

# Induction of labour

**Clinical Guideline**

July 2008

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# Induction of labour

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

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for Health and Clinical Excellence

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**Update information:** some sections have been removed as they have been replaced by the October 2021 update. These are marked accordingly.

This updates and replaces the 2001 guideline.



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# Guideline Development Group membership and acknowledgements

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## Guideline Development Group

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## Stakeholder organisations

Action on Pre-Eclampsia  
Acute Care Collaborating Centre  
Addenbrooke's NHS Trust  
All Wales Birth Centre Group  
Alliance Pharmaceuticals  
Association for Continence Advice  
Association for Improvements in the Maternity Services  
Association of Radical Midwives  
Baby Lifeline  
Birth Trauma Association  
Bradford & Airedale PCT  
Bristol Health Services Plan  
British Association of Perinatal Medicine  
British Maternal and Fetal Medicine Society  
British National Formulary (BNF)  
CASPE  
CEMACH  
National Collaborating Centre for Chronic Conditions (NCC-CC)  
City Hospitals Sunderland NHS Trust  
Cochrane Pregnancy & Childbirth Group  
Commission for Social Care Inspection  
Connecting for Health  
Controlled Therapeutics  
Conwy & Denbighshire Acute Trust  
Cotswold and Vale PCT  
County Durham and Darlington Acute Trust  
Department of Health  
Doula UK  
English National Forum of LSA Midwifery Officers  
Evidence based Midwifery Network  
Ferring Pharmaceuticals  
Gloucestershire Acute Trust  
Group B Strep Support  
Health and Safety Executive  
Healthcare Commission  
Heart of England NHS Foundation Trust  
Independent Midwives Association  
King's College Acute Trust  
Liverpool Women's NHS Trust  
Luton and Dunstable Hospital NHS Trust  
Maidstone and Tunbridge Wells NHS Trust  
Medicines and Healthcare products Regulatory Agency (MHRA)  
Mental Health Act Commission  
National Collaborating Centre for Mental Health (NCCMH)  
Mid and West Regional Maternity Service Liaison Committee (MSLC)  
MIDIRS (Midwives Information & Resource Service)  
Midwifery Studies Research Unit  
National Patient Safety Agency National  
Perinatal Epidemiology Unit National  
Public Health Service – Wales  
National Treatment Agency for Substance Misuse  
National Collaborating Centre for Cancer (NCC-C)  
National Coordinating Centre for Health Technology Assessment (NCCHTA)  
Newcastle Upon Tyne Hospitals NHS Foundation Trust  
NHS Health and Social Care Information Centre  
NHS Plus

NHS Quality Improvement Scotland  
North Tees and Hartlepool Acute Trust  
Northumbria Acute Trust  
Northwest London Hospitals NHS Trust  
National Collaborating Centre for Nursing and Supportive Care (NCC-NSC)  
Obstetric Anaesthetists Association  
Patient and Public Involvement Programme for NICE  
PERIGON (formerly The NHS Modernisation Agency)  
Pfizer  
National Collaborating Centre for Primary Care (NCC-PC)  
Princess Alexandra Hospital NHS Trust  
RCM Consultant Midwives Forum  
Regional Public Health Group – London  
Royal College of Anaesthetists  
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 Devon & Exeter NHS Foundation Trust  
School of Midwifery  
Scottish Intercollegiate Guidelines Network (SIGN)  
Sheffield PCT  
Sheffield Teaching Acute Trust  
Staffordshire Moorlands PCT  
Stockport PCT  
Tameside and Glossop Acute Trust  
Association of Anaesthetists of Great Britain & Ireland  
Association of the British Pharmaceuticals Industry (ABPI)  
Dudley Group of Hospitals NHS Trust  
National Childbirth Trust  
Pelvic Partnership  
Royal Society of Medicine  
Survivors Trust  
Tissue Viability Nurses Association  
United Lincolnshire Hospitals NHS Trust  
University College London Hospitals (UCLH) Acute Trust  
University Hospitals of Leicester  
Welsh Assembly Government  
Welsh Scientific Advisory Committee (WSAC)  
West Middlesex University Hospital NHS Trust  
West Yorkshire Strategic Health Authority  
Wirral Hospital Acute Trust  
National Collaborating Centre for Women's and Children's Health (NCC-WCH)  
Women's Health Research Group  
Worcestershire Acute Hospitals NHS Trust  
Worthing Hospital



# Abbreviations

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<b>41<sup>+3</sup> weeks</b>	41 completed weeks plus 3 days of gestation, etc.
<b>ARM</b>	artificial rupture of the membranes
<b>BNF</b>	British National Formulary
<b>CI</b>	confidence interval
<b>CS</b>	caesarean section
<b>EFM</b>	electronic fetal monitoring
<b>EL</b>	evidence level (level of evidence)
<b>FHR</b>	fetal heart rate
<b>GA</b>	gestational age
<b>GDG</b>	Guideline Development Group
<b>ICER</b>	incremental cost-effectiveness ratio
<b>IMN</b>	isosorbide mononitrate
<b>IUFD</b>	intrauterine fetal death
<b>IV</b>	intravenous
<b>LSCS</b>	lower segment caesarean section
<b>MAD</b>	minimum analgesic dose
<b>NCC-WCH</b>	National Collaborating Centre for Women's and Children's Health
<b>NHS</b>	National Health Service
<b>NICE</b>	National Institute for Health and Clinical Excellence
<b>NICU</b>	neonatal intensive care unit
<b>NNT</b>	number needed to treat
<b>NS</b>	not significant
<b>OR</b>	odds ratio
<b>PCT</b>	primary care trust
<b>PG</b>	prostaglandin
<b>PGE<sub>2</sub></b>	prostaglandin E <sub>2</sub>
<b>PGF<sub>2α</sub></b>	prostaglandin F <sub>2</sub> alpha
<b>PPIP</b>	Patient and Public Involvement Programme
<b>QALY</b>	quality-adjusted life year
<b>RCOG</b>	Royal College of Obstetricians and Gynecologists
<b>RCT</b>	randomised controlled trial
<b>RR</b>	relative risk
<b>SD</b>	standard deviation
<b>SIGN</b>	Scottish Intercollegiate Guidelines Network
<b>SPC</b>	summary of product characteristics
<b>VE</b>	vaginal examination
<b>WHO</b>	World Health Organization
<b>WMD</b>	weighted mean difference

# Glossary of terms

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<b>Algorithm</b>	A step-by-step problem solving procedure designed to guide users through clinical decision pathways.
<b>Amniotomy</b>	Artificial rupture of the membranes to initiate or speed up labour.
<b>Analgesia</b>	Pain relief without loss of consciousness.
<b>Antenatal</b>	Before birth.
<b>Apgar score</b>	A scoring system devised by Dr Virginia Apgar (1909–74) based on five criteria (heart rate, respiration, colour, muscle tone and response to stimulation) and used as a marker of a newborn baby's need for resuscitation at birth. A score of 0, 1 or 2 is awarded for each criterion, with a total score out of ten. The score is assessed at 1 and 5 minutes after birth.
<b>Augmentation of labour</b>	A process where the progress of labour is enhanced by administration of an infusion of <b>oxytocin</b> .
<b>Balloon catheter</b>	A flexible tube with an inflatable balloon at one end. This can be introduced through the cervix and the balloon inflated, holding the catheter in place. Drugs or fluids may then be infused via the catheter.
<b>Bias</b>	Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias occurs as a result of defects in the study design or the way the study is carried out. It can occur at various stages in the research process, for example in the collection, analysis, interpretation, publication or review of research data.
<b>Bishop score</b>	A group of measurements made at internal examination, used to determine whether the <b>cervix</b> is <b>favourable</b> or not. The score is based on the station, dilation, effacement (or length), position and consistency of the cervix. A score of 8 or more generally indicates that the cervix is ripe See <b>cervical ripeness</b> .
<b>Blinding or masking</b>	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 <b>bias</b> .
<b>Breech presentation</b>	Initial presentation of the fetal buttocks or feet ('footling breech') in the birth canal.
<b>Caesarean section</b>	Operative delivery of the fetus through an abdominal incision.
<b>Cardiotocography (CTG)</b>	A method of monitoring the fetal heart rate (FHR) pattern in relation to the pattern and intensity of uterine contractions. The FHR can be monitored non-invasively using a sensor attached to the woman's abdomen, or invasively using an electrode attached to the presenting part of the fetus (usually the fetal scalp). The uterine contractions are recorded using an external sensor held in place on the woman's abdomen. Changes in FHR that suggest fetal compromise may prompt the need for an instrumental or operative birth of the baby. Also referred to as <b>electronic fetal monitoring (EFM)</b> .
<b>Case-control study</b>	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, for example things that might be related to getting the disease under investigation. Such studies are also called <b>retrospective</b> as they look back in time from the outcome to the possible causes.
<b>Case series</b>	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison ( <b>control</b> ) group of patients.
<b>Cervical ripeness</b>	The extent to which the cervix has softened and shortened in the early phase of labour. It is assessed using the <b>Bishop score</b> .
<b>Cervical ripening</b>	A prelude to the onset of labour whereby the cervix becomes soft and compliant. This allows its shape to change from being long and closed, to being thinned out (effaced) and starting to open (dilate). It either occurs naturally or as a result of physical or pharmacological interventions.
<b>Cervix</b>	The neck of the uterus where it joins the vagina.

<b>Chorioamnionitis</b>	Inflammation of the fetal membranes caused by infection as a result of, or causing rupture of the membranes. It is associated with preterm birth and potentially serious neonatal morbidity, including congenital pneumonia and brain injury, as well as maternal infection (endometritis).
<b>Clinical audit</b>	A <b>systematic</b> 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.
<b>Clinical effectiveness</b>	The extent to which a specific treatment or intervention, when used under <i>usual or everyday conditions</i> , 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 <b>efficacy</b> .
<b>Clinical question</b>	A 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 <b>focused question</b> .
<b>Clinical trial</b>	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 <b>controlled clinical trials</b> and <b>randomised controlled trials</b> .
<b>Clinician</b>	A qualified healthcare professional providing patient care, for example doctor, nurse, physiotherapist.
<b>Cohort</b>	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.
<b>Cohort study</b>	An observational study that takes a group ( <b>cohort</b> ) 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, for example 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.
<b>Confidence interval (CI)</b>	A way of expressing the degree of 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.
<b>Confounder or confounding factor</b>	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.
<b>Consensus methods</b>	A variety of techniques that aim to reach an agreement on a particular issue. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic.
<b>Consensus statement</b>	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.
<b>Consistency</b>	The extent to which the conclusions of a collection of studies used to support a guideline recommendation are in agreement with each other.

<b>Control group</b>	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a <b>placebo</b> (dummy treatment) – in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
<b>Controlled clinical trial (CCT)</b>	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 <b>control group</b> ) receives an alternative treatment, a <b>placebo</b> (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 <b>randomised controlled trial</b> .
<b>Corticosteroid</b>	A group of chemical substances produced in the body by the adrenal glands. They have many actions, including regulation of carbohydrate, fat and protein metabolism, water and electrolyte balance, and the development and maintenance of sex characteristics. They can be made artificially and have many clinical uses – when given to pregnant women (antenatal corticosteroids), they can enhance fetal lung maturation, thus helping to reduce the incidence of respiratory distress in babies born preterm.
<b>Cost-effectiveness</b>	Value for money. A specific healthcare 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.
<b>Cost-effectiveness analysis</b>	A type of <b>economic evaluation</b> 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.
<b>Decidua</b>	The inner layer of the wall of the uterus.
<b>Decision analysis</b>	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 <b>decision trees</b> .
<b>Decision tree</b>	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.
<b>Declaration of interest</b>	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, for example if their position or department is funded by a pharmaceutical company.
<b>Dehiscence of uterine scar</b>	Splitting open during labour of the site of a previous incision in the uterus. There may be catastrophic bleeding with potential death of the woman and/or baby.
<b>Dominance</b>	A term used in <b>health economics</b> 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’.
<b>Doppler ultrasound</b>	A widely used clinical investigation where <b>ultrasound</b> , utilising the Doppler effect, is used to measure blood flow velocity in fetal blood vessels. A probe is placed on the woman’s abdomen and the area in question, such as the umbilical arteries, is identified with the ultrasound beam. The Doppler effect is employed to determine the speed and direction of blood flow in the vessel. Absent or reversed flow in the umbilical artery may indicate potential fetal compromise.
<b>Economic evaluation</b>	A comparison of alternative courses of action in terms of both their costs and consequences. In <b>health economic</b> evaluations the consequences should include health outcomes.
<b>Effacement</b>	Softening and shortening of the cervix.
<b>Effectiveness</b>	See <b>clinical effectiveness</b> .
<b>Efficacy</b>	The extent to which a specific treatment or intervention, under <i>ideally controlled conditions</i> (e.g. in a laboratory), has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care.
<b>Elective</b>	A term for clinical procedures that are planned rather than becoming necessary as emergencies.
<b>Electronic fetal monitoring (EFM)</b>	See <b>cardiotocography</b> .
<b>Endometritis</b>	Inflammation of the inner layer of the uterus (endometrium) caused by infection. It is characterised by maternal fever, tender uterus and drainage of foul-smelling liquor.
<b>Epidemiology</b>	The study of diseases within a population, covering the causes and means of prevention.

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<b>Epidural</b>	Epidural analgesia is a clinical intervention made to relieve the pain of labour. A thin catheter is inserted by an anaesthetist through the lower back into a space around the outer covering of the spinal cord (the epidural space). Analgesic drugs are injected via the catheter and repeated at intervals as necessary during labour.
<b>Evidence based</b>	The process of systematically finding, appraising and using research findings as the basis for clinical decisions.
<b>Evidence-based clinical practice</b>	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.
<b>Evidence table</b>	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.
<b>Expectant management</b>	Allowing labour to develop and progress under supervision without intervention, unless clinically indicated.
<b>Extra-amniotic infusion</b>	Introduction of fluids or drugs between the uterus and the fetal membranes, but not in contact with the amniotic fluid or fetus.
<b>Extrapolation</b>	The application of research evidence based on studies of a specific population to another population with similar characteristics.
<b>Failed induction</b>	Failure to establish labour after one cycle of treatment, consisting of the insertion of two vaginal PGE <sub>2</sub> tablets (3 mg) or gel (1–2 mg) at 6-hourly intervals, or one PGE <sub>2</sub> pessary (10 mg) within 24 hours.
<b>Favourable cervix</b>	The cervix is said to be favourable when its characteristics suggest there is a high chance of spontaneous onset of labour, or of responding to interventions made to induce labour.
<b>Fetal growth restriction</b>	Failure of adequate growth of the fetus in the womb. Ultrasound is used to estimate fetal weight and other measures of somatic growth. These measurements are compared with those expected for the gestational age of the fetus. A fetus can be smaller than expected but entirely normal. Poor growth of the fetus on repeated measurement usually indicates inadequate delivery of nutrition from the placenta, but can also be due to other processes such as intrauterine infection or chromosomal disorders. A fetus with growth restriction may be at a greater risk of stillbirth, birth asphyxia, neonatal complications and abnormal neurodevelopment. Previously known as intrauterine growth restriction (IUGR).
<b>Fetal monitoring</b>	The wellbeing of the fetus may be monitored during labour, by intermittent auscultation with a <b>Pinard stethoscope</b> , continuous <b>cardiotocography</b> or as required by <b>ultrasound</b> . Disturbances of heart rate pattern may indicate a need for intervention.
<b>Focused question</b>	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 nitric oxide donors (intervention) improve cervical scores (outcome) in women undergoing induction of labour (population) when compared with vaginal prostaglandins (comparison)? See also <b>clinical question</b> .
<b>Gestational age (GA)</b>	The age of the fetus or newborn calculated from the number of completed weeks since the first day of the woman's <b>last menstrual period</b> .
<b>Glyceryl trinitrate</b>	A liquid chemical that is used therapeutically to relax smooth muscle, particularly as a treatment for angina pectoris (cardiac pain).
<b>Grand multipara</b>	A woman who has given birth to six or more babies.
<b>Group B streptococcus (GBS)</b>	GBS is a bacterium that is found normally in the vagina or rectum of 25% of women. Untreated, it can cause serious illness or death in the baby.
<b>Guideline</b>	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.
<b>Guideline recommendation</b>	Course of action advised by the Guideline Development Group on the basis of their assessment of the supporting evidence.
<b>Health economics</b>	A branch of economics that studies decisions about the use and distribution of healthcare resources.

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<b>Hierarchy of evidence</b>	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 <b>randomised controlled trials</b> (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.
<b>Incremental cost-effectiveness ratio (ICER)</b>	A ratio of the extra (incremental) cost incurred for an additional unit of benefit gained (e.g. cost per life year gained or cost per QALY) of an intervention relative to an appropriate comparator.
<b>Induction agent</b>	A substance used to initiate labour.
<b>Induction of labour</b>	The artificial initiation of labour.
<b>Intention-to-treat analysis</b>	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 because they maintain the balance in basic characteristics between groups achieved by random allocation. Moreover, they mirror the non-compliance and treatment changes that are likely to occur when the treatment is used in practice.
<b>Intervention</b>	Healthcare action intended to benefit the patient, for example drug treatment, surgical procedure, psychological therapy, etc.
<b>Intracervical catheter</b>	A flexible tube that is passed through the cervix to allow introduction of drugs or fluids into the uterus.
<b>Intrapartum</b>	During labour.
<b>Intrauterine death</b>	Death of the fetus inside the uterus before birth.
<b>Intrauterine infection</b>	An infection of the fetus acquired while it is in the womb. The infection may cross the placenta from the mother's circulation (e.g. many viral infections) or enter via the birth canal particularly when the membranes have ruptured prematurely (e.g. some bacterial infections).
<b>Intravaginal</b>	Placed into the vagina
<b>Isosorbide mononitrate (IMN)</b>	A nitric oxide donor, which acts to dilate smooth muscle.
<b>Laminaria tent</b>	A stick-shaped preparation made from dried stems of Laminaria seaweeds. They absorb fluid and swell to 3–5 times their original diameter, and thus when placed through the cervix they can produce cervical dilation as they expand. Their use has been associated with maternal or neonatal infection.
<b>Last menstrual period</b>	Pregnancies are dated in weeks starting from the first day of a woman's last menstrual period. If her menstrual periods are regular and ovulation occurs on day 14 of her cycle, conception takes place about 2 weeks after her last menstrual period. The calculation of dates may be less accurate if the woman has irregular periods or has conceived after discontinuing the oral contraceptive pill.
<b>Level of evidence</b>	A code (e.g. 1++, 1+) linked to an individual study, indicating where it fits into the <b>hierarchy of evidence</b> and how well it has adhered to recognised research principles.
<b>Literature review</b>	A process of collecting, reading and assessing the quality of published (and unpublished) articles on a given topic.
<b>Macrosomia</b>	This describes a large fetus or baby whose weight is greater than the 90th percentile for the gestational age.
<b>Mechanical methods</b>	Non-pharmacological means of inducing labour.
<b>Meconium staining</b>	Meconium is the greenish-black sticky material passed from the baby's bowels after birth. In some instances, the fetus will pass meconium into the amniotic fluid while still in the womb, indicated by the presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so. During fetal distress, fetal acidosis may stimulate the fetus to gasp and inhale meconium into the airways and lungs, a condition known as neonatal meconium aspiration syndrome.
<b>Membrane sweeping</b>	A procedure where a midwife or doctor will 'sweep' a finger around the cervix during an internal examination. The aim is to separate the fetal membranes from the cervix, leading to a release of prostaglandins and subsequent onset of labour.

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<b>Meta-analysis</b>	The 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, for example 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 <b>systematic review</b> .
<b>Methodological quality</b>	The extent to which a study has conformed to recognised good practice in the design and execution of its research methods.
<b>Methodology</b>	The overall approach of a research project, for example the study will be a <b>randomised controlled trial</b> , of 200 people, over 1 year.
<b>Multicentre study</b>	A study where subjects were selected from different locations or populations, for example a cooperative study between different hospitals; an international collaboration involving patients from more than one country.
<b>Multiparous</b>	A woman who has given birth to more than one baby.
<b>Neonate</b>	A newborn baby aged 0–28 days.
<b>Nulliparous</b>	A woman who has never given birth to a live infant.
<b>Number needed to treat (NNT)</b>	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. For example, 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. For example, if the NNH = 4, then four patients would have to be treated for one bad outcome to occur.
<b>Odds ratio (OR)</b>	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 <b>confidence interval</b> ) 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 <b>relative risk</b> (which uses actual risks and not odds) will be very similar. See also <b>relative risk</b> , <b>risk ratio</b> .
<b>Oestrogens</b>	Female sex hormones produced by the ovary and placenta. They are involved in making the uterus ready for the implantation and support of the early embryo. They can be produced artificially and have a number of clinical uses, such as oral contraceptives and hormone replacement therapy.
<b>Outcome</b>	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.
<b>Oxytocin</b>	A hormone released naturally from the pituitary gland that stimulates the contraction of the uterus during labour and facilitates ejection of milk from the breast during nursing. It can be made artificially and is used therapeutically to induce or augment labour.
<b>P value</b>	If a study is done to compare two treatments then the <i>P</i> 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 <i>P</i> 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 <i>P</i> is below 0.05 (i.e. less than 5%) the result is seen as statistically significant. Where the value of <i>P</i> is 0.001 or less, the result is seen as highly significant. <i>P</i> 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 <b>confidence interval</b> .
<b>Parity</b>	The number of times a woman has given birth. A woman who has given birth a particular number of times is referred to as para 1, para 2, etc.
<b>Parous</b>	Pertaining to parity.
<b>Perinatal</b>	The perinatal period is the time between 28 weeks of gestation and 7 completed days after birth.

