Royal College of Obstetricians and Gynaecologists

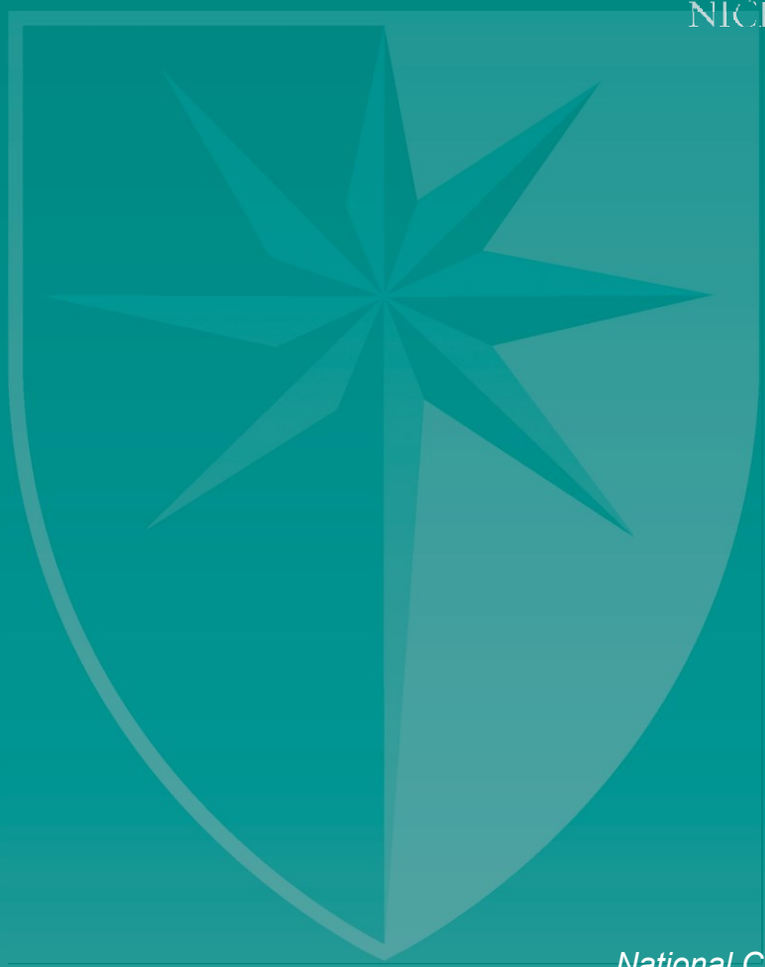
Bringing to life the best in women's health care

The Royal College of Midwives

Caesarean section

November 2011

NICE Clinical Guideline



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

Caesarean section

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

Commissioned by the National Institute for Health and Clinical Excellence

November 2011

Update information
August 2012: We have removed recommendations 40 and 41 from this guideline. The topic 'place of birth' will be addressed by the update of the clinical guideline 'Intrapartum care' which is currently in development. In the meantime, please see the current intrapartum care guideline (www.nice.org.uk/guidance/CG55) for current guidance on place of birth. In this document, the change is marked with black strikethrough.

October 2012: We have added a footnote to recommendation 113 to indicate that healthcare professionals should consult the guideline on surgical site infection (www.nice.org.uk/guidance/CG74) for more recent recommendations on wound care.

June 2018: The advice on which analgesia to use for post-operative pain has been updated.

April 2019: Recommendation 1.4.6.17 has been updated by recommendation 1.3.21 in the NICE guideline on surgical site infection.

August 2019: Recommendation 1.6.3.2 on patient-controlled analgesia after caesarean section has beenwithdrawn because of safety concerns and changes in practice in the UK. We will be looking at analgesia after caesarean section as part of the planned 2020 update of this guideline.

These changes can be seen in the short version of the guideline at:
http://www.nice.org.uk/guidance/cg132

September 2019: Recommendations 1.2.2.1 and 1.2.2.2 on multiple pregnancy have been updated by section 1.10 on mode of birth in NICE's guideline on twin and triplet pregnancy.

See https://www.nice.org.uk/guidance/ng137 for more information.

July 2021: We removed reference to the Joel–Cohen transverse incision in the recommendation on abdominal wall incision to clarify what should be done while the recommendation is being updated. See www.nice.org.uk/guidance/NG192 for more information, including the exceptional surveillance review on surgical opening technique.

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This guideline has been fully funded by NICE. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient.

Implementation of this guidance is the responsibility of local commissioners and/or providers.

Contents

Appendices A–K are in a separate file.

1 Guideline summary

1.1 Guideline development group membership, NCC-WCH staff and acknowledgements

Original (2004) version

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Updated (2011) version

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1.2 Foreword

This guidance is a partial update of NICE clinical guideline 13 (published April 2004) and will replace it.

New and u pdated recommendations have been included on t he diagnosis and management of morbidly adherent placenta; the care of women with HIV; the appropriate decision-to-delivery interval for unplanned caesarean section (CS); the timing of antibiotic prophylaxis provision; the risks and benefits of CS and vaginal birth; the risks and benefits of vaginal birth following a previous CS; and the appropriate care pathway for women requesting a CS in the absence of an obstetric or medical indication.

Recommendations are marked to indicate the year of the last evidence review:

- **[2004]** if the evidence has not been reviewed since the original guideline.
- **[2004]**, amended **[2011]** if the evidence has not been reviewed, but an essential change has been made that affects the meaning of the recommendation.
- **[2011]** if the evidence has been reviewed but no change has been made to the recommendation.
- **[new 2011]** if the evidence has been reviewed and the recommendation has been updated or added.

Appendix J contains recommendations from the 2004 guideline that NICE has deleted in the 2011 update. This is because the evidence has been reviewed and the recommendation has been updated or because NICE has updated other relevant guidance and has replaced the original recommendations. Where recommendations have been replaced, details are provided. Where there is no replacement recommendation, an explanation for the proposed deletion is given.

A grey bar down the side of the page indicates those sections of the guideline which are new or have been updated. Material from the original guideline which has been d eleted can be f ound in Appendix I.

2011 Update

1.3 Algorithm

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

1.4 Key priorities for implementation

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

1.5 Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

1.6 Key research recommendations

Number	Research recommendation	See section
	Risks and benefits of CS	

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation	See section
	Maternal request for CS	
RR 15	What support or psychological interventions would be appropriate for women who have a f ear of vaginal childbirth and request a CS? Interventions for evaluation could include: • support from a named member of the maternity team • continuity of carer • formal counselling • cognitive behavioural therapy. Outcomes could include: • mode of birth planned at term • psychological outcomes (postnatal depression, post-traumatic stress disorder, self-esteem, mother-infant bonding) • breastfeeding. Why this is important Fear of vaginal childbirth may stem from: • fear of damage to the maternal pelvic floor • damage to the baby during childbirth • self-doubt on the ability to physically achieve vaginal birth • previous childbirth experience • unresolved issues related to the genital area. Currently there is a wide variation in practice and limited resources lead to limited availability of effective interventions. Interventions that may be appropriate include: • antenatal clinics dedicated to providing care for women with no obstetric indications who request a CS • referral to a psychologist or a mental health professional • referral to an obstetric anaesthetist • intensive midwifery support. Continuity of healthcare professional support from the antenatal to the intrapartum periods and 'one to one' midwifery care during labour are also often lacking and may make a difference to women who are anxious or afraid. All of these interventions have different resource implications and there is no clear evidence to suggest that any are of benefit. The proposed research would compare in a r andomised controlled trial two or more of these interventions in women requesting a CS. In the absence of any evidence, there is a case for comparing these interventions with routine antenatal care (that is, no special intervention). This research is relevant because it would help to guide the optimal use of these limited resources and future guideline recommendations.	5.9

Number	Research recommendation	See section
	Decision-to-delivery interval for unplanned CS	
RR 28	What factors influence the decision-to-delivery interval when there is a category 1 level of urgency for CS? Factors to be investigated could include: • staff grade/level of experience • skill mix within the multidisciplinary team • task allocation • methods of communication • time of day • availability of ongoing staff training about emergency procedures and levels of attendance. The research could be conducted using simulation methods and video observation to determine what factors influence the decision-to-delivery interval for category 1 CS. The videos could also be used to train staff. Why this is important 'Crash' CS is a ps ychologically traumatic event for women and their partners and is also stressful for clinical staff. Staff and resources may have to be obtained from other areas of clinical care. This should be undertaken as efficiently and effectively as possible, minimising anxiety and ensuring the safety of the mother and her baby. For category 1 C S there is a r ecognised urgency to deliver as quickly as is reasonably possible. The majority of research in this area is quantitative and looks at the impact of the decision-to-delivery interval on various aspects of fetal and maternal outcomes rather than the interplay of factors that can affect this time period itself. Much of this evidence is retrospective. Although some work has been c onducted in the UK to examine where the systematic delays lie and how to avoid them (Tuffnell et al., 2001), more work is needed to determine how to optimise the decision-to-delivery interval. This work should use qualitative as well as quantitative research methods to assess which factors influence the decision-to-delivery interval for a c ategory 1 CS. Evaluation of these factors could be used to inform future NICE guidance, for example specific guidance for management of category 1 CS. Such information could also be used by hospitals for maternity services planning and at a team level would assist with audit and ongoing evaluation and training of the multidisciplinary team. A large amount of NHS and other state funding is used to provide continuing care for infants who are disabled as a r esult of birth asphyxia and in providing lifelong support for the child and their family. In addition, large sums of public money are spent on litigation and compensation in some of these cases through the Clinical Negligence Scheme for Trusts (CNST). If research helped to minimise the impact of birth asphyxia this would reduce the costs of continuing care to the state and t he burden to the child, their family and the wider community.	7.3

Number	Research recommendation	See section
	More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate in the legal system and may help to reduce the cost to the state of related litigation.	
RR 29	A prospective study to determine whether the decision-to-delivery interval has an impact on maternal and neonatal outcomes when there is a category 2 level of urgency for CS. Important primary outcomes would be • fetal wellbeing (such as cord blood gases, Apgar score at 5 minutes, hypoxic encephalopathy, neonatal respiratory problems, unanticipated admission to neonatal intensive care unit (NICU), duration of stay in the NICU) • maternal wellbeing (such as haemoglobin levels on day 2, need f or blood transfusion, duration of hospital stay controlled for prolonged neonatal stay and general health/wellbeing). Valuable secondary outcomes could include: • fetal trauma at delivery • iatrogenic maternal bladder or bowel injury • postoperative maternal infectious morbidity • establishment of breast-feeding • psychological outcomes for women, such as the development of postnatal depression/post-traumatic stress disorder. **Why this is important** This research is important to inform the ongoing debate about the management of category 2 CS. The 'continuum of risk' in this setting has been recognised. However, the majority of work in this area, looking at maternal and fetal outcomes, generally considers unplanned caesarean sections as a whole group without making any distinction between degrees of urgency. Furthermore much of this work is retrospective. The majority of women who undergo intrapartum CS fall into the category 2 level of urgency (Thomas et al., 2001) and therefore specific information for this group could affect and benefit many women and contribute to the delivery of equity of care. Delay in delivery with a c ompromised fetus may result in major and long-term harm including cerebral palsy and other major long-term disability. The immediate and long-term effect on a family of the birth of a b aby requiring life-long specialised care and support is enormous. If such harm could be avoided by appropriate haste this would be an i mportant improvement in outcome. However, if such haste is of no benefit then any related risk of adverse maternal outcome needs to be minimised. A large amount of NHS and other state funding is used to provide continuing care for infants who are disabled as a result of delay in delivery and in providing lifelong support for the child and their family. In addition, large sums of public money are spent on	7.3

Number	Research recommendation	See section
	litigation and compensation in some of these cases through the Clinical Negligence Scheme for Trusts (CNST). If research helped to minimise the impact of delay in delivery this would reduce the costs of continuing care to the state and the burden to the child, their family and the wider community. More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate within the legal system and may help to reduce the cost to the state of related litigation.	
RR 30	Repeat of the National Caesarean Section Sentinel Audit The original CS guideline included a set of 'auditable standards'. It would be a straightforward task to produce an up dated set of auditable standards based on the important topics covered in the updated guideline. These could include: • consent • indications (including maternal request) • procedural aspects • maternal and fetal outcomes. Many of the outcomes documented in a ne w CS audit would relate directly to recommendations in this CS guideline update. Researchers may also want to consider categorising different reasons underlying maternal request for CS such as previous poor childbirth experience, longstanding fear of childbirth, belief that CS is safer for the baby etc. An additional useful feature of the audit would be to record key related data, such as the proportion of CS for a breech presentation that had an attempted external cephalic version. Why this is important During the 10 years since the National Caesarean Section Sentinel Audit was undertaken (2000–2001), many of the findings may have changed significantly. The audit examined who was having a C S and why, as well as the views of women having babies and the obstetricians looking after them. The audit found that a 20% CS rate was considered too high by 51% of obstetricians. UK CS rates now average about 25%. A repeat of the CS Sentinel Audit would reveal any changes in indications and t he views of women and obs tetricians. The current literature does not adequately address the issue of maternal request for CS and this is one aspect the audit may address. Women's views on maternal request for CS for when there are no o bstetric indications are particularly relevant. Such requests may be o n the rise and t he reasons are not always clearly expressed or documented. The methodology of the audit is established, making a r epeat feasible. This should be given high priority because the benefit to the NHS would be significant.	7.3

2011 Update

1.7 Research recommendations

Number	Research recommendation	See section
	Risks and benefits of CS	
RR 1	This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.	
RR 2	Further evaluation is needed to determine the impact of demographic and clinical factors (such as ethnic group, increase in body mass index) and attitudinal factors on CS rates.	4.2
	Breech presentation	
RR 3	Further research is needed to determine the effect of caesarean section compared with vaginal birth for women with: • preterm breech • a breech presentation that is diagnosed in the second stage of labour.	5.1
	Multiple pregnancy	
RR 4	RCTs are needed to evaluate the benefits and r isks to mothers and babies of CS for delivery of twin and triplet pregnancies.	5.2
	Preterm birth and CS	
RR 5	RCTs are needed to evaluate the impact of CS on the benefits and risks to mothers and babies born preterm.	5.3
	Small for gestational age	
RR 6	RCT evidence is needed to determine the effect of planned CS on neonatal mortality and morbidity for 'small for gestational age' babies.	5.4
	Morbidly adherent placenta	
RR 7	How accurate is 3D ultrasound compared with 2D ultrasound or MRI scanning for diagnosing morbidly adherent placenta?	5.6
RR 8	What is the effectiveness of procoagulant agents (such as recombinant factor VIIa, beriplex, tranexamic acid, fibrinogen concentrate) in reducing blood loss in women with morbidly adherent placenta?	5.6
RR 9	What is the effectiveness of point of care testing for haematological indices in women with an established postpartum haemorrhage and in cases of morbidly adherent placenta in reducing maternal morbidity?	5.6
RR 10	What is the effectiveness of the components of the package of care for morbidly adherent placenta such as imaging techniques (e.g. interventional radiology including balloon catheters), stenting of ureters, removal of the placenta, and cell salvage in reducing morbidity associated with maternal blood loss?	5.6
RR 11	What is the appropriate gestational age of elective birth for babies of women with a morbidly adherent placenta?	5.6
RR 12	What is the effectiveness of performing an el ective hysterectomy to reduce morbidity associated with blood loss in women with morbidly adherent placenta?	5.6

2011 update

2011 update

Number	Research recommendation	See section
	Mother-to-child transmission of maternal infections	
RR 13	RCTs are needed to evaluate the effect of planned CS in addition to immunoglobulin and vaccination on MTCT of hepatitis B.	5.8
RR 14	RCTs are needed t o determine whether planned CS should be offered to prevent MTCT of HSV to women with recurrence of HSV at birth and in women in whom the primary HSV infection occurs in the first trimester of pregnancy.	5.9
	Maternal request for CS	
RR 15	What support or psychological interventions would be appropriate for women who have a fear of vaginal childbirth and request a CS?	5.9
RR 16	Medium to long term quality of life study comparing psychological and physical outcomes in women who have had a requested and given birth by CS compared with women who plan a vaginal birth.	5.9
RR 17	Qualitative and quantitative research should be carried out to look at the reasons that lead to pregnant women's request for CS.	5.9
RR 18	The effect of counselling and other interventions such as second opinion and provision of support on the likelihood of CS for women who express a preference for CS need further evaluation.	5.9
	Place of birth	
RR 19	RCTs comparing planned birth in a stand-alone birthing centre to birth in conventional maternity facilities or midwifery led units.	6.1
RR 20	Qualitative research is needed to explore women's opinions on place of birth and the impact of place of birth on their birth experiences.	6.1
RR 21	Further RCTs are needed to determine the effect of 'delayed admission in labour' on the likelihood of CS.	6.1
	Factors reducing the likelihood of CS	
RR 22	RCT evidence is needed to determine the impact of partograms based on d ifferent curves of labour on C S rates and m orbidity outcomes.	6.2
	No influence on likelihood of CS	
RR 23	RCT evidence is required to evaluate the effect of parenteral analgesia (intramuscular and intravenous morphine based analgesia) used during childbirth on the likelihood of CS.	6.3
RR 24	RCTs are needed to establish the safety and efficacy of complementary therapies used during labour.	6.3
	'Failure to progress' in labour and CS	
RR 25	More RCTs are required to determine the effect of oxytocin augmentation as single interventions or as part of a package of interventions (such as "active management of labour") on the likelihood of CS and other outcomes including women's satisfaction with care.	6.4

Number	Research recommendation	See section
RR 26	Further research on t he short and longer term health impacts of CS during the second stage compared to operative vaginal delivery are needed.	6.4
	Eating during labour	
RR 27	RCTs that evaluate the effects of eating during labour compared with restricting intake on l abour outcomes are needed. Cohort or case control studies on the risk factors for aspiration and other morbidities for women having CS are needed.	6.5
	Decision-to delivery-interval for unplanned CS	
RR 28	What factors influence the decision-to-delivery interval when there is a category 1 level of urgency for CS?	7.3
RR 29	A prospective study to determine whether the decision-to-delivery interval has an impact on maternal and neonatal outcomes when there is a category 2 level of urgency for CS.	7.3
RR 30	Repeat of the National Caesarean Section Sentinel Audit.	7.3
	Surgical techniques for CS	
RR 31	RCTs are required to determine the effectiveness of adhesive drapes at CS in reducing blood spillage and cross infection and improving safety for staff in the operating room.	7.6
RR 32	RCTs are needed to evaluate the effectiveness of incisions made with diathermy compared with surgical knife in terms of operating time, wound infection, wound tensile strength, cosmetic appearance and women's satisfaction with the experience.	7.6
RR 33	RCTs are needed to determine the effect of delayed cord clamping on neonatal outcomes including transient tachypnoea of the newborn and risk of maternal fetal transfusion in rhesus negative women for term and preterm births.	7.6
RR 34	RCTs are required to determine the effectiveness of mass closure compared to layered closure of the abdominal wall incision at CS particularly for transverse abdominal incisions.	7.6
RR 35	Research is required to assess the effect of the various surgical techniques for CS on f uture surgery such as repeat CS and the incidence of complications during future surgery such as hysterectomy and urogynaecological procedures.	7.6
RR 36	More RCTs are needed to determine the effect of wound drainage of postoperative morbidity especially in women more at risk of this outcome such as obese women.	7.6
RR 37	More RCTs are needed to determine the effect of staples compared to subcuticular sutures for skin closure at CS on postoperative pain, cosmetic appearance and removal of sutures and staples.	7.6
RR 38	What is the most effective antibiotic to prevent maternal infectious morbidity post-CS when given prior to incision.	7.6
RR 39	What is the physical, psychological and social impact of maternal infectious morbidity post-CS?	7.6

2011

2011

Number	Research recommendation	See section
RR 40	More evaluation of interventions such as seeing baby born via a lowered screen; music playing in theatre; silence in theatre so mother's voice is the first baby hears and l owering the lights in theatre during CS are needed.	7.6
	Neonatal encephalopathy and cerebral palsy	
RR 41	Further evaluation of the long and short term risks and benefits of CS compared with vaginal birth for babies is required.	8.2
	Thermal care for babies born by CS	
RR 42	Research is required to establish the thermal care requirements for babies born by CS.	8.4
	Pain management after CS	
RR 43	Further research is needed to determine the effect of wound infiltration with local anaesthetic at CS on the need for post-CS analgesia.	9.2
	Respiratory physiotherapy after CS	
RR 44	Research is needed to establish the effect of non-respiratory physiotherapy for women following CS on post-CS recovery.	9.5
	Debriefing for women after CS	
RR 45	More RCT evidence is required to determine the effect of midwifery-led debriefing following CS.	9.6
	Pregnancy and childbirth after CS	
RR 46	A comparison of the long term psychological and physical outcomes between women who have chosen and/or been advised towards a VBAC or a planned repeat CS.	11.2
RR 47	An evaluation of the effectiveness of continuity of carer on t he proportion of women planning and achieving a VBAC, and the short and l ong term psychological and p hysical outcomes of women following a planned VBAC.	11.2

2011 Update

1.8 Other versions of the guideline

Details about the other versions of the guideline will be included here once the guideline is published.

1.9 Schedule for updating the guideline

Clinical guidelines commissioned by NICE are published with a review date 3 years from the date of publication. Reviewing may begin before 3 years have elapsed if significant evidence that affects guideline recommendations is identified sooner.

2 Introduction

2.1 Caesarean section

In the UK 20–25% of births are undertaken by caesarean section (CS). The indications for the procedure vary. This evidence-based guideline has been developed to help ensure consistency and quality of care experienced by women in these groups:

- women who have had a CS in the past and are now pregnant again
- women who have a clinical indication for a CS
- women who are considering a CS in the absence of a clinical indication.

It provides evidence-based information for healthcare professionals and women about:

- the risks and benefits of planned CS compared with planned vaginal birth
- specific indications for CS
- effective management strategies to avoid CS
- anaesthetic and surgical aspects of care
- interventions to reduce morbidity from CS
- organisational and environmental factors that affect CS rates.

For the update the following topics have been addressed:

- the risks and benefits of planned CS compared with planned vaginal birth
- care of women considered at risk of a morbidly adherent placenta
- appropriate care and choices for women who are HIV positive
- care of women requesting a CS in the absence of a clinical indication
- audit standards with respect to the decision-to-delivery interval
- timing of the administration of antibiotics for CS
- appropriate care and choices for those women who have previously had a CS.

This guideline links with other relevant NICE guidelines such as Antenatal care (NCC-WCH, 2008), Induction of labour (NCC-WCH, 2008), Intrapartum care (NCC-WCH, 2007), Diabetes in pregnancy (NCC-WCH, 2008), Hypertension in pregnancy (NCC-WCH, 2010) and P ostnatal care (NCC-PC, 2006). It also links with the published NICE interventional procedure Intra-operative blood salvage in obstetrics (NICE, 2005), the findings of the National Sentinel Caesarean Section Audit (NSCSA)[4] and the National Service Framework for Children, Young People and Maternity Services: Maternity services (Department of Health, 2004).

In 1980, the CS rate in England was 9%: this increased to 13% in 1992 (Treffers PE & Pel M, 1993), 21% in 2000 (RCOG, 2001), 23% in 2004 (Quick Stats, 2005) and 24.8%* in 2009 (Department of Health, 2009). Similar increases have been seen in all developed countries although the absolute rates vary; for example, the rate is about 14% in Nordic countries and over 40% in Italy (Quick Stats, 2005). However, in developing countries CS rates are generally less than 5% (Buekens et al., 2003). There are a num ber of possible reasons for the increased rates in developed countries including

* This is based on all deliveries taking place in NHS hospitals (in England), but excludes home births and those taking place in independent sector hospitals.

changes in socio-demographic factors, clinical practices and the attitudes of professionals and women to the procedure.

Many of the factors contributing to CS rates are often poorly understood. The guideline has not sought to define acceptable CS rates. Instead, the purpose of this guideline is to enable clinicians to give appropriate, research-based advice to women and their families. This will enable the woman to make properly informed decisions about her care.

2.2 For whom is this guideline intended

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

- primary, community and secondary healthcare professionals who are involved in the care of women during pregnancy and birth, and in the postnatal period, who may need or have had a CS
- those with responsibilities for commissioning and p lanning health services, such as primary care trust commissioners (UK) and Welsh Assembly Government officers
- public health and trust managers
- pregnant women, their families, birth supporters and other carers.

2.3 Related NICE guidance

- Antenatal and postnatal mental health. NICE clinical guideline 45 (2007). Available from http://guidance.nice.org.uk/CG45
- Antenatal care. NICE clinical guideline 62 (2008). Available from http://guidance.nice.org.uk/CG62
- Diabetes in pregnancy. NICE clinical guideline 63 (2008). Available from http://guidance.nice.org.uk/CG63
- Hypertension in pregnancy. NICE clinical guideline 107 (2010). Available from http://guidance.nice.org.uk/CG107
- Induction of labour. NICE clinical guideline 70 (2008). Available from http://guidance.nice.org.uk/CG70
- Intrapartum care. NICE clinical guideline 55 (2007). Available from http://www.nice.org.uk/CG55
- Multiple pregnancy. NICE clinical guideline 129 (2011). Available from http://www.nice.org.uk/CG129
- Postnatal care. NICE clinical guideline 37 (2006). Available from http://guidance.nice.org.uk/CG37
- Surgical site infection. NICE clinical guideline 74 (2008). Available from http://guidance.nice.org.uk/CG74
- Venous thromboembolism – reducing the risk. NICE clinical guideline 92 (2010). Available from http://guidance.nice.org.uk/CG92

3 Guideline development methodology

3.1 Original (2004) methodology

The guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups.[13]

Literature search strategy

The aim of the literature review was to identify and synthesise relevant evidence within the published literature, in order to answer specific clinical questions. Searches were performed using generic and specially developed filters, relevant medical subject heading terms and free-text terms. Details of all literature searches are available on application to the NCC-WCH.

The National Guidelines Clearinghouse database, the Turning Research into Practice database, and the Organising Medical Networked Information service on the Internet were searched for guidelines produced by other development groups. The reference lists in these guidelines were checked against our searches to identify any missing evidence.

Searches were carried out for each topic of interest. The Cochrane Library (up to Issue 4, 2003) was searched to identify systematic reviews (with or without meta-analyses) of randomised controlled (clinical) trials (RCTs) and individual RCTs. The electronic databases MEDLINE (Ovid version for the period January 1966 to January 2004), EMBASE (Ovid version for the period between 1988 to January 2004), the Cumulative Index to Nursing and Allied Health Literature, the British Nursing Index and PsychInfo were also searched, as was the Database of Abstracts and Reviews of Effectiveness.

There was no systematic attempt to search the 'grey literature' (conferences, abstracts, theses and unpublished trials). A preliminary scrutiny of titles and abstracts was undertaken and full papers were obtained if the research question addressed the guideline development group's (GDG's) question relevant to the topic. Following a further review of the full version of the study, articles that did not address the Group's question were excluded. Studies that did not report relevant outcomes were also excluded. Submitted evidence from stakeholders was included where the evidence was relevant to the Group's clinical question and was of equivalent or better quality than the research identified in the literature searches.

The economic evidence presented in this guideline is not a systematic review of all the economic evidence around CS, but a review of evidence relating to specific aspects of CS In addition to the databases listed above, the Health Economic Evaluations Database and the NHS Economic Evaluations Database were searched for relevant economic studies.

The search strategies were designed to find any economic study related to CS. Relevant references in the bibliographies of reviewed papers were also identified. Abstracts and database reviews of papers found were reviewed by the health economists and were excluded if they appeared not to contain any cost data relevant to the UK setting or did not relate to the precise topic or question being considered. Studies were included if they focused on the appropriate clinical question and were generalisable to the England and Wales setting. The review of the evidence included cost-effectiveness studies, cost–consequence studies (cost of present and f uture costs only) and high quality systematic reviews of the evidence (see below).

Clinical effectiveness

For all subject areas, evidence from the study designs least subject to bias was included. Where possible, the highest levels of evidence were used, but all papers were reviewed using established guides.[14–20] Published systematic reviews or meta-analyses were used where available. For subject areas where neither was available, other appropriate experimental or observational studies were sought.

Identified articles were assessed methodologically and the best available evidence was used to form and support the recommendations. The highest level of evidence was selected for each clinical question. The retrieved evidence was graded according to the evidence-level structure shown in Table 3.1.

Table 3.1 Levels of evidence

Level	Evidence
1a	Systematic review or meta-analysis of randomised controlled trials
1b	At least one randomised controlled trial
2a	At least one well-designed controlled study without randomisation
2b	At least one well-designed quasi-experimental study, such as a cohort study
3	Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case–control studies, and case series
4	Expert committee reports, or opinions and/or clinical experience of respected authorities

The clinical question dictated the highest level of evidence that could be sought. For issues of therapy or treatment the highest possible level of evidence was a meta-analysis of RCTs or an i ndividual RCT.

For issues of prognosis, a cohort study was the best possible level of evidence. This equates to a grade B recommendation (see below). However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of evidence attainable for that type of clinical question.

For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an e valuation of the effectiveness of the test in the management and o utcome was required, evidence from RCTs or cohort studies was sought. For questions about women's beliefs, attitudes and experiences of childbirth and CS, qualitative research was reviewed.

All retrieved articles were appraised methodologically using established guides. Where appropriate, if a systematic review, meta-analysis or RCT existed in relation to a topic, studies of a weaker design were excluded.

The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers in the form of evidence tables and agreeing brief statements that accurately reflected the relevant evidence. Quantitative synthesis (meta-analysis) was performed where appropriate. Meta-analyses based on dichotomous outcomes are presented as relative risks with 95% confidence intervals.

For the purposes of this guideline, data are presented as absolute risks, risk ratios or odds ratios where relevant (that is, in RCTs and cohort studies). Where the data are statistically significant they are also presented as numbers needed to treat (for beneficial outcomes) or numbers need to harm (for adverse effects of treatment) if relevant.

Health economics

The purpose of including economic evidence in a clinical guideline is to allow recommendations to be made not just on the clinical effectiveness of different forms of care, but also on their cost effectiveness. The aim is to produce guidance that uses scarce health service resources efficiently, that is providing the best possible care within resource constraints.

There is economic literature that has considered the economic costs and consequences of different modes of birth. The economic evidence is focused around the cost of CS compared to vaginal birth. The economic evidence presented in this guideline is not a systematic review of all the economic evidence around CS. Specific topics were considered where it was thought that economic evidence would help them to inform decision making.

Topics for economic analysis were selected on t he following basis by the guideline development group:

- Does the proposed topic have major resource implications?
- Is there a change of policy involved?
- Are there sufficient data of adequate quality to allow useful review or modelling?
- Is there a lack of consensus amongst clinicians?
- Is there a particular area with a large amount of uncertainty?

Where the above answers are “yes”, this indicated that further economic analysis including modelling was more likely to be useful.

