence of association with low pH
- the presence of accelerations – some evidence of association with good neonatal outcomes
- recurrent late decelerations with decreased variability – predictive of low pH
- the presence of late decelerations – associated with low pH and adverse neonatal outcomes
- the presence of variable decelerations – associated with low pH.

The guidelines development group felt that current practice assumes CTG has greater accuracy than the evidence demonstrates. Individual parameters are probably interpreted with an impression of precision that is not supported by the evidence. It is superficially attractive to suggest each parameter can be defined in terms of its severity and then a classification attached, but the available evidence does not support the assumption that the CTG tracing can be viewed that precisely. The classification presented in the original version of this guideline

takes no account of the stage or progress of labour, the presence or absence of meconium or signs of infection, and little account of the contractions or the woman's condition. This can have adverse effects on the care delivered. For example, if a cardiotocograph is only considered abnormal after an arbitrary period of time, a clearly abnormal pattern may be left when in fact intervention is required. The converse example would be the unnecessary intervention that takes place with some CTG patterns in a second stage of labour that is progressing normally. In a rapidly progressing labour, fetal heart rate changes are common. The inclusion in the classification in the original guideline of both 'suspicious' and 'pathological' has led to the view that there are 2 distinct categories of 'abnormal'. By definition, a 'suspicious' cardiotocograph was intended to be one that required consideration of risk factors and whether any change in management might avoid a worsening change in the future rather than indicating the baby is at risk of compromise at that time. It is for these reasons that the group felt that the classification should be less complex and less rigid.

Consideration of health benefits and resource uses

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

Quality of evidence

The quality of the evidence reviewed varied from moderate to very low. The guideline development group noted several factors that limit the usefulness of the research findings. First, the outcomes of importance are rare so that a large numbers of cases would be needed to show a difference, if one were to exist, especially in terms of long term neurodevelopment. Second, there is likely to be a 'treatment effect'. Because of prior knowledge and experience, many clinicians would feel it inappropriate to not act in the presence of a significant CTG 'abnormality' if it is associated with a poor outcome. Thus, if a case of adverse outcome is avoided by intervention before the damage occurs, it might be thought to be a 'false positive' when this is not the case. However, this belief has led to the situation where a technology with limitations as a screening test is being widely used without good evidence of benefit.

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

Fourth, this guideline recommends the use of CTG only in high risk labours (see section 10.1). However, the majority of the studies reported in this review were in low or moderate risk populations only.

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

At present, the evidence base for the use of CTG by itself to monitor high risk labours is not strong. The guideline development group drafted a number of research recommendations in order to address the key gaps in the evidence, including the lack of data regarding the natural frequencies of rare, potentially preventable, serious intrapartum adverse events. Furthermore, the group noted that there are no randomised trials in higher risk women to measure the advantages and harms of CTG monitoring in terms of long term child health and included a research recommendation to look at the use of CTG in labours where there is meconium. The rationale for its use in such labours has been based on both the association of certain abnormal CTG features with adverse fetal/neonatal outcomes and the theoretical reasoning that it provides more information than is available from intermittent auscultation. In addition, no better alternative is available to clinicians.

Other considerations

The guideline development group was aware that the reliability of interpretation of CTG recordings, both between different users and when carried out by the same person, has been shown to be variable (see section 10.9). This suggests that there will be differences between healthcare professionals regarding interpretation of cardiotocographs, including baseline variability and categorisation of decelerations. This means care should be taken when interpreting cardiotocographs so that appropriate action is taken where there are signs that cause concern, and so that unnecessary actions and interventions are avoided.

The group noted that medico-legal practice affects custom and practice in clinical care and it would be very difficult to defend a case of intrapartum fetal hypoxia leading to acidosis if a CTG had not been used in the management of a high risk labour. However, the group noted that part of the reason that CTG has become a key point of medical-legal practice is precisely because it has previously been recommended as part of good practice. The group agreed that best medico-legal practice should follow good evidence-based medical practice and so did not feel that it was appropriate to make a recommendation based on current medico-legal practice.

Although the guideline development group considered it would be more appropriate to establish principles of interpretation, they appreciated that they would have to produce practical guidance to influence clinical practice. In developing the recommendations for definition, interpretation and management of women being monitored with a cardiotocograph, the GDG relied on the evidence as far as they could, but they also had to use a consensus process because of the wide variation in the definitions used in the studies reviewed. They noted that this combination of evidence and opinion was a feature of all cardiotocography scoring systems.

Accelerations

There was moderately good evidence that the presence of fetal heart rate accelerations were associated with no adverse fetal/neonatal outcomes.

There was conflicting evidence about whether the absence of fetal heart rate accelerations was associated with or predicted adverse outcomes

Baseline heart rate

There were significant associations with adverse fetal/neonatal outcomes with values above 160 bpm. There was also some evidence that this threshold predicted adverse outcomes. There was some limited evidence that values above 180 bpm were predictive of adverse outcomes. Therefore the group recommended that the upper limit of the normal baseline heart rate should be 160 bpm.

Empirically the group felt that if fetal hypoxia/acidosis was associated with a fetal tachycardia, that risk would be greater at values above 180 bpm than values between 161 bpm and180 bpm, though there was no evidence to confirm that. The group therefore distinguished 2 categories of fetal tachycardia: 161–180 bpm and more than 180 bpm.

There was some limited evidence that a baseline of less than 110 bpm was associated with adverse fetal/neonatal outcomes. However, the evidence was much stronger when the value was less than 100 bpm, with most of the studies in this category actually looking at values below 90 bpm. The group therefore recommended the lower limit of the baseline should be less than 100 bpm. In addition, from their clinical experience, the group members were aware that a stable baseline of 90–99 bpm, with normal variability and no decelerations, may be a normal feature in a few pregnancies, especially those that were past 40 weeks.

Baseline variability

There was good evidence that baseline fetal heart rate variability of 5 bpm or more for up to 30 or 40 minutes was both associated with and predicted good fetal/neonatal outcomes.

Variability of less than 5 bpm lasting for 90 minutes or more was both associated with and predicted adverse outcomes, so the guideline development group agreed that a variability of less than 5 bpm lasting for 90 minutes or more should be considered to be abnormal.
However, there was less evidence for the significance of a baseline variability of less than 5 bpm lasting between 30 or 40 minutes and up to 90 minutes. Nevertheless, the group felt this could not be regarded as normal and decided to call it 'non-reassuring'. Furthermore, if it was an indicator of fetal hypoxia/acidosis, then it was reasonable to consider that the hypoxic risk was less than if the poor variability lasted for over 90 minutes. In addition, although most of the studies looked at 40 minutes as the upper time limit of 'normal' for the duration of low variability, from a practical point of view, and to align with the time limits set for decelerations (see below) and some of the published studies, the group decided to set this at 30 minutes.
There was no evidence relating to the upper limit of baseline variability, so the group was unable to make a recommendation about this.
There was evidence that mild ('pseudo') sinusoidal patterns (oscillations of 5–15 bpm) were not associated with adverse outcomes, but there were no data on other sinusoidal patterns and fetal/neonatal outcome. Therefore the group could only make a recommendation about the mild type.

Decelerations
There was good evidence that variable decelerations were both associated with and predicted adverse outcomes. There was no evidence relating the characteristics of the variable decelerations to the outcomes. Nevertheless, the guideline development group argued that, given variable decelerations were associated with a risk of fetal hypoxia/acidosis, then the risk was greater when the decelerations were deeper, the time to recovery was greater and they were present for longer. By consensus, therefore, the guideline development group set 2 thresholds to distinguish severe variable decelerations from the less severe; namely 60 bpm for the depth and 60 seconds for the duration. In addition, the group felt that there should be a time limit for the duration of variable decelerations that would prompt intervention. For the 'severe' variable decelerations (decelerations of more than 60 bpm lasting for more than 60 seconds) they felt this should be 30 minutes. For the 'mild' variable (decelerations of less than 60 bpm lasting for less than 60 seconds) they felt this should be 90 minutes.
There was good evidence than late decelerations were both associated with and predicted adverse fetal/neonatal outcomes. Again, the group reasoned that the longer the duration of late decelerations, the greater the risk of fetal hypoxia/acidosis, although there was no evidence to confirm this view. Therefore the group empirically set this threshold at 30 minutes.
Although there was very little evidence of the relationship between the number of decelerations to outcome, the group was aware that in practice many interventions occur unnecessarily early; perhaps after only 2 or 3 decelerations. They felt that it was important that decelerations should only be regarded as significant if they occurred with the majority of the contractions. They therefore made a recommendation that decelerations should occur with over 50% of contractions.
The group also noted that a prolonged late deceleration would only be distinguishable from a bradycardia if it recovered. In practice, irrespective of the terminology, a persistent fall in the fetal heart rate would inevitably be associated with fetal hypoxia and acidosis. The group arbitrarily chose 3 minutes as the interval when action should be taken on the basis of other evidence that fetuses could possibly withstand up to 10 minutes of absolute hypoxia without sustaining irreversible neurodevelopmental injury.
Only 1 small study examined atypical decelerations and it failed to show any relationship with adverse outcomes, so the group felt that describing variable decelerations as 'typical' and 'atypical' was not of value in clinical practice.

Patterns/combinations

There was good evidence that 'scoring' systems that took account of more than 1 fetal heart rate feature demonstrated a relationship between an abnormal 'score' and adverse fetal/neonatal outcomes, and such systems also predicted adverse outcomes. The guideline development group therefore felt it was important to consider all features of the fetal heart rate when using it to predict fetal health.

Key conclusions

The best available evidence to guide interpretation of CTG is limited because:

- The adverse outcomes are rare, especially in low or moderate risk populations.
- One principle of use of CTG in practice is for it to be used for monitoring fetuses in high risk pregnancies. However, only a minority of the studies reviewed were of high risk pregnancies. Only late and variable decelerations and accelerations were studied in high risk populations. Baseline, baseline variability and combinations were studied in pregnancies that were low or moderate risk only.
- There is a 'treatment paradox' that intervention will have occurred before the clinically significant adverse outcome takes place – that was the aim of the surveillance. This might be offset, however, by the assertion that without proper testing, the good outcomes associated with an intervention might be wrongly attributed to it and the harm it is causing may go unnoticed.
- The fetal heart rate is not a good surrogate for hypoxia and acidosis – it can be affected by a number of other factors and may be unaffected with some types of hypoxia.
- Looking at CTG in isolation is too simplistic and does not take account of the whole clinical picture.

Despite these serious limitations, the guideline development group felt that, on balance, the potential benefits of continuous CTG probably outweigh the risks and the use of CTG in high risk labours should be recommended in the absence of a better alternative.

The guideline development group reasoned that when making the recommendations for the interpretation of CTGs:

- There are certain pregnancies where there is an increased risk of intrapartum fetal acidosis ('high risk' or 'at risk' labours) (see section 3.4).
- The fetal heart rate is the only parameter by which the fetal condition can be continuously assessed and monitored. The role of the fetal ECG was reviewed as part of this guideline update and was not recommended for use in practice (see section 10.8).
- There is some evidence that the likelihood of adverse outcome from intrapartum fetal acidosis is greater with certain abnormal features of CTG, although the risk of false positives is high with many features.
- Importantly, the absence of certain abnormal features on a cardiotocograph is very reassuring that fetal acidosis is absent.
- Given that abnormalities of fetal heart rate are not only due to fetal hypoxia, various conservative actions are recommended in the first instance which will ameliorate some of the non-hypoxic and hypoxic factors. This is discussed in section 11.7 (Intrauterine Resuscitation).
- Fetal blood sampling is the only single assessment which directly assesses whether the observed fetal heart rate abnormality is due to hypoxia severe enough to cause acidosis. This test is discussed in section 10.5, as is the value of fetal scalp stimulation as an adjunctive test of fetal health in labour (section 10.4). Although the guideline development group could not recommend its routine use in practice, they did feel that the absence of a

fetal heart rate acceleration during a fetal blood sampling procedure would be a feature of concern.

Recommendations

106. Use tables 92 and 93 to define and interpret cardiotocograph traces and to guide the management of labour for women who are having continuous cardiotocography. These tables include and summarise individual recommendations about fetal monitoring (106 to 130), fetal scalp stimulation (134 and 135), fetal blood sampling (136 to 149) and intrauterine resuscitation (132 to 134 and 185) in this guideline. [new 2014]

Table 92: Description of cardiotocograph trace features

Overall care

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

Principles for intrapartum CTG trace interpretation

- When reviewing the CTG trace, assess and document all 4 features (baseline fetal heart rate, baseline variability, presence or absence of decelerations, presence of accelerations).
- It is not possible to categorise or interpret every CTG trace. **Senior obstetric input is important in these cases.**

Accelerations

- The presence of fetal heart rate accelerations is generally a sign that the unborn baby is healthy.
- If a fetal blood sample is indicated and the sample cannot be obtained, but the associated scalp stimulation results in fetal heart rate accelerations, decide whether to continue the labour or expedite the birth in light of the clinical circumstances and in discussion with the woman.

Description	Feature		
	Baseline (beats/ minute)	**Baseline variability (beats/ minute)**	**Decelerations**
Normal/ reassuring	100–160	5 or more	None or early
Non-reassuring	161–180	Less than 5 for 30–90 minutes	Variable decelerations: • dropping from baseline by 60 beats/minute or less and taking 60 seconds or less to recover • present for over 90 minutes • occurring with over 50% of contractions. **OR** Variable decelerations: • dropping from baseline by more than 60 beats/minute or taking over 60 seconds to recover • present for up to 30 minutes • occurring with over 50% of contractions. **OR** Late decelerations: • present for up to 30 minutes • occurring with over 50% of contractions.
Abnormal	Above 180 **or** below 100	Less than 5 for over 90 minutes	Non-reassuring variable decelerations (see row above): • still observed 30 minutes after starting conservative measures • occurring with over 50% of contractions. **OR** Late decelerations • present for over 30 minutes • do not improve with conservative measures • occurring with over 50% of contractions. OR Bradycardia or a single prolonged deceleration lasting 3 minutes or more.

Abbreviation: CTG, cardiotocography.

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Table 93: Management based on interpretation of cardiotocograph traces

Category	Definition	Interpretation	Management
CTG is normal/ reassuring	All 3 features are normal/ reassuring	Normal CTG, no non-reassuring or abnormal features, healthy fetus	• Continue CTG and normal care. • If CTG was started because of concerns arising from intermittent auscultation, remove CTG after 20 minutes if there are no non-reassuring or abnormal features and no ongoing risk factors.
CTG is non-reassuring and suggests need for conservative measures	1 non-reassuring feature AND 2 normal/ reassuring features	Combination of features that may be associated with increased risk of fetal acidosis; if accelerations are present, acidosis is unlikely	• Think about possible underlying causes. • If the baseline fetal heart rate is over 160 beats/minute, check the woman's temperature and pulse. If either are raised, offer fluids and paracetamol. • Start 1 or more conservative measures: o encourage the woman to mobilise or adopt a left-lateral position, and in particular to avoid being supine o offer oral or intravenous fluids o reduce contraction frequency by stopping oxytocin if being used and/or offering tocolysis. o Inform coordinating midwife and obstetrician.
CTG is abnormal and indicates need for conservative measures AND further testing	1 abnormal feature OR 2 non-reassuring features	Combination of features that is more likely to be associated with fetal acidosis	• Think about possible underlying causes. • If the baseline fetal heart rate is over 180 beats/minute, check the woman's temperature and pulse. If either are raised offer fluids and paracetamol. • Start 1 or more conservative measures (see 'CTG is non-reassuring…' row for details). • Inform coordinating midwife and obstetrician • Offer to take an FBS (for lactate or pH) after implementing conservative measures, or expedite birth if an FBS cannot be obtained and no accelerations are seen as a result of scalp stimulation • Take action sooner than 30 minutes if late decelerations are accompanied by tachycardia and/or reduced baseline variability. • Inform the consultant obstetrician if any FBS result is abnormal. • Discuss with the consultant obstetrician if an FBS cannot be obtained or a third FBS is thought to be needed.
CTG is abnormal and indicates need for urgent intervention	Bradycardia or a single prolonged deceleration with baseline below 100 beat/minute, persisting for 3 minutes or more*	An abnormal feature that is very likely to be associated with current fetal acidosis or imminent rapid development of fetal acidosis	• Start 1 or more conservative measures (see 'CTG is non-reassuring…' row for details). • Inform coordinating midwife • Urgently seek obstetric help • Make preparations for urgent birth • Expedite birth if persists for 9 minutes • If heart rate recovers before 9 minutes, reassess decision to expedite birth in discussion with the woman.

Abbreviations: CTG, cardiotocography; FBS, fetal blood sample.

** A stable baseline value of 90–99 beats/minute with normal baseline variability (having confirmed that this is not the maternal heart rate) may be a normal variation; obtain a senior obstetric opinion if uncertain.*

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107. If continuous cardiotocography is needed:

- explain to the woman that it will restrict her mobility, particularly if conventional monitoring is used
- encourage and help the woman to be as mobile as possible and to change position as often as she wishes
- remain with the woman in order to continue providing one-to-one support
- monitor the condition of the woman and the baby, and take prompt action if required
- ensure that the focus of care remains on the woman rather than the cardiotocograph trace
- ensure that the cardiotocograph trace is of high quality, and think about other options if this is not the case
- bear in mind it is not possible to categorise or interpret every cardiotocograph trace: senior obstetric input is important in these cases.[new 2014]

108. Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone. [new 2014]

109. Any decision about changes to a woman's care in labour when she is on a cardiotocograph monitor should also take into account the following:

- the woman's report of how she is feeling
- the woman's report of the baby's movements
- assessment of the woman's wellbeing and behaviour
- the woman's temperature, pulse and blood pressure
- whether there is meconium or blood in the amniotic fluid
- any signs of vaginal bleeding
- any medication the woman is taking
- the frequency of contractions
- the stage and progress of labour
- the woman's parity
- the results of fetal blood sampling if undertaken (see recommendations 136 to 149)
- the fetal response to scalp stimulation if performed (see recommendations 134 and 135). [new 2014]

110. When reviewing the cardiotocograph trace, assess and document all 4 features (baseline fetal heart rate, baseline variability, presence or absence of decelerations, and presence of accelerations). [new 2014]

111. Supplement ongoing care with a documented systematic assessment of the condition of the woman and unborn baby (including any cardiotocography findings) every hour. If there are concerns about cardiotocography findings, undertake this assessment more frequently. [new 2014]

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112. Be aware that if the cardiotocography parameters of baseline fetal heart rate and baseline variability are normal, the risk of fetal acidosis is low. [new 2014]

Baseline fetal heart rate

113. Take the following into account when assessing baseline fetal heart rate:

- this will usually be between 110 and 160 beats/minute
- a baseline fetal heart rate between 100 and 109 beats/minute (having confirmed that this is not the maternal heart rate) with normal baseline variability and no variable or late decelerations is normal and should not prompt further action
- a stable baseline fetal heart rate between 90 and 99 beats/minute with normal baseline variability (having confirmed that this is not the maternal heart rate) may be a normal variation; obtain a senior obstetric opinion if uncertain. [new 2014]

114. If the baseline fetal heart rate is between 161 and 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph:

- think about possible underlying causes (such as infection) and appropriate investigation
- check the woman's temperature and pulse; if either are raised, offer fluids and paracetomol
- start one or more conservative measures (see recommendation 132). [new 2014]

115. If the baseline fetal heart rate is between 161 and 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph and the woman's temperature and pulse are normal, continue cardiotocography and normal care, since the risk of fetal acidosis is low. [new 2014]

116. If the baseline fetal heart rate is between 100 and 109 beats/minute or above 160 beats/minute and there is 1 other non-reassuring feature on the cardiotocograph, start conservative measures (see recommendation 132) to improve fetal wellbeing. [new 2014]

117. If the baseline fetal heart rate is above 180 beats/minute with no other non-reassuring or abnormal features on the cardiotocograph:

- think about possible underlying causes (such as infection) and appropriate investigation
- check the woman's temperature and pulse; if either are raised, offer fluids and paracetamol
- start one or more conservative measures (see recommendation 132).
- offer fetal blood sampling to measure lactate or pH (see recommendation 136 to 149) if the rate stays above 180 beats/minute despite conservative measures [new 2014]

118. If there is a bradycardia or a single prolonged deceleration with the fetal heart rate below 100 beats/minute for 3 minutes or more:

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- start conservative measures (see recommendation 132)
- urgently seek obstetric help
- make preparations for urgent birth
- expedite the birth (see recommendations 220 to 223) if the bradycardia persists for 9 minutes.

If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman. [new 2014]

Baseline variability

119. Take the following into account when assessing fetal heart rate baseline variability:

- baseline variability will usually be 5 beats/minute or more
- intermittent periods of reduced baseline variability are normal, especially during periods of quiescence ('sleep')
- mild or minor pseudo-sinusoidal patterns (oscillations of amplitude 5-15 beats/minute) are of no significance. [new 2014]

120. If there is reduced baseline variability of less than 5 beats/minute with a normal baseline fetal heart rate and no variable or late decelerations:

- start conservative measures (see recommendation 132) if this persists for over 30 minutes and
- offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) if it persists for over 90 minutes. [new 2014]

121. If there is reduced baseline variability of less than 5 beats/minute for over 30 minutes together with 1 or more of tachycardia (baseline fetal heart rate above 160 beats/minute), a baseline fetal heart rate below 100 beats/minute or variable or late decelerations:

- start conservative measures (see recommendation 132) **and**
- offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149). [new 2014]

Decelerations

122. When describing decelerations in fetal heart rate, specify:

- the depth and duration of the individual decelerations
- their timing in relation to the peaks of the contractions
- whether or not the fetal heart rate returns to baseline
- how long they have been present for
- whether they occur with over 50% of contractions. [new 2014]

123. Describe decelerations as 'early', 'variable' or 'late'. Do not use the terms 'typical' and 'atypical' because they can cause confusion. [new 2014]

124. Take the following into account when assessing decelerations in fetal heart rate:

- early decelerations are uncommon, benign and usually associated with head compression
- early decelerations with no non-reassuring or abnormal features on the cardiotocograph trace should not prompt further action. [new 2014]

125. If variable decelerations are observed that begin with the onset of a contraction:

- be aware that these are very common, can be a normal feature in an otherwise uncomplicated labour and birth, and are usually a result of cord compression
- think about asking the woman to change position or mobilise. [new 2014]

126. Start conservative measures (see recommendation 132) if variable decelerations are observed with a normal baseline fetal heart rate and normal baseline variability that are:

- dropping from baseline by 60 beats/minute or less and taking 60 seconds or less to recover
- present for over 90 minutes
- occurring with over 50% of contractions. [new 2014]

127. Start conservative measures (see recommendation 132) if variable decelerations are observed with a normal baseline fetal heart rate and normal baseline variability that are:

- dropping from baseline by more than 60 beats/minute or taking over 60 seconds to recover,
- present for up to 30 minutes
- occurring with over 50% of contractions. [new 2014]

128. Offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) if non-reassuring variable decelerations (see recommendation 125 and 126) are:

- still observed 30 minutes after starting conservative measures or
- accompanied by tachycardia (baseline fetal heart rate above 160 beats/minute) and/or reduced baseline variability (less than 5 beats/minute). [new 2014]

129. If late decelerations (decelerations that start after a contraction and often have a slow return to baseline) are observed:

- start conservative measures (see recommendation 132) if the late decelerations occur with over 50% of contractions
- offer fetal blood sampling to measure lactate or pH (see recommendations 136 to 149) and/or expedite the birth (see recommendations 220 to 223) if the late decelerations persist for over 30 minutes and occur with over 50% of contractions
- take action sooner if the late decelerations are accompanied by an abnormal baseline fetal heart rate and/or reduced baseline variability. [new 2014]

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130. Take into account that the longer, the later and the deeper the individual decelerations, the more likely the presence of fetal acidosis (particularly if the decelerations are accompanied by tachycardia and/or reduced baseline variability), and take action sooner than 30 minutes if there is concern about fetal wellbeing. [new 2014]

Accelerations

131. Take the following into account when assessing accelerations in fetal heart rate:

- the presence of fetal heart rate accelerations is generally a sign that the baby is healthy
- the absence of accelerations in an otherwise normal cardiotocograph trace does not indicate acidosis. [new 2014]

Conservative measures

132. If there are any concerns about the baby's wellbeing, think about the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s):

- encourage the woman to mobilise or adopt a left-lateral position, and in particular to avoid being supine
- offer oral or intravenous fluids
- offer paracetamol if the woman has a raised temperature
- reduce contraction frequency by:
  - stopping oxytocin if it is being used (the consultant obstetrician should decide whether and when to restart oxytocin) **and/or**
  - offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg). **[new 2014]**

133. Inform the coordinating midwife and an obstetrician whenever conservative measures are implemented. [new 2014]

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

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Predictive value of fetal scalp stimulation

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

- electronic fetal monitoring alone
- electronic fetal monitoring plus ECG?

Description of included studies

Nineteen studies are included in this review (Arulkumaran et al., 1987; Clark et al., 1982, Clark et al., 1984; Elimian et al., 1997; Lazebnik et al., 1992; Spencer 1991; Trochez et al., 2005; Anyaegbunam et al., 1994; Bartelsmeyer et al., 1995; Chauhan et al., 1999; Ingemarsson and Arulkumaran 1989; Irion et al., 1996; Lin et al., 2001; Polzin et al., 1988; Sarno et al., 1990; Smith et al., 1986; Tannirandorn et al., 1993; Edersheim et al., 1987;

Umstad et al., 1992). One of the included studies was a randomised controlled trial (Anyaegbunam et al., 1994), 2 of the studies were prospective comparative observational studies (Smith et al., 1986; Tannirandorn et al., 1993) and the remaining studies were case series. Six of the case series were consecutive, of which 4 were prospective (Elimian et al., 1997; Irion et al., 1996; Sarno et al., 1990; Umstad et al., 1992), and 2 were retrospective (Spencer 1991; Trochez et al., 2005). Two studies were specifically reported as being non-consecutive case series (Chauhan et al., 1999; Polzin et al., 1988), and in the remaining 8 studies it was unclear.

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

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

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

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

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

Evidence profile

Data is reported in GRADE profiles below for the following tests.

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

The majority of included studies used absence of an acceleration following stimulation as a positive predictive test result in order to calculate predictive values. For those studies that used presence of an acceleration as a positive predictive test result, these were reported in the evidence table and the NCC-WCH technical team then calculated predictive values using no acceleration as a positive predictive test result in order to provide consistency of interpretation across all studies.

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

Evidence from randomised controlled trials, prospective comparative observational studies or prospective consecutive case series started at high quality and was then downgraded if there were any issues identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies or retrospective consecutive case series started at moderate quality and was then downgraded if there were any quality-related issues. Evidence from non-consecutive case series started at low quality and was then downgraded if there were any issues.

Table 94: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following fetal scalp blood sampling puncture as stimulus

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH<7.20								
1 study (Edersheim et al., 1987)	case series	pH<7.20 = 6/188 (3% of samples)	188 samples; 127 women & baby pairs	100% (Not calculable [NC])[a]	43.41% (36.21 to 50.61)[a]	1.77 (1.56 to 2.01)[a]	0 (NC)[a]	Very low
1 study (Elimian et al., 1997)	case series	pH<7.20 = 15/108 (14%)	108	100% (NC)[b]	53.76% (43.63 to 63.9)[b]	2.16 (1.73 to 2.69)[a]	0 (NC)[a] Useful	Low
1 study (Lazebnik et al., 1992)	case series	pH<7.20 = 15/104 (14%)	104	73% (50.95 to 95.71)[b]	17% (9.08 to 24.63)[b]	0.88 (0.64 to 1.21)[a]	1.58 (0.61 to 4.12)[a]	Very low
1 study (Spencer et al., 1991)	case series	pH<7.20 = 6/138 (4%)	138	100% (NC)[a]	52.27% (43.75 to 60.79)[a]	2.10 (1.75 to 2.50)[a]	0 (NC)[a]	Very low
1 study (Umstad et al., 1992)	case series	pH<7.20 = 8/60 (13%)	60	62.5% (28.95 to 96.05)[b]	67.3% (54.56 to 80.06)[b]	1.91 (0.98 to 3.71)[a]	0.56 (0.22 to 1.39)[a]	Moderate
Fetal scalp pH<7.21								
1 study (Clark et al., 1982)	case series	pH<7.21 = 19/200 (10%)	200	100% (NC)[a]	93.37% (89.75 to 96.99)[a]	15.08 (8.73 to 26.06)[a]	0 (NC)[a] Useful	Very low
Fetal scalp pH<7.25								
1 study (Spencer et al., 1991)	case series	pH<7.25 = 17/138 (5%)	138	65.38% (47.10 to 83.67)[a]	53.57% (44.33 to 62.81)[a]	1.41 (1.00 to 1.96)[a]	0.87 (0.79 to 0.95)[a]	Very low
1 study (Umstad et al., 1992)	case series	pH<7.25 = 23/60 (38%)	60	82.6% (67.12 to 98.10)[b]	91.9% (83.10 to 100)[b]	10.19 (3,39 to 30.63)[a]	0.19 (0.08 to 0.46)[a]	Moderate

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

CI confidence interval, NC not calculable

a. Calculated by NCC
b. As reported in study, confidence intervals calculated by NCC

Table 95: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following digital massage as stimulus

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH<7.20								
1 study (Elimian et al., 1997)	case series	pH<7.20 = 15/108 (14%) 15 sec of stimulation	108	100% (Not calculable [NC])[a]	54.84% (44.72 to 64.95)[a]	2.21 (1.77 to 2.77)[b]	0 (NC)[b]	Low
Fetal scalp pH ≤7.20								
1 study (Trochez et al., 2005)	case series	pH<7.20 = 5/70 (7% of samples) Vaginal examination (VE) acting as stimulus	70 samples; 54 women & baby pairs	40% (7.26 to 82.96)[a]	69.23% (56.4 to 79.76)[a]	1.3 (0.27 to 6.24)[a]	0.87 (0.44 to 1.70)[a]	Very low

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

NC not calculable, VE vaginal examination

a. As reported in study, confidence intervals calculated by NCC
b. Calculated by NCC

Table 96: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following Allis clamp as stimulus

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

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

NC not calculable

a Calculated by NCC

Table 97: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following 3 or 5 seconds of vibroacoustic stimulation (VAS)

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH<7.20								
1 study (Edersheim et al., 1987)	case series	pH<7.20 = 6/188 (3%) 3-sec VAS	188 samples; 127 woman & baby pairs	100% (Not calculable[NC])[a]	63.74% (56.75 to 70.72)[a]	2.76 (2.27 to 3.24)[a]	0 (NC)[a]	Very low
1 study (Lin et al., 2001)	case series	pH<7.20 = 31/113 (27%) 3-sec VAS	113	39% (21.56 to 55.86)[b]	93% (87.05 to 98.32)[b]	5.29 (2.18 to 12.86)[a]	0.66 (0.50 to 0.88)[a]	Very low
1 stud (Umstad et al., 1992)	case series	pH<7.20 = 8/60 (13%) 3-sec VAS	60	100% (NC)[b]	59.6% (46.28 to 72.95)[b]	2.48 (1.78 to 3.45)[a]	0 (NC)[a]	Moderate
1 study (Bartelsmeyer et al., 1995)	case series	pH<7.20 = 14/104 (13%) 5-sec VAS	104	79% (57.08 to 100)[a]	52.22% (41.9 to 62.54)[a]	1.64 (1.12 to 2.33)[a]	0.41 (0.15 to 1.14)[a]	Low

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Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Ingermarsson and Arulkumaran, 1989)	case series	pH<7.20 = 4/51 (8%) 5-sec VAS	51	50% (1 to 99)[a]	68.97% (52.13 to 85.80)[a]	1.61 (0.53 to 4.94)[a]	0.73 (0.26 to 1.99)[a]	Very low
1 study (Irion et al., 1996)	case series	pH<7.20 = 31/421 (7.4%) 5-sec VAS	421 samples; 253 woman & baby pairs	77.42% (62.70 to 92.14)[a]	51.54% (46.58 to 56.50)[a]	1.60 (1.29 to 1.98)[a]	0.44 (0.23 to 0.85)[a]	Moderate
1 study (Polzin et al., 1988)	case series	pH<7.20 = 10/100 (10%) 5-sec VAS	100	90% (71.41 to –100)[a]	84.44% (76.96 to 91.93)[a]	5.79 (3.43 to 9.77)[a]	0.11 (0.02 to 0.76)[a]	Very low
Fetal scalp pH<7.25								
1 study (Smith et al., 1986)	case series	pH<7.25 = 18/64 (28%) < 3 sec VAS	64	100% (NC)[a]	65.22% (51.45 to 78.98)[a]	2.88 (1.94 to 4.27)[a]	0 (NC)[a]	Very low
1 study (Umstad et al., 1992)	case series	pH<7.20 = 8/60 (13%) 3-sec VAS	60	100% (NC)[b]	83.8% (71.91 to 95.66)[b]	6.17 (2.96 to 12.83)[a]	0 (NC)[a]	Moderate
1 study (Irion et al., 1996)	case series	pH<7.25 = 130/421 (31%) 5-sec VAS	421 samples; 253 women & baby pairs	65.38% (57.21 to 73.56)[a]	56.01% (50.31 to 61.72)[a]	1.49 (1.24 to 1.78)[a]	0.62 (0.48 to 0.80)[a]	Moderate
1 study (Polzin et al., 1988)	case series	pH<7.25 = 22/100 (22%) 5-sec VAS	100	45.45% (24.65 to 66.26)[a]	83.33% (75.06 to 91.60)[a]	2.73 (1.39 to 5.36)[a]	0.65 (0.44 to 0.97)[a]	Very low
Umbilical cord pH<7.10								
1 study (Chauhan et al., 1999)	case series	pH<7.10 = 8/271 (3%) 3-sec VAS	271	44% (11.98 to 76.91)[b]	91% (87.79 to 94.65)[b]	5.06 (2.21 to 11.59)[a]	0.61 (0.34 to 1.09)[a]	Low

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Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Umbilical cord pH<7.00								
1 study (Chauhan et al., 1999)	case series	pH<7.00 = 4/271 (1.5%) 3-sec VAS	271	50% (1 to 99)[b]	91% (87.14 to 94.13)[b]	5.34 (1.87 to 15.24)[a]	0.55 (0.21 to 1.47)[a]	Low
1 study (Anyaegbunam et al., 1994)	case series[c]	pH<7.20 = 18/316 (6%) 5-sec VAS	316	22.2% (3.02 to 41.43)[a]	77.18% (72.42 to 81.95)[a]	0.97 (0.40 to 2.37)[a]	1.00 (0.78 to 1.30)[a]	Low
Caesarean section								
1 study (Chauhan et al., 1999)	case series	N caesarean sections = 8/271 (3%) 3-sec VAS	271	37% (3.95 to 71.05)[b]	92% (87.39 to 94.35)[b]	4.11 (1.55 to 10.87)[a]	0.69 (0.40 to 1.18)[a]	Low
1 study (Sarno et al., 1990)	case series	N caesarean sections = 16/201 (8%) 3-sec VAS	201	31.2% (8.54 to 53.96)[b]	95.1% (92.04 to 98.24)[b]	6.42 (2.44 to 16.89)[a]	0.72 (0.52 to 1.01)[a]	Low
Apgar score <7 at 5 minutes								
1 study (Lin et al., 2001)	case series	Apgar <7 = 3/113 (3%) 3-sec VAS	113	100% (NC)b	86% (79.95 to 92.78)[b]	7.33 (4.58 to 11.74)[a]	0 (NC)[a]	Very low
1 study (Sarno et al., 1990)	case series	Apgar <7 = 6/201 (3%) 3-sec VAS	201	33.3% (0 to 71.50)[b]	93.8% (90.47 to 97.22)[b]	5.42 (1.54 to 19.05)[a]	0.71 (0.40 to 1.25)[a]	Moderate
1 study (Anyaegbunam et al., 1994)	case series[c]	Apgar <7 = 10/316 (3%) 5-sec VAS	316	30% (1.60 to 58.40)[a]	77.45% (72.77 to 82.13)[a]	1.33 (0.50 to 3.51)[a]	0.90 (0.60 to 1.36)[a]	Low
1 study (Bartelsmeyer et al., 1995)	case series	Apgar <7 = 6/104 (6%) 5-sec VAS	104	83.33% (53.51 to 100)[a]	52.04% (42.15 to 61.93)[a]	1.74 (1.15 to 2.62)[a]	0.32 (0.05 to 1.93)[a]	Low

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Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Polzin et al., 1988)	case series	Apgar <7 = 6/100 (6%) 5-sec VAS	100	50% (9.99 to 90.01)[a]	57.45% (47.45 to 67.44)[a]	1.18 (0.51 to 2.71)[a]	0.87 (0.38 to 1.97)[a]	Very low
Poor perinatal outcome[d]								
1 study (Tannirandorn et al., 1993)	case series	Poor perinatal outcome = 7/140 (5%) 3-sec VAS	140	71.4% (37.96 to 100)[b]	99.2% (97.78 to 100)[b]	95 (12.75 to 707.63)[a]	0.29 (0.09 to 0.93)[a]	Very low

NC not calculable, VAS vibroacoustic stimulation

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

Update 2014

Evidence statements

Fetal scalp stimulation

Neonatal outcomes

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

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

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

Maternal outcomes

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

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Vibroacoustic stimulation

Neonatal outcomes

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

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

Evidence from 5 studies (n=834) showed that the lack of fetal heart rate acceleration following vibroacoustic stimulation (for 3 or 5 seconds) has low to high sensitivity and specificity for Apgar score less than 7 at 5 minutes, with more studies showing low and moderate sensitivity and specificity than high sensitivity and specificity. The positive likelihood ratio is not useful, but 1 study showed a useful negative likelihood ratio. The evidence was of moderate to very low quality.

Maternal outcomes

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

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

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

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

Consideration of clinical benefits and harms

The evidence is varied for the usefulness of fetal stimulation for predicting low pH values. The negative likelihood ratios for fetal stimulation ranged from useful to not useful, with no clear evidence one way or the other. Similarly, there was no consistent finding for sensitivity and specificity. This means that if an acceleration is observed, this may indicate that the fetal pH value is not low (a reassuring finding) but this is not a certain finding. Positive likelihood ratios were more often than not found to be not useful for predicting low pH values. Again the sensitivity and specificity were also varied, ranging from high to low with no consistent pattern of findings. This means that if an acceleration is not observed, this cannot be relied upon as an indicator for the fetal pH value. The group recognised that the act of fetal scalp pH sampling is simultaneously an act of scalp stimulation, and thus even if it is not possible to obtain a result from a scalp sample (for example because not enough blood is taken), if an acceleration is observed, this should still be treated as a potentially reassuring feature to take into account when considering the whole clinical picture.

Consideration of health benefits and resource uses

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

Quality of evidence

The evidence was of mixed quality, ranging from moderate to very low (with the majority of studies rated as low or very low). The group was concerned about the poor quality of the evidence available and noted that the results of the different studies varied greatly. Many results had wide or very wide confidence interval (95% CI). This led the guideline development group to exercise caution in the wording of the recommendations.

Other considerations

The guideline development group did not feel that the evidence provided a clear indication for the effectiveness of fetal scalp stimulation, nor when fetal scalp stimulation should be used as an adjunct to monitoring. As a result, they did not wish to recommend that scalp stimulation should be used in its own right in certain circumstances. Instead, the group recognised that

there are occasions when the baby's scalp will be stimulated anyway – such as when performing a vaginal examination or when taking a fetal blood sample – and that on these occasions the healthcare professional should be alert to accelerations as a potential indication of fetal wellbeing.

Recommendations

135. If fetal scalp stimulation leads to an acceleration in fetal heart rate, regard this as a reassuring feature. Take this into account when reviewing the whole clinical picture (see recommendation 109). [new 2014]

136. Use the fetal heart rate response after fetal scalp stimulation during a vaginal examination to elicit information about fetal wellbeing if fetal blood sampling is unsuccessful or contraindicated. [new 2014]

Fetal blood sampling

Fetal blood sampling as an adjunct to electronic fetal monitoring

Review question

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

- Electronic fetal monitoring alone
- Electronic fetal monitoring plus electrocardiogram (ECG)

Description of included studies

Four studies (Alfirevic et al., 2012; Stein et al., 2006; Noren, et al., 2007; Becker et al., 2011) are included in this review. Two studies (Alfirevic et al., 2012; Stein et al., 2006) evaluated the use of fetal blood sampling as an adjunct to CTG when compared to CTG or intermittent auscultation. Two studies (Noren et al., 2007; Becker, et al., 2011) examined the use of fetal blood sampling as an adjunct to CTG plus ECG.

Of the 2 studies that evaluated the use of fetal blood sampling as an adjunct to CTG compared with continuous CTG or intermittent auscultation, 1 is a systematic review (Alfirevic et al., 2012) with 13 component trials from a variety of locations. Of these 13 included trials, none reported data for fetal blood sampling as an adjunct to CTG compared with CTG alone. Eight of the included trials reported a subgroup analysis for women who had fetal blood sampling as an adjunct to CTG compared with intermittent auscultation. An additional observational study conducted in Germany (Stein et al., 2006) compared the impact of CTG alone versus CTG with additional fetal blood sampling in vaginal births complicated by pathologic fetal heart rate.

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

Evidence profile

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

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

- CTG plus fetal blood sampling versus CTG or intermittent auscultation alone in labour.

Fetal blood sampling as an adjunct to CTG plus ECG

- Distribution of fetal blood sampling and ECG guideline (ST waveform analysis) indication to intervene. Marked acidosis (cord artery pH<7.06) versus control.
- Distribution of fetal blood sampling and ST guideline indication to intervene. Moderate acidosis (cord artery pH 7.06 –7.09) versus control.
- Cases with abnormal CTG and their relation to normal and abnormal fetal blood sampling and ST waveform analysis.
- Additional fetal blood sampling when using ST analysis of fetal electrocardiogram.

Table 98: Summary GRADE profile for comparison CTG plus fetal blood sampling (FBS) with intermittent auscultation (IA) (Alfirevic et al., 2012) or CTG alone in labour (Stein et al., 2006)

Number of studies	Design	Other considerations: CTG or IA	Number of women		Effect		Quality
			Continuous CTG and FBS	IA or CTG with no FBS	Relative (95% CI)	Absolute (95% CI)	
Instrumental vaginal birth							
1 meta-analysis of 5 studies (Alfirevic et al., 2012)	randomised trials	IA	895/7905 (11.3%)	693/7850 (8.8%)	RR 1.25 (1.13 to 1.38)	24 more per 1000 (from 14 more to 34 more)	Moderate
1 study (Stein et al., 2006)	observational study	EFM	4790/12893 (37.2%)	15015/36667 (40.9%)	RR 0.91 (0.88 to 0.93)	37 fewer per 1000 (from 29 fewer to 49 fewer)	Very low
Caesarean section							
1 meta-analysis of 6 studies (Alfirevic et al., 2012)	randomised trials	IA	323/8027 (4%)	234/7974 (2.9%)	RR 1.50 (1.10 to 2.06)	10 more per 1000 (from 4 more to 17 more)	Low
Cord blood acidosis (pH<7.0)							
1 study (Alfirevic et al., 2012)	randomised trials	IA	5/540 (0.93%)	11/535 (2.1%)	RR 0.45 (0.16 to 1.29)	11 fewer per 1000 (from 17 fewer to 6 more)	Moderate
1 study (Stein et al., 2006)	observational studies	EFM	64/12893 (0.5%)	307/36667 (0.8%)	RR 0.59 (0.45 to 0.78)	3 fewer per 1000 (from 2 fewer to 5 fewer)	Very low
Cerebral palsy							
1 meta-analysis of 2 studies (Alfirevic et al., 2012)	randomised trials	IA	28/6609 (0.42%)	17/6643 (0.26%)	RR 1.74 (0.97 to 3.11)	2 more per 1000 (from 0 fewer to 5 more)	Low

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Number of studies	Design	Other considerations: CTG or IA	Number of women		Effect		Quality
			Continuous CTG and FBS	IA or CTG with no FBS	Relative (95% CI)	Absolute (95% CI)	
Neonatal resuscitation							
1 study (Stein, et al., 2006	observational studies	EFM	652/12893 (5.1%)	2273/36667 (6.2%)	RR 0.82 (0.75 to 0.89)	11 fewer per 1000 (from 7 fewer to 15 fewer)	Very low
Neonatal seizures							
1 meta-analysis of 5 studies (Alfirevic, et al., 2012)	randomised trials	IA	19/7542 (0.25%)	39/7462 (0.52%)	RR 0.49 (0.29 to 0.84)	3 fewer per 1000 (from 1 fewer to 4 fewer)	Moderate
Apgar 5 min <7							
1 study (Stein, et al., 2006	observational studies	EFM	78/12893 (0.6%)	314/36667 (0.86%)	RR 0.71 (0.55 to 0.9)	2 fewer per 1000 (from 1 fewer to 4 fewer)	Very low

CI confidence interval, EFM electronic fetal monitoring, FBS fetal blood sampling, IA intermittent auscultation, RR relative risk

1.1.1.1.1 *Fetal blood sampling as an adjunct to CTG plus ECG*

The data presented in the following GRADE profiles are taken from papers reporting secondary analyses of sub-groups taken from larger studies in order to investigate the role of fetal blood sampling when used as an adjunct to CTG with ECG analysis. These studies were not designed as intervention studies comparing CTG with ECG analysis plus fetal blood sampling versus CTG with ECG analysis without fetal blood sampling. The first 3 tables present findings from Noren et al. (2007) which is a case controlled study. Cases are defined as babies born with marked acidosis (cord artery pH less than 7.06; n=53) or moderate acidemia (cord artery pH 7.06 to 7.09; n=44); controls are babies with cord artery pH of 7.20 or more.

Table 99: Summary GRADE profile for distribution of fetal blood sampling (FBS) findings and ST guideline indication to intervene[a]: Marked acidemia: cord artery pH<7.06

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

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

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

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

Table 100: Summary GRADE profile for distribution of fetal blood sampling (FBS) and ST guideline indication to intervene-. Moderate acidemia cord artery pH 7.06 – 7.09

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidemia	Control	Relative (95% CI)	Absolute (95% CI)	
Women with abnormal FBS (pH<7.20)						
1 study (Noren, et al., 2007)	observational studies	15/44 (34.1%)	0/44 (0%)	RR 31 (1.91 to 502.54)	NC	Very low
ST indication to intervene[a]						
1 study (Noren, et al., 2007)	observational studies	24/44 (54.5%)	10/44 (22.7%)	RR 2.4 (1.31 to 4.41)	318 more per 1000 (from 70 more to 775 more)	Very low
No ST indication to intervene (adequately monitored)						
1 study (Noren, et al., 2007)	observational studies	16[b]/40 (40%)	22/32 (68.8%)	RR 0.58 (0.37 to 0.91)	289 fewer per 1000	Very low

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Number of studies	Design	Number of women		Effect		Quality
		Moderate acidemia	Control	Relative (95% CI)	Absolute (95% CI)	
					(from 62 fewer to 433 fewer)	

CI confidence interval, RR relative risk

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

Table 101: Summary GRADE profile for cases with abnormal or intermediary CTGa noted at start of ST analysis recording

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidemia + marked acidosis	Control	Relative (95% CI)	Absolute (95% CI)	
Normal FBS and normal ST analysis						
1 study (Noren, et al., 2007)	observational studies	20/37 (54.1%)	23/24 (95.8%)	RR 0.56 (0.41 to 0.77)	422 fewer per 1000 (from 220 fewer to 565 fewer)	Very low
Normal FBS and abnormal ST analysis						
1 study (Noren, et al., 2007)	observational studies	1/37 (2.7%)	0/24 (0%)	RR 1.97 (0.08 to 46.55)	NC	Very low
Abnormal FBS and normal ST analysis						
1 study (Noren, et al., 2007)	observational studies	3/37 (8.1%)	0/24 (0%)	RR 1.97 (0.08 to 46.55)	NC	Very low
Abnormal FBS and abnormal ST analysis						
1 study (Noren, et al., 2007)	observational studies	13/37 (35.1%)	1/24 (4.2%)	RR 8.43 (1.18 to 60.35)	310 more per 1000 (from 7 more to 1000 more)	Very low

CI confidence interval, FBS fetal blood sampling, RR relative risk, ST electrocardiographic analysis

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

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

Table 102: Summary GRADE profile for additional fetal blood sampling (FBS) when using ST analysis of fetal electrocardiogram

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

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

a. In the trial protocol FBS was recommended in three situations:

- *Start of ST analysis registration with an intermediary or abnormal CTG trace*
- *Abnormal CTG trace for more than 60 minutes without ST-events*
- *Poor ECG signal quality in the presence of an intermediary or abnormal CTG trace.*

b. Classification at sample level not at patient level
c. n=19/96 had at least one ST event, n=77/96 had no ST indication to intervene
d. n=5/15 had at least one ST event, n=10/15 had no ST indication to intervene
e. n=8/10 had at least one ST event, n=2/10 had no ST indication to intervene

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

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Evidence statements

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

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

Fetal blood sampling as an adjunct to CTG plus fetal ECG

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

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

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

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

Cases with abnormal CTG noted at start of fetal ECG recording

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

ST analysis of fetal electrocardiogram plus fetal blood sampling

Evidence from 1 study (n=297) showed that the number of women with a fetal blood sample pH of more than 7.25 was lower where fetal blood samples were performed according to the ST analysis trial protocol compared with women where fetal blood sampling was not

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performed according to the ST analysis trial protocol. However, this difference was not observed for women with a fetal blood sample pH of 7.25 or less. The evidence was of very low quality.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

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

Quality of evidence

Although the comparison of interest was fetal blood sampling as an adjunct to CTG compared with CTG alone (or CTG plus ECG), only 1 observational study was identified which investigated this specific comparison, and the quality of its findings was very low for each of the relevant outcomes. The decision was made to also include a large systematic review which compared CTG plus fetal blood sampling with intermittent auscultation, as it was felt that this review might contain relevant information for the guideline development group to consider. The group was aware that a majority of the population in the systematic review consisted of women with a high risk pregnancy. In addition, women with preterm pregnancy and multiple pregnancy were also included. Because of the way the data were reported in the individual studies, it was not possible to perform a sub-group analysis for women with a low risk pregnancy, term pregnancy or singleton pregnancy. Furthermore, of 13 trials included in the systematic review, none reported data for fetal blood sampling as an adjunct to CTG compared with CTG alone, which was really the focus of the review question. Eight of the included trials reported a subgroup analysis for women who had fetal blood sampling as an adjunct to CTG compared with intermittent auscultation. Given these problems, the group did not feel that it was appropriate to consider the findings of the large systematic review when developing its recommendations.

One further case controlled study (Noren et al., 2007) was identified which took the findings from the experimental arm of a randomised trial where women received fetal blood sampling as an adjunct to CTG plus ECG, and compared them with a group of controls. This was not the most appropriate study design, and the group also noted that the numbers of women included in the study were very small, making it difficult to extrapolate from. Again, the group did not feel that it was appropriate to consider the findings from this study when developing its recommendations.

Consideration of clinical benefits and harms

The 1 observational study which looked at the direct comparison of interest showed that there was a statistically significant reduction in the number of instrumental vaginal births in the group which received fetal blood sampling in addition to CTG compared with the group which did not receive fetal blood sampling. The study also showed a statistically significant reduction in the rate of cord blood acidosis, neonatal resuscitation and 5 minute Apgar score of less than 7.

Although the group recognised that the quality of the evidence for all of these outcomes was very low, they felt that the findings matched their clinical experience. They agreed that fetal blood sampling as an adjunctive test helps clinicians to identify those babies where additional intervention may be required, and thereby reduces the rates of poor neonatal outcomes while at the same time reducing the number of women receiving unnecessary interventions.

Consideration of health benefits and resource uses

No formal cost effectiveness analysis was performed for this review. However, it was agreed that as fetal blood sampling is not an expensive test and does not require a large amount of additional clinician time, its use is likely to be cost effective, given the gains in quality adjusted life years (QALY) to be made by avoiding poor neonatal outcomes and unnecessary interventions.

Recommendations

For all fetal blood sampling recommendations, see section 10.5.4.6.

Time from decision to take a fetal blood sample to result

Review question

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

For further details on the evidence review protocol, please see appendix E.

Description of included studies

Two studies are included in this review (Annappa et al., 2008; Tuffnell et al., 2006). Both studies were prospective studies conducted in the UK which documented consecutive attempts at fetal blood sampling.

Evidence profile

Table 103: Summary GRADE profile for the time from the decision to perform a fetal blood sample to having the scalp pH result

Number of studies	Design	Number of women (number of samples)	Median / minutes (IQR) or number of events/total (%)	Quality
Time from decision to result of fetal blood sample				
1 study (Tuffnell et al., 2006)	case series	74 (100)	18 (12–25)	Very low
1 study (Annappa et al., 2008)	case series	72 (107)	17 (11–22)	Very low
Proportion of samples where the time from decision to result of fetal blood sample was longer than 30 minutes				
1 study (Tuffnell et al., 2006)	case series	74 (100)	8/89[a] (9.0%)	Very low
1 study (Annappa et al., 2008)	case series	72 (107)	5/107 (4.7%)	Very low

IQR interquartile range

a. 11 out of the 100 samples were not adequate for analysis

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Evidence statements

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

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group felt that the most important outcome was the average time from the decision to perform a fetal blood sample to having the result. They agreed that it was useful to have the supplementary information about the proportion of samples where the time from decision to result was longer than 30 minutes.

Consideration of clinical benefits and harms

The aim of this review was to identify the average time taken from decision to perform a fetal blood sample to having the result. This was in order that clinicians could take this information into account when deciding whether or not they should perform a fetal blood sample. In instances where a clinician was concerned about a baby's condition, it might be felt that 18 minutes would be too long to wait, and thus the baby's birth ought to be expedited sooner. The evidence available supported the recommendation made in the previous guideline and so the group agreed that no changes were necessary.

Consideration of health benefits and resource uses

This question addresses the time from the decision to perform a fetal blood sample to having the result to provide information for clinicians. As this is not a comparison of alternatives, no economic analysis was conducted. The review gives information on timing only, so there are no health benefit or resource implications related to this question.

Quality of evidence

The quality of evidence for this review was very low as it was derived from case series. However, the guideline development group felt that this was an appropriate study methodology for this question and agreed that it was sufficient to underpin the recommendation.

Recommendations

For all fetal blood sampling recommendations, see section 10.5.5.2.

Predictive value of fetal blood sampling

Review question

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

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

Description of included studies

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

One of the included studies is a systematic review which included 2 randomised controlled trials, both from Sweden (East et al., 2011). One of the other included studies is a further report of 1 of the trials included in the systematic review, which was included as an individual

paper because additional data were reported (Wiberg-Itzel et al., 2008). One of the included studies is a prospective comparative observational study from Egypt (Bakr et al., 2005). Two of the included studies are retrospective consecutive case series from Germany (Brandt-Niebelschutz and Saling, 1994) and Canada (Young et al., 1980). The remaining 4 included studies are case series from the USA in which it is not clear whether the cases were consecutive (Hon et al., 1969; Kerenyi et al., 1970; Khazin et al., 1969; Kubli, 1968).
The systematic review (East et al., 2011) incorporated trials which randomised women to have either the lactate level or the pH of the fetal blood sample measured. Clinical outcomes for both mother and baby are reported for this comparison. The remaining included studies evaluated the predictive value of fetal blood pH, lactate, base deficit or base excess values for neonatal outcomes. For predictive value data, only studies reporting data for samples taken within 1 hour of birth were included. The time interval between fetal blood sampling and birth was up to 60 minutes in 6 studies (Bakr et al., 2005; Brandt-Niebelschutz and Saling, 1994; Hon et al., 1969; Kerenyi et al., 1970; Wiberg-Itzel et al., 2008; Young et al., 1980) and up to 30 minutes in 2 studies (Khazin et al., 1969; Kubli, 1968).
One study (Wiberg-Itzel et al., 2008) reported excluding women with multiple pregnancies or who were in labour prior to 34 weeks, but in the remaining studies, the inclusion/exclusion criteria and characteristics of the study populations are poorly reported, so it is not possible to judge whether women would have been classified as low risk prior to the onset of labour.

Evidence profile

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

- Comparative clinical outcome data for women randomised to fetal blood lactate or pH testing (table 104).
- Predictive accuracy and correlation data:
  - Composite neonatal outcomes: predictive value of fetal blood pH at different thresholds (table 105).
  - 5 minute Apgar score: predictive value of fetal blood pH, lactate and base deficit at different thresholds (table 106) and correlation of fetal blood pH and base deficit measurements with Apgar score (table 107).
  - Umbilical arterial pH at birth: predictive value of fetal blood pH, lactate and base deficit at different thresholds (table 108) and correlation of fetal blood pH and base-excess measurements with umbilical arterial measurements (table 109).

Evidence from randomised controlled trials, prospective comparative observational studies or prospective consecutive case series started at high quality and was then downgraded if there were any issues identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies or retrospective consecutive case series started at moderate quality and was then downgraded if there were any issues. Evidence from non-consecutive case series started at low quality and was then downgraded if there were any issues.

Comparative clinical outcome data

Table 104: Summary GRADE profile for lactate compared with pH for fetal blood sampling

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

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

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Number of studies	Design	Number of women		Effect		Quality
		Lactate	pH	Relative (95% CI)	Absolute (95% CI)	
Umbilical arterial base deficit >19.2[b]						
1 study (East et al., 2011)	randomised trial	1/171 (0.58%)	3/156 (1.9%)	RR 0.3 (0.03 to 2.89)	13 fewer per 1000 (from 19 fewer to 36 more)	Very low

CI confidence interval, RR relative risk

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

Predictive accuracy and correlation data

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

Table 105: Summary GRADE profile for predictive accuracy of fetal blood sampling for composite neonatal outcomes

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

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

CI confidence interval, NICU neonatal intensive care unit

a. Calculated by NCC-WCH technical team

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Table 106: Summary GRADE profile for predictive accuracy of fetal blood sampling for Apgar score at 5 minutes

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

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Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Base deficit >10 mEq/l									
1 study (Kerenyi et al., 1970)	case series	Apgar score <7	60	19	0[a] (NC)	83.33% (66.12 to 100)[a]	0[a] (NC)	1.20 (0.98 to 1.48)[a]	Very low
Base deficit >12.5 mEq/l									
1 study (Kerenyi et al., 1970)	case series	Apgar score <7	60	19	0[a] (NC)	94.44% (83.86 to 100)[a]	0[a] (NC)	1.06 (0.95 to 1.18)[a]	Very low
1 study (Khazin et al., 1969)	case series	Apgar score <7	30	130	42.86% (6.20 to 79.52)[a]	90.24% (85.00 to 95.49)[a]	4.39 (1.60 to 12.06)[a]	0.63 (0.33 to 1.21)[a]	Very low

CI confidence interval, NC not calculable, NR not reported

a. Calculated by NCC-WCH technical team

Table 107: Summary GRADE profile for correlation of fetal blood sampling with high and low Apgar scores at 5 minutes

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
Correlation of fetal scalp pH with low Apgar scores						
1 study (Hon et al., 1969)	case series	Apgar score of 1–6	60	41	r: 0.3880 (p<0.01)	Very low
1 study (Hon et al., 1969)	case series	Apgar score of 1–6	45	41	r: 0.3880 (p<0.01)	Very low
1 study (Hon et al., 1969)	case series	Apgar score of 1–6	30	40	r: 0.3591 (p<0.05)	Very low

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

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Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
1 study (Hon et al., 1969)	case series	Apgar score of 7–10	5	151	r: −0.0534 (p>0.05)	Very low
Correlation of fetal scalp base deficit with high Apgar scores						
1 study (Khazin et al., 1969)	case series	Apgar score of 7–10	60	309	r: −0.0960 (p>0.05)	Very low
1 study (Khazin et al., 1969)	case series	Apgar score of 7–10	45	287	r: −0.0663 (p>0.05)	Very low
1 study (Khazin et al., 1969)	case series	Apgar score of 7–10	30	253	r: −0.1383 (p<0.05)	Very low
1 study (Khazin et al., 1969)	case series	Apgar score of 7–10	15	197	r: −0.1454 (p>0.05)	Very low
1 study (Khazin et al., 1969)	case series	Apgar score of 7–10	5	84	r: −0.1517 (p>0.05)	Very low

NA not applicable

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Table 108: Summary GRADE profile for predictive accuracy of fetal blood sampling for arterial pH at birth

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH≤7.25									
1 study (Wiberg-Itzel et al., 2008)	randomised trial	metabolic acidaemia, defined as pH<7.05 and base deficit >12 mmol/l	60	508	65.00% (44.10 to 85.90)[a]	56.15% (51.74 to 60.55)[a]	1.48 (1.06 to 2.08)[a]	0.62 (0.34 to 1.14)[a]	Moderate
1 study (Kerenyi et al., 1970)	case series	pH<7.10	60	21	100%[a] (NC)	22.22% (3.02 to 41.43)[a]	1.29 (1.00 to 1.65)[a]	0[a] (NC)	Very low
1 study (Wiberg-Itzel et al., 2008)	randomised trial	pH<7.00	60	508	63.64% (35.21 to 92.06)[a]	55.73% (51.37 to 60.10)[a]	1.44 (0.91 to 2.27)[a]	0.65 (0.30 to 1.43)[a]	Moderate
Fetal scalp pH<7.21									
1 study (Wiberg-Itzel et al., 2008)	randomised trial	metabolic acidaemia, defined as pH<7.05 and base deficit >12 mmol/l	60	508	50.00% (28.09 to 71.91)[a]	74.39% (70.51 to 78.26)[a]	1.95 (1.23 to 3.10)[a]	0.67 (0.43 to 1.05)[a]	Moderate
1 study (Bakr et al., 2005)	prospective observational study	pH≤7.15	Unknown	150	72% (58 to 82)	53% (42 to 63)	1.54 (1.17 to 2.02)[a]	0.53 (0.34 to 0.83)[a]	Low
1 study (Kerenyi et al., 1970)	case series	pH<7.10	60	21	100%[a] (NC)	66.67% (44.89 to 88.44)[a]	3.00 (1.56 to 5.77)[a]	0.00[a] (NC)	Very low

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Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Wiberg-Itzel et al., 2008)	randomised trial	pH<7.00	60	508	45.45% (16.03 to 74.88)[a]	73.84% (69.98 to 77.71)[a]	1.74 (0.89 to 3.38)[a]	0.74 (0.43 to 1.27)[a]	Moderate
Fetal scalp pH<7.10									
1 study (Kerenyi et al., 1970)	case series	pH<7.10	60	21	33.33% (0 to 86.68)[a]	94.44% (83.86 to 100)[a]	6.00 (0.50 to 72.21)[a]	0.71 (0.31 to 1.58)[a]	Very low
Fetal scalp lactate ≥4.2 mmol/l									
1 study (Wiberg-Itzel et al., 2008)	randomised trial	metabolic acidaemia, defined as pH<7.05 and base deficit >12 mmol/l	60	684	100%[a] (NC)	51.04% (47.26 to 54.81)[a]	2.04 (1.89 to 2.21)[a]	0.00[a] (NC)	Moderate
1 study (Wiberg-Itzel et al., 2008)	randomised trial	pH<7.00	60	684	76.00% (59.26 to 92.74)[a]	51.29% (47.47 to 55.11)[a]	1.56 (1.24 to 1.97)[a]	0.47 (0.23 to 0.94)[a]	Moderate
Fetal scalp lactate >4.8 mmol/l									
1 study (Wiberg-Itzel et al., 2008)	randomised trial	metabolic acidaemia, defined as pH<7.05 and base deficit >12 mmol/l	60	684	76.00% (59.26 to 92.74)[a]	62.37% (58.67 to 66.07)[a]	2.02 (1.59 to 2.57)[a]	0.38 (0.19 to 0.78)[a]	Moderate
1 study (Wiberg-Itzel et al., 2008)	randomised trial	pH<7.00	60	684	100%[a] (NC)	61.87% (58.20 to 65.54)[a]	2.62 (2.38 to 2.89)[a]	0.00[a] (NC)	Moderate
Fetal scalp base deficit >10 mEq/l									

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Kerenyi et al., 1970)	case series	pH<7.10	60	18	0%[a] (NC)	81.25% (62.12 to 100)[a]	0[a] (NC)	1.23 (0.97 to 1.56)[a]	Very low
Fetal scalp base deficit >12.5 mEq/l									
1 study (Kerenyi et al., 1970)	case series	pH<7.10	60	18	0%[a] (NC)	93.75% (81.89 to 100)[a]	0[a] (NC)	1.07 (0.94 to 1.21)[a]	Very low

CI confidence interval, NC not calculable, NR not reported

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

Table 109: Summary GRADE profile for correlation of fetal scalp blood sample values with umbilical artery values at time of birth

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

Evidence statements

Comparative clinical outcome data

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

Predictive accuracy of fetal blood sampling for composite neonatal outcomes

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

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

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

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

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

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

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

Evidence from 1 study (n=13) showed that base deficit taken within 60 minutes of birth was highly negatively correlated with low Apgar at 5 minutes, regardless of at what point the measurement was taken. However, the study sample size was very small. In contrast, there was very low or no correlation between base excess and high Apgar score at 5 minutes. The quality of the evidence was very low.

Update 2014

Predictive accuracy of fetal blood sampling for arterial pH at birth

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

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

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

Correlation of fetal blood sampling with umbilical artery values at birth

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

Health economic profile

No published economic evaluations were identified for this question.

A cost analysis was developed in Excel – further details of the cost inputs can be found in appendix A 5.3.

Lactate levels can be measured on some blood gas analysers, but not all. Therefore it is likely that new lactate test meters will be needed. The blood gas analyser is a standard device in an obstetric unit. Based on their experience, the guideline development group estimated that fetal blood sampling would represent approximately one-tenth of the use of the machine. Therefore the analyser would still be needed even if it was not used for fetal blood sampling. The costs of purchasing a lactate meter and the associated consumables (£1.74 per sample taken) were compared to the consumable costs related to using a blood gas analyser for pH measurements (£0.74 per sample taken).

A capillary sample of the baby's blood is taken from the scalp. The technique is the same regardless of whether lactate or pH is measured. The costs for staff to take a sample were estimated (£13 to £20 for 20 minutes of a specialty trainee or registrar's time).

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

Under these assumptions the cost per test was lower for the pH sample when using a blood gas analyser, but as the success rates were lower than for taking a lactate sample this analysis showed lactate sampling was slightly less expensive than pH testing. The difference in cost per test was small (£0.66 less for lactate).

Evidence to recommendations

Relative value placed on the outcomes considered

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

Update 2014

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

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

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

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

The group did not place much value on the correlation findings, except to note that they confirmed what the group would have expected from their clinical experience, which is that there was an increasingly high correlation between a poor fetal blood sample result and a poor outcome when the interval between the sample being taken and birth got shorter.

Consideration of clinical benefits and harms

With this topic, the guideline development group wished to strike the right balance between ensuring that babies at genuine risk would be identified and treated accordingly, and ensuring that women weren't asked to undergo caesarean sections unnecessarily. The group noted that the systematic review (with 2 included trials) showing a direct comparison between lactate and pH measurements showed no statistically significant difference between the 2 for any clinical outcomes. In other words, the choice of test did not make a significant difference to the numbers of babies experiencing poor outcomes in either arm of the study. The previous recommendation in the guideline had only made reference to measuring pH. However, given the equivalence of the 2 tests, the group felt that it was appropriate to reference lactate measurements as well.

The group considered the evidence comparing the diagnostic accuracy of the tests. They noted that although the measures were similar for pH and lactate, lactate appeared to be associated with a slightly higher negative likelihood ratio. In addition, in a study that evaluated both tests (Wiberg-Itzel et al., 2008) the use of lactate was associated with higher sensitivities for both low Apgar score and arterial pH. The group members were also aware from their clinical experience that the use of lactate could potentially reduce the time for taking a sample as much less blood needs to be taken and fewer repeat samples are required (although not included in the evidence review as one of the priority outcomes, the Cochrane review [East et al., 2011] reported that lactate had a statistically significantly higher success rate than pH

[95% compared with 89%]). As the process of taking a fetal blood sample is invasive, the group felt that it would be a positive step if the time required for this process could be reduced.

Ultimately, the group did not feel that they could recommend that only lactate be used as a diagnostic test. They did not feel that there was strong enough evidence in its favour and, as noted above, its use did not lead to an improvement in clinical outcomes. Furthermore, the group recognised that pH is the standard test used in the UK for this indication and that there was not sufficient justification for a complete change in practice. However, the group agreed that if clinicians did have the means available to test lactate, and they had received sufficient training, it should be used as the first line diagnostic test.

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

The group discussed the practicalities of performing a fetal blood sample and agreed that the procedure was generally easier to perform, and more comfortable for the woman, with the woman in a left lateral position. They also recognised that the procedure was more likely to be successful if the woman's cervix was dilated 4 cm or more. The group also made a number of recommendations about repeat sampling. Although the evidence did not look specifically at the use of repeat samples, the group felt that they formed a key part of standard clinical practice. Although the group members acknowledged that sampling is an invasive procedure, they agreed that performing further samples when indicated by the CTG was preferable to performing unnecessary instrumental or caesarean births. The particular thresholds that the group chose for repeat sampling and the timing of this were derived from their own clinical practice and experience. Appropriate actions following failed sampling or findings of fetal acidosis were also discussed and recommendations made accordingly. It was also noted that there are certain instances where the risk of performing fetal blood sampling would outweigh any potential benefits, for example where there is an increased risk of passing infection to the baby, and added this to the recommendations.

Consideration of health benefits and resource uses

No formal cost effectiveness modelling was performed for this question but a cost analysis was developed. The guideline development group considered the likely cost impact of its recommendations and agreed that it would be minimal. Although lactate was recommended as a first line diagnostic test, this is only in units where the equipment and training is already available. Otherwise, there would not necessarily be a large change in practice. The group felt that it would be possible to have a clearer understanding of the likely cost impact of using lactate rather than pH measurements once there was better quality outcome data available from UK studies.

Quality of evidence

The evidence was of mixed quality, ranging from very low to moderate for the various outcomes. The evidence supporting the change in the recommendation in favour of lactate was drawn from a study of moderate quality. However, as the study was from a different setting (Sweden) and was not particularly large, the guideline development group did not feel it was sufficient to make a stronger recommendation.

Other considerations

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

The group felt it important that women be fully informed of the nature of the procedure required to obtain a fetal blood sample and its risks and benefits, particularly the risk of a 'failed' sample and the possible actions that may be considered once a result is obtained.

Key conclusions – fetal blood sampling

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

Recommendations

137. When offering fetal blood sampling, explain the following to the woman:

- Why the test is being advised.
- The blood sample will be used to measure the level of acid in the baby's blood, to see how well the baby is coping with labour.
- The procedure will require her to have a vaginal examination using a small device similar to a speculum.
- A sample of blood will be taken from the baby's head by making a small scratch on the baby's scalp. This will heal quickly after birth, but there is a small risk of infection.
- The procedure can help to reduce the need for further, more serious interventions.
- What the different outcomes of the test may be (normal, borderline and abnormal) and the actions that will follow each result.
- There is a small chance that it will not be possible to obtain a blood sample (especially if the cervix is less than 4 cm dilated). If a sample cannot be obtained, a caesarean section or instrumental birth (forceps or ventouse) may be needed because otherwise it is not possible to find out how well the baby is coping. [new 2014]

138. Do not carry out fetal blood sampling if any contraindications are present, including risk of maternal-to-fetal transmission of infection or risk of fetal bleeding disorders. [new 2014]

139. Take fetal blood samples with the woman in the left-lateral position. [2014]

140. Measure either lactate or pH when performing fetal blood sampling. Measure lactate if the necessary equipment and suitably trained staff are available; otherwise measure pH. [new 2014]

141. Use the classification of fetal blood sample results shown in table 110. [new 2014]

Table 110: Classification of fetal blood sample results

Lactate (mmol/l)	pH	Interpretation
≤ 4.1	≥ 7.25	Normal
4.2–4.8	7.21–7.24	Borderline
≥ 4.9	≤ 7.20	Abnormal

Update 2014

142. Interpret fetal blood sample results taking into account any previous lactate or pH measurement, the rate of progress in labour and the clinical features of the woman and baby. [new 2014]

143. Inform the consultant obstetrician if any fetal blood sample result is abnormal. [new 2014]

144. Discuss with the consultant obstetrician if:

- a fetal blood sample cannot be obtained **or**
- a third fetal blood sample is thought to be needed. [new 2014]

145. If the fetal blood sample result is normal, offer repeat sampling no more than 1 hour later if this is still indicated by the cardiotocograph trace, or sooner if additional non-reassuring or abnormal features are seen. [2014]

146. If the fetal blood sample result is borderline, offer repeat sampling no more than 30 minutes later if this is still indicated by the cardiotocograph trace, or sooner if additional non-reassuring or abnormal features are seen. [2014]

147. Take into account the time needed to take a fetal blood sample when planning repeat sampling. [2014]

148. If the cardiotocograph trace remains unchanged and the fetal blood sample result is stable (that is, lactate or pH is unchanged) after a second test, further samples may be deferred unless additional non-reassuring or abnormal features are seen. [new 2014]

149. If a fetal blood sample is indicated and the sample cannot be obtained, but the associated scalp stimulation results in fetal heart rate accelerations, decide whether to continue the labour or expedite the birth in light of the clinical circumstances and in discussion with the consultant obstetrician and the woman. [new 2014]

150. If a fetal blood sample is indicated but a sample cannot be obtained and there is no improvement in the cardiotocograph trace, advise the woman that the birth should be expedited (see recommendations 220 to 223). [new 2014]

Cardiotocography using telemetry compared with conventional cardiotocography

Review question

What is the effectiveness of cardiotocography using telemetry compared with conventional cardiotocography?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

Update 2014

Seven studies were included in this review (Calvert et al., 1982; Flynn et al., 1978; Frenea et al., 2004; Haukkamaa et al., 1982; Hodnett, 1982; Karraz, 2003; MacLennan et al., 1994). All of the studies were randomised controlled trials, with 2 conducted in the UK (Calvert et al., 1982; Flynn et al., 1978), 2 in France (Frenea et al., 2004; Karraz, 2003) and 1 each in Finland (Haukkamaa et al., 1982), Canada (Hodnett,1982) and Australia (MacLennan et al., 1994).

Three of the studies were specifically evaluating the comparison of cardiotocography (CTG) using telemetry with conventional CTG (Calvert et al., 1982; Haukkamaa et al., 1982; Hodnett, 1982). In 2 further studies the comparison of interest was primarily ambulation versus recumbency during labour, but this was implemented by monitoring women with telemetry or conventionally (Flynn et al., 1978; MacLennan et al., 1994). In the last 2 studies, the aim was to evaluate ambulatory anaesthesia and therefore all women had an epidural and then were randomised to ambulation monitored using telemetry or recumbency monitored conventionally (Frenea et al., 2004; Karraz, 2003).

The samples in 4 studies were restricted to low risk women, or women with uncomplicated or 'uneventful' pregnancies (Frenea et al., 2004; Haukkamaa et al., 1982; Hodnett, 1982; Karraz, 2003). In 2 studies, the authors did not report restricting the study population to low risk women but did exclude certain categories of higher risk women (Calvert et al., 1982; MacLennan et al., 1994). In 1 study, all of the women were in spontaneous labour but the authors did not report their inclusion and exclusion criteria so it is not clear how closely the study population matches the population of interest (Flynn et al., 1978).

Evidence profile

A fixed effects model was used for the majority of meta-analyses, with the exception of 2 outcomes (use of narcotic analgesia or pethidine; use of no pain relief) where there was high heterogeneity (I^2 more than 60%) and so a random effects model was used.

Outcomes relating to pain relief are reported only for studies where ambulatory anaesthesia was not the intervention being investigated.

The findings from the included studies are reported in two separate GRADE tables:

- Table 111 contains data for clinical outcomes and women's views and experience where comparative data were reported.
- Table 112 contains qualitative findings about women's experience and details about degree of mobility, in addition to any outcomes for which comparative data was unavailable.