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<b>Pessary</b>	A drug-containing suppository that is placed in the vagina.
<b>Pinard stethoscope</b>	A trumpet-shaped device used to listen to the fetal heart. The bell-shaped end is placed on the woman's abdomen and the user's ear placed to the other. It is named after Adolphe Pinard (1844–1934), a French obstetrician.
<b>Placebo</b>	Placebos are fake or inactive treatments received by participants allocated to the <b>control group</b> 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 <b>placebo effect</b> due to receiving care or attention.
<b>Placenta</b>	The afterbirth. This is a complex vascular structure that allows passage of nutrients and oxygen from the woman's circulation to the fetus, and waste substances from the fetus to the woman, without direct contact between their two circulations. In addition, the placenta is metabolically active, producing hormones and other substances essential to the maintenance of the pregnancy.
<b>Postpartum</b>	After birth.
<b>Power</b>	See <b>statistical power</b> .
<b>Precipitate labour</b>	Rapid progression of labour leading to birth of the baby.
<b>Pre-eclampsia</b>	A disorder specific to pregnancy. It is usually of rapid onset and characterised by raised blood pressure, excess protein in the urine, headache, puffiness of the tissues and visual disturbance. It may lead to convulsions. The cause is still not completely understood.
<b>Prelabour rupture of membranes</b>	Rupture of the membranes before the onset of labour. This might be caused by infection, or predispose the fetus to infection entering the womb. The membranes may rupture close to term or prematurely (before 37 weeks). The latter may be associated with preterm birth and with serious neonatal respiratory morbidity.
<b>Primary care</b>	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.
<b>Primary care trust (PCT)</b>	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 <b>primary care</b> ) and making sure that other appropriate health services are in place to meet local people's needs.
<b>Priming</b>	Cervical priming is a process where the cervix is made softer and shorter, leading to onset of labour.
<b>Primiparous</b>	A woman who is giving birth for the first time.
<b>Probability</b>	How likely an event is to occur, for example how likely a treatment or intervention will alleviate a symptom.
<b>Prolapsed cord</b>	When the umbilical cord passes through the cervix before the presenting part of the fetus (usually the head). As there is a risk of cord obstruction and fetal death or disability, an emergency caesarean section is indicated.
<b>Prolonged pregnancy</b>	A pregnancy that has progressed beyond 42 <sup>+0</sup> weeks of gestation.
<b>Prospective study</b>	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 <b>retrospective</b> .
<b>Prostaglandin</b>	Any member of a group of hormone-like substances that mediate a wide range of physiological functions, such as contraction of smooth muscle. Prostaglandin E <sub>2</sub> (PGE <sub>2</sub> ; dinoprostone) ripens the cervix and stimulates uterine muscle, and is a pharmaceutical preparation used to induce labour.
<b>Protocol</b>	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.
<b>Quality-adjusted life years (QALYs)</b>	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.
<b>Random allocation or randomisation</b>	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. The aim of random allocation is to ensure that the intervention and control groups are similar with respect to all potential confounding variables.



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<b>Randomised controlled trial (RCT)</b>	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 <b>control group</b> ) receiving an alternative treatment, a <b>placebo</b> (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.)
<b>Relative risk (RR)</b>	A summary measure that 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 <b>risk ratio</b> .
<b>Retrospective study</b>	A retrospective study deals with the present/past and does not involve studying future events. This contrasts with studies that are prospective.
<b>Review</b>	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.
<b>Risk ratio</b>	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 <b>relative risk</b> is sometimes used as a synonym for risk ratio.
<b>Royal Colleges</b>	In the UK medical/nursing world the term Royal Colleges, as for example in 'The Royal College of ...', refers to organisations that usually combine an educational standards and examination role with the promotion of professional standards.
<b>Rupture of membranes</b>	When the membranes around the baby break, either spontaneously in labour (SROM) or artificially to start labour (ARM). See also <b>prelabour rupture of membranes</b> .
<b>Sample</b>	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.
<b>Scottish Intercollegiate Guidelines Network (SIGN)</b>	SIGN was established in 1993 to sponsor and support the development of evidence-based clinical guidelines for the NHS in Scotland.
<b>Selection criteria</b>	Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.
<b>Small for gestational age (SGA)</b>	When the weight of the fetus or baby is lower than expected for gestation, below the 10th or 3rd percentile for gestational age (see <b>fetal growth restriction</b> ).
<b>Standard deviation</b>	A measure of the spread, scatter or variability of a set of measurements. Usually used with the mean (average) to describe numerical data.
<b>Statistical power</b>	The ability of a study to demonstrate an association or causal relationship between two <b>variables</b> , given that an association exists. For example, 80% power in a clinical trial means that the study has an 80% chance of ending up with a <i>P</i> 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 <b>P value</b> .
<b>Suppository</b>	A medicated substance usually in a tapered shape that can be introduced into the rectum or vagina. It is solid at room temperature but melts at body temperature, releasing the medication.
<b>Survey</b>	A study in which information is systematically collected from people (usually from a sample within a defined population).
<b>Systematic</b>	Methodical, according to plan; not random.
<b>Systematic review</b>	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 <b>meta-analysis</b> .
<b>Term</b>	Gestational age when a baby is normally due. Defined as being between 37 and 42 weeks of gestation.

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<b>Tocolysis</b>	The use of short-acting uterine relaxants such as terbutaline, in the management of uterine hyperstimulation.
<b>Ultrasound</b>	The use of ultrasonic waves to image the fetus in the womb.
<b>Unfavourable cervix</b>	An unfavourable (unripe) cervix is suggestive that spontaneous onset of labour is unlikely. The cervix is long and firm in consistency. It must be made softer and shorter (priming) to allow labour to begin. The degree of cervical ripeness is assessed using the <b>Bishop score</b> .
<b>Uterine hyperstimulation</b>	Overactivity of the uterus as a result of induction of labour. It is variously defined as uterine tachysystole (more than five contractions per 10 minutes for at least 20 minutes) and uterine hypersystole/hypertonicity (a contraction lasting at least 2 minutes). These may or not be associated with changes in the fetal heart rate pattern (persistent decelerations, tachycardia or decreased short term variability).
<b>Uterine hypertonicity</b>	See <b>uterine hyperstimulation</b> .
<b>Validity</b>	Assessment of how well a tool or instrument measures what it is intended to measure.
<b>Variable</b>	A measurement that can vary within a study, for example 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 which can be assessed or measured.

# 1 Introduction

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## 1.1 Introduction

This guideline is a review of an inherited guideline<sup>1</sup> that was published in 2001 (*NICE Inherited Guideline D*) and in need of updating because some of its content has been superseded by changes in both the evidence base and clinical practice.

The clinical requirement for induction of labour arises from circumstances in which it is believed that the outcome of the pregnancy will be better if it is artificially interrupted rather than being left to follow its natural course. Induction of labour is perhaps unique in medicine because it seeks to advance a process which in the natural course of events is inevitable unless the pregnancy is terminated by caesarean section or the mother dies before giving birth.

Induced labour has an impact on the birth experience of women. It may be less efficient and is generally more painful than spontaneous labour. It is also more likely to require epidural analgesia and assisted birth. Induction of labour is a relatively common procedure. In 2004–05, 19.8% of all deliveries in the UK were induced. This includes induction for all medical reasons. Where labour was induced by drugs, whether or not surgical induction was also attempted, fewer than two-thirds of women gave birth without further intervention, with about 15% having instrumental births and 22% having emergency caesarean sections.<sup>2</sup>

Induction of labour can place more strain on labour wards than spontaneous labour. Traditionally, induction is undertaken during daytime when labour wards are often already busy. The policy of induction, including indications, methods and care to be offered, thus needs to be reviewed.

Historically, and for various reasons, ways to bring forward the process of birth have always been sought. Not all ways have been successful. As understanding of the process of birth has advanced, techniques have been introduced that replicate the natural process and are more likely to achieve successful results.

The continuation of a woman's pregnancy requires that her cervix remains closed and rigid and that her uterus quiet and not contracting. Both these conditions need to be reversed to initiate labour. The ways in which this is achieved are unknown but there is evidence that suggests the fetus itself plays an integral part. A woman's cervix, which contains little smooth muscle and is predominantly connective tissue with collagen as its main component, must undergo a process called ripening, where it becomes soft and pliable. This allows its shape to change from being long and closed to being thinned (effaced) and opening (dilating). In parallel with this, the uterus, which is predominantly smooth muscle cells, must begin to respond to the stimuli which cause these cells to contract in the waves that characterise labour.

In recent years it has been recognised that both these components of labour (cervical and uterine changes) involve prostaglandins, inflammatory mediators and other agents. Most methods of induction seek to exploit these components in order to initiate labour.

A review of the range of methods that have historically been applied to induction of labour reveals that they can be classified into four categories:

- techniques that have been proven to be ineffective through clinical trials
- techniques for which there are no clinical trials of efficacy
- successful techniques that provoke the release of a woman's naturally occurring prostaglandin and oxytocin
- successful techniques that introduce pharmacological prostaglandin and oxytocin into a woman's body.

Because the transition from maintenance of a woman's pregnancy to the onset of her labour is a gradual one occurring over several weeks, it is important to recognise that the further that process

has already progressed, the easier and more successful it will be to induce her labour. How close a woman is to the onset of labour (and the prospects for successful induction of labour) is most easily judged by assessing the progress of cervical ripening. This offers the best prognostic index of successful induction of labour. The introduction by Bishop of his scoring system to measure the degree of cervical ripeness more than 40 years ago represented a major advance in this clinical area (see Appendix B). To put it in its most simple terms, if the Bishop score is high, reflecting a high degree of cervical ripeness, induction of labour usually can be achieved with very simple types of intervention. If, on the other hand, the Bishop score is very low (regardless of the gestational age of the pregnancy), it is much more difficult to bring about the conditions in which labour will begin and consequently those efforts are much more likely to fail.

### **Indications**

Although a variety of specific clinical circumstances may indicate the need for induction of labour with a greater or lesser degree of urgency, the essential judgment that the clinician and the pregnant woman must make is whether the interests of the mother or the baby, or both, will be better served by ending or continuing the pregnancy. In making that judgment, it is necessary to factor in the attitude and wishes of the woman in response to her understanding of the actual risk of continuing the pregnancy, as well as the possible consequences of the method employed and the response to induction of labour. If the prospects for success are not good, especially if the woman's cervix is unripe, or if the response to early attempts to start labour are disappointing, it may be necessary to reconsider the wisdom of proceeding and perhaps to resort to birth by caesarean section. Indeed, in some circumstances, the attempt to induce labour may be regarded as not justified at all. Induction of labour has a major health impact on the woman and on her baby. The decision to undertake induction of labour needs to be clear and clinically justified.

### **Assessment**

For induction of labour to be considered and to be offered, there must be evidence that such an intervention carries benefits for the mother and/or her baby and this requires careful consideration of the clinical evidence in discussion with the woman. The interests of the mother may occasionally run counter to those of the baby and vice versa, so that consideration of the offer of induction of labour requires a careful weighing up of the evidence and sensitive discussion of the issues with the mother. In all cases, there is a clear need for the provision of information to allow women being considered for induction of labour to make a fully informed choice.

It is also imperative that the most accurate information is obtained concerning the gestational age of the pregnancy. In most instances, there will be reliable menstrual data supported by evidence from an ultrasound examination made in the early weeks of pregnancy and, indeed, nowadays the information from the latter source will take precedence from the clinician's perspective even though many women are clear about their own due dates. Where evidence from these sources is lacking and the gestational age is in doubt, extra care should be taken in assessing the balance of risks.

The state of the woman's cervix should be assessed on the basis of a vaginal examination using the Bishop score or a modification of this (Appendix B).

If, after discussion of the relevant issues, the woman chooses to decline the offer of induction of labour, she must not be made to feel alienated from her healthcare professionals and further discussion is required regarding the measures needed for ongoing monitoring of the pregnancy. It is also important to inform the woman that induction of labour is not always successful and she should be given information as to the likely management should the intervention prove unsuccessful.

The purpose of this guideline is to review all aspects of the methodology of induction of labour and the appropriateness of different approaches in the various clinical circumstances that may call for such an intervention.

## 1.2 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'.<sup>3</sup> The guideline has been developed with the aim of providing guidance on the:

- clinical indications for induction of labour
- appropriate place and timing of induction of labour
- care that should be offered to women during the induction process, including when to consider fetal and maternal monitoring, analgesia and emotional support; this includes providing information for pregnant women (and their partners/families)
- effectiveness of methods used for cervical priming; this includes intracervical and intravaginal prostaglandins
- effectiveness of methods used for induction of labour; this includes membrane sweeping, drugs (such as prostaglandins and oxytocin) and amniotomy; the guideline considers all relevant methods and routes of administration
- management offered if the cervix is unfavourable
- management of complications of induction, such as failed induction.

The groups that are covered in this guideline are women undergoing induction of labour in the following circumstances:

- prolonged pregnancy
- preterm prelabour rupture of membranes
- prelabour rupture of membranes
- presence of fetal growth restriction
- previous caesarean section
- history of precipitate labour
- maternal request
- breech presentation
- intrauterine fetal death
- suspected macrosomia.

Where relevant evidence exists, the guideline addresses induction of labour in women with favourable or unfavourable cervix separately.

## 1.3 Areas outside of the remit of the guideline

The following groups that are not covered in this guideline:

- women with diabetes
- women with multifetal pregnancy
- women undergoing augmentation (rather than induction) of labour.

## 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:

- professional groups who are involved in the care of women considering and undergoing induction of labour, such as antenatal educators, obstetricians and gynaecologists, neonatologists, midwives, general practitioners, anaesthetists, birth supporters and maternity care assistants
- those responsible for commissioning and planning healthcare services, including primary care trust commissioners, Health Commission Wales commissioners and public health and trust managers
- pregnant women seeking advice on induction of labour.

A version of this guideline for pregnant women, their families and the public is available from the National Institute for Health and Clinical Excellence (NICE) website ([www.nice.org.uk/CG070publicinfoenglish](http://www.nice.org.uk/CG070publicinfoenglish)) or from NICE publications on 0845 003 7783 (quote reference number N1626).

## 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:

- two obstetricians/gynaecologists
- two specialists in fetal and maternal medicine
- one neonatologist
- three midwives
- three women's representatives
- one external adviser.

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

All GDG members' interests were recorded on a declaration form provided by NICE and are listed in Appendix A. 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 other existing and proposed works of relevance, including related NICE clinical guidelines on:

- caesarean section
- antenatal care
- antenatal and postnatal mental health
- intrapartum care
- diabetes in pregnancy.

## 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.<sup>4</sup>

### 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 that 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), PsycINFO (1967 onwards), Cochrane Central Register of Controlled Trials (1st quarter 2007), Cochrane Database of Systematic Reviews (1st quarter 2007), and Database of Abstracts of Reviews of Effects (1st quarter 2007).

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 re-run, thereby including evidence published and included in the databases up to 9 October 2007. 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.

The search strategies, including the methodological filters employed, have been included on the CD-ROM that accompanies this guideline.

### Synthesis of clinical effectiveness evidence

Evidence relating to clinical effectiveness was reviewed using established guides<sup>4-10</sup> and classified using the established hierarchical system shown in Table 1.1.<sup>10</sup> This system reflects the susceptibility to bias that is inherent in particular study designs.

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 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 economic evaluations, no standard system of grading the quality of evidence exists. Economic evaluations that are included in the review have been assessed using a quality assessment checklist based on good practice in decision-analytic modelling.<sup>11</sup>

Evidence was synthesised qualitatively by summarising the content of identified papers in a narrative manner with brief statements accurately reflecting the evidence and by producing evidence tables. 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

**Table 1.1** Levels of evidence for intervention studies<sup>10</sup>

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

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) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs.

### **Health economics**

The aim of the economic input into the guideline was to inform the GDG of potential economic issues relating to induction of labour. 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 and are incorporated within the relevant evidence statement and recommendations. For some questions, no published evidence was identified, and decision-analytic modelling was undertaken.

Economic evaluations in this guideline have been conducted in the form of a cost-effectiveness analysis, with the health effects measured in an appropriate non-monetary outcome indicator. The NICE technology appraisal programme measures outcomes in terms of quality-adjusted life years (QALYs). Where possible, this approach has been used in the development of this guideline. However, where it has not been possible to estimate QALYs gained as a result of an intervention, an alternative measure of effectiveness has been used.

Cost-effectiveness analysis, with the units of effectiveness expressed in QALYs (known as cost-quality of life analysis) is widely recognised as a useful approach for measuring and comparing the efficiency of different health interventions. The QALY is a measure of health outcome which assigns to each period of time (generally 1 year) a weight, ranging from 0 to 1, corresponding to health-related quality of life during that period. It is one of the most commonly used outcome measures in health economics. A score of 1 corresponds to full health and a score of 0 corresponds to a health state equivalent to death. Negative valuations, implying a health state worse than death, are possible. Health outcomes using this method are measured by the number of years of life in a given health state multiplied by the value of being in that health state.

The key economic question addressed in this guideline is ‘what is the cost-effective date during pregnancy to first offer the woman the choice of induction of labour?’. The model compares different strategies for offering pharmaceutical induction based on the number of completed weeks and days of pregnancy. Details of this modelling are presented in Appendix D.

### **Interpretation of the evidence and formulation of recommendations**

The evidence tables and narrative summaries for the clinical questions being reviewed were made available to the GDG members for their perusal 1 week before the scheduled GDG meeting. For each clinical question, recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree clinical and cost-effectiveness evidence statements. Statements summarising the GDG’s interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared. The process by which the evidence statements informed the recommendations is summarised in the ‘Interpretation of evidence’ section. In areas where no substantial research evidence was identified, the GDG considered other evidence-based guidelines and consensus statements or used their collective clinical experience to form recommendations, based on current best practice. Where evidence was limited or lacking to answer particular clinical questions, the GDG formulated recommendations for future research.

Shortly before the consultation period, formal consensus methods were used to agree on guideline recommendations, using a modified Delphi method, and to select five key recommendations considered as priorities for implementation, using a nominal group technique.



### External review

This guideline has been developed in accordance with the NICE guideline development process. This has included giving registered stakeholder organisations the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage. The developers have carefully considered and responded to all of the comments during these two stages. The GDG's responses to the stakeholders' comments were reviewed independently by the Guideline Review Panel convened by NICE.

### Outcome measures used in the guideline

For this guideline, the management and care of women undergoing induction of labour has been assessed against a variety of obstetric and birth outcomes. The justification for using these outcomes is based on their relevance to women and consensus among the GDG members, reflecting the measures of both success and failure of induction. These outcomes are also informed by the Cochrane Pregnancy and Childbirth Group. In assessing the effectiveness of a particular intervention, information about the effect of that intervention on one or more primary outcomes was sought. Where such information was not available, secondary outcomes were used.

Primary outcomes considered in this guideline included:

- vaginal birth not achieved within 24 hours
- uterine hyperstimulation with fetal heart rate (FHR) changes
- operative delivery rates: caesarean birth
- serious neonatal morbidity or perinatal death (seizures, birth asphyxia defined by triallists, neonatal encephalopathy, disability in childhood)
- serious maternal morbidity or death (uterine rupture, admission to intensive care unit, septicaemia).

Secondary outcomes included:

- cervix unfavourable/unchanged after 12–24 hours
- oxytocin augmentation
- uterine hyperstimulation without FHR changes
- epidural analgesia
- instrumental vaginal birth
- genital trauma
- failed induction
- meconium-stained liquor
- 5 minute Apgar score < 7
- neonatal intensive care unit admission
- all maternal adverse effects
- nausea, vomiting, diarrhoea, pyrexia (maternal)
- postpartum haemorrhage (as defined by triallists)
- measures of maternal satisfaction
- measures of caregiversatisfaction
- cost-effectiveness.

## 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

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### 2.1 Key priorities for implementation (key recommendations)

This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.

### 2.2 Summary of recommendations

This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.

### 2.3 Key priorities for research

#### **Prolonged pregnancy (Section 4.1)**

Research is needed to identify babies at particularly high risk of morbidity and mortality who will benefit from induction and therefore avoid induction for babies who do not need it.

#### *Research question*

Pregnancies that continue after term run a higher risk of fetal compromise and stillbirth; can ways be found to identify pregnancies within that population that are at particular risk of these complications?

#### *Why is this important?*

Although the risks of fetal compromise and stillbirth rise steeply after 42 weeks, this rise is from a low baseline. Consequently, only a comparatively small proportion of that population is at particular risk. Because there is no way to precisely identify those pregnancies, delivery currently has to be recommended to all such women. If there were better methods of predicting complications in an individual pregnancy, induction of labour could be more precisely directed towards those at particular risk.

#### **Preterm prelabour rupture of membranes (Section 4.2)**

A large study is needed to compare immediate induction of labour with expectant management beyond 34 weeks, taking into account duration of preterm prelabour rupture of membranes, gestational age, and maternal steroid and antibiotic treatment.

#### *Research question*

What are the relative risks and benefits of delivery versus expectant management in women whose membranes have ruptured spontaneously between 34 and 37 weeks?

#### *Why is this important?*

Intrauterine sepsis is more likely to develop in pregnancies that continue after the membranes

have ruptured, putting both the woman and the baby at risk. In some such pregnancies, labour begins spontaneously at a variable interval after the membranes have ruptured, avoiding the need for induction. The value of antibiotic therapy and the administration of corticosteroids to the woman is unclear in this situation. A randomised study of active versus expectant management, taking account of time since membrane rupture, gestational age and maternal therapy, would be valuable.

### **Setting for induction of labour (Section 6.1)**

Studies are needed to assess the safety, efficacy and clinical and cost-effectiveness of outpatient and inpatient induction in the UK setting, taking into account women's views.

#### *Research question*

Is it safe, effective and cost-effective to carry out induction of labour in an outpatient setting? What are the advantages and disadvantages of such an approach, taking into account women's views?

#### *Why is this important?*

In line with the way healthcare has developed in many areas of acute care, there is an increasing desire to reduce the time women spend in hospital. Several units are already exploring outpatient induction of labour policies and there is a need to study this approach in order to determine relative risks and benefits, as well as acceptability to women.

### **Membrane sweeping (Section 5.2.1)**

Research is needed to assess effectiveness, maternal satisfaction and acceptability of:

- multiple versus once-only membrane sweeping, at varying gestational ages, stratifying for parity
- cervical massage when membrane sweeping is not possible, in women with unfavourable cervix.

#### *Research question*

What are the effectiveness and acceptability of, and maternal satisfaction with, the following:

- multiple versus once-only membrane sweeping, at varying gestational ages, depending on parity
- membrane sweeping versus cervical massage?

#### *Why is this important?*

Membrane sweeping is considered to be a relatively simple intervention that may positively influence the transition from maintenance of pregnancy to the onset of labour, reducing the need for formal induction of labour. However, there are disadvantages, such as possible vaginal bleeding and discomfort. Research into when and how frequently membrane sweeping should be carried out to maximise its effectiveness and acceptability would be of value.

### **Vaginal PGE<sub>2</sub> (Section 5.1.1)**

Research is needed to assess the effectiveness, safety, maternal satisfaction and acceptability of different regimens of vaginal PGE<sub>2</sub>, stratified by clinical indications, cervical and membrane status, parity and previous caesarean section.

