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

Intrapartum care

care of healthy women and their babies during childbirth

Clinical Guideline

September 2007

Funded to produce guidelines for the NHS by NICE

Intrapartum care

care of healthy women and their babies during childbirth

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

Commissioned by the National Institute for Health and Clinical Excellence

September 2007

RCOG Press

Published by the **RCOG Press** at the Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, Regent's Park, London NW1 4RG

www.rcog.org.uk

Registered charity no. 213280

First published 2007, revised reprint 2008 (pages 106 and 108 and evidence tables page 176)

ISBN 978-1-904752-36-3

RCOG Editor: Andrew Welsh
Original design: FiSH Books, London
Typesetting: Andrew Welsh
Proofreading: Katharine Timberlake (Reedmace Editing)
Index: Jan Ross (Merrall-Ross (Wales) Ltd)
Printed by Henry Ling Ltd, The Dorset Press, Dorchester DT1 1HD

Contents

Guideline Development Group membership and acknowledgements

Guideline Development Group

GDG members

Sara Kenyon	Senior Research Fellow/Guideline Development Group Leader
Tony Ducker	Consultant Neonatologist
Simon Grant	Consultant in Obstetrics and Fetal Medicine
Gill Gyte	Women's Representative (resigned June 2007)
Jayne Jempson	Labour Ward Matron
Carolyn Markham	Women's Representative
Geraldine O'Sullivan	Obstetric Anaesthetist
Julia Sanders	Consultant Midwife
Maureen Treadwell	Women's Representative
Derek Tuffnell	Consultant in Obstetrics
Steve Walkinshaw	Consultant in Obstetrics
Marina Wells	Recruitment and Retention Midwife

National Collaborating Centre for Women's and Children's Health (NCC-WCH) technical team

Martin Whittle	Clinical Co-Director for Women's Health
Martin Dougherty	Executive Director
Rintaro Mori	Research Fellow
Roz Ullman	Senior Research Fellow
Paul Jacklin	Senior Health Economist
Peny Retsa	Health Economist
Debbie Pledge	Senior Information Specialist
Samantha Vahidi	Senior Work Programme Coordinator

Acknowledgements

Additional support was received from Hannah-Rose Douglas, Sjokvist Garcia-Steward, Eva Gautam, Anuradha Sekhri, Rosie Crossley, Paula Broughton-Palmer and Jane Thomas at the NCC-WCH, Wendy Riches, Francoise Cluzeau, Joanne Lord and Phil Alderson at the National Institute for Health and Clinical Excellence (NICE), Sam Richmond at Sunderland Hospital, Peter Brocklehurst and Rona McCandlish at the National Perinatal Epidemiology Unit (NPEU) and Pat Doyle at the London School of Hygiene & Tropical Medicine. We would particularly like to thank Sonja Henderson and the Pregnancy and Childbirth Cochrane Collaboration for access to their reviews prior to publication, Jo Greene and Helen Baston from York and Stavros Petrou from NPEU for their expertise. We also thank the Patient and Public Involvement Programme (PPIP) for NICE whose glossary was adapted for use in this guideline.

Stakeholder organisations

Academic Division of Midwifery, University of Nottingham
Action on Pre-Eclampsia
Addenbrooke's NHS Trust
Airedale General Hospital – Acute Trust

All Wales Birth Centre Group
Alliance Pharmaceuticals Ltd
Anglesey Local Health Board
Association for Continence Advice
Association for Improvements in Maternity Services (AIMS)
Association of Anaesthetists of Great Britain and Ireland
Association of Baby Charities
Association of Chartered Physiotherapists in Women's Health
Association of Clinical Biochemists
Association of Radical Midwives
Association of the British Pharmaceuticals Industry (ABPI)
Baby Lifeline
Barnsley Acute Trust
Barnsley PCT
Bedfordshire & Hertfordshire NHS Strategic Health Authority
Birmingham Women's Hospital
Birth Centre Network UK
Birth Trauma Association
Birthchoice UK
BLISS – the premature baby charity
British Association for Counselling and Psychotherapy (BACP)
British Association of Perinatal Medicine
British Committee for Standards in Haematology
British Dietetic Association
British Maternal and Fetal Medicine Society
British National Formulary (BNF)
British Psychological Society
British Society of Interventional Radiology
Carmarthenshire Acute Trust
CASPE Research
Chartered Society of Physiotherapy (CSP)
CIS'ters
City Hospitals Sunderland NHS Trust
Cochrane Pregnancy & Childbirth Group
Commission for Social Care Inspection
Confidential Enquiry into Maternal and Child Health (CEMACH)
Connecting for Health
Conwy & Denbighshire Acute Trust
Co-operative Pharmacy Association
Cotswold and Vale PCT
County Durham and Darlington Acute Trust
Cymdeithas Tai Hafan
Denbighshire Local Health Board
Department of Health
Depression Alliance
Derbyshire Mental Health Trust
Diabetes UK
Diagnostic Ultrasound (UK) Ltd
Down's Syndrome Association
Dudley Group of Hospitals NHS Trust
Eli Lilly and Company Ltd
English National Forum of LSA Midwifery Officers
Epsom & St Helier University Hospitals NHS Trust
Faculty of Public Health
Ferring Pharmaceuticals Ltd
Fibroid Network Charity
Gloucestershire Acute Trust
Gorlin Syndrome Group
Great Ormond Street Hospital for Children NHS Trust
Group B Strep Support
Guy's and St Thomas' NHS Trust

Health Professions Wales
Healthcare Commission
Heart of England NHS Foundation Trust
Hospital Infection Society
Huntleigh Healthcare
Independent Midwives Association
Infection Control Nurses Association of the British Isles
King's College Acute Trust
La Leche League
Leeds Teaching Hospitals NHS Trust
Liverpool PCT
Liverpool Women's NHS Trust
Luton and Dunstable Hospital NHS Trust
Maidstone and Tunbridge Wells NHS Trust
Maternity Education and Research Group
Maternity Health Links
Medeus Pharma Ltd
Medicines and Healthcare products Regulatory Agency (MHRA)
Medway NHS Trust
Mid and West Regional Maternity Service Liasion Committee (MSLC)
Mid Essex Hospitals NHS Trust
Mid Staffordshire General Hospitals NHS Trust
MIDIRS (Midwives Information & Resource Service)
Midwifery Studies Research Unit
National Childbirth Trust
National Collaborating Centre for Acute Care
National Collaborating Centre for Cancer (NCC-C)
National Collaborating Centre for Chronic Conditions (NCC-CC)
National Collaborating Centre for Mental Health (NCCMH)
National Collaborating Centre for Nursing and Supportive Care (NCC-NSC)
National Collaborating Centre for Primary Care (NCC-PC)
National Collaborating Centre for Women's and Children's Health (NCC-WCH)
National Coordinating Centre for Health Technology Assessment (NCCHTA)
National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)
National Patient Safety Agency
National Perinatal Epidemiology Unit
National Public Health Service – Wales
National Screening Committee
Neoventa Medical
Newcastle Upon Tyne Hospitals NHS Foundation Trust
NHS Direct
NHS Health and Social Care Information Centre
NHS Pathways
NHS Quality Improvement Scotland
NICE – Guidelines HE for information
NICE – Implementation Consultant – Region East
NICE – Implementation Consultant – Region London/SE
NICE – Implementation Consultant – Region SW
NICE – Implementation Consultant – Region NW & NE
NICE – Implementation Consultant – Region West Midlands
NICE – Implementation Co-ordination for information
NICE – R&D for information
NICE – Technical Appraisals (Interventional Procedures) for information
North Middlesex Hospital University Trust
North Tees and Hartlepool Acute Trust
North West London Hospitals NHS Trust
Northern Lincolnshire and Goole NHS Trust
Northwest London Hospitals NHS Trust
Nottingham City PCT
Nutrition Society
Obstetric Anaesthetists Association

OKB Medical Ltd
Patient and Public Involvement Programme for NICE
Pelvic Partnership
PERIGON (formerly The NHS Modernisation Agency)
Pfizer Limited
Princess Alexandra Hospital NHS Trust
PromoCon (Disabled Living)
Queen Charlottes Hospital
Queen Mary's Hospital NHS Trust (Sidcup)
RCM Consultant Midwives Forum
Regional Public Health Group – London
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Psychiatrists
Royal Devon & Exeter NHS Foundation Trust
Royal Shrewsbury Hospital NHS Trust
Royal Society of Medicine
Royal West Sussex Trust
School of Midwifery
Scottish Executive Health Department
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield PCT
Sheffield Teaching Acute Trust
Southhampton University Hospitals Trust
St Mary's Acute Trust
Staffordshire Moorlands PCT
Stockport PCT
Sunderland Royal Hospital NHS Trust
Sure Start Ashfield
Sure Start Tamworth
Surrey & Sussex NHS Trust
Survivors Trust
Sussex Ambulance Services NHS Trust
Syner-Med
Tameside and Glossop Acute Trust
Tissue Viability Nurses Association
UK Anaemia
UK Specialised Services Public Health Network
UNICEF UK Baby Friendly Initiative
United Lincolnshire Hospitals NHS Trust
University College London Hospitals (UCLH) Acute Trust
University Hospitals of Leicester
VBAC Information and Support
Welsh Assembly Government
Wirral Hospital Acute Trust
Womens Health Research Group
Worcestershire Acute Hospitals NHS Trust
Worthing Hospital
Yorkshire and Humber Local Supervising Authorities (LSA)
Young Minds

Abbreviations

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 Postnatal Depression Scale
FBS	fetal blood sampling
FHR	fetal heart rate
GDG	Guideline Development Group
GP	general practitioner
IAS	internal anal sphincter
IM	intramuscular
IPPM	intrapartum-related perinatal mortality
IQR	interquartile range
IV	intravenous
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 Clinical Excellence
NICU	neonatal intensive care unit
NS	not significant
NSAIDs	nonsteroidal anti-inflammatory drugs
OASIS	obstetric anal sphincter injuries
PCA	patient-controlled analgesia
PCEA	patient-controlled epidural analgesia
PPH	postpartum haemorrhage
OA	occiput anterior
OP	occiput posterior
OR	odds ratio
OT	occiput transverse
PPI	Present Pain Intensity
PRoM	prelabour rupture of membranes
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
VAS	visual analogue scale
VE	vaginal examination
WMD	weighted mean difference

Glossary of terms

Absolute risk Measures the probability of an event or outcome occurring (e.g. an adverse reaction to the drug being tested) in the group of people under study. Studies that compare two or more groups of patients may report results in terms of the **absolute risk reduction**.

Absolute risk reduction (ARR) The ARR is the difference in the risk of an event occurring between two groups of patients in a study – for example if 6% of patients die after receiving a new experimental drug and 10% of patients die after having the old drug treatment then the ARR is 10% – 6% = 4%. Thus by using the new drug instead of the old drug 4% of patients can be prevented from dying. Here the ARR measures the risk reduction associated with a new treatment. See also **absolute risk**.

Acute sector Hospital-based health services which are provided on an in-patient, day case or outpatient basis.

Acute trust A trust is an NHS organisation responsible for providing a group of healthcare services. An acute trust provides hospital services (but not mental health hospital services which are provided by a **mental health trust**).

Advised A woman should be advised to accept an intervention when the evidence or professional opinion suggests that one particular option is more beneficial than others. See also **offered**, and **supported in their choice**.

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, etc. (Formerly known as professions allied to medicine or PAMs.)

Amniotomy Amniotomy refers to artificial rupturing of the membranes. This is done 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 in the belief that it can stimulate stronger contractions and thus shorten the duration of labour.

Applicability The extent to which the results of a study or review can be applied to the target population for a clinical guideline.

Appraisal of evidence Formal assessment of the quality of research evidence and its relevance to the clinical question or guideline under consideration, according to predetermined criteria.

Best available evidence The strongest research evidence available to support a particular guideline recommendation.

Bias Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias in research can make a treatment look better or worse than it really is. Bias can even make it look as if the treatment works when it actually does not. Bias can occur by chance or as a result of **systematic errors** in the design and execution of a study. Bias can occur at different stages in the research process, e.g. in the collection, analysis, interpretation, publication or review of research data. For examples see **selection bias**, **performance bias**, **information bias**, **confounding factor**, **publication bias**.

Blinding or masking The practice of keeping the investigators or subjects of a study ignorant of the group to which a subject has been assigned. For example, a clinical trial in which the participating patients or their doctors are unaware of whether they (the patients) are taking the experimental drug or a **placebo** (dummy treatment). The purpose of 'blinding' or 'masking' is to protect against **bias**. See also **double-blind study**, **single-blind study**, **triple-blind study**.

Case–control study A study that starts with the identification of a group of individuals sharing the same characteristics (e.g. people with a particular disease) and a suitable comparison (**control**) group (e.g. people without the disease). All subjects are then assessed with respect to things that happened to them in the past, e.g. things that might be related to getting the disease under investigation. Such studies are also called **retrospective** as they look back in time from the outcome to the possible causes.

Case report (or case study) Detailed report on one patient (or case), usually covering the course of that person's disease and their response to treatment.

Case series Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (**control**) group of patients.

Causal relationship Describes the relationship between two **variables** whenever it can be established that one causes the other. For example there is a causal relationship between a treatment and a disease if it can be shown that the treatment changes the course or outcome of the disease. Usually **randomised controlled trials** are needed to ascertain causality. Proving cause and effect is much more difficult than just showing an association between two variables. For example, if it happened that everyone who had eaten a particular food became sick, and everyone who avoided that food remained well, then the food would clearly be associated with the sickness. However, even if leftovers were found to be contaminated, it could not be proved that the food caused the sickness – unless all other possible causes (e.g. environmental factors) had been ruled out.

Control event rate (CER) See **event rate**.

Checklist See **study checklist**.

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 effectiveness The extent to which a specific treatment or intervention, when used under *usual* or *everyday conditions*, has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care. (Clinical trials that assess effectiveness are sometimes called management trials.) Clinical 'effectiveness' is not the same as **efficacy**.

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.

Clinical impact The effect that a guideline recommendation is likely to have on the treatment, or treatment outcomes, of the target population.

Clinical importance The importance of a particular guideline recommendation to the clinical management of the **target population**.

Clinical question This term is sometimes used in guideline development work to refer to the questions about treatment and care that are formulated in order to guide the search for research evidence. When a clinical question is formulated in a precise way, it is called a **focused question**.

Clinical trial A research study conducted with patients which tests out a drug or other intervention to assess its effectiveness and safety. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease. This general term encompasses **controlled clinical trials** and **randomised controlled trials**.

Clinician A qualified healthcare professional providing patient care, e.g. doctor, nurse, physiotherapist.

Cluster A group of patients, rather than an individual, used as the basic unit for investigation. See also **cluster design**, **cluster randomisation**.

Cluster design Cluster designs are those where research subjects are not sampled or selected independently, but in a group. For example a clinical trial where patients in a general practice are allocated to the same intervention; the general practice forming a cluster. See also **cluster**, **cluster randomisation**.

Cluster randomisation A study in which groups of individuals (e.g. patients in a GP surgery or on a hospital ward) are randomly allocated to treatment groups. Take, for example, a smoking cessation study of two different interventions – leaflets and teaching sessions. Each GP surgery within the study would be randomly allocated to administer one of the two interventions. See also **cluster**, **cluster design**.

Cochrane Collaboration An international organisation in which people find, appraise and review specific types of studies called **randomised controlled trials**. The Cochrane Database of Systematic Reviews contains regularly updated reviews on a variety of health issues and is available electronically as part of the **Cochrane Library**.

Cochrane Library The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of **randomised controlled trials** prepared by the **Cochrane Collaboration**). The Cochrane Library is available on CD-ROM and the Internet.

Cohort A group of people sharing some common characteristic (e.g. patients with the same disease), followed up in a research study for a specified period of time.

Cohort study
An **observational study** that takes a group (cohort) of patients and follows their progress over time in order to measure outcomes such as disease or mortality rates and make comparisons according to the treatments or interventions that patients received. Thus within the study group, subgroups of patients are identified (from information collected about patients) and these groups are compared with respect to outcome, e.g. comparing mortality between one group that received a specific treatment and one group which did not (or between two groups that received different levels of treatment). Cohorts can be assembled in the present and followed into the future (a 'concurrent' or '**prospective**' cohort study) or identified from past records and followed forward from that time up to the present (a 'historical' or '**retrospective**' cohort study). Because patients are not randomly allocated to subgroups, these subgroups may be quite different in their characteristics and some adjustment must be made when analysing the results to ensure that the comparison between groups is as fair as possible.

Combined modality
Use of different treatments in combination (for example surgery, chemotherapy and radiotherapy used together for cancer patients).

Commercial 'in confidence' material
Information (e.g. the findings of a research project) defined as 'confidential' as its public disclosure could have an impact on the commercial interests of a particular company. (Academic 'in confidence' material is information (usually work produced by a research or professional organisation) that is pending publication.)

Co-morbidity
Co-existence of a disease or diseases in the people being studied in addition to the health problem that is the subject of the study.

Confidence interval
A way of expressing certainty about the findings from a study or group of studies, using statistical techniques. A confidence interval describes a range of possible effects (of a treatment or intervention) that are consistent with the results of a study or group of studies. A wide confidence interval indicates a lack of certainty or precision about the true size of the clinical effect and is seen in studies with too few patients. Where confidence intervals are narrow they indicate more precise estimates of effects and a larger sample of patients studied. It is usual to interpret a '95%' confidence interval as the range of effects within which we are 95% confident that the true effect lies.

Confounder or confounding factor
Something that influences a study and can contribute to misleading findings if it is not understood or appropriately dealt with. For example, if a group of people exercising regularly and a group of people who do not exercise have an important age difference then any difference found in outcomes about heart disease could well be due to one group being older than the other rather than due to the exercising. Age is the confounding factor here and the effect of exercising on heart disease cannot be assessed without adjusting for age differences in some way.

Consensus development conference
A technique used for the purpose of reaching an agreement on a particular issue. It involves bringing together a group of about ten people who are presented with evidence by various interest groups or experts who are not part of the decision making group. The group then retires to consider the questions in the light of the evidence presented and attempts to reach a consensus. See also **consensus methods**.

Consensus methods
A variety of techniques that aim to reach an agreement on a particular issue. Formal consensus methods include **Delphi** and **nominal group techniques**, and **consensus development conferences**. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic.

Consensus statement
A statement of the advised course of action in relation to a particular clinical topic, based on the collective views of a body of experts.

Considered judgement
The application of the collective knowledge of a guideline development group to a body of evidence, to assess its **applicability** to the **target population** and the strength of any recommendation that it would support.

Consistency
The extent to which the conclusions of a collection of studies used to support a guideline recommendation are in agreement with each other. See also **homogeneity**.

Control event rate (CER)
See **event rate**.

Control group
A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a **placebo** (dummy treatment) – in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.

Controlled clinical trial (CCT)
A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or **control group**) receives an alternative treatment, a **placebo** (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A CCT where patients are randomly allocated to treatment and comparison groups is called a **randomised controlled trial**.

Cost–benefit analysis	A type of **economic evaluation** where both costs and benefits of health care treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-effectiveness	Value for money. A specific health care treatment is said to be 'cost-effective' if it gives a greater health gain than could be achieved by using the resources in other ways.
Cost-effectiveness analysis	A type of **economic evaluation** comparing the costs and the effects on health of different treatments. Health effects are measured in 'health-related units', for example, the cost of preventing one additional heart attack.
Cost-utility analysis	A special form of **cost-effectiveness analysis** where health effects are measured in **quality-adjusted life years**. A treatment is assessed in terms of its ability to both extend life and to improve the quality of life.
Crossover study design	A study comparing two or more interventions in which the participants, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, half the participants are randomly allocated to receive them in the order A, B and half to receive them in the order B, A. A problem with this study design is that the effects of the first treatment may carry over into the period when the second is given. Therefore a crossover study should include an adequate 'wash-out' period, which means allowing sufficient time between stopping one treatment and starting another so that the first treatment has time to wash out of the patient's system.
Cross-sectional study	The observation of a defined set of people at a single point in time or time period – a snapshot. (This type of study contrasts with a **longitudinal study**, which follows a set of people over a period of time.)
Data set	A list of required information relating to a specific disease.
Decision analysis	Decision analysis is the study of how people make decisions or how they *should* make decisions. There are several methods that decision analysts use to help people to make better decisions, including **decision trees**.
Decision tree	A decision tree is a method for helping people to make better decisions in situations of uncertainty. It illustrates the decision as a succession of possible actions and outcomes. It consists of the probabilities, costs and health consequences associated with each option. The overall effectiveness or overall cost-effectiveness of different actions can then be compared.
Declaration of interest	A process by which members of a working group or committee 'declare' any personal or professional involvement with a company (or related to a technology) that might affect their objectivity e.g. if their position or department is funded by a pharmaceutical company.
Delphi method	A technique used for the purpose of reaching an agreement on a particular issue, without the participants meeting or interacting directly. It involves sending participants a series of postal questionnaires asking them to record their views. After the first questionnaire, participants are asked to give further views in the light of the group feedback. The judgements of the participants are statistically aggregated, sometimes after weighting for expertise. See also **consensus methods**.
District General Hospital (DGH)	Non-teaching hospital.
Diagnostic study	A study to assess the effectiveness of a test or measurement in terms of its ability to accurately detect or exclude a specific disease.
Dominance	A term used in **health economics** describing when an option for treatment is both less clinically effective and more costly than an alternative option. The less effective and more costly option is said to be 'dominated'.
Double-blind study	A study in which neither the subject (patient) nor the observer (investigator/clinician) is aware of which treatment or intervention the subject is receiving. The purpose of **blinding** is to protect against **bias**.
Economic evaluation	A comparison of alternative courses of action in terms of both their costs and consequences. In **health economic** evaluations the consequences should include health outcomes.
Effectiveness	See **clinical effectiveness**.
Efficacy	The extent to which a specific treatment or intervention, under *ideally controlled conditions*, e.g. in a laboratory), has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care.
Elective	Name for clinical procedures that are regarded as advantageous to the patient but not urgent.
Empirical	Based directly on experience (observation or experiment) rather than on reasoning alone.
Epidemiology	Study of diseases within a population, covering the causes and means of prevention.

Event rate	The proportion of patients in a group for whom a specified health event or outcome is observed. Thus, if out of 100 patients, the event is observed in 27, the event rate is 0.27 or 27%. Control event rate (CER) and experimental event rate (EER) are the terms used in control and experimental groups of patients, respectively.
Evidence based	The process of systematically finding, appraising, and using research findings as the basis for clinical decisions.
Evidence-based clinical practice	Evidence-based clinical practice involves making decisions about the care of individual patients based on the best research evidence available rather than basing decisions on personal opinions or common practice (which may not always be evidence based). Evidence-based clinical practice therefore involves integrating individual clinical expertise and patient preferences with the best available evidence from research
Evidence level	A code (e.g. 1++, 1+) linked to an individual study, indicating where it fits into the **hierarchy of evidence** and how well it has adhered to recognised research principles. Also called level of evidence.
Evidence table	A table summarising the results of a collection of studies which, taken together, represent the evidence supporting a particular recommendation or series of recommendations in a guideline.
Exclusion criteria	See **selection criteria**.
Expectant management	Awaiting events to take their natural course. This would usually include observation of the woman and/or baby's condition.
Experimental event rate (EER)	See **event rate**.
Experimental study	A research study designed to test if a treatment or intervention has an effect on the course or outcome of a condition or disease – where the conditions of testing are to some extent under the control of the investigator. **Controlled clinical trial** and **randomised controlled trial** are examples of experimental studies.
Experimental treatment	A treatment or intervention (e.g. a new drug) being studied to see if it has an effect on the course or outcome of a condition or disease.
External validity	The degree to which the results of a study hold true in non-study situations, e.g. in routine clinical practice. May also be referred to as the **generalisability** of study results to non-study patients or populations.
Extrapolation	The application of research evidence based on studies of a specific population to another population with similar characteristics.
Focus group	A **qualitative research** technique. It is a method of group interview or discussion of between 6–12 people focused around a particular issue or topic. The method explicitly includes and uses the group interaction to generate data.
Focused question	A study question that clearly identifies all aspects of the topic that are to be considered while seeking an answer. Questions are normally expected to identify the patients or population involved, the treatment or intervention to be investigated, what outcomes are to be considered, and any comparisons that are to be made. For example, do insulin pumps (intervention) improve blood sugar control (outcome) in adolescents with type 1 diabetes (population) compared with multiple insulin injections (comparison)? See also **clinical question**.
Forest plot	A graphical display of results from individual studies on a common scale, allowing visual comparison of results and examination of the degree of **heterogeneity** between studies.
Funnel plot	Funnel plots are simple scatter plots on a graph. They show the treatment effects estimated from separate studies on the horizontal axis against a measure of sample size on the vertical axis. **Publication bias** may lead to asymmetry in funnel plots.
Generalisability	The extent to which the results of a study hold true for a population of patients beyond those who participated in the research. See also **external validity**.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available.
Grey literature	Reports that are unpublished or have limited distribution, and are not included in bibliographic retrieval systems.
Guideline	A systematically developed tool that describes aspects of a patient's condition and the care to be given. A good guideline makes recommendations about treatment and care based on the best research available, rather than opinion. It is used to assist clinician and patient decision making about appropriate health care for specific clinical conditions.
Guideline recommendation	Course of action advised by the guideline development group on the basis of their assessment of the supporting evidence.
Health economics	A branch of economics that studies decisions about the use and distribution of health care resources.

Health technology Health technologies include medicines, medical devices such as artificial hip joints, diagnostic techniques, surgical procedures, health promotion activities (e.g. the role of diet versus medicines in disease management) and other therapeutic interventions.