Table 111: Summary GRADE profile for the comparison of cardiotocography using telemetry with conventional cardiotocography

Number of studies	Design	Number of women/babies		Effect		Quality
		Telemetry	Conventional	Relative (95% CI)	Absolute (95% CI) (and p-value if reported)	
Mode of birth: spontaneous vaginal birth						
1 meta-analysis of 5 studies (Calvert et al., 1982; Flynn et al., 1978; Frenea et al., 2004; Karraz, 2003; MacLennan et al., 1994)	randomised trials	308/401 (76.8%)	251/339 (74%)	RR 1.02 (0.94 to 1.12)	15 more per 1000 (from 44 fewer to 89 more)	Low
Mode of birth: instrumental vaginal birth						
1 meta-analysis of 6 studies (Calvert et al., 1982; Flynn et al., 1978; Frenea et al., 2004; Haukkamaa et al., 1982; Karraz, 2003; MacLennan et al., 1994)	randomised trials	67/432 (15.5%)	59/368 (16%)	RR 1.06 (0.77 to 1.46)	10 more per 1000 (from 37 fewer to 74 more)	Very low
Mode of birth: caesarean section						
1 meta-analysis of 6 studies (Calvert et al., 1982; Flynn et al., 1978; Frenea et al., 2004; Haukkamaa et al., 1982; Karraz, 2003; MacLennan et al., 1994)	randomised trials	29/432 (6.7%)	33/368 (9%)	RR 0.69 (0.44 to 1.11)	28 fewer per 1000 (from 50 fewer to 10 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Telemetry	Conventional	Relative (95% CI)	Absolute (95% CI) (and p-value if reported)	
Use of pain relief: epidural						
1 meta-analysis of 5 studies (Calvert et al., 1982; Flynn et al., 1978; Haukkamaa et al., 1982; Hodnett, 1982; MacLennan et al., 1994)	randomised trials	71/276 (25.7%)	102/278 (36.7%)	RR 0.71 (0.57 to 0.9)	106 fewer per 1000 (from 37 fewer to 158 fewer)	Very low
Use of pain relief: narcotic analgesia or pethidine						
1 meta-analysis of 5 studies (Calvert et al., 1982; Flynn et al., 1978; Haukkamaa et al., 1982; Hodnett, 1982; MacLennan et al., 1994)	randomised trials	142/276 (51.4%)	163/278 (58.6%)	RR 0.8 (0.58 to 1.09)	117 fewer per 1000 (from 246 fewer to 53 more)	Very low
Use of pain relief: nitrous oxide						
1 meta-analysis of 2 studies (Calvert et al., 1982; Haukkamaa et al., 1982)	randomised trials	38/131 (29%)	34/129 (26.4%)	RR 1.08 (0.76 to 1.51)	21 more per 1000 (from 63 fewer to 134 more)	Very low
Use of pain relief: no pain relief						
1 meta-analysis of 2 studies (Calvert et al., 1982; Flynn et al., 1978)	randomised trials	22/134 (16.4%)	2/134 (1.5%)	RR 5.77 (0.09 to 369.48)	71 more per 1000 (from 14 fewer to 1000 more)	Very low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Telemetry	Conventional	Relative (95% CI)	Absolute (95% CI) (and p-value if reported)	
Length of labour (in hours)						
1 study (MacLennan et al., 1994)	randomised trial	Mean 8.9 (SD 5.2) n=96	Mean 8.5 (SD 4.4) n=100	not calculable (NC)	MD 0.4 higher (0.95 lower to 1.75 higher)	Moderate
Cervical dilatation rate (in cm/hour)						
1 study (Frenea et al., 2004)	randomised trial	Mean 1.9 (SD 1.1) n=25	Mean 2.5 (SD 1.7) n=28	NC	MD 0.6 lower (1.36 lower to 0.16 higher) p=0.17	Low
Length of first stage of labour (in hours)						
1 meta-analysis of 2 studies (Calvert et al., 1982; Haukkamaa et al., 1982)	randomised trials	n=131	n=129	NC	MD 0.41 lower (1.43 lower to 0.62 higher)[a,b]	Low
1 study (Flynn et al., 1978)	randomised trial	Mean 4.1 (SD not reported [NR]) n=34	Mean 6.7 (SD NR) n=34	NC	Mean 2.6 lower (confidence intervals NC) p<0.01	Low
Length of second stage of labour (in minutes)						
1 study (Calvert et al., 1982)	randomised trial	Mean 30.2 (SD 25) n=77	Mean 26 (SD 19) n=78	NC	MD 4.2 higher (2.8 lower to 11.2 higher)[b]	Low
1 study (Frenea et al., 2004)	randomised trial	Mean 56 (SD 42) n=25	Mean 62 (SD 59) n=28	NC	MD 6 lower (33.36 lower to 21.36 higher) p=0.65	Low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Telemetry	Conventional	Relative (95% CI)	Absolute (95% CI) (and p-value if reported)	
Perinatal death						
1 study (MacLennan et al., 1994)	randomised trial	0/96 (0%)	0/100 (0%)	NC	NC	Low
Admission to neonatal intensive care unit						
1 study (MacLennan et al., 1994)	randomised trial	6/96 (6.3%)	4/100 (4%)	RR 1.56 (0.45 to 5.37)	22 more per 1000 (from 22 fewer to 175 more)	Very low
Umbilical artery pH						
1 study (Frenea et al., 2004)	randomised trial	Mean 7.27 (SD 0.06) n=30	Mean 7.24 (SD 0.09) n=31	NC	MD 0.03 higher (0.01 lower to 0.07 higher) p=0.16	Low
Women's views and experiences of monitoring						
Satisfaction regarding electronic fetal monitoring (out of 10 – better indicated by higher values)						
1 study (MacLennan et al., 1994)	randomised trial	Mean 8.2 (SD 2.39) n=96	Mean 7.7 (SD 3.0) n=100	NC	MD 0.5 higher (0.26 lower to 1.26 higher)[c]	Moderate
Fetal monitor had a positive effect on labour experience						
1 study (Hodnett, 1982)	randomised trial	14/15 (93.3%)	5/15 (33.3%)	RR 2.8 (1.35 to 5.8)	600 more per 1000 (from 117 more to 1000 more)	Very low
Reassurance from monitoring (out of 100 – better indicated by higher values)						
1 study (Calvert et al., 1982)	randomised trial	Mean 74 (SD NR) (n=100)	Mean 71 (SD NR) (n=100)	NC	MD 3 higher (confidence interval NC) [NS but p-value NR]	Low

Update 2014

Number of studies	Design	Number of women/babies		Effect		Quality
		Telemetry	Conventional	Relative (95% CI)	Absolute (95% CI) (and p-value if reported)	
Anxiety score (out of 100 – better indicated by lower values)						
1 study (Calvert et al., 1982)	randomised trial	Mean 54 (SD 32) n=100	Mean 45 (SD 29) n=100	NC	MD 9 higher (0.54 higher to 17.46 higher)	Low
Restriction score (out of 100 – better indicated by lower values)						
1 study (Calvert et al., 1982)	randomised trial	Mean 28.8 (SD NR)	Mean 31 (SD NR)	NC	MD 2.2 lower (confidence interval NC)	Low
Labour Agentry score[d]						
1 study (Hodnett, 1982)	randomised trial	Mean 148.07 (SD NR)	Mean 128.87 (SD NR)	NC	Mean 19.2 higher (confidence interval NR)	Very low
Maintenance of control during labour						
1 study (Hodnett, 1982)	randomised trial	10/15 (66.7%)	4/15 (26.7%)	RR 2.5 (1 to 6.23)	400 more per 1000 (from 0 more to 1000 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, NR not reported, NS not significant, RR relative risk, SD standard deviation

a. For Haukkamaa et al. (1982), mean and standard deviations were reported for nulliparous women and multiparous women separately; therefore, pooled means and standard deviations had to be calculated by the technical team. Full details of the data as reported by the study can be found in the evidence tables.
b. For Calvert et al. (1982), in the telemetry group the mean and standard deviation were reported separately for women who chose to be out of bed for any period of labour (n=45) and women who chose not to get out of bed (n=55). Pooled means and standard deviations were calculated by the technical team. In addition, for length of the first stage, data was reported as hours.minutes; therefore, these had to be converted to decimals by the technical team. Full details of the data as reported by the study can be found in the evidence tables.
c. For MacLennan et al. (1994), satisfaction scores in the telemetry arm were reported separately for those choosing to ambulate (n=37) and those choosing to remain recumbent (n=59); therefore pooled means and standard deviations had to be calculated by the technical team. Full details of the data as reported by the study can be found in the evidence tables.
d. The authors report that this was a 28-item revised scale with an estimated reliability of 0.98; however, they do not report the range of possible scores

Update 2014

Table 112: Further findings for women's experience and mobility outcomes for the comparison of cardiotocography using telemetry with conventional cardiotocography

Study	Summary of findings
Degree of mobility	
1 study (Calvert et al., 1982) [Low]	45/100 (45%) of the women allocated to telemetry chose to get out of bed. These women spent a mean time of 104 minutes (range 3 – 260) out of bed and 34/45 (75%) of them chose to stay in bed by the time they were 7 cm dilated.
1 study (Flynn et al., 1978) [Low]	Women in the telemetry group spent a mean of 2.2 hours ambulant (range 0.8 – 8.3).
1 study (Haukkamaa et al., 1982) [Low]	The authors reported that 6/31 (19%) of women in the telemetry arm refused to get out of bed; this was thought to be a result of exhaustion due to pain. The time spent in the upright position ranged from 10% to 90% of the time.
1 study (Hodnett et al., 1982) [Very low]	0/15 (0%) of women in the telemetry group and 9/15 (60%) of women in the conventional monitoring group chose not to get out of bed during labour. The mean time spent out of bed was 142.7 minutes (range 30 – 300) in the telemetry group and 8.7 minutes in the conventional monitoring group ($p<0.0005$ reported by authors).
1 study (MacLennan et al. 1994) [Moderate]	37/96 (39%) of the women allocated to ambulation with telemetry chose to ambulate for at least 30 minutes. These women spent a mean time of 1.5 (SD 0.8) hours upright.
Women's views and experiences	
1 study (Frenea et al., 2004) [Low]	28/30 (93%) of women allocated to ambulatory epidural would choose to walk again in a future labour. The authors report no significant difference in the proportion of women who were "extremely satisfied" in the two groups.
1 study (Calvert et al., 1982) [Low]	The authors report an overall mean comfort score of 47 (SD 29) on a scale of 0-100, where 100 is the maximum possible comfort. They report that there was no significant difference between the two arms but no further details are given. 15/28 (53.6%) of the telemetry group and 3/29 (10.3%) of the conventional monitoring group found the method preferable to their previous labour where they had been conventionally monitored. In the telemetry arm, 4/28 (14.3%) of women felt more restricted, 15/28 (53.6%) felt less restricted and 9/28 (32.1%) of women felt the same level of restriction when compared to their last labour. In the telemetry arm 3/28 (10.7%) of women felt more anxious, 15/28 (53.6%) of women felt less anxious and 10/28 (35.7%) felt the same level of anxiety when compared to their last labour.
1 study (Hodnett et al., 1982) [Very low]	Telemetry group: Positive responses to the monitor centred around the condition of the baby and freedom from restraint Control group: Positive responses centred around reassurance about the baby Negative responses were linked to discomfort about the tocodynamometer belt during contractions, inability to move or attain a comfortable position, and anxiety

SD standard deviation

Update 2014

Evidence statements

There was evidence of no difference (n=800) in mode of birth for women who were monitored using telemetry compared with women who were monitored using conventional CTG. Women monitored using telemetry had lower rates of epidural use (n=554) than women monitored using conventional CTG, but there was no difference in the use of other forms of pain relief. There was no difference in measures of the length of labour (n=196). There was no evidence of a difference in neonatal outcomes (perinatal death [n=196], admission to neonatal intensive care unit [n=196], umbilical artery pH [n=61]), but each of these outcomes was only reported by 1 small study. The evidence was of moderate to very low quality.

One study (n=30) found that the proportion of women reporting that the monitor had a positive effect on labour experience was increased in women monitored with telemetry, but this study was small and had significant limitations. Most measures of women's experience did not show a difference between the 2 groups. However, 1 study (n=200) found that women who were monitored using telemetry generally felt that they were equally or less restricted and anxious than in a previous labour when they had been monitored using conventional CTG. There was consistent evidence across studies that not all women monitored with telemetry chose to get out of bed and that the time spent mobile varied, but non-comparative data from one study (n=200) found that most women who were monitored using telemetry would choose to be mobile again in a future labour. The evidence was of moderate to very low quality.

Health economics profile

No published economic evaluations were identified for this question.

A simple decision tree model was developed to consider the cost differences between the 2 forms of cardiotocography:

- conventional cardiotocography
- cardiotocography using telemetry.

The use of cardiotocography was not recommended for low risk pregnancies in any setting in the previous edition of the guideline. The full report of this analysis can be found in appendix A.

The clinical review found no evidence of a difference in mode of birth, length of labour or neonatal outcomes. Women monitored using telemetry had lower rates of epidural use than women monitored using conventional CTG (see table 113).

Table 113: Relative risk of epidural given method of CTG (meta-analysis of 5 studies, Calvert et al., 1982; Flynn et al., 1978; Haukkamaa et al., 1982; Hodnett, 1982; MacLennan et al., 1994)

CTG	Epidural	No epidural	Risk of epidural
Conventional	102	176	0.37
Telemetry	71	205	0.26
RR			0.7

CTG cardiotocography, RR relative risk

Information was obtained about the number of CTG units used on a labour ward and the cost of the different monitoring systems from a commercial distributor's sales team for an obstetric unit in England in 2013. The obstetric unit had around 6000 births per year. The unit has 6 telemetry systems all acquired in the last 2 years, as well as an additional 6 older conventional CTG systems.

The cost of a wireless telemetry system was around £6300 (table 114). In addition, the detached tocography and ultrasound transducers cost £910 each and the ECG transducers cost £804 each. The risk with detached transducers is that they are more likely to be lost (1 birth

unit had to replace 3 lost transducers in a year). However, the guideline development group believed that this could be avoided with better education on the use of the equipment.
The conventional CTG system, including attached tocography and ultrasound transducers, costs around £5400 (table 114). Any additional transducers cost £350. The risk of losing a transducer is far lower than for telemetry because they are attached to the monitor.

Table 114: Costs of acquiring conventional and telemetry CTG systems, 2013 prices

Cardiotocography system	Monitor	Transducers	Cost per system
Wireless telemetry system	£6254	2 x £910 1 x £804	£8878
CTG system	£5353	Included in price of the monitor	£5353
Cost difference (assuming no loss of wireless transducers)			£3524

CTG cardiotocography

As the only outcome identified with a difference was epidurals, a simple cost minimisation analysis was developed. Continuous monitoring is not routinely recommended for low risk women. However, the group believed that in an obstetric unit approximately 50% of all women will be monitored during labour. Only 5% of women in the obstetric unit would be low risk and go on to require continuous monitoring.
This analysis is based on a unit with 6000 births, requiring 12 CTG systems. Of these 6000 women, approximately 50% would require continuous monitoring. Of the 3000 women who require continuous monitoring, approximately 300 would be considered low risk: the analysis will focus on this group of women.
For this population of 300 low risk women requiring continuous monitoring, it is expected that 33 more epidurals would be needed if the women were monitored using a conventional system (110 compared with 77). The difference in the cost of epidurals is £6225 per year (table 115).

Table 115: Annual cost difference of epidurals per cardiotocography system, based on 5% of low risk women requiring CTG monitoring (n=300) in an obstetric unit with 6000 births per year

	Number of epidurals	Cost of epidurals
Conventional CTG	110	£20,828
Telemetry CTG	77	£14,603
Difference	33	£6225

CTG cardiotocography

Purchasing a CTG system is a capital cost, requiring an up-front payment. The expected lifespan of both types of CTG system would be at least 7 years and could be up to 15 years. The annual equivalent cost of both systems has been calculated in table 116 and this has been used to determine the cost per use.

Table 116: Annual cost per CTG system and cost per use assuming 3000 women are monitored per year in a unit with 6000 live births

Cardiotocography system	Cost per system	Annual equivalent value (7 year life expectancy)	Cost per use	Annual equivalent value (15 year life expectancy)	Cost per use
Conventional CTG system	£5353	£875	£3.50	£465	£1.86

Cardiotocography system	Cost per system	Annual equivalent value (7 year life expectancy)	Cost per use	Annual equivalent value (15 year life expectancy)	Cost per use
Telemetry CTG system	£8878	£1452	£5.81	£771	£3.08

CTG cardiotocography

The staff cost of an epidural was calculated through consensus among the guideline development group (appendix A). The mean cost was £108 (£69 to £247). The cost of consumables (such as epidural pack, gloves, syringes, IV drip) was taken from the Birthplace study and the prices uplifted to 2013. The total cost of an epidural was calculated as £189 (£149 to £328).

The cost per epidural is much greater than incremental cost per use of the telemetry CTG, and so telemetry is found to be cost saving by £5533 in this analysis (table 117).

Table 117: Annual cost difference based on 5% of low risk women requiring CTG monitoring (n=300) in an obstetric unit with 6000 births per year with 12 CTG monitors

	Cost of monitoring for low risk women n=300	Cost of epidurals	Total cost saving
Conventional CTG	£1051	£20,828	
Telemetry CTG	£1742	£14,603	
Difference	-£692	£6225	£5533

CTG cardiotocography

Sensitivity analyses were carried out to test the results and the full analyses are presented in appendix A. If the cost of an epidural is lower than these estimates, then using telemetry remains cost effective when the cost of an epidural is £25 or more.

The outcomes for the analysis were based on clinical evidence from a meta-analysis. Women monitored using telemetry had fewer epidurals than women monitored with conventional CTG (77 compared with 110). When using data from a clinical trial there is likely to be uncertainty as the trial setting is unlikely to match the care received in the real world. If the difference in rate of epidurals was smaller, then the cost saving from using telemetry reduces. However, even if the study has over-estimated the effect, telemetry remains cost saving as long as 4 fewer epidurals are performed (106 compared with 110) when using a telemetry system, if all other assumptions in the model are true.

It was suggested that the equipment lasted longer than the 7 years used in the base case scenario. If the monitoring equipment is expected to last 10 years rather than 7 years then the cost per use will be reduced (conventional system £2.57 compared with £3.50; telemetry system £4.27 compared with £5.81) and the cost savings increase when using the telemetry system. A lifespan of 15 years was also suggested, and this would further increase the savings seen with the telemetry system.

Conventional CTG equipment is being replaced by complete telemetry systems. There are also add-on telemetry kits which can be used to adapt conventional systems. Therefore the question of cost effectiveness relates to when telemetry equipment should be bought by a unit. Where a unit finds epidurals are reduced at a rate reflected by the clinical evidence reported here, it is likely that cost savings would be achieved by switching to telemetry before conventional equipment has reached the end of its lifespan.

Using a telemetry system allows women greater mobility than when using a conventional CTG system. This increased movement translates into fewer epidurals according to the clinical evidence. As the cost of an epidural has been estimated at £189, which is considerably greater than the incremental cost per use of telemetry CTG (£2.30 more than the cost per use of a conventional system) then using telemetry is likely to result in cost savings.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that outcomes relating to mode of birth and length of labour were clinically important outcomes, and that outcomes relating to women's experience of labour, birth and mobility during labour would additionally be priorities for women. They also felt that it was vital to assess the comparative effectiveness of telemetry and conventional monitoring for preventing adverse neonatal outcomes.

Consideration of clinical benefits and harms

The guideline development group discussed the fact that monitoring with telemetry did not appear to have an effect on mode of birth, when compared with conventional CTG. The group did note that there was a significant reduction in the proportion of women using epidural in the telemetry group, although this did not translate into a reduction in women using other forms of pain relief or a significant difference in the number of women using no pain relief.

The group discussed the evidence around length of labour and concluded that there was evidence of little difference between the 2 types of monitoring. While they noted that Flynn et al. (1978) found a significantly shorter first stage in the telemetry arm, it was a small study which was poorly reported and did not report restricting its study population to low risk women. All of the other studies reporting measures of length of labour did not find a difference between women monitored with telemetry and those monitored conventionally.

The group noted that no differences had been found for the neonatal outcomes reported, but that overall the neonatal outcomes had been quite poorly reported in the studies and the studies were underpowered for rare adverse outcomes. From their clinical experience, the group members agreed that there was no particular reason to suspect that neonatal outcomes would be different between the 2 groups, provided that mobilisation was appropriate.

The group discussed the evidence that was reported about women's experience. They agreed that there was weak evidence that women might prefer being monitored with telemetry, but that overall the quality of the evidence was quite poor. From their clinical experience, they agreed that women tended to prefer telemetry as they valued the opportunity to be more mobile and not be restricted during labour. Anecdotally, they felt that this tended to have a positive effect on progress of labour and might affect women's need for pain relief. The group did acknowledge that even with telemetry women are not fully mobile during labour, but their ability to be mobile is better than with conventional CTG monitoring.

Consideration of health benefits and resource uses

Conventional CTG systems can now only be replaced with complete telemetry monitoring systems. Additionally, there is add-on telemetry equipment that can be used to adapt a conventional monitoring system. Therefore, it is likely that obstetric units will be moving towards greater use of telemetry systems.

It has been demonstrated that using a telemetry system for monitoring results in a reduction in the need for epidurals as women have more mobility than with conventional monitoring. Telemetry systems are more expensive than conventional equipment but the increased capital costs are offset by savings due to the reduced rate of epidurals. The cost per use of a telemetry system is far less than the cost per epidural (£5.81 compared with £380). The evidence has demonstrated that the move to telemetry for monitoring is likely to result in cost savings. Where telemetry is introduced, it is important that staff are educated in the use of the equipment to avoid transducers being lost.

Quality of evidence

The evidence was generally of low or very low quality and the guideline development group was disappointed that better quality evidence was not available. The group noted that the studies were generally small, had methodological weaknesses and were quite old. In addition, they noted issues of indirectness in the study populations – in particular, they discussed the fact that Hodnett et al. only included married women with an uncomplicated vaginal birth, and

that Flynn et al. did not report its inclusion or exclusion criteria. They agreed that this undermined the applicability of the evidence to low risk women in labour, but when combined with their clinical experience, the group members felt that overall the evidence was sufficient to make recommendations. In order to try and prompt further research in this area, they drafted a research recommendation to directly compare conventional CTG with CTG using telemetry.

Recommendations

151. Offer telemetry to any woman who needs continuous cardiotocography during labour. [new 2014]

Research recommendations

18. In women that require continuous electronic fetal monitoring during labour, what is the effectiveness of cardiotocography using telemetry compared with conventional cardiotocography?

Population: all women requiring continuous electronic fetal monitoring during labour
Intervention: continuous cardiotocography using telemetry
Comparator: conventional cardiotocography
Primary Outcome: neonatal outcomes (including long term outcomes at 2 years)
Secondary outcomes: length of labour, use of pain relief, women's experiences.
Study design: observational study

Why this is important

The use of telemetry to monitor the fetal heart rate and uterine contractions in labour has the potential to enable women to be more mobile and active than with conventional monitoring. There is very little recent research evidence exploring whether the use of telemetry in labour to continuously monitor the fetal heart rate and uterine contractions has any effect on neonatal outcomes, length of labour or use of pain relief. Women's experiences of telemetry also remain an area for investigation. Both quantitative and qualitative aspects of telemetry use in labour should be explored and the cost effectiveness of telemetry cardiotocography evaluated.

Women's views and experiences of fetal monitoring

Review question

What are women's views and experiences of fetal monitoring in labour?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

Five studies (Parisaei et al., 2011; Mangesi et al., 2009; Hindley et al., 2008; Hansen, et al., 1985; Shields, 1978) are included in this review. Of the studies, 2 were conducted in the UK (Parisaei et al., 2011; Hindley et al., 2008), 1 in South Africa (Mangesi et al., 2009), 1 in Denmark (Hansen, et al., 1985) and 1 in Canada (Shields, 1978).
Each of the 5 studies looked at different comparisons. A recent descriptive study (Parisaei et al., 2011) evaluated the acceptability of a fetal electrocardiographic (STAN) monitoring system by women at a London Hospital. One study (Shields, 1978) examined women's views and experiences of internal (using a fetal scalp electrode) electronic fetal monitoring during labour. One study (Hindley et al., 2008) surveyed women's preferences of fetal heart rate monitoring methods before and after labour by means of antenatal and postnatal questionnaires. One study (Hansen, et al., 1985) compared women's views of cardiotocography (CTG) with intermittent auscultation. A final study (Mangesi et al., 2009) examined women's preferences regarding 3 methods used to monitor their baby's heart rate: CTG, a fetal stethoscope and a hand-held Doppler ultrasound fetal heart rate monitor. Each

method was applied for only 10 minutes and then the women's preference was assessed. For further details of the included studies see the evidence table (appendix I).
All included studies are observational studies with considerable limitations.

Evidence profile

The findings for the women's views and experiences of fetal monitoring in labour are categorised in 2 sections:

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

Table 118: Findings for women's views and experiences of fetal monitoring in labour

Women's views/experiences of STAN	
Parisaei et al., 2011 [Very low quality][a,b]	Acceptability: 95% of women felt that the ST analysis device was an acceptable way of monitoring their babies in labour. Reassurance: 96% of women felt reassured by having a fetal electrocardiogram (ECG) as an adjunct to electronic fetal monitoring (EFM) to monitor their babies in labour Women's understanding: 95% of women felt that they understood the physiological basis behind the ST analysis device Midwife: 93% of women reported that the midwife explained why their babies were being monitored continuously. Doctor: 99% of women reported that obstetricians explained why their baby was being monitored continuously. Future use: 93% of women reported that they would consent to be monitored in the same way in their future labours. Recommendations: 89% of women reported that they would recommend the system to their friends who were pregnant. The majority would only recommend it if their friends were high risk and needed continuous fetal monitoring.
Women's views and preferences for different methods of fetal monitoring (fetal stethoscope, Doppler ultrasound monitor, CTG	
Mangesi et al., 2009 [Very low quality][c]	First maternal preference: Doppler n=72/97; fetal stethoscope n=13/97; CTG n=12/97 p=0.001 (Doppler vs. fetal stethoscope) p=0.08 (fetal stethoscope vs. ECG) Second maternal preference: fetal stethoscope n=58/97; CTG n=22/97; Doppler n=17/97 The fetal stethoscope was disliked because of causing discomfort during its use and CTG was disliked because it often confined women to bed and the use of the securing belts associated with CTG restricted women's movements.
Women's views and experiences of CTG compared with intermittent auscultation (IA)	
Hansen, et al., 1985 [Very low quality][d]	Maternal preference antenatal interview (total n=655): CTG n=259/655 (39.5%); IA n=212/655 (32%); undecided 184/655 n=(28%) Postnatal interview total (n=385): From CTG preferred antenatally (CTG-p) and IA preferred antenatally (IA-p), n=179 had IA and n=102 had CTG. Of the n=104 undecided antenatally n=69 had IA and n=35 CTG.

	Advantage and disadvantages of IA mentioned postpartum by women who had their labour monitored by IA (IA-p n=85 and CTG-p n=94): No pain to the baby IA-p: 11% CTG-p: 3% p<0.05 No discomfort from sensors and belt IA-p: 58% CTG-p: 30% p<0.05 Increased contact with the personnel IA-p: 25% CTG-p: 15% p<0.05 More natural childbirth IA-p: 72% CTG-p: 45% p<0.05 Advantage and disadvantages of EFM mentioned postpartum by women who had their labour monitored by EFM (IA-p n=36 and CTG-p n=66): EFM promoting husband involvement IA-p: 25% CTG-p: 45% p<0.05 More positively influenced by EFM signal (sound/trace of heartbeat) IA-p: 31% CTG-p: 67% p<0.01 Possibility of quick intervention IA-p: 44% CTG-p: 62% p<0.05 Continuous precise surveillance IA-p: 45% CTG-p: 70% p<0.05 Enforced immobility IA-p: 22% CTG-p: 20% p<0.05

	"Technical milieu" IA-p: 25% CTG-p: 3% p<0.05 Disturbance from EFM signals (sound) IA-p: 20% CTG-p: 3% p<0.05 Fear of the trauma to the child IA-p: 5% CTG-p: 2% p<0.05 Distribution of postpartum preference as to future fetal surveillance CTG-p who had their labour monitored by IA - preference in future pregnancy Prefer IA again: 53% Prefer CTG: 42% Undecided: 5% IA-p who had their labour monitored by CTG - preference in future pregnancy Prefer IA: 59% Prefer CTG again: 32% Undecided: 9% Women who were undecided who had their labour monitored by IA - preference in future pregnancy Prefer IA again: 55% Prefer CTG: 27% Undecided: 19% Women who were undecided who had their labour monitored by CTG - preference in future pregnancy Prefer IA: 17% Prefer CTG again: 60% Undecided: 23%
Hindley et al., 2008 [Very low quality][e]	Sources of information Antenatal survey: Felt midwife had not explicitly given any information on monitoring n=41/63 (65%) Felt had the information from media n=36/63 (57%) Women relied on their past experience n=29/63 (46%) Women's preference for CTG Antenatal survey (n=63):

	Women did not prefer one specific option, the majority preferred a combination of intermittent and continuous CTG n=35/63 (56%) Postnatal survey (n=38): Number of women received CTG (intermittent or continuous) n=23/38 (61%) Women's preference for decision making about intrapartum fetal monitoring Antenatal survey: Women wanted to make the final decision after considering midwife's view: n=28/63 (44%) Postnatal survey: Women had conceded decision making to midwife in intrapartum period n=14/38 (37%) Choice/control preference Antenatal survey: Not received enough information and discussion to make a choice regarding fetal monitoring method n=25/ 63 (40%) Postnatal survey: Felt that they have been given informed choice n=15/38 (39%) Importance of information Antenatal survey: Women were aware of different types of monitoring n=59/63 (94%) Knew all type of monitoring except pinnard's stethoscope n=46/63 (73%) Felt it is very important to have information on intrapartum fetal monitoring n=54/63 (86%) Postnatal survey: Felt it is very important to have information on intrapartum fetal monitoring n=15/38 (39%)
Shields, 1978 [Very low quality][f]	Women's experiences of internal electronic monitoring Women's responses categorised as positive: n=22/30 (Includes 3 classed as highly positive) Women's responses categorised as negative: n=8/30 (Includes 2 classed as highly negative) From the 3 women who had a highly positive score, one woman said she "knew exactly what was going on and therefore was not afraid". The second woman was "a little frightened" but, she thought it was "exciting idea" and compared with her other birth "monitoring seemed to make it shorter and more interesting", and the third woman considered monitoring "a fantastic, good idea" From the 2 women who had highly negative scores, both only partially understood why they were monitored. One woman quoted "too little information about the equipment" and "didn't like the idea of attaching it to the baby's head" and the other

	woman stated that she “felt like a battery being charged with all those wires and connections”. Understanding the reason for monitoring Good understanding: n=27/30 Partially understood: n=3/30 (n=2/3 were women with high negative score in category above) Information received Adequate: n=27/30 (20 said that had full information and 7 said they received as much as they requested) Inadequate information received: n=3/30 Worries about monitoring No worries n=7/30 Some worries different from pregnancy n=11/30 (4 expressed fears related to the electrodes) Some worries same as pregnancy n=12/30 (fearing that baby would be deformed in some way or die) Complaints about monitoring Unable to get comfortable Noise of fetal heart beat (n=2, both had fears that heartbeat would stop. One woman stated “worried the whole time that baby’s heart would stop if the machine stopped”) Presence of nurse as a support All women wanted the nurse with them much or most of the time and n=17/30 women wanted the nurse only for supportive care, they wanted “someone to hold onto”; “someone who cares”. Complaints about caregivers n=4 women expressed negative views about the clinicians. Two out of these 4 women considered the facial expression of physician was frightening. The other 2 women thought that some staff were unfamiliar with the machine and found this disturbing. One woman thought that clinicians had more interest in the machine than they did in her, she said "they all came with the machine and they all left with the machine".

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

a. Population consisted of women with high-risk pregnancy (diabetes, pre-eclampsia, previous caesarean section) or intrapartum risk factors (meconium stained liquor, oxytocin augmentation). 78% of the population were believed to be low risk at their antenatal booking
b. Unclear if the questionnaire was a validated tool or not. Questionnaire response rate was 61% (77/125). Unclear how and by whom data were analysed. Unclear what explanation given to women about reasons why her baby was monitored continuously in labour. 13.3% of study population had difficulty understanding English. Unclear if women received unbiased information about ST analysis and how the way baby’s wellbeing was assessed
c. No sample characteristics reported. Women provided with the study information when they were in labour. Consent obtained verbally. Intervention applied for a very short period of time (10 min each monitoring method). Not clear when participants were asked about their preference. Women’s parity and previous experience not reported. Poor report with limited information provided
d. Unclear if the outcome assessors were blinded to the study group allocation. No inclusion and exclusion criteria specified. Significantly more women in EFM-p group had high-risk pregnancy. No subgroup analysis performed based on women’s parity and their previous experience. 41% of study population were not available for postnatal interview, the reason is not specified.
e. Participants recruited from two different hospitals, the potential influence of different setting should be considered when interpreting the data. 50% of the study population were multigravida, the potential influence of previous experiences of fetal monitoring are not taken account of by the authors. 40% loss to follow up.

f. Data and results poorly reported. Very old study, advances in technology should be considered when interpreting the data. A self-developed scale used with unclear validity. 18/30 women were multiparous.

Evidence statements

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

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

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

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

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that it was fundamental to consider women's views of, and satisfaction with, the type of fetal monitoring they receive. Monitoring has the potential to reduce a woman's fear and anxiety and provide reassurance. However, the group was aware that often monitoring can have the opposite effect and increase a woman's anxieties and discomfort. It is therefore important to identify how best to ensure women's satisfaction with the monitoring that they receive and how best to support evidence-based informed choice.

Consideration of clinical benefits and harms

The guideline development group recognised that 1 study investigating the use of ST wave analysis as a component of fetal monitoring demonstrated extremely positive findings. However, the group felt the findings from the study did not reflect their experience in practice and questioned the validity of the study. They noted that a large proportion of the study sample was made up of women with some form of risk factor and felt that this had the potential to impact on the findings (see below).

The group recognised that some of the comments from the surveys highlighted the importance of information giving and providing reassurance to women. The group acknowledged the importance of giving women accurate information about what cardiotocography (CTG) can and can't achieve, so that women understand the reasons for considering the use of continuous

electronic monitoring and that their expectations are valid. They queried whether it would be appropriate for a midwife to have a discussion with a woman about choice of monitoring when she is in labour. It was agreed that it would be more appropriate if the discussion and provision of information was to happen antenatally, and therefore did not feel it was appropriate to make a recommendation for provision of information regarding women's plans for monitoring in the intrapartum period.

In terms of women's monitoring preference, the group noted a general trend in the evidence in favour of intermittent auscultation. Although the group felt that this should be recognised and supported by healthcare professionals, they did not feel that there was sufficient evidence to support a recommendation.

The group considered women's views on CTG monitors. In 1 qualitative study, women expressed their concerns that the CTG monitor can become the focus of attention in labour rather than the woman. This matched the experience of all of the guideline development group members who reflected that they were all aware of this phenomenon. The group agreed that whatever form of monitoring is used, it is important to ensure that the woman and her baby remain the focus of attention. The group was also aware that the monitor can often be incorrectly used in place of one-to-one care, with women left alone on the monitor. The group agreed that this was poor practice and that it is important that healthcare professionals should stay with the woman in order to provide one-to-one support and to monitor both her condition and the baby's condition.

Consideration of health benefits and resource uses

There were no specific considerations relating to resource use for this question.

Quality of evidence

The evidence available for this review consisted of retrospective and prospective observational studies. There was general agreement that the quality of the studies was extremely poor. It was noted that the studies had considerable limitations and a high risk of bias in both data collection and analysis. The guideline development group also noted that a number of studies included a significant proportion of high risk women. It was felt that this could potentially impact on the results as women identified as being high risk might be more likely to want the reassurance of electronic fetal monitoring.

The group recognised the difficulty in trying to determine women's preferences for a particular type of monitoring when each individual woman will generally only experience a single type. They noted that 1 study had tried to ensure that women experienced all types of monitoring but expressed frustration that each type of monitoring had only been used for 10 minutes.

Other considerations

The guideline development group acknowledged that the evidence base for this question was very poor and that it was a topic that merited further investigation. They also noted that the use of central electronic fetal monitoring systems and telemetry was increasing and felt that little was known about how these might impact upon a woman's experience of birth and the care she receives. In light of this, the group drafted research recommendations to explore women's perceptions and experiences of different types of fetal monitoring, and to evaluate its impact on the communication between the midwife and the woman and the provision of one-to-one care.

Recommendations

See recommendation 108.

Cardiotocography with fetal electrocardiogram analysis compared with cardiotocography alone

Review question

Does the use of fetal electrocardiogram (ECG) analysis with continuous electronic fetal monitoring (EFM) improve outcomes when compared with continuous EFM alone?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

One study (Neilson, 2013) is included in this review. Neilson (2013) is a systematic review with 6 component trials from a variety of locations. All of the included trials in the systematic review compared the use in labour of continuous electronic fetal monitoring plus fetal electrocardiogram (ECG) with continuous electronic fetal monitoring alone. Five trials of ST waveform analysis and 1 trial of PR interval analysis are included in the systematic review (Neilson, 2013). All women included in the trials were at high risk of developing complications in labour. The duration of the monitoring using continuous electronic fetal monitoring and ECG is not reported in the included trials.
Although the wording of this question refers to electronic fetal monitoring it is apparent that in practice studies are referring to electronic fetal monitoring plus monitoring of contractions. This is more accurately termed cardiotocography (CTG) and therefore this term will be used in this evidence summary and throughout the guideline.

Evidence profile

A fixed effects model was used for these analyses, with the exception of 1 outcome (cord PH less than 7.05 plus base deficit more than 12 mmol/L) for which a random effects model was used due to high heterogeneity (I2 equal to 62%).
Sub-group analysis was performed for:

- PR analysis
- ST analysis.

Table 119: Summary GRADE profile for comparison of continuous CTG plus fetal electrocardiogram (ECG) PR interval analysis with continuous CTG alone in labour

Number of studies	Design	Number of women		Effect		Quality
		CTG plus fetal ECG	CTG alone	Relative (95% CI)	Absolute (95% CI)	
Caesarean section - PR analysis						
1 study (Neilson, 2013)	randomised trials	79/482 (16.4%)	98/475 (20.6%)	RR 0.79 (0.61 to 1.04)	43 fewer per 1000 (from 80 fewer to 8 more)	Very Low
Operative vaginal delivery - PR analysis						
1 study (Neilson, 2013)	randomised trials	116/482 (24.1%)	122/475 (25.7%)	RR 0.94 (0.75 to 1.17)	15 fewer per 1000 (from 64 fewer to 44 more)	Very Low
Fetal and neonatal death - PR analysis						
1 study (Neilson, 2013)	randomised trials	1/482[a] (0.21%)	0/475 (0%)	RR 2.96 (0.12 to 72.39)	NC	Very Low
Admission neonatal special care unit - PR analysis						
1 study (Neilson, 2013)	randomised trials	22/482 (4.6%)	28/475 (5.9%)	RR 0.77 (0.45 to 1.33)	14 fewer per 1000 (from 32 fewer to 19 more)	Very Low
Apgar score <7 at 5 minutes - PR analysis						
1 study (Neilson, 2013)	randomised trials	3/482 (0.62%)	7/475 (1.5%)	RR 0.42 (0.11 to 1.62)	9 fewer per 1000 (from 13 fewer to 9 more)	Low
Neonatal intubation - PR analysis						

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Number of studies	Design	Number of women		Effect		Quality
		CTG plus fetal ECG	CTG alone	Relative (95% CI)	Absolute (95% CI)	
1 study (Neilson, 2013)	randomised trials	6/482 (1.2%)	8/475 (1.7%)	RR 0.74 (0.26 to 2.11)	4 fewer per 1000 (from 13 fewer to 19 more)	Low

CI confidence interval, CTG cardiotocography, ECG electrocardiogram, NC not calculable, RR relative risk

a. Baby was born by forceps, the cord blood pH was 7.14 and the base excess was -12 mmol/l. Apgar was 8 at 1 min and 9 at 5 min. The baby was in good condition for 36 hours, then had respiratory arrest on the postnatal ward and died 12 hours later. No reason for this sudden death was found.

Table 120: Summary GRADE profile for comparison of continuous CTG plus fetal electrocardiogram (ECG) ST waveform analysis (STAN) with continuous CTG alone in labour

Number of studies	Design	Number of women		Effect		Quality
		CTG plus fetal ECG	CTG alone	Relative (95% CI)	Absolute (95% CI)	
Caesarean section - ST analysis						
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	876/7697 (11.4%)	878/7641 (11.0%)	RR 0.99 (0.91 to 1.08)	1 fewer per 1000 (from 9 fewer to 8 more)	Low
Instrumental vaginal birth - ST analysis						
1 meta-analysis of 4 studies (Neilson, 2013)	randomised trials	660/4870 (13.6%)	731/4801 (15.5%)	RR 0.89 (0.81 to 0.98)	18 fewer per 1000 (from 3 fewer to 31 fewer)	Moderate
Fetal and neonatal death - ST analysis						
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	8/7697 (0.1%)	5/7641 (0.1%)	RR 1.49 (0.53 to 4.18)	0 more per 1000 (from 0 fewer to 3 more)	Low
Cord pH<7.05 + base deficit >12 mmol/l - ST analysis						
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	78/7318 (1.0%)	113/7256 (1.5%)	RR 0.78 (0.44 to 1.37)	3 fewer per 1000 (from 7 fewer to 4 more)	Very Low
Neonatal encephalopathy - ST analysis						

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Number of studies	Design	Number of women		Effect		Quality
		CTG plus fetal ECG	CTG alone	Relative (95% CI)	Absolute (95% CI)	
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	8/7678 (0.1%)	15/7624 (0.2%)	RR 0.54 (0.24 to 1.25)	1 fewer per 1000 (from 2 fewer to 1 more)	Moderate
Admission neonatal special care unit - ST analysis						
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	615/7678 (8%)	685/7624 (9%)	RR 0.89 (0.81 to 0.99)	4 fewer per 1000 (from 0 fewer to 7 fewer)[a]	Low
Apgar score <7 at 5 minutes - ST analysis						
1 meta-analysis of 5 studies (Neilson, 2013)	randomised trials	103/7678 (1.3%)	107/7624 (1.4%)	RR 0.95 (0.73 to 1.24)	1 fewer per 1000 (from 3 fewer to 3 more)	Low
Neonatal intubation - ST analysis						
1 study (Neilson, 2013)	randomised trials	7/714 (0.98%)	9/722 (1.2%)	RR 0.79 (0.29 to 2.1)	3 fewer per 1000 (from 9 fewer to 14 more)	Moderate

CI confidence interval, CTG cardiotocography, ECG electrocardiogram, RR relative risk

a. 39 fewer per 10,000 (from 4 fewer to 68 fewer)

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Evidence statements

PR analysis

Findings from 1 study (n=957) indicated that there was no evidence of a significant difference in the rate of caesarean section and operative vaginal birth for women and fetal and neonatal death, admission to neonatal intensive care unit (NICU), Apgar score less than 7 at 5 minutes and neonatal intubation for babies born to women who received continuous CTG plus fetal ECG compared with women who received continuous CTG only. The evidence was of low to very low quality.

ST analysis

There was evidence from over 15,000 women that the rate of instrumental birth for women and admission to NICU was significantly lower for babies born to women who received continuous CTG plus fetal ECG compared with babies born to women who received continuous CTG only. There was no evidence of a difference in the rate of caesarean section, fetal and neonatal death, Apgar score less than 7 at 5 minutes, cord arterial pH less than 7.05 plus base deficit more than 12, hypoxic ischaemic encephalopathy and neonatal intubation for babies born to women who received continuous electronic fetal monitoring plus fetal CTG compared with women who received continuous CTG only. The evidence was of moderate to very low quality.

Review of published evaluations

The literature search identified 2 cost effectiveness analyses comparing CTG with ST analysis to CTG alone (Heintz et al., 2008; Vijgen et al., 2011). Neither of the analyses was set in the UK and so they were not useful as evidence for this guideline.

New economic evaluation

In the previous guideline a costing analysis was developed for ECG ST analysis. This compared the additional equipment costs in purchasing ST analysis equipment to the potential savings from reduced operative vaginal births and caesarean sections (NICE 2007). The net cost of ECG ST analysis was £3.4 million.

Given the updated clinical evidence now available, it was decided that a new economic evaluation should be developed for this guideline. The purpose of monitoring is to identify hypoxia before it is sufficient to lead to damaging acidosis and long-term neurological adverse outcome for the baby. Monitoring should provide a balance between correctly identifying the babies who require intervention without over-identifying resulting in levels of intervention that are too high. A full description of this analysis can be found in the appendix.

For women where monitoring is indicated, which method of monitoring is most cost effective? The following comparisons are considered:

- CTG alone
- CTG plus ECG ST waveform analysis.

Monitoring is necessary to identify babies in distress. In these cases intervention is necessary. Good monitoring will allow accurate identification of these situations and prevent unnecessary intervention where possible.

The number of instrumental vaginal births and admissions to neonatal special care units were statistically significantly lower for CTG plus ECG ST analysis. No other outcomes were found to be statistically significantly different. For PR analysis there was no statistically or clinically significant difference for any of the outcomes reported and so no benefit was demonstrated. Therefore, the model was developed for ST analysis only.

The main cost will be purchase of equipment for ST analysis. The cost of purchasing an ST monitor is approximately £25,000 per unit (see appendix A.3.4.1). The ST monitor is fully automated, but if the ST analysis shows a problem then training would be required to interpret

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the scan in order to decide whether to intervene. Midwives would be trained to interpret the ST analysis, with obstetricians called if there is a problem.
The clinical review included serious outcomes such as neonatal death and neonatal encephalopathy. This model should include the long-term costs for these outcomes. Identifying good quality inputs for long-term costs of neonatal intubation was a problem for previous economic evaluations in NICE guidelines (NICE 2011, NICE 2012) and for the Birthplace study (Schroeder et al., 2012) and so long-term costs have not been included in this analysis.
As with the costs, long-term outcomes such as life-years lost and reduced quality of life should be included in the model. Again, no good quality evidence of the long-term effects has been identified. Therefore the estimates used in the Caesarean Section guideline (NICE 2011) have been used for this model. The estimate used in the Caesarean Section guideline was for mild cerebral palsy as a proxy for neonatal encephalopathy.
The incremental cost effectiveness results show CTG plus ECG ST is less expensive but has worse health outcomes than CTG alone (table 121). The number of fetal and neonatal deaths was slightly higher in the CTG plus ECG ST group (0.104% compared with 0.065%; the difference was not statistically significant) and this drives the loss of quality adjusted life years (QALYs).

Table 121: Deterministic costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST analysis

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£2032	27.659			
CTG plus ECG ST	£2020	27.652	–£11.65	–0.007	£1671[a]

CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio

a, An incremental cost-effectiveness ratio can be calculated, however it is important to note that this relates to a cost saving but with a health loss.

If the rate of mortality was the same between the 2 monitoring strategies then CTG plus ECG ST dominates CTG alone, being both less expensive and more effective (table 122).

Table 122: Sensitivity analysis – Rate of fetal and neonatal death is equal in both groups. Costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST monitoring

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£2032	27.648			
CTG plus ECG ST	£2014	27.652	–£11.65	0.004	Dominant

CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio

As the majority of outcomes were not found to be statistically significantly different, the model was run with these outcomes equal for both groups, and only instrumental vaginal births and admissions to special care units included in the analysis. In this analysis, CTG plus ECG ST remains the lowest cost option, but still results in fewer QALYs gained than with CTG alone (table 123).

Table 123: Sensitivity analysis – all outcomes not statistically significantly different are held the same. Costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST monitoring

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£1817	27.669			
CTG plus ECG ST	£1790	26.892	–£26.97	–0.777	£35[a]

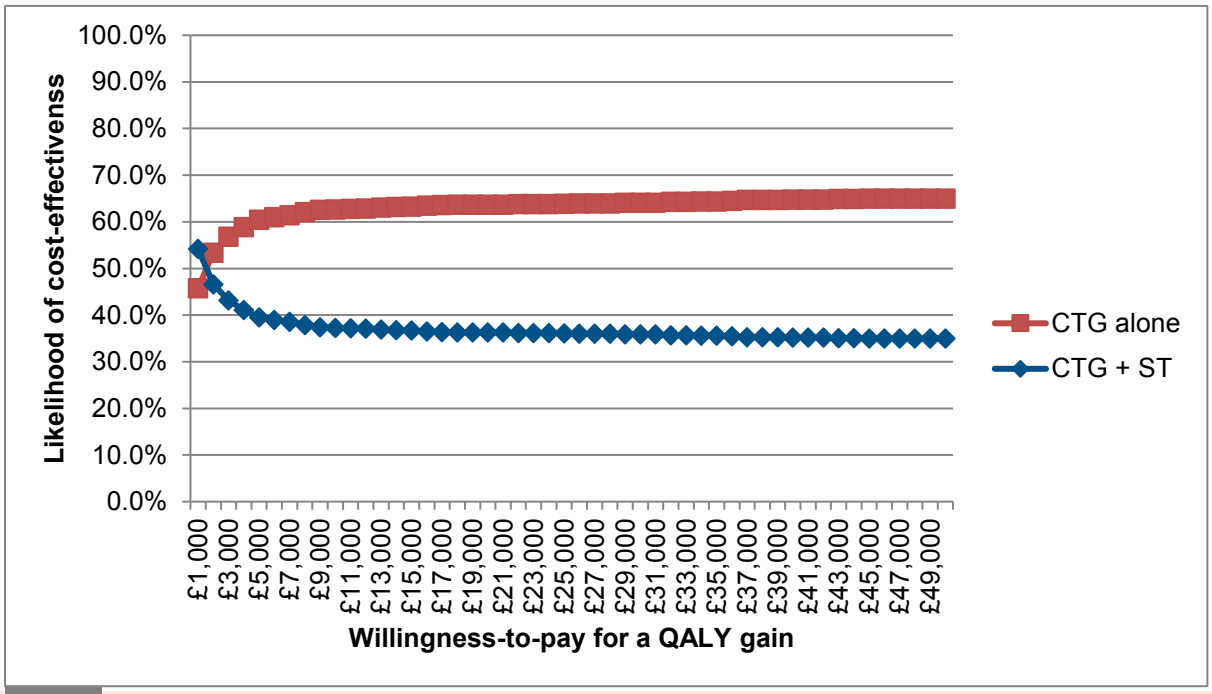
CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio

a. An incremental cost effectiveness ratio can be calculated, however it is important to note that this relates to a cost saving but with a health loss.

Adding ECG ST monitoring to CTG monitoring results in cost savings due to fewer instrumental births and caesarean sections, and fewer neonatal intubations. However, in the base case more fetal and neonatal deaths occur when ECG ST monitoring is added to CTG monitoring and so more QALYs are lost.

The following outcome rates showed no statistically significant difference: caesarean section, neonatal encephalopathy, neonatal intubation, and fetal and neonatal death. The other 2 main outcomes – instrumental births and admission to neonatal intensive care – were close to unity. This introduces considerable uncertainty to the results. The results of the probabilistic sensitivity analysis demonstrated that CTG alone would be the most cost-effective option above a threshold of approximately £2000 per QALY, but with a likelihood of approximately 65% (see figure 1). When the mortality rate is equal between the 2 strategies, adding ECG ST analysis will dominate CTG alone.

Figure 1: Threshold analysis of CTG monitoring and CTG plus ECG ST monitoring



Long term costs of neonatal encephalopathy were not included because data on long term outcomes and costs could not be identified. As neonatal encephalopathy was reduced when ECG ST monitoring is added to CTG monitoring, then adding these long term costs and outcomes would strengthen the case for adding ECG ST monitoring.

Other clinical outcomes were not reported in the studies and could impact the cost effectiveness results. ECG analysis requires invasive procedures: amniotomy, which may increase the pain of contractions; and the application of a fetal scalp electrodes, which can be associated with a small increase in the risk of infection in the baby.

This analysis has shown that adding ECG ST monitoring results in cost savings due to fewer interventions in birth, but also reduced effectiveness due to increased fetal and neonatal death (although the clinical results were not statistically significant). However, given the uncertainty in the clinical results due to a number of outcomes not reaching a statistically significant difference, these cost effectiveness results should be used with caution as the study results may not transfer to the real world. Further evidence taken from a UK setting where the outcomes of women can be followed through a pathway of care would help with understanding how monitoring could improve final outcomes.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised the outcomes of mode of birth and neonatal encephalopathy. These were felt to be both clinically significant and mode of birth also important for the woman's experience of labour and birth. The group did not feel that it was appropriate to identify 'the need for use of fetal blood sampling' as a priority outcome because the need for fetal blood sampling is reduced when fetal electrocardiogram (ECG) is used according to the ST analysis protocol.

Consideration of clinical benefits and harms

For PR waveform analysis, the guideline development group noted there was no statistically or clinically significant difference for any of the outcomes reported, thus no benefit has been demonstrated for this type of ECG analysis.

The group next considered ST waveform analysis of the fetal ECG. The group considered the evidence from the original IPC guideline for this intervention. It noted that there was new evidence available since the publication of the original guideline, and that meta-analysis of these trials had altered the statistical significance of 2 priority outcomes. The rate of neonatal encephalopathy, which was reported as statistically significantly lower for babies monitored using CTG plus ECG in the previous review, was non-significant in the updated review, with 2 more trials contributing to the findings for this outcome. In contrast, the rate of admission to the neonatal care unit was significantly lower in the CTG plus ECG group, which was reported as non-significant in the previous guideline. The guideline development group noted that, in line with findings from the original review, women in the CTG plus ECG group had a significantly lower incidence of instrumental vaginal birth compared with women monitored with CTG only. The guideline development group also recognised that there was no significant difference observed between the CTG plus ECG group and CTG alone group for other outcomes, including caesarean section rate and neonatal death. However, it was noted that the total number of women in the meta-analyses remains underpowered for rare events such as neonatal death.

The guideline development group recognised that 2 outcomes suggested a benefit of using ST wave analysis of the fetal ECG in conjunction with CTG, 1 maternal (vaginal instrumental birth) and 1 neonatal (admission to a neonatal special care unit). They considered the numbers needed to treat to avoid an admission to a neonatal special care unit. An estimated 101 women would need to be monitored with CTG plus ECG rather than CTG alone to avoid 1 neonatal admission to neonatal intensive care. The number needed to treat to avoid 1 vaginal instrumental vaginal birth was estimated as 60. For the priority outcome of neonatal encephalopathy there were approximately half the number of incidences observed in the CTG plus ECG group compared with the CTG alone group (number needed to treat = 1105), although this difference was not statistically significant. The guideline development group noted that the severity of this encephalopathy was not reported in the paper.

The guideline development group also recognised the potential disadvantages of using ECG analysis in conjunction with CTG. In order to monitor using ECG analysis, the invasive procedures of amniotomy and the insertion of a fetal scalp electrode need to be performed. Amniotomy was felt by some guideline development group members to be associated with an increase in the pain of contractions and the application of a fetal scalp electrode was acknowledged to be associated with a small increase in the risk of trauma to, and infection in, the baby,

Consideration of health benefits and resource uses

The guideline development group noted that use of ECG analysis involved the capital cost of purchasing the ST analysis monitors (approximately £25,000 per machine), and investment in training all midwives and obstetricians (those involved in providing intrapartum care in the obstetric unit) how to use the monitors. Although the cost of purchasing the ST analysis monitors is high, the cost per use will be minimal given the lifetime of the machine and number of births requiring monitoring. However, where there were differences in clinical outcomes between the two monitoring strategies, they were small (for instrumental births it was 15.2% using CTG alone compared with 13.6% when using ST monitoring; and for admission to neonatal special care unit it was 9% with CTG alone compared with 8% using ST monitoring) and in most outcomes there was no difference (caesarean section, fetal and neonatal death, neonatal encephalopathy, neonatal intubation). The capital costs may be offset by downstream cost reductions through fewer interventions during birth and reduced admission to neonatal special care, but there is considerable uncertainty as the differences between the monitoring strategies are so small.

Quality of evidence

The guideline development group noted that the quality of evidence varied, being moderate or low for the critical outcomes considered priorities for this review. This lack of high quality evidence, particularly the lack of power for the meta-analysis to provide valid findings in relation to rare adverse neonatal outcomes, contributed towards the group's reticence in recommending the use of ECG analysis.

Other considerations

The group was aware of a large ongoing trial in the US which was designed to evaluate the use of ST waveform analysis in conjunction with CTG compared with CTG alone. The group felt that this trial was likely to provide pertinent results which had the potential to affect any recommendations that the group made and therefore felt it inappropriate to make recommendations prior to these findings being published.

Key conclusions

Given the available evidence, the finding of no significant differences observed for the majority of key outcomes and the poor quality of studies, along with the high degree of uncertainty associated with the health economic analysis, the guideline development group felt that recommending the use of ECG in conjunction with CTG is not justified.

Computerised systems versus human interpretation

Introduction

A new review of computerised systems in FHR trace interpretation was undertaken.

Previous guideline

The Use of Electronic Fetal Monitoring guideline includes computerised interpretation of FHR tracings.[460] The same six studies are included as are reviewed here. The summary of evidence concludes that: The use of computerised systems for FHR analysis improves consistency of interpretation. A research recommendation was for further evaluation of the effectiveness of computerised analysis, or decision analysis programs, in the interpretation of the CTG.

Description of included studies

Six studies were identified for review in this section. Five of these studies compared computerised interpretation of FHR tracings with expert interpretation. All studies included women with pregnancy and/or intrapartum complications.

Review findings

A rigorous multicentre comparative study undertaken in the UK investigated whether a computerised system could obtain a performance in labour management comparable with experts when using FHR tracings, obstetric information and FBS. It also investigated the degree of agreement between experts.[495] [EL = II] Seventeen peer-nominated experts were selected from 16 UK maternity units to review 50 complete intrapartum FHR tracings. The 50 tracings were selected to represent a range of possible variables and outcomes and all were obtained from women with high-risk labours. The expert reviewers were also given clinical information pertaining to the progress of labour, and could request findings from FBS to supplement this information. Each expert performed the assessments twice (in a different order), with an interim period of 1 month in order to assess intra-rater reliability. Consistency (intra-rater reliability) of ratings for each reviewer was high, ranging from 73.18% to 89.04% (kappa 0.43 to 0.77). Consistency of ratings for the computerised system was 99.16%. Agreement between reviewers (inter-rater reliability) ranged from 58.17% to 74.27% (kappa 0.12 to 0.46). Agreement between the computerised system and the obstetricians was 67.33% (kappa 0.31). In the 11 cases where the computerised system recommended CS, on average 18/34 (52.9%) of the expert reviews also recommended CS within 15 minutes of the system. An average of 23/34 (67.6%) did so within 30 minutes of the system. Only two reviewers and the computerised system consistently recommended no unnecessary intervention. Twelve examples of poor outcome were included in the sample. Poor outcome fell into one of three categories as follows: birth asphyxia (cord arterial pH < 7.05 and base deficit ≥ 12, Apgar score at 5 minutes ≤ 7 with neonatal morbidity); metabolic acidosis (cord arterial pH < 7.05 and base deficit ≥ 12, Apgar score at 5 minutes > 7 with no neonatal morbidity); acidosis (cord arterial pH < 7.05 and base deficit < 12 with neonatal morbidity). The system detected two of the three incidents of birth asphyxia, two of the four incidents of metabolic acidosis and two of the five incidents of acidosis with no significant metabolic component. This was as good as the majority of experts for birth asphyxia, but fewer than for all reviewers for metabolic acidosis, and fewer than all but one of the reviewers for acidosis.

A small prospective observational study (UK, 2000) compared computerised interpretation of 24 intrapartum FHR tracings with expert ratings.[496] [EL = II] Analysis was performed on 25 minute sections of tracing.

Inter-rater reliability between the seven experts was good for baseline FHR (r = 0.93), number of decelerations (r = 0.93) and type of decelerations (r = 0.93). Inter-rater reliability for baseline variability was poor (kappa = 0.27), as it was for accelerations (r = 0.27). Computerised interpretation of the tracings showed good agreement with the experts regarding baseline FHR (r = 0.91 to 0.98) and the number of decelerations (r = 0.82 to 0.91). Intra-class correlations were lower for the number of late decelerations (r = 0.68 to 0.85) and the number of accelerations (r = 0.06 to 0.80). There was no agreement between computerised interpretation and expert interpretation for baseline variability (kappa = 0.00 to 0.34).

A similar observational study conducted in Italy (1996) compared interpretations of 63 FHR tracings made by two experts (obstetric consultants), two non-experts (obstetricians with 1 year of experience) and a computerised system.[497] [EL = III] The study population included women with pregnancy complications and preterm labour. 'Randomly' selected 25 minute sections of tracing were used for analysis. Reliability between expert and non-expert observers for FHR, baseline variability, number of accelerations and number of decelerations was fair to good (kappa ratings ranging from 0.38 to 0.67). Only 17 tracings included decelerations. Agreement regarding type of deceleration was poor (kappa = 0.05). Agreement

between computerised interpretation and observers was fair to good for most ratings of variability (kappa = 0.16 to 0.74), number of accelerations (0.37 to 0.64) and number of decelerations (0.41 to 0.54). Agreement for FHR baseline and type of decelerations was poor (kappa = 0.18 to 0.48 and kappa = 0.01 to 0.25, respectively).

A UK retrospective observational study assessed the ability of a computerised system for FHR tracing analysis to predict fetal acidosis at birth.[498] [EL = III] Analysis was undertaken of 73 complete FHR tracings for labours lasting more than 3 hours. An umbilical artery pH of < 7.15 was used to define acidosis at birth. Using this definition, 8/73 babies (11%) were found to have acidosis and 65 (89%) were classified as normal. The computer system classified 50 babies (69%) as normal, of whom 49 (98%) had an umbilical artery pH > 7.15. Of the 23 babies (31%) identified by the computer system as having acidosis, 7 (30%) had a pH < 7.15. The overall accuracy of the computer system was 77%, with a sensitivity of 88% and a specificity of 75%. Similar calculations were performed for base excess, with < −8 mmol/l as the cut-off point. Fifty-six of the 73 babies (77%) had a normal base excess and 17 (23%) were classified as abnormal. The computer system identified 50 (69%) babies as normal, 46 (92%) of whom had a base excess of ≥ −8 mmol/l. Of the 23 babies (31%) classified by the computer system as abnormal, 13 (57%) had a base excess < −8 mmol/l. The overall accuracy was 81% with a sensitivity of 76% and a specificity of 82%.

A retrospective observational study (Denmark, 1988) compared interpretations of FHR tracings made by four experienced obstetricians with those made by a computerised system.[499] [EL = III] 50 FHR tracings of the last 30 minutes of the first stage of labour were used for the study. These were classified as either normal or abnormal. The obstetricians were informed of the number of compromised babies within the sample (n = 16), the criterion by which a baby was judged to be compromised and the length of the pregnancies. Babies were considered to be compromised if the 1 minute Apgar score was < 7, the umbilical artery pH was < 7.15 or the standard base excess was < −10 mEq/l, or primary resuscitation was needed. Based on the 30 minute segment of FHR tracing, the computer system was able to indicate whether a baby would be born in a healthy state or compromised with 86% accuracy. However, while the system has a high specificity (94%), positive predictive value (85%) and negative predictive value (86%), its sensitivity is quite low (69%), i.e. it did not identify five of the 16 compromised babies. This was higher than that obtained from the four obstetricians, the best of whom achieved the same degree of sensitivity but only 59% specificity, i.e. correctly identifying 20 of the 34 healthy babies from their FHR tracing.

A retrospective observational study compared FHR tracing interpretations of 12 clinical experts with computerised interpretation (UK/Hong Kong, 1997).[500] [EL = III] Sixty 40 minute sections were classified to determine the baseline FHR. There was high concordance between expert ratings and between computer interpretation and that of experts (r > 0.9). The 95% confidence interval for the difference between computer and expert ratings was −12 to 15 bpm compared with −10 to 10 bpm for the difference between experts.

Evidence statement

Computerised systems have not been demonstrated to be superior to expert interpretation of the FHR trace and no comparisons have been undertaken with routine care.

Research recommendation on computerised system

19. Further study investigating computerised expert systems should be undertaken

Record keeping for electronic fetal monitoring

Review question

How should record keeping be carried out for electronic fetal monitoring?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

No evidence was identified that addressed this question.

Evidence statements

No evidence was identified that addressed this question.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

In addressing this question, the guideline development group hoped to identify evidence which would show the most effective method for record keeping when performing electronic fetal monitoring. In particular, the group had hoped to identify the most effective way of keeping comprehensive and useful notes without imposing an unnecessary administrative burden on healthcare professionals which might be detrimental to the woman's care. The group was aware that there was a view amongst some healthcare professionals that the recommendations from the previous version of the guideline had led to unnecessary duplication of notes.

Unfortunately, no studies were available which addressed this topic.

Consideration of clinical benefits and harms

The guideline development group recognised that the primary intention of medical records is to ensure that all relevant aspects of the woman's care are recorded in order to ensure that she is provided with optimum care, particularly with respect to handover of care from one member of staff to another. They recognised that the records can also be used in medico-legal cases as a record of all of the decisions that were made, and the time that all actions were performed. They felt that it was this second purpose which had been a driver for more comprehensive record keeping and the subsequent duplication of information on both the woman's notes and the CTG trace. The information recorded during the intrapartum period can be of vital importance in these cases, and so it was felt likely that there was a move to record information in 2 places to ensure that if one document was lost, a second document would contain all of the relevant details.

The group agreed that although this is important, the primary focus should always be the care of the woman at the time at which she is receiving care. They noted that there is a recommendation from the previous guideline which states that the CTG trace should be stored securely with the woman's medical records, and that if this is followed, there should be less of a need to duplicate notes.

From their clinical experience, the group members were aware that there can be a large amount of information which needs to be recorded, even during simple labours. If all of this information has to be recorded on both the CTG trace and in the woman's notes, this can result in a significant amount of time spent focusing on writing, rather than on caring directly for the woman. This can be a greater problem in more complicated labours where the number of events which need to be recorded can mount up very quickly.

It was recognised that the recommendations from the previous guideline had placed an emphasis on recording intrapartum events which may affect the CTG trace, and noting the time at which they occurred. This is to make it easier to identify which events were likely to have caused a change in the fetal heart rate, and which actions were undertaken as a response to a changing fetal heart rate. The group agreed that this remains an important principle of record keeping and should be continued.

Taking all of the above into account, the group ultimately agreed that rather than trying to be prescriptive about the precise method of record keeping that should be undertaken, it was more appropriate to set out some important general principles that should be applied in all cases, and then recommend that individual units develop their own systems for recording

notes. It would be at their discretion whether this was done in the woman's notes or on the CTG trace. However, it would then be the responsibility of each unit to ensure that all of its staff used a consistent approach.

Consideration of health benefits and resource uses

The guideline development group did not feel that there was a large issue about resource use for this question, although the group noted that duplication of work without an evident clinical benefit was not a good use of resources.

Quality of evidence

No studies were identified which addressed this question and so the guideline development group developed recommendations based on their clinical expertise and judgement.

Other considerations

The guideline development group noted that the previous recommendation about record keeping in relation to fetal heart rate monitoring did not include mention of the maternal pulse. The group agreed that this was a valuable piece of information to have recorded at the start of monitoring and so amended the recommendations accordingly.

Recommendations

152. To ensure accurate record keeping for cardiotocography:

- make sure that date and time clocks on the cardiotocograph monitor are set correctly
- label traces with the woman's name, date of birth and hospital number or NHS number, the date and the woman's pulse at the start of monitoring. [new 2014]

Update 2014

153. Individual units should develop a system for recording relevant intrapartum events (for example, vaginal examination, fetal blood sampling and siting of an epidural) in standard notes and/or on the cardiotocograph trace. [new 2014]

Risk management in monitoring babies in labour

Introduction

Obstetric litigation is expensive because of the number of cases and the costs of each case. The majority of obstetric litigation claims revolve around FHR trace abnormalities and interpretation. Litigation can ensue many years after alleged harm has been suffered. In order to provide a fair assessment of a case for all parties, FHR traces need to be available and as much information as possible obtained about the causes of poor outcome.

Storage of FHR traces

Description of included studies

This was reviewed in the EFM guideline.[460] No new studies were identified.

Evidence statement (from the NICE EFM guideline)

Storage of FHR traces is complicated due to issues of security, retrieval, space and conservation. FHR traces related to an adverse outcome for mother or baby are more likely to go missing. The quality of some FHR traces deteriorates over time. This could be due to a number of factors including poor quality storage, paper, intense heat, light or moisture.

Recommendations on risk management in monitoring babies in labour

154. Keep cardiotocograph traces for 25 years and, if possible, store them electronically. [2007, amended 2014]

Update 201

155. In cases where there is concern that the baby may experience developmental delay, photocopy cardiotocograph traces and store them indefinitely in case of possible adverse outcomes. [2007, amended 2014]

156. Ensure that tracer systems are available for all cardiotocograph traces if stored separately from the woman's records. [2007, amended 2014]

157. Develop tracer systems to ensure that cardiotocograph traces removed for any purpose (such as risk management or for teaching purposes) can always be located. [2007, amended 2014]

First stage of labour

Introduction

Care during labour should be aimed towards achieving the best possible physical, emotional and psychological outcome for the woman and baby.
The onset of labour is a complex physiological process and therefore it cannot be easily defined by a single event. Although labour is a continuous process, it is convenient to divide it into stages. Definitions of the stages of labour need to be clear in order to ensure that women and the staff providing their care have an accurate and shared understanding of the concepts involved, enabling them to communicate effectively. In order to facilitate this, the guideline aims to provide practical definitions of the stages of labour.

Recommendations on normal labour

158. Do not offer or advise clinical intervention if labour is progressing normally and the woman and baby are well. [2007]

159. In all stages of labour, women who have left the normal care pathway because of the development of complications can return to it if/when the complication is resolved. [2007]

Definition of first stage of labour

Review question

What are the appropriate definitions of the latent and active phases of the first stage, the second stage, and the third stage of labour?

Previous guideline

No previous guideline has considered definitions of the stages of labour.

Description of included studies

No relevant study was identified that investigated outcomes of different definitions of labour. The GDG explored various definitions that have been used in practice and research. Definitions of stages of labour used in six descriptive studies, investigating duration of labour, were used to inform the discussion on definitions of labour.

Review findings

Definitions of the onset of labour may involve the onset of contractions,[277–280] evidence of cervical change[281] or both.[277] While the consideration of contractions alone in defining the onset of labour enables this decision to be reached by women themselves, the inclusion of cervical change means that the onset of labour requires professional confirmation. Within the literature, and in clinical practice, an early or 'latent' phase of labour is recognised. This has been defined as 0–2 cm cervical dilatation[279] and 0–4 cm dilatation,[282–284] and is characterised by a slow rate of cervical dilatation and effacement and contractions that may be irregular in strength and frequency. This is followed by an active first stage of labour. Again, this can be defined solely in terms of cervical dilatation, e.g. 2–10 cm dilatation[279] or 4–10 cm dilatation[282–284] or in a way which includes the experience of the labouring woman, e.g. the onset of regular contractions as perceived by the woman until the commencement of pushing at full dilatation.[280]

GDG interpretation of the evidence

The GDG have adopted the following definition of normal birth for the purpose of this guideline – it is the WHO definition: 'Labour is normal when it is spontaneous in onset, low risk at the start and remaining so throughout labour and birth. The baby is born spontaneously and in the vertex position between 37–42 completed weeks of pregnancy. After birth woman and baby are in good condition'.[285]

Where labour is progressing normally and both woman and baby are well the midwife's role is to offer support (physical and psychological) and to observe the woman and baby. Should it be necessary to offer an intervention it should one that is known, as far as is possible, to be of benefit.

Recommendations on definitions of the first stage of labour

160. For the purposes of this guideline, use the following definitions of labour:

- Latent first stage of labour – a period of time, not necessarily continuous, when:
  - there are painful contractions **and**
  - there is some cervical change, including cervical effacement and dilatation up to 4 cm.
- Established first stage of labour – when:
  - there are regular painful contractions **and**
  - there is progressive cervical dilatation from 4 cm. **[2007]**

Duration of the first stage of labour

Introduction

In considering 'normal' labour, it is important to define the boundaries that distinguish what is normal from what is abnormal. These limits can then be used to inform women and their carers about what to expect, and when it is appropriate for midwives to refer women for an obstetric opinion.

Review question

Do duration and progress of the first and second stages of labour affect outcomes?

Previous guideline

Duration of labour has not been considered in any previous guideline.

Description of included studies

One large (n = 10,979) US cross-sectional study examined duration of the early first stage of labour (unestablished labour) and its effect on outcomes.[278] [EL = 3] A second, much smaller study (n = 30) investigated the effect of duration of the first stage of labour on maternal anxiety.[286] [EL = 3] A further three studies were identified that investigated the total duration of labour and its impact on clinical outcomes.[287–289] In addition, six observational studies were reviewed that described lengths of the first stage of labour and some factors associated with length of the first stage.[277,279,280,282–284] One descriptive study described progress of labour in multiparous women with uncomplicated pregnancies and labours.[290]

Review findings

One US cross-sectional study (n = 10,979) investigated prolonged latent phase of labour and intrapartum outcomes.[278] [EL = 3] Logistic regression analysis controlling for confounding factors showed some evidence of associations of prolonged latent phase of labour (defined as over 12 hours for nulliparous women and over 6 hours for multiparous women) with higher CS rates (RR 1.65 [95% CI 1.32 to 2.06]), increased need for newborn resuscitation (RR 1.37 [95% CI 1.15 to 1.64]) and more babies with an Apgar score less than 7 at 5 minutes (RR 1.97 [95% CI 1.23 to 3.16]).

A second US cross-sectional study (n = 30) found no evidence of an association between the duration of first stage of labour (cervical dilatation 3–10 cm) and maternal anxiety score.[286] [EL = 3]

There are three studies that did not specify stages of labour. A small matched case–control study (n = 34) conducted in the UK showed some evidence of a longer duration of labour being associated with puerperal psychosis (MD 4.6 hours, $P < 0.05$).[287] [EL = 2−] One US

cross-sectional study (n = 198) using controls matched for age, parity and birthweight (n = 198) demonstrated that short labour (less than 3 hours of first and second stage of labour) was not associated with major (defined as those of the external anal sphincter or of the rectal mucosa) perineal lacerations (RR 0.5, P = NS), PPH (RR 0.72, P = NS) or Apgar scores less than 7 at 5 minutes (RR 1.5, P = NS).[288] [EL = 3]

One nested case–control study performed in the USA demonstrated that prolonged labour was associated with maternal intrapartum complications (women having vaginal birth RR 12.5 [95% CI 4.94 to 23.38]; women having CS RR 28.89 [95% CI 20.00 to 39.43]).[289] [EL = 2−]

Six observational studies were identified that described the total duration of labour. [EL = 3] In some cases, factors associated with length of labour were also investigated.

A large (n = 932), prospective study carried out in Germany in 1994–95 aimed to describe factors associated with the duration of normal labour.[280] Labours and births occurred in a midwife-led maternity unit or at home. The mean duration of the first stage of labour, excluding women defined as having 'prolonged' labour by their upper limits, was found to be 7.3 hours for nulliparous women [range 1.0 to 17.0 hours] and 3.9 hours [range 0.5 to 12.0 hours] for multiparous women. Regression analysis showed that multiparous women had shorter first stages than nulliparous women but no other demographic variables were found to be associated with duration of the first stage of labour (ethnicity was not considered). A short interval between onset of labour and start of midwifery care was associated with a shorter duration of the first stage of labour, the effect more pronounced, especially in multiparous women, if membranes ruptured prior to the onset of midwifery care.

A large US study described spontaneous term labour lasting more than 3 hours in 1162 nulliparous women.[284] The median duration of the first stage of labour was 7.3 hours (10th and 90th percentiles: 3.3 and 13.7 hours, respectively).

A second US study aimed to describe the duration of the active stages of labour and the clinical factors associated with longer labours.[283] Data were collected from 2511 women from nine midwifery practices during 1996, in spontaneous labour at term, at low risk of developing complications during labour and who did not receive oxytocin or epidural analgesia. The mean length and upper limits (two standard deviations) of the active first stage of labour was 7.7 hours and 17.5 hours for nulliparous women, and 5.6 hours and 13.8 hours for multiparous women. Multivariate analysis by logistic regression showed that continuous electronic fetal monitoring and ambulation in labour were significantly associated with longer labour. The use of narcotic analgesia was significantly associated with longer labours in multiparous women. These are associations only and do not imply causality.

Earlier work undertaken in the USA (1991–1994) examined length of labour in 1473 low-risk women by ethnicity (non-Hispanic white, Hispanic and American Indian women).[282] The overall mean length and upper limit (defined as two standard deviations) of the first stage of labour was 7.7 hours and 19.4 hours for nulliparous women, and 5.7 hours and 13.7 hours for multiparous women. There were no statistically different findings between the ethnic groups.

A secondary analysis of US birth data collected from 1976 – 1987 described lengths of labour for 6991 term women giving birth normally. Oxytocin was not used and analysis included parity and conduction analgesia (95% epidural analgesia). The mean lengths and upper limits (95th percentile) of the active first stage of labour were as follows: nulliparous women – no conduction anaesthesia 8.1 hours (16.6 hours); with regional anaesthesia 10.2 hours (19.0 hours); multiparous women – no conduction anaesthesia 5.7 hours (12.5 hours); with conduction anaesthesia 7.4 hours (14.9 hours).

A smaller, older US study described the length of the latent and first stages of 100 first labours.[279] The sample was very mixed and included one breech birth, one set of twins, four induced labours and only 29 spontaneous births. The latent period of labour was found to range from 1.7 to 15.0 hours, with a mean of 7.3 hours (SD = 5.5 hours). The length of the

active first stage of labour was found to range from 1.8 to 9.5 hours, with a mean of 4.4 hours (SD = 1.9 hours).

A recent UK observational study described progress in labour for multiparous women giving birth in a midwife-led unit.[290] [EL = 3] Based on findings from 2 hourly vaginal examinations for 403 women in established labour, a simple regression model showed the mean rate of cervical dilatation to be 2.9 cm/hour; median 1.9 cm/hour (10th centile 0.7 cm/hour; 5th centile 0.5 cm/hour). For women who entered the trial at a cervical dilatation of less than 4 cm, rates of cervical dilatation tended to increase over time. Several individual profiles showed periods of no progress followed by progress. Taking a cervical dilatation of 4 cm as the beginning of the active phase of labour and using the median rate of dilatation, this would give a median duration of the active first stage of labour of 3 hours 9 minutes. Using the 10th centile as the upper limit, this would extrapolate to duration of active first stage of labour of 13 hours.

Pooling findings from the descriptive studies summarised above, the range of upper limits for the duration of normal labour are as follows: women giving birth to their first baby 8.2–19.4 hours; women giving birth to second or subsequent babies 12.5–14.9 hours (Table 124). These figures are flawed, however, since they include some calculations based on standard deviations, which assumes a normal distribution, which is not the case when considering duration of labour.

Table 124: Summary table showing ranges for duration of stages of labour

	Lower value	Upper value
Nulliparous		
Latent phase	1.7 hours	15.0 hours
Active first stage	1.0 hour	19.4 hours
Parous		
Latent phase	Not studied	Not studied
Active first stage	0.5 hour	14.9 hours

N = 6 descriptive studies; includes women with epidural analgesia

Evidence statement

The duration of established labour varies from woman to woman, and is influenced by parity. Progress is not necessarily linear.

In established labour, most women in their first labour will reach the second stage within 18 hours without intervention. In their second and subsequent labours, most women will reach the second stage within 12 hours without intervention.

Recommendation on duration of the first stage of labour

161. Inform women that, while the length of established first stage of labour varies between women:

- first labours last on average 8 hours and are unlikely to last over 18 hours
- second and subsequent labours last on average 5 hours and are unlikely to last over 12 hours. [2007]

Research recommendation on duration of labour

20. A prospective cohort study on impact of length of labour on outcomes is needed.

Observations during the established first stage of labour

Introduction

It is usual practice to carry out a number of maternal and fetal observations during the first stage of labour, to detect changes in maternal or fetal health. These provide an important

overview of how the woman is progressing during her labour and what her needs are over time. These observations can be recorded in the woman's records or on a pre-designed chart (partogram).

Review question

Is there evidence that the assessment of the following on admission, and throughout labour and the immediate postnatal period, affect outcomes?

- observation of vital signs
- bladder care
- palpation and presentation/position of baby
- frequency and duration of contractions
- membrane and liquor assessment/placental examination
- maternal behaviour
- vaginal examination
- length, strength and frequency of contractions
- assessment of cervical effacement, dilatation and position
- presentation and descent of the presenting part
- assessment of liquor if membranes ruptured.

Women's observation (including women's behaviour)

No relevant study was identified.

Palpation and presentation/position of the baby

No relevant study was identified.

Contractions

No relevant study was identified.

Membrane and liquor assessment

No relevant study was identified.

Bladder care

No relevant study was identified.

Evidence statement

There was no evidence found concerning the impact upon outcomes of performing maternal observations during the first stage of labour.

Vaginal examinations

Introduction

A vaginal examination during labour often raises anxiety and interrupts the woman's focus in labour.

Description of included studies

One UK RCT was identified which compared 2 hourly and 4 hourly vaginal examinations (VEs) and their effect on the duration of labour (n = 109).[298] [EL = 1−] A small Swedish case–control study (n = 68) also investigated number of vaginal examinations as a possible predictor of neonatal sepsis.[299] [EL = 2−]

Review findings

A UK RCT (1996) involving 109 nulliparous women in spontaneous labour at term, compared 2 hourly and 4 hourly VEs and found that there was no significant difference in duration of labour between the two groups.[298] [EL = 1−] However, the study also found there was no difference in the number of VEs performed between the two groups. A case–control study (1988) was also found which sought to determine predictive factors in neonatal sepsis.[299] The study samples comprised 26 neonates with sepsis, compared with 42 controls. The study is of

low quality (including inappropriate statistical analysis). [EL = 2−] The authors considered seven intrapartum variables as possible predictive factors of sepsis, including VEs. No predictive factors of neonatal sepsis were confirmed. However, where there is term prelabour rupture of membranes (PRoM), increasing numbers of VEs have been found to be associated with neonatal sepsis (refer to section 14.6).[300] [EL = 2++]

Evidence statement

There is low-quality evidence on the frequency of vaginal examinations during labour, with some evidence that the number of digital vaginal examinations is associated with neonatal and maternal sepsis, where the membranes rupture prior to the onset of labour.

Evidence to recommendations

The guideline development group discussed ongoing observations during labour with particular reference to ensuring that these were appropriate for all birth settings and that thresholds for transfer to obstetric care in an obstetric unit were identified and included in the guideline recommendations. They considered the existing recommendations from the original guideline for observations in established labour in conjunction with the new recommendations made for initial assessment and thresholds for transfer at initial assessment and used these as a basis for compiling recommendations for ongoing assessment during labour and thresholds for transfer to obstetric care. They noted that when a woman is labouring outside an obstetric unit, the time taken for transfer and the stage of labour both need to be taken into account and transfer only undertaken if safe to do so and bearing in mind the likelihood of the woman giving birth while in transit.

Recommendations

162. Record the following observations during the first stage of labour:

- half-hourly documentation of frequency of contractions
- hourly pulse
- 4-hourly temperature and blood pressure
- frequency of passing urine
- offer a vaginal examination (see recommendation 45) 4-hourly or if there is concern about progress or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss). [2007]

If any of the indications for transfer are met (see recommendation 163), transfer the woman to obstetric-led care if she is at home or in a midwifery unit. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

Update 2014

163. Transfer the woman to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50) if any of the following are observed at any point, unless the risks of transfer outweigh the benefits:

- Observations of the woman:
  - pulse over 120 beats/minute on 2 occasions 30 minutes apart
  - a single reading of either raised diastolic blood pressure of 110 mmHg or more or raised systolic blood pressure of 160 mmHg or more
  - either raised diastolic blood pressure of 90 mmHg or more or raised systolic blood pressure of 140 mmHg or more on 2 consecutive readings taken 30 minutes apart

  - a reading of 2+ of protein on urinalysis and a single reading of either raised diastolic blood pressure (90 mmHg or more) or raised systolic blood pressure (140 mmHg or more)
  - temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive occasions 1 hour apart
  - any vaginal blood loss other than a show
  - the presence of significant meconium (see recommendation 164)
  - pain reported by the woman that differs from the pain normally associated with contractions
  - confirmed delay in the first or second stage of labour
  - request by the woman for additional pain relief using regional analgesia
  - obstetric emergency – including antepartum haemorrhage, cord prolapse, postpartum haemorrhage, maternal seizure or collapse, or a need for advanced neonatal resuscitation
  - retained placenta
  - third-degree or fourth-degree tear or other complicated perineal trauma that needs suturing.
- Observations of the unborn baby:
  - any abnormal presentation, including cord presentation
  - transverse or oblique lie
  - high (4/5-5/5 palpable) or free-floating head in a nulliparous woman
  - suspected fetal growth restriction or macrosomia
  - suspected anhydramnios or polyhydramnios
  - fetal heart rate below 110 or above 160 beats/minute
  - a deceleration in fetal heart rate heard on intermittent auscultation.

If none of these are observed, continue with midwifery-led care unless the woman requests transfer (see also recommendation 55) [new 2014]

164. As part of ongoing assessment, document the presence or absence of significant meconium. This is defined as dark green or black amniotic fluid that is thick or tenacious, or any meconium-stained amniotic fluid containing lumps of meconium. [new 2014]

165. If significant meconium is present, ensure that:

- healthcare professionals trained in fetal blood sampling are available during labour **and**
- healthcare professionals trained in advanced neonatal life support are readily available for the birth. [2014]

166. If significant meconium is present, transfer the woman to obstetric-led care provided that it is safe to do so and the birth is unlikely to occur before transfer is completed. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

Update 2014

167. Give ongoing consideration to the woman's emotional and psychological needs, including her desire for pain relief. [2007]

168. Encourage the woman to communicate her need for analgesia at any point during labour. [2007]

Charting of observations

Introduction

Most UK labour wards use some form of formal charting of observations during established labour. These are usually referred to as partograms. A partogram usually contains up to three charts or graphs onto which the midwife records a woman's physical observations, frequency and strength of contractions, descent of the fetal head as felt on abdominal palpation, and cervical dilatation. A number of different partograms have evolved for use, some of which contain lines drawn to guide interventions, usually referred to as alert or action lines. These action lines are drawn to the right of the line which denotes progress by cervical dilatation at a rate of 1 cm/hour. A 2 hour action line would be displaced 2 hours to the right of the progress line and if progress then slows so as to cross the action line interventions for delay in the first stage of labour would be considered. For a 4 hourly action line this line is drawn 4 hours to the right of the progress line, i.e. more time is given before interventions would be considered.