A simple economic model was developed for each of the specific topic areas for which the economic evidence was reviewed, in order to present the guideline development group with a coherent picture of the costs and consequences of the decisions based on t he clinical and economic evidence. The health economist undertook the literature review in these specific areas and obtained cost data considered to be the closest to current UK opportunity cost (the value of the resources used, rather than the price or charge). The criteria for assessing the economic papers was based on that developed by Drummond et al (1997)[21] and the format of the abstract follows that of the NHS Economic Evaluation Database (NHS EED) managed by the NHS Centre for Reviews and Dissemination (http://nhscrd.york.ac.uk/).

Health economics evidence was available for the following areas:

- external cephalic version for breech presentation at term
- CS in the management of women with breech presentation
- HIV/AIDS
- herpes simplex virus
- vaginal birth after CS
- maternal request for CS
- use of antibiotics at CS
- intrathecal diamorphine.

The economic evidence is based not only on the economic literature, but is also consistent with the clinical effectiveness evidence presented in the guideline.

Forming and grading recommendations

The GDG was presented with the summaries (text and evidence tables) of the best available research evidence to answer each clinical question. Recommendations were based on, and explicitly linked to, the evidence that supported them. Where possible, the GDG worked on an informal consensus basis. Formal consensus methods (the nominal group technique) were employed when required (e.g. grading recommendations and agreeing audit criteria).

The strength of evidence corresponding to each level of recommendation is shown in Table 3.2. The grading of recommendations follows that outlined in the Health Technology Assessment 'How to develop cost conscious guidelines'.[22]

Summary results are presented in the guideline text. More detailed results and other data are presented in the relevant evidence tables.

Table 3.2 Grading of recommendations

Grade	Strength of evidence
A	Based directly based on level 1 evidence
B	Based directly on level 2 evidence or extrapolated from level 1 evidence
C	Based directly on level 3 evidence or extrapolated from level 1 or level 2 evidence
D	Based directly on level 4 evidence or extrapolated from level 1, level 2 or level 3 evidence
GPP	Good practice point based on the view of the guideline development group
NICE TA	Recommendation taken from a NICE Technology Appraisal

External review

The guideline has been developed in accordance with the NICE guideline development process. This has included the opportunity for registered stakeholders to comment on the scope of the guideline, the first draft of the full and summary guidelines and the second draft of all versions of the guideline. In addition the drafts were reviewed by an independent Guideline Review Panel and the Patient Involvement Unit established by NICE. The summary of recommendations was reviewed the NICE Executive.

The comments made by the stakeholders, peer reviewers, the Guideline Review Panel and NICE were collated and presented anonymously for consideration by the GDG. All comments were considered systematically by the GDG and the resulting actions and responses were recorded.

3.2 Methodology for 2011 update

This guidance was commissioned by NICE and developed in accordance with the guideline development process outlined in the 2009 edition of The Guidelines Manual (www.nice.org.uk/guidelinesmanual)

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

Developing review questions and protocols and identifying evidence

The GDG formulated review questions based on the scope (see Appendix A) and prepared a protocol for each review question (see Appendix D). These formed the starting point for systematic reviews of relevant evidence. Published evidence was identified by applying systematic search strategies (see Appendix E) to the following databases: Medline, Medline In-Process, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects). Searches to identify economic studies were undertaken using Medline, Embase, the Cochrane Central Register of Controlled Trials, the NHS Economic Evaluation Database (NHS EED) and the Health Technology Assessment (HTA) database. Dates of searching and database coverage are given with the details of the search strategies in Appendix E.

Where appropriate, review questions were grouped together for searching. Animal studies were excluded from Medline and both Medline and Embase were limited to English-language studies only. Searches designed to update sections of the existing guideline were limited to 2003 onwards; searches for new review areas were not limited by date. Scottish Intercollegiate Guidelines Network (SIGN) search filters were used to identify particular study designs, such as randomised controlled trials (RCTs). There was no systematic attempt to search grey literature (conference abstracts, theses or unpublished trials), nor was hand searching of journals not indexed on the databases undertaken.

Towards the end of the guideline development process, the searches were updated and re-executed to include evidence published and indexed in the databases by 17 March 2011.

Reviewing and synthesising evidence

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

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

The type of review question determines the highest level of evidence that may be sought. For issues of therapy or treatment, the highest possible evidence level is a well-conducted systematic review or meta-analysis of RCTs, or an individual RCT. In the GRADE approach, a body of evidence for a given outcome based entirely on such studies has an initial quality rating of high, and this may be downgraded to moderate, low or very low if factors listed above are not addressed adequately. For issues of prognosis, the highest possible level of evidence is a c ontrolled observational study (a cohort study or case–control study), and a body of evidence for a particular outcome based on such studies would have an initial quality rating of low, which might be downgraded to very low or upgraded to moderate or high, depending on the factors listed above.

For each review question the highest available level of evidence was sought. Where appropriate, for example, if a systematic review, meta-analysis or RCT was identified to answer a question directly, studies of a weaker design were not considered. Where systematic reviews, meta-analyses and RCTs were not identified, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the accuracy of the test was required, but where an e valuation of the effectiveness of the test in the clinical management of the condition was required, evidence from RCTs or cohort studies was optimal. For studies evaluating the accuracy of a d iagnostic test, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and likelihood ratios for positive and negative test results (LR+ and LR–, respectively) were calculated or quoted where possible (see Table 3.3).

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

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

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

Table 3.3 '2 x 2' table for calculation of diagnostic accuracy parameters

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

Incorporating health economics

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

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

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

- diagnosis of morbidly adherent placenta (see Sections 5.6 for summary and 13.2 for full details)
- maternal request for CS (see Sections 5.9 for summary and 13.3 for full details)
- vaginal birth after CS (see Sections 11.2 for summary and 13.4 for full details).

Evidence to recommendations

For each review question recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, short clinical and, where appropriate, cost effectiveness evidence statements were drafted by the technical team and presented alongside the evidence profiles, and then agreed by the GDG. Statements summarising the GDG's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared to ensure transparency in the decision-making process. The criteria used in moving from evidence to recommendations are summarised as:

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

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

Towards the end of the guideline development process, formal consensus methods incorporating anonymous voting were used to consider all the clinical care recommendations and research recommendations that had been drafted previously. The GDG identified ten 'key priorities for implementation' (key recommendations) and five high-priority research recommendations. The key priorities for implementation were those recommendations thought likely to have the biggest impact on clinical care and outcomes in the NHS as a whole. The priority research recommendations were selected in a similar way.

Stakeholder involvement

Registered stakeholder organisations were invited to comment on t he draft scope and the draft guideline. Stakeholder organisations were also invited to undertake a pr e-publication check of the final guideline to identify factual inaccuracies. The GDG carefully considered and responded to all comments received from stakeholder organisations. The comments and responses, which were reviewed independently for NICE by a Guidelines Review Panel, are published on the NICE website.

4 Woman-centred care

4.1 Provision of information

In 1993, the Expert Maternity Group from the Department of Health (DH) released the Changing Childbirth report which made explicit the right of women to be i nvolved in decisions regarding all aspects of their care during pregnancy and childbirth.[23] One of the priorities of the report is to enable women to make informed decisions about their care.[24] To make these decisions women require access to evidence-based information so that they can take part in discussions with caregivers about these decisions.

In a survey, pregnant women were asked their views about childbirth. This included questions about the information they wanted or had received. About 40% of women reported that they had sufficient information on the risks and benefits of caesarean section (CS): however, almost 50% reported that they would have liked more information on reasons for CS, what to expect and the risks and benefits of CS[4] [evidence level 3]. Information from randomised controlled trials (RCTs) on antenatal education suggests that the provision of information is often seen as inadequate by women[25] [evidence level 3]. About 1 in 4 pregnant women will be delivered by CS (Department of Health, 2009) therefore when planning the birth of their baby women need i nformation on both vaginal birth and C S. For women who experience a fear of childbirth, it is possible that building up confidence during pregnancy in her ability to give birth has the potential to influence her choices for the birth of her baby and the interventions she receives during birth.[26]

Information leaflets

An RCT assessed the impact of evidence-based leaflets to promote informed decision making among pregnant women.[27] The leaflets were designed to be used in a conscious and controlled way (i.e. not left in a rack at an antenatal clinic or GP office) and the information provided was based on results of systematic reviews of the best available evidence and they were peer-reviewed. No differences were detected in the proportion of women who reported that they had exercised informed choice or among those who reported an ‘ active’ decision making role during antenatal care between the women that received these leaflets and those that did not. However, satisfaction with the amount of information received was higher among women who had received the leaflets [evidence level 1b]. Qualitative assessment within the RCT of the use of the leaflets found that their potential as decision aids was reduced due to competing demands within the clinical environment.[28] Time pressures limited discussion and the hierarchical nature of the relationship between healthcare professionals and patients determined which ‘choices’ were available. This meant that women complied with their carer’s choice rather than making an informed decision [evidence level 3].

Antenatal education

A systematic review based on s ix RCTs (n = 1443) assessed the effects of antenatal education on knowledge acquisition, anxiety, sense of control, pain, support, breastfeeding, infant care abilities, and psychological and social adjustment.[29] The largest RCT (n = 1275) examined an educational intervention to increase vaginal birth after CS. The other five RCTs (combined n = 168, range RCT n = 10 t o 67) included more general educational interventions; however the methodological quality of these RCTs is uncertain as they do not report randomisation procedures, allocation concealment or accrual/loss of participants. None of the RCTs included labour and birth outcomes, anxiety, breastfeeding success, or general social support. The effects on k nowledge acquisition and infant care competencies were measured but interpretation is difficult because of the size and methodological quality of the RCTs.[29] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

4.2 Planning mode of birth

Risks and benefits of planned CS compared with planned vaginal birth for women with an uncomplicated pregnancy

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 1	This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.
RR 2	Further evaluation is needed to determine the impact of demographic and c linical factors (such as ethnic group, increase in body mass index) and attitudinal factors on CS rates.

Consent for CS

Provision of information is central to the consent process, this should include information about the patient's condition, possible investigations and treatment options; the risks or benefits of these options, including the risk of doing nothing.[30–32] [evidence level 4] Information should be given in a way that patients can understand.[32,33] [evidence level 4] The amount of information provided will vary between patients according to the nature of the condition, the complexity of the treatment, the associated risk of the procedure, the patient's own wishes and individual needs. For the process of seeking consent to be meaningful, refusal of treatment needs to be one of the patient's options. Competent adults are entitled to refuse treatment even when the treatment would clearly benefit their health. Therefore a competent pregnant woman may refuse CS, even if this would be detrimental to herself or the fetus.[30] [evidence level 4] Ethical guidance for obtaining consent, points of law and model documentation are available in the above guidance.[30–32,34] [evidence level 4]

Tubal ligation at CS

It is estimated tubal ligation overall has a failure rate of 1 in 200 lifetime risk.[49] We did not identify any studies that describes the failure rate of tubal ligation at CS. Other guidelines recommend that tubal ligation should have been requested before or during pregnancy and agreed at least one week prior to the procedure. This advice is based on expert opinion.[49] [evidence level 4]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

5 Planned caesarean section

This chapter considers the evidence related to decisions about planned mode of birth. Other aspects of management of specific conditions or complications of pregnancy are not included because they are outside the scope of the guideline.

5.1 Breech presentation

About 4% of all singleton pregnancies are breech presentation. The proportion of breech presentation fetuses decreases with increasing gestation: 3% of term infants, 9% for those born at 33–36 weeks of gestation, 18% of those born at 28–32 weeks and 30% of those born at less than 28 weeks[4]. Breech presentation, is associated with cerebral palsy and handicap, due principally to the association with preterm birth and congenital malformations.[57,58]

Breech presentation is the primary indication for 10% of all caesarean sections (CSs). Overall 88% of pregnancies with breech presentation in England and Wales are delivered by CS (56% planned and 44% unplanned CS). However CS rates vary with gestational age, at term 91% women with a breech presentation had a CS, while at less than 28 weeks the CS rate was less than 40%.[4] [evidence level 3]

External cephalic version

Interventions to promote cephalic version of babies in the breech position include external cephalic version (ECV), moxibustion and postural management. The research basis for these interventions is included in the guideline on antenatal care of healthy pregnant women.[1]

External cephalic version involves applying pressure to the mother's abdomen to turn the fetus in either a forward or backward somersault to achieve a vertex presentation. Recognised complications of ECV attributable to the procedure (and incidence) include:

- fetal heart rate abnormalities: the commonest is transient bradycardia (1.1% to 16%)[59–62]
- placental abruption (0.4% to 1%)[59,61]
- painless vaginal bleeding (1.1%)[61]
- admission for induction of labour (3%).[62]

Two systematic reviews examined the effect of ECV at term and before term. Performing ECV at term reduced the number of non-cephalic births by 60% when compared with no ECV (6 randomised controlled trials [RCTs], n = 612 women, risk ratio [RR] 0.42, 95% confidence interval [CI] 0.35 to 0.50).[63] [evidence level 1a] A reduction in caesarean section is also observed in the ECV group when compared with no ECV (6 RCTs, n = 612, RR 0.52, 95% CI 0.39 to 0.71). ECV before 37 weeks gestation does not reduce non-vertex births at term (RR 1.02, 95% CI 0.89 to 1.17).[64] [evidence level 1a]

Success rates following ECV in primiparous women range from 35% to 57% and from 52% to 84% in multiparous women[59–62,65] [evidence level 2b]. Interventions to improve the success rates of ECV include the routine or selective use of tocolysis, the use of regional analgesia and t he use of vibroacoustic stimulation.[68] None of the RCTs has used newer tocolytics and the effectiveness of these is uncertain[66] [evidence level 1a]. Further guidance on ECV may be found in the RCOG greentop guideline on the management of breech presentation.[67]

In the National Sentinel Caesarean Section Audit (NSCSA) external cephalic version was offered to 33% of women having a CS for breech presentation at term, this was the same irrespective of the woman's parity. ECV was provided by consultants, specialist registrars or staff grade obstetricians.[4] [evidence level 4] If ECV was offered to all women at term, assuming a 50% success rate then it is likely this would reduce the overall CS rate by 1%.

Cost effectiveness of ECV

Six cost-effectiveness studies were identified that considered the role of ECV in decreasing the rate of CS, two in the United Kingdom and four in the USA.

The UK studies reported the cost of ECV.[53] The first was a cost study that reported an expected cost of £1,452 for ECV versus £1,828 for not having ECV, an ex pected saving of around £380.53. The results were insensitive (i.e. did not alter the result) to changes in the cost of an ECV. The cost of CS would need to fall by £8,576 (a fall of 56%, again, a highly unlikely scenario) for the non-ECV option to be t he less costly option. However, the sensitivity analysis showed that the ECV success rate would only have to fall by around 5% for the ECV option to be the less favourable option. Therefore the cost analysis cannot categorically determine which option is least costly overall. The second UK study (much smaller) found that the cost of birth with a successful ECV was £2,230 and £2,595 for an unsuccessful ECV, a cost saving of around £360 per birth.[68]

Four American studies have been published. One used a dec ision analytic modelling technique to determine the overall costs of four management options for breeches at term: ECV with planned vaginal birth, ECV with CS, selected vaginal birth and planned CS.[69] The decision model used hospital charges (not costs) for vaginal birth of US$6000 and US$10,000 for CS (a wider ratio than the reported UK cost data). The expected CS rate was 25.4% (± 5.4) for ECV plus planned vaginal birth; 31.9% (± 6.6) for ECV plus planned vaginal birth; 62.6% (± 5.9) for selected vaginal birth and 88.6% (± 3.4) for planned CS. The model estimated the expected cost for each pathway (the cost of vaginal birth and CS for each option arm) and found that ECV with planned vaginal birth was the least costly option, due to the lower proportion of CS for this group (US$8071) and planned CS to be the most costly (US$9544). Whether these reported costs were statistically different is not reported. The validity of the range of probabilities used in the decision analysis were subsequently questioned.[70]

A study in the same year considered the costs of failed and successful ECV separately and reported a cost of US$8042 for women with failed ECV and US$5059 for women with successful ECV.[71] However, the effectiveness data on which this study was based was a cohort study and not an RCT.

An American study also presented data to show that successful ECV would yield savings over unsuccessful ECV.[72] The most recent US study was a much larger study of 695 women.[73] This was a decision-analytic model to calculate the potential cost savings from ECV (in terms of reduced CS rates). The authors assumed that ECV would be successful in 44% of cases, of which 67% would proceed to vaginal birth and 33% to a CS. They further assumed that ECV would be unsuccessful in 56% of cases, of which only 7% would proceed to a successful vaginal birth. Given these assumptions, the model calculated a s avings (in US hospital charges) of around $650 per birth. Savings from every ECV attempted (even if not successful) versus ECV not attempted were around US$3000 per birth (these are greater due to higher reported rates of CS for women not attempting ECV).

Therefore in conclusion ECV yields cost savings in comparison with CS. There is no U K-based economic evaluation comparing ECV with vaginal breech birth.

Term breech pregnancy and CS

A systematic review identified 3 RCTs (n = 2396) that evaluated the effect of mode of birth for term breech pregnancies.[36,43,44,48] [evidence level 1a] The majority of the information about the effect of planned CS in the review comes from one i nternational multi-centre RCT which is of good methodological quality (n = 2088 women, 121 centres in 26 countries).[48] [evidence level 1b]

Offering planned CS reduced perinatal or neonatal death (excluding fatal anomalies) or serious neonatal morbidity (RR 0.33, 95% CI 0.19 to 0.56).[36] The risk of perinatal/neonatal mortality or serious morbidity was 1.6% in the planned CS group and 5.0% in the planned vaginal birth group. The absolute risk reduction in perinatal/neonatal mortality or serious neonatal morbidity was 3.4%,

therefore for every 29 CS for term breech pregnancy one baby will avoid death or serious morbidity.[36] [evidence level 1a] These findings are consistent with findings from cohort studies[74,75]

The findings of the RCT and t he systematic review are the subject of continued debate. Therefore more details about this RCT are outlined here. The RCT included a number of maternity units in the UK. About 40% of women recruited to the trial were in labour at time of randomisation. The women in labour were not further divided into stages of labour so there is no information on how many were in the second stage of labour. However advanced labour was not listed as an exclusion criterion. The RCT protocol provided guidance on m anagement of labour. This included intermittent fetal heart monitoring (every 15 minutes in the first stage and ev ery 5 minutes in the second stage), adequate progress in labour was defined as 0.5 cm dilatation per hour and descent of the breech to the pelvic floor within 2 hours of full cervical dilatation. Delivery of the breech could be spontaneous or assisted; the after coming head could be controlled using the Mauriceau–Smellie–Veit manoeuvre or forceps. The position of the woman for the second stage of labour was not stipulated by the protocol nor was this information collected during the trial.[48] [evidence level 1b]

Sub group analysis within this RCT has been undertaken to evaluate if the effect on perinatal mortality or morbidity could be explained by specific factors.[48] These effects remain consistent and are therefore not explained by differences in:

- operator experience
- prolonged labour
- induction of labour with oxytocin or prostaglandins
- augmentation of labour
- type of breech presentation (footling or uncertain)
- the use of epidural analgesia.

Women who were in labour were included in the RCT (therefore the findings of the trial are generalisable to women in labour); however the effect of CS on neonatal outcomes is not reported separately for this group. It is possible that the benefits and r isks of caesarean section particularly during the second stage are different. Therefore further research that specifically addressed this issue was sought; however no s tudies evaluating the effect of CS for undiagnosed breech compared to expectant management were identified. An RCT to address this issue would require randomisation of at least 4230 women with undiagnosed breech pregnancy to either CS or vaginal birth in order to detect at least a 40% difference in neonatal morbidity.

The effects of planned CS for term breech on maternal health are less clear. The RCTs included in the systematic review assessed the impact of CS on maternal health using a variety of measures and combining the results across studies is not always possible. Where the estimates could be combined, no difference is detected in the measures of maternal morbidity (such as blood loss, blood transfusion, infection) between planned CS and planned vaginal birth.[36] Estimates of composite measures of morbidity have previously been reported[36] however these pooled estimates are not included in the guideline because it is unclear whether these estimates are based on person or event data. It is possible that the same woman may have more than one morbidity (for example a woman who needs additional surgery is more likely to need a blood transfusion or admission to ITU) so that composite morbidity measures based on s ummation of event rates rather than number of women affected can lead to spurious results.[48] [evidence level 1b] Data for individual women was reported in one RCT, it did not detect any difference in composite maternal morbidity between women in the planned CS group or women in the planned vaginal birth group (RR 1.24, 95% CI 0.79 to 1.95).[48] [evidence level 1b] The specific estimates of the effect of planned CS on maternal health are outlined in Table 4.5.

Preterm breech

Breech presentation, is associated with cerebral palsy and handicap, due principally to the association with preterm birth and congenital malformations.[57,58] The proportion of breech presentation fetuses decreases with increasing gestation: 9% for those born at 33–36 weeks of gestation, 18% of those born at 28–32 weeks and 30% of those born at less than 28 weeks.[4,76]

Overall 88% of pregnancies with breech presentation were delivered by CS. However CS rates varied by gestational age, 87% for babies born at 33–36 weeks, 81% of those born at 28–32 weeks, and 39% for babies born at less than 28 weeks.[4] [evidence level 3]

The results of the term breech trial RCT are relevant for term breech pregnancies, extrapolation to preterm breech babies is inappropriate. In the Confidential enquiry into stillbirths and deaths in infancy (CESDI) Project 27/28 report, survival rates were lower for babies who were breech (84.5%) when compared to babies who were cephalic presentation (89.4%). Survival for breech presentation was significantly greater in those delivered by CS (86.5%) than those delivered vaginally (77.4%).[76] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 3	Further research is needed to determine the effect of caesarean section compared with vaginal birth for women with: • preterm breech • a breech presentation that is diagnosed in the second stage of labour.

5.2 Multiple pregnancy

About 15 per 1000 pregnancies are multiple gestations; the majority of these are twin pregnancies (twins 14.4 per 1000, triplets 4 per 10,000).[4] There have been increases in the rates of multiple pregnancy in the last ten years that are attributed to the use of ovulation induction in fertility treatments.[77,78] Perinatal mortality and morbidity such as cerebral palsy are higher among multiple births than singleton births (stillbirths: multiple: 2%. singleton: 0.5%; neonatal deaths multiple: 2.5. singleton 0.3%; RR cerebral palsy twins 4.63 (3.32–6.46.)[79,80] [evidence level 3] Some of the observed increase is explained by the association of multiple pregnancy with preterm birth.[4,80] Other factors which have been associated with poorer outcome in twin pregnancy include low birth weight, discordant growth between twins, monochorionic twins and being a second born twin.[81–85] The management of complications (such as discordant growth, monochorionic twins) and other obstetric complications in pregnancy (such as pre-eclampsia) will influence the mode of delivery decisions, however these are outside the scope of this guideline and are therefore not discussed further in this section.

Multiple pregnancy is the primary indication for 1% of caesarean sections.[4] Overall 59% of twin pregnancies were delivered by CS. (37% planned and 63% unplanned CS). CS for delivery of the second twin following vaginal birth of the first baby was carried out in 3.5% of twins (n = 75). CS rates vary by gestational age, at term 60% women with a twin pregnancy had a CS, while at less than 28 weeks the CS rate was less than 29%.[4] [evidence level 3] Where CS was planned for multiple pregnancy, breech presentation of the first twin was the most commonly reported indication (14%),

together with previous CS (7%) and maternal request (9%). Of the unplanned caesarean sections, fetal distress was the most influential factor in 29% and “failure to progress” in 12%. Almost all triplet pregnancies (92%) were delivered by CS.[4] [evidence level 3]

A systematic review that included 1 RCT (n = 60) compared CS for a second twin with a non vertex presentation to vaginal birth.[37] [evidence level 1b] The methodological quality of this trial is uncertain because ‘randomisation was according to a pr otocol that was changed randomly by a no n-involved person, without prior notice, on a t ime basis’.[45] No difference was detected in any of the baby outcome measures, however the study is too small to accurately estimate the effect on out comes such as neonatal birth trauma and per inatal death The study reported no difference in the average length of hospital stay (8 days compared to 5 days) and no difference in need for blood transfusion (RR 1.5 95% CI 0.27 to 8.28). Women in the planned CS group had increased risk of puerperal pyrexia compared to women in the planned vaginal birth group (RR 3.67 95% CI 1.15 to 11.69).[45] [evidence level 1b]

A large number of observational studies using population based registers have been published. However the majority of these studies are analysed by actual mode of delivery rather than intended mode of delivery, the reports provide insufficient data on neonatal outcome for women who had planned CS[85,86] and in the analysis paired tests have not been used to take into account that the outcome within twin pairs maybe related.[87,88] One systematic review included only studies where the intended mode of delivery could be identified. The review included 3 retrospective cohort studies[89–91] and the RCT discussed above.[45] The results from these studies were consistent and did not detect differences in neonatal morbidity such as low 5-minute Apgar score, birth trauma, neurological complications, hyperbilirubinaemia, hypoglycaemia, transient tachypnoea or secondary apnoea. The studies are too small to evaluate perinatal mortality.

Triplet and higher order multiple births are rare. They most frequently are the result of ovulation induction for treatment of fertility problems.[78] Triplets are almost always born preterm and some of the poorer outcomes such as cerebral palsy seen in these infants are due to preterm birth. These and other complicating factors may influence the mode of delivery decisions. Almost all triplet pregnancies (92%) were delivered by CS.[4] [evidence level 3] We identified 3 small retrospective case control studies which compared baby outcomes according to mode of birth for triplet pregnancies (119 sets of triplets in total). The babies born vaginally tended to have better outcomes such as higher Apgar scores than those delivered by CS. However these studies are analysed by actual mode of delivery rather than intended mode of delivery and do not use analysis to take into account that the outcome within triplets will be related.[92–94] [evidence level 2b]

Women who have multiple pregnancies have an increased risk of maternal mortality and morbidity. CEMD estimates maternal mortality is increased with multiple pregnancy (20.3 per 100 000 twin pregnancies; 215 per 100 000 t riplet pregnancies, compared with 11.2 per 100 000 f or singleton pregnancies).[95] [evidence level 3] The effect of mode of delivery on this outcome is uncertain.

Timing of planned CS for twin pregnancy

Planned CS of twins between 36–37 weeks and 6 days is associated with increased risk of respiratory disorders (transient tachypnea [TTN] or respiratory distress syndrome [RDS]) in one or both of the twins compared to CS between 38 and 40 weeks (RR 5.94, 95% CI 0.78 to 45.01).[96] [evidence level 2b] Multiple pregnancy is an established risk factor for preterm birth. About 29% of twin pregnancies are likely go into spontaneous labour before 37 weeks however CS in labour is associated with a reduced risk of respiratory disorders.[4] We did not identify any studies that had evaluated the optimal timing for CS in higher order multiple births.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 4	RCTs are needed to evaluate the benefits and risks to mothers and babies of CS for delivery of twin and triplet pregnancies.

5.3 Preterm birth and CS

Preterm birth is the most common cause of neonatal mortality (47% of neonatal deaths are due t o immaturity).[76] Babies born preterm are also at increased risk of morbidity (such as cerebral palsy) however the impact of mode of delivery on outcomes is uncertain.[97,98] Preterm birth may result from spontaneous preterm labour or because delivery is thought to be beneficial to the mother's (such as severe pre-eclampsia or HELLP) or baby's health (for example presumed fetal compromise). Other obstetric complications (such as multiple pregnancies and br eech presentation) are associated with preterm birth and will influence the mode of delivery decisions, however detailed discussion of the appropriate management of all these situations is outside the scope of this guideline. Changing the mode of birth for preterm infants to CS has been proposed as a means of reducing the morbidity and mortality[40] [evidence level 3] However when the infant is very small delivery can be difficult at CS.[76] In addition upper segment caesarean section (classical) may be needed in about 10% of babies born at 27–28 weeks which may have a significant impact on future pregnancies of these women.[76]

A systematic review of planned CS versus expectant management for birth of the small baby identified six RCTs (n = 122).[35] [evidence level 1a] Three RCTs included only breech presentation and three included only cephalic presentations. All trials were discontinued before reaching their projected sample size because of difficulties in recruitment or difficulties in weight estimation where trial entry criteria were based on b irthweight.[41] [evidence level 1b] About 1 i n 6 of the babies allocated to CS were born vaginally, and vice versa. The findings of the review are inconclusive because there were too few events to give sufficiently precise estimates of effect that would be clinically useful.

A large number of observational studies evaluating mode of birth of preterm infants on mortality and morbidity (such as cerebral palsy) have been published. However the impact of mode delivery on neonatal outcome remains uncertain.[76,97,99–102] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 5	RCTs are needed to evaluate the impact of CS on the benefits and risks to mothers and babies born preterm.

5.4 Small for gestational age

Small for gestational age (SGA) refers to a fetus that has failed to achieve a specific biometric measurement (for example abdominal circumference) or estimated weight threshold by a specific gestational age. The commonly used threshold is the tenth centile. About half of these babies are constitutionally small, others are fetuses that are not achieving their growth potential (fetal growth restriction, FGR). SGA fetuses are at greater risk of stillbirth, birth hypoxia, neonatal complications and impaired neurodevelopment. However, most term SGA infants do not have significant morbidity or mortality.[103] It is beyond the scope of this guideline to consider the investigation and management of small for gestational age infants other than the effect of CS on neonatal outcome, however this topic is covered by another guideline.[103]

No RCTs were identified that directly reported on baby outcomes for planned CS versus planned vaginal birth for SGA babies. One RCT has compared delayed versus immediate delivery after diagnosis of fetal growth restriction. This trial reported that delayed delivery resulted in fewer CS (OR 2.7, 95% CI 1.6 to 4.5).[104] [evidence level 1b] Observational data has suggested that SGA babies exposed to labour are more at risk of neonatal death than those not exposed to labour (RR 1.79, 95% CI 1.54 to 1.86).[105] [evidence level 3] CS may reduce the need for neonatal resuscitation (OR 0.2, 95% CI 0.08 to 0.66).[106] [evidence level 3]

The effect of CS on cerebral palsy in low birth weight babies is not certain. CS is not associated with a difference in rates of cerebral palsy.[107,108] [evidence level 3] Currently available guidelines do not recommend a mode of birth for SGA babies.[103] [evidence level 4]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 6	RCT evidence is needed to determine the effect of planned CS on neonatal mortality and morbidity for 'small for gestational age' babies.

5.5 Placenta praevia

Placenta praevia is the primary indication for about 3% of all CS (2.2% not actively bleeding and 0.9% actively bleeding).[4] The majority of low lying placenta detected at 20 weeks of gestation will resolve. If the placenta extends over the os, a repeat US should offered at 32 weeks of gestation.* (NCC-WCH,

2011

* The original guideline indicated that the repeat scan should be offered at 36 weeks. This sentence has now been updated in line with the updated Antenatal Care guideline (RCOG, 2008).

2008) Placenta praevia may also present with painless bleeding. CS is usually necessary when the placenta covers the internal os at 36 weeks of gestation (minor or major placenta praevia).