Health technology appraisal (HTA) A health technology appraisal, as undertaken by The National Institute for Health and Clinical Excellence (NICE), is the process of determining the clinical and cost-effectiveness of a **health technology**. NICE health technology appraisals are designed to provide patients, health professionals and managers with an authoritative source of advice on new and existing health technologies.

Heterogeneity Or lack of **homogeneity**. The term is used in **meta-analyses** and **systematic reviews** when the results or estimates of effects of treatment from separate studies seem to be very different – in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of **variables** or duration of follow-up.

Hierarchy of evidence An established hierarchy of study types, based on the degree of certainty that can be attributed to the conclusions that can be drawn from a well-conducted study. Well-conducted **randomised controlled trials** (RCTs) are at the top of this hierarchy. (Several large statistically significant RCTs which are in agreement represent stronger evidence than say one small RCT.) Well-conducted studies of patients' views and experiences would appear at a lower level in the hierarchy of evidence.

Homogeneity This means that the results of studies included in a **systematic review** or **meta-analysis** are similar and there is no evidence of **heterogeneity**. Results are usually regarded as homogeneous when differences between studies could reasonably be expected to occur by chance. See also **consistency**.

Inclusion criteria See **selection criteria**.

In-depth interview A **qualitative research** technique. It is a face-to-face conversation between a researcher and a respondent with the purpose of exploring issues or topics in detail. Does not use pre-set questions, but is shaped by a defined set of topics or issues.

Information bias Pertinent to all types of study and can be caused by inadequate questionnaires (e.g. difficult or biased questions), observer or interviewer errors (e.g. lack of **blinding**), response errors (e.g. lack of blinding if patients are aware of the treatment they receive) and measurement error (e.g. a faulty machine).

Intention-to-treat analysis An analysis of a clinical trial where patients are analysed according to the group to which they were initially randomly allocated, regardless of whether or not they had dropped out, fully complied with the treatment, or crossed over and received the alternative treatment. Intention-to-treat analyses are favoured in assessments of **clinical effectiveness** as they mirror the non-compliance and treatment changes that are likely to occur when the treatment is used in practice.

Internal validity Refers to the integrity of the study design.

Intervention Healthcare action intended to benefit the patient, e.g. drug treatment, surgical procedure, psychological therapy, etc.

Interventional procedure A procedure used for diagnosis or treatment that involves making a cut or hole in the patient's body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers). The National Institute for Health and Clinical Excellence (NICE) has the task of producing guidance about whether specific interventional procedures are safe enough and work well enough for routine use.

Level of evidence See **evidence level**.

Literature review A process of collecting, reading and assessing the quality of published (and unpublished) articles on a given topic.

Longitudinal study A study of the same group of people at more than one point in time. (This type of study contrasts with a **cross-sectional study**, which observes a defined set of people at a single point in time.)

Masking See **blinding**.

Mental health trust A trust is an NHS organisation responsible for providing a group of healthcare services. A mental health trust provides both hospital and community based mental health services.

Meta-analysis Results from a collection of independent studies (investigating the same treatment) are pooled, using statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible e.g. because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to statistically pool results in this way. See also **systematic review** and **heterogeneity**.

Methodology The overall approach of a research project, e.g. the study will be a **randomised controlled trial**, of 200 people, over one year.

Methodological quality The extent to which a study has conformed to recognised good practice in the design and execution of its research methods.

Multicentre study A study where subjects were selected from different locations or populations, e.g. a co-operative study between different hospitals; an international collaboration involving patients from more than one country.

Negative predictive value (NPV) The proportion of people with a negative test result who do not have the disease (where not having the disease is indicated by the 'gold' standard test being negative).

Number needed to harm (NNH) See **number needed to treat**.

Number needed to treat (NNT) This measures the impact of a treatment or intervention. It states how many patients need to be treated with the treatment in question in order to prevent an event which would otherwise occur. E.g. if the NNT = 4, then four patients would have to be treated to prevent one bad outcome. The closer the NNT is to 1, the better the treatment is. Analogous to the NNT is the number needed to harm (NNH), which is the number of patients that would need to receive a treatment to cause one additional adverse event. e.g. if the NNH = 4, then four patients would have to be treated for one bad outcome to occur.

Nominal group technique A technique used for the purpose of reaching an agreement on a particular issue. It uses a variety of postal and direct contact techniques, with individual judgements being aggregated statistically to derive the group judgement. See also **consensus methods**.

Non-experimental study A study based on subjects selected on the basis of their availability, with no attempt having been made to avoid problems of **bias**.

Non-systematic review See **review**.

Objective measure A measurement that follows a standardised procedure that is less open to subjective interpretation by potentially biased observers and study participants.

Observation Observation is a research technique used to help understand complex situations. It involves watching, listening to and recording behaviours, actions, activities and interactions. The settings are usually natural, but they can be laboratory settings, as in psychological research.

Observational study In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. There is a greater risk of **selection bias** than in **experimental studies**.

Odds ratio (OR) Odds are a way of representing probability, especially familiar for betting. In recent years odds ratios have become widely used in reports of clinical studies. They provide an estimate (usually with a **confidence interval**) for the effect of a treatment. Odds are used to convey the idea of 'risk' and an odds ratio of 1 between two treatment groups would imply that the risks of an adverse outcome were the same in each group. For rare events the odds ratio and the **relative risk** (which uses actual risks and not odds) will be very similar. See also **relative risk**, **risk ratio**.

Off-label prescribing When a drug or device is prescribed outside its **specific indication**, to treat a condition or disease for which it is not specifically licensed.

Offered A woman should be offered an intervention when the evidence or professional opinion suggests that it is of benefit and there is little risk of harm. See also **advised** and **supported in their choice**.

Outcome The end result of care and treatment and/or rehabilitation. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care/treatment/rehabilitation. Researchers should decide what outcomes to measure before a study begins; outcomes are then assessed at the end of the study.

***P* value** If a study is done to compare two treatments then the *P* value is the probability of obtaining the results of that study, or something more extreme, if there really was no difference between treatments. (The assumption that there really is no difference between treatments is called the 'null hypothesis'.) Suppose the *P* value was $P = 0.03$. What this means is that if there really was no difference between treatments then there would only be a 3% chance of getting the kind of results obtained. Since this chance seems quite low we should question the validity of the assumption that there really is no difference between treatments. We would conclude that there probably is a difference between treatments. By convention, where the value of *P* is below 0.05 (i.e. less than 5%) the result is seen as statistically significant. Where the value of *P* is 0.001 or less, the result is seen as highly significant. *P* values just tell us whether an effect can be regarded as statistically significant or not. In no way do they relate to how big the effect might be, for which we need the **confidence interval**.

Peer review Review of a study, service or recommendations by those with similar interests and expertise to the people who produced the study findings or recommendations. Peer reviewers can include professional and/or patient/carer representatives.

Performance bias Systematic differences in care provided apart from the intervention being evaluated. For example, if study participants know they are in the **control group** they may be more likely to use other forms of care; people who know they are in the experimental group may experience **placebo effects**, and care providers may treat patients differently according to what group they are in. Masking (**blinding**) of both the recipients and providers of care is used to protect against performance bias.

Pilot study A small scale 'test' of the research instrument. For example, testing out (piloting) a new questionnaire with people who are similar to the population of the study, in order to highlight any problems or areas of concern, which can then be addressed before the full scale study begins.

Placebo Placebos are fake or inactive treatments received by participants allocated to the **control group** in a clinical trial that 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.

Point estimate A best single estimate (taken from research data) for the true value of a treatment effect or other measurement. For example, researchers in one clinical trial take their results as their best estimate of the real treatment effect – this is their estimate at their point in time. The precision or accuracy of the estimate is measured by a **confidence interval**. Another clinical trial of the same treatment will produce a different point estimate of treatment effect.

Positive predictive value (PPV) The proportion of people with a positive test result who have the disease (where having the disease is indicated by the 'gold' standard test being positive).

Power See **statistical power**.

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.

Primary care trust (PCT) A primary care trust is an NHS organisation responsible for improving the health of local people, developing services provided by local GPs and their teams (called **primary care**) and making sure that other appropriate health services are in place to meet local people's needs.

Probability How likely an event is to occur, e.g. how likely a treatment or intervention will alleviate a symptom.

Prognostic factor Patient or disease characteristics, e.g. age or **co-morbidity**, which influence the course of the disease under study. In a randomised trial to compare two treatments, chance imbalances in **variables** (prognostic factors) that influence patient outcome are possible, especially if the size of the study is fairly small. In terms of analysis these prognostic factors become **confounding factors**. See also **prognostic marker**.

Prognostic marker A **prognostic factor** used to assign patients to categories for a specified purpose – e.g. for treatment, or as part of a clinical trial, according to the likely progression of the disease. For example, the purpose of randomisation in a clinical trial is to produce similar treatment groups with respect to important prognostic factors. This can often be achieved more efficiently if randomisation takes place within subgroups defined by the most important prognostic factors. Thus if age was very much related to patient outcome then separate randomisation schemes would be used for different age groups. This process is known as stratified random allocation.

Prospective study A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are **retrospective**.

Protocol A plan or set of steps that defines appropriate action. A research protocol sets out, in advance of carrying out the study, what question is to be answered and how information will be collected and analysed. Guideline implementation protocols set out how guideline recommendations will be used in practice by the NHS, both at national and local levels.

Publication bias Studies with statistically significant results are more likely to get published than those with non-significant results. **Meta-analyses** that are exclusively based on published literature may therefore produce biased results. This type of bias can be assessed by a **funnel plot**.

Qualitative research
Qualitative research is used to explore and understand people's beliefs, experiences, attitudes, behaviour and interactions. It generates non-numerical data, e.g. a patient's description of their pain rather than a measure of pain. In health care, qualitative techniques have been commonly used in research documenting the experience of chronic illness and in studies about the functioning of organisations. Qualitative research techniques such as **focus groups** and **in-depth interviews** have been used in one-off projects commissioned by guideline development groups to find out more about the views and experiences of patients and carers.

Quality-adjusted life years (QALYS)
A measure of health outcome that looks at both length of life and quality of life. QALYS are calculated by estimating the years of life remaining for a patient following a particular care pathway and weighting each year with a quality of life score (on a zero to one scale). One QALY is equal to one year of life in perfect health, or two years at 50% health, and so on.

Quantitative research
Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the national Census that counts people and households.

Quasi-experimental study
A study designed to test whether a treatment or intervention has an effect on the course or outcome of disease. It differs from a **controlled clinical trial** and a **randomised controlled trial** in that:

- the assignment of patients to treatment and comparison groups is not done randomly, or patients are not given equal probabilities of selection, or
- the investigator does not have full control over the allocation and/or timing of the intervention, but nonetheless conducts the study as if it were an experiment, allocating subjects to treatment and comparison groups.

Random allocation or randomisation
A method that uses the play of chance to assign participants to comparison groups in a research study, for example, by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual (or each unit in the case of **cluster randomisation**) being entered into a study has the same chance of receiving each of the possible interventions.

Randomised controlled trial (RCT)
A study to test a specific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or **control group**) receiving an alternative treatment, a **placebo** (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study.)

Relative risk (RR)
A summary measure which represents the ratio of the risk of a given event or outcome (e.g. an adverse reaction to the drug being tested) in one group of subjects compared with another group. When the 'risk' of the event is the same in the two groups the relative risk is 1. In a study comparing two treatments, a relative risk of 2 would indicate that patients receiving one of the treatments had twice the risk of an undesirable outcome than those receiving the other treatment. Relative risk is sometimes used as a synonym for **risk ratio**.

Reliability
Reliability refers to a method of measurement that consistently gives the same results. For example someone who has a high score on one occasion tends to have a high score if measured on another occasion very soon afterwards. With physical assessments it is possible for different clinicians to make independent assessments in quick succession – and if their assessments tend to agree then the method of assessment is said to be reliable.

Retrospective study
A retrospective study deals with the present/past and does not involve studying future events. This contrasts with studies that are **prospective**.

Review
Summary of the main points and trends in the research literature on a specified topic. A review is considered non-systematic unless an extensive literature search has been carried out to ensure that all aspects of the topic are covered and an objective appraisal made of the quality of the studies.

Risk ratio
Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison (**control**) group. The term **relative risk** is sometimes used as a synonym of risk ratio.

Royal Colleges
In the UK medical world, the term Royal Colleges, as for example in 'The Royal College of …', refers to organisations which usually combine an educational standards and examination role with the promotion of professional standards. The nursing/midwifery colleges do not have responsibility for standards of training.

Sample
A part of the study's **target population** from which the subjects of the study will be recruited. If subjects are drawn in an unbiased way from a particular population, the results can be generalised from the sample to the population as a whole.

Sampling
Refers to the way participants are selected for inclusion in a study.

Sampling frame
A list or register of names that is used to recruit participants to a study.

Scottish Intercollegiate Guidelines Network (SIGN) SIGN was established in 1993 to sponsor and support the development of evidence-based clinical guidelines for the NHS in Scotland.

Secondary care Care provided in hospitals.

Selection bias Selection bias has occurred if:
- the characteristics of the **sample** differ from those of the wider population from which the sample has been drawn, or
- there are systematic differences between comparison groups of patients in a study in terms of prognosis or responsiveness to treatment.

Selection criteria Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.

Semi-structured interview Structured interviews involve asking people pre-set questions. A semi-structured interview allows more flexibility than a structured interview. The interviewer asks a number of open-ended questions, following up areas of interest in response to the information given by the respondent.

Sensitivity In diagnostic testing, it refers to the chance of having a positive test result given that you have the disease. 100% sensitivity means that all those with the disease will test positive, but this is not the same the other way around. A patient could have a positive test result but not have the disease – this is called a 'false positive'. The sensitivity of a test is also related to its '**negative predictive value'** (true negatives) – a test with a sensitivity of 100% means that all those who get a negative test result do not have the disease. To fully judge the accuracy of a test, its **specificity** must also be considered.

Single-blind study A study in which *either* the subject (patient/participant) *or* the observer (clinician/investigator) is not aware of which treatment or intervention the subject is receiving.

Specific indication When a drug or a device has a specific remit to treat a specific condition and is not licensed for use in treating other conditions or diseases.

Specificity In diagnostic testing, it refers to the chance of having a negative test result given that you do not have the disease. 100% specificity means that all those without the disease will test negative, but this is not the same the other way around. A patient could have a negative test result yet still have the disease – this is called a 'false negative'. The specificity of a test is also related to its '**positive predictive value'** (true positives) – a test with a specificity of 100% means that all those who get a positive test result definitely have the disease. To fully judge the accuracy of a test, its **sensitivity** must also be considered.

Standard deviation A measure of the spread, scatter or variability of a set of measurements. Usually used with the mean (average) to describe numerical data.

Statistical power The ability of a study to demonstrate an association or causal relationship between two **variables**, given that an association exists. For example, 80% power in a clinical trial means that the study has a 80% chance of ending up with a ***P* value** of less than 5% in a statistical test (i.e. a statistically significant treatment effect) if there really was an important difference (e.g. 10% versus 5% mortality) between treatments. If the statistical power of a study is low, the study results will be questionable (the study might have been too small to detect any differences). By convention, 80% is an acceptable level of power. See also ***P* value**.

Structured interview A research technique where the interviewer controls the interview by adhering strictly to a questionnaire or interview schedule with pre-set questions.

Study checklist A list of questions addressing the key aspects of the research methodology that must be in place if a study is to be accepted as valid. A different checklist is required for each study type. These checklists are used to ensure a degree of consistency in the way that studies are evaluated.

Study population People who have been identified as the subjects of a study.

Study quality See **methodological quality**.

Study type The kind of design used for a study. **Randomised controlled trials**, **case–control studies**, and **cohort studies** are all examples of study types.

Subject A person who takes part in an experiment or research study.

Supported in their choice Where this is a service that will not be routinely provided by the maternity units, women should be able to do so. See also **advised** and **offered**.

Survey A study in which information is systematically collected from people (usually from a sample within a defined population).

Systematic Methodical, according to plan; not random.

Systematic error Refers to the various errors or biases inherent in a study. See also **Bias**.

Systematic review A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. May or may not include a **meta-analysis**.

Systemic Involving the whole body.

Target population The people to whom guideline recommendations are intended to apply. Recommendations may be less valid if applied to a population with different characteristics from the participants in the research study – e.g. in terms of age, disease state, social background.

Tertiary centre A major medical centre providing complex treatments which receives referrals from both primary and secondary care. Sometimes called a tertiary referral centre. See also **primary care** and **secondary care**.

Triangulation Use of three or more different research methods in combination; principally used as a check of validity. The more the different methods produce similar results, the more valid the findings.

Triple-blind study A study in which the statistical analysis is carried out without knowing which treatment patients received, in addition to the patients and investigators/**clinicians** being unaware which treatment patients were getting.

Trust A trust is an NHS organisation responsible for providing a group of healthcare services. An **acute trust** provides hospital services. A **mental health trust** provides most mental health services. A **primary care trust** buys hospital care on behalf of the local population, as well as being responsible for the provision of community health services.

Validity Assessment of how well a tool or instrument measures what it is intended to measure. See also **external validity**, **internal validity**.

Variable A measurement that can vary within a study, e.g. the age of participants. Variability is present when differences can be seen between different people or within the same person over time, with respect to any characteristic or feature that can be assessed or measured.

1 Introduction

Birth is a life-changing event and the care given to women has the potential to affect them both physically and emotionally in the short and longer term.

This guideline covers the care of healthy women in labour at term (37–42 weeks of gestation). About 600 000 women give birth in England and Wales each year, of whom about 40% are having their first baby.[1,2] 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. Most women (about two-thirds) go into labour spontaneously. Thus the majority of women giving birth in the UK fall under the scope of this guideline.

More than 90% of births take place in designated consultant wards or combined consultant/GP wards. In England in 2002–2003, 1% of births took place in GP wards, 3% in midwife wards and 2% at home.[3]

An estimated 47% of births were described as 'normal births' in England in 2002–2003. Normal birth is defined as that without surgical intervention, use of instruments, induction, or epidural or general anaesthetic.[3]

In total, 22% of births in England in 2002–2003 were by caesarean section and about 11% were instrumental births, including forceps or ventouse. Instrumental births were associated with a longer hospital stay in England and Wales in 2002–2003.[3]

About one-third of women had an epidural, general or spinal anaesthetic during labour in England in 2002–2003.[3]

The importance of effective communication between women and caregivers during intrapartum care has been identified by the GDG as one of the most important themes that runs through the guideline. To facilitate good practice and the implementation of this issue, the GDG has developed 'recommendations on implementing good communication' at important points within the guideline.

1.1 Aim of the guideline

Clinical guidelines have been defined as 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'.[4] The guideline has been developed with the aim of providing guidance on care of healthy women and their babies during childbirth.

1.2 Areas within the remit of the guideline

1.2.1 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.

1.2.2 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.

1.2.3 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.

1.2.4 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.

1.2.5 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.

1.3 Areas outside of 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.

1.4 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.

A version of this guideline for women, their families and the public is available, entitled 'Understanding NICE guidance: Care of women and their babies during labour'. It can be downloaded from the National Institute for Health and Clinical Excellence (NICE) website (www.nice.org.uk/CG055) or ordered via the NHS Response Line (0870 1555 455) quoting reference number N1327.

1.5 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.

1.6 Other relevant documents

This guideline is intended to complement the maternity section of the Children's National Service Framework (NSF) as well as other existing and proposed works of relevance. It will also link to relevant clinical guidelines issued by the Institute, including:

- *Pregnancy and Childbirth – Induction of Labour* (NICE clinical guideline D, 2001)[5]
- *Infection Control: Prevention of Healthcare-Associated Infection in Primary and Community Care* (NICE clinical guideline 2, 2003)[7]
- *Antenatal Care: Routine Care for the Healthy Pregnant Woman* (NICE clinical guideline 6, 2003)[8]
- *Caesarean Section* (NICE clinical guideline 13, 2004)[6]
- *Postnatal Care: Routine Postnatal Care of Women and Their Babies* (NICE clinical guideline 37, 2006)
- *Antenatal and Postnatal Mental Health: Clinical Management and Service Guidance* (NICE clinical guideline 45, 2007).

This guideline provides an update of *The Use of Electronic Fetal Monitoring: the Use and Interpretation of Cardiotocography in Intrapartum Fetal Surveillance* (inherited clinical guideline C) issued in 2001. Inherited clinical guideline C will be withdrawn upon publication of this new guideline.

1.7 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]

1.7.1 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 clinical 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 clinical questions and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical 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.

1.7.2 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 1.1.[16] This system reflects the susceptibility to bias that is inherent in particular study designs.

Table 1.1 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 clinical 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 clinical 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 1.2).[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

Table 1.2 Levels of evidence for studies of the accuracy of diagnostics tests[9]

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.

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.

1.7.3 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.

1.7.4 Forming and grading recommendations

For each clinical 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 clinical 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).

1.7.5 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.

1.7.6 Outcome measures used in the 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.

1.8 Schedule for updating the guideline

Clinical guidelines commissioned by NICE are published with a review date 4 years from date of publication. Reviewing may begin earlier than 4 years if significant evidence that affects guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

2 Summary of recommendations and care pathway

2.1 Key priorities for implementation (key recommendations)

2.1.1 Key practice recommendations

Communication between women and healthcare professionals

All women in labour should be treated with respect and should be in control of and involved in what is happening to them, and the way in which care is given is key to this. To facilitate this, healthcare professionals and other caregivers should establish a rapport with the labouring woman, asking her about her wants and expectations for labour, being aware of the importance of tone and demeanour, and of the actual words they use. This information should be used to support and guide her through her labour.

Support in labour

A woman in established labour should receive supportive one-to-one care.

A woman in established labour should not be left on her own except for short periods or at the woman's request.

Normal labour

Clinical intervention should not be offered or advised where labour is progressing normally and the woman and baby are well.

Planning place of birth

Women should be offered the choice of planning birth at home, in a midwife-led unit or in an obstetric unit. Women should be informed:

- That giving birth is generally very safe for both the woman and her baby.
- That the available information on planning place of birth is not of good quality, but suggests that among women who plan to give birth at home or in a midwife-led unit there is a higher likelihood of a normal birth, with less intervention. We do not have enough information about the possible risks to either the woman or her baby relating to planned place of birth.
- That the obstetric unit provides direct access to obstetricians, anaesthetists, neonatologists and other specialist care including epidural analgesia.
- Of locally available services, the likelihood of being transferred into the obstetric unit and the time this may take.
- That if something does go unexpectedly seriously wrong during labour at home or in a midwife-led unit, the outcome for the woman and baby could be worse than if they were in the obstetric unit with access to specialised care.
- That if she has a pre-existing medical condition or has had a previous complicated birth that makes her at higher risk of developing complications during her next birth, she should be advised to give birth in an obstetric unit.

Clinical governance structures should be implemented in all places of birth (see Boxes 3.1 and 3.2).

Coping with pain

The opportunity to labour in water is recommended for pain relief.

Before choosing epidural analgesia, women should be informed about the risks and benefits, and the implications for their labour.

Perineal care

If genital trauma is identified following birth, further systematic assessment should be carried out, including a rectal examination.

Delay in the first stage of labour

When delay in the established first stage of labour is confirmed in nulliparous women, advice should be sought from an obstetrician and the use of oxytocin should be considered. The woman should be informed that the use of oxytocin following spontaneous or artificial rupture of the membranes will bring forward her time of birth but will not influence the mode of birth or other outcomes.

Instrumental birth

Instrumental birth is an operative procedure that should be undertaken with tested effective anaesthesia.

2.1.2 Key research recommendations

Planning place of birth

The best possible studies comparing different places of birth should be undertaken in the UK. Prospective research to assess clinical outcomes, including safety, for all places of birth should be undertaken, as well as qualitative data collection to assess women's experiences of birth.

Wellbeing of women

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.

Delay in the first stage of labour

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.

2.2 Summary of recommendations

Chapter 3 Planning place of birth

3.2 Benefits and risks of planning each place of birth

Women should be offered the choice of planning birth at home, in a midwife-led unit or in an obstetric unit. Women should be informed:

- That giving birth is generally very safe for both the woman and her baby.
- That the available information on planning place of birth is not of good quality, but suggests that among women who plan to give birth at home or in a midwife-led unit there is a higher likelihood of a normal birth, with less intervention. We do not have enough information about the possible risks to either the woman or her baby relating to planned place of birth.
- That the obstetric unit provides direct access to obstetricians, anaesthetists, neonatologists and other specialist care including epidural analgesia.
- Of locally available services, the likelihood of being transferred into the obstetric unit and the time this may take.

- That if something does go unexpectedly seriously wrong during labour at home or in a midwife-led unit, the outcome for the woman and baby could be worse than if they were in the obstetric unit with access to specialised care.
- That if she has a pre-existing medical condition or has had a previous complicated birth that makes her at higher risk of developing complications during her next birth, she should be advised to give birth in an obstetric unit.

Clinical governance structures should be implemented in all places of birth (see Boxes 3.1 and 3.2).

Box 3.1 Clinical governance in all settings

- Multidisciplinary clinical governance structures, of which the Labour Ward Forum is an example, should be in place to enable the oversight of all places of birth. These structures should include, as a minimum, midwifery (ideally a supervisor of midwives), obstetric, anaesthetic and neonatal expertise, and adequately supported user representation.
- Rotating staff between obstetric and midwife-led units should be encouraged in order to maintain equivalent competency and experience.
- Clear referral pathways should be in place to enable midwives to inform or seek advice from a supervisor of midwives when caring for a woman who may have risk factors but does not wish to labour in an obstetric unit.
- If an obstetric opinion is sought by either the midwife or the woman on the appropriate place of birth, this should be obtained from a consultant obstetrician.
- All healthcare professionals should document discussions with the woman about her chosen place of birth in the hand-held maternity notes.
- In all places of birth, risk assessment in the antenatal period and when labour commences should be subject to continuous audit.
- Monthly figures of numbers of women booked for, being admitted to, being transferred from and giving birth in each place of birth should be audited. This should include maternal and neonatal outcomes.
- The clinical governance group should be responsible for detailed root-cause analysis of any serious maternal or neonatal adverse outcomes (for example, intrapartum-related perinatal death or seizures in the neonatal period) and consider any 'near misses' identified through risk-management systems. The Confidential Enquiry into Maternal and Child Health (CEMACH) and the National Patient Safety Agency (NPSA)'s 'Seven steps to patient safety' provide a framework for meeting clinical governance and risk-management targets.
- Data must be submitted to the national registries for either intrapartum-related perinatal mortality or neonatal encephalopathy once these are in existence.