#### *Research question*

What are the effectiveness, safety and maternal acceptability of:

- different regimens of vaginal PGE<sub>2</sub>, stratified by: clinical indications; cervical and membrane status; parity; and previous caesarean section
- different management policies for failed induction of labour with vaginal PGE<sub>2</sub> (additional PGE<sub>2</sub>, oxytocin, elective caesarean or delay of induction, if appropriate)?

### *Why is this important?*

Despite extensive studies carried out over the past 30 years to determine the most effective ways of inducing labour with vaginal PGE<sub>2</sub>, uncertainties remain about how best to apply these agents in terms of their dosage and timing. It would be particularly useful to understand more clearly why vaginal PGE<sub>2</sub> fails to induce labour in some women.

## 2.4 Summary of research recommendations

### **Information and decision making (Section 3.1)**

Studies are needed to compare women's views and experiences on the different methods of induction of labour with those during spontaneous labour.

Studies are needed to assess the needs of pregnant women throughout the induction of labour experience to identify the support they require and prefer.

### **Induction of labour in specific circumstances (Chapter 4)**

#### *Prolonged pregnancy (Section 4.1)*

Studies should be undertaken to compare effectiveness, safety, maternal satisfaction and compliance of different expectant management protocols.

Research is needed to identify babies at particularly high risk of morbidity and mortality who will benefit from induction and therefore avoid induction for babies who do not need it.

Research is needed into racial differences in the UK to identify the possible differences in the distribution of perinatal risk specific to gestational weeks and possible benefits of intervention before 41 weeks.

#### *Preterm prelabour rupture of membranes (Section 4.2)*

A large study is needed to compare immediate induction of labour with expectant management beyond 34 weeks, taking into account duration of preterm prelabour rupture of membranes, gestational age, and maternal steroid and antibiotic treatment.

Research is needed to compare effectiveness, cost-effectiveness, safety and maternal satisfaction of different management policies for induction of labour.

#### *Previous caesarean section (Section 4.4)*

Studies should compare the effectiveness, cost-effectiveness, safety and maternal satisfaction of induction of labour by different methods, repeat elective lower segment caesarean section and expectant management in women with previous caesarean section.

#### *Maternal request for induction of labour (Section 4.5)*

Audit research is needed to assess the prevalence of maternal request for induction of labour and the reasons for such request.

#### *History of precipitate labour (Section 4.8)*

Studies are needed to quantify the risks for women with history of precipitate labour, and to compare effectiveness, safety and maternal satisfaction of different management policies.

### **Methods of induction of labour (Chapter 5)**

#### *Pharmacological-based methods – vaginal PGE<sub>2</sub> (Section 5.1.1)*

Research is needed to assess the effectiveness, safety, maternal satisfaction and acceptability of different regimens of PGE<sub>2</sub>, stratified by clinical indications, cervical and membrane status, parity and previous caesarean section.

### *Non-pharmacological methods – membrane sweeping (Section 5.2.1)*

Research is needed to assess effectiveness, maternal satisfaction and acceptability of:

- multiple versus once-only membrane sweeping, at varying gestational ages, stratifying for parity
- cervical massage when membrane sweeping is not possible, in women with unfavourable cervix.

### *Non-pharmacological methods – herbal supplements (Section 5.2.2)*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of the use of herbal supplements as a method of induction of labour.

### *Non-pharmacological methods – acupuncture (Section 5.2.3)*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of acupuncture as a method of induction of labour.

### *Non-pharmacological methods – homeopathy (Section 5.2.4)*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of homeopathy as a method of induction of labour.

### *Non-pharmacological methods – castor oil, hot bath and enemas (Section 5.2.5)*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of the use of castor oil, hot baths and enemas as methods of induction of labour.

### *Non-pharmacological methods – sexual intercourse (Section 5.2.6)*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of sexual intercourse as a method of induction of labour.

### *Non-pharmacological methods – breast stimulation (Section 5.2.7)*

Further research is required to evaluate the effectiveness, timing, methods, frequency, safety and maternal satisfaction of breast stimulation as a method of induction of labour.

### *Mechanical methods (Section 5.3.2)*

Future trials on the use of mechanical methods should include women in whom prostaglandins during labour would pose increased risks, such as women with previous caesarean birth. These trials should clearly stratify groups by parity, cervical status and previous vaginal birth.

## **Setting for induction of labour (Section 6.1)**

Studies are needed to assess the safety, efficacy and clinical and cost-effectiveness of outpatient and inpatient induction in the UK setting, taking into account women's views.

## **Monitoring of induction of labour (Section 7.1)**

Studies are needed to identify the most effective way of monitoring women during the induction of labour process.

## **Pain relief for induction of labour (Section 7.2)**

Research is needed to evaluate the effects of regional analgesia on progress and outcome of induced labour, stratified for differing cervical status.

Studies are needed to assess the role support plays in alleviation of pain during induction of labour.

## **Prevention and management of complications of induction of labour (Chapter 8)**

### *Failed induction (Section 8.2)*

Research is needed to establish frequency and interval of vaginal PGE<sub>2</sub> to achieve successful induction of labour.

Research is needed to examine different management policies for failed vaginal PGE<sub>2</sub> induction (additional PGE<sub>2</sub>, amniotomy, oxytocin, elective caesarean section or delay of induction if appropriate).

## 2.5 Care pathway

**This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

# 3 Information and decision making

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## 3.1 Information and decision making

### *Clinical questions*

- What are women's views and experiences of induction of labour?
- How should information be given to women and their partners concerning induction of labour?
- What information should be given?

Women who experience spontaneous labour and those who need to be considered for induction represent different populations, the latter having usually been identified as having additional risk factors. Caution should therefore be exercised in making comparisons in terms of outcomes. Nevertheless, compared with spontaneous labour, induction of labour is associated with a higher incidence of additional technological interventions, such as electronic fetal monitoring, analgesia usage and assisted instrumental birth.

It has long since been recognised by the maternity services that women and their partners require information upon which to make choices and decisions regarding their care<sup>12</sup> and induction of labour is no exception. Without such information, clinical care risks becoming compromised and women are not in control. Once in receipt of accurate information, in a comprehensive format, women are able to make decisions relevant to their individual circumstances. This information will be of vital importance as women build their birth plans.

### **Overview of available evidence**

Four UK surveys, three published before 1990, exploring women's view on issues relating to induction of labour were identified. No evidence was identified which assessed the best methods of information giving or emotional support specifically related to the induction of labour process. Reference is made to the NICE clinical guidelines on antenatal care<sup>37</sup> and intrapartum care<sup>17</sup> as supplementary evidence.

### *Women's views and experiences of induced labour*

A UK survey in 1977 ( $n = 137$ ) assessed women's experiences of planned induction of labour (amniotomy with oxytocin or oxytocin with delayed amniotomy) 24 hours before and 12 hours after birth. Twenty percent of women had not heard of induction before their pregnancy. 32% considered they had not been given enough information about the reasons for their induction and 46% felt they were not given enough information about the method of their induction. The majority of women had no firm opinions on induction of labour or the electronic equipment used but were glad to have their pregnancy ended (66%). Only six percent accepted that induction was for the baby's benefit. Although 45% of women considered that labour was more painful than expected, 80% found analgesia was adequate in labour. Those who did not receive adequate analgesia were likely to be women who had either short or long labours.<sup>13</sup> [EL = 3]

Another survey in the UK in 1977 assessed women's experiences of pregnancy, labour and birth. Of the sub-sample of women who underwent induction of labour ( $n = 524$ ), two-fifths reported that they would like more information about induction; a similar proportion said they had not discussed induction with a doctor, midwife, or nurse during their pregnancy. Only 17% of women would prefer to be induced again. However, 63% of those who had epidural analgesia would opt for the same procedure next time.<sup>14</sup> [EL = 3]

A UK questionnaire survey in 1987 of women who had recently given birth ( $n = 1920$ ) assessed women's preferences for and satisfaction with procedures in childbirth. About 83% of women

preferred not to have induction by drugs and hoped that it would not be necessary, the figure for amniotomy was 72%. A preference for being able to move around freely during the first stage of labour was expressed by 72% of women. About 45% of women who were monitored during labour were pleased with the monitoring. Overall, a high proportion of women, regardless of their reported preferences and the actual course of events, described their labour experiences as being satisfactory.<sup>15</sup> [EL = 3]

Another questionnaire survey in 2005 in Scotland evaluated the understanding and expectations of women undergoing induction of labour at term ( $n = 314$ ), to assess their actual experience of the process and to compare their satisfaction with labour to those labouring spontaneously ( $n = 385$ ). In the induction group, 35% were satisfied with the information they received about the induction prior to the procedure and 27% expected to give birth within 12 hours of administration of the inducing agent. With hindsight, 40% of women felt that speed of the induction to be the most important aspect, if they were to have induction again. Some women preferred to have oral induction agents (14%) and fewer vaginal examinations (7%). Caesarean birth rates were 26% and 21% in the induction and spontaneous labour groups, respectively. Women with spontaneous labour were significantly more likely to be satisfied with their labour than the induction group (80% versus 70%, RR 0.89, 95% CI 0.8 to 0.96).<sup>16</sup> [EL = 2+]

The NICE guidelines on antenatal care<sup>37</sup> and intrapartum care<sup>17</sup> provide guidance on information giving and support to women throughout pregnancy.

### Evidence statements

Evidence from four UK surveys suggested that up to 40% of women felt they were not given adequate information relating to issues about induction of labour, and induction by drug was disliked by 80% of women; overall maternal satisfaction was low. [EL = 2+ to 3]

### Interpretation of evidence

There is a dearth of good up-to-date evidence relating to information giving and emotional support to women and their families/partners during the induction of labour process.

The limited available evidence suggests that women feel less satisfaction with the experience of induced labour than women who go into spontaneous labour. Some women who have undergone formal induction of labour feel that they were not given sufficient information before being induced. In the light of the limited evidence base, the GDG placed a high value on the need for information provision for women and considered that women should receive information concerning induction of labour that includes the reasons, methods and options.

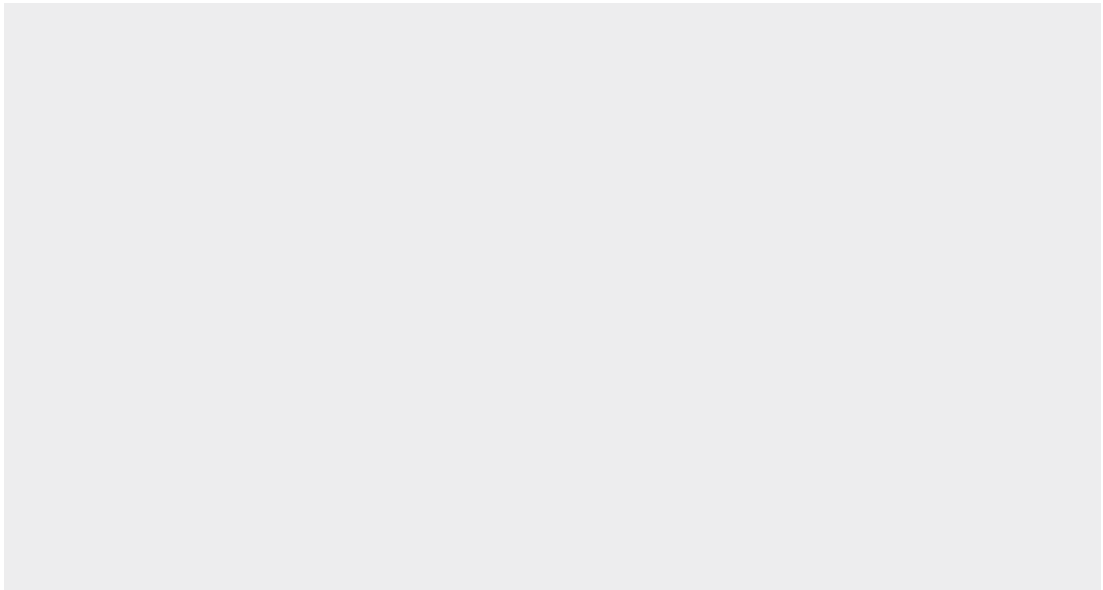
The GDG agrees with and supports the recommendations made in the NICE guidelines on antenatal care<sup>37</sup> and intrapartum care<sup>17</sup> relating to information giving and support for women and their families/partners throughout pregnancy.

The GDG agrees with and supports the generic principles of women-centred care relating to accessible and culturally sensitive information giving, informed decision making and informed consent as discussed in the shorter NICE version of this guideline.

### Recommendations on information and decision making

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**





**Research recommendations on information and decision making**

Studies are needed to compare women's views and experiences on the different methods of induction of labour with those during spontaneous labour.

Studies are needed to assess the needs of pregnant women throughout the induction of labour experience to identify the support they require and prefer.

# 4 Induction of labour in specific circumstances

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## 4.1 Prolonged pregnancy

### *Clinical questions*

- What are the risks of prolonged pregnancy?
- What are the harms and benefits of induction of labour for the prevention of prolonged pregnancy?

In this guideline, prolonged pregnancy is defined as a pregnancy that continues beyond 42 weeks, the gestational age having been established by an ultrasound scan in the first trimester (or no later than 16 weeks of gestation) (Refer to the NICE antenatal care clinical guideline<sup>37</sup>). By this definition, prolonged pregnancy occurs in between 5% and 10% of all women.<sup>18</sup>

### **Overview of available evidence**

Ten recent epidemiological studies were identified that examined the associated risks when a pregnancy goes beyond 40 weeks of gestation. One systematic review and an additional RCT assessed the relative effectiveness of induction of labour and expectant management. One study examined women's attitudes to the conservative management of prolonged pregnancy. One population study was identified that examined the racial variation in perinatal mortality associated with prolonged pregnancy. Reference is made to the NICE clinical guideline on antenatal care<sup>37</sup> as supplementary evidence.

### *Risks of prolonged pregnancy: epidemiological studies*

There is strong epidemiological evidence pointing to an increased risk for mother and baby as a pregnancy continues beyond 40 weeks (Tables 4.1 and 4.2).<sup>19–29</sup> [EL = 3] Data from these studies included both induced labours and spontaneous labours. The overall risks of perinatal death associated with prolonged pregnancy remain small (2–3/1000).

### *Racial variation in perinatal mortality associated with post-term birth*

A UK prospective study of maternity records from 1988 to 2000 ( $n = 197\,061$ ; 81% white women, 13% south Asian women and 6% black women) examined the relationship between perinatal mortality and gestation weeks in women who gave birth to a singleton weighing at least 500 g at 24–43 weeks of gestation. Logistic regression analyses showed that the three racial groups differed significantly in their gestation-specific perinatal mortality from term onwards. Perinatal mortality among black women was lower than white women before 32 weeks of gestation but higher thereafter. Among the three groups, perinatal mortality was highest in south Asian women at all gestational ages and increased more rapidly from term onwards. After adjusting for confounders (placental abruption, congenital abnormality, low birthweight, birthweight < 10th centile, meconium passage, fever, maternal body mass index  $\geq 30$  kg/m<sup>2</sup> and maternal age  $\geq 30$  years), south Asian women still had a significantly higher risk of antepartum stillbirth (OR 1.8, 95% CI 1.2 to 2.7) from 37 weeks onwards. This study suggests that the proposed policy of induction to prevent prolonged pregnancy at 41–42 weeks of gestation may not be appropriate for all women.<sup>30</sup> [EL = 2+]

### *Induction of labour versus expectant management*

One systematic review (19 RCTs, 7984 women) assessed the effectiveness and safety of induction of labour in reducing the risks associated with pregnancy at and beyond term. This review reported that a policy of induction of labour at 41 completed weeks (41<sup>+0</sup>) or beyond was associated with

**Table 4.1** Outcomes of pregnancy beyond 39 weeks of gestation: maternal complications per 1000 births

Study	Gestational age (weeks)					Denominator
	39	40	41	42	43 44 45	
<i>Caesarean section</i>						
Norway <sup>a,28</sup>	41	44	19	128	–	27 514 births
USA <sup>b,29</sup>	92	104	141	181	–	32 828 births
Israel <sup>c,24</sup>	61	54	58	79	82	36 160 births
USA <sup>d,19</sup>	–	126	190	270	–	56 317 births
Denmark <sup>e,27</sup>	37–41 weeks: 82		42–45 weeks: 128 34 140			births (GA 37–41 weeks); 77 956 births (GA 42–45 weeks)
<i>Instrumental vaginal birth</i>						
Norway <sup>a,28</sup>	70	92	128	152	–	27 514 births
USA <sup>b,29</sup>	148	164	174	202	–	32 828 births
Israel <sup>c,24</sup>	61	54	58	79	82	36 160 births
USA <sup>e,19</sup>	60	80	90	–	–	56 317 births
<i>Haem &gt; 500 ml</i>						
Norway <sup>a,28</sup>	57	69	86	117	–	27 514 births
USA <sup>b,29</sup>	18	15	23	22	–	32 828 births
Denmark <sup>e,27</sup>	37–41 weeks: 36		42–45 weeks: 49			34 140 births (GA 37–41 weeks); 77 956 births (GA 42–45 weeks)

GA = gestational age.

<sup>a</sup> Induced labours included: 9%.

<sup>b</sup> Induced labours included: 12%.

<sup>c</sup> Unclear whether study included induced labours.

<sup>d</sup> Induced labours included, number not reported.

<sup>e</sup> Induced labours excluded.

fewer (all-cause) perinatal deaths when compared with expectant management (1/2986 versus 9/2953; RR 0.30, 95% CI 0.09 to 0.99). Excluding death due to congenital abnormality ( $n = 3$ , one in the induction group and two in the expectant management group), there were no deaths in the induction group versus seven deaths in the no induction group. The causes for the perinatal deaths in the expectant management groups were meconium aspiration (four), intrauterine death at 292 days of gestation (one), stillbirth with abnormal maternal glucose tolerance test (one) and neonatal pneumonia (one). In the group induced at 41 completed weeks of gestation, the number of perinatal deaths in the group was 0/2835 compared with 6/2808 in the expectant management group (RR 0.25, 95% CI 0.05 to 1.18; ten RCTs). This implies that 469 women would have to be induced to prevent one perinatal death (95% CI 215 to 1279). In the group induced at 42 completed weeks of gestation there was only one perinatal death (excluding congenital abnormality) in the expectant management group (0/151 versus 1/145, RR 0.32, 95% CI 0.01 to 7.80; two RCTs).<sup>31</sup> [EL = 1++]

There was no significant difference in the incidence of caesarean section for women induced at 41 completed weeks (559/2883 induced versus 630/2872 expectant management, RR 0.92, 95% CI 0.76 to 1.12) or at 42 completed weeks (110/407 versus 111/403, RR 0.97, 95% CI 0.72 to 1.31). There were fewer babies with meconium aspiration syndrome reported among those induced at 41 completed weeks (RR 0.29, 95% CI 0.12 to 0.68; four RCTs) and at 42 completed weeks (RR 0.66, 95% CI 0.24 to 1.81; two RCTs). In most of the trials included in this review, there was up to 30% protocol violation, for example, women who were assigned to the induction of labour group but went into labour spontaneously. Seventeen of the 19 trials had unclear allocation concealment, two trials were abstracts, and sample size was small (fewer than 100) in two trials.<sup>31</sup> [EL = 1++]

This systematic review<sup>31</sup> included two RCTs<sup>32,33</sup> from developed countries published after 1990 comparing induction of labour with expectant management. The gestational age was verified by early ultrasound and there was sufficient information given on the types of fetal monitoring received by the women. The results were broadly consistent with the overall finding that adverse

## Induction of labour

**Table 4.2** Outcomes of pregnancy beyond 39 weeks of gestation: perinatal complications per 1000 births

Study	Gestational age (weeks)						Denominator
	39	40	41	42	43	44 45	
<i>5 minute Apgar score &lt; 7</i>							
Norway <sup>a,28</sup>	12	18	18	30			27 514 births
USA <sup>d,19</sup>	–	2	2	3	–	–	56 317 births
<i>Meconium aspiration</i>							
Norway <sup>a,28</sup>	18	29	51	47	–	–	27 514 births
<i>Meconium-stained liquor</i>							
Israel <sup>c,24</sup>	125	175	215	250	377	–	30 478 births
<i>Septicaemia/sepsis</i>							
Denmark <sup>e,27</sup>	37–41 weeks: 3.6			42–45 weeks: 5.2			34 140 births (GA 37–41 weeks); 77 956 births (GA 42–45 weeks)
USA <sup>d,19</sup>	–	1	1	3	–	–	56 317 births
<i>Admission to neonatal intensive care unit</i>							
USA <sup>d,19</sup>	–	4	5	6			56 317 births
<i>Antepartum stillbirth and stillborn/1000 ongoing pregnancies</i>							
Scotland <sup>d,26</sup>	0.4	0.6	0.7	1.0	3	–	700 878 ongoing pregnancies
UK <sup>d,21</sup>	0.5	0.9	1.3	1.6	2.1	–	171 527 births
USA <sup>c,20</sup>	2.5	2.0	2.1	2.3	2.7	–	367 597 live births
USA <sup>d,19</sup>	–	2	1	2	–	–	56 317 births
Denmark <sup>e,27</sup>	37–41 weeks: 1.8			42–45 weeks: 2.2			34 140 births (GA 37–41 weeks); 77 956 births (GA 42–45 weeks)
Norway <sup>a,28</sup>	4	5	8	15	–	–	27 514 births
<i>Intrapartum stillbirth/1000 live births</i>							
Scotland <sup>d,26</sup>	0.2	0.3	0.3	0.4	0	–	700 878 ongoing pregnancies
<i>Neonatal deaths</i>							
Scotland <sup>d,26</sup>	0.48	0.6	0.6	0.6	0.8	–	700 878 ongoing pregnancies
UK <sup>d,21</sup>	1.2	1.2	0.7	1.8	1.6	–	171 527 births
USA <sup>d,19</sup>	–	0.2	0.2	0.6	–	–	56 317 births
Denmark <sup>e,27</sup>	37–41 weeks: 0.9			42–45 weeks: 1.5			34 140 births (GA 37–41 weeks); 77 956 births (GA 42–45 weeks)
Ireland <sup>c,35</sup>	37–42 weeks: 0.7			> 42 weeks: 1.6			56 248 live births (GA 37–42 weeks); 6269 live births (GA > 42 weeks)
<i>Perinatal deaths</i>							
UK <sup>d,21</sup>	5.3	4.2	3.7	6.0	5.8		171 527 births
Ireland <sup>c,35</sup>	37–42 weeks: 4.5			> 42 weeks: 6.7			56 248 live births (GA 37–42 weeks); 6269 live births (GA > 42 weeks)

GA = gestational age.