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- formal charting of fetal and maternal observations.

Previous guideline

The NICE clinical guideline on Caesarean Section reviewed this intervention.[6] Three RCTs were included.[301–303] The guideline recommended: A partogram with a 4-hour action line should be used to monitor progress of labour of women in spontaneous labour with an uncomplicated singleton pregnancy at term, because it reduces the likelihood of CS.

Description of included studies

A cluster RCT conducted in South-East Asia (n = 8 hospitals; 35,484 women) compared the use of the WHO partogram (a partogram that has an action line) with no use of a partogram.[301] [EL = 1+]

Review findings

The trial presented the results for nulliparous and parous women separately. For all nulliparous women, use of the partogram seemed to reduce the proportion of women with prolonged labour (women whose labour lasted > 18 hours, RR 0.56 [95% CI 0.47 to 0.67]), use of augmentation (RR 0.43 [95% CI 0.39 to 0.47]), rate of postpartum sepsis (RR 0.09 [95% CI 0.03–0.31]), and rate of CS (RR 0.70 [95% CI 0.61 to 0.81]), whereas it increased rate of spontaneous cephalic birth (RR 1.05 [95% CI 1.03 to 1.08], when compared with no use of a partogram. For all parous normal women, the findings were similar.

No studies have been identified that examine outcomes using partograms without action or alert lines.

Evidence statement

Evidence from low income settings show that the use of pictorial representations of progress in labour (partograms), that have an action line, increases vaginal birth and reduces maternal morbidity. A 4 hour action line is associated with fewer intrapartum interventions than a 2 hour action line with the same outcomes.

There is no current evidence on the efficacy or otherwise of partograms without action or alert lines.

GDG interpretation of the evidence

The benefits offered by use of the partogram which provides a pictorial summary of labour were felt to be applicable to the UK, even though the evidence was drawn from low income countries.

Research recommendations on charting of observations

21. Studies looking at the efficacy of the use of the partogram, and the comparison of a partogram with an action line and one without, should be carried out.

Pain assessment during labour

Use of pain scales during labour

Introduction

This systematic review was undertaken to answer the review question: does the use of pain scales during labour affect outcomes? In addition, the impact of pain scales on women's experience of labour, validity and reliability of pain scales used during labour, predictive value of pain scores, acceptability of using pain scales during labour, observer ratings versus self-ratings and comparison of pain scales were also investigated.

Previous guidelines

The use of pain scales has not been considered in any previous guideline.

Description of included studies

The review included 13 papers providing evidence of a fair to poor quality regarding the use of pain scales during labour. This low level of evidence can be explained by the fact that the impact of pain scales on labour outcome is not the main focus of the studies under review, many of which are descriptive in nature.

Review findings

Impact on women's experience of labour

A large-scale prospective survey of women's expectations and experiences of labour conducted in Finland included women's experiences of pain and pain relief (n = 1091; 33% nulliparous women).[123] [EL = 3] Pain was measured using an 11-point box scale (BS-11) and a 5-point verbal rating scale (VRS) (anchor points 'no pain' and 'intolerable pain'). Despite the regular use of pain scales (every 30 minutes), after administration of pain relief 50% of multiparous women still reported pain scores of 8–10 on the BS-11 (this figure was 19% for nulliparous women). 18% of women rated their pain relief as poor, 37% rated it as moderate, and 45% as good. Views of pain relief were not related to parity. Ratings of overall satisfaction were not related to parity, level of pain experienced or pain relief received.

A small US study (n = 23) of women giving birth with no pharmacological analgesia asked women to rate labour pain sensation intensity and pain affect (unpleasantness).[304] [EL = 2−] Women were asked to state what they had been thinking about in the few minutes prior to pain assessment: the pain/avoiding pain or having the baby. Women who focused on having the baby had significantly lower pain affect scores than those who focused on the pain of labour or avoiding pain in all stages of labour.

Validity and reliability of pain scales used during labour

Research conducted in France compared observer ratings of pain intensity with women's self-ratings on a 5-point numerical scale, the Present Pain Intensity (PPI) scale.[305] [EL = III] The study involved 100 nulliparous women asked to rate their labour pain at 30 minute intervals from the onset of labour (defined as 3 cm cervical dilatation) until full dilatation was confirmed. Mean PPI ratings increased significantly with increasing cervical dilatation.

A US descriptive correlational study was undertaken to investigate the sensory and emotional aspects of labour pain.[306] [EL = 3] The study involved a convenience sample of 79 women in established labour. Pain was assessed by each woman using four methods: a 10 cm visual analogue scale (VAS); the question 'What does your pain feel like?'; the question 'How strong is your pain?'; and by an observer (research assistant) using the Behavioural Index of Pain (BIP). All four measures of pain showed a significant difference between early and late established labour.

A recent German study examined women's experience of pain and feeling of 'fitness' (mental and physical energy) during labour.[307] [EL = 3] Fifty women were asked to complete a VAS every 45 minutes during both stages of labour. The mean pain score increased steadily as labour progressed. The administration of pharmacological analgesia had the effect of reducing pain scores. This was more marked for epidural analgesia than intramuscular analgesia.

Secondary analysis of data obtained from three RCTs compared pain scores reported before and after the administration of epidural analgesia (n = 311).[308] [EL = III] Pain was measured using a 10-point verbal numeric scale. Findings showed that 2% of women with a pain score of 0 or 1 wanted additional analgesia, 51% of women with a score of 2 or 3 wanted additional analgesia and 93% of women with a score of > 3 wanted additional analgesia.

A small US study of 33 adolescent women measured pain using a small plastic hand-held tool incorporating pain descriptors (e.g. cramping, agonising) and a 10 cm numerical scale.[309] [EL = 3] Scores obtained using the numeric visual analogue scale (VAS) increased with cervical dilatation. There were significant increases in VAS scores for pain sensation intensity from early to active labour and from first stage of labour to transition. This increase in score was not seen from transition to pushing.

The effect of pethidine on women's ability to use the VAS reliably has been investigated as part of a small UK study.[310] [EL = III] Two subgroups of women in labour were asked ten times to judge one-fifth of the length of a 15 cm VAS line. They were also asked to rate their current pain level on two occasions, 5 minutes apart. Group One (n = 10) conducted the test approximately half an hour after the administration of 150 mg of pethidine, Group Two (n = 10) did so without pethidine. There were no significant differences between the mean error nor variance of women's ratings of one-fifth along the 15 cm line, whether the woman had pethidine or not. Women's assessment of current pain made 5 minutes apart also showed no significant differences.

Predictive value of pain scores

A Canadian study of 115 low-risk women from a single institution examined the relationship between pain scores obtained in the latent phase of labour and labour outcomes, including length of labour and mode of birth.[311] [EL = II] Pain intensity assessed during the early phase of labour (= 3 cm cervical dilatation) was positively correlated with the duration of the latent phase ($r = 0.58$, $P < 0.0001$) and the duration of active labour ($r = 0.50$, $P < 0.0001$). Analysis of variance showed that latent labour pain was prognostic of the dilatation levels at which analgesia was requested, the number of requests for analgesia and the mode of birth. The incidence of spontaneous birth declined with each increase in pain category recorded during the latent phase ($\chi^2 = 12.09$, $df = 4$, $P = 0.01$).

Acceptability of using pain scales during labour

The recent German study described above also asked for women's opinions regarding using the pain assessment scale during labour.[307] [EL = 3] Written evaluations (n = 28, response rate 56%) suggested that most women (n = 21) felt positive about their participation in the research. However, three women felt it had interfered with their own needs and six expressed negative views regarding the timing of the assessments (too frequent/at the wrong time).

A small-scale study (n = 13 women and nine midwives) carried out in Australia compared the perceptions of pain of labouring women with those of their attendant midwife.[312] [EL = III] Women were asked to rate their labour pain at 15 minute intervals throughout the first and second stages of labour using three pain scales. While most women were able to complete the pain scales during the first stage of labour, 12 of the 13 women were not able to complete the scales towards the end of the first stage. Unfortunately, women were not asked their views of completing the scales so frequently during labour.

A US study which investigated the congruence between intrapartum and postnatal labour pain scores also reported briefly on women's responses to being asked to complete the pain scales during the first stage of labour.[313] [EL = 3] Fifty women were asked to complete a 6-point PPI (anchors 'no pain' and 'excruciating') and a scale involving scoring of 20 adjectives. The authors reported that the women 'responded favourably' to administration of the tool and were usually able to complete both scales between contractions until late into the first stage of labour.

A small-scale study conducted in Scotland also used a list of 20 pain descriptors.[314] [EL = 3] In this case, the words were presented verbally and women (n = 23) were asked to choose words which best described their current experience of pain. Women were reported as having 'little difficulty' in selecting and reporting words that described their pain.

Observer ratings versus self-ratings

A descriptive cohort study carried out in Israel investigated the effect of ethnic differences between labouring women and their care provider on the carers' perceptions of pain.[315] [EL = 2−] Two groups of women in early established labour (4–5 cm cervical dilatation) at term were compared, one group included Jewish women (n = 255), the other comprised Bedouin women (n = 192). Despite marked differences in demographic variables and pregnancy education, self-assessments of pain were found to be similar for the two groups of women. Clinical staff (Jewish doctors and/or midwives) rated Bedouin women's experience of labour pain as lower than that of Jewish women (6.89 versus 8.52, $P < 0.001$). For Jewish women, 60% of self-assessments of labour pain agreed with assessments made by carers, this agreement was just 30% for Bedouin women.

The French study described above, conducted to validate an observer-rated behavioural pain index, compared observer ratings (midwife or obstetrician) of pain intensity with women's self-ratings on a 5-point numerical scale.[305] [EL = 3] Significant positive correlations were obtained between self-ratings and observer ratings for each phase of labour. However, self-ratings were significantly higher than observer ratings for all phases of labour, F values obtained from analysis of variance being 354.62, 348.34, 360.95 and 396.78, respectively, $P < 0.0005$ for all values. These findings suggest staff were underestimating the woman's experience of pain throughout the first stage of labour.

The US study discussed in the validity of pain scales subsection above compared different pain scales used during labour.[306] [EL = 3] It was found that observer ratings of pain using the BIP, although closely correlated with self-rated pain scores, were consistently lower, suggesting that carers may underestimate the pain a woman is experiencing.

A small-scale but detailed study carried out in Australia compared the perception of pain of labouring women with those of their attendant midwife.[312] [EL = 2−] There was a significant positive correlation between women's and midwives' assessments of pain on all three pain scales used. However, for two of the scales, although there was no significant difference between women's and midwives' scores for mild–moderate pain, there was a significant difference between the two sets of scores when pain intensity was severe, with midwives consistently giving lower ratings of pain intensity (VAS: $t(30) = 2.157$, $P < 0.05$; PPI: $t(25) = 2.301$, $P < 0.05$).

Evidence statement

Evidence is drawn from mostly descriptive studies of variable methodological quality. There is some evidence that pain scales provide a valid measurement of women's pain during labour. No study evaluated their effect on clinical outcomes.
There is also evidence that caregivers tend to underestimate women's level of pain during labour.
Focusing on pain and pain relief has a negative impact on some women's experience of labour.
There is some support for the use of a verbal scale over a pencil and paper scale for use by women during labour.
There may be some correlation between high pain scores in early labour and prolonged labour and instrumental birth.

GDG interpretation of the evidence

The evidence for the use of formal pain scores as a routine method of assessing a woman's needs in managing her pain is not convincing, even allowing for some evidence that healthcare professionals may underestimate the severity of a woman's pain.

Recommendation on verbal assessment of pain

169. Do not routinely use verbal assessment using a numerical pain score. [2007]

Research recommendation on assessment of pain

22. Further studies are required to investigate methods of assessing pain relief, attitudes to pain, effects of labour pain, and long-term outcomes.

Recommendations on observations during the established first stage of labour

170. Use a pictorial record of labour (partogram) once labour is established. [2007]

171. Where the partogram includes an action line, use the World Health Organization recommendation of a 4-hour action line[r]. [2007]

Possible routine interventions in first stage of labour

Introduction

Although most would not intervene in normal labour, a number of policies have been examined in attempts to reduce unnecessary interventions, particularly in nulliparous women.

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- active management
- amniotomy
- oxytocin.

Active management of the first stage of labour

Introduction

Active management includes:

r Anonymous (1994) World Health Organization partograph in management of labour. World Health Organization Maternal Health and Safe Motherhood Programme. Lancet 343: 1399–404. See also the WHO Multicountry Survey on Maternal and Newborn Health.

- one-to-one continuous support
- strict definition of established labour
- early routine amniotomy
- routine 2 hourly cervical examination
- oxytocin if labour becomes slow.

Description of included studies

There were four trials identified: a US trial[316] involved 1934 nulliparous women in labour (intervention n = 1017; control n = 917) with mixed ethnicity; a Mexican trial[317] involved 405 nulliparous women (intervention n = 200; control n = 205) also with mixed ethnicity; a New Zealand trial[318] involved 651 nulliparous women (intervention n = 320; control n = 331) with mixed ethnicity; and a Nigerian trial[319] that involved 448 nulliparous women (intervention n = 221; control n = 227) in labour with a black population.

Review findings

Based on reasonable homogeneity of the trials, a series of meta-analyses were conducted. The analyses showed that active management does not reduce the rate of CS (four trials, RR 0.83 [95% CI 0.67 to 1.03]) or increase spontaneous vaginal birth (four trials, RR 1.04 [95% CI 0.99 to 1.08]). The analyses also showed that active management of labour shortens the length of first stage (two trials, WMD −121.93 minutes [95% CI −134.54 to −109.31 minutes]), but not the second stage (two trials, WMD −2.11 minutes [95% CI−4.49 to 0.26 minutes]. There was no evidence of difference in use of epidural (three trials, RR 1.03 [95% CI 0.92 to 1.16]) or neonatal outcome (admission to neonatal unit two trials, RR 0.93 [95% CI 0.89 to 1.73]). One trial reported maternal satisfaction, although there was no evidence of differences (satisfied with labour and birth care RR 1.04 [95% CI 0.94 to 1.15]; would choose the same management plan RR 1.05 [95% CI 0.94 to 1.18]).[318]

Evidence statement

The package known as active management of labour (one-to-one continuous support, diagnosis of labour, early amniotomy, 2 hourly vaginal examinations and oxytocin if labour becomes slow) appears to reduce the duration of the first stage of labour but has no effect on the incidence of CS. There was no assessment of pain for women, nor of neonatal outcomes. Overall, there is no evidence of any other effect from 'the package' to either woman or baby.

GDG interpretation of the evidence

It is the view of the GDG that the component of the package known as the active management of labour that most influenced outcomes was one-to-one care. Other components of the package have not been shown to be of benefit. The high level of routine interventions associated with active management of labour do not justify its use.

Recommendation on active management of the first stage of labour

172. Do not routinely offer the package known as active management of labour (one-to-one continuous support; strict definition of established labour; early routine amniotomy; routine 2-hourly vaginal examination; oxytocin if labour becomes slow). [2007]

Partogram line placement

Description of included studies

Two RCTs were identified that compared different action line placements. The first trial was conducted in Liverpool (UK) and comprised 928 women in labour.[302] [EL = 1++] The study

compared use of 2 hour and 3 hour action lines with a 4 hour action line. A second trial conducted in South Africa (n = 694) compared a single action line at 2 hours with the WHO partogram (4 hour action line).[303] An additional recent UK RCT compared a partogram with a 2 hour action line with one using a 4 hour action line.[320] [EL = 1+] The trial involved 2975 nulliparous women and compared outcomes of labour following use of a partogram with an action line 2 or 4 hours to the right of the alert line. If progress crossed the action line a diagnosis of prolonged labour was made and labour managed according to a standard protocol. Primary outcome measures were caesarean section rate and women's satisfaction. Postal questionnaires were completed 2–10 days postnatally by 1929 women (65%).

Review findings

Findings from the UK RCT suggested that use of the 2 hour action line, compared with the 3 hour line, seemed to increase women's satisfaction (satisfaction score MD 3.5 [95% CI 1.7 to 5.3]), but there is no evidence of a difference in interventions, e.g. amniotomy: OR 0.9 [95% CI 0.6 to 1.3]; epidural OR 1.3 [95% CI 0.9 to 1.8]; CS for failure to progress OR 0.7 [95% CI 0.4 to 1.3]; or instrumental birth OR 0.9 [95% CI 0.6 to 1.4]).[302] [EL = 1++] There was no evidence of differences in neonatal outcomes between use of the 2 and 3 hour action line. Use of the 3 hour action line compared with the 4 hour action line seemed to increase the rate of CS (OR 1.8 [95% CI 1.1 to 3.2]), but not rates for CS for fetal distress (OR 1.8 [95% CI 0.6 to 5.5]) or for failure to progress (OR 1.8 [95% CI 0.9 to 3.4]). There is no evidence of a difference in other interventions, women's satisfaction or neonatal outcome. Use of a 2 hour action line compared with a 4 hour action line seemed to increase women's satisfaction (satisfaction score MD 5.2 [95% CI 3.4 to 7.0]). There was no evidence of a difference in rate of interventions or neonatal outcome.

A second trial conducted in South Africa showed that use of a single action line reduced the rate of CS (RR 0.68 [95% CI 0.50 to 0.93]), and instrumental births (RR 0.73 [95% CI 0.56 to 0.96]), and increased use of oxytocin (RR 1.51 [95% CI 1.10 to 2.07]).[303] There was no evidence of differences in use of analgesia (RR 1.01 [95% CI 0.93 to 1.11]) or neonatal outcomes (Apgar < 8 at 1 minute (RR 1.24 [95% CI 0.93 to 1.65]); perinatal death RR 7.12 [95% CI 0.37 to 137.37]).

For the UK RCT,[320] there was no evidence of difference for either of the primary outcomes between the 2 and 4 hour action line trial groups: caesarean birth RR 1.0 (CI 0.80 to 1.26); women dissatisfied with labour experience RR 0.89 [95% CI 0.66 to 1.21]. More women in the 2 hour action line group crossed the partogram action line (854/1490 versus 673/1485; RR 1.27 [95% CI 1.18 to 1.37]) and therefore received more interventions to augment labour (772/1490 versus 624/1486; RR 1.23 [95% CI 1.14 to 1.33]). There were no significant differences between groups for instrumental birth, cord pH < 7.1, Apgar score < 7 at 5 minutes or admission to SCBU.

Evidence statement

There are no studies which involve the use of a partogram with no action line. Placing an action line earlier than that recommended by the WHO (at 4 hours) increases interventions without any benefit in outcomes to either woman or baby.

Recommendation on partogram line placement

See recommendation 169

Routine amniotomy

Early routine amniotomy with selective oxytocin versus conservative management

Introduction
For this review, the intervention was defined as routine early amniotomy, with oxytocin if labour becomes slow compared with conservative management (no routine amniotomy).

Description of included studies
Two trials were identified for inclusion in this review: a Belgian study[321] involving 306 nulliparous women (intervention n = 152; control n = 154) and a US trial[322] involving 705 nulliparous women in labour (intervention n = 351; control n = 354). Based on reasonable homogeneity in study designs, a series of meta-analyses were conducted.

Review findings
The meta-analyses showed that there was no evidence of differences in mode of birth (CS (two trials): RR 0.80 [95% CI 0.55 to 1.17]; spontaneous vaginal birth (two trials): RR 1.06 [95% CI 0.97 to 1.16]; use of epidural (two trials): RR 1.02 [95% CI 0.92 to 1.12]; length of first stage of labour (two trials): WMD −65.06 minutes [95% CI −134.83 to 4.71 minutes]; length of second stage of labour (two trials): WMD 1.80 minutes [95% CI −1.83 to 5.44 minutes]; or neonatal outcomes (Apgar score less than 7 at 5 minutes: (two trials): RR 1.22 [95% CI 0.38 to 3.93]; admission to neonatal unit (two trials): RR 0.90 [95% CI 0.47 to 1.72]). No other findings relating to major outcomes were available.

Evidence statement
There is no evidence of differences in mode of birth, use of epidural, length of labour or neonatal outcomes between early routine amniotomy plus selective use of oxytocin, and more conservative management.

Recommendation on routine amniotomy

173. In normally progressing labour, do not perform amniotomy routinely. [2007]
Routine 'amniotomy and oxytocin'

Early routine amniotomy and oxytocin

Introduction
Early routine amniotomy and oxytocin was defined as routine use of oxytocin, in addition to early routine amniotomy for normal healthy women at the beginning of labour.

Description of included studies
One US RCT was identified.[323] The study population involved 150 (intervention n = 75; control n = 75) nulliparous women in labour with mixed ethnicity.

Review findings
The results showed no evidence of a difference in mode of birth (spontaneous vaginal birth RR 0.97 [95% CI 0.82 to 1.14]; CS RR 0.91 [95% CI 0.41 to 2.01]). There was no strong evidence on duration of labour (latent phase MD −0.73 hours [95% CI −0.84 to −0.62 hours]; active phase MD 0.24 hours [95% CI 0.12 to 0.36 hours]; deceleration phase MD 0.00 hours [−0.02 to 0.02 hours]) and Apgar score (at 1 minute MD 0.35 [95% CI 0.30 to 0.40]; at 5 minutes MD 0.02 [95% CI 0.00 to 0.04]). There was no other outcome available.

Evidence statement
Limited evidence showed no substantial benefit for early amniotomy and routine use of oxytocin compared with conservative management of labour.

Recommendation on routine 'amniotomy and oxytocin'

174. Do not use combined early amniotomy with use of oxytocin routinely. [2007]

Interventions for perceived delay in the first stage of labour

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- amniotomy
- oxytocin.

Previous guideline

The NICE clinical guideline Caesarean Section[6] reviewed evidence from one RCT and two observational studies on oxytocin, as well as one systematic review on amniotomy. The guideline recommended that the following aspects of intrapartum care have not been shown to influence the likelihood of caesarean section (CS) for 'failure to progress' and should not be offered for this reason, although they may affect other outcomes which are outside the scope of this guideline: early amniotomy. A research recommendation was also developed as more RCTs are required to determine the effect of oxytocin augmentation as single interventions or as part of a package of interventions (such as 'active management of labour') on the likelihood of CS and other outcomes including women's satisfaction with care. Further research on the short- and longer-term health impacts of CS during the second stage, compared with instrumental vaginal birth, is needed.

Amniotomy versus expectant management

Description of included studies

One systematic review including nine trials, published in 1999, was identified. The review was of good quality.[537] The results were stratified by parity of the women. The intervention was amniotomy targeting women in labour who required augmentation, compared with expectant management.

Review findings

Nulliparous women

Meta-analysis of included trials showed strong evidence that amniotomy significantly reduced the time to birth: randomisation and birth interval (two trials, n = 117 women): MD −53.67 minutes [95% CI −66.50 to −40.83 minutes]; randomisation and full dilatation interval (three trials, n = 298 women): MD −39.45 minutes [95% CI −50.10 to −28.80 minutes]; rate of dystocia (one trial, n = 925 women): OR 0.63 [95% CI 0.48 to 0.82]); rate of cord prolapse (one trial, n = 925 women): OR 0.14 [95% CI 0.00 to 6.84]); and the proportion of women whose labour pain was unbearable (three trials, n = 1283 women): OR 0.76 [95% CI 0.60, 0.97]. There was no evidence of differences in any other maternal variable: oxytocin use, use of analgesia, CS rate, instrumental birth rate, incidence of abnormal or suspect fetal heart rate (FHR), maternal febrile morbidity, maternal blood transfusion, or maternal satisfaction (see evidence tables). For the babies, there was no evidence of differences in: malrotation of the fetal head (one trial, n = 32 women): OR 0.47 [95% CI 0.12 to 1.89]; Apgar score less than 7 at 5 minutes (five trials, n = 2518 women): OR 0.94 [95% CI 0.67 to 1.33]; neonatal jaundice (three trials, n = 2383 women): OR 1.05 [95% CI 0.70 to 1.58]; rate of admission to special care nursery (four trials, n = 1996 women): OR 1.13 [95% CI 0.78 to 1.62]; incidence of

cephalhaematoma (two trials, n = 1022 women): OR 1.66 [95% CI 0.86 to 3.21]; and neonatal infective morbidity (two trials, n = 1353 women): OR 1.43 [95% CI 0.85 to 2.41].

Multiparous women

The evidence for multiparous women is limited, although it showed significant reduction in the interval between randomisation and full dilatation (one trial, n = 269 women): MD −54.00 minutes [95% CI −101.37, −6.63 minutes]. Otherwise, there was no evidence of differences in the: use of oxytocin (one trial, n = 940 women): OR 1.22 [95% CI 0.67 to 2.21]; use of analgesia (epidural/narcotics) (one trial, 940 women): OR 1.14 [95% CI 0.80 to 1.63]; rate of CS (one trial 940 women): OR 2.65 [95% CI 0.75 to 9.29]; rate of instrumental vaginal birth (one trial 940 women): OR 1.20 [95% CI 0.65 to 2.21]; or incidence of neonatal jaundice (one trial 531 women): OR 3.61 [95% CI 0.89 to 14.75].

Evidence statement

When there is delay in the established first stage of labour, there is high-level evidence that the duration is shortened by amniotomy.

Amniotomy and oxytocin versus oxytocin

Description of included studies

One RCT conducted in the USA was identified (n = 118: amniotomy = 58; control = 60).[538] The study population involved both nulliparous and parous women with active phase arrest. The intervention of routine amniotomy followed by oxytocin was compared with oxytocin followed by selective amniotomy.

Review findings

There is no evidence of a difference in the interval between randomisation and birth (MD −0.70 hours [−1.55 to 0.15 hours]); rate of CS (RR 1.21 [95% CI 0.34 to 4.28]) and neonatal infection (RR 4.83 [95% CI 0.58 to 40.13]), although there was significantly more women with postpartum infection in the intervention group than in the control group (amniotomy = 7/60; control = 0/58, P = 0.01).

Amniotomy versus amniotomy plus oxytocin

Description of included studies

Three UK trials were identified. The first study involved 926 nulliparous and parous women requiring augmentation (oxytocin = 465; control = 461).[539] The second trial involved 61 nulliparous women progressing slowly (amniotomy + high-dose oxytocin = 19; amniotomy + low-dose oxytocin = 21; control = 20).[540] The third trial involved nulliparous and multiparous women requiring augmentation (oxytocin + amniotomy = 21; amniotomy only = 20).[541]

Review findings

Meta-analysis of the trials showed no evidence of differences in the rate of CS (three trials, RR 0.82 [95% CI 0.47 to 1.40]); use of epidural (two trials, RR 1.01 [95% CI 0.79 to 1.30]); proportion of the babies with an Apgar score less than 7 at 5 minutes (two trials, RR 0.95 [95% CI 0.13 to 7.09]); admissions to the neonatal unit (one trial, RR 3.00 [95% CI 0.12 to 78.04]); and maternal satisfaction score (one trial, MD 9.00 [95% CI −6.73 to 24.73]).

Amniotomy and oxytocin versus delayed amniotomy and oxytocin

Description of included studies

The UK trial included in the above review also investigated this comparison.[541] The population comprised 61 nulliparous and multiparous women requiring augmentation (oxytocin and amniotomy = 21; expectant = 19).

Review findings

The trial showed a significant reduction in the interval between randomisation and giving birth (intervention = 266 minutes (SD 166), control = 463 minutes (SD 164 minutes), P < 0.001) and an increase in maternal satisfaction (satisfaction score intervention = 149 (SD 23), control = 118 (SD 33), P = 0.002), although there was no evidence of differences in the use of

epidural (RR 0.55 [95% CI 0.12 to 2.4]), rate of CS (RR 2.6 [95% CI 0.4 to 30.9]) and neonatal outcomes (Apgar < 7 at 5 minutes intervention = 1/21, control = 0/19; admission to SCBU, intervention = 1/21, control = 0/19).

Evidence statement

There is evidence that where labour is delayed, amniotomy followed by an oxytocin infusion with a low-dose regimen (0–3 mU per minute) shortens the duration of the first stage of labour but it does not appear to improve the chance of vaginal birth or any other outcome. Where ruptured membranes have occurred, there is no evidence that giving oxytocin in the first 8 hours after this alters anything except the duration of labour.

Effect of augmentation on electronic FHR abnormalities

Amniotomy for delay in labour

Description of included studies

There is one systematic review including nine trials identified.[537] The systematic review was of good quality. [EL = 1+] Among the included studies, three trials assessed effect of amniotomy for shortening labour on FHR tracing.

Review findings

There was no evidence of a difference in incidence of abnormal or suspect FHR trace (all women including nulliparous and multiparous RR 1.06 [95% CI 0.80 to 1.42]; only nulliparous women RR 0.93 [95% CI 0.67 to 1.31]).

Evidence statement

There is no evidence of a difference in abnormal FHR tracing following amniotomy for delay in the first stage of labour.

Oxytocin

Description of included studies

No trial was found that assessed directly the effect of oxytocin augmentation on FHR. There were two trials identified that assessed the effect of oxytocin augmentation on CS rate for fetal distress.[539,541] The first trial was conducted in the UK and published in 1998 (n = 41).[541] The second trial was also conducted in the UK, and published in 1990 (n = 926).[539] Both trials showed good quality. [EL = 1+]

Review findings

There was no evidence of a difference in incidence of CS for fetal distress in either trial (first trial, RR 2.86 [95% CI 0.32 to 25.24]; second trial, nulliparous RR 0.40 [95% CI 0.45 to 1.03]; the second trial, multiparous women only RR 0.66 [95% CI 0.20 to 2.13]).

Evidence statement

There is no direct evidence of abnormal FHR tracing with the use of oxytocin augmentation. There is no evidence of differences on rate of CS for fetal distress by oxytocin augmentation.

GDG interpretation of the evidence (augmentation by oxytocin and fetal monitoring)

This lack of evidence does not detract from the clinical need to continuously monitor the fetal heart when oxytocin is being used for augmentation.

Oxytocin administration

High- versus low-dose oxytocin for augmentation

Introduction

For this review, amount of oxytocin was defined as below:

- high dose defined as starting dose and increment of equal to or more than 4 mU per minute

- low dose defined as starting dose and an increment of up to 2 mU per minute
- the increase interval should be between 15 and 40 minutes.

Description of included studies

There were four RCTs identified that compared high versus low doses of oxytocin infusion for augmentation of labour.[540,542–544] Table 125 summarises the dosages employed.

Table 125: Low- and high-dose oxytocin protocols used for augmentation of labour in included studies

Study	Low dose	High dose
Jamal (2004)[544]	Start at 1.5 mU/minute Increase by 1.5 mU/30 minutes	Start at 4.5 mU/minute Increase by 4.5 mU/30 minutes
Merrill (1999)[542]	Start at 1.5 mU/minute Increase by 1.5 mU/30 minutes	Start at 4.5 mU/minute Increase by 4.5 mU/30 minutes
Xenakis (1995)[543]	Start at 1.5 mU/minute Increase by 1.5 mU/30 minutes until 4 mU/minute Wait for 120 minutes Increase by 1.5 mU/30 minutes	Start at 4.5 mU/minute Increase by 4.5 mU/15 minutes
Bidgood (1987)[540]	Start at 2 mU/minute Increase by 2 mU/15 minutes	Start at 7 mU/minute Increase by 7 mU/15 minutes

Review findings

Women's outcomes

Meta-analysis of the trials showed no evidence of difference in oxytocin to birth interval (two trials, MD −98.45 minutes [95% CI −269.71 to 72.82 minutes]), but a higher maximum oxytocin dose for the higher-dose group than the lower-dose group (three trials, MD 7.49 mU/minute [95% CI 7.06 to 7.91 mU/minute]). There was a reduction in incidence of CS, especially CS for dystocia, and an increase in spontaneous vaginal birth with the higher dose: total CS (four trials):
RR 0.76 [95% CI 0.62 to 0.92]; CS for dystocia (three trials): RR 0.72 [95% CI 0.57 to 0.91]; CS for fetal distress (three trials): RR 0.91 [95% CI 0.58 to 1.40]; and spontaneous vaginal birth (two trials): RR 1.13 [95% CI 1.07 to 1.20]). There were more women with hyperstimulation (four trials): RR 1.35 [95% CI 1.21 to 1.50]) but less women with chorioamnionitis (three trials): RR 0.71 [95% CI 0.56 to 0.90]) with the higher dose, while there was no evidence of a difference in incidence of shoulder dystocia (two trials): RR 1.36 [95% CI 0.63 to 2.95]).

Newborn outcomes

There was no evidence of differences in the proportion of: babies who were admitted to neonatal units (two trials, RR 0.95 [95% CI 0.68 to 1.32]); babies with Apgar scores less than 7 at 5 minutes (four trials, RR 0.98 [95% CI 0.42 to 2.28]); and perinatal deaths (four trials, RR 1.45 [95% CI 0.37 to 5.74]).

Women's satisfaction and other psychological outcomes

No identified study investigated these outcomes.

Evidence statement

There is reasonable quality evidence on high- or low- doses of oxytocin. Women with high dose of oxytocin for augmentation complete their labours quicker but had higher maximum oxytocin dose than those with the lower dose.
Women with high-dose oxytocin for augmentation had less CS, most of which contributed by CS for dystocia, more spontaneous vaginal birth, and less chorioamnionitis, but had more hyper-stimulation than those with the lower dose. The studies are underpowered to examine serious neonatal morbidity or mortality.
There is no evidence on women's satisfaction and long-term outcomes.

GDG interpretation of evidence (high- versus low-dose of oxytocin for augmentation)

There is evidence on high- versus low-dose oxytocin, but studies are heterogeneous. Women whose labours are augmented with high-dose oxytocin may have shorter labours, less CS and more spontaneous vaginal birth than those receiving a low dose. However, the GDG remain cautious about the use of higher doses of oxytocin because there is insufficient evidence on neonatal outcomes and none on pain for women receiving high-dose oxytocin (4 mU/minute or greater) for augmentation.

Comparing different oxytocin dosage regimens

Description of included studies

There are five RCTs identified investigating different oxytocin dosages apart from the above studies.[545–549] Because of the heterogeneity of the studies, it was not possible to conduct a meta-analysis, hence a descriptive summary is presented.

Review findings

A trial conducted in Zimbabwe (2001) involved 258 nulliparous women who required augmentation in labour, and compared different high doses of oxytocin use.[545] [EL = 1-] The lower dose started at 4 mU/minute, doubled every 30 minutes until 16 mU/minute, and then 64 mU/minute, while the higher dose started at 10 mU/minute and doubled every 60 minutes until 40 mU/minute. The trial showed a significant reduction in the proportion of women with more than 6 hours from augmentation to giving birth (RR 0.36 [95% CI 0.21 to 0.62]). No difference was found for CS rate (RR 0.95 [95% CI 0.42 to 2.15]) or neonatal outcomes.

A US RCT (1994) involving 1167 women who required augmentation in labour, compared women's and babies' outcomes for different increment times of oxytocin: 20 minute dose (start at 6 mU/minute, increase by 6 mU/20 minutes until 42 mU/minute) versus 40 minute dose (start at 6 mU/minute, increase by 6 mU/40 minutes until 42 mU/minute).[546] [EL = 1+] The findings showed a reduction in incidence of CS for dystocia with quicker dosage than slower dosage (OR 0.65 [95% CI 0.43 to 0.97]), and there was borderline evidence of more uterine hyper-stimulation with faster rates (OR 1.3 [95% CI 0.98 to 1.7]), but there is no evidence of difference in chorioamnionitis (OR 0.97 [95% CI 0.66 to 1.4]) and babies admitted to the neonatal unit (OR 1.3 [95% CI 0.77 to 2.4])

A second US RCT involving 487 women who required augmentation in labour, compared a 15 minute dose (start at 1 mU/minute, increase 1 mU/15 minutes until 5 mU/minute, increase by 1–2 mU/15 minutes) and a 40 minute dose (start at 1 mU/minute, increase 1.5 mU/40 minutes until 7 mU/minute, then increase by 1.5–3.0 mU/40 minutes).[547] [EL = 1+]

The results showed more women reached higher maximum dose of oxytocin (mean 15 minutes = 8.2 mU/minute; 40 minutes = 6.5 mU/minute, $P < 0.001$), and experienced fetal distress (RR 1.68, $P < 0.005$) and uterine hyperstimulation (RR 1.69, $P < 0.001$) with the 15 minute dose, compared with the 40 minute dose.

A third RCT conducted in the USA (n = 94) compared continuous infusion of oxytocin (start at 1 mU/minute, increase by 1 mU/20 minutes) and repeated pulsatile injection of oxytocin (start at 1 mU per pulse (10 seconds every 8 minutes), doubled every 24 minutes).[548] [EL = 1+] Women with the pulsatile regimen required less amount of oxytocin: average level of oxytocin pulsatile = 2.1 mU/minute (SD 0.4 mU/minute), continuous = 4.1 mU/minute (SD 0.4 mU/minute), $P < 0.001$; total amount of oxytocin pulsatile = 1300 mU (SD 332 mU), continuous = 1803 mU (SD 302 mU), $P < 0.001$); compared with the continuous regimen, with no differences in dysfunctional contractions (RR 1.04, NS).

There was one RCT in the UK identified.[549] [EL = 1-] The study population consisted of 68 nulliparous women who required augmentation in labour. The oxytocin was started at 2.5 mU/minute, and increased by 2.5 mU/30 minutes for both arms. The comparison was made as the oxytocin was increased either until uterine contraction was 6 in 15 minutes or until uterine activity was 1750 kPas/15 minute measured by an intrauterine catheter. The study was

underpowered and found no difference in: maximum oxytocin dose frequency = 8.3 mU/minute (SD 3.7 mU/minute); uterine activity = 8.0 mU/minute (SD 3.1 mU/minute); hyperstimulation (RR 0.54, NS); rate of CS (RR 2.00, NS); and Apgar score < 5 at 1 minute (RR 0.33, NS).

Evidence statement

The evidence on different oxytocin dosage regimens for augmentation is limited as the studies tended to be underpowered and use too many different regimens. Women with quicker increments of oxytocin dose for augmentation appeared to have more hyperstimulation, compared with those with slower increments. Women with quicker increments of a high dose of oxytocin seemed to have less CS for dystocia than those with a slower dose, but there is no evidence of a difference in this comparison for low dose. Women with quicker increments of low doses of oxytocin seemed to experience fetal distress, compared with those with the slower increments. There was limited evidence on pulsatile oxytocin compared with continuous infusion. The limited evidence showed a smaller amount of oxytocin was required with pulsatile injections, but there was no evidence of differences in other outcomes. There was insufficient evidence on other outcomes including neonatal outcomes and women's satisfaction on different oxytocin regimens.

GDG interpretation of the evidence (different doses of oxytocin for augmentation)

The evidence on dose regimens for augmentation is limited as the studies are underpowered and use different comparisons. Increasing the rate more frequently than every 20 minutes may be associated with more uterine hyperstimulation and more non-reassuring fetal heart rate patterns.

Recommendations on interventions for perceived delay in first stage of labour

175. If delay in the established first stage is suspected, take the following into account:

- parity
- cervical dilatation and rate of change
- uterine contractions
- station and position of presenting part
- the woman's emotional state
- referral to the appropriate healthcare professional.

Offer the woman support, hydration, and appropriate and effective pain relief. [2007]

176. If delay in the established first stage is suspected, assess all aspects of progress in labour when diagnosing delay, including:

- cervical dilatation of less than 2 cm in 4 hours for first labours
- cervical dilatation of less than 2 cm in 4 hours or a slowing in the progress of labour for second or subsequent labours
- descent and rotation of the baby's head
- changes in the strength, duration and frequency of uterine contractions. [2007]

Update 2014

If delay is diagnosed, transfer the woman to obstetric-led care. Follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

Update 2014

177. If delay in the established first stage of labour is suspected, amniotomy should be considered for all women with intact membranes, after explanation of the procedure and advice that it will shorten her labour by about an hour and may increase the strength and pain of her contractions. [2007]

178. Whether or not a woman has agreed to an amniotomy, advise all women with suspected delay in the established first stage of labour to have a vaginal examination 2 hours later, and diagnose delay if progress is less than 1 cm. [2007]

179. For women with intact membranes in whom delay in the established first stage of labour is confirmed, advise the woman to have an amniotomy, and to have a repeat vaginal examination 2 hours later whether her membranes are ruptured or intact. [2007]

180. For all women with confirmed delay in the established first stage of labour:

- transfer the woman to obstetric-led care for an obstetric review and a decision about management options, including the use of oxytocin (follow the general principles for transfer of care described in recommendations 46 to 50) [new 2014]
- explain to her that using oxytocin after spontaneous or artificial rupture of the membranes will bring forward the time of birth but will not influence the mode of birth or other outcomes. [2007]

Update 2014

181. For a multiparous woman with confirmed delay in the established first stage of labour, an obstetrician should perform a full assessment, including abdominal palpation and vaginal examination, before a decision is made about using oxytocin. [2007]

182. Offer all women with delay in the established first stage of labour support and effective pain relief. [2007]

183. Inform the woman that oxytocin will increase the frequency and strength of her contractions and that its use will mean that her baby should be monitored continuously. Offer the woman an epidural before oxytocin is started. [2007]

184. If oxytocin is used, ensure that the time between increments of the dose is no more frequent than every 30 minutes. Increase oxytocin until there are 4–5 contractions in 10 minutes. (See also recommendation 101) [2007]

185. Advise the woman to have a vaginal examination 4 hours after starting oxytocin in established labour:

- If cervical dilatation has increased by less than 2 cm after 4 hours of oxytocin, further obstetric review is required to assess the need for caesarean section.
- If cervical dilatation has increased by 2 cm or more, advise 4-hourly vaginal examinations. [2007]

Research recommendation on oxytocin for augmentation of labour

23. **The start dose of oxytocin for augmentation, and the increments, should be the subject of further research.**

24. **Studies are needed that investigate the effectiveness of any strategies to increase spontaneous vaginal birth where diagnosis is made of delay in the first stage of labour.**

Intrauterine resuscitation

Review question

What is the effectiveness of different methods of intrauterine resuscitation for babies with and without meconium-stained liquor?
For further details on the evidence review protocol, please see appendix E.

Intrauterine resuscitation in babies with meconium-stained liquor

Description of included studies

This review included 2 studies (Choudhary et al., 2010; Hofmeyr and Xu, 2010). This updates and replaces the review from the previous guideline.
The included studies consist of 1 systematic review (Hofmeyr and Xu, 2010), with 13 component trials from a variety of locations (USA [6 trials], South Africa [2 trials], India [2 trials], Spain [1 trial], Zimbabwe [1 trial], multicentre [1 trial]) and 1 randomised controlled trial from India (Choudhary et al., 2010).
All of the included studies compared amnioinfusion with no amnioinfusion for the management of babies with meconium-stained liquor. The level of meconium staining was 'more than a trace' in 1 trial, 'grades I to III' in 1 trial (uniformly stained to thickly stained), moderate to thick in 7 trials, and thick in 5 trials. Amnioinfusion was with saline and the protocols involved an initial infusion of 500–1000 ml over a period of 20 minutes to 1 hour (although 1 trial reported infusion over 4 hours), usually followed by maintenance at 2–3 ml per minute. Other methods of intrauterine resuscitation for babies with meconium-stained liquor were searched for, but no relevant studies were identified (for full details of the interventions that were considered see protocol in appendix E).
One of the trials reported restricting its study population to women with an 'uncomplicated antepartum course' and another reported excluding women with 'medical or surgical conditions'. The remaining trials did not restrict their studies to low risk women, but they did exclude various higher risk groups (full details of inclusion and exclusion criteria can be found in the evidence tables in appendix I).

Evidence profile

The authors of the systematic review performed a subgroup analysis by looking at whether the study was conducted in a setting with standard peripartum surveillance (11 trials) or limited peripartum surveillance (2 trials). The additional trial identified by the NCC-WCH search fell into the latter category, which is characterised by the lack of availability of continuous CTG.
The GRADE profile below presents the meta-analysis of all of the studies, pooled by the technical team (the authors of the systematic review did not present an overall effect), the subgroup of studies with standard peripartum surveillance performed by the authors of the systematic review, and an additional subgroup analysis performed by the technical team including only the 2 trials of low risk women.
As with the analyses performed by the authors of the systematic review, a fixed effects model was used unless there was high heterogeneity, in which case a random effects model was used.

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Table 126: Amnioinfusion compared with no amnioinfusion for babies with meconium-stained liquor

Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Perinatal death						
All studies						
1 meta-analysis of 10 studies (Choudhary et al., 2010; Hofmeyr & Xu, 2010)	randomised trials	12/1942 (0.62%)	35/1971 (1.8%)	RR 0.35 (0.18 to 0.66)	12 fewer per 1000 (from 6 fewer to 15 fewer)	Low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 7 studies (Hofmeyr & Xu, 2010)	randomised trials	5/1372 (0.36%)	5/1390 (0.36%)	RR 1 (0.29 to 3.45)	0 fewer per 1000 (from 3 fewer to 9 more)	Moderate
Studies of low risk women in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	0/77 (0%)	0/88 (0%)	not calculable (NC)	NC	Low
Perinatal death or serious morbidity[b]						
All studies						
1 study (Hofmeyr & Xu, 2010)	randomised trial	112/986 (11.4%)	99/989 (10%)	RR 1.13 (0.88 to 1.47)	13 more per 1000 (from 12 fewer to 47 more)	Low
Studies in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	112/986 (11.4%)	99/989 (10%)	RR 1.13 (0.88 to 1.47)	13 more per 1000 (from 12 fewer to 47 more)	Low
Studies of low risk women in settings with standard peripartum surveillance						
0	No evidence available					

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Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Neonatal encephalopathy						
All studies						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	1/350 (0.29%)	16/359 (4.5%)	RR 0.09 (0.02 to 0.49)	41 fewer per 1000 (from 23 fewer to 44 fewer)	Low
Studies in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	0/30 (0%)	2/30 (6.7%)	RR 0.2 (0.01 to 4)	53 fewer per 1000 (from 66 fewer to 200 more)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	0/30 (0%)	2/30 (6.7%)	RR 0.2 (0.01 to 4)	53 fewer per 1000 (from 66 fewer to 200 more)	Very low
Meconium aspiration syndrome						
All studies						
1 meta-analysis of 14 studies (Choudhary et al., 2010; Hofmeyr & Xu, 2010)	randomised trials	72/2241 (3.2%)	150/2277 (6.6%)	RR 0.38 (0.19 to 0.76)	41 fewer per 1000 (from 16 fewer to 53 fewer)	Very low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 11 studies (Hofmeyr & Xu, 2010)	randomised trials	61/1672 (3.6%)	84/1702 (4.9%)	RR 0.52 (0.26 to 1.06)	24 fewer per 1000 (from 37 fewer to 3 more)	Low
Studies of low risk women in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	2/77 (2.6%)	12/88 (13.6%)	RR 0.19 (0.04 to 0.83)	110 fewer per 1000 (from 23 fewer to 131 fewer)	Low

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Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Meconium below the vocal cords						
All studies						
1 meta-analysis of 11 studies (Hofmeyr & Xu, 2010)	randomised trials	109/1734 (6.3%)	282/1764 (16%)	RR 0.32 (0.2 to 0.52)	109 fewer per 1000 (from 77 fewer to 128 fewer)	Very low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 10 studies (Hofmeyr & Xu, 2010)	randomised trials	99/1634 (6.1%)	258/1664 (15.5%)	RR 0.31 (0.18 to 0.53)	107 fewer per 1000 (from 73 fewer to 127 fewer)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	2/47 (4.3%)	33/58 (56.9%)	RR 0.07 (0.02 to 0.3)	529 fewer per 1000 (from 398 fewer to 558 fewer)	Moderate
Significant meconium staining						
All studies						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	1/65 (1.5%)	55/73 (75.3%)	RR 0.03 (0.01 to 0.15)	731 fewer per 1000 (from 640 fewer to 746 fewer)	Moderate
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	1/65 (1.5%)	55/73 (75.3%)	RR 0.03 (0.01 to 0.15)	731 fewer per 1000 (from 640 fewer to 746 fewer)	Moderate
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	0/46 (0%)	42/52 (80.8%)	RR 0.01 (0 to 0.21)	800 fewer per 1000 (from 638 fewer to 808 fewer)	Moderate

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Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Neonatal ventilation or neonatal intensive care unit admission						
All studies						
1 meta-analysis of 5 studies (Hofmeyr & Xu, 2010)	randomised trials	54/651 (8.3%)	112/674 (16.6%)	RR 0.51 (0.38 to 0.68)	81 fewer per 1000 (from 53 fewer to 103 fewer)	Moderate
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 3 studies (Hofmeyr & Xu, 2010)	randomised trials	10/230 (4.3%)	25/242 (10.3%)	RR 0.45 (0.23 to 0.9)	57 fewer per 1000 (from 10 fewer to 80 fewer)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	4/47 (8.5%)	11/58 (19%)	RR 0.45 (0.15 to 1.32)	104 fewer per 1000 (from 161 fewer to 61 more)	Very low
Cord blood gas values: umbilical artery pH<7.20						
All studies						
1 meta-analysis of 7 studies (Hofmeyr & Xu, 2010)	randomised trials	188/903 (20.8%)	226/885 (25.5%)	RR 0.62 (0.4 to 0.96)	97 fewer per 1000 (from 10 fewer to 153 fewer)	Very low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 7 studies (Hofmeyr & Xu, 2010)	randomised trials	188/903 (20.8%)	226/885 (25.5%)	RR 0.62 (0.4 to 0.96)	97 fewer per 1000 (from 10 fewer to 153 fewer)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	4/45 (8.9%)	12/50 (24%)	RR 0.37 (0.13 to 1.07)	151 fewer per 1000 (from 209 fewer to 17 more)	Low

Update 2014

Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Maternal death or serious morbidity[c]						
All studies						
1 study (Hofmeyr & Xu, 2010)	randomised trial	15/986 (1.5%)	15/989 (1.5%)	RR 1 (0.49 to 2.04)	0 fewer per 1000 (from 8 fewer to 16 more)	Moderate
Studies in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	15/986 (1.5%)	15/989 (1.5%)	RR 1 (0.49 to 2.04)	0 fewer per 1000 (from 8 fewer to 16 more)	Moderate
Studies of low risk women in settings with standard peripartum surveillance						
0	no evidence available					
Mode of birth: caesarean section for any indication						
All studies						
1 meta-analysis of 14 studies (Choudhary et al., 2010; Hofmeyr & Xu, 2010)	randomised trials	577/2245 (25.7%)	682/2272 (30%)	RR 0.72 (0.56 to 0.93)	84 fewer per 1000 (from 21 fewer to 132 fewer)	Very low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 11 studies (Hofmeyr & Xu, 2010)	randomised trials	483/1682 (28.7%)	516/1698 (30.4%)	RR 0.78 (0.6 to 1.02)	67 fewer per 1000 (from 122 fewer to 6 more)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	26/77 (33.8%)	25/88 (28.4%)	RR 1.15 (0.74 to 1.80)	43 more per 1000 (from 74 fewer to 227 more)	Very low

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Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Mode of birth: caesarean section for fetal distress						
All studies						
1 meta-analysis of 11 studies (Choudhary et al., 2010; Hofmeyr & Xu, 2010)	randomised trials	196/1943 (10.1%)	295/1969 (15%)	RR 0.42 (0.25 to 0.73)	87 fewer per 1000 (from 40 fewer to 112 fewer)	Low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 8 studies (Hofmeyr & Xu, 2010)	randomised trials	151/1376 (11%)	174/1389 (12.5%)	RR 0.4 (0.19 to 0.86)	75 fewer per 1000 (from 18 fewer to 101 fewer)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	4/77 (5.2%)	12/88 (13.6%)	RR 0.36 (0.12 to 1.05)	87 fewer per 1000 (from 120 fewer to 7 more)	Low
Mode of birth: instrumental vaginal birth for any indication						
All studies						
1 meta-analysis of 9 studies (Choudhary et al., 2010; Hofmeyr & Xu, 2010)	randomised trials	63/1021 (6.2%)	95/1038 (9.2%)	RR 0.68 (0.5 to 0.91)	29 fewer per 1000 (from 8 fewer to 46 fewer)	Low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 6 studies (Hofmeyr & Xu, 2010)	randomised trials	45/455 (9.9%)	63/459 (13.7%)	RR 0.73 (0.51 to 1.04)	37 fewer per 1000 (from 67 fewer to 5 more)	Very low

Update 2014

Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Studies of low risk women in settings with standard peripartum surveillance						
1 meta-analysis of 2 studies (Hofmeyr & Xu, 2010)	randomised trials	2/77 (2.6%)	10/88 (11.4%)	RR 0.25 (0.06 to 1.07)	85 fewer per 1000 (from 107 fewer to 8 more)	Low
Mode of birth: instrumental vaginal birth for fetal distress						
All studies						
1 meta-analysis of 3 studies (Hofmeyr & Xu, 2010)	randomised trials	60/1136 (5.3%)	56/1150 (4.9%)	RR 1.09 (0.76 to 1.55)	4 more per 1000 (from 12 fewer to 27 more)	Moderate
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 3 studies (Hofmeyr & Xu, 2010)	randomised trials	60/1136 (5.3%)	56/1150 (4.9%)	RR 1.09 (0.76 to 1.55)	4 more per 1000 (from 12 fewer to 27 more)	Moderate
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	1/47 (2.1%)	5/58 (8.6%)	RR 0.25 (0.03 to 2.04)	65 fewer per 1000 (from 84 fewer to 90 more)	Very low
Mode of birth: normal vaginal birth						
All studies						
1 study (Choudhary et al., 2010)	randomised trial	103/146 (70.5%)	46/146 (31.5%)	RR 2.24 (1.72 to 2.91)	391 more per 1000 (from 227 more to 602 more)	Very low
Studies in settings with standard peripartum surveillance						
0	no evidence available					
Studies of low risk women in settings with standard peripartum surveillance						
0	no evidence available					

Update 2014

Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Fetal heart pattern: variable decelerations						
All studies						
1 meta-analysis of 5 studies (Hofmeyr & Xu, 2010)	randomised trials	328/1050 (31.2%)	385/1051 (36.6%)	RR 0.67 (0.47 to 0.96)	121 fewer per 1000 (from 15 fewer to 194 fewer)	Very low
Studies in settings with standard peripartum surveillance						
1 meta-analysis of 5 studies (Hofmeyr & Xu, 2010)	randomised trials	328/1050 (31.2%)	385/1051 (36.6%)	RR 0.67 (0.47 to 0.96)	121 fewer per 1000 (from 15 fewer to 194 fewer)	Very low
Studies of low risk women in settings with standard peripartum surveillance						
1 study (Hofmeyr & Xu, 2010)	randomised trial	2/47 (4.3%)	10/58 (17.2%)	RR 0.25 (0.06 to 1.07)	129 fewer per 1000 (from 162 fewer to 12 more)	Low

CI confidence interval, NC not calculable, RR relative risk

a. Very few details are reported about the control groups, only that they received no amnioinfusion or received standard care
b. Defined as the presence of at least one of the following: perinatal death, moderate or severe meconium aspiration syndrome, hypotonia, assisted ventilation or intubation of more than 5 minutes duration, 5 minute Apgar score <7, umbilical cord artery pH<7.05, abnormal consciousness, need for tube feeding, convulsions, blood or lumbar culture positive for bacteria, major trauma including basal skull or long-bone fracture, spinal cord injury, and facial or brachial palsy
c. Defined as the presence of any of the following: uterine rupture, amniotic fluid embolism, antepartum haemorrhage needing urgent delivery, postpartum haemorrhage needing transfusion (this occurred in 11 [1.1%] women in each arm of the trial), hysterectomy, admission to intensive care unit, or disseminated intravascular coagulation

Update 2014

Evidence statements

Amnioinfusion compared with no amnioinfusion

Perinatal death or serious morbidity
There was some evidence that amnioinfusion might reduce rates of perinatal death (n=3913) and serious morbidity such as neonatal encephalopathy (n=709), but this benefit was not demonstrated in settings with standard peripartum surveillance. The evidence was of moderate and low quality.

Meconium aspiration syndrome
There was consistent evidence that the rates of meconium below the vocal cords (n=3498) and significant meconium staining (n=138) were reduced following amnioinfusion, but the evidence for a reduction in meconium aspiration syndrome (n=4518) was slightly more mixed. A meta-analysis of 2 studies of low risk women (n=138) in settings with standard peripartum surveillance demonstrated a reduction in meconium aspiration syndrome following amnioinfusion, as did the overall meta-analysis, but a meta-analysis of 11 studies (n=3374) in settings with standard peripartum surveillance failed to show an effect. The evidence was of moderate to very low quality.

Neonatal ventilation/neonatal intensive care unit admission
For the outcomes of neonatal ventilation/neonatal intensive care unit admission (n=1325), low artery pH at birth (n=1758) and the occurrence of variable decelerations (n=2101), a reduction in incidence was found overall and in the subgroup of studies with standard peripartum surveillance, but not when restricted to studies of low risk women. The evidence was of moderate and very low quality.

Mode of birth
The evidence around mode of birth was also mixed. There was some evidence that rates of instrumental vaginal birth (n=2059) and caesarean section (n=4517) might be reduced with the use of amnioinfusion, but generally there was no effect demonstrated when the analysis was restricted to those studies in settings with standard peripartum surveillance. The evidence was of moderate to very low quality.

Methods of amnioinfusion

Amnioinfusion with antibiotic solution did not improve outcomes when compared to amnioinfusion with saline. Similarly, no benefit was demonstrated when amnioinfusion with lactated Ringer's solution was compared with amnioinfusion using saline, although the evidence was from a small trial with 20 women in each arm. No clinical benefit was identified to support the use of infusion pumps or solution warmers, although the studies did not investigate this as their primary objective. The evidence was of moderate to very low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group agreed that the primary aim of amnioinfusion for meconium-stained liquor is to try to prevent neonatal morbidity and mortality associated with meconium aspiration, and therefore they placed greatest weight on these outcomes. In particular, they agreed that outcomes such as neonatal death, meconium aspiration syndrome and admission to a neonatal intensive care unit (NICU) were more helpful than 'meconium below the vocal cords' and 'heavy meconium staining' which are more subjective.

Update 2014

Consideration of clinical benefits and harms

The guideline development group considered the evidence around perinatal death. They discussed the significant reduction in perinatal death after amnioinfusion use that was shown in the overall meta-analysis, but noted that the only study showing a significant effect was Choudhary et al. (2010), a study conducted in India which had an 11% mortality rate in the control group The group was disappointed that a similar reduction in mortality was not demonstrated in the subgroup analysis of studies in settings with standard peripartum surveillance. They also noted that there was no effect of amnioinfusion on the composite outcome of perinatal death and serious morbidity that was reported in the largest trial. When considering neonatal morbidity, the group agreed that when considering the evidence overall, there were potentially promising trends in terms of a reduction in neonatal encephalopathy, meconium aspiration syndrome and admission to NICU. They also noted that there was some evidence of a reduction in the rates of caesarean section and instrumental vaginal birth in women given amnioinfusion, although the effects were less consistent in the subgroup analysis of studies conducted in settings with standard peripartum surveillance. However, the group had serious reservations about the quality of the body of evidence and felt that the strongest benefits were shown in resource-poor settings, rather than settings with standard peripartum surveillance which might be more comparable to England and Wales. They noted the inclusion of a number of small trials with a high risk of bias, and placed more emphasis on the findings of Fraser et al. (2005; included in Hofmeyr and Xu, 2010), which was the largest study and had the most robust methodology. They noted that Fraser et al. (2005) had consistently failed to demonstrate any benefit of amnioinfusion, and had even found a slightly higher (but not significantly) rate of meconium aspiration syndrome in the babies who received amnioinfusion. Given all of these issues, the group did not feel that there was any evidence to change the recommendation against using amnioinfusion that was made in the 2007 guideline.

Consideration of health benefits and resource uses

The guideline development group noted that amnioinfusion requires resources in terms of staff time and necessary equipment. Given the uncertainty surrounding clinical benefit, they agreed that it would not be appropriate to recommend its use.

Quality of evidence

The guideline development group noted that there was variation in the quality of the studies included in the Cochrane review, with most of the trials judged by the authors to be at a high risk of bias. In addition, they discussed the fact that some of the trials had been conducted in settings with limited peripartum surveillance (for example no electronic fetal monitoring and restricted or no access to neonatologist support) and therefore that the results might be less applicable to England and Wales. In particular, they noted that in Choudhary et al. (2010), only about 50% of women were booked antenatally and also that the study had been conducted in a teaching hospital providing services to underprivileged women in India. The resulting high neonatal mortality undermined the group's confidence in the generalisability of the results. The group concluded that Fraser et al. (2005) – a large, multicentre trial with robust methodology – provided the best evidence to inform recommendations for women in England and Wales.

Other considerations

Considering the trends towards improvement in some outcomes that was demonstrated in the evidence, the guideline development group discussed making a research recommendation. However, they noted that the strongest evidence of benefit came from studies conducted in resource-poor settings. They also discussed the fact that Fraser et al. (2005) was a well-conducted multicentre trial, which had failed to show a benefit of amnioinfusion. They

concluded that if there was a true benefit of amnioinfusion, it would have been demonstrated and therefore that no further research in this area was needed.

Intrauterine resuscitation in babies without meconium-stained liquor

Description of included studies

This review included 12 studies (Abdel-Aleem et al., 2005; Afschar et al., 2004; Briozzo et al., 2007; Burke et al., 1989; Hidaka et al., 1987; Kulier et al., 1997; Magann et al., 1993; Mercier et al., 1997; Miyazaki et al., 1985; Patriarco et al., 1987; Pullen et al., 2007; Regi et al., 2009).

Of the included studies, 9 were randomised controlled trials (Abdel-Aleem et al., 2005; Afschar et al., 2004; Briozzo et al., 2007; Kulier et al., 1997; Magann et al., 1993; Miyazaki et al., 1985; Patriarco et al., 1987; Pullen et al., 2007; Regi et al., 2009), 1 was a clinical trial with allocation in alternate months (Burke et al., 1989) and the remaining 2 were prospective comparative observational studies (Hidaka et al., 1987; Mercier et al., 1997). The non-randomised studies have been included in this systematic review because they evaluate interventions that have not been evaluated in randomised controlled trials.

The studies were conducted in Austria (Afschar et al., 2004), France (Mercier et al., 1997), USA (Burke et al., 1989; Magann et al., 1993; Miyazaki et al., 1985; Patriarco et al., 1987; Pullen et al., 2007), Japan (Hidaka et al., 1987), Egypt (Abdel-Aleem et al., 2005), South Africa (Kulier et al., 1997), India (Regi et al., 2009) and Uruguay (Briozzo et al., 2007).

This review evaluated the use of intrauterine resuscitation for suspected fetal compromise not caused by meconium-stained liquor. In all of the included studies the diagnosis of 'fetal distress' was made based on the fetal heart rate pattern (full details of criteria can be found in the evidence tables in appendix I), with the exception of 1 which additionally used a fetal scalp pH less than 7.25 as an inclusion criterion (Patriarco et al., 1987). Some of the studies included a minority of women with meconium-stained liquor (Abdel-Aleem et al., 2005; Burke et al., 1989; Kulier et al., 1997; Patriarco et al., 1987; Regi et al., 2009), but it is not clear whether this was identified before or after the diagnosis of fetal distress – and hence recruitment for the study – had been done. Outcomes are not reported separately for babies with and without meconium-stained liquor and so the studies have been included but downgraded for indirectness. Similarly, none of the studies restricted their populations to women with a low risk pregnancy (although some excluded specific high risk groups) and therefore they have been downgraded for indirectness. It should be noted that the majority of the evidence is of low or very low quality, because many of the studies have small sample sizes and/or methodological flaws.

In 4 of the studies, the decision had already been taken to perform a caesarean section and therefore the studies are evaluating the intervention (in each case tocolysis) during the interval in which preparations for a caesarean section are being made (Burke et al., 1989; Kulier et al., 1997; Magann et al., 1993; Patriarco et al., 1987). Where details are reported about the interval between intervention and birth, this is noted below the GRADE table.

Evidence profile

Evidence is presented for the following comparisons for which studies were identified:

- amnioinfusion compared with no amnioinfusion (Abdel-Aleem et al., 2005; Miyazaki et al., 1985; Regi et al., 2009)
- tocolysis (with hexoprenaline or terbutaline) compared with no tocolysis (Burke et al., 1989; Kulier et al., 1997; Patriarco et al., 1987)
- tocolysis compared with emergency delivery (Briozzo et al., 2007)
- comparison of two tocolytics:
  - atosiban compared with hexoprenaline (Afschar et al., 2004)
  - terbutaline compared with nitroglycerin (Pullen et al., 2007)

  - terbutaline compared with magnesium sulphate (Magann et al., 1993)
  - 60 micrograms compared with 90 micrograms of nitroglycerin (Mercier et al., 1997)
- isoxsuprine compared with oxygen administration (Hidaka et al., 1987)

Table 127: Amnioinfusion compared with no amnioinfusion for relieving 'fetal distress'

Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Neonatal death						
1 study (Abdel-Aleem et al., 2005)	randomised trial	0/219 (0%)	1/219 (0.46%)	RR 0.33 (0.01 to 8.14)	3 fewer per 1000 (from 5 fewer to 33 more)	Moderate
Meconium aspiration syndrome						
1 study (Abdel-Aleem et al., 2005)	randomised trial	0/219 (0%)	3/219 (1.4%)	RR 0.14 (0.01 to 2.75)	12 fewer per 1000 (from 14 fewer to 24 more)	Moderate
Meconium below vocal cords						
1 study (Abdel-Aleem et al., 2005)	randomised trial	5/219 (2.3%)	14/219 (6.4%)	RR 0.36 (0.13 to 0.97)	41 fewer per 1000 (from 2 fewer to 56 fewer)	Low
Admission to neonatal intensive care unit						
1 study (Abdel-Aleem et al., 2005)	randomised trial	14/219 (6.4%)	31/219 (14.2%)	RR 0.45 (0.25 to 0.83)	78 fewer per 1000 (from 24 fewer to 106 fewer)	Low
Fetal heart pattern: relief of repetitive variable decelerations						
1 meta-analysis of 2 studies (Miyazaki et al., 1985; Regi et al., 2009)	randomised trials	83/122 (68%)	4/122 (3.3%)	RR 20.74 (7.87 to 54.67)	647 more per 1000 (from 225 more to 1000 more)	Low
Fetal heart pattern: abnormal fetal heart rate after amnioinfusion or control measures						
1 study (Abdel-Aleem et al., 2005)	randomised trial	105/219 (47.9%)	149/219 (68%)	RR 0.7 (0.6 to 0.83)	204 fewer per 1000 (from 116 fewer to 272 fewer)	Low

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Number of studies	Design	Number of women or babies		Effect		Quality
		Amnioinfusion	No amnioinfusion[a]	Relative (95% CI)	Absolute (95% CI)	
Cord blood gas values: umbilical artery pH≤7.2						
1 study (Regi et al., 2009)	randomised trial	20/23 (87%)	32/34 (94.1%)	RR 0.92 (0.77 to 1.11)	75 fewer per 1000 (from 216 fewer to 104 more)	Low
Mode of birth: caesarean section for any indication						
1 study (Regi et al., 2009)	randomised trial	28/73 (38.4%)	28/75 (37.3%)	RR 1.03 (0.68 to 1.55)	11 more per 1000 (from 119 fewer to 205 more)	Very low
Mode of birth: caesarean section for fetal distress						
1 meta-analysis of 3 studies (Abdel-Aleem et al., 2005; Miyazaki et al., 1985; Regi et al., 2009)	randomised trials	129/341 (37.8%)	185/341 (54.3%)	RR 0.7 (0.6 to 0.82)	163 fewer per 1000 (from 98 fewer to 217 fewer)	Low

CI confidence interval, RR relative risk

a. In Abdel-Aleem et al. (2005) the control group received standard care, which consisted of stopping oxytocin, administering oxygen and turning women on to their left side to increase cardiac output. In Miyazaki et al. (1985) very few details are given about the care given to the control group, apart from the fact that they were allowed to change position. In Regi et al. (2009) it is reported that women in the control group received standard care, but not what this comprised.

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Table 128: Tocolysis (hexoprenaline or terbutaline) compared with no tocolysis for relieving 'fetal distress' while preparations for caesarean section are being made

Number of studies	Design	Details of tocolytic administered	Number of women or babies		Effect		Quality
			Tocolysis	No tocolysis[a]	Relative (95% CI)	Absolute (95% CI)	
Perinatal death[b]							
1 study (Kulier et al., 1997)	randomised trial	10 micrograms IV hexoprenaline	0/17 (0%)	2/20 (10%)	RR 0.23 (0.01 to 4.55)	77 fewer per 1000 (from 99 fewer to 355 more)	Very low

Number of studies	Design	Details of tocolytic administered	Number of women or babies		Effect		Quality
			Tocolysis	No tocolysis[a]	Relative (95% CI)	Absolute (95% CI)	
1 study (Patriarco et al., 1987)	randomised trial	0.25 mg subcutaneous terbutaline	0/11 (0%)	0/9 (0%)	not calculable (NC)	0 more per 1000 (CI NC)	Very low
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	0/31 (0%)	0/21 (0%)	NC	0 more per 1000 (CI NC)	Very low
Admission to neonatal intensive care unit							
1 study (Kulier et al., 1997)	randomised trial	10 micrograms IV hexoprenaline	1/17 (5.9%)	0/20 (0%)	RR 3.5 (0.15 to 80.71)	59 more per 1000 (CI NC)	Very low
Fetal heart pattern: no further decelerations							
1 study (Patriarco et al., 1987)	randomised trial	0.25 mg subcutaneous terbutaline	5/11 (45.5%)	0/9 (0%)	RR 9.17 (0.57 to 146.4)	455 more per 1000 (CI NC)	Very low
Fetal heart pattern: not improved							
1 study (Kulier et al., 1997)	randomised trial	10 micrograms IV hexoprenaline	5/13 (38.5%)	9/10 (90%)	RR 0.43 (0.21 to 0.88)	513 fewer per 1000 (from 108 fewer to 711 fewer)	Very low
1 study (Patriarco et al., 1987)	randomised trial	0.25 mg subcutaneous terbutaline	1/11 (9.1%)	9/9 (100%)	RR 0.13 (0.03 to 0.59)	870 fewer per 1000 (from 410 fewer to 970 fewer)	Low
Fetal blood sample values: pH							
1 study (Patriarco et al., 1987)	randomised trial	0.25 mg subcutaneous terbutaline	Mean 7.15 (SE 0.02) n=11	Mean 7.18 (SE 0.02) n=9	NC	MD 0.03 lower (0.09 lower to 0.03 higher)[c]	Low

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Number of studies	Design	Details of tocolytic administered	Number of women or babies		Effect		Quality
			Tocolysis	No tocolysis[a]	Relative (95% CI)	Absolute (95% CI)	
Cord blood gas values: umbilical artery pH							
1 study (Patriarco et al., 1987)	randomised trial	0.25 mg subcutaneous terbutaline	Mean 7.25 (SE 0.03) n=11	Mean 7.17 (SE 0.02) n=9	NC	MD 0.08 higher (0.01 higher to 0.15 higher)[c] p<0.025	Very low
Cord blood gas values: low umbilical artery pH[d]							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	21/28 (75%)	12/19 (63.2%)	RR 1.19 (0.79 to 1.78)	120 more per 1000 (from 133 fewer to 493 more)	Very low
1 study (Kulier et al., 1997)	randomised trial	10 micrograms IV hexoprenaline	6/16 (37.5%)	10/17 (58.8%)	RR 0.64 (0.3 to 1.35)	212 fewer per 1000 (from 412 fewer to 206 more)	Very low
Cord blood gas values: arterial base excess < −10							
1 study (Kulier et al., 1997)	randomised trial	10 micrograms IV hexoprenaline	3/16 (18.8%)	7/16 (43.8%)	RR 0.43 (0.13 to 1.37)	249 fewer per 1000 (from 381 fewer to 162 more)	Very low
Cord blood gas values: venous pH <7.25							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	9/31 (29%)	11/20 (55%)	RR 0.53 (0.27 to 1.04)	259 fewer per 1000 (from 402 fewer to 22 more)	Very low
Cord blood gas values: venous CO_2 >55 (units not reported)							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	3/29 (10.3%)	6/20 (30%)	RR 0.34 (0.1 to 1.22)	198 fewer per 1000 (from 270 fewer to 66 more)	Very low

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Number of studies	Design	Details of tocolytic administered	Number of women or babies		Effect		Quality
			Tocolysis	No tocolysis[a]	Relative (95% CI)	Absolute (95% CI)	
Cord blood gas values: arterial CO_2 >55 (units not reported)							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	11/28 (39.3%)	9/19 (47.4%)	RR 0.83 (0.43 to 1.61)	81 fewer per 1000 (from 270 fewer to 289 more)	Very low
Cord blood gas values: venous O_2 <25 (units not reported)							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	10/29 (34.5%)	9/20 (45%)	RR 0.77 (0.38 to 1.54)	104 fewer per 1000 (from 279 fewer to 243 more)	Very low
Postpartum haemorrhage (blood loss >1000 ml)							
1 study (Burke et al., 1989)	non-randomised trial	0.25 mg IV terbutaline	0/31 (0%)	6/19 (31.6%)	RR 0.05 (0 to 0.81)	300 fewer per 1000 (from 60 fewer to 316 fewer)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SE standard error

Note: Patriarco et al. (1987) do not provide any details about the decision to delivery interval. In Kulier et al. (1997) the mean time between randomisation and birth was 60 minutes (SE 6.2) in the tocolysis arm and 54 minutes (SE 3.1) in the control arm (p=0.38). In Burke et al. (1989) all babies were born within 30 minutes of intrauterine resuscitation (this was an inclusion criterion).

a. In Burke et al. (1989), the control group received standard procedures of maternal positioning, oxygen administration, intravenous fluids and stopping oxytocin. In Kulier et al. (1997) and Patriarco et al. (1987), no details are given about how the control group were managed apart from the fact that they did not receive any medication.
b. Kulier et al. (1997) reported stillbirth and neonatal death separately and these were summed by the technical team. Burke et al. (1989) only reported neonatal death
c. In order to calculate the confidence interval around the mean difference, standard deviations were calculated by the technical team from the reported standard errors
d. Threshold used was <7.25 in Burke et al. (1989) and <7.2 in Kulier et al. (1997)

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Table 129: Tocolysis (fenoterol) compared with emergency birth

Number of studies	Design	Number of women or babies		Effect		Quality
		Fenoterol[a]	Emergency birth[b]	Relative (95% CI)	Absolute (95% CI)	
Admission to neonatal intensive care unit						
1 study (Briozzo et al., 2007)	randomised trial	16/193 (8.3%)	35/197 (17.8%)	RR 0.47 (0.27 to 0.81)	94 fewer per 1000 (from 34 fewer to 130 fewer)	Low
Cord blood gas values: umbilical artery pH<7.1						
1 study (Briozzo et al., 2007)	randomised trial	28/193 (14.5%)	42/197 (21.3%)	RR 0.68 (0.44 to 1.05)	68 fewer per 1000 (from 119 fewer to 11 more)	Low
Cord blood gas values: umbilical artery base excess < −12						
1 study (Briozzo et al., 2007)	randomised trial	33/193 (17.1%)	50/197 (25.4%)	RR 0.67 (0.46 to 1)	84 fewer per 1000 (from 137 fewer to 0 more)	Low
Mode of birth: spontaneous vaginal birth						
1 study (Briozzo et al., 2007)	randomised trial	9/193 (4.7%)	19/197 (9.6%)	RR 0.48 (0.22 to 1.04)	50 fewer per 1000 (from 75 fewer to 4 more)	Low
Mode of birth: caesarean section						
1 study (Briozzo et al., 2007)	randomised trial	175/193 (90.7%)	159/197 (80.7%)	RR 1.12 (1.04 to 1.22)	97 more per 1000 (from 32 more to 178 more)	Moderate
Mode of birth: forceps delivery						
1 study (Briozzo et al., 2007)	randomised trial	9/193 (4.7%)	19/197 (9.6%)	RR 0.48 (0.22 to 1.04)	50 fewer per 1000 (from 75 fewer to 4 more)	Low
Postpartum haemorrhage (not defined)						
1 study (Briozzo et al., 2007)	randomised trial	0/193 (0%)	0/197 (0%)	not calculable (NC)	NC	Very low

CI confidence interval, NC not calculable, RR relative risk

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Note: The mean time between diagnosis of non-reassuring fetal status and birth was 34.54 minutes (SD 11.7) in the fenoterol group and 16.92 minutes (SD 7.63) in the emergency delivery group. The authors report that this was a statistically significant difference.

a. Fenoterol: 0.5 mg of fenoterol bromhydrate diluted in 500 ml of saline and administered intravenously
b. The delivery was performed in the "shortest time possible" either by caesarean or forceps

Table 130: Atosiban compared with hexoprenaline for relieving 'fetal distress'

		Number of women or babies		Effect		
Number of studies	**Design**	**Atosiban[a]**	**Hexoprenaline[b]**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
Perinatal death						
1 study (Afschar et al., 2004)	randomised trial	0/13 (0%)	0/13 (0%)	not calculable (NC)	0 more per 1000 (CI NC)	Very low
Admission to neonatal intensive care unit						
1 study (Afschar et al., 2004)	randomised trial	0/13 (0%)	1/13 (7.7%)	RR 0.33 (0.01 to 7.5)	52 fewer per 1000 (from 76 fewer to 500 more)	Very low
Fetal heart pattern: recovery to normal fetal heart rate						
1 study (Afschar et al., 2004)	randomised trial	12/13 (92.3%)	13/13 (100%)	RR 0.93 (0.75 to 1.14)	70 fewer per 1000 (from 250 fewer to 140 more)	Low
Cord blood gas values: umbilical artery pH						
1 study (Afschar et al., 2004)	randomised trial	Mean 7.2 (SD 0.08) n=13	Mean 7.2 (SD 0.06) n=13	NC	MD 0 higher (0.05 lower to 0.05 higher)	Low
Mode of birth: forceps delivery						
1 study (Afschar et al., 2004)	randomised trial	0/13 (0%)	1/13 (7.7%)	RR 0.33 (0.01 to 7.5)	52 fewer per 1000 (from 76 fewer to 500 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation

a. Atosiban: 6.75 mg diluted in 4.9 ml of saline administered over 1 minute
b. Hexoprenaline: 5 micrograms diluted in 10 ml of saline administered over 5 minutes

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Table 131: Terbutaline compared with nitroglycerin for relieving 'fetal distress'

Number of studies	Design	Number of women		Effect		Quality
		Terbutaline[a]	Nitroglycerin[b]	Relative (95% CI)	Absolute (95% CI)	
'Success' of intrauterine resuscitation[c]						
1 study (Pullen et al., 2007)	randomised trial	41/57 (71.9%)	34/53 (64.2%)	RR 1.12 (0.87 to 1.45)	77 more per 1000 (from 83 fewer to 289 more)	Very low
Mode of birth: caesarean section for any indication						
1 study (Pullen et al., 2007)	randomised trial	30/57 (52.6%)	29/53 (54.7%)	RR 0.96 (0.68 to 1.36)	22 fewer per 1000 (from 175 fewer to 197 more)	Very low
Mode of birth: caesarean section for non-reassuring fetal heart trace						
1 study (Pullen et al., 2007)	randomised trial	19/57 (33.3%)	17/53 (32.1%)	RR 1.04 (0.61 to 1.78)	13 more per 1000 (from 125 fewer to 250 more)	Very low
Mode of birth: instrumental vaginal delivery for non-reassuring fetal heart trace						
1 study (Pullen et al., 2007)	randomised trial	8/57 (14%)	8/53 (15.1%)	RR 0.93 (0.38 to 2.3)	11 fewer per 1000 (from 94 fewer to 196 more)	Very low
Postpartum haemorrhage (not defined)						
1 study (Pullen et al., 2007)	randomised trial	3/57 (5.3%)	2/53 (3.8%)	RR 1.39 (0.24 to 8.02)	15 more per 1000 (from 29 fewer to 265 more)	Very low

CI confidence interval, RR relative risk

a. Terbutaline: 250 micrograms intravenously
b. Nitroglycerin: 400 micrograms intravenously
c. Defined as complete resolution of the non-reassuring trace within 10 minutes, no recurrence of the non-reassuring trace within 30 minutes of drug administration and no operative delivery for non-reassuring trace within 1 hour of drug administration

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Table 132: Terbutaline compared with magnesium sulphate for relieving 'fetal distress' while preparations for caesarean section are being made

Number of studies	Design	Number of women		Effect		Quality
		Terbutaline[a]	Magnesium sulphate[b]	Relative (95% CI)	Absolute (95% CI)	
Fetal heart pattern: resolution of signs of fetal distress						
1 study (Magann et al., 1993)	randomised trial	21/23 (91.3%)	16/23 (69.6%)	RR 1.31 (0.97 to 1.77)	216 more per 1000 (from 21 fewer to 536 more)	Low
Cord blood gas values: umbilical artery pH<7.20						
1 study (Magann et al., 1993)	randomised trial	2/23 (8.7%)	7/23 (30.4%)	RR 0.29 (0.07 to 1.23)	216 fewer per 1000 (from 283 fewer to 70 more)	Low

CI confidence interval, RR relative risk

Note: Emergency caesarean section was started within 10-15 minutes of tocolytic administration

a. Terbutaline: single dose of 0.25 mg by subcutaneous injection
b. Magnesium sulphate: 4g intravenous bolus

Table 133: Nitroglycerin (NTG) 60 micrograms compared with NTG 90 micrograms for relieving 'fetal distress'

Number of studies	Design	Number of women		Effect		Quality
		60 micrograms NTG	90 micrograms NTG	Relative (95% CI)	Absolute (95% CI)	
Need for further doses of nitroglycerin						
1 study (Mercier et al., 1997)	observational study	4/6 (66.7%)	5/18 (27.8%)	RR 2.4 (0.94 to 6.12)	389 more per 1000 (from 17 fewer to 1000 more)	Very low
Fetal heart rate pattern: resolution of fetal distress within 4-5 minutes (after multiple doses)						
1 study (Mercier et al., 1997)	observational study	6/6 (100%)	18/18 (100%)	RR 1 (0.8 to 1.24)	0 fewer per 1000 (from 200 fewer to 240 more)	Very low

CI confidence interval, NTG nitroglycerin, RR relative risk

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Table 134: Beta-stimulant (isoxsuprine) compared with oxygen for relieving 'fetal distress'

Number of studies	Design	Number of women		Effect		Quality
		Isoxsuprine[a]	Oxygen[b]	Relative (95% CI)	Absolute (95% CI)	
Fetal heart rate pattern: recovery from late decelerations within 30 minutes						
1 study (Hidaka et al., 1987)	observational study	54/57 (94.7%)	8/44 (18.2%)	RR 5.21 (2.78 to 9.78)	765 more per 1000 (from 324 more to 1000 more)	Very low

CI confidence interval, RR relative risk

a. Isoxsuprine: 5 mg + 5% glucose 20 ml over at least 30 seconds
b. Oxygen: inhalation by mask (6 litres per minute) for 10 minutes

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Evidence statements

Amnioinfusion compared with no amnioinfusion

The evidence of a benefit of amnioinfusion in terms of neonatal outcomes was mixed. Although evidence from 1 study (n=438) demonstrated a reduction in the incidence of meconium below the vocal cords and rates of admission to a neonatal intensive care unit (NICU), this did not translate into an effect on neonatal death or meconium aspiration syndrome. There was more consistent evidence that amnioinfusion could relieve abnormal fetal heart rate patterns (n=438). The evidence demonstrated that the rate of caesarean sections for fetal distress (n=682) was reduced, but the effect on overall caesarean section rate is unclear. The evidence was of moderate to very low quality.