Box 3.2 Clinical governance for settings other than an obstetric unit

- Clear pathways and guidelines on the indications for, and the process of transfer to, an obstetric unit should be established. There should be no barriers to rapid transfer in an emergency.
- Clear pathways and guidelines should also be developed for the continued care of women once they have transferred. These pathways should include arrangements for times when the nearest obstetric or neonatal unit is closed to admissions.
- If the emergency is such that transfer is not possible, open access must be given on-site for any appropriate staff to deal with whatever emergency has arisen.
- There should be continuous audit of the appropriateness of, the reason for and speed of transfer. Conversely, audit also needs to consider circumstances in which transfer was indicated but did not occur. Audit should include time taken to see an obstetrician or neonatologist and the time from admission to birth.

A national surveillance scheme which allows appropriate comparisons, including safety and cost-effectiveness, of all places of birth should be established to address the poor quality and lack of coverage of current data.

National registries of the root-cause analysis findings relating to all intrapartum-related deaths over 37 weeks of gestation should be established.

A definition of neonatal encephalopathy should be agreed and a national register commenced. The information collected should also include data on transfer during labour from each of the different birth settings.

3.3 Assessment for choosing place of birth

Tables 3.7 to 3.10 should be used as part of an assessment for choosing place of birth.

Tables 3.7 and 3.8 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 3.9 and 3.10 are not reasons in themselves for advising birth within an obstetric unit but indicate that further consideration of birth setting may be required.

These risks and the additional care that can be provided in the obstetric unit should be discussed with the woman so that she can make an informed choice about place of birth.

Table 3.7 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 100 000 Von Willebrand's disease Bleeding disorder in the woman or unborn baby Atypical antibodies which carry a risk of haemolytic disease of the newborn
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
Endocrine	Hyperthyroidism Diabetes
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 3.8 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
	Pre-eclampsia or pregnancy-induced hypertension
	Preterm labour or preterm prelabour rupture of membranes
	Placental abruption
	Anaemia – haemoglobin less than 8.5 g/dl 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
	Body mass index at booking of greater than 35 kg/m^2
	Recurrent antepartum haemorrhage
Fetal indications	Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound)
	Abnormal fetal heart rate (FHR)/Doppler studies
	Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	Myomectomy
	Hysterotomy

Table 3.9 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 8.5–10.5 g/dl 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 3.10 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)
	Body mass index at booking of 30–34 kg/m^2
	Blood pressure of 140 mmHg systolic or 90 mmHg diastolic on two occasions
	Clinical or ultrasound suspicion of macrosomia
	Para 6 or more
	Recreational drug use
	Under current outpatient psychiatric care
	Age over 40 at booking
Fetal indications	Fetal abnormality
Previous gynaecological history	Major gynaecological surgery
	Cone biopsy or large loop excision of the transformation zone
	Fibroids

Indications for intrapartum transfer

The following risks and benefits should be assessed when considering transfer to an obstetric unit, bearing in mind the likelihood of birth during the transfer:

- indications for electronic fetal monitoring (EFM) including abnormalities of the fetal heart rate (FHR) on intermittent auscultation
- delay in the first or second stages of labour
- significant meconium-stained liquor
- maternal request for epidural pain relief
- obstetric emergency – antepartum haemorrhage, cord presentation/prolapse, postpartum haemorrhage, maternal collapse or a need for advanced neonatal resuscitation
- retained placenta
- maternal pyrexia in labour (38.0 °C once or 37.5 °C on two occasions 2 hours apart)
- malpresentation or breech presentation diagnosed for the first time at the onset of labour, taking into account imminence of birth
- either raised diastolic blood pressure (over 90 mmHg) or raised systolic blood pressure (over 140 mmHg) on two consecutive readings taken 30 minutes apart
- uncertainty about the presence of a fetal heartbeat
- third- or fourth-degree tear or other complicated perineal trauma requiring suturing.

Chapter 4 Care throughout labour

4.1 Communication between women and healthcare professionals

All women in labour should be treated with respect and should be in control of and involved in what is happening to them, and the way in which care is given is key to this. To facilitate this, healthcare professionals and other caregivers should establish a rapport with the labouring woman, asking her about her wants and expectations for labour, being aware of the importance of tone and demeanour, and of the actual words they use. This information should be used to support and guide her through her labour.

To establish communication with the labouring woman, healthcare professionals should:

- Greet the woman with a smile and a personal welcome, establish her language needs, introduce themselves and explain their role in her care.
- Maintain a calm and confident approach so that their 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 partner how to summon help and reassure her that she may do so whenever and as often as she needs to. When leaving the room, healthcare professionals should let her know when they 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.

4.2 Mobilisation and position

Women should be encouraged and helped to move and adopt whatever positions they find most comfortable throughout labour.

4.3 Support in labour

A woman in established labour should receive supportive one-to-one care.

A woman in established labour should not be left on her own except for short periods or at the woman's request.

Women should be encouraged to have support by birth partner(s) of their choice.

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.

4.4 Eating and drinking in labour

Controlling gastric acidity

Neither H2-receptor antagonists nor antacids should be given routinely to low-risk women.

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.

Eating and drinking in labour

Women may drink during established labour and be informed that isotonic drinks may be more beneficial than water.

Women may eat a light diet in established labour unless they have received opioids or they develop risk factors that make a general anaesthetic more likely.

4.5 Hygiene measures during labour

Tap water may be used if cleansing is required prior to vaginal examination.

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.

Selection of protective equipment should be based on an assessment of the risk of transmission of microorganisms to the woman, and the risk of contamination of the healthcare practitioner's clothing and skin by women's blood, body fluids, secretions or excretions.*

Chapter 5 Coping with pain in labour: non-epidural

5.2 Women's views and experiences of pain and pain relief in childbirth

Healthcare professionals should consider how their own values and beliefs inform their attitude to coping with pain in labour and ensure their care supports the woman's choice.

5.3 Pain-relieving strategies

Women who choose to use breathing and relaxation techniques in labour should be supported in their choice.

Women who choose to use massage techniques in labour that have been taught to birth partners should be supported in their choice.

The opportunity to labour in water is recommended for pain relief.

For women labouring in water, the temperature of the woman and the water should be monitored hourly to ensure that the woman is comfortable and not becoming pyrexial. The temperature of the water should not be above 37.5 °C.

Any bath or birthing pool should be kept clean using a protocol agreed with the microbiology department and, in the case of birthing pools, in accordance with the manufacturer's guidelines.

The use of injected water papules is not recommended.

Acupuncture, acupressure and hypnosis should not be provided, but women who wish to use these techniques should not be prevented from doing so.

The playing of music of the woman's choice in the labour ward should be supported.

5.4 Non-pharmacological analgesia

Transcutaneous electrical nerve stimulation (TENS) should not be offered to women in established labour.

5.5 Inhalational analgesia

Entonox (a 50 : 50 mixture of oxygen and nitrous oxide) should be available in all birth settings as it may reduce pain in labour, but women should be informed that it may make them feel nauseous and light-headed.

5.6 Intravenous and intramuscular use of opioids for labour

Pethidine, diamorphine or other opioids should be available in all birth settings. Women should be informed that these will provide limited pain relief during labour and may have significant side effects for both the woman (drowsiness, nausea and vomiting) and her baby (short-term respiratory depression and drowsiness which may last several days).

Women should be informed that pethidine, diamorphine or other opioids may interfere with breastfeeding.

If an intravenous or intramuscular opioid is used, it should be administered with an antiemetic.

Women should not enter water (a birthing pool or bath) within 2 hours of opioid administration or if they feel drowsy.

* This recommendation is from 'Infection control: prevention of healthcare-associated infection in primary and community care' (NICE clinical guideline 2).

Chapter 6 Pain relief in labour: regional analgesia

6.2 Regional analgesia versus other types of analgesia in labour

Before choosing epidural analgesia, women should be informed about the risks and benefits, and the implications for their labour.

This information about choosing epidural analgesia should include the following:

- It is only available in obstetric units.
- It provides more effective pain relief than opioids.
- It is associated with a longer second stage of labour and an increased chance of vaginal instrumental birth.
- 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 will be accompanied by a more intensive level of monitoring and intravenous access.
- Modern epidural solutions contain opioids and, whatever the route of administration, all opioids cross the placenta and in larger doses (greater than 100 micrograms in total) may cause short-term respiratory depression in the baby and make the baby drowsy.

6.3 Timing of regional analgesia

Women in labour who desire regional analgesia should not be denied it, including women in severe pain in the latent first stage of labour.

6.4 Care and observations for women with regional analgesia in labour

Intravenous access should always be secured prior to commencing regional analgesia.

Preloading and maintenance fluid infusion need not be administered routinely before establishing low-dose epidural analgesia and combined spinal–epidural analgesia.

The following additional observations should be undertaken for women with regional analgesia:

- During establishment of regional analgesia or after further boluses (10 ml or more of low-dose solutions) blood pressure should be measured every 5 minutes for 15 minutes.
- If the woman is not pain free 30 minutes after each administration of local anaesthetic/opioid solution, the anaesthetist should be recalled.
- Hourly assessment of the level of the sensory block should be undertaken.

Women with regional analgesia should be encouraged to move and adopt whatever upright positions they find comfortable throughout labour.

Once established, regional analgesia should be continued until after completion of the third stage of labour and any necessary perineal repair.

Upon confirmation of full cervical dilatation in women 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 pushing during contractions should be actively encouraged.

Following the diagnosis of full dilatation in a woman with regional analgesia, a plan should be agreed with the woman in order to ensure that birth will have occurred within 4 hours regardless of parity.

Oxytocin should not be used as a matter of routine in the second stage of labour for women with regional analgesia.

Continuous EFM is recommended for at least 30 minutes during establishment of regional analgesia and after administration of each further bolus of 10 ml or more.

6.6–6.8 Establishing and maintaining regional analgesia

Either patient-controlled epidural analgesia or intermittent bolus given by healthcare professionals are the preferred modes of administration for maintenance of epidural analgesia.

Either epidural or combined spinal–epidural analgesia is recommended for establishing regional analgesia in labour.

If rapid analgesia is required, combined spinal–epidural analgesia is recommended.

It is recommended that combined spinal–epidural analgesia is established with bupivacaine and fentanyl.

It is recommended that epidural analgesia is established 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 and as such should be administered cautiously to ensure that inadvertent intrathecal injection has not occurred.

Low-concentration local anaesthetic and opioid solutions (0.0625–0.1% bupivacaine or equivalent combined with 2.0 micrograms per ml fentanyl) are recommended for maintaining epidural analgesia in labour.

High concentrations of local anaesthetic solutions (0.25% or above of bupivacaine or equivalent) should not be used routinely for either establishing or maintaining epidural analgesia.

Chapter 7 Normal labour: first stage

7.1 Normal labour

Clinical intervention should not be offered or advised where labour is progressing normally and the woman and baby are well.

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

7.2 Definition of the first stage of labour

For the purposes of this guideline, the following definitions of labour are recommended:

- 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.

7.3 Duration of the first stage of labour

Women should be informed 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.

Definition of delay in the first stage of labour [repeated from Section 14.1]

A diagnosis of delay in the established first stage of labour needs to take into consideration all aspects of progress in labour and should include:

- 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 fetal head
- changes in the strength, duration and frequency of uterine contractions.

7.4 Observations on presentation in suspected labour

The initial assessment of a woman by a midwife should include:

- listening to her story, considering her emotional and psychological needs, and reviewing her clinical records
- physical observation – temperature, pulse, blood pressure, urinalysis
- length, strength and frequency of contractions
- abdominal palpation – fundal height, lie, presentation, position and station
- vaginal loss – show, liquor, blood
- assessment of the woman's pain, including her wishes for coping with labour along with the range of options for pain relief.

In addition:

- The FHR should be auscultated for a minimum of 1 minute immediately after a contraction. The maternal pulse should be palpated to differentiate between maternal and FHR.
- If the woman does not appear to be in established labour, after a period of assessment it may be helpful to offer a vaginal examination.
- If the woman appears to be in established labour, a vaginal examination should be offered.

Healthcare professionals who conduct vaginal examinations should :

- be sure that the vaginal examination is really necessary and will add important information to the decision-making process
- be aware that for many women who may already be in pain, highly anxious and in an unfamiliar environment, vaginal examinations can be very distressing
- ensure the woman's consent, privacy, dignity and comfort
- explain the reason for the examination and what will be involved, and
- explain the findings and their impact sensitively to the woman.

Some women have pain without cervical change. Although these women are described as not being in labour, they may well consider themselves 'in labour' by their own definition. Women who seek advice or attend hospital with painful contractions but who are not in established labour should be offered individualised support and occasionally analgesia, and encouraged to remain at or return home.

The use of admission cardiotocography (CTG) in low-risk pregnancy is not recommended in any birth setting.

7.6 Observations during the established first stage of labour

Verbal assessment using a numerical pain score is not recommended routinely.

A pictorial record of labour (partogram) should be used once labour is established.

Where the partogram includes an action line, the World Health Organization recommendation of a 4 hour action line should be used.* [repeated from Section 7.7]

Observations by a midwife during the first stage of labour include:

- 4 hourly temperature and blood pressure
- hourly pulse
- half-hourly documentation of frequency of contractions
- frequency of emptying the bladder
- vaginal examination offered 4 hourly, or where there is concern about progress or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss).

In addition:

- Intermittent auscultation of the fetal heart after a contraction should occur for at least 1 minute, at least every 15 minutes, and the rate should be recorded as an average. The maternal pulse should be palpated if an FHR abnormality is detected to differentiate the two heart rates. (See recommendations in Section 7.8 for reasons to transfer to continuous EFM.)

* Anonymous. World Health Organization partograph in management of labour. World Health Organization Maternal Health and Safe Motherhood Programme. *Lancet* 1994;343(8910):1399–404. See also www.who.int/reproductive-health/impac/Clinical_Principles/Normal_labour_C57_C76.html.

Ongoing consideration should be given to the woman's emotional and psychological needs, including her desire for pain relief.

Women should be encouraged to communicate their need for analgesia at any point during labour.

7.7 Possible routine interventions in first stage of labour

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) should not be offered routinely.

Where the partogram includes an action line, the World Health Organization recommendation of a 4 hour action line should be used.*

In normally progressing labour, amniotomy should not be performed routinely.

Combined early amniotomy with use of oxytocin should not be used routinely.

7.8 Fetal heart assessment and reasons for transfer to continuous EFM

Intermittent auscultation of the FHR is recommended for low-risk women in established labour in any birth setting.

Initial auscultation of the fetal heart is recommended at first contact in early labour and at each further assessment undertaken to determine whether labour has become established.

Once a woman is in established labour, intermittent auscultation of the fetal heart after a contraction should be continued as detailed in Section 7.6.

Intermittent auscultation can be undertaken by either Doppler ultrasound or Pinard stethoscope.

Changing from intermittent auscultation to continuous EFM in low-risk women should be advised for the following reasons:

- significant meconium-stained liquor, and this change should also be considered for light meconium-stained liquor (see recommendations in Section 12.1)
- abnormal FHR detected by intermittent auscultation (less than 110 beats per minute [bpm]; greater than 160 bpm; any decelerations after a contraction)
- maternal pyrexia (defined as 38.0 °C once or 37.5 °C on two occasions 2 hours apart)
- fresh bleeding developing in labour
- oxytocin use for augmentation
- the woman's request.

Chapter 8 Normal labour: second stage

8.1 Definition of the second stage of labour

For the purposes of this guideline, the following definitions of labour are recommended:

- Passive second stage of labour:
  - the finding of full dilatation of the cervix prior to 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.

* Anonymous. World Health Organization partograph in management of labour. World Health Organization Maternal Health and Safe Motherhood Programme. *Lancet* 1994;343(8910):1399–404. See also www.who.int/reproductive-health/impac/Clinical_Principles/Normal_labour_C57_C76.html.

8.2 Duration and definition of delay in the second stage of labour

Nulliparous women:

- Birth would be expected to take place within 3 hours of the start of the active second stage in most women.
- A diagnosis of delay in the active second stage should be made when it has lasted 2 hours and women should be referred to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent.

Parous women:

- Birth would be expected to take place within 2 hours of the start of the active second stage in most women.
- A diagnosis of delay in the active second stage should be made when it has lasted 1 hour and women should be referred to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent.

If full dilatation of the cervix has been diagnosed in a woman without epidural analgesia, but she does not get an urge to push, further assessment should take place after 1 hour.

8.3 Observations for women and babies in the second stage of labour

All observations should be documented on the partogram. Observations by a midwife of a woman in the second stage of labour include:

- hourly blood pressure and pulse
- continued 4 hourly temperature
- vaginal examination offered hourly in the active second stage or in response to the woman's wishes (after abdominal palpation and assessment of vaginal loss)
- half-hourly documentation of the frequency of contractions
- frequency of emptying the bladder
- ongoing consideration of the woman's emotional and psychological needs.

In addition:

- Assessment of progress should include maternal behaviour, effectiveness of pushing and fetal wellbeing, taking into account fetal position and station at the onset of the second stage. These factors will assist in deciding the timing of further vaginal examination and the need for obstetric review.
- Intermittent auscultation of the fetal heart should occur after a contraction for at least 1 minute, at least every 5 minutes. The maternal pulse should be palpated if there is suspected fetal bradycardia or any other FHR anomaly to differentiate the two heart rates.
- Ongoing consideration should be given to the woman's position, hydration, coping strategies and pain relief throughout the second stage.

8.4 Women's position and pushing in the second stage of labour

Women should be discouraged from lying supine or semi-supine in the second stage of labour and should be encouraged to adopt any other position that they find most comfortable.

Women should be informed that in the second stage they should be guided by their own urge to push.

If pushing is ineffective or if requested by the woman, strategies to assist birth can be used, such as support, change of position, emptying of the bladder and encouragement.

8.5 Intrapartum interventions to reduce perineal trauma

Perineal massage should not be performed by healthcare professionals in the second stage of labour.

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.

Lidocaine spray should not be used to reduce pain in the second stage of labour.

A routine episiotomy should not be carried out during spontaneous vaginal birth.

Where 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.

An episiotomy should be performed if there is a clinical need such as instrumental birth or suspected fetal compromise.

Tested effective analgesia should be provided prior to carrying out an episiotomy, except in an emergency due to acute fetal compromise.

Women with a history of severe perineal trauma should be informed that their risk of repeat severe perineal trauma is not increased in a subsequent birth, compared with women having their first baby.

Episiotomy should not be offered routinely at vaginal birth following previous third- or fourth-degree trauma.

In order for a woman who has had previous third- or fourth-degree trauma to make an informed choice, discussion with her about the future mode of birth should encompass:

- 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.

Women with infibulated genital mutilation should be informed of the risks of difficulty with vaginal examination, catheterisation and application of fetal scalp electrodes. They should also be informed 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.

8.6 Water birth

Women should be informed that there is insufficient high-quality evidence to either support or discourage giving birth in water.

Chapter 9 Normal labour: third stage

9.1 Definition and duration of the third stage of labour

For the purposes of this guideline, the following definitions are recommended:

- 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 which includes all of these three components:
  - routine use of uterotonic drugs
  - early clamping and cutting of the cord
  - controlled cord traction.
- Physiological management of the third stage involves a package of care which includes all of these three components:
  - no routine use of uterotonic drugs
  - no clamping of the cord until pulsation has ceased
  - delivery of the placenta by maternal effort.

The third stage of labour is diagnosed as prolonged if not completed within 30 minutes of the birth of the baby with active management and 60 minutes with physiological management.

9.2 Observations in the third stage of labour

Observations by a midwife of a woman in the third stage of labour include:

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

In addition, in the presence of haemorrhage, retained placenta or maternal collapse, frequent observations to assess the need for resuscitation are required.

9.3 Physiological and active management of the third stage

Active management of the third stage is recommended, which includes the use of oxytocin (10 international units [IU] by intramuscular injection), followed by early clamping and cutting of the cord and controlled cord traction.*

Women should be informed that active management of the third stage reduces the risk of maternal haemorrhage and shortens the third stage.

Women at low risk of postpartum haemorrhage who request physiological management of the third stage should be supported in their choice.

Changing from physiological management to active management of the third stage is indicated in the case of:

- haemorrhage
- failure to deliver the placenta within 1 hour
- the woman's desire to artificially shorten the third stage.

Pulling the cord or palpating the uterus should only be carried out after administration of oxytocin as part of active management.

In the third stage of labour neither umbilical oxytocin infusion nor prostaglandin should be used routinely.

Chapter 10 Normal labour: care of the baby and woman immediately after birth

10.2 Initial assessment of the newborn baby and mother–infant bonding

The Apgar score at 1 and 5 minutes should be recorded routinely for all births.

If the baby is born in poor condition (the Apgar score at 1 minute is 5 or less), then the time to the onset of regular respirations should be recorded and the cord double-clamped to allow paired cord blood gases to be taken. The Apgar score should continue to be recorded until the baby's condition is stable.

Women should be encouraged to have skin-to-skin contact with their babies as soon as possible after the birth.†

In order to keep the baby warm, he or she should be dried and covered with a warm, dry blanket or towel while maintaining skin-to-skin contact with the woman.

Separation of a woman and her baby within the first hour of the birth for routine postnatal procedures, for example weighing, measuring and bathing, should be avoided unless these measures are requested by the woman, or are necessary for the immediate care of the baby.†

Initiation of breastfeeding should be encouraged as soon as possible after the birth, ideally within 1 hour.†

* At the time of publication (September 2007), oxytocin did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

† Recommendations relating to immediate postnatal care (within 2 hours of birth) have been extracted 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.

Head circumference, body temperature and birthweight should be recorded soon after the first hour following birth.

An initial examination should be undertaken by a healthcare professional to detect any major physical abnormality and to identify any problems that require referral.

Any examination or treatment of the baby should be undertaken with the consent and in the presence of the parents or, if this is not possible, with their knowledge.

10.3 Initial assessment of the mother following birth

Observations taken following the birth of the baby should include:

- maternal observation – temperature, pulse, blood pressure, uterine contraction, lochia
- examination of placenta and membranes – assessment of their condition, structure, cord vessels and completeness
- early assessment of maternal emotional/psychological condition in response to labour and birth
- successful voiding of the woman's bladder.

10.4 Perineal care

Perineal or genital trauma caused by either tearing or episiotomy should be defined 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.

Before assessing for genital trauma, healthcare professionals should:

- explain to the woman what they plan to do 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.

The initial examination should be performed gently and with sensitivity and may be done in the immediate period following birth.

If genital trauma is identified following birth, further systematic assessment should be carried out, including a rectal examination.

Systematic assessment of genital trauma should include:

- further explanation of what the healthcare professional plans to do 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.

The timing of this systematic assessment should not interfere with mother–infant bonding unless the woman has bleeding that requires urgent attention.

The woman should usually be in lithotomy to allow adequate visual assessment of the degree of the trauma and for the repair. This position should only be maintained for as long as is necessary for the systematic assessment and repair.

The woman should be referred to a more experienced healthcare professional if uncertainty exists as to the nature or extent of trauma sustained.

The systematic assessment and its results should be fully documented, possibly pictorially.

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

Women should be advised 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.

Women should be advised that in the case of second-degree trauma, the muscle should be sutured in order to improve healing.

Repair of the perineum should be undertaken as soon as possible to minimise the risk of infection and blood loss.

Perineal repair should only be undertaken with tested effective analgesia in place using infiltration with up to 20 ml of 1% lidocaine or equivalent, or topping up the epidural (spinal anaesthesia may be necessary).

If the woman reports inadequate pain relief at any point this should immediately be addressed.

If the skin is opposed following suturing of the muscle in second-degree trauma, there is no need to suture it.

Where the skin does require suturing, this should be undertaken using a continuous subcuticular technique.

Perineal repair should be undertaken using a continuous non-locked suturing technique for the vaginal wall and muscle layer.

An absorbable synthetic suture material should be used to suture the perineum.

The following basic principles should be observed when performing perineal repairs:

- Perineal trauma should be repaired using aseptic techniques.
- Equipment should be checked and swabs and needles counted before and after the procedure.
- Good lighting is essential to see and identify the structures involved.
- Difficult trauma should be repaired by an experienced practitioner in theatre under regional or general anaesthesia. An indwelling catheter should be inserted for 24 hours to prevent urinary retention.
- Good anatomical alignment of the wound should be achieved, and consideration given to the cosmetic results.
- Rectal examination should be carried out after completing the repair to ensure that suture material has not been accidentally inserted through the rectal mucosa.
- Following completion of the repair, an accurate detailed account should be documented covering the extent of the trauma, the method of repair and the materials used.
- Information should be given to the woman regarding the extent of the trauma, pain relief, diet, hygiene and the importance of pelvic-floor exercises.

Rectal nonsteroidal anti-inflammatory drugs should be offered routinely following perineal repair of first- and second-degree trauma provided these drugs are not contraindicated.

Chapter 11 Prelabour rupture of membranes at term

11.1 Prelabour rupture of membranes at term

There is no reason to carry out a speculum examination with a certain history of rupture of the membranes at term.

Women with an uncertain history of prelabour rupture of the membranes should be offered a speculum examination to determine whether their membranes have ruptured. Digital vaginal examination in the absence of contractions should be avoided.