<sup>a</sup> Induced labours included: 9%.

<sup>b</sup> Induced labours included: 12%.

<sup>c</sup> Unclear whether study included induced labours.

<sup>d</sup> Induced labours included, number not reported.

<sup>e</sup> Induced labours excluded.

perinatal outcome relating to morbidity and mortality was very low. Neither study was large enough to independently detect any possible differences in perinatal deaths as there were no deaths in 400 women randomised in the US study<sup>32</sup> and only two deaths in 3407 women in the Canadian study (both in the expectant management group).

The caesarean section rate was not significantly different in the two groups in the US study.<sup>32</sup> [EL = 1+] In the Canadian study,<sup>33</sup> there were significantly fewer caesarean births in the induction group than in the expectant management group (21.2% versus 24.5%,  $P = 0.03$ ) and this difference resulted from a higher rate of caesarean birth for fetal distress in the expectant management

group (5.7% versus 8.3%,  $P = 0.03$ ). Excluding congenital anomalies, there was no significant difference between the two groups in perinatal deaths (0/1701 versus 2/1706). The babies in the expectant management group were thought to be at higher risk than those in the induction group and as a consequence use of prostaglandins in the expectant group was considered to be contraindicated. The perception of high risk and oxytocin-only inductions may have been a source of bias in this unblinded study, leading to the higher caesarean section rate with expectant management. Seven women in this study whose infants had major congenital anomalies were excluded from the analysis of perinatal and neonatal outcomes.<sup>33</sup> [EL = 1+]

One additional RCT in Sweden was identified that compared the effects of induction of labour ( $n = 254$ ) with serial antenatal fetal monitoring ( $n = 254$ ) in women with uncomplicated pregnancies at 289 days of gestation (41<sup>+2</sup> weeks) and mixed parity. Women in the monitored group were assessed by cardiotocography and amniotic fluid index every third day until spontaneous birth occurred or labour was induced on day 300. This study reported no significant difference between the two groups in the following outcomes: caesarean births, operative vaginal births, severe perineal injury, haemorrhage above 500 ml, meconium-stained liquor, 5 minute Apgar score < 7, neonatal intensive care admission, intrauterine death (0 versus 0) and neonatal death (0 versus 1 due to asphyxia from true knot in umbilical cord).<sup>34</sup> [EL = 1+]

The increase in perinatal mortality with expectant management was also highlighted by a retrospective study of 62 804 births in Dublin between 1979 and 1986. Perinatal mortality rates were 6.7/1000 (42 deaths: 21 antepartum, 11 intrapartum and 10 early neonatal deaths) in births after 42 weeks of gestation compared with 4.5/1000 in term births at 37–42 weeks (257 deaths) (OR 1.57, 95% CI 1.08 to 2.30). Of the 21 deaths (11 intrapartum, 10 within first week of life), seven intrapartum deaths were related to asphyxia with meconium, and during the first week of life there were two deaths due to asphyxia with meconium, three due to meconium aspiration and three due to intracranial haemorrhage. The excess in mortality could not be explained by increased fetal weight and macrosomia because only one baby in this series of 42 deaths weighed over 4.5 kg.<sup>35</sup> [EL = 3]

#### *Acceptability of induction of labour to women*

Acceptability of induction of labour was evaluated in a UK questionnaire survey of 500 pregnant women at 37 weeks of gestation who were considered suitable for the potential conservative management of prolonged pregnancy. Initially, 45% of women thought that they would agree to expectant management, but this changed with advancing gestational age irrespective of parity and uncertainty in gestational age (45% at 37 weeks versus 31% at 41 weeks,  $P < 0.05$ ). The main reasons given included 'could not stand the thought of being pregnant for more than 42 weeks', 'no benefit in waiting', 'no risk involved in having labour induced', 'concern regarding fetal size' and 'no member of the family available after 42 weeks of gestation'.<sup>36</sup> [EL = 3]

The NICE antenatal care guideline<sup>37</sup> provides guidance relating to monitoring of women who decline induction beyond 42 weeks.

#### *Health economic evaluation*

A state-transition (Markov) model has been used to estimate the cost-effectiveness of four strategies for induction of labour. The strategies investigated were expectant management and induction to be offered for the first time at 41 weeks, 41<sup>+3</sup> weeks and at 42 weeks (for details of the four strategies, refer to Appendix D). A Markov model allows for the estimation of costs and benefits that accrue over time and was considered to be the most appropriate approach for answering this question. In this case, each model cycle is 1 day long. The cycle length and strategies considered in the model were selected based on the available evidence, the expert opinion of the GDG and current practice for the management of prolonged pregnancy.

When the analysis was done with the baseline parameter values used in the model, then first offering induction to all women at 41 weeks can be considered cost-effective if the willingness to pay per quality-adjusted life year (QALY) is £20 000, in line with previous recommendations from NICE. This strategy has an incremental cost-effectiveness ratio (ICER) of £8,571 (Table D.3). All three intervention strategies that were tested are more effective but more costly than not routinely offering induction, although all would be cost-effective when compared with expectant management used as a common comparator (Table D.4).

The parameters with the greatest degree of uncertainty in the model included the overall cost of an induction and the acceptance rate for the first offer of induction. These values were tested in a series of one-way sensitivity analyses. Under each of the alternative scenarios tested, the relative cost-effectiveness of the strategies remained unchanged (Tables D.5 to D.10).

The potential gain in health benefit of inducing pregnant women from 41 completed weeks of pregnancy onwards outweighs the additional cost. The average cost per birth and health benefit gained decrease with time as fewer inductions are performed and more women labour spontaneously. Waiting until later than 42 completed weeks of pregnancy to first offer induction is unlikely to be cost-effective. Given the small differences in outcomes of the induction strategies tested in the economic model and taking into consideration the local needs of maternity services, the GDG felt that it was not possible to recommend a particular strategy and this is reflected in the recommendation for induction to be first offered between 41 and 42 completed weeks of pregnancy.

Guidance on monitoring of pregnancy when women decline induction of labour from 42 weeks is provided in the NICE guideline on antenatal care.<sup>37</sup>

### Evidence statements

Epidemiological evidence supports the view that a pregnancy which goes beyond 40 weeks of gestation is associated with increased perinatal risks. [EL = 3]

The odds of increased perinatal mortality may be higher for south Asian women than for white or black women, and at term the odds increased fastest in south Asian women. [EL = 2+]

Compared with expectant management, induction of labour after 41 completed weeks is associated with fewer perinatal deaths (0/2986 versus 7/2953), excluding congenital abnormality. The absolute risk is extremely small. [EL = 1++] One large RCT included in the systematic review reported a lower caesarean section rate in the induction group when compared with expectant management. [EL = 1+]

Compared with serial antenatal monitoring, induction of labour at 41<sup>+2</sup> weeks of gestation results in comparable maternal and fetal outcomes. There was one neonatal death in the monitoring group due to a knot in the umbilical cord. [EL = 1+]

Births after 42 weeks of gestation are associated with an increased risk of intrapartum and neonatal deaths. [EL = 3]

One study reported that women are less likely to agree to expectant management at 41 weeks when compared with 37 weeks (31% versus 45%), although the majority would still want to await spontaneous labour. [EL = 3]

The differences in outcome between each of the three induction strategies for first offering induction of labour is small. However, it is clear that inducing labour does produce additional health gain and that this health gain can be achieved at less than £20,000 per QALY, the willingness to pay threshold considered by NICE to represent a cost-effective use of NHS resources.

### Interpretation of evidence

Epidemiological evidence suggests that, as pregnancy goes beyond 40 weeks of gestation, the risks for the baby begin to slowly increase. In addition, the risk for the mother of requiring interventions such as caesarean section also increases. These risks, however, are small and systematic review data indicate no evidence that induction of labour reduces them, although the studies were insufficiently powered to address this question. Nevertheless, there are palpable benefits of induction and these need to be balanced with risk and complications.

There is evidence from one UK cohort study that found increased perinatal mortality from term onwards in some ethnic groups such as black and south Asian women.

The GDG reached a consensus, supported by the epidemiological data, trial data and health economic analysis, that, on balance, induction of labour for prevention of prolonged pregnancy should be offered from 41<sup>+0</sup> weeks onwards.

Some women may be unwilling to await spontaneous labour when they go beyond 41 weeks, and others will be keen to avoid induction and will be happy to wait.

The GDG agrees and supports the recommendations made in the NICE antenatal care guideline<sup>37</sup> relating to the monitoring protocol of women who decline induction of labour from 42 weeks.

#### Recommendations on prolonged pregnancy

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

#### Research recommendations on prolonged pregnancy

Studies should be undertaken to compare effectiveness, safety, maternal satisfaction and compliance of different expectant management protocols.

Research is needed to identify babies at particularly high risk of morbidity and mortality who will benefit from induction and therefore avoid induction for babies who do not need it.

##### *Research question*

Pregnancies that continue after term run a higher risk of fetal compromise and stillbirth; can ways be found to identify pregnancies within that population that are at particular risk of these complications?

##### *Why is this important?*

Although the risks of fetal compromise and stillbirth rise steeply after 42 weeks, this rise is from a low baseline. Consequently, only a comparatively small proportion of that population is at particular risk. Because there is no way to precisely identify those pregnancies, delivery currently has to be recommended to all such women. If there were better methods of predicting complications in an individual pregnancy, induction of labour could be more precisely directed towards those at particular risk.

Research is needed into racial differences in the UK to identify the possible differences in the distribution of perinatal risk specific to gestational weeks and possible benefits of intervention before 41 weeks.

## 4.2 Preterm prelabour rupture of membranes

### *Clinical question*

- What are the harms and benefits of induction of labour in women with preterm prelabour rupture of membranes?

Preterm prelabour rupture of membranes is defined as rupture of the amniotic membranes prior to 37 weeks of gestation.<sup>38,39</sup> Preterm prelabour rupture of membranes occurs in approximately 3% of pregnancies and is responsible for a third of all preterm births.<sup>40</sup> Effective treatment relies on accurate diagnosis and is gestational age dependent. Preterm prelabour rupture of membranes is associated with significant maternal and neonatal morbidity and mortality from infection,

<sup>37</sup> This recommendation is from 'Antenatal care: routine care for the healthy pregnant woman' (NICE clinical guideline 62). Available from [www.nice.org.uk/CG062](http://www.nice.org.uk/CG062).

umbilical cord compression, placental abruption, preterm birth and the complications of prematurity. There is some evidence that expectant management beyond 34 weeks of gestation is associated with an increased risk of chorioamnionitis, but little evidence that intentional delivery after 34 weeks adversely affects neonatal outcome.<sup>41</sup>

### Overview of available evidence

Five RCTs were identified that assessed the effects of induction of labour compared with expectant management, and different methods of induction in women with preterm prelabour rupture of membranes. Reference is made to one RCOG guideline as supplementary evidence.

No evidence was identified that examined whether cerebral palsy was more likely in babies born to women with preterm prelabour rupture of membranes after 32 weeks of gestation. No evidence was identified that examined whether steroids were effective in preventing perinatal death in women with preterm prelabour rupture of membranes at 34 weeks of gestation or more.

#### *Induction versus expectant management*

One RCT in the USA compared the effects of induction of labour (intravenous oxytocin) ( $n = 46$ ) with expectant management ( $n = 47$ ) in women with preterm prelabour rupture of membranes at 32–36 weeks of gestation. Expectant management included hospitalisation, assessment of fetal heart rate and assessment of chorioamnionitis and uterine contractions. Digital cervical examinations were prohibited until labour was established. Women with suspected chorioamnionitis were excluded. Tocolysis was not used. Expectant management was significantly associated with prolonged randomisation-to-labour and randomisation-to-birth intervals, and maternal hospitalisation, as well as increased neonatal hospitalisation at 2–5 days after birth. The antepartum onset of chorioamnionitis and fetal heart abnormalities were significantly higher in the expectant management (15% versus 0%,  $P = 0.01$  and 13% versus 0%,  $P = 0.03$ , respectively). Infants received significantly more frequent and prolonged antimicrobial therapy after expectant management with no reduction in proven sepsis (7% versus 4%). The caesarean section rate was comparable and there were no stillbirths. Data analyses were not stratified according to different weeks of gestational age.<sup>42</sup> [EL = 1+]

Another RCT in the USA compared the effects of intentional birth (oxytocin or caesarean birth) ( $n = 61$ ) with expectant management ( $n = 68$ ) in women with preterm prelabour rupture of membranes at 30–34 weeks of gestation. No tocolytics, corticosteroids or prophylactic antibiotics were used during the trial. The admission-to-birth intervals were significantly shorter in the intentional birth group and the caesarean birth rate was similar between the two groups. However, there was a significant increase in the incidence of chorioamnionitis in the women who were managed expectantly (15% versus 2%,  $P = 0.009$ ). Perinatal outcomes were similar between the two groups. Data analyses were not stratified according to different weeks of gestational age. There was one stillbirth due to *Escherichia coli* sepsis in the expectant group, and three neonatal deaths in the intentional birth group (one from group B streptococcal sepsis, one from *Staphylococcus aureus* and one from pulmonary hypoplasia).<sup>43</sup> [EL = 1+]

One RCT in the USA compared induction of labour (intravenous oxytocin) ( $n = 57$ ) with conservative management by observation ( $n = 63$ ) in women with preterm prelabour rupture of membranes between 34 and 37 weeks of gestation (mixed parity). All women were given intravenous antibiotics for group B streptococcal prophylaxis. Tocolysis and corticosteroid treatment were not used. Women in the induction group were significantly more likely to have a shorter admission-to-birth interval (10 versus 119 hours), a lower incidence of chorioamnionitis (2% versus 16%) and shorter hospital stay (2.6 versus 5.2 days). Birth by caesarean section was comparable between the two groups (7% versus 5%). Neonatal outcomes such as Apgar score at 5 minutes, neonatal intensive care unit admission, sepsis (0% versus 5%, NS) and total hospital stay were comparable between the two groups.<sup>44</sup> [EL = 1+]

#### *Vaginal misoprostol versus vaginal PGE<sub>2</sub>*

One RCT in the USA compared the effects of induction of labour with vaginal misoprostol ( $n = 54$ ) and vaginal prostaglandin E<sub>2</sub> (PGE<sub>2</sub>) ( $n = 55$ ) in women with preterm prelabour rupture of membranes at 34 weeks of gestation or more (median 36 weeks). Women with evidence of intrauterine infection were excluded in this trial. The mean time from insertion to birth and



birth within 12 hours were significantly shorter in the misoprostol group (16.4 versus 22.0 hours,  $P = 0.01$  and 41% versus 16%,  $P = 0.05$ , respectively). Tachysystole and uterine hyperstimulation were significantly more likely in the misoprostol group (20% versus 6%,  $P = 0.02$  and 9% versus 0%,  $P = 0.02$ , respectively). There were no significant differences between the two groups in caesarean section rate or neonatal outcomes. Data analyses were not stratified according to different weeks of gestational age.<sup>45</sup> [EL = 1+]

#### *Vaginal misoprostol versus intravenous oxytocin*

One RCT in Iran compared the effects of induction of labour with vaginal misoprostol 25 mg ( $n = 54$ ) and intravenous oxytocin ( $n = 54$ ) in women with preterm prelabour rupture of membranes and unfavourable cervix at 29–36 weeks of gestation. All women received antibiotics and dexamethasone if gestation was less than 34 weeks. Women given vaginal misoprostol were significantly more likely to have shorter admission-to-birth intervals and were less likely to need caesarean section owing to failed induction (9% versus 19%,  $P < 0.004$ ). Vaginal birth rate and Apgar scores were similar. Data analyses were not stratified according to different weeks of gestational age.<sup>46</sup> [EL = 1+]

#### *Timing of induction after preterm prelabour rupture of membranes*

A US retrospective review was conducted to determine a consensus gestational age for induction of labour in women with preterm prelabour rupture of membranes ( $n = 236$ ) at between 32 and 36 weeks of gestation who were managed expectantly. In this study, prolongation of pregnancy by at least 1 week was infrequent in all cases when membrane rupture occurred after 34 weeks of gestation. Reductions in neonatal length of stay and the incidence of hyperbilirubinaemia were observed at 34 weeks of gestation, suggesting a natural ‘break point’ in neonatal morbidity at 34 weeks of gestation, which would support induction of labour at some time at or during this gestational age. There were no perinatal deaths.<sup>47</sup> [EL = 3]

One RCOG Green-top guideline provides guidance on the management and care of women with preterm prelabour rupture of membranes.<sup>41</sup>

### **Evidence statements**

Evidence suggested that, in women with preterm prelabour rupture of membranes, immediate induction of labour was associated with shorter admission-to-birth interval, reduced occurrence of chorioamnionitis and reduced duration of hospitalisation in both mothers and neonates, when compared with expectant management. [EL = 1+]

Compared with vaginal prostaglandins, vaginal misoprostol was more likely to be associated with birth within 12 hours, and with tachysystole and uterine hyperstimulation. The caesarean birth rate and neonatal outcomes were similar between the two groups. [EL = 1+]

Compared with intravenous oxytocin, vaginal misoprostol was associated with shorter admission-to-birth interval and reduced caesarean birth rate. [EL = 1+]

A natural ‘break point’ in neonatal morbidity was observed at 34 weeks of gestation, which may support induction of labour from this gestation age. [EL = 3]

An RCOG Green-top guideline on management of women with preterm prelabour rupture of membranes is available from the RCOG.

### **Interpretation of evidence**

The GDG considered that elective induction of labour ‘immediately’ after rupture of membranes at or before 32–34 weeks is inappropriate unless there is clinical evidence of sepsis (such as pyrexia) or a complete course of antenatal steroids has been given, and there is an available neonatal cot.

There is limited evidence on the preferred method of induction. It is noted that there is no evidence that directly compares vaginal PGE<sub>2</sub> with intravenous oxytocin in this situation. Compared with vaginal misoprostol, vaginal PGE<sub>2</sub> is less likely to achieve vaginal birth within 12 hours but vaginal misoprostol is associated with tachysystole and uterine hyperstimulation. The GDG recognised that women with preterm prelabour rupture of the membranes have for over two decades derived benefit from the widespread use of vaginal PGE<sub>2</sub> to induce labour in this situation.

In addition, the GDG also considered the comfort, convenience and acceptability of vaginal PGE<sub>2</sub> to the woman undergoing induction of labour. Vaginal PGE<sub>2</sub> is less invasive than oxytocin, which requires intravenous access and continuous electronic fetal monitoring (EFM), thus reducing women's mobility during induction. On balance, the GDG reached a consensus that a vaginal PGE<sub>2</sub> regimen is the preferred method of induction of labour for women with preterm prelabour rupture of membranes (refer to Section 5.1.1).

### Recommendations on preterm prelabour rupture of membranes

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

### Research recommendations on preterm prelabour rupture of membranes

A large study is needed to compare immediate induction of labour with expectant management beyond 34 weeks, taking into account duration of preterm prelabour rupture of membranes, gestational age, and maternal steroid and antibiotic treatment.

#### *Research question*

What are the relative risks and benefits of delivery versus expectant management in women whose membranes have ruptured spontaneously between 34 and 37 weeks?

#### *Why is this important?*

Intrauterine sepsis is more likely to develop in pregnancies that continue after the membranes have ruptured, putting both the woman and the baby at risk. In some such pregnancies, labour begins spontaneously at a variable interval after the membranes have ruptured, avoiding the need for induction. The value of antibiotic therapy and the administration of corticosteroids to the woman is unclear in this situation. A randomised study of active versus expectant management, taking account of time since membrane rupture, gestational age and maternal therapy, would be valuable.

Research is needed to compare effectiveness, cost-effectiveness, safety and maternal satisfaction of different management policies for induction of labour.

## 4.3 Prelabour rupture of membranes at term

### *Clinical question*

- What are the harms and benefits of induction of labour in women with prelabour rupture of membranes at term?

Prelabour rupture of membranes at term is defined as rupture of the membranes prior to the onset of labour in women at or over 37 weeks of gestation,<sup>48,49</sup> with an overall incidence of 8–10% of all pregnancies.<sup>50,51</sup> Infection of the lower genital tract and/or amniotic cavity is one of the most important aetiologies of prelabour rupture of membranes at term.<sup>52</sup>

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\* Vaginal PGE<sub>2</sub> has been used in UK practice for many years in women with ruptured membranes. However, the SPCs (July 2008) advise that in this situation, the use of vaginal PGE<sub>2</sub> is either not recommended or should be used with caution, depending on the preparation (gel, tablet or pessary). Healthcare professionals should refer to the individual SPCs before prescribing vaginal PGE<sub>2</sub> for women with ruptured membranes, and informed consent should be obtained and documented.

### Overview of available evidence

One NICE clinical guideline was identified that addressed this question. No studies were identified that assessed different methods of induction in women with prelabour rupture of membranes.

#### *Induction versus expectant management*

The NICE clinical guideline on intrapartum care<sup>17</sup> provides guidance on appropriate management and care of women with prelabour rupture of membranes. The evidence reviewed in that guideline found that, in women with prelabour rupture of membranes at term, maternal and fetal outcomes between planned induction of labour and expectant management were similar, and women need to have appropriate information to make informed choices.

It recommends that 'induction of labour is appropriate approximately 24 hours after [prelabour] rupture of the membranes [at term]'.<sup>17</sup>

### Evidence statements

The NICE guidance on intrapartum care recommends that women with prelabour rupture of the membranes at term (at or over 37 weeks) should be offered a choice of induction of labour or expectant management, and that if labour has not commenced approximately 24 hours after rupture of membranes, induction of labour is appropriate.<sup>17</sup>

No evidence was identified that assessed different methods of induction in women with prelabour rupture of membranes.

### Interpretation of evidence

The GDG agrees and supports the recommendations made in the NICE intrapartum care guideline relating to the strategy for induction of labour in women with prelabour rupture of the membranes at term.

In the absence of any evidence to inform the GDG on the appropriate method of induction, the GDG recognised that women with prelabour rupture of the membranes at term have for over two decades derived benefit from the widespread use of vaginal PGE<sub>2</sub> to induce labour in this situation.

In addition, the GDG also considered the comfort, convenience and acceptability of vaginal PGE<sub>2</sub> to the woman undergoing induction of labour. Vaginal PGE<sub>2</sub> is less invasive than oxytocin, which requires intravenous access and continuous EFM, thus reducing women's mobility during induction. On balance, the GDG reached a consensus that a vaginal PGE<sub>2</sub> regimen is the preferred method of induction of labour for women with prelabour rupture of membranes at terms (refer to Section 5.1.1).