Women having a CS for placenta praevia are at increased risk of blood loss of greater than 1000 ml compared with women having a CS for other indications (RR 3.97, 95% CI 3.24 to 4.85).[4] In the last triennial report from the Confidential Enquiry into Maternal Deaths in the UK, four deaths occurred in women with placenta praevia, three as a result of haemorrhage.[95] Hence, they should have the CS carried out by an experienced operator with a consultant readily available and at a maternity unit with on-site blood transfusion services.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

5.6 Morbidly adherent placenta

Introduction

Women who become pregnant after a s ingle previous CS have a 0. 6–1.3% risk of developing placenta praevia: of these women, 11–14% will have a m orbidly adherent placenta (Guise et al., 2010). With two previous CSs, there is a 1.1–2.3% risk of placenta praevia in a subsequent pregnancy and of these women, 23–40% will have a morbidly adherent placenta (Guise et al., 2010). With three or more previous caesarean sections, there is a 1. 8–3.7% risk of placenta praevia in a subsequent pregnancy: of these women, 35–67% will have a m orbidly adherent placenta (Guise et al., 2010).

Against this backdrop of incremental risk, CS is becoming an increasingly common mode of delivery in the UK, both as a pr imary and a repeat procedure. Thus, clinicians can expect to see a gr adual increase in the number of women presenting in pregnancy with a morbidly adherent placenta.

Morbidly adherent placenta is associated with serious maternal morbidity including major obstetric haemorrhage, transfusion of large quantities of blood products, hysterectomy and admission to an intensive care unit. However, exsanguination and maternal death from morbidly adherent placenta is now rare in the UK (Cantwell R. et al., 2011). It is hoped that improved prenatal identification of such cases has contributed to this.

This section will review the evidence for the accuracy of imaging techniques in diagnosing morbidly adherent placenta in a pregnant woman with a previous CS who present with placenta praevia. It also reviews the evidence relating to the optimum management once the diagnosis has been made.

Accuracy of diagnostic tests

Review question

What is the accuracy of imaging techniques (colour flow ultrasound [US] and magnetic resonance imaging [MRI]) for diagnosis of a morbidly adherent placenta in pregnant women who have had a previous CS and are currently diagnosed with placenta praevia?

Overview of evidence

Five studies were included in this review (Warshak et al., 2006; Twickler et al., 2000; Masselli et al., 2008; Shih et al., 2009; Comstock et al., 2009).

Three studies were conducted in the USA (Warshak et al., 2006; Twickler et al., 2000; Comstock et al., 2009), one in Italy (Masselli et al., 2008) and one in Taiwan (Shih et al., 2009). One retrospective study examined the diagnostic accuracy of transvaginal ultrasound for diagnosis of placenta accreta in pregnant women with antenatal diagnosis of placenta praevia who had prior CS (Comstock et al., 2009). One retrospective study reported on t he diagnostic accuracy of ultrasound (grey scale or

colour Doppler) and MRI for diagnosis of placenta accreta in pregnant women with antenatal diagnosis of low anterior placenta and placenta praevia who had had at least one prior CS (Warshak et al., 2006). One prospective study compared the value of pelvic ultrasound with colour Doppler and MRI for diagnosis of placenta accreta, increta and percreta (Masselli et al., 2008). One prospective study introduced additional criteria for diagnosis of placenta accreta using 3D power Doppler complementary to grey scale and colour Doppler technique (Shih et al., 2009). One prospective study evaluated the diagnostic accuracy of Doppler colour-flow mapping for diagnosis of placenta accreta in pregnant women with prior CS and diagnosis of anterior low lying placenta and placenta praevia (Twickler et al., 2000).

Table 5.1 GRADE summary of findings for diagnostic accuracy of tests for placenta accreta, increta and percreta

Number of studies	Number of women	Measure of diagnostic accuracy						Quality
		Sensitivity	Specificity	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio	
Grey scale transabdominal ultrasound (mean age of gestation at diagnosis = 30 ± 2.2 weeks)								
1 study (Shih et al., 2009)	72	95 (79 to 100)[a]	76 (52 to 92)[a]	82 (47 to 89)[a]	93 (85 to 100)[a]	4.02 (2.18 to 7.41)[a]	0.06 (0.01 to 0.26)[a]	Low
Grey scale transvaginal ultrasound (age of gestation at diagnosis = 15 to 20 weeks)								
1 study (Comstock et al., 2009)	33	86 (0.67 to 1.04)[a]	NC	63 (0.41 to 0.84)[a]	NC	NC	NC	Low
Grey scale transvaginal ultrasound (age of gestation at diagnosis = 15 to 40 weeks)								
1 study (Comstock et al., 2009)	33	100 (100 to 100)[a]	NC	48 (0.41 to 0.84)[a]	NC	NC	NC	Low
Grey scale or colour Doppler ultrasound (mean age of gestation at diagnosis = 25 weeks, range 11 to 37 weeks)								
1 study (Warshak et al., 2006)	453	77 (60 to 88)	96 (93 to 97)	65 (49 to 78)	98 (95 to 98)	0.20 (0.11 to 0.33)	0.24 (0.13 to 0.42)	Low
US colour Doppler (for mean age of gestation see table footnote)[b]								
1 study (Masselli et al., 2008)	50	91 (68 to 94)	100 (85 to 100)	100 (87 to 100)	97 (75 to 100)	infinity	0.08 (0.01 to 0.54)[a]	Moderate
1 study (Twickler et al., 2000)	20	100 (100 to 100)[a]	72 (46 to 99)[a]	75 (50 to 99)[a]	100 (100 to 100)[a]	3.60 (1.39 to 9.26)[a]	0	Low

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Number of studies	Number of women	Measure of diagnostic accuracy						Quality
		Sensitivity	Specificity	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio	
1 study (Shih et al., 2009)	72	92 (83 to 100)	68 (53 to 83)	76 (63 to 88)	88 (77 to 100)	2.93 (1.78 to 4.82)[a]	0.11 (0.03 to 0.34)[a]	Low
MRI (for mean age of gestation see table footnote)[c]								
1 study (Masselli et al., 2008)	50	100 (86 to 100)	100 (90 to 100)	100 (88 to 100)	100 (89 to 100)	infinity	0	Moderate
1 study (Warshak et al., 2006)	40	88 (80 to 100)	100 (76 to 100)	100 (85 to 100)	82 (64 to 100)	infinity[a]	0.11 (0.03 to 0.33)	Low
3D power colour sonography (mean age of gestation at diagnosis 30 ± 2.2 weeks)								
1 study (Shih et al., 2009)	72	100 (100 to 100)	85 (73 to 97)	88 (78 to 97)	100 (100 to 100)	6.80 (3.02 to 15.27)[a]	0	Low

[a] NCC calculation

[b] Masselli et al., 2008: mean age of gestation at diagnosis = 30 weeks, range 20 to 37 weeks; Twickler. et al., 2000: age of gestation at diagnosis not reported; Shih et al., 2009: mean age of gestation at diagnosis 30 ± 2.2 weeks

[c] Masselli et al., 2008: mean age of gestation at diagnosis = 30 weeks, range 20 to 37 weeks; Warshak et al., 2006: mean age of gestation at diagnosis = 28 weeks, range 18 to 37 weeks)

NC not calculable

Evidence statements

In the following statements these definitions have been used when summarising the levels of sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV):

- high: 90% and above
- moderate: 75% to 89%

Evidence was identified using a variety of ultrasounds to determine diagnostic accuracy for placenta accreta in women diagnosed with placenta praevia who had at least one prior CS. The quality of the evidence ranged from moderate to low for the included studies.

Grey scale transabdominal ultrasound

One study evaluated the diagnostic accuracy of grey scale ultrasound for placenta accreta in women diagnosed with placenta praevia who had a prior CS. The study reported a high sensitivity, a moderate specificity, a moderate PPV and a high NPV. The evidence for this test was of low quality.

Grey scale transvaginal ultrasound

One study evaluated the diagnostic accuracy of grey scale transvaginal ultrasound for placenta accreta in women at 15 to 20 weeks of gestation who were diagnosed with placenta praevia and had a prior CS. The study reported a moderate sensitivity and a low PPV. Specificity and NPV were not reported. The evidence for this test was of low quality.

One study evaluated the diagnostic accuracy of grey scale transvaginal ultrasound for placenta accreta in women at 15 to 40 weeks of gestation who were diagnosed with placenta praevia and had a prior CS. The study reported a moderate sensitivity and a low PPV. Specificity and NPV were not reported. The evidence for this test was of low quality.

Grey scale or colour Doppler ultrasound

One study evaluated the diagnostic accuracy of grey scale or colour Doppler ultrasound to diagnose placenta accreta in women diagnosed with placenta praevia who had a prior CS. The study reported a moderate sensitivity, a high specificity, a low PPV and a high NPV. The evidence for this test was of low quality.

Ultrasound colour Doppler

Three studies evaluated the diagnostic accuracy of ultrasound colour Doppler to diagnose placenta accreta in women diagnosed with placenta praevia who had a prior CS. One study reported a high sensitivity and specificity with a high PPV and a high NPV. A second study reported high sensitivity, moderate specificity, a moderate PPV and a high NPV. A third study reported a high sensitivity, a low specificity, a moderate PPV and a moderate NPV. The evidence for this test was of moderate quality in the first study and low quality in the other two studies.

MRI

Two studies evaluated the diagnostic accuracy of MRI to diagnose placenta accreta in women diagnosed with placenta praevia who had a prior CS. The first moderate quality study reported a high sensitivity, specificity, PPV and NPV, while the second reported a moderate sensitivity with a high specificity, a high PPV and a moderate NPV. The evidence for this test was of moderate quality.

3D power colour sonography

One study evaluated the diagnostic accuracy of 3D power colour sonography to diagnose placenta accreta in women diagnosed with placenta praevia who had a prior CS. The study reported a high sensitivity, a moderate specificity, a moderate PPV and a high NPV. The evidence for this test was of low quality.

Evidence to recommendations

Relative value placed on the tests considered

The GDG felt that in current practice grey scale ultrasound would not generally be used to make a decision about placenta accreta. Instead, the healthcare professional would use colour-flow ultrasound in order to highlight movement.

Trade-off between clinical benefits and harms

The GDG noted evidence from one m oderate quality study and one large study of low quality that colour ultrasound is moderately accurate at ruling out morbidly adherent placenta. MRI scan is better for a more complete diagnosis (that is, considering both accurately ruling in and ruling out morbidly adherent placenta).

The GDG noted that evidence from one moderate quality prospective study showed that the diagnostic accuracy of MRI was 100% without the use of contrast dye. However, the GDG also understood that women may not wish to undergo an MRI scan for a number of reasons (such as discomfort at being enclosed in a s mall space, the risk of supine hypotension, the noise of the machine and the length of the procedure). The GDG therefore recognised the importance of discussing the procedure with the woman beforehand, explaining both the potential benefits and risks. This discussion should include an explanation of the degree of accuracy that can be expected, and information that the use of an MRI should enable better accuracy determining the degree of adherence.

The GDG noted that MRI is more accurate at identifying women who have a morbidly adherent placenta and therefore better able to help decision making regarding the choice of hospital advised for giving birth (local hospital or tertiary centre).

The GDG agreed with the generally held opinion that both MRI and ultrasound are safe for use in pregnancy.

Trade off between net health benefits and resources

Conclusions relating to cost effectiveness of diagnosing morbidly adherent placenta are presented in Section 13.2 where evidence relating to diagnostic accuracy of ultrasound and MRI and evidence relating to the effectiveness of antenatal diagnosis are considered together to inform the health economic modelling.

Quality of evidence

The GDG noted that in the majority of the studies, the imaging techniques were carried out prior to 30 weeks of gestation, whereas in clinical practice these scans would be more likely to be carried out after 32 weeks of gestation (since the low lying placenta scan won't generally occur until after a repeat scan for low lying placenta, which is usually carried out at 32–34 weeks).

The GDG noted that in the Warshak (2006) study looking at MRI, the person interpreting the MRI scans wasn't blinded to the results of the earlier colour ultrasound, thus potentially enhancing the diagnostic accuracy findings in favour of MRI.

The GDG noted that in all of the studies, while the high level of suspicion about morbidly adherent placenta in these women might be thought to inflate the figures for diagnostic accuracy, since this is the clinically relevant population, the figures reported are credible when generalised to clinical practice.

Other considerations

The GDG felt that as there was only one study investigating the use of 3D ultrasound, and given that it is not widely available throughout the UK, it was not appropriate to recommend its use.

The GDG also considered the relevance of evidence reviewed and recommendations to woman with other uterine scars (for example myomectomy) but in the absence of evidence pertaining specifically to this group, they did not feel this was possible.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guidelin

Number	Research recommendation
RR 7	How accurate is 3D ultrasound compared with 2D ultrasound or MRI scanning for diagnosing morbidly adherent placenta?

Effect of diagnosis on outcomes

Review question

Does a diagnosis of morbidity adherent placenta using imaging techniques lead to improved outcomes in pregnant women with a previous caesarean section currently diagnosed with placenta praevia?

Overview of evidence

Two studies were included in this review (Warshak et al., 2009; Wong et al., 2008). One study was conducted in the USA (Warshak et al., 2009) and one in New Zealand (Wong et al., 2008). One observational study examined the effects of antenatal diagnosis of placenta accreta on m aternal outcomes (Wong et al., 2008) and the other observational study compared maternal and neonatal outcomes in women with an antenatal diagnosis of placenta accreta (managed by planned caesarean hysterectomy) with women in whom an antenatal diagnosis was not made (Warshak et al., 2009).

In the US study all women diagnosed with placenta accreta were offered a planned CS with hysterectomy (without attempted removal of the placenta). A caesarean hysterectomy was scheduled for 34–35 weeks of gestation after a 48 hour course of betamethasone to enhance fetal lung maturity. A multidisciplinary team involving specialists from perinatology, anaesthetics, gynaecological oncology, interventional radiology and neonatology were involved in women's care. Hysterectomies were performed under general anaesthesia. Internal iliac balloon catheters were passed pre-operatively and inflated during surgery only if significant bleeding was encountered. Most women spent the first day postoperatively in the intensive care unit and stayed longer if clinically indicated. The diagnosis of placenta accreta in all women was confirmed post delivery with a histological test.

In the New Zealand study women diagnosed with placenta accreta were offered a planned CS. Five women had a h ysterectomy and the uterus was conserved in two. No further details are reported regarding the package of care offered.

Maternal outcomes

Table 5.2 GRADE summary of findings for antenatal diagnosis of placenta accreta compared with no antenatal diagnosis (maternal outcomes)

Number of studies	Number of women		Effect		Quality
	Antenatal diagnosis of placenta accreta	No antenatal diagnosis of placenta accreta	Relative (95% CI)	Absolute (95% CI)	
Estimated blood loss					
1 study (Warshak et al., 2009)	Mean (litre) ± SD 2.3 ± 1.7 n = 62	Mean (litre) ± SD 2.9 ± 1.8 n = 37	Not calculable (NC)	MD 0.6 lower (1.32 lower to 0.12 higher) *P* = 0.053	Very low
1 study (Wong et al., 2008)	Mean (litre) ± SD 1.4 ± 1.0 n = 7	Mean (litre) ± SD 3.6 ± 1.3 n = 9	NC	MD 2.20 lower (3.48 lower to 0.92 lower) *P* = 0.003	Very low
Number of units of blood transfused					
1 study (Warshak et al., 2009)	Mean ± SD 4.7 ± 2.2 n = 62	Mean ± SD 6.9 ± 1.8 n = 37	NC	MD 2.20 lower (3.05 lower to 1.35 lower) *P* = 0.02	Very low

Number of studies	Number of women		Effect		Quality
	Antenatal diagnosis of placenta accreta	No antenatal diagnosis of placenta accreta	Relative (95% CI)	Absolute (95% CI)	
1 study (Wong et al., 2008)	2.3 ± 2.9 n = 7	5.1 ± 2.9 n = 9	NC	MD 2.80 lower (5.93 lower to 0.33 higher) *P* = 0.07	Very low
Emergency hysterectomy					
1 study (Wong et al., 2008)	1/7 (14%) n = 7	9/9 (100%) n = 9	RR 0.14 (0.02 to 0.55)	857 fewer per 1000 (from 975 fewer to 435 fewer)[a] *P* = 0.001	Very low
Intensive care unit [ICU] admission					
1 study (Warshak et al., 2009)	43/62 (69%)	22/37 (59%)	RR 1.16 (0.86 to 1.64)[a]	98 more per 1000 (from 92 fewer to 293 more)[a] *P* = 0.49	Very low
1 study (Wong et al., 2008)	1/7 (14%)	1/9 (11%)	RR 1.28 (0.14 to 11)[a]	31 more per 1000 (from 344 fewer to 443 more)[a] *P* = 1.0	Very low
Length of hospital stay					
1 study (Warshak et al., 2009)	7.4 days (SD 1.8) n = 62	5.5 days (SD 1.6) n = 37	NC	MD 1.90 higher (1.19 lower to 2.61 higher) *P* = 0.92	Very low
1 study (Wong et al., 2008)	8.6 days (SD 1.36) n = 7	9.9 days (SD 4.9) n = 9	NC	MD 1.30 lower (5.41 lower to 2.81 higher) *P* value not reported	Very low
Bladder injuries					
1 study (Warshak et al., 2009)	14/62 (22%)	3/37 (8.1%)	RR 2.78 (0.94 to 8.71)[a]	144 more per 1000 (from 11 fewer to 280 more)[a]	Very low
1 study (Wong et al., 2008)	1/7 (14%)	1/9 (11%)	RR 1.28 (0.14 to 11)[a]	31 more per 1000 (from 344 fewer to 443 more)[a]	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; MD mean difference; NC not calculable; RR risk ratio; SD significant difference

Neonatal outcomes

Table 5.3 GRADE summary of findings for antenatal diagnosis of placenta accreta compared with no antenatal diagnosis (neonatal outcomes)

Number of studies	Number of neonates		Effect		Quality
	Antenatal diagnosis of placenta accreta	No antenatal diagnosis of placenta accreta	Relative (95% CI)	Absolute (95% CI)	
Neonatal intensive care unit [NICU] admission					
1 study (Warshak et al., 2009)	50/62 (80%)	19/37 (51%)	RR 1.57 (1.16 to 2.28)	292 more per 1000 (from 102 more to 437 more)[a]	Very low
NICU length of stay					
1 study (Warshak et al., 2009)	9.8 days (SD 2.5) n = 62	6.3 days (SD 3.5) n = 37	Not calculable	MD 3.50 higher (2.30 lower to 4.70 higher) *P* = 0.13	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; MD mean difference; RR risk ratio; SD significant difference

Evidence statements

Maternal outcomes

Estimated blood loss

One study found that the mean blood loss in women with an antenatal diagnosis of placenta accreta was lower than in women with no a ntenatal diagnosis of placenta accreta. This finding was statistically significant. A second study did not find a statistically significant difference for this outcome. The evidence for this outcome was of very low quality.

Number of units of blood transfused

One study found that women with an antenatal diagnosis of placenta accreta had a lower number of packed red blood cell transfusions compared with the women who had no a ntenatal diagnosis of placenta accreta. This finding was statistically significant. A second study did not find a statistically significant difference for this outcome. The evidence for this outcome was of low quality.

Emergency hysterectomy

One study found that the incidence of emergency hysterectomy was lower among women with an antenatal diagnosis of placenta accreta compared with those who had no antenatal diagnosis of placenta accreta. This finding was statistically significant. The evidence for this outcome was of very low quality.

Intensive care unit (ICU) admission

Two studies did not find a statistically significant difference in the rate of ICU admission for women with an antenatal diagnosis of placenta accreta compared with women who had no antenatal diagnosis of placenta accreta. The evidence for this outcome was of very low quality.

Length of hospital stay

Two studies did not find a statistically significant difference in length of hospital stay for women with an antenatal diagnosis of placenta accreta compared with women who had no antenatal diagnosis of placenta accreta. The evidence for this outcome was of very low quality.

Bladder injuries

Two studies did not find a statistically significant difference in the rate of bladder injuries for women with an antenatal diagnosis of placenta accreta compared with women who had no antenatal diagnosis of placenta accreta. The evidence for this outcome was of very low quality.

Neonatal outcomes

Neonatal intensive care unit (NICU) admission

One study found that the rate of NICU admission was higher in neonates born to women with an antenatal diagnosis of placenta accreta than in neonates born to women with no antenatal diagnosis of placenta accreta. This finding was statistically significant. The evidence for this outcome was of very low quality.

NICU length of stay

One study did not find a statistically significant difference in NICU length of stay for neonates born to women with an antenatal diagnosis of placenta accreta compared to neonates born to women with no antenatal diagnosis of placenta accreta. The evidence for this outcome was of very low quality.

Health economics

A de novo model to compare different diagnostic strategies for morbidly adherent placenta in praevia was developed for this guideline. The results of this analysis are summarised here; further details are provided in Chapter 13.

The model compared the following diagnostic strategies:

- none
- ultrasound
- MRI
- ultrasound followed by MRI in ultrasound test positives.

There is an absence of evidence about how much a diagnosis of morbidly adherent placenta leads to improved outcomes. Even if it does, the 'downstream' saving and quality adjusted life years (QALY) gain from averting 'adverse outcomes' are further unknowns. Therefore, the model took a 'what-if' approach to assess what would be considered cost effective in different scenarios. There is also some uncertainty about the precise diagnostic accuracy of the different diagnostic tests, although there is at least some evidence for these, which perhaps make this uncertainty of secondary importance in terms of making guideline recommendations.

The model suggested that a diagnostic strategy of ultrasound alone was dominated by other alternatives, which meant that other strategies were likely to be cheaper and more effective. Although it has the lowest diagnostic cost, the high cost of false positives in a low prevalence population makes it the most expensive strategy overall. Furthermore, the evidence suggests that such a strategy would miss more cases than a s trategy of MRI alone. This finding did not depend on assumptions about improved outcomes arising from the detection of cases.

The 'what-if' analysis started from the premise that identifying cases would lead to improved outcomes. Although there is an absence of evidence for this and an effect size can't be estimated, the GDG was strongly of the opinion that 'being prepared' offered some protection from risk. Under that premise, there were scenarios where 'do nothing', ultrasound plus MRI and MRI alone could be considered cost effective. However, in general a much lower effect size, QALY gain and 'downstream' cost saving from averting 'adverse outcomes' was necessary for ultrasound plus MRI to be cost effective than for MRI alone.

Evidence to recommendations

Relative value placed on the outcomes considered

The GDG recognised that although blood loss is an important outcome, the way that it has been reported is not useful for its decision making. The GDG members were particularly concerned about identifying the number of women where blood loss could be po tentially life-threatening but this was not reported.

The GDG recognised that although the differences in the rates of hysterectomies appeared to be a significant finding, these results were due to the local protocol at the hospital (that is, where a placenta accreta was first discovered when performing the CS, the clinicians would perform an elective hysterectomy). The group felt that this was not a common approach and so did not wish to place any value on the differences reported.

The GDG did not feel that the findings related to ICU admission and length of hospital stay, for both women and neo nates, were particularly helpful as the decision about length of stay will often be determined by local protocols.

The GDG felt that the number of bladder injuries was an important outcome. However, it recognised that neither of the studies showed a statistically significant difference for this outcome.

Trade-off between clinical benefits and harms

The GDG members believed from their experience that the main benefit of diagnosing a m orbidly adherent placenta is that this allows clinicians to be prepared and to ensure that appropriate measures are taken in cases of extreme blood loss. These include ensuring that there is sufficient cross-matched blood available and that experienced specialist clinicians are available to provide support when needed.

Trade-off between net health benefits and resource use

There is insufficient evidence to determine the cost effectiveness of different diagnostic strategies for morbidly adherent placenta. The modelling undertaken for this guideline suggested that ultrasound alone was likely to be d ominated (that is, there was likely to be a diagnostic strategy which was cheaper and more effective) because of a higher false positive rate. There is some evidence to support a v iew that ultrasound has a l ower specificity than MRI, although it is not conclusive. The model also suggested that a sequential strategy of ultrasound followed by a confirmatory MRI where an ultrasound test is positive is cheaper than a strategy of MRI alone. This is because the sequential MRI test removes the costs of false positives which more than offsets the costs associated with an additional test. The sequential strategy involves a much smaller number of MRI scans than a strategy based on MRI alone and because of the substantial difference in costs between an ultrasound and MRI this means that the sequential strategy has markedly lower diagnostic costs, even if the total number of tests undertaken is higher.

Economic evaluation should consider benefits as well as costs but such evidence does not exist. Therefore, the model took a 'what-if' approach towards the benefits of correct diagnosis. The GDG members were strongly of the opinion that identifying cases was likely to lead to better outcomes. The model suggested that much smaller gains were necessary for ultrasound plus MRI to reach a cost-effectiveness threshold relative to "do-nothing" than for MRI alone to be considered cost effective relative to ultrasound plus MRI. Therefore, it would be d ifficult to justify a r ecommendation for a diagnostic strategy of MRI alone given existing evidence. Such a strategy is not common in current UK practice and there could be capacity issues which would hinder the implementation of such a recommendation. Although current UK practice varies, ultrasound plus MRI is an approach used in some centres. Although further evidence is required, a r ecommendation of ultrasound plus MRI seems to make pragmatic sense given current practice, GDG opinion and the insights available from the model produced for this guideline.

Quality of evidence

The GDG recognised that there were only two studies that provided evidence for this question, and that the quality of the evidence for the findings from these studies was very low. GDG members noted that one of the studies only contained a small number of women in each arm and so was likely to be underpowered for rare outcomes such as bladder injury.

Given the poor quality of the evidence and lack of detail in one study about the specific management regimes used, the GDG did not feel able to make a strong recommendation for specific interventions. It was noted that in one study (Warshak, 2009) the management strategy of elective caesarean hysterectomy was used for all women, an approach which is not usual practice and thus findings from this study are not generalisable to situations where conservative management is undertaken.

In light of the large amount of blood loss associated with both arms of each study, the GDG agreed that there were steps that should be taken to minimise morbidity associated with this.

Other considerations

The group recognised that there are a number of interventions that are used in to reduce blood loss during surgery, such as balloon catheters and interventional radiology. In addition, some trusts have cell salvage equipment available that can also be used to reduce the need for cross-matched blood. There is variation in practice concerning the use of these interventions in the management of morbidly adherent placenta and a lack of evidence to support their use. Consequently, the GDG felt it important to recommend that further research is conducted in this area.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 8	What is the effectiveness of procoagulant agents (such as recombinant factor VIIa, beriplex, tranexamic acid, fibrinogen concentrate) in reducing blood loss in women with morbidly adherent placenta?
RR 9	What is the effectiveness of point of care testing for haematological indices in women with an established postpartum haemorrhage and in cases of morbidly adherent placenta in reducing maternal morbidity?
RR 10	What is the effectiveness of the components of the package of care for morbidly adherent placenta such as imaging techniques (e.g. interventional radiology including balloon catheters), stenting of ureters, removal of the placenta, and cell salvage in reducing morbidity associated with maternal blood loss?
RR 11	What is the appropriate gestational age of elective birth for babies of women with a morbidly adherent placenta?
RR 12	What is the effectiveness of performing an elective hysterectomy to reduce morbidity associated with blood loss in women with morbidly adherent placenta?

5.7 Predicting CS for cephalopelvic disproportion in labour

Pelvimetry (clinical or X-ray) has been used to predict the need for CS in pregnant women. A systematic review of four RCTs (n = 895) assessed the effects of X-ray pelvimetry on mode of birth. Two RCTs included women with a previous CS. The women on whom pelvimetry was performed were more likely to be delivered by CS (Peto OR 2.17, 95% CI 1.63 to 2.88); There were no differences in neonatal outcomes (asphyxia, admission to neonatal unit, scar dehiscence).[109] [evidence level 1a] Guidelines have recommended that pelvimetry is not used except in rare circumstances such as if the woman has had a previous fracture of the pelvis.[110]

Other tests to predict failure to progress (FTP) have included shoe size, maternal height and size of fetus. Observational studies have not demonstrated their value in predicting FTP in labour.[111,112] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

5.8 Mother-to-child transmission of maternal infections

This section addresses CS as an intervention to reduce mother-to-child transmission (MTCT) of viral infections (such as human immunodeficiency virus [HIV]). Other interventions also impact on the risk of the mother-to-child transmission of viral infections (such as anti-retrovirals for HIV) but these topics are outside the scope of this guideline.

HIV

Introduction

Approximately 86,500 people in the UK are carriers of the human immunodeficiency virus (Health Protection Agency, 2010). About 1 in 450 pregnant women nationally are HIV positive and this rises to about 1 in 250 pregnant women in London. In general, around one quarter of all people carrying the HIV virus is unaware of their HIV positive status.

Current NICE guidelines for routine antenatal care recommend that screening for HIV should be offered to all pregnant women in the UK because various interventions can decrease the maternal to fetal (vertical) transmission of the virus (Antenatal care guideline, NCC-WCH, 2008). The previous version of this guideline recommended that 'HIV-positive women who are pregnant should be offered a planned CS because it reduces the risk of mother-to-child transmission of HIV'. However, since the publication of the original guideline there has been a growing body of evidence suggesting that for some women taking antiretroviral therapy (ART) or highly active antiretroviral therapy (HAART), the chance of vertical transmission is reduced so effectively that CS may no longer be associated with reduced vertical transmission rates compared with vaginal birth, even in the presence of a detectable viral load.

This new evidence is reviewed in this section, together with an update of the recommendations for clinical practice.

Review question

What is the effectiveness of planned caesarean section compared with planned vaginal birth at decreasing the mother-to-child transmission of the virus in pregnant women with HIV, for both low and high viral load?

Overview of evidence

Four studies were included in this review which investigated the effectiveness of planned CS compared with vaginal birth at decreasing the rates of mother-to-child transmission of the virus in pregnant women with HIV for both low and high viral load (Boer et al., 2010; Warszawski et al., 2008; Islam et al., 2010; Townsend et al., 2008).

One study was a prospective observational study (Boer et al., 2010) and three were retrospective observational studies (Townsend et al., 2008; Warszawski et al., 2008; Islam et al., 2010). Two of the studies were conducted in the UK (Islam et al., 2010; Townsend et al., 2008), one in France (Warszawski et al., 2008) and one (Boer et al., 2010) in eight Western European countries (Italy, Spain, Belgium, Netherlands, UK, Germany, Denmark and Sweden). All four studies reported mother-to-child transmission rate, viral load count and mode of birth. Two studies investigated planned CS versus planned vaginal birth (Islam et al., 2010; Townsend et al., 2008) and the other two compared planned CS with vaginal birth (planned and unplanned) (Boer et al., 2010; Warszawski et al., 2008).

Three studies reported on mother-to-child transmission rate and mode of birth in HIV infected pregnant women with low viral load defined as undetectable viral load (less than 50 copies/ml) (Boer et al., 2010; Islam et al., 2010; Townsend et al., 2008). One study reported on mother-to-child transmission rate and mode of birth in women with low viral load defined as less than 400 copies/ml (Warszawski et al., 2008).

Table 5.4 is the summary of the evidence by mother-to-child transmission rate for all the published studies identified for this review question. The results have been divided by plasma viral load count.