Women presenting with prelabour rupture of the membranes at term should be advised 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* is appropriate approximately 24 hours after rupture of the membranes.

Until the induction is commenced or if expectant management beyond 24 hours is chosen by the woman:

- lower vaginal swabs and maternal C-reactive protein should not be offered
- to detect any infection that may be developing women should be advised to record their temperature every 4 hours during waking hours and to report immediately any change in the colour or smell of their vaginal loss
- women should be informed that bathing or showering are not associated with an increase in infection, but that having sexual intercourse may be.

Fetal movement and heart rate should be assessed at initial contact and then every 24 hours following rupture of the membranes while the woman is not in labour, and the woman should be advised to report immediately any decrease in fetal movements.

If labour has not started 24 hours after rupture of the membranes, women should be advised to give birth where there is access to neonatal services and advised to stay in hospital for at least 12 hours following the birth.

If there are no signs of infection in the woman, antibiotics should not be given to either the woman or the baby, even if the membranes have been ruptured for over 24 hours.

If there is evidence of infection in the woman, a full course of broad-spectrum intravenous antibiotics should be prescribed.

Women with prelabour rupture of the membranes should be asked to inform their healthcare professionals immediately of any concerns they have about their baby's wellbeing in the first 5 days following birth, particularly in the first 12 hours when the risk of infection is greatest.

Blood, cerebrospinal fluid and/or surface culture tests should not be performed in an asymptomatic baby.

Asymptomatic term babies born to women with prelabour rupture of the membranes (more than 24 hours before labour) should be closely observed for the first 12 hours of life (at 1 hour, 2 hours and then 2 hourly for 10 hours). These observations should include:

- general wellbeing
- chest movements and nasal flare
- skin colour including perfusion, by testing capillary refill
- feeding
- muscle tone
- temperature
- heart rate and respiration.

A baby with any symptom of possible sepsis, or born to a woman who has evidence of chorioamnionitis, should immediately be referred to a neonatal care specialist.

Chapter 12 Meconium-stained liquor

12.1 Monitoring and treatment of women with meconium-stained liquor

Continuous EFM should be advised for women with significant meconium-stained liquor, which is defined as either dark green or black amniotic fluid that is thick or tenacious, or any meconium-stained amniotic fluid containing lumps of meconium.

Continuous EFM should be considered for women with light meconium-stained liquor depending on a risk assessment which should include as a minimum their stage of labour, volume of liquor, parity, the FHR and, where applicable, transfer pathway.

Amnioinfusion should not be used for the treatment of women with meconium-stained liquor.

* Care of women who have their labour induced is covered by 'Induction of labour' (inherited clinical guideline D).

12.2 Resuscitation of babies with meconium-stained liquor

If significant meconium-stained liquor is identified, healthcare professionals trained in FBS should be available in labour and healthcare professionals trained in advanced neonatal life support should be readily available for the birth.

Suctioning of the nasopharynx and oropharynx prior to birth of the shoulders and trunk should not be carried out.

The upper airways should only be suctioned if the baby has thick or tenacious meconium present in the oropharynx.

If the baby has depressed vital signs, laryngoscopy and suction under direct vision should be carried out by a healthcare professional trained in advanced neonatal life support.

If there has been significant meconium staining and the baby is in good condition, the baby should be closely observed for signs of respiratory distress. These observations should be performed at 1 and 2 hours of age and then 2 hourly until 12 hours of age, and should include:

- general wellbeing
- chest movements and nasal flare
- skin colour including perfusion, by testing capillary refill
- feeding
- muscle tone
- temperature
- heart rate and respiration.

If there has been light meconium staining, the baby should be similarly observed by the healthcare professional at 1 and 2 hours and should be reviewed by a neonatologist if the baby's condition causes concern at any time.

Chapter 13 Complicated labour: monitoring babies in labour

13.2 Women's views on fetal monitoring and mobility

Women should be informed that continuous fetal monitoring will restrict their mobility.

13.4 EFM and record-keeping

In order to ensure accurate record-keeping regarding EFM:*

- The date and time clocks on the EFM machine should be correctly set.
- Traces should be labelled with the mother's name, date and hospital number.
- Any intrapartum events that may affect the FHR should be noted at the time on the FHR trace, which should be signed and the date and time noted (for example, vaginal examination, FBS or siting of an epidural).
- Any member of staff who is asked to provide an opinion on a trace should note their findings on both the trace and the woman's medical records along with the date, time and signature.
- Following birth, the healthcare professional should sign and note the date, time and mode of birth on the FHR trace.
- The FHR trace should be stored securely with the woman's medical records at the end of the monitoring process.

* This guideline updates and replaces 'The use of electronic fetal monitoring: The use and interpretation of cardiotocography in intrapartum fetal surveillance' (inherited clinical guideline C), issued in 2001.

13.5 Interpretation of FHR traces

The recommended definitions and classifications of the FHR trace/cardiotocograph produced during EFM are shown in Tables 13.1 and 13.2.

Table 13.1 Definition of normal, suspicious and pathological FHR traces

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

Table 13.2 Classification of FHR trace features

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

Further information about classifying FHR traces is given below.

- If repeated accelerations are present with reduced variability, the FHR trace should be regarded as reassuring.
- True early uniform decelerations are rare and benign, and therefore they are not significant.
- Most decelerations in labour are variable.
- If a bradycardia occurs in the baby for more than 3 minutes, urgent medical aid should be sought and preparations should be made to urgently expedite the birth of the baby, classified as a category 1 birth. This could include moving the woman to theatre if the fetal heart has not recovered by 9 minutes. If the fetal heart recovers within 9 minutes the decision to deliver should be reconsidered in conjunction with the woman if reasonable.
- A tachycardia in the baby of 160–180 bpm, where accelerations are present and no other adverse features appear, should not be regarded as suspicious. However, an increase in the baseline heart rate, even within the normal range, with other non-reassuring or abnormal features should increase concern.

For women having continuous EFM, a documented systematic assessment based on these definitions and classifications should be undertaken every hour.

During episodes of abnormal FHR patterns when the woman is lying supine she should be advised to adopt the left-lateral position.

Prolonged use of maternal facial oxygen therapy may be harmful to the baby and should be avoided. There is no research evidence evaluating the benefits or risks associated with the short-term use of maternal facial oxygen therapy in cases of suspected fetal compromise.

In the presence of abnormal FHR patterns and uterine hypercontractility not secondary to oxytocin infusion, tocolysis should be considered. A suggested regimen is subcutaneous terbutaline 0.25 mg.*

In cases of suspected or confirmed acute fetal compromise, delivery should be accomplished within a time appropriate for the clinical condition.

Continuous EFM in the presence of oxytocin:

- If the FHR trace is normal, oxytocin may be continued until the woman is experiencing 4 or 5 contractions every 10 minutes. Oxytocin should be reduced if contractions occur more frequently than 5 contractions in 10 minutes.
- If the FHR trace is classified as suspicious, this should be reviewed by an obstetrician and the oxytocin dose should only continue to increase to achieve 4 or 5 contractions every 10 minutes.
- If the FHR trace is classified as pathological, oxytocin should be stopped and a full assessment of the fetal condition undertaken by an obstetrician before oxytocin is recommenced.

13.6 Adjuncts to the use of continuous EFM including FBS

Digital stimulation of the fetal scalp by the healthcare professional during a vaginal examination should be considered as an adjunct to continuous EFM.

If fetal death is suspected despite the presence of an apparently recorded FHR, then fetal viability should be confirmed with real-time ultrasound assessment.

FBS should be advised in the presence of a pathological FHR trace, unless there is clear evidence of acute compromise.

Where assisted birth is contemplated because of an abnormal FHR pattern, in cases of suspected fetal acidosis FBS should be undertaken in the absence of technical difficulties or any contraindications.

Where there is clear evidence of acute fetal compromise (for example, prolonged deceleration greater than 3 minutes), FBS should not be undertaken and urgent preparations to expedite birth should be made.

Fetal blood samples should be taken with the woman in the left-lateral position.

The classification of FBS results shown in Table 13.4 is recommended.

Table 13.4 The classification of fetal blood sample results

Fetal blood sample result (pH)	Interpretation of the results
≥ 7.25	Normal FBS result
7.21–7.24	Borderline FBS result
≤ 7.20	Abnormal FBS result

These results should be interpreted taking into account the previous pH measurement, the rate of progress in labour and the clinical features of the woman and baby.

After an abnormal FBS result, consultant obstetric advice should be sought.

After a normal FBS result, sampling should be repeated no more than 1 hour later if the FHR trace remains pathological, or sooner if there are further abnormalities.

After a borderline FBS result, sampling should be repeated no more than 30 minutes later if the FHR trace remains pathological or sooner if there are further abnormalities.

The time taken to take a fetal blood sample needs to be considered when planning repeat samples.

* At the time of publication (September 2007), terbutaline did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

If the FHR trace remains unchanged and the FBS result is stable after the second test, a third/further sample may be deferred unless additional abnormalities develop on the trace.

Where a third FBS is considered necessary, consultant obstetric opinion should be sought.

Contraindications to FBS include:

- maternal infection (for example, HIV, hepatitis viruses and herpes simplex virus)
- fetal bleeding disorders (for example, haemophilia)
- prematurity (less than 34 weeks).

13.8 Risk management when using continuous EFM in labour

Clinicians should take into account the time that it will take to achieve birth by both instrumental vaginal birth and caesarean section when making decisions regarding concern over fetal well-being during labour.

FHR traces should be kept for 25 years and, where possible, stored electronically.

In cases where there is concern that the baby may suffer developmental delay, FHR traces should be photocopied and stored indefinitely in case of possible adverse outcomes.

Tracer systems should be available for all FHR traces if stored separately from women's records.

Tracer systems should be developed to ensure that FHR traces removed for any purpose (such as risk management or for teaching purposes) can always be located.

Paired cord blood gases do not need to be taken routinely. They should be taken when there has been concern about the baby either in labour or immediately following birth.

An additional clamp to facilitate double-clamping of the cord should be available at all birth settings.

Chapter 14 Complicated labour: first stage

14.1 Definition of delay in the first stage of labour

A diagnosis of delay in the established first stage of labour needs to take into consideration all aspects of progress in labour and should include:

- 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 fetal head
- changes in the strength, duration and frequency of uterine contractions.

14.2 Interventions for perceived delay in first stage of labour

Where delay in the established first stage is suspected the following should be considered:

- 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,

and women should be offered support, hydration, and appropriate and effective pain relief.

If delay in the established first stage of labour is suspected, amniotomy should be considered for all women with intact membranes, following 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.

Whether or not a woman has agreed to an amniotomy, all women with suspected delay in the established first stage of labour should be advised to have a vaginal examination 2 hours later, and if progress is less than 1 cm a diagnosis of delay is made.

In women with intact membranes in whom delay in the established first stage of labour is confirmed, amniotomy should be advised to the woman, and she should be advised to have a repeat vaginal examination 2 hours later whether her membranes are ruptured or intact.

When delay in the established first stage of labour is confirmed in nulliparous women, advice should be sought from an obstetrician and the use of oxytocin should be considered. The woman should be informed that the use of oxytocin following spontaneous or artificial rupture of the membranes will bring forward her time of birth but will not influence the mode of birth or other outcomes.

Multiparous women with confirmed delay in the first stage should be seen by an obstetrician who should make a full assessment, including an abdominal palpation and vaginal examination, before making a decision about the use of oxytocin.

All women with delay in the established first stage of labour should be offered support and effective pain relief.

Women should be informed that oxytocin will increase the frequency and strength of their contractions and that its use will mean their baby should be monitored continuously. Women should be offered an epidural before oxytocin is started.

Where oxytocin is used, the time between increments of the dose should be no more frequent than every 30 minutes. Oxytocin should be increased until there are 4–5 contractions in 10 minutes. (See also Chapter 13 on monitoring babies in labour.)

The woman should be advised to have a vaginal examination 4 hours after commencing oxytocin in established labour. If there is less than 2 cm progress after 4 hours of oxytocin, further obstetric review is required to consider caesarean section. If there is 2 cm or more progress, vaginal examinations should be advised 4 hourly.

Amniotomy alone for suspected delay in the established first stage of labour is not an indication to commence continuous EFM.

Where a diagnosis of delay in the established first stage of labour is made, continuous EFM should be offered.

Continuous EFM should be used when oxytocin is administered for augmentation.

Chapter 15 Complicated labour: second stage

15.1 Delay in the second stage of labour

Duration and definition of delay in the second stage of labour

Nulliparous women:

- Birth would be expected to take place within 3 hours of the start of the active second stage in most women.
- A diagnosis of delay in the active second stage should be made when it has lasted 2 hours and women should be referred to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [repeated from Section 8.2]

Parous women:

- Birth would be expected to take place within 2 hours of the start of the active second stage in most women.
- A diagnosis of delay in the active second stage should be made when it has lasted 1 hour and women should be referred to a healthcare professional trained to undertake an operative vaginal birth if birth is not imminent. [repeated from Section 8.2]

Where 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.

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.

In nulliparous women, if after 1 hour of active second stage progress is inadequate, delay is suspected. Following vaginal examination, amniotomy should be offered if the membranes are intact.

Women with confirmed delay in the second stage should be assessed by an obstetrician but oxytocin should not be started.

Following initial obstetric assessment for women with delay in the second stage of labour, ongoing obstetric review should be maintained every 15–30 minutes.

Instrumental birth

Instrumental birth should be considered if there is concern about fetal wellbeing, or for prolonged second stage.

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.

The choice of instrument depends on a balance of clinical circumstance and practitioner experience.

Instrumental birth is an operative procedure that should be undertaken with tested effective anaesthesia.

If a woman declines anaesthesia, a pudendal block combined with local anaesthetic to the perineum can be used during instrumental birth.

Where there is concern about fetal compromise, either tested effective anaesthesia or, if time does not allow this, a pudendal block combined with local anaesthetic to the perineum can be used during instrumental birth.

Caesarean section should be advised if vaginal birth is not possible.*

Chapter 16 Complicated labour: immediate care of newborn

16.1 Basic neonatal resuscitation

All relevant healthcare professionals caring for women during birth should attend a course in neonatal resuscitation at least annually, which is consistent with the algorithm adopted in the 'Newborn life support course' developed by the Resuscitation Council (UK).†

Basic resuscitation of newborn babies should be initiated with air.

Oxygen should be available for babies who do not respond once adequate ventilation has been established.

Emergency referral pathways for both the woman and the baby should be developed and implemented for all birth settings.

Chapter 17 Complicated labour: third stage

17.1 Definition of delay in the third stage of labour

Prolonged third stage:

The third stage of labour is diagnosed as prolonged if not completed within 30 minutes of the birth of the baby with active management and 60 minutes with physiological management. [repeated from Section 9.1]

* See 'Caesarean section' (NICE clinical guideline 13).

† Available from www.resus.org.uk/siteindx.htm.

17.2 Treatment of women with a retained placenta

Intravenous access should always be secured in women with a retained placenta.

Intravenous infusion of oxytocin should not be used to assist the delivery of the placenta.

For women with a retained placenta oxytocin injection into the umbilical vein with 20 IU of oxytocin in 20 ml of saline is recommended, followed by proximal clamping of the cord.

If the placenta is still retained 30 minutes after oxytocin injection, or sooner if there is concern about the woman's condition, women should be offered an assessment of the need to remove the placenta. Women should be informed that this assessment can be painful and they should be advised to have analgesia or even anaesthesia for this assessment.

If a woman reports inadequate pain relief during the assessment, the healthcare professional must immediately stop the examination and address this need.

If manual removal of the placenta is required, this must be carried out under effective regional anaesthesia (or general anaesthesia when necessary).

17.3 Risk factors for postpartum haemorrhage

Women with risk factors for postpartum haemorrhage should be advised 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 8.5 g/dl at onset of labour
  - body mass index 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 (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.

If a woman has risk factors for postpartum haemorrhage, these should be highlighted in her notes and a care plan covering the third stage of labour should be made and discussed with the woman.

The unit should have strategies in place in order to respond quickly and appropriately should a postpartum haemorrhage occur.

17.4 Management of postpartum haemorrhage

Immediate treatment for postpartum haemorrhage should include:

- calling for appropriate help
- uterine massage
- intravenous fluids
- uterotonics.

No particular uterotonic drug can be recommended over another for the treatment of postpartum haemorrhage.

Treatment combinations for postpartum haemorrhage might include repeat bolus of oxytocin (intravenous), ergometrine (intramuscular, or cautiously intravenously), intramuscular oxytocin

with ergometrine (Syntometrine), misoprostol,* oxytocin infusion (Syntocinon) or carboprost (intramuscular).

Additional therapeutic options for the treatment of postpartum haemorrhage include tranexamic acid (intravenous) and rarely, in the presence of otherwise normal clotting factors, rFactor VIIa, after seeking advice from a haematologist.*

If possible, a member of the healthcare team should be allocated to remain with the woman and her partner during postpartum haemorrhage to ensure communication and offer support throughout the emergency situation.

No particular surgical procedure can be recommended above another for the treatment of postpartum haemorrhage.

2.3 Research recommendations

Chapter 3 Planning place of birth

The best possible studies comparing different places of birth should be undertaken in the UK. Prospective research to assess clinical outcomes, including safety, for all places of birth should be undertaken, as well as qualitative data collection to assess women's experiences of birth.

There is a need to establish a single generic health-related quality of life index value for the multi-attribute perinatal and maternal outcomes of intrapartum care.

Chapter 4 Care throughout labour

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.

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.

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.

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.

Hygiene rituals around the time of vaginal examination and birth would benefit from further research.

Chapter 5 Coping with pain in labour: non-epidural

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.

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).

* At the time of publication (September 2007), misoprostol and rFactor VIIa did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented; however, if this is not possible, follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). It may be appropriate to get consent in the antenatal period.

Chapter 6 Pain relief in labour: regional analgesia

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.

Chapter 7 Normal labour: first stage

A prospective cohort study on impact of length of labour on outcomes is needed.

Studies to examine the clinical efficacy of the initial contact observations/examination

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.

Further studies are required to investigate methods of assessing pain relief, attitudes to pain, effects of labour pain, and long-term outcomes.

Chapter 8 Normal labour: second stage

Studies are needed to investigate strategies to reduce the chance of having perineal trauma.

Chapter 9 Normal labour: third stage

Studies should be carried out to investigate the timing of cord clamping and balance of risk/benefit to both mother and baby.

Chapter 10 Normal labour: care of the baby and woman immediately after birth

Research is needed into the optimum analgesia required during perineal repair.

Chapter 11 Prelabour rupture of membrane at term

A randomised controlled trial to evaluate the effect of routine administration of prophylactic antibiotics on neonatal infection, in women with term prelabour rupture of membranes, over 24 hours.

The investigation and management of babies born with risk factors for infection requires further evaluation.

Chapter 12 Meconium-stained liquor

There is a need for development of a standardised scoring system for degree of meconium staining and association with neonatal outcomes.

Chapter 13 Complicated labour: monitoring babies in labour

A further randomised controlled trial of ST segment analysis should be undertaken.

Further study investigating computerised expert systems should be undertaken.

Chapter 14 Complicated labour: first stage

The start dose of oxytocin for augmentation, and the increments, should be the subject of further research.

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.

Chapter 17 Complicated labour: third stage

Further randomised controlled trials investigating the effectiveness of the use of nitro-glycerine in the treatment of retained placenta should be conducted.

Further research should identify the best drug combinations, route and dose for the treatment of postpartum haemorrhage.

2.4 Care pathway

The following care pathway has been developed to outline how the recommendations in this guideline should be applied in clinical practice. The care pathway includes recommendations for both normal labour and complicated labour, and when to exit from and return to the normal care pathway. This care pathway is available in a separate document, the Intrapartum Care Quick Reference Guide, available from NICE and on the NICE website (www.nice.org.uk/CG055quickrefguide).

Normal labour and birth

Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

Care throughout labour
Ask the woman about her wants and expectations for labour

Don't intervene if labour is progressing normally

Tell the women that first labour lasts on average 8 hours and second labour lasts on average 5 hours

Ensure supportive one-to-one care

Do not leave the woman on her own

Encourage involvement of birth partner(s)

Encourage the woman to mobilise and adopt comfortable positions

Take routine hygiene measures

Do not give H_2-receptor antagonists or antacids routinely to low-risk women

For coping with pain, see pages 10–11

Vaginal exam
Tap water may be used for cleansing prior to exam

Ensure exam is really necessary

Ensure consent, privacy, dignity and comfort

Explain reason for the exam and what's involved

Explain findings sensitively

Initial assessment
Listen to the woman. Ask about vaginal loss and contractions

Review clinical records

Check temperature, pulse, BP, urinalysis

Observe contractions, fetal heart rate (FHR)

Palpate abdomen

Offer vaginal exam

For coping with pain, see pages 10–11

Women not in established labour
If initial assessment normal, offer individualised support and encourage these women to remain at/return home

For prelabour rupture, see page 14

↓

First stage of labour
Use a partogram once labour is established

If a partogram action line is used, this should be a 4-hour action line

Every 15 min after a contraction check FHR

Every 30 min: document frequency of contractions

Every hour: check pulse

Every 4 hours: check BP, temperature and offer vaginal exam

Regularly: check frequency of bladder emptying

Consider the woman's emotional and psychological needs

For coping with pain, see pages 10–11

Concerns OB
Indications for electronic fetal monitoring (EFM) in low-risk women, e.g. significant meconium-stained liquor, abnormal FHR, maternal pyrexia, fresh bleeding; see pages 17 –18

↑ diastolic BP (over 90 mmHg) or
↑ systolic BP (over 140 mmHg) twice, 30 min apart

Uncertainty about the presence of a fetal heartbeat

Suspected delay
Nulliparous: < 2 cm dilatation in 4 hours

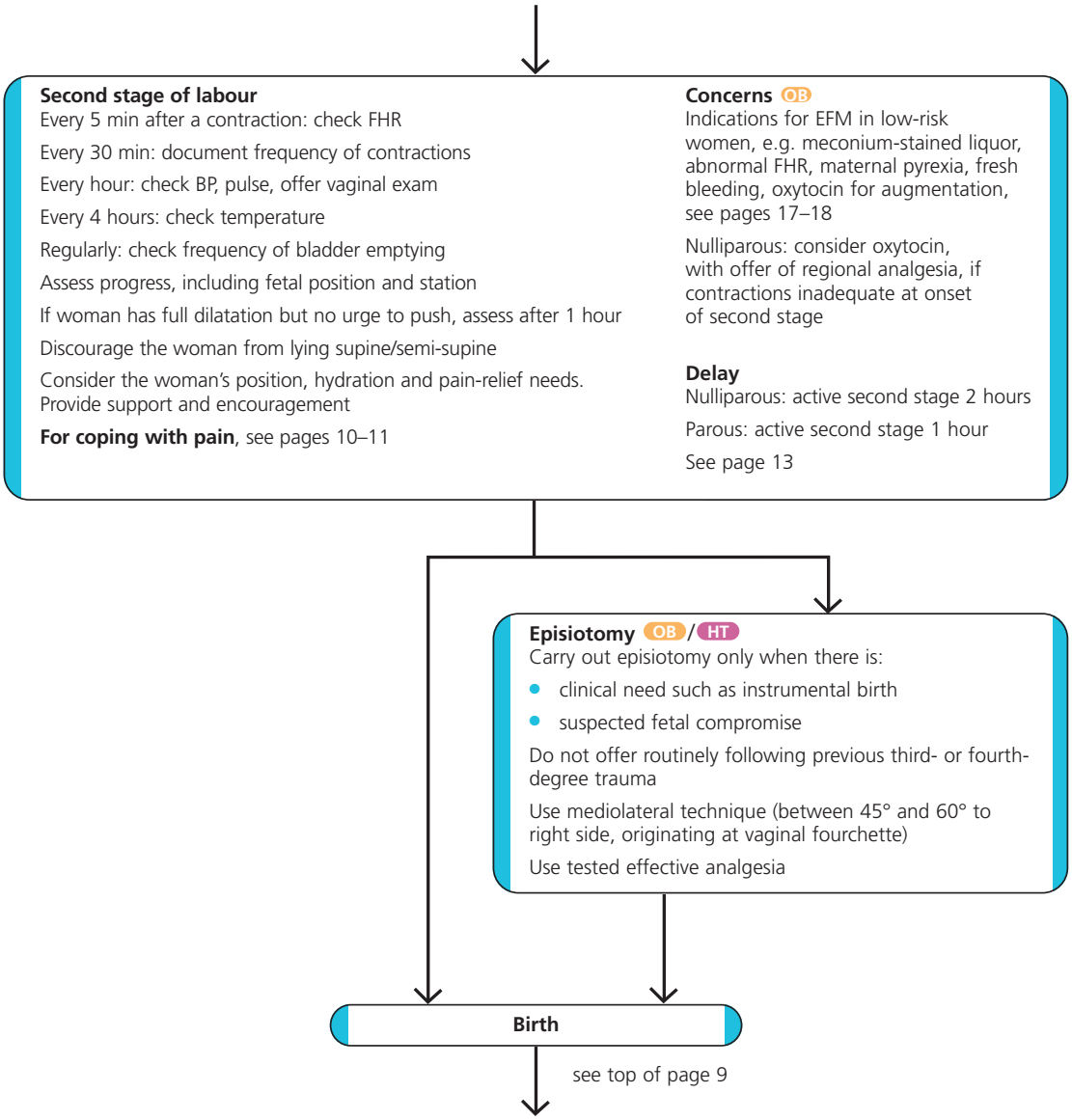
Parous: < 2 cm dilatation in 4 hours or slowing in progress

See page 12

↓

see top of page 8

Intrapartum care | Normal labour and birth



Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

Intrapartum care | Normal labour and birth

Third stage of labour
Observe physical health

Check vaginal loss

Active management: oxytocin (10 IU IM), early cord clamping/cutting and controlled cord traction; advise that this reduces risk of haemorrhage and shortens third stage

Physiological management: if requested by low-risk woman. No oxytocin/no early cord clamping; delivery by maternal effort. Do not pull cord or palpate uterus

Concerns OB
Retained placenta

Active management: > 30 min

Physiological management: > 1 hour

See page 16

Care after birth
Woman: observe general physical condition, colour, respiration, how she feels; check temperature, pulse, BP, uterine contractions, lochia, bladder voiding. Examine cord, placenta and membranes. Assess maternal emotional/psychological condition

Baby: record Apgar score at 1 and 5 min; keep warm

Encourage skin-to-skin contact between woman and baby as soon as possible

Don't separate the woman and baby in the first hour

Initiate breastfeeding within the first hour

After 1 hour, record baby's head circumference, body temperature and weight

Concerns OB
Suspected postpartum haemorrhage: take emergency action, see page 20

Basic resuscitation of newborn babies should be started with air, see page 19

Perineal care
Carry out systematic assessment of any trauma, including a rectal examination, sensitively. Explain assessment to the woman and confirm analgesia is effective. Document extent and findings

Lithotomy, if required, only to be used for assessment and repair

First-degree trauma: suture skin unless well opposed

Second-degree trauma: suture vaginal wall and muscle for all second-degree tears. Suture skin unless well opposed

Use continuous non-locked technique for suturing vaginal wall and muscle

Use continuous subcuticular technique for suturing skin

Offer rectal NSAIDs following perineal repair

For coping with pain, see pages 10–11

Concerns OB
Refer if uncertain of nature/extent of trauma

Third- or fourth-degree trauma

Coping with pain

Supporting women

- Consider your attitude to coping with pain in labour and ensure your care supports the woman's choice.
- Offer support and encouragement.
- Encourage her to ask for analgesia at any point during labour.