#### **Recommendation on prelabour rupture of membranes at term**

**These recommendations were updated and replaced in 2021. Please see the NICE**

## 4.4 Previous caesarean birth

### *Clinical question*

- What are the harms and benefits of induction of labour in women with a previous caesarean birth?

As the proportion of women who give birth by caesarean section continues to rise, significant numbers of pregnant women with a previous caesarean birth may develop an indication for the

<sup>17</sup>Vaginal PGE<sub>2</sub> has been used in UK practice for many years in women with ruptured membranes. However, the SPCs (July 2008) advise that in this situation, the use of vaginal PGE<sub>2</sub> is either not recommended or should be used with caution, depending on the preparation (gel, tablet or pessary). Healthcare professionals should refer to the individual SPCs before prescribing vaginal PGE<sub>2</sub> for women with ruptured membranes, and informed consent should be obtained and documented.

<sup>18</sup>This recommendation is from 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55). Available from [www.nice.org.uk/CG055](http://www.nice.org.uk/CG055).

induction of labour. The choice between induction of labour, awaiting spontaneous labour and elective caesarean birth is a difficult one and risks and benefits have to be considered carefully.

### Overview of available evidence

Six recent studies were identified that assessed the risk of induction of labour in women with previous caesarean births. Four systematic reviews of RCTs and cohort and case series studies compared different induction methods in women with previous caesarean births. There was some degree of overlap in the studies included in these reviews. Reference is made to one RCOG guideline as supplementary evidence.

#### *Risks of induction of labour in women with previous caesarean section*

A UK study of registry data of women with a previous caesarean section who underwent induction of labour with prostaglandins ( $n = 130$ ) reported spontaneous vaginal birth in 50% of cases, with 11% requiring instrumental birth and 39% requiring caesarean sections. There were no cases of uterine rupture.<sup>60</sup> [EL = 3]

A UK 5 year retrospective review of hospital birth records ( $n = 205$ ) concerning outcomes of induction of labour (vaginal PGE<sub>2</sub>, PGE<sub>2</sub> plus oxytocin, artificial rupture of the membranes (ARM), ARM plus oxytocin) in women with one previous vaginal birth reported an overall success rate of 61%. In women with no previous vaginal births, the success rate was 41% compared with 83% in women who had had a previous vaginal birth (OR 6.8, 95% CI 3.4 to 13.9). There were four cases of uterine rupture and one of dehiscence (2.4%), all occurring in the group of women with no previous vaginal births, despite monitoring with intrauterine pressure catheter.<sup>61</sup> [EL = 3]

Analysis of the Morbidity and Stillbirth and Infant Survey of birth ( $n = 35\ 854$ ) in Scotland for 1985–98 of women with one previous caesarean birth who choose to labour at or after 41 weeks of gestation reported overall rates of vaginal births and uterine rupture of 74.2% and 0.35%, respectively. The risk of intrapartum uterine rupture was higher among women who had not previously given birth vaginally (adjusted OR 2.5, 95% CI 1.6 to 3.9) and in those whose labour was induced with prostaglandin (OR 2.9, 95% CI 2.0 to 4.3). The risk of perinatal death due to uterine rupture was significantly higher in hospitals with fewer than 3000 births a year than in hospitals with 3000 or more births a year (1/1300 births versus 1/4700 births; OR 3.4, 95% CI 1.0 to 14.3).<sup>62</sup> [EL = 3]

A cohort study from caesarean birth registry data in the USA compared the risks associated with attempting vaginal birth in women with previous caesarean section ( $n = 17\ 898$ ) with the risks in those women with elective caesarean section without labour ( $n = 15\ 801$ ). There were 48 uterine ruptures in women attempting vaginal birth after induction of labour ( $n = 4708$ ) compared with 24 in women with spontaneous labour ( $n = 6685$ ) (1% versus 0.4%; OR 2.86, 95% CI 1.75 to 4.67).<sup>63</sup> [EL = 2+]

One US multicentre prospective cohort study compared the outcomes of induction of labour on vaginal birth in women with one previous caesarean birth who had had no previous vaginal birth ( $n = 6132$ ) and those who had had prior vaginal birth ( $n = 5646$ ). Vaginal birth was significantly less likely after induction of labour both in women without and with a previous vaginal birth (51% versus 65%; OR 0.57, 95% CI 0.51 to 0.63 and 83% versus 88%; OR 0.6, 95% CI 0.56 to 0.78, respectively). There was an increased risk of uterine rupture after induction of labour in women with no previous spontaneous vaginal birth (1.5% versus 0.8%; OR 1.84, 95% CI 1.11 to 3.05). Blood transfusions, venous thromboembolism and hysterectomy were also more common in women with no previous vaginal birth. In both groups, an unfavourable cervix at induction of labour was not associated with any adverse outcomes except an increase in caesarean birth.<sup>64</sup> [EL = 2+]

#### *Methods of induction for women with previous caesarean birth*

Four systematic reviews compared the effects of elective repeat caesarean section with induction of labour in women with a previous caesarean birth. These reviews included RCTs, cohort studies (comparing induction of labour and no induction) and case series studies.<sup>65–68</sup> There was some degree of overlap in the papers included in these reviews. From these reviews, three RCTs were identified comparing different methods of induction of labour in women with previous caesarean births, and one RCT comparing induction with expectant management. One RCT<sup>69</sup>

was excluded because induction with mifepristone has been associated with fetal kidney damage (see Section 5.1.9) and was considered unsuitable for use in current practice in the UK.

*Vaginal PGE<sub>2</sub> 2.5 mg followed by amniotomy versus amniotomy plus intravenous oxytocin*

This RCT compared vaginal PGE<sub>2</sub> 2.5 mg followed by amniotomy ( $n = 21$ ) with amniotomy plus intravenous oxytocin ( $n = 21$ ) in women with a previous caesarean birth undergoing induction of labour because of prolonged pregnancy or pre-eclampsia (Bishop score < 9). There was no significant difference between the two groups in the induction-to-birth interval, mode of birth, caesarean section rate, operative vaginal birth, use of epidural analgesia or Apgar score < 7 at 5 minutes. However, of the six women who required a repeat caesarean section in the oxytocin group, five were for failure to establish labour whereas none of the four women in the PGE<sub>2</sub> group required a repeat caesarean section ( $P < 0.05$ ): the indication for the previous caesarean section may have influenced the outcome. There was one case of uterine rupture in the PGE<sub>2</sub> group after oxytocin augmentation.<sup>70</sup> [EL = 1+]

*Vaginal misoprostol 25 micrograms 6-hourly versus intravenous oxytocin*

This RCT compared vaginal misoprostol 25 micrograms 6-hourly ( $n = 17$ ) with intravenous oxytocin ( $n = 21$ ) in women with a previous caesarean birth. There were two uterine ruptures in the misoprostol group and none in the oxytocin group (2/17 (12%) versus 0/21; OR 6.11, 95% CI 0.31 to 119.33). The trial was stopped early after 38 women had been recruited because of safety concerns.<sup>71</sup> [EL = 1-]

*Weekly intracervical PGE<sub>2</sub> versus expectant management*

This RCT compared weekly intracervical PGE<sub>2</sub> gel 0.5 mg ( $n = 143$ ), repeated at weekly office visits for up to three doses, with expectant management ( $n = 151$ ) in women at term who had one previous caesarean birth and unfavourable cervix (Bishop score < 6). There was no significant difference in the initiation-to-birth interval, rate of vaginal birth (57% versus 55%,  $P = 0.68$ ) or in other maternal and fetal outcomes. No uterine rupture occurred.<sup>72</sup> [EL = 1+]

Twelve cohort studies were included in one review,<sup>67</sup> which reported that induction of labour (vaginal PGE<sub>2</sub>, intravenous oxytocin, intravenous oxytocin plus amniotomy, misoprostol) in women with previous caesarean section was more likely to result in caesarean section (20% (range 11–35%) of spontaneous labour compared with 32% (range 18–44%) of oxytocin induction; 24% (range 18–51%) of spontaneous labour compared with 48% (range 28–51%) of vaginal PGE<sub>2</sub> induction). There was a non-significant increase in uterine rupture among women who were induced compared with spontaneous labours.<sup>67</sup> [EL = 2+] Three additional cohort studies were identified in another review,<sup>68</sup> which reported vaginal birth rates of between 50% and 84% after PGE<sub>2</sub> induction and with no uterine rupture. [EL = 2+]

**Evidence statements**

Epidemiological data suggested that in women with previous caesarean birth, vaginal birth is successful in 50–70% of women. With no previous vaginal birth, successful vaginal birth following caesarean birth ranged from 44% to 61%. Uterine rupture is more likely to be associated with induction of labour in women with no previous vaginal birth than in women with previous vaginal birth. Particular care should be directed to women with previous caesarean because of the risk of uterine rupture. [EL = 2+–3]

Overall, for women with previous caesarean section, there is a limited evidence base of RCTs that the GDG considered was insufficient to determine the preferred method for induction. Evidence from small RCTs suggested that, in women with a previous caesarean section, vaginal PGE<sub>2</sub> followed by amniotomy may provide a more effective method of induction of labour when compared with amniotomy plus intravenous oxytocin. Vaginal misoprostol was associated with a high frequency of uterine rupture compared with intravenous oxytocin. Weekly intracervical PGE<sub>2</sub> and expectant management achieved similar maternal and fetal outcomes. [EL = 1+] Non-randomised studies reported increased caesarean section rates associated with various methods of induction of labour. Uterine rupture was similar between groups. [EL = 2+]

### Interpretation of evidence

Induction of labour in women with a previous caesarean birth is associated with higher rates of uterine rupture when compared with women who labour spontaneously, or choose elective caesarean birth. In the event of uterine rupture, babies may have better outcomes in units with more than 3000 births per year. However, this is from a single study and may not be generalisable.

The evidence base is too small and limited to inform the GDG on the most effective method of induction in women with previous caesarean section. One small RCT reported that vaginal PGE<sub>2</sub> may reduce the need for repeat caesarean birth when compared with amniotomy plus intravenous oxytocin. In addition, evidence from non-randomised studies reviewed has a likelihood of bias owing to confounders such as population groups with different cervix favourability and membrane status, which could bias the results in identifying the most effective induction methods studied.

Notwithstanding the poor evidence base, the GDG recognised that vaginal PGE<sub>2</sub> has been widely used in obstetric practice to induce labour for over two decades to good effect in women with a history of previous caesarean section.

The GDG also considered the comfort, convenience and acceptability of vaginal PGE<sub>2</sub> to the woman undergoing induction of labour. Vaginal PGE<sub>2</sub> is less invasive than amniotomy and oxytocin, with the latter requiring intravenous access and continuous EFM, thus reducing women's mobility during induction. On balance, the GDG reached a consensus that a vaginal PGE<sub>2</sub> regimen is the preferred method of induction of labour for women with a history of previous caesarean section.

#### Recommendation on previous caesarean birth

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

#### Research recommendation on previous caesarean birth

Studies should compare the effectiveness, cost-effectiveness, safety and maternal satisfaction of induction of labour by different methods, repeat elective lower segment caesarean section and expectant management in women with previous caesarean section.

## 4.5 Maternal request for induction of labour

### *Clinical question*

- What are the harms and benefits of induction of labour at maternal request?

Induction of labour at term without medical indication continues to be widely criticised on the basis that it is an unnecessary intervention and it carries risks.<sup>75</sup> Some women request elective induction of labour for pragmatic, social and emotional reasons,<sup>76,77</sup> to allow advance scheduling of domestic matters, the partner's presence during labour and birth and avoidance of distant journeys. Such logistic factors may be more common in areas with a large armed forces base, and are relevant to women whose partners are about to be posted abroad. It has been reported that about 50% of women with uncomplicated pregnancies opted for elective induction when offered the opportunity.<sup>78</sup> These women appeared to have more complaints during their pregnancy, more complications in their obstetric history and were more anxious about their labour than women

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<sup>75</sup>Vaginal PGE<sub>2</sub> has been used in UK practice for many years in women with a history of previous caesarean section. However, the SPCs (July 2008) advises that the use of vaginal PGE<sub>2</sub> is not recommended in women with a history of previous caesarean section. Informed consent on the use of vaginal PGE<sub>2</sub> in this situation should therefore be obtained and documented.

who chose a spontaneous onset of labour. The predominant motives were a feeling of safety and the desire to shorten the duration of pregnancy. The women who chose elective induction of labour were influenced by the positive information they had received about the procedure, and by the opportunity to have a degree of choice and control in the process.<sup>78</sup>

### Overview of available evidence

No evidence was identified that assessed the effects of induction of labour at maternal request. However, three RCTs from one systematic review were identified that assessed the effects of elective induction of labour at term (37–40 weeks of gestation) in women with no medical reasons but who were randomised to the induction arm of the trial. The GDG considered that this evidence could be extrapolated to women who request induction of labour for non-medical reasons.

#### *Induction of labour versus expectant management at 37–40 weeks of gestation*

In a systematic review<sup>31</sup> that assessed the effects of induction of labour versus expectant management from 37 to 42 weeks of gestation, three RCTs ( $n = 1300$ )<sup>79–81</sup> included women at 37–40 weeks of gestation. Meta-analysis of these three trials found no significant difference in perinatal death (RR 0.32, 95% CI 0.03 to 3.09; two RCTs) between the induction and expectant management group. There were two deaths in the expectant management group, one from a congenital heart condition and one from cord compression. However, the induction group was significantly less likely to have caesarean birth (RR 0.58, 95% CI 0.34 to 0.99; three RCTs) but more likely to require assisted vaginal birth (RR 1.71, 95% CI 1.23 to 2.39; two RCTs).<sup>31</sup> [EL = 1++]

### Evidence statement

Indirect evidence suggested that, compared with expectant management, elective induction of labour at 37–40 completed weeks of gestation without medical reasons was associated with a higher incidence of assisted vaginal birth and a lower incidence of caesarean birth. [EL = 1+]

### Interpretation of evidence

There is no evidence to determine the effects of induction of labour on maternal request. Evidence on induction of labour at 37–40 completed weeks without a medical indication is limited.

The decision should allow medical carers to use their judgment in the light of the women's exceptional circumstances. The GDG considered the dialogue between the woman and the clinician in making any decision about management to be important, and a case-by-case approach, taking into account the woman's clinical and personal circumstances, is appropriate.

#### **Recommendation on maternal request for induction of labour**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

#### **Research recommendation on maternal request for induction of labour**

Audit research is needed to assess the prevalence of maternal request for induction of labour and the reasons for such request.

## 4.6 Breech presentation

### *Clinical question*

- What are the harms and benefits of induction of labour in women with breech presentation?

The management of breech presentation in term pregnancy is controversial and the issue of vaginal breech birth has been debated for many years. A retrospective review of patient records ( $n = 641$ ) in Ireland reported that safe breech vaginal birth can be achieved with strict selection

criteria and adherence to a careful intrapartum protocol and with an experienced obstetrician in attendance.<sup>82</sup> Compared with planned vaginal birth, planned caesarean birth reduced perinatal or neonatal death and serious neonatal morbidity (RR 0.33, 95% CI 0.19 to 0.56), at the expense of increased short-term maternal morbidity (RR 1.29, 95% CI 1.03 to 1.61).<sup>83</sup>

### Overview of available evidence

One RCT from a systematic review was identified. Two case-control studies were identified. Reference is made to two NICE clinical guidelines as supplementary evidence.

#### *Induced vaginal birth versus planned caesarean section*

One RCT from the previous systematic review<sup>83</sup> included women with breech presentation who were randomised to vaginal birth (induced with oxytocin or prostaglandin) or planned caesarean section. However, no meaningful conclusion can be made because data were not analysed separately from those who were randomised to a planned vaginal birth without induction.<sup>84</sup> [EL = 1+]

#### *Induction with extra-amniotic saline instillation plus oxytocin*

One retrospective match-paired study compared the effects of breech induction ( $n = 23$ ) and vertex induction ( $n = 46$ ) with extra-amniotic saline instillation started concomitantly with oxytocin in women with unfavourable cervix. Fifty-two percent of the women in the breech induction group gave birth vaginally compared with 83% of the vertex induction group (OR 0.23, 95% CI 0.07 to 0.8) and the data for caesarean birth rate were 48% versus 17% (OR 4.3, 95% CI 1.3 to 15.6). Apgar scores and rates of birth trauma and maternal morbidity were similar in the groups.<sup>85</sup> [EL = 2-]

#### *Other induction methods*

One retrospective case-control study compared the effects of induction of labour (nipple stimulation, vaginal PGE<sub>2</sub> and oxytocin) in women with breech induction ( $n = 53$ ), breech birth ( $n = 58$ ) and breech elective caesarean section ( $n = 64$ ). It reported no significant differences in the rates of vaginal birth between induction and breech birth (66% versus 68%), caesarean birth (34% versus 32%) or 5 minute Apgar score < 7.<sup>86</sup> [EL = 2-]

The NICE clinical guideline on antenatal care<sup>37</sup> provides guidance on the management of breech presentation by external cephalic version at 36 weeks of gestation, and the NICE clinical guideline on caesarean section<sup>87</sup> provides guidance on planned caesarean section at term.

### Evidence statements

In women with breech presentation, there is no evidence available to quantify the effects of induction of labour compared with spontaneous vaginal birth. [EL = 1+]

There is no good-quality evidence to determine the effects of induction of labour (extra-amniotic saline instillation, nipple stimulation, vaginal PGE<sub>2</sub> and oxytocin) compared with breech birth in women with breech presentation. [EL = 2-]

### Interpretation of evidence

The evidence on induction of labour in women with breech presentation is poor.

Breech presentation is not an indication in itself for induction of labour. There are considerable risks of maternal and neonatal morbidity associated with induction of labour in the presence of breech presentation. However, in very particular circumstances, such as when the woman declines caesarean section, the decision needs to be made on a case-by-case basis, after full discussion of the associated risks.

#### **Recommendation on breech presentation**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**



## 4.7 Fetal growth restriction

### *Clinical question*

- What are the harms and benefits of induction of labour in women with presence of fetal growth restriction?

Fetal growth restriction is defined as occurring when a fetus has failed to reach its growth potential, and may be associated with serious intrapartum and neonatal complications.<sup>53–55</sup> It results mostly from chronic placental insufficiency and these fetuses are identified by the presence of growth below the 10th centile with umbilical artery Doppler abnormalities usually associated with reduced amniotic fluid volume.<sup>54,56</sup> The optimal timing of birth in a preterm fetus with growth restriction is controversial, requiring careful consideration of the severity of the growth restriction and its impact on fetal wellbeing balanced against the gestational age. The condition needs to be distinguished from normal small-for-gestation-age (SGA) babies, who are identified as small babies having a normal umbilical artery Doppler and normal amniotic fluid volume. In the compromised fetus, it is likely that there will be abnormal cardiotocography changes

### Overview of available evidence

Two RCTs were identified, one of which assessed the effects of early versus delayed birth in preterm pregnancies identified with fetal growth restriction. This study was based on the premise that there may be advantages to delaying birth so that the fetus might gain maturity. The second RCT compared the effects of induction of labour with expectant management in women with a fetus with growth restriction at term.

### *Early versus late birth*

The multicentre Growth Restriction Intervention Trial (GRIT) compared the effects of immediate ( $n = 273$ ) versus delayed birth ( $n = 274$ ) in women with fetal growth restriction between 24 and 36 weeks of gestation. It reported a lack of difference in overall fetal mortality between immediate and delayed birth in women with fetal growth restriction between 24 and 36 weeks of gestation. Total caesarean births were significantly higher in the immediate birth group (OR 2.7, 95% CI 1.6 to 4.5).<sup>57</sup> At 2 years, the overall rate of death and severe disability was similar in both groups (19% in the early group versus 16% in the delayed group; adjusted OR 1.1, 95% CI 0.7 to 1.8).<sup>58</sup> There was insufficient evidence to determine whether immediate or delayed birth was beneficial in this case.

### *Induction versus expectant management*

One small RCT (Disproportionate Intrauterine Growth Intervention Trial at Term (DIGITAT)) in the Netherlands assessed the short-term effects of induction of labour (PGE<sub>2</sub> gel for cervical priming and amniotomy and intravenous oxytocin) ( $n = 16$ ) and expectant management ( $n = 17$ ) in women with fetal growth restriction at term. No significant difference was reported in obstetric interventions such as caesarean section or in neonatal morbidity rate between the two groups.<sup>59</sup> [EL = 1+]

### Evidence statement

For fetal growth restriction identified between 24 and 36 weeks of gestation, there is insufficient evidence to determine whether immediate or delayed birth is beneficial. [EL = 1+]

For fetal growth restriction at term, one small RCT reported that induction of labour (with PGE<sub>2</sub> and amniotomy/intravenous oxytocin) and expectant management achieved similar maternal and fetal outcomes. [EL = 1+]

### Interpretation of evidence

There is little evidence of benefit for induction of labour in the presence of severe fetal growth restriction.

The GDG considered that labour in the presence of fetal growth restriction may result in perinatal loss and that, in such cases, induction of labour should thus be avoided.

### Recommendation on fetal growth restriction

If there is severe fetal growth restriction with confirmed fetal compromise, induction of labour is not recommended.

## 4.8 History of precipitate labour

### *Clinical question*

- What are the harms and benefits of induction of labour in women with a history of precipitate labour?

Precipitate labour is defined as expulsion of the fetus within less than 3 hours of commencement of contractions.<sup>73</sup> Labours of 3 hours or less in duration were strongly associated with placental abruption but were otherwise not major contributors to maternal and fetal morbidity.<sup>73</sup> Precipitate labour has an incidence of about 2% in women with spontaneous non-augmented labours.<sup>74</sup>

### Overview of available evidence

No studies were identified that compared induction of labour with no induction of labour in women with a history of precipitate labour.

### Evidence statements

There was no evidence identified to determine whether induction of labour is of benefit in preventing precipitate labour.

### Interpretation of evidence

Research evidence on the effects of induction of labour in women with a history of precipitate labour is lacking, and thus there is no evidence to suggest that inducing labour can prevent precipitate labour. Women with a history of precipitate labour may request induction of labour in order to be certain of giving birth in hospital and avoid unattended birth.

### Recommendation on history of precipitate labour

Induction of labour to avoid a birth unattended by healthcare professionals should not be routinely offered to women with a history of precipitate labour.

### Research recommendation on history of precipitate labour

Studies are needed to quantify the risks for women with history of precipitate labour, and to compare effectiveness, safety and maternal satisfaction of different management policies.