Tocolysis compared with no tocolysis

There was evidence that tocolysis was associated with a reduction in the number of babies whose heart pattern on CTG did not improve (n=23). There was also evidence that the mean umbilical artery pH (n=99) was improved following tocolysis, but this did not translate into a benefit in terms of the proportion of babies with a low umbilical artery pH. Evidence from 3 studies (n=101) showed no difference for any other neonatal outcomes, but given the small size of the studies and the fact that the evidence was consistently of low or very low quality, the true effect is unclear. There was very low quality evidence of a lower rate of postpartum haemorrhage (n=50) in the women receiving tocolysis, but this outcome was only reported in 1 small study. The evidence was of low to very low quality.

Tocolysis compared with emergency delivery

Evidence from 1 study (n=390) showed that the rate of admission to NICU was reduced in babies who received tocolysis compared with those who were born by an emergency delivery. However, the rate of caesarean section was actually higher in the tocolysis arm than the emergency delivery arm. There was little evidence of an effect on cord blood gas values, and rates of forceps and spontaneous vaginal birth were similar between the 2 groups. There were no incidences of postpartum haemorrhage. The evidence was of moderate to very low quality.

Atosiban compared with hexoprenaline

There was no evidence from 1 study (n=26) of a difference between atosiban and hexoprenaline for relieving fetal distress, either in terms of neonatal outcomes or the rate of forceps birth. However, the evidence was from 1 small trial and was of low or very low quality, so the true effect is unclear.

Terbutaline compared with nitroglycerin

There was no evidence from 1 study (n=110) of a difference in effect of terbutaline compared with nitroglycerin, either in terms of the success of intrauterine resuscitation or a reduction in caesarean sections or instrumental vaginal births. There was also no difference in the rate of postpartum haemorrhage. The evidence was of very low quality.

Terbutaline compared with magnesium sulphate

There was no evidence from two studies (n=46) of a difference between terbutaline and magnesium sulphate either in terms of resolution of fetal distress or cord blood gas values. The evidence was of low quality.

Nitroglycerin: 60 micrograms compared with 90 micrograms

Evidence from 1 study (n=24) showed the effect of the initial dose of nitroglycerin on the need for further doses is unclear, but all of the babies in the study showed a resolution of fetal distress within 5 minutes with multiple doses. The evidence was of very low quality.

Isoxsuprine compared with oxygen

Evidence from 1 study (n=101) showed that more babies recovered from late decelerations within 30 minutes after isoxsuprine than after oxygen, but the evidence was from a study of very low quality and no additional priority outcomes were reported.

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Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The guideline development group prioritised neonatal morbidity and mortality outcomes, but noted that these were often not well reported. For example, the group did not find cord blood gas values being reported as mean values to be particularly helpful, because mean values do not give any indication of the proportion of babies born in poor condition and are too heavily influenced by outliers, particularly given the small sample size of the studies. The group also agreed that it was important to consider mode of birth, as successful intrauterine resuscitation could reduce the need to perform a caesarean section or otherwise intervene to expedite birth.

Consideration of clinical benefits and harms

When considering the evidence around the use of amnioinfusion for relieving suspected fetal compromise (termed 'fetal distress' in most studies) in the absence of meconium, the guideline development group discussed the fact that some outcomes, such as incidence of meconium below the vocal cords and fetal heart rate patterns, seemed to show a benefit from the use of amnioinfusion, but noted that these outcomes might be subject to bias due to the lack of blinding of outcome assessors. They also noted that the studies employed a wide range of controls and the majority of the evidence came from lower income countries (Abdel-Aleem et al. [2005] was conducted in Egypt, where fetal blood sampling facilities were not available, and Regi et al. [2009] was conducted in India): it is therefore unclear how comparable the settings were to England and Wales. The group concluded that the evidence was not strong enough to support a recommendation for the use of amnioinfusion for this indication. They felt that although it could usefully form part of a recommendation for future research, its use for meconium-stained liquor had been evaluated in a large, well-conducted trial showing no benefit, so this research might not be a priority for funding bodies.

The group then considered the evidence base around the use of tocolytics. Although uterine hypertonicity is commonly secondary to the use of oxytocin, it can occur in spontaneous labour. They noted that all 3 of the studies evaluating the comparison of tocolysis with no tocolysis were performed in women in which the decision to perform a caesarean section had already been taken. They also noted that there was some evidence of an improvement in cord blood gas values and fetal heart rates, although the small sample sizes of the studies limited the group's ability to make definitive conclusions. They were surprised by the reduction in the incidence of postpartum haemorrhage in the tocolysis group, but felt that this was likely to be due to the short half-life of the tocolytics. From their clinical experience, the group members felt that tocolytics could sometimes be used to 'buy time' while preparations for a caesarean section are being made, which might facilitate the use of regional analgesia instead of a general anaesthetic and/or improve women's experience by making the preparations for a caesarean less rushed and stressful. They agreed that this would be beneficial, although did not feel able to make a strong recommendation for the use of tocolytics, given the poor quality of the evidence and the lack of demonstrated benefit in most outcomes.

The guideline development group discussed the evidence for the use of different tocolytics. They noted that terbutaline and nitroglycerin are most commonly used in the UK, but given the tiny sample sizes of the studies and the lack of evidence of a difference in outcomes, the group did not feel able to recommend any particular tocolytic over any other.

The group noted the lack of evidence evaluating the use of maternal oxygenation for intrauterine resuscitation. From their clinical experience, they recognised there are circumstances when maternal oxygenation is indicated for maternal reasons, such as conditions associated with hypoxia and pre-oxygenation prior to a caesarean section. They noted that these are valid indications. But there is no evidence of it being of value in the setting of fetal compromise. Furthermore, the group was aware of other evidence that

supported their position of not recommending maternal oxygenation for intrauterine fetal resusciation:

- Fetal compromise is rarely due to maternal hypoxaemia, but instead due to the interference of normal utero-placental transfer of oxygen due to uterine contractions on the placental circulation, placental separation or cord compression (Wilkening et al., 1983; Hamel et al., 2014).
- Hyperoxaemia can have adverse effects in humans. There is some limited data on this topic (Thorp et al, 1995; Khaw et al., 2002).
- Hyperoxaemia can have adverse effects in animals. There is more data in animals showing that (except when fetal hypoxia is secondary to maternal hypoxia) maternal supplemental oxygen causes increase in free radical formation, with the potential risk of increasing reperfusion and cell damage (Suzuki et al., 2000; Kjellmer et al., 1989; Yamada et al., 2003).
- The effects of hyperoxaemia in neonates are of enough concern that it is now recommended to resuscitate the newborn with air rather than oxygen (Davis et al., 2004; Rabi et al., 2007).

Other relevant factors are that women find maternal oxygenation frightening and that it can sometimes divert attention from the preparations for the caesarean section and/or cause delays. The guideline development group did not wish to stop units from using oxygen for maternal indications (which falls out of the scope of this guideline) but agreed that it would be appropriate to recommend against the use of maternal facial oxygen therapy specifically for the purposes of intrauterine resuscitation, given the lack of evidence and the concern over possible risk.

Consideration of health benefits and resource uses

The guideline development group noted that atosiban was a more expensive tocolytic, but given the lack of clinical evidence they did not feel able to make specific recommendations for or against specific drugs. They discussed the fact that amnioinfusion requires staff time and equipment, and currently there is little evidence of an effect on outcomes, so they chose not to recommend its use for intrauterine resuscitation without further research.

Quality of evidence

The guideline development group was very disappointed with the quality of the evidence available for this review question. None of the studies were conducted in purely low risk populations, and the majority of the trials contained very few women.

Other considerations

It was the guideline development group's experience that tocolytics are generally used as part of a package of care (in conjunction with interventions such as stopping oxytocin, maternal repositioning and fluids), with the aim of allowing labour to continue and a normal vaginal birth to be achieved. They also agreed that tocolytics could be used during preparations for a caesarean section, so that the process is less rushed and a general anaesthetic might be avoided, although the evidence was not sufficiently strong to support a recommendation to this effect.

Recommendations

186. Do not offer amnioinfusion for intrauterine fetal resuscitation. [new 2014]

For more on starting conservative measures, see recommendation 133.

Scoring systems for meconium-stained liquor

Review questions

What is the intra-rater and inter-rater reliability of scoring systems for meconium-stained liquor?

What is the effectiveness of scoring/grading systems for improving neonatal and maternal outcomes when there is meconium-stained liquor?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

This review included 3 studies (Morad et al., 1998; Trimmer and Gilstrap, 1991; van Heijst et al., 1995). All of these studies were included in the 2007 Intrapartum Care guideline; no relevant additional studies were identified for this update.
All of the included studies are observational studies, conducted in Israel (Morad et al., 1998), USA (Trimmer and Gilstrap, 1991) and Australia (van Heijst et al., 1995).
One of the included studies evaluated the intra- and inter-observer reliability of a meconium grading system, by giving 20 midwives samples of meconium and asking them to classify the degree of staining as clear, thin, moderate or thick on 2 separate occasions (van Heijst et al., 1995). Agreement was assessed by comparing the assessment of the midwives with the standard classification performed by the authors, and by evaluating the degree of agreement between the individual midwife's classifications of duplicate samples. Another of the included studies evaluated the level of agreement between a clinical assessment (thin, moderate, thick) by the attending physician and a calculation of 'meconiumcrit' using the ratio of the solid volume to total volume (Trimmer and Gilstrap, 1991). The last study was a prospective study with retrospective controls, evaluating whether a scoring system to determine management of meconium-stained liquor improved outcomes when compared to no scoring system (Morad et al., 1998).

Evidence profile

Data for the following comparisons are presented in separate GRADE tables:

- inter- and intra-observer agreement on a grading system for samples of meconium-stained liquor
- agreement between a clinical estimate and 'meconiumcrit' for classifying degree of meconium staining
- clinical outcomes following the use of a scoring system to determine management compared with the use of no scoring system.

Table 135: Summary GRADE profile for inter- and intra-observer agreement on a grading system for meconium-stained liquor samples

Number of studies	Design	Number of meconium samples	Degree of agreement (measured as either a proportion or a kappa statistic[a])	Quality
Inter-observer agreement (rate of agreement of midwives with standard classification performed by authors)				
First assessment				
1 study (van Heijst et al., 1995)	observational study	32 samples graded by 20 midwives	Exact agreement with standard: mean 20.5/32 (range 11 to 27) Kappa: mean 0.52 (range 0.13 to 0.79)	Very low
Second assessment				
1 study (van Heijst et al., 1995)	observational study	32 samples graded by 20 midwives	Exact agreement with standard: mean 21.8/32 (range 13 to 27) Kappa: mean 0.57 (range 0.21 to 0.79)	Very low
Overall agreement with standard, split by degree of staining[b]				
1 study (van Heijst et al., 1995)	observational study	32 samples graded twice by 20 midwives	Clear: 294/320 (91.9%) Thin: 188/320 (58.8%) Moderate: 134/320 (41.9%) Thick: 233/320 (72.8%)	Very low

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Number of studies	Design	Number of meconium samples	Degree of agreement (measured as either a proportion or a kappa statistic[a])	Quality
Intra-observer agreement (rate of agreement of midwife with herself on duplicate samples within a set)				
First assessment				
1 study (van Heijst et al., 1995)	observational study	16 pairs of duplicate samples graded by 20 midwives	Exact agreement on duplicate sample: mean 23.7/32 (range 14 to 30) Kappa: mean 0.64 (range 0.24 to 0.91)	Very low
Second assessment				
1 study (van Heijst et al., 1995)	observational study	16 pairs of duplicate samples graded by 20 midwives	Exact agreement on duplicate sample: mean 23.5/32 (range 18 to 30) Kappa: mean 0.63 (range 0.42 to 0.91)	Very low

a. The authors report that the kappa statistic can be interpreted as follows: 0: no agreement; <0.20: poor agreement; 0.21-0.40: fair agreement; 0.41-0.60: moderate agreement; 0.61-0.80: good agreement; 0.81-1.00: very good agreement; 1.00: complete agreement.
b. Out of the samples judged to be clear, thin, moderate or thick by the authors' standard, on how many individual occasions were these judged correctly by the midwives. The classifications were described as follows: Thin: pale green to yellow without lumps; Moderate: any liquor falling in between thin and thick or with any doubt; Thick: dark green to black in colour with a thick or "tenacious" appearance, and/or any liquor that contained lumps of meconium (Note: definition for 'clear' is not described)

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Table 136: Summary GRADE profile for agreement between a clinical estimate and 'meconiumcrit' for judging degree of meconium staining

Number of studies	Design	Number of women with meconium-stained liquor	Proportion of women in each category and degree of agreement	Quality
Agreement between a clinical estimate of degree of staining and calculation of 'meconiumcrit'[a]				
1 study (Trimmer & Gilstrap, 1991)	observational study	106	Thin Meconiumcrit: 61/106 (58%) Clinical estimate: 58/106 (55%) Moderate Meconiumcrit: 36/106 (34%)	Very low

Number of studies	Design	Number of women with meconium-stained liquor	Proportion of women in each category and degree of agreement	Quality
			Clinical estimate: 38/106 (36%) Thick Meconiumcrit: 9/106 (8%) Clinical estimate: 10/106 (9%) Spearman's p=1.00 Pearson's r=0.997 p=0.047	

a. Meconiumcrit was measured by dividing the solid volume by the total volume and then grading it as thin (< 10%), moderate (10% - 30%) or thick (30%) based on that. The cut-offs had been selected arbitrarily before the start of the study. Criteria for the clinical estimates are not provided

Table 137: Summary GRADE profile for comparison of scoring system compared with no scoring system as part of the care of babies with meconium-stained liquor

Number of studies	Design	Number of women/babies		Effect		Quality
		Scoring[a]	Control[b]	Relative (95% CI)	Absolute (95% CI)	
Neonatal mortality						
1 study (Morad et al., 1998)	observational study	0/80 (0%)	0/100 (0%)	Not calculable (NC)	NC	Very low
Neonatal intubation						
1 study (Morad et al., 1998)	observational study	18/80 (22.5%)	30/100 (30%)	RR 0.75 (0.45 to 1.24)	75 fewer per 1000 (from 165 fewer to 72 more)	Very low
Meconium aspiration syndrome						
1 study (Morad et al., 1998)	observational study	4/80 (5%)	6/100 (6%)	RR 0.83 (0.24 to 2.85)	10 fewer per 1000 (from 46 fewer to 111 more)	Very low
Meconium aspiration syndrome requiring ventilation						
1 study (Morad et al., 1998)	observational study	2/80 (2.5%)	2/100 (2%)	RR 1.25 (0.18 to 8.68)	5 more per 1000 (from 16 fewer to 154 more)	Very low

Number of studies	Design	Number of women/babies		Effect		Quality
		Scoring[a]	Control[b]	Relative (95% CI)	Absolute (95% CI)	
Mode of birth: spontaneous vaginal birth						
1 study (Morad et al., 1998)	observational study	67/80 (83.8%)	89/100 (89%)	RR 0.94 (0.84 to 1.06)	53 fewer per 1000 (from 142 fewer to 53 more)	Very low
Mode of birth: instrumental vaginal birth[c]						
1 study (Morad et al., 1998)	observational study	3/80 (3.8%)	5/100 (5%)	RR 0.75 (0.18 to 3.04)	13 fewer per 1000 (from 41 fewer to 102 more)	Very low
Mode of birth: caesarean section						
1 study (Morad et al., 1998)	observational study	9/80 (11.3%)	6/100 (6%)	RR 1.88 (0.7 to 5.05)	53 more per 1000 (from 18 fewer to 243 more)	Very low

CI confidence interval, NC not calculable, RR relative risk

a. Babies received a score based on presence of fetal distress during prenatal monitoring, whether oropharyngeal suction was performed before the first breath, whether meconium was thin or thick, and the clinical condition of the baby. A score of 0-1 indicated the need for gentle, short duration oropharyngeal suctioning. A score of at least 2 indicated immediate intubation and suctioning of the upper and lower airways
b. Laryngoscopy was performed on all babies for direct visualisation of the neonatal glottis, and then endotracheal suctioning was done if meconium staining of the vocal cords was observed

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Evidence statements

The mean intra-observer agreement for 20 midwives grading 32 meconium samples was classed as good, but it ranged from fair to very good depending on the individual midwife. The average agreement of midwives with the standard was only moderate, and ranged from poor to good. There was good agreement on the definition of clear meconium-stained liquor, but 27% of 'thick' samples, 41% of 'thin' samples and 58% of 'moderate' samples were classified incorrectly by midwives when compared with the standard. The evidence was of very low quality.

There was high correlation (r=0.997) between the classification of meconium staining by clinical estimate and through calculation of 'meconiumcrit'. The evidence for this outcome was of very low quality.

Evidence from 1 study (n=180) showed that the use of a meconium scoring system was not found to improve neonatal outcomes or reduce rates of caesarean section and instrumental vaginal birth when compared with the use of no scoring system. The evidence was of very low quality.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised neonatal morbidity and mortality outcomes, but they were aware that these outcomes were not well reported in the literature on this topic. In terms of comparing different scoring systems, the group was also interested in the intra- and inter-observer reliability of different systems, as these measures provided an indication of how consistently the system could be implemented in practice.

Consideration of clinical benefits and harms

The guideline development group was disappointed that the intra and inter-observer agreement for the meconium scoring system reported in van Heijst et al. (1995) was not better. In particular, they noted that agreement was poor in the thin and moderate categories, which are the most contentious in terms of how they should be managed. They also felt that having the meconium samples in jars, rather than on pads, limited the applicability of the research to clinical practice. Similarly, the group did not feel that the paper by Trimmer and Gilstrap (1991) provided any evidence on the effectiveness of scoring systems that could be usefully translated into clinical practice, as in their experience 'meconiumcrit' is not a widely used system.

The group considered the evidence around the effectiveness of a scoring system compared with no scoring system for improving outcomes, and noted that there was no evidence of a difference in any of the outcomes. Part of the drive to do the review evaluating scoring systems was to identify women and babies in need of more care, for example to assess whether women in labour outside an obstetric unit required transfer. Given that the scoring system of Morad et al. (1998) incorporated criteria such as whether oropharyngeal suctioning had been performed at birth and the clinical condition of the baby, the group felt that it had limited utility for this purpose.

Consideration of health benefits and resource uses

Had there been evidence of improved neonatal outcomes with the use of a scoring system, implementation of the system could have resulted in cost savings linked to a reduced need for resources such as the neonatal intensive care unit. However, there was no evidence of any benefit linked to the use of scoring systems for meconium-stained liquor, and therefore the guideline development group did not feel able to make a recommendation for practice.

Quality of evidence

The evidence for this review was all of very low quality.

The guideline development group was disappointed that no new research had been published since the 2007 guideline.

Other considerations

The guideline development group noted that the 2007 guideline had made a recommendation for more research into the use of scoring systems for meconium-stained liquor. They considered whether this was still a priority for research, but concluded that there was unlikely to be a benefit of incorporating formalised scoring systems into clinical practice and therefore decided to step down the existing research recommendation.

Second stage of labour

Definition of the second stage of labour

Introduction

Definitions of the stages of labour need to be clear in order to ensure that women and the staff providing their care have an accurate and shared understanding of the concepts involved and can communicate effectively. In order to facilitate this, the guideline aims to provide practical definitions of the stages of labour.

Review question

What are the appropriate definitions of the latent and active phases of the first stage, the second stage, and the third stage of labour?

Previous guideline

No previous guideline has considered definitions of the stages of labour.

Description of included studies

No relevant study was identified that investigated outcomes of different definitions of labour. The GDG explored various definitions that have been used in practice and research. Definitions of stages of labour, used in six descriptive studies investigating duration of labour, were used to inform the discussion on definitions of labour.

Review findings

Definitions of the second stage of labour may commence with a fully dilated cervix, e.g. from full dilatation of the cervix to the birth of the baby.[277] Alternatively, they may take into account maternal effort e.g. from the commencement of maternal pushing and full dilatation of the cervix to the birth of the baby.[280] The latter differentiates an active second stage from an early or passive second stage. This may be useful when a woman enters the second stage with the baby's head still relatively high in the pelvis, i.e. with no urge to push, or with epidural analgesia.

Recommendations on definitions of the second stage of labour

187. For the purposes of this guideline, use the following definitions of labour:

- Passive second stage of labour:
  - the finding of full dilatation of the cervix before or in the absence of involuntary expulsive contractions.
- Onset of the active second stage of labour:
  - the baby is visible
  - expulsive contractions with a finding of full dilatation of the cervix or other signs of full dilatation of the cervix
  - active maternal effort following confirmation of full dilatation of the cervix in the absence of expulsive contractions. **[2007]**

Observations for women and babies in the second stage of labour

Introduction

For many women, the physical demands and the psychological challenge of labour are increased during the second stage. For this reason, combined with the increased vulnerability of the baby, the second stage of labour has traditionally been associated with increased surveillance of the fetal condition and intensive support and encouragement for the labouring woman.

Review question

Is there evidence that the assessment of the following on admission, and throughout labour and the immediate postnatal period, affect outcomes?

- observation of vital signs
- bladder care
- palpation and presentation/position of baby
- frequency and duration of contractions
- membrane and liquor assessment/placental examination
- maternal behaviour
- vaginal examination
- length, strength and frequency of contractions
- assessment of cervical effacement, dilatation and position
- presentation and descent of the presenting part
- assessment of liquor if membranes ruptured.

Women's observations (including women's behaviour)

No relevant study was identified.

Palpation and presentation/position of baby

No relevant study was identified.

Contractions

No relevant study was identified.

Membrane and liquor assessment and assessment of liquor if membranes ruptured

No relevant study was identified.

Bladder care

No relevant study was identified.

Wellbeing of babies

No relevant good-quality study was identified.

Recommendations on observations during the second stage of labour

188. Carry out the following observations in the second stage of labour, record all observations on the partogram and assess whether transfer of care may be needed (see recommendation 163) [2007, amended 2014]:

- half-hourly documentation of the frequency of contractions [2007]
- hourly blood pressure and pulse [2007]
- continued 4-hourly temperature [2007]
- frequency of passing urine [2007]
- offer a vaginal examination (see recommendation 45) hourly in the active second stage, or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss) [2007]

In addition:

- Continue to take the woman's emotional and psychological needs into account. [2007]
- Assess progress, which should include the woman's behaviour, the effectiveness of pushing and the baby's wellbeing, taking into account

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the baby's position and station at the onset of the second stage. These factors will assist in deciding the timing of further vaginal examination and any need for transfer to obstetric-led care. [2007, amended 2014]

- Perform intermittent auscultation of the fetal heart rate immediately after a contraction for at least 1 minute, at least every 5 minutes. Palpate the woman's pulse every 15 minutes to differentiate between the two heart rates. [2007, amended 2014]
- Ongoing consideration should be given to the woman's position, hydration, coping strategies and pain relief throughout the second stage. [2007]

Women's position and pushing in the second stage of labour

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- pushing techniques in the second stage (including not pushing).

Position in the second stage of labour

Previous guideline

Position in the second stage of labour was reviewed in the NICE Caesarean Section guideline.[6] One systematic review (including 18 RCTs) was reviewed. The guideline recommended that women should be informed that adopting a non-supine position during the second stage of labour has not been shown to influence the likelihood of CS.

Description of included studies and review findings

Evidence for the effect of different positions and mobilisation during the second stage of labour on labour outcomes is drawn from one systematic review of 19 RCTs.[336] One large (n = 2595) observational cohort study also informs this subsection regarding the use of the lateral position for birth.[337] [EL = 2+] An important confounder may be the way the woman pushes and this information was not available.

A systematic review has been recently updated which assesses the benefits and risks of the use of different positions during the second stage of labour.[336] [EL = 1+] The review included 19 trials involving 5764 women. Caution is advised in interpreting the findings, since the quality of the included trials is variable. Sources of potential bias include non-random allocation (three trials), random allocation on admission to the labour ward rather than late in the first stage of labour (seven trials) and the exclusion of subjects following randomisation in some trials. In addition, the data from most trials were not normally distributed, further contributing to possibly unreliable findings. Upright positions included: sitting (including birthing chair/stool); semi-recumbent (trunk tilted backward 30 degrees to the vertical); squatting (unaided or using bars); squatting (using birthing cushion). For the purpose of this review, upright positions were combined with the lateral position for comparison with supine or lithotomy positions. The use of any upright or lateral position compared with supine or lithotomy was associated with: reduced duration of second stage of labour (ten trials): weighted mean reduction 4.29 minutes [95% CI 2.95 to 5.64 minutes] (this reduction was mainly attributable to the large reduction associated with use of the birthing cushion (two trials): weighted mean reduction in duration 16.9 minutes [95% CI 14.3 to 19.5 minutes]); a reduction in assisted births (18 trials): RR 0.84 [95% CI 0.73 to 0.98]; a reduction in episiotomies (12 trials): RR 0.84 [95% CI 0.79 to 0.91]; an increase in second-degree tears (11 trials): RR 1.23 [95% CI 1.09 to 1.39]; increased estimated blood loss greater than 500 ml (11 trials): RR 1.68 [95% CI 1.32 to 2.15]; reduced reporting of severe pain during the second stage (one trial): RR 0.73 [95% CI 0.60 to 0.90] and fewer abnormal FHR patterns (one trial): RR 0.31 [95% CI 0.08 to 0.98]. No significant differences were demonstrated for: analgesia or anaesthesia used during the second stage of labour (seven trials); third- or fourth-degree

perineal tears (four trials); need for blood transfusion (two trials); manual removal of placenta (three trials); unpleasant birth experience (one trial); dissatisfaction with the second stage of labour (one trial); feeling out of control (one trial); admission to NICU (two trials); birth injuries (one trial); or and neonatal death (three trials).

A prospective cohort study undertaken in the USA, collected data for women cared for intrapartum at three nurse-midwifery services (all clinical teaching sites) during a 12 month period (n = 3049).[337] [EL = 2+] Data collection was carried out using a standardised, validated tool. Multivariate analysis by logistic regression was used to identify predictors of episiotomy and spontaneous tears. Forty-four percent of women were having their first baby. Episiotomy was performed in 11.2% of births and tears occurred in 43.4%. Findings suggested that the lateral position for giving birth was associated with a lower incidence of spontaneous tears among nulliparous women (n = 919) (OR 0.6 [95% CI 0.2 to 1.0]). This trend towards a protective value was not found for multiparous women (findings from statistical analysis not reported).

A multicentre RCT investigated the effects of a hands-and-knees position during the second stage of labour for nulliparous women with a baby in the occipitoposterior position in labour.[338] [EL = 1+] Women allocated to the hands-and-knees position (n = 70) were asked to maintain this position for at least 30 minutes during a study period of 1 hour during the second stage of labour. The control group (n = 77) were actively discouraged from adopting this position during the 1 hour study period, and could adopt any other position they wished. The primary outcome was a baby in the occipitoanterior position (as determined by ultrasound) following the 1 hour study period. There was no significant difference between the two trial groups with respect to this main outcome (17% in intervention group versus 7% in control group; RR 2.4 [95% CI 0.88 to 6.62]). The secondary outcome of persistent back pain during the second stage was measured using three pain scores, all of which were lower for women allocated to the hands-and-knees group (VAS: mean difference −0.85 [95% CI −1.47 to −0.22], P = 0.0083; PPI score: mean difference −0.50 [95% CI −0.89 to −0.10], P = 0.014; SF-MPQ score: mean difference −2.60 [95% CI −4.91 to −0.28], P = 0.028). There were no significant differences seen in any other maternal or neonatal outcomes.

A recent RCT undertaken in Sweden investigated the effects of a hands-and-knees position, compared with a sitting position, on the duration of the second stage of labour.[339] [EL = 1+] Women were required to maintain their allocated position throughout the second stage, until the baby was crowning (hands-and-knees n = 138; sitting n = 133). There was no significant difference in the length of the second stage of labour between the two trial groups (kneeling 48.5 minutes [SD 27.6 minutes]; sitting 41 minutes [SD 23.4 minutes]). However, a number of positive outcomes were noted for the hands-and knees position regarding women's experience of the second stage. Women allocated to the hands-and-knees position were more likely to report that they found the position comfortable for giving birth (OR 0.5 [95% CI 0.1 to 0.9], P = 0.030); were less likely to report their second stage as being long (despite there being no significant difference in the actual length of second stage between the two groups) (OR 1.4 [95% CI 0.8 to 0.9], P = 0.002); reported the second stage as less painful (OR 1.3 [95% CI 1.1 to 1.9], P = 0.01); and reported less postpartum perineal pain in first 3 days following birth (OR 1.9 [95% CI 1.3 to 2.9], P = 0.001) compared with women in the control group. There were no significant differences in clinical outcomes for either women (including degree of perineal trauma) or their babies.

Evidence statement

There is high-level evidence that remaining supine in the second stage of labour increases vaginal instrumental birth, increases pain and may increase the incidence of fetal heart rate abnormalities although there is no information on how women pushed. There is no difference in the proportion of women who give birth with an intact perineum. There is also some high-level evidence that using the hands-and-knees position in the second stage of labour, reduces women's reported pain and has no adverse effects on maternal or neonatal outcomes. The use

of a rigid birthing chair or stool, but not upright positions per se, is associated with recorded blood loss greater than 500 ml.

Recommendation on position in the second stage of labour

189. Discourage the woman from lying supine or semi-supine in the second stage of labour and encourage her to adopt any other position that she finds most comfortable. [2007]

Pushing in the second stage

Introduction

These studies considered women without epidural.

Description of included studies

Two US RCTs of good quality compared coached with uncoached pushing in the second stage of labour.[340,341] [both EL = 1+] Three further RCTs were also identified that investigated pushing in the second stage of labour.[342–344] However, the methodological quality of these studies was poor [all EL = 1−].

Review findings

A recent US RCT compared coached and uncoached pushing in the second stage of labour.[340] [EL = 1+] Nulliparous women who were allocated to the coached pushing group (n = 163) received standardised closed glottis coached pushing instructions during contractions and were encouraged to breathe normally between contractions. The uncoached group of women (n = 157) were attended by the same group of midwives who gave no instructions on pushing, and were encouraged to do 'what comes naturally'. The mean duration of the second stage of labour was significantly shorter for women in the coached group compared with the uncoached group (46 minutes versus 59 minutes, P = 0.014). There were no differences noted in any other maternal or neonatal outcomes.

A US RCT was conducted to determine whether refraining from coaching second stage pushing affects postpartum urogynaecological measures of pelvic floor structure and function (n = 128).[341] [EL = 1+] Women were randomised when they were found to be fully dilated, to receive either coached or uncoached pushing during the second stage of labour. Pelvic floor assessment was carried out 3 months postpartum by nurses blinded to the second stage management. There were no significant differences between the two groups regarding demographic factors, incidence of prolonged second stage of labour (> 2 hours), episiotomy, tears involving the anal sphincter, second stage epidural, forceps birth, oxytocin augmentation of the second stage or babies weighing over 4.0 kg. Urodynamic testing revealed decreased bladder capacity (P = 0.051) and decreased first urge to void (P = 0.025) in the coached group. No other significant differences were found.

A Danish RCT compared spontaneous pushing (n = 151) with a 'forced' breath-holding technique (n = 155) in the late second stage of labour, in women giving birth vaginally for the first time (this sample included women who had had a previous caesarean section but the numbers involved were not given).[342] [EL = 1−] The allocated method of pushing was not encouraged until the baby's head was visible. Up until that point, women were able to push as they wished without direction or encouragement from the midwife. Recruitment into the study was difficult, with only 350 of the 1413 women eligible to join taking part. Reasons given for this include women's reluctance to be allocated to the spontaneous pushing group with its perceived lack of midwifery guidance/encouragement, and midwives' lack of support for the trial. A further 44 women were lost to follow-up, following randomisation, mainly because they gave birth by caesarean section. These difficulties undermine the reliability of the findings. The two study groups were well matched for maternal and baby characteristics. No significant differences were found between the two groups in length of labour, length of second stage, length of expulsive second stage (from vertex visible to birth of the baby), mode

of birth, perineal trauma, Apgar scores, umbilical arterial pH or arterial standard base excess. The authors explain these similarities in terms of non-compliance with the allocated pushing technique. The frequent use of oxytocin (40.1% in the spontaneous group and 45.8% in the forced group) and episiotomy (36% in the spontaneous group and 30% in the forced group) may have also contributed to these findings.

A small UK RCT also investigated the effects of spontaneous (n = 15) versus directed, breath-holding pushing (n = 17).[343] [EL = 1−] The two groups were well matched for a number of maternal and baby characteristics, but these did not include fetal position or station. The duration of the first stage of labour was significantly longer in the spontaneous pushing group (means [SD]: 12.32 hours [5.13 hours] versus 7.88 hours [2.62 hours], P = 0.005). There were no other significant differences noted regarding the first stage of labour including use of Entonox, use of pethidine or the need for an intravenous infusion. No mention is made of the use of oxytocin augmentation. A researcher was present throughout the second stage in order to ensure trial allocation was adhered to by the midwife providing care. Analysis was carried out on an intention-to-treat basis. There was no difference in outcome between the two groups for type of birth, perineal trauma, estimated maternal blood loss, resuscitation of baby at birth, cord venous blood as levels and cord blood pH. Women's views of the second stage of labour (e.g. 'What was the pushing part of your labour like?', 'How satisfied do you feel with the way you coped during the pushing part of your labour?'), as expressed using a 10 cm visual analogue scale, were also similar for the two groups. The second stage of labour was significantly longer in the spontaneous pushing group (means [SD]: 121.4 minutes [58.4 minutes] versus 58 minutes [42 minutes], P = 0.002). This may have been contributed to by differences which also led to significantly longer first stages of labour in this group, rather than be attributable to the different pushing techniques employed.

A small US randomised trial compared women encouraged to use a breath-holding pushing technique (n = 10) with those encouraged to use an exhalation pushing technique (n = 17).[344] [EL = 1−] All women gave birth sitting on a birthing chair. This final sample of women represents a fairly small proportion of the 94 women who originally agreed to participate in the study. It is not clear from the paper when randomisation was carried out, but it appears that a number of women were dropped from the analysis after randomisation for not complying with the study protocol, e.g. for not using the birthing chair for the second stage (n = 20) or not using the designated style of pushing (n = 9). No significant differences were found in the length of the second stage of labour between the two groups (mean = 45.6 minutes for both groups). Some differences were described in FHR patterns between the two groups, e.g. an increase in variable decelerations being noted in the breath-holding pushing group (30% versus 17.6%, no P value given). However, the clinical significance of this is not discussed and no clinical outcomes were examined, e.g. Apgar scores, need for resuscitation, admission to NICU.

Evidence statement

There is no high-level evidence that directed pushing affects outcomes.

Recommendations on pushing in the second stage of labour

190. Inform the woman that in the second stage she should be guided by her own urge to push. [2007]

191. If pushing is ineffective or if requested by the woman, offer strategies to assist birth, such as support, change of position, emptying of the bladder and encouragement. [2007]

Duration and definition of delay in the second stage of labour

Introduction

In considering labour, it is important to define the boundaries that distinguish what is normal from what is abnormal. These boundaries can then be used to inform women and their carers about what to expect, and when it is appropriate for midwives to refer women to obstetricians for advice and support regarding the management of labour.

Review question

Do duration and progress of the first and second stages of labour affect outcomes?

Previous guideline

Duration of labour has not been considered in any previous guideline.

Description of included studies

Ten observational studies that investigated the association between the duration of the second stage of labour and the defined outcomes were identified. The quality of the studies varied.

Review findings

A large US cross-sectional study (n = 15,759) investigated prolonged duration of the second stage (more than 4 hours) and the defined outcomes.[326] [EL = 3] Logistic regression analysis, controlling for various confounders, showed that there was moderate evidence of an association between a prolonged second stage and chorioamnionitis (OR 1.79 [95% CI 1.44 to 2.22]), third- or fourth-degree lacerations (OR 1.33 [95% CI 1.07 to 1.67]), CS (OR 5.65 [95% CI 4.46 to 7.16]), instrumental vaginal birth (OR 2.83 [95% CI 2.38 to 3.36]), and low Apgar score (< 7 at 5 minutes OR 0.45 [95% CI 0.25 to 0.84]). There was no evidence of an association between prolonged second stage of labour and endomyometritis (OR 0.79 [95% CI 0.49 to 1.26]), PPH (OR 1.05 [95% CI 0.84 to 1.31]), meconium-stained liquor (OR 1.11 [95% CI 0.93 to 1.33]), or admission to the neonatal unit (OR 0.59 [95% CI 0.35 to 1.03]).

A large US cross-sectional study (n = 7818) compared prolonged second stage of labour (121+ minutes) with normal duration (1–120 minutes) on the defined outcomes. The associations between two levels of prolonged second stage (121–240 minutes versus 241+ minutes) on the defined outcomes were also compared.[327] [EL = 3] The analysis, which did not control for confounding variables, showed some evidence that a longer second stage of labour (more than 120 minutes) is associated with various medical interventions. For prolonged duration of second stage, the analysis (again without controlling for confounding factors) showed some evidence that duration of more than 240 minutes is associated with various medical interventions.

A German cross-sectional study (n = 1200) investigated prolonged second stage of labour (more than 2 hours) and intrapartum outcomes.[328] [EL = 3] The results showed evidence of an association of prolonged second stage with a low Apgar score at 1 minute, PPH, perineal tears and postpartum fever, although the analyses did not control for confounding factors.

A cross-sectional study conducted in Taiwan (n = 1915) investigated prolonged second stage of labour and intrapartum outcomes.[329] [EL = 3] The results showed no evidence of an association between a prolonged second stage and neonatal and maternal intrapartum outcomes, although the analyses did not control for any confounding factors.

One retrospective case–control study (n = 173) found no evidence of an association between stress urinary incontinence and the duration of the second stage of a woman's first labour, when followed up 7–8 years following the birth (OR 1.07 [95% CI 0.9 to 1.3]).[330] [EL = 2+] It is notable that the study was unable to evaluate parity as an independent risk factor for urinary incontinence.

A large Canadian cross-sectional study (n = 6041) investigated the duration of the second stage of labour and perinatal outcomes.[331] [EL = 2+] There was no evidence of associations between the duration of second stage and low Apgar scores at 5 minutes, neonatal seizures or admission to neonatal units.

One large UK cross-sectional study (n = 25,069) investigated prolonged second stage of labour and perinatal outcomes.[332,333] [EL = 2+] Logistic regression analysis showed that there was evidence of association between a longer duration and a higher rate of PPH (durations: 120–179 minutes OR 1.6 [95% CI 1.3 to 1.9]; 180–239 minutes 1.7 [95% CI 1.3 to 2.3]; 240+ minutes OR 1.9 [95% CI 1.2 to 2.8]), but there was no evidence of an association with postpartum infection (120–179 minutes OR 1.1 [95% CI 0.9 to 1.4]; 180–239 minutes OR 1.1 [95% CI 0.7 to 1.6]; 240+ minutes OR 1.2 [95% CI 0.7 to 2.0]), or an Apgar score less than 7 at 5 minutes (120–179 minutes OR 1.3 [95% CI 0.8 to 2.0]; 180–239 minutes OR 0.9 [95% CI 0.3 to 2.3]; 240+ minutes OR 1.9 [95% CI 0.8 to 4.7]).
A US population-based study (n = 1432) investigated prolonged second stage of labour (more than 120 minutes) and intrapartum outcomes.[334] [EL = 2+] Analysis, without controlling for confounding factors, showed evidence of association with increased rates of CS and instrumental vaginal birth. There was no association with any adverse neonatal outcomes.
A small US longitudinal descriptive study (n = 30) investigated the association between the duration of the second stage of labour (cervical dilatation 10 cm to birth) and anxiety scores.[286] [EL = 2−] The study found no significant association between the duration of the second stage of labour and anxiety scores (inter-correlation −0.24).
A large cross-sectional study conducted in the USA (n = 4403) investigated different lengths of the second stage of labour and their association with intrapartum outcomes.[335] [EL = 2−] The analyses, without controlling for confounding factors, showed no evidence of an association between the duration of the second stage and neonatal outcomes, apart from low Apgar scores at 1 minute ($P < 0.03$). Both puerperal haemorrhage and febrile morbidity showed evidence of an association with length of labour ($P < 0.001$ for both).
There are three studies that did not specify stages of labour.
A small, matched case–control study (n = 34) conducted in the UK investigated the association between length of labour and puerperal psychosis.[287] [EL = 2−] It showed some evidence of a longer duration of labour being associated with puerperal psychosis (MD 4.6 hours, $P < 0.05$).
One US cross-sectional study (n = 198) investigated the impact of short labour (less than 3 hours of first and second stage of labour) upon perinatal outcomes, with matched controls (matched for maternal age, parity and birthweight).[288] [EL = 3] There was no evidence of associations between short labour and major (defined as those of the external anal sphincter or of the rectal mucosa) perineal lacerations, PPH or Apgar scores less than 7 at 5 minutes.
One nested case–control study, performed in the USA, investigated the effects of prolonged labour on maternal complications in the intrapartum period.[289] [EL = 2−] Both For women who had a vaginal birth or CS, prolonged labour was associated with maternal complications (women with vaginal birth RR 12.5 [95% CI 4.94 to 23.38]; women with CS RR 28.89 [95% CI 20.00 to 39.43]).

Descriptive studies

Three studies were identified for review that described the duration of the second stage of labour. In some cases, factors associated with the duration of labour were also investigated. By definition, all studies in this subsection are evidence level 3.
A US study aimed to describe the duration of the active stages of labour and the clinical factors associated with longer labours.[283] Data were collected from 2511 women, in spontaneous labour at term, at low risk of developing complications during labour and who did not receive oxytocin or epidurals. The data were collected from nine US midwifery practices in 1996. The mean length of the second stage was 54 minutes for nulliparous women and 18 minutes for parous women (upper limits: 146 and 64 minutes, respectively). It should be noted, for this and other studies, that the use of means and SDs is inappropriate as data for the duration of labour is not normally distributed (it has a long right hand tail). Multivariate analysis by logistic regression showed that continuous electronic fetal monitoring and

ambulation in labour were significantly associated with longer labour. The use of narcotic analgesia was significantly associated with longer labours in parous women. Maternal age over 30 years was associated with a longer second stage, particularly in women giving birth to a first baby. It should be remembered that these are associations only and do not imply causality.

Earlier work undertaken in the USA (1991–94) examined the duration of labour in 1473 low-risk women in an attempt to identify differences between ethnic groups.[282] The three ethnic groups were non-Hispanic white, Hispanic and American Indian women. The mean duration of the second stage of labour was 53 minutes for nulliparous women and 17 minutes for parous women (upper limits: 147 and 57 minutes, respectively). American Indian women having their first baby had significantly shorter second stages than non-Hispanic white women giving birth for the first time ($P < 0.05$).

A secondary analysis carried out in the USA using birth data collected from 1976 to 1987 described lengths of labour for 6991 women.[277] All included labours were at term, did not involve the use of oxytocin and babies were born spontaneously. Four subgroups were analysed, comprising nulliparous and parous women with or without conduction anaesthesia (95% of which was epidural anaesthesia). The mean lengths and upper limits (95th percentile) of the second stage were as follows: nulliparous women – no conduction anaesthesia 54 minutes (132 minutes), with conduction anaesthesia 79 minutes (185 minutes); parous women – no conduction anaesthesia 19 minutes (61 minutes), with conduction anaesthesia 45 minutes (131 minutes).

A summary showing mean duration and upper limits for the duration of the second stage of labour for women without epidural analgesia calculated using data from all three descriptive studies discussed above is given in Table 138.

Table 138: Summary table showing duration of the second stage of labour

	Mean (SD) (minutes)	Upper limit (mean + 2SDs) (minutes
Nulliparous women (n = 3664)	54 (44)	142
Parous women (n = 6389)	18 (21)	60

n = 3 descriptive studies. Excludes women with epidural analgesia and/or oxytocin.

Evidence statement

Limited quality of evidence makes it difficult to assess the significance of a prolonged second stage of labour on perinatal outcomes for both woman and baby. The woman's position and whether pushing was directed or not are unclear from the studies.

GDG interpretation of the evidence (duration and definition of delay in the second stage of labour)

Pooling findings from the descriptive studies summarised above, the range of upper limits for the normal duration of the active second stage of labour are as follows:

- women giving birth to their first baby – about 0.5–2.5 hours for women without epidural, and 1–3 hours for women with epidural
- women giving birth to second or subsequent babies – up to about 1 hour for women without epidural, and 2 hours for women with epidural.

Unfortunately, these figures are flawed since they are calculated using SDs, the use of which assumes a normal distribution, which is not the case when considering the duration of labour.

Recommendations on duration and definition of delay in the second stage of labour

192. For a nulliparous woman:

- birth would be expected to take place within 3 hours of the start of the active second stage in most women
- diagnose delay in the active second stage when it has lasted 2 hours and refer the woman to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [2007]

193. For a multiparous woman:

- birth would be expected to take place within 2 hours of the start of the active second stage in most women
- diagnose delay in the active second stage when it has lasted 1 hour and refer the woman to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [2007]

194. If full dilatation of the cervix has been confirmed in a woman without regional analgesia, but she does not get an urge to push, carry out further assessment after 1 hour. [2007]

Delay in the second stage of labour

Indication for instrument-assisted vaginal birth

Overview of available evidence

No randomised controlled trial was identified.

Evidence statement

There is no high-quality evidence to compare indications for assisted vaginal birth.

Interventions for delay in the second stage

Introduction

The review refers to women without epidural analgesia, and who have not had a previous caesarean section.

Oxytocin versus expectant management

Description of included studies

There is no study identified comparing oxytocin infusion with expectant management, for management of women without epidural analgesia who have a delayed second stage of labour.

Evidence statement

There are no high-quality studies looking at the use of oxytocin for delay in the second stage of labour, for women without epidural analgesia.

Oxytocin versus instrumental births

Description of included studies

There is no study identified comparing these two interventions.

Evidence statement

There is no high-level evidence on effectiveness and safety of oxytocin infusion for management of the second stage of labour, compared with instrumental vaginal birth.

GDG interpretation of the evidence

While there is no evidence on starting oxytocin in the second stage of labour for parous women, the GDG consider the potential risks of uterine rupture are such that we cannot recommend it.

Recommendations on interventions for delay in the second stage of labour

195. If there is delay in the second stage of labour, or if the woman is excessively distressed, support and sensitive encouragement and the woman's need for analgesia/anaesthesia are particularly important. [2007]

196. Consideration should be given to the use of oxytocin, with the offer of regional analgesia, for nulliparous women if contractions are inadequate at the onset of the second stage. [2007]

197. For a nulliparous woman, suspect delay if progress (in terms of rotation and/or descent of the presenting part) is inadequate after 1 hour of active second stage. Offer vaginal examination and then offer amniotomy if the membranes are intact. [2007, amended 2014]

198. For a multiparous woman, suspect delay if progress (in terms of rotation and/or descent of the presenting part) is inadequate after 30 minutes of active second stage. Offer vaginal examination and then offer amniotomy if the membranes are intact. [new 2014]

Update 2014

199. An obstetrician should assess a woman with confirmed delay in the second stage (after transfer to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50) before contemplating the use of oxytocin. [new 2014]

200. After initial obstetric assessment of a woman with delay in the second stage, maintain ongoing obstetric review every 15–30 minutes. [2007]

Instrument to be used

Review question

What are the indications for the use of ventouse or forceps?

Ventouse versus forceps

Description of included studies

The evidence for this subsection was drawn from a good quality systematic review[550] including ten trials, plus three additional recent trials.[551–553] [EL = 1+] The systematic review was published in April 1999, and the last search was performed in February 1999. The trials included in the systematic review were conducted in USA, Denmark, Sweden, UK, South Africa and Greece. The recent trials were conducted in Sri Lanka,[551] Pakistan[552] and Ireland.[553] There are two follow-up studies of trials using the same population that were included in the systematic review, which investigated long-term outcomes of mothers and their children. These studies were conducted in the UK (published in 1999 and 1998).[554,555]

Review findings

Labour events

Meta-analysis of nine trials showed that ventouse-assisted birth was more likely to be associated with failed birth with selected instruments compared with forceps-assisted birth (n = 2849, OR 1.69 [95% CI 1.31, 2.19]).[556] Another recent trial in Pakistan showed the same association (n = 442, RR 2.04 [95% CI 1.14, 3.70]).[552] There was no evidence of differences in rates of CS (meta-analysis of seven trials, n = 1662, OR 0.56 [95% CI 0.31, 1.02]). Meta-

analysis of 12 trials showed a significant reduction of the use of anaesthesia with ventouse-assisted birth (n = 5051, OR 0.59 [95% CI 0.51, 0.68]).

Women's complications

Meta-analysis of trials in the systematic review showed that ventouse-assisted birth significantly reduced significant maternal injury (seven trials, n = 2582): OR 0.41 [95% CI 0.33 to 0.50] and severe perineal pain at 24 hours (two trials, n = 495): OR 0.54 [95% CI 0.31 to 0.93]. The Pakistani trial showed that ventouse-assisted birth significantly reduced cervical tears (n = 442: RR 0.19 [95% CI 0.04 to 0.86]) and third-degree perineal trauma (n = 442): RR 0.58 [95% CI 0.04 to 0.86]) compared with forceps-assisted birth.

Newborn outcomes

Meta-analysis of trials in the systematic reviews showed that ventouse-assisted birth increased incidence of cephalhaematoma (six trials, n = 1966): OR 2.38 [95% CI 1.68 to 3.37] and retinal haemorrhage (five trials, n = 445): OR 1.99 [95% CI 1.35 to 2.96]. The Pakistani trial also showed an increase in the incidence of cephalhaematoma with the use of ventouse (n = 442): RR 7.14 [95% CI 1.59 to 33.33]. There was a non-significant increase in the number of babies whose birth was assisted with ventouse who had a lower Apgar score at 5 minutes (five trials, n = 1545): OR 1.67 [95% CI 0.99 to 2.81]. Meta-analysis of trials showed that there was no evidence of a difference in Apgar score less than 7 at 1 minute (meta-analysis of three trials, n = 822): OR 1.13 [95% CI 0.76 to 1.68]; and the Sri Lanka trial (n = 50): RR 0.85 [95% CI 0.24 to 3.03]; scalp or face injuries (not cephalhaematoma) (six trials, n = 2330): OR 0.89 [95% CI 0.70 to 1.13]; use of phototherapy (four trials, n = 1648): OR 1.08 [95% CI 0.66 to 1.77]; perinatal death (seven trials, n = 1800): OR 0.80 [95% CI 0.18 to 3.52]; follow-up/re-admission by hospital (one trial,[557] n = 232): OR 1.33 [95% CI 0.58 to 3.05]; hearing abnormal (confirmed/suspected) (one trial,[557] n = 232):OR 1.66 [95% CI 0.54 to 5.06]; and strabismus or vision abnormality suspected (one trial,[557] n = 232): OR 1.38 [95% CI 0.47 to 4.05]. The Sri Lanka study also showed no evidence of differences in neonatal complications (n = 50): RR 1.00 [95% CI 0.72 to 1.39].

Mental and psychological outcomes and women's satisfaction

Meta-analysis of three trials showed that maternal worries about the baby, significantly increased with ventouse-assisted birth (n = 561): OR 2.17 [95% CI 1.19 to 3.94]. The Irish study investigated women's satisfaction and showed no evidence of a difference (would choose CS for next birth): RR 0.53 [95% CI 0.23 to 1.27]. In the systematic review, only two trials included women's assessment of pain during birth.[558,559] One trial comparing methods of instrumental birth contained a substudy of the views of women and obstetric and midwifery staff.[559] A subsample of 66 of the 304 women participating in the trial were interviewed between the first and eighth day postpartum. Women scored the pain of the birth itself on a 4-point scale ranging from 'not painful at all' to 'extremely painful'. Despite receiving more analgesia, 12 of the 33 women who had undergone a forceps birth considered the birth had been 'very' or 'extremely' painful compared with seven of the 33 who had undergone a vacuum extraction. Similar findings were reported by another study, which found 27% (n = 28) of women considered their forceps birth to have been 'unbearable' compared with 18% (n = 19) of women who had undergone vacuum extraction: OR 1.5 [95% CI 0.5 to 4.2].[558]
A third study concluded that there were significantly fewer women in the vacuum extractor group requiring epidural or spinal anaesthesia (25.4% versus 32.7%) or general anaesthetics (1% versus 4%) compared with the forceps group.[560] The authors concluded that less analgesia is required for vacuum extraction compared with the use of forceps. However, the results reflect the choice of analgesia made prior to the start of the procedure by the attending anaesthetist and obstetrician rather than that requested or desired by the women themselves.

No assessment was made of the pain experienced during the procedure and the women's views on the type of analgesia provided were not recorded.

Medium- and long-term outcome

The UK follow-up study of the trial showed a significantly lower incidence with use of ventouse of anal sphincter defects (RR 0.58 [95% CI 0.32 to 0.92]); and higher maximum anal squeeze pressure (ventouse mean = 38, forceps mean = 53, P = 0.02); but no evidence of difference in anal incontinence (RR 1.47 [95% CI 0.44 to 4.92]); and maximum anal resting pressure (ventouse mean = 55, forceps mean = 60, P = 0.32) at the end of the 5-year follow-up period.[555] Another study using the same population showed no evidence of differences in both bowel and urinary habits of the women after 5 years.[554] This study also investigated long-term outcome of the babies, and showed no evidence of differences in visual problems among the children (OR 0.9 [95% CI 0.38 to 2.5]) or child development.

The Irish long-term study (follow-up = 3 months) showed that there was a significant reduction in altered continence (RR 0.35 [95% CI 0.17 to 0.71]) and a tendency of higher anal pressure among women who had given birth assisted by ventouse compared with forceps-assisted birth: resting pressure (mmHg) (ventouse median = 63, forceps median = 54, P = 0.05); squeeze pressure (mmHg) (ventouse median = 96, forceps median = 86, P = 0.11); squeeze increment (mmHg) (ventouse median = 25, forceps median = 27, P = 0.12); vector symmetry index (RR 0.77 [95% CI 0.39 to 1.54]). There was no evidence of differences in continence score (ventouse mean = 3, forceps mean = 3, P = 0.17); faecal urgency less than 5 minutes (RR 0.72 [95% CI 0.34 to 1.54]); and perineal discomfort (RR 0.78 [95% CI 0.37 to 1.64]).

Soft ventouse versus hard ventouse

Description of included studies

One good quality systematic review including nine trials and 1375 women was identified.[561] [EL = 1+] This was published in February 2000 and the last search was performed in February 2000. The included trials were conducted in Saudi Arabia, Nepal, the UK, Sweden, South Africa, the Netherlands, Malaysia, Greece and Thailand.

Review findings

Labour events

Meta-analysis of nine trials showed there was a significant increase of failure to deliver when the instrument chosen was with the soft cups, as oppose to the hard cups (n = 1368 women): OR 1.65 [95% CI 1.19 to 2.29]. No other outcome was reported.

Women's outcomes

Meta-analysis of six trials showed there was no evidence of a difference in significant maternal injury (n = 1137 women): OR 0.85 [95% CI 0.57 to 1.27].

Newborn outcomes

Meta-analysis of eight trials showed that use of soft cups significantly reduced significant scalp trauma (n = 1337): OR 0.45 [95% CI 0.34 to 0.60]. Otherwise, meta-analysis showed no evidence of a difference in Apgar score less than 7 at 1 minute (four trials, n = 866): OR 1.21 [95% CI 0.80 to 1.83]; less than 7 at 5 minutes (five trials, n = 765): OR 0.68 [95% CI 0.35 to 1.33]; incidence of cephalhaematoma (four trials, n = 538): OR 0.70 [95% CI 0.34 to 1.44]; incidence of phototherapy or jaundice (six trials, n = 1137): OR 0.73 [95% CI 0.50 to 1.07]; severe retinal/intracranial haemorrhage (two trials, n = 218): OR 0.84 [95% CI 0.27 to 2.64]; and neonatal death (one trial, n = 72): OR 1.26 [95% CI 0.08 to 20.85].

Evidence statement

There is high-quality evidence comparing ventouse- and forceps-assisted birth. Ventouse is associated with a lower incidence of success, less perineal/genital injury, less perineal pain in the short- and long-term, but with more cephalhaematoma and retinal haemorrhage in babies. When there is failure to achieve birth with the first instrument, there is an increased risk of trauma to the baby with the use of sequential instruments.
There is no evidence of differences between ventouse and forceps in CS rate, long-term babies' outcomes and women's satisfaction and psychological outcomes.
There is moderate level of evidence on soft versus hard ventouse-assisted birth. Soft cup ventouse seems to be associated with higher failure to achieve vaginal birth, but with lower significant scalp trauma on babies. There is no evidence of differences in other major outcomes including long-term outcomes.

Failed/successful instrumental vaginal birth and CS

Description of included studies

One UK cohort study compared women with successful instrumental vaginal birth (n = 184), immediate CS (n = 102) and attempted instrumental vaginal birth and then CS (n = 107).[562] [EL = 2+]

Review findings

CS versus assisted vaginal birth

The UK study showed that women with CS had more blood loss (blood loss more than 1 litre) (OR 2.82 [95% CI 1.10 to 7.62]); more opiates required (OR 10.93 [95% CI 6.44 to 18.91]); more incidents of urinary catheter required for longer than 24 hours (OR 3.09 [95% CI 1.39 to 6.88]); and a longer hospital stay (6 days or more) (OR 3.47 [95% CI 1.58 to 7.62]); compared with instrumental birth, controlling for various confounders. More babies born via CS were admitted to a neonatal unit (OR 2.64 [95% CI 1.16 to 6.02]); but less babies with CS had trauma from the birth (OR 0.37 [95% CI 0.20 to 0.70]; or serious trauma OR 0.34 [95% CI 0.08 to 1.42]), compared with babies who had had an instrumental birth. There is no evidence of a difference in Apgar score < 7 at 5 minutes (OR 2.81 [95% CI 0.48 to 16.74]).

Evidence statement

There is limited evidence on assisted vaginal birth on women's and babies' outcomes, compared with CS. Limited evidence showed women with CS were more likely to lose more blood, and stay in hospital longer, while babies born with CS were more likely to be admitted to a neonatal unit, but less likely to have trauma, compared with assisted vaginal birth.

Recommendations on instruments used for delay in the second stage of labour

201. Think about offering instrumental birth if there is concern about the baby's wellbeing or there is a prolonged second stage. [2007]

202. Recognise that, on rare occasions, the woman's need for help in the second stage may be an indication to assist by offering instrumental birth when supportive care has not helped. [2007]

203. The choice of instrument depends on a balance of clinical circumstance and practitioner experience. [2007]

204. Because instrumental birth is an operative procedure, advise the woman to have tested effective anaesthesia. [2007]

205. If a woman declines anaesthesia, offer a pudendal block combined with local anaesthetic to the perineum during instrumental birth. [2007]

206. If there is concern about fetal compromise, offer either tested effective anaesthesia or, if time does not allow this, a pudendal block combined with local anaesthetic to the perineum during instrumental birth. [2007]

207. Advise the woman to have a caesarean section if vaginal birth is not possible[s]. [2007]

Intrapartum interventions to reduce perineal trauma

Review question

What is the effectiveness on perineal or genital trauma (including previous third- or fourth-degree trauma or female genital mutilation) of the following techniques?

- perineal massage
- hand position
- heat
- cold
- maternal position
- analgesia
- episiotomy
- operative vaginal delivery.

Previous guideline

No previous guidelines have considered interventions related to perineal care during childbirth.

Intrapartum perineal massage

Description of included studies

One RCT was identified which investigated the effects of perineal massage in the second stage of labour upon perineal outcomes.[345] [EL = 1+] This Australian study enrolled 1340 women across three trial sites. For women allocated to the experimental group (n = 708), perineal massage was performed by the attending midwife during each contraction of the second stage of labour, unless this was uncomfortable for the woman in which case the massage would not be performed. Midwives at each hospital were instructed on perineal massage through use of verbal instruction, a specially made video and an illustrated pamphlet. Compliance with trial group allocation is not detailed.

Review findings

There were no significant differences between groups for most perineal outcomes (massage group versus control group): intact perineum: 198/708 versus 171/632, RR 1.03 [95% CI 0.87 to 1.23]; first-degree tear: 122/708 versus 106/632, RR 1.03 [95% CI 0.81 to 1.30]; second-degree tear: 190/708 versus 164/632, RR 1.03 [95% CI 0.86 to 1.24]; episiotomy: 176/708 versus 170/632, RR 0.92 [95% CI 0.77 to 1.11]. There was a difference in incidence of third-degree tears, with these being less frequent in the massage group: 12/708 versus 23/632; RR 0.47 [95% CI 0.23 to 0.93], although the trial was underpowered to detect a statistically significant difference in this rare outcome. No significant differences were found between pain outcomes at 3 days, 10 days or 3 months postpartum: at 3 days: vaginal pain: 416/597 versus 359/499, RR 0.97 [95% CI 0.90 to 1.05]; at 10 days: vaginal pain: 184/632 versus 187/555, RR 0.86 [95% CI 0.73 to 1.02]; at 3 months: vaginal pain: 58/503 versus 54/436, RR

s See Caesarean section (NICE clinical guideline 132).

0.93 [95% CI 0.66 to 1.32]; dyspareunia: 78/503 versus 68/436; RR 0.9 [95% CI 0.74 to 1.34]; intercourse not resumed: 49/503 versus 60/436; RR 0.71 (0.50 to 1.01). There were also no significant differences regarding urinary and bowel control.

Recommendation on perineal massage

208. Do not perform perineal massage in the second stage of labour. [2007]

Heat/cold

Description of included studies

A large observational cohort study conducted in the USA investigated perineal care measures that were associated with perineal trauma during childbirth.[337] [EL = 2+] Statistical analysis was performed on a subset of births that included all spontaneous vaginal term births (n = 2595).

Review findings

Data were collected for women cared for intrapartum, at three nurse-midwifery services (all clinical teaching sites) during a 12 month period. Multivariate analysis by logistic regression was used to identify predictors of episiotomy and spontaneous tears. Findings suggested (at borderline level of significance) that application of warm compresses to the perineum during the second stage of labour was protective against spontaneous tears in women who did not have an episiotomy (n = 2363), for both nulliparous women (OR 0.7 [95% CI 0.4 to 1.0]) and multiparous women (OR 0.6 [0.3 to 0.9]). Application of warm compresses was also found to be protective against episiotomy for nulliparous women (OR 0.3 [95% CI 0.0 to 0.8]). For multiparous women, the findings are of borderline significance (OR 0.3 [95% CI 0.0 to 1.0]).

Hand position during birth of baby

Description of included studies

A large UK RCT (n = 5471) compared two methods of perineal management used during spontaneous vaginal birth – a 'hands on' method whereby the midwife's hands were used to put pressure on the baby's head (to flex the head) and support ('guard') the perineum; and a 'hands poised' method where the midwife keeps her hands poised but not touching the head or perineum.[346] [EL = 1+] A similar quasi-randomised trial conducted in Austria also investigated the effects of the hands on versus hands poised techniques of perineal care during birth (n = 1076).[347] [EL = 1+]

An RCT conducted in the USA compared three perineal care measures undertaken during the second stage of labour: warm compresses to the perineal area; massage with lubricant; and no touching of the perineal area until the baby's head was crowned.[348] [EL = 1+] The study involved 1211 women allocated to midwife care during labour. Forty percent of participants were nulliparous women. Warm compresses or massage with lubricant were applied as continuously as possible until crowning of the baby's head, unless the woman requested that they be stopped or the technique changed. Data collection included details of allocated technique, what was actually done and for how long, also whether the woman asked for the technique to be stopped or changed.

Review findings

The large UK RCT compared hands on with hands poised methods for midwife care during the birth of the baby.[346] [EL = 1+] Compliance with the allocated trial group was very good for the hands on group (95.3%) and somewhat lower in the hands poised group (70.1%), reflecting the greater number of midwives who expressed a preference for the hands on technique. The main outcome measure for the trial was perineal pain in the previous 24 hours reported by the woman at 10 days. This was found to be significantly lower in the hands on group compared with the hands poised group: 910/2669 versus 823/2647, RR 1.10 [95% CI 1.01 to 1.18]. This represents an absolute difference of 3% [95% CI 0.5% to 5.0%]. The difference resides predominantly in the category of mild pain (23.5% versus 20.9%; moderate

pain: 9.2% versus 8.8%; severe pain: 1.4% versus 1.4%). There were no other significant differences in pain outcomes, e.g. at 2 days: pain felt in previous 24 hours: some pain: 70.0% versus 71.3%, NS; mild: 27.5% versus 28.8%, NS; moderate: 37.0% versus 37.4%, NS; severe: 5.2% versus 5.1%, NS. Incidences of reported pain were also very similar at 3 months postpartum. Stratified analyses showed that more of the differences between groups for reported pain at 10 days were apparent for women having their first vaginal birth, for women without epidural analgesia in the second stage of labour and in the latter part of the trial (after the first 6 months). There was also evidence of an effect of midwives' practice preferences biasing the findings to favour the expressed preference, with the hands on technique only being significantly better (in terms of reported pain at 10 days) when the midwife favoured this technique (heterogeneity test P = 0.03).

While the rates of second-degree trauma (including episiotomy) were similar between the two groups (36.9% versus 36.6%), the episiotomy rate was higher in the hands on group (10.2% versus 12.9%, RR 0.79 [99% CI 1.02 to 2.78]). The rates of third-degree trauma were similar for the two groups (1.5% versus 1.2%), as were incidences of vaginal and anterior genital trauma. The manual removal of the placenta was performed significantly more frequently for women in the hands poised group: n = 71 (2.6%) versus 42 (1.5%), RR 1.69 (99% CI 1.02 to 2.78). While this result is difficult to explain, the authors point out that the difference was evident in both trial centres, supporting its validity as a 'true' finding. A large number of other outcomes were investigated with no differences found between study groups. These included neonatal outcomes (Apgar scores, need for resuscitation at birth, additional neonatal care, breastfeeding at 2 days, 10 days and 3 months) and women's outcomes at 3 months (dyspareunia, urinary problems, bowel problems, treatment for perineal trauma; postnatal depression).

A quasi-randomised trial conducted in Austria has also investigated this intervention (n = 1076).[347] [EL = 1+] Only midwives who agreed with the aims of the trial participated in the study. Quasi-randomisation was carried out by alternating hands on and hands poised policies according to the date the woman entered the second stage of labour. Compliance with trial group allocation was high (92% and 94%). The rate of first- and second-degree perineal trauma was similar for the two trial groups (hands on 29.8%; hands poised 33.7%, NS), although there was a higher rate of third-degree trauma in the hands on group (n = 16 (2.7%) versus n = 5 (0.9%)). The study was underpowered to detect the statistical significance of this rare event. Women in the hands on group were more likely to have an episiotomy performed than women in the hands poised group: 17.9% versus 10.1%, P < 0.01. No difference was observed between groups regarding labial and vaginal trauma, length of the second stage of labour or manual removal of placenta (hands on n = 10 (1.7%) versus hands poised n = 7 (1.3%)). Neonatal outcomes were very similar between the two groups with only one baby in each group having an Apgar score < 7 at 5 minutes.

Findings from the US RCT comparing warm compresses, massage with lubricant and no touching of the perineal area showed that overall compliance with the allocated technique was very high, 94.5% by self-report and 95.5% in an observed group (25% of whole study sample). In 5.8% of all births the midwife was asked by the woman to stop using the allocated technique; 75% of these requests were made by women allocated to the perineal massage with lubricant technique. The overall episiotomy rate was very low in the study (0.8%). Twenty-three percent of women (n = 278) had no genital trauma, and the genital tract trauma profiles were the same across all three study groups. Twenty percent of women (n = 242) experienced more severe levels of trauma (defined as second-, third- or fourth-degree perineal tear, a tear of the mid or inner vaginal vault, or a cervical tear), and 57% (n = 691) had minor trauma (defined as a first-degree perineal tear, outer vaginal or external genitalia tear). No differences were found when comparing warm compresses with the hands off technique: RR 1.04 [95% CI 0.81 to 1.35] or massage versus hands off technique: RR 1.05 [95% CI 0.81 to 1.35].

Stratified analysis and adjusted relative risks controlling for parity, epidural usage, infant birthweight or first year versus later years of the study also showed no differences between study groups. For the warm compress group the mean time the technique was used was 17.8 minutes (SD 19.5 minutes) among women with trauma compared with 13.4 minutes (SD 16.1 minutes) for women without trauma (P = 0.06). For the massage group the mean time this technique was used was 11.6 minutes (SD 14.0 minutes) for women with trauma compared with 5.8 minutes (SD 6.8 minutes) among women without trauma (P < 0.01). A final regression model demonstrated two care measures that were protective for perineal trauma, a sitting position for birth and birth of the fetal head between (rather than during) contractions.

Evidence statement

There is high-level evidence that intrapartum perineal massage or application of warm compresses in the second stage of labour does not improve perineal outcomes.

There is limited high-level evidence that women allocated to a 'hands on' perineal management group reported less mild pain at 10 days, compared with those allocated to a 'hands poised' group. The rates of reported perineal trauma (including episiotomy) were similar between the two groups but episiotomy was higher in the 'hands on' group.

Recommendation on hand position

209. Either the 'hands on' (guarding the perineum and flexing the baby's head) or the 'hands poised' (with hands off the perineum and baby's head but in readiness) technique can be used to facilitate spontaneous birth. [2007]

Local anaesthetic spray

Description of included studies and review findings

One RCT was reviewed which evaluated the effectiveness and acceptability of lidocaine spray in reducing perineal pain during spontaneous vaginal birth.[349] [EL = 1+] Women were randomised to receive either an application (five sprays) of lidocaine spray to the perineum and inside aspect of the labia when birth was thought to be imminent (n = 93), or application of a placebo spray, identical in appearance to the treatment spray (n = 92).

The primary outcome for the trial was reported pain during birth, as measured using a 0–100 numeric scale.[349] Trial groups were comparable for most obstetric and sociodemographic variables considered, although some differences did arise, namely parity, smoking, augmentation, induction, use of pethidine prior to randomisation and birthweight. These differences were adjusted for in the secondary analyses. In both trial groups, the mean number of sprays received was 4.8 and approximately two-thirds of women in each group received the intervention as intended. No difference was found between groups for the main outcome, pain during birth (mean [SD]: lidocaine: 76.9 [21.6] versus placebo 72.1 [22.2], difference between means 4.8 [95% CI −1.7 to 11.2], P = 0.14). A slightly larger difference between means is seen if adjustments are made for the differences between trial groups, but this still fails to reach statistical significance: 6.3 [95% CI −0.8 to 13.3], P = 0.081. Most secondary outcomes were similar between groups, including vaginal trauma, neonatal resuscitation, feelings during birth, overall rating of birth experience, sutured after birth and perineal pain 1 week after birth. There was, however, a significantly lower incidence of second-degree perineal trauma in the lidocaine group: 28.0% versus 44.6%, RR 0.63 [95% CI 0.42 to 0.93], P = 0.019. Women in the lidocaine spray group were also less likely to report dyspareunia on resumption of sexual intercourse: 27.1% versus 52.7%, RR 0.52 [95% CI 0.35 to 0.76], P = 0.0004. The authors, however, pointed out that the large number of secondary analyses undertaken means these differences could be chance findings.

Evidence statement

There is a small amount of high-level evidence that the use of lidocaine spray during the second stage of labour is not associated with a reduction in perineal pain, but may be associated with a reduction in perineal trauma during birth.

Recommendation on local anaesthetic spray

210. Do not offer lidocaine spray to reduce pain in the second stage of labour. [2007]

Routine use of episiotomy

Description of included studies

One systematic review including seven RCTs and eight cohort studies, plus an additional RCT, inform this subsection. The findings from the systematic review supersede an earlier (1999) previous systematic review including six of the seven RCTs.[350]

A recent systematic review has been published which considers maternal outcomes following routine, compared with restrictive, use of episiotomy.[351] [EL = 1+] The review included evidence from seven RCTs involving a total of 5001 women and eight cohort studies involving 6463 women. Six of the trials studied mediolateral episiotomy and only one used midline episiotomy. Three trials included only women having their first baby. All studies focused on spontaneous vaginal births, although a small proportion of instrumental vaginal births were included in most trials (0–5% in four trials and 5–15% in three trials).

Review findings

Evidence from the trials is usually summarised descriptively rather than meta-analysed. All trials achieved a wide difference in episiotomy use, between the trial aims in the direction expected, ranging from 7.6% in the restrictive group to 93.7% in the routine group. In the trial judged by the authors to be the strongest (best quality) (n = 1000), the incidence of intact perineum was 33.9% in the restrictive group versus 24% in the routine group. In the largest trial (n = 2606), the need for surgical repair was reported as 63% in the restrictive group compared with 88% in the routine group. In the other five trials, the need for perineal repair was less frequent in the restrictive group: RR 0.46 [95% CI 0.30 to 0.70]. The need for any suturing was 26% higher in routine groups (three trials): RR 1.26 [95% CI 1.08 to 1.48].

All trials were underpowered to detect any differences in third- or fourth-degree tears, with an incidence of 105/5001 (seven trials).

Women's experiences of pain were considered in five trials. In the largest trial, pain outcomes were found to be very similar between the two groups. Routine use group: mild pain 14.6%, moderate pain 7.8% and severe pain 0.2% versus restrictive use group: 14.1%, 7.5% and 0.9%, respectively (n = 885 and n = 1000, respectively). The use of oral analgesia and pain ratings at 3 months were also similar. Three other trials reported pain as higher in the routine use groups, each trial using a different pain outcome measure. The largest trial (n = 2422 and n = 2606, respectively) reported 'pain on the day of discharge'. In the routine use of episiotomy group, this was found to be 42.5% of women reporting pain, compared with 30.7% in the restrictive group. A second trial assessed pain using a VAS for four activities (day 1 to 5 postpartum) as follows: bed rest: routine 39 mm (SD 28 mm) versus restrictive 22 mm (SD 21 mm); sitting down: 69 mm (SD 23 mm) versus 51 mm (SD 25 mm); walking: 56 mm (SD 24 mm) versus 37 mm (SD 24 mm); opening bowels: 36 mm (SD 30 mm) versus 21 mm (SD 21 mm). Across all activities, the restrictive use group experienced less perineal pain than the routine use group (P = 0.005 to 0.048).

Urinary incontinence was investigated by two RCTs. The largest trial (n = 895 and n = 1000, respectively) reported involuntary loss of urine at 3 months and use of a pad for incontinence. Both outcomes had very similar findings for the two study groups (involuntary loss of urine: routine 19.0% versus restrictive 18.9%). Meta-analysis of findings from the two trials shows no difference in incidence of urinary incontinence between routine versus restrictive use of episiotomy: RR 1.02 [95% CI 0.83 to 1.26].

Five prospective cohort studies also examined self-reported urinary incontinence. No difference was found between groups of women who had an episiotomy versus those who had a spontaneous tear (five studies): RR 0.88 [95% CI 0.72 to 1.07]. Four cohort studies asked women about rectal incontinence. None found episiotomy to be associated with a statistically

significant reduced risk of incontinence of stool or flatus. Pooling of data from the two cohort studies with comparable outcome measures indicates an increase in risk associated with use of episiotomy: RR 1.91 [95% CI 1.03 to 3.56].
Two trials reported sexual function on an intention-to-treat basis. The largest trial (n = 895 and n = 1000, respectively) found that women allocated to the restrictive use of episiotomy group were more likely to have resumed sexual intercourse at 1 month compared with women allocated to the routine group: routine 27% versus restrictive 37%, P < 0.01. No differences were found between groups regarding resumption of sexual intercourse by 3 months, dyspareunia at 3 months, or 'ever suffering painful intercourse' at 3 years. Five prospective cohort studies found no differences in sexual function between women who had had an episiotomy and women with spontaneous tears. Dyspareunia at 3 months was also found to be similar between the two groups of women (two trials): RR 1.53 [95% CI 0.93 to 2.51].
A recent RCT conducted in Germany compared restrictive use of episiotomy (fetal indications only) (n = 49) with more liberal use (fetal indications and if a tear was deemed imminent) (n = 60).[352] [EL = 1+] Episiotomy rates were 41% in the restrictive group and 77% in the liberal group (RR 0.47 [95% CI 0.3 to 0.7]. The incidences of intact perinea and 'minor' perineal trauma (defined as intact perinea or first-degree tears) were more frequent in the restrictive policy group: intact perineum: 14/49 versus 6/60, RR 2.9 [95% CI 1.2 to 6.9]; intact perineum or first-degree tear: 19/49 versus 8/60, RR 2.9 [95% CI 1.6 to 10.5]. There was no significant difference regarding anterior trauma: 27/49 versus 25/60, RR 1.1 [95% CI 0.8 to 1.8]. Pain was found to be significantly lower for women allocated to the restrictive episiotomy group: sitting (mean): 51 mm [SD 25 mm] versus 69 mm [SD 23 mm]; mean difference 18 mm [95% CI 5 to 31 mm], P = 0.009; walking (mean): 37 mm [SD 24 mm] versus 56 mm [SD24 mm]; mean difference 19 mm [95% CI 6 to 33 mm], P = 0.005. No difference was noted between groups for babies' Apgar scores or umbilical artery pH.
Owing to similarities between studies and outcome measures, it was possible to pool some of the findings from the single RCT[352] and the 1999 systematic review[350] and perform a meta-analysis. The meta-analysis was performed using a random effects model owing to the significant heterogeneity between study outcome measures and uncertainty regarding reliability of classification of outcome measures, e.g. diagnosis of third-degree tears and ratings made on a pain VAS. Findings are as follows:

- severe perineal trauma (third- and fourth-degree tears): RR 0.74 [95% CI 0.42 to 1.28] (six trials, one with no incidents)
- any posterior perineal trauma: RR 0.87 [95% CI 0.83 to 0.91] (five trials)
- anterior trauma: RR 1.75 [95% CI 1.52 to 2.01] (five trials)
- Apgar score < 7 at 1 minute: RR 1.05 [95% CI 0.76 to 1.45].

Owing to differences in outcome measures, data relating to perineal pain could not be pooled.