Pain-relieving strategies

- Encourage labouring in water to reduce pain.
- Support women's use of breathing/relaxation techniques, massage, music.
- Acupuncture, acupressure and hypnosis should not be provided, but do not prevent women if they wish to use these.
- Do not offer TENS to women in established labour.

Inhalation analgesia and opioids

- Ensure access to Entonox and opioids such as pethidine or diamorphine. Explain that:
  - they provide limited pain relief
  - Entonox may make the woman feel nauseous and light-headed
  - opioids may cause drowsiness, nausea and vomiting in the woman
  - opioids may cause short-term respiratory depression and drowsiness for several days in the baby
  - opioids may interfere with breastfeeding.
- Provide antiemetic if opioids used.
- No birthing pool or bath within 2 hours of opioids or if drowsy.

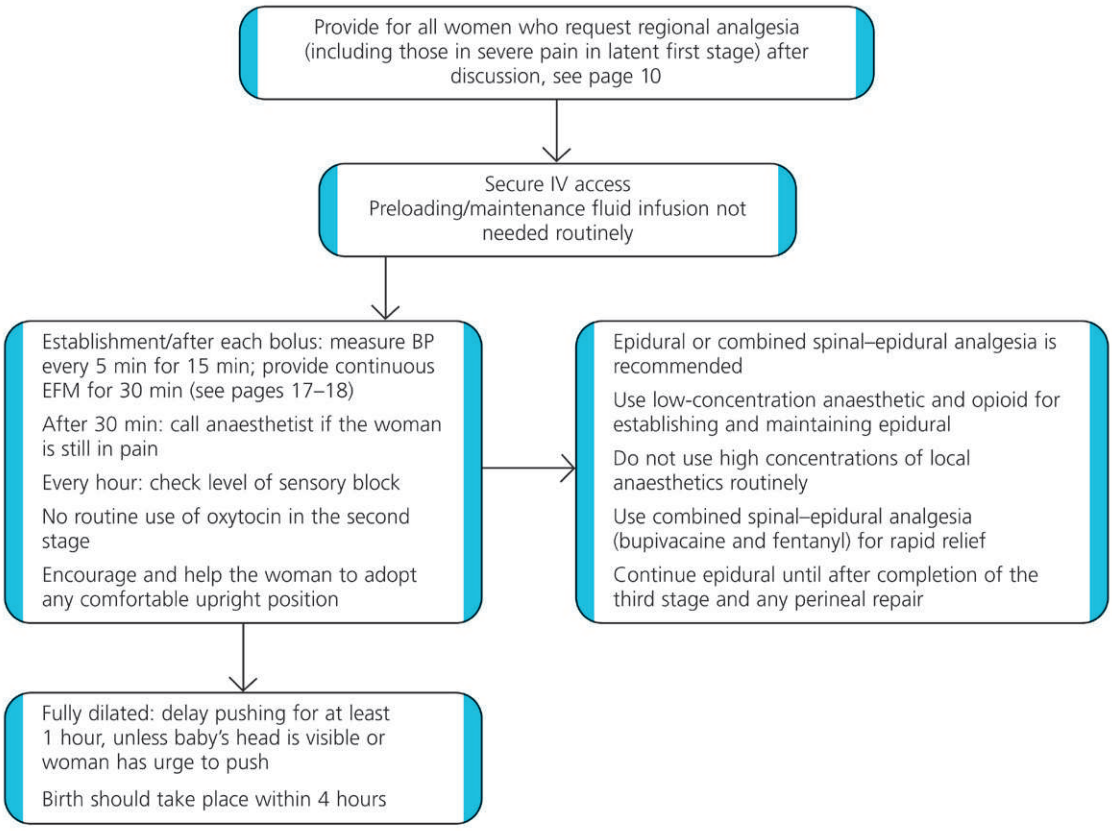
Before choosing epidural

- Inform women that epidural:
  - is only available in obstetric units
  - provides more effective pain relief than opioids
  - is associated with a longer second stage of labour and an increased chance of vaginal instrumental birth
  - is not associated with long-term backache
  - is not associated with a longer first stage of labour or an increased chance of caesarean birth
  - is accompanied by a more intensive level of monitoring and IV access
  - large amounts of epidural opioid may cause short-term respiratory problems in the baby and make the baby drowsy.

See page 11.

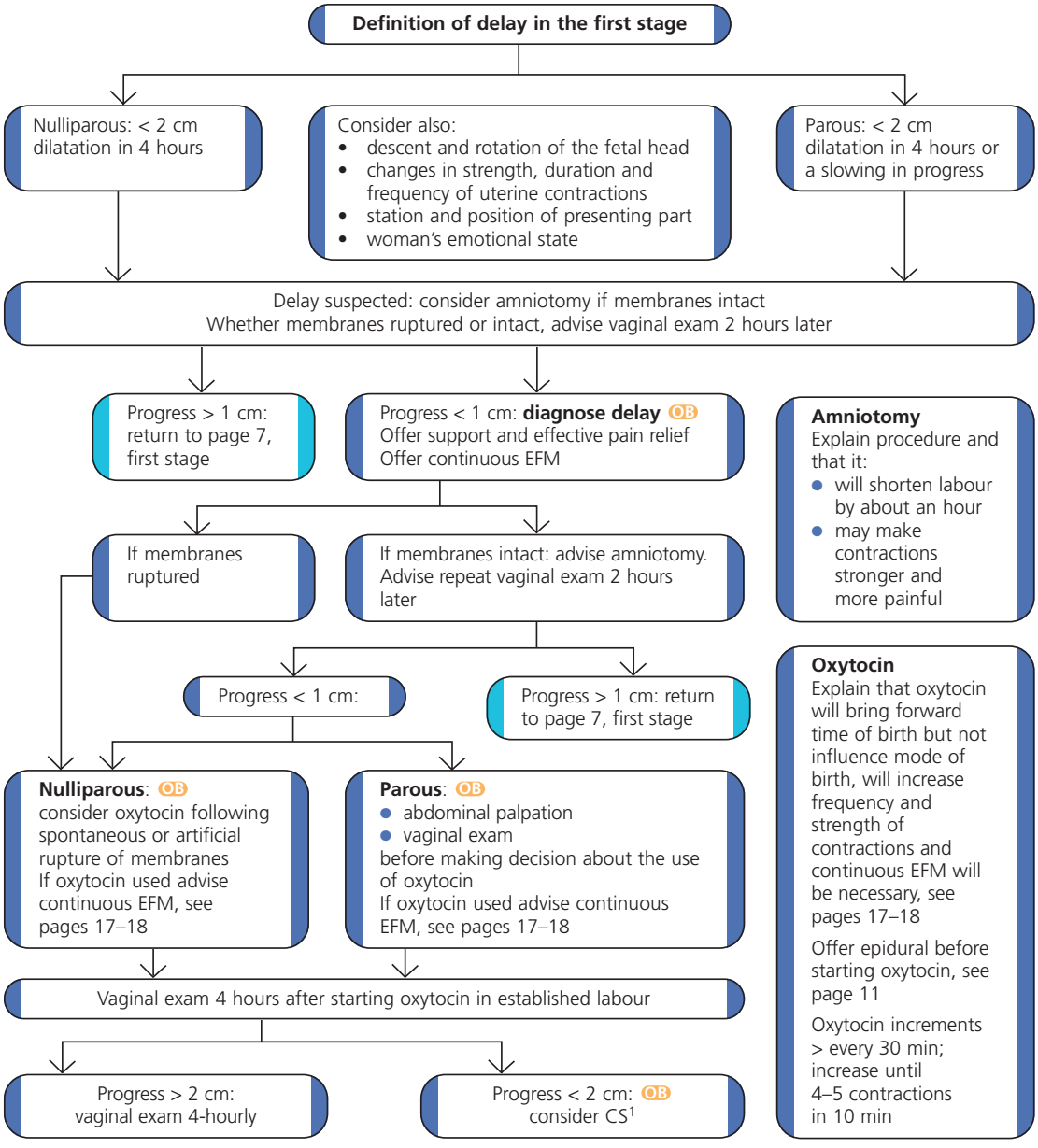
Regional analgesia

(Regional analgesia is only available in obstetric units, administered by an anaesthetist.)



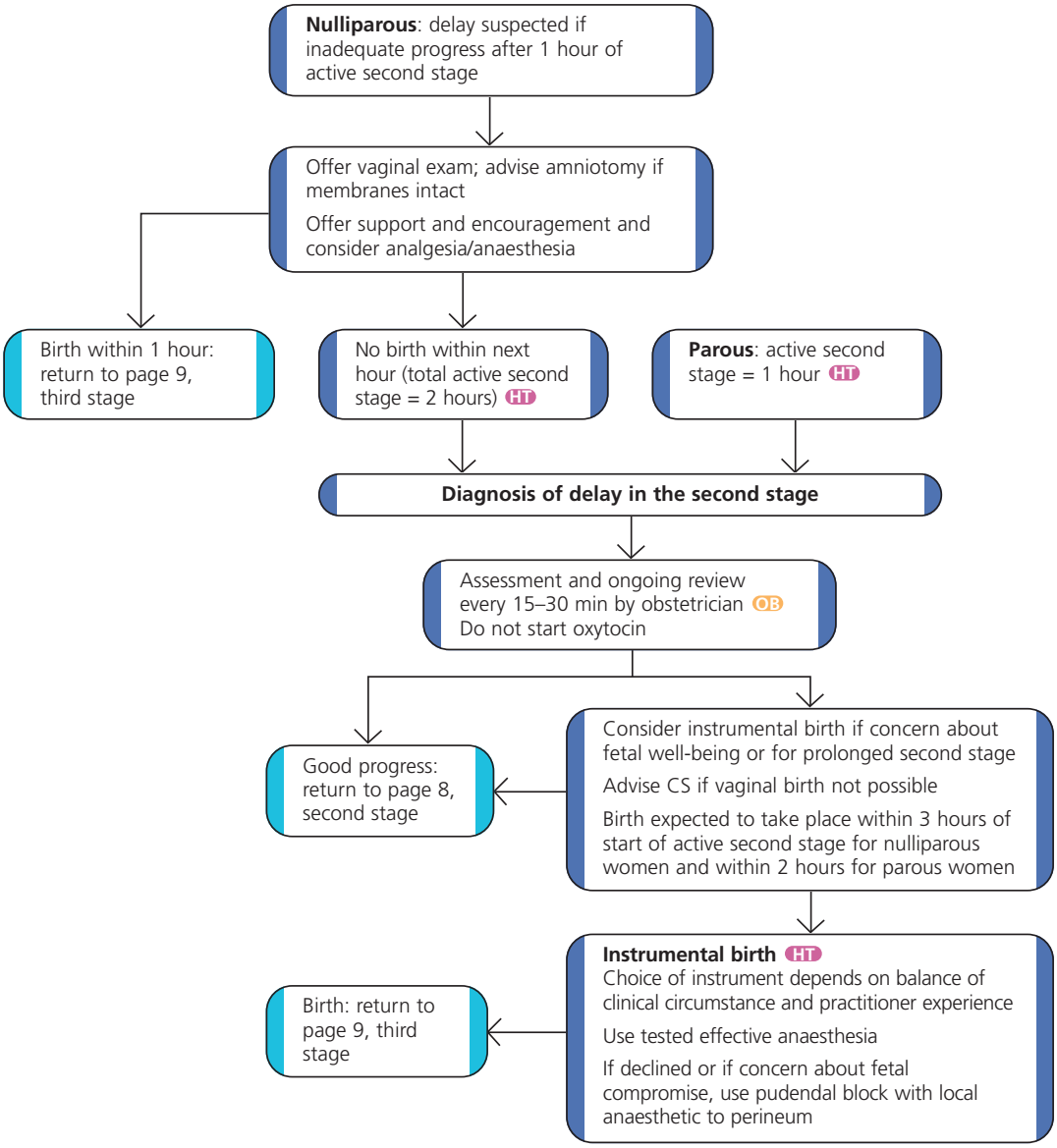
Complications

Delay in the first stage



[1] See 'Caesarean section' (NICE clinical guideline 13).

Delay in the second stage

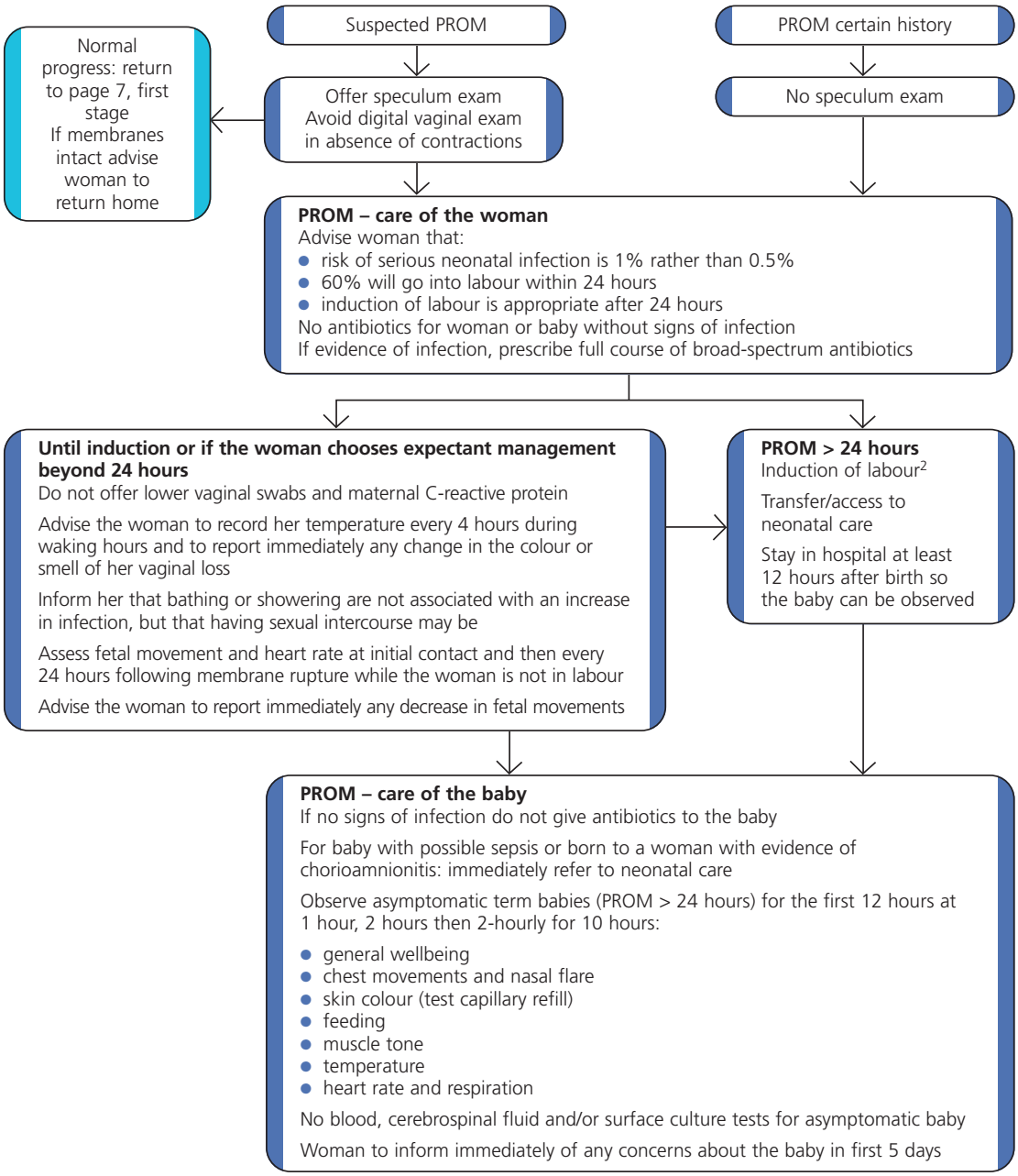


Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

Prelabour rupture of the membranes (PROM) at term



[2] Care of women who have their labour induced is covered by 'Induction of labour' (NICE inherited clinical guideline D).

Meconium-stained liquor

Light meconium-stained liquor

Consider continuous EFM based on risk assessment: stage of labour, volume of liquor, parity, FHR, transfer pathway; see pages 17–18

Baby in good condition
1 and 2 hours, observe:
- general wellbeing
- chest movements and nasal flare
- skin colour (test capillary refill)
- feeding
- muscle tone
- temperature
- heart rate and respiration

Review by a neonatologist if baby's condition causes concern at any time

Significant meconium-stained liquor
Dark green or black amniotic fluid that is thick or tenacious, or any meconium-stained fluid containing lumps of meconium OB

Advise continuous EFM, see pages 17–18

FBS available in labour and advanced neonatal life support available for birth

Do not suction nasopharynx and oropharynx before birth of the shoulders and trunk

Suction upper airways only if thick/tenacious meconium in oropharynx

Baby has depressed vital signs
Laryngoscopy and suction under direct vision by a healthcare professional trained in advanced neonatal life support

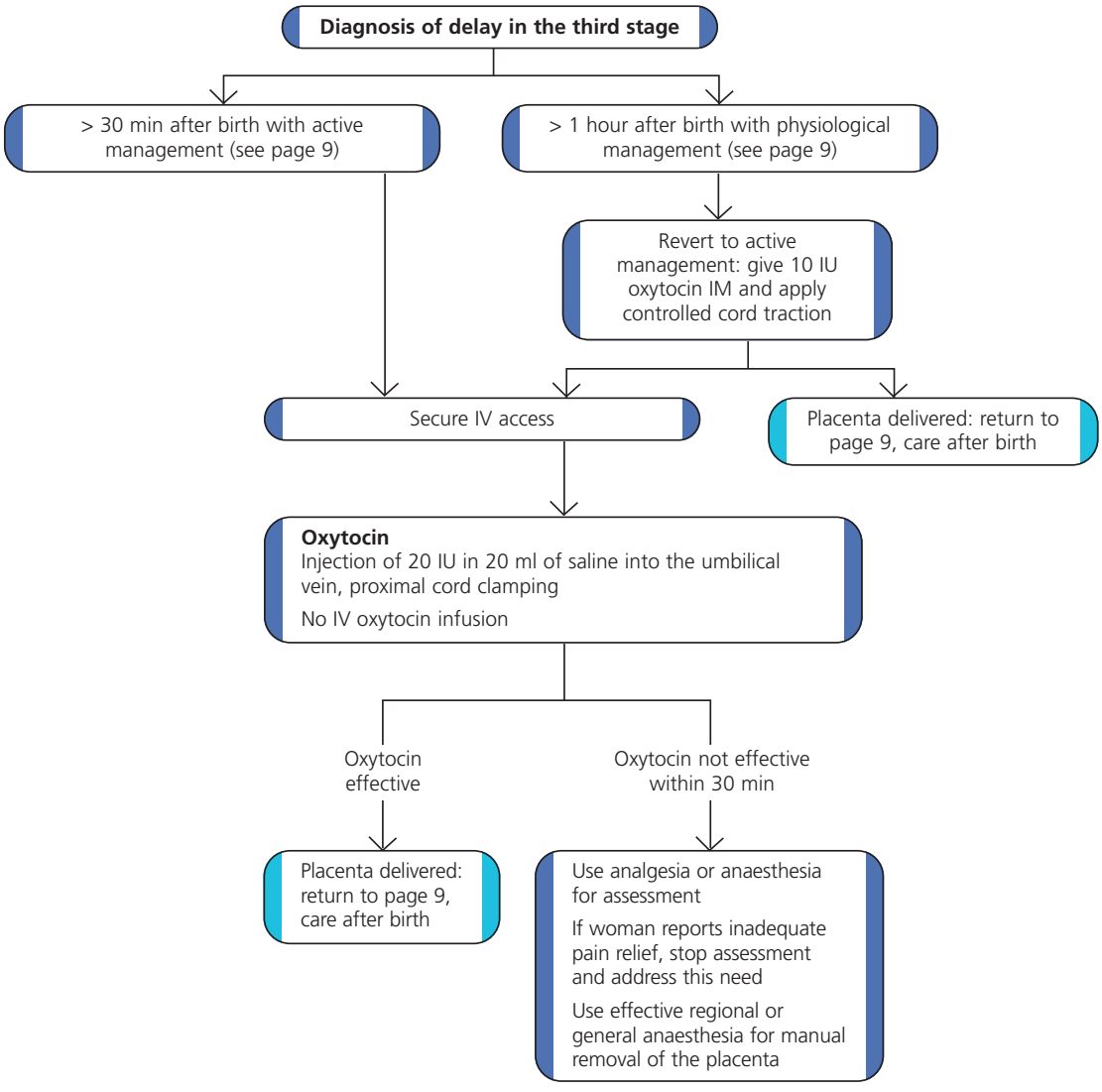
Baby in good condition
1 hour, 2 hours then 2-hourly until 12 hours old, observe:
- general wellbeing
- chest movements and nasal flare
- skin colour (test capillary refill)
- feeding
- muscle tone
- temperature
- heart rate and respiration

Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

Retained placenta OB



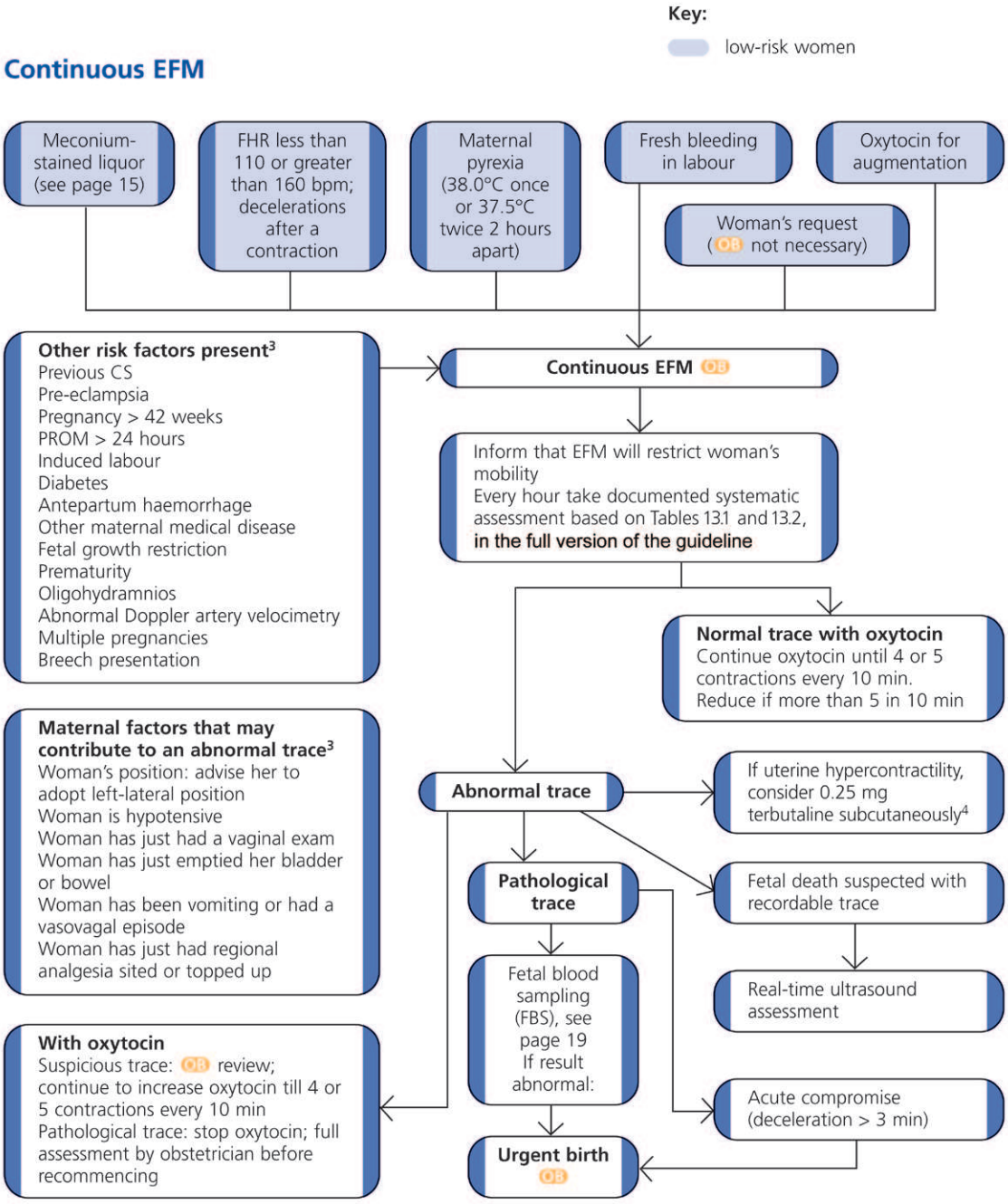
Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