Table 5.4 GRADE summary of findings for mother-to-child transmission (MTCT) of HIV

Number of studies	Number of women		Effect		Quality
	Planned CS	Vaginal birth	Relative (95% CI)	Absolute (95% CI)	
Mother-to-child transmission (MTCT) in women with viral load < 50 copies/ml on highly active anti-retroviral therapy (HAART)					
1 study (Boer et al., 2010)	1/238 (0.4%)	1/321 (0.3 %)	OR 1.35 (0.08 to 21.6)[b]	1 more per 1000 (from 1 fewer to 60 more)	Very low
1 study (Townsend et al., 2008)	2/1135 (0.2%)	1/417[a] (0.2%)	OR 0.73 (0.06 to 8.12) [b]	Not calculable (NC)	Very low
MTCT in women with viral load < 50 copies/ml; 14/23 on HAART					
1 study (Islam et al., 2010)	Not reported (NR)	0/23 (0%)[a]	NC	NC	Very low
MTCT in women with viral load ≥ 50 and < 1000 copies/ml on HAART					
1 study (Townsend et al., 2008)	4/417 (0.95%)	2/81[a] (2.5%)	OR 0.39 (0.07 to 2.17) [b]	15 fewer per 1000 (from 23 fewer to 27 more)	Very low

Number of studies	Number of women		Effect		Quality
	Planned CS	Vaginal birth	Relative (95% CI)	Absolute (95% CI)	
MTCT in women with viral load < 400 copies/ml with and without HAART					
1 study (Boer et al., 2010)	4/571 (0.7%)	11/242 (4.5%)	OR 0.14 (0.04 to 0.47) [b]	38 fewer per 1000 (from 24 fewer to 44 fewer)	Very low
MTCT in women with viral load < 400 copies/ml on antenatal antiretroviral therapy (ART) (term birth)					
1 study (Warszawski et al., 2008)	7/1296 (0.5%)	7/1083 (0.6%)	OR 0.83 (0.29 to 2.38) [b]	1 fewer per 1000 (from 5 fewer to 9 more)	Very low
MTCT women with viral load < 1000 copies/ml on HAART					
1 study (Boer et al., 2010)	3/424 (0.7%)	0/155 (0%)	NC	NC	Very low
MTCT in women with viral load ≥ 1000 copies/ml on HAART					
1 study (Boer et al., 2010)	11/822 (1.3%)	2/310 (0.6%)	OR 2.08 (0.46 to 9.47) [b]	7 more per 1000 (from 3 fewer to 50 more)	Very low
MTCT in women with viral load ≥ 10,000 copies/ml on antenatal ART including HAART (term birth)					
1 study (Warszawski et al., 2008)	10/203 (4.9%)	5/72 (6.9%)	OR 0.69 (0.22 to 2.10) [b]	20 fewer per 1000 (from 53 fewer to 60 more)	Very low

[a] planned vaginal birth

[b] calculated by NCC technical team

CI confidence interval; NC not calculable; OR odds ratio

Evidence statements

Mother-to-child transmission in women with viral load less than 50 copies/ml on HAART

Two studies did not find a statistically significant difference in the rates of mother-to-child transmission in women on HAART having a planned CS compared with those having a vaginal birth (planned or unplanned; including intrapartum CS) with viral load less than 50 copies/ml.

One study found no reported incidences of mother-to-child transmission of HIV for women having planned vaginal birth in women with viral load less than 50 copies/ml, of whom 14 out of 23 were on HAART. The evidence for this outcome was of very low quality.

Mother-to-child transmission in women with viral load of 50 copies/ml or more up to 1000 copies/ml on HAART

One study did not find a statistically significant difference between transmission rates for women on HAART with viral load of 50 copies/ml or more up to 1000 copies/ml having a planned CS compared with those having a planned vaginal birth. The evidence for this outcome was of very low quality.

2011 Update

Mother-to-child transmission in women with viral load less than 400 copies/ml with and without HAART

One study found that planned CS reduces the risk of mother-to-child transmission compared with vaginal birth (planned or unplanned; including intrapartum CS) when maternal viral load is less than 400 copies/ml (some women receiving HAART, some receiving ART, a f ew receiving no ART; numbers not reported). This finding was statistically significant. The evidence for this outcome was of very low quality.

Mother-to-child transmission in women with viral load less than 400 copies/ml on ART

One study did not find a statistically significant difference in transmission rate for women on ART with a viral load less than 400 copies/ml having a p lanned CS compared with those having a p lanned vaginal birth. The evidence for this outcome was of very low quality.

Mother-to-child transmission in women with viral load less than 1000 copies/ml on HAART

One study reported transmission rates in women on HAART with a viral load less than 1000 copies/ml. This was slightly higher for women having a planned CS but the statistical significance was not calculable. The evidence for this outcome was of very low quality.

Mother-to-child transmission in women with viral load 1000 copies/ml or more on HAART

One study did not find a statistically significant difference between transmission rates for women on HAART with viral load of 1000 copies/ml or more having a planned CS compared with those having a vaginal birth (planned or unplanned; including intrapartum CS). The evidence for this outcome was of very low quality.

Mother-to-child transmission in women with viral load 10,000 copies/ml or more on ART (including HAART)

One study did not find a statistically significant difference between transmission rates for women on ART (including HAART) with a viral load of 10,000 copies/ml or more having a planned CS compared with those having a planned vaginal birth. The evidence for this outcome was of very low quality.

Evidence to recommendations

Relative value placed on outcomes considered

The only relevant outcome for consideration in this question was the rate of mother-to-child transmission of HIV. This outcome was then split according to the viral load (number of copies per ml) reported in each study (and in some cases further subdivided according to the treatment used).

Trade-off between clinical benefits and harms

The evidence provided a number of results, both for different viral loads and different therapies. For women with a viral load of less than 50 copies/ml on HAART, there was no significant difference in mother-to-child transmission rates between women who gave birth vaginally and those who gave birth by CS. The GDG members felt that this matched their clinical experience and so were confident in recommending that women on HAART with a viral load of less than 50 copies/ml should not be offered a CS.

The group noted that one study with the majority of women on ART (Warszawski et al., 2008) did not show a s tatistically significant difference in the mother-to-child transmission rate between women giving birth vaginally and those giving birth by CS in women with a viral load of less than 400 copies/ml. However, the group recognised that the study did include a number of women on HAART and that this might have affected the results. As a result, the group agreed that either a vaginal birth or CS could be considered for women on ART with a viral load of 50–400 copies/ml.

The evidence also suggested that for women on HAART with a viral load of 50 copies/ml or more up to 1000 copies/ml there was no significant difference in transmission rates between women who gave birth vaginally and those who gave birth by CS. Further discussion of all the evidence pertaining to viral loads of more than 400 copies/ml led the GDG members to decide that the evidence was of too low a quality to change current practice and they felt it important to remain cautious in these instances. They agreed that women on HAART with a viral load less than 400 copies/ml should not be offered a CS on the grounds of their HIV status but that all women with a viral load of more than 400 copies/ml should be offered a CS regardless of the therapy being received.

One study that included women receiving different therapies showed a significant reduction in the risk of mother-to-child transmission with planned CS (Boer et al., 2010). The GDG felt that this difference was likely to be due to the fact that the study included women receiving no therapy. As a result, the group agreed that it was appropriate to adopt a cautious approach and recommended that women on no therapy should be offered a CS regardless of their viral load.

Trade-off between health benefits and resources

The economic modelling for CS compared with vaginal birth for women with healthy, uncomplicated pregnancy suggests vaginal birth may be more cost effective, although the evidence for this is not strong and is based upon incomplete outcome data. However, where a w oman is HIV positive the balance may be tipped in favour of CS in order to reduce the risk of mother-to-child transmission of HIV and t he subsequent long-term health loss and treatment costs for the baby. The point at which the balance favours CS above vaginal birth depends upon the relative risk of HIV transmission. The GDG members decided, based on the evidence reviewed plus their own experience, that this tipping point comes at viral loads of more than 400 copies/ml, regardless of therapy. The use of HAART reduces the risk of transmission and so where there is low viral load (less than 400 copies/ml) it is appropriate to advise vaginal birth.

Quality of evidence

All evidence reviewed for this question was of very low quality. This was mostly due to the studies being retrospective observational studies that were underpowered and had flaws in reporting, meaning it was not always possible to determine actual mode of birth for all women within each study group. The low quality of evidence meant the GDG remained cautious with its recommendations.

Other considerations

The GDG agreed that further UK-based data about the diagnosis of HIV in pregnant women, its treatment, the mode of birth chosen in different circumstances and mother-to-child transmission rates were all required. The GDG was aware that some of this information is currently collected by the RCOG and so included a recommendation that this data continue to be collected.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Hepatitis B virus

Serological screening for hepatitis B should be offered to all pregnant women.[1] The prevalence of hepatitis B surface antigen (HBsAg) in pregnant women in the UK has been found to range from 0.5 to 1%.[129,130] [evidence level 3]. The wide range in prevalence rates is most likely due to wide variation in prevalence among different ethnic groups.[131] [evidence level 3]

Hepatitis B immunoglobulin and hepatitis B vaccine reduce mother-to-child transmission (MTCT). The vaccine and immunoglobulin are given to the infant at birth followed by either a one month and s ix month dose or at 5 weekly intervals.[132,133] [evidence level 1b]

Most MTCT occurs at birth or postnatally. Transmission at birth may be due to microperfusion of maternal blood into the infant's circulation during placental separation or by the infant swallowing maternal blood, amniotic fluid or vaginal secretions at vaginal birth.[134] It has been suggested that CS could further reduce MTCT however no RCTs have addressed this issue. One cohort study was identified (n = 447 infants). The methodology of this study is not clearly reported and the generalisability of the findings is not clear.[135] [evidence level 2a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 13	RCTs are needed to evaluate the effect of planned CS in addition to immunoglobulin and vaccination on MTCT of hepatitis B.

Hepatitis C virus

Women are not routinely offered screening for hepatitis C infection in the UK.[1] The prevalence of hepatitis C virus (HCV) in women of child-bearing age is not known as large scale serological studies have not been done. It is however estimated that 1–2% of women of child-bearing age in the US are positive for antibody to HCV.[136] An estimate for EU countries is 0.9% (0.1–3%).[136]

Mother-to-child transmission (MTCT) of HCV was first described in the early 1990s and is now widely recognized. The risk of MTCT of HCV is usually low at 3–5% but higher rates of 10–20% are observed among HIV co-infected women.[136] [evidence level 3] A cohort study involving 441 mother-child pairs from the UK and Ireland of which 5% were known to be HIV-positive, estimated overall MTCT risk at 6.7% (95% CI 4.1 to 10.2). Women co-infected with HIV and HCV had a 3.8 times higher risk of transmitting HCV to their infants than HIV-negative women.[137] [evidence level 2b]

The effect of mode of birth on t he risk of MTCT of HCV has not been evaluated in RCTs. We identified a poo led retrospective analysis of prospectively collected data on 1474 H CV infected women from 36 centres in eight European countries.[138] [evidence level 3] For women with hepatitis C infection, there was no difference in risk of vertical transmission by mode of birth (OR 1.19, 95% CI 0.64 to 2.20). This lack of association persisted with adjustment for breastfeeding status, geographic region and maternal age at birth (OR 1.26, 95% CI 0.68 to 2.34), (OR 1.29, 95% CI 0.69 to 2.42) and (OR 1.17, 95% CI 0.59 to 2.31).[138] [evidence level 3]

Within this study subgroup analysis of women co-infected with HIV (n = 503, 35.4%), reported that the risk of vertical transmission for HCV was reduced by 60% with CS (OR 0.43, 95% CI 0.23 to 0.80). Of the HIV co-infected women, 14 (7.3%) were classified as clinical stage C, the remainder of the women

are described as being asymptomatic. There is no m ention of whether any of the women were on anti-retroviral therapy. Thirteen (2.6%) of the HIV co-infected women breastfed their infants.[138] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Genital herpes simplex virus

Genital herpes simplex virus (HSV) infection is an ulcerative sexually transmitted infection which can recur and i s associated with considerable physical and psychological morbidity. Genital ulcers may cause pain but can be asymptomatic (for example cervical lesions). Between 1972 and 2001, there was a 9 –fold increase in the incidence of genital HSV diagnosed in women in the UK.[139] [evidence level 3] Currently HSV-2 antibody prevalence in England and Wales is 3% in men and 5% in women.[140] [evidence level 3]

Neonatal HSV can cause severe systemic disease and is associated with a high mortality rate. Active surveillance in the UK suggests that neonatal HSV infection occurs in 1.65 per 100,000 live births.[141] [evidence level 3] Neonatal HSV may result from contact of the newborn with the birth canal of an infected mother.

Primary HSV infection and MTCT of HSV

The accepted practice of offering CS to women with HSV infection is based on three case series. The first study included 101 pregnant women with HSV (both primary and recurrent disease). This study found the risk of neonatal herpes to be highest for women who acquired primary infection during the third trimester (3 cases of neonatal infection out of 9 c ases of exposure).[142] [evidence level 3] Subsequently a study evaluating screening for HSV identified 94 w omen who acquired HSV during pregnancy but with no MTCT to the infants. There were an additional 9 women who acquired genital HSV near the onset of labour and in this group, 4 of the 9 infants developed neonatal HSV infection.[143] [evidence level 3] A study of 15,923 asymptomatic women in early labour reported isolating HSV from 56 women of whom 18 (35%) had a primary infection. Neonatal HSV developed in 6 infants (33%).[144] [evidence level 3] None of the studies are large enough to address the effect of mode of birth on MTCT.

Despite limited evidence the high mortality associated with neonatal herpes means there is consensus about current practice to offer CS for primary infection.[145,146]

Recurrent HSV infection and history of HSV infection and MTCT

Observational data suggests that the risk of neonatal infection with recurrent HSV is lower than with primary HSV infection (8% with recurrent infection and 33% with primary HSV infection).[147,148] [evidence level 3] In the Netherlands there has not been a policy of CS for women with recurrent HSV since 1987, and this practice has not resulted in an associated increase in HSV neonatal infections.[149] [evidence level 3]

Recurrent HSV may not cause symptomatic lesions, for example with cervical ulceration. A study of 15923 asymptomatic women in early labour reported isolating HSV from 34 women, neonatal HSV developed in 1of the infants (3%).[144] [evidence level 3] To prevent MTCT of HSV in asymptomatic women antenatal screening using HSV cultures was proposed, but this test also did not predict infants risk at birth.[150] [evidence level 3]

Three RCTs evaluate using oral acyclovir from 36 weeks to prevent recurrence of HSV at the time of birth. These found a r eduction in CS for HSV; however do not report the effect of acyclovir on MTCT.[151–153] [evidence level 1b]

A survey of obstetricians in the UK found there was no consensus of opinion or practice for recurrent disease or a history of disease.[146] [evidence level 3]

Cost effectiveness of CS to prevent MTCT of HSV

Three American studies have considered the factors that promote or inhibit the cost-effectiveness of various strategies to prevent MTCT of HSV.[154–156] Two studies by the same author have examined the additional efficacy, risks, and costs of CS for three groups of women: those presenting with primary HSV; women with a history of HSV; and women with no clinical HSV or history of HSV. The first study was a decision analytic model using data from a review of 19 studies.[154] Marginal (additional) costs and benefits over and above standard delivery were calculated.

Adopting a pr ogramme of offering routine CS for women with a h istory of HSV, 9 ne onatal cases would be averted per million births at an estimated cost of US$2.5 million per case of neonatal HSV averted. For women with primary HSV, 18 neonatal cases prevented per million with estimated cost saving of US$38,000 per case of neonatal HSV averted.[154] However more data on transmission rates and the efficacy of CS are required to make these estimates robust.[154]

A later study[155] modelled the cost-effectiveness of four strategies to prevent MTCT of HSV in women with at least one previous episode of HSV. CS only, acyclovir prophylaxis in late pregnancy with vaginal birth, acyclovir prophylaxis in late pregnancy with screening and follow-up, and a 'do nothing' option. The incremental cost per case prevented compared with 'do nothing' was highest for CS with 2.8 cases prevented at an additional cost of US$1.3 million, and lowest for acyclovir prophylaxis with screening and follow-up of neonates (an additional cost of US$400,300). This suggests that acyclovir therapy with follow-up was a more cost-effective strategy than CS alone.

The third paper examined whether acyclovir suppression was a more cost-effective option compared to offering CS only to women with a history of HSV.[156] The analysis showed that CS rate was the most sensitive variable (since it represents a high proportion of the total costs). The authors concluded that acyclovir suppression was a cost-effective alternative to CS for women with a history of genital herpes in agreement with analysis of the authors of the previous two papers. However, given the lack of data around the estimates of costs, the small sample size (46 women presenting with HSV or with a history of HSV) and the setting of the study, the findings are of limited value to this guideline.

In conclusion CS is the preferred (the most cost-effective and cost-saving) option in women presenting with primary HSV late in pregnancy. Acyclovir prophylaxis may be a more cost-effective option for women with recurrent HSV.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 14	RCTs are needed t o determine whether planned CS should be offered to prevent MTCT of HSV to women with recurrence of HSV at birth and in women in whom the primary HSV infection occurs in the first trimester of pregnancy.

5.9 Maternal request for CS

Introduction

In general, CS is a safe operation, especially when performed as a planned procedure. CS rates are rising worldwide, with an increasing proportion being undertaken in response to maternal request, in contrast to those that are performed for obstetric indications. There are many reasons for such requests but these are not always revealed by the women or adequately explored and clearly documented by their carers. This chapter addresses the issue of CS requested by women who have no apparent clinical reason for requesting a CS or who report fear of giving birth vaginally.

Rates of maternal request for CS

We identified 19 observational studies that report rates of maternal request for CS. Twelve of these are included in a systematic review (n = 13285)[157] and seven studies have been published since the review.[4,157–162] The largest of these studies were a survey of women attending antenatal clinics in Sweden (n = 3061)[160] and a s urvey of women's views of childbirth carried out within the National Sentinel Caesarean Section Audit [NSCSA] (n = 2475).[4]

The rates of preference for CS expressed by the women that were surveyed during pregnancy in UK, Australia and Sweden range from 6% - 8%.[4,157,158,160] [evidence level 3]

Within these studies there was a c onsistent relationship between women's preference for CS and either previous CS, previous negative birth experience, a complication in the current pregnancy or a fear of giving birth.[4,157,160] The main reason given for preference for CS was that it was perceived to be safest for the baby. The main reason given by those who expressed a preference for vaginal birth was the experience of a natural event. One study[157] concluded that maternal request for CS seems to be a marker for previously negative birth experiences and s hould prompt enquiries to address any issues or concerns.[157] [evidence level 3]

Fear of childbirth

It is estimated that about 6%–10% of pregnant women experience fear of childbirth.[163,164] [evidence level 3] Fears concerning childbirth such as pain, obstetric injury, unplanned CS, health care staff and the effects on family life have been reported to be more common among primiparous compared to multiparous women, and among those who had not attended antenatal classes.[165] [evidence level 3] Fear of health care workers was reported to be more common among women who either had problems in the current pregnancy or those who were intending a planned CS.[165] [evidence level 3] Manifestations of this fear included stress symptoms influencing everyday life, nightmares, a wish to have CS and a wish to avoid the current pregnancy and childbirth.[165] [evidence level 3]

Fear of childbirth has been measured using different scoring systems.[167] One case–control study found that women who requested planned CS due to fear of child birth were more likely to have also experienced a s pontaneous miscarriage (OR 1.73, 95% CI 1.05 to 2.85), a l onger time between pregnancies (OR 1.44, 95% CI 1.19 to 1.75), a longer duration of second stage of labour and a previous assisted vaginal birth (OR 4.50, 95% CI 2.18 to 9.31) or "emergency" CS (OR 26.91, 95% CI 11.86 to 61.07).[166] [evidence level 3] Previous infertility, induction of labour, epidural analgesia, duration or intervention in the third stage of labour in a pr evious pregnancy were not found to be associated with fear of childbirth in this study.[166]

Another study reported that women who had "emergency" CS had higher scores for fear of childbirth during pregnancy compared to those who had vaginal births.[167] However a prospective study carried

out in the U.K. did not find an association between fear of child birth and 'emergency' CS (OR 1.00, 95% CI 0.98 to 1.01).[26] [evidence level 3]

One RCT randomised women referred to an ant enatal clinic for fear of child birth to receive either cognitive behavioural therapy or usual care. No difference was detected in the proportion of women who chose to deliver by CS (OR 0.82, 95% CI 0.50 to 1.36), however fewer women in the intervention group who had vaginal births reported fear of pain in labour and had shorter labours.[168] [evidence level 1b]

Responding to requests for CS

Obstetricians estimate that they agree to perform a CS for about half of the requests they receive.[4] [evidence level 3] A woman's request for CS is the 'start of a continuing dialogue and process' during which a negotiated plan of care can be developed which enables women to continue to feel in control with the support of her healthcare providers.[169] [evidence level 4]

When a woman requests a CS the first response should be to determine the reason for the request and the factors that are contributing to the request. This can then be followed by the provision of information that compares the risks and benefits of planned CS and vaginal birth (see Tables 4.5 and 4.6).

Review question

What is the appropriate care pathway for women who request a primary caesarean section where there is no obstetric or medical indication?

Overview of evidence

When addressing this question for the guideline, the GDG hoped to find evidence relating to the effectiveness of interventions for providing care for women requesting a CS. Unfortunately, no such evidence was identified.

One prospective cohort study conducted in Sweden investigated postpartum outcomes in women having their first baby planning CS in the absence of medical indication compared to those planning a vaginal birth (Wiklund et al., 2007). Questionnaires were completed by the women on r ecruitment prior to giving birth, and at two days and three months postpartum. The outcomes recorded included their reason for the request, self-estimated health, expectations of birth and experience of delivery as well as duration of breastfeeding and time to re-establishment of sexual life. The study also had a secondary aim which was to study whether postpartum depression was more common in the group planning CS.

Evidence profile

Tables 5.5 and 5.6 summarise the evidence from this study which included 91 women who planned to have a CS and 266 consecutively recruited controls who were planning a vaginal birth.

Maternal outcomes

Table 5.5 GRADE summary of findings for comparison of planned CS versus vaginal birth (maternal outcomes)

Number of studies	Results		Effect		Quality
	Maternal request CS	Planned vaginal birth	Comparative t test/chi^2 (*P* value)	Absolute	
Maternal hospital stay (mean days)					
1 study (Wiklund et al., 2007)	3.6	2.8	34.40 (0.001)	0.8 days more	Very low
Birth experience (at 2 days postpartum) (mean Likert scale score where1 = worst, 10 = best)					
1 study (Wiklund et al., 2007)	8.3	6.7	31.25 (0.001)	1.6 more	Very low
Birth experience (at 3 months postpartum) (mean Likert scale score where1 = worst, 10 = best)					
1 study (Wiklund et al., 2007)	8.1	6.6	14.66 (0.002)	1.5 more	Very low
Uncomplicated breastfeeding (at 2 days postpartum)					
1 study (Wiklund et al., 2007)	50/92 (54%)	162/237 (68%)	10.95 (0.052)	1.4/1000 fewer	Very low
Breastfeeding (at 3 months postpartum)					
1 study (Wiklund et al., 2007)	79%[a]	248/266 (93%)	22.65 (0.001)	1.4/1000 fewer	Very low
Coitus (at 3 months postpartum)					
1 study (Wiklund et al., 2007)	57%[a]	67%[a]	2.61 (0.106)	1.0/1000 fewer	Very low
Family planning (plans for a sibling at 3 months postpartum)					
1 study (Wiklund et al., 2007)	52%[a]	81%[a]	28.13 (0.001)	2.9/1000 fewer	Very low
Depression (Edinburgh Postnatal Depression Scale)					
1 study (Wiklund et al., 2007)	not reported (NR)	NR	*P* = 0.877	not calculable	Very low

[a] Total number in case and/or control group not provided. Percentage reported by authors presented here

Neonatal outcomes

Table 5.6 GRADE summary of findings for comparison of planned CS versus vaginal birth (neonatal outcomes)

Number of studies	Number of neonates (%)		Effect		Quality
	Maternal request CS	Planned vaginal birth	Comparative t test/chi^2	Absolute	
Neonatal intensive care unit (NICU) care					
1 study (Wiklund et al., 2007)	5/99 (5%)	12/237 (5%)	*P* = 0.996	0/1000	Very low

Evidence statements

Maternal outcomes

The evidence for all of the following maternal outcomes was of very low quality.

Maternal hospital stay

One study found that women who had a planned CS remained in hospital for longer than women having a planned vaginal birth. This finding was statistically significant.

Birth experience

One study found that women with a planned CS reported a higher satisfaction score regarding their birth experience 2 d ays after birth compared with women having a planned vaginal birth and t his effect remained at 3 months. These findings were both statistically significant.

Uncomplicated breastfeeding

One study did not find a statistically significant difference in breastfeeding rates at 2 days postpartum between women who had a pl anned vaginal birth compared with women who had a planned CS. However, the same study found that more women who had a planned vaginal birth were breastfeeding at 3 months postpartum compared with women who had a p lanned CS. This finding was statistically significant.

Coitus

One study did not find a statistically significant difference in the numbers of women resuming coitus at 3 months following a planned CS compared with those who had a planned vaginal birth.

Family planning

One study found that more women who had a planned vaginal birth had plans for a second child at 3 months postpartum compared to women having a pl anned CS. This finding was statistically significant.

Depression

One study did not find a statistically significant difference in signs of postnatal depression comparing women who had given birth by planned CS compared with those who had had a pl anned vaginal birth.

Neonatal outcomes

Neonatal intensive care unit care

One study found did not find a s tatistically significant difference in the number of neonates who received neonatal intensive care following planned CS compared with planned vaginal birth. The evidence for this outcome was of very low quality.

Health economics

A model to compare the cost effectiveness of maternal request CS versus planned vaginal birth in primiparous women without any medical or obstetric indication for CS was developed. Full details of this model are presented in Chapter 13 but a summary is provided here.

Risks for the two modes of birth were taken from a clinical review undertaken for this guideline update comparing outcomes by planned mode of birth rather than actual mode of birth (see Section 4.2). The analysis considered the costs of birth and 'downstream' costs associated with the outcomes reported in the clinical review and found that a planned vaginal birth was approximately £700 cheaper than a maternal request CS. This implies that the NHS could save £4.9 million for every percentage point reduction in CSs if the characteristics of the population were similar to those of women included within the guideline model. A cost utility analysis found that planned vaginal birth dominated maternal request CS.

However, there may be other outcomes, such as urinary incontinence, which were not reported in the studies that were included in the clinical review which make the findings reported above more uncertain. Sensitivity analysis suggested that this could, under certain assumptions, produce a different cost effectiveness result.

Evidence to recommendations

Relative value placed on outcomes considered

The GDG agreed that the most important outcomes to consider were women's birth experience along with women's satisfaction and experiences of care. The GDG members noted that these are difficult outcomes to measure, given the disparate reasons that women request a CS.

The GDG also felt that women's mental health was an important outcome to consider. It was acknowledged that not agreeing to a request for a CS could have a negative impact on a woman's mental health and potentially lead to a long-term need for psychological support postnatally.

The GDG noted that the length of hospital stay will not always be an important consideration for women (as they felt that women would be aware and accept that a s urgical procedure will be associated with inpatient stay). However, GDG members agreed that it was important to recognise the increased cost and resources required associated with CS.

Trade-off between clinical benefits and harms

From the evidence reviewed for maternal request, the GDG noted that CS is associated with a longer hospital stay and a higher rate of women not breastfeeding at 3 months. However, the GDG weighed this against the finding that women who had a CS described a significantly better birthing experience, both immediately postnatally and 3 months after birth.

The GDG noted that the findings for breastfeeding might have been influenced by the different demographic profile of the two groups of women. Women in the planned CS group were significantly older than those in the planned vaginal birth group, more likely to have come from abroad, less likely to have received parenthood education and less likely to report their perceived health as good compared with women in the planned vaginal birth group.

The GDG members noted that the findings for depression were poorly reported and they did not feel that they were helpful. They were aware from their own experience that if some women did not receive a requested CS it could lead to poorer mental health outcomes, such as anxiety, both during and after the pregnancy, and difficulty bonding with their baby.

Trade-off between net health benefits and resource use

The GDG noted that there was likely to be an increased resource use with CS due to the increased length of hospital stay.

An economic model developed for this guideline suggested that planned vaginal birth was cost effective compared to a maternal request CS. However, this finding was limited to outcomes that were reported in the included studies for the clinical review undertaken for this guideline (see Section 4.2). A sensitivity analysis suggested that the inclusion of adverse outcomes not reported, such as urinary incontinence, could make the conclusion regarding cost effectiveness less certain. On balance, this

model does not provide strong evidence to refuse a woman's request for CS on cost effectiveness grounds.

The GDG agreed that there was likely to be a cost associated with providing psychological support to those women who experience mental health problems as a result of not receiving a CS on request. However, it noted that this was only likely to be the case for a small proportion of women. The GDG's experience of caring for women requesting a CS was that anxiety about giving birth vaginally was often at the root of the request; for example as a result of a previous poor birth experience. The GDG believed that when women are given the opportunity to discuss these anxieties in a supportive environment, the anxieties can often be reduced to the point where the woman is able to choose a planned vaginal birth. The GDG agreed this was the preferred approach. It was not felt to be necessary for the person providing this psychological support to be a mental health expert unless clinically indicated, but rather that it could be provided by a member of the maternity team, such as a midwife or obstetrician. It was felt that the extra resource required to provide this support would be offset by resources saved where a request for planned CS was appropriately changed to a planned vaginal birth as a r esult of addressing a woman's anxieties or concerns antenatally. However, in situations where a woman persists in her request for a C S following provision of the opportunity to discuss and explore her reasons for the request, the GDG believed that the potential for psychological harm caused by denying this request was sufficient to warrant this unacceptable in terms of the woman's health: it also has the potential to be c ostly in terms of long-term need f or psychological support. It was concluded, therefore, that if a vaginal birth is not an acceptable option to the woman after discussion and the offer of support, she should be supported in her choice of a planned CS.

The GDG was aware of instances where women had been offered referral to a perinatal mental health expert and t hat this expert had not been granted access to the planned place of birth. The GDG recognised that having this access is important in order to provide appropriate support and adequately address any anxieties regarding the birth setting. As a result, the group agreed that it was appropriate to recommend that the healthcare professional providing this care be given access to the planned place of birth.

Quality of the evidence

The GDG was hoping to find evidence of the effectiveness of antenatal interventions aimed at supporting women who request a CS in the absence of medical indications. Unfortunately, no such evidence was identified. The one included study compared outcomes for women requesting and receiving a C S with those who had a pl anned vaginal birth. This information was only marginally useful in helping the GDG to decide its recommendations.

The women in the two groups were significantly different in a number of characteristics at baseline: compared to the planned vaginal birth group, the women who had a planned CS were older, more had come from abroad and more had had IVF, although fewer reported their pregnancy was planned or that they had received parenthood education or perceived their health as good. The groups were only similar in terms of having a university education and in the number of smokers.

Analysis was not performed to assess the effects of these differences on the results obtained from the questionnaires. In addition, a sub-group/per protocol analysis was not performed to estimate outcomes separately for women who planned a vaginal birth but subsequently had an unplanned CS (n = 29, 11%) or an instrumental delivery (n = 36, 13%).