Angle of episiotomy

Description of included studies
One prospective observational study was identified which aimed to identify risk factors associated with third- and fourth-degree perineal tears following childbirth.[353] [EL = 3] The study involved 241 women giving birth vaginally for the first time. Following birth an experienced researcher performed a perineal and rectal examination in order to identify and classify perineal trauma. Dimensions and direction of episiotomy was noted and obstetric variables recorded prospectively.

Review findings

Of the 241 women included in the study, 59 (25%) sustained anal sphincter injury. Multiple logistic regression identified higher birthweight (P = 0.021) and mediolateral episiotomy (OR 4.04 [range 1.71 to 9.56] as independent risk factors for sphincter injury. Further investigation revealed that episiotomies angled closer to the midline were significantly associated with anal sphincter injuries (26 versus 37 degrees, P = 0.01). No midwife and only 22% of obstetricians performed 'true' mediolateral episiotomies (defined as being at least 40 degrees from the midline).

Evidence statement

There is considerable high-level evidence that the routine use of episiotomy (trial mean 71.6%; range 44.9% to 93.7%) is not of benefit to women either in the short or longer term, compared with restricted use (trial mean 29.1%; range 7.6% to 53.0%).

Recommendations on episotomy

211. Do not carry out a routine episiotomy during spontaneous vaginal birth. [2007]

212. If an episiotomy is performed, the recommended technique is a mediolateral episiotomy originating at the vaginal fourchette and usually directed to the right side. The angle to the vertical axis should be between 45 and 60 degrees at the time of the episiotomy. [2007]

213. Perform an episiotomy if there is a clinical need, such as instrumental birth or suspected fetal compromise. [2007]

214. Provide tested effective analgesia before carrying out an episiotomy, except in an emergency because of acute fetal compromise. [2007]

Vaginal birth following previous third- or fourth-degree perineal trauma

Description of included studies

No studies were found assessing care of women with genital mutilation.

Two descriptive studies were identified that investigated the incidence of repeat third- and fourth-degree perineal tears following previous severe trauma. A third retrospective cohort study examined the incidence of anal incontinence following previous third- or fourth-degree tears.

Review findings

A retrospective US population study described the incidence of recurrence of third- and fourth-degree perineal tears, in subsequent births, following a previous third- or fourth-degree tear.[354] [EL = 3] All cases of third- and fourth-degree lacerations (termed 'severe' lacerations) for the 2 year period 1990–91 were identified (n = 18,888; 7.31% incidence rate). These women were then traced over the following 10 years, which included a further 16 152 births. Of these, 14 990 were vaginal births with an incidence rate of repeat severe laceration of 5.67% (n = 864), this being significantly lower than the original incidence rate (OR 1.29 [95% CI 1.2 to 1.4]). It should be noted, however, that all women in the second group were multiparous and over the same time period there was a 69% fall in the forceps birth rate (from 7.75% to 2.4%), a 28% fall in the rate of use of vacuum extraction, and a 24% reduction in the episiotomy rate. Women with a prior fourth-degree tear had a higher incidence of recurrent severe laceration than women with a previous third-degree tear (410/5306 (7.73%) versus 454/9684 (4.69%)). The association between a number of risk factors and recurrent severe perineal laceration was calculated. A number of significant associations were found: episiotomy (global): OR 2.6 [95% CI 2.25 to 3.04]; episiotomy alone without instruments: OR 1.7 [95% CI 1.46 to 1.92]; all forceps: OR 3.0 [95% CI 2.2 to 4.0]; forceps + episiotomy: OR

3.6 [95% CI 2.6 to 5.1]; all vacuum: OR 2.2 [95% CI 1.76 to 2.69]; vacuum + episiotomy: OR 2.7 [95% CI 2.14 to 3.39]. The use of forceps or vacuum extraction without episiotomy was not found to be significantly associated with recurrent severe laceration: forceps, no episiotomy: OR 1.4 [95% CI 0.7 to 2.9]; vacuum, no episiotomy: OR 1.0 [95% CI 0.6 to 1.7]. Multivariate logistic regression was used to estimate the association of the use of forceps, vacuum extraction, episiotomy, woman's age and year of birth as independent risk factors for recurrent laceration. All were found to be significant independent risk factors. The authors pointed out that some other important confounders were not included in the model, e.g. parity, birthweight and indication for instrumental vaginal birth.

A second prospective descriptive study has also investigated the risk of subsequent anal sphincter disruption following a previous severe laceration.[355] [EL = 3] This study, conducted in Ireland, did not distinguish between third- and/or fourth-degree perineal trauma. From 20,111 consecutive vaginal births, 342 (1.7%) women were identified as having sustained a third-degree tear. Each of these women underwent a series of investigations at 3 months postpartum to ascertain perineal functioning (e.g. continence scoring and manometry) and identify anal defects (using ultrasound imaging). Fifty-six of these women gave birth to a subsequent child during the following 3 years and formed the study sample. Forty-two (75%) women had sustained the initial trauma during birth of their first child, 34 cases following extended mediolateral episiotomy. All of these 56 women underwent continence symptom scoring, anal manometry and endosonography during the last trimester of their subsequent pregnancy. Nine were identified as having an anal defect of greater than one quadrant of the external sphincter (deemed large), five had resting manometric pressures ≤ 25 mmHg and two had squeeze pressures ≤ 40 mmHg. Six of these 56 women had significant symptoms of faecal incontinence (scores of 5 or more on the continence scoring system). How symptoms related to manometric pressures and/or evidence of anal sphincter defect is not described. Four of these women gave birth by elective caesarean section, along with three other women who wished to avoid perineal trauma. Of this group of 45 women who gave birth vaginally, following previous third-degree trauma, the scores for faecal incontinence following previous birth versus following subsequent birth were as follows: score 0–2: 39 versus 33; score 3–4: 3 versus 4; score 5–6: 1 versus 0; score 6–10: 2 versus 3; not assessed: 0 versus 5. The episiotomy rate among this group was 62% (n = 28), 7% (n = 4) had an instrumental birth and 27% (n = 12) sustained a perineal tear of which two were third-degree tears (an incidence of 4.4%), both associated with spontaneous vaginal births. The authors reported that, following repair of a subsequent third-degree tear, the outcome for both women was 'excellent' in terms of faecal continence. Two women who had reported severe symptoms of faecal incontinence antenatally, and went on to give birth to the subsequent child vaginally, remained symptomatic (scoring in the 6–10 range). The one extra case of severe faecal incontinence following a subsequent birth was due to the development of irritable bowel syndrome rather than as a consequence of perineal trauma.

A retrospective cohort study conducted in Switzerland investigated the incidence of anal incontinence in women who had had a vaginal birth following a previous third- or fourth-degree tear.[356] [EL = 3] Women were identified using the computer records of one hospital, and eligible women were contacted by telephone to request their participation in the study. Of the 448 women identified, 208 (46%) were contacted. Of these, 177 agreed to participate (response rate = 86%). The mean age of the respondents was 40.7 years [range 32 to 54 years] and ten women considered themselves as menopausal. Of this sample, 114 had had subsequent vaginal births. Findings suggest that, while subsequent births are not associated with increased incidence of anal incontinence in women with previous third-degree perineal tears, there is a trend towards an increased incidence following previous fourth-degree tears. While 17/49 (34.7%) women with no subsequent births had symptoms of anal incontinence (incontinence or urgency), this was true of 12/80 (15%) women who went on to have more

babies (P = 0.02). For women following a fourth-degree tear, the reverse was seen. Symptoms of anal incontinence or urgency were reported by 2/14 (14.3%) women who had not given birth subsequently, compared with 16/34 (47.1%) who had had subsequent births (NS, P = 0.07). The authors noted that the majority of third- and fourth-degree tears in this study were extensions of midline episiotomies (third: 101/129; fourth: 45/48). They suggested that these tears might carry a different functional prognosis to sphincter tears, complicating a spontaneous tear or mediolateral episiotomy. They also pointed out that the questionnaire asked only for information regarding anal incontinence, and therefore mode of subsequent vaginal birth or any related perineal trauma is not known. It is also very surprising that only 15% women who sustained a third-degree tear and 21% who sustained a fourth-degree tear could remember this, suggesting little was done at the time of the trauma or postnatally to ensure the women had adequate knowledge of this fact.

Evidence statement

For women with previous severe perineal trauma, the rate of repeat severe trauma is similar to the original incidence.

There is no evidence about the use of episiotomy for birth following third- or fourth-degree trauma.

There is low-level evidence that in asymptomatic women a vaginal birth following previous severe perineal trauma does not increase the risk of subsequent urgency or continence symptoms.

There is low-level evidence that in symptomatic women vaginal birth following previous severe perineal trauma does increase the risk of subsequent urgency or continence symptoms.

Recommendations on vaginal birth following previous third- or fourth-degree perineal trauma

215. Inform any woman with a history of severe perineal trauma that her risk of repeat severe perineal trauma is not increased in a subsequent birth, compared with women having their first baby. [2007]

216. Do not offer episiotomy routinely at vaginal birth after previous third- or fourth-degree trauma. [2007]

217. In order for a woman who has had previous third- or fourth-degree trauma to make an informed choice, talk with her about the future mode of birth, encompassing:

- current urgency or incontinence symptoms
- the degree of previous trauma
- risk of recurrence
- the success of the repair undertaken
- the psychological effect of the previous trauma
- management of her labour. [2007]

218. Inform any woman with infibulated genital mutilation of the risks of difficulty with vaginal examination, catheterisation and application of fetal scalp electrodes. Inform her of the risks of delay in the second stage and spontaneous laceration together with the need for an anterior episiotomy and the possible need for defibulation in labour. [2007]

Research recommendation on prevention of perineal trauma

25. Studies are needed to investigate strategies to reduce the chance of having perineal trauma.

Water birth

Introduction

While the Winterton report recommended that all maternity units should provide women with the option to labour and give birth in water, the number of women in England and Wales who choose to actually give birth in water is not known.[95] A survey between April 1994 and March 1996 identified 0.6% of births in England and Wales occurring in water, 9% of which were home births.[126] It is known, however, that in some birth settings this proportion is much higher, with one birth centre reporting up to 79% of women giving birth in water.[127]

Review question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- water (including temperature regulation).

Description of included studies

There was one systematic review, one RCT and one cross-sectional study identified for inclusion in the review. The systematic review included eight trials.[128] [EL = 1+] Out of the eight trials, six examined immersion in water in the first stage of labour, one examined immersion in water in the second stage of labour and one investigated the timing of the use of water in the first stage of labour. Another RCT was conducted since the systematic review was updated.[357] [EL = 1+] The RCT examined effectiveness of water birth in the second stage of labour. A population-based cross-sectional study in England and Wales investigated perinatal mortality and morbidity of babies, who were born in water, using a postal survey.[126] [EL = 3]

Review findings

Two trials evaluated immersion in water during the second stage of labour.[128,357] In the latter trial, only 23 women out of 60 received the allocation to be immersed in water. There is no evidence of differences in interventions or complications for either women or their babies during labour.

The cross-sectional study reported a perinatal mortality of 1.2 [95% CI 0.4 to 2.9] per 1000 and an admission rate to the neonatal unit of 8.4 [95% CI 5.8 to 11.8] per 1000 for babies born in water, compared with three previously reported perinatal mortalities (from 0.8 to 4.6 per 1000) and an admission rate of (9.2 to 64 per 1000) from other studies of low-risk populations.[126]

Evidence statement

There is insufficient evidence on the use of water in the second stage of labour, particularly its effect on neonatal outcomes.

Recommendation on water birth

219. Inform women that there is insufficient high-quality evidence to either support or discourage giving birth in water. [2007]

Decision to delivery interval for vaginal birth

Review question

When the need to intervene to expedite birth has been identified, what is the appropriate decision to delivery interval for a vaginal birth?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

This review included 4 studies (Eldridge and Johnson, 2004; Murphy and Koh, 2007; Okunwobi-Smith et al., 2000; Olagundoye and Mackenzie, 2007). Two of the studies (Eldridge and Johnson, 2004; Okunwobi-Smith et al., 2000) were included in the 2007 guideline and 2 are new to the updated guideline (Murphy and Koh, 2007; Olagundoye and Mackenzie, 2007).

Three of the included studies were prospective observational studies and 1 was retrospective (Murphy and Koh, 2007). Three of the studies were conducted in the UK. The fourth did not definitively report its location but the authors were based in England and Ireland.

None of the studies restricted their populations to low risk women. Eldridge and Johnson (2004) included all attempted instrumental vaginal births. Murphy and Koh (2007) restricted their study population to singleton babies in vertex, cephalic presentation at term (at least 37 weeks). The remaining 2 studies included all singleton pregnancies with vertex presentation (Okunwobi-Smith et al., 2000; Olagundoye and Mackenzie, 2007).

One study only included births where the indication for expediting delivery was fetal distress (Murphy and Koh, 2007). In the remaining 3 studies, between 34% and 59% of the births were indicated for fetal distress, with the remainder indicated for other reasons (such as delay in second stage, meconium-stained liquor and maternal exhaustion).

Evidence profile

The following modified GRADE profiles are presented:

- Decision to delivery interval (DDI) for different modes of birth: where reported (or calculable) decision to delivery interval is reported by planned mode of birth, otherwise decision to delivery interval for actual mode of birth is reported.
- Maternal and neonatal outcomes following a decision to delivery interval of less than or equal to 15 minutes, 16–30 minutes and more than 30 minutes.
- Association (however reported in the study) of neonatal outcomes with different decision to delivery intervals.

Update 2014

Table 139: Summary GRADE profile for decision to delivery interval (DDI) for different modes of birth

Number of studies	Design	Decision to delivery interval (minutes)	Quality
Planned mode of birth: forceps			
1 study (Okunwobi-Smith et al., 2000)	observational study	Mean 29.9 (SD 19.0)[a] n=90	Very low
1 study (Olagundoye & Mackenzie, 2007)	observational study	Mean 28.7 (SD 21.5)[b] n=95	Very low
Planned mode of birth: ventouse			
1 study (Okunwobi-Smith et al., 2000)	observational study	Mean 35.4 (SD 17.1)[a] n=135	Very low
1 study (Olagundoye & Mackenzie, 2007)	observational study	Mean 33.4 (SD 22.3)[b] n=134	Very low
Actual mode of birth: forceps (non-rotational)			
1 study (Eldridge & Johnson, 2004)	observational study	Mean 16.5 (SD 8.3)[c] Range: 6 to 32 n=8	Very low
1 study (Murphy & Koh, 2007)	observational study	0–15 minutes: 301/528 (57.0%) 16–30 minutes: 182/528 (34.5%)[d] >30 minutes: 45/528 (8.5%) Mean 16.6 (SD 10.6) Median 15 (IQR 9–22)	Very low
Actual mode of birth: ventouse (non-rotational)			
1 study (Eldridge & Johnson, 2004)	observational study	Mean 22.7 (SD 15.8)[c] Range: 8 to 84 n=33	Very low

Update 2014

Number of studies	Design	Decision to delivery interval (minutes)	Quality
1 study (Murphy & Koh, 2007)	observational study	0–15 minutes: 177/268 (66.0%) 16–30 minutes: 77/268 (28.7%)[d] >30 minutes: 14/268 (5.2%) Mean 14.9 (SD 11.7) Median 13 (IQR 9–18)	Very low
Actual mode of birth: rotational delivery			
1 study (Eldridge & Johnson, 2004)	observational study	Mean 54.8 (SD 31.9)[c] Range: 17 to 85 n=4	Very low
1 study (Murphy & Koh, 2007)	observational study	0–15 minutes: 66/169 (39.1%) 16–30 minutes: 58/169 (34.3%)[d] >30 minutes: 45/169 (26.6%) Mean 22.8 (SD 14.7) Median 20 (IQR 12–31)	Very low
Actual mode of birth: rotational ventouse followed by forceps			
1 study (Eldridge & Johnson, 2004)	observational study	Mean 50 (SD 26.9)[c] Range: 31 to 69 n=2	Very low
Actual mode of birth: caesarean section after unsuccessful attempt at instrumental vaginal birth			
1 study (Eldridge & Johnson, 2004)	observational study	Mean 55.0 (SD 8.5)[c] Range: 49 to 61 n=2	Very low
1 study (Murphy & Koh, 2007)	observational study	0–15 minutes: 13/33 (39.4%) 16–30 minutes: 4/33 (12.1%)[d] >30 minutes: 16/33 (48.5%) Mean 28.5 (SD 18.3) Median 29 (IQR 10–45)	Very low

IQR interquartile range, SD Standard deviation

Update 2014

a. Mean difference between DDI for planned forceps and planned ventouse is -5.5 minutes (-10.37 to -0.63); p=0.03. Of the 90 attempted forceps deliveries, 87 (97%) were successful at the first attempt, 1 (1%) was successful at a repeat attempt, and 2 (2%) resulted in a caesarean section. Of the 135 attempted ventouse deliveries, 113 (84%) were successful at the first attempt, 17 (13%) led to a forceps following a failed attempt at ventouse, and 5 (4%) resulted in caesarean section.
b. Mean difference between DDI for planned forceps and planned ventouse is -4.7 minutes (95% CI -10.44 to 1.04); p=0.11. Of the 95 attempted forceps deliveries, 91 (96%) were successful at the first attempt, 2 (2%) had a ventouse following a failed first attempt, and 2 (2%) resulted in caesarean section. Of the 134 attempted ventouse deliveries, 104 (78%) were successful at the first attempt, 2 (1%) were successful at a repeat attempt, 21 (16%) led to a forceps delivery following a failed attempt at ventouse, and 7 (5%) resulted in caesarean section.
c. Calculated by NCC-WCH technical team based on data reported in figure 1 of the paper
d. Calculated by NCC-WCH technical team based on data on mode of birth for DDI of 0-15 minutes, 0-30 minutes and >30 minutes

Table 140: Summary GRADE profile for comparison of shorter decision to delivery interval (DDI) with longer decision to delivery interval

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
Third or fourth degree tear							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	19/557 (3.4%)	23/441 (5.2%)	RR 0.65 (0.36 to 1.19)	18 fewer per 1000 (from 33 fewer to 10 more)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	36/878 (4.1%)	6/120 (5%)	RR 0.82 (0.35 to 1.91)	9 fewer per 1000 (from 33 fewer to 45 more)	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	19/557 (3.4%)	17/321 (5.3%)	RR 0.64 (0.34 to 1.22)	19 fewer per 1000 (from 35 fewer to 12 more)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	17/321 (5.3%)	6/120 (5%)	RR 1.06 (0.43 to 2.62)	3 more per 1000 (from 29 fewer to 81 more)	Very low

Update 2014

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
Perinatal death							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	2/557[b] (0.36%)	0/441 (0%)	RR 3.96 (0.19 to 82.28)	NC	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	2/878[b] (0.23%)	0/120 (0%)	RR 0.69 (0.03 to 14.25)	NC	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	2/557[b] (0.36%)	0/321 (0%)	RR 2.89 (0.14 to 59.91)	NC	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	0/321 (0%)	0/120 (0%)	NC	NC	Very low
Admission to neonatal intensive care unit							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	15/557 (2.7%)	22/441 (5%)	RR 0.54 (0.28 to 1.03)	23 fewer per 1000 (from 36 fewer to 1 more)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	29/878 (3.3%)	8/120 (6.7%)	RR 0.5 (0.23 to 1.06)	33 fewer per 1000 (from 51 fewer to 4 more)	Very low

Update 2014

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	15/557 (2.7%)	14/321 (4.4%)	RR 0.62 (0.3 to 1.26)	17 fewer per 1000 (from 31 fewer to 11 more)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	14/321 (4.4%)	8/120 (6.7%)	RR 0.65 (0.28 to 1.52)	23 fewer per 1000 (from 48 fewer to 35 more)	Very low
Neonatal resuscitation[c]							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	138/557 (24.8%)	109/441 (24.7%)	RR 1 (0.81 to 1.25)	0 fewer per 1000 (from 47 fewer to 62 more)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	210/878 (23.9%)	37/120 (30.8%)	RR 0.78 (0.58 to 1.04)	68 fewer per 1000 (from 130 fewer to 12 more)	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	138/557 (24.8%)	72/321 (22.4%)	RR 1.1 (0.86 to 1.42)	22 more per 1000 (from 31 fewer to 94 more)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	72/321 (22.4%)	37/120 (30.8%)	RR 0.73 (0.52 to 1.02)	83 fewer per 1000 (from 148 fewer to 6 more)	Very low

Update 2014

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
Severe neonatal morbidity							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	1/557[d] (0.18%)	0/441 (0%)	RR 2.38 (0.1 to 58.19)	NC	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	1/878d (0.11%)	0/120 (0%)	RR 0.41 (0.02 to 10.08)	NC	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	1/557[d] (0.18%)	0/321 (0%)	RR 1.73 (0.07 to 42.37)	NC	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	0/321 (0%)	0/120 (0%)	NC	NC	Very low
Neonatal trauma[e]							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	19/557 (3.4%)	43/441 (9.8%)	RR 0.35 (0.21 to 0.59)	63 fewer per 1000 (from 40 fewer to 77 fewer)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	44/878 (5%)	18/120 (15%)	RR 0.33 (0.2 to 0.56)	101 fewer per 1000 (from 66 fewer to 120 fewer)	Very low

Update 2014

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	19/557 (3.4%)	25/321 (7.8%)	RR 0.44 (0.25 to 0.78)	44 fewer per 1000 (from 17 fewer to 58 fewer)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	25/321 (7.8%)	18/120 (15%)	RR 0.52 (0.29 to 0.92)	72 fewer per 1000 (from 12 fewer to 107 fewer)	Very low
Cord blood gas values: umbilical artery pH<7.10							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	50/557 (9%)	31/441 (7%)	RR 1.28 (0.83 to 1.96)	20 more per 1000 (from 12 fewer to 67 more)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	77/878 (8.8%)	4/120 (3.3%)	RR 2.63 (0.98 to 7.06)	54 more per 1000 (from 1 fewer to 202 more)	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	50/557 (9%)	27/321 (8.4%)	RR 1.07 (0.68 to 1.67)	6 more per 1000 (from 27 fewer to 56 more)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	27/321 (8.4%)	4/120 (3.3%)	RR 2.52 (0.9 to 7.06)	51 more per 1000 (from 3 fewer to 202 more)	Very low

Update 2014

Number of studies	Design	Definitions of 'shorter' and 'longer' DDI	Number of women or babies		Effect		Quality
			Shorter DDI	Longer DDI	Relative (95% CI)	Absolute (95% CI)	
Cord blood gas values: umbilical artery base excess < −2.0[f]							
1 study (Murphy & Koh, 2007)	observational study	Shorter: ≤15 minutes Longer: >15 minutes	55/557 (9.9%)	42/441 (9.5%)	RR 1.04 (0.71 to 1.52)	4 more per 1000 (from 28 fewer to 50 more)	Very low
		Shorter: ≤30 minutes Longer: >30 minutes	90/878 (10.3%)	7/120 (5.8%)	RR 1.76 (0.83 to 3.7)	44 more per 1000 (from 10 fewer to 157 more)	Very low
		Shorter: ≤15 minutes Longer: 16 – 30 minutes[a]	55/557 (9.9%)	35/321 (10.9%)	RR 0.91 (0.61 to 1.35)	10 fewer per 1000 (from 43 fewer to 38 more)	Very low
		Shorter: 16 – 30 minutes[a] Longer: >30 minutes	35/321 (10.9%)	7/120 (5.8%)	RR 1.87 (0.85 to 4.09)	51 more per 1000 (from 9 fewer to 180 more)	Very low
Acidosis at birth (arterial pH≤7.10 and base excess < −12 mmol/litre[g])							
1 study (Olagundoye & Mackenzie, 2007)	observational study	Shorter: ≤46 minutes Longer: >46 minutes	10/183 (5.5%)	2/46 (4.3%)	RR 1.26 (0.29 to 5.54)	11 more per 1000 (from 31 fewer to 197 more)	Very low

CI confidence interval, DDI decision to delivery interval, NC not calculable, RR relative risk

a. Calculated by NCC-WCH technical team based on data reported on outcomes for DDI of 0-15 minutes, 0-30 minutes and >30 minutes
b. Details of the two deaths and the associated DDIs are reported in the text of the paper, allowing the proportions in each DDI category to be calculated by the technical team. One baby had a DDI of 3 minutes – the baby was delivered by forceps for a fetal bradycardia due to vasa previa. The bradycardia first occurred in a peripheral midwifery unit resulting in a 55 minute transfer time. The baby had no cardiac output for 20 minutes, but was resuscitated and transferred to NICU; however it had multi-organ failure and died 2 days later. The second baby had a DDI of 11 minutes. The baby was delivered by forceps in the operating room for bradycardia, and was declared stillborn following attempts at resuscitation.
c. Defined as any out of bag-and-mask ventilation, intubation with intermittent positive pressure ventilation and full cardiac arrest procedures

Update 2014

d. Details of adverse events and the associated DDIs are reported in the text of the paper, allowing the proportions in each DDI category to be calculated by the technical team. The baby was born with a DDI of 3 minutes (using lift out forceps), following a fetal bradycardia secondary to placental abruption. The baby developed severe hypoxic ischemic encephalopathy (HIE) and was diagnosed with cerebral palsy at follow-up.
e. Composite outcome that included bruising, cephalhaematoma, lacerations, intra- or extra-cranial haemorrhage, facial nerve palsy, brachial plexus injury, or fractures (note: forceps marks were not considered traumatic, nor was a chignon, unless there was additional bruising or lacerations)
f. Units not directly reported in study; however, likely to be mmol/litre or mEq/litre
g. In the text of the paper, the definition of acidosis is reported as a base excess > −12 mmol/litre. However, given that a more extreme (i.e. more negative) base excess indicates worse acidosis, and that the authors' notation does not match that of the paper that they reference for the definition (which refers to a base deficit >12), the NCC-WCH technical team have made the assumption that they are referring to a more negative base excess and therefore that the definition should be < −12 mmol/litre.

Update 2014

Table 141: Summary GRADE profile for association of neonatal outcomes with decision to delivery interval (DDI)

Number of studies	Design	Effect Measure of association of DDI with neonatal outcomes		Quality
Cord blood gas values: umbilical artery pH				
1 study (Olagundoye & Mackenzie, 2007)	observational study	Correlation of DDI (10 minute intervals) and mean pH: r^2=0.0222 r= −0.15[a] n=189 values		Very low
1 study (Okunwobi-Smith et al., 2000)	observational study	Mean pH in different DDI categories, split by indication for expedited birth:[b]		Very low
		Distress: ≤10 minutes: 7.20 11 - 20 minutes: 7.17 21 - 30 minutes: 7.20 31 - 40 minutes: 7.16 41 - 50 minutes: 7.13 51 - 60 minutes: 7.24 ≥ 61 minutes: 7.19	No distress: ≤10 minutes: 7.23 11 - 20 minutes: 7.19 21 - 30 minutes: 7.23 31 - 40 minutes: 7.23 41 - 50 minutes: 7.21 51 - 60 minutes: 7.22 ≥ 61 minutes: 7.16	
Cord blood gas values: umbilical artery base excess				
1 study (Olagundoye & Mackenzie, 2007)	observational study	Correlation of DDI (10 minute intervals; measured in mmol/litre) and mean base excess: r^2=0.0611 r= −0.25[a] n=179 values		Very low

Update 2014

Number of studies	Design	Effect		Quality
		Measure of association of DDI with neonatal outcomes		
1 study (Okunwobi-Smith et al., 2000)	observational study	Mean base excess (units reported as nmol/litre) in different DDI categories, split by indication for expedited birth:[b]		Very low
		Distress ≤ 10 minutes: −7.0 11 - 20 minutes: −8.7 21 - 30 minutes: −8.0 31 - 40 minutes: −8.9 41 - 50 minutes: −11.3 51 - 60 minute: −5.1 ≥ 61 minutes: −7.2	No distress ≤ 10 minutes: −6.2 11 - 20 minutes: −5.5 21 - 30 minutes: −7.0 31 - 40 minutes: −6.3 41 - 50 minutes: −7.4 51 - 60 minutes: −5.5 ≥ 61 minutes: −7.0	

DDI decision to delivery interval

a. The r-values were calculated by the NCC-WCH technical team, based on the reported r2 values and the graph in the paper which illustrated that the correlation was negative.
b. The authors report that, in babies with fetal distress, over the first hour the longer the DDI the more acidaemic the arterial values became, although this did not reach statistical significance (p=0.4). There were too few births after 60 minutes to evaluate trends further than that. For babies without fetal distress, the authors report that increasing acidaemia was not observed until the interval was greater than 60 minutes.

Update 2014

Evidence statements

Decision to delivery for different modes of birth

There was consistent evidence from 2 studies (n=484) that planning a forceps birth was associated with a shorter decision to delivery interval (DDI) than planning a ventouse birth. For actual mode of birth, 1 study (n=928) reported that over 90% of non-rotational births were completed within 30 minutes of the decision to expedite birth, whereas this proportion was 73% for rotational instrumental vaginal births and 52% for caesarean sections following an unsuccessful attempt at an instrumental vaginal birth. The mean time taken to perform a non-rotational forceps was consistently reported as around 17 minutes in 2 studies (n=1,047), whereas for non-rotational ventouse there was slightly more variation (reported means were 23 minutes and 15 minutes). The same 2 studies reported mean DDI for other modes of birth, but 1 study had fewer than 5 women in each category which severely limited the usefulness of the results. The second study (n=998) reported a mean DDI of 23 minutes for rotational deliveries and 29 minutes for caesarean section following an unsuccessful attempt at an instrumental vaginal birth. The evidence was of very low quality.

Outcomes after shorter decision to delivery interval compared with longer decision to delivery interval

Evidence from 1 study (n=998) showed no difference in the risk of a third or fourth degree tear following different DDIs. Similarly, there was no difference in most neonatal outcomes (admission to neonatal intensive care unit [NICU], neonatal resuscitation, low arterial pH or base excess at birth, severe neonatal morbidity and perinatal death). However, for the latter 2 outcomes the event rates were very low, and the vast majority of the evidence on neonatal outcomes came from 1 study. There was evidence of a difference in the risk of neonatal trauma following different DDIs, with shorter DDIs consistently associated with a reduced risk of trauma. The evidence was of very low quality.

Association of neonatal outcomes with decision to delivery interval

One study (n=229) reported very low/no correlation between DDI and mean pH, and low correlation between DDI and base excess. Another study (n=225) reported that, for babies with fetal distress, there was a trend towards babies becoming more acidemic as the DDI increased up to 60 minutes, whereas this trend was not demonstrated until after 60 minutes for babies without fetal distress. However, because the number of babies in each DDI category is not known, it is not possible to determine how valid these conclusions are. The evidence was of very low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

The primary aim of this review was to identify whether the DDI, from the point at which the need to intervene has been identified, has an impact on neonatal outcomes. In particular, the guidelines development group hoped to see whether there was any difference in the rates of major neonatal morbidity, such as hypoxic ischaemic encephalopathy or birth asphyxia, as well as longer term outcomes, such as cerebral palsy or developmental delay. The group recognised that not all of these outcomes would necessarily be reported and so also looked for proxy indicators of poor outcomes, such as admission to NICU and metabolic acidosis at birth.

The group also wanted to identify whether the DDI has any impact on maternal outcomes, as a faster delivery might lead to an increased risk of injury as a result. To this end, they looked for evidence relating to perineal trauma and injury to the uro-genital tract.

Consideration of clinical benefits and harms

The evidence from the studies which looked at the mean DDIs for different modes of birth showed that the length of the interval was greater for ventouse births than for forceps births. The guideline development group felt that this was to be expected because ventouse births take place over a number of contractions and so more time is required.

Overall, there was little evidence that a difference in the DDI leads to a difference in outcomes. One study did show that babies born at shorter DDIs had less neonatal trauma than babies born at longer DDIs. The group felt that this could potentially be explained by the fact that larger babies (who have an increased risk of neonatal trauma) who are born instrumentally generally require some rotation, which then lengthens the DDI. The group noted that there is a general treatment paradox when looking at DDI findings, as the findings are affected by the state of the babies; that is, babies born in poorer health are those whose births clinicians attempt to expedite faster, but they are also subsequently the ones who are more likely to have poorer outcomes. In other words, it is difficult to identify whether poor outcomes reported in the studies are a direct consequence of the DDI, or whether they are instead caused by the poor health of the baby.

Consideration of health benefits and resource uses

As there are no differences in resource use for the time at which interventions to expedite birth are performed, and given the uncertainty surrounding the clinical benefits, there was nothing for the guideline development group to consider in relation to trade-offs between health benefits and resource use.

Quality of evidence

The quality of evidence for all of the outcomes reported was very low. This was owing to a number of factors, including the papers not addressing the right population and poor reporting of the data. The guideline development group recognised that the majority of the studies in the review were purely descriptive and so it was not possible to determine what effect having a shorter or longer DDI would have had on the neonatal outcomes.

Given the poor quality of the evidence and that there was no clear indication that any one DDI interval led to better outcomes than another, the group agreed that it would not be appropriate to recommend a particular time threshold in which all births should be performed once the decision to expedite birth has been made. They underlined that this is a complex decision-making process which needs to be made on an individual basis for each woman. However, the group did agree that it would be helpful if the recommendations could be more explicit about the different factors that clinicians should take into account when looking to expedite birth. It was agreed that these should include a number of elements, including:

- the perceived urgency based on the baby's and woman's clinical condition
- the time needed for transfer to obstetric care in an obstetric unit if relevant
- the position of the baby and station of the baby's head determined by abdominal and vaginal examination
- the time needed to transfer to theatre where this is necessary
- the anticipated degree of difficulty in the procedure
- the possibility of a failed instrumental vaginal birth
- any need for additional anaesthesia or analgesia.

The group agreed that it is of key importance when looking to expedite birth that there is clear communication between all of the maternity team about what needs to be done and clarity about the degree of urgency. There also needs to be clear communication with the woman to explain what is happening, the reasons for needing to expedite the birth and the options for birth, and to obtain her consent. If it is the woman's wish, her birth companion(s) should be involved in the discussions.

It was felt that, for audit purposes, it is helpful for clinicians to record the time at which the decision to expedite the birth is made.

Recommendations

220. If the birth needs to be expedited for maternal or fetal reasons, assess both the risk to the baby and the safety of the woman. Assessments should include:

- the degree of urgency
- clinical findings on abdominal and vaginal examination
- choice of mode of birth (and whether to use forceps or ventouse if an instrumental birth is indicated)
- anticipated degree of difficulty, including the likelihood of success if instrumental birth is attempted
- location
- any time that may be needed for transfer to obstetric-led care
- the need for additional analgesia or anaesthesia
- the woman's preferences. [new 2014]

221. Talk with the woman and her birth companion(s) about why the birth needs to be expedited and what the options are. [new 2014]

222. Inform the team about the degree of urgency. [new 2014]

223. Record the time at which the decision to expedite the birth is made. [new 2014]

Third stage of labour

Active compared with physiological management of the third stage of labour

Review question

Is active management of the third stage of labour more effective than physiological management?

For further details on the evidence review protocol, please see appendix E.

Description of included studies

This review included 4 studies (de Groot et al., 1996; Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993).

The included studies are all randomised controlled trials, 3 of which were conducted in the UK (Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993) and 1 in the Netherlands (de Groot et al., 1993).

The aim of this review was to compare active management and physiological management for the third stage of labour. For the purposes of this review, active management is defined as 1 or more of the package of interventions that includes administration of an intramuscular uterotonic, early cord clamping and controlled cord traction. Conversely, physiological management is defined as delivery of the placenta without the routine use of those components of care.

Three of the included studies compare physiological management with a package of active management; that is, the administration of an uterotonic, early cord clamping and controlled cord traction (Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993). The majority of women received syntometrine, but in 2 of the trials, a small proportion of women received syntocinon (Prendiville et al., 1988; Rogers et al., 1998). The placenta was considered to be retained, leading to a change in management strategy, after 30 minutes in 1 study (Thilaganathan et al., 1993) and 1 hour in 2 studies (Prendiville et al., 1988; Rogers et al., 1998).

In the fourth included study (de Groot et al., 1996), women were randomised to receive intramuscular oxytocin or a placebo, with no other components of active management reported; therefore, the placebo arm is comparable to women receiving physiological management. The definition of retained placenta and protocol for subsequent management were not reported in this trial.

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Evidence profile

Table 142: Summary GRADE profile for comparison of a package of active management with physiological management

Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
Postpartum haemorrhage ≥500 ml						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	101/1594 (6.3%)	278/1613 (17.2%)	RR 0.37 (0.3 to 0.46)	109 fewer per 1000 (from 93 fewer to 121 fewer)	Low
Postpartum haemorrhage ≥1000 ml						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	20/1594 (1.3%)	46/1613 (2.9%)	RR 0.44 (0.26 to 0.74)	16 fewer per 1000 (from 7 fewer to 21 fewer)	Very low
Need for further intervention: blood transfusion						
1 meta-analysis of 3 studies (Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993)	randomised trials	23/1697 (1.4%)	68/1703 (4%)	RR 0.34 (0.22 to 0.55)	26 fewer per 1000 (from 18 fewer to 31 fewer)	Moderate
Need for further intervention: manual removal of the placenta						
1 meta-analysis of 3 studies (Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993)	randomised trials	32/1697 (1.9%)	35/1703 (2.1%)	RR 0.92 (0.58 to 1.48)	2 fewer per 1000 (from 9 fewer to 10 more)	Moderate
Need for further intervention: therapeutic uterotonics						

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Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
1 meta-analysis of 3 studies (Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993)	randomised trials	79/1697 (4.7%)	420/1703 (24.7%)	RR 0.19 (0.15 to 0.24)	200 fewer per 1000 (from 187 fewer to 210 fewer)	Moderate
Need for further intervention: surgical evacuation of retained products of conception						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	20/1594 (1.3%)	22/1613 (1.4%)	RR 0.92 (0.5 to 1.67)	1 fewer per 1000 (from 7 fewer to 9 more)	Moderate
Readmission due to bleeding						
1 study (Rogers et al., 1998)	randomised trial	12/748 (1.6%)	5/764 (0.65%)	RR 2.45 (0.87 to 6.92)	9 more per 1000 (from 1 fewer to 39 more)	Moderate
Side effects: nausea						
1 study (Rogers et al., 1998)	randomised trial	86/748 (11.5%)	45/764 (5.9%)	RR 1.95 (1.38 to 2.76)	56 more per 1000 (from 22 more to 104 more)	Moderate
Side effects: vomiting						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	149/1594 (9.3%)	72/1613 (4.5%)	RR 2.09 (1.59 to 2.74)	49 more per 1000 (from 26 more to 78 more)	Moderate
Side effects: headache						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	18/1594 (1.1%)	11/1613 (0.68%)	RR 1.65 (0.78 to 3.48)	4 more per 1000 (from 2 fewer to 17 more)	Moderate

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Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
Side effects: hypertension (diastolic blood pressure >100 mmHg)						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	23/1594 (1.4%)	9/1613 (0.56%)	RR 2.57 (1.2 to 5.54)	9 more per 1000 (from 1 more to 25 more)	Moderate
Birth weight (grams)						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	Means 3337 (SD 451) and 3454 (SD 465) n=1594	Means 3422 (SD 444) and 3521 (SD 470) n=1613	not calculable (NC)	MD 76.9 lower (from 108.51 lower to 45.3 lower)	Low
Apgar score ≤6 at 5 minutes						
1 study (Prendiville et al., 1988)	randomised trial	8/846 (0.95%)	8/849 (0.94%)	RR 1 (0.38 to 2.66)	0 fewer per 1000 (from 6 fewer to 16 more)	Low
Neonatal packed cell volume <0.50						
1 study (Prendiville et al., 1988)	randomised trial	19/127 (15%)	11/166 (6.6%)	RR 2.26 (1.11 to 4.57)	83 more per 1000 (from 7 more to 237 more)	Very low
Neonatal packed cell volume >0.65						
1 study (Prendiville et al., 1988)	randomised trial	15/127 (11.8%)	64/166 (38.6%)	RR 0.31 (0.18 to 0.51)	266 fewer per 1000 (from 189 fewer to 316 fewer)	Low
Admission to neonatal special/intensive care unit						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	68/1562 (4.4%)	84/1580 (5.3%)	RR 0.82 (0.6 to 1.11)	10 fewer per 1000 (from 21 fewer to 6 more)	Moderate
Neonatal jaundice: need for phototherapy						

Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
1 study (Rogers et al., 1998)	randomised trial	32/716 (4.5%)	25/731 (3.4%)	RR 1.31 (0.78 to 2.18)	11 more per 1000 (from 8 fewer to 40 more)	Moderate
Neonatal jaundice: bilirubin >428 µmol/l						
1 study (Prendiville et al., 1988)	randomised trial	39/846 (4.6%)	54/849 (6.4%)	RR 0.72 (0.49 to 1.08)	18 fewer per 1000 (from 32 fewer to 5 more)	Low
Breastfeeding: baby put to breast within 2 hours of birth						
1 study (Rogers et al., 1998)	randomised trial	487/748 (65.1%)	497/764 (65.1%)	RR 1 (0.93 to 1.08)	0 fewer per 1000 (from 46 fewer to 52 more)	Moderate
Breastfeeding: any breastfeeding at discharge						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	1191/1594 (74.7%)	1174/1613 (72.8%)	RR 1.03 (0.98 to 1.07)	22 more per 1000 (from 15 fewer to 51 more)	Moderate
Breastfeeding: exclusive breastfeeding at 6 weeks						
1 study (Rogers et al., 1998)	randomised trial	265/748 (35.4%)	272/764 (35.6%)	RR 1 (0.87 to 1.14)	0 fewer per 1000 (from 46 fewer to 50 more)	Moderate
Maternal haemoglobin: fall between 32-37 weeks gestation and postpartum						
1 meta-analysis of 2 studies (Prendiville et al., 1988; Rogers et al., 1998)	randomised trials	Means 0.1 (SD 2.1) and -0.9 (SD 1.28)[a] n=1293	Means 0.6 (SD 1.3) and 0.4 (SD 1.56)[a] n=1304	NC	MD 0.99 lower (0.87 lower to 1.11 lower)	Very low
Maternal haemoglobin: fall in haemoglobin (reported postpartum)						
1 study (Thilaganathan et al., 1993)	randomised trial	Median 0.5 (IQR -0.1 to 1.2)	Median 0.7 (IQR -0.3 to 1.4)	NC	Median 0.2 lower (CI NC) p>0.5	Low

Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
Maternal haemoglobin: proportion of women with haemoglobin ≤10 g/dl on second postpartum day						
1 study (Rogers et al., 1998)	randomised trial	107/702 (15.2%)	204/718 (28.4%)	RR 0.54 (0.44 to 0.66)	131 fewer per 1000 (from 97 fewer to 159 fewer)	Moderate
Maternal haemoglobin: proportion of women with haemoglobin ≤9 g/dl at 24-48 hours postpartum[b]						
1 study (Prendiville et al., 1988)	randomised trial	27/685 (3.9%)	51/694 (7.3%)	RR 0.54 (0.34 to 0.84)	34 fewer per 1000 (from 12 fewer to 49 fewer)	Low
Maternal haemoglobin: proportion of women with haemoglobin <9 g/dl postpartum						
1 study (Thilaganathan et al., 1993)	randomised trial	1/103 (0.97%)	5/90 (5.6%)	RR 0.17 (0.02 to 1.47)	46 fewer per 1000 (from 54 fewer to 26 more)	Very low

CI confidence interval, IQR interquartile range, MD mean difference, NC not calculable, RR relative risk, SD standard deviation

a. Data from one study (Prendiville et al., 1988) had to be converted into g/dl by the technical team. Standard errors reported in one study (Rogers et al., 1998) had to be converted in standard deviations for use in meta-analysis.
b. Reported as proportion with haemoglobin ≤90 g/litre by the study and converted to g/dl by technical team for consistency

Table 143: Summary GRADE profile for comparison of a single component of active management (oxytocin administration) with physiological management (placebo administration)

Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
Postpartum haemorrhage ≥500 ml						
1 study (de Groot et al., 1996)	randomised trial	25/78 (32.1%)	55/143 (38.5%)	RR 0.83 (0.57 to 1.22)	65 fewer per 1000 (from 165 fewer to 85 more)	Low
Postpartum haemorrhage ≥1000 ml						
1 study (de Groot et al., 1996)	randomised trial	7/78 (9%)	16/143 (11.2%)	RR 0.8 (0.34 to 1.87)	22 fewer per 1000 (from 74 fewer to 97 more)	Very low
Need for further intervention: blood transfusion						
1 study	randomised trial	2/78	3/143	RR 1.22	5 more per 1000	Very low

Number of studies	Design	Number of women or mean (SD)		Effect		Quality
		Active	Physiological	Relative (95% CI)	Absolute (95% CI)	
(de Groot et al., 1996)		(2.6%)	(2.1%)	(0.21 to 7.16)	(from 17 fewer to 129 more)	
Need for further intervention: manual removal of the placenta						
1 study (de Groot et al., 1996)	randomised trial	1/78 (1.3%)	0/143 (0%)	RR 5.47 (0.23 to 132.66)	13 more per 1000 (from 15 fewer to 69 more)[a]	Very low
Need for further intervention: therapeutic uterotonics						
1 study (de Groot et al., 1996)	randomised trial	14/78 (17.9%)	26/143 (18.2%)	RR 0.99 (0.55 to 1.78)	2 fewer per 1000 (from 82 fewer to 142 more)	Very low
Birth weight (in grams)						
1 study (de Groot et al., 1996)	randomised trial	Mean 3534 (SD 410) n=78	Mean 3498 (SD 444) n=43	not calculable (NC)	MD 36 higher (80.51 lower to 152.51 higher)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation

a. Calculated by NCC-WCH technical team

Evidence statements

Active (package of intervention) compared with physiological management

There was consistent evidence from 3 studies (n=3400) that active management of the third stage of labour was associated with a reduced risk of blood loss, as measured by the incidence of postpartum haemorrhage (of at least 500 ml and of at least 1000 ml), the rate of blood transfusion and measures of postpartum haemoglobin. One smaller study (n=193) did not find a difference in maternal haemoglobin between the 2 groups, but it demonstrated similar trends. In terms of the need for further intervention, there was evidence from 3 studies of a reduction (n=3400) in the need for therapeutic uterotonics following active management, but no difference in the rates of manual removal of the placenta or surgical evacuation of retained products of conception between the 2 groups. Side effects (n=1512) were more common in women receiving active management of the third stage of labour.

There was evidence that babies born to women receiving active management had a lower mean birth weight (n=3207) compared with babies born to women receiving physiological management. There was also evidence from 1 study (n=293) that babies born to women receiving active management had increased risk of a low packed cell volume and a reduced risk of a high packed cell volume. For other neonatal outcomes (5 minute Apgar score [n=1695], admission to neonatal intensive care unit [NICU] [n=3142], rates of breastfeeding [n=3207], measures of neonatal jaundice [n=1695]), there was no evidence of a difference between babies born to women receiving active management and babies born to women receiving physiological management. The evidence was of moderate to very low quality.

Active (uterotonic only) compared with physiological management

There was no evidence of a difference in measures of maternal blood loss or need for further intervention (in the form of manual removal of the placenta or therapeutic uterotonics) between women receiving a uterotonic and women receiving physiological management, but only one small study (n=321) reported this comparison. Birth weight was the only neonatal outcome of interest reported and there was no evidence of a difference between the 2 groups. The evidence was of low to very low quality.

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Health economics

No published economic evaluations were identified for this question. In terms of the cost of immediate management, the only additional cost of active management when compared with physiological management is the cost of administering the uterotonic (£0.92 including drug cost and associated consumables). The midwife would be present already and so staff costs are not considered. Given the increased rates of postpartum haemorrhage in the physiological management arm (costing £488 up to £2700, depending on severity of postpartum haemorrhage), the guideline development group thought it was likely that active management would be more cost effective.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group agreed that measures of significant blood loss, such as the incidence of postpartum haemorrhage, postnatal haemoglobin and the need for a blood transfusion, were priority outcomes. Additionally, the group felt that side effects would be an important consideration for women in terms of their birth experience.

Consideration of clinical benefits and harms

The guideline development group first discussed the study that compared oxytocin with placebo. They noted that there was no significant difference between the 2 arms for any of the outcomes and that the sample size was not as large as in some of the other trials. Birth weight was the only neonatal outcome reported and the authors did not provide sufficient details of when the cord was clamped, therefore it was not informative in terms of a package of active

management. On balance, the group felt that this study was of limited utility when compared to the other included studies.

The guideline development group then discussed the 3 studies that compared a package of active management with physiological management. They noted that in each case the 3 components of active management were: the injection of uterotonic drugs as soon as the baby delivered; the cord was immediately clamped (30 seconds after birth in 1 study); and the placenta was delivered with controlled cord traction. The components of physiological management varied in the studies, but comprised 1 or more of the following items:

- no use of uterotonic drugs
- no clamping of the cord until pulsations had ceased
- no controlled cord traction or any manual interference with the uterus at the fundus
- leaving the cord attached to the baby until the placenta was delivered
- encouraging the mother to await the next contraction or the urge to push before pushing
- when she started to push, encourage the woman to adopt a position to incorporate gravity in the expulsive effort.

When these 2 approaches – active management and physiological management – were compared, the rates of postpartum haemorrhage (defined as either 'at least 500 ml' or 'at least 1000 ml') were significantly lower in women who were allocated to receive active management. However, the group noted that no study was blinded and that the method of calculating blood loss was through estimation by midwives in 1 study and not reported in the other studies They felt that this might have undermined the validity of the results, and therefore the group also considered more objective measures of blood loss (that is, the need for a blood transfusion). The group noted that there was a significantly lower rate of blood transfusion in women allocated to active management and that 2 of the trials also showed both a significantly smaller mean drop in haemoglobin and a reduced proportion of women with low haemoglobin in women allocated to active management. The group was aware that another of the included studies (Thilaganathan et al., 1993) did not show a significant difference in maternal haemoglobin between the 2 arms. However, due to the study's limitations and small sample size, the evidence was graded as low or very low quality and in fact demonstrated the same trend in results. Overall, the group felt that the consistency of effect demonstrated across the various measures of blood loss was sufficient to suggest that there was a true difference between active and physiological management in terms of blood loss in favour of active management.

The guideline development group considered maternal side effects and noted that rates of nausea, vomiting and hypertension were all higher in women allocated to receive active management. They agreed that this might be a significant consideration for women in terms of their birth experience and that it was important that women were informed about these possible side effects. However, they also noted that most of the studies used oxytocin plus ergometrine, which is associated with a higher incidence of side effects when compared with the recommended uterotonic of oxytocin.

The group noted that active management was associated with a significantly higher rate of neonatal packed cell volume less than 0.50, but a significantly lower rate of packed cell volume greater than 0.65. However, given that packed cell volume figures can change over time, the group did not feel that these findings were particularly helpful. They also considered the fact that the mean birth weight was 77 grams lower in babies born to women allocated to active management. The group discussed the possibility that this was due to the increased blood flow from the placenta with delayed cord clamping and that mean values could be heavily influenced by outliers. On balance, they did not feel that this would translate to a

meaningful difference in the longer term, but noted this would be considered further in relation to timing of cord clamping (see section 13.3 Timing of cord clamping).
In terms of other neonatal outcomes, the group noted that, in general, there was no significant difference between babies born to women allocated to active management and women allocated to physiological management.

Consideration of health benefits and resource uses

Even though there are no costs related to physiological management as a 'treatment', due to the more serious adverse events, such as postpartum haemorrhage, this management of the third stage is likely to be more expensive than active management. The costs of providing active management are low, oxytocin is a low cost drug and the practice of cord clamping followed by controlled cord traction shortens the third stage of labour, thus potentially shortening the time that a midwife needs to be in attendance, although this is not certain. Adverse events related to active management are mainly minor and transient. Although hypertension is more likely with active management, the numbers appear small (1.4% compared to 0.56%). Also, active management prevents serious blood loss in the third stage. The use of active management is likely to be cost saving for the NHS when compared with physiological management.

Quality of evidence

The quality of evidence for this review ranged from moderate to very low. The guideline development group was concerned about the low adherence in the physiological arm of the trials, in particular in Prendiville et al. (1988) where only 48% of women allocated to physiological management actually received it. The group felt that this was an important consideration when interpreting the results, but noted that, if anything, this would have resulted in a dilution of the demonstrated effect on blood loss. Therefore, the group felt that the evidence was sufficient to make a recommendation in favour of active management.

Other considerations

The guideline development group members discussed the fact that, from their experience, active management of the third stage could sometimes result in midwives being busy administering the uterotonic and clamping the cord rather than focusing on assessing the newborn and facilitating skin-to-skin contact. It was highlighted that this was not investigated in the included studies. However, they noted that deferring cord clamping for up to 5 minutes may help to mitigate some of this impact and that it is possible to facilitate skin-to-skin contact within the context of active management. Given this and the findings from the review looking at the appropriate timing of cord clamping (see section 13.3), the group agreed that the traditional form of active management (which involved immediate clamping of the cord) should be modified so that clamping of the cord be deferred by at least 1 minute following the birth of the baby. They noted also that the timing of administration of a uterotonic in relation to the timing of cord clamping did not make a significant different to any of the priority outcomes and so decided to recommend that a uterotonic should be administered at the birth of the anterior shoulder or immediately after the birth of the baby to be in line with current practice for active management of the third stage of labour.
The guideline development group noted that, although exclusion criteria were applied to exclude women at higher risk, all of the trials were conducted in hospital settings. Because a proportion of women in England and Wales give birth in midwife-led units or at home, the group felt that it was important to investigate the risks and benefits of different modes of management of the third stage in other settings and therefore decided to make a relevant research recommendation. In addition to investigating the effect of setting, the group felt that this research would also be an important contribution to the whole evidence base for management of the third stage, because physiological management is now more widely accepted than in the 1990s when the included studies were conducted. Therefore, any trial

conducted now would be likely to have higher adherence rates and more closely represent the comparison of true physiological management compared to active management.

Key conclusions

For all women, the group felt that it was vital that women be informed antenatally about the risks and benefits and what to expect with each package of care. On balance, the guideline development group felt that the evidence of an increase in postpartum haemorrhage with physiological management and the lack of evidence of harm to the baby with active management was sufficient to support that active management should be recommended. However, they also recognised that some women may wish to experience a birth with minimal intervention and therefore might request physiological management, and for women at low risk of haemorrhage, the group felt that it was important that women be supported in this choice. However, the group felt a time limit for the delivery of the placenta should be advised, since prolonged retention of the placenta is associated with a risk of post-partum haemorrhage. By consensus, the group agreed that limit should be 1 hour.

Oxytocin use in the active management of the third stage of labour

Review question

Is synthetic oxytocin (syntocinon) 10 IU intramuscular more effective than synthetic oxytocin plus ergometrine (syntometrine) in the active management of the third stage of labour?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

One systematic review (McDonald et al., 2009), with 6 component trials from a variety of locations was included in this review. This systematic review is an updated version of McDonald et al. (2004) with no new studies added.
In all included trials in the systematic review, women received the oxytocic intramuscularly in the intervention and control group, except in 1 trial where oxytocin was administered intravenously in the control group. When a sensitivity analysis was performed, excluding the trial with intravenous administration, this trial was found not to have an effect on the significance of the results for all reported outcomes.
In 4 trials from the systematic review, women received either ergometrine-oxytocin 1 ml or oxytocin 10 IU. In 2 further included trials women received either ergometrine-oxytocin 1 ml or oxytocin 5 IU. In 1 of these 2 trials women received OCM[t] 505 1 ml instead of ergometrine-oxytocin.
Oxytocics were administrated in all included trials at the time of the birth of the baby's anterior shoulder.

Update 2014

t Experimental drug, similar in structure and function to ergometrine and oxytocin, which was developed for the management of the third stage of labour.

Evidence profile

The review evaluated the following comparisons:

- ergometrine-oxytocin versus oxytocin (any dose)
- ergometrine-oxytocin versus oxytocin (5 IU)
- ergometrine-oxytocin versus oxytocin (10 IU).

Table 144: Summary GRADE profile for ergometrine-oxytocin compared with oxytocin (any dose)

Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin	Relative (95% CI)	Absolute	
Blood loss 500 ml or more						
1 meta-analysis of 6 studies (McDonald et al., 2009)	randomised trials	392/4661 (8.4%)	469/4671 (10%)	RR 0.84 (0.74 to 0.95)	16 fewer per 1000 (from 5 fewer to 26 fewer)	Moderate
Blood loss 1000 ml or more						
1 meta-analysis of 5 studies (McDonald et al., 2009)	randomised trials	86/3972 (2.2%)	111/3982 (2.8%)	RR 0.78 (0.59 to 1.03)	6 fewer per 1000 (from 11 fewer to 1 more)	Moderate
Manual removal of placenta						
1 meta-analysis of 6 studies (McDonald et al., 2009)	randomised trials	130/4661 (2.8%)	127/4671 (2.7%)	RR 1.03 (0.81 to 1.31)	1 more per 1000 (from 5 fewer to 8 more)	Moderate
Blood transfusion						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	49/3735 (1.3%)	36/3747 (0.96%)	RR 1.36 (0.89 to 2.09)	3 more per 1000 (from 1 fewer to 10 more)	High

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Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin	Relative (95% CI)	Absolute	
Elevated diastolic blood pressure[a]						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	65/3737 (1.7%)	26/3749 (0.69%)	RR 2.47 (1.58 to 3.86)	10 more per 1000 (from 4 more to 20 more)	Moderate
Vomiting						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	373/2721 (13.7%)	66/2737 (2.4%)	RR 5.72 (4.44 to 7.38)	114 more per 1000 (from 83 more to 154 more)	Low
Vomiting + nausea combined						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	874/3737 (23.4%)	198/3749 (5.3%)	RR 4.47 (3.88 to 5.15)	183 more per 1000 (from 152 more to 219 more)	Low
Therapeutic oxytocics						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	397/2726 (14.6%)	466/2739 (17%)	RR 0.86 (0.76 to 0.97)	24 fewer per 1000 (from 5 fewer to 41 fewer)	Low
3rd stage >30 minutes						
1 meta-analysis of 5 studies (McDonald et al., 2009)	randomised trials	80/3645 (2.2%)	75/3659 (2%)	RR 1.07 (0.78 to 1.46)	1 more per 1000 (from 5 fewer to 9 more)	Moderate
3rd stage >60 minutes						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	34/2419 (1.4%)	31/2442 (1.3%)	RR 1.11 (0.68 to 1.8)	1 more per 1000 (from 4 fewer to 10 more)	Moderate

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Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin	Relative (95% CI)	Absolute	
Apgar score ≤6 at 5 minutes						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	48/2729 (1.8%)	48/2739 (1.8%)	RR 1 (0.67 to 1.49)	0 fewer per 1000 (from 6 fewer to 9 more)	Moderate
Jaundice						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	453/2729 (16.6%)	466/2739 (17%)	RR 0.98 (0.87 to 1.1)	3 fewer per 1000 (from 22 fewer to 17 more)	Moderate
Not breastfed at discharge						
1 study (McDonald et al., 2009)	randomised trials	252/1713 (14.7%)	235/1727 (13.6%)	RR 1.08 (0.92 to 1.27)	11 more per 1000 (from 11 fewer to 37 more)	Low
Admission to neonatal intensive care unit						
1 study (McDonald et al., 2009)	randomised trials	317/1713 (18.5%)	309/1727 (17.9%)	RR 1.03 (0.9 to 1.19)	5 more per 1000 (from 18 fewer to 34 more)	Moderate

CI confidence interval, RR relative risk

Update 2014

Table 145: Summary GRADE profile for ergometrine-oxytocin compared with oxytocin (5 IU)

Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (5 IU)	Relative (95% CI)	Absolute	
Blood loss ≥500 ml						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	11/919 (1.2%)	26/920 (2.8%)	RR 0.42 (0.21 to 0.85)	16 fewer per 1000 (from 4 fewer to 22 fewer)	Moderate

Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (5 IU)	Relative (95% CI)	Absolute	
Blood loss ≥1000 ml						
1 study (McDonald et al., 2009)	randomised trials	0/230 (0%)	1/231 (0.43%)	RR 0.33 (0.01 to 8.18)	3 fewer per 1000 (from 4 fewer to 31 more)	Low
Manual removal of the placenta						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	23/919 (2.5%)	15/920 (1.6%)	RR 1.54 (0.81 to 2.92)	9 more per 1000 (from 3 fewer to 31 more)	Moderate
3rd stage >30 minutes						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	9/919 (0.98%)	12/920 (1.3%)	RR 0.75 (0.32 to 1.77)	3 fewer per 1000 (from 9 fewer to 10 more)	Moderate
3rd stage >60 minutes						
1 study (McDonald et al., 2009)	randomised trials	4/689 (0.58%)	6/689 (0.87%)	RR 0.67 (0.19 to 2.35)	3 fewer per 1000 (from 7 fewer to 12 more)	Moderate

CI confidence interval, IU international units, RR relative risk

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Table 146: Summary GRADE profile for comparison ergometrine-oxytocin versus oxytocin (10 IU)

Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (10 IU)	Relative (95% CI)	Absolute	
Blood loss ≥500 ml						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	372/3742 (9.9%)	432/3751 (11.5%)	RR 0.87 (0.76 to 0.99)	15 fewer per 1000 (from 1 fewer to 28 fewer)	Moderate

Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (10 IU)	Relative (95% CI)	Absolute	
Blood loss ≥1000 ml						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	86/3742 (2.3%)	110/3751 (2.9%)	RR 0.79 (0.6 to 1.04)	6 fewer per 1000 (from 12 fewer to 1 more)	Moderate
Manual removal of the placenta						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	107/3742 (2.9%)	112/3751 (3%)	RR 0.96 (0.74 to 1.25)	1 fewer per 1000 (from 8 fewer to 7 more)	Moderate
Blood transfusion						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	49/3735 (1.3%)	36/3747 (0.96%)	RR 1.36 (0.89 to 2.09)	3 more per 1000 (from 1 fewer to 10 more)	High
Elevated of diastolic blood pressure						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	65/3737 (1.7%)	26/3749 (0.69%)	RR 2.47 (1.58 to 3.86)	10 more per 1000 (from 4 more to 20 more)	Moderate
Vomiting						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	373/2721 (13.7%)	66/2737 (2.4%)	RR 5.72 (4.44 to 7.38)	114 more per 1000 (from 83 more to 154 more)	Low
Nausea						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	487/2721 (17.9%)	128/2737 (4.7%)	RR 3.85 (3.2 to 4.63)	133 more per 1000 (from 103 more to 170 more)	Low

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Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (10 IU)	Relative (95% CI)	Absolute	
Vomiting + nausea combined						
1 meta-analysis of 4 studies (McDonald et al., 2009)	randomised trials	874/3737 (23.4%)	198/3749 (5.3%)	RR 4.47 (3.88 to 5.15)	183 more per 1000 (from 152 more to 219 more)	Low
Therapeutic oxytocics						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	397/2726 (14.6%)	466/2739 (17%)	RR 0.86 (0.76 to 0.97)	24 fewer per 1000 (from 5 fewer to 41 fewer)	Low
3rd stage >30 minutes						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trials	71/2726 (2.6%)	63/2739 (2.3%)	RR 1.13 (0.81 to 1.58)	3 more per 1000 (from 4 fewer to 13 more)	Moderate
3rd stage >60 minutes						
1 study (McDonald et al., 2009)	randomised trials	30/1730 (1.7%)	25/1753 (1.4%)	RR 1.22 (0.72 to 2.06)	3 more per 1000 (from 4 fewer to 15 more)	Moderate
Apgar ≤6 at 5 minutes						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	48/2729 (1.8%)	48/2739 (1.8%)	RR 1 (0.67 to 1.49)	0 fewer per 1000 (from 6 fewer to 9 more)	Moderate
Jaundice						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trials	453/2729 (16.6%)	466/2739 (17%)	RR 0.98 (0.87 to 1.1)	3 fewer per 1000 (from 22 fewer to 17 more)	Moderate

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Number of studies	Design	Number of women		Effect		Quality
		Oxytocin plus ergometrine	Oxytocin (10 IU)	Relative (95% CI)	Absolute	
Not breastfed at discharge						
1 study (McDonald et al., 2009)	randomised trials	252/1713 (14.7%)	235/1727 (13.6%)	RR 1.08 (0.92 to 1.27)	11 more per 1000 (from 11 fewer to 37 more)	Moderate
Admission to neonatal intensive care unit						
1 study (McDonald et al., 2009)	randomised trials	317/1713 (18.5%)	309/1727 (17.9%)	RR 1.03 (0.9 to 1.19)	5 more per 1000 (from 18 fewer to 34 more)	Moderate

CI confidence interval, IU international units, RR relative risk

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Evidence statements

Ergometrine-oxytocin versus oxytocin (any dose)

Maternal outcomes

The incidence of blood loss greater than or equal to 500 ml (n=9332) was lower in women who received oxytocin plus ergometrine compared with women who received oxytocin alone. However, no significant difference was found between the 2 groups in the incidence of blood loss of 1000 ml or more (n=7954). The evidence was of moderate quality.
There was evidence from 4 studies (n=7486) that the incidence of elevated diastolic blood pressure and of vomiting and nausea were found to be increased in women who received oxytocin plus ergometrine compared with women who received oxytocin alone. However, it was also found that the use of therapeutic oxytocics was lower in this group of women. The evidence was of moderate quality.
No significant difference in the number of women with a third stage of labour lasting more than 30 minutes (n=7304) or more than 60 minutes (n=4861), the need for manual removal of the placenta (n=9332), or the need for a blood transfusion (n=7482) when comparing women who received oxytocin plus ergometrine with women who received oxytocin alone. The evidence was of moderate quality.

Neonatal outcomes

No significant difference was found in the number of babies with an Apgar score less than or equal to 6 at 5 minutes, the proportion of babies with jaundice (n=5468) or the rate of admission to a neonatal intensive care unit (n=3440) in babies whose mother received oxytocin plus ergometrine compared with those whose mother received oxytocin alone. The evidence was of moderate quality.

Ergometrine-oxytocin versus oxytocin (5 IU)

There was evidence from 2 studies (n=1839) that the incidence of blood loss greater than or equal to 500 ml was lower in women who received oxytocin plus ergometrine compared with women who received oxytocin (5 IU) alone. However, 1 study (n=461) did not find a significant difference in the incidence of blood loss of 1000 ml or more between the two groups. The evidence was of moderate quality.
The evidence from 2 studies (n=1839) found no significant difference in the number of women with a third stage of labour lasting more than 30 minutes, nor the need for manual removal of the placenta, in women who received oxytocin plus ergometrine compared with women who received oxytocin (5 IU) alone. The evidence was of moderate quality.

Ergometrine-oxytocin versus oxytocin (10 IU)

Maternal outcomes

Moderate quality evidence from 1 systematic review of 4 studies (n=7493) found that the incidence of blood loss of 500 ml or more was decreased in women who received oxytocin plus ergometrine compared with women who received oxytocin (10 IU) alone. However, it did not find a significant difference in the incidence of blood loss of 1000 ml or more in the 2 groups.
Moderate and low quality evidence from 1 systematic review of 4 studies (n=7486) found that the incidence of elevated diastolic blood pressure and the incidence of vomiting and nausea were increased in women who received oxytocin plus ergometrine compared with women who received oxytocin (10 IU) alone. However, it was also found that the use of therapeutic oxytocics was lower in this group of women.
Moderate and high quality evidence from 1 systematic review of 4 and 3 studies did not find a significant difference in the number of women with a third stage of labour lasting more than 30 minutes (n=7482), or the number of women requiring a blood transfusion (n=5465), in

women who received oxytocin plus ergometrine compared with those who received oxytocin (10 IU) alone.

Neonatal outcomes

No difference was found in the number of babies with an Apgar score of 6 or less at 5 minutes, or in the proportion of babies with jaundice (n=5468) in babies whose mother received oxytocin plus ergometrine compared with those whose mother received oxytocin (10 IU) alone. The quality of the evidence was moderate.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised the outcomes of blood loss and side effects. These were felt to be both clinically significant and important for the woman's experience of birth.

Consideration of clinical benefits and harms

The guideline development group first considered the evidence for oxytocin use in the active management of third stage, as recommended in the original guideline. The group noted that there was no new evidence available since the publication of the original guideline, but that there had been some concern expressed by clinicians about an association of oxytocin use with increased haemorrhage. Reviewing the evidence, the guideline development group noted that women in the oxytocin group had a significantly higher incidence of postpartum haemorrhage of 500 ml and also a higher need for therapeutic oxytocics. However, they recognised that there was no significant difference observed between the oxytocin group and the oxytocin plus ergometrine group for women with blood loss of 1000 ml or more. Conversely, the group recognised that there were significantly higher rates of elevated blood pressure, vomiting and nausea observed in the group receiving oxytocin plus ergometrine. The guideline development group considered the numbers needed to treat to avoid a blood loss of 500 ml (an estimated 66 women would need to be treated with oxytocin plus ergometrine rather than oxytocin to avoid 1 woman having a blood loss of 500 ml), and the number needed to harm to avoid nausea and vomiting that would be expected with the use of oxytocin + ergometrine (on average, for every 5 women treated with oxytocin plus ergometrine rather than oxytocin, there would be 1 experiencing nausea and vomiting).

In weighing up these benefits and harms, the group recognised that although postpartum haemorrhage is a serious condition, a loss of 500–1000 ml would not be a cause for undue concern. On balance, they agreed that the adverse effects of nausea and vomiting on a woman's health and ability to enjoy and care for her baby during the important period immediately following the birth justified not recommending oxytocin plus ergometrine.

Consideration of health benefits and resource uses

The costs of oxytocin and oxytocin plus ergometrine are similar, with oxytocin slightly cheaper. Given this, and given the fact that there did not appear to be any major downstream costs associated with adverse outcomes from using oxytocin, the group felt that it was likely that its use would be cost-effective.

Quality of evidence

The guideline development group noted that the quality of evidence varied, but that in the majority of cases it was of moderate quality. The group felt that this was sufficient to support its recommendations.

Timing of cord clamping

Review question

Does deferred cord clamping in active management of the third stage of labour improve maternal and neonatal outcomes compared to early cord clamping?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

This review included 4 studies (Jahazi et al., 2008; Jaleel et al., 2009; McDonald et al., 2013; Andersson et al., 2011).
The included studies consisted of 1 systematic review with 15 component trials from a variety of locations (McDonald et al., 2013) and 3 randomised controlled trials, of which there was 1 each from Iran (Jahazi et al., 2008), Pakistan (Jaleel et al., 2009) and Sweden (Andersson et al., 2011).
All included trials evaluated the effect of timing of umbilical cord clamping of term infants on maternal and neonatal outcomes. The timing of cord clamping varied between the studies. 'Early' cord clamping was defined as immediate clamping of the cord ranging from 5 seconds to 1 minute after birth of the baby. 'Deferred' cord clamping was defined as clamping the cord from 1 to 5 minutes after the birth of the baby or after the cord had stopped pulsating. The type of uterotonic, the dose used and the timing of administration also varied between the included studies. Some studies did not specify whether a uterotonic was used or not.
The level at which the baby was positioned prior to cord clamping was noted in most trials and reported in the systematic review (McDonald et al., 2013). In 4 trials the baby was held at the level of the uterus or vagina, in 6 trials the baby was held below the level of the uterus (ranging from 10 cm to 30 cm below) and in 4 trials the baby was held by the woman or placed on her abdomen. For the 2 remaining trials the position of the baby in relation to the uterus was not reported.
For details of study interventions and comparisons please see the evidence tables in appendix I.

Evidence profile

The findings for effect of 'early' versus 'deferred' cord clamping on maternal and neonatal outcomes are reported in 1 GRADE profile. The following subgroup analysis was performed based on the timing of uterotonic administration:

- uterotonic before cord clamping
- uterotonic at, or after, cord clamping
- not specified whether uterotonic used.