## 4.9 Intrauterine fetal death

### *Clinical questions*

- What are the harms and benefits of induction of labour in women with intrauterine fetal death?
- What are the best methods of induction of labour in women with intrauterine fetal death?
  - What are the best methods of induction of labour in women with intrauterine fetal death, and who had a previous caesarean birth? **This question was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

Intrauterine fetal death (IUFD) is defined as fetal demise at 24 weeks of gestation or later based on last menstrual period and is estimated to occur in 1% of all pregnancies. Over 90% of women in this situation will spontaneously deliver within 3 weeks of the intrauterine death<sup>88</sup> and thus expectant management may be an option in certain circumstances. Particular problems related to delayed labour may arise, such as intrauterine infection if the membranes are ruptured, and a

time-related risk of disseminated intravascular coagulopathy; the latter has been reported in 25% of women who retain a dead fetus for more than 4 weeks.<sup>89</sup>

The management of induction of labour in women with IUFD and a favourable cervix is often uncomplicated. The risks of failed induction and uterine rupture increase when the cervix is unfavourable, particularly in women with previous caesarean birth. Women should receive appropriate psychological support from healthcare professionals.

### Overview of available evidence

Three RCTs, two non-RCTs and three observational studies were identified that compared the effects of induction methods in women with IUFD at 24 weeks or later.

No evidence was identified that compared the effects of induction methods in women with IUFD at 24 weeks or later and previous caesarean section.

#### *Mifepristone versus placebo*

One RCT in South Africa compared the effects of oral mifepristone 200 mg three times a day ( $n = 48$ ) with placebo ( $n = 46$ ) for induction of labour in women with IUFD at later than 16 weeks of gestation (mean gestation 28 weeks). Labour occurred within 72 hours after 2 days of treatment in significantly more women in the mifepristone group (63% versus 17%,  $P < 0.001$ ). Clinical tolerance was good in the mifepristone group, although there was a report of minimal/moderate uterine bleeding which did not require blood transfusion. Disseminated intravascular coagulation occurred in one woman in the placebo group who had not expelled the fetus within 72 hours. Haemodynamic parameters and hepatic enzymes were comparable between the two groups.<sup>90</sup> [EL = 1+]

#### *Oral versus vaginal misoprostol*

One RCT in South Africa compared the effects of oral misoprostol 200 micrograms ( $n = 20$ ) with vaginal misoprostol 200 micrograms ( $n = 18$ ), both 6-hourly up to four doses, in women after IUFD (mean gestation 29 weeks). Women in the vaginal misoprostol group were significantly more likely to have shorter induction-to-birth time (21 versus 14 hours,  $P < 0.05$ ), less likely to need oxytocin augmentation (56% versus 20%,  $P < 0.05$ ) and less likely to experience gastrointestinal side effects (45% versus 20%,  $P < 0.05$ ).<sup>91</sup> [EL = 1+]

One RCT in Thailand compared the effects of oral misoprostol 400 micrograms every 4 hours ( $n = 40$ ) with vaginal misoprostol 200 micrograms every 12 hours ( $n = 40$ ) in women with IUFD at 16–41 weeks of gestation (mean gestation 23–24 weeks). A significantly shorter mean induction-to-birth time was achieved with oral misoprostol (14 versus 19 hours,  $P < 0.001$ ) and success in induction at 24 hours was significantly higher in the oral misoprostol group (93% versus 68%,  $P < 0.001$ ). All women delivered within 48 hours. Subgroup analyses showed no significant differences in the mean induction-to-birth time between the 16–22 weeks and over 28 weeks gestational age groups using either oral or vaginal misoprostol. The mean induction-to-birth time in the 23–28 weeks group differed significantly, favouring oral misoprostol (14 versus 20 hours,  $P = 0.027$ ). Significantly more women in the oral group reported diarrhoea. However, other effects (nausea, vomiting, fever, postpartum haemorrhage and analgesia) were similar between the two treatment groups.<sup>92</sup> [EL = 1+]

#### *Combined oral mifepristone and vaginal misoprostol*

A cohort study in the UK compared the effects of oral mifepristone 200 mg plus vaginal misoprostol 400 micrograms (up to four doses) (Group 1,  $n = 29$ ) with oral mifepristone 200 mg plus vaginal misoprostol 50 micrograms (up to four doses) (Group 2,  $n = 18$ ) in women after IUFD (median gestation 28 weeks in Group 1 and 31 weeks in Group 2, range 2–41 weeks). All women delivered vaginally. The mean induction-to-birth interval was 7 hours in Group 1 and 10 hours in Group 2, and the latter experienced fewer gastrointestinal side effects than Group 1.<sup>93</sup> [EL = 2+]

#### *Vaginal misoprostol versus vaginal sulprostone*

A cohort study in the Netherlands compared the effects of vaginal misoprostol ( $n = 47$ ) with vaginal sulprostone ( $n = 47$ ) in women after IUFD at 15–38 weeks of gestation (mean 24 weeks of gestation). There were no significant differences between the two groups in time to birth (hazard

rate ratio (HRR) 0.86, 95% CI 0.57 to 1.3), blood loss of 1000 ml (two versus three women), operative removal of the placenta (32% versus 26%; RR 0.80, 95% CI 0.41 to 1.6) or need for pain relief (55% versus 45%; RR 0.82, 95% CI 0.54 to 1.2).<sup>94</sup> [EL = 2+]

### *Combination of mifepristone and vaginal misoprostol*

A UK case series study assessed the effects of a combination of oral mifepristone followed by vaginal misoprostol in women after IUFD after 24 weeks of gestation ( $n = 96$ ). For gestations of 24–34 weeks, 200 micrograms of vaginal misoprostol was administered, followed by four oral doses of 200 micrograms at 3-hourly intervals. Women with gestations over 34 weeks were given a similar regimen but a reduce dose of 100 micrograms of misoprostol. Nearly 99% of the women delivered within 72 hours. The induction-to-birth interval was shorter with increasing gestation ( $P = 0.04$ ). About 8% of women reported mild gastrointestinal side effects.<sup>95</sup> [EL = 3]

Vaginal misoprostol (up to 400 micrograms) was reported in two further case-series studies<sup>96,97</sup> to be a safe and effective method of induction in women with IUFD. [EL = 3]

A narrative review, based on RCTs and cohort and case series studies, assessed methods for induction of labour in IUFD from the second trimester onwards (14–40 weeks of gestation). It suggested that prostaglandin analogues such as gemeprost and misoprostol can provide a safe and effective method for induction of second trimester abortion and intrauterine death. Gemeprost is licensed for this purpose but misoprostol may be a cheaper alternative.<sup>98</sup> [EL = 3]

A report reviewed the use of vaginal misoprostol for IUFD beyond 12 weeks of gestation and recommended a dosage regimen of vaginal misoprostol 200 micrograms (6-hourly  $\times$  4) for IUFD at 13–17 weeks of gestation, 100 micrograms (6-hourly  $\times$  4) for IUFD at 18–26 weeks of gestation and 25–50 micrograms (4-hourly  $\times$  6) for IUFD at 27–43 weeks of gestation.<sup>99</sup> [EL = 4]

### *IUFD at or after 24 weeks of gestation and a previous caesarean birth*

The risk of scar rupture at the time of medical induction of labour in women with IUFD and in the presence of previous uterine scar ranged from 3.8% in a retrospective review of hospital records to 4.3% in a cohort study,<sup>100,101</sup> compared with 0.2% in women with an intact uterus.<sup>100</sup>

No evidence was identified that compared the effects of induction methods in women with IUFD at or after 24 weeks and previous caesarean section.

## **Evidence statements**

For women with IUFD at or after 24 weeks of gestation, evidence from RCTs suggested that oral misoprostol is more effective than placebo as an induction agent to achieve labour. Vaginal misoprostol was associated with a shorter induction-to-birth duration than oral misoprostol. However, very high oral doses (400 micrograms every 4 hours) are more effective in terminating labour within 48 hours compared with lower vaginal doses. Gastrointestinal side effects appear to be dose related. [EL = 1+]

Evidence from non-RCTs suggested that a combination of oral mifepristone with relatively low doses of vaginal misoprostol is as effective as oral mifepristone with high doses of vaginal misoprostol. Vaginal misoprostol and vaginal sulprostone achieved comparable results. [EL = 2+]

Evidence from case-series studies suggested that the combination of oral mifepristone and vaginal misoprostol, or vaginal misoprostol alone, for induction of labour appeared to be effective and safe. [EL = 3]

## **Interpretation of evidence**

The GDG acknowledged the sensitive and upsetting circumstances that exist for the woman and her family at the time of intrauterine fetal death.

There seems to be little evidence to suggest that immediate induction of labour should be undertaken although this is often the woman's wish. Should she prefer delay, this can be supported as long as she is well, the membranes are intact and there is no evidence of infection. The use of mifepristone seems to be likely to reduce the dosage of prostaglandins required to induce labour. Misoprostol seems to be particularly effective. The choice and doses of prostaglandins, including

vaginal PGE<sub>2</sub>, will depend on the clinical circumstances, availability of preparations and local protocol and experience.

Care should be taken when the woman has had a previous caesarean birth and the dose of prostaglandins adjusted accordingly. **This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**Recommendations on intrauterine fetal death**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

#### **4.10 Suspected fetal macrosomia**

**This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

# 5 Methods of induction of labour

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## 5.1 Pharmacological-based methods

This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.

## 5.2 Non-pharmacological methods

### *Clinical question*

- What are the harms and benefits of non-pharmacological methods in induction of labour?  
**This section was partially updated (except for the evidence and recommendations on membrane-sweeping) and replaced in 2021. Please see the NICE website for the updated guideline.**

### 5.2.1 Membrane sweeping

Stripping/sweeping of the membranes was used as a method for inducing labour at least as early as 1810.<sup>144</sup> Increased local production of prostaglandins following vaginal examination for membrane sweeping provides a plausible explanation for the effect of this procedure on pregnancy duration.<sup>145</sup> Vaginal examination allows an assessment of the condition of the cervix which informs clinical decision making. Carried out in late pregnancy, when consideration is being given to induction, it offers the opportunity to undertake membrane sweeping. If the woman is on the threshold of spontaneous labour, a membrane sweep may be all that is required to initiate it, thus reducing the need for formal induction of labour. The procedure entails passage of the examining finger through the cervix so that it can be rotated against the wall of the uterus beyond the internal cervical os, thereby stripping the chorion away from the decidua (the decidua is the richest source of  $\text{PGF}_{2\alpha}$  within the uterus). Clearly if the cervix will not admit a finger it may not be possible to strip the membranes but in such cases massaging around the cervix in the vaginal fornices may achieve a similar effect.

For the purpose of this guideline, membrane sweeping is regarded as an adjunct to induction of labour rather than as a method per se.

### Overview of available evidence

One systematic review and one additional RCT were identified. Reference is made to the NICE clinical guideline on antenatal care as supplementary evidence.

One systematic review (22 RCTs involving 2797 women, Bishop score ranged from 'closed' to 6 or less, mixed parity) compared sweeping of membranes with no treatment (20 RCTs) and compared membrane sweeping with prostaglandins (three RCTs) and oxytocin (one RCT). Two studies reported more than one comparison. Women at 37–40 weeks and those at 40 weeks or more of gestation were included in 16 studies and six studies, respectively. Unfavourable cervix (as defined by triallists) was reported in seven studies. The interventions included weekly membrane sweeping (seven RCTs), sweeping every 3 days (one RCT) and daily sweeping (two RCTs). The control groups received cervical assessment or gentle vaginal examination.<sup>146</sup>

All studies in this review,<sup>147–153</sup> irrespective of sweeping frequency, reported that membrane sweeping was associated with a reduced number of pregnancies beyond 41 weeks (RR 0.59, 95% CI 0.46 to 0.74) and 42 weeks (RR 0.28, 95% CI 0.15 to 0.50). To avoid one formal induction of labour, sweeping of membranes would be performed in eight women (number needed to treat (NNT) = 8). There were no significant differences between the sweeping and no-treatment groups in terms of caesarean births (RR 0.90, 95% CI 0.70 to 1.15) or risks of maternal or neonatal infection. There were four perinatal deaths (two in each group, one stillbirth with meconium-stained liquor in the sweeping group, one with double nuchal cord in the control group and two from congenital heart defects). More women in the sweeping group reported discomfort during vaginal examination and other adverse effects such as bleeding and irregular contractions.<sup>146</sup> [EL = 1++]

Women with an unfavourable cervix and gestational age between 38 and 42 weeks<sup>154–157</sup> were significantly less likely to require formal induction of labour (RR 0.51, 95% CI 0.37 to 0.71; three RCTs, 226 women) when they underwent membrane sweeping. There were no significant differences between sweeping and no sweeping for caesarean births (RR 0.98, 95% CI 0.49 to 1.95; three RCTs, 200 women), epidural usage (RR 0.70, 95% CI 0.42 to 1.18; one RCT, 65 women), instrumental vaginal births (RR 0.87, 95% CI 0.33 to 2.24; two RCTs, 135 women), 5 minute Apgar score < 7 (RR 0.97, 95% CI 0.06 to 4.85; one RCT, 65 women) or neonatal intensive care unit admissions (RR 0.97, 95% CI 0.15 to 6.47; one RCT, 65 women). There was no maternal or perinatal mortality.<sup>146</sup> [EL = 1++]

There were limited data available in studies comparing membrane sweeping versus vaginal prostaglandins (two RCTs) or intravenous oxytocin (one RCT) in women with an unfavourable cervix. These studies did not show any significant differences in the need for formal induction, caesarean birth rates or other maternal and fetal outcomes.<sup>146</sup> [EL = 1++]

One additional RCT from the Netherlands,<sup>151</sup> not included in the review,<sup>146</sup> evaluated the effects of membrane sweeping, repeated every 48 hours ( $n = 375$ ) and no membrane sweeping (routine monitoring) ( $n = 367$ ) in women with low-risk pregnancy at 41 weeks of gestation and a median Bishop score of 4. Serial sweeping significantly reduced the proportion of post-term pregnancies (defined as 42 weeks or more gestational age) (23% versus 41%; RR 0.57, 95% CI 0.46 to 0.71) in both nulliparous and multiparous women. The need for induction of labour at or after 42 weeks was 15% in the sweeping group and 26% in the control group (RR 0.56, 95% CI 0.42 to 0.75). Sweeping significantly increased the likelihood of birth in a primary care setting in parous women (67% versus 51%; RR 1.32, 95% CI 1.11 to 1.58) but not in nulliparous women. Sweeping reduced the incidence of induction of labour in parous women (15% versus 27%; RR 0.57, 95% CI 0.37 to 0.86) with no effect in nulliparous women (29% versus 31%; RR 0.92, 95% CI 0.68 to 1.25). Adverse effects were similar in both the sweeping and control groups in analgesia use and fever during labour, mode of birth and adverse neonatal outcomes. However, uncomplicated bleeding was reported significantly more frequently in the sweeping group (34% versus 5%; RR 6.58, 95% CI 3.98 to 10.87). There were two perinatal deaths in each group, one due to possible group B streptococcal infection in the sweeping group and one unexplained death at 42 weeks after a failed vacuum extraction. Membrane sweeping was reported to be 'not painful' in 31%, 'somewhat painful' in 51%, and 'painful' or 'very painful' in 17% of women.

After birth, 88% of them would choose this procedure in a next pregnancy. Of the women who described sweeping as painful (all 'painful' categories), 88% reported that they would choose sweeping again in the next pregnancy.<sup>151</sup> [EL = 1+]

### Evidence statements

In women with an unfavourable cervix, evidence suggested that membrane sweeping and no membrane sweeping achieve comparable maternal and fetal outcomes including analgesia use. However, membrane sweeping is associated with:

- reduced need for formal induction of labour, especially in multiparous women
- increased rate of spontaneous labour, if performed more than once from 38 weeks of gestation; the most appropriate regimen is not clear from the evidence
- increased incidence of uncomplicated bleeding
- increased reports of pain but most women would still choose sweeping in a future pregnancy and recommend it to friends.

Evidence also suggests benefits for repeated sweeping attempts. There is also evidence that one attempt may be sufficient.

Data were limited with regard to providing evidence of benefits in comparisons between sweeping and vaginal PGE<sub>2</sub> or intravenous oxytocin. [EL = 1++]

### Interpretation of evidence

Compared with no sweeping, sweeping reduces the need for formal induction of labour. Additional membrane sweeping may be beneficial.

Membrane sweeping is an important and integral part of preventing prolonged pregnancy, and should be scheduled to be discussed with the woman at her routine antenatal visit.

The GDG considered it important to offer women information relating to the possibility of induction of labour to prevent prolonged pregnancy at their 38 week antenatal visit, to give women time to consider the options such as vaginal examination for membrane sweeping, before their next scheduled antenatal visits. Women may accept or decline this offer of information, and the options.

### Recommendations on membrane sweeping

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

### Research recommendation on membrane sweeping

Research is needed to assess effectiveness, maternal satisfaction and acceptability of:

- multiple versus once-only membrane sweeping, at varying gestational ages, stratifying for parity
- cervical massage when membrane sweeping is not possible, in women with unfavourable cervix.

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<sup>151</sup>This recommendation is from 'Antenatal care: routine care for the healthy pregnant woman' (NICE clinical guideline 62). Available from [www.nice.org.uk/CG062](http://www.nice.org.uk/CG062).



*Research question*

What are the effectiveness and acceptability of, and maternal satisfaction with, the following:

- multiple versus once-only membrane sweeping, at varying gestational ages, depending on parity
- membrane sweeping versus cervical massage?

*Why is this important?*

Membrane sweeping is considered to be a relatively simple intervention that may positively influence the transition from maintenance of pregnancy to the onset of labour, reducing the need for formal induction of labour. However, there are disadvantages, such as possible vaginal bleeding and discomfort. Research into when and how frequently membrane sweeping should be carried out to maximise its effectiveness and acceptability would be of value.

### 5.2.2 Herbal supplements

The use of herbal supplements to promote health has become popular. It is believed by some that drinking herbal beverage teas while pregnant nourishes and tones the uterus, supporting optimal health in pregnancy.

#### Evidence statements

No evidence was identified relating to the effects of herbal supplements in cervical priming/induction of labour.

#### Interpretation of evidence

There is no evidence available to determine the effects of herbal supplements as an induction agent. The GDG considered that the unsupervised use of herbal preparations, which may contain active ingredients with undesirable effects, should be treated with caution.

#### Recommendation on herbal supplements

Herbal supplements as a method of induction of labour should not be offered.

#### Research recommendation on herbal supplements

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of the use of herbal supplements as a method of induction of labour.

### 5.2.3 Acupuncture

Acupuncture involves the insertion of very fine needles into specific points of the body. It has been hypothesised that neuronal stimulation by acupuncture may increase uterine contractility. It is also gaining acceptance as a method to alleviate labour pain and ripen the cervix.<sup>158</sup>

#### Overview of available evidence

One systematic review and an additional RCT were identified.

One systematic review (one RCT involving 56 women, Bishop score < 5, mixed parity) that assessed the effects of acupuncture in women undergoing induction at term found no meaningful data on the effectiveness of acupuncture as a cervical priming method, owing to methodological limitations and drop-out rates.<sup>159</sup> [EL = 1++]

One additional RCT was identified in the USA that compared the effects of usual medical care alone (not specified) ( $n = 26$ ) and usual care plus three outpatient acupuncture treatments ( $n = 30$ ) in nulliparous women with uncomplicated pregnancies at term with a median Bishop score of 4. Women continued to receive medical care in either group (for example, membrane sweeping, timing of inductions or herbal supplementation for cervical ripening). There were no significant

differences between the acupuncture group and the control group in spontaneous labour (70% versus 50%; OR 2.33, 95% CI 0.78 to 6.98) or caesarean birth rates (17% versus 39%; OR 3.13, 95% CI 0.99 to 10.8).<sup>160</sup> [EL = 1+]

### Evidence statements

The available evidence is insufficient to determine the effectiveness of acupuncture in cervical priming/induction of labour. [EL = 1++]

### Interpretation of evidence

In the absence of sufficient evidence that proves either effectiveness or harm, acupuncture as a method of induction is not recommended to be offered.

#### Recommendation on acupuncture

Acupuncture as a method of induction of labour should not be offered.

#### Research recommendation on acupuncture

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of acupuncture as a method of induction of labour.

## 5.2.4

### Homeopathy

Homeopathy involves the administration in dilution of substances aimed at the alleviation of symptoms that the same substances generally cause in their undiluted form. It has been suggested that the herbs belonging to the *Caulophyllum* genus are useful in establishing labour, when uterine contractions are short and/or irregular or when they stop.<sup>161</sup>

### Overview of available evidence

One systematic review was identified.

One systematic review (two RCTs involving 133 women, cervical dilation up to 3 cm) assessed the effects of caulophyllum for cervical priming and induction of labour. There was insufficient methodological information for the studies included and clinically meaningful outcomes were limited.<sup>162</sup> [EL = 1++]

### Evidence statements

The available evidence was poor and insufficient to determine the effectiveness of homeopathy as a method of induction of labour. [EL = 1++]

### Interpretation of evidence

In the absence of sufficient evidence to prove either effectiveness or harm, homeopathy as a method of induction is not recommended to be offered.

#### Recommendation on homeopathy

Homeopathy as a method of induction of labour should not be offered.

#### Research recommendation on homeopathy

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of homeopathy as a method of induction of labour.

### 5.2.5 Castor oil, hot baths and enemas

Castor oil has been widely used as a traditional method of initiating labour in midwifery practice. However, the mechanism is poorly understood.

#### Overview of available evidence

One systematic review and an additional RCT were identified. No evidence was identified which assessed the effects of hot baths and enemas in induction of labour.