The study was conducted in a middle-to-high income urban area in Sweden and the women were highly educated. The GDG considered the results to be relevant to a UK population but noted that the study was not representative of women from a l ow socio-economic background. The GDG agreed that the quality of the study means that it is of limited relevance.

The GDG noted that there was no evidence comparing women who requested a CS and received one with those who wanted a CS and didn't receive one. This would have been a useful comparison.

It was also noted that there appeared to be incomplete reporting of some of the findings, such as postnatal depression, which undermined the validity of those findings.

Other considerations

The GDG was aware that some groups of women, such as women who don't speak English as a first language, can find it more difficult to express their concerns. They recognised the importance of ensuring that all women are encouraged to discuss their concerns with a healthcare professional at an early stage in pregnancy. Discussions with women requesting a CS need to sensitively explore reasons behind the request, including: previous birth trauma, women's perceptions of the risks of both vaginal birth and CS; women's perceptions of vaginal birth, including misconceptions and lack of knowledge about birth; and planning a date for giving birth and convenience.

The GDG also believed it was important for an individual obstetrician to be able to exercise their own beliefs about what is the best course of action in any given situation. Thus, if an obstetrician feels a woman's request for CS is not appropriate after the woman has received appropriate counselling and support, then the obstetrician should be able to decline to support the women's request. However, this does not overrule the woman's rights to express a preference for a C S, and in this instance the obstetrician should transfer care of the woman to an obs tetrician who is happy to support the woman's choice.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideli

Number	Research recommendation
RR 15	What support or psychological interventions would be appropriate for women who have a fear of vaginal childbirth and request a CS? Interventions for evaluation could include: • support from a named member of the maternity team • continuity of carer • formal counselling • cognitive behavioural therapy.

Outcomes could include:

- mode of birth planned at term
- psychological outcomes (postnatal depression, post-traumatic stress disorder, self-esteem, mother-infant bonding)
- breastfeeding.

Why this is important

Fear of vaginal childbirth may stem from:

- fear of damage to the maternal pelvic floor
- damage to the baby during childbirth
- self-doubt on the ability to physically achieve vaginal birth
- previous childbirth experience
- unresolved issues related to the genital area.

Currently there is a wide variation in practice and limited resources lead to limited availability of effective interventions. Interventions that may be appropriate include:

- antenatal clinics dedicated to providing care for women with no obstetric indications who request a CS
- referral to a psychologist or a mental health professional
- referral to an obstetric anaesthetist
- intensive midwifery support.

Continuity of healthcare professional support from the antenatal to the intrapartum periods and 'one to one' midwifery care during labour are also often lacking and may make a difference to women who are anxious or afraid.

All of these interventions have different resource implications and t here is no clear evidence to suggest that any are of benefit. The proposed research would compare in a randomised controlled trial two or more of these interventions in women requesting a CS. In the absence of any evidence, there is a c ase for comparing these interventions with routine antenatal care (that is, no special intervention).

This research is relevant because it would help to guide the optimal use of these limited resources and future guideline recommendations.

RR 16 Medium to long term quality of life study comparing psychological and physical outcomes in women who have had a requested and given birth by CS compared with women who plan a vaginal birth.

RR 17 Qualitative and quantitative research should be carried out to look at the reasons that lead to pregnant women's request for CS

RR 18 The effect of counselling and other interventions such as second opinion and provision of support on the likelihood of CS for women who express a preference for CS need further evaluation.

6 Factors affecting likelihood of caesarean section during intrapartum care

6.1 Place of birth

Planned home birth

One systematic review that includes one small randomised controlled trial (RCT) comparing planned home birth to planned hospital birth was identified (n = 11). The RCT included operative delivery but not specifically caesarean section (CS). No difference was reported for any of the outcomes measured however this was a small RCT and has limited power to detect a difference.[171] [evidence level 1b]

A systematic review of observational studies evaluating the safety planned home births (in countries with good health resources) versus planned hospital births identified six cohort studies (n = 24,092)[172] [evidence level 2b] Outcome measures included perinatal and maternal mortality, Apgar scores and incidence of maternal lacerations. The review also reported other outcomes including CS rates. No difference was detected in perinatal mortality in any of the individual studies, nor in the pooled data. In the home birth group, both low 5 minute Apgar and maternal lacerations were less frequent in all studies. The odds of CS were lower in the planned home birth group in five studies (reported crude odds ratio [OR] of CS in studies: 0.04; 0.09; 0.31; 0.05; 0.27). No maternal deaths occurred but the studies are underpowered to evaluate this outcome.[172] [evidence level 2a]

A subsequent cohort study in Canada (n = 2176) reported on CS rates and maternal and perinatal morbidity between 3 groups, women who had a planned home birth, women who were attended by a physician in hospital and women who were attended by a midwife in hospital. They reported that less women in the home birth group had a CS, compared with women in the physician-attended hospital group (adjusted OR 0.3, 0.22 to 0.43) and compared with the midwife attended hospital group (adjusted OR 0.66, 0.44 to 0.99). Odds ratios were adjusted for maternal age, lone parent status, income quintile, substance use and parity. No difference was detected between the groups for maternal or perinatal morbidity.[173] [evidence level 2a]

A large prospective case controlled UK study of 5971 planned home births and 4724 planned hospital births reported that planning a home birth halved the chance of having a CS (unadjusted OR 0.49, 95% confidence interval [CI] 0.39 to 0.62).[174] [evidence level 2b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

‘Midwifery-led unit’ or ‘birthing centre’

Current convention in the UK is that the term “midwifery-led units” refers to units that are near to or adjacent to a hospital maternity facility and that “birthing centres” are stand alone units. However, this convention is not standardised in the in the literature. The centres are intended for “low risk” women. The care is midwife led with minimal medical intervention, sometimes described in the literature as ‘home like’. Case series have reported reduced CS or operative delivery in ‘midwifery-led units’ or’ birthing centres’.[175–180] [evidence level 4]

A systematic review that included six RCTs (n = 8677) compared clinical outcomes between women delivering in a midwife led unit or in a hospital.181 [evidence level 1a] The RCTs were conducted in Stockholm[182], Australia[183], United Kingdom[184–186] and Canada.[187] The centre in each of the RCTs was situated close to the conventional labour ward within the same hospital setting. The RCTs all describe the environment as ‘home like’ and that the care was aimed at women retaining control and choice with minimal medical intervention. Three of the studies do not describe the study environment any further.[182,183,185] Three of the studies describe the furnishings in detail (for example “furnished to appear like a nor mal household bedroom”)[184,186,187] and one RCT also mentions specifically interventions that were avoided such as enemas, perineal shaving, intravenous infusion and electronic fetal monitoring.[187] [evidence level 1b]

All RCTs (n = 8646) reported on CS rates, a further 39 outcomes are also reported. No difference was detected in CS rates between ‘midwifery-led unit’ and conventional birth settings (risk ratio [RR] 0.85, 0.72 to 1.00). The review has a 90% power to detect a difference of at least 2% in CS rates if such a difference exists. No difference in instrumental vaginal deliveries was detected (OR 0.87, 0.74 to 1.01). Birth in a ‘midwife-led unit’/’birth centre’ was associated with lower rates of intrapartum analgesia (OR 0.82, 0.72 to 0.93); less augmented labour (OR 0.72, 0.64 to 0.81); and fewer women ‘less than completely satisfied with care’ (OR 0.62, 0.55 to 0.70).[181] [evidence level 1a]

A further UK RCT (n = 2578) comparing care ‘midwifery-led unit’ or in a conventional labour ward did not evaluate mode of delivery but assessed maternal satisfaction using a postal questionnaire. No difference was detected in rates of satisfaction between the groups. Women who had their babies in the ‘midwifery-led unit’/’birthing centre saw fewer medical staff, were more likely to report having had a choice as to moving around during childbirth and alternative positions for birth and more likely to have made their own decisions regarding analgesia.[188] [evidence level 1b]

We did not identify any RCTs that compared birthing centres which are stand alone to conventional maternity facilities. However we did identify a case series following women admitted for labour and delivery at 84 ‘free standing’ birthing centres in the United States (n = 11,814). The overall rate of CS was 4.4%. The rate of transfer to other maternity facilities before birth was 11.9%. Other morbidity outcomes reported include 5-minute Apgar of less than 7 occurred in less than 0.5% of births.[178] [evidence level 4]

An Australian postnatal survey of women’s views about their birth experience (n = 395) reports that women who had given birth at home or at a ‘midwifery-led unit’ were more likely to feel that the birth place affected the bonding process and l ess likely to see birth as a m edical condition compared to women who gave birth in a conventional labour ward. Women who gave birth at home were older, more educated, more likely to be multiparous and better informed about childbirth compared to the women who gave birth in the ‘midwife-led unit’ or in the conventional labour ward. Adjusting for these differences, place of birth correlated with women’s satisfaction with healthcare providers.[189] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 19	RCTs comparing planned birth in a stand-alone birthing centre to birth in conventional maternity facilities or midwifery led units.
RR 20	Qualitative research is needed to explore women's opinions on place of birth and the impact of place of birth on their birth experiences.

Delayed admission to labour ward

A systematic review included one RCT (n = 209) compared a labour assessment program in a separate unit within the hospital and d elayed admission to labour ward until labour is in the active phase, with direct admission to the labour ward.[190,191] The RCT did not detect a difference in CS rates between the two groups (OR 0.70, 95% CI 0.27 to 1.79). At least two thousand women would be needed in each group to detect a 3% difference in CS therefore this RCT is underpowered to detect this difference in CS rates. There were differences in other outcomes such as length of time spent in the labour ward, analgesia requirements, oxytocic use and m aternal satisfaction, measured using sense of control (see evidence table). [evidence level 1b]

An observational study (n = 3220) reported a r educed likelihood of CS with increased cervical dilatation at the time of presentation in labour The CS rates for nulliparous women presenting at 0–3 cm was 10% compared with 4% for those presenting at 4–10 cm (p = 0.001). This was consistent for nulliparous and parous women.[192] [evidence level 2b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

6.2 Factors reducing the likelihood of CS

One-to-one support

One-to-one support in labour had b een evaluated in recently published systematic review;[193] this current review replaces the previous review on this subject by the same authors.[194] [evidence level 1a]. The first review included 14 RCTs (n = 5000), the new review includes 15 RCTs (n = 12,791) the newly included study is a multi centre RCT (n = 6915 women) conducted in Canada and the US (13 centres). The trial evaluated the effectiveness of continuous labour support by a specially trained nurse/midwives to usual care. Each hospital in the RCT had a C S rate of at least 15%. The main outcome measure was CS rate. The study did not detect a d ifference in CS rate between the two groups. The use of continuous electronic fetal monitoring higher in the usual care group (79%) compared to those in the continuous support group (75%, p < 0.001). All comparisons of women's likes and dislikes, and their future preference for amount of nursing support, favoured the continuous labour support group.[195] [evidence level 1a]

The new systematic review (15 RCTs, n = 12,791 women) evaluates the effects of one-to-one support on women and their babies. In addition the new review also considers whether the effects of continuous support are influenced by routine practices and policies in the birth environment that may affect a w oman's autonomy, freedom of movement and ab ility to cope with labour; whether the caregiver is a member of staff and whether the continuous support begins early or late in labour.[193] [evidence level 1a] The RCTs in the review included support persons that varied in terms of their experience, qualifications and relationship to the women in childbirth. In eight RCTs the support was provided by a member of hospital staff. The remaining 7 RCTs included women from the community

("doulas"), with or without prior training, a childbirth educator, or a close female relative. Half of the RCTs were conducted in developed countries, where hospital policy permitted women to be accompanied by their husband/partners or other family members during labour. The remaining RCTs were conducted in developing countries in settings in which only the support person allocated by the study was allowed to accompany the woman during labour. No RCT evaluated the effects of husbands or partners as providers of support.

The results of the review reported that women who had continuous one-to-one support during labour were less likely to have a CS (15 trials, n = 12,791, RR 0.90, 95% CI 0.82 to 0.99). The effects of continuous support on CS appeared to be stronger in settings which did not permit the presence of additional support people (chi squared = 4.46, $p < 0.05$) and when epidural was not routinely available (chi squared 4.97, $p < 0.05$). The routine use of EFM did not affect the impact of one-to-one support on CS rates. The reduction in CS was influenced by who was giving the support and the reduction was only seen in the RCTs where the support was not provided by members of staff (RR 0.74, 95% CI 0.61 to 0.9). The difference between different sub-groups of non medical providers of support was not statistically significant. The impact of timing of onset of continuous support was of borderline statistical significance (chi squared = 5.93, $p = 0.05$) favouring support that began before active labour. Thirty other outcomes were considered in the review, but are not reported here.[193] [evidence level 1a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Pregnancy after 41 weeks

A systematic review of 26 RCTs compared induction of labour with expectant management after 41 weeks. Offering routine induction after 41 weeks reduced perinatal death (19 RCTs, n = 7925. Peto OR 0.20, 95% CI 0.06 to 0.70) and the rate of CS (9 RCTs, n = 5954 Peto OR 0.87, 95% CI 0.77 to 0.99).[196] [evidence level 1a]

It is estimated that by 41 weeks 74% of women have given birth, this increases to 82% by 42 weeks. The risk of stillbirth increases from 1 per 3000 ong oing pregnancies at 37 w eeks to 3 per 3000 ongoing pregnancies at 42 weeks to 6 per 3000 with ongoing pregnancies at 43 weeks. A similar increase in neonatal mortality is also reported.[197] [evidence level 2a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Partogram

Progress in labour can be assessed using the clinical parameters of descent of the presenting part and dilatation of the cervix. No study has evaluated tests based on maternal and fetal outcomes. The partogram is derived from a c urve describing normal labour (Friedman's curve). The original Freidman's curve was developed using observational data from 100 American primigravid women at term in spontaneous labour (included 98 singleton cephalic, 1 breech presentation and 1 m ultiple pregnancy). Twenty two percent of the women received caudal anaesthesia and 10 percent received oxytocin augmentation. Cervical dilatation was determined using rectal examination predominantly at

10, 30 or 60 minute intervals. Curves of dilatation versus time were produced and resulted in a sigmoid curve of progress of labour with average progress during the active phase of 1.1cm per hour and average length of labour of 12 hours for nulliparous women and 6 hours for multiparous women.[198] [evidence level 3] More recent observational studies from the USA (n = 2511) measured the length of labour in women who had not received oxytocin or epidurals and report average length of labour for nulliparous women to be 19.4 hours and 13.7 hours for multiparous women. This is longer than the originally described normal labour curve.[199] [evidence level 3]

On a partogram cervical dilatation and descent of the presenting part are plotted graphically against time. The partogram was initially proposed as a screening tool for use in poorly resourced countries to identify women who needed referral to hospital. The partogram includes two lines, an alert line and an action line. The alert line is set at a rate of 1cm per hour (derived from Friedman's curve). The action line is drawn 4 h ours to the right of the alert line. If the progress of labour crossed the action line women were referred to hospital for either augmentation of labour or CS.[200,201] [evidence level 3]

Three RCTs have evaluated the use of partograms in the management of labour. The first RCT compared using a partogram with a four hour action line to not using a partogram in the management of labour. This was a c luster randomised trial where the unit of randomisation was a m aternity hospital. Four pairs of hospitals participated. Each hospital had a practice of active management of labour including oxytocin use. The effect of the partogram was analysed in a before and after design which compared labour outcome data on 10,049 women who delivered before implementation of the partogram (4 hour action line) with data on 9130 women who delivered after implementation. This RCT did not report CS rates but did report rates of spontaneous vaginal birth. The number of spontaneous cephalic births was increased after implementation of the partogram (83% vs. 86.3%, $p < 0.001$). There was a decrease in the proportion of women with labours of more than 18 hours (551 versus 249, $p < 0.001$), labours augmented by oxytocin ($p = 0.041$) and t he number of intrapartum stillbirths (0.5% vs. 0.31%, $p = 0.024$). There was no change in the overall duration of labour or other neonatal indices. Similar patterns were noted for multiparous and primiparous women.[202] [evidence level 1b]

The second RCT (n = 928 women) compared partograms with different action lines (either 2, 3 or 4 hours to the right of the alert line set at 1 c m per hour). The primary outcomes were CS rate and maternal satisfaction. CS rate was lowest when labour was managed using a partogram with a 4 hour action line. Women in the 2 hour arm were most satisfied with their labour experience. No difference was found in the secondary outcomes of neonatal and maternal morbidity.[203] [evidence level 1b]

The third RCT conducted in South Africa (n = 694) compared management using a single alert line partogram offering oxytocin if the alert line was crossed (with 2 hour vaginal examinations) to management using a 4 hour action line. CS was a primary outcome. Women in the intervention group were less likely to have a CS (RR 0.68, 95% CL 0.50 to 0.93).[204] [evidence level 1b]

Meta-analysis of the 2 RCTs that included comparison of the two hour action line with a four hour action line partogram showed no difference in CS rate between the use of 2 or 4 hour action lines (RR 0.93, 95% CI 0.48 to 1.78).[203,204] [evidence level 1b] The use of a 4 hour partogram reduces the number of vaginal examinations that women would undergo during labour.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 22	RCT evidence is needed to determine the impact of partograms based on di fferent curves of labour on CS rates and morbidity outcomes.

Decision making for unplanned CS

Second opinion has been proposed as an intervention to decrease CS rates. Second opinion refers to a doctor needing the agreement of another usually more senior second opinion before a decision for CS can be made. A large multi centred RCT in five South American countries has recently been completed however the results have not been reported.

Using the NSCSA data the proportion of CS cases with consultant involvement varied between maternity units, although in the majority of CS, the consultant was the most senior obstetrician involved in the decision (see table).

In maternity units where consultant obstetricians were frequently involved either in the decision for CS or present in theatre for “emergency” CS the crude and adjusted CS rates (having taken into account case mix differences) were lower (see Tables 6.1 and 6.2).

Table 6.1 Proportion of CS with consultant involvement in maternity units

	Median (%)	**IQR** (%)
Consultant present in theatre		
All CS	12.6	7.6 – 18.5
“Emergency” CS	8.7	5.8 – 13.3
“Emergency” CS out of hours (1800 – 0700)	4.8	2.1 – 8.8
Consultant involved on decision making to perform CS		
All CS	76.4	63.0 – 89.2
“Emergency” CS	75.0	57.2 – 87.5
“Emergency” CS out of hours (1800 – 0700)	72.4	52.0 – 87.5

IQ Interquartile range

Table 6.2 Relationship between proportion of CS where there was consultant involvement and CS rates

	Crude CS rate		**Adjusted CS rate**	
	Spearman’s rank correlation coefficient	**P value**	**Spearman’s rank correlation coefficient**	**P value**
Consultant present in theatre				
All CS	-0.01	0.85	-0.05	0.48
“Emergency” CS	-0.12	0.06	-0.14	0.04
“Emergency” CS out of hours (1800 – 0700)	-0.12	0.07	-0.14	0.04
Consultant involved in decision making to perform CS				
All CS	-0.19	< 0.01	-0.19	< 0.01
“Emergency” CS	-0.18	< 0.01	-0.17	0.01
“Emergency” CS out of hours (1800 – 0700)	-0.19	< 0.01	-0.17	0.01

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Electronic fetal monitoring and fetal blood sampling

Systematic reviews of 9 RCTs (conducted between 1976–1993, n = 18,561 women) have compared the use of electronic fetal monitoring (EFM) during labour to intermittent auscultation. No difference is detected in perinatal mortality (RR 0.89, 95% CI 0.60 to 1.33). The use of EFM during intrapartum care results in increased CS rates (RR 1.4, 95% CI 1.23 to 1.61) This increase is less marked if fetal blood sampling (FBS) is used (RR 1.27, 95% CI 1.08 to 1.51 for EFM with FBS, compared with RR 1.41, 95% CI 1.23 to 1.61 for EFM without FBS).[205,206] It is therefore recommended that where delivery is contemplated because of an abnormal fetal heart rate pattern, in cases of suspected fetal acidosis, FBS should be undertaken in the absence of technical difficulties or any contraindications. Contraindications to FBS include maternal infection (such as HIV, hepatitis viruses or herpes simplex virus); fetal bleeding disorders such as haemophilia and prematurity (less than 34 weeks). Where there is clear evidence of acute fetal compromise, e.g. prolonged decelerations (longer than 3 minutes), FBS should not be undertaken and the baby should be delivered urgently.[2]

The NSCSA measured practice against this audit standard for CS.[4] Overall an abnormal CTG was noted in 69% of singleton cephalic pregnancies delivered by CS for presumed fetal compromise. If the CTG was noted to be severely abnormal or cervical dilatation was less than 4cm these cases were not included (50%). Overall practice concorded with the audit standard in 44% of cases. However there was marked variation in practice. Five percent of maternity units met the standard in all cases (100%), in 9% the standard was not reached for any case. Units and regions which used FBS more frequently before CS had lower CS rates. Overall, cases in which this recommendation was not met contributed 4.6% to the overall CS rate or about 1% of all births.[4]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

6.3 No influence on likelihood of CS

The following interventions during intrapartum care have not been shown to influence the likelihood of CS. These interventions may have other effects (beneficial or harmful) which are outside the scope of this guideline and are not considered here.

Walking in labour

Two RCTs have evaluated the effect of walking in labour to usual care, one conducted in the UK (n = 68)[207] [evidence level 1b] and the other conducted in the USA (n = 1067)[208] [evidence level 1b]. No difference was detected in the CS rates between women who walked around during labour and those who did not (RR 0.71, 95% CI 0.43 to 1.20). Most of the weight of the pooled RR in the meta-analysis comes from the larger RCT. Therefore it is not surprising that the US RCT did not detect a difference in CS rates between groups (RR 0.73, 95% CI 0.43 to 1.24). The study has 80% power to detect a difference of at least 4% in CS rate, therefore if walking in labour has an impact on CS rates it is likely

to be less than 4%. The RCT did not detect a difference in other outcomes including length of the first stage of labour and need for analgesia. The results were similar for parous and multiparous women.[208] [evidence level 1b]

Position in the second stage of labour

A systematic review[209] of 18 RCTs evaluated the effect of different positions for the second stage of labour. No difference was detected between any upright or lateral position during second stage on CS rates compared to supine or lithotomy positions (12 RCTs; n = 2250; RR 0.87, 95% CI 0.52 to 1.45). Use of any upright or lateral position, compared with supine or lithotomy positions, was associated with the following: reduced duration of second stage of labour (12 RCTs. Weighted mean difference: 5.4 minutes, 95% CI 3.9, 6.9 minutes); a reduction in assisted deliveries (17 RCTs. OR 0.82, 95% CI 0.69 to 0.98); a reduction in episiotomies (11 RCTs: OR 0.73, 95% CI 0.64 to 0.84); an increase in second degree perineal tears (10 RCTs: OR 1.30, 95% CI 1.09 to 1.54); increased estimated risk of blood loss greater than 500 ml (10 RCTs: OR 1.76, 95% CI 1.34 to 3.32); reduced reporting of severe pain during second stage of labour (1 RCT: OR 0.59, 95% CI 0.41 to 0.83) and fewer abnormal fetal heart rate patterns (1 RCT: OR 0.31, 95% CI 0.11 to 0.91).[209] [evidence level 1a]

Immersion in water in labour

Water births and the use of immersion in water during labour comprise 0.6% of births in the UK.[210] [evidence level 3] A systematic review[211] [evidence level 1a] that included three RCTs (n = 988) compared immersion in water during labour (no births occurred in the water) to conventional care. Another RCT (n = 1237) on this topic has been published since this review.[212] [evidence level 1b] The CS rate in the intervention arm of these RCTs ranged from 1.8% to 8.9%, in the control group it ranged from 0% to 7.9%. A new meta-analysis of the findings from these 4 RCTs (n = 2225) did not detect a difference in CS rates between the two groups (RR 1.31, 95% CI 0.89 to 1.93) [evidence level 1a]. Overall these studies have a 90% power to detect a difference of at least 4% in CS rates between the two groups therefore if water birth has an effect on CS rate it is likely to be less than 4%.

One of the above RCTs interviewed a subset of women about their use and satisfaction with care in labour. Women most liked the presence of a support person and immersion in water.[213]

A national cohort study using regional UK survey data compared the perinatal mortality and morbidity of 4032 births either in water (or following labours in water) to births not in water. They report no difference in perinatal mortality (RR 0.9, 99% CI 1.2 to 3.6). There were two cases of water aspiration which required admission to NICU.[214] [evidence level 3] A prospective observational study in Switzerland of 7508 bi rths of which 2014 were water births showed no increased risk for women or their babies. The study reported: lower episiotomy rates, higher rates of intact perineum, lower blood loss and lower use of pain killers in women who had a waterbirth.[215] [evidence level 3]

A number of position papers have provided guidelines for water births in the absence of adequate evidence, and have suggested the continued reporting of adverse events.[216,217] [evidence level 4]

Analgesia during labour

There has been an increase in the use of epidural analgesia in labour and there has been concern that this may have contributed to an increase in CS. Observational data provides conflicting results.[218–227] [evidence level 3]

Two systematic reviews have included RCTs of women in spontaneous labour who requested analgesia and were randomised to receive either epidural analgesia or usual analgesia (such as intravenous or intramuscular pethidine). The first review of 10 R CTs (n = 2369) did not detect a difference in CS rates between the two groups (OR 1.5, 95% CI 0.81 to 2.76).[228] [evidence level 1a]. A subsequent review includes 11 RCTs (n = 3157, it includes 6 RCTs from the previous review, 2 new RCTs[229,230] and 2 RCTs not included in the first review[231–234]). It also did not detect a difference in CS rates (OR 1.30, 95% CI 0.93 to 1.83).[235] [evidence level 1a]

We did not identify any RCTs that had compared parenteral analgesia (intravenous or intramuscular opiate derived analgesia) to placebo or complementary therapies on mode of birth and risk of CS.

Raspberry leaf during labour

An RCT (n = 192) was conducted that looked at the use of raspberry leaf, given in tablet form during labour. No difference was detected in length of labour or mode of birth, including "emergency" CS[236] [evidence level 1b]. Earlier descriptive studies of raspberry leaf used in labour excluded women who had a CS from their analysis.[237] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 23	RCT evidence is required to evaluate the effect of parenteral analgesia (intramuscular and intravenous morphine based analgesia) used during childbirth on the likelihood of CS.

Complementary therapies during labour

Complementary therapies used during pregnancy include acupuncture, aromatherapy, hypnosis, Chinese medicines, herbal products and nut ritional supplements, homeopathic medicines and raspberry leaf (discussed previously). We have only considered their use during labour in this guideline. The antenatal use of complementary therapies is included in the NICE Antenatal Care Guideline.[1]

We identified a systematic review of complementary therapies for pain management in labour which includes seven RCTs (n = 366) using different modalities of pain management[238] [evidence level 1a]. CS rates were considered as secondary outcomes in two of the included studies: one R CT using acupuncture (n = 90), one aromatherapy RCT (n = 22), neither showed any difference in CS rates however the trials were underpowered to evaluate this outcome. Two RCTs (n = 125) have compared the use of hypnosis to usual analgesia. CS was not reported. However women in the hypnosis group were more likely to have a spontaneous vaginal birth (RR 1.38, 95% CI 1.13 to 2.47).[238] [evidence level 1b]

A large survey (n = 8058) of women views on the effect of using aromatherapy during labour. Effect was measured using a Likert scale. About half of the women reported aromatherapy was helpful, a minority (14%) found it unhelpful.[239] [evidence level 4]

The suggested benefits of Chinese medicines in labour include prevention of nausea and vomiting, heartburn and fatigue. We did not identify any RCTs on t heir use in labour. We identified a c ohort study on the use of Chinese medicines during pregnancy which reported no effect on mode of birth.[240] [evidence level 2b]

Surveys from the USA and Australia suggest that there is widespread use of herbal products and nutritional supplements during pregnancy, 12% of women in Australia[241] [evidence level 4] and 7% in the USA.[242] [evidence level 3] A UK survey of midwives estimated that 34% of midwives offer some

form of complementary medicine to women during pregnancy or childbirth.[243] [evidence level 4] The majority of this use is antenatal with only certain herbal products used during labour or to induce labour. We did not identify any RCTs on the use of herbs during labour but a number of expert opinion papers offer advice and suggested guidelines for their use. Using information from midwives surveys they recommend caution with the use of blue cohosh (due to reports of dizziness, fainting, nausea and meconium stained liquor as well as case reports of neonatal heart failure); black cohosh and castor oil to induce labour.[244] [evidence level 4] There have not been reported complications with either evening primrose oil or raspberry leaf.[245,246] [evidence level 4]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 24	RCTs are needed to establish the safety and efficacy of complementary therapies used during labour.

6.4 'Failure to progress' in labour and CS

In the NSCSA, "failure to progress" in labour (FTP) was the primary indication for CS in 35% (n = 4896) of women with term cephalic pregnancies and no ut erine scar. For 17% (n = 811) of these women cervical dilatation at the time of CS was less than 4 cm. While 74% of these women had their labour augmented (65% were given oxytocin and amniotomy, 7% amniotomy only, 2% oxytocin only), 24% (n = 193) had no augmentation of labour before CS. The majority (98%) of women with cervical dilatation of at least 4 c m at the time of CS had ei ther amniotomy or oxytocin or both. Twenty-five percent (n = 1231) of CS for FTP were done at a cervical dilatation of 10 cm, 28% (n = 345) of these women did not have oxytocin before CS. These cases in which labour augmentation with oxytocin was not used contributed 3.2% to the overall CS rate.[4] [evidence level 3]

We searched for research that evaluated the impact of packages of interventions such as active management of labour and interventions such as routine amniotomy or oxytocin infusion used together or alone are included.

Active management of labour

Active management of labour refers to a labour ward protocol that includes routine amniotomy and early augmentation with oxytocin as well as strict criteria for the diagnosis of labour, abnormal progress in labour and f etal compromise. It also includes the continual presence of a midwife or support person during labour and peer review of assisted deliveries. Observational studies by the initiators of active management reported lower CS rates, reduction in the number of women having prolonged labour, better neonatal outcomes and improved maternal satisfaction.[247] Subsequent observational studies did not replicate these findings.[248,249] It has remained an area of controversy.[250] [evidence level 3]

A systematic review of 10 RCTs (n = 5111) evaluated the effects of a package intervention of early augmentation of labour with amniotomy and oxytocin in nulliparous women compared to usual care

('care at the discretion of the individual doctor/midwife attending the woman in labour'). Overall there was no r eduction in the likelihood of CS with early amniotomy and early oxytocin infusion (OR 0.9, 95% CI 0.7 to 1.1). Subgroup analysis of the therapy RCTs (recruited women in whom a de lay in progress was diagnosed) (3 RCTs, n = 109) and prevention RCTs (7 RCTs, n = 5002) were undertaken. No difference in CS rate was apparent in these subgroups. However the therapy subgroup is too small and is therefore underpowered to evaluate this outcome.[251] [evidence level 1a] None of the RCTs had maternal satisfaction as an outcome measure.[251] [evidence level 1a]

A recently published RCT from South Africa (n = 694) compared using a single line partogram, two-hourly vaginal examinations and us e of oxytocin if the partogram line was crossed in nulliparous women to usual management (4 hour vaginal examinations). CS rates in the intervention group were lower (RR 0.68 95% CI 0.50 to 0.93) Analysis is by intention to treat but it was noted that there was a high proportion of protocol violations in both groups (about 30%)[204] [evidence level 1b]. It was not possible to include this RCT with the earlier RCTs as the descriptions of management of labour were not consistent.