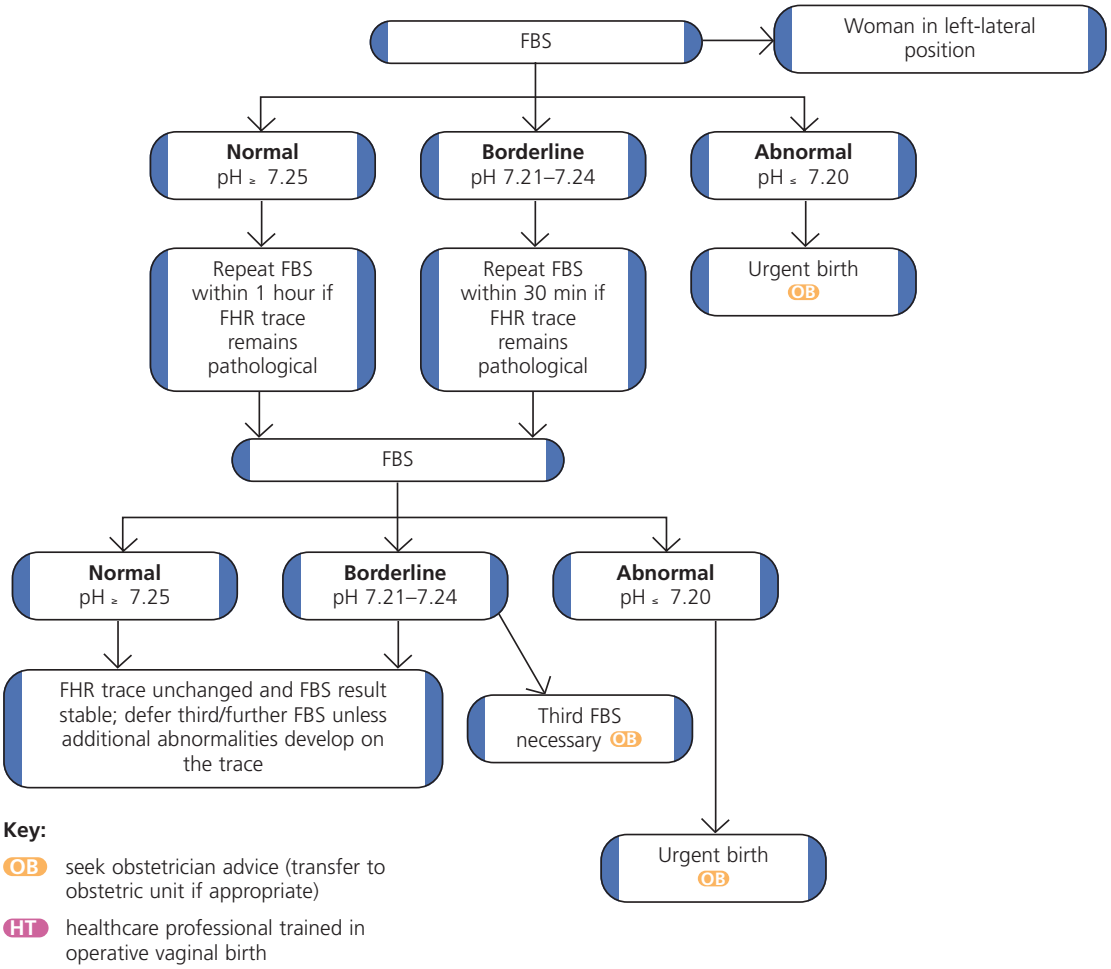
Intrapartum care | Complications

Continuous EFM



[3] These factors (risk factors for women outside the scope of this guideline and maternal factors that may contribute to an abnormal trace) are from 'Electronic fetal monitoring' (NICE inherited guideline C) which this guideline updates and replaces.
[4] At the time of publication (September 2007), terbutaline did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

Fetal blood sampling (FBS)



Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

Neonatal resuscitation

- Start basic resuscitation of newborn babies with air.
- Use oxygen for babies who do not respond.
- Attend a neonatal resuscitation course at least once a year[5].

[5] Consistent with the algorithm adopted in the 'Newborn life support course' developed by the Resuscitation Council (UK), available from www.resus.org.uk/siteindx.htm

Postpartum haemorrhage

Risk factors for postpartum haemorrhage

Antenatal risk factors for which women should be advised to give birth in an obstetric unit:
- previous retained placenta or postpartum haemorrhage
- maternal haemoglobin level below 8.5 g/dl at onset of labour
- increased body mass index
- 4 or more previous babies
- antepartum haemorrhage
- overdistention or abnormalities of the uterus
- low-lying placenta
- woman 35 years or older

Risk factors in labour:
- induction
- prolonged first, second or third stage of labour
- oxytocin use
- precipitate labour
- operative birth or CS

→ Have strategies in place to respond quickly and appropriately to a postpartum haemorrhage
Highlight risk factors in the notes
Plan and discuss care

Managing postpartum haemorrhage

Immediate treatment:
- call for help OB
- uterine massage
- IV fluids

→ Uterotonic options:
- repeat bolus of oxytocin (IV)
- ergometrine (IM/cautiously IV)
- IM oxytocin with ergometrine (Syntometrine)
- misoprostol[6]
- oxytocin infusion (Syntocinon)
- carboprost (IM)

↓ Additional treatment options:
- tranexamic acid (IV)
- rFactor VIIa on advice from haematologist[6]

Key:

OB seek obstetrician advice (transfer to obstetric unit if appropriate)

HT healthcare professional trained in operative vaginal birth

[6] At the time of publication (September 2007), misoprostol and rFactor VIIa did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented; however, if this is not possible, follow the Department of Health guidelines 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). It may be appropriate to get consent in the antenatal period.

3 Planning place of birth

3.1 Introduction

Prior to 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 hospitalisation of birth accelerated in the 1960s such 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] In 2004 the National Service Framework (NSF) for Children, Young People and Maternity Services, and Maternity Matters in 2007,[625] 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 currently 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.

3.2 Benefits and risks of planning each place of birth

Clinical question
What are the outcomes (benefits and harms) and costs related to each birth setting?

Terminology used in the reviews
The terms used to define place of birth in the literature are not consistent and are a source of confusion. Planned place of birth incorporates both *booked* place of birth and *intended* place of birth at the onset of labour. The *booked* place of birth is the place of birth chosen at the first appointment or during pregnancy.

The *actual* place of birth is where the baby is born.

3.2.1 Planned home versus hospital birth

Introduction
The difficulty of conducting a randomised controlled trial (RCT) evaluating effectiveness and safety of planning home birth compared with hospital birth is evident from the lack of papers in the literature. Thus only observational studies were considered in the systematic review below. Predefined criteria were used to assess the validity of the identified studies, some of which were significantly flawed and thus excluded from the systematic review. It should be noted that any systematic review containing only observational data has inherent bias and confounding factors, and the results should be interpreted with great caution.

Previous guideline
Planned home birth was reviewed in the NICE clinical guideline *Caesarean Section*.[6] Two systematic reviews; one cohort study and one case–control study were included. The guideline

recommended that 'during their discussions about options for birth, healthy pregnant women with anticipated uncomplicated pregnancies should be informed that delivering at home reduced the likelihood of CS.'.

Searching the literature

Two systematic reviews[27,28] and 16 studies[26,29–45] were identified from the search. Each of these publications was graded according to a validity (quality) index (see Appendix C) and five studies[29,30,32,35,36,45] were selected for inclusion in this review. Excluded papers and the reasons for their exclusion are presented in Appendix C. An explanation of the methodological reasons for excluding three large studies from the current review is given below.

One of the systematic reviews by Olsen[27] was a Cochrane review which included the only small randomised controlled trial.[26] The trial, rather than the Olsen Cochrane review, was included.

Another systematic review[28] by the same author (Olsen) included six observational studies. This was also excluded because it included studies with significant methodological weakness in the meta-analysis. In particular, although the original study included in the Olsen review did attempt to put the data (raw perinatal mortality data) into a regression analysis, the data were directly included in the meta-analysis in the Olsen review. This makes the analysis invalid.

There was one large population-based UK study[31] conducted in 1994 (n = 8010) that compared a planned home birth population with a planned hospital birth population. Although the study matched some of the demographic background of these women, there were over 1000 unmatched women who planned home birth and they were included in the analysis. The inclusion of an excess of women planning home birth who were not matched to women planning hospital birth makes the matching process invalid. Moreover, the study showed significant differences in demographic and obstetric risks between the planned home and hospital groups, and the analysis did not employ any means to control confounding and, following assessment against the pre-defined criteria, this study was, therefore also excluded from this review.

Description of included studies

There are six included studies and that these were published in seven papers. Details of the included papers were given in Appendix C and in the evidence tables.

All were observational studies,[29,30,32,35,36,45] except one pilot randomised controlled trial.[26] Two of the studies were conducted in the UK,[26,45] two in Australia,[30,35,36] one in Switzerland[32] and one in Canada.[29] Three of the studies reported women's outcomes[26,29,32] and two babies' outcomes[30,45] with two reporting both.[35,36]

The Canadian study[29] and one of the Australian studies[30] compared intended places of birth at the onset of labour, while all the others compared booked places of birth.[26,32,35,36,45]

In addition, for the purpose of obtaining transfer rates between planned and actual place of birth, any study conducted in the UK since 1980 reporting transfer rates during labour was selected, so that a point estimate could be obtained. Two UK studies conducted since 1980[31,43] were used to obtain the rates of transfer from the home birth setting to hospital during labour.

Review findings

Mode of birth and other obstetric interventions

Four included studies reported women's outcomes and these are summarised in Table 3.1.

A pilot randomised controlled trial (Dowswell) conducted in the UK in 1994 compared 11 women (planned home birth = 5; planned hospital birth = 6).[26] The study was a pilot and underpowered to show any differences in relevant outcomes. [EL = 1+]

As this study does not give sufficient information, we considered other studies.

A cross-sectional study (Janssen) conducted in Canada between January 1998 and December 1999 compared 862 women who intended a home birth at the onset of labour with a matched control group of 571 women with a planned midwife-led unit birth and 743 women with a planned obstetric unit birth.[29] [EL = 3] Women were matched by age, parity and lone parent status. After controlling for various confounding factors, the comparison of planned home birth

Table 3.1 Summary of women's outcomes on planned home versus hospital birth

Outcome	Dowswell[26]	Janssen[29]	Ackermann-Liebrich[32]	Woodcock[35,36]
Comparisons	**Booked place of birth**	**Intended place of birth at the onset of labour**	**Booked place of birth**	**Booked place of birth**
Mode of birth and other obstetric interventions				
Mode of birth	Neither instrumental birth (forceps or ventouse) nor CS occurred in the study	CS: adjusted OR 0.31 [95% CI 0.22 to 0.43]	CS: OR 0.45 [95% CI 0.19 to 1.00] Instrumental vaginal birth: OR 0.41 [95% CI 0.14 to 1.04]	Instrumental vaginal birth: adjusted OR 0.14 [95% CI 0.10 to 0.18] Emergency CS: adjusted OR 0.25 [95% CI 0.17 to 0.38] Elective CS: adjusted OR 0.06 [95% CI 0.03 to 0.14]
Analgesia	Use of pethidine: OR 0.16; 95% CI 0.00 to 8.19	Epidural analgesia: adjusted OR 0.20 [95% CI 0.14 to 0.27]	Analgesics: OR 0.16 [95% CI 0.07 to 0.33]	Not reported
Oxytocin	Not reported	Induction of labour: adjusted OR 0.16 [95% CI 0.11 to 0.24] Augmentation of labour: adjusted OR 0.33 [95% CI 0.23 to 0.47]	Induction of labour: OR 0.18 [95% CI 0.06 to 0.43] Use of oxytocin/ demoxytocin during expulsion period: OR 0.34 [95% CI 0.18 to 0.61]	Induction of labour: adjusted OR 0.05 [95% CI 0.03 to 0.08]
Episiotomy	Not reported	Adjusted OR 0.22 [95% CI 0.13 to 0.33]	OR 0.09 [95% CI 0.04 to 0.18]	Not reported
Maternal mortality and other women's complications				
Maternal mortality	Not reported	Not reported	Not reported	Not reported
Maternal infection	Not reported	Adjusted OR 0.23 [95% CI 0.09 to 0.57]	Not reported	Not reported
Perineal tears	Perineal sutures: OR 0.69; 95% CI 0.07 to 6.73	Third- or fourth-degree perineal tear: adjusted OR 0.86 [95% CI 0.45 to 1.63]	Perineal lesion: OR 3.25 [95% CI 1.83 to 6.10] Perineal and vaginal lesion: OR 0.25 [95% CI 0.05 to 2.53] Intact perineum: OR 6.22 [95% CI 3.05 to 14.31]	Third-degree perineal tears: adjusted OR 0.54 [95% CI 0.12 to 2.49]
PPH	Not reported	Adjusted OR 0.91 [95% CI 0.57 to 1.44]	Not reported	Adjusted OR 3.83 [95% CI 2.59 to 5.66]
Duration of labour	Not reported	Not reported	Not reported	Long labour (> 18 hours): adjusted OR 5.57 [95% CI 3.80 to 8.18]
Fetal distress	Not reported	Not reported	Not reported	Adjusted OR 0.38 [95% CI 0.28 to 0.52]
Retained placenta	Not reported	Not reported	Not reported	Adjusted OR 1.96 [95% CI 1.16 to 3.32]
Shoulder dystocia	Not reported	Not reported	Not reported	Adjusted OR 0.45 [95% CI 0.18 to 1.10]

CS = caesarean section; PPH = postpartum haemorrhage.

with planned hospital birth showed evidence that women who planned home birth had less use of epidural analgesia, less induced labour, less augmented labour, less use of episiotomy, and a lower rate of CS.

A cohort study (Ackermann-Liebrich) conducted in Switzerland between 1989 and 1992 comprised 489 women with a booked home birth and 385 women with a booked hospital birth.[32] [EL = 2+] The sample included 214 pairs matched by age, parity, gynaecological/obstetric history, medical history, presence/absence of a partner, social class and nationality. There were no significant differences between matched pairs for birth complications or duration of labour. Women in the booked home birth group had fewer inductions of labour, a lower rate of CS, less analgesic, less use of oxytocin/demoxytocin, fewer instrumental vaginal births, and fewer episiotomies.

A cross-sectional study (Woodcock) conducted in Western Australia between 1981 and 1987 compared 976 women with a booked home birth (all booked home births for that period) with 2928 matched controls (1 : 3), matching by year of birth, parity, previous stillbirth, previous death of liveborn child, maternal age, maternal height, marital status and postcode.[35,36] [EL = 3] Women who booked a home birth were had fewer instrumental births and CS.

Maternal mortality and women's complications

No comparative studies with high or reasonable quality that reported maternal mortality was identified. Other women's complications were reported in the above one small pilot trial and three observational studies.

The pilot randomised trial reported incidence of perineal tears, although the study is underpowered to show any significant difference. [EL = 1+]

The Janssen study showed a lower incidence of women's infection, although there was no evidence of difference in the rate of third- or fourth-degree perineal tear or incidence of postpartum haemorrhage (PPH). [EL = 3]

The Ackermann-Liebrich study showed fewer perineal tears with more women having an intact perineum. [EL = 2+]

In the Woodcock study, women who booked a home birth were more likely to have a long labour (> 18 hours), less fetal distress, with a higher incidence of PPH and of retained placenta. In addition, there was a trend towards reduced incidence of shoulder dystocia. [EL = 2+]

Women's satisfaction and psychological/mental health

No comparative study with high or reasonable quality that reported women's satisfaction and/or other psychological/mental outcomes.

Perinatal mortality that is directly related to intrapartum events and other neonatal complications

Two included studies reported intrapartum-related perinatal mortality (IPPM) and one study reported intrapartum perinatal mortality. Therefore the review did not consider perinatal mortality or other neonatal complications. (See Appendix C for details.) Intrapartum-related perinatal mortality is defined as deaths from intrapartum 'asphyxia', 'anoxia' or 'trauma', derived from the extended Wigglesworth classification 3.[600] This includes stillbirths and death in the first week. The denominator was all births (live births and stillbirths). Intrapartum perinatal mortality is defined as perinatal mortality excluding deaths of low birthweight infants and babies with congenital malformations. The results of the included studies are summarised below and in Table 3.2.

A UK cross-sectional population-based study (NRPMSCG) compared perinatal mortality of booked home births with overall rate in the Northern Region.[45] The intrapartum-related perinatal mortality (IPPM) rate for women who booked home birth in the Northern Region in 1983 was compared with that for all of those who had a birth in the region. [EL = 3] This reported an IPPM rate, of 1.86 per 1000 births (5/2689) for women who booked at home compared with an overall rate of 1.23 per 1000 (642/520 280). The RR was 1.51 [95% CI 0.63 to 3.63]).

A cross-sectional population-based study (Bastian) (n = 1 502 756) conducted in Australia between 1985 and 1990 [EL = 3] comprised population-based data and included a comparison of intended home birth at the onset of labour with data for the whole country, including details

Table 3.2 Intrapartum perinatal mortality and intrapartum-related perinatal mortality (IPPM) rates for planned home birth compared with planned hospital birth or overall birth

Authors	Year	Country	Notes on study design	Planned home birth	Planned hospital birth or overall births	Summary statistics
NCC-WCH (Appendix D)	1999–2003	UK	Booked place of birth A population-based study in the UK. Internal validity was improved by using IPPM rates to control background risk, but the number of planned home birth was drawn from transfer rates in previous studies. Sensitivity analyses were conducted to examine the uncertainty in the transfer rates.	IPPM rate 1.37/1000; upper 1.58, lower 0.82 *Subgroups:* Completed home birth: IPPM rate 0.50/1000; upper 0.45, lower 0.56 Transferred group: IPPM rate 6.59/1000; upper 9.12, lower 1.31	IPPM rate Overall: 0.68/1000	IPPM rate RR 2.01; upper 2.32, lower 1.21
	1994–1998	UK		IPPM rate 1.18/1000; upper 1.36, lower 0.71 *Subgroups:* Completed home birth: IPPM rate 0.46/1000; upper 0.52, lower 0.41 Transferred group: IPPM rate 5.52/1000; upper 8.67, lower 1.92	IPPM rate Overall: 0.90/1000	IPPM rate RR 1.31; upper 1.51, lower 0.79
NRPMSCG[45]	1981–1994	UK	Booked place of birth A population-based study in the Northern Region on a planned home birth population. Internal validity was improved by using IPPM rates to control background risk.	IPPM rate 1.86/1000 (5/2689)	IPPM rate Overall: 1.23/1000 (642/520 280)	IPPM rate RR 1.51 [95% CI 0.63 to 3.63]
Bastian[30]	1985–1990	Australia	Intended place of birth at the onset of labour A population-based study conducted in Australia on an intended home birth population. Internal validity was improved by using IPPM rates to control background risk. However the intended home birth group included a small number of high-risk women, which may have contributed the excess. It could also be assumed that there was higher proportion of high-risk women in overall birth group.	Intrapartum perinatal mortality rate 2.7/1000 [95% CI 1.5 to 3.9/1000]	Intrapartum perinatal mortality rate Overall: 0.9/1000 [95% CI 0.85 to 0.95/1000]	Intrapartum perinatal mortality rate RR 3.02 [95% CI 1.92 to 4.74]

of perinatal deaths for home births.[30] Excluding perinatal mortality associated with congenital malformation and/or extreme immaturity, the intrapartum perinatal mortality rate was higher for babies born at home (home birth: 2.7 per 1000 live births [95% CI 1.5 to 3.9]; overall: 0.9 per 1000 live births [95% CI 0.85 to 0.95]). Intrapartum asphyxia was responsible for about half (24 out of 50 deaths) of infants dying after an intended home birth at the onset of labour in Australia between 1985 and 1990. The study reported that the two largest contributors to the excess mortality were underestimation of the risks associated with post-term birth, twin pregnancy and breech presentation, and a lack of response to fetal distress. However, it could also be possible that the practice in Australia between 1985 and 1990 was for a higher proportion of high-risk women to give birth at home.

In order to address the GDG's concern about the lack of any relevant UK study, the NCC-WCH conducted an analysis at the request of the GDG to obtain the best estimate of IPPM rate in the UK. The analysis is described in full in Appendix D.

All births in England and Wales, including home births (intended or unintended) occurring between 1994 and 2003 were obtained from National Statistics. All IPPM data were derived from the Confidential Enquiry into Maternal and Child Health (CEMACH). Denominators were derived by using unintended home births and transfer rates from home to hospital, using estimates from previous studies, with sensitivity analyses. It should be noted that the calculated IPPM rates are sensitive to transfer rates, which themselves are particularly uncertain. The overall IPPM rate for England and Wales improved between 1994 and 2003. The IPPM rate for booked home births (1.37 per 1000 births [range 0.72 to 1.78]) appeared to be higher than the overall IPPM rate (0.68 per 1000 births [95% CI 0.65 to 0.71]) in the period 1999–2003 (RR 2.01 [range 1.01 to 2.74]), although there was no evidence of difference in the period 1994–1998 (RR 1.31 [range 0.67 to 1.78]). IPPM rate for subgroups of home birth were also considered. The analysis showed the highest IPPM rate for women who had transferred their care from home to hospital during pregnancy or labour (6.59 per 1000 [range 1.10 to 12.19] between 1999 and 2003). However those who had booked and completed the home birth showed relatively low IPPM rate (0.50 per 1000 [range 0.41 to 0.62] between 1999 and 2003) The details of the method and the results of this analysis are described in Appendix D. [EL = 3]

The IPPM rates of the included studies are summarised in Table 3.2. It was not possible to conduct a meta-analysis of the included studies on IPPM rates, because of heterogeneity in study design, difference in clinical practice in difference countries and different time periods.

Transfer rates

Two studies[31,43] were identified that reported transfer rates and these are summarised in Table 3.3. [EL = 3]

Evidence statement on planned home versus hospital birth

There is a lack of good-quality evidence relating to women's and babies' short- or long-term outcomes for birth at home compared with hospital and there is no evidence on serious maternal morbidity and mortality. Limited low-quality evidence shows less intervention with a planned home birth compared with a planned birth in hospital. Transfer rates between home and hospital settings show great variation.

While only three low-quality studies reported IPPM or intrapartum perinatal mortality rates, the findings suggest that there may be a trend towards higher rates when birth was planned at home.

The unreliability of these data means that these findings should be interpreted with caution. Factors leading to the unreliability of the data include:

- a lack of routine collection of data on place of birth
- the mix of high- and low-risk women in the home-birth studies

Table 3.3 Transfer rates during labour for home birth

Region	Year	Transfer rate during labour
Northern Region[43]	1993	20.9% (nulliparous 56.3%; parous 17.4%)
England and Wales[31]	1994	12.5%

- the majority of women in these studies were self-selected populations, which questions the generalisability of the studies
- inconsistent definitions
- questionable relevance to the UK setting.

3.2.2 Midwife-led unit (birth centre) versus obstetric unit

Introduction

A midwife-led unit (sometimes called a birth centre) was defined as a place that offers care to women with a predefined uncomplicated pregnancy and where midwives are the lead professionals for intrapartum care.

During labour and birth, medical services including obstetric, neonatal and anaesthetic care are available, should they be needed, but they may be in a separate area within the same building (midwife-led unit alongside obstetric unit), or in a separate building (standalone midwife-led unit), which may involve transfer by car or ambulance.

Standard definitions have recently been adopted by the Health Care Commission (2007) for obstetric units, and alongside and standalone midwife-led units.

Previous guideline

Care provided in a midwife-led unit was reviewed in the *Caesarean Section* guideline.[5] Two case series, one systematic review of six RCTs and one cross-sectional study were included. It was recommended that 'during their discussions about options for birth, healthy pregnant women with anticipated uncomplicated pregnancies should be informed that planned childbirth in a midwife-led unit does not reduce the likelihood of CS.'.

Standalone midwife-led unit (standalone unit) versus obstetric unit

Searching the literature

Thirteen studies, all included in recent structured reviews,[46,47] were identified from the search. Each of these publications was graded according to a validity (quality) index (see Appendix C) and five publications were selected for inclusion in this review. Excluded papers and the reasons for their exclusion are presented in Appendix C.

A series of studies by Rooks[48–51] (National Birth Centre Study) were large case series in the USA and did not employ any controlled design and therefore were excluded from the review.

The difficulty of conducting a randomised controlled trial (RCT) evaluating effectiveness and safety of planning standalone unit birth compared with planning obstetric unit birth is also evident from the literature. No RCTs were identified for standalone units. Two structured reviews were identified that evaluated the evidence for midwife-led units including standalone midwife-led units.[46,47] All studies included in the Stewart review[46] as well as in the Walsh review[47] were appraised. However it should also be noted that any systematic review containing only observational data has inherent bias and confounding factors, and therefore the results should be interpreted with great caution.