The systematic review (one quasi-RCT involving 103 women, Bishop score < 4, intact membranes, parity unknown) compared the effects of a 60 ml single dose of castor oil (diluted in orange or apple juice) versus no treatment in women requiring induction of labour. There was no evidence of differences between the two groups in caesarean birth rate, meconium-stained liquor or Apgar score < 7 at 5 minutes. All women who ingested castor oil felt nauseous (RR 97.08, 95% CI 6.16 to 1530.41).<sup>163</sup> [EL = 1++]

A small RCT in Iran compared the effects of castor oil ( $n = 24$ ) and control (no intervention) ( $n = 23$ ) in women at 40–42 weeks of gestation (Bishop score  $\leq 4$ , parity unknown). It reported a significant increase in the initiation of labour in the castor oil group compared with the control group (54.2% versus 4.3%,  $P < 0.001$ ) and an increase in the mean Bishop score in the castor oil group (from  $2.50 \pm 1.29$  to  $6.79 \pm 3.20$ ,  $P < 0.001$ ). There were no significant differences between the two groups in Apgar scores, meconium-stained liquor or methods of birth. Women given castor oil were significantly more likely to report nausea (45.8% versus 0%).<sup>164</sup> [EL = 1+]

#### Evidence statements

Evidence suggested that women given castor oil for induction of labour achieve similar maternal and fetal outcomes as women given placebo. [EL = 1++] One small RCT reported improved Bishop scores in women given castor oil. [EL = 1+] However, both studies reported that castor oil was associated with nausea. [EL = 1++]

#### Interpretation of evidence

There is limited and conflicting evidence relating to the effects of castor oil for cervical priming and induction of labour. Castor oil is unpleasant to ingest and causes nausea. There is no available evidence relating to hot baths or enemas as induction agents.

#### Recommendation on castor oil, hot baths and enemas

Castor oil, hot baths and enemas as methods of induction should not be offered.

#### Research recommendation on castor oil, hot bath and enemas

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of the use of castor oil, hot baths and enemas as methods of induction of labour.

### 5.2.6 Sexual intercourse

The role of sexual intercourse in stimulating labour is not well understood. It has been suggested that human semen is a biological source of high prostaglandin concentrations and the action of sexual intercourse may stimulate uterine contractions. There may be an endogenous release of oxytocin as a result of orgasm.

#### Overview of available evidence

One systematic review was identified.

One systematic review (one RCT involving 28 women, Bishop score and parity not known) assessed the effects of sexual intercourse for cervical priming and induction of labour. Data were

limited and the review reported no significant differences in changes in Bishop score (1.0 versus 0.5,  $P > 0.05$ ), Apgar scores  $< 7$  at 5 minutes (0% versus 0%) or number of women delivered within 3 days of intervention (46% versus 47%; RR 0.99, 95% CI 0.45 to 2.20) between the group who had sexual intercourse for three consecutive nights with vaginal sperm deposit and the control group who abstained from sexual intercourse.<sup>165</sup> [EL = 1++]

### Evidence statements

One small study with limited data found no significant difference in labour outcomes between sexual intercourse and no sexual intercourse. [EL = 1++]

### Interpretation of evidence

In the absence of sufficient evidence to prove either effectiveness or harm, sexual intercourse as a method of induction of labour is not recommended.

### Recommendation on sexual intercourse

Sexual intercourse as a method of induction of labour should not be used.

### Research recommendation on sexual intercourse

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of sexual intercourse as a method of induction of labour.

## 5.2.7 Breast stimulation

It is known that breast stimulation results in the production of endogenous oxytocin in both pregnant and non-pregnant women,<sup>166,167</sup> causing uterine contractions.

### Overview of available evidence

One systematic review was identified.

One systematic review (six RCTs, 719 women, Bishop score 5–7) assessed the effects of breast stimulation for cervical priming and induction of labour. Breast stimulation was significantly associated with increased numbers of women achieving labour by 72 hours (93.6% versus 62.7%; RR 5.79, 95% CI 3.41 to 9.81; four RCTs) and a reduction in the rate of postpartum haemorrhage (0.7% versus 6%; RR 0.16, 95% CI 0.03 to 0.87) when compared with no breast stimulation. No significant differences were detected in the rates of caesarean birth or meconium staining. There were no instances of uterine hyperstimulation. For women with unfavourable cervix, one small trial<sup>168</sup> in this review<sup>169</sup> reported three perinatal deaths in the breast stimulation group (1.8% versus 0%; RR 8.17, 95% CI 0.45 to 147.77; one RCT, 37 women).

When comparing breast stimulation with oxytocin alone, the analysis found no differences in caesarean birth rates or the number of women not in labour after 72 hours. There was one perinatal death in the oxytocin group. None of the RCTs included in this review reported on women's satisfaction with the treatment. The methods and frequency of breast stimulation varied in these studies. [EL = 1++]

### Evidence statements

Evidence suggested that breast stimulation appears to be beneficial in increasing the number of women in labour by 72 hours and in reducing postpartum haemorrhage rates when compared with control. Caesarean birth rates were similar between breast stimulation and intravenous oxytocin. [EL = 1++] One small RCT reported three perinatal deaths in the breast stimulation group and one in the oxytocin group.

### **Interpretation of evidence**

There is evidence that breast stimulation may be effective as a method of induction. However, interpretation of the results was problematic owing to the poor quality of the studies reviewed and the heterogeneous populations, including high-risk women from developing countries. There is inconsistency in the timing, methods and frequency of breast stimulation described in these studies, making guidance on this method difficult. The GDG made a research recommendation.

#### **Research recommendation on breast stimulation**

Further research is required to evaluate the effectiveness, timing, methods, frequency, safety and maternal satisfaction of breast stimulation as a method of induction of labour.

## **5.3 Surgical methods**

**This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

# 6 Setting and timing for induction of labour

## 6.1 Setting and timing for induction of labour

### *Clinical questions*

- What are the effects (harms and benefits) when induction of labour is carried out in different settings (outpatient, inpatient)?
- What are the effects (harms and benefits) when induction of labour is carried out at different days of week and at different times of day?

### **Overview of available evidence**

Two RCTs comparing inpatient and outpatient induction were included. One audit study examining the potential for outpatient induction was identified. Two RCTs and a cohort study comparing effects of induction in mornings and evenings were included. No comparative studies were identified relating to induction at home.

### *Outpatient versus inpatient induction of labour: vaginal PGE<sub>2</sub>*

One RCT in Canada compared the effects of inpatient ( $n = 150$ ) and outpatient ( $n = 150$ ) induction of labour with controlled release PGE<sub>2</sub> in women with uncomplicated pregnancy at term with a Bishop score  $\leq 6$ . Women in the outpatient group were monitored for 1 hour after controlled release PGE<sub>2</sub> insertion and then allowed to go home with instructions to report to the fetal assessment unit by telephone if they experienced regular contractions, ruptured membranes, vaginal bleeding, reduced fetal movements or tachysystole. They were also instructed how to remove the insert if necessary. There were no significant differences between the two groups in any maternal or fetal adverse outcomes. Maternal satisfaction was significantly higher in the outpatient group (56% versus 39%,  $P = 0.008$ ) and ratings of pain and anxiety during the first 12 hours of induction were similar.<sup>174</sup> [EL = 1+]

One US RCT compared the feasibility and efficacy of inpatient cervical priming ( $n = 50$ ) and outpatient cervical priming ( $n = 61$ ) with transcervical Foley catheter in women with uncomplicated pregnancy at term and a Bishop score of  $< 5$ . Women in the outpatient group were given detailed written and oral instructions before discharge. These included 24 hour telephone access to a physician or nurse for any questions or concerns, such as vaginal bleeding, rupture of membranes, painful contractions and extrusion of the catheter. There were no significant differences in any maternal or fetal outcomes, including maternal discomfort. There were no adverse events in either group.<sup>175</sup> [EL = 1+]

A UK clinical audit of outpatient cervical priming ( $n = 100$ , 86% induced for post maturity, induction methods not specified) suggested that elective admissions to birth ward were reduced by 75% with the introduction of outpatient cervical priming, thus allowing more efficient use of major resources. The experience improved women's perception of the process of induction of labour.<sup>176</sup> [EL = 3]

### *Inpatient induction of labour: morning versus evening*

One RCT in Australia (part of a trial comparing oral misoprostol with vaginal PGE<sub>2</sub>) compared the effects of morning admission (8 a.m.) for induction of labour ( $n = 280$ ) with evening admission (8 p.m.) ( $n = 340$ ) in women at or after 36<sup>+6</sup> weeks of gestation. There were no significant differences in outcomes such as achieving vaginal birth within 24 hours, incidence of uterine hyperstimulation with FHR changes or caesarean birth rates between admission and commencing



induction of labour in the morning or in the evening. However, women in the morning induction group were significantly less likely to require oxytocin infusion (45% versus 54%; RR 0.83, 95% CI 0.70 to 0.97). Nulliparous women induced in the morning were also less likely to need operative vaginal birth (16% versus 34%; RR 0.45, 95% CI 0.25 to 0.90). Maternal and fetal complications were comparable between the two groups. Overall, women were satisfied with the care they received but disliked the lack of sleep associated with evening induction (4.4% versus 0.4%; RR 0.08, 95% CI 0.01 to 0.61).<sup>177</sup> [EL = 1+]

One RCT in the Netherlands compared the effects of inpatient induction of labour with endocervical PGE<sub>2</sub> gel 0.5 mg in the morning between 8 and 9 a.m. (*n* = 58, 30 nulliparous) and the evening between 10 and 11 p.m. (*n* = 68, 46 nulliparous) in women at term (Bishop score < 6) scheduled for induction of labour. Administration of PGE<sub>2</sub> gel in the evening did not significantly reduce birth between 11 p.m. and 8 a.m. No multiparous woman induced in the evening delivered between 6 p.m. and 11 p.m. A greater number of nulliparous women induced in the evening delivered by vacuum or forceps (19 versus 3; RR 4.2, 95% CI 1.4 to 13). More women induced in the morning were satisfied with the timing of gel administration than women induced in the evening (77% versus 62%). Dissatisfaction with the time of gel administration was reported by 4% of women in the morning group and 20% in the evening group (RR 4.8, 95% CI 1.1 to 20). Quality of sleep was reported to be bad in 34% of the morning group as compared with 73% of the evening group (RR 1.7, 95% CI 1.1 to 2.5). The wish to choose another time for induction of labour in a future pregnancy was 8% in the morning group and 23% in the evening group (RR 2.4, 95% CI 0.86 to 6.6).<sup>178</sup> [EL = 1+]

A UK study compared the outcomes of induction of labour with vaginal PGE<sub>2</sub> gel 2 mg inserted at 10 p.m. (*n* = 40) and at 2 p.m. (*n* = 40) in women at 37–42 weeks of gestation scheduled for induction of labour. Inductions earlier in the day at 2 p.m. were associated with significantly shorter hospital stay (4.4 versus 5.3 days, *P* < 0.01) and reduced overall cost of admission. Other maternal outcomes were similar between the two groups. No fetal outcomes were reported.<sup>179</sup> [EL = 2+]

### Evidence statements

Evidence from two RCTs suggested that inpatient and outpatient induction achieve comparable maternal and fetal outcomes. Maternal satisfaction was higher in the outpatient induction group. [EL = 1+] Outpatient cervical priming has the potential to reduce admission to delivery wards and improve women's perception of induction of labour. [EL = 3]

Evidence from one RCT suggested that induction of labour carried out in the morning or in the evening achieve similar outcomes and in terms of preventing birth during evening and night shifts. One RCT reported that morning induction is associated with a reduced need for oxytocin and operative vaginal birth, the latter in nulliparous women. There may be an increased risk of instrumental birth when induced in the evening. Women's satisfaction was significantly higher when induction of labour took place in the morning. [EL = 1+]

Induction (vaginal PGE<sub>2</sub>) at 2 p.m. reduces the duration of hospital stay and admission costs when compared with induction at 10 p.m. [EL = 2+]

### Interpretation of evidence

The GDG is aware that outpatient induction of labour is commonly offered to women with prolonged pregnancy. Evidence from the UK setting is very limited and more safety data are needed.

The available evidence from other countries appears to support induction of labour for this group of women in the outpatient setting. However, these data may not be generalisable to the UK setting.

There is evidence to favour morning admission for induction if vaginal PGE<sub>2</sub> is used. Women were more satisfied when induction of labour took place in the morning. Small cost savings to the NHS might be realised as a result of reduced length of stay and lower admission costs.



**Recommendations on setting and timing for induction of labour**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**Research recommendation on setting for induction of labour**

Studies are needed to assess the safety, efficacy and clinical and cost-effectiveness of outpatient and inpatient induction in the UK setting, taking into account women's views.

*Research question*

Is it safe, effective and cost-effective to carry out induction of labour in an outpatient setting? What are the advantages and disadvantages of such an approach, taking into account women's views?

*Why is this important?*

In line with the way healthcare has developed in many areas of acute care, there is an increasing desire to reduce the time women spend in hospital. Several units are already exploring outpatient induction of labour policies and there is a need to study this approach in order to determine relative risks and benefits, as well as acceptability to women.

# 7 Monitoring and pain relief for induction of labour

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## 7.1 Monitoring of induction of labour

### *Clinical question*

- How should labour be monitored at/during induction of labour?

The assessment of fetal wellbeing is an important component of care during labour, providing accurate information to prevent risks to both mother and baby. Induction of labour has unwanted effects, one of the most common being uterine hyperstimulation. Monitoring regimens will depend on the method of induction. The intensity of uterine contractions was reported to be lower in spontaneous labour than in elective induction in a cohort study.<sup>180</sup> Uterine contractions after vaginal prostaglandins usually begin within the first few hours, reaching a peak at 5–6 hours after insertion. Across all the different preparations of induction methods reviewed in this guideline, there is level 1+ evidence that the incidence of uterine hyperstimulation with or without FHR changes ranged from 1% to 5%.

### **Overview of available evidence**

No evidence on the effectiveness of the monitoring regimens during induction was identified. Reference is made to the NICE clinical guideline on intrapartum care, which provides guidance on maternal and fetal monitoring during labour.<sup>17</sup>

### **Evidence statements**

No direct evidence was identified relating to the most effective monitoring regimen for women undergoing induction of labour.

### **Interpretation of evidence**

While there is no direct evidence, there is expert opinion on the most appropriate monitoring protocol for women at and/or during induction of labour.

The GDG agrees and supports the recommendations made in the NICE intrapartum care guideline relating to maternal and fetal monitoring protocols once active labour begins.

### **Recommendations on monitoring of induction of labour**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**Research recommendation on monitoring of induction of labour**

Studies are needed to identify the most effective way of monitoring women during the induction of labour process.

**7.2 Pain relief during induction of labour***Clinical questions*

- What is the evidence that induced labours are more painful than spontaneous labour?
- What are the harms and effects of early (at induction) and late (active labour) administration of epidural analgesia?

Women may experience induced labour as being more painful than spontaneous labour. Each labour needs to be managed on a case-by-case basis.

**Overview of available evidence**

One RCT and one cohort study were identified relating to analgesic requirements in induced and spontaneous labour. Two RCTs compared early and late epidural. A systematic review of vaginal prostaglandins and oxytocin relating to epidural requirement was included. Reference is made to the NICE clinical guideline in intrapartum care as supplementary evidence.

No studies were identified that examined the use of satisfactory analgesia available to women who are progressing rapidly in labour after induction and whose birth is expected within 2–3 hours from the time of induction.

*Analgesic requirements in induced and in spontaneous labour*

One cohort study in Italy compared the effects of spontaneous ( $n = 31$ ) and prostaglandin-induced labour ( $n = 30$ ) on the minimum analgesic dose (MAD) of epidural sufentanil in the first stage of labour in women (at or after 37 weeks of gestation with cervical dilation 2–4 cm) requesting epidural pain relief in labour. The initial dose was sufentanil 25 micrograms and analgesic effectiveness was assessed using 100 mm visual analogue scale (VAS) pain scores. The MAD of sufentanil in spontaneous labour was 22.2 micrograms (95% CI 19.6 to 22.8 micrograms) and 27.3 micrograms (95% CI 23.8 to 30.9 micrograms) in induced labour, and the latter was significantly greater than that in spontaneous labour ( $P = 0.0014$ ) by a factor of 1.3 (95% CI 1.1 to 1.5). Reported sedation/drowsiness effects were significantly higher in the induced group ( $P = 0.024$ ). This suggests that prostaglandin induction of labour produces a greater analgesic requirement than does spontaneous labour.<sup>181</sup> [EL = 2+]

*Effects of epidural analgesia on induced labour*

One RCT in Taiwan assessed the efficacy of epidural (fentanyl) ( $n = 60$ , Group A) and no epidural ( $n = 60$ , Group B) to relieve labour pain during the early period of the first stage of induced labour (intravenous oxytocin). Results were also compared with a control group ( $n = 198$ , Group C) who refused randomisation and did not receive analgesia during the entire labour course. There were no significant differences between the three groups in duration of labour, modes of birth or fetal outcomes. Throughout the entire labour course, particularly in the first 4 hours, pain scores

assessed with VAS were significantly lower in Group A than in Groups B and C ( $P < 0.001$ ) and analgesia quality, as assessed by the women, was significantly better in Group A than in Group B (80% versus 0% rated it 'excellent',  $P < 0.001$ ).<sup>182</sup> [EL = 1+]

One RCT in France compared the effects of epidural analgesia given at the beginning of induction (oxytocin) ( $n = 41$ ) versus epidural analgesia given when labour entered the active phase ( $n = 47$ ). There were no significant differences between the two groups in the length of labour or mode of birth.<sup>183</sup> [EL = 1+]

One RCT in the USA compared the effects of early ( $n = 74$ ) versus late ( $n = 75$ ) administration of epidural analgesia in nulliparous women undergoing induction of labour with intravenous oxytocin at or after 36 weeks of gestation and cervical dilation 3–5 cm. There were no significant differences between early (bupivacaine) and late (intravenous nalbuphine followed by late epidural) administration of epidural analgesia in the interval between randomisation and the diagnosis of full cervical dilation (318 versus 273 minutes), incidence of spontaneous birth (39% versus 32%), instrumental vaginal birth (43% versus 49%) or caesarean birth rate (18% versus 19%; RR 0.94, 95% CI 0.48 to 1.84). Women in the early epidural group experienced lower pain scores between 30 and 120 minutes after randomisation, better quality analgesia and higher satisfaction, but they were more likely to experience transient hypotension. Apgar scores  $\geq 7$  at 5 minutes were similar between the two groups.<sup>184</sup> [EL = 1+]

### *Intravenous oxytocin versus vaginal PGE<sub>2</sub>*

Data from one systematic review suggested that a significantly higher epidural usage was associated with induction of labour with intravenous oxytocin than with vaginal PGE<sub>2</sub> (RR 1.11; 95% CI 1.04 to 1.19, nine RCTs) in women with different parity, cervical and membranes status.<sup>117</sup> [EL = 1++]

Guidance on pain relief strategies for women during labour is provided in the NICE guideline on intrapartum care.<sup>17</sup>

### **Evidence statements**

There is no evidence concerning analgesia requirement during the induction process and before the onset of labour.

Women in spontaneous labour are more likely to require a smaller minimum effective dose of epidural sufentanil than women after induction of labour. [EL = 2+]

Epidural analgesia was associated with lower pain scores and higher maternal satisfaction when compared with no epidural analgesia in women during the early stage of induced labour. [EL = 1+]

Early, rather than late, administration of epidural analgesia does not prolong labour or increase the incidence of instrumental or caesarean section births. There is no benefit in waiting until labour has started to give epidural. [EL = 1+]

Induction with oxytocin may be more painful than induction with vaginal PGE<sub>2</sub>. [EL = 1++]

### **Interpretation of evidence**

Although there was no evidence of analgesia requirement during the induction process and before the onset of labour, women need the pain relief appropriate to them and their pain. This can range from simple analgesia to epidural analgesia.

There is evidence that women in whom labour is induced have greater analgesia requirements than those with spontaneous onset of labour.

Early compared with late administration of epidural analgesia does not prolong labour or increase the need for assisted birth in women whose labours were induced, but is associated with greater maternal satisfaction.

Oxytocin-induced labours may have greater analgesia requirements than those induced with vaginal prostaglandins.

The GDG agrees and supports the recommendations made in the NICE intrapartum care guideline relating to pain relief strategies during labour.

**Recommendations on pain relief during induction of labour**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**Research recommendations on analgesia consideration during induction of labour**

Research is needed to evaluate the effects of regional analgesia on progress and outcome of induced labour, stratified for differing cervical status.

Studies are needed to assess the role support plays in alleviation of pain during induction of labour.

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\* This recommendation is from 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55). Available from [www.nice.org.uk/CG055](http://www.nice.org.uk/CG055).

# 8 Complications of induction of labour

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## *Clinical question*

- How are the complications of induction of labour prevented and managed?

The following complications of induction of labour were reviewed: uterine hyperstimulation, failed induction, umbilical cord prolapse and uterine rupture.

## 8.1 Uterine hyperstimulation

Uterine hyperstimulation can appear as tachysystole or hypertonus, which may lead to FHR changes. Across all the different preparations used for induction reviewed in this guideline, there is level 1+ evidence that the incidence of uterine hyperstimulation with or without FHR changes ranged from 1% to 5%.

### Overview of available evidence

One study assessed the effects of tocolytics in the management of uterine hyperstimulation caused by induction with PGE<sub>2</sub>. No evidence was identified relating to management of uterine hyperstimulation caused by induction with intravenous oxytocin.

No evidence was identified evaluating the use of intravenous magnesium sulfate, or swabbing or irrigating the vagina after uterine hyperstimulation in an attempt to wash out vaginal PGE<sub>2</sub>. No evidence was identified on the management of prolapse of cord, cord compression, vasa praevia or the use of oxygen therapy.

### *PGE<sub>2</sub>-induced uterine hyperstimulation*

A retrospective study of case notes ( $n = 3099$ ) investigated women who underwent induction with low-dose PGE<sub>2</sub> (vaginal tablet, gel and intracervical gel). Uterine hyperstimulation (defined as contraction frequency being more than five in 10 minutes or contractions exceeding 2 minutes in duration) occurred in 181 cases (5.8%), of which 57 (31.5%) were associated with FHR abnormalities. Administration of tocolytic treatment with  $\beta_2$ -adrenergic drugs (hexoprenaline at 0.3 micrograms/minute or a single dose of terbutaline 250 micrograms intravenously or subcutaneously) was successful in normalising uterine contractions and reversing any FHR abnormality in 178 cases (98.3%). Improvement usually began within 5 minutes regardless of hyperstimulation patterns. Three cases required caesarean section and there were no postpartum complications.<sup>185</sup> [EL = 3]

Guidance is provided by the NICE clinical guideline on intrapartum care relating the management of suspicious or pathological EFM traces once active labour is established.<sup>17</sup>

### Evidence statements

Evidence suggested that uterine hyperstimulation after low-dose PGE<sub>2</sub> therapy is uncommon and usually rapidly reversible with  $\beta_2$ -adrenergic therapy without apparent maternal and fetal complications. [EL = 3]

### Interpretation of evidence

For uterine hyperstimulation, tocolytics can be effective for PGE<sub>2</sub>-induced uterine hyperstimulation. Methods of tocolysis should follow the local standard protocol.