Oxytocin

Most RCTs identified incorporate the use of oxytocin into active management of labour. However we identified one RCT (n = 60) that looked at the effect of oxytocin without other components of active management of labour in women in whom there was a del ay in labour progress. Women whose cervical dilatation was less than 0.5 cm per hour were randomised to one of three groups: group one – oxytocin was deferred for 8 hours; group two – low-dose oxytocin infusion (2mu/minute) or group three – high-dose oxytocin (7mu/minute). The CS rates between the three groups were not statistically different (45%, 35% and 26% respectively X^2 1.6346 2df). There were no differences between the groups in terms of neonatal outcomes.[252] [evidence level 1b] This RCT is underpowered to assess these outcomes.

Observational data from the original active birth management study suggested benefit of the early use of high dose oxytocin infusions.[247] [evidence level 3] Subsequent observational studies that looked at the use of oxytocin alone in labour suggested that it decreased the CS rates[253] and did not result in increased neonatal morbidity.[254,255] [evidence level 3]

Amniotomy

A systematic review of nine RCTs looked at the impact of early routine amniotomy.[256] CS rate was reported in 8 of the included RCTs (n = 4008). No difference in CS rates was found between early routine amniotomy and no routine amniotomy (OR 1.26, 95% CI 0.96 to 1.66). Amniotomy was associated with a reduction in labour duration of between 60 and 120 minutes, reduction in the likelihood of 5 minute Apgar of less than 7 (OR 0.54, 95% CI .0.30 to 0.96) and a decrease in the use of oxytocin (OR 0.79, 95% CI 0.67 to 0.92). Groups were similar with respect to other neonatal indicators.[256] [evidence level 1a]

Operative delivery in the second stage

Four percent (n = 1203) of all CS were performed for failure to progress in the second stage of labour (in women without a previous CS who had a term singleton cephalic infant). In the majority 55% (n = 661) no other method of delivery had been attempted before CS. In 35% (n = 427) of these occurrences, CS followed a failed attempt at ventouse, in 7% (n = 81) both ventouse and forceps had been attempted prior to CS and in 2% (n = 27) CS followed a failed attempt at forceps delivery. Overall in the UK while CS rates have increased, operative vaginal delivery rates have remained relatively constant (about 10–11%).[4,257] [evidence level 3] However there has been a marked reduction in the use of forceps and an increase in the use of ventouse since the early nineties.[4,257] [evidence level 3] Within RCTs the use of ventouse is associated with an increase in failure to achieve a vaginal delivery but it is not associated with a concomitant increase in CS rates.[258,259] [evidence level 1a]

A cohort study has compared the maternal and neonatal outcomes following either instrumental vaginal delivery or CS in the second stage of labour (n = 393 women, 184 had a vaginal delivery, 209 CS).[260] [evidence level 2a] Major haemorrhage (blood loss > 1000 ml) was more common after CS than vaginal delivery (adjusted OR 2.82, 95% CI 1.1 to 7.62). Length of hospital stay was increased

with CS. No difference was detected in wound infection, blood transfusion, need for opiate analgesia or rates of breastfeeding. Odds ratios were adjusted for maternal body mass index, pre-eclampsia, maternal diabetes, duration of second stage, station and position of the presenting part, demographic differences and experience of the operator.[260] [evidence level 2a] A further study following up the same women after 3 years reported half had achieved a further pregnancy after 3 years. There was no difference the proportion of women who had difficulty conceiving but there was an increase in involuntary infertility of more than 1 year. Of women who choose not to have more children there was no difference in the proportion that stated they "could not go through childbirth again". Of women who had a further pregnancy those who had had a previous instrumental vaginal birth were more likely to aim for and ac hieve a vaginal birth again (adjusted OR 15.55, 95% CI 5.25 to 46.04; adjusted OR 9.50, 95% CI 3.48 to 25.97).[261] Qualitative research of women views on t he impact of operative delivery in the second stage of labour (n = 27) described that women felt unprepared for operative delivery and that antenatal education had not adequately prepared them for this event.[262]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 25	More RCTs are required to determine the effect of oxytocin augmentation as single interventions or as part of a package of interventions (such as "active management of labour") on t he likelihood of CS and other outcomes including women's satisfaction with care.
RR 26	Further research on the short and longer term health impacts of CS during the second stage compared to operative vaginal delivery are needed.

Female genital mutilation

Female genital mutilation is defined by the World Health Organization (WHO) as, 'all procedures that involve partial or total removal of the female external genitalia or other injury to the female genital organs whether for cultural, religious or other non-therapeutic reasons'. An estimated 10,000 to 20,000 girls in the UK are thought to have undergone genital mutilation.[263] [evidence level 3]

The association between female genital mutilation and i ntrapartum complications has been systematically reviewed by the WHO.[264] Possible complications include obstructed labour, fetal distress and increased perinatal mortality however the evidence for these are contradictory.[264–266] [evidence level 3] [267] [evidence level 2a] No RCTs or observational studies have addressed the effect on health outcomes of CS in the management of female genital mutilation. It is outside the scope of this guideline to address the antenatal or intrapartum management of female genital mutilation.

6.5 Eating during labour

The practice of encouraging women to eat and drink during labour in order to maintain their strength for the second stage changed following publication of a case series (n = 66) of aspiration pneumonitis. In this paper Mendelson suggested that mortality due to aspiration pneumonitis could be reduced if women did not eat and drink during labour.[268,269] [evidence level 3] This work continues to influence practice both in the UK and elsewhere. In the UK less than 5% (12/268) maternity hospitals have a policy of unrestricted intake during labour,[270] this is also usual practice in many other countries.[271,272] [evidence level 3] An exception to this is the Netherlands where a survey reported that the majority of obstetricians and midwives had an unrestrictive policy on fluid and food intake. The Netherlands do not have a higher mortality rate due to aspiration pneumonitis than other countries.[273] [evidence level 3] A UK survey of women's views about eating in labour reported that 31% of women said that would have liked to have eaten during labour.[274] [evidence level 3] Many historical overviews, comments, surveys or non-systematic literature reviews have been written discussing the benefits and harms of eating during labour.[275–277] [evidence level 3]

One RCT (n = 94) compared offering a low residue diet of toast cereal, crackers and low fat cheese during labour to offering a range of drinks to women during labour (water, tea, coffee, cocoa). Women included in the trial were in spontaneous labour, at term with singleton cephalic presentation and who did not request parenteral opioids (because opioids can delay gastric emptying). Outcome measures used were women's metabolic profile, volume of gastric contents as well as labour outcomes such as length of labour, use of oxytocin and mode of birth.[274] [evidence level 1b] Women who had a low residue diet were less likely to have ketosis and had higher plasma glucose at the end of labour than women in the drinks only group. Gastric contents were significantly higher in those eating a l ow residue diet and these women were more likely to vomit at birth, vomit higher volumes and vomit more solid material. Higher gastric volumes could be of importance if unexpected general anaesthesia was needed. No differences were detected in labour outcomes between the two groups but the study is underpowered to evaluate these outcomes.[278] [evidence level 1b] This issue is currently being evaluated in another RCT.[279]

A further RCT (n = 60) compared drinking an isotonic drink to drinking water only during labour. Metabolic indices and g astric volumes were measured. Isotonic drinks reduced ketosis but did not increase gastric volume. There was no change in labour outcomes but the study was underpowered to assess these outcomes.[280] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
27	RCTs that evaluate the effects of eating during labour compared with restricting intake on l abour outcomes are needed. Cohort or case control studies on t he risk factors for aspiration and other morbidities for women having CS are needed.

7 Procedural aspects of caesarean section

7.1 Timing of planned caesarean section

Babies born preterm are at increased risk of respiratory distress syndrome. One UK survey (n = 179,701) of babies born at 34 weeks of gestation or more reported 0.08% (149 babies) had respiratory distress requiring surfactant therapy. Of these babies, 24% (n = 36) were born at or after 37 weeks but 88% (n = 32) of these babies were born by planned caesarean section (CS).[281] [evidence level 3]

Babies born by planned CS at term (37–42 weeks of gestation) are at risk of respiratory distress syndrome and t his decreases with increasing gestational age.[282] A large prospective UK survey looked at all cases of respiratory distress syndrome (RDS) or transient tachypnoea of the newborn (TTN) at term requiring neonatal intensive care unit (NICU). This study found a decrease in respiratory morbidity from 39 weeks onwards (from 42.3 per 1000 at 38 weeks to 17.8 per 1000 at 39 weeks – odds ratio [OR] 8.2 and 3.5 respectively). Respiratory morbidity among neonates born by CS before the onset of labour across the different gestational ages was increased.[282] [evidence level 3] Figure 7.1 shows respiratory morbidity per 1000 for CS before labour.[282] [evidence level 3]

From the National Sentinel Caesarean Section Audit (NSCSA) data it is estimated that about 18% of women went into spontaneous labour between 37–39 weeks (see figure 7.2). The average planned CS rate is about 10%. Therefore between 1–2% of women booked for a planned CS after 39 weeks would be expected to go into labour before this time. For an average hospital with 3000 births this would prevent 1 case of TTN or RDS per year and would increase unscheduled CS rate by 18% (assuming timing of planned CS goes from 37 to 39 weeks).

Figure 7.1 Respiratory morbidity per 1000 for CS before labour[282] [evidence level 3]

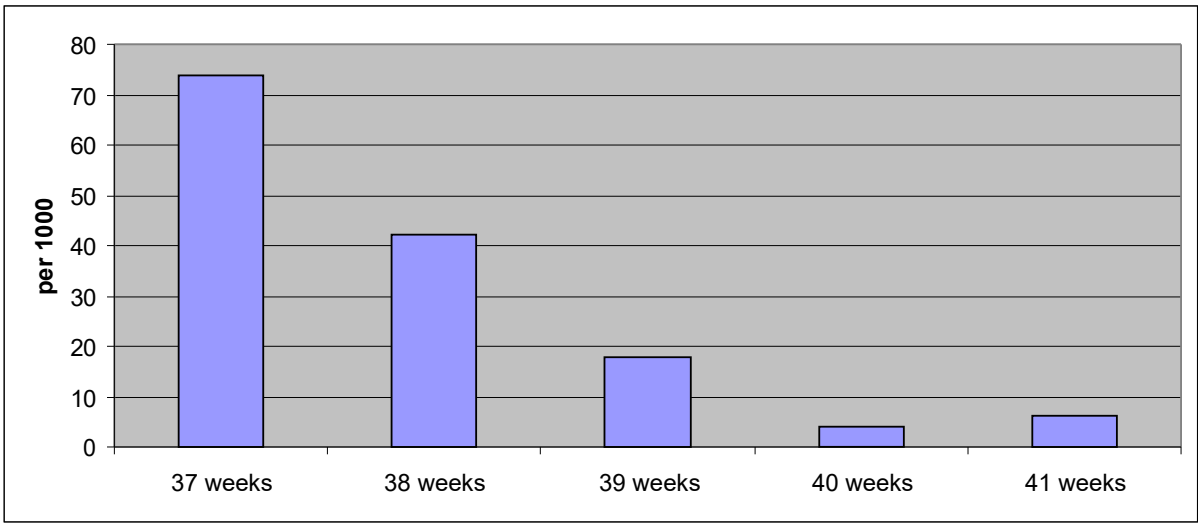
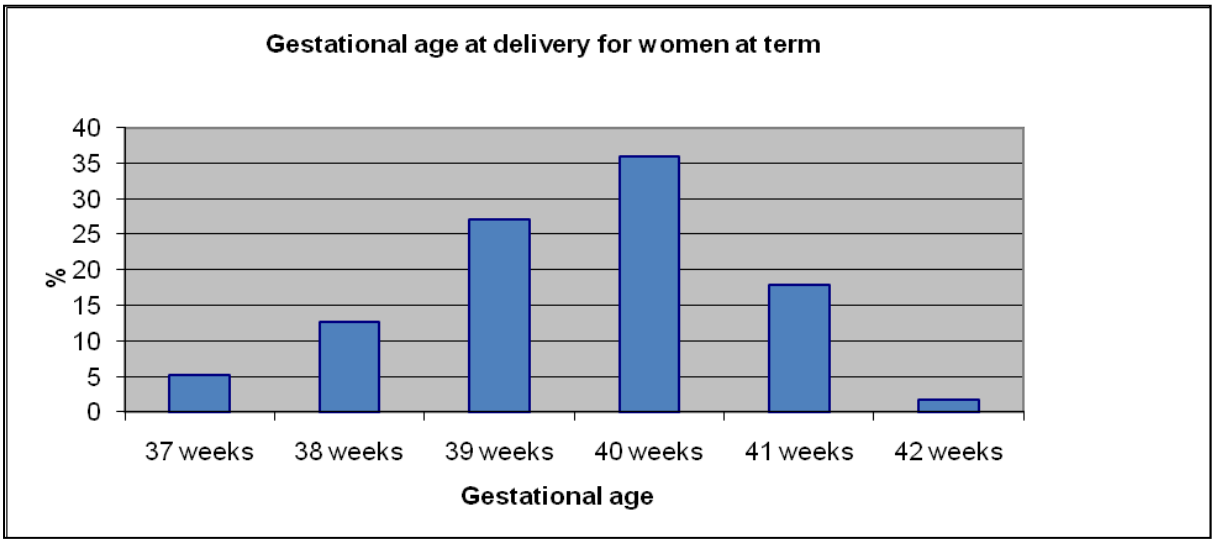


Figure 7.2 Distribution of gestational age at birth in England and Wales[4]



Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

7.2 Classification of urgency

CS has traditionally been divided into either elective or emergency procedures. More recently these terms have been replaced by “planned” and “unplanned” The unplanned category is broad, as it may include procedures done within minutes to save the life of a woman or baby as well as those in which woman and baby are well but where early delivery is needed, (for example, a woman with a planned CS who is admitted in labour). A clear classification of the perceived degree of urgency of the CS can facilitate communication and reduce misunderstanding between health care professionals. The NCEPOD classification system recommended the categorisation of operations into four grades of urgency.[55] This categorisation scheme has been pi loted and evaluated.[4,56] Although new to most maternity units, there was consistent use of the new scheme when compared with the binary categories and indication for CS. The categorisation also independently predicted baby outcome.[4] The categories are:

1. immediate threat to the life of the woman or fetus
2. maternal or fetal compromise which was not immediately life-threatening
3. no maternal or fetal compromise but needs early delivery
4. delivery timed to suit woman or staff

Grade 1 (immediate threat to the life of the woman or fetus) includes CS for acute severe bradycardia, cord prolapse, uterine rupture, fetal blood sampling pH less than 7.2. Grade 2 (maternal or fetal compromise which was not immediately life-threatening), there is ‘urgency’ to deliver the baby in order to prevent further deterioration of either the mother or baby’s condition (e.g. antepartum haemorrhage, ‘failure to progress’ in labour with maternal or fetal compromise). Grade 3 (no maternal or fetal compromise but needs early delivery) includes CS carried out where there is no maternal or fetal compromise but early delivery is necessary (e.g. a woman booked for planned CS who is admitted with pre-labour SROM or ‘failure to progress’ with no maternal or fetal compromise). Grade 4

(delivery timed to suit woman or staff) includes all CS carried out 'electively' at a planned time to suit the mother and clinicians.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

7.3 Decision-to-delivery interval for unplanned CS

Introduction

The appropriate decision-to-delivery interval in unplanned (category 1 and 2) CS remains a controversial issue. This is especially true of the 30 minute interval which has become a c ritical clinical threshold in clinical practice, despite the fact that in the original guideline it was intended to be an audit standard and not a r ecommendation for practice. A further concern is the current lack of distinction between the category 1 and 2 CS in practice. The RCOG Good Practice Guideline no 11, 'Classification of urgency of caesarean section – a continuum of risk' (2010) has advised and strongly recommended that the 'continuum of risk' be r ecognised in the unplanned situation. With these considerations it was felt timely to review the current NICE recommendations in this area.

Review question

What is the appropriate decision-to-delivery interval (DDI) for unplanned caesarean section?

Overview of evidence

Ten studies were included in this review (Holcroft et al., 2005; Nasrallah et al., 2004; Bloom et al., 2006; Roy et al., 2008; Thomas et al., 2004; Kolas et al., 2006; Hillemanns et al., 2005; Leung et al., 2009; Chauleur et al., 2009; Hillemanns et al., 2003).

Three studies were conducted in the USA (Holcroft et al., 2005; Nasrallah et al., 2004; Bloom et al., 2006), one in India (Roy et al., 2008), one in the UK (Thomas et al., 2004), one in Norway (Kolas et al., 2006), two in Germany (Hillemanns et al., 2003; 2005), one in China (Leung et al., 2009) and one in France (Chauleur et al., 2009).

Six observational studies examined the effects of DDIs of less than and more than 30 minutes on neonatal and maternal outcomes (Holcroft, et al. 2005; Nasrallah et al., 2004; Bloom et al., 2006; Hillemanns et al., 2003; Roy et al., 2008; Chauleur et al., 2009). Two studies examined the association between different DDIs (ranging from less than 15 minutes to higher than 75 minutes) on neonatal and maternal outcomes (Thomas et al., 2004; Kolas et al., 2006). One study retrospectively examined the correlation between umbilical cord arterial blood pH and decision-to-delivery time (Hillemanns et al., 2005). One retrospective study investigated the relation between bradycardia to delivery interval and adverse perinatal outcomes (Leung et al., 2009).

Maternal and neonatal outcomes were chosen by the GDG as being of priority to inform recommendations and the results for these are presented in the evidence profile.

Evidence profile

Maternal outcomes

Table 7.1 GRADE findings for comparison of a decision-to-delivery (DDI) interval of less than 30 minutes with a decision-to-delivery interval of more than 30 minutes (maternal outcomes)

Number of studies	Number of women		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion					
1 study (Nasrallah et al., 2004)	6/83 (7.2%)	0/28 (0%)	Not calculable (NC)	NC	Very low
1 study (Hillemanns et al., 2003)	11/109 (10.1%)	1/109 (0.9%)	11 (1.8 to 68)[a]	92 more per 1000 (from 7 more to 615 more)[a]	Very low
Uterine/bladder rupture					
1 study (Hillemanns et al., 2003)	7/109 (6.4%)	8/109 (7.3%)	0.87 (0.34 to 2.24)[a]	1 fewer per 1000 (from 6 fewer to 11 more)[a]	Very low
Ureteric injuries					
1 study (Bloom et al., 2006)	2/1814 (0.1%)	1/994 (0.1%)	1.09 (0.14 to 8.35)[a]	1 fewer per 1000 (from 1 fewer to 7 more)[a]	Very low
Cystotomy					
1 study (Bloom et al., 2006)	2/1814 (0.1%)	3/994 (0.3%)	0.36 (0.07 to 1.82)[a]	2 fewer per 1000 (from 3 fewer to 2 more)[a]	Very low
Wound complication					
1 study (Bloom et al., 2006)	23/1814 (1.3%)	9/994 (0.9%)	1.40 (0.66 to 2.96)[a]	4 more per 1000 (from 3 fewer to 18 more)[a]	Very low
Urinary tract infection					
1 study (Hillemanns et al., 2003)	3/109 (2.8%)	2/109 (1.8%)	1.5 (0.30 to 7.40)[a]	9 more per 1000 (from 13 fewer to 117 more)[a]	Very low

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Number of studies	Number of women		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
Wound infection					
1 study (Hillemanns et al., 2003)	1/109 (0.9%)	5/109 (4.6%)	0.2 (0.03 to 1.26)[a]	37 fewer per 1000 (from 44 fewer to 12 more)[a]	Very low
Surgical injuries					
1 study (Nasrallah et al., 2004)	10/83 (12%)	1/28 (4%)	3.37 (0.61 to 20.1)[a]	85 more per 1000 (from 14 fewer to 682 more)[a]	Very low
Caesarean hysterectomy					
1 study (Nasrallah et al., 2004)	2/83 (2.4%)	0/28 (0%)	NC	NC	Very low
Postpartum haemorrhage					
1 study (Hillemanns et al., 2003)	2/109 (1.8%)	1/109 (0.9%)	2 (0.26 to 15.1)[a]	9 more per 1000 (from 7 fewer to 129 more)[a]	Very low
Bowel laceration					
1 study (Bloom et al., 2006)	1/1814 (0.1%)	1/994 (0.1%)	0.54 (0.05 to 5.24)[a]	0 fewer per 1000 (from 1 fewer to 4 more)[a]	Very low
Intensive care unit					
1 study (Hillemanns et al., 2003)	11/109 (10.1%)	5/109 (4.6%)	2.2 (0.82 to 5.90)[a]	55 more per 1000 (from 8 fewer to 225 more)[a]	Very low
Endometritis					
1 study (Hillemanns et al., 2003)	3/109 (2.8%)	2/109 (1.8%)	1.5 (0.30 to 7.40)[a]	9 more per 1000 (from 13 fewer to 117 more)[a]	Very low
Special care requirements[b]					
1 study (Thomas. et al., 2004)	495/3958 (12.5%)	1587/12,606 (12.5%)	0.99 (0.90 to 1.09)[a]	1 fewer per 1000 (from 13 fewer to 11 more)[a]	Very low

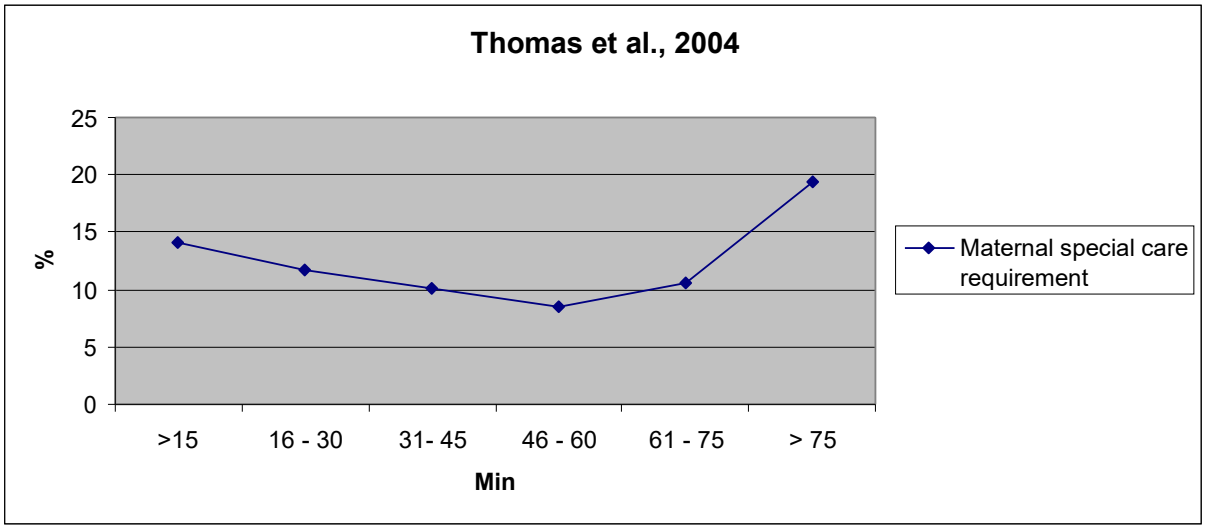
[a] Calculated by NCC-WCH

[b] Defined as care following CS that was additional to 'routine' post-operative care

CI confidence interval; DDI decision to delivery interval; NC not calculable

2011 Update

Figure 7.3 Maternal special care requirement* findings from Thomas et al., 2004



Maternal special care requirement†: total n = 17,780; 15 minutes or less n = 194 /1381 (14.1%); 16 to 30 minutes n = 301/2577 (11.7%); 31 t o 45 minutes n = 361/3589 (10.1%); 46 t o 60 minutes n = 277/3261 (8.5%); 61 to 75 minutes n = 197/1865 (10.6%); more than 75 minutes n = 752/3891 (19.4%)

A logistic regression analysis was performed adjusting data for primary indication for CS, cardiotocography findings, grade of urgency and type of anaesthesia. There was no statistically significant difference in the adjusted odds ratios for maternal requirement for special care in women with a DDI less than 15 minutes compared with women with a DDI of 16 to 75 minutes. However, there was a significantly increased risk of maternal requirement for special care in women with a DDI of more than 75 minutes (OR = 1.5, 95% CI 1.2 to 1.8) compared with neonates born after less than 15 minutes (OR = 1).

Neonatal outcomes

Table 7.2 GRADE summary of findings for comparison of a decision-to-delivery interval (DDI) of less than 30 minutes with a decision-to-delivery interval of more than 30 minutes (neonatal outcomes)

Number of studies	Number of neonates		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
Neonatal deaths					
1 study (Holcroft et al., 2005)	1/34 (2.9%)	0/83 (0%)	Not calculable (NC)	NC	Very low
1 study (Bloom et al., 2006)	7/1814 (0.4%)	1/994 (0.1%)	3.83 (0.61 to 23.8)[a]	3 more per 1000 (from 0 fewer to 23 more)[a]	Very low
Stillbirth					
1 study (Roy et al., 2008)	1/121 (0.8%)	0/96 (0%)	NC	NC	Very low

* Maternal special care requirement is defined as any care above or under standard postnatal care
† Maternal special care requirement is defined as any care above or under standard postnatal care

Number of studies	Number of neonates		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
1 study (Thomas. et al., 2004)	27/3958 (0.68%)	23/12,606 (0.18%)	3.73 (2.16 to 6.46)[a]	5 more per 1000 (from 2 more to 10 more)[a]	Very low
Fetal death in labour					
1 study (Bloom et al., 2006)	3/1814 (0.2%)	0/994 (0%)	NC	NC	Very low
Perinatal mortality					
1 study (Hillemanns et al., 2003)	7/124 (5.6%)	3/124 (2.4%)	2.33 (0.67 to 8.15)[a]	32 more per 1000 (from 8 fewer to 173 more)[a]	Very low
5 minutes Apgar score less than 7					
1 study (Holcroft et al., 2005)	3/34 (8.8%)	8/83 (9.6%)	0.91 (0.27 to 2.93)[a]	9 fewer per 1000 (from 70 fewer to 186 more)[a]	Very low
1 study (Hillemanns et al., 2003)	21/124 (16.9%)	9/124 (7.3%)	2.33 (1.13 to 4.84)[a]	97 more per 1000 (from 9 more to 279 more)[a]	Very low
1 study (Nasrallah et al., 2004)	8/83 (9.5%)	1/28 (3.6%)	2.69 (0.48 to 16.4)	60 more per 1000 (from 19 fewer to 550 more)	Very low
1 study (Roy et al., 2008)	18/121 (14.9%)	15/96 (15.6%)	0.95 (0.51 to 1.77)[a]	8 fewer per 1000 (from 77 fewer to 120 more)[a]	Very low
1 study (Kolas. et al., 2006)	50/624 (8%)	8/576 (1.4%)	5.76 (2.81 to 11.8)[a]	66 more per 1000 (from 25 more to 150 more)[a]	Very low
1 study (Thomas. et al., 2004)	226/3958 (5.7%)	328/12606 (2.6%)	2.19 (1.85 to 2.58)[a]	31 more per 1000 (from 22 more to 41 more)[a]	Very low
5 minute Apgar score 3 or less					
1 study (Bloom et al., 2006)	18/1814 (1%)	9/994 (0.9%)	1.09 (0.50 to 2.38)[a]	1 more per 1000 (from 5 fewer to 12 more)[a]	Very low
Cord pH less than 7.0					
1 study (Hillemanns et al., 2003)	10/124 (8.1%)	0/124 (0%)	NC	NC	Very low

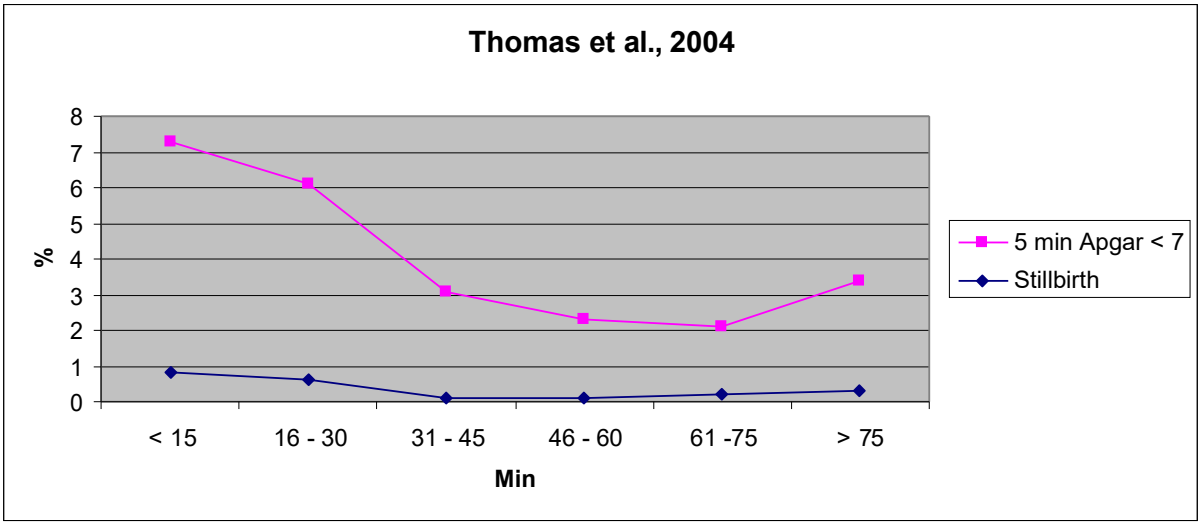
Number of studies	Number of neonates		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
1 study (Holcroft et al., 2005)	6/34 (17.6%)	2/83 (2.4%)	8.20 (1.97 to 34.2)[a]	173 more per 1000 (from 23 more to 800 more)[a]	Very low
1 study (Roy et al., 2008)	8/121 (6.6%)	5/96 (5.2%)	1.26 (0.45 to 3.59)[a]	14 more per 1000 (from 29 fewer to 135 more)[a]	Very low
1 study (Bloom et al., 2006)	52/1814 (2.9%)	9/994 (0.9%)	3.16 (1.59 to 6.31)[a]	20 more per 1000 (from 5 more to 48 more)[a]	Very low
1 study (Nasrallah et al., 2004)	5/83 (6%)	0/28 (0%)	NC	NC	Very low
Admission to neonatal intensive care unit (NICU)					
1 study (Hillemanns et al., 2003)	74/124 (59.7%)	65/124 (52.4%)	1.13 (0.91 to 1.42)[a]	68 more per 1000 (from 74 fewer to 220 more)[a]	Very low
1 study (Nasrallah et al., 2004)	21/83 (25.3%)	6/28 (21.4%)	1.18 (0.56 to 2.67)[a]	39 more per 1000 (from 94 fewer to 358 more)[a]	Very low
1 study (Roy et al., 2008)	26/121 (21.5%)	7/96 (7.3%)	2.94 (1.38 to 6.43)[a]	141 more per 1000 (from 28 more to 396 more)[a]	Very low
1 study (Kolas. et al., 2006)	147/624 (23.6%)	104/576 (18.1%)	1.30 (1.04 to 1.63)	54 more per 1000 (from 7 more to 114 more)	Very low
1 study (Chauleur et al., 2009)	24/25 (96%)	35/46 (76%)	1.26 (1.02 to 1.55)[a]	198 more per 1000 (from 15 more to 418 more)[a]	Very low
Seizures					
1 study (Nasrallah et al., 2004)	2/34 (5.9%)	5/83 (6%)	0.97 (0.22 to 4.08)[a]	2 fewer per 1000 (from 47 fewer to 176 more)[a]	Very low
Encephalopathy					
1 study (Nasrallah et al., 2004)	5/83 (6%)	0/28 (0%)	NC	NC	Very low
1 study (Bloom et al., 2006)	12/1814 (0.7%)	5/994 (0.5%)	1.31 (0.48 to 3.57)[a]	2 more per 1000 (from 3 fewer to 13 more)[a]	Very low

Number of studies	Number of neonates		Effect		Quality
	DDI < 30 minutes	DDI > 30 minutes	Relative (95% CI)	Absolute (95% CI)	
Median NICU stay (days)					
1 study (Nasrallah et al., 2004)	13 (range 1-40)	9 (range 3-35)	NC	4 more days	Very low
Neonate requiring immediate ventilation					
1 study (Roy et al., 2008)	4/121 (3.3%)	2/96 (2.1%)	1.58 (0.34 to 7.31)[a]	12 more per 1000 (from 14 fewer to 121 more)[a]	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; DDI decision to delivery interval; NC not calculable

Figure 7.4 Stillbirth and 5 minute Apgar score less than 7; findings from Thomas et al., 2004



Series 1 = Stillbirth: Total n = 17,780; 15 minutes or less n = 11/1381 (0.8%); 16 to 30 minutes n = 16/2577 (0.6%); 31 to 45 minutes n = 5 /3589 (0.1%); 46 to 60 minutes n = 3/3261 (0.1%); 61 to 75 minutes n = 4/1865 (0.2 %); more than 75 minutes n = 11/3891 (0.3 %)

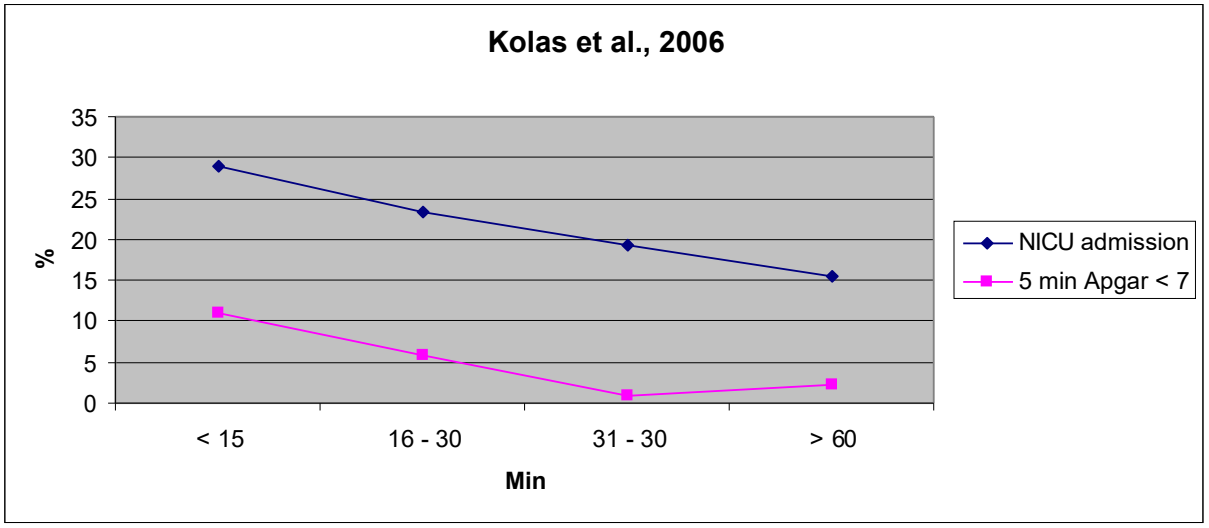
Series 2 = 5 minute Apgar score less than 7: 15 minutes or less n = 87/1381 (6.5%); 16 to 30 minutes n = 139/2577 (5.5%); 31 to 45 minutes n = 106/3589 (3%); 46 to 60 minutes n = 71 /3261 (2.2%); 61 to 75 minutes n = 35 /2577 (1.9%); more than 75 minutes n = 116/3891 (3.1%).