Description of included studies

A total of five cohort studies, one of which was conducted in the UK,[52] were included in this review. Three studies were conducted in the US[53–55] and the other one was in Germany.[56] [EL = 2+] See Appendix C for further details of studies included in this review. A list of included and excluded studies is also presented in Appendix C. The UK study[52] compared booked places of birth, although all the other included studies compared intended places of birth at the onset of labour.

In addition, for the purpose of obtaining transfer rates, any study conducted in the UK since 1980 reporting transfer rates from all identified studies were selected, so that an estimate could be obtained. Two UK studies[52,627] were used to obtain transfer rates in this way.

Review findings

A summary of the review findings is shown in Table 3.4.

Mode of birth and other obstetric interventions

Analgesia use in standalone midwife-led units was considered by two retrospective cohort studies, one in the USA[53] (*n* = 149) and the other in the UK[52] (*n* = 20 118). Both studies reported that women in the midwife-led unit groups were significantly less likely to use any type of analgesia. In four cohort studies, there was a statistically significant increase in the number of spontaneous vaginal births in standalone units.

Maternal mortality and other women's complications

None of the studies reported maternal mortality. Perineal trauma was considered by four cohort studies. Statistically, there was a significant increase in the proportion of women who had an intact perineum, with planned birth in a standalone midwife-led unit. There was no evidence of difference in blood loss or PPH in two cohort studies.

Women's satisfaction and psychological/mental health

One cohort study reported women's psychosocial outcomes.[52] Of the 248 (52%) women who responded, 88% agreed that the birth centre had considerable advantages over a hospital birth, and 96% said they would recommend the birth centre to a friend. Women commented positively on the home-like environment of the birth centre, on the confidence they had in their midwives, on the fact that they felt they were treated as an individual, and on their sense of control over the labour and birth.

Perinatal mortality that is directly related to intrapartum events and other neonatal complications

None of the included studies reported any form of perinatal mortality. Two studies reported Apgar score of the babies. The German[56] study reported fewer babies with Apgar score less than 7 at 1 minute in the intended standalone unit group, compared with the control group, but no evidence of difference at 5 and 10 minutes. The US study by Feldman[53] showed no evidence of difference in Apgar score between the two groups.

Transfer rates

There were two studies[52,627] identified, one[52] of which was included in the structured review.[46] The reported transfer rate is summarised in Table 3.5. [EL = 3]

Table 3.5 Transfer rates during labour for standalone units

Region	Period	Transfer rate in labour
London[52]	1997–1999	11.8%
All United Kingdom[627]	2001–2002	18.0% (IQR 18.5 to 24.8)

dowsw

Evidence statement on standalone midwife-led units versus obstetric units

There is a lack of good-quality evidence available on maternal and baby outcomes for standalone midwife-led units. When compared with planned birth in obstetric units, the available data show a reduction in analgesia use and an increase in vaginal birth and intact perineum rates. There is no evidence on serious maternal morbidity or mortality, or perinatal mortality.

The intrapartum transfer rate in two studies was reported as 12% up to 25%.

Midwife-led unit alongside obstetric unit (alongside unit) versus obstetric unit

Description of included studies

One recently published systematic review that included five RCTs and one quasi-controlled trial was identified.[57] [EL = 1+] These six trials involved 8677 women from the UK (three trials), Sweden, Australia and Canada. The structured review[46] cited earlier also reviewed alongside units, and included this systematic review by Hodnet *et al*. The systematic review involved comprehensive searches and was good quality. The included trials varied considerably in the scope of the intervention (some study groups differed solely in intrapartum care whereas in others there were

Table 3.4 Summary of outcomes of women who planned birth at standalone midwife-led units compared with those who planned birth at obstetric units; data from Stewart *et al.*[46]

	UK Studies	Studies from other countries			
Authors	**Saunders[52]**	**David[56]**	**Feldman[53]**	**Scupholme[54]**	**Stone[55]**
Region/country	**London/UK**	**Berlin/Germany**	**New York City/USA**	**USA**	**USA**
Study design	**Cohort study**	**Cohort study**	**Cohort study**	**Cohort study**	**Cohort study**
Total number of women and characteristics of women	20 118 women: Booked place of birth 589 booked to give birth at standalone midwife-led units and 19 529 who received standard care or had home birth	4072 women Intended place of birth at the onset of labour All women who gave birth in two birth centres between 1992 and 1994, compared with matched sample of women who gave birth in the same area over same time period and who planned to give birth in a standard setting	149 women Intended place of birth at the onset of labour All women booked to give birth in birth centre over a 3-month period in 1981, compared with control group who met same low-risk criteria at 37 weeks and who planned to give birth in a standard setting	500 women Intended place of birth at the onset of labour Women who commenced at birth centre over 15 months period, compared with women who gave birth during the same time period and met same booking criteria and who planned to give birth in standard setting	146 women Intended place of birth at the onset of labour All women met same low-risk birth centre eligibility criteria and had themselves selected either midwifery or obstetric led care
Comparison	Standalone midwife-led let unit vs obstetric unit	Standalone midwife-led unit vs obstetric unit	Standalone midwife-led unit vs obstetric unit	Standalone midwife-led unit vs obstetric unit	Standalone midwife-led unit vs obstetric unit
Mode of birth and other obstetric interventions					
Mode of birth	Women in the midwife-led unit group had more vaginal birth (86% vs 72% (difference 13.3% [95% CI 10.2% to 16.2%]), less instrumental (forceps or ventouse) birth (4% vs 15%) and less CS (6% vs 13%)	Rate of spontaneous vaginal birth: 91% in the midwife-led unit group, compared with 84% in the hospital group, $P < 0.001$ Rate of CS: 3% vs 5% Rate of instrumental (forceps or ventouse) birth: 5% vs 11% $P < 0.001$	There were no statistically significant differences between rates of vaginal birth (94% for the midwife-led unit group vs 89% for the control group) or CS (7% vs 11%). Women in the midwife-led unit group were statistically less likely to have instrumental (forceps or ventouse) birth (3% vs 10%), $P < 0.001$	Women in the midwife-led unit group were more likely to have vaginal birth (92% vs 83%), less likely to have instrumental (forceps or ventouse) birth (2% vs 3%) and less likely to have CS (6% vs 14%)	Not reported
Analgesia use	Women in the midwife-led unit group were less likely to use epidural (11% of midwife-led unit group vs 31% of comparison group (difference 19.3% [95% CI 16.5% to 22%]), less likely to use pethidine (8% vs 26% (difference 17.7% [95% CI 15.4% to 20%]), less likely to use Entonox® (53% vs 67% (difference 14.3% [95% CI 10.1% to 18.5%]), and more likely to use TENS (67% vs 4% (difference 2.9% [95% CI 1% to 5%])	Not reported	There was a statistically significant difference in the number of women who had an epidural for pain relief: 31% of the midwife-led unit group vs 75% of the control group, $P < 0.01$	Not reported	Not reported

Maternal mortality and other women's complications					
Maternal mortality	Not reported	Not reported	Not reported	Not reported	Not reported
Perineal trauma	Women in the midwife-led unit group were less likely to have an episiotomy (5% vs 19% in the comparison group, $P < 0.001$), but there were no significant differences in levels of intact perineum, or perineal tears	Women in the midwife-led unit group were less likely to have an episiotomy (16% vs 55% for the standard care group, $P < 0.001$) There was no significant difference in levels of third- and fourth-degree perineal tears	Women in the midwife-led unit group were significantly more likely to have an intact perineum (25% vs 6% in the standard care group, $P < 0.01$), less likely to have an episiotomy (47% vs 78%, $P < 0.0001$), and more likely to have a tear not involving the anal sphincter (26% vs 6%, $P < 0.01$)	Not reported	Women in the midwife-led unit group were more likely to have an intact perineum (12/54; 22%) than women receiving standard care (4/52; 8%), $P < 0.01$
Blood loss or PPH	There was no difference in the rate of women who had a PPH (7% in the midwife-led unit group vs 7% in the comparison group)	Not reported	There was no statistically significant difference in the number of women who had PPH (3% in the midwife-led unit group vs 2% in the standard care group)	Not reported	Not reported
Women's satisfaction and psychological/mental health					
Women's satisfaction	248 (52%) women responded: Of these, 88% agreed that the midwife-led unit had considerable advantages over a hospital birth and 96% said they would recommend the midwife-led unit to a friend; women commented positively on the home-like environment of the midwife-led unit, on the confidence they had in their midwives, on the fact that they felt treated as an individual, and on their sense of control over the labour and birth	Not reported	Not reported	Not reported	Not reported
Perinatal mortality that is directly related to intrapartum events and other neonatal complications					
Any form of perinatal mortality	Not reported	Not reported	Not reported	Not reported	Not reported
Apgar score	Not reported	There were a statistically significant reduced number of babies in the midwife-led unit group with a 1 minute Apgar score < 7 (2% vs 4%, $P = 0.002$) However, Apgar scores at 5 and 10 minutes showed no evidence of differences	There were no statistically significant differences in Apgar scores between the two groups	Not reported	Not reported

CS = caesarean section; PPH = postpartum haemorrhage.

differences in antenatal and/or postnatal care as well as intrapartum care) and the length of time between randomisation and onset of 'treatment', but all trials shared one common aspect of the intervention: intrapartum care in a home-like setting. Two sets of meta-analyses were conducted by the NCC-WCH, one including all six trials, and one including only the three UK trials[58–60] to examine any difference in effectiveness between UK trials and trials in other countries. Another subgroup analysis conducted in the above Cochrane review stratified the results on the basis of whether the staff in the alongside unit were shared with the main obstetric unit or functioned as a separate team.[57] The Cochrane review included only four outcomes but the NCC-WCH analysed all the outcomes in the original review [EL = 1+]. A summary of results from the meta-analysis of all six included trials, as well as that of three UK trials, is presented below. Two UK RCTs[58,59] and three UK observational studies[61,62,626] were included in the structured review to obtain transfer rates.[46] [EL = 3]

Review findings

Mode of birth and other obstetric interventions

The results in Table 3.6 summarising both meta-analyses comparing planning birth between alongside midwife-led units and obstetric units showed no statistical difference in rates of induction, augmentation, instrumental vaginal birth, and CS. There was a statistically significant reduction in epidural usage, increase in normal vaginal birth, and an increase in women with no analgesia/anaesthesia in the alongside units compared with the obstetric units. There was also a significant reduction in episiotomy.

When stratifying the results on the basis of the staffing arrangements there were statistically significant reductions in use of induction/augmentation, epidural and opioid analgesia, and episiotomy in trials involving units that had separate staffing while in trials which include units that had the same staff between the two settings there was only a statistically significant reduction in episiotomy.

Maternal mortality and other women's complications

None of the studies reported maternal mortality.

The meta-analyses comparing planning birth between alongside midwife-led units and obstetric units showed no statistical difference in incidence of prolonged first stage of labour, prolonged second stage of labour and PPH. There was a significant reduction in vaginal/perineal tears with an increase in the intact perineum rates.

When stratifying the results on the basis of the staffing arrangements there were statistically significant reductions in incidence of perineal tears in trials involving units that had separate staffing, while in trials which include units that had the same staff between the two settings there was no evidence of difference in other complications.

Women's satisfaction and psychological/mental health

One UK trial[59] that had the same staff between the two settings reported women's satisfaction and assessment of birth experience, although these were poorly defined and poorly measured. This showed, with borderline significance, an increase in the proportion of women who felt involved in decisions about care and who rated their intrapartum care highly. One Swedish trial[63,64] that had different staffing between the two settings reported that significantly more women preferred the same setting for birth the next time.

Perinatal mortality directly related to intrapartum events and other neonatal complications

None of the studies reported perinatal mortality directly related to intrapartum events

A meta-analysis[57] that included six trials [EL = 1+] found that there was no statistical difference in the number of babies with an Apgar score less than 7 at either 1 minute or 5 minutes, or in the number of babies admitted to a neonatal unit. There was a tendency (not statistically significant) towards an increase in perinatal mortality, although this included deaths from all causes including stillbirths due to intrauterine death before labour.

When stratifying the results on the basis of the staffing arrangements, there were no statistically significant differences in Apgar scores of the babies in either subgroup. However, in trials from

Table 3.6 Summary of meta-analyses for alongside units compared with obstetric units

Outcome	All trials			UK trials			Separate staff and greater continuity of carer in alongside unit			Same staff and degree of continuity of carer between alongside and obstetric units		
	Number of trials	Pooled RR	95% CI	Number of trials	Pooled RR	95% CI	Number of trials	Pooled RR	95% CI	Number of trials	Pooled RR	95% CI
Mode of birth and other obstetric interventions												
Spontaneous vaginal birth	5	1.03	1.01 to 1.06	2	1.03	1.00 to 1.06	3	1.04	1.01 to 1.06	2	1.03	0.98 to 1.07
Instrumental vaginal birth	5	0.88	0.77 to 1.01	2	0.88	0.76 to 1.02	3	0.87	0.72 to 1.05	2	0.89	0.74 to 1.08
Caesarean section	6	0.85	0.73 to 1.00	3	0.89	0.74 to 1.06	3	0.87	0.72 to 1.06	3	0.83	0.65 to 1.05
Induction	4	0.89	0.72 to 1.09	2	0.97	0.80 to 1.17	3	0.82	0.68 to 0.98	1	1.06	0.90 to 1.24
Augmentation	5	0.81	0.67 to 1.00	3	0.86	0.63 to 1.17	3	0.70	0.62 to 0.79	2	1.02	0.85 to 1.22
Opioid analgesia	5	0.74	0.55 to 1.00	3	0.95	0.80 to 1.14	3	0.81	0.74 to 0.88	2	1.05	0.98 to 1.13
Epidural analgesia	6	0.83	0.75 to 0.92	3	0.84	0.74 to 0.95	3	0.81	0.72 to 0.92	3	0.87	0.72 to 1.04
No analgesia/anaesthesia	4	1.19	1.01 to 1.40	3	1.22	0.95 to 1.57	2	1.13	0.94 to 1.36	2	1.42	0.96 to 2.10
Episiotomy	5	0.85	0.74 to 0.99	2	0.81	0.71 to 0.93	3	0.82	0.73 to 0.91	2	0.86	0.75 to 0.97
Maternal mortality and other women's complications												
Maternal mortality	Not reported			Not reported			Not reported			Not reported		
Prolonged first stage	(Only UK trials)			2	1.11	0.90 to 1.38	1	1.06	0.87 to 1.29	1	1.42	0.86 to 2.34
Prolonged second stage	(Only UK trials)			2	0.95	0.79 to 1.16	1	0.94	0.74 to 1.18	1	0.99	0.71 to 1.40
Vaginal/perineal tears	4	1.08	1.03 to 1.13	2	1.09	0.98 to 1.21	3	1.10	1.04 to 1.16	1	1.03	0.94 to 1.13
Intact perineum	4	1.10	0.91 to 1.33	2	1.14	1.04 to 1.25	2	1.11	0.99 to 1.25	2	1.18	1.01 to 1.39
PPH	(Only trial with separate staff)			1	0.93	0.69 to 1.25	2	0.97	0.80 to 1.18	(No trial with same staffing)		
Women's satisfaction and psychological/mental health												
Women preferred the same setting next time	(Only trial with separate staff)			(No UK trials)			1	1.81	1.65 to 1.98	(No trial with same staffing)		
Women felt involved in decisions about care	(Only UK trials)			1	1.04	1.00 to 1.08	(No trial with separate staffing)			1	1.04	1.00 to 1.08
High rating of the care	(Only UK trials)			1	1.14	1.07 to 1.21	(No trial with separate staffing)			1	1.14	1.07 to 1.21
Perinatal mortality directly related to intrapartum events and other neonatal complications												
Perinatal mortality directly related intrapartum events	Not reported			Not reported			Not reported			Not reported		
Perinatal mortality	5	1.83	0.99 to 3.38	2	1.52	0.77 to 3.00	3	2.38	1.05 to 5.41	2	1.24	0.48 to 3.19
Apgar score less than 7 at 1 minute	(Only trial with the same staff)			(No UK trials)			(No trial with separate staffing)			1	0.35	0.04 to 3.22
Apgar score less than 7 at 5 minutes	(Only trial with separate staff)			(No UK trials)			2	1.19	0.53 to 2.64	(No trial with same staffing)		
Admission to neonatal unit	3	1.00	0.70 to 1.43	1	1.06	0.80 to 1.40	2	1.23	0.94 to 1.63	2	0.76	0.34 to 1.71

PPH = postpartum haemorrhage.

units that had separate staffing between the two settings there was a significant increase in perinatal mortality, while in trials from units that had the same staff between the two settings there was no statistically difference in perinatal mortality.

Transfer rates

Four studies[58,59,61,62] reported transfer rates, as shown in Table 3.7. [EL = 3]

Table 3.7 Transfer rates during labour for alongside units

Region	Period	Transfer rate during labour
Leicester[58]	1989–1990	28.6%
Aberdeen[59]	1991–1992	25.8%
East Dorset[626]	1992–1993	12.4%
Kirkcaldy[61]	1995–1996	26.4% (nulliparous 38.6%; parous 12.8%)
London[62]	2003	30.6%

Evidence statement on alongside midwife-led units versus obstetric units

The quality of evidence for alongside midwife-led units is better than that for other non-obstetric settings because it is derived from RCTs conducted in the early 1990s. Overall, meta-analyses of RCTs showed an increase in the number of women with intact perineum, an increase in the proportion of women without analgesia and an increase in spontaneous vaginal birth, when care in alongside units is compared with obstetric units.

The analysis of data from all five trials was of borderline statistical significance, but suggested a possible increase in overall perinatal mortality in alongside units compared with obstetric units (RR 1.83 [95% CI 0.99 to 3.38], $P = 0.05$). However, none of the trials reported perinatal mortality that is directly related to intrapartum events and analysis of data restricted to the two UK trials did not reveal any statistically significant difference in perinatal mortality rates for babies born in alongside units compared with obstetric units (RR 1.52 [95% CI 0.77 to 3.0]).

Further subgroup analysis of the Cochrane review has suggested that staffing arrangements may influence outcomes. In trials that had the same staff shared between an alongside unit and an obstetric unit, there were no significant differences in women's and babies' outcomes including perinatal mortality. In trials that had separate staff in an alongside unit from an obstetric unit and a team midwifery model, there was evidence of significant reduction in interventions including induction of labour, augmentation of labour, use of opioid and epidural analgesia, rate of episiotomy, and rate of vaginal/perineal tears and increase in spontaneous vaginal birth, but a statistically significant increase in perinatal mortality. There is no indication as to which component or components of care might contribute to this.

Transfer rates to obstetric units within these studies ranged from 12.4% to 31% in labour. When stratified by parity, transfer rates in labour were 38.6% for nulliparous women and 12.8% for parous women.

3.2.3 Economic evaluation of planning place of birth

Searching the literature

One structured review was identified that provided information about the cost-effectiveness of different models of maternity care.[46] The majority of the economic evaluations included in this review are limited by narrow, short-term perspective and incomplete data. This has led to inconclusive or contradictory findings. Given the limitations of this review, a new systematic literature review to identify the best available economic evidence as regards all the existing birth settings was undertaken.

Description of included studies

This review identified two full economic evaluations. Both studies relate to the US healthcare setting and they sought to evaluate which place of birth is the most cost-effective option for low-risk women.

Review findings

One study[65] compared hospital, home and birth centres, in terms of their cost-effectiveness. Outcome data, derived from earlier published studies, were based on women with low-risk pregnancies. However, there is a serious concern that the authors have not adequately controlled for risk, as outcomes for hospital birth are based on post-date pregnancies, which are at a higher level of risk than term pregnancies. Therefore, there may be systematic differences between the pregnancies in the birth setting comparators in this analysis. Costs were based on charges to the mother for a routine birth. Effectiveness was defined as a birth without intrapartum fetal or neonatal mortality. The authors reported that their analysis showed that, in terms of intrapartum fetal and neonatal mortality, home births and birth centres dominate hospital births, meaning that home and birth centre births are both less expensive and safer than hospital births. They also suggested an incremental cost-effectiveness ratio for birth centres relative to home births of $2.3 million per intrapartum and neonatal death avoided. The authors' conclusion that home birth is a cost-effective health care alternative may not be warranted as the comparison of intrapartum and neonatal mortality is being made without adequately controlling for risk between the different birth settings.

The second study[66] used a decision analytic approach in order to assess which place of birth is the most cost-effective. In this paper there were two comparators: hospital, which was regarded as a traditional birth setting; and birth centre. The authors reported that the average cost of delivery at the birth centre ($3,385) was lower than hospital births ($4,673). They also reported that the utility for average low risk was greater in the birth centre than at the hospital (0.92592 and 0.79507 respectively). However, these utilities do not seem to be based on health-related quality of life and it is not clear how they were derived. They may simply reflect the subjective assessment of the authors. The study suggested that the birth centre dominated in this model, being cheaper and more effective than the hospital alternative. A threshold sensitivity analysis suggested that the transfer rates from birth centres to hospital would have to reach an "unrealistic" 62% before birth centres ceased to dominate the hospital setting. Sensitivity analysis also demonstrated that the dominance of birth centres was contingent on lower charges in that setting compared with hospital. However, no sensitivity analysis was undertaken on utilities and given the concerns about how these were derived more generally, the conclusions of this paper may be in doubt.

As is evident from the above commentary, there are a number of limitations with the above studies. Both studies relate to a US setting and results may not be generalisable to the UK. In particular, costs may differ from those faced in the NHS and place of birth comparisons do not reflect current clinical practice in the UK. For the purpose of this guideline we developed a model that would better reflect NHS costs and place of birth settings available in the UK.

Economic modelling

In order to maximise the health gain from scarce healthcare resources, it is important to consider cost-effectiveness. The economic model described in more detail in Appendix E illustrates the decision-analytic approach that could be used to assess the cost-effectiveness of different places of birth from the perspective of the NHS. However, the output from any such model can only be as good as the inputs with which it is populated.

Evidence statement on economic evaluation of planning place of birth

There is at present insufficient evidence to make a like-for-like comparison of place of birth in terms of clinical effectiveness. Therefore, the model cannot currently inform recommendations for place of birth based on cost-effectiveness, and better outcomes data are needed to inform future decision making.

GDG interpretation of the evidence (advantages and disadvantages of planning each place of birth)

The quality of evidence available is not as good as it should be for such an important healthcare issue and most studies do not report complete or consistent outcome data. Of particular concern is the lack of reliable data, relating to relatively rare but serious outcomes such as perinatal mortality that is directly related to intrapartum events or serious maternal morbidity in all places of birth. Uncontrolled confounding and selection bias are particular methodological limitations of most studies.

However, this situation should be improved once the results of a prospective study evaluating outcomes of home births, births in midwife-led units and obstetric units which is currently being

undertaken by National Perinatal Epidemiology Unit. Birthplace Study) and following improved collection of data by CEMACH of the place of birth.

Planning birth outside an obstetric unit seems to be associated with an increase in spontaneous vaginal births, an increase in women with an intact perineum and, for home births, improved maternal satisfaction.

The GDG was unable to determine whether planning birth in a non-obstetric setting is as safe as birth in an obstetric unit. This was because the data from the included studies consistently showed a non-significant increase in perinatal mortality (including perinatal mortality that is directly related to intrapartum events) in non-obstetric settings.

Recommendations on planning place of birth

Women should be offered the choice of planning birth at home, in a midwife-led unit or in an obstetric unit. Women should be informed:

- That giving birth is generally very safe for both the woman and her baby.
- That the available information on planning place of birth is not of good quality, but suggests that among women who plan to give birth at home or in a midwife-led unit there is a higher likelihood of a normal birth, with less intervention. We do not have enough information about the possible risks to either the woman or her baby relating to planned place of birth.
- That the obstetric unit provides direct access to obstetricians, anaesthetists, neonatologists and other specialist care including epidural analgesia.
- Of locally available services, the likelihood of being transferred into the obstetric unit and the time this may take.
- That if something does go unexpectedly seriously wrong during labour at home or in a midwife-led unit, the outcome for the woman and baby could be worse than if they were in the obstetric unit with access to specialised care.
- That if she has a pre-existing medical condition or has had a previous complicated birth that makes her at higher risk of developing complications during her next birth, she should be advised to give birth in an obstetric unit.

Clinical governance structures should be implemented in all places of birth (see Boxes 3.1 and 3.2).

Box 3.1 Clinical governance in all settings

- Multidisciplinary clinical governance structures, of which the Labour Ward Forum is an example, should be in place to enable the oversight of all places of birth. These structures should include, as a minimum, midwifery (ideally a supervisor of midwives), obstetric, anaesthetic and neonatal expertise, and adequately supported user representation.
- Rotating staff between obstetric and midwife-led units should be encouraged in order to maintain equivalent competency and experience.
- Clear referral pathways should be in place to enable midwives to inform or seek advice from a supervisor of midwives when caring for a woman who may have risk factors but does not wish to labour in an obstetric unit.
- If an obstetric opinion is sought by either the midwife or the woman on the appropriate place of birth, this should be obtained from a consultant obstetrician.
- All healthcare professionals should document discussions with the woman about her chosen place of birth in the hand-held maternity notes.
- In all places of birth, risk assessment in the antenatal period and when labour commences should be subject to continuous audit.
- Monthly figures of numbers of women booked for, being admitted to, being transferred from and giving birth in each place of birth should be audited. This should include maternal and neonatal outcomes.
- The clinical governance group should be responsible for detailed root-cause analysis of any serious maternal or neonatal adverse outcomes (for example, intrapartum-related perinatal death or seizures in the neonatal period) and consider any 'near misses' identified through risk-management systems. The Confidential Enquiry into Maternal and Child Health (CEMACH) and the National Patient Safety Agency (NPSA)'s 'Seven steps to patient safety' provide a framework for meeting clinical governance and risk-management targets.
- Data must be submitted to the national registries for either intrapartum-related perinatal mortality or neonatal encephalopathy once these are in existence.