**Recommendation on uterine hyperstimulation**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**8.2 Failed induction**

The criteria for failed induction are not generally agreed. It is estimated that a failed induction in the presence of an unfavourable cervix is found in 15% of cases.<sup>188</sup>

Failed induction of labour must be differentiated from failure of labour progress due to cephalopelvic disproportion or malposition. In this guideline, failed induction is defined as failure to establish labour after one cycle of treatment, consisting of the insertion of two vaginal PGE<sub>2</sub> tablets (3 mg) or gel (1–2 mg) at 6-hourly intervals, or one PGE<sub>2</sub> controlled released pessary (10 mg) over 24 hours (see Section 5.1.1).

**Overview of available evidence**

No evidence was identified relating to management of failed induction.

Reference is made to the NICE clinical guideline on intrapartum care as supplementary evidence.<sup>17</sup>

**Interpretation of evidence**

When induction fails, the GDG considered it important, as in all clinical practice, to review the situation for subsequent management options on a case-by-case basis. A further attempt to induce labour can be considered, and the timing should depend on the woman's wishes and her clinical situation.

The GDG agrees with and supports the recommendations made in the NICE intrapartum care guideline relating to the management of suspicious or pathological EFM traces, once labour is established.<sup>17</sup>

**Recommendations on failed induction**

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

**Research recommendations on failed induction**

Research is needed to establish frequency and interval of vaginal PGE<sub>2</sub> to achieve successful induction of labour.

Research is needed to examine different management policies for failed vaginal PGE<sub>2</sub> induction (additional PGE<sub>2</sub>, amniotomy, oxytocin, elective caesarean section or delay of induction if appropriate).

### 8.3 Cord prolapse

Prolapsed cord is always a potential risk at the time of membrane rupture, especially when the membranes are ruptured artificially.

#### Overview of available evidence

No evidence was identified relating to management of prolapsed cord

#### Recommendations on cord prolapse

**These recommendations were updated and replaced in 2021. Please see the NICE website for the updated guideline.**

### 8.4 Uterine rupture

Uterine rupture at the time of induction of labour is an unusual event (see Section 4.4 on induction of labour in women with a previous caesarean section).

#### Overview of available evidence

No evidence was identified relating to the management of uterine rupture.

#### Recommendation on uterine rupture

If uterine rupture is suspected during induced labour, the baby should be delivered by emergency caesarean section (refer to 'Caesarean section' (NICE clinical guideline 13)).



# Appendix A

## Declarations of interest

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This appendix includes all interests declared on or before 8 August 2007.

### A.1 GDG members

#### **Zarko Alfirevic**

RCT of misoprostol vaginal insert (local co-ordinator)

RCT of misoprostol tablets for induction of labour (local co-ordinator)

Payments per recruited participants to the University of Liverpool/Liverpool Women's Hospital

#### **Jackie Baxter**

No interests declared

#### **Andrew Calder**

Longstanding (inherited) shareholding in pharmaceutical company

Research funding in respect of clinical trial to department of obstetricians and gynaecologists

#### **Judith Green**

No interests declared

#### **Stacia Smales Hill**

No interests declared

#### **Carolyn Markham**

Co-applicant on HOLDS trial (high dose versus low dose oxytocin) for augmentation

#### **Carol McCormick**

No interests declared

#### **Hassan Shehata**

No interests declared

#### **Mary Stewart**

No interests declared

#### **Peter Stewart**

Has participated in drug trial of low-dose misoprostol for induction of labour. Payments received went to a Research and Education Fund.

In the past (last occasion in 1991) received honoraria for speaking at scientific meetings and received travel grants to attend scientific meetings related to the use of prostaglandin gel and prostaglandin vaginal tablets for the induction of labour.

#### **Richard Tubman**

No interests declared

## **A.2 NCC-WCH staff and contractors**

### **Martin Whittle**

Chair of the National Screening Committee Steering group on ultrasound screening.

### **Irene Kwan**

No interests declared

### **Debbie Pledge**

No interests declared

### **Paul Jacklin**

No interests declared

### **Jeff Round**

No interests declared

### **Rosie Crossley**

No interests declared

## **A.3 External advisers**

### **Felicity Platt**

No interests declared

## **A.4 Peer reviewers**

None

# Appendix B

## Bishop score

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**Table B.1** The Bishop score<sup>189</sup>

Cervical feature	Bishop score			
	0	1–2	3–4	5–6
Dilation (cm)	0	1	2	3
Effacement (%)	0–30	40–50	60–70	80
Station (relative to ischial spines)	–3	–2	–1/0	+1/+2
Consistency	Firm	Medium	Soft	–
Position	Posterior	Mid	Anterior	–

**Table B.2** The modified Bishop score<sup>1</sup>

Cervical feature	Modified Bishop score			
	0	1	2	3
Dilation (cm)	< 1	1–2	2–4	> 4
Length of cervix (cm)	> 4	2–4	1–2	< 1
Station (relative to ischial spines)	–3	–2	–1/0	+1/+2
Consistency	Firm	Average	Soft	–
Position	Posterior	Mid/anterior	–	–

# Appendix C

## Costs of vaginal prostaglandin (PGE<sub>2</sub>)

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**This section was updated and replaced in 2021. Please see the NICE website for the updated guideline.**

# Appendix D

## Cost-effectiveness of the timing of the first offer of induction of labour

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The question addressed in this appendix is ‘what is the cost-effective time/date during pregnancy to first offer the woman the choice of induction of labour?’ The comparison in this model is between various strategies for offering pharmaceutical induction of labour, based on the number of completed weeks and days of pregnancy.

### D.1 The model

A state-transition (Markov) model, developed in TreeAge Pro 2007<sup>®</sup>, is used to simulate the cost-effectiveness of the four strategies being considered. The strategies compared in the model are:

1. expectant management, induction not routinely offered
2. to first offer women induction at 41 weeks, and for those who decline offer induction again at 41<sup>+3</sup> weeks and at 42 weeks
3. to first offer women induction at 41<sup>+3</sup> weeks and for those who decline offer induction again at 42 weeks
4. to offer all women induction at 42 weeks.

Markov models used in decision analysis describe random processes that occur over time<sup>190</sup> and comprise a series of model cycles of equal fixed length. This allows the estimation and comparison of the costs and effects of treatments for health states that may change over time. In such a model, the patient spends each cycle in a particular health state where they accrue both costs and benefits. In this model, benefits are measured in quality-adjusted life years (QALYs). A 1 day cycle length has been used in the model. The cycle length and strategies considered in the model have been selected based on the available evidence, the expert opinion of the GDG and current practice for the management of prolonged pregnancy. This approach to modelling is appropriate given the nature of prolonged pregnancy, where birth may occur on any given day and as the relative risk of an adverse outcome increases with gestation beyond 42 weeks.\*

A Markov model is divided into a number of cycles of equal, fixed length. A hypothetical cohort of patients spend each cycle in a particular health state (e.g. good health, poor health, death). Patients can move between health states with given probabilities estimated from clinical data on the effectiveness and risks of treatment. Each health state potentially accrues both costs (of treatment) and health benefits associated with being in that state (measured in QALYs if possible). Each woman begins the Markov process in a particular health state; in this model each women entering the model is in the state ‘pregnant’. After each cycle in the model, there is a probability, based as far as possible on the evidence, that the woman will either change states or continue in the same state.

A cycle length of 1 day has been used as it allows the most flexibility when examining different strategies (41 weeks, 41<sup>+3</sup> weeks and 42 weeks). Although most clinical results are presented in terms of the number of weeks of gestation it is possible to estimate the daily probability of an event occurring.

All women who decline induction at 42 weeks would be offered expectant management and increased levels of monitoring in line with the recommendations made elsewhere in this guideline (Section 4.1).

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\* Note that, while relative risk increases with advancing gestational age, the absolute risk of an adverse outcome remains low, as detailed in Section 4.1 of this guideline.

Outcomes for the model are expressed in terms of QALYs. The key intermediate outcomes that are considered to have an important bearing on the number of QALYs generated by each strategy are perinatal death, meconium aspiration, caesarean birth and instrumental birth. QALYs combine quantity and quality of life. For example, while it is important to know how many babies are born by caesarean section, this information tells us nothing about their state of health and it is necessary to go one step further and consider how many babies born this way are relatively healthy, have a serious morbidity, are stillborn or die shortly after birth.

Maternal satisfaction is an important consideration in the induction process. While there are some studies that have included information on the health-related quality of life (or maternal satisfaction) of those women that have undergone induction, to date none of the studies identified in the economic literature review use this information to estimate the utility gain or loss of women as a result of induction. In the absence of any data that enables an estimation of a woman's utility relating to induction, this important consideration has been considered exogenous to the model. The GDG considered the impact of maternal wellbeing as part of the discussion on any recommendations following on from the model.

### D.1.1 Health states

The various health states in the Markov model are discussed below.

#### *Offer of induction and booking induction*

The cost for this aspect of the pathway is dependent on the health professional making the offer (midwife or consultant) and the setting, for example during a routine antenatal appointment or over the telephone. It was initially assumed that the offer will be made by a midwife at the routine 41 week antenatal appointment and the offer and booking process will take on average 5 minutes of this appointment; the timetable for appointments is taken from the NICE antenatal care guideline.<sup>37</sup> All subsequent offers also assumed 5 minutes of midwife time in the context of a routine appointment as recommended by current guidelines.

#### *Induction*

Induction was assumed to take place in an inpatient setting. It was initially assumed that all inductions of labour are undertaken over a 24 hour period in fitting with the model cycle length. Although some women who undergo induction of labour will clearly require more or less time for labour to begin, this is a necessary simplification of the model.

As per the guideline recommendations, the first-line induction agent is prostaglandins. For the purpose of the model, it was assumed that all women will be given a 3 mg tablet one or two times, at an interval of 2–6 hours. Actual practice may vary between units and according to the needs of individual women.

Not all women will progress to labour following the use of prostaglandins and in some cases the use of oxytocin will be required. Oxytocin was initially assumed to be required for an average time of 8 hours.

#### *Labour*

A certain proportion of births will be by caesarean section or assisted birth; this was estimated in line with the evidence in the systematic review for the guideline. There is a risk of complications with any birth. The proportion of births with complications, regardless of what those complications are, were estimated based on NHS Hospital Episode Statistics (HES) data for the purposes of calculating the costs of the birth. Additional costs associated with the specific risks and clinical outcomes identified were calculated as appropriate. Birth-related costs were estimated from the NHS tariff.

#### *Healthy live birth*

Those babies that are born without complications related to induction as identified above were assumed not to incur any further healthcare costs. This is of course a simplification of real life as some babies will require various long-term treatments but the concern here is only with those costs related to the process of induction.

*Death and serious morbidity*

The clinical reviews for the guideline were used to estimate the likelihood of neonatal mortality and serious morbidity related to induction. There is a cost associated with a neonatal death and this was estimated from the NHS tariff. For serious morbidity, a period of time was assumed to be spent in the neonatal nursery (30 days) and costs were again estimated from NHS tariffs.

**D.1.2 Model parameters**

Wherever possible, the parameter values used to populate the model were taken from peer-reviewed articles or other sources freely available in the public domain, such as the Office for National Statistics (ONS) and HES. The primary source of clinical data is the systematic review undertaken for the relevant questions in the guideline (Table D.1). Data on costs were taken from published literature identified in the systematic review of economics evidence, as well as other key sources such as the British National Formulary (BNF) for drug costs and the Public and Social Services Research Unit (PSSRU) for labour costs. In all cases, the source of the data is given alongside the listed values in Table D.2.

Outcomes for this model are measured in QALYs and these have been estimated for the otherwise healthy infant as follows: average life expectancy is approximately 76 years, with all years lived assumed to be at full health and discounted at a rate of 3.5% per year. This gives a figure of approximately 25 discounted QALYs per individual through their lifetime. Future health gains are discounted to reflect the fact that an individual would typically value health more in the present than in the future. Although it does not seem realistic to assume that all years lived will be at full health, the process of discounting health gains means that most of the QALYs gained are accrued when the individual is young, and very little health gain is accrued at an older age. The QALY decrement for babies born with serious morbidity is initially assumed to be 0.25 of a full QALY – that is, a baby that survives with a serious morbidity is assumed to only gain 0.75 QALYs for each 1 QALY gained by a healthy baby.

**D.2 Results****D.2.1 Baseline**

When the analysis was done with the baseline parameter values used in the model, then first offering induction to all women at 41 weeks should be considered cost-effective if the willingness to pay per QALY is £20,000, in line with previous recommendations from NICE. This strategy

**Table D.1** Clinical data and sources

Description	Value	Source
Probability of assisted birth when not induced	0.122	HES
Probability of caesarean section when not induced	0.24	Thomas <i>et al.</i> (2001) <sup>191</sup>
Probability of caesarean section after induction	0.19	Thomas <i>et al.</i> (2001) <sup>191</sup>
Probability of meconium aspiration at 40 weeks	0.029	Heimstad <i>et al.</i> (2006) <sup>28</sup>
Probability of meconium aspiration at 41 weeks	0.051	Heimstad <i>et al.</i> (2006) <sup>28</sup>
Probability of meconium aspiration at 42 weeks	0.047	Heimstad <i>et al.</i> (2006) <sup>28</sup>
Probability of perinatal death at 40 weeks	0.024	Hilder <i>et al.</i> (1998) <sup>21</sup>
Probability of perinatal death at 41 weeks	0.028	Hilder <i>et al.</i> (1998) <sup>21</sup>
Probability of perinatal death at 42 weeks	0.048	Hilder <i>et al.</i> (1998) <sup>21</sup>
Probability of perinatal death at 43 weeks or greater	0.058	Hilder <i>et al.</i> (1998) <sup>21</sup>
Probability of accepting induction at 41 weeks	0.6	GDG estimate
Probability of accepting induction at 41 <sup>+3</sup> weeks	0.6	GDG estimate
Probability of accepting induction at 42 weeks	0.9	GDG estimate
Probability of spontaneous labour	No fixed estimate	HES
Relative risk of vaginal birth not achieved within 24 hours of induction with PGE <sub>2</sub>	0.12	Kelly <i>et al.</i> (2006) <sup>109</sup>
Probability of using oxytocin	0.5	Expert opinion from GDG

has an incremental cost-effectiveness ratio (ICER) of £8,571 (Table D.3). All three intervention strategies that have been tested are more effective but more costly than not routinely offering induction, although all would be cost-effective when compared with no routine induction used as a common comparator (Table D.4).

### D.2.2 Sensitivity analysis

#### *Induction acceptance rates*

No published data were available on the rate of acceptance of an offer to induce in labour and so an estimate was provided by the GDG. The use of expert opinion in setting parameter values for a model results in a high degree of uncertainty over the parameter's true value. To examine how

**Table D.2** Cost data and sources

Description	Value	Source
Normal birth (no complications)	£735.00	NHS Tariff (2006–07)
Normal birth (with complications)	£1,097.00	NHS Tariff (2006–07)
Assisted birth	£1,147.00	NHS Tariff (2006–07)
Caesarean birth (no complications)	£1,370.00	NHS Tariff (2006–07)
Caesarean birth (with complications)	£1,879.00	NHS Tariff (2006–07)
3 mg dinoprostone (per tablet)	£13.28	BNF 54 (2007) <sup>111</sup>
10 mg dinoprostone pessary (within retrieval device)	£30.00	BNF 54 (2007) <sup>111</sup>
1 mg dinoprostone vaginal gel	£13.28	BNF 54 (2007) <sup>111</sup>
2 mg dinoprostone vaginal gel	£13.28	BNF 54 (2007) <sup>111</sup>
Midwife – home visit <sup>a</sup> (per minute)	£56.00 (£0.93)	PSSRU (2006) <sup>192</sup>
Midwife - hospital appointment <sup>a</sup> (unit cost/minute)	£53.00 (£0.88)	PSSRU (2006) <sup>192</sup>
Consultant (unit cost/minute)	£79 (£1.32)	PSSRU (2006) <sup>192</sup>
Oxytocin – 3 × 10 units/ml, 1ml ampoule <sup>b</sup>	£3.03	BNF 54 (2007) <sup>111</sup>
Cost of perinatal death <sup>c</sup>	£2,568	NHS Tariff 2006; NHS Reference Costs 2004
Hospital admission for induction (hospital hotel costs)	£300	
Cost of admission to neonatal nursery (per day)	£838	NHS Reference Costs 2004

<sup>a</sup> This is based on Agenda for Change Band 6 cost of a community nurse on either home visit or in a hospital setting. A unit cost for a midwife was unavailable, although it is understood that a midwife would be on a similar rate of pay.

<sup>b</sup> For 8 hours, with dosage as specified in the previous guidance.

<sup>c</sup> From NHS Reference Costs 2004 FCE data; assume that 25% of neonatal deaths are within 2 days ( $n = 974$ ). NHS Reference Costs gives this as £527. For the remaining 75%, assume 2 days of neonatal intensive care (£838 × 2 = £1,676) and that the neonate has one major diagnosis that has an NHS Tariff of £1,572. The total weighted cost of a death is then calculated as  $(0.25 \times £527) + (0.75 \times [£1,676 + £1,572]) = £2,568$ .

**Table D.3** Incremental cost-effectiveness of the four induction strategies

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,118	£119	24.861	0.035	£3,400
41 <sup>+3</sup> weeks	£1,217	£99	24.900	0.039	£2,538
41 weeks	£1,517	£300	24.935	0.035	£8,571

**Table D.4** Results with each strategy compared with a common baseline (no induction)

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,118	£119	24.861	0.035	£3,400
41 <sup>+3</sup> weeks	£1,217	£218	24.900	0.074	£2,946
41 weeks	£1,517	£518	24.935	0.109	£4,752



the results of the model exercise might be affected by the uncertainty in this parameter, sensitivity analysis of the acceptance rates was carried out. The acceptance rates varied from 100% (i.e. all women accept the first offer of induction) to 40%. The details of each acceptance rate tested and the results of the analysis are provided in the Tables D.5 to D.10.

Under each of the scenarios examined, the results did not differ greatly from the baseline analysis. In each case, the strategy of offering induction is both more costly and more effective than not offering induction. A strategy of offering induction to all women at 41 weeks is cost-effective in each scenario when compared with the next most effective strategy. When each strategy is compared with a common baseline of not offering induction routinely (not reported in the tables), all strategies are cost-effective under all acceptance rates examined.

### Costs

No sources of data on the cost of induction were identified in the systematic review of the literature for this question. Costs were estimated in line with GDG recommendations on methods of induction. To address the uncertainty in the costs of induction, a sensitivity analysis was conducted. In this additional analysis, all costs relating to the induction process itself were doubled (cost of hospital admission for induction, cost of 3 mg dinoprostone and cost of oxytocin) and the results are presented in Table D.11.

## D.3 Discussion

Offering all women an induction at 41 weeks is the most cost-effective strategy. Sensitivity analysis suggests that this finding is not particularly sensitive to changes in induction acceptance or the costs of induction.

Offering all women an induction at 41 weeks is the strategy with the greatest benefit as, within the time frame of this model, the probability of experiencing an adverse event is a positive function of time. Even though the absolute risk of adverse events remains low, the risk is a cumulative one. Therefore, women who induce at the earliest point in the model experience fewer adverse outcomes and have a concomitantly higher expected QALY. Conversely, waiting longer to offer induction reduces the treatment cost of induction. This is because an ever-diminishing pool of women requires induction with the passage of time. As the treatment costs of earlier induction outweigh any 'downstream' cost saving from a reduction in adverse events, earlier induction leads to higher overall cost. However, because the cost differential between the various approaches is relatively small, the more effective strategy is also the most cost-effective, even if a doubling in the costs of induction is assumed. Therefore, offering induction to all women at 41 weeks is justifiable on economic grounds. Clearly women cannot be forced to have an induction if they do not want one but, by delaying induction, no opportunity cost is imposed on other health services users and therefore such decisions are also reasonable in terms of economic efficiency.

**Table D.5** Sensitivity analysis: induction acceptance = 100%

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,130	£131	24.865	0.039	£3,359
41 <sup>+3</sup> weeks	£1,288	£158	24.926	0.061	£2,590
41 weeks	£1,678	£390	24.956	0.030	£13,000

**Table D.6** Sensitivity analysis: induction acceptance = 90% at 41 weeks, 90% at 41<sup>+3</sup> weeks, 95% at 42 weeks

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,124	£125	24.863	0.037	£3,378
41 <sup>+3</sup> weeks	£1,271	£147	24.920	0.057	£2,579
41 weeks	£1,645	£374	24.952	0.032	£11,688

**Table D.7** Sensitivity analysis: induction acceptance = 80% at 41 weeks, 80% at 41<sup>+3</sup> weeks, 90% at 42 weeks

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,118	£119	24.861	0.035	£3,400
41 <sup>+3</sup> weeks	£1,253	£135	24.913	0.052	£2,596
41 weeks	£1,607	£353	24.945	0.032	£11,031

**Table D.8** Sensitivity analysis: induction acceptance = 70% at 41 weeks, 70% at 41<sup>+3</sup> weeks, 90% at 42 weeks

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,118	£119	24.861	0.035	£3,400
41 <sup>+3</sup> weeks	£1,235	£117	24.906	0.045	£2,600
41 weeks	£1,564	£329	24.941	0.035	£9,400

**Table D.9** Sensitivity analysis: induction acceptance = 50% at 41 weeks, 50% at 41<sup>+3</sup> weeks, 80% at 42 weeks

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,107	£108	24.857	0.031	£3,484
41 <sup>+3</sup> weeks	£1,194	£87	24.892	0.035	£2,486
41 weeks	£1,461	£267	24.925	0.033	£8,091

**Table D.10** Sensitivity analysis: induction acceptance = 40% at 41 weeks, 40% at 41<sup>+3</sup> weeks, 70% at 42 weeks

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,097	£98	24.853	0.027	£3,630
41 <sup>+3</sup> weeks	£1,168	£71	24.882	0.029	£2,448
41 weeks	£1,398	£230	24.913	0.031	£7,419

**Table D.11** Sensitivity analysis: doubling the induction costs

Strategy	Cost	Incremental cost	Effect (QALYs)	Incremental effect (QALYs)	ICER
No induction	£999	–	24.826	–	–
42 weeks	£1,206	£207	24.861	0.035	£5,914
41 <sup>+3</sup> weeks	£1,393	£187	24.900	.0.039	£4,795
41 weeks	£1,902	£509	24.935	0.035	£14,543

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