A logistic regression analysis was performed adjusting data for primary indication for CS, cardiotocography findings, grade of urgency and type of anaesthesia.

There was no statistically significant difference in the adjusted odds ratios for 5 minutes Apgar score of less than 7 in neonates born at less than 15 minutes compared with the neonates born with DDIs of 16 to 75 minutes. However, there was a significantly higher odds ratio of a 5 minutes Apgar score of less than 7 in neonates born with DDIs of more than 75 minutes (OR 1.7, 95% CI 1.2 to 2.4) compared with neonates born at less than 15 minutes (OR 1).

There was no statistically significant difference in the adjusted odds ratios for stillbirth in neonates born at less than 15 minutes compared with the neonates born with DDIs of 16 to 75 minutes.

Figure 7.5 NICU admission and 5 minutes Apgar score less than 7; findings from Kolas et al., 2006



Series 1 = NICU admission: DDI less than 15 minutes n = 242 (29.0 %); DDI 16 to 30 minutes n = 382 (23.4%); DDI 31 to 60 minutes n = 394 (19.3); DDI more than 60 minutes n = 182 (15.5%) *P* < 0.01

Series 2 = 5 minutes Apgar score less than 7: DDI less than 15 minutes n = 242 (11.0 %); DDI 16 to 30 minutes n = 382 (5.9 %); DDI 31 to 60 minutes n = 394 (1.0 %); DDI more than 60 minutes n = 182 (2.2%) *P* < 0.001

One retrospective cohort study (Hillemanns et al., 2005) examined the effect of the DDI of less than 30 minutes of 'crash emergency' CS on Apgar scores and umbilical artery pH. A very short DDI of less than 20 minutes was inversely correlated to fetal outcome. Babies born by 'emergency' CS performed within 19 minutes presented with lower Apgar scores after 5 and 10 minutes than those born after a DDI of 20 minutes or more (*P* = 0.003 and *P* = 0.01 respectively). The umbilical cord pH was not significantly related to decision-to-delivery time (correlation coefficient r = 0.36, *P* >0.05).

One retrospective cohort study examined the effects on cord arterial pH of different fetal bradycardia to delivery intervals, and of different decision to delivery intervals, according to different causes of fetal distress (Leung et al., 2009). The causes of the bradycardia were reviewed and categorised into: 'irreversible' (median DDI of 10 minutes); 'potentially reversible' (median DDI of 11.5 minutes); and 'unknown cause' (median DDI of 11 minutes).

The median cord arterial pH was lower in babies born in the 'irreversible' group than in the 'potentially reversible' group or 'unknown' group (*P* < 0.001). No relationship was found between cord arterial pH and base excess with either bradycardia to delivery interval or DDI in 'irreversible', 'potentially reversible' and 'unknown cause'. However, in subgroup analysis, the cord arterial pH was significantly inversely correlated with bradycardia to delivery interval in the 'irreversible' group (Spearman's rho = −0.354; *P* = 0.027) but no significant inverse correlation was seen in the other two groups.

Evidence statements

Maternal outcomes

The evidence for all maternal outcomes was of very low quality.

Blood transfusion

One study found that blood transfusion in women with a DDI of less than 30 minutes was higher than in women with a DDI of more than 30 minutes. This finding was statistically significant. Another study investigated this outcome but the statistical significance was not calculable.

Uterine/bladder rupture

One study did not find a statistically significant difference in the rate of uterine/bladder rupture for women with a D DI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Ureteric injuries

One study did not find a statistically significant difference in the rate of ureteric injuries for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Cystotomy

One study did not find a statistically significant difference in the rate of inadvertent cystotomy for women with a D DI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Wound complication

One study did not find a statistically significant difference in the rate of wound complication for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Urinary tract infection

One study did not find a statistically significant difference in the rate of urinary tract infection for women with a D DI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Wound infection

One study did not find a statistically significant difference in the rate of wound infection for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Surgical injuries

One study did not find a statistically significant difference in surgical injuries for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes. The evidence for this outcome was of very low quality.

Caesarean hysterectomy

One study investigated the outcome of caesarean hysterectomy in women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes. The statistical significance of this finding was not calculable in this study.

Postpartum haemorrhage

One study did not find a statistically significant difference in postpartum haemorrhage for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Bowel laceration

One study did not find a statistically significant difference in the rate of bowel laceration for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Intensive care unit admission

One study did not find a statistically significant difference in the rate of intensive care unit admission for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Endometritis

One study did not find a statistically significant difference in the rate of endometritis for women with a DDI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Special care requirements

One study did not find a statistically significant difference in maternal requirements for special care for women with a D DI of less than 30 minutes compared with women with a DDI of more than 30 minutes.

Neonatal outcomes

The evidence for all neonatal outcomes was of very low quality.

Neonatal deaths

One study did not find a statistically significant difference in the number of neonatal deaths in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more

than 30 minutes. Another study investigated the same outcome but the statistical significance was not calculable.

Stillbirth

One study found a higher number of stillbirths in neonates born with a DDI of less than 30 minutes compared with neonates born with a D DI of more than 30 minutes. This finding was statistically significant. A second study investigated the same outcome but the statistical significance was not calculable.

One study did not find a significant difference in the number of stillbirths in neonates born with a DDI of less than 15 minutes compared with neonates born with a DDI of 16–75 minutes.

Fetal death in labour

One study investigated the outcome of fetal death in neonates born with a D DI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. The statistical significance of this finding was not calculable.

Perinatal mortality

One study did not find a statistically significant difference in the perinatal mortality in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes.

5 minutes Apgar score less than 7

Three studies found a higher rate of 5 minutes Apgar scores of less than 7 in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. This finding was statistically significant. Three further studies did not find a s tatistically significant difference in this outcome between the two groups.

One study did not find a statistically significant difference in the adjusted odds ratio of 5 m inutes Apgar scores of less than 7 in neonates born with a DDI of less than 15 minutes compared with neonates born with a DDI of 16–75 minutes. However, there were significantly higher odds of 5 minutes Apgar scores being less than 7 in neonates born with a DDI of more than 75 minutes.

One study found a higher rate of 5 minutes Apgar scores of less than 7 in neonates born with a DDI of less than 15 minutes compared with neonates born with a DDI of 16–30 minutes, a DDI of 31–60 minutes and a DDI of more than 60 minutes. This finding was statistically significant.

5 minutes Apgar scores of 3 or less

One study did not find a statistically significant difference in the number of neonates with 5 minutes Apgar scores of 3 or less in neonates born with DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes..

One study did not find a statistically significant difference in lower Apgar scores after 5 and 10 minutes in neonates born within 19 minutes compared with neonates born at 20 minutes or more.

Cord pH

Two studies found a higher rate of cord pH less than 7.0 in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. This finding was statistically significant. A third study did not find a statistically significant difference for this outcome. Two further studies investigated this outcome but the statistical significance was not calculable.

One study did not find a statistically significant relationship between a low umbilical cord pH and the DDI interval.

One study did not find a statistically significant difference in median cord arterial pH in neonates born with median DDI of 10 minutes, median DDI of 11 minutes and median DDI of 11.5 minutes.

NICU admissions

Three studies found a higher number of NICU admissions in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. This finding was statistically significant. Two further studies did not find a s tatistically significant difference for this outcome.

One study found a h igher rate of NICU admissions in neonates born with a DDI of less than 15 minutes compared with neonates born with a DDI of 16–30 minutes, a DDI of 31–60 minutes and a DDI of more than 60 minutes. This finding was statistically significant.

Seizures

One study investigated the number of seizures in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. The statistical significance of this finding was not calculable.

Encephalopathy

Two studies investigated the incidence of encephalopathy in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes. One study did not find a statistically significant difference between the two groups and in the other study the statistical significance of the finding was not calculable.

NICU stay

One study did not find a statistically significant difference in the length of NICU stay in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes.

Neonate requiring immediate ventilation

One study did not find a statistically significant difference in the length of NICU stay in neonates born with a DDI of less than 30 minutes compared with neonates born with a DDI of more than 30 minutes.

Evidence to recommendations

Relative value placed on outcomes considered

The GDG was keen to see whether there was any evidence that a DDI of less than 30 minutes was related to poorer maternal outcomes as there is a concern that performing CS too quickly can lead to iatrogenic injury. Given this, the GDG rated all of the maternal outcomes as being important in determining whether or not this is the case.

In terms of neonatal outcomes, the group recognised that there is a treatment paradox: the babies who are delivered the quickest are likely to be the ones who are most compromised and are therefore more likely to have poorer outcomes. As a r esult, samples of babies born within 30 minutes will consistently contain a higher proportion of babies in poorer condition. Thus, differences in findings between groups might reflect this disparity, rather than being due to differences in speed of delivery. Given this, the GDG did not feel able to attach as much weight to the neonatal findings.

Trade-off between clinical benefits and harms

The GDG noted there is a trade-off between the baby being born as quickly as possible against the risk of injuring the mother or the baby.

The GDG went on to consider appropriate DDIs in relation to varying degrees of urgency as classified in this guideline and repeated in the RCOG Good Practice Guideline no 11, Classification of urgency of caesarean section – a continuum of risk (2010). There was no evidence that performing a C S within 30 minutes resulted in greater injury to the woman. However, while they agreed that, in general, a CS should be accomplished as quickly as reasonably possible, the GDG members still felt that there are occasions in which a very rapid delivery could do harm. The GDG did not feel therefore that it was appropriate to recommend a time within which a category 1 CS should be performed.

It was agreed that a 30 minute DDI is useful as an audit standard. However, it was felt important to highlight that this should only be used as a s tandard by which to measure the performance of an obstetric unit as a whole. It should not be used as a clinical standard and should not be used to judge the quality of care in individual cases.

The group recognised that there was evidence of adverse neonatal and maternal outcomes in category 2 CSs which have a DDI longer than 75 minutes. While the GDG recognised that there are particular instances where it would not be appropriate to perform a category 2 CS before 75 minutes (for example where maternal blood pressure needs stabilising or essential specialist health care is being awaited), in the large majority of cases, clinicians should aim to perform category 2 CS within this time.

Trade-off between net health benefits and resource use

The trade-off being considered in the clinical situation where an unplanned CS is necessary is to ensure safe birth of the baby in as good a condition as possible without causing harm to the woman or her baby through iatrogenic injury or mistakes made due t o carrying out the procedure with too much haste. Issues of resource use mirror these considerations in that iatrogenic injury has the potential to be costly as well as causing pain and distress to the woman. Conversely, unwarranted delay also has the potential to be hugely damaging in terms of the baby's health. Thus optimal timing of birth will be bot h clinically effective in terms of the health outcomes for the woman and her baby and cost effective in terms of resource use.

Quality of evidence

The GDG recognised that the quality of the evidence was low as all of the studies included in the review were retrospective observational studies.

While there were statistically significant findings which indicated poorer outcomes for babies born before 30 minutes, the GDG agreed that this was due to the treatment paradox noted above; that is, the most compromised babies are those who require the fastest intervention.

The GDG had anticipated that there might be evidence to show that there were more iatrogenic injuries to the woman where the CS had been performed with a DDI of less than 30 minutes. However, in the evidence reviewed, surgical injury was found not to be significantly different between the two groups (under 30 minutes compared with over 30 minutes). The low quality of all the included studies meant the GDG was less certain of the reliability of this finding; although it was noted that it was a consistent finding across a number of studies reporting different types of injury.

There was evidence from one study of a significantly higher need for blood transfusion in women with a DDI of less than 30 minutes. However, it was not possible to determine the reasons for this. The GDG felt that it was not possible to determine whether this was a consequence of the rapid delivery, or a reason for it.

Other considerations

The GDG wished to distinguish between a c linical standard and an a udit standard. While a clinical standard indicates the care which should be provided in each individual case, an au dit standard indicates the overall level of care which should be pr ovided by a u nit. In the case of the DDI of 30 minutes, the GDG recognised that this was inappropriate as a c linical standard as in a num ber of instances (for example complete cord occlusion) a DDI of 30 minutes would be too long, while in others some delay would be appr opriate (such as when necessary to stabilise the woman's clinical condition). However, the GDG agreed that 30 minutes was a useful standard by which to assess the performance of a unit: while in individual cases, a DDI of 30 minutes might not be appropriate, overall there would be cause for concern if the vast majority of category 1 CSs were not carried out within this time.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline

Number	Research recommendation
RR 28	What factors influence the decision-to-delivery interval when there is a c ategory 1 level of urgency for CS? Factors to be investigated could include: • staff grade/level of experience • skill mix within the multidisciplinary team • task allocation • methods of communication • time of day • availability of ongoing staff training about emergency procedures and levels of attendance. The research could be conducted using simulation methods and video observation to determine what factors influence the decision-to-delivery interval for category 1 CS. The videos could also be used to train staff. Why this is important 'Crash' CS is a psychologically traumatic event for women and their partners and is also stressful for clinical staff. Staff and r esources may have to be obtained from other areas of clinical care. This should be undertaken as efficiently and effectively as possible, minimising anxiety and ensuring the safety of the mother and her baby. For category 1 CS there is a recognised urgency to deliver as quickly as is reasonably possible. The majority of research in this area is quantitative and looks at the impact of the decision-to-delivery interval on various aspects of fetal and maternal outcomes rather than the interplay of factors that can affect this time period itself. Much of this evidence is retrospective. Although some work has been conducted in the UK to examine where the systematic delays lie and how to avoid them (Tuffnell et al., 2001), more work is needed to determine how to optimise the decision-to-delivery interval. This work should use qualitative as well as quantitative research methods to assess which factors influence the decision-to-delivery interval for a category 1 CS. Evaluation of these factors could be used to inform future NICE guidance, for example specific guidance for management of category 1 CS. Such information could also be used by hospitals for maternity services planning and at a team level would assist with audit and ongoing evaluation and training of the multidisciplinary team. A large amount of NHS and other state funding is used to provide continuing care for infants who are disabled as a result of birth asphyxia and in providing lifelong support for the child and their family. In addition, large sums of public money are spent on litigation and compensation in some of these cases through the Clinical Negligence Scheme for Trusts (CNST). If research helped to minimise the impact of birth asphyxia this would reduce the costs of continuing care to the state and the burden to the child, their family and the wider community. More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate in the legal system and may help to reduce the cost to the state of related litigation.

RR 29

A prospective study to determine whether the decision-to-delivery interval has an impact on m aternal and neonatal outcomes when there is a c ategory 2 level of urgency for CS.

Important primary outcomes would be

- fetal wellbeing (such as cord blood gases, Apgar score at 5 minutes, hypoxic encephalopathy, neonatal respiratory problems, unanticipated admission to neonatal intensive care unit (NICU), duration of stay in the NICU)
- maternal wellbeing (such as haemoglobin levels on day 2, need for blood transfusion, duration of hospital stay controlled for prolonged neonatal stay and general health/wellbeing).

Valuable secondary outcomes could include:

- fetal trauma at delivery
- iatrogenic maternal bladder or bowel injury
- postoperative maternal infectious morbidity
- establishment of breast-feeding
- psychological outcomes for women, such as the development of postnatal depression/post-traumatic stress disorder.

Why this is important

This research is important to inform the ongoing debate about the management of category 2 CS. The 'continuum of risk' in this setting has been recognised. However, the majority of work in this area, looking at maternal and fetal outcomes, generally considers unplanned caesarean sections as a whole group without making any distinction between degrees of urgency. Furthermore much of this work is retrospective. The majority of women who undergo intrapartum CS fall into the category 2 level of urgency (Thomas et al., 2001) and therefore specific information for this group could affect and benefit many women and contribute to the delivery of equity of care.

Delay in delivery with a compromised fetus may result in major and long-term harm including cerebral palsy and other major long-term disability. The immediate and long-term effect on a family of the birth of a baby requiring life-long specialised care and support is enormous. If such harm could be avoided by appropriate haste this would be an important improvement in outcome. However, if such haste is of no benefit then any related risk of adverse maternal outcome needs to be minimised.

A large amount of NHS and other state funding is used to provide continuing care for infants who are disabled as a r esult of delay in delivery and in providing lifelong support for the child and their family. In addition, large sums of public money are spent on litigation and compensation in some of these cases through the Clinical Negligence Scheme for Trusts (CNST). If research helped to minimise the impact of delay in delivery this would reduce the costs of continuing care to the state and the burden to the child, their family and the wider community.

More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate within the legal system and m ay help to reduce the cost to the state of related litigation.

RR 30

Repeat of the National Caesarean Section Sentinel Audit

The original CS guideline included a s et of 'auditable standards'. It would be a straightforward task to produce an updated set of auditable standards based on the important topics covered in the updated guideline. These could include:

- consent
- indications (including maternal request)
- procedural aspects
- maternal and fetal outcomes.

Many of the outcomes documented in a new CS audit would relate directly to recommendations in this CS guideline update. Researchers may also want to consider categorising different reasons underlying maternal request for CS such as previous poor childbirth experience, longstanding fear of childbirth, belief that CS is safer for the baby etc.

An additional useful feature of the audit would be to record key related data, such as the proportion of CS for a breech presentation that had an attempted external cephalic version.

Why this is important

During the 10 years since the National Caesarean Section Sentinel Audit was undertaken (2000–2001), many of the findings may have changed significantly. The audit examined who was having a C S and why, as well as the views of women having babies and the obstetricians looking after them. The audit found that a 20% CS rate was considered too high by 51% of obstetricians. UK CS rates now average about 25%.

A repeat of the CS Sentinel Audit would reveal any changes in indications and the views of women and ob stetricians. The current literature does not adequately address the issue of maternal request for CS and this is one aspect the audit may address. Women's views on maternal request for CS for when there are no obstetric indications are particularly relevant. Such requests may be on the rise and the reasons are not always clearly expressed or documented.

The methodology of the audit is established, making a repeat feasible. This should be given high priority because the benefit to the NHS would be significant.

7.4 Preoperative testing and preparation for CS

Full blood count and haemoglobin

Recommendations for antenatal screening include measuring haemoglobin (Hb) at booking and repeating this at 28 weeks of gestation to screen for anaemia.[1] Pregnancy increases maternal iron requirements and an tenatal screening enables women who have anaemia to receive appropriate treatment before birth. Women who are anaemic at the time of birth are likely to be l ess able to tolerate blood loss.[95] [evidence level 3]

Overall it is estimated that about 1.3% of all women giving birth have blood loss in excess of 1000 ml,[291] while 0.7% have blood loss in excess of 1500 ml however measurements of blood loss at birth are reliant on visual estimations and are usually underestimations.[292] In the NSCSA 32% of women who had CS had an estimated blood loss between 500–1000 ml, while for 4% it was in excess of 1000 ml. Haemorrhage remains an important cause of maternal mortality.[95] [evidence level 3]

Two pragmatic RCTs comparing planned CS to planned vaginal birth report blood loss as an outcome measure.[44,48] (n = 2281) No difference in blood loss greater than 1000 ml or 1500 ml between the two groups was detected (0.5% planned CS; 0.7% planned vaginal birth group, pooled RR 0.80, 95% CI 0.29 to 2.18. For blood loss greater than 1500 ml, pooled RR 1.32, 95% CI 0.39 to 4.42). [evidence level 1a] Non intention to treat analysis (by actual rather than intended mode of delivery) indicate that blood loss greater than 1000 ml occurred in 2.7% of women who had CS and 1.6% of women who had vaginal birth. Blood loss greater than 1500 ml occurred in 2% of women who had CS compared to none of the women who had vaginal birth.[44] [evidence level 2]

A large UK cohort study[291] reported that compared to women who had spontaneous vaginal deliveries, the risk of blood loss in excess of 1000ml was greater among women who had either planned CS (RR 3.94, 99% CI 2.52 to 6.17), CS in labour (RR 8.84, 99% CI 6.74 to 11.6) or assisted vaginal birth (RR 2.39, 95% CI 1.64 to 3.48). Compared with women who had planned CS, risk of blood loss in excess of 1000 ml was higher among women who had CS in labour (RR 2.24, 95% CI 1.43 to 3.53) [evidence level 2b]. However these relative risks do not take into account any other

factors that may also affect blood loss, for example the reasons for performing CS in labour such as placental abruption or ante partum haemorrhage.

No studies have evaluated the effect of preoperative Hb or full blood count (FBC) on management or maternal health outcomes. Guidelines for preoperative testing in general surgery have been developed.[293] [evidence level 3] The guideline divides surgical procedures into four grades; minor, intermediate, major, major+, neurosurgery and cardiovascular surgery. CS would be classed as major surgery. Patients are then classified according to American Society of Anaesthesia (ASA) grades. In most instances women having CS are ASA grade 1; that is a normal healthy patient without any co-morbidity. The recommendations in the guideline are based on c ase series, indirect evidence and consensus methodology. The guideline recommends full blood count before major surgery in healthy adults aged 16–40 years.

Availability of blood and group and saving of serum

Blood transfusion may be necessary in cases of severe obstetric haemorrhage and i s a s urrogate marker for heavy blood loss. Six RCTs report on t he need for blood transfusion as an outcome measure[40,42–45,48] (n = 2469). 1.4% of women in the planned CS group compared to 1.8% in the planned vaginal birth group required blood transfusion. No difference was detected in this outcome measure between the two groups (pooled RR 0.86, 95% CI 0.48 to 1.53). [evidence level 1a] Non intention to treat analysis (by actual rather than intended mode of delivery), indicate the rate of blood transfusion for women who had CS was 9–10% compared to 0–2% for women who had a vaginal birth.[43,44] One cohort study reported on peripartum blood transfusion by mode of birth.[294] The overall incidence of blood transfusion following birth was 0.99%. Compared to women who had spontaneous vaginal birth, the relative risk of blood transfusion for women who had CS was 5.6 (95% CI 2.9 to 10.8) and for women who had assisted vaginal birth it was increased (RR 15.5, 95% CI 8.3 to 29.0). [evidence level 2b]

National data on CS for the United Kingdom shows women who had CS for antepartum haemorrhage, placenta praevia or uterine rupture accounted for 21% of occurrences of blood loss greater than 1000 ml.[4] [evidence level 3] Women with a prior diagnosis of placenta praevia, abruption, uterine rupture or APH are at increased risk of blood loss of more than 1000 ml (RR 5.31, 95% CI 4.67 to 6.04) compared with women without these conditions. Other predictive factors for haemorrhage during CS include pre-eclampsia, obesity, amnionitis and prolonged active phase of labour.[295,296] [evidence level 3]

Haemorrhage is still an important cause of maternal mortality and it is recommended that all obstetric units should have a protocol for the management of obstetric haemorrhage and that women at high risk of haemorrhage should be delivered at a unit with a blood bank on site.[95] [evidence level 3] The majority (95%) of maternity units in England and Wales report having on-site cross matching facilities at all times with 3% of maternity units cross matching facilities during the day only and the remainder keeping O-negative blood on labour ward at all times.[4] [evidence level 3] There is also a wide range of blood ordering practices.[297] [evidence level 3] Blood transfusion service guidelines do no t address preoperative cross matching, rather provide recommendations for safer blood transfusion practices.[298] [evidence level 4]

We did not identify any studies that looked at whether all women having CS should have group and save taken preoperatively. Women who are at high risk of having a blood loss of greater than 1000 ml at CS should be d elivered at a s ite with blood transfusion services. Studies set in circumstances where there are no blood transfusion services suggest that availability of blood is of importance in reducing the morbidity associated with haemorrhage.[299] [evidence level 3]

Other blood tests

We did not identify any evidence on the value of clotting screen or other blood tests prior to CS. Extrapolation from the preoperative testing guideline for major surgery mentioned previously would not recommend clotting screen or other tests such as urea and electrolytes prior to CS.[293] [evidence level 3]

Routine ultrasound before CS

Preoperative ultrasound has been proposed for placental localisation, presentation and as a method of predicting the integrity of a previous CS scar. A cohort study looked at whether routine preoperative ultrasound at CS impacted on CS outcomes. The study performed preoperative ultrasound scans on 124 women and compared them with matched controls, retrospectively. The outcomes they considered were incidence of incision through the placenta, blood loss of more than 1000 ml, difficult birth; injury of the infant, injury to the cord or to other adjacent structures. No difference in these outcomes was detected between the two groups.[300] [evidence level 2b]

It has been reported that about a quarter (28%) of transverse uterine scars can be seen on ultrasound, vertical uterine scars cannot be v isualised on ultrasound.[301] [evidence level 2b] The clinical usefulness of this is not clear.[302] [evidence level 2a].[303] [evidence level 1b]

Ultrasound has been used for the antenatal diagnosis of placenta accreta however the predictive value of this remains uncertain.[304,305] [evidence level 3]

Urinary catheter use at CS

A UK survey of obstetricians reports that for CS with epidural anaesthesia the majority (82%) use an indwelling urethral catheter for both the procedure and postoperatively, a minority would use an indwelling catheter for either the duration of the procedure only (10.6%) or an in–out catheter (7.3%). This was similar for both unplanned or planned CS and for CS with general anaesthesia.[306] [evidence level 3]

An RCT (n = 50) of women undergoing planned caesarean section under epidural analgesia who were randomised prospectively to be c atheterised with an ‘ in-out’ or an indwelling urethral catheter removed the after the CS. Of the women who had catheterisation for the time of surgery alone 44% subsequently required re-catheterisation, whereas all women with indwelling catheters voided spontaneously on their removal. The frequency of significant bacteriuria was the same in both groups.[307] [evidence level 1b]

Another RCT from Iran (n = 270) included women having a CS with general or regional anaesthesia. Women were randomised into two groups: group I were not catheterised but were encouraged to void urine immediately prior to the CS; group II had indwelling catheters removed the day after the CS. Outcomes measured were discomfort at first voiding post-CS, time of ambulation, time of hospital stay and need for re-catheterisation. Of women who were not catheterised 4% required catheterisation postoperatively. There was no d ifference in ambulation time and women who did not have an indwelling catheter had a slightly shorter hospital stay (17 hours).[308] [evidence level 1b]

Preoperative shaving

No RCTs have compared pre-CS shaving of the abdomen to no s having. A systematic review included 2 RCTs (n = 539) to assess the effects of routine perineal shaving on admission in labour on maternal and neonatal outcomes. In the earlier trial, 389 women were alternately allocated to receive either skin preparation and perineal shaving (control) or clipping of vulval hair only (experimental). In the second trial, which included 150 participants, perineal shaving was compared with the cutting of long hairs for procedures only. The primary outcome for both trials was maternal febrile morbidity. No differences were found (combined OR 1.26, 95% CI 0.75 to 2.12). In the smaller trial, fewer women who had not been shaved had gram negative bacterial colonisation compared with women who had been shaved (OR 0.43, 95% CI 0.20 to 0.92).[309] [evidence level 1a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

59 Pregnant women having CS for antepartum haemorrhage, abruption, uterine rupture and placenta praevia are at increased risk of blood loss of more than 1000 ml and should have the CS carried out at a m aternity unit with on-site blood transfusion services. [C] **[2004]**

60 Pregnant women who are healthy and who have otherwise uncomplicated pregnancies should not routinely be offered the following tests before CS:

- grouping and saving of serum
- cross-matching of blood
- a clotting screen
- preoperative ultrasound for localisation of the placenta, because this does not improve CS morbidity outcomes (such as blood loss of more than 1000 ml, injury of the infant, and injury to the cord or to other adjacent structures). [C] **[2004]**

61 Women having CS with regional anaesthesia require an indwelling urinary catheter to prevent over-distension of the bladder because the anaesthetic block interferes with normal bladder function. [GPP] **[2004]**

7.5 Anaesthesia for CS

Planning post-CS analgesia

The different options for post-CS analgesia should be discussed with the woman before her CS using available obstetric anaesthesia and analgesia patient information booklets[310] so that the individual analgesic needs of each woman can be met.[310] [evidence level 3] Post-CS pain relief should be prescribed prior to discharge from the anaesthetic recovery area to a general ward.[311] [evidence level 3]

General versus regional anaesthesia for CS

The NSCSA reported that 77% of unplanned and 91% of planned CS are performed using regional anaesthesia.[4] [evidence level 3] Of the CS that were reported to be gr ade 1 urgency (immediate threat to the life of the woman or fetus), 41% were performed using general anaesthesia, 54% had regional anaesthesia and 3% had general anaesthesia following regional anaesthesia. A UK survey of anaesthetic techniques for CS reported an overall failure rate of epidural anaesthesia of 7.1%, for combined spinal epidural's it was 2% and for single shot spinal anaesthetic 1.9%. Failure of regional anaesthesia accounted for 10% of general anaesthetic cases for CS.[312] [evidence level 3]

Three RCTs have compared the impact of general versus regional anaesthesia for CS on maternal and neonatal morbidity. One RCT (n = 341) randomised women into three groups: general anaesthesia, epidural anaesthesia or spinal anaesthetic. The maternal and neonatal outcomes were reported separately.[313,314] [evidence level 1b] General anaesthesia resulted in increased blood loss, lower postoperative haematocrit and higher proportion of women with postoperative haematocrit of less than 30%. There was no difference in neonatal cord blood gas analysis, Apgar and a Neurologic Adaptive Capacity Score (4 hours after birth).[314] [evidence level 1b] The second RCT (n = 47) randomised women to have either general or epidural anaesthesia, the trial measured neonatal outcomes only. No difference was detected in the incidence of low Apgar scores and umbilical artery gas analysis.[315] [evidence level 1b] The third RCT (n = 104) randomised women having planned repeat CS to either general anaesthesia or spinal anaesthesia. The RCT measured short term neonatal outcomes only. This RCT is poorer quality because it has 20% loss to follow-up. Of the 84 infants followed up n o difference was detected in neonatal outcomes between the two groups.[316] [evidence level 1b] All the RCTs are underpowered to look at neonatal outcomes.