Table 147: Summary GRADE profile for the effect of early versus deferred cord clamping on maternal and neonatal outcomes

		Quality		Effect		
Number of studies	Design	Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	Quality
PPH/blood loss 500 ml or more – overall						
1 meta-analysis of 5 studies (McDonald et al., 2013)	randomised trials	144/1060 (13.6%)	147/1200 (12.2%)	RR 1.17 (0.94 to 1.44)	21 more per 1000 (from 7 fewer to 54 more)	Moderate
PPH/blood loss 500 ml or more - uterotonic before clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	43/492 (8.7%)	41/540 (7.6%)	RR 1.11 (0.74 to 1.67)	8 more per 1000 (from 20 fewer to 51 more)	Low
PPH/blood loss 500 ml or more - uterotonic at, or after, clamping						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trials	77/478 (16.1%)	63/478 (13.1%)	RR 1.22 (0.90 to 1.65)	29 more per 1000 (from 13 fewer to 90 more)	Moderate
PPH/blood loss 500 ml or more - use of uterotonic not specified						
1 study (McDonald et al., 2013)	randomised trial	24/90 (26.7%)	43/182 (23.6%)	RR 1.13 (0.73 to 1.74)	31 more per 1000 (from 64 fewer to 175 more)	Very low

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Severe PPH/blood loss 1000 ml or more - overall						
1 meta-analysis of 6 studies (McDonald et al., 2013)	randomised trials	34/975 (3.5%)	37/1091 (3.4%)	RR 1.04 (0.65 to 1.65)	1 more per 1000 (from 12 fewer to 22 more)	Low
Severe PPH/blood loss 1000 ml or more - uterotonic before clamping						
1 study McDonald et al., 2013)	randomised trial	9/236 (3.8%)	8/244 (3.3%)	RR 1.16 (0.46 to 2.96)	5 more per 1000 (from 18 fewer to 64 more)	Very low
Severe PPH/blood loss 1000 ml or more - uterotonic at, or after, clamping						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trials	20/478 (4.2%)	19/478 (4%)	RR 1.06 (0.57 to 1.95)	2 fewer per 1000 (from 17 fewer to 38 more)	Low
Severe PPH/blood loss 1000 ml or more - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	5/261 (1.9%)	10/369 (2.7%)	RR 0.85 (0.29 to 2.49)	4 fewer per 1000 (from 19 fewer to 40 more)	Low
Mean blood loss (ml) – overall						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trials	n=669	n=676	NC	MD 5.11 higher (23.18 lower to 33.39 higher) p=NS	Moderate
Mean blood loss (ml) - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	373 (SD 366) n=236	351 (SD 372) n=244	NC	MD 22 higher (40.16 lower to 84.16 higher) p=NS	Moderate

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Mean blood loss (ml) - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	n=433	n=432	NC	MD 0.7 higher (31.06 lower to 32.46 higher) p=NS	Moderate
Maternal haemoglobin (g/dl) 24 to 72 hours postpartum - overall						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trials	n=557	n=571	NC	MD 0.12 lower (0.3 lower to 0.06 higher) p=NS	High
Maternal haemoglobin (g/dl) 24 to 72 hours postpartum - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	10.8 (SD 1.8) n=236	10.8 (SD 1.6) n=244	NC	MD 0 higher (0.31 lower to 0.31 higher) p=NS	High
Maternal haemoglobin (g/dl) 24 to 72 hours postpartum - uterotonic at, or after, clamping						
1 study (McDonald et al., 2013)	randomised trial	11.1 (SD 1.7) n=244	11.2 (SD 1.9) n=239	NC	MD 0.1 lower (0.42 lower to 0.22 higher) p=NS	High
Maternal haemoglobin (g/dl) 24 to 72 hours postpartum - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	n=77	n=88	NC	MD 0.28 lower (0.6 lower to 0.04 higher) p=NS	High
Need for blood transfusion - overall						
1 study meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	10/669 (1.5%)	10/676 (1.5%)	RR 1.02 (0.44 to 2.37)	0 more per 1000 (from 8 fewer to 20 more)	High

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Need for blood transfusion - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	3/236 (1.3%)	2/244 (0.82%)	RR 1.55 (0.26 to 9.2)	5 more per 1000 (from 6 fewer to 67 more)	Low
Need for blood transfusion - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	7/433 (1.6%)	8/432 (1.9%)	RR 0.89 (0.34 to 2.35)	2 fewer per 1000 (from 12 fewer to 25 more)	High
Need for manual removal of placenta - overall						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	18/736 (2.4%)	12/779 (1.5%)	RR 1.59 (0.78 to 3.26)	9 more per 1000 (from 3 fewer to 35 more)	Moderate
Need for manual removal of placenta - uterotonic before clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	16/492 (3.3%)	8/540 (1.5%)	RR 2.17 (0.94 to 5.01)	17 more per 1000 (from 1 fewer to 59 more)	Moderate
Need for manual removal of placenta - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	14/669 (2.1%)	12/676 (1.8%)	RR 1.18 (0.55 to 2.52)	3 more per 1000 (from 8 fewer to 27 more)	High
Length of third stage >30 mins - overall						
1 study (McDonald et al., 2013)	randomised trial	5/480 (1%)	5/483 (1%)	RR 1 (0.29 to 3.41)	0 fewer per 1000 (from 7 fewer to 25 more)	High

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Length of third stage >30 mins - uterotonic before clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	11/433 (2.5%)	11/432 (2.5%)	RR 1.1 (0.44 to 2.29)	0 more per 1000 (from 14 fewer to 33 more)	Low
Length of third stage >30 mins - uterotonic at, or after, clamping						
1 study (McDonald et al., 2013)	randomised trial	2/244 (0.82%)	4/239 (1.7%)	RR 0.49 (0.09 to 2.65)	9 fewer per 1000 (from 15 fewer to 28 more)	High
Length of third stage >60 mins - overall						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	12/669 (1.8%)	10/676 (1.5%)	RR 1.11 (0.33 to 3.74)	2 more per 1000 (from 10 fewer to 41 more)	Low
Length of third stage >60 mins - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	6/236 (2.5%)	6/244 (2.5%)	RR 1.03 (0.34 to 3.16)	1 more per 1000 (from 16 fewer to 53 more)	Low
Length of third stage >60 mins - uterotonic at, or after clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	6/433 (1.4%)	4/432 (0.9%)	RR 1.68 (0.09 to 31.66)	6 more per 1000 (from 8 fewer to 284 more)	High
Need for therapeutic uterotonics - overall						
1 study (McDonald et al., 2013)	randomised trial	100/480 (20.8%)	107/483 (22.2%)	RR 0.94 (0.74 to 1.2)	13 fewer per 1000 (from 58 fewer to 44 more)	Moderate
Need for therapeutic uterotonics - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	52/236 (22%)	49/244 (20.1%)	RR 1.1 (0.78 to 1.55)	20 more per 1000 (from 44 fewer to 110 more)	Moderate

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Need for therapeutic uterotonics - uterotonic at, or after, clamping						
1 study (McDonald et al., 2013)	randomised trials	48/244 (19.7%)	58/239 (24.3%)	RR 0.81 (0.58 to 1.14)	46 fewer per 1000 (from 102 fewer to 34 more)	Moderate
Apgar score <7 at 5 mins - overall						
1 meta-analysis of 4 studies (McDonald et al., 2013)	randomised trials	30/700 (4.3%)	24/699 (3.4%)	RR 1.23 (0.73 to 2.07)	8 more per 1000 (from 10 fewer to 38 more)	Very low
Apgar score <7 at 5 mins - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	5/236 (2.1%)	3/244 (1.2%)	RR 1.72 (0.42 to 7.13)	9 more per 1000 (from 7 fewer to 75 more)	Low
Apgar score <7 at 5 mins - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	8/272 (2.9%)	4/268 (1.5%)	RR 1.96 (0.6 to 6.42)	14 more per 1000 (from 6 fewer to 81 more)	Very low
Apgar score <7 at 5 mins - use of uterotonic not specified						
1 study (McDonald et al., 2013)	randomised trial	17/192 (8.9%)	17/187 (9.1%)	RR 0.97 (0.51 to 1.85)	3 fewer per 1000 (from 45 fewer to 77 more)	Low
Admission to SCN (special care baby nursery) or NICU - overall						
1 meta-analysis of 5 studies (McDonald et al., 2013)	randomised trials	25/788 (3.2%)	38/887 (4.3%)	RR 0.79 (0.48 to 1.31)	9 fewer per 1000 (from 22 fewer to 13more)	High

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Admission to SCN or NICU - uterotonic before clamping						
1 study (McDonald et al., 2013)	randomised trial	7/236 (3%)	5/244 (2%)	RR 1.45 (0.47 to 4.5)	9 more per 1000 (from 11 fewer to 72 more)	Low
Admission to SCN or NICU - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	14/433 (3.2%)	19/432 (4.4%)	RR 0.74 (0.37 to 1.46)	11 fewer per 1000 (from 28 fewer to 20 more)	Low
Admission to SCN or NICU - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	4/119 (3.4%)	14/211 (6.6%)	RR 0.57 (0.2 to 1.6)	29 fewer per 1000 (from 53 fewer to 40 more)	Low
Respiratory distress - overall						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trial	29/466 (6.2%)	28/369 (7.6%)	RR 0.7 (0.22 to 2.19)	23 fewer per 1000 (from 59 fewer to 90 more)	Very low
Respiratory distress - uterotonic at, or after, clamping						
1 study (Andersson et al., 2001)	randomised trial	8/197 (4.1%)	6/197 (3%)	RR 1.33 (0.47 to 3.77)	10 more per 1000 (from 16 fewer to 84 more)	Low
Jaundice requiring phototherapy - overall						
1 meta-analysis of 8 studies (McDonald et al., 2013; 1 study Andersson et al., 2011)	randomised trials	31/1131 (2.7%)	52/1193 (4.4%)	RR 0.62 (0.41 to 0.96)	17 fewer per 1000 (from 2 fewer to 26 fewer)	Moderate

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Jaundice requiring phototherapy - uterotonic before clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	15/492 (3%)	27/540 (5%)	RR 0.59 (0.32 to 1.11)	21 fewer per 1000 (from 34 fewer to 6 more)	Moderate
Jaundice requiring phototherapy - uterotonic at, or after, clamping						
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies McDonald et al., 2013; 1 study Andersson et al., 2001)	randomised trials	15/549 (2.7%)	24/559 (4.3%)	RR 0.64 (0.35 to 1.18)	15 fewer per 1000 (from 28 fewer to 8 more)	Moderate
Clinical jaundice - overall						
1 meta-analysis of 6 studies (McDonald et al., 2013)	randomised trials	97/977 (9.9%)	129/1121 (11.5%)	RR 0.84 (0.66 to 1.07)	18 fewer per 1000 (from 39 fewer to 8 more)	Moderate
Clinical jaundice - uterotonic before clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	57/484 (11.8%)	75/538 (13.9%)	RR 0.86 (0.62 to 1.18)	20 fewer per 1000 (from 53 fewer to 25 more)	Moderate
Clinical jaundice - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	33/286 (11.5%)	41/290 (14.1%)	RR 0.87 (0.57 to 1.31)	18 fewer per 1000 (from 61 fewer to 44 more)	Low

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Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Clinical jaundice - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	7/207 (3.4%)	13/293 (4.4%)	RR 0.64 (0.29 to 1.39)	16 fewer per 1000 (from 32 fewer to 17 more)	Very low
Polycythaemia (haematocrit greater than 65%) - overall						
1 meta-analysis of 5 studies (McDonald et al., 2013)	randomised trials	3/459 (0.7%)	14/566 (2.5%)	RR 0.39 (0.12 to 1.27)	15 fewer per 1000 (from 22 fewer to 7 more)	Very low
Polycythaemia - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	1/280 (0.4%)	4/297 (1.3%)	RR 0.38 (0.06 to 2.48)	8 fewer per 1000 (from 13 fewer to 20 more)	Low
Polycythaemia - use of uterotonic not specified						
1 study (McDonald et al., 2013)	randomised trial	2/179 (1.1%)	10/269 (3.7%)	RR 0.4 (0.09 to 1.8)	22 fewer per 1000 (from 34 fewer to 30 more)	Very low
Neonatal haemoglobin at birth (g/dl) - overall						
1 meta-analysis of 3 studies (McDonald et al., 2013)	randomised trials	n=276	n=395	NC	MD 2.17 lower (4.06 to 0.28 lower) p=0.02	Moderate
Neonatal haemoglobin at birth (g/dl) - uterotonic at, or after, clamping						
1 study (McDonald et al., 2013)	randomised trial	16.8 (SD 1.27) n=15	21.25 (SD 1.67) n=30	NC	MD 4.45 lower (5.33 to 3.57 lower) p<0.00001	Low

Update 2014

Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Neonatal haemoglobin at birth (g/dl) - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	n=261	n=365	NC	MD 1.07 lower (2.03 to 0.12 lower) p=0.02	Low
Neonatal haemoglobin at 24-48 hours (g/dl) - overall						
1 meta-analysis of 4 studies (2 studies McDonald et al., 2013; 1 study Andersson et al., 2011)	randomised trials	n=385	n=499	NC	MD 1.49 lower (1.78 to 1.21 lower) p<0.00001	High
Neonatal haemoglobin at 24-48 hours (g/dl) - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (1 study McDonald et al., 2013; 1 study Andersson et al., 2011)	randomised trials	n=206	n=220	NC	MD 1.4 lower (1.75 to 1.05 lower) p<0.00001	High
Neonatal haemoglobin at 24-48 hours (g/dl) - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	n=179	n=279	NC	MD 1.68 lower (2.18 to 1.19 lower) p<0.00001	Moderate
Neonatal haemoglobin at 2-4 months (g/dl) - overall						
1 study (Andersson et al., 2011)	randomised trials	11.3 (07) n=175	11.3 (08) n=168	NC	MD 0 higher 0.16 lower to 0.16 higher) p=ns	High

Update 2014

Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Neonatal haemoglobin at 3 - 6 months (g/dl) - overall						
1 meta-analysis of 6 studies (McDonald et al., 2013)	randomised trials	n=546	n =569	lower	MD 0.15 higher (0.48 lower to 0.19 higher) p=NS	High
Neonatal haemoglobin at 3 - 6 months (g/dl) - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	n=220	n=214	NC	MD 0.03 higher (0.17 lower to 0.22 higher) p=NS	High
Neonate haemoglobin at 3 - 6 months (g/dl) - use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	n=326 (SD 0.9) n=171	n=355 (SD 1.1) n=185	NC	MD 0.26 lower (0.79 lower to 0.26 higher) p=NS	High
Low neonatal haemoglobin at 3 - 6 months - overall						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trials	73/469 (15.6%)	72/485 (14.8%)	RR 1.05 (0.79 to 1.39)	7 more per 1000 (from 31 fewer to 58 more)	Moderate
Low neonatal haemoglobin at 3 - 6 months - uterotonic at, or after, clamping						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	42/220 (19.1%)	44/218 (20.2%)	RR 0.96 (0.67 to 1.36)	8 fewer per 1000 (from 67 fewer to 73 more)	Low
Low neonatal haemoglobin at 3 - 6 months – use of uterotonic not specified						
1 meta-analysis of 2 studies (McDonald et al., 2013)	randomised trial	31/249 (12.2%)	28/267 (10.5%)	RR 1.19 (0.74 to 1.92)	20 more per 1000 (from 27 fewer to 96 more)	Low

Update 2014

Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Neonatal Hb <14 at 6 hours of life - use of uterotonic not specified						
1 study (Jaleel, 2009)	randomised trial	49/100 (49%)	37/100 (37%)	RR 1.32 (0.96 to 1.83)	118 more per 1000 (from 15 fewer to 307 more)	Very low
Neonatal Hb <10.5 g/litre at 4 months - uterotonic at, or after, cord clamping						
1 study (Andersson et al., 2011)	randomised trial	21/175 (12%)	21/172 (12.2%)	RR 0.98 (0.56 to 1.73)	2 fewer per 1000 (from 54 fewer to 89 more)	Very low
Infant haematocrit <45% at 6 hours - use of uterotonic not specified						
1 study (McDonald et al., 2013)	randomised trial	8/90 (8.9%)	1/182 (0.55%)	RR 16.18 (2.05 to 127.37)	83 more per 1000 (from 6 more to 694 more)	Moderate
Infant haematocrit <45% at 24-48 hours - use of uterotonic not specified						
1 study (McDonald et al., 2013)	randomised trial	15/89 (16.9%)	5/179 (2.8%)	RR 6.03 (2.27 to 16.07)	141 more per 1000 (from 35 more to 421 more)	Moderate
Infant haematocrit 2 hours of life - uterotonic at, or after, cord clamping						
1 study (Jahazi, 2008)	randomised trials	61 (SD 4.9) n=34	62.2 (SD 4.5) n=30	NC	MD 1.2 lower (3.5 lower to 1.1 higher) p=NS	Very low
Infant haemotocrit at 18 hours of life - uterotonic at, or after, cord clamping						
1 study (Jahazi, 2008)	randomised trial	56.9 (SD 3.9) n=34	56.2 (SD 3.9) n=30	NC	MD 0.7 higher (1.21 lower to 2.61 higher)	Low
Infant ferritin <20 µg/litre at 4 months - uterotonic at, or after, cord clamping						
1 study (Andersson et al., 2011)	randomised trial	13/175 (7.4%)	0/172 (0%)	RR 26.54 (1.59 to 442.97)	NC	Moderate

Update 2014

Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Infant iron deficiency at 3 – 6 months						
1 meta-analysis of 5 studies (McDonald et al., 2009)	randomised trial	75/532 (14.1%)	49/620 (7.9%)	RR 2.65 (1.04 to 6.73)	130 more per 1000 (from 3 fewer to 453 more)	Very low
Infant iron deficiency at 3 – 6 months - uterotonic at, or after cord clamping						
1 meta-analysis of 2 studies (McDonald et al., 2009)	randomised trial	38/214 (17.8%)	28/211 (13.3%)	RR 2.73 (0.19 to 40.19)	230 more per 1000 (from 107 fewer to 1000 more)	Very low
Infant iron deficiency at 3 – 6 months - use of uterotonic not specified						
1 meta-analysis of 3 studies (McDonald et al., 2009)	randomised trial	37/318 (11.6%)	21/409 (5.1%)	RR 2.91 (1.18 to 7.2)	98 more per 1000 (from 9 more to 318 more)	High
Neurodevelopment at 4 months – ASQ fine motor score						
1 study (McDonald et al., 2009)	randomised trial	M 257.5 (29.2) n=180	M 258.9 (28.4) n=185	NC	98 more per 1000 (from 9 more to 318 more)	Moderate
Exclusive breastfeeding at discharge - uterotonic before cord clamping						
1 study (McDonald et al., 2009)	randomised trial	212/236 (89.8%)	216/244 (88.5%)	RR 1.01 (0.95 to 1.08)	9 more per 1000 (from 44 fewer to 71 more)	High
Not breastfeeding at discharge						
1 study (McDonald et al., 2013)	randomised trial	140/792 (17.7%)	139/841 (16.5%)	RR 1.11 (0.90 to 1.36)	18 more per 1000 (from 17 fewer to 60 more)	Moderate

Update 2014

Number of studies	Design	Quality		Effect		Quality
		Early cord clamping	Deferred cord clamping	Relative (95% CI)	Absolute (95% CI)	
Not breastfeeding at 1 month						
1 study (McDonald et al., 2013)	randomised trial	82/90 (91.1%)	148/178 (83.1%)	RR 1.1 (1 to 1.2)	83 more per 1000 (from 0 more to 166 more)	Moderate
Not breastfeeding at 2 months						
1 study (McDonald et al., 2013)	randomised trial	0/41 (0%)	2/43 (4.6%)	RR 0.21 (0.01 to 4.24)	37 fewer per 1000 (from 46 fewer to 151 more)	Very low
Not breastfeeding at 3 months						
1 meta-analysis of 2 studies (McDonald & Middleton, 2009)	randomised trials	7/69 (10.1%)	8/75 (10.6%)	RR 10.93 (0.36 to 2.42)	7 fewer per 1000 (from 68 fewer to 151 more)	Very low
Not breastfeeding at 4 months						
1 study (McDonald et al., 2013)	randomised trial	102/186 (54.8%)	128/205 (62.4%)	RR 1 (0.74 to 1.04)	75 fewer per 1000 (from 162 fewer to 25 more)	Very low
Not breastfeeding at 6 months						
1 study (McDonald et al., 2013)	randomised trial	152/208 (73%)	162/222 (72.9%)	RR 0.99 (0.89 to 1.11)	7 fewer per 1000 (from 80 fewer to 92 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, NICU neonatal intensive care unit, NS not significant, PPH postpartum haemorrhage, RR relative risk, SCN special care baby nursery, SD standard deviation

Update 2014

Further analysis

Developed countries

Subgroup analysis was performed looking at developed countries only for the reported outcomes.

One meta-analysis of 3 studies found the number of neonates with jaundice requiring phototherapy was statistically significantly lower in those allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping.

One study from a developed country found statistically significantly lower levels of haemoglobin at birth in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping. Another study found significantly lower levels of haemoglobin at 24-48 hours in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping.

One further study from a developed country found statistically significantly lower number of neonates with ferritin <20 µg/litre at 4 months in those allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping.

No statistically significant differences were observed between the early cord clamping and the deferred cord clamping groups for all other reported outcomes.

Evidence statements

Maternal outcomes

None of the studies found a significant difference between women allocated to the early cord clamping group and the deferred cord clamping group for the following outcomes: blood loss of 500 ml (n=2260); blood loss of 1000 ml or more (n=2066); mean blood loss (n=1345); maternal haemoglobin 24 to 72 hours postpartum (n=1128); blood transfusion (n=1345); manual removal of placenta (n=1515); length of third stage of labour over 30 minutes (n=963) and 60 minutes (n=1345); need for therapeutic uterotonics (n=963). These findings were not affected by the timing of the administration of the uterotonic. The evidence was of high to very low quality.

Neonatal outcomes

High quality evidence found that the incidence of jaundice requiring phototherapy (n=2324) was lower in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping. Levels of haemoglobin at 24–48 hours of life (n=884) were also lower in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping (evidence quality for this outcome was high or moderate). However, no significant differences were found between the 2 groups in the level of haemoglobin at 2–4 months (n=343) or 6 months after birth (n=1115) and ferritin levels at 4 months of life (n=347) (high to low quality evidence). Very low quality evidence found that infant iron deficiency (n=1152) was significantly higher in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping

None of the studies found a significant difference between neonates allocated to the early cord clamping group and the deferred cord clamping group for the following outcomes: incidence of clinical jaundice (n=2098); Apgar score less than 7 at 5 minutes (n=1399); admission to neonatal intensive care unit (NICU) (n=1675); respiratory distress (n=835); polycythaemia (n=1052); no breast feeding at discharge (n=1623) and at 2, 4 and 6 months (n=430). These findings were not affected by the timing of the administration of the uterotonic. The evidence was of high to very low quality.

Health economic profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the main maternal outcomes of interest were blood loss (which was measured in a number of different ways) and need for a further intervention.

The main neonatal outcomes of interest were admission to NICU and some measure of the infant's blood levels including jaundice, haemoglobin levels and ferritin levels. However, on seeing the evidence, the guideline development group felt that the jaundice finding may not be particularly relevant as clinicians would now use higher thresholds than those used in the studies. In addition, although the group had felt that ferritin levels might be useful as a proxy for indicating iron deficiency, it was noted that there is a large normal range for ferritin levels and thus that it is not particularly reliable as an outcome alone, and so greater emphasis was placed on findings for haemoglobin levels.

Consideration of clinical benefits and harms

The guideline development group noted that the majority of the studies defined deferred cord clamping as 'after 3 minutes'. The group considered that there is a time range in which cord clamping is generally conducted in active management. One local audit that the group were aware of had indicated a range between 10 seconds and 3 minutes. The group felt that in clinical practice, cord clamping is generally conducted between 30 and 60 seconds following the birth of the baby.

Reviewing the evidence, the guideline development group noted that there was no significant difference between the two groups for a large number of the outcomes reported. They recognised that there was a statistically significantly higher rate of jaundice requiring phototherapy in the deferred cord clamping group, although there was no statistically significant difference in other measures of jaundice or in rates of polycythaemia. Furthermore, as noted above, the guideline development group did not feel that the jaundice findings reported were relevant to current clinical practice.

There were statistically significant differences in a number of measures of neonatal haemoglobin (with lower rates in the early cord clamping group). However, these differences did not cross the guideline development group's pre-agreed thresholds (0.2 g/l) for a minimally important clinical difference for neonatal haemoglobin at 24–48 hours, 2–4 months and 3–6 months. There was a statistically significantly higher rate of infant haematocrit less than 45% at both 6 hours and 24–48 hours in the early cord clamping group. There were also statistically significantly lower rates of infant ferritin levels at 3, 4 and 6 months in the early cord clamping group. Although this suggests a potential harm, the guideline development group did not feel that ferritin level was a particularly helpful outcome because of a large normal range for ferritin levels.

The guideline development group was aware that 6 out of 14 included studies were from developed countries and subgroup analysis looking at developed countries showed that the number of neonates with jaundice requiring phototherapy was significantly lower in those allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping.

The guideline development group noted that 1 study from a developed country found statistically significantly lower levels of haemoglobin at birth in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping. Another study from a developed country found significantly lower levels of haemoglobin at 24-48 hours in neonates allocated to receive early cord clamping compared with those allocated to receive deferred cord clamping. However, the guideline development group did not feel that there was evidence to show that a slightly lower haemoglobin level early in life led to worse long term outcomes.

The guideline development group noted that 1 meta-analysis demonstrated a significantly higher rate of exclusive breastfeeding at 1 month in the early cord clamping group, but there

was no significant difference at 2–6 months. The group agreed that the breastfeeding finding was unhelpful as the result came close to touching unity and there was no difference observed in later months.

The guideline development group recognised some discrepancies within the evaluated trials. These mainly related to the use of different definitions of terms 'early cord clamping' and 'deferred (or 'late') cord clamping' and to the outcome variables included. Most trials did not follow the same definition for timings of cord clamping. Furthermore, those trials which reported jaundice as an outcome did not indicate what (if any) phototherapy treatment protocol was followed.

Overall, the guideline development group felt that the evidence showed that the timing of cord clamping does not make a difference to maternal outcomes. In terms of neonatal outcomes, the evidence showed a slight increase in haemoglobin levels of infants in the deferred cord-clamping group but also a slight increase in the rates of jaundice requiring phototherapy. However, it was felt that there was less likely to have been a significant jaundice finding had current UK treatment thresholds been used. The guideline development group also noted that the timing of administration of a uterotonic in relation to the timing of cord clamping did not seem to make a significant difference to any of the outcomes of interest, although there was a suggestion of an increased risk of retained placenta with early cord clamping following early administration of a uterotonic.

The guideline development group identified that a key advantage of deferred cord clamping is that placental transfusion allows new-born infants to continue to receive oxygen via the placenta as long as the cord is pulsing. This is especially relevant in cases when fetal compromise occurs in later stages of labour, where it is believed that the passage of blood in the first minute can contribute to better resuscitation. Given this, the guideline development group agreed that in most cases, clamping should not take place before 1 minute from the birth of the baby. The group recognised that if there was concern about the integrity of the cord, it would be appropriate to cut the cord sooner than 1 minute and highlighted this in its recommendation.

The evidence did not indicate an upper limit for when the cord could be cut, although it was noted that most studies did not look at deferred cord clamping later than 3 minutes after birth. However, the guideline development group felt that there would be no additional benefit beyond 5 minutes from birth to cord clamping but timing can be guided by maternal choice if the woman expresses a preference for cord clamping to be delayed.

Consideration of health benefits and resource uses

If deferred cord clamping leads to an increase in the number of babies with jaundice then this strategy would increase resource use. Babies with jaundice will require monitoring and in some cases treatment with phototherapy. However, as the treatment thresholds used in the studies do not correspond to UK practice, these differences in cases of jaundice, and consequent increases in resource use, may not be seen in a UK setting.

Quality of evidence

The guideline development group noted that the quality of the evidence varied considerably. One of the main reasons for the studies being downgraded was due to the fact that their reported findings had wide confidence intervals.

Other considerations

Although the guideline development group was of the view that 'deferred' cord clamping was associated with better outcomes, they noted that the studies reviewed for the timing of cord clamping question set different thresholds for the 'deferred clamping' group. The shortest was 1 minute and the longest was 5 minutes. In the light of this evidence, the guideline development group decided to recommend deferred cord clamping, setting a time limit of no earlier than 1 minute and no later than 5 minutes after birth.

Recommendations

224. Recognise that the time immediately after the birth is when the woman and her birth companion(s) are meeting and getting to know the baby. Ensure that any care or interventions are sensitive to this and minimise separation or disruption of the mother and baby. [new 2014]

225. For the purposes of this guideline, use the following definitions:

- The third stage of labour is the time from the birth of the baby to the expulsion of the placenta and membranes.
- Active management of the third stage involves a package of care comprising the following components:
  - routine use of uterotonic drugs
  - deferred clamping and cutting of the cord
  - controlled cord traction after signs of separation of the placenta.
- Physiological management of the third stage involves a package of care that includes the following components:
  - no routine use of uterotonic drugs
  - no clamping of the cord until pulsation has stopped
  - delivery of the placenta by maternal effort. **[new 2014]**

226. Diagnose a prolonged third stage of labour if it is not completed within 30 minutes of the birth with active management or within 60 minutes of the birth with physiological management. Follow recommendations 244 to 251 on managing a retained placenta. [new 2014]

227. Record the following observations for a woman in the third stage of labour:

- her general physical condition, as shown by her colour, respiration and her own report of how she feels
- vaginal blood loss. [new 2014]

228. If there is postpartum haemorrhage, a retained placenta or maternal collapse, or any other concerns about the woman's wellbeing:

- transfer her to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50)
- carry out frequent observations to assess whether resuscitation is needed. [new 2014]

229. Explain to the woman antenatally about what to expect with each package of care for managing the third stage of labour and the benefits and risks associated with each. [new 2014]

230. Explain to the woman that active management:

- shortens the third stage compared with physiological management
- is associated with nausea and vomiting in about 100 in 1000 women

- is associated with an approximate risk of 13 in 1000 of a haemorrhage of more than 1 litre
- is associated with an approximate risk of 14 in 1000 of a blood transfusion. [new 2014]

231. Explain to the woman that physiological management:

- is associated with nausea and vomiting in about 50 in 1000 women
- is associated with an approximate risk of 29 in 1000 of a haemorrhage of more than 1 litre
- is associated with an approximate risk of 40 in 1000 of a blood transfusion. [new 2014]

232. Discuss again with the woman at the initial assessment in labour (see recommendations 41 to 45 and 51 to 58) about the different options for managing the third stage and ways of supporting her during delivery of the placenta, and ask if she has any preferences. [new 2014]

233. Advise the woman to have active management of the third stage, because it is associated with a lower risk of a postpartum haemorrhage and/or blood transfusion. [new 2014]

234. If a woman at low risk of postpartum haemorrhage requests physiological management of the third stage, support her in her choice. [2014]

235. Document in the records the decision that is agreed with the woman about management of the third stage [new 2014].

236. For active management, administer 10 IU of oxytocin by intramuscular injection with the birth of the anterior shoulder or immediately after the birth of the baby and before the cord is clamped and cut. Use oxytocin as it is associated with fewer side effects than oxytocin plus ergometrine. [new 2014]

237. After administering oxytocin, clamp and cut the cord:

- Do not clamp the cord earlier than 1 minute from the birth of the baby unless there is concern about the integrity of the cord or the baby has a heartbeat below 60 beats/minute that is not getting faster.
- Clamp the cord before 5 minutes in order to perform controlled cord traction as part of active management.
- If the woman requests that the cord is clamped and cut later than 5 minutes, support her in her choice. [new 2014]

238. After cutting the cord, use controlled cord traction. [new 2014]

239. Perform controlled cord traction as part of active management only after administration of oxytocin and signs of separation of the placenta. [new 2014]

240. Record the timing of cord clamping in both active and physiological management. [new 2014]

241. Advise a change from physiological management to active management if either of the following occur:

- haemorrhage
- the placenta is not delivered within 1 hour of the birth of the baby. [new 2014]

242. Offer a change from physiological management to active management if the woman wants to shorten the third stage. [new 2014]

243. Do not use either umbilical oxytocin infusion or prostaglandin routinely in the third stage of labour. [2014]

Research recommendations

26. What are the risks and benefits for women and babies of physiological management of the third stage of labour compared to 'modified' active management for women giving birth outside an obstetric unit?

Population: Women in labour at low risk of developing intrapartum complications giving birth outside an obstetric unit
Intervention: Physiological management of the third stage of labour
Comparator: Active management of the third stage of labour
Primary outcomes: Woman's haemoglobin levels, health and wellbeing of baby at 2 years
Secondary outcomes: Need for blood transfusion, length of time from birth of baby to birth of placenta, retained placenta, postpartum haemorrhage, neonatal jaundice, breastfeeding rates, women's experiences, midwives experiences.
Study design: randomised controlled trial or prospective observational study
Secondary analyses might include: birth of placenta in water, squatting, use of birthing stool, kneeling, semi-recumbent, lying.
In a 2x2x2 factorial design in physiological management have 2 sub-groups one for leaving cord intact until birth of placenta and one for cutting cord after pulsation of the cord stops. Divide these sub groups into diagnosing retained placenta at 30 minutes and 60 minutes, giving IM syntocinon.

Why this is important
Whilst the risks associated with physiological management of the third stage of labour have been reported there has been little focus of the potential benefits and so to date the balance of risks and benefits has not been fully established. Management of the third stage involves a number of different factors and the timing of these may influence the ultimate outcomes for the woman and her baby. These could be studied at the same time using a nested factorial study design as described above.

Management of retained placenta

Review question

What is the most effective management of retained placenta in women who have had active management of the third stage of labour:

- With PPH
- Without PPH

For further details on the evidence review protocol, please see appendix E.

Update 2014

Description of included studies

This review included 9 studies (Bullarbo et al., 2005; Harara et al., 2011; Nardin et al., 2011; van Beekhuizen et al., 2006; van Beekhuizen et al., 2013; Visalyaputra et al., 2011; van Stralen et al., 2013; Samanta et al., 2013; Lim et al., 2011).
The included studies consist of 1 systematic review, with 15 component trials from a variety of countries (Nardin et al., 2011), and 8 further randomised controlled trials from Sweden (Bullarbo et al., 2005), Tanzania (van Beekhuizen et al., 2013), Holland (van Beekhuizen et al., 2006; van Stralen et al., 2013), Egypt (Harara et al., 2011), Thailand (Visalyaputra et al., 2011); India (Samanta et al., 2013) and Malaysia (Lim et al., 2011).
The majority of trials evaluated the management of women with retained placenta following active management of the third stage of labour. However, in 2 trials within the systematic review, not all women received an oxytocic during the third stage. In a further 4 trials from the systematic review, no details were given about third stage management. The definition of retained placenta varied between the studies, ranging from 15 minutes to 60 minutes after birth of the baby. None of the included studies reported that women with postpartum haemorrhage were included, so sub-group analysis could not be performed for this variable.

Evidence profile

The included studies evaluated the following comparisons:

- umbilical vein injection (UVI) oxytocin versus expectant management (Nardin et al., 2011)
- UVI oxytocin versus UVI saline (Nardin et al., 2011; Samanta et al., 2013; Lim et al., 2011)
- UVI oxytocin versus UVI prostaglandin (misoprostol or $PGF_2\alpha$) (Harara et al., 2011; Nardin et al., 2011)
- UVI oxytocin versus UVI plasma expander (Nardin et al., 2011)
- UVI oxytocin versus UVI ergometrine (Harara et al., 2011)
- UVI saline versus expectant management (Nardin et al., 2011)
- prostaglandin (misoprostol, $PGF_2\alpha$ or sulprostone) versus saline, either UVI (Nardin et al., 2011) or intravenous (IV) (van Beekhuizen et al., 2006)
- UVI prostaglandin (misoprostol) versus UVI ergometrine (Harara et al., 2011)
- nitroglycerin versus placebo, either intravenous (IV) (Visalyaputra et al., 2011) or sublingually (Bullarbo et al., 2005)
- oral misoprostol versus placebo (van Stralen et al., 2013; van Beekhuizen et al., 2013) 2013)

There was a lot of variation in the included studies with regards to the type of active management of the third stage of labour, the time to diagnosis of a retained placenta, the dose used and the time after which the clinicians judged that the intervention had failed and performed a manual removal. For this reason, a random effects model was used for all meta-analyses. For details of study interventions and comparisons please see the evidence tables in appendix I.
Each comparison is presented in turn in the GRADE profiles below.

Table 148: Summary GRADE profile for comparison UVI oxytocin with expectant managementa

Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	Expectant management	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	0/45 (0%)	0/48 (0%)	not calculable (NC)	NC	Very low
Need for further intervention: Manual removal of the placenta						
1 meta-analysis of 5 studies (Nardin et al., 2011)	randomised trials	117/234 (50%)	123/210 (58.6%)	RR 0.82 (0.65 to 1.05)	105 fewer per 1000 (from 205 fewer to 29 more)	Very low
Need for further intervention: Surgical removal of retained products of conception						
1 study (Nardin et al., 2011)	randomised trial	23/94 (24.5%)	31/88 (35.2%)	RR 0.69 (0.44 to 1.09)	109 fewer per 1000 (from 197 fewer to 32 more)	Low
Need for further intervention: Blood transfusion						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	18/120 (15%)	19/117 (16.2%)	RR 0.89 (0.5 to 1.58)	18 fewer per 1000 (from 81 fewer to 94 more)	Very low
Serious maternal morbidity (hysterectomy, admission to intensive care, renal or respiratory failure, other additional procedures to treat postpartum haemorrhage other than manual removal)						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	0/45 (0%)	0/45 (0%)	NC	NC	Very low
Blood loss ≥500 ml (minor postpartum haemorrhage)						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	26/96 (27.1%)	15/89 (16.9%)	RR 1.51 (0.88 to 2.61)	86 more per 1000 (from 20 fewer to 271 more)	Low

Update 2014

Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	Expectant management	Relative (95% CI)	Absolute (95% CI)	
Blood loss ≥1000 ml (major postpartum haemorrhage)						
1 study (Nardin et al., 2011)	randomised trial	6/70 (8.6%)	4/60 (6.7%)	RR 1.29 (0.38 to 4.34)	19 more per 1000 (from 41 fewer to 223 more)	Very low
Haemoglobin at 24 – 48 hours postpartum (g%)						
1 study (Nardin et al., 2011)	randomised trial	Mean 9.7 (SD 1.9) n=85	Mean 9.7 (SD 2.1) n=81	NC	MD 0 higher (0.61 lower to 0.61 higher)	Moderate
Infection						
1 study (Nardin et al., 2011)	randomised trial	5/93 (5.4%)	4/86 (4.7%)	RR 1.16 (0.32 to 4.16)	7 more per 1000 (from 32 fewer to 147 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation, UVI umbilical vein injection

a. In the five trials, the duration of expectant management before a manual removal was: 15 minutes, 30 minutes, 45 minutes, based on clinical judgement, and not reported

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Table 149: Summary GRADE profile for comparison UVI oxytocin with UVI saline

Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	UVI saline	Relative (95% CI)	Absolute (95% CI)	
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies [Nardin et al., 2011]; 1 study [Samantra et al., 2013]	randomised trials	1/398 (0.3%)	0/384 (0%)	RR 2.93 (0.12 to 71.59)	3 more per 1000 (from 8 fewer to 15 more)[a]	High

Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	UVI saline	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 meta-analysis of 13 studies (1 meta-analysis of 12 studies [Nardin et al., 2011]; 1 study [Lim et al., 2011])	randomised trials	364/685 (53.1%)	392/652 (60.1%)	RR 0.88 (0.80 to 0.97)	72 fewer per 1000 (from 18 fewer to 120 fewer)	Moderate
Need for further intervention: Additional therapeutic uterotonics						
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies [Nardin et al., 2011]; 1 study [Lim et al., 2011])	randomised trials	53/376 (14.1%)	66/362 (18.2)	RR 0.69 (0.43 to 1.13)	56 fewer per 1000 (from 104 fewer to 24 more)	Moderate
Need for further intervention: Surgical evacuation of retained products of conception						
1 meta-analysis of 4 studies (Nardin et al., 2011)	randomised trials	27/420 (6.4%)	29/406 (7.1%)	RR 0.88 (0.56 to 1.4)	9 fewer per 1000 (from 31 fewer to 29 more)	Moderate
Need for further intervention: Blood transfusion						
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies [Nardin et al., 2011]; 1 study [Samantra et al., 2013])	randomised trials	64/475 (13.5%)	56/463 (12.1%)	RR 1.13 (0.81 to 1.58)	16 more per 1000 (from 23 fewer to 70 more)	Moderate
Serious maternal morbidity (hysterectomy, admission to intensive care, renal or respiratory failure, other additional procedures to treat postpartum haemorrhage other than manual removal)						
1 meta-analysis of 4 studies (Nardin et al., 2011)	randomised trials	0/369 (0%)	1/355 (0.28%)	RR 0.33 (0.01 to 7.95)	2 fewer per 1000 (from 3 fewer to 20 more)	High

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Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	UVI saline	Relative (95% CI)	Absolute (95% CI)	
Blood loss ≥500 ml (minor postpartum haemorrhage)						
1 meta-analysis of 5 studies (Nardin et al., 2011); 1 study (Lim et al., 2011)	randomised trials	137/454 (30.0%)	135/436 (31%)	RR 0.95 (0.69 to 1.32)	15 fewer per 1000 (from 96 fewer to 99 more)	Low
Blood loss ≥1000 ml (major postpartum haemorrhage)						
1 meta-analysis of 4 studies (Nardin et al., 2011); 1 study (Lim et al., 2011)	randomised trials	38/421 (9.0%)	34/406 (8.4%)	RR 1.09 (0.7 to 1.69)	8 more per 1000 (from 25 fewer to 58 more)	Low
Haemoglobin at 24 – 48 hours postpartum (g%)						
1 study (Nardin et al., 2011)	randomised trial	Mean 9.7 (SD 1.9) n=85	Mean 9.8 (SD 2.4) n=82	NC	MD 0.1 lower (0.76 lower to 0.56 higher)	Moderate
Fall in haemoglobin levels of greater than 10%						
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies [Nardin et al., 2011]); 1 study [Samantra et al., 2013])	randomised trial	185/303 (61.1%)	180/296 (60.8%)	RR 1 (0.89 to 1.13)	0 fewer per 1000 (from 67 fewer to 79 more)	High
Infection						
1 meta-analysis of 3 studies (Nardin et al., 2011)	randomised trials	43/417 (10.3%)	31/403 (7.7%)	RR 1.34 (0.87 to 2.08)	26 more per 1000 (from 10 fewer to 83 more)	Moderate
Side effects: Nausea						
1 study (Nardin et al., 2011)	randomised trial	0/32 (0%)	0/28 (0%)	NC	NC	Low

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Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	UVI saline	Relative (95% CI)	Absolute (95% CI)	
Side effects: Headache						
1 study (Nardin et al., 2011)	randomised trial	0/32 (0%)	0/28 (0%)	NC	NC	Low
Side effects: Hypertension						
1 meta-analysis of 5 studies (1 meta-analysis of 4 studies [Nardin et al., 2011]; 1 study [Samantra et al., 2013])	randomised trial	0/61 (0%)	0/57 (0%)	NC	NC	Low
Length of third stage of labour (minutes)						
1 study (Nardin et al., 2011)	randomised trial	Mean 111.4 (SD 43.2) n=15	Mean 95.2 (SD 44.6) n=15	NC	MD 16.2 higher (15.22 lower to 47.62 higher)	Moderate

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation, UVI umbilical vein injection

a. calculated by NCC using Excel calculator (not GRADE)

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Table 150: Summary GRADE profile for comparison of UVI oxytocin with UVI prostaglandin (misoprostol or PGF2α)

Number of studies	Design	Number of women		Effect		Quality
		UVI oxytocin	UVI prostaglandin	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 meta-analysis of 3 studies (Harara et al., 2011; Nardin et al., 2011)	randomised trials	28/57 (49.1%)	14/56 (25%)	RR 1.82 (1.14 to 2.92)	205 more per 1000 (from 35 more to 480 more)	Low
Need for further intervention: Additional therapeutic uterotonics						
1 study (Nardin et al., 2011)	randomised trials	5/11 (45.5%)	6/10 (60%)	RR 0.76 (0.33 to 1.72)	144 fewer per 1000 (from 402 fewer to 432 more)	Very low

Number of studies	Design	Number of women		Effect		Quality
		UVI oxytocin	UVI prostaglandin	Relative (95% CI)	Absolute (95% CI)	
Postpartum haemorrhage						
1 study (Harara et al., 2011)	randomised trial	0/26 (0%)	0/25 (0%)	not calculable (NC)	NC	Low
Side effects: Any						
1 study (Harara et al., 2011)	randomised trial	0/26 (0%)	0/25 (0%)	NC	NC	Low
Time interval between injection and placental delivery (minutes)						
1 meta-analysis of 2 studies (Harara et al., 2011; Nardin et al., 2011)	randomised trials	n=30	n=30	NC	MD 6.07 higher (4.47 to 7.66 higher)	Moderate

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, UVI Umbilical vein injection

Table 151: Summary GRADE profile for comparison UVI oxytocin with UVI plasma expander

Number of studies	Design	Number of women		Effect		Quality
		UVI oxytocin	UVI plasma expander	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 study (Nardin et al., 2011)	randomised trial	49/68 (72.1%)	22/41 (53.7%)	RR 1.34 (0.97 to 1.85)	182 more per 1000 (from 16 fewer to 456 more)	Low
Blood loss >1000 ml (major postpartum haemorrhage)						
1 study (Nardin et al., 2011)	randomised trial	8/68 (11.8%)	5/41 (12.2%)	RR 0.96 (0.34 to 2.75)	5 fewer per 1000 (from 80 fewer to 213 more)	Very low

CI confidence interval, RR relative risk, UVI umbilical vein injection

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Table 152: Summary GRADE profile for comparison UVI oxytocin with UVI ergometrine

Number of studies	Design	Number of women or average		Effect		Quality
		UVI oxytocin	UVI ergometrine	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 study (Harara et al., 2011)	randomised trial	7/26 (26.9%)	10/27 (37%)	RR 0.73 (0.33 to 1.62)	100 fewer per 1000 (from 248 fewer to 230 more)	Very low
Postpartum haemorrhage						
1 study (Harara et al., 2011)	randomised trial	0/26 (0%)	0/27 (0%)	NC	NC	Low
Side effects: Any						
1 study (Harara et al., 2011)	randomised trial	0/26 (0%)	0/27 (0%)	NC	NC	Low
Time interval between injection and spontaneous separation (minutes)						
1 study (Harara et al., 2011)	randomised trial	Mean 13.1 (SD 3.76) n=19	Mean 22.5 (SD 4.37) n=17	NC	MD 9.4 lower (12.08 lower to 6.72 lower)	Moderate

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation, UVI umbilical vein injection

Table 153: Summary GRADE profile for comparison UVI saline with expectant managementa

Number of studies	Design	Number of women or average		Effect		Quality
		UVI saline	Expectant management	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	0/42 (0%)	0/45 (0%)	NC	NC	Very low
Need for further intervention: Manual removal of the placenta						
1 meta-analysis of 4 studies (Nardin et al., 2011)	randomised trials	114/206 (55.3%)	113/197 (57.4%)	RR 0.97 (0.84 to 1.12)	17 fewer per 1000 (from 92 fewer to 69 more)	Low

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Number of studies	Design	Number of women or average		Effect		Quality
		UVI saline	Expectant management	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Surgical removal of retained products of conception						
1 study (Nardin et al., 2011)	randomised trial	25/90 (27.8%)	31/88 (35.2%)	RR 0.79 (0.51 to 1.22)	74 fewer per 1000 (from 173 fewer to 78 more)	Low
Need for further intervention: Blood transfusion						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	15/118 (12.7%)	19/117 (16.2%)	RR 0.76 (0.41 to 1.39)	39 fewer per 1000 (from 96 fewer to 63 more)	Very low
Serious maternal morbidity (hysterectomy, admission to intensive care, renal or respiratory failure, other additional procedures to treat postpartum haemorrhage other than manual removal)						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	0/42 (0%)	0/45 (0%)	NC	NC	Very low
Blood loss ≥500 ml (minor postpartum haemorrhage)						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	15/88 (17%)	15/89 (16.9%)	RR 1 (0.53 to 1.86)	0 fewer per 1000 (from 79 fewer to 145 more)	Very low
Blood loss ≥1000 ml (major postpartum haemorrhage)						
1 study (Nardin et al., 2011)	randomised trial	3/62 (4.8%)	4/60 (6.7%)	RR 0.73 (0.17 to 3.11)	18 fewer per 1000 (from 55 fewer to 141 more)	Very low
Haemoglobin at 24 – 48 hours postpartum						
1 study (Nardin et al., 2011)	randomised trial	Mean 9.8 (SD 2.4) n=82	Mean 9.7 (SD 2.1) n=81	NC	MD 0.1 higher (0.59 lower to 0.79 higher)	Moderate
Infection						
1 study (Nardin et al., 2011)	randomised trial	2/90 (2.2%)	4/86 (4.7%)	RR 0.48 (0.09 to 2.54)	24 fewer per 1000 (from 42 fewer to 72 more)	Very low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation, UVI umbilical vein injection

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a. In the four trials, the duration of expectant management before a manual removal was: 30 minutes; 45 minutes; based on clinical judgement; and not reported

Table 154: Summary GRADE profile for comparison UVI prostaglandin (misoprostol or PGF2α) with UVI saline

Number of studies	Design	Number of women		Effect		Quality
		UVI prostaglandin	UVI saline	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 meta-analysis of 2 studies (Nardin et al., 2011)	randomised trials	9/31 (29%)	14/20 (70%)	RR 0.24 (0.01 to 6.41)	532 fewer per 1000 (from 693 fewer to 1000 more)	Very low
Need for further intervention: Additional therapeutic uterotonics						
1 study (Nardin et al., 2011)	randomised trial	6/10 (60%)	4/7 (57.1%)	RR 1.05 (0.46 to 2.38)	29 more per 1000 (from 309 fewer to 789 more)	Very low

CI confidence interval, RR relative risk, UVI umbilical vein injection

Table 155: Summary GRADE profile for comparison IV prostaglandin (sulprostone) with IV saline

Number of studies	Design	Number of women		Effect		Quality
		IV sulprostone	IV saline	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 study (van Beekhuizen et al., 2006)	randomised trial	11/24 (45.8%)	22/26 (84.6%)	RR 0.54 (0.34 to 0.86)	389 fewer per 1000 (from 118 fewer to 558 fewer)	Low
Need for further intervention: Hysterectomy						
1 study (van Beekhuizen et al., 2006)	randomised trial	0/24 (0%)	0/26 (0%)	NC	NC	Low
Need for further intervention: Blood transfusion						
1 study (van Beekhuizen et al., 2006)	randomised trial	6/24 (25%)	8/26 (30.8%)	RR 0.81 (0.33 to 2)	58 fewer per 1000 (from 206 fewer to 308 more)	Very low

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Number of studies	Design	Number of women		Effect		Quality
		IV sulprostone	IV saline	Relative (95% CI)	Absolute (95% CI)	
Side effects: Nausea						
1 study (van Beekhuizen et al., 2006)	randomised trial	0/24 (0%)	1/26 (3.8%)	RR 0.36 (0.02 to 8.43)	25 fewer per 1000 (from 38 fewer to 286 more)	Very low

CI confidence interval, IV intravenous, NC not calculable, RR relative risk

Table 156: Summary GRADE profile for comparison UVI prostaglandin (misoprostol) with UVI ergometrine

Number of studies	Design	Number of women or average		Effect		Quality
		UVI misoprostol	UVI ergometrine	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 study (Harara et al., 2011)	randomised trial	5/25 (20%)	10/27 (37%)	RR 0.54 (0.21 to 1.36)	170 fewer per 1000 (from 293 fewer to 133 more)	Low
Postpartum haemorrhage						
1 study (Harara et al., 2011)	randomised trial	0/25 (0%)	0/27 (0%)	NC	NC	Low
Side effects: Any						
1 study (Harara et al., 2011)	randomised trial	0/25 (0%)	0/27 (0%)	NC	NC	Low
Time interval between injection and spontaneous separation (in minutes)						
1 study (Harara et al., 2011)	randomised trial	Mean 7.0 (SD 2.2) n=20	Mean 22.5 (SD 4.37) n=17	NC	MD 15.5 lower (17.79 to 13.21 lower)	Moderate

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation, UVI umbilical vein injection

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Table 157: Summary GRADE profile for comparison of nitroglycerin (IV or sublingual) with placebo

Number of studies	Design	Number of women		Effect		Quality
		Nitroglycerin	Placebo	Relative (95% CI)	Absolute (95% CI)	
Need for further intervention: Manual removal of the placenta						
1 study (Bullarbo et al., 2005)	randomised trial	0/12 (0%)	11/12 (91.7%)	RR 0.04 (0 to 0.66)	880 fewer per 1000 (from 312 fewer to 917 fewer)	High
1 study (Visalyaputra et al., 2011)	randomised trial	17/20 (85%)	16/20 (80%)	RR 1.06 (0.8 to 1.41)	48 more per 1000 (from 160 fewer to 328 more)	Moderate
Need for further intervention: Repeat manual removal or uterine curettage						
1 study (Visalyaputra et al., 2011)	randomised trial	3/20 (15%)	0/20 (0%)	RR 7 (0.38 to 127.32)	150 more per 1000 (from 38 fewer to 360 more)[a]	Low
Side effects: Severe hypotension (systolic BP <80 mmHg)						
1 study (Visalyaputra et al., 2011)	randomised trial	2/20 (10%)	2/20 (10%)	RR 1 (0.16 to 6.42)	0 fewer per 1000 (from 84 fewer to 542 more)	Low
Side effects: Headache						
1 study (Visalyaputra et al., 2011)	randomised trial	1/20 (5%)	0/20 (0%)	RR 3 (0.13 to 69.52)	50 more per 1000 (from 116 fewer to 236 more)[a]	Very low

BP blood pressure, CI confidence interval, RR relative risk

a. calculated by NCC-WCH using Excel calculator (not GRADE)

Table 158: Summary GRADE profile for comparison of oral misoprostol with placebo

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol	Placebo	Relative (95% CI)	Absolute (95% CI)	
Manual removal of the placenta						
2 studies: (van Stralen et al., 2013; van Beekhuizen et al., 2013)	randomised trials	50/113 (44.2%)	38/84 (45.2%)	1.05 (0.76 to 1.44)	23 more per 1000 (109 fewer to 199 more)	Low

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol	Placebo	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion						
2 studies: (van Stralen et al., 2013; van Beekhuizen et al., 2013)	randomised trials	16/113 (14.2%)	16/74 (21.6%)	0.83 (0.27 to 1.84)	82 fewer per 1000 (from 199 fewer to 30 more)	Very low
Postpartum haemorrhage >1000						
2 studies: (van Stralen et al., 2013; van Beekhuizen et al., 2013)	randomised trial	37/113 (32.7%)	35/88 (39.8%)	0.87 (0.6 to 1.26)	52 fewer per 1000 (from 159 fewer to 103 more)	Very low
Side effects of oral misoprostol						
Nausea						
1 study (van Stralen et al., 2013)	RCT	6/42 (14%)	1/32 (3%)	4.8 (0.58 to 36.1)	119 more per 1000 (13 fewer to 1000 more)	Very low
Vomiting						
1 study (van Stralen et al., 2013)	RCT	3/42 (7.1%)	0/32 (0%)	5.4 (0.29 to 100.4)	71 more per 1000 (91 fewer to 233 more)[a]	Very low
Abdominal pain						
1 study (van Stralen et al., 2013)	RCT	8/42 (19%)	8/32 (25%)	0.76 (0.3 to 1.8)	60 fewer per 1000 (175 fewer to 200 more)	Very low
Headache						
1 study (van Stralen et al., 2013)	RCT	1/42 (2.3%)	1/32 (3.1%)	0.76 (0.05 to 11.8)	8 fewer per 1000 (30 fewer to 338 more)	Very low
Dizziness						
1 study (van Stralen et al., 2013)	RCT	5/42 (12%)	3/32 (9.3%)	1.26 (0.33 to 4.93)	37 more per 1000 (96 fewer to 561 more)	Very low

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Number of studies	Design	Number of women		Effect		Quality
		Misoprostol	Placebo	Relative (95% CI)	Absolute (95% CI)	
Dyspepsia						
1 study (van Stralen et al., 2013)	RCT	4/42 (9.5%)	0/32 (0%)	6.91 (0.39 to 123.8)	95 more per 1000 (66 fewer to 257 more)[a]	Very low
Shivering						
1 study (van Stralen et al., 2013)	RCT	15/42 (35%)	1/28 (3.5%)	10 (1.4 to 71.5)	321 more per 1000 (14 more to 1000 more)	Very low

CI confidence interval, RCT randomised control trial

a. calculated by NCC using Excel calculator (not GRADE)

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Evidence statements

UVI oxytocin versus expectant management

There was no evidence of a difference in outcomes for women receiving UVI oxytocin and women receiving expectant management. There were no incidences of maternal mortality (n=93) or serious maternal morbidity (n=90) in the studies that reported these outcomes, but the sample size was very small. The evidence was of very low to moderate quality.

UVI oxytocin versus UVI saline

There was evidence from 1 systematic review (n=1,377) showed that the risk of manual removal of the placenta was lower in women who received UVI oxytocin compared with women who received UVI saline. There were no incidences of side effects (nausea [n=60], headache [n=60], hypertension [n=118]) in the studies that reported these outcomes, but the sample size of 1 of the studies was very small. The evidence was of very low to high quality.

UVI oxytocin versus UVI prostaglandin (misoprostol or $PGF_2\alpha$)

There was evidence that the risk of requiring manual removal of the placenta was higher in women who received UVI oxytocin when compared with women who received UVI prostaglandin, although the sample size of the study was small (n=113). There was no difference between the 2 groups in the risk of requiring additional therapeutic uterotonics (n=22). No incidences of postpartum haemorrhage or side effects were reported, however the sample size of the study was very small (n=51). The demonstrated difference in the time interval between injection and placental delivery (n=60) was not considered clinically significant. The evidence was of very low to moderate quality.

UVI oxytocin versus UVI plasma expander

Evidence from 1 study (n=109) showed no difference in the proportion of women requiring removal of the placenta following UVI oxytocin and UVI plasma expander. There was also no difference in the risk of a major postpartum haemorrhage. No further outcomes of interest were reported. The evidence was of very low quality.

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UVI oxytocin versus UVI ergometrine

There was no evidence of a difference in the risk of requiring a manual removal of the placenta following UVI oxytocin and UVI ergometrine, but the study reporting this outcome was very small (n=53). The demonstrated difference in the time interval between injection and placental delivery (n=36) was not considered clinically significant. No incidences of postpartum haemorrhage or side effects (n=53) were reported. The evidence was of very low to moderate quality.

UVI saline versus expectant management

There was no evidence of a difference in outcomes for women receiving UVI saline and women receiving expectant management. There were no incidences of maternal mortality or serious maternal morbidity in the studies that reported these outcomes, but the sample size was very small (n=87). The evidence was of very low to moderate quality.

UVI prostaglandin (misoprostol or $PGF_2\alpha$) versus UVI saline

There was no evidence of a difference in the risks of requiring a manual removal of the placenta or requiring additional therapeutic uterotonics between women receiving UVI prostaglandin and those receiving UVI saline, however the sample size of the study was less than 20 and therefore the true effect is uncertain. The evidence was of very low quality.

IV prostaglandin (sulprostone) versus IV saline

There was evidence that women receiving IV sulprostone were less likely to require a manual removal of the placenta, although the comparison was only reported in 1 small study (n=50). There was no evidence of a difference in the other outcomes reported. The evidence was of very low to low quality.

UVI prostaglandin (misoprostol) versus UVI ergometrine

There was no evidence of a difference in outcomes for women receiving UVI misoprostol and women receiving UVI ergometrine, because the demonstrated difference in the time interval between injection and placental delivery was not considered clinically significant. The sample size of the study was very small (n=37). The evidence was of very low to moderate quality.

Nitroglycerin (IV or sublingual) versus placebo

There was evidence from 1 study (n=24) that women receiving nitroglycerin were less likely to require a manual removal of the placenta, although another study (n=40) did not find a difference in risk for women receiving nitroglycerin and women receiving a placebo. Both of the studies were small; therefore there is uncertainty about the true effect. The evidence from the same study (n=40) showed no differences in the risk of side effects and the risk of needing a repeat manual removal or uterine curettage. The evidence of very low to high quality.

Comparison of oral misoprostol versus placebo

There was no evidence of difference in the incidence of manual removal of the placenta (n=197), blood transfusion (n=187) and postpartum haemorrhage over 1000 ml (n=201) for women who received oral misoprostol compared with women who received placebo. The incidence of shivering (n=70) was significantly higher for women who received misoprostol compared with those who received placebo. The evidence was of very low to low quality.

Health economics profile

No published economic evaluations were identified for management of retained placenta for women with or without postpartum haemorrhage.

The review of the clinical evidence for UVI oxytocin versus expectant management reported that no outcomes were statistically significantly different between these 2 treatment options. This comparison was the most important for the update of the question on management of retained placenta as the previous guideline recommended oxytocin injection in to the umbilical vein.

Therefore for this model the comparison of interest was between the following:

- expectant management – no uterotonic administered
- UVI oxytocin.

The perspective of the analysis is the UK NHS and only includes costs to the NHS. The discount rate used is 3.5% and the cost year is 2012/13.

The main outcomes the guideline development group considered to be clinically significant, although not statistically significantly different, were manual removal of the placenta and major postpartum haemorrhage.

No incidences of maternal mortality were reported, although the studies were underpowered for this outcome. A large study would be needed to detect differences in mortality. Given that major postpartum haemorrhage is an important outcome, it was still necessary to consider maternal mortality in a model. Therefore data on hysterectomies and mortality were identified in the Saving Mothers' Lives report (CMACE 2011) and the relative risk for major postpartum haemorrhage was applied to the data in the base case analysis.

The outcomes in the analysis did not have a specific NHS reference cost as they were included within the reference costs for birth, for instance manual removal of placenta would be included in the cost of a birth with complications. Therefore, bottom up costing has been used where possible. Consensus from the guideline development group provided staff costs for various procedures related to birth and these costs are reported in appendix A. For these procedures the consumables costs were taken from the Birthplace cost-effectiveness analysis (Schroeder 2011) and uplifted using the inflation index reported in the Unit Costs of Health and Social Care 2013 (Curtis 2013).

The following health states were considered to be short term and so no decrement in quality of life was applied:

- manual removal of placenta
- minor postpartum haemorrhage
- infection.

Major postpartum haemorrhage and surgical removal of products of conception were considered to be more significant. However, quality of life utility scores were only identified for hysterectomy (Roberts et al., 2011). Women who have a hysterectomy have a significant reduction in quality of life in the month of the operation, for the next 11 months their quality of life reflects convalescence after the operation. And for subsequent years these women are assumed to have a reduced quality of life.

The quality of life decrement for hysterectomy was applied to major postpartum haemorrhage, for 4 days, with 1 day for surgical removal of products of conception. After these few days quality of life would then return to full health for the rest of the year, and subsequent years.

Expectant management of the third stage of labour results in more manual removals (number needed to treat [NNT]=12) and more incidences of surgical removal of retained products of conception (NNT=9) than with UVI oxytocin. With oxytocin UVI there are more incidences of postpartum haemorrhage, both minor (NNT=4) and major (NNT=53), and more infections (NNT=138).

The incremental cost effectiveness results using the base case inputs show UVI oxytocin is less expensive, but also less effective than expectant management.

Table 159: Costs, effects, incremental costs and effects per woman with retained placenta and incremental cost-effectiveness ratio for the comparison of expectant management and oxytocin UVI

	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER
Expectant management	£97,029	1,222.18			
UVI oxytocin	£89,061	1,217.09	-£7,967	-5.09	£1,565[a]

ICER incremental cost effectiveness ration, QALY quality adjusted life year

a. an incremental cost effectiveness ratio can be calculated, however it is important to note that this relates to a cost saving but with a health loss.

Expectant management may be more expensive in terms of increased manual removal of placentas and surgical removal of retained products of conception, but UVI oxytocin results in more serious outcomes, such as major postpartum haemorrhage, which are associated with higher costs and a worse birth experience for the woman.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised the outcomes of need for manual removal of the placenta and postpartum haemorrhage. These were felt to be both clinically significant and important for the woman's experience of birth.

Consideration of clinical benefits and harms

The guideline development group first considered the evidence for the efficacy of umbilical vein injection (UVI) of oxytocin, as recommended in the original guideline. They noted that it was associated with significantly fewer manual removals when compared with UVI saline and that there was a similar trend observed when compared to expectant management (although that finding did not reach statistical significance). Although there was no statistically significant difference between UVI oxytocin and either expectant management or UVI saline with regards to the incidence of postpartum haemorrhage of 500 ml or 1000 ml, the guideline development group recognised that there was a trend for UVI oxytocin to be associated with more postpartum haemorrhages, when compared with expectant management, and felt the

differences reported were clinically significant. They considered the numbers needed to treat to avoid a manual removal (an estimated 12 women would need to be treated with UVI oxytocin rather than expectant management to avoid 1 manual removal), and the number of additional postpartum haemorrhages that would be expected with the use of UVI oxytocin (on average, for every 53 women treated with UVI oxytocin rather than expectant management, there would be 1 additional postpartum haemorrhage greater than 1000 ml). On balance, the group agreed that the adverse effects of severe postpartum haemorrhage on a woman's health and ability to care for her baby justified not recommending UVI oxytocin, despite the evidence suggesting that it might reduce the need for manual removal of the placenta.

The guideline development group noted that 1 meta-analysis demonstrated a significant reduction in the need for manual removal of the placenta following UVI prostaglandin when compared to UVI oxytocin, and following IV sulprostone when compared to IV saline. However, they recognised that this evidence was from only a few trials, with small sample sizes, and that the effect was not consistent, as a trial of UVI prostaglandin compared with UVI saline did not show a significant benefit. The group was also disappointed that there were no trials evaluating the use of prostaglandin compared with expectant management. They discussed the fact that prostaglandins are not currently widely used in the UK setting, and, due to the lack of good evidence, did not feel that a recommendation of a shift in practice towards the use of prostaglandins was warranted.

In 1 trial, sublingual nitroglycerin was shown to be associated with a significant reduction in manual removal of the placenta, when compared with placebo. However, the guideline development group noted that this trial involved only 24 women, and despite the significant benefit demonstrated in a 2005 trial, no further research had been conducted on this intervention. Another small trial of intravenous nitroglycerin demonstrated no benefit. The group did not feel that they could make any kind of recommendation based on this evidence.

From their clinical experience, the group was aware that, in some cases, placentas can appear to be retained but in fact might be separated and at least part of the placenta might be present in the vagina. They wanted to avoid the situation where these women were taken to theatre unnecessarily for a manual removal and noted that this would be a particular consideration for women giving birth outside an obstetric unit, for whom a manual removal would necessitate transfer. The group agreed that recommending a vaginal examination to assess the need for a manual removal would help minimise unnecessary intervention. They felt that women should be offered analgesia for this procedure if they wanted it and noted that women's choice and uptake of pain relief might depend on their birth setting and willingness to be transferred. Anecdotally, they were aware of women having had bad experiences of placentas being removed without proper pain relief. The group was of the strong opinion that this vaginal examination should be distinct from the procedure of uterine exploration and manual removal, which should be conducted in an obstetric unit with anaesthetic.

Consideration of health benefits and resource uses

In the comparison of oxytocin to expectant management, the evidence did not demonstrate a significant benefit in terms of reduced manual removals. The guideline development group considered the increased incidence of postpartum haemorrhage was clinically significant, even though it was not statistically significant. Major guideline development group is associated with considerable resource use and costs in terms of treatment and increased length of stay in hospital. As described above, guideline development group has adverse effects on a woman's health and ability to care for her baby that, in the group's view, outweigh the potential adverse effects of manual removal. Therefore, the guideline development group concluded that oxytocin was unlikely to be cost effective compared to expectant management.

Quality of evidence

The guideline development group noted that the evidence was of varying quality, but considering the number of trials that evaluated UVI oxytocin, the group was confident that the

demonstrated lack of significant overall benefit was likely to be a trustworthy finding. The low quality and small numbers of participants in the trials evaluating prostaglandins and nitroglycerin meant that the group did not have confidence in the results, and did not feel that a recommendation for their use was warranted.

Other considerations

The guideline development group agreed that women with retained placenta should have intravenous access secured. Although they recognised that some midwives might be less confident about inserting cannulas, they felt that it was a reasonable recommendation. They thought that midwives attending home births would be competent to secure intravenous access, and in other birth settings there would be an option of seeking assistance from colleagues. The group noted that securing intravenous access becomes more difficult if the woman begins bleeding heavily, and the consensus was that it was a small and reasonably non-invasive intervention with the potential to confer significant benefit in the event that fluids or a blood transfusion are required.

Recommendations

244. Secure intravenous access if the placenta is retained, and explain to the woman why this is needed. [new 2014]

245. Do not use umbilical vein agents if the placenta is retained. [new 2014]

246. Do not use intravenous oxytocic agents routinely to deliver a retained placenta. [new 2014]

247. Give intravenous oxytocic agents if the placenta is retained and the woman is bleeding excessively. [new 2014]

248. If the placenta is retained and there is concern about the woman's condition:

- offer a vaginal examination to assess the need to undertake manual removal of the placenta
- explain that this assessment can be painful and advise her to have analgesia. [new 2014]

249. If the woman reports inadequate analgesia during the assessment, stop the examination and address this immediately. [2014]

250. If uterine exploration is necessary and the woman is not already in an obstetric unit, arrange urgent transfer (following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]

251. Do not carry out uterine exploration or manual removal of the placenta without an anaesthetic. [new 2014]

Update 2014

Postpartum haemorrhage

Risk factors for postpartum haemorrhage

Introduction

Risk factors for developing PPH were reviewed.

Review question

Are there effective ways of identifying women at increased risk of postpartum haemorrhage antenatally and during labour?

What is the effective management of women at increased risk of postpartum haemorrhage to minimise this risk?

Multiple factors study

Description of included studies

There were seven studies (two case–control studies[571,572] and five cross-sectional studies[573–577]) looking at multiple risk factors for PPH in high income countries, although three of them were inconclusive.

Review findings

A population based cross-sectional study was conducted in the Netherlands including 3464 nulliparous women between 1990 and 1994.[573] [EL = 3] The study investigated risk factors for standard (more than or equal to 500 ml of blood loss) and severe (more than or equal to 1000 ml of blood loss) PPH. Multivariate logistic regression analyses showed significant risk factors for standard PPH as: retained placenta (adjusted OR 7.83 [95% CI 3.78 to 16.22]); prolonged third stage (longer than 30 minutes) (adjusted OR 2.61 [95% CI 1.83 to 3.72]); multiple pregnancy (adjusted OR 2.60 [95% CI 1.06 to 6.39]); episiotomy (adjusted OR 2.18 [95% CI 1.68 to 2.81]); macrosomia (weight more than or equal to 4 kg) (adjusted OR 2.11 [95% CI 1.62 to 2.76]); perineal trauma (laceration severer than or equal to first-degree) (adjusted OR 1.40 [95% CI 1.04 to 1.87]); and West European race (adjusted OR 1.32 [95% CI 1.00 to 1.73]). Risk factors for severe PPH were reported as: retained placenta (adjusted OR 11.73 [95% CI 5.67 to 24.1]); prolonged third stage (longer than or equal to 30 minutes) (adjusted OR 4.90 [95% CI 2.89 to 8.32]); macrosomia (adjusted OR 2.55 [95% CI 1.57 to 4.18]); and perineal trauma (laceration severer than or equal to first-degree) (adjusted OR 1.82 [95% CI 1.01 to 3.28]). When stratified by background risk of the women, a multiple regression model showed risk factors of severe PPH for low-risk women were: retained placenta (adjusted OR 21.6 [95% CI 5.99 to 78.00]); and prolonged third stage (longer than 30 minutes) (adjusted OR 3.59 [95% CI 1.60 to 8.03]); while those for high-risk women were reported as retained placenta (adjusted OR 9.29 [95% CI 3.69 to 23.4]); prolonged third stage (longer than 30 minutes) (adjusted OR 6.11 [95% CI 2.94 to 12.7]); macrosomia (adjusted OR 2.75 [95% CI 1.52 to 4.97]); induction (adjusted OR 1.74 [95% CI 1.06 to 2.87]); and prolonged second stage (more than or equal to 30 minutes) (adjusted OR 2.74 [95% CI 1.37 to 5.49]).

A cross-sectional study was conducted in the USA including 763 pregnancy related deaths from haemorrhage associated with intrauterine pregnancies between 1979 and 1992.[574] [EL = 3] Although the study found black race and increased age were related to risk of death from haemorrhage, analysis did not control confounding factors and hence this study was inconclusive.

A case–control study was conducted in the UK including 86 PPH cases and 351 non-PPH controls.[571] [EL = 2-] Although the study suggested significant risk factors were nulliparous, labour induction, forceps birth, prolonged first and second stages, and oxytocin compared with oxytocin with ergometrine as significant risk factors, the analysis did not properly control confounding factors with unmatched controls and hence was inconclusive.

A cross-sectional study was conducted in the UK including 36,312 women between 1967 and 1981.[575] [EL = 3] The study investigated complications of the third stage. Although the study reported nulliparous and induction of labour as risk factors for PPH, the analysis did not control confounding factors and hence was inconclusive.

A case–control study was conducted in Australia including 125 PPH cases versus 125 controls in 2003.[572] [EL = 2+] Multivariate logistic regression analyses showed risk factors for developing PPH (blood loss 500 ml or greater) were: past history of PPH (adjusted OR 14.11 [95% CI 1.62 to 123.06]); prolonged second stage (longer than or equal to 60 minutes)

(adjusted OR 2.68 [95% CI 1.27 to 5.64]); forceps birth (adjusted OR 3.47 [95% CI 1.35 to 8.91]); and incomplete/ragged membranes (adjusted OR 3.56 [95% CI 1.52 to 8.36]).
A cross-sectional study was conducted in Australia including 13 868 women between 1998 and 2002.[576] [EL = 3] The study investigated risk factors for developing PPH (blood loss 1000 ml or greater and/or need for a transfusion). Multivariate logistic regression analyses showed risk factors as: Asian race (adjusted OR 1.8 [95% CI 1.4 to 2.2]); maternal blood disorders (adjusted OR 1.3 [95% CI 1.1 to 1.6]); prior PPH (adjusted OR 1.8 [95% CI 1.4 to 2.2]); history of retained placenta (adjusted OR 6.2 [95% CI 4.6 to 8.2]); multiple pregnancy (adjusted OR 2.2 [95% CI 1.5 to 3.2]); antepartum haemorrhage (adjusted OR 1.8 [95% CI 1.3 to 2.3]); genital tract lacerations (adjusted OR 1.7 [95% CI 1.4 to 2.1]); macrosomia (4 kg or greater) (adjusted OR 1.8 [95% CI 1.4 to 2.3]); induction of labour (adjusted OR 1.8 [95% CI 1.4 to 2.2]); chorioamnionitis (adjusted OR 1.3 [95% CI 1.1 to 1.7]); intrapartum haemorrhage (adjusted OR 1.5 [95% CI 1.0 to 2.3]); intrauterine fetal deaths (adjusted OR 2.6 [95% CI 1.1 to 5.7]); compound fetal presentation (adjusted OR 3.0 [95% CI 1.1 to 7.3]); epidural anaesthesia (adjusted OR 1.3 [95% CI 1.0 to 1.6]); prolonged first/second stage of labour (first stage) (adjusted OR 1.6 [95% CI 1.0 to 1.6]); second stage (adjusted OR 1.6 [95% CI 1.1 to 2.1]); and forceps birth after failed vacuum-assisted birth (adjusted OR 1.9 [95% CI 1.1 to 3.2]).
A cross-sectional study was conducted in the UK including 37,497 women in 1988, investigating risk factors for PPH (blood loss 1000 ml or greater).[577] [EL = 3] Although the study reported placental abruption, placenta praevia, multiple pregnancy, retained placenta, labour induction, episiotomy and macrosomia, the analysis did not control confounding factors and hence was inconclusive.

Anaemia

Description of included studies and review findings

A cohort study was conducted in New Zealand in 1996 comparing haemoglobin levels at 4 weeks prior to birth on PPH (blood loss 600 ml or greater within 24 hours of birth).[578] [EL = 2-] Although the study reported no difference, the analysis did not control confounding factors and hence was inconclusive.

Low-lying placenta

Description of included studies and review findings

A cross-sectional study was conducted in Canada between 1997 and 1999 investigating obstetric implications of low-lying placentas diagnosed in the second trimester.[579] [EL = 3] Multivariate logistic regression analysis showed significant increased risk of PPH (blood loss 500 ml or greater for vaginal birth, 100 ml or greater) for caesarean section (adjusted OR 1.72 [95% CI 1.12 to 2.66], adjusted for maternal age and birthweight).

Smoking

Description of included studies and review findings

A cohort study was conducted in the UK comparing obstetric outcomes of 400 smoking women with 400 non-smoking women.[580] [EL = 2-] Although the study reported higher incidence of PPH for smoking women, the analysis did not control for major confounding factors and hence was inconclusive.

Prolonged second stage of labour

Description of included studies

There were five observational studies identified (five cross-sectional studies)[327,328,332,333,335] on duration of second stage of labour on the defined outcomes with various quality.

Review findings

A cross-sectional study (n = 15,759) in the USA investigated prolonged duration of second stage (more than 4 hours) on the defined outcomes.[326] [EL = 3] Logistic regression analysis controlling various confounders showed there was no evidence of associations of prolonged second stage of labour with PPH (RR 1.05 [95% CI 0.84 to 1.31]).

One cross-sectional study in the Germany (n = 1200) investigated prolonged second stage of labour (more than 2 hours) on intrapartum outcomes.[328] [EL = 3] The results showed evidence of association of prolonged second stage with low Apgar score at 1 minute, PPH, perineal tears and postpartum fever, although the analyses did not control confounding factors.

One cross-sectional study (n = 25,069) in the UK investigated prolonged second stage of labour on perinatal outcomes.[332,333] [EL = 3] Logistic regression analysis showed that there was evidence of association between longer duration and higher rate of PPH (duration: 120–179 minutes, OR 1.6 [95% CI 1.3 to 1.9]; 180–239 minutes, 1.7 [95% CI 1.3 to 2.3]; 240 or more minutes, OR 1.9 [95% CI 1.2 to 2.8]).

One cross-sectional study in the USA (n = 4403) investigated different length of labour on intrapartum outcomes.[335] [EL = 3] The analyses without controlling confounding factors showed no evidence of association of length of second stage with neonatal outcomes apart from low Apgar score at 1 minute ($P < 0.03$). Both puerperal haemorrhage and febrile morbidity showed evidence of association with length of labour ($P < 0.001$ for both), but analysis did not consider confounding effects.

One cross-sectional study was conducted in the USA (n = 7818) investigated maternal and neonatal outcomes in women with prolonged second stage of labour.[327] [EL = 3] Although the analysis of women with longer than 120 minutes of second stage had higher incidence of PPH (RR 2.70, $P < 0.001$), the analysis did not control confounding factors and hence was inconclusive.

Prolonged third stage of labour

Refer to section 13.4

Body mass index and body weight

Description of included studies

There were four cross-sectional studies (three studies investigated overweight women[581–583] and one study investigated underweight women[584]) identified.

Review findings

One cross-sectional study was conducted in the UK between 1990 and 1999 including 60,167 childbirths.[582] [EL = 3] The study investigated outcome of pregnancy in a woman with an increased body mass index (BMI) (greater than 30 kg/m^2). The study reported significant increased risk of developing PPH (blood loss greater than 500 ml) with BMI over 30 kg/m^2 (OR 1.5 [95% CI 1.2 to 1.8]), although the analysis did not control any confounding.

One cross-sectional study was conducted in Canada between 1988 and 2002, including 142,404 women.[583] [EL = 3] Multivariate logistic regression analyses showed that moderately overweight women (90 – 120 kg) had increased risk of PPH (adjusted OR 1.12 [95% CI 1.02 to 1.22]), but there is no evidence of difference in incidence of PPH by severely overweight women (heavier than 120 kg) (adjusted OR 1.07 [95% CI 0.80 to 1.42]).

One cross-sectional study was conducted in the UK between 1989 and 1997, including 325,395 pregnancies.[581] [EL = 3] Multivariate logistic regression analyses showed increased risk of PPH (greater than 1000 ml) with increased BMI: BMI 25–30 kg/m^2, adjusted OR 1.16 [99% CI 1.12 to 1.21]; BMI more than 30 kg/m^2, adjusted OR 1.39 [99% CI 1.32 to 1.46], controlling for other factors including ethnicity, parity, age and history of hypertension.

Another cross-sectional study was conducted in the UK between 1988 and 1997 by using the same population as the study above[581] including 215,105 women.[584] [EL = 3] Multivariate

logistic regression analysis showed that women with low BMI (BMI 20–25 kg/m^2) have less PPH (PPH, adjusted OR 0.85 [99% CI 0.80 to 0.90]; severe PPH, adjusted OR 0.83 [99% CI 0.72 to 0.95]).

Post-term birth

Description of included studies and review findings

One cross-sectional study was identified.[585] [EL = 3] The data were collected between 1978 and 1993 to investigate association between post-term birth and maternal complication. Multivariate logistic regression analysis showed significantly higher risk of developing PPH in post-term pregnancy (adjusted OR 1.37 [95% CI 1.28 to 1.46]).

Macrosomia

Description of included studies

There were four observational studies identified.[586–589]

Review findings

One cross-sectional study was conducted in the UK.[586] [EL = 3] The study investigated risk factors and clinical consequences of macrosomia, involving 350,311 pregnancies, between 1988 and 1997. Multivariate logistic regression analysis showed that women with babies whose birth-weight were more than 4 kg had higher risk of developing PPH (adjusted OR 2.01 [99% CI 1.93 to 2.10]), and the analysis also showed that women with babies whose birthweight was more than the 90th centile had higher risk of developing PPH (adjusted OR 1.63 [99% CI 1.56 to 1.71]) compared with women whose babies were of normal weight.

One cross-sectional study conducted in the UK was identified.[587] [EL = 3] The study investigated clinical consequences of oversized babies, involving 7992 births between 1963 and 1964. Although the study reported double the risk of developing PPH for women with oversized babies than normal sized ones, the analysis did not control confounding factors and hence was inconclusive.

One US cross-sectional study was identified.[588] [EL = 3] The study investigated obstetric complications associated with macrosomia, including 146 526 live births. Multivariate logistic regression analysis showed higher risk of developing PPH by increased birthweight of babies (4000–4499 g birthweight, adjusted OR 1.69 [95% CI 1.58 to 2.10]; 4500–4999 g birthweight, adjusted OR 2.15 [95% CI 1.86 to 2.48]; 5000 g or greater birthweight, adjusted OR 2.03 [95% CI 1.33 to 3.09]).

One cross-sectional study conducted in Germany was identified.[589] [EL = 3] The study described maternal complications of fetal macrosomia, involving 956 between 1990 and 1997. Although the study reported association between macrosomia and PPH, the analysis did not control any confounding and hence was inconclusive.

Age

Description of included studies

There were two cross-sectional studies identified.[590,591] Both studies showed moderate quality. [EL = 3] One study was conducted in the UK[590] and the other study was conducted in Japan.[591]

Review findings

The UK study[590] investigated obstetric risk of women aged 35 years or greater, including 385,120 pregnancies. Multivariate logistic regression analysis showed significant positive association of women's age and risk of developing PPH (age 35–40 years and moderate PPH, adjusted OR 1.14 [99% CI 1.09 to 1.19]; age greater than 40 years and moderate PPH, adjusted OR 1.27 [99% CI 1.15 to 1.39]; age 35–40 years and severe PPH, adjusted OR 1.28

[99% CI 1.16 to 1.41]; age greater than 40 years and severe PPH, adjusted OR 1.55 [99% CI 1.29 to 1.88]).
The Japanese study[591] also investigated effect of maternal age on blood loss, involving 10,053 women. Multivariate regression analysis showed that women of 35 years or more had higher risk of developing: PPH (vaginal birth, adjusted OR 1.5 [95% CI 1.2 to 1.9]; CS, adjusted OR 1.8 [95% CI 1.2 to 2.7]) compared with women under 30 years.

Parity

Description of included studies

There were eight cross-sectional studies identified.[592–599] [EL = 3] Three of them were conducted in the UK,[593,595,597] three were in the USA,[592,598,599] and two in Australia.[594,596]

Review findings

One US study[592] investigated effect of parity on obstetric risk factors in 133 great-grandparous (defined as parity more than ten), 314 grandparous and 2195 parous women. Although the study reported significant increased incidence of PPH in grandparous than parous women, the analysis did not control important confounding factors such as age and hence is inconclusive.
One control-matched study in the UK was identified,[593] which compared 397 grandparous women with 397 age-matched parous women to investigate effect of parity on obstetric risk factors. The study reported that there was no evidence of difference in incidence of PPH between these two groups (OR 1.18 [95% CI 0.6 to 2.4]).
One Australian study was conducted between 1974 and 1975 to investigate obstetric performance of grand multiparous women.[594] Although the study reported no evidence of difference in incidence of PPH by parity, the analysis did not control confounding factors and hence is inconclusive.
One UK study was published in 1987, compared 216 grandparous women with lesser parity matched for age and ethnicity.[595] There was a higher incidence of developing PPH (blood loss greater than 500 ml) for grandparous women compared with parous women ($P < 0.01$), although there was significant difference in gestational age at booking.
One Australian study was conducted between 1992 and 2001.[596] The study investigated obstetric risk of 653 grand multiparous women, compared with 15 255 women with lower parity. Multivariate logistic regression analyses showed borderline increased risk of developing PPH by high parity (OR 1.36 [95% CI 0.99 to 1.87]).
One UK study investigated obstetric risk of 229 grand multiparous women with controls matched for age with one parity, between 1990 and 1991.[597] The study reported no evidence of difference in incidence of PPH, although the proportion of women who had oxytocin administration in the third stage was different and hence the analysis was inconclusive.
One US study investigated obstetric outcomes of 382 grandparous women, compared with age-matched controls with parity of between two and four, between 1989 and 1991.[598] There was no evidence of difference in incidence of PPH between these two groups (OR 0.97 [95% CI 0.57 to 1.63]).
A third US study investigated perinatal outcomes of 25,512 grandparous women, compared with 265,060 parous women aged 30 years or greater between 1997 and 1998.[599] Multivariate logistic regression analysis showed increased risk of developing PPH by grand multiparity, compared with multiparity (adjusted OR 1.2 [1.1 to 1.3]).
A second UK study investigated complications of the third stage of vaginal birth among 36,312 women between 1967 and 1981. There was evidence that higher incidence of PPH in nulliparous women and after induced labour. Analysis of the risks of 6615 women with two or three live births between 1967 and 1980 showed women with a history of PPH and/or retained placenta had higher risks of PPH in a subsequent birth, by between two and four times as much, compared with women without such a history.

Evidence statement (all risk factors for postpartum haemorrhage)

The following conditions are associated with increased risk of postpartum haemorrhage. The list is not exhaustive.
Antenatal: previous retained placenta, or PPH, maternal haemoglobin less than 85 g/litre at onset of labour; increased BMI; grand multiparity (parity four or more); antepartum haemorrhage; over-extension of the uterus (e.g. multiple pregnancy, polyhydramnios, macrosomia), existing uterine abnormalities; low-lying placenta; and age (35 years or older).
In labour: induction, prolonged first, second or third stage of labour, oxytocin use, precipitate labour, operative birth or caesarean section.

Recommendations on risk factors for postpartum haemorrhage

252. Advise women with risk factors for postpartum haemorrhage to give birth in an obstetric unit, where more emergency treatment options are available.

- Antenatal risk factors:
  - previous retained placenta or postpartum haemorrhage
  - maternal haemoglobin level below 85 g/litre at onset of labour
  - BMI greater than 35 kg/m^2
  - grand multiparity (parity 4 or more)
  - antepartum haemorrhage
  - overdistention of the uterus (for example, multiple pregnancy, polyhydramnios or macrosomia)
  - existing uterine abnormalities
  - low-lying placenta
  - maternal age of 35 years or older.
- Risk factors in labour:
  - induction
  - prolonged first, second or third stage of labour
  - oxytocin use
  - precipitate labour
  - operative birth or caesarean section. **[2007]**

253. If a woman has risk factors for postpartum haemorrhage, highlight these in her notes, and make and discuss with her a care plan covering the third stage of labour. [2007]

Management of postpartum haemorrhage

Medical management of postpartum haemorrhage

Review question

What are the most effective medical and other first line interventions in managing primary postpartum haemorrhage (arresting bleeding) due to uterine atony?
For further details on the evidence review protocol, please see appendix E.

Update 2014

Description of included studies

Eight studies were included in this review (Baruah and Cohn et al., 2008; Blum et al., 2010; Ducloy-Bouthors et al., 2011; Mousa and Alfirevic, 2009; Prata et al., 2005; Widmer et al., 2010; Winikoff et al., 2010; Zuberi et al., 2008).

The studies consist of 1 systematic review, with 3 component trials from South Africa and Gambia (Mousa and Alfirevic, 2009); 3 multicentre randomised trials, 1 conducted in Argentina, Egypt, South Africa, Thailand and Vietnam (Widmer et al., 2010), 1 in Ecuador, Egypt and Vietnam (Winikoff et al., 2010) and 1 in Burkina Faso, Egypt, Turkey and Vietnam (Blum et al., 2010); 2 randomised controlled trials conducted in France (Ducloy-Bouthors et al., 2011) and Pakistan (Zuberi et al., 2008); and 2 observational studies from Tanzania (Prata et al., 2005) and the USA (Baruah and Cohn et al., 2008).

Four trials and 1 systematic review evaluated the effectiveness of different doses of misoprostol taken by different routes for treatment of postpartum haemorrhage compared with standard treatment alone, a matched placebo or oxytocin treatment. One trial assessed the efficacy of tranexamic acid in the reduction of blood loss in postpartum haemorrhage and its effects on maternal outcomes. One observational study assessed the efficacy of 800 micrograms of misoprostol administrated rectally in the management of primary postpartum haemorrhage compared with methylergonovine maleate. One observational study examined the safety of management of postpartum haemorrhage in a home setting with 1000 micrograms of rectal misoprostol, and assessed its effect on the reduction of referrals and the need for additional interventions. No comparative studies were found that looked at the effectiveness of other first line treatments, such as nipple stimulation/putting the baby to the breast or uterine massage.