Box 3.2 Clinical governance for settings other than an obstetric unit

- Clear pathways and guidelines on the indications for, and the process of transfer to, an obstetric unit should be established. There should be no barriers to rapid transfer in an emergency.
- Clear pathways and guidelines should also be developed for the continued care of women once they have transferred. These pathways should include arrangements for times when the nearest obstetric or neonatal unit is closed to admissions.
- If the emergency is such that transfer is not possible, open access must be given on-site for any appropriate staff to deal with whatever emergency has arisen.
- There should be continuous audit of the appropriateness of, the reason for and speed of transfer. Conversely, audit also needs to consider circumstances in which transfer was indicated but did not occur. Audit should include time taken to see an obstetrician or neonatologist and the time from admission to birth.

A national surveillance scheme which allows appropriate comparisons, including safety and cost-effectiveness, of all places of birth should be established to address the poor quality and lack of coverage of current data.

National registries of the root-cause analysis findings relating to all intrapartum-related deaths over 37 weeks of gestation should be established.

A definition of neonatal encephalopathy should be agreed and a national register commenced. The information collected should also include data on transfer during labour from each of the different birth settings.

Research recommendations on planning place of birth

The best possible studies comparing different places of birth should be undertaken in the UK. Prospective research to assess clinical outcomes, including safety, for all places of birth should be undertaken, as well as qualitative data collection to assess women's experiences of birth.

There is a need to establish a single generic health-related quality of life index value for the multi-attribute perinatal and maternal outcomes of intrapartum care.

3.3 Assessment for choosing place of birth

Clinical 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 in labour?

3.3.1 Choosing place of birth

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 thus the GDG discussed each condition related to place of birth.

GDG 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

Tables 3.7 to 3.10 should be used as part of an assessment for choosing place of birth.

Tables 3.7 and 3.8 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 3.9 and 3.10 are not reasons in themselves for advising birth within an obstetric unit but indicate that further consideration of birth setting may be required.

These risks and the additional care that can be provided in the obstetric unit should be discussed with the woman so that she can make an informed choice about place of birth.

Table 3.7 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 100 000
	Von Willebrand's disease
	Bleeding disorder in the woman or unborn baby
	Atypical antibodies which carry a risk of haemolytic disease of the newborn
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
Endocrine	Hyperthyroidism
	Diabetes
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 3.8 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
	Pre-eclampsia or pregnancy-induced hypertension
	Preterm labour or preterm prelabour rupture of membranes
	Placental abruption
	Anaemia – haemoglobin less than 8.5 g/dl 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
	Body mass index at booking of greater than 35 kg/m^2
	Recurrent antepartum haemorrhage
Fetal indications	Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound)
	Abnormal fetal heart rate (FHR)/Doppler studies
	Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	Myomectomy
	Hysterotomy

Table 3.9 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 8.5–10.5 g/dl 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 3.10 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)
	Body mass index at booking of 30–34 kg/m^2
	Blood pressure of 140 mmHg systolic or 90 mmHg diastolic on two occasions
	Clinical or ultrasound suspicion of macrosomia
	Para 6 or more
	Recreational drug use
	Under current outpatient psychiatric care
	Age over 40 at booking
Fetal indications	Fetal abnormality
Previous gynaecological history	Major gynaecological surgery
	Cone biopsy or large loop excision of the transformation zone
	Fibroids

Indications for intrapartum transfer

The following risks and benefits should be assessed when considering transfer to an obstetric unit, bearing in mind the likelihood of birth during the transfer:

- indications for electronic fetal monitoring (EFM) including abnormalities of the fetal heart rate (FHR) on intermittent auscultation
- delay in the first or second stages of labour
- significant meconium-stained liquor
- maternal request for epidural pain relief
- obstetric emergency – antepartum haemorrhage, cord presentation/prolapse, postpartum haemorrhage, maternal collapse or a need for advanced neonatal resuscitation
- retained placenta
- maternal pyrexia in labour (38.0 °C once or 37.5 °C on two occasions 2 hours apart)
- malpresentation or breech presentation diagnosed for the first time at the onset of labour, taking into account imminence of birth
- either raised diastolic blood pressure (over 90 mmHg) or raised systolic blood pressure (over 140 mmHg) on two consecutive readings taken 30 minutes apart
- uncertainty about the presence of a fetal heartbeat
- third- or fourth-degree tear or other complicated perineal trauma requiring suturing.

4 Care throughout labour

4.1 Communication between women and healthcare professionals

Introduction

Effective communication in all its forms is a fundamental aspect in 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, as to whether the experience 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.

Clinical 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.

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 patient.

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

All women in labour should be treated with respect and should be in control of and involved in what is happening to them, and the way in which care is given is key to this. To facilitate this, healthcare professionals and other caregivers should establish a rapport with the labouring woman, asking her about her wants and expectations for labour, being aware of the importance of tone and demeanour, and of the actual words they use. This information should be used to support and guide her through her labour.

To establish communication with the labouring woman, healthcare professionals should:

- Greet the woman with a smile and a personal welcome, establish her language needs, introduce themselves and explain their role in her care.
- Maintain a calm and confident approach so that their 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 partner how to summon help and reassure her that she may do so whenever and as often as she needs to. When leaving the room, healthcare professionals should let her know when they 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.

4.2 Mobilisation and position

Clinical 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

Women should be encouraged and helped to move and adopt whatever positions they find most comfortable throughout labour.

4.3 Support in labour

Clinical 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.

4.3.1 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 12 791 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 postpartum 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 privinding 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 the 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

A woman in established labour should receive supportive one-to-one care.

A woman in established labour should not be left on her own except for short periods or at the woman's request.

Women should be encouraged to have support by birth partner(s) of their choice.

Research recommendation on one-to-one care

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.

4.3.2 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 know 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 4.1.

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 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.

Table 4.1 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 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 as standard care midwives	Not reported	Overall – 2.2%	No	No	Care provided by a variety of obstetricians and midwives antenatally, often also involved GP. 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 midwives with care led by one midwife)

EFM = electronic fetal monitoring.

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 4.2.

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.

Table 4.2 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

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 the 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	= $(1/26 - 1/33) \times n = 0.008 \times n$
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$_{\text{conventional birth}}$	= 64 995/513 022 = 0.127
Odds of instrumental$_{\text{TM birth}}$	= 0.84 OR from meta-analysis × 0.127 = 0.107
Number of instrumental$_{\text{TM}}$ 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 expen-

sive 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.

There is little evidence about its cost-effectiveness.

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

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.

Research recommendations on continuity of care

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.

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.

4.4 Eating and drinking in labour

Clinical question

What is the effectiveness of the following interventions or techniques in labour on outcomes?

- restricting fluids and nutrition.

4.4.1 Reducing 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.

Recommendation on reducing gastric aspiration

Neither H2-receptor antagonists nor antacids should be given routinely to low-risk women.

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.

Research recommendation on reducing gastric aspiration

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.

4.4.2 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 cm^2 [95% CI 0.81 to 2.88 cm^2], $P = 0.001$) 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-hydroxybutyrate 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.

4.4.3 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, pCO_2, pO_2, HCO_3 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 in labour

Women may drink during established labour and be informed that isotonic drinks may be more beneficial than water.

Women may eat a light diet in established labour unless they have received opioids or they develop risk factors that make a general anaesthetic more likely.

4.5 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.

Clinical 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.

4.5.1 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

Tap water may be used if cleansing is required prior to vaginal examination.

4.5.2 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.

Recommendation on double-gloving

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.

Selection of protective equipment should be based on an assessment of the risk of transmission of microorganisms to the woman, and the risk of contamination of the healthcare practitioner's clothing and skin by women's blood, body fluids, secretions or excretions.*

Research recommendation on hygiene measures during labour

Hygiene rituals around the time of vaginal examination and birth would benefit from further research.

4.6 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
- PPH
- shoulder dystocia
- massive obstetric haemorrhage
- maternal collapse
- monitoring suggesting fetal compromise
- undiagnosed breech.

* This recommendation is from 'Infection control: prevention of healthcare-associated infection in primary and community care' (NICE clinical guideline 2).

5 Coping with pain in labour: non-epidural

5.1 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.

Clinical 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).

5.2 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 intrapartum 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)
This section offers advice to clinicians caring for women in labour regarding non-epidural pain relief, based on the GDG's work and deliberations.

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

Healthcare professionals should consider how their own values and beliefs inform their attitude to coping with pain in labour and ensure their care supports the woman's choice.

5.3 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 Section 4.3.1 on support in labour.

5.3.1 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

Women who choose to use breathing and relaxation techniques in labour should be supported in their choice.

5.3.2 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

Women who choose to use massage techniques in labour that have been taught to birth partners should be supported in their choice.

5.3.3 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.

Recommendations on labouring in water

The opportunity to labour in water is recommended for pain relief.

For women labouring in water, the temperature of the woman and the water should be monitored hourly to ensure that the woman is comfortable and not becoming pyrexial. The temperature of the water should not be above 37.5 °C.

Any bath or birthing pool should be kept clean using a protocol agreed with the microbiology department and, in the case of birthing pools, in accordance with the manufacturer's guidelines.

5.3.4 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.

5.3.5 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

The use of injected water papules is not recommended.

5.3.6 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

Acupuncture, acupressure and hypnosis should not be provided, but women who wish to use these techniques should not be prevented from doing so.

The playing of music of the woman's choice in the labour ward should be supported.

Research recommendation on non-invasive techniques in labour

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.

5.4 Non-pharmacological analgesia

Introduction
This section covers TENS, which once again does not require professional oversight.

Clinical 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.

5.4.1 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.

Recommendation on TENS

Transcutaneous electrical nerve stimulation (TENS) should not be offered to women in established labour.

5.5 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.

5.5.1 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

Entonox (a 50 : 50 mixture of oxygen and nitrous oxide) should be available in all birth settings as it may reduce pain in labour, but women should be informed that it may make them feel nauseous and light-headed.

5.6 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.

5.6.1 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.[141142] [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.

5.6.2 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.

5.6.3 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.

Recommendations on intravenous/intramuscular opioids

Pethidine, diamorphine or other opioids should be available in all birth settings. Women should be informed that these will provide limited pain relief during labour and may have significant side effects for both the woman (drowsiness, nausea and vomiting) and her baby (short-term respiratory depression and drowsiness which may last several days).

Women should be informed that pethidine, diamorphine or other opioids may interfere with breastfeeding.

If an intravenous or intramuscular opioid is used, it should be administered with an antiemetic.

Women should not enter water (a birthing pool or bath) within 2 hours of opioid administration or if they feel drowsy.

Research recommendation on intravenous/intramuscular opioids

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).

6 Pain relief in labour: regional analgesia

6.1 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.

Clinical 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?

6.2 Regional analgesia versus other types of analgesia in labour

6.2.1 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.

6.2.2 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 pateint-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 ($n = 37\ 985$). 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

Before choosing epidural analgesia, women should be informed about the risks and benefits, and the implications for their labour.

This information about choosing epidural analgesia should include the following:

- It is only available in obstetric units.
- It provides more effective pain relief than opioids.
- It is associated with a longer second stage of labour and an increased chance of vaginal instrumental birth.
- 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 will be accompanied by a more intensive level of monitoring and intravenous access.
- Modern epidural solutions contain opioids and, whatever the route of administration, all opioids cross the placenta and in larger doses (greater than 100 micrograms in total) may cause short-term respiratory depression in the baby and make the baby drowsy.

6.3 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

Women in labour who desire regional analgesia should not be denied it, including women in severe pain in the latent first stage of labour.

6.4 Care and observations for women with regional analgesia in labour

6.4.1 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.

CSE

There was no evidence of differences reported between the two groups in the CSE trials (spinal/opioid trial: RR for women's hypotension 0.89 [95% CI 0.43 to 1.83]; *n* = 40 women; RR for fetal heart rate abnormalities 0.70 [95% CI 0.36 to 1.37]; *n* = 32 women). There were no reported incidents of hypotension or fetal heart rate abnormalities in the opioid-only study (*n* = 30 women).

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.

Recommendations on preloading for regional analgesia

Intravenous access should always be secured prior to commencing regional analgesia.

Preloading and maintenance fluid infusion need not be administered routinely before establishing low-dose epidural analgesia and combined spinal–epidural analgesia.

6.4.2 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

The following additional observations should be undertaken for women with regional analgesia:

- During establishment of regional analgesia or after further boluses (10 ml or more of low-dose solutions) blood pressure should be measured every 5 minutes for 15 minutes.
- If the woman is not pain free 30 minutes after each administration of local anaesthetic/opioid solution, the anaesthetist should be recalled.
- Hourly assessment of the level of the sensory block should be undertaken.

For monitoring babies' wellbeing for women with regional analgesia, refer to Section 6.4.6 later in this chapter. For general observations for women in the first, second and third stages of labour, refer to Sections 7.6, 8.3 and 9.2, respectively.

6.4.3 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.

6.4.4 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

Women with regional analgesia should be encouraged to move and adopt whatever upright positions they find comfortable throughout labour.

Once established, regional analgesia should be continued until after completion of the third stage of labour and any necessary perineal repair.

Upon confirmation of full cervical dilatation in women 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 pushing during contractions should be actively encouraged.

Following the diagnosis of full dilatation in a woman with regional analgesia, a plan should be agreed with the woman in order to ensure that birth will have occurred within 4 hours regardless of parity.

For position and pushing for women without regional analgesia, refer to Section 8.4.

6.4.5 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

Oxytocin should not be used as a matter of routine in the second stage of labour for women with regional analgesia.

For other recommendations regarding use of oxytocin in the first and second stage of labour, refer to Sections 14.2.6 and 15.1.2, respectively.

6.4.6 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 lock-up 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

Continuous EFM is recommended for at least 30 minutes during establishment of regional analgesia and after administration of each further bolus of 10 ml or more.

6.5 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

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.

6.6 Mode of administration

6.6.1 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.

6.6.2 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.

6.6.3 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.

6.6.4 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)

Either patient-controlled epidural analgesia or intermittent bolus given by healthcare professionals are the preferred modes of administration for maintenance of epidural analgesia.

6.7 Establishing regional analgesia in labour

6.7.1 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.

6.7.2 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.

6.7.3 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.

6.7.4 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.

6.7.5 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.

6.8 Maintenance of regional analgesia

6.8.1 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%).

6.8.2 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.

Levobupivacaine versus ropivacaine

Description of included studies

There were seven trials identified for this comparison.[232,234,237–241] Among included trials, three were initiated with CSE analgesia,[232,234,239,240] and the rest with epidural analgesia. One trial was with PCEA.[239] All the trials were of reasonable quality. Meta-analyses were conducted to summarise the results. [EL = 1+]

Review findings

All regional analgesia

There was no evidence of differences in the onset of analgesia, duration of analgesia, incidence of hypotension, motor block or abnormal fetal heart trace, except incidence of vomiting, which were higher in the ropivacaine group than the levobupivacaine group. There was no evidence of differences in the mode of birth or in NACS for newborn babies. There was also no evidence of difference in women's satisfaction.

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]), onset of analgesia (one trial WMD −1.00 minutes [95% CI −4.93 to 2.93 minutes]) or neonatal outcome (umbilical arterial pH one trial WMD 0.01 [95% CI −0.03 to 0.05]), although there was a significant reduction in duration of analgesia (two trials WMD −12.14 minutes [95% CI −21.23 to 3.05 minutes]), as well as incidence of nausea and/or vomiting (two trials RR 0.41 [95% CI 0.20 to 0.84]), by levobupivacaine. There was no evidence of differences in other adverse outcomes including hypotension (two trials RR 2.09 [95% CI 0.73 to 5.97]) and motor block (Bromage score = 0 three trials RR 1.05 [95% CI 0.81 to 1.36]).

Evidence statement

There is no strong evidence of a difference between ropivacaine and levobupivacaine for 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 underpowered 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

Either epidural or combined spinal–epidural analgesia is recommended for establishing regional analgesia in labour.

If rapid analgesia is required, combined spinal–epidural analgesia is recommended.

It is recommended that combined spinal–epidural analgesia is established with bupivacaine and fentanyl.

It is recommended that epidural analgesia is established 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 and as such should be administered cautiously to ensure that inadvertent intrathecal injection has not occurred.

Low-concentration local anaesthetic and opioid solutions (0.0625–0.1% bupivacaine or equivalent combined with 2.0 micrograms per ml fentanyl) are recommended for maintaining epidural analgesia in labour.

High concentrations of local anaesthetic solutions (0.25% or above of bupivacaine or equivalent) should not be used routinely for either establishing or maintaining epidural analgesia.

7 Normal labour: first stage

7.1 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

Clinical intervention should not be offered or advised where labour is progressing normally and the woman and baby are well.

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

7.2 Definition of the first stage of labour

Clinical 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

For the purposes of this guideline, the following definitions of labour are recommended:

- 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.

For definitions of second and third stages of labour, refer to Sections 8.1 and 9.1.1, respectively.

7.3 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.

Clinical 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 7.1). 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 7.1 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

Women should be informed 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.

Research recommendation on duration of labour

A prospective cohort study on impact of length of labour on outcomes is needed.

For duration of second and third stages of labour, refer to Sections 8.2 and 9.1.2, respectively.

7.4 Observations on presentation in suspected labour

Introduction

It is traditional to carry out a number of routine observations of the woman and the baby. These are aimed at assessing maternal and fetal health, determining the stage and progress of labour, evaluating the woman's needs, determining whether admission to her chosen place of birth is required, and, if not, what follow-up observation and advice is required.

Clinical questions

Is there evidence that the timing of admission to maternity units, and of cervical dilatation, affects outcomes?

- Subgroups include nulliparous women and multiparous women.

Is there evidence that midwife assessment at home affects outcomes?

- Subgroups include nulliparous women and multiparous women.

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.

7.4.1 Women's observations (including women's behaviour)

No relevant study was identified.

7.4.2 Palpation and presentation/position of baby

No relevant study was identified.

7.4.3 Presentation and descent of the presenting part

No relevant study was identified.

7.4.4 Membrane and liquor assessment and assessment of liquor if membranes ruptured

No relevant study was identified.

7.4.5 Contractions

No outcome-related studies were identified for inclusion in this section of the review. However, a small (n = 24 women) US study of low quality [EL = 2–] was found which compared transabdominal electromyography (EMG) with transabdominal pressure transducers (TOCO) for differentiating between 'true' and 'false' labour.[291] While transabdominal tocography was found to be unable to distinguish between 'true' and 'false' labours, EMG-recorded (electrical) energy levels of contractions were found to be significantly predictive of birth before 48 hours ($P < 0.0001$), with positive and negative predictive values of 94% and 88%, respectively.

7.4.6 Vaginal examinations

Introduction

The intimate nature of any vaginal examination should never be forgotten and, as with any procedure, consent obtained. While they may be useful in assessing progress in labour, to many women who may already be in pain, frightened and in an unfamiliar environment, they can be very distressing. The adverse effect on the woman may be reduced by having due regard for the woman's privacy, dignity and comfort. Good communication, as in all aspects of care, is vital and caregivers should explain the reason for the examination and what will be involved. Caregivers should also be sure that the vaginal examination is really necessary and will add important information to the decision-making process. The findings, and their impact, should also be explained sensitively to the woman – using the word 'only' when referring to the amount of dilatation may not be a good start and could easily dishearten or even frighten her.

Overview of available evidence
No relevant studies were identified that investigated vaginal examinations on initial contact with healthcare professionals.

7.4.7 Assessment of cervical effacement, dilatation and position

No relevant study was identified.

7.4.8 Admission CTG

Admission CTG versus auscultation at admission

Description of included studies
One systematic review including three randomised controlled trials and 11 observational studies was identified.[292] The systematic review, assessing prognostic value of labour admission test (admission CTG) and its effectiveness compared with auscultation only, was published in December 2005 and is of good quality. All trials targeted low-risk women. Two trials were conducted in Scotland, and the other in Ireland.

Review findings
Meta-analyses of the three trials included showed evidence that women with admission CTG were more likely to have epidural analgesia (RR 1.2 [95% CI 1.1 to 1.4]), continuous EFM (RR 1.3 [95% CI 1.2 to 1.5]) and fetal blood sampling (RR 1.3 [95% CI 1.1 to 1.5]). There was also borderline evidence that women with continuous EFM were more likely to have an instrumental birth (RR 1.1 [95% CI 1.0 to 1.3]) and CS (RR 1.2 [95% CI 1.0 to 1.4]), compared with the auscultation group, although there was no evidence of differences in augmentation (RR 1.1 [95% CI 0.9 to 1.2]), perinatal mortality (RR 1.1 [95% CI 0.2 to 7.1]) or other neonatal morbidities.

7.4.9 Timing of admission to place of birth

Description of included studies
One Canadian RCT was identified that investigated timing of admission to maternity hospital.[293] [EL = 1–] The study was identified from a systematic review. The study population comprised 209 low-risk pregnant women. Three observational studies also identified for review, relating to cervical dilatation and timing of admission, consisted of two poor-quality cohort studies conducted in Canada[294,295] [both EL = 2–] and one cross-sectional study conducted in the USA.[296] [EL = 3] One poor-quality RCT (n = 237) conducted in Canada was identified that considered the impact of the first contact being at home.[297] [EL = 1–] The study investigated intrapartum outcomes of women in early labour who received a home visit by an obstetric nurse (n = 117), compared with women who received telephone triage (n = 120).

Review findings
A Canadian RCT allocated women to one of two groups: early assessment of labour status (active phase or latent phase) or direct hospital admission.[293] [EL = 1–] Those not in active labour were given encouragement and advice and told to return home or walk outside until labour became more active. Women in the early assessment group had significantly reduced medical interventions including use of oxytocin (OR 0.44 [95% CI 0.24 to 0.80]) and use of any anaesthesia/analgesia (OR 0.36 [95% CI 0.16 to 0.78]). Women in the early labour assessment group reported being more satisfied with their care (Labour Agentry Scale, P = 0.001). There was no evidence of differences in neonatal outcomes owing to the small sample size.

One Canadian cohort study (n = 3220) reported intrapartum outcomes of women whose cervix was dilated by 3 cm or less at initial presentation, compared with women with cervical dilatation of 4 cm or more.[294] [EL = 2–] Women presenting early had a longer length of labour (MD 3.10 hours, $P < 0.001$), higher rate of oxytocin use (RR 1.58, $P < 0.001$) and higher CS rate (RR 2.45, P = 0.001). A second Canadian cohort study (n = 3485) compared intrapartum outcomes for two groups of low-risk pregnant women. The first group were booked under the care of family physicians who had 50% or more of their patients admitted to maternity units early (defined as a cervical dilatation of less than 3 cm). The second group were booked under family

physicians who had fewer than 50% of their patients admitted early.[295] [EL = 2–] Adjusted logistic regression analysis showed women under care of physicians who admitted their patients early had higher rates of epidural (OR 1.34 [95% CI 1.15 to 1.55]), CS (OR 1.33 [95% CI 1.00 to 1.65]) and EFM (OR 1.55 [95% CI 1.27 to 1.89]). A US cross-sectional study (n = 8818) also compared intrapartum outcomes of women presenting in the active phase in labour with those presenting in the latent phase.[296] [EL = 3] Women presenting in the latent phase of labour had more active phase arrest (OR 2.2 [95% CI 1.6 to 2.6]), use of oxytocin (OR 2.3 [95% CI 2.1 to 2.6]) and epidural anaesthesia (OR 2.2 [95% CI 2.0 to 2.4]). There were more newborns who were intubated after birth (OR 1.2 [95% CI 1.0 to 1.4]), women with amnionitis (OR 2.7 [95% CI 1.5 to 4.7]) and maternal postpartum infection (OR 1.7 [95% CI 1.0 to 2.9]) in the latent phase admission group.

One RCT investigated intrapartum outcomes of women in early labour who received a home visit by an obstetric nurse (n = 117) compared with women who received telephone triage (n = 120).[297] [EL = 1–] Women who received a home visit had less opiate analgesia (OR 0.55 [95% CI 0.32 to 0.96]) and fewer babies admitted to neonatal units (OR 0.13 [95% CI 0.03 to 0.60]). There were no other significant differences, including costs.

Evidence statement

There is little evidence for the use of routine observations or examinations on first presentation to healthcare professionals of women in suspected labour.

There is high-level evidence that women who had routine admission CTGs were more likely to have interventions during labour, although there were no statistical differences in neonatal outcomes.

There was no good-quality evidence for timing of admission. Limited quality of evidence showed that early assessment by a midwife, compared with early admission to maternity units, appeared to reduce medical intervention rates and increase women's satisfaction. There was insufficient evidence on morbidity and mortality of both women and their babies.

There was little evidence for the effect on outcome of a home visit by a midwife in early labour.

Recommendations on initial observations

The initial assessment of a woman by a midwife should include:

- listening to her story, considering her emotional and psychological needs, and reviewing her clinical records
- physical observation – temperature, pulse, blood pressure, urinalysis
- length, strength and frequency of contractions
- abdominal palpation – fundal height, lie, presentation, position and station
- vaginal loss – show, liquor, blood
- assessment of the woman's pain, including her wishes for coping with labour along with the range of options for pain relief.

In addition:

- The FHR should be auscultated for a minimum of 1 minute immediately after a contraction. The maternal pulse should be palpated to differentiate between maternal and FHR.
- If the woman does not appear to be in established labour, after a period of assessment it may be helpful to offer a vaginal examination.
- If the woman appears to be in established labour, a vaginal examination should be offered.

Healthcare professionals who conduct vaginal examinations should :

- be sure that the vaginal examination is really necessary and will add important information to the decision-making process
- be aware that for many women who may already be in pain, highly anxious and in an unfamiliar environment, vaginal examinations can be very distressing
- ensure the woman's consent, privacy, dignity and comfort
- explain the reason for the examination and what will be involved, and
- explain the findings and their impact sensitively to the woman.