Three of the included studies evaluated first line medical treatment; that is, initial treatment used on diagnosis of postpartum haemorrhage. All studies involved misoprostol. Each study reported different routine management of the third stage of labour (see below). A further 4 studies evaluated second line medical treatment (3 involving misoprostol and 1 involving tranexamic acid – see below). In these studies the experimental drug was administered after the 'standard treatment' given to arrest bleeding. These standard treatments varied between the different studies but always involved administration of uterotonics. Other standard interventions included rubbing the uterus, commencing an intravenous infusion and emptying the bladder. Again, management of the third stage varied between studies.

In 1 study comparing misoprostol with intramuscular syntometrine plus syntocinon infusion, it was not clear whether the intervention being evaluated was being used as a first or second line treatment of postpartum haemorrhage and no details were reported describing management of the third stage.

For further details of study interventions and comparisons see the evidence tables in appendix I.

Evidence profile

The findings for the effectiveness of medical treatments for postpartum haemorrhage on maternal and neonatal outcomes are reported in 8 GRADE profiles. The following comparisons were considered based on whether the intervention is a first or second line treatment and the medication used, route and dose of the administration:

First line treatment

- misoprostol 1000 micrograms (rectal) versus standard treatment (following physiological management of third stage)
- misoprostol 800 micrograms (sublingual) versus oxytocin 40 IU (IV infusion) (prophylactic oxytocics not given)
- misoprostol 800 micrograms (sublingual) versus oxytocin 40 IU (IV infusion) (prophylactic oxytocics given).

Second line treatment

- misoprostol 600 micrograms (sublingual) versus placebo (both groups received active management of third stage and standard uterotonic after postpartum haemorrhage diagnosis)
- misoprostol 1000 micrograms (200 micrograms oral plus 400 micrograms sublingual plus 400 micrograms rectal) compared with placebo (both groups received routine active management of third stage and standard uterotonic after postpartum haemorrhage diagnosis)
- misoprostol 800 micrograms (rectal) versus methylergonovine maleate 2 milligrams (intramuscular) (management of third stage not reported; both groups received standard uterotonic after postpartum haemorrhage diagnosis)
- tranexamic acid 10 grams (intravenous infusion) versus standard treatment (42% women in each group received 'oxytocin at delivery'; both groups received standard uterotonic after postpartum haemorrhage diagnosis).

Unclear whether first or second line treatment

- misoprostol 800 micrograms (rectal) versus syntometrine (intramuscular) plus syntocinon (IV infusion) (dose not reported; no mention of drugs used in the third stage of labour or any standard treatment after diagnosis of postpartum haemorrhage).

First line treatment

Table 160: Summary GRADE profile for the effect of misoprostol 1000 micrograms (rectal) compared with standard treatment (following physiological management of third stage)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 1000 micrograms (rectal)	Standard treatment	Relative (95% CI)	Absolute	
Hysterectomy						
1 study (Prata et al., 2005)	observational study	0/111 (0%)	1/73 (1.4%)	RR 0.22 (0.01 to 5.33)	11 fewer per 1000 (from 14 fewer to 59 more)	Very Low
Blood transfusion						
1 study (Prata et al., 2005)	observational study	1/111 (0.9%)	16/73 (21.9%)	RR 0.04 (0.01 to 0.3)	210 fewer per 1000 (from 153 fewer to 217 fewer)	Low

CI confidence interval, RR relative risk

Table 161: Summary GRADE profile for the effect of misoprostol 800 micrograms (sublingual) compared with oxytocin 40 IU (IV infusion) (prophylactic oxytocic not given)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 800 micrograms (sublingual)	Oxytocin 40 IU (IV infusion)	Relative (95% CI)	Absolute	
Maternal death						
1 study (Winikoff et al., 2010)	randomised trial	0/488 (0%)	0/490 (0%)	NC	NC	Low
Hysterectomy/other surgery (not specified)						
1 study (Winikoff et al., 2010)	randomised trial	0/488 (0%)	0/490 (0%)	NC	NC	Low

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 800 micrograms (sublingual)	Oxytocin 40 IU (IV infusion)	Relative (95% CI)	Absolute	
Additional blood loss ≥500 after treatment						
1 study (Winikoff et al., 2010)	randomised trial	53/488 (10.9%)	20/490 (4.1%)	RR 2.66 (1.62 to 4.38)	68 more per 1000 (from 25 more to 138 more)	Moderate
Additional blood loss ≥1000 after treatment						
1 study (Winikoff et al., 2010)	randomised trial	5/488 (1%)	3/490 (0.6%)	RR 1.67 (0.4 to 6.96)	4 more per 1000 (from 4 fewer to 36 more)	Very Low
Blood transfusion						
1 study (Winikoff et al., 2010)	randomised trial	41/488 (8.4%)	26/468 (5.6%)	RR 1.51 (0.94 to 2.43)	28 more per 1000 (from 3 fewer to 79 more)	Low
Additional uterotonic needed						
1 study (Winikoff et al., 2010)	randomised trial	61/488 (12.5%)	31/490 (6.3%)	RR 1.98 (1.31 to 2.99)	62 more per 1000 (from 20 more to 126 more)	Moderate
Bimanual compression						
1 study (Winikoff et al., 2010)	randomised trial	294/488 (60.2%)	283/490 (57.8%)	RR 1.04 (0.94 to 1.16)	23 more per 1000 (from 35 fewer to 92 more)	Moderate

CI confidence interval, IU intrauterine, IV intravenous, NC not calculable, RR relative risk

Update 2014

Table 162: Summary GRADE profile for the effect of misoprostol 800 micrograms (sublingual) compared with oxytocin 40 IU (IV infusion) (routine active management of third stage)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 800 micrograms (sublingual)	Oxytocin 40 IU (IV infusion)	Relative (95% CI)	Absolute	
Maternal death						
1 study (Blum et al., 2010)	randomised trials	1/407 (0.2%)	1/402 (0.2%)	RR 0.99 (0.06 to 15.74)	0 fewer per 1000 (from 2 fewer to 37 more)	Low
Hysterectomy						
1 study (Blum et al., 2010)	randomised trials	4/407 (1%)	2/402 (0.5%)	RR 1.98 (0.36 to 10.72)	5 more per 1000 (from 3 fewer to 48 more)	Low
Additional blood loss ≥500 ml after treatment						
1 study (Blum et al., 2010)	randomised trials	58/407 (14.3%)	53/402 (13.2%)	RR 1.08 (0.76 to 1.53)	11 more per 1000 (from 32 fewer to 70 more)	Low
Additional blood loss ≥1000 ml after treatment						
1 study (Blum et al., 2010)	randomised trials	11/407 (2.7%)	3/402 (0.7%)	RR 3.62 (1.02 to 12.88)	20 more per 1000 (from 0 more to 89 more)	Low
Blood transfusion						
1 study (Blum et al., 2010)	randomised trials	24/407 (5.9%)	18/402 (4.5%)	RR 1.32 (0.73 to 2.39)	14 more per 1000 (from 12 fewer to 62 more)	Low
Additional uterotonic needed						
1 study (Blum et al., 2010)	randomised trials	40/407 (9.8%)	46/402 (11.4%)	RR 0.86 (0.58 to 1.28)	16 fewer per 1000 (from 48 fewer to 32 more)	Low
Bimanual compression						
1 study (Blum et al., 2010)	randomised trials	39/407 (9.6%)	31/402 (7.7%)	RR 1.24 (0.79 to 1.95)	19 more per 1000 (from 16 fewer to 73 more)	Low

IU intrauterine, IV intravenous, CI confidence interval, RR relative risk

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Second line treatment

Table 163: Summary GRADE profile for the effect of misoprostol 600 micrograms (sublingual) compared with placebo (following routine active management of third stage and standard uterotonic after PPH diagnosis)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 600 micrograms (sublingual)	Placebo (sublingual)	Relative (95% CI)	Absolute	
Maternal death						
1 meta-analysis of 2 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010)	randomised trials	2/784 (0.3%)	0/798 (0%)	RR 5.08 (0.24 to 105.73)	NC	Very Low
Hysterectomy (hysterectomy or admission to intensive care unit)						
1 study (Widmer et al., 2010)	randomised trials	8/705 (1.1%)	10/717 (1.4%)	RR 0.81 (0.32 to 2.05)	3 fewer per 1000 (from 9 fewer to 15 more)	Moderate
Additional blood loss ≥500 ml after randomisation						
1 meta-analysis of 3 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	164/811 (20.2%)	189/830 (22.8%)	RR 0.89 (0.74 to 1.07)	25 fewer per 1000 (from 59 fewer to 16 more)	Low
Additional blood loss ≥1000 ml after randomisation						
1 meta-analysis of 3 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	19/784 (2.4%)	27/798 (3.1%)	RR 0.72 (0.4 to 1.28)	9 fewer per 1000 (from 20 fewer to 9 more)	Moderate

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Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 600 micrograms (sublingual)	Placebo (sublingual)	Relative (95% CI)	Absolute	
Blood transfusion after randomisation						
1 meta-analysis of 3 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	120/811 (14.8%)	132/830 (15.9%)	RR 0.93 (0.74 to 1.17)	11 fewer per 1000 (from 41 fewer to 27 more)	Low
Surgical management needed (uterine packing and/or balloon tamponade)						
1 meta-analysis of 2 studies (Mousa & Alfirevic, 2009; Zuberi et al., 2008	randomised trials	4/59 (6.8%)	9/64 (14.1%)	RR 0.5 (0.16 to 1.5)	70 fewer per 1000 (from 118 fewer to 76 more)	Very Low
Any additional uterotonic after randomisation						
1 meta-analysis of 2 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010)	randomised trials	191/784 (24.4%)	208/798 (26.1%)	RR 0.93 (0.79 to 1.1)	18 fewer per 1000 (from 55 fewer to 26 more)	Moderate
Nausea (any)						
1 meta-analysis of 3 studies (Mousa & Alfirevic, 2009; Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	65/812 (8%)	56/830 (6.7%)	RR 1.19 (0.84 to 1.67)	13 more per 1000 (from 11 fewer to 45 more)	Low

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Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 600 micrograms (sublingual)	Placebo (sublingual)	Relative (95% CI)	Absolute	
Vomiting (any)						
1 meta-analysis of 2 studies (Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	47/733 (6.4%)	25/749 (3.3%)	RR 1.9 (1.19 to 3.04)	30 more per 1000 (from 6 more to 68 more)	Low
Diarrhoea (any)						
1 meta-analysis of 2 studies (Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	6/733 (0.82%)	5/749 (0.67%)	RR 1.22 (0.37 to 3.99)	1 more per 1000 (from 4 fewer to 20 more)	Moderate
Shivering (severe)						
1 meta-analysis of 2 studies (Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	99/733 (13.5%)	13/749 (1.7%)	RR 7.53 (4.3 to 13.17)	113 more per 1000 (from 57 more to 211 more)	Moderate
Temperature (>40° C)						
1 meta-analysis of 2 studies (Widmer et al., 2010; Zuberi et al., 2008)	randomised trials	51/733 (7%)	3/749 (0.4%)	RR 15.11 (5.14 to 44.45)	57 more per 1000 (from 17 more to 174 more)	Moderate

CI confidence interval, NC not calculable, RR relative risk

Update 2014

Table 164: Summary GRADE profile for the effect of misoprostol 1000 micrograms (200 micrograms oral + 400 micrograms sublingual + 400 micrograms rectal) compared with placebo (following routine active management of third stage and standard uterotonic after PPH diagnosis)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 1000 micrograms (oral - sublingual - rectal)	Placebo	Relative (95% CI)	Absolute	
Maternal death						
1 study (Mousa & Alfirevic, 2009)	randomised trials	3/117 (2.6%)	0/121 (0%)	RR 7.24 (0.38 to 138.6)	NC	Very Low
Hysterectomy						
1 study (Mousa & Alfirevic, 2009)	randomised trials	3/117 (2.6%)	0/121 (0%)	RR 7.24 (0.38 to 138.6)	NC	Very Low
Additional blood loss ≥500 ml after randomisation						
1 study (Mousa & Alfirevic, 2009)	randomised trials	6/117 (5.1%)	11/120 (9.2%)	RR 0.56 (0.21 to 1.46)	40 fewer per 1000 (from 73 fewer to 42 more)	Very Low
Additional blood loss ≥1000 ml after randomisation						
1 study (Mousa & Alfirevic, 2009)	randomised trials	1/117 (0.85%)	0/120 (0%)	RR 3.08 (0.13 to 74.76)	NC-	Very Low
Blood transfusion						
1 study (Mousa & Alfirevic, 2009)	randomised trials	19/115 (16.5%)	15/119 (12.6%)	RR 1.31 (0.7 to 2.45)	39 more per 1000 (from 38 fewer to 183 more)	Very Low
Additional uterotonic						
1 study (Mousa & Alfirevic, 2009)	randomised trials	63/111 (56.8%)	63/112 (56.3%)	RR 1.01 (0.8 to 1.27)	6 more per 1000 (from 113 fewer to 152 more)	Very Low

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Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 1000 micrograms (oral - sublingual - rectal)	Placebo	Relative (95% CI)	Absolute	
Manual removal of placenta						
1 study (Mousa & Alfirevic, 2009)	randomised trials	1/117 (0.85%)	4/121 (3.3%)	RR 0.26 (0.03 to 2.28)	24 fewer per 1000 (from 32 fewer to 42 more)	Very Low
Maternal pyrexia (over 38.5° C)						
1 study (Mousa & Alfirevic, 2009)	randomised trials	11/114 (9.6%)	2/118 (1.7%)	RR 5.69 (1.29 to 25.12)	80 more per 1000 (from 5 more to 410 more)	Low
Shivering						
1 study (Mousa & Alfirevic, 2009)	randomised trials	63/116 (54.3%)	30/118 (25.4%)	RR 2.14 (1.5 to 3.04)	290 more per 1000 (from 127 more to 518 more)	Low

CI confidence interval, NC not calculable, RR relative risk

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Table 165: Summary GRADE profile for the effect of misoprostol 800 micrograms (rectal) compared with methylergonovine maleate 2 milligrams (intramuscular) (management of third stage not reported; both groups received standard uterotonic after PPH diagnosis)

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 800 micrograms (rectal)	Methergine 2 mg (IM)	Relative (95% CI)	Absolute	
Hysterectomy						
1 study (Baruah & Cohn et al., 2008)	observational studies	1/40 (2.5%)	1/18 (5.6%)	RR 0.45 (0.03 to 6.8)	31 fewer per 1000 (from 54 fewer to 322 more)	Very Low

Number of studies	Design	Number of women		Effect		Quality
		Misoprostol 800 micrograms (rectal)	Methergine 2 mg (IM)	Relative (95% CI)	Absolute	
Blood transfusion						
1 study (Baruah & Cohn et al., 2008)	observational studies	5/40 (12.5%)	0/18 (0%)	RR 5.1 (0.3 to 87.55)	NC	Very Low
Uterine packing						
1 study (Baruah & Cohn et al., 2008)	observational studies	2/40 (5%)	0/18 (0%)	RR 2.32 (0.12 to 45.95)	NC	Very Low
Surgical intervention (excluding hysterectomy)						
1 study (Baruah & Cohn et al., 2008)	observational studies	5/40 (12.5%)	4/18 (22.2%)	RR 0.56 (0.17 to 1.85)	98 fewer per 1000 (from 184 fewer to 189 more)	Very Low

CI confidence interval, IM intramuscular, NC not calculable, RR relative risk

Table 166: Summary GRADE profile for the effect of tranexamic acid 10 grams (intravenous infusion) compared with standard treatment (42% women in each group received 'oxytocin at delivery'; both groups received standard uterotonic after PPH diagnosis)

Number of studies	Design	Number of women		Effect		Quality
		Tranexamic acid 5 grams (IV infusion)	Standard treatment	Relative (95% CI)	Absolute	
Maternal death						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	0/77 (0%)	0/74 (0%)	NC	NC	Very Low
Evolution to severe PPH (>1000ml)						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	27/77 (35.1%)	37/74 (50%)	RR 0.7 (0.48 to 1.03)	150 fewer per 1000 (from 260 fewer to 15 more)	Very Low

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Number of studies	Design	Number of women		Effect		Quality
		Tranexamic acid 5 grams (IV infusion)	Standard treatment	Relative (95% CI)	Absolute	
Fall in haemoglobin >4 g/dl (tested before day 42 postnatally)						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	19/77 (24.7%)	32/74 (43.2%)	RR 0.57 (0.36 to 0.91)	186 fewer per 1000 (from 39 fewer to 277 fewer)	Very Low
Packed red blood cell (PRBC) transfusion within 6 hours of randomisation						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	10/77 (13%)	13/74 (17.6%)	RR 0.74 (0.35 to 1.58)	46 fewer per 1000 (from 114 fewer to 102 more)	Very Low
Surgical arterial ligature or hysterectomy						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	0/77 (0%)	2/74 (2.7%)	RR 0.19 (0.01 to 3.94)	22 fewer per 1000 (from 27 fewer to 79 more)	Very Low
Arterial embolisation						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	5/77 (6.5%)	5/74 (6.8%)	RR 0.96 (0.29 to 3.18)	3 fewer per 1000 (from 48 fewer to 147 more)	Very Low
Intensive care unit stay						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	3/77 (3.9%)	5/74 (6.8%)	RR 0.58 (0.14 to 2.33)	28 fewer per 1000 (from 58 fewer to 90 more)	Very Low
Renal failure						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	0/77 (0%)	0/74 (0%)	NC	NC	Very Low
Total non-severe adverse effects (Nausea/vomiting, phosphenes, dizziness)						
1 study (Ducloy-Bouthors et al., 2011)	randomised trials	18/77 (23.4%)	4/74 (5.4%)	RR 4.32 (1.54 to 12.18)	179 more per 1000 (from 29 more to 604 more)	Low

CI confidence interval, IV intravenous, NC not calculable, PPH postpartum haemorrhage, PRBC packed red blood cell, RR relative risk

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Unclear whether first or second line treatment

Table 167: Summary GRADE profile for the effect of misoprostol 800 micrograms (rectal) compared with syntometrine (intramuscular) + syntocinon (intravenous infusion) (dose not reported) (no mention of drugs used in the third stage of labour or any standard treatment for PPH)

		Number of patients		Effect		
Number of studies	Design	Misoprostol 800 micrograms (rectal)	Syntometrine + syntocinon (intramuscular)	Relative (95% CI)	Absolute	Quality
Hysterectomy						
1 study (Mousa & Alfirevic, 2009)	randomised trials	0/32 (0%)	1/32 (3.1%)	RR 0.33 (0.01 to 7.89)	21 fewer per 1000 (from 31 fewer to 215 more)	Very Low
Additional uterotonic needed						
1 study (Mousa & Alfirevic, 2009)	randomised trials	2/32 (6.3%)	11/32 (34.4%)	RR 0.18 (0.04 to 0.76)	282 fewer per 1000 (from 83 fewer to 330 fewer)	Very Low
Surgical intervention (excluding hysterectomy)						
1 study (Mousa & Alfirevic, 2009)	randomised trials	2/32 (6.3%)	2/32 (6.3%)	RR 1 (0.15 to 6.67)	0 fewer per 1000 (from 53 fewer to 354 more)	Very Low

CI confidence interval, RR relative risk

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Evidence statements

First line treatment

Misoprostol 1000 micrograms (rectal) compared with standard treatment (following physiological management of third stage)

Low quality evidence from 1 study (n=184) found that the incidence of blood transfusion was lower in women who received rectal misoprostol compared with women who received standard treatment. However, no difference was found between the 2 groups in the incidence of hysterectomy.

Misoprostol 800 micrograms (sublingual) compared with oxytocin 40 IU (IV infusion) (prophylactic oxytocics not given)

Moderate quality evidence from 1 study (n=978) found that the incidence of further blood loss of 500 ml or more and additional uterotonic administration was higher in women who received sublingual misoprostol compared with women who received oxytocin infusion. However, no differences were found between the 2 groups in the incidence of maternal death, hysterectomy, further blood loss of 1000 ml, blood transfusion or bimanual compression.

Misoprostol 800 micrograms (sublingual) compared with oxytocin 40 IU (IV infusion) (routine active management of third stage)

Low quality evidence from 1 study (n=809) found that the incidence of further blood loss of 1000 ml or more was higher in women who received sublingual misoprostol compared with women who received oxytocin infusion. However, no differences were found between the 2 groups in the incidence of maternal death, hysterectomy, further blood loss of 500 ml, blood transfusion, bimanual compression or additional uterotonic administration.

Second line treatment

Misoprostol 600 micrograms (sublingual) compared with placebo (following routine active management of third stage and standard uterotonics after postpartum haemorrhage diagnosis)

Moderate and low quality evidence from one systematic review (n=1482) found that the incidence of vomiting, pyrexia over 40°C and severe shivering was higher in women who received sublingual misoprostol compared with women who received placebo treatment. However, no differences were found between the 2 groups for any other reported outcomes.

Misoprostol 1000 micrograms (200 micrograms oral plus 400 micrograms sublingual plus 400 micrograms rectal) versus placebo (following routine active management of third stage of labour and standard uterotonics after postpartum haemorrhage diagnosis)

Low quality evidence from 1 study (n=238) found that the incidence of pyrexia over 38.5°C and shivering was higher in women who received misoprostol (oral plus sublingual plus rectal) compared with women who received placebo treatment. However, no differences were found between the 2 groups for any other reported outcomes.

Misoprostol 800 micrograms (rectal) compared with methylergonovine maleate 2 milligrams (intramuscular) (management of third stage not reported; both groups received standard uterotonic after postpartum haemorrhage diagnosis)

Very low quality evidence from 1 study (n=58) found that the incidence of hysterectomy, blood transfusion and uterine packing were not found to be different in women who received rectal misoprostol compared with women who received methylergonovine maleate treatment.

Tranexamic acid 10 grams (intravenous infusion) compared with standard treatment only (42% women in each group received 'oxytocin at delivery'; both groups received standard uterotonic after postpartum haemorrhage diagnosis)

Low and very low quality evidence from 1 study (n=151) found that the incidence of a fall in haemoglobin level greater than 0.4 g/litre was lower in women who received tranexamic acid

compared with women who received standard treatment. Low quality evidence also found that the incidence of non-severe outcomes (nausea/vomiting, phosphenes and dizziness) was increased in those women who received tranexamic acid. No differences were found between the 2 groups for any other reported outcomes.

Unclear whether first or second line treatment

Misoprostol 800 micrograms (rectal) versus syntometrine (intramuscular) plus syntocinon (intravenous infusion) (management of third stage and standard treatment on diagnosis of postpartum haemorrhage not reported)

Very low quality evidence from 1 study (n=64) found that the need for additional uterotonic was lower in women who received rectal misoprostol compared with women who received intramuscular syntometrine plus syntocinon infusion. However, no differences were found between the 2 groups in the incidence of hysterectomy or surgical intervention.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the main maternal outcomes of interest were the blood loss (which was measured in a number of different ways) and the need for a surgical intervention. No neonatal outcomes were reported or considered to be relevant for this review.

Consideration of clinical benefits and harms

Reviewing the evidence for the first line treatment, the guideline development group recognised that 1 study showed a significant reduction in the need for blood transfusion in those women who received misoprostol compared with those who received standard treatment. However, the group noted that women in the control arm who had a blood loss of 500 ml were transferred to a clinic when standard UK practice would have been to provide further treatment first. As a result, they felt that the need for a blood transfusion was likely to be less in the UK setting than the study indicated.

In 2 further studies where sublingual misoprostol was compared with intravenous oxytocin, misoprostol was shown to be associated with a significantly higher rate of blood loss (greater than 500 ml in one study and greater than 1000 ml in another), as well as a significantly greater need for an additional uterotonic. Given this, the group felt that oxytocin should be the preferred treatment option in favour of misoprostol as a first line treatment for postpartum haemorrhage.

A further study showed that misoprostol was not significantly better than a placebo for improving a number of key outcomes, but that it was associated with a higher rate of vomiting, shivering and pyrexia. Given this, the group agreed that misoprostol should not be recommended as a first line treatment for postpartum haemorrhage.

The previous guideline had included a list of possible treatments for postpartum haemorrhage which could be used with no indication that any one was better than another. In principle, the intervention procedure chosen to deal with primary postpartum should be determined by the severity of the condition. Neverthess, the group felt that there was now sufficient evidence to stratify the treatments into those which should be used as either first or second line. As well as oxytocin, the group agreed that it was appropriate to continue to recommend the use of intramuscular ergometrine and intramuscular oxytocin combined with ergometrine as first line treatments. Although there was no evidence looking specifically at the use of ergometrine or ergometrine combined with oxytocin, the group was aware that both of these treatments are

currently commonly used in UK practice and the group members' clinical experience is that these treatments are effective and so they felt confident in recommending their use.
For second line treatments, the group felt that it was appropriate to offer an increased range of treatments which have different mechanisms of action to increase the likelihood that a second line treatment would succeed where a first line treatment fails. For this reason, the group retained the list of possible treatments which had been included in the original guideline as potential second line treatments. These included both misoprostol and carboprost.
The guideline development group noted that in 1 study for the second line treatment of postpartum haemorrhage, tranexamic acid was associated with a significant reduction in decreased haemoglobin over 0.4 g/litre compared with the standard treatment. However, it was also associated with significantly higher adverse outcomes (nausea, vomiting and dizziness). The group was aware of an ongoing international trial (the World Maternal Antifibrinolytic [WOMAN] trial) which will evaluate the use of tranexamic acid for the treatment of postpartum haemorrhage. However, they were aware that the findings would not be available by the publication date of the guideline. Given this and the currently available evidence, the group agreed not to change the previous recommendation which indicated that tranexamic acid should be considered as an adjuvant treatment in consultation with a haematologist.
The group discussed the previous recommendation which indicated the appropriate immediate care for postpartum haemorrhage. The group agreed that more detail should be provided about the order in which care should be provided, and that reference should be made to providing supplementary oxygen as this is good clinical practice. The group also agreed that during an emergency situation, one of the medical team should be allocated the responsibility of communicating with the woman and her partner to provide information and support. The group wished to stress the importance of specifically designating this team member to ensure that this important part of the woman's care is not neglected.

Consideration of health benefits and resource uses
The drugs for first-line treatment of postpartum haemorrhage are low cost (Misoprostol £0.17 per 200 microgram tablet [NHS Electronic Drug Tariff February 2014]; Oxytocin 10 units/ml 1 ml ampoule £0.91; Syntometrine 10 units/ml 1 ml ampoule £1.57 [BNF 2014]) A primary postpartum haemorrhage would require, as a minimum, an obstetric registrar to be present and an additional midwife. If blood loss increases then more senior staff are needed, and possibly a blood transfusion, with associated longer stay in hospital. As oxytocin has been shown to limit blood loss compared to misoprostol then it will be the more cost-effective treatment if it prevents further intervention and reduces hospital stay.
For second line treatment, the same drugs are recommended as well as tranexamic acid, which again is low cost (£0.11 per 500 mg tablet [NHS Electronic Drug Tariff February 2014]), and also carboprost, which is more expensive (250 micrograms/ml 1 ml ampoule £18.20).

Quality of evidence
The guideline development group noted that the quality of the evidence was generally low or very low (although the quality of the evidence for some of the statistically significant findings of interest to the group was moderate). One of the main reasons for the quality of the studies being downgraded was due to the fact that their reported findings had wide confidence intervals.

Other considerations
The guideline development group agreed that it would be helpful to have better data about the optimum dose of IV oxytocin infusion to use and recommended research in this area. They

were aware that large doses of oxytocin can be associated with water retention, and thus it would be helpful to identify a minimum effective dose.
The group was disappointed that there were no trials evaluating the use of carboprost and that no studies compared prostaglandins for the treatment of postpartum haemorrhage. Therefore the group recommended a cross-over trial comparing different uterotonic agents to be used in conjunction with oxytocin, including carboprost and misoprostol.
The group also felt that it would be helpful to have more data of better quality relating to the physical and psychological impact on women of the different treatments for postpartum haemorrhage and so recommended that further research is conducted looking at this topic.

Surgical management of post-partum haemorrhage

Review question

What are the most effective surgical and 'mechanical' interventions in managing primary postpartum haemorrhage (arresting bleeding) due to uterine atony?

Description of included studies

Two studies were included in this review (Soltan et al., 2007; Chantrapitak et al., 2009).
The included studies were each randomised trials, 1 conducted in Egypt (Soltan et al., 2007) and 1 in Thailand (Chantrapitak et al., 2009).
One included trial (Soltan et al., 2007) evaluated the efficacy of an air inflated balloon in the treatment of postpartum haemorrhage. The other included trial (Chantrapitak et al., 2009) examined the effectiveness of external manual uterine compression method in the treatment of primary postpartum haemorrhage. For both studies the intervention was used as an adjunct to standard treatment and the comparison group received the standard treatment alone. For further details of study interventions and comparisons please see the evidence tables in appendix I.
No comparative evidence was found investigating the effectiveness of other surgical or mechanical procedures in women presenting in labour with low risk of complications.

Evidence profile

The findings for the effectiveness of surgical and mechanical management of postpartum haemorrhage on maternal outcomes are reported in 2 GRADE profiles.

Table 168: Summary GRADE profile for the effect of external manual lower uterine segment compression on maternal outcomes

Number of studies	Design	Number of women		Effect		Quality
		Lower uterine segment compression	Control (standard treatment alone)	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion						
1 study (Chantrapitak et al., 2009)	randomised trials	7/32 (21.9%)	3/32 (9.4%)	RR 2.33 (0.66 to 8.23)	125 more per 1000 (from 32 fewer to 680 more)	Very Low
Blood loss after treatment (ml)						
1 study (Chantrapitak et al., 2009)	randomised trials	Median 120 (IQR±211) n=32	Median 225 (IQR±401) n=32	NC	Median difference 105 lower p=0.026	Low

CI confidence interval, IQR interquartile range, NC not calculable, RR relative risk

Table 169: Summary GRADE profile for the effect of air inflated balloon on maternal outcomes

Number of studies	Design	Number of women / mean value		Effect		Quality
		El-Menia inflated balloon	Control (standard treatment alone)	Relative (95% CI)	Absolute (95% CI)	
Maternal death						
1 study (Soltan et al., 2007)	randomised trials	0/120 (0%)	0/120 (0%)	NC	NC	Low
Surgical interventions (i.e. laparotomy, B. Lynch suture, artery ligation, hysterectomy)						
1 study Soltan et al., 2007)	randomised trials	0/120 (0%)	5/120 (4.2%)	RR 0.09 (0.01 to 1.63)	38 fewer per 1000 (from 42 fewer to 26 more)	Low
Blood units transfused						
1 study (Soltan et al., 2007)	randomised trials	Mean 4.1 (SD 0.86) n=120	Mean 7.4 (SD 1.8) n=120	NC	MD 3.3 lower (3.66 lower to 2.94 lower) p<0.0001	Low

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Number of studies	Design	Number of women / mean value		Effect		Quality
		El-Menia inflated balloon	Control (standard treatment alone)	Relative (95% CI)	Absolute (95% CI)	
Women's haemoglobin at discharge						
1 study (Soltan et al., 2007)	randomised trials	Mean 9.7 (SD 0.2) n=120	Mean 8.8 (SD 1.6) n=120	NC	MD 0.91 higher (0.62 higher to 1.2 higher) p<0.0001	Very Low
Syntocinon units used						
1 study (Soltan et al., 2007)	randomised trials	Mean 37 (SD 5.6) n=120	Mean 63.9[a] (SD 23.3) n=120	NC	MD 26.9 lower (31.19 lower to 22.61 lower) p=0.001	Low
Intensive care unit stay (days)						
1 study (Soltan et al., 2007)	randomised trials	Mean1 (SD 0) n=120	Mean 1.5 (SD 0.5) n=120	NC	MD 0.5 p=0.001	Low
Hospital stay (days)						
1 study (Soltan et al., 2007)	randomised trials	Mean 2.3 (SD 0.5) n=120	Mean 3.5 (SD 0.5) n=120	NC	MD 1.2 lower (1.33 lower to 1.07 lower) p=0.001	Low

CI confidence interval, MD mean deviation, NC not calculable, RR relative risk, SD standard deviation

a. 639 reported in the paper however as the reported range is 40 – 110, the technical team assumed the correct value is 63.91

Update 2014

Balloon use complications

The use of the balloon was associated with complications in 3 women; 2 cervical tears and 1 rise of uterine size above umbilicus resulting in tachycardia and hypotension. The cervical tears were repaired under general anaesthesia and the increase in uterine size resolved after deflation of the balloon. Complications in the control group were not reported.

Evidence statements

External manual lower uterine segment compression
Low quality evidence from 1 study (n=64) found that the median blood loss was lower in women who received lower uterine segment compression compared with women who received standard treatment. However, no difference was found between the 2 groups in the incidence of blood transfusion.

Air inflated balloon
Low quality evidence from 1 study (n=280) found that the mean number of blood units transfused and the mean number of units of syntocinon used was lower in women who received treatment with an air inflated balloon compared with women who received standard treatment. The mean length of intensive care unit stay and mean length of hospital stay were also shorter in women who were treated using an air inflated balloon compared with women who received standard treatment. No differences were found between the 2 groups in the incidence of surgical interventions.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered
For this review, the guideline development group agreed that measures of significant blood loss, such as the need for a blood transfusion, women's haemoglobin at discharge and need for further surgery were priority outcomes.

Consideration of clinical benefits and harms
The guideline development group considered the effectiveness of external manual uterine compression in the treatment of primary postpartum haemorrhage compared with standard treatment. They noted that there was a significantly lower amount of blood loss after treatment in the manual uterine compression group compared with the standard treatment group. However, this did not lead to a significant difference between the 2 groups in the blood transfusion rate. The guideline development group noted that the study was very small with a low statistical power and serious study design limitations, and therefore they felt it was not informative in determining the appropriate management of postpartum haemorrhage. On balance, the guideline development group felt that this study was of limited utility for making evidence based recommendations.
The group then considered the efficacy of an air inflated balloon for the treatment of postpartum haemorrhage compared with standard treatment. Significantly better outcomes were reported for blood units transfused, women's haemoglobin at discharge, syntocinon units used and the length of intensive care unit and hospital stay in women who received treatment with an air inflated balloon compared with women who received standard treatment. The group considered maternal side effects and noted that the use of the balloon was associated with complications in 3 women. They agreed that this might be a significant consideration for women in terms of their birth experience. However, on balance, the group felt that the demonstration of benefit of balloon tamponades across the various outcome measures in the study was sufficient to suggest that a balloon tamponade should be used before other surgical options.

Update 2014

Consideration of health benefits and resource uses
The air inflated balloon is low cost (Foley catheter with balloon and syringe £2.16, saline solution 1000 ml bottle £0.97 [NHS Electronic Drug Tariff February 2014]). This is a less invasive intervention than surgery. The evidence shows that using the balloon to treat postpartum haemorrhage can reduce length of stay. The weighted average cost of a bed day associated with normal or assisted delivery with complications is £396 per day. The cost of using an air balloon is considerably lower and therefore it is likely to be cost effective as a third line intervention.

Quality of evidence
The quality of evidence for this review ranged from low to very low. As noted above, the guideline development group felt that given both the small size and the design limitations of the study relating to manual compression, there was insufficient evidence to make a recommendation about its use. Although the evidence for balloon tamponades was also graded as low quality, the group felt more confident in the study due to its larger sample size and clearer details about the study population. Taken together with the group's clinical experience, they felt able to make a weak recommendation that balloon tamponades should be considered before other surgical options.

Recommendations

254. If a woman has a postpartum haemorrhage:

- call for help
- give immediate clinical treatment:
  - emptying of the bladder **and**
  - uterine massage **and**
  - uterotonic drugs **and**
  - intravenous fluids **and**
  - controlled cord traction if the placenta has not yet been delivered
- continuously assess blood loss and the woman's condition, and identify the source of the bleeding
- give supplementary oxygen
- arrange for transfer of the woman to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]

255. Administer a bolus of one of the following as first-line treatment for postpartum haemorrhage:

- oxytocin (10 IU intravenous) **or**
- ergometrine (0.5 mg intramuscular) **or**
- combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular). [new 2014]

256. Offer second-line treatment for postpartum haemorrhage if needed. No particular uterotonic drug can be recommended over any other; options include:

- repeat bolus of:
  - oxytocin (intravenous)

Update 2014

  - ergometrine (intramuscular, or cautiously intravenously)
  - combined oxytocin and ergometrine (intramuscular)
- misoprostol
- oxytocin infusion
- carboprost (intramuscular). [new 2014]

257. Assess the need for adjuvant options for managing significant continuing postpartum haemorrhage, including:

- tranexamic acid (intravenous)
- rarely, in the presence of otherwise normal clotting factors, rFactor VIIa, in consultation with a haematologist. [new 2014]

258. Allocate a member of the healthcare team to stay with the woman and her birth companion(s), explain what is happening, answer any questions and offer support throughout the emergency situation. [new 2014]

259. If the haemorrhage continues:

- perform examination under anaesthetic
- ensure that the uterus is empty and repair any trauma
- consider balloon tamponade before surgical options. [new 2014]

260. Be aware that no particular surgical procedure can be recommended over any other for treating postpartum haemorrhage. [new 2014]

261. The maternity service and ambulance service should have strategies in place in order to respond quickly and appropriately if a woman has a postpartum haemorrhage in any setting. [new 2014]

Update 2014

Research recommendations

27. What is the most effective treatment of primary postpartum haemorrhage?

Why this is important

There is uncertainty about the most effective drug treatments and dosage regimes, and about which other treatments should be used, for women who develop a postpartum haemorrhage. The most effective sequencing of interventions is also uncertain. The psychological impact of postpartum haemorrhage for women can be significant, and identifying the approach that minimises this impact is important. Randomised controlled trials comparing different dosage regimes for oxytocin and misoprostol, as well as comparisons with ergometrine and carboprost, are needed. Trials of mechanical measures such as intrauterine balloons or interventional radiology as early second-line treatment (rather than an alternative drug treatment) are also needed. Alternatively, a trial comparing the effectiveness of a complex intervention (for example, an educational component, sequence of interventions, immediate feedback and quality improvements) compared with standard care could be undertaken. Important outcomes include blood and blood product transfusion, need for further intervention, need for hysterectomy and psychological outcomes for the woman.

28. What is the optimum dosing regimen of oxytocin when used as an intravenous infusion to manage primary post-partum haemorrhage (PPH) in women after vaginal birth?

Population: women with a singleton pregnancy at term with a low risk of developing intrapartum complications experiencing a primary postpartum haemorrhage.
Intervention: reduced dosing regimens of oxytocin e.g. using a 20 iu infusion over a four hour compared to 40 iu over the same period
Comparator: commonly used standard regimens (e.g. 40 i.u. infused over 4 hours)
Outcomes: need for blood transfusion, need for further uterotonics, need for other further treatment.
Study design: randomised controlled trial

Why this is important

Post-partum haemorrhage is the commonest cause of maternal morbidity in the UK and remains a significant cause of maternal mortality. Uterotonic agents, in particular oxytocin, are an intrinsic part of the management of most causes of postpartum haemorrhage. A wide variety (total dose and infusion rate) of intravenous regimens are used with a very limited evidence base. Oxytocin has important cardiovascular effects when given as an intravenous bolus and also has a mild anti-diuretic effect which can lead to hyponatremia when given in larger doses. Recently some evidence has emerged that lower doses of oxytocin may be as effective as standard doses. Randomised controlled trials are required to assess whether reduced dosing regimens compared with commonly used standard regimens are effective in the management of postpartum haemorrhage.

29. What is the most effective additional uterotonic agent used in conjunction with oxytocin to manage postpartum haemorrhage in women after vaginal delivery where oxytocin alone has failed to stop the bleeding?

Population: women with a singleton pregnancy at term experiencing a primary postpartum haemorrhage.
Intervention: Additional uterotonic agent used after oxytocin where further medical treatment is needed e.g. carboprost, misoprostol
Comparison: alternative additional uterotonic
Outcomes: need for blood transfusion, need for further uterotonics, need for other further treatment.
Study design: Cross-over randomised controlled trial

Why this is important

Post-partum haemorrhage is the commonest cause of maternal morbidity in the UK and remains an important cause of maternal mortality. Uterine atony is the most significant cause of PPH and uterotonic agents are the first line of treatment. Oxytocin is usually the initial drug with the addition of a variety of other agents when escalation treatment is required. However the most effective combination of drugs has not been elucidated. Randomised cross-over trials are required to assess the most effective combination of drugs (oxytocin plus carboprost versus oxytocin plus misoprostol) to manage postpartum haemorrhage following vaginal delivery, in terms of requirement for additional uterotonics, need for further treatment and blood transfusion.

Update 2014

Care of the baby and woman immediately after birth

Introduction

Birth is an immensely important, often life-changing, event. Not only does the process of labour and birth present challenges to the baby but there are also major rapid physiological changes that take place to enable the baby to adapt to life after birth. These include the establishment of respirations, changes to the cardiovascular system, the regulation of body temperature, digestion and absorption and the development of a resistance to infections. The vast majority of babies make this transition uneventfully but vigilance on the part of health-care professionals, and timely intervention when necessary, can influence the baby's longer term health and development.

Care of the baby immediately after birth in the intrapartum period is discussed in this chapter. Further care thereafter is discussed in the NICE clinical guideline on Postnatal Care,[414] including promotion of breastfeeding, infant and mother bonding, and vitamin K supplementation for newborn babies.

Care of the woman immediately after birth includes assessment of her physical and emotional condition, as well as assessment (and possible repair) of trauma sustained during birth. It is also crucially important that appropriate assessment and treatment of any complications is undertaken, as failure to do so can have long-term consequences for the woman's physical, emotional and psychological wellbeing. As with the immediate care of the newborn baby, this should be balanced between assessing the woman's physical needs (and intervening should that be required) and giving the new mother/parents the opportunity to savour and enjoy this momentous and life-changing event.

Initial assessment of the newborn baby

Apgar score

Introduction

The Apgar score was developed in 1953 and has been widely adopted to assess the baby at the time of birth.[415] It was first planned as an indicator for the need for resuscitation. It was not originally intended to predict longer term prognosis and includes assessment of colour, heart rate, tone, respiratory rate and reflex irritability.[415–417]

Review question

What is the evidence that different methods of initial neonatal assessment and examination influence outcomes?

- Including cardiovascular-respiratory and abnormalities assessment.

Description of included studies

A total of five cohort studies and one systematic review (containing 16 cohort studies) were identified.[418–423] Only studies comparing the Apgar score with neonatal death and diagnosis were considered homogeneous enough to provide a new meta-analysis of the data. [EL = 2+]

Review findings

The results of meta-analyses on neonatal mortality and diagnosis of cerebral palsy are shown in Tables 166 and 167. Overall, the Apgar score appeared to be a moderate level predictor for neonatal deaths and the development of cerebral palsy, with the Apgar at 5 minutes having better predictive value than at 1 minute. Surprisingly, only one study was identified that examined predictive values of the Apgar score on longer term neurological development of the infants. There was no high-level study that examined the correlation between Apgar score and immediate neonatal outcomes.

Table 170: Meta-analysis on predictive value of Apgar score (neonatal mortality)

Cut-off of Apgar score	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	Diagnostic OR [95% CI]	Number of studies
1 minute Apgar				
0–3 vs. 4–10	46.0 [43.7 to 48.3]	95.4 [95.3 to 95.5]	17.71 [16.07 to 19.51]	11
0–6 vs. 7–10	66.9 [64.7 to 69.1]	84.2 [83.9 to 84.4]	10.73 [9.72 to 11.85]	11
5 minute Apgar				
0–3 vs. 4–10	36.2 [34.9 to 37.5]	99.7 [99.7 to 99.8]	218.42 [203.09 to 234.90]	11
0–6 vs. 7–10	55.5 [54.1 to 56.8]	98.7 [98.7 to 98.8]	97.16 [91.58 to 103.07]	11

Table 171: Meta-analysis on predictive value of Apgar score (cerebral palsy)

Cut-off of Apgar score	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	Diagnostic OR [95% CI]	Number of studies
1 minute Apgar				
0–3 vs. 4–10	24.8 [18.1 to 31.6]	95.3 [95.1 to 95.5]	6.67 [4.63 to 9.61]	1
0–6 vs. 7–10	42.7 [34.9 to 50.4]	81.9 [81.5 to 82.2]	3.36 [2.44 to 4.61]	1
5 minute Apgar				
0–3 vs. 4–10	8.5 [5.9 to 11.1]	99.8 [99.8 to 99.8]	39.90 [28.37 to 56.11]	2
0–6 vs. 7–10	25.0 [21.0 to 29.0]	98.9 [98.9 to 98.9]	29.59 [23.80 to 36.78]	3

Evidence statement

There is low-level evidence that the Apgar score at 5 minutes is moderately accurate at predicting neonatal death and cerebral palsy with reasonable specificity but low sensitivity. No high-level evidence could be found on immediate or longer term neonatal outcomes.

Neonatal resuscitation

Timing of cord clamping

Review question

When should neonatal resuscitation be instigated with respect to the timing of cord clamping?

Description of included studies

No evidence was identified that addressed this question.

Oxygen compared with air

Review question

Is air more effective than oxygen when used for neonatal resuscitation (a) initially and (b) after a period of no/poor response?

Description of included studies

This review included 8 papers (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003; Saugstad et al., 1998; Saugstad et al., 2003; Vento et al., 2001; Vento et al., 2003; Vento et al., 2005). These papers represent the same evidence that was available for the 2007 guideline, although in 2007 the trials were included in the form of a systematic review plus 1 additional study, rather than the individual papers.

The papers reported 7 randomised controlled trials – 6 of them were single centre trials conducted in Spain (Vento et al., 2001; Vento et al., 2003; Vento et al., 2005) and India (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003). The seventh trial was a multicentre trial (Saugstad et al., 1998) with an 18–24 month follow-up study (Saugstad et al., 2003).
All of the included studies compared the use of air (or 21% oxygen) with 100% oxygen for the initial resuscitation of babies. None of the studies identified evaluated the different resuscitation techniques in babies after a period of no/poor response.
Two studies (Vento et al., 2001; Vento et al., 2003) restricted their study populations to term babies, but the remaining studies included some babies born prior to 37 weeks. One study (Saugstad et al., 1998) reports the proportion of preterm babies (24%), but the remaining studies merely report mean gestational age (full details can be found in the evidence table in appendix I). No sub-group analyses were performed by gestational age; therefore, where applicable, the evidence has been downgraded for indirectness. None of the studies restricted their populations to babies born to women at low risk of developing complications, but it was pre-specified in the review protocol that babies born to women at high risk could be included.

Evidence profile

Table 172: Summary GRADE profile for comparison of room air with oxygen for neonatal resuscitation

Number of studies	Design	Number of babies		Effect		Quality
		Room air	100% oxygen	Relative (95% CI)	Absolute (95% CI)	
Neonatal death: overall[a]						
1 meta-analysis of 5 studies (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003; Saugstad et al., 1998; Vento et al., 2005)	randomised trials	88/664 (13.3%)	126/703 (17.9%)	RR 0.74 (0.58 to 0.95)	47 fewer per 1000 (from 9 fewer to 75 fewer)	Very low
Neonatal death: related to asphyxia[a]						
1 meta-analysis of 3 studies (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003)	randomised trials	32/359 (8.9%)	42/360 (11.7%)	RR 0.77 (0.5 to 1.19)	27 fewer per 1000 (from 58 fewer to 22 more)	Very low
Hypoxic ischaemic encephalopathy (HIE): any						
1 meta-analysis of 4 studies (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003; Saugstad et al., 1998)	randomised trials	162/647 (25%)	173/681 (25.4%)	RR 0.97 (0.81 to 1.16)	8 fewer per 1000 (from 48 fewer to 41 more)	Low
HIE: grade II or III[b]						
1 meta-analysis of 3 studies (Bajaj et al., 2005; Ramji et al., 1993; Saugstad et al., 1998)	randomised trials	80/437 (18.3%)	81/460 (17.6%)	RR 1.02 (0.78 to 1.35)	4 more per 1000 (from 39 fewer to 62 more)	Very low

Number of studies	Design	Number of babies		Effect		Quality
		Room air	100% oxygen	Relative (95% CI)	Absolute (95% CI)	
1 study (Ramji et al., 2003)	randomised trial	17.2% (raw data NR)	24.7% (raw data NR)	NC	75 fewer per 1000 (CI NC)	Low
Abnormal neurological examination (at short term follow-up)[c]						
1 meta-analysis of 2 studies (Bajaj et al., 2005; Ramji et al., 1993)	randomised trials	22/117 (18.8%)	16/122 (13.1%)	RR 1.44 (0.8 to 2.6)	58 more per 1000 (from 26 fewer to 210 more)	Very low
Cerebral palsy (at 18-24 month follow-up)						
1 study (Saugstad et al., 2003)	randomised trial	9/91 (9.9%)	8/122 (6.6%)[d]	RR 1.51 (0.61 to 3.76)	33 more per 1000 (from 26 fewer to 181 more)	Very low
Development: abnormal development overall (at 18-24 month follow-up)[e]						
1 study (Saugstad et al., 2003)	randomised trial	14/91 (15.4%)	12/122 (9.8%)	RR 1.56 (0.76 to 3.22)	55 more per 1000 (from 24 fewer to 218 more)	Very low
Development: not pulling-up (at 18-24 month follow-up)						
1 study (Saugstad et al., 2003)	randomised trial	12/91 (13.2%)	10/122 (8.2%)	RR 1.61 (0.73 to 3.56)	50 more per 1000 (from 22 fewer to 210 more)	Very low
Development: having no words (at 18-24 month follow-up)						
1 study (Saugstad et al., 2003)	randomised trial	6/91 (6.6%)	3/122 (2.5%)	RR 2.68 (0.69 to 10.44)	41 more per 1000 (from 8 fewer to 232 more)	Very low
Resuscitation failure (including switching gas)[f]						
1 meta-analysis of 5 studies (Bajaj et al., 2005; Ramji et al., 1993; Ramji et al., 2003; Saugstad et al., 1998; Vento et al., 2001)	randomised trials	165/662 (24.9%)	181/676 (26.8%)	RR 0.95 (0.8 to 1.13)	13 fewer per 1000 (from 54 fewer to 35 more)	Low

Number of studies	Design	Number of babies		Effect		Quality
		Room air	100% oxygen	Relative (95% CI)	Absolute (95% CI)	
Further intervention: chest compressions						
1 study (Bajaj et al., 2005)	randomised trial	7/107 (6.5%)	9/97 (9.3%)	RR 0.71 (0.27 to 1.82)	27 fewer per 1000 (from 68 fewer to 76 more)	Very low
Further intervention: adrenaline use						
1 study (Bajaj et al., 2005)	randomised trial	2/107 (1.9%)	3/97 (3.1%)	RR 0.6 (0.1 to 3.54)	12 fewer per 1000 (from 28 fewer to 79 more)	Very low
Further intervention: intubation during resuscitation						
1 meta-analysis of 2 studies (Bajaj et al., 2005; Ramji et al., 1993)	randomised trials	59/149 (39.6%)	37/139 (26.6%)	RR 1.46 (1.06 to 2.01)	122 more per 1000 (from 16 more to 269 more)	Very low
Heart rate at 1 minute						
1 meta-analysis of 3 studies (Bajaj et al., 2005; Ramji et al., 2003; Saugstad et al., 1998)	randomised trials	n=605[g]	n=639[g]	NC	MD 2.74 higher (3.77 lower to 9.25 higher)	Very low
Heart rate at 5 minutes						
1 meta-analysis of 2 studies (Bajaj et al., 2005; Ramji et al., 2003)	randomised trials	n=317[h]	n=318[h]	NC	MD 0.99 higher (1.43 lower to 3.41 higher)	Low
Apgar score at 5 minutes						
Proportion of babies with Apgar score <7						
1 study (Saugstad et al., 1998)	randomised trial	71/286 (24.8%)	102/321 (31.8%)	RR 0.78 (0.6 to 1.01)	70 fewer per 1000 (from 127 fewer to 3 more)	Very low
Mean Apgar score						

Number of studies	Design	Number of babies		Effect		Quality
		Room air	100% oxygen	Relative (95% CI)	Absolute (95% CI)	
1 study (Bajaj et al., 2005)	randomised trial	Mean 6.8 (SD 2.0) n=107	Mean 7.1 (SD 1.6) n=97	NC	MD 0.3 lower (0.79 lower to 0.19 higher) p=0.27	Low
Median Apgar score						
1 study (Vento et al., 2001)	randomised trial	Median 8 (5th – 95th percentile: 7 - 9)	Median 7 (5th – 95th percentile: 5 - 8)	NC	Median 1 higher (CI NC) not significant (p value NR)	Moderate
1 study (Ramji et al., 1993)	randomised trial	Median 8 (25th – 75th percentile: 7 – 9)	Median 7 (25th – 75th percentile: 6 – 8)	NC	Median 1 higher (CI NC) p=0.03	Low
1 study (Ramji et al., 2003)	randomised trial	Median 7 (5th – 95th percentile: 3 – 10)	Median 7 (5th – 95th percentile: 2 – 10)	NC	Median 0 higher (CI NC) p=0.19	Low
1 study (Vento et al., 2003)	randomised trial	Median 6 (5th – 95th percentile: 5 - 8)	Median 6 (5th – 95th percentile: 4 - 8)	NC	Median 0 higher (CI NC) not significant (p value NR)	Very low
1 study (Vento et al., 2005)	randomised trial	Median 5 (5th – 95th percentile: 3 - 5)[i]	Median 4 (5th – 95th percentile: 3 – 5)[i]	NC	Median 1 higher (CI NC) p<0.05	Very low

CI confidence interval, HIE hypoxic ischaemic encephalopathy, MD mean difference, NC not calculable, NR not reported, RR relative risk, SD standard deviation

a. Bajaj et al. (2005) reports death before discharge; Ramji et al. (1993) and Ramji et al. (2003) report the deaths that occurred in the first week of life; Saugstad et al. (1998) and Vento et al. (2005) report deaths within the first 28 days of life
b. Individual rates of HIE grades II and III were summed by the NCC-WCH technical team for Ramji et al. (1993) and Ramji et al. (2003)
c. Bajaj et al. (2005) defined abnormal neurological examination at discharge as the need for anticonvulsants, hypotonia, hypertonia, or visual/hearing deficit. The authors reported the denominator excluding the babies who died; however, using the full denominator of babies randomised does not affect the direction or significance of the effect (meta-analysed relative risk becomes 1.29 [95% CI 0.71 to 2.34]). Ramji et al. (1993) defined abnormal neurology in the first week of life as the baby being hypotonic, hypertonic, having reflex responses inappropriate for gestation (Moro, sucking, rooting) or having convulsions
d. One additional baby in the oxygen group had hemiparesis (following a capsula interna)
e. This includes the babies with cerebral palsy, plus other babies with delays such as gross motor delay or mental retardation

f. Bajaj et al. (2005) defined failure in the air group as having to switch to oxygen, but did not report how failure in the oxygen group was defined. Ramji et al. (1993) reported that babies in the air group who failed to respond and were cyanosed and/or bradycardic (< 100 beats per minute) after 90 seconds were switched to oxygen (no babies were switched from oxygen). Ramji et al. (2003) reported the proportion of babies who remained bradycardic (< 100 beats per minute) and/or cyanosed after 90 seconds – those in the air group were switched and those in the oxygen group were recorded for comparability. In Saugstad et al. (1998) treatment failure was defined as heart rate <80 beats per minute and/or central cyanosis at 90 seconds – those in the air group were switched and those in the oxygen group were recorded for comparability. Vento et al. (2001) reported the number of babies that needed to be switched from one gas to the other

g. Mean heart rates (in beats per minute) at 1 minute in the individual studies were: Bajaj et al. (2003) - Room air: 113, 100% oxygen: 108; Ramji et al. (2003) - Room air: 94.4, 100% oxygen: 87.7; Saugstad et al. (1998) - Room air: 90, 100% oxygen: 93

h. Mean heart rates (in beats per minute) at 5 minutes in the individual studies were: Bajaj et al. (2003) - Room air: 134, 100% oxygen: 132; Ramji et al. (2003) - Room air: 131.5, 100% oxygen: 131.1

i. This is reported as an outcome in the paper; however, the inclusion criteria for this trial required babies to be severely asphyxiated as defined by pale colour, bradycardia, non-responsiveness to stimuli, cord pH of ≤7.0 at birth, and Apgar score of 5 or less for more than 5 minutes

Evidence statements

There was evidence that resuscitation with room air was associated with lower rates of neonatal death overall (n=1367) and a similar trend was demonstrated when only mortality related to asphyxia (n=719) was considered. There was no evidence of a difference in the risk of hypoxic ischaemic encephalopathy (overall [n=1328], or more severe grades [n=897]) following resuscitation with room air or oxygen. Similarly, shorter and longer term neurological and developmental outcomes (n=213) did not show a difference between the 2 groups, but this evidence was mainly from 1 trial. There was evidence from 1 study (n=204) that more babies received intubation as part of the resuscitation procedure following resuscitation with room air, but there were no other differences in terms of the further interventions used in the 2 groups of babies, either in terms of resuscitation failure or the need for adrenaline and/or chest compressions. No difference was found in the mean heart rate at 1 and 5 minutes (n=635). The evidence around 5 minute Apgar score was mixed. Five trials (n=1390) reported no difference in Apgar score between babies resuscitated with room air and 100% oxygen, but 2 trials (n=123) found a higher median Apgar score in the babies resuscitated with room air. The evidence was of moderate to very low.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised outcomes relating to neonatal mortality and morbidity. In particular, they were concerned with serious morbidities such as hypoxic ischaemic encephalopathy and cerebral palsy.

This review formed part of the original 2007 guideline, but for the update the search was expanded to cover air compared with oxygen after a period of no or poor response. However, no additional papers were identified which addressed this issue.

Update 2014

Consideration of clinical benefits and harms

One relatively large meta-analysis of 5 studies found that there were significantly fewer deaths when using room air compared with using oxygen. The guideline development group agreed that this was an extremely important finding. Although they recognised that there was a statistically significant increase in the need for intubation during resuscitation when using room air compared with oxygen, they agreed that this was outweighed by the mortality finding and so concluded that resuscitation should be performed with air rather than oxygen. The group's clinical experience was that if a baby requires resuscitation, it will often be taken into a separate room and that this can cause a great deal of anxiety for the mother. The group recognised that in some situations this may be unavoidable, but felt that it was important that where possible this separation should be minimised. Given the anxiety that the need for neonatal resuscitation can cause, the group felt that it was important that in this situation one of the healthcare professionals present should be allocated to stay with the woman to provide ongoing support and be responsible for communicating with the woman and her birth companion(s) throughout the resuscitation.

Consideration of health benefits and resource uses

There were no specific resource use issues related to the treatment alternatives addressed for this question in terms of staff time and equipment needed. However, use of oxygen may be more expensive, especially where tanks of oxygen are used rather than piped oxygen. Given the significant difference between the 2 groups in terms of neonatal mortality, it was a straightforward assessment that the benefits from use of air was likely to be cost effective, owing to the gain in quality adjusted life years (QALYs) as a result.

Quality of evidence

The evidence for this question ranged in quality from moderate to very low, although the evidence for the majority of reported outcomes was low or very low. The group recognised that the quality of the evidence for the neonatal mortality outcome was graded very low, owing to inadequate randomisation and concealment of treatment allocation in the majority of the included studies. However, given the severity of the outcome, the group did not feel that they could disregard the finding.

Other considerations

In the previous edition of the guideline, it had been recommended that oxygen should be available for all babies who do not respond once adequate ventilation has been established. The group did not feel that the studies provided evidence for when oxygen might be required and so chose to remove the recommendation. With such limited evidence, they did not feel that it was appropriate that midwives attending a homebirth should be required to bring oxygen. However, the guideline development group also acknowledged that there may be situations in which the use of oxygen is clinically appropriate and so did not wish to specifically recommend that oxygen should not be used.

The group agreed that it was important that healthcare professionals be reminded about the importance of calling for help if a baby requires resuscitation.

The group chose to make a recommendation detailing the features that should be assessed in order to determine whether resuscitation is required. They noted that the guideline contained other recommendations detailing the different observations that should be made at birth. However, they felt it important to highlight that respiration, heart rate and tone are particularly relevant when deciding about whether resuscitation is necessary.

Recommendations

262. In the first minutes after birth, evaluate the condition of the baby – specifically respiration, heart rate and tone – in order to determine whether resuscitation is needed according to nationally accredited guidelines on neonatal resuscitation. [new 2014]

263. All relevant healthcare professionals caring for women during birth should attend annually a course in neonatal resuscitation that is consistent with nationally accredited guidelines on neonatal resuscitation. [new 2014]

264. In all birth settings:

- bear in mind that it will be necessary to call for help if the baby needs resuscitation, and plan accordingly
- ensure that there are facilities for resuscitation, and for transferring the baby to another location if necessary
- develop emergency referral pathways for both the woman and the baby, and implement these if necessary. [new 2014]

265. If a newborn baby needs basic resuscitation, start with air. [2014]

266. Minimise separation of the baby and mother, taking into account the clinical circumstances. [new 2014]

267. Throughout an emergency situation in which the baby needs resuscitation, allocate a member of the healthcare team to talk with, and offer support to, the woman and any birth companion(s). [new 2014]

Routine paired cord-blood gas analysis

Review question

Is routine paired cord blood gas analysis predictive of perinatal or longer term outcomes?
Does routine paired cord blood analysis improve perinatal outcomes?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

This review includes 8 studies (Hefler et al., 2007; Keski-Nisula et al., 2012; Malin et al., 2010; Svirko et al., 2008; White et al., 2010; Wiberg et al., 2010; Wildschut et al., 2005; Yeh et al., 2012).
One of the included studies is a systematic review (Malin et al., 2011) which comprised 51 observational studies from different countries with a variety of study designs. For the purpose of this review, only the results from the 14 included studies in the systematic review with a term population are reported here. Of the 7 other included studies, 1 is a prospective comparative observational study from the Netherlands (Wildschut et al., 2005) and 3 are retrospective consecutive case control and case series from Sweden (Wiberg et al., 2010), Australia (White et al., 2010) and Finland (Keski-Nisula et al., 2012). The remaining 3 included studies are retrospective comparative observational studies, 2 of which are from the UK (Svirko et al., 2008; Yeh et al., 2012) and one from Australia (Hefler et al., 2007).
The systematic review (Malin et al., 2011) incorporated trials that evaluated the predictive value of either arterial or venous cord blood pH, or base excess for neonatal outcomes. Two studies examined whether umbilical artery cord pH is related to child and adult intelligence (Svirko et al., 2008; Hefler et al., 2007). One study evaluated the impact of introducing universal umbilical cord blood gas analysis at birth on perinatal outcomes (White et al., 2010). The remaining included studies examined the association between umbilical cord pH at birth with short and long term neonatal outcomes.
One study (Wildschut et al., 2005) reported excluding women with multiple pregnancies or who had a complicated pregnancy, but in the remaining studies the inclusion/exclusion criteria and characteristics of the study populations are poorly reported. Therefore, it is not possible to judge whether women would have been classified as low risk prior to the onset of labour. Clinical outcomes for the woman are not reported in any of the included studies for this comparison.
Umbilical artery pH was used as selection criterion in all included studies. It was optimal that both arterial and venous samples be obtained as this allows confirmation of which vessel was sampled. The difference between umbilical arterial pH value and umbilical venous pH measured immediately after birth as an indicator of neonatal outcomes was not investigated in any included studies.
While 4 studies (Hefler et al., 2007; Keski-Nisula et al., 2012; Malin et al., 2010; Wildschut et al., 2005) did not specify the time of cord clamping, 2 studies (Svirko et al., 2008; Yeh et al., 2012) stated that the umbilical cord was clamped immediately after birth and others (White et al., 2010; Wiberg et al., 2010) indicated that the cord was clamped “immediately after birth preferably before the newborn’s first breath”.

Evidence profile

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

- The odds ratios of association between umbilical arterial blood pH at birth and neonatal outcomes
- Comparative clinical outcome data for association between umbilical arterial blood pH at birth with short and long term neonatal/child outcomes

Update 2014

- Effect of Introducing universal umbilical cord blood gas analysis at birth on neonatal outcomes
- Correlation of neonatal umbilical arterial blood pH with intellectual function.

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

Predictive accuracy and correlation data

In the following table (table 173), the predictive accuracy data (data to generate a 2x2 table: true positive, false positive, true negative, false negative) were used to calculate the odds of an association between the different pH thresholds and the specific neonatal outcome.

Table 173: Summary GRADE profile showing the odds ratios of association between umbilical arterial blood pH at birth and neonatal outcomes

Number of studies	Design	Number of women		Effect		Quality
		True positive/Total affected (with disease/TP + FN)	False positive/Total unaffected (with no disease/FP + TN)	Relative (95% CI)	Absolute (95% CI)	
Neonatal mortality: pH<7.00						
1 meta-analysis of 3 studies (Malin et al., 2010)	observational studies	14/210 (6.7%)	1603/464453 (0.35%)	OR 16.09 (8.94 to 28.95)[a]	49 more per 1000 (from 27 more to 88 more)	Low
Neonatal mortality: pH 7.10 - 7.20						
1 meta-analysis of 3 studies (Malin et al., 2010)	observational studies	16/23 (69.6%)	810/1865 (43.4%)	OR 4.71 (0.89 to 25.1)[a]	349 more per 1000 (from 28 fewer to 516 more)	Low
Cerebral palsy: pH<7.00						
1 study (Malin et al., 2010)	observational studies	0/2 (0%)	139/200 (69.5%)	OR 0.45 (0.02 to 9.59)[a]	140 fewer per 1000 (from 296 fewer to 503 more)	Very Low
HIE plus seizure: pH<7.00						
1 study (Malin et al., 2010)	observational studies	7/7 (100%)	7/56 (12.5%)	OR 99 (5.11 to 1918.03)[b]	809 more per 1000 (from 297 more to 871 more)	Low
HIE: pH≤7.00						
1 meta-analysis of 5 studies (Malin et al., 2010) and one study (Wiberg et al., 2010)	observational studies	38/187 (20%)	213/14266 (1.3%)	OR 10.45 (4.83 to 22.62)[a]	122 more per 1000 (from 53 more to 240 more)	Low

Update 2014

Number of studies	Design	Number of women		Effect		Quality
		True positive/Total affected (with disease/TP + FN)	False positive/Total unaffected (with no disease/FP + TN)	Relative (95% CI)	Absolute (95% CI)	
HIE grade 2-3: pH<7.05						
1 study (Wiberg et al., 2010)	observational studies	2/6 (33%)	127/12923 (1.0%)	OR 50.38 (9.14 to 277)[a]	324 more per 100 (from 73 more to 723 more)	Very low
HIE grade 2-3: pH<7.10						
1 study (Wiberg et al., 2010)	observational studies	3/6 (50%)	560/12929 (4.3%)	OR 22.08 (4.45 to 109)[a]	446 more per 1000 (from 124 more to 788 more)	Very low
Seizure: pH<7.00						
1 meta-analysis of 4 studies (Malin et al., 2010)	observational studies	19/20 (95%)	114/3007 (3.8%)	OR 43.66 (5.69 to 335.1)[a]	595 more per 1000 (from 145 more to 892 more)	Low
Seizure: pH<7.20						
1 meta-analysis of 3 studies (Malin et al., 2010)	observational studies	48/67 (71.6%)	727/1632 (44.5%)	OR 3.13 (1.83 to 5.34)[a]	270 more per 1000 (from 150 more to 365 more)	Low

CI confidence interval, FN false negative, FP false positive, HIE hypoxic ischemic encephalopathy, NC not calculable, NR not reported, OR odds ratio, TN true negative, TP true positive

a. Calculated by NCC-WCH technical team
b. Values for OR and CI reported in the study do not match the 2x2 data reported, therefore NCC calculation is quoted here

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Table 174: Summary GRADE profile for association between umbilical arterial blood pH at birth with short and long term neonatal/child outcomes

Number of studies	Design	Number of women		Effect		Quality
		Lower arterial pH	Higher arterial pH	Relative (95% CI)	Absolute (95% CI)	
Encephalopathy with seizures and/or death: pH≤7.00 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	33/1120 (2.9%)	20/12369 (0.16%)	RR 18.22 (10.49 to 31.65)	28 more per 1000 (from 15 more to 50 more)	Very low
Encephalopathy with seizures and/or death: pH 7.01 to 7.10 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	19/4435 (0.43%)	20/12369 (0.16%)	RR 2.65 (1.42 to 4.96)	3 more per 1000 (from 1 more to 6 more)	Very low
Encephalopathy with seizures and/or death: pH 7.11 to 7.20 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	35/15419 (0.23%)	20/12369 (0.16%)	RR 1.4 (0.81 to 2.43)	1 more per 1000 (from 0 fewer to 2 more)	Very low
Encephalopathy with seizures and/or death: pH 7.21 to 7.25 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	34/12903 (0.26%)	20/12369 (0.16%)	RR 1.63 (0.94 to 2.83)	1 more per 1000 (from 0 fewer to 3 more)	Very low
Neonatal unit admission: pH≤7.00 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	392/1120 (35%)	679/12369 (5.5%)	RR 6.38 (5.72 to 7.1)	295 more per 1000 (from 259 more to 335 more)	Very low
Neonatal unit admission: pH 7.01 to 7.10 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	495/4435 (11.2%)	679/12369 (5.5%)	RR 2.03 (1.82 to 2.27)	57 more per 1000 (from 45 more to 70 more)	Very low
Neonatal unit admission: pH 7.11 to 7.20 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	1085/15419 (7%)	679/12369 (5.5%)	RR 1.28 (1.17 to 1.41)	15 more per 1000 (from 9 more to 23 more)	Very low

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Number of studies	Design	Number of women		Effect		Quality
		Lower arterial pH	Higher arterial pH	Relative (95% CI)	Absolute (95% CI)	
Neonatal unit admission: pH 7.21 to 7.25 versus pH 7.26 - 7.30						
1 study (Yeh et al., 2012)	observational studies	754/12903 (5.8%)	679/12369 (5.5%)	RR 1.06 (0.96 to 1.18)	3 more per 1000 (from 2 fewer to 10 more)	Very low
Neurodevelopment at 3 months (better indicated by lower values): pH<7.10 versus pH≥7.10						
1 study (Wildschut et al., 2005)	observational studies	Median 4.0 n=21	Median 3.0 n=23	NC	NC p=0.10	Very low
Asthma, allergic rhinitis, atopic eczema: pH<7.19 versus pH 7.26 - 7.29						
1 study (Keski-Nisula et al., 2012)	observational studies	106/217 (48.8%)	101/229 (44.1%)	OR[b] 1.1 (0.76 to 1.6)	24 more per 1000 (from 66 fewer to 117 more)	Very low
Asthma: pH<7.19 versus pH 7.26 - 7.29						
1 study (Keski-Nisula et al., 2012)	observational studies	44/73 (60.3%)	32/77 (44.6%)	OR[b] 3.22 (1.51 to 6.87)	923 more per 1000 (from 212 more to 1000 more)	Very low
Movement (manual dexterity, ball skills, balance) at 3 months (better indicated by lower values): pH<7.10 versus pH≥7.10						
1 study (Wildschut et al., 2005)	observational studies	Median 7.75 n=20	Median 6.0 n=23	NC	NC p=0.79	Very low
Overall intelligence at age 18 (better indicated by lower values) pH 7.00 – 7.11 versus pH≥7.21[a]						
1study (Hefler et al., 2007)	observational studies	Mean 5.2 (SD 2) n=37	Mean 5.0 (SD 1.0) n=1199	NC	MD 0.2 higher (0.45 lower to 0.85 higher) p=0.5	Very low
Overall performance[a] at age 18 (better indicated by lower values): pH 7.00 – 7.11 versus pH≥7.21[a]						
1 study (Hefler et al., 2007)	observational studies	Mean 5.3 (SD 2.1) n=37	Mean 5.1 (SD 1.9) n=1199	NC	MD 0.2 higher (0.49 lower to 0.89 higher) p=0.6	Very low

CI confidence interval, MD mean difference, NC not calculable, OR odds ratio, RR relative risk, SD standard deviation

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a. The Austrian military uses various standard tests assessing the draftees' performance on a Stanine scale (score range 1 – 9) designed to meet the needs of the Austrian military. No further information on the content of the tests provided.
b. Adjusted for gender, current age, maternal parity, maternal current smoking, education, gestational age at birth, mode of birth, need for neonatal intensive care unit, season of birth and parental allergy.

Table 175: Summary GRADE profile for the effect of introducing universal umbilical arterial blood gas analysis at birth on perinatal outcome

		Number of women		Effect		
Number of studies	Design	After introducing universal umbilical arterial blood gas analysis (Year 2006)	Before introducing universal umbilical arterial blood gas analysis (Year 2003)	Relative (95% CI)	Absolute (95% CI)	Quality
NICU admission						
1 study (White et al., 2010)	observational studies	283/3808 (7.4%)	186/2906 (6.4%)	OR 1.17 (0.9 to 1.42) adjusted[a] OR 1.13 (0.86 to 1.47)	11 more per 1000 (from 7 fewer to 2 more)[b]	Very low
Term NICU admission						
1 study (White et al., 2010)	observational studies	40/3808 (1.1%)	35/2906 (1.2%)	OR 0.87 (0.55 to 1.37) adjusted[a] OR 0.77 (0.47 to 1.26)	2 fewer per 1000 (from 5 fewer to 4 more)[b]	Very low
Special care nursery admission						
1 study (White et al., 2010)	observational studies	575/3808 (15.1%)	520/2906 (17.9%)	OR 0.81 (0.71 to 0.92) adjusted[a] OR 0.75 (0.65 to 0.86)	25 fewer per 1000 (from 10 fewer to 39 fewer)[b]	Very low

CI confidence interval, NICU neonatal intensive care unit, OR odds ratio

a. Adjusted for maternal age, gestational age, fetal presentation, induction and augmentation, mode of birth, mode of anaesthesia, and/or analgesia, obstetric, fetal and intrapartum complications, maternal medical and obstetric history, and parity
b. Absolute risk is calculated based on OR not adjusted OR

Update 2014

Table 176: Summary GRADE profile for correlation of umbilical arterial blood pH and intellectual function

Number of studies	Design	Outcome measure	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
Correlation of umbilical arterial pH with cognitive measures at age 6 to 8 years: pH≥7.0 (lower scores show better function)					
1 study (Svirko et al., 2008)	case series	Literacy (WORD)	84	r: −0.30 (p=0.005)	Very low
1 study (Svirko et al., 2008)	case series	Grammar comprehension (TROG)	111	r: −0.13 (p=0.187)	Very low
1 study (Svirko et al., 2008)	case series	Non-verbal intelligence (NNAT)	107	r: −0.23 (p=0.017)	Very low
Correlation of umbilical arterial pH with cognitive measures at age 6 to 8 years: pH≥7.0 (adjusted[a]) (lower scores show better function)					
1 study (Svirko et al., 2008)	case series	Literacy (WORD)	78	r: −0.36[b] (p=0.001)	Very low
1 study (Svirko et al., 2008)	case series	Grammar comprehension (TROG)	105	r: −0.09[c] (p=0.366)	Very low
1 study (Svirko et al., 2008)	case series	Non-verbal intelligence (NNAT)	101	r: −0.21[d] (p=0.033)	Very low

NNAT Naglieri non verbal ability, TROG test for comprehension of grammar, WORD Wechsler objective reading dimensions

a. Extremely acidemic neonates (arterial pH<7.00) were excluded and data adjusted
b. Controlling for social class, breast feeding, maternal age and epidural/spinal
c. Controlling for social class, breast feeding, and single parent
d. Controlling for maternal age, breast feeding, and single parent

Update 2014

Evidence statements

Predictive accuracy of umbilical arterial blood sampling for neonatal outcomes

There is evidence of a positive association between an arterial cord pH less than 7.00 and neonatal mortality (n=464,663), hypoxic ischaemic encephalopathy and seizure (n=63). However, no association was found between a pH of less than 7.00 and cerebral palsy (n=202). Evidence from a meta-analysis of 3 studies (1,888) found no association between a pH of 7.10–7.20 and neonatal mortality. Using a threshold of a pH of 7.00 or lower (n=14,453), pH less than 7.05 (n=12,929) and pH less than 7.10 (n=12,935) evidence from the studies found a positive association between the cord pH and hypoxic ischaemic encephalopathy. There was evidence from a meta-analysis of 4 studies showed that a pH threshold of less than 7.00 (n=3027) or less than 7.20 (n=1699) had a positive association with seizure. The evidence was of low and very low quality.

Association between umbilical arterial blood pH at birth with short and long term neonatal/child outcomes

There was evidence from 1 study (n=51,519) that a higher number of neonates with lower pH (7.0 or less, 7.01–7.10) had encephalopathy with seizures and/or death and admission to a neonatal intensive care unit compared with neonates born with higher pH (7.26–7.30). Evidence from the same study found no difference in the rate of encephalopathy with seizures and/or death in neonates born with a pH of 7.11–7.20 and 7.21–7.25 compared with neonates born with pH 7.26–7.30.

Evidence from 1 study (n=1,236) found no significant effect on overall performance and overall intelligence at the age of 18 in young people born with an umbilical artery pH of less than 7.12 compared with those born with an umbilical cord pH of 7.21 or higher. Another study found no significant effect on the development of asthma, allergic rhinitis and atopic eczema at the age of 5 to 6 years, as a composite outcome, in children born with an umbilical cord pH of less than 7.19 compared with those born with an umbilical artery pH of 7.26–7.29. However, more children born with a pH of less than 7.12 developed asthma at the age of 5 to 6 years compared with children born with a pH of 7.26–7.29.

One small study (n=43) found no association between arterial cord pH (thresholds of less than 7.1 compared with 7.1 or higher) and neurodevelopment and movement at 3 months.

Evidence from 1 study (n=6714) found introducing universal umbilical artery blood gas analysis at birth had no significant effect on rate of neonatal intensive care unit admission at birth. The evidence across all outcomes was of very low quality.

Correlation of umbilical arterial blood pH with intellectual function

Evidence from 1 study (n=316) found low and very low correlation between pH (7 or higher) and cognitive measures at age 6 to 8 years. The evidence was of very low quality.

Health economics profile

No published economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group had hoped to find studies investigating the difference between umbilical arterial and venous blood pH as a predictor for poor outcomes. However, all of the included studies had only looked at the arterial blood results – paired gases had only been obtained in order to ensure that an arterial sample had been taken. As a result, the group focussed on the arterial blood pH values as predictors of poor neonatal outcomes. In particular, the group felt evidence relating to severe neonatal morbidity such as hypoxic ischaemic encephalopathy and seizures was particularly important. In addition, the group also focussed on evidence relating to longer term outcomes such as developmental delay.

Consideration of clinical benefits and harms

The studies consistently reported significantly poorer neonatal outcomes for babies with an umbilical arterial blood pH of less than 7.00, including mortality, hypoxic ischaemic encephalopathy, seizures and admission to a neonatal unit. In addition, a number of the studies reported significantly poor outcomes for babies with an arterial blood gas pH of less than 7.10. Given this, the group felt confident that a finding of a low pH is a clear indicator of a baby born in poor condition. The group agreed that identifying when a baby is at increased risk of encephalopathy and seizure is clinically valuable as it then allows for prompt treatment, which may include therapeutic cooling, to try to improve the baby's condition and prevent potentially serious adverse outcomes.

Consideration of health benefits and resource uses

As noted, the benefit of taking a cord blood analysis is that it allows clinicians to identify babies who are at risk of poor outcomes, and therefore provides the opportunity for them to perform further interventions to try to prevent those outcomes from occurring. Given the potential QALY gain associated with preventing cases of hypoxic ischaemic encephalopathy and subsequently cerebral palsy, there is therefore a strong health economic case for taking cord blood gases.

The guideline development group discussed whether it would be appropriate to recommend universal cord blood analysis. The evidence for this approach was of poor quality and the group did not feel it was appropriate to place much value on it (see below). They noted that current practice is only to perform cord blood analysis if there has been concern about the baby's condition. Given the limitations of the evidence, the group agreed that it would not be appropriate to recommend performing cord blood analysis in all babies.

Quality of evidence

The guideline development group had hoped to find more evidence for outcomes associated with an umbilical cord blood pH in the range 7.00 to 7.10 since this is an area where there is greater clinical uncertainty. The lack of evidence in this area meant the group had to extrapolate from evidence relating to other thresholds plus their own clinical judgement to help draft recommendations.

The group considered that not all the included studies had performed an adjustment for confounding factors, which can lead to a biased estimate of the effect.

The group noted that 1 of the included studies (Hefler et al., 2007) excluded from its analysis babies with a pH of less than 7.00 and babies who had died. In addition, its long-term analysis at 18 years was only conducted in males (army recruits) without severe mental or physical disability. Given all of these issues, the group felt that the findings were biased and unlikely to be generalisable to the population as a whole and so disregarded the study from their discussions.

One review (White et al., 2010) compared various outcomes before and after the introduction of universal umbilical arterial blood gas analysis. This study found a statistically significant reduction in the rate of special care nursery admission. However, the group noted that the proportion of babies admitted to special care was unusually high in this study and felt that although the study had tried to adjust for confounding features, given the time difference between the 2 study periods, it was extremely difficult to be sure that the finding was caused by the universal analysis as opposed to another factor. Given this, the group did not attach much value to the finding and did not feel that it provided compelling evidence to move to a practice of cord blood analysis in all babies.

The group noted the findings from 1 study (Svirko et al., 2008) which showed that there was low or very low correlation between various cognitive measures and pH values of 7.00 or higher. The study excluded neonates with a pH of less than 7.00 and did not report further subgroup analysis by different pH values. Given this, the group felt that the findings were not helpful in identifying whether pH values were predictive of longer term outcomes.

Other considerations

The guideline development group discussed whether double cord clamping was necessary in order to obtain a cord blood sample. Some group members were aware of research which has suggested that the blood sample could be taken without clamping the umbilical cord. However, as current UK practice is to double clamp the cord and the group had not formally reviewed the literature looking at whether cord clamping is necessary, they did not feel it was appropriate to recommend a change of practice in this area.

The group also discussed the appropriate time to clamp the cord in light of the updated recommendations for routine management of the third stage, which now state that clamping should not be performed until 1 minute after the birth of the baby (see section 13.3.6). The group agreed that even when there was concern about the condition of the baby, it would be appropriate to wait 1 minute before clamping the cord. Based on their clinical knowledge, they did not think that waiting for 1 minute would affect the blood sample but thought the wait would benefit the baby. Furthermore, they agreed that in the first minute following birth, the healthcare professional should focus on assessing the needs of baby rather than taking a cord blood sample.

Key conclusions

The guideline development group agreed that it is clinically valuable to know the umbilical arterial pH at birth in order to provide additional information that can help plan appropriate neonatal care for babies where there is a suspicion that there has been a period of hypoxia.

Recommendations

268. Record the time from birth to the onset of regular respirations. [new 2014]

269. If the baby is born in poor condition (on the basis of abnormal breathing, heart rate or tone):

- follow recommendations 262 to 267 on neonatal resuscitation **and**
- take paired cord-blood samples for blood gas analysis, after clamping the cord using 2 clamps.

Continue to evaluate and record the baby's condition until it is improved and stable. [new 2014]

270. Do not take paired cord blood samples (for blood gas analysis) routinely. [new 2014]

271. Ensure that a second clamp to allow double-clamping of the cord is available in all birth settings. [2014]

Care of babies born with meconium-stained liquor

Review question

What is the appropriate care of babies born with meconium-stained liquor?
For further details on the evidence review protocol, please see appendix E.

Description of included studies

Five studies are included in this review (Daga et al., 1994; Liu and Harrington, 1998; Linder et al., 1988; Vain et al., 2004; Wiswell et al., 2000). These papers represent the same evidence that was available for the 2007 guideline.

All of the included studies were randomised controlled trials, although in 1 of the studies it was the paediatricians who were randomised rather than the babies (Linder et al., 1988). Two of the studies were conducted in the USA (Liu and Harrington, 1998; Wiswell et al., 2000) and one was conducted in India (Daga et al., 1994). One further trial was conducted primarily in Argentina but with 1 centre (out of 12) located in the USA (Vain et al., 2004). The last trial

did not report the study location but the authors came from Canada and Israel (Linder et al., 1988).

One of the trials compared a policy of suctioning of the oropharynx and nasopharynx before delivery of the shoulders with a policy of no suctioning (Vain et al., 2004). Four of the trials compared a policy of routine intubation, with one of no intubation (Daga et al., 1994; Liu and Harrington, 1998; Linder et al., 1988) or one of intubation only when indicated (Wiswell et al., 2000). In the latter 4 studies, the protocol was for all babies to have oronasopharyngeal suctioning and for only babies who were vigorous at birth to be included (for full details of inclusion and exclusion criteria, see the evidence tables in appendix I).

One trial only included babies born through non-significant ('thin') meconium (Liu and Harrington, 1998), 1 trial only included babies born through significant ('thick') meconium (Daga et al., 1994) and 3 trials included babies born through meconium of any consistency (Linder et al., 1988; Vain et al., 2004; Wiswell et al., 2000). Four trials restricted their study populations to term babies, but in the fifth trial 45% of babies were born at 34–37 weeks (Daga et al., 1994). No details were reported about cord clamping in the included studies and therefore it was not possible to evaluate what impact this might have had on outcomes.

Evidence profile

The following GRADE profiles are presented below:

- suctioning of the oropharynx and nasopharynx before delivery of the shoulders compared with no suctioning
- intubation compared with no intubation or selective intubation.

Subgroup analyses by the degree of meconium staining have been reported where the data were available in the trials. (Vain et al. [2004] reported a subgroup analysis for 3 outcomes only).

Sensitivity analyses were performed, removing in turn Daga et al. (1994) which had a high proportion of preterm babies and Linder et al. (1988) which randomised paediatricians rather than babies and included babies treated by non-participating physicians in the intubation arm. Unless indicated in a footnote, the sensitivity analyses did not change the direction or significance of the demonstrated effects.

Table 177: Summary GRADE profile for comparison of suctioning of the oropharynx and nasopharynx before delivery of the shoulders with no suctioning

Number of studies	Design	Number of babies		Effect		Quality
		Suctioning	No suctioning	Relative (95% CI)	Absolute (95% CI)	
Neonatal death[a]						
All babies						
1 study (Vain et al., 2004)	randomised trial	9/1263 (0.71%)	4/1251 (0.32%)	RR 2.23 (0.69 to 7.22)	4 more per 1000 (from 1 fewer to 20 more)	High
Babies with non-significant ('thin' or 'moderate') meconium staining[b]						
1 study (Vain et al., 2004)	randomised trial	4/1111 (0.36%)	1/1083 (0.09%)	RR 3.90 (0.44 to 34.83)	3 more per 1000 (from 1 fewer to 31 more)	High
Babies with significant ('thick') meconium staining						
1 study (Vain et al., 2004)	randomised trial	5/151 (3.3%)	3/168 (1.8%)	RR 1.85 (0.45 to 7.63)	15 more per 1000 (from 10 fewer to 118 more)	Moderate
Meconium aspiration syndrome						
All babies						
1 study (Vain et al., 2004)	randomised trial	52/1263 (4.1%)	47/1251 (3.8%)	RR 1.1 (0.74 to 1.61)	4 more per 1000 (from 10 fewer to 23 more)	High
Babies with non-significant ('thin' or 'moderate') meconium staining[b]						
1 study (Vain et al., 2004)	randomised trial	30/1111 (2.7%)	24/1083 (2.2%)	RR 1.22 (0.72 to 2.07)	5 more per 1000 (from 6 fewer to 24 more)	High
Babies with significant ('thick') meconium staining						
1 study (Vain et al., 2004)	randomised trial	22/151 (14.6%)	23/168 (13.7%)	RR 1.06 (0.62 to 1.83)	8 more per 1000 (from 52 fewer to 114 more)	Low

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Suctioning	No suctioning	Relative (95% CI)	Absolute (95% CI)	
Mechanical ventilation for meconium aspiration syndrome						
All babies						
1 study (Vain et al., 2004)	randomised trial	24/1263 (1.9%)	18/1251 (1.4%)	RR 1.32 (0.72 to 2.42)	5 more per 1000 (from 4 fewer to 20 more)	High
Babies with non-significant ('thin' or 'moderate') meconium staining[b]						
1 study (Vain et al., 2004)	randomised trial	14/1111 (1.3%)	10/1083 (0.92%)	RR 1.36 (0.61 to 3.06)	3 more per 1000 (from 4 fewer to 19 more)	High
Babies with significant ('thick') meconium staining						
1 study (Vain et al., 2004)	randomised trial	10/151 (6.6%)	8/168 (4.8%)	RR 1.39 (0.56 to 3.43)	19 more per 1000 (from 21 fewer to 116 more)	Low
Endotracheal intubation, suction and positive pressure ventilation in delivery room						
1 study (Vain et al., 2004)	randomised trial	106/1263 (8.4%)	113/1251 (9%)	RR 0.93 (0.72 to 1.2)	6 fewer per 1000 (from 25 fewer to 18 more)	High
Other respiratory disorders						
1 study (Vain et al., 2004)	randomised trial	61/1263 (4.8%)	79/1251 (6.3%)	RR 0.76 (0.55 to 1.06)	15 fewer per 1000 (from 28 fewer to 4 more)	Moderate
Pneumothorax						
1 study (Vain et al., 2004)	randomised trial	3/1263 (0.24%)	3/1251 (0.24%)	RR 0.99 (0.2 to 4.9)	0 fewer per 1000 (from 2 fewer to 9 more)	High
Duration of oxygen treatment (days)						
1 study (Vain et al., 2004)	randomised trial	Mean 5.7 (SD 8.8) n=52	Mean 5.1 (SD 7.1) n=47	NC	MD 0.6 higher (from 2.54 lower to 3.74 higher)	Very low

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Suctioning	No suctioning	Relative (95% CI)	Absolute (95% CI)	
Duration of mechanical ventilation (days)						
1 study (Vain et al., 2004)	randomised trial	Mean 5.1 (SD 4.9) n=21	Mean 4.2 (4.6) n=14	NC	MD 0.9 higher (from 2.29 lower to 4.09 higher)	Low
Duration of hospital care (days)						
1 study (Vain et al., 2004)	randomised trial	Mean 8.2 (SD 10.7) n=50	Mean 9.0 (SD 8.6) n=43	NC	MD 0.8 lower (from 4.72 lower to 3.12 higher)	Low

CI confidence interval, MD mean difference, NC not calculable, RR relative risk, SD standard deviation,

a. Causes of death in the suctioning group were respiratory failure (n=4), congenital malformations (n=2) and sepsis (n=3). Causes of death in the no suctioning group were respiratory failure (n=2), sepsis (n=1) and congenital malformation (n=1)
b. Calculated by the NCC-WCH technical team based on data on all babies and those with significant (' thick') meconium reported in the paper

Table 178: Summary GRADE profile for comparison of routine intubation with no intubation or selective intubation

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Neonatal death						
All babies						
1 meta-analysis of 3 studies (Daga et al., 1994; Linder et al., 1988; Wiswell et al., 2000)	randomised trials	3/1385 (0.22%)	3/1330 (0.23%)	RR 0.96 (0.22 to 4.25)	0 fewer per 1000 (from 2 fewer to 7 more)	Moderate
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Babies with significant ('thick') meconium staining						
1 study (Daga et al., 1994)	randomised trial	1/26 (3.8%)	0/23 (0%)	RR 2.67 (0.11 to 62.42)	NC	Very low
Meconium aspiration syndrome						
All babies						
1 meta-analysis of 2 studies (Linder et al., 1988; Wiswell et al., 2000)	randomised trials	38/1359 (2.8%)	28/1307 (2.1%)	RR 1.33 (0.82 to 2.14)	7 more per 1000 (from 4 fewer to 24 more)	Moderate
Babies with non-significant ('thin') meconium staining						
1 study (Wiswell et al., 2000)	randomised trials	5/447 (1.1%)	2/453 (0.44%)	RR 2.53 (0.49 to 12.99)	7 more per 1000 (from 2 fewer to 53 more)	Very low
Babies with non-significant ('moderate') meconium staining						
1 study (Wiswell et al., 2000)	randomised trials	7/301 (2.3%)	6/307 (2%)	RR 1.19 (0.4 to 3.5)	4 more per 1000 (from 12 fewer to 49 more)	Very low
Babies with significant ('thick') meconium staining						
1 study (Wiswell et al., 2000)	randomised trials	22/303 (7.3%)	20/283 (7.1%)	RR 1.03 (0.57 to 1.84)	2 more per 1000 (from 30 fewer to 59 more)	Very low
Other respiratory symptoms						
All babies						
1 meta-analysis of 2 studies (Liu & Harrington, 1998; Wiswell et al., 2000)	randomised trials	42/1128 (3.7%)	48/1135 (4.2%)	RR 0.87 (0.58 to 1.31)	5 fewer per 1000 (from 18 fewer to 13 more)	Moderate

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Babies with non-significant ('thin') meconium staining						
1 meta-analysis of 2 studies (Liu & Harrington, 1998; Wiswell et al., 2000)	randomised trials	8/524 (1.5%)	9/545 (1.7%)	RR 0.93 (0.36 to 2.37)	1 fewer per 1000 (from 11 fewer to 23 more)	Moderate
Babies with non-significant ('moderate') meconium staining						
1 study (Wiswell et al., 2000)	randomised trial	10/301 (3.3%)	15/307 (4.9%)	RR 0.68 (0.31 to 1.49)	16 fewer per 1000 (from 34 fewer to 24 more)	Very low
Babies with signficant ('thick') meconium staining						
1 study (Wiswell et al., 2000)	randomised trial	24/303 (7.9%)	24/283 (8.5%)	RR 0.93 (0.54 to 1.61)	6 fewer per 1000 (from 39 fewer to 52 more)	Very low
Hypoxic ischaemic encephalopathy (HIE)						
All babies						
1 study (Daga et al., 1994)	randomised trial	1/26 (3.8%)	0/23 (0%)	RR 2.67 (0.11 to 62.42)	NC	Very low
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					
Babies with significant ('thick') meconium staining						
1 study (Daga et al., 1994)	randomised trial	1/26 (3.8%)	0/23 (0%)	RR 2.67 (0.11 to 62.42)	NC	Very low
Stridor						
All babies						
1 study (Linder et al., 1988)	randomised trial	2/308 (0.65%)	0/264 (0%)	RR 4.29 (0.21 to 88.92)	NC	Very low

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					
Babies with significant ('thick') meconium staining						
0	no evidence available					
Pneumothorax[a]						
All babies						
1 meta-analysis of 2 studies (Daga et al., 1994; Linder et al., 1988)	randomised trials	2/334 (0.6%)	2/287 (0.7%)	RR 0.87 (0.16 to 4.92)	1 fewer per 1000 (from 6 fewer to 27 more)	Low
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					
Babies with significant ('thick') meconium staining						
1 study (Daga et al., 1994)	randomised trial	1/26 (3.8%)	2/23 (8.7%)	RR 0.44 (0.04 to 4.56)	49 fewer per 1000 (from 83 fewer to 310 more)	Very low
Use of extracorporeal membrane oxygenation						
All babies						
1 study (Wiswell et al., 2000)	randomised trial	1/1051 (0.1%)	1/1043 (0.1%)	RR 0.99 (0.06 to 15.84)	0 fewer per 1000 (from 1 fewer to 14 more)	Moderate
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Babies with significant ('thick') meconium staining						
0	no evidence available					
Use of supplemental oxygen						
All babies						
1 meta-analysis of 2 studies (Linder et al., 1988; Liu & Harrington, 1998)	randomised trials	5/385 (1.3%)	0/356 (0%)	RR 5.82 (0.68 to 49.93)	NC	Very low
Babies with non-significant ('thin') meconium staining						
1 study (Liu & Harrington, 1998)	randomised trial	1/77 (1.3%)	0/92 (0%)	RR 3.58 (0.15 to 86.57)	NC	Very low
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					
Babies with significant ('thick') meconium staining						
0	no evidence available					
Oxygen administration for at least 4 days[b]						
All babies						
1 study (Daga et al., 1994)	randomised trial	12/26 (46.2%)	12/23 (52.2%)	RR 0.88 (0.5 to 1.57)	63 fewer per 1000 (from 261 fewer to 297 more)	Very low
Babies with non-significant ('thin') meconium staining						
0	no evidence available					
Babies with non-significant ('moderate') meconium staining						
0	no evidence available					

Update 2014

Number of studies	Design	Number of babies		Effect		Quality
		Intubation	No or selective intubation	Relative (95% CI)	Absolute (95% CI)	
Babies with significant ('thin') meconium staining						
1 study (Daga et al., 1994)	randomised trial	12/26 (46.2%)	12/23 (52.2%)	RR 0.88 (0.5 to 1.57)	63 fewer per 1000 (from 261 fewer to 297 more)	Very low

CI confidence interval, NC not calculable, RR relative risk

a. Sensitivity analysis removing Daga et al. (1994) changes the direction, although not the significance, of the effect. The relative risk becomes 2.57 (95% CI 0.11 to 62.89)
b. Because of the way the data are reported (babies requiring oxygen for 0-3 days; babies requiring oxygen for at least 4 days), it is not possible to calculate the proportion of babies requiring any oxygen in order to meta-analyse it with the data reported by other studies

Update 2014

Evidence statements

Suctioning of the oropharynx and nasopharynx before delivery of the shoulders compared with no suctioning

One large, well-conducted randomised controlled trial (n=2514) did not find a difference in the incidence of neonatal death, meconium aspiration syndrome, other respiratory disorders, need for intubation, suction or positive pressure ventilation in the delivery room, use of mechanical ventilation for meconium aspiration syndrome and pneumothorax between babies randomised to receive suctioning before delivery of the shoulders and those randomised to no suctioning. Similarly, when considering duration of oxygen treatment, mechanical ventilation and hospital care among babies with meconium aspiration syndrome, no difference was found between the 2 groups. Where reported, the evidence was consistent for both subgroups of babies born through non-significant ('thin') or 'moderately' stained meconium liquor and those born through significant ('thick') meconium. The evidence was of high to very low quality.

Intubation compared with no intubation or selective intubation

Evidence from 4 studies (n=2884) showed no clinical benefit of a routine intubation policy for meconium-stained liquor for any of the outcomes considered. This was consistent for the subgroup analysis of trials including only babies born through non-significant ('thin') meconium and the subgroup analysis of trials including only babies born through significant ('thick') meconium, although there were only a small number of babies in the latter group. The evidence was of moderate to very low quality.

Health economics profile

No published health economic evaluations were identified for this question.

Evidence to recommendations

Relative value placed on the outcomes considered

For this review, the guideline development group prioritised outcomes relating to neonatal mortality and morbidity – in particular, respiratory morbidity. They had hoped that longer term outcomes would also be available but none were reported in the studies. They had also hoped that evidence would be available relating to the timing of cord clamping for these babies. However, despite conducting a broad search, no data were identified. The group was also frustrated that no new evidence had become available since the publication of the previous guideline.

Consideration of clinical benefits and harms

The guideline development group recognised that neither suctioning the oropharynx and nasopharynx before delivery of the shoulders nor routine intubation appeared to make a statistically or clinically significant difference to any outcomes for babies born with meconium stained liquor.

The group noted that the overall incidence of poor outcomes was low as the trials all explicitly excluded babies that were born in a depressed state. They felt that this indicated a gap in the evidence as it is not clear whether either suctioning or intubation would be of benefit to babies born in poor condition (that is, babies born with poor tone, having difficulty with respiration or with reduced heart rate). The group acknowledged that there are guidelines produced by the Resuscitation Council (UK) regarding the appropriate methods for neonatal resuscitation. Given the lack of evidence for babies born without normal tone and respiration, the group agreed that it was appropriate that healthcare professionals follow the relevant guideline from the Resuscitation Council UK which acknowledges that, for these babies, early laryngoscopy and suction under direct vision may be appropriate.

Consideration of health benefits and resource uses

There were no specific resource use issues addressed for this question and there was limited evidence of effectiveness. However, the guideline development group recognised the general

principle that it is not a good use of resources for clinicians to perform interventions unnecessarily. This therefore supported their view to recommend that suctioning should not be performed and that intubation should not be performed routinely.

Quality of evidence

Overall, the evidence was of mixed quality. The study from Vain et al. (2004) was relatively large, and was graded high or moderate quality for most reported outcomes. As a result, the guideline development group had confidence in the findings for the comparison of suctioning the upper airways compared with no suctioning (although, as noted above, they recognised that this evidence did not include babies that were born in a depressed state). However, the quality of the evidence for the comparison of routine intubation with no, or selective, intubation was generally of lower quality, with the majority of studies graded as low or very low quality for most outcomes. Ultimately, though, as no differences were observed between the groups for any of the outcomes, the quality of the evidence was less of a concern as the group did not wish to make a positive recommendation in favour of intubation.

Other considerations

In updating the recommendations from the 2007 guideline, the guideline development gorup agreed that the definition of 'significant meconium' should be clearer and so made a recommendation to this effect.

The previous recommendations had mainly been written from the perspective of giving birth in an obstetric unit. However, the group noted that recommendations were also required for women giving birth outside a hospital setting with significant meconium-stained liquor. The group agreed that in this situation, it would be appropriate to make preparations for transfer but that transfer should only occur if the healthcare professional believes that it can be done before the birth occurs. This is because, in the group's clinical judgement, the woman and baby are likely to be at risk of greater harm if the birth occurs in an ambulance than if the birth occurs at home or in a freestanding midwifery unit.

The group agreed that the recommendations saying not to use suctioning of the upper airways or intubation should specify that this is in babies born with normal tone and heart rate. The group was aware that guidelines from the Resuscitation Council (UK) indicate that for babies without normal tone or respiration, it can be appropriate to perform early laryngosocopy and suction under direct vision. The group felt that this matched their own clinical experience and so agreed that this was a sensible recommendation to make.

Recommendations

272. In the presence of any degree of meconium:

- do not suction the baby's upper airways (nasopharynx and oropharynx) before birth of the shoulders and trunk
- do not suction the baby's upper airways (nasopharynx and oropharynx) if the baby has normal respiration, heart rate and tone
- do not intubate if the baby has normal respiration, heart rate and tone. [new 2014]

273. If there has been significant meconium (see recommendation 164) and the baby does not have normal respiration, heart rate and tone, follow nationally accredited guidelines on neonatal resuscitation, including early laryngoscopy and suction under direct vision. [new 2014]

274. If there has been significant meconium and the baby is healthy, closely observe the baby within a unit with immediate access to a neonatologist. Perform these

observations at 1 and 2 hours of age and then 2-hourly until 12 hours of age. [new 2014]

275. If there has been non-significant meconium, observe the baby at 1 and 2 hours of age in all birth settings. [new 2014]

276. If any of the following are observed after any degree of meconium, ask a neonatologist to assess the baby (transfer both the woman and baby if they are at home or in a freestanding midwifery unit, following the general principles for transfer of care described in recommendations 46 to 50):

- respiratory rate above 60 per minute
- the presence of grunting
- heart rate below 100 or above 160 beats/minute
- capillary refill time above 3 seconds
- body temperature of 38°C or above, or 37.5°C on 2 occasions 30 minutes apart
- oxygen saturation below 95% (measuring oxygen saturation is optional after non-significant meconium)
- presence of central cyanosis, confirmed by pulse oximetry if available. [new 2014]

277. Explain the findings to the woman, and inform her about what to look out for and who to talk to if she has any concerns. [new 2014]

Care of babies born to women with prelabour rupture of the membranes at term

Prolonged rupture of membranes and intrapartum fever as risk factors of neonatal infection

Description of included studies

There was one cohort study within a randomised controlled trial[300] and six observational studies that were identified.[451–456] Among them, two were conducted in the UK.[453,455] All the studies, except for one,[456] investigated GBS-related disease as an outcome.

Review findings

Babies of women with PRoM, who enrolled in the international, multicentre RCT comparing induction of labour and expectant management, were observed to investigate various risk factors for developing neonatal infection.[300] [EL = 2+] Multivariate analysis showed the following as risk factors for neonatal infection: clinical chorioamnionitis (OR 5.89, P < 0.001); positive maternal GBS status (versus negative or unknown, OR 3.08, P < 0.001); seven to eight vaginal digital examinations (versus 0 to 2, OR 2.37, P = 0.04); 24 to less than 48 hours from membrane rupture to active labour (versus less than 12 hours, OR 1.97, P = 0.02); 48 hours or less from membrane rupture to active labour (versus less than 12 hours, OR 2.25, P = 0.01); and maternal antibiotics before birth (OR 1.63, P = 0.05).

A UK cross-sectional study was conducted in 2000/2001 involving all babies with GBS disease in the UK and Ireland, younger than 90 days.[453] [EL = 3] Among the total of 568 babies, incidence of GBS disease was assumed to be 0.72 per 1000 live births [95% CI 0.66 to 0.78]. Mothers of 140 babies (44%) had prolonged rupture of membranes.

A UK case–control study was conducted between 1998 and 2000.[455] [EL = 2+] A total of 37 cases of early onset neonatal GBS sepsis were compared with 147 hospital controls. A logistic regression analysis showed that risk of developing early onset neonatal GBS sepsis for babies

from women with prolonged rupture of membranes longer than 18 hours was RR 4.8 [95% CI 0.98 to 23.1], and with rupture of membranes before onset of labour: RR 3.6 [95% CI 0.7 to 17.6].

A Danish cross-sectional study was conducted between 1992 and 2001.[454] [EL = 3] A total of 61 babies with blood-culture-positive GBS sepsis/meningitis were investigated (incidence 0.76 per 1000 live births [95% CI 0.0 to 1.91]). Nineteen percent of the babies had a mother with prolonged rupture of membranes (longer than 18 hours) and 16% of those had maternal pyrexia (higher than 38 °C).

A Dutch case–control study was conducted between 1988 and 1995.[451] [EL = 2+] A total of 41 neonatal early onset GBS-related cases were compared with 123 hospital controls. A multivariate analysis showed that there was an increased risk of developing early onset GBS-related disease when maternal temperature increased by 0.1 above 37.4 °C (OR 2.0 [95% CI 1.4 to 2.8]), but there was no evidence of association between interval from rupture of membranes to birth (OR per hour between 8 and 24 hours 1.0 [95% CI 0.92 to 1.1]) and prolonged rupture of membranes (OR 2.0 [95% CI 0.47 to 9.6]).

A US cohort study was conducted in 1987/88.[456] [EL = 2−] Babies of 205 women with a history of prolonged rupture of membranes were compared with 8586 babies of women without a history of prolonged rupture of membranes. Among 175 out of 205 babies following prolonged rupture of membranes of 24 hours or more, 8.2% yielded positive blood culture. In comparison, 0.1% had positive blood culture from the remaining 8586 babies of women without prolonged rupture of membranes.

A US case–control study was conducted between 1991 and 1992.[452] [EL = 2+] Ninety-nine cases of early onset GBS disease were compared with 253 matched hospital controls. A multivariate logistic regression analysis showed strong evidence of association between increased risk of developing early onset GBS disease and prolonged rupture of membranes (OR 8.7, $P < 0.001$) and intrapartum fever (OR 4.3, $P < 0.05$).

Evidence statement

There is medium-level evidence that risk of developing early onset GBS-related disease, for babies born to women with prolonged rupture of membranes, ranges between 2.0 and 8.7 times higher than those born to women without. The risk of developing fever is about four-fold higher in babies born to women with PRoM when compared with babies born to women without. Up to 40% of babies with early onset GBS-related disease were born to women with prolonged rupture of membranes in the UK.

Clinical manifestation of babies

Description of included studies

One cohort study and two case series were identified, all of which were conducted in the USA,[456–458] One study compared laboratory test results between symptomatic and asymptomatic babies.[456] The other two studies investigated time of onset of symptoms for neonatal infection.

Review findings

Symptoms and laboratory tests

One cohort study was conducted in the USA.[456] [EL = 2+] In the 175 babies born to women with prolonged rupture of membranes, using blood culture and complete blood counts results, six symptomatic infants were compared with nine asymptomatic babies. Out of the six symptomatic babies, all had abnormal complete blood counts (two with abnormal white blood cell counts; five with abnormal neutrophil count; four with high band/metamyelocyte count; four with increased immature to total neutrophil ratio). Of the nine asymptomatic babies, seven had abnormal complete blood counts, five with a high white blood cell count, five with a high neutrophil count, two had a high band/metamyelocyte count and one with a high

immature to total neutrophil ratio. The sensitivity of the complete blood count was 86% and specificity 66%.

Onset of symptoms

The other two studies investigated time of onset of symptoms for early onset neonatal GBS disease. The first study was conducted between 1995 and 1996, targeting babies with 2000 g birthweight or more.[458] [EL = 3] The study reported that 75.8% of babies with sepsis were first noted to be at risk for sepsis before or at the moment of birth, and 91.2% were identified by 12 hours of age. The second study specifically investigated early onset GBS disease.[457] [EL = 3] The population included 37% of preterm babies. The study reported that the median age at onset was 20 minutes ranging from 0 to 77 hours. Sixty-three percent of the babies showed clinical signs within 1 hour of age and 90% were symptomatic within 12 hours.

Evidence statement

There is low-level evidence that over 90% of neonatal sepsis presents within 12 hours of age. The majority of babies with sepsis were first noted to be at risk before or at the moment of birth. There is insufficient evidence on the diagnostic value of tests for neonatal sepsis.

Postnatal prophylactic antibiotics for babies

Description of included studies

One systematic review with two trials[459] and one observational study[458] were identified. One of the trials included assessed effectiveness of prophylactic antibiotics on babies born to women with GBS colonisation, hence excluded from this review. The other trial investigated effectiveness of prophylactic antibiotics (intramuscular penicillin and kanamycin for 7 days, n = 24), compared with no prophylactics (n = 25).[459] [EL = 1−] The second study, a population-based cohort study in the USA, investigated the relationship between predictors and neonatal bacterial infection.[458] [EL = 2+]

Review findings

The trial that investigated the effectiveness of prophylactic antibiotics compared with no antibiotics reported no neonatal mortality. It was underpowered to show any differences in incidence of neonatal sepsis (RR 0.12 [95% CI 0.01 to 2.04]).

The US cohort study evaluated 2785 out of 18,299 newborns of 2000 g or more, without major abnormalities for sepsis, with a complete blood count and/or blood culture. Multivariate analysis showed that among 1568 babies whose mothers did not receive antibiotics, initial asymptomatic status was associated with decreased risk of infection (OR 0.27 [95% CI 0.11 to 0.65]). However, there was evidence of an increased risk of neonatal sepsis by antepartum fever (highest ante-partum temperature 101.5 °F (38.6 °C) or higher (OR 5.78 [95% CI 1.57 to 21.29]), rupture of membranes for 12 hours or longer (OR 2.05 [95% CI 1.06 to 3.96]), low absolute neutrophil count for age (OR 2.82 [95% CI 1.50 to 5.34]), and meconium in amniotic fluid (OR 2.24 [95% CI 1.19 to 4.22]).

Evidence statement

There is no high-level evidence from trials on prophylactic antibiotics for babies born to women with prolonged rupture of membranes at term.

There is medium-level evidence that, if the baby is asymptomatic at birth, there is a significantly lower risk of it developing neonatal sepsis.

Evidence to recommendations

As part of the process of updating the guideline the GDG considered the applicability of all recommendations for each of the four birth settings. The recommendations for care of babies following prolonged rupture of membranes was amended through GDG consensus and it was agreed these should be aligned with the updated recommendations made for observations of the newborn following birth with meconium. In addition the GDG discussed the practicalities of making additional observations in settings outside an obstetric unit and agreed a regimen for making observations that was felt to be both safe and practical.

Recommendations

278. Closely observe any baby born to a woman with prelabour rupture of the membranes (more than 24 hours before the onset of established labour) at term for the first 12 hours of life (at 1 hour, 2 hours, 6 hours and 12 hours) in all settings. Include assessment of:

- temperature
- heart rate
- respiratory rate
- presence of respiratory grunting
- significant subcostal recession
- presence of nasal flare
- presence of central cyanosis, confirmed by pulse oximetry if available
- skin perfusion assessed by capillary refill
- floppiness, general wellbeing and feeding.

If any of these are observed, ask a neonatologist to assess the baby (transfer both the woman and baby if they are at home or in a freestanding midwifery unit, following the general principles for transfer of care described in recommendations 46 to 50). [new 2014]

279. If there are no signs of infection in the woman, do not give antibiotics to either the woman or the baby, even if the membranes have been ruptured for over 24 hours. [2007]

280. If there is evidence of infection in the woman, prescribe a full course of broad-spectrum intravenous antibiotics. [2007]

281. Advise women with prelabour rupture of the membranes to inform their healthcare professionals immediately of any concerns they have about their baby's wellbeing in the first 5 days after birth, particularly in the first 12 hours when the risk of infection is greatest. [2007]

282. Do not perform blood, cerebrospinal fluid and/or surface culture tests in an asymptomatic baby. [2007]

283. Refer a baby with any symptom of possible sepsis, or born to a woman who has evidence of chorioamnionitis, to a neonatal care specialist immediately. [2007]

Mother–infant bonding and promoting breastfeeding

Introduction

Immediate skin-to-skin contact of mothers and babies to promote bonding and breastfeeding was reviewed in the NICE Postnatal Care guideline.[414] For ease the relevant recommendations from that guideline are reproduced.

Review question

Are there effective ways of encouraging mother–infant bonding following birth?

- Including skin to skin contact with mothers, breastfeeding.

Description of included studies

There was one systematic review identified that considered intrapartum interventions for promoting the initiation of breastfeeding, although there was no relevant intervention that this guideline covers.[424]

Recommendations on initial assessment of the baby and mother-infant bonding

284. Record the Apgar score routinely at 1 and 5 minutes for all births. [2007]

285. Encourage women to have skin-to-skin contact with their babies as soon as possible after the birth.[u] [2007]

286. In order to keep the baby warm, dry and cover him or her with a warm, dry blanket or towel while maintaining skin-to-skin contact with the woman. [2007]

287. Avoid separation of a woman and her baby within the first hour of the birth for routine postnatal procedures, for example, weighing, measuring and bathing, unless these measures are requested by the woman, or are necessary for the immediate care of the baby.[v] [2007]

288. Encourage initiation of breastfeeding as soon as possible after the birth, ideally within 1 hour.[w] [2007]

289. Record head circumference, body temperature and birth weight soon after the first hour following birth. [2007]

290. Undertake an initial examination to detect any major physical abnormality and to identify any problems that require referral. [2007]

291. Ensure that any examination or treatment of the baby is undertaken with the consent of the parents and either in their presence or, if this is not possible, with their knowledge. [2007]

Initial assessment of the mother following birth

Introduction

Appropriate maternal observations immediately after birth are discussed in this section. Advice on further appropriate maternal observations thereafter in the postnatal period are discussed in the NICE Postnatal Care guideline.[414]

Review question

Is there evidence that the assessment of the following, on admission, and throughout labour and the immediate postnatal period, affect outcomes?

- observation of vital signs.

u Recommendations relating to immediate postnatal care (within 2 hours of birth) have been adapted from Routine postnatal care of women and their babies (NICE clinical guideline 37). Please see NICE clinical guideline 37 for further guidance on care after birth.

v Recommendations relating to immediate postnatal care (within 2 hours of birth) have been adapted from Routine postnatal care of women and their babies (NICE clinical guideline 37). Please see NICE clinical guideline 37 for further guidance on care after birth.

w Recommendations relating to immediate postnatal care (within 2 hours of birth) have been adapted from Routine postnatal care of women and their babies (NICE clinical guideline 37). Please see NICE clinical guideline 37 for further guidance on care after birth.

Description of included studies

There was no relevant study identified to investigate effectiveness of each component of maternal observations immediately following birth.

Evidence statement

There is no high-level study investigating appropriate maternal observations immediately after birth.

Recommendation on initial assessment of the mother

Update 2014

292. Carry out the following observations of the woman after birth:

- Record her temperature, pulse and blood pressure. Transfer the woman (with her baby) to obstetric-led care if any of the relevant indications listed in recommendation 164 are met.
- Uterine contraction and lochia.
- Examine the placenta and membranes: assess their condition, structure, cord vessels and completeness. Transfer the woman (with her baby) to obstetric-led care if the placenta is incomplete.
- Early assessment of the woman's emotional and psychological condition in response to labour and birth.
- Successful voiding of the bladder. Assess whether to transfer the woman (with her baby) to obstetric-led care after 6 hours if her bladder is palpable and she is unable to pass urine.

Update 2014

If transferring the woman to obstetric-led care, follow the general principles for transfer of care described in recommendations 46 to 50. [new 2014]

Perineal care

Previous guideline

No previous guidelines have considered interventions related to perineal or genital care immediately following childbirth.

Definition of perineal or genital trauma

Review question

What is the appropriate definition of perineal or genital trauma?

Overview of available evidence and evidence statement

The GDG discussed this and reached consensus to use the following recommendation for the definition of perineal or genital trauma, taken from the Green Top Guideline by the Royal College of Obstetricians and Gynaecologists on methods and materials used in perineal repair.[425]

Recommendation on definition of perineal/genital trauma

293. Define perineal or genital trauma caused by either tearing or episiotomy as follows:

- first degree – injury to skin only
- second degree – injury to the perineal muscles but not the anal sphincter
- third degree – injury to the perineum involving the anal sphincter complex:
  - 3a – less than 50% of external anal sphincter thickness torn
  - 3b – more than 50% of external anal sphincter thickness torn
  - 3c – internal anal sphincter torn.

- fourth degree – injury to the perineum involving the anal sphincter complex (external and internal anal sphincter) and anal epithelium. [2007]

Assessment of perineal trauma

Review question

Is there evidence that the type of assessment used to identify perineal or genital trauma affects outcomes?

Description of available evidence

Three studies are reviewed in this subsection. The first is an evaluation of a perineal assessment and repair course. The other two prospective intervention studies examine the incidence of third- and fourth-degree perineal trauma and highlight under-diagnosis as a problem in this aspect of care.

Review findings

A recent UK before and after study evaluated the effectiveness of a perineal repair course.[426] [EL = 2+] The one-day course included lectures, video demonstrations and hands-on teaching of rectal examination and suturing skills using foam pads and models. Participants completed a self-assessment questionnaire prior to the course and 8 weeks afterwards. Findings for the evaluation are based on responses to 147 pairs of pre- and post-course questionnaires (response rate = 71%). Most respondents were midwives (95%), 68% of whom had been qualified for more than 5 years. Seven junior doctors and three students also attended the courses. Following attendance at the course, self-assessed responses showed an improvement in the correct classification of tears depending upon degree of anal sphincter injury: external anal sphincter (EAS) partially torn: 77% versus 85%, P = 0.049; EAS completely torn: 70% versus 85%, P = 0.001; internal anal sphincter (IAS) exposed but not torn: 63% versus 82%, P < 0.001; IAS torn: 45% versus 67%, P < 0.001; anal sphincter and mucosa torn: 80% versus 89%, P = 0.031. There was also a significant change in practice reported with more respondents performing a rectal examination prior to repairing perineal trauma after attending the course: 28% versus 89%, P < 0.001, McNemar's test). There was also a significant shift in favour of a continuous suture to the perineal muscle and skin: continuous suture to muscle: 32% versus 84%, P < 0.001; continuous suture to skin 39% versus 81%, P < 0.001. The paper does not mention two-stage perineal repair as an option.

A prospective intervention study recently conducted in the UK involved re-examination by an experienced research fellow of nulliparous women who sustained perineal trauma in order to ascertain the prevalence of clinically recognisable and true occult anal sphincter injuries.[427] [EL = 2+] Women were initially assessed by the attending clinician. Where obstetric anal sphincter injuries (OASIS) were identified, this was confirmed by a specialist registrar or consultant. All participating women (n = 241; response rate = 95%) had an endoanal ultrasound scan performed immediately following birth (prior to suturing). Most of these women (n = 208 (86%)) attended for a repeat ultrasound scan at 7 weeks postpartum. One hundred and seventy-three of the 241 births were attended by midwives, 75% of these births being attended by midwives with at least 5 years of experience. Of the 68 births attended by obstetricians, 63 were instrumental births. The prevalence of OASIS increased significantly from 11% to 24.5% when women were re-examined by the research fellow. Of the 173 births attended by midwives, eight women were diagnosed as having sustained an OASIS. Only four of these were confirmed by the research fellow. Of the remaining 26 women who sustained OASIS, the midwife made a diagnosis of second-degree tear in 25 cases and first-degree tear in one case. All 30 incidents of OASIS were confirmed by the specialist registrar/consultant. Of the 68 births attended by obstetricians, 22 women (32%) had OASIS diagnosed and confirmed by the research fellow. A further seven cases of OASIS were identified by the research fellow, three of these cases had been missed by the duty specialist registrar but were

subsequently confirmed by the specialist consultant. Of the 68 births attended by an obstetrician, the midwife caring for the woman was also asked to perform an examination. Only one of the 29 OASIS was identified by a midwife and no midwife performed a rectal examination. All women with OASIS had a defect detected by endoanal ultrasound performed immediately after birth. In addition, there were three defects seen on ultrasound that were not seen clinically. No additional defects were seen at the 7 week follow-up.

A UK prospective observational study was undertaken to assess whether clinical diagnosis of third-degree tears could be improved by increased vigilance in perineal assessment.[428] [EL = 3] The study involved assessment of perineal trauma sustained by women having their first vaginal birth at one large teaching hospital. A group of 121 women were assessed initially by the obstetrician or midwife attending the birth and then again by a single independent assessor (a clinical research fellow). Findings from this group were compared with all other women giving birth over the same 6 month period who were assessed by the attending clinician only (i.e. usual care) (n = 362). Both groups were similar for a number of key characteristics, including gestation, mode of birth, analgesia used, duration of labour, birthweight, and head circumference. Episiotomies which extended to involve the anal sphincter were classified as third-degree tears. There were significantly more third-degree tears identified in the assessed group, 14.9%, compared with 7.5% in the control group. The study was underpowered to show statistical significance. In the assessed group, only 11 of the 18 third-degree tears were identified by the clinician attending the birth. Once the diagnosis was made there was no disagreement between attending clinician and research fellow. Third-degree tears were most often associated with instrumental births, especially forceps births. The percentages of women sustaining a third-degree tear for each mode of birth was spontaneous vaginal birth 3.2%, ventouse 14.9% and forceps 22%. Comparing study data with findings for a similar group of women during the 6 months before and after the study period, the overall rates of third-degree tears were before 2.5%, during 9.3%, and after 4.6%, again suggesting that many third-degree tears go undiagnosed.

Evidence statement

There is low-level evidence that suggests the systematic assessment of the vagina, perineum and rectum is required to adequately assess the extent of perineal trauma.

There is low-level evidence that current training is inadequate regarding assessment of perineal trauma.

Practitioners who are appropriately trained are more likely to provide a consistent, high standard of perineal care.

Recommendations on assessment of perineal trauma

294. Before assessing for genital trauma:

- explain to the woman what is planned and why
- offer inhalational analgesia
- ensure good lighting
- position the woman so that she is comfortable and so that the genital structures can be seen clearly. [2007]

295. Perform the initial examination gently and with sensitivity. It may be done in the immediate period after birth. [2007]

296. If genital trauma is identified after birth, offer further systematic assessment, including a rectal examination. [2007]

297. Include the following in a systematic assessment of genital trauma:

- further explanation of what is planned and why
- confirmation by the woman that tested effective local or regional analgesia is in place
- visual assessment of the extent of perineal trauma to include the structures involved, the apex of the injury and assessment of bleeding
- a rectal examination to assess whether there has been any damage to the external or internal anal sphincter if there is any suspicion that the perineal muscles are damaged. [2007]

298. Ensure that the timing of this systematic assessment does not interfere with mother–baby bonding unless the woman has bleeding that requires urgent attention. [2007]

299. Assist the woman to adopt a position that allows adequate visual assessment of the degree of trauma and for repair. Only maintain this position for as long as necessary for systematic assessment and repair. If it is not possible to adequately assess the trauma, transfer the woman (with her baby) to obstetric-led care, following the general principles for transfer of care described in recommendations 46 to 50. [2007, amended 2014]

Update 2014

300. Seek advice from a more experienced midwife or obstetrician if there is uncertainty about the nature or extent of the trauma. Transfer the woman (with her baby) to obstetric-led care (following the general principles for transfer of care described in recommendations 46 to 50) if the repair needs further surgical or anaesthetic expertise. [2007, amended 2014]

301. Document the systematic assessment and its results fully, possibly pictorially. [2007]

302. All relevant healthcare professionals should attend training in perineal/genital assessment and repair, and ensure that they maintain these skills. [2007]

Perineal repair

Review question

Is there evidence that undertaking repair, the timing, analgesia and method and material of perineal repair affect outcomes?

Previous guideline

No previous guideline has considered performing perineal repair following childbirth.

Undertaking repair

Description of included studies

Two studies are reviewed under this heading. One RCT compared suturing of first- and second-degree perineal tears with non-suturing, and one qualitative study explored women's experiences of perineal repair.

Review findings

One UK RCT compared suturing with non-suturing of first- and second-degree perineal tears (SUNS trial).[429] [EL = 1+] Randomisation was carried out across two hospital labour wards with stratification for degree of tear to produce a group of nulliparous women who had perineal tears sutured (n = 33) and nulliparous women whose perineal trauma was not sutured (n = 41). Suturing was conducted in accordance with the hospital protocols, which included continuous subcutaneous sutures to the perineal skin. No differences were apparent between trial groups at any time point postnatally regarding level of pain as measured using the McGill

Pain Questionnaire. The median total pain scores and point difference in medians for sutured versus unsutured groups were: day 1: 11 [range 0 to 33] versus 10 [range 0 to 44]; 1 [95% CI −2 to 4.999]; day 10: 0 [range 0 to 18] versus 0 [range 0 to 33]; 0 [95% CI 0 to 0.001]; 6 weeks: 0 [range 0 to 28] versus 0 [range 0 to 7]; 0 [95% CI 0 to 0]. Scores obtained using a 10 cm VAS also showed no differences between groups. Healing was measured using a standardised and validated tool, the REEDA scale. Findings showed significantly better wound edge approximation for women in the sutured group (again expressed in terms of median for scores): day 1: 1 [range 0 to 3] versus 2 [range 1 to 3]; −1 [95% CI −1.0001 to 0], P < 0.001; day 10: 1 [range 0 to 2] versus 2 [range 0 to 3]; −1 [95% CI −1.0001 to −0.0003], P = 0.003; 6 weeks: 1 [range 0 to 1] versus 1 [range 0 to 3]; 0 [95% CI −0.9999 to 0.0001], P = 0.001. Total healing scores suggested a tendency towards better wound healing in the sutured group at days 1 and 10: day 1: [range 0 to 9] versus 5 [range 1 to 10]; −1 [95% CI −2 to 0], NS; day 10: 1 [range 0 to 6] versus 2 [range 0 to 8]; 0 [95% CI −1 to 0], NS. At 6 weeks women in the sutured group had significantly better healing scores than those in the unsutured group: 0 [range 0 to 3] versus 1 [range 0 to 3]; 0 [95% CI −1.0001 to −0.0003], P = 0.003. The authors conclude that, despite the small sample size for this trial, the findings show significantly improved healing following perineal suturing compared with non-suturing.
One qualitative study was identified which explored women's experiences of perineal trauma both during its repair and in the immediate postnatal period.[430] [EL = 3] This small (n = 6), in-depth, unstructured interview-based study is limited by its reliance on the snowballing technique, which tends to result in a sample of people with similar experiences and/or views. It does, however, highlight the intense and far-reaching effects of bad experiences of care. The importance of interpersonal relationships between women and their carers was illustrated through four emergent themes:

- the importance of communication between women and health professional
- the importance of good pain relief during suturing
- women feeling 'being patched up'
- women having to endure a procedure that had to be 'got through'.

Postnatally, women described the feelings associated with coming to terms with perineal trauma. The themes here comprised:

- the severity of negative emotions (anger, upset, frustration)
- concerns about the degree of skill of practitioners
- failing to be heard and taken seriously when there were problems with perineal healing.

Evidence statement

There is limited high-level evidence that not suturing first- or second-degree perineal trauma is associated with poorer wound healing at 6 weeks.
There is no evidence as to long-term outcomes.

Recommendations on perineal repair

303. Advise the woman that in the case of first-degree trauma, the wound should be sutured in order to improve healing, unless the skin edges are well opposed. [2007]

304. Advise the woman that in the case of second-degree trauma, the muscle should be sutured in order to improve healing. [2007]

Timing of repair

Description of included studies

No study was identified which considered the timing of perineal repair following childbirth.

Evidence statement

There is no high-level evidence on timing of perineal repair following childbirth.

Recommendations on timing of repair

305. Undertake repair of the perineum as soon as possible to minimise the risk of infection and blood loss. [2007]

Analgesia used during perineal repair

Description of included studies

There is no evidence regarding the use of analgesia during perineal repair.

Evidence statement

There is no high-level evidence on use of analgesia during perineal repair.

Recommendations on analgesia for perineal repair

306. When carrying out perineal repair:

- ensure that tested effective analgesia is in place, using infiltration with up to 20 ml of 1% lidocaine or equivalent
- top up the epidural or insert a spinal anaesthetic if necessary. [2007]

307. If the woman reports inadequate pain relief at any point, address this immediately. [2007]

Method of perineal repair

Description of included studies

A systematic review of four RCTs plus an additional RCT investigated the effects of continuous subcuticular with interrupted transcutaneous sutures for perineal repair. Two further RCTs compared a two-layer repair technique (leaving the skin unsutured) with a three-layer repair technique.

Review findings

One systematic review (1998) was identified which compared the effects of continuous subcuticular with interrupted transcutaneous sutures for perineal repair.[431] [EL = 1+] Four RCTs were included in the review involving a total of 1864 women. The continuous subcuticular method was found to be associated with less short-term pain (up to day 10 postpartum) compared with interrupted sutures (three trials): 160/789 versus 218/799, OR 0.68 [95% CI 0.53 to 0.86]. No other differences were apparent between the two trials groups for the outcomes tested: analgesia up to day 10 (two trials): 56/527 versus 65/541, OR 0.86 [95% CI 0.58 to 1.26]; reported pain at 3 months (one trial): 58/465 versus 51/451, OR 1.12 [95% CI 0.75 to 1.67]; removal of suture material (up to 3 months) (one trial): 121/465 versus 16/451, OR 0.61 [95% CI 0.46 to 0.80]; failure to resume pain-free intercourse (up to 3 months) (one trial): 157/465 versus 144/451, OR 1.09 [95% CI 0.82 to 1.43]; resuturing (up to 3 months) (two trials, one with no incidents): 3/487 versus 3/531, OR 1.11 [95% CI 0.22 to 5.53]; dyspareunia (up to 3 months) (three trials): 172/775 versus 184/749, OR 0.88 [95% 0.69 to 1.12]. The authors concluded that the continuous subcuticular technique of perineal repair may be associated with less pain in the immediate postpartum period than the interrupted suture technique. The long-term effects are less clear. It is also noted that, while three studies used the same suture material (Dexon) throughout the repair, one trial compared repair using chromic catgut with repair using Dexon. Also, there was considerable heterogeneity between studies regarding skill and training of persons carrying out the repair.

The single trial that demonstrated a statistically significant reduction in short-term pain for women in the continuous subcuticular repair group was the trial that also ensured staff were trained and practised in this technique prior to the trial.

A recent UK RCT compared continuous versus interrupted perineal repair with standard or rapidly absorbed sutures.[432] [EL = 1+] The study was a 2 × 2 factorial design to allow both comparisons to be made. Findings from the trial relating to method of repair will be reported here (see the next subsection for findings from the materials arm of the trial). A continuous suturing technique for perineal repair (vaginal wall, perineal muscle and skin repaired with one continuous suture) (n = 771) was compared with interrupted sutures (continuous suture to vaginal wall, interrupted sutures to perineal muscle and skin) (n = 771). The trial included women with first- or second-degree tears or an episiotomy following a spontaneous birth. Continuous subcuticular sutures were associated with significantly less short-term perineal pain compared with interrupted sutures: pain at 2 days: 530/770 versus 609/770, OR 0.59 [95% CI 0.44 to 0.79]; pain at 10 days: 204/770 versus 338/769, OR 0.47 [95% CI 0.35 to 0.61]. This reduction in pain at 10 days was noted while sitting, walking, passing urine and opening bowels. No difference was noted between groups regarding long-term pain measures, for example: pain at 3 months: 70/751 versus 96/741, OR 0.70 [95% CI 0.46 to 1.07]; pain at 12 months: 31/700 versus 47/689, OR 0.64 [95% CI 0.35 to 1.16]; dyspareunia at 3 months: 98/581 versus 102/593, OR 0.98 [95% CI 0.72 to 1.33]; dyspareunia at 12 months: 94/658 versus 91/667, OR 1.05 [95% CI 0.77 to 1.43]. Fewer women with continuous sutures reported that the sutures were uncomfortable 2 days post-repair: 273/770 versus 318/770, OR 0.78 [95% CI 0.64 to 0.96]. This difference was slightly more marked at 10 days (OR 0.58 [95% CI 0.46 to 0.74]). Significantly more women in the interrupted group reported tight sutures both at 2 and 10 days, although the numbers were quite small. The need for suture removal was significantly higher in the interrupted group: suture removal between 10 days and 3 months: 22/751 versus 63/741, OR 0.36 [95% CI 0.23 to 0.55]. Wound gaping was more frequent following repair using the continuous technique, although again the numbers were quite small (wound gaping at 10 days: 23/770 versus 50/769, OR 0.46 [95% CI 0.29 to 0.74]). Significantly more women were satisfied with their perineal repair following repair using a continuous suture technique both at 3 months: 628/751 versus 560/741, OR 1.64 [95% CI 1.28 to 2.11] and 12 months: 603/700 versus 542/689, OR 1.68 [95%1.27 to 2.21]. Women in the continuous repair group were also more likely to report that they felt 'back to normal' at 3 months postpartum: 414/700 versus 332/689, OR 1.55 [95% CI 1.26 to 1.92]. It is noted that senior midwives (Grade G) were significantly more likely to use the continuous suturing technique compared with Grade E and F midwives. Subsequent analyses were undertaken taking this into consideration.

A UK RCT published in 1998 compared a two-stage perineal repair (n = 890) with the more usual three-stage repair (n = 890).[433] [EL = 1+] This trial also employed a 2 × 2 factorial design comparing both the method of repair and suture material used (findings regarding the latter are reported in the following subsection). At 2 days no differences were noted between the trial groups for any of the pain measures investigated: any pain in last 24 hours: 545/885 (62%) versus 569/889 (64%); analgesia in last 24 hours: 400/885 (45%) versus 392/889 (44%); tight stitches: 162/885 (18%) versus 196/889 (22%). Significantly more women in the two-stage repair group had a gaping perineal wound: 203/885 (23%) versus 40/889 (4%), $P < 0.00001$. At 10 days, while there were no significant differences in reported pain and analgesia use (reported pain in last 24 hours: 221/886 (25%) versus 244/885 (28%); analgesia in last 24 hours: 73/886 (8%) versus 69/885 (8%)), significantly more women in the three-stage repair group reported tight stitches: 126/886 (14%) versus 163/885 (18%), RR 0.77 [95% CI 0.62 to 0.96], $P = 0.02$. Incidence of perineal gaping was still higher in the two-stage repair group at 10 days: 227/886 (26%) versus 145/885 (16%), $P < 0.00001$. Women in the two-stage repair group were also significantly less likely to have had suture material removed:

26/886 (3%) versus 67/885 (8%), P < 0.0001. Incidences of repair breakdown were very low and similar for the two groups (n = 5 versus n = 7). At 3 months postpartum there were no differences in most pain measures, for example: any pain in last week: 64/828 (8%) versus 87/836 (10%); resumption of sexual intercourse: 704/828 (85%) versus 712/836 (85%); resumption of pain-free intercourse: 576/828 (70%) versus 551/836 (66%). There was, however, a difference in reported dyspareunia: 128/890 (14.3%) versus 162/890 (18.2%), RR 0.80 [95% CI 0.65 to 0.99], P = 0.04. The difference for removal of suture material was still apparent at 3 months in favour of the continuous method group: 59/828 (7%) versus 98/836 (11%), RR 0.61 [95% CI 0.45 to 0.83]. There was little resuturing required and no difference between groups (n = 4 versus n = 9).

A 1 year postal questionnaire follow-up study was carried out for the above trial, involving 793 women.[434] [EL = 1+] The follow-up sample was deliberately biased to include 31% women who had had an instrumental birth (compared with 17% in the original sample). There was no difference between groups regarding persistent pain at 1 year: 28/396 versus 26/396. Women who had undergone the three-stage perineal repair were significantly more likely to report that the perineal area 'felt different' than women who had undergone two-stage repair: 17/395 versus 157/396, RR 0.75 [95% CI 0.61 to 0.91]. Subgroup analyses showed this difference to be more marked following spontaneous births compared with instrumental births: instrumental: 45/123 versus 55/124, RR 0.82 [95% CI 0.61 to 1.12]; spontaneous: 72/272 versus 102/272, RR 0.71 [95% CI 0.55 to 0.91]; and more marked following repair using interrupted sutures compared with mixed technique or subcuticular technique: interrupted technique: 57/209 versus 87/202, RR 0.63 [95% CI 0.48 to 0.83]; mixed technique: 46/133 versus 55/136, RR 0.86 [95% CI 0.63 to 1.17]; subcuticular: 14/53 versus 15/58, RR 1.02 [95% CI 0.55 to 1.91]. There were no significant differences between groups for dyspareunia, failure to resume pain-free intercourse or need for resuturing.

A second RCT conducted in Nigeria (2003) also compared two-stage repair with three-stage repair.[435] [EL = 1+] The trial was conducted across four sites and recruited 1077 women, 823 of whom were followed up to 3 months postnatally (response rate = 76.4%). As with the UK trial, midwives and labour ward obstetricians were trained in the two-stage repair technique prior to the study. Where skin repair was undertaken, a continuous technique was taught and encouraged. Most repairs were undertaken using chromic catgut. Postnatal assessments of wound healing were carried out by a researcher blinded to the trial allocation of the woman. Compared with three-stage repair, two-stage repair was associated with less pain and fewer reports of tight sutures at 48 hours postnatally (perineal pain: 57% versus 65%, RR 0.87 [95% CI 0.78 to 0.97); tight sutures: 25% versus 38%, RR 0.67 [95% CI 0.54 to 0.82)). Analgesia use and degree of inflammation and bruising were also significantly less in the two-stage group (analgesia use: 34% versus 49%, RR 0.71 [95% CI 0.60 to 0.83]; inflammation/bruising: 7% versus 14%, RR 0.50 [95% CI 0.33 to 0.77]). Wound gaping (skin edges > 0.5 cm apart) was more prevalent in the two-stage repair group: 26% versus 5%, RR 4.96 [95% CI 3.17 to 7.76]. The differences regarding perineal pain and analgesia were still apparent at 14 days and 6 weeks postpartum in favour of the two-stage repair group. The difference in wound gaping was much smaller by 14 days: 21% versus 17%, RR 1.25 [95% CI 0.94 to 1.67]. There was no difference in wound breakdown: 3% versus 2%, RR 1.27 [95% CI 0.56 to 2.85]. At 3 months postpartum, women in the two-stage repair group reported a lower incidence of dyspareunia compared with women in the three-stage repair group: 10% versus 17%, RR 0.61 [95% CI 0.43 to 0.87]. The authors pointed out that the differences in short-term pain found in this study may be due to the fact they used catgut for most of the perineal repairs rather than a synthetic absorbable suture material.

Evidence statement

There is high-level evidence that a continuous non-locked suturing technique for repair of perineal muscle is associated with less short-term pain. More women who were repaired with a continuous non-locked technique were also satisfied with their perineal repair and felt back to normal at 3 months.
A two-stage repair (where the skin is opposed but not sutured) is associated with no differences in the incidence of repair breakdown but is associated with less dyspareunia at 3 months. There is some evidence that it is also associated with less short-term perineal pain when compared with skin repair undertaken using chromic catgut sutures.
Continuous subcuticular skin repair is associated with less short-term pain when compared with interrupted skin repair.

Recommendations on methods of perineal repair

308. If the skin is opposed after suturing of the muscle in second-degree trauma, there is no need to suture it. [2007]

309. If the skin does require suturing, use a continuous subcuticular technique. [2007]

310. Undertake perineal repair using a continuous non-locked suturing technique for the vaginal wall and muscle layer. [2007]

Materials for perineal repair

Description of included studies

One systematic review and two additional RCTs have compared the effects of absorbable synthetic suture material with catgut or chromic catgut. An additional UK RCT compared rapidly absorbed synthetic suture material with standard synthetic suture material.

Review findings

One systematic review (1999) has been conducted to assess the effects of absorbable synthetic suture material compared with catgut on short- and long-term pain experienced by women following perineal repair.[436] [EL = 1+] The review included eight trials involving 3642 women. Seven trials used polyglycolic acid (Dexon) and one trial used polyglactin (Vicryl). Women allocated to groups using absorbable synthetic suture material reported significantly less short-term pain compared with those sutured using catgut: day 3 or before: OR 0.62 [95% CI 0.54 to 0.71], eight trials; days 4–10: OR 0.71 [95% CI 0.58 to 0.87], three trials; analgesia use up to day 10: OR 0.63 [95% CI 0.52 to 0.77], five trials. Women allocated to perineal repair using absorbable synthetic suture material also reported less suture dehiscence up to day 10: OR 0.45 [95% CI 0.29 to 0.70], five trials; and need for resuturing of the perineal wound up to 3 months: OR 0.26 [95% CI 0.10 to 0.66], four trials. However, the need for removal of suture material up to 3 months was greater in the absorbable synthetic group: OR 2.01 [95% CI 1.56 to 2.58], two trials. There was no difference reported for long-term pain: OR 0.81 [95% CI 0.61 to 1.08], two trials. The authors of the review noted that the skill level of clinicians may be very different between trials, e.g. suture dehiscence in one trial was 37/71 for the control group and 12/77 for the experimental group, while in another trial there were no incidents of suture dehiscence.
One additional RCT has been conducted in Australia comparing absorbable synthetic suture material (polyglactin) (n = 194) with chromic catgut (n = 197).[437] [EL = 1+] Women with a third-degree tear or an instrumental birth were excluded from the trial. Owing to chance imbalance in the proportion of nulliparous women between the two trial groups, parity-adjusted odds ratios were calculated. There was a tendency towards reduced short-term pain in women allocated to the polyglactin group, but differences did not reach statistical

significance: perineal pain at 1 day: adjusted OR 0.64 [95% CI 0.39 to 1.06]; perineal pain at 3 days: adjusted OR 0.70 [95% CI 0.46 to 1.08]. No significant differences were seen between groups for any of the longer-term pain outcomes (any perineal pain, resumed intercourse, dyspareunia) at 6 weeks, 3 months or 6 months. At 6 weeks postpartum, eight women repaired with polyglactin reported problems with their sutures compared with three women in the catgut group (one woman in each group reported infection at wound site, the remainder reported tight sutures that required removal) (adjusted OR 2.61 [95% CI 0.59 to 12.41]).

A recent US RCT compared the healing characteristics of chromic catgut with fast-absorbing polyglactin 910.[438] [EL = 1+] Although women were recruited and randomised into trial groups during labour, analysis was only performed for those women requiring perineal repair (polyglactin 910: 459/684; chromic catgut: 49/677). This study is unusual in that pain outcomes were measured both for the perineal area (referred to as 'vaginal' pain) and uterine cramping. No differences were found between groups for vaginal pain at 24–48 hours, 10–14 days or 6–8 weeks. There were, however, some differences in uterine pain, with significantly more women in the chromic catgut group reporting moderate/severe uterine pain at 24–48 hours: no pain: n = 81 (18%) versus n = 63 (14%), NS; a little/some pain: n = 264 (58%) versus n = 232 (52%), NS; moderate/severe pain: n = 114 (25%) versus n = 154 (34%), P = 0.006. This significant difference was also evident at 6–8 weeks. No differences in uterine pain were noted at 10–14 days. The authors have no explanation for the observed differences in uterine cramping between groups based on suture material used. Given that this difference was only seen at one of the two study sites they conclude that it may simply be an anomaly of the data. At 6–8 weeks no difference was found between groups for persistent suture material (n = 2 women in each group) or perineal wound breakdown (n = 4 versus n = 3).

A UK RCT compared rapidly absorbed synthetic suture material (n = 772) with a standard form of the synthetic suture material (n = 770) within a 2 × 2 factorial study design also comparing suture method.[432] [EL = 1+] The study involved women who had sustained either a second-degree tear or an episiotomy. There was no significant difference between the two groups for the primary outcome of pain at 10 days postnatally, although findings favoured the rapidly absorbed suture material: OR 0.84 [95% CI 0.68 to 1.04]. There was, however, a significant reduction in analgesia used in the previous 24 hours reported at 10 days for women in the rapidly absorbed suture material group: OR 0.55 [95% CI 0.36 to 0.83]; and a significant reduction in pain on walking for this group: OR 0.74 [95% CI 0.56 to 0.97]. The need for removal of sutures in the 3 months following birth was also less for women sutured with the rapidly absorbed suture material: OR 0.26 [95% CI 0.18 to 0.37].

Evidence statement

There is high-level evidence that a rapidly absorbable synthetic suture material is associated with less short-term pain, less suture dehiscence and less need for resuturing of the perineum up to 3 months postpartum.

Recommendations on material for perineal repair

311. Use an absorbable synthetic suture material to suture the perineum. [2007]

312. Observe the following basic principles when performing perineal repairs:

- Repair perineal trauma using aseptic techniques.
- Check equipment and count swabs and needles before and after the procedure.
- Good lighting is essential to see and identify the structures involved.

- Ensure that difficult trauma is repaired by an experienced practitioner in theatre under regional or general anaesthesia.
- Insert an indwelling catheter for 24 hours to prevent urinary retention.
- Ensure that good anatomical alignment of the wound is achieved and that consideration is given to the cosmetic results.
- Carry out rectal examination after completing the repair to ensure that suture material has not been accidentally inserted through the rectal mucosa.
- After completion of the repair, document an accurate detailed account covering the extent of the trauma, the method of repair and the materials used.
- Give the woman information about the extent of the trauma, pain relief, diet, hygiene and the importance of pelvic-floor exercises. [2007]

Research recommendation on analgesia during perineal repair

30. Research is needed into the optimum analgesia required during perineal repair.

Analgesia for perineal pain following perineal repair

Description of included studies

A systematic review of three RCTs and one additional RCT were identified which assessed the effectiveness of analgesic rectal suppositories for pain from perineal trauma following childbirth.

Review findings

A systematic review including 249 women assessed the effectiveness of analgesic rectal suppositories for pain from perineal trauma following childbirth.[439] [EL = 1+] All trials used nonsteroidal anti-inflammatory analgesia suppositories, one trial (Saudi Arabia) compared indometacin with a placebo, while the other two trials (UK) compared diclofenac (Voltarol) with a placebo. All trials administered a suppository immediately after perineal repair was complete. In one UK trial, a single dose of 100 mg was given, in the second (Saudi) trial, 2 × 100 mg suppositories were inserted together immediately following perineal repair, and in the third trial (UK), one suppository was given immediately after suturing and another 12 hours later. Findings suggest that nonsteroidal anti-inflammatory drugs (NSAIDs) administered as rectal suppositories provide effective pain relief following perineal repair (two trials). For indometacin the incidence of perineal pain in the first 24 hours was 6/30 versus 30/30, RR 0.20 [95% CI 0.10 to 0.41]; for diclofenac: RR 0.65 [95% CI 0.50 to 0.85]. The meta-analysis of these two findings produces a wide confidence interval that crosses 1 (RR 0.37 [95% CI 0.10 to 1.38] (two trials)). Findings from the other trial are reported as median scores obtained using a VAS. Women in the diclofenac group reported significantly less pain at 24 hours than women in the placebo group (diclofenac: median 1 [range 0 to 2.5], placebo: median 1 [range 0 to 3], $P < 0.05$ using Mann–Whitney U test). Only one trial included the outcome of any pain experienced 24–72 hours after perineal repair, with the effect of treatment just failing to reach statistical significance: RR 0.73 [95% CI 0.53 to 1.02]. Findings from a stratified analysis for level of pain experienced within the first 24 hours following perineal repair suggest that NSAIDs have their best level of effect for moderate pain compared with mild or severe pain: mild: RR 1.12 [95% CI 0.70 to 1.80] (two trials); moderate: RR 0.13 [95% CI 0.02 to 0.76] (two trials); severe: RR 0.21 [95% CI 0.01 to 4.12] (two trials). Use of additional analgesia was also measured as an outcome in two trials, although not in a way that allows pooling of data. Both trials showed a significant reduction in use of additional

analgesia up to 48 hours postpartum. None of the trials reported longer term outcomes such as breastfeeding, effects on mother–infant interactions, postnatal depression or return to pain-free intercourse. All three trials reported that there were no side effects associated with the treatment, although none investigated this as an identified outcome.
An RCT conducted in Australia (2004) also evaluated the effectiveness of rectal diclofenac compared with a placebo.[440] [EL = 1+] Women in the treatment group (n = 67) received a diclofenac suppository immediately after perineal repair (of a second-degree tear, third-degree tear or episiotomy). Women randomised to the control group received a placebo (Anusol) suppository. Both groups received a second suppository 12–24 hours later. Pain was measured in three ways – using the Short-form McGill Pain Questionnaire (SF-MPQ), using a 10 cm VAS and using the Present Pain Inventory (PPI). At 24 hours postnatally, women's pain scores were significantly lower for the treatment group compared with the control group, although this was not evident across all measurement scales: at rest: SF-MPQ total score: median 6 [IQR 3 to 11] versus 7 [IQR 3 to 12], NS; VAS: mean 2.8 [SD 0.3] versus 3.9 [SD 0.3]: RR −1.1 [95% CI −1.9 to −0.3], P = 0.01; PPI: mean 31 [SD 53.4] versus 32 [57.1]; RR 0.9 [95% CI 0.7 to 1.3], P = 0.69. For pain scores with movement at 24 hours both the VAS and the PPI score were significantly lower in the treatment group, although this difference was not evident for total SF-MPQ scores. By 48 hours there were no differences in reported pain between the two groups for any of the pain outcome measures. There was also no difference between groups regarding the use of additional analgesia prior to discharge: 81% versus 86%, RR 0.9 [95% CI 0.8 to 1.1] or time from birth to first analgesia (hours): median 6.4 [IQR 3.5 to 10.5] versus 5.8 [IQR 2.9 to 10.2]. Pain outcomes during activities at 10 days and 6 weeks postnatally were also similar for the two groups.

Evidence statement

There is high-level evidence that rectal NSAIDs reduce immediate perineal pain following repair.

Recommendation on analgesia for perineal pain following perineal repair

313. Offer rectal non-steroidal anti-inflammatory drugs routinely after perineal repair of first- and second-degree trauma provided these drugs are not contraindicated. [2007]

Glossary and abbreviations

Glossary

Term	Definition
Active management of the third stage	A package of care comprising the following components: • routine use of uterotonic drugs • clamping and cutting of the cord • controlled cord traction after signs of separation of the placenta.
Acute sector	Hospital-based health services which are provided on an in-patient, day case or outpatient basis.
Allied health professionals	Healthcare professionals, other than doctors and nurses, directly involved in the provision of healthcare. Includes several groups such as physiotherapists, occupational therapists, dieticians. (Formerly known as professions allied to medicine or PAMs.)
Alongside midwifery-led unit (AMU)	A birth centre in the same hospital as the obstetric unit but separate from the obstetric unit. This may be adjacent or could be in a separate building. Care is only provided by midwives. An AMU should not contain any equipment for conducting

Term	Definition
	cardiotocography and it is not possible to administer an epidural in an AMU. For interventions such as these, the woman will need to be transferred to an obstetric unit for obstetric-led care.
Amnioinfusion	A method of diluting meconium-stained liquor through an infusion of fluid into the amniotic cavity.
Amniotomy	Amniotomy refers to artificial rupturing of the membranes. This is performed during a vaginal examination using an elongated plastic hook which is used to pierce the membranes, thus releasing the amniotic fluid. This is carried out to shorten the duration of labour.
Bradycardia	For the fetus, this is defined as a heart rate of less than 110 beats per minute.
Cardiotocography	Electronic recording of the fetal heart rate using either a Doppler ultrasound transducer strapped to the woman's abdomen, or an electrode attached to the fetal scalp, plus a second toco transducer strapped to the woman's abdomen to record uterine contractions.
Clinical audit	A systematic process for setting and monitoring standards of clinical care. Whereas 'guidelines' define what the best clinical practice should be, 'audit' investigates whether best practice is being carried out. Clinical audit can be described as a cycle or spiral. Within the cycle there are stages that follow a systematic process of establishing best practice, measuring care against specific criteria, taking action to improve care and monitoring to sustain improvement. The spiral suggests that as the process continues, each cycle aspires to a higher level of quality.
Clinical governance	A framework through which NHS organisations are accountable for both continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Clinician	A healthcare professional providing patient care, such as a doctor, nurse or physiotherapist.
Coordinating midwife	The senior midwife who is in charge of labour unit or ward with responsibility for supporting, guiding and coordinating the work of the midwives and other healthcare professionals working in the unit/ward.
Decision to delivery interval	The time taken between the decision to expedite a birth and the birth.
Elective	Name for clinical procedures that are regarded as advantageous but not urgent and can be planned.
Electrocardiogram (ECG)	A method for measuring the electrical activity of the baby's heart. Normally, it is measured by attached an electrode to the baby's scalp.
Established labour	Labour is established when: • there are regular painful contractions, and • there is progressive cervical effacement and dilatation beyond 4 cm.
Expectant management	Awaiting events to take their natural course. This would usually include observation of the woman and/or baby's condition.
Fetal blood sampling	A technique to measure the level of acid-base status of the baby's blood. A sample of blood is taken from the baby's scalp and either the pH or lactate value is measured. It is used as an adjunct to cardiotocography to help to clarify whether the baby is developing an acidosis when may cause additional interventions to be required.
Freestanding midwifery-led unit (FMU)	A birth centre which is located away from hospital buildings where care is provided for pregnant women by midwives only. These can vary in size from a dedicated room to a large unit. An FMU should not contain any equipment for undertaking cardiotocography or the facilities to administer an epidural. For interventions such as these, the woman will need to be transferred by ambulance to an obstetric unit for obstetric-led care.
High fetal head	The guideline development group defines this as the circumstance where the fetal head is fully ('five-fifths') palpable on abdominal examination.

Term	Definition
Home birth	Birth which occurs in the woman's own home. Care for birth is provided by 2 midwives.
Intermittent auscultation	Intermittent measurement of the fetal heart rate using a Doppler ultrasound or a Pinard stethoscope. The time between measurements depends on the stage of labour.
Latent phase	A period of time, not necessarily continuous, when: • there are painful contractions, and • there is some cervical change, including cervical effacement and dilatation up to 4 cm.
Meconium-stained liquor	Amniotic fluid which contains meconium. This guideline defines the presence of meconium-stained liquor as either 'non-significant' or 'significant': • Non-significant meconium is pale green or yellow amniotic fluid that is thin and with no lumps of meconium present. It is sometimes referred to as 'light' or 'thin' meconium. • Significant meconium is dark green or black amniotic fluid that is thick or tenacious or any meconium-stained amniotic fluid containing lumps of meconium. It is sometimes referred to as 'heavy' or 'thick' meconium.
Midwife-led care	Care in labour where a midwife is responsible for the woman's care. This can be provided in a home setting, in a freestanding midwifery-led unit, in an alongside midwifery-led unit or in an obstetric-led unit (if a low-risk woman gives birth in an obstetric-led unit, it is likely that she will receive midwife-led care).
Obstetric-led care	Care in labour where the obstetrician is responsible for the woman's care. This should only be provided in an obstetric-led unit in a hospital. Much of the woman's care will still be provided by a midwife.
One-to-one care	Care provided for the woman throughout labour exclusively by a midwife solely dedicated to her care (not necessarily the same midwife for the whole of labour).
p value	A statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing 2 treatments found that 1 seems more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance) it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant. If the p value shows that there is likely to be a difference between treatments, the confidence interval describes how big the difference in effect might be.
Physiological management of the third stage	A package of care comprising the following components: • no routine use of uterotonic drugs • no clamping of the cord until pulsation has stopped • delivery of the placenta by maternal effort.
Placebo	Placebos are fake or inactive treatments received by participants allocated to the control group in a clinical trial which are indistinguishable from the active treatments being given in the experimental group. They are used so that participants are ignorant of their treatment allocation in order to be able to quantify the effect of the experimental treatment over and above any placebo effect due to receiving care or attention.
Placebo effect	A beneficial (or adverse) effect produced by a placebo and not due to any property of the placebo itself.
Postpartum haemorrhage	Blood loss over 500 ml from the vagina following labour.
Primary care	Healthcare delivered to patients outside hospitals. Primary care covers a range of services provided by GPs, nurses and other healthcare professionals, dentists, pharmacists and opticians.

Term	Definition
Prolonged third stage of labour	Third stage of labour which hasn't completed within 30 minutes of the birth of the baby with active management and within 60 minutes with physiological management.
Quality adjusted life years (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a zero to 1 scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.
Second stage of labour	This guideline uses the following definitions: • Passive phase of the second stage of labour is the time/period/interval: o from full dilatation of the cervix prior to or in the absence of involuntary expulsive contractions. • Active phase of the second stage of labour is the time/period/interval when: o the baby's head is visible at the introitus OR o there are expulsive contractions at full dilatation of the cervix OR o there is active maternal effort at full dilatation of the cervix.
Secondary care	Care provided in hospitals.
Sensitivity	In diagnostic testing, sensitivity is the proportion of true positive results that are correctly identified as positive by the test. 100% sensitivity means that all those with a negative test result do not have the disease. Specificity should be considered alongside sensitivity to fully judge the accuracy of a test.
Sinusoidal fetal heart rate trace	A fluctuating persistent fetal heart rate pattern 2–5 cycles per minute (peak-to-peak) and more than 5 cycles per minute (peak-to-nadir). Baseline variability is reduced and the peaks are rounded. This pattern is commonly associated with significant pathology including fetal anaemia (in the antenatal period), acute blood loss or fetal acidosis/hypoxia. Traditionally a 'pseudosinusoidal' pattern is characterised by being intermittent, baseline variability is not lost and the peaks are often pointed or irregular. The pattern is commonly benign, being associated with fetal breathing or other movements or maternal narcotic analgesic use. Although this is the traditional distinction between 'sinusoidal' and 'pseudosinusoidal' patterns, some studies use the term 'pseudosinusoidal' when it really is 'sinusoidal'. In addition, such 'pseudosinusoidal' patterns are classified on the amplitude of oscillations and frequency of the cycles (minor being peak to nadir of 5–15 beats per minute (bpm); intermediate being 16–24 bpm; major being 25 bpm or more).*
Specificity	In diagnostic testing, specificity is the proportion of true negative results that are correctly identified as negative by the test. 100% specificity means that all those with a positive test result have the disease. Sensitivity should be considered alongside specificity to fully judge the accuracy of a test.
ST analysis	ST analysis is a method of assessing the fetal condition in labour using the characteristics of the ST segment of the fetal electrocardiogram.
Tachycardia	For the fetus, this is defined as a heart rate of over 160 beats per minute.
Telemetry	A method of continuous electronic fetal monitoring using a wireless system.
Third stage of labour	The interval from the birth of the baby to the expulsion of the placenta and membranes.
Tocolytic	A drug used to prevent or lessen uterine contractions
Transfer	This term indicates where responsibility for the woman's care passes from one healthcare professional to another. This may or may not also involve a physical transfer of the woman from one birth setting to another.
Uterotonic	A drug used to induce uterine contractions.

**See section 10.3*

Abbreviations

AMU	Alongside midwifery unit
BIP	Behavioural Index of Pain
BMI	Body mass index
BP	Blood pressure
CEMACH	Confidential Enquiry into Maternal and Child Health
CI	Confidence interval
CS	Caesarean section
CSE	Combined spinal-epidural
CTG	Cardiotocography
DCC	Delayed cord clamping
df	Degrees of freedom
EAS	External anal sphincter
ECC	Early cord clamping
ECG	Electrocardiogram
EFM	Electronic fetal monitoring
EL	Evidence level (level of evidence)
Entonox®	50:50 mixture of oxygen and nitrous oxide
EPDS	Edinburgh Posntatal Depression Scale
FBS	Fetal blood sampling
FHR	Fetal heart rate
FMU	Freestanding midwifery unit
GDG	Guideline development group
GP	General practitioner
IA	Intermittent auscultation
IAS	Internal anal sphincter
IM	Intramuscular
IPPM	Intrapartum-related perinatal mortality
IQR	Interquartile range
IU	International unit
IV	Intravenous
LR	Likelihood ratio
MAS	Meconium aspiration syndrome
MBI	Maslach Burnout Inventory
MD	Mean difference
MLAC	Minimum local analgesic concentration
MSL	Meconium-stained liquor
NACS	Neurological and adaptive capacity score
NCC-WCH	National Collaborating Centre for Women's and Children's Health
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICU	Neonatal intensive care unit
NS	Not significant
NSAIDS	Nonsteroidal anti-inflammatory drugs

OA	Occiput anterior
OASIS	Obstetric anal sphincter injuries
OP	Occiput posterior
OR	Odds ratio
OT	Occiput transverse
OU	Obstetric unit
PCA	Patient-controlled analgesia
PCEA	Patient-controlled epidural analgesia
PPH	Postpartum haemorrhage
PPI	Present pain intensity
PRoM	Prelabour rupture of membranes
QALY	Quality adjusted life year
RCT	Randomised controlled trial
RR	Relative risk
SCBU	Special care baby unit
SD	Standard deviation
TENS	Transcutaneous electrical nerve stimulation
TRIP	Turning Research into Practice
UVI	Umbilical vein injection
VAS	Visual analogue scale
VE	Vaginal examination
W-DEQ	Wijma Delivery Expectancy/Experience Questionnaire
WMD	Weighted mean difference

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