A large observational study from the US (n = 3940) reported that infants born by CS with general anaesthesia are more likely to have an Apgar less than 7 and to need resuscitation compared to those born by CS with regional anaesthesia (1-minute Apgar less than 7: RR 3.13, 95% CI 2.5 to 3.88. 5-minute Apgar less than 7: RR 3.6, 95% CI 1.81 to 7.00. Need for resuscitation RR 2.02, 95% CI 1.39 to 2.9).[317] [evidence level 3]

Two RCTs compared regional and general anaesthetic for specific clinical conditions; severe pre-eclampsia and placenta praevia. One RCT (n = 80) compared general, epidural or combined spinal epidural anaesthetic for CS in women with severe pre-eclampsia. They found no significant difference in maternal (BP or urine output) or fetal complications (umbilical artery pH, Apgar score) between the three groups.[318] [evidence level 1b] The second RCT (n = 25) randomised women having CS for placenta praevia to receive either general or epidural anaesthesia. Women who received general anaesthesia had lower postoperative haematocrit (28.1% versus 32.5%) and were more likely to need blood transfusion (42% versus 15%; RR 2.71, 95% CI 0.64 to 11.4). There was no difference in neonatal outcomes.[319] [evidence level 1b] Two large scale retrospective surveys comparing regional to general anaesthesia for CS for placenta praevia showed that general anaesthesia was an independent predictor for increased blood loss, decreased postoperative haemoglobin and increased need for blood transfusion. One of the surveys was conducted in the USA (514 women)[320] [evidence level 3] and one in the UK (350 women).[321] [evidence level 3]

A UK-based retrospective survey of 137 women reported that the mean time for surgical readiness for regional anaesthesia 27.6 minutes (range 13–55 minutes) compared with 15.4 minutes (range 2–44 minutes) for general anaesthesia, $p < 0.01$. Time for surgical readiness is defined as time between leaving the delivery room to skin incision.[322] [evidence level 3]

Monitoring during anaesthesia for CS

For CS under regional block the following monitoring is recommended; continuous pulse oximetry, non-invasive blood pressure capable of one minute cycles (preferably with printout) and continuous ECG are required during induction, maintenance and recovery. The fetal heart rate should be recorded during the initiation of regional block and u ntil the abdominal skin preparation is begun in unplanned CS.[323] [evidence level 4]

During general anaesthesia, the woman should be m onitored in accordance with the recommendations of the Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines for obstetric anaesthesia services. The recommendations include continual assessment of the patient's physiological state, depth of anaesthesia and function of equipment. Monitoring devices supplement clinical observations.[324] [evidence level 4]

No economic studies comparing the cost effectiveness of general and regional anaesthesia for CS were identified. However we identified one ec onomic study from America using effectiveness data from a case note review comparing spinal and epidural anaesthesia for planned CS. Spinal anaesthesia took up l ess operating time, required less intraoperative analgesia, and led to fewer complications than epidural. The only dimension which was not different between spinal anaesthesia and epidural was in the need f or postoperative analgesia. Therefore spinal anaesthesia was associated with lower cost than epidural anaesthesia (postoperative analgesia was not included in the costs). A full cost-effectiveness analysis was not undertaken.[325]

Place of induction of anaesthesia

There are no RCTs looking at the use of anaesthetic rooms in obstetric anaesthesia. One RCT (n = 100) patients having minor or intermediate operative procedures who were randomised to induction of anaesthesia in an anaesthetic room versus in theatre. The outcomes included patient anxiety assessed using physical parameters (such as heart rate) and questionnaire. There was no difference detected between the two groups.[326] [evidence level 1b]

A survey of 115 women having a planned CS under regional anaesthesia in the UK reported that stress scores were higher in theatre. Women reported this to be due to anxiety about pain and the well being of themselves and their babies and not from the environment.[327] [evidence level 3] Anaesthetic rooms for induction of anaesthesia have been used in the United Kingdom for many years and are currently more commonly used than theatre for induction (4% of UK hospitals induce anaesthesia in theatre).[328] [evidence level 3]

Converting epidural analgesia to anaesthesia for CS

There were no studies that addressed the issue of place of top-up. A survey of current UK practice is being conducted.[329] Key issues in relation to the place of topping up of epidural or spinal are

monitoring and safety. Two RCTs have compared different drugs to convert epidural analgesia for labour to epidural anaesthesia for CS. One RCT (n = 90) compared 3 groups. Group 1: bupivacaine 0.5% alone, group 2: bupivacaine 0.5% with lignocaine 2% and adrenalin and group 3: lignocaine 2% with adrenalin. The outcome was time to adequate block (loss of cold sensation to T4). No difference was detected between the groups but group 3 had 6 adverse events (3 high blocks and 3 patients requiring general anaesthesia).[330] [evidence level 1b] Another RCT (n = 84) compared epidural conversion with or without alkalinising agents (bicarbonate v saline). Outcome assessed was time to adequate surgical block. Time to adequate block was less in the alkalinated group (mean difference 4.5 minutes).[331] [evidence level 1b].

Procedures to avoid hypotension

Current practice in the UK includes the use of lateral tilt and intravenous ephedrine infusion to prevent and manage hypotension. Pre -loading and leg binders are not commonly used.[312] [evidence level 3]

Lateral tilt of the operating table at CS is used to decrease compression of the inferior vena cava by a gravid uterus and r esultant hypotension.[332] [evidence level 3] Lateral tilt is standard practice in UK units for CS.[312] [evidence level 3] A systematic review that includes 3 RCTs (n = 293) has evaluated the effect of lateral tilt at CS on Apgar scores or umbilical artery pH measurements. All of the RCTs were methodologically poor with inadequate allocation concealment and poorly reported randomisation methods. All of the RCTs were conducted in the 1970s. Meta analysis was limited as different outcomes were measured. There were no differences in low Apgar scores (Peto OR 0.53, 95% CI 0.25 to 1.16) or umbilical artery pH measurements (weighted mean difference 0.03, 95% CI 0.01 to 0.04) when lateral tilt was used.[333] [evidence level 1a]

We identified one RCT published after the most recent update of the review. In this RCT fetal heart rate patterns, uterine activity, umbilical artery, acid base status, newborn evaluation and maternal parameters were compared between left lateral tilt and no tilt at “emergency” CS. No difference was found when lateral tilt was used.[334] [evidence level 1b]

A 15° wedge under the women’s right hip is sometimes used instead of lateral tilt at CS. Two RCTs (n = 100) considered the effect of lateral tilt versus a 15° wedge on aortocaval compression as measured by incidence of hypotension after spinal anaesthetic for CS. No difference was detected between the methods.[335,336] [evidence level 1b]

A systematic review that included 20 RCTs evaluating techniques for preventing hypotension during spinal anaesthesia for CS reported that the following interventions reduce the incidence of hypotension under spinal anaesthesia for CS: pre load with crystalloid 20 ml/kg vs. control (1 RCT, n = 140; RR 0.78, 95% CI 0.6 to 1.0); pre emptive colloid vs. crystalloid (4 RCTs, n = 126; RR 0.54, 95% CI 0.37 to 0.78); ephedrine vs. control (3 RCTs, n = 146; RR 0.70, 95% CI 0.57 to 0.85); lower limb compression vs. control (5 RCTs, 181 women, RR 0.75, 95% CI 0.59 to 0.94). No difference in maternal or neonatal side effects were reported, however the RCTs were not large enough to evaluate these. A further 26 were excluded from this review the main reason given for these exclusions was that the spinal technique was uncontrolled.[337] [evidence level 1a].

Subsequent to the review two RCTs have been published that evaluate the use of elastic stockings for prevention of hypotension (n = 20)[338] [evidence level 1b] and elastic stockings plus a sequential compression device (n = 100).[339] [evidence level 1b] Neither RCT detected a difference in the incidence of hypotension with the use of elastic stockings alone or together with a compression device. The RCTs used different outcome measure to the RCTs included in the systematic review and therefore could not be added to the meta-analysis.

The use of bolus phenylephrine is a s uggested alternative to ephedrine in maintaining maternal arterial blood pressure during regional anaesthesia. This was evaluated in an RCT (n = 38) which reported maternal blood pressure was similar in both groups.[340] [evidence level 1b] A further RCT (n = 50) looked at the use of prophylactic epidural ephedrine to decrease the incidence of hypotension. They did not detect a d ifference in the incidence of hypotension between the groups.[341] [evidence level 1b]

Procedures to manage hypotension

Despite methods to prevent hypotension it does still occur. A systematic review of 7 RCTs (n = 292) compare the use of ephedrine to phenylephrine for the management of hypotension during spinal anaesthesia for CS. The review did not detect a difference between the two vasopressors for the management of hypotension (RR 1.00, 95% CI 0.96 to 1.06). Maternal bradycardia was more common with phenylephrine (RR 4.79, 95% CI 1.47 to 15.6) and neonates born to women given phenylephrine less likely to be acidotic (RR 0.78, 95% CI 0.16 to 3.92).[342] [evidence level 1a].

A further RCT published since the review (n = 30) also compared intravenous ephedrine infusion with bolus ephedrine if hypotension developed. They reported a reduced incidence of hypotension when ephedrine infusion was used and less nausea and vomiting. There was no d ifference in neonatal heart rate or blood pressure.[343] [evidence level 1b] Current guidelines advise that maternity departments should have guidelines for management of hypotension.[323] [evidence level 4]

Failed intubation

Failed intubation remains a cause of maternal death.[95] A survey of cases of failed tracheal intubation for the six year period 1993 to 1998 reports 36 cases of failed intubation in 8790 obstetric anaesthetics (incidence 1/249).[344] This incidence was constant for the six year period. In the majority of cases there had be en no preoperative assessment of the patient for intubation risk. There is no single test that on its own has a hi gh predictive value for difficult intubation. Use of two or more abnormal airway findings are needed for prediction of difficult intubation and in this situation regional anaesthesia should be considered although that is no guarantee that intubation will not be needed.[345] [evidence level 4]

A number of opinion-based papers have proposed the use of laryngeal masks in cases of failed intubation with CS.[346,347] [evidence level 4] We identified a case series of 1067 women undergoing planned CS which used laryngeal masks instead of endotracheal intubation. They reported that an effective airway was obtained in 99% of women at the first attempt, 7% required intubation during the CS and there were no episodes of hypoxia, aspiration, regurgitation or laryngospasm.[348] [evidence level 3]

National anaesthetic obstetric guidelines recommend that each unit has their own drill for failed intubation[323] such as described in recent literature.[349–351] This together with predictive tools and innovative training tools such as anaesthetic emergency simulators[352] should reduce mortality associated with failed intubation. [evidence level 4]

Use of antacids before CS

Antacid prophylaxis forms part of routine practice at most units in the UK. NSCSA reports that 99% of UK units routinely use antacids and dr ugs to reduce the gastric volume and acidity for planned CS and 98% for unplanned CS. Ninety eight percent use histamine H2 receptor blockers (ranitidine or cimetidine), 2% proton pump inhibitors (omeprazole) and 99% a non-particulate antacid such as sodium citrate.[4] [evidence level 3] Ranitidine currently costs £0.64 and omeprazole £2.04 per dose to reduce acidity of gastric contents.[353]

The risk of developing acid aspiration syndrome is increased when the volume aspirated into the lungs exceeds 25 ml and has an acidic pH (less than 2.5).[354] [evidence level 3] No studies have used maternal aspiration pneumonitis as an outcome measure as this is rare and would require large numbers of women to be included. Antacids are used to decrease the acidity of gastric contents. An RCT (n = 32) comparing sodium citrate with no antacid reported reduced acidity and no difference in gastric volume.[355] [evidence level 1a] A study of 20 women undergoing CS reported that women who received cimetidine preoperatively had an average pH of 5.05 compared to pH 2.97 in women who did not receive antacid. There was no di fference in gastric volume measured by intraoperative aspiration of stomach contents.[356] [evidence level 2b]

An RCT (n = 595) compared ranitidine with sodium citrate to sodium citrate alone. Women who had acidic gastric contents (pH < 3.5) or a gastric volume > 25ml were defined as “at risk of aspiration”. The “risk of aspiration” was reduced in the group who had ranitidine and sodium citrate compared to sodium citrate alone (5.6% vs. 0.3%, $p < 0.05$)[357] [evidence level 1b]. Another RCT (n = 541) compared omeprazole to placebo on the same “risk of aspiration” outcome. They reported a reduction

in the women “at risk of aspiration” (4.3% v 1.4% OR 3.08 95% CI 1.02 to 9.29)[358] [evidence level 1b]. A further 3 RCTs have compared ranitidine to omeprazole. Omeprazole results in a higher mean pH than ranitidine, however cost issues make ranitidine with sodium citrate a more cost effective option.[359–361] [evidence level 1b]

Use of antiemetics

Nausea and vomiting commonly occur during CS due to aortocaval compression and resultant hypotension (see section on procedures to avoid hypotension during CS).

Routine practice in UK maternity units includes using an antacid and metoclopramide (a phenothiazine like antiemetic).[4] [evidence level 3] An early RCT (n = 58) in women undergoing planned CS with general anaesthetic compared using metoclopramide to no treatment. The RCT did not detect a difference in gastric volume between the groups.[362] [evidence level 1b] Later RCTs in women having CS with spinal anaesthesia show reduced incidence of nausea and vomiting in women who were given metoclopramide before induction of anaesthesia (14% vs. 81%).[363] [evidence level 1b]

We identified five RCTs comparing different antiemetics to placebo: propofol;[364] granisetron, droperidol and m etoclopramide;[365] ondansetron and dr operidol;[366] metoclopramide and ondansetron;[367] ondansetron.[368] Meta-analysis of these RCTs showed compared to placebo, any antiemetic reduced nausea and vomiting. [evidence level 1b] Ondansetron appears to be more effective than metoclopramide in reducing nausea (2 RCTs. RR 0.54, 95% CI 0.33 to 0.87). No difference was detected between ondansetron and droperidol in reducing nausea (2 RCTs. RR 1.0, 95% CI 0.44 to 2.27). However considering cost and safety in prescribing the cost of metoclopramide £0.28 per 10mg parenteral dose.[353] Metoclopramide is not known to be harmful but its use should be limited to situation where there is known benefit. 5HT3 antagonists (ondansetron) is £12.89 per 8 mg parenteral dose, it is advised to avoid use during pregnancy and breastfeeding.[353] Therefore metoclopramide should be offered if a pharmacological antiemetic is used during CS.

One RCT (n = 75) compared acupressure with placebo and metoclopramide for the prevention of nausea and vomiting during CS. Compared to placebo either acupressure or metoclopramide reduced nausea. No difference was detected between acupressure and metoclopramide (RR 1.5, 95% CI 0.5 to 4.7)[369] [evidence level 1b]

Use of pre-oxygenation, rapid sequence induction and cricoid pressure

Standard UK practice for unplanned CS includes pre oxygenation, rapid-sequence induction and cricoid pressure for CS under general anaesthetic.[312] [evidence level 3] We did not identify any RCT that compared use of these interventions to non use. A number of discussion papers were identified[370–372] which included results of experimental work but no outcomes based studies. [evidence level 4]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

7.6 Surgical techniques for CS

A national survey of surgical techniques used during CS in the UK reports a wide range of surgical techniques being used in practice.[306] [evidence level 3] This section presents the evidence on surgical techniques for lower segment CS in uncomplicated first procedures. Discussion of surgical techniques for specific clinical situations such as CS for preterm birth (classic uterine incision) or CS in women with previous CS (bladder adhesions) are outside the scope of this guideline.

Methods to prevent HIV transmission in theatre

Prevention of transmission of HIV from a woman undergoing CS who is known to be HIV-positive to staff carrying out the CS has been evaluated using a mathematical model[373] and current UK HIV data[374] the estimated cumulative probability of occupationally acquired HIV infection is less than 1%. This is calculated at a skin puncture rate of 0.025 per procedure. However this estimate does not take into account the more common mode of contact with contaminated blood in obstetrics which is face contamination. One paper estimated the incidence of face shield contamination during CS as 50%. The incidence of cases of definite occupational acquisition of HIV in the United Kingdom has been small (1 in 319 percutaneous exposures and 1 in 3000 mucocutaneous exposures).[375] [evidence level 3]

The use of surgical pass trays and double gloving have been tested in RCTs to determine whether their use decreases the risk of glove perforation and hence risk of infection. The use of surgical pass trays was considered in an RCT (n = 192 CS, 444 pairs of gloves) that did not detect any difference in the number of glove perforations (19% vs. 16.1% of gloves perforated, RR 1.2, 95% CI 0.8 to 1.8).[376] [evidence level 1b]

A systematic review of wearing double gloves to reduce surgical cross infection included 18 RCTs that looked a glove perforation as an indirect measure of surgical infection. The results of the review showed that double latex gloving reduces the number of perforations to the innermost glove (OR 3.72, 95% CI 2.82, 4.91).[377] [evidence level 1a]

In addition to the above evidence there are recommendations for safer surgical practices in general which include post exposure prophylaxis[378] [evidence level 4]

Recommendations

Number	Recommendation
72	Healthcare professionals should wear double gloves when performing or assisting at CS on women who have tested positive for HIV, to reduce the risk of HIV infection of healthcare professionals during surgery. [A] **[2004]**

73	General recommendations for safe surgical practice should be followed at CS to reduce the risk of HIV infection of staff. [C] **[2004]**

Use of adhesive drapes

We identified two RCTs on the use of adhesive drapes. Both studies addressed the impact of the use of adhesive drapes only on the incidence of postoperative wound infection. Other issues such as staff safety in the operating theatre related to spillage of blood were not addressed in these RCTs. One study described the use of adhesive drapes at CS as an isolated intervention and found the incidence of post-CS wound infection to be unchanged by their use.[379] [evidence level 1b] The other RCT described the use of adhesive drapes together with repeat disinfection of the skin before skin closure. This RCT did not find any decrease in the incidence of wound infection with the use of adhesive drapes.[380] [evidence level 1b] Neither RCT commented on the HIV status of the women that were included in the studies.

Recommendations

Number	Research recommendation
RR 31	RCTs are required to determine the effectiveness of adhesive drapes at CS in reducing blood spillage and cross infection and improving safety for staff in the operating room.

Abdominal-wall incision

Vertical incisions for CS are uncommon in the UK (less than 1% of skin incisions are vertical) and have been replaced by transverse incisions.[306] [evidence level 3] No RCTs have compared midline to transverse incisions for CS. A meta-analysis of general surgical RCTs has compared midline, oblique and transverse incisions for their effect on postoperative pain, wound infection rates, incisional hernias and wound dehiscence.[381] Seven RCTs included postoperative pain as an outcome measure. Two RCTs (n = 209) compared midline and transverse incisions and found that the group with transverse incisions had lower pain scores and required less pethidine for analgesia ($p < 0.001$). Ten RCTs (n = 3586) reported on the incidence of wound infection and found no difference between the different types of incisions. Wound dehiscence and incisional hernias were reported in 9 RCTs (n = 2551) and there was no difference detected for these outcomes.[381] [evidence level 1a]

A case–control study of 48 cases of fascial dehiscence after CS described risk factors for dehiscence using stepwise logistic regression and did not find transverse incisions to have a lower risk of dehiscence than vertical incisions.[382] [evidence level 3]

An observational study (n = 89) reported on women's perceptions of the cosmetic outcome of scar formation after either percutaneous or subcuticular sutures for CS. They found that the factor that impacted most on w omen's perception of scar appearance was whether the scar was midline or transverse with transverse being more favoured.[383] [evidence level 2b]

Pfannenstiel, Maylard and Joel Cohen all described transverse abdominal wall incisions used for CS. The Pfannenstiel incision consists of a curved skin incision, two fingers breadths above the symphysis pubis, transverse incision of the sheath, rectus muscles are separated bluntly and the parietal peritoneum is incised is the midline. Maylard incision is similar but the rectus muscles are cut transversely with a knife. The Joel Cohen incision is a straight skin incision 3 cm above the pubic symphysis, then subsequent layers are opened bluntly and if necessary extended with scissors and not a knife.[384]

Four RCTs have compared different transverse incisions for CS. Two RCTs compared Pfannenstiel incision with the Joel Cohen incision. Both RCT's reported that the Joel Cohen incision is associated with shorter operating time (SMD –0.29 minutes, 95% CI –0.54 to –0.04385; SMD –0.87 minutes, 95% CI –1.28 to –0.46).[386] Both RCTs also reported reduced postoperative febrile morbidity with the Joel Cohen incision (Pooled RR 0.35, 95% CI 0.19 to 0.64).[385,386] [evidence level 1b] Two RCTs

compared Pfannenstiel with Maylard incisions and showed no difference in terms of operative and postoperative morbidity.[387,388] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Instruments for skin incision

No RCTs have addressed which instruments should be used for skin incision at CS. An RCT that included patients undergoing elective general surgical compared 'one versus two scalpels' technique (first scalpel for the skin and the second scalpel for deeper tissue) (n = 277). This RCT did not detect any difference in wound infection.[389] [evidence level 1b] No other outcomes were reported. An experimental study showed that scalpels remained sterile after skin incision supporting the view that there was no need to discard the skin scalpel to prevent wound infection.[390] [evidence level 3]

Two general surgical RCTs comparing abdominal entry using a s calpel with electrocautery did not detect any difference in any wound outcomes such as infection and strength. However the time required for the incision and incisional blood loss was less with electrocautery.[391,392] [evidence level 1b]

Another RCT compared incision using a surgical knife with diathermy at cholecystectomy (n = 200).[393] The results from this RCT showed that postoperative pain at 4, 8, 12, 16 and 24 hours and the need for morphine analgesia was less in the diathermy group. [evidence level 1b] This RCT did not assess the impact of diathermy on time to surgically open the abdomen.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 32	RCTs are needed t o evaluate the effectiveness of incisions made with diathermy compared with surgical knife in terms of operating time, wound infection, wound tensile strength, cosmetic appearance and women's satisfaction with the experience.

Extension of the uterine incision

In the UK 53% of clinicians use blunt dissection to extend the uterine incision and 47% use sharp dissection.[306] [evidence level 3] Two RCTs have compared sharp versus blunt extension of the uterine incision at CS.[394,395] [evidence level 1b]

One RCT (n = 945) reports that sharp extension is associated with greater estimated blood loss (886 ml versus 843 ml, p = 0.001); greater change in haematocrit (6.1% vs. 5.5%, p = 0.003); incidence in postpartum haemorrhage (13% vs. 9%, RR 1.23, 95% CI 1.03 to 1.46) and need for transfusion (2% vs. 0.4%, RR 1.65, 95% CI 1.25 to 2.21).[394] [evidence level 1b]

The other RCT (n = 286) found no difference between sharp and blunt extension for the outcomes of unintended extension, postoperative endometritis, duration of surgery or estimated blood loss.[395] [evidence level 1b] This RCT was however underpowered to detect a difference in these outcomes. It was not possible to meta-analyse the data from these two RCTs because the outcomes are measured and reported differently in the trials.

Stapling devices can be used during incision of the uterus to decrease the blood loss from the cut edges of the uterine wall. They are not commonly used in the United Kingdom. A systematic review that included four RCTs (n = 526 women)[396] reported no difference in the total operating time between the groups which used a stapling device and those that did not (weighted mean difference: 1.17 minutes, 95% CI –3.57 minutes to 1.22 minutes). However stapling devices increased the time to deliver the baby (weighted mean difference 0.85 minutes, 95% CI 0.48 minutes to 1.23 minutes). Blood loss was less with the use of staples (weighted mean difference 41.22 ml, 95% CI –50.63 ml to –31.8 ml). There was no difference for other perinatal outcomes. These RCTs were funded by the manufacturers of surgical staples. [evidence level 1a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Fetal laceration

The RCTs comparing sharp to blunt extension of the uterine incision do not report on i ncidence of trauma to the neonate, however three descriptive studies report on the incidence of fetal lacerations at CS. One study was from the UK[397] [evidence level 3] and two of the studies were from the US (115).[398] [evidence level 3] The UK study reports an incidence of fetal lacerations of 1.5% which is similar to the US studies (1.9% and 0.74% respectively). The UK study reported that the incidence of lacerations was independent of type of CS (unplanned or planned), fetal presentation cervical dilatation and operator grade. One US study reported that the incidence of lacerations increased to 6% with a non-cephalic presentation.[399] [evidence level 3]

Recommendations

Number	Recommendation
78	Women who are having a CS should be informed that the risk of fetal lacerations is about 2%. [C] **[2004]**

Use of forceps

The use of forceps at CS has been suggested as a method of easing delivery of the fetal head, particularly for preterm infants or when the lower segment of the uterus is poorly formed.[400] [evidence level 3]

A small RCT (n = 44) of women undergoing planned repeat CS were randomised to vacuum, forceps or manual delivery of the fetal head.[401] [evidence level 1b] There was no difference detected between the groups in the incidence of extension of the uterine scar, maternal blood loss or neonatal outcomes (including neonatal injuries). However women in the vacuum group reported less pain. The trial is however underpowered to evaluate these outcomes. [evidence level 1b]

Recommendations

Number	Recommendation
79	Forceps should only be used at CS if there is difficulty delivering the baby's head. The effect on neonatal morbidity of the routine use of forceps at CS remains uncertain. [C] **[2004]**

Cord clamping

Suggested benefits of delayed cord clamping include decreased neonatal anaemia; better systemic and pulmonary perfusion; and better breastfeeding outcomes. Possible harms are polycythaemia, hyperviscosity, hyperbilirubinaemia, transient tachypnoea of the newborn and risk of maternal fetal transfusion in rhesus negative women.[402]

One RCT based in the UK randomised women having a vaginal birth to either early or delayed cord clamping (n = 554). There was no difference detected in the duration of cord adherence, neonatal or maternal outcomes.[403] [evidence level 1b]

Two RCTs have compared the likelihood of infant anaemia between delayed and early cord clamping in preterm neonates delivered by CS. The trials use different outcome measures.[404,405] [evidence level 1b One of the RCTs, from Germany (n = 40)[404] reports that delayed cord clamping of 45 s econds results in a reduced need for packed cell transfusions during the first six weeks of life (RR 3.33, 95% CI 1.07 to 10.03). The second RCT from Australia (n = 46)[405] found no difference in infant haematocrit between the two groups. Both RCTs found delayed cord clamping to be feasible at CS. Both RCTs were underpowered for the outcomes measured.

Recommendations

Number	Research recommendation
RR 33	RCTs are needed to determine the effect of delayed cord clamping on neonatal outcomes including transient tachypnoea of the newborn and risk of maternal fetal transfusion in rhesus negative women for term and preterm births.

Use of uterotonics

The licensed dose of oxytocin for CS is 5 iu by slow intravenous injection.[353] Oxytocin is used to ensure uterine contraction, minimise delay in delivering the placenta, reduce intra operative blood loss and prevent postpartum haemorrhage A survey of UK lead obstetric anaesthetists[406] (n = 179) reports that 87% gave 10 un its at CS, half of them administered this by rapid bolus injection.[406] [evidence level 3] The risks of Syntocinon® (oxytocin), especially given by rapid injection, have been highlighted.[95] Oxytocin has a direct relaxant effect on vascular smooth muscle. Under normal circumstances there is a reflex tachycardia and increased cardiac output that accompanies the transient decrease in blood pressure. The hypovolaemic woman may not respond in the normal way

and in some circumstances profound hypotension may occur with resultant compromise of cardiac function.[95]

Five RCTs have compared the use of different uterotonics at CS. Uterotonics used in these RCTs include oxytocin, oxytocin with ergometrine, misoprostol and pr ostaglandin F2a. No placebo controlled RCTs were identified. The use of ergometrine at uncomplicated CS is not common practice in the UK and therefore the RCT that included ergometrine is not discussed further.[406] [evidence level 3]

One RCT (n = 40) compared oxytocin administered as an intravenous bolus of 5 iu compared with intramyometrial injection of 20 iu. This is not a licensed dose or route of administration. The intramyometrial injection was associated with more hypotension(mean decrease in systolic blood pressure one m inute after oxytocin was 8.4mmHg in the intravenous group and 14.6mmHg in the intramyometrial group, $p < 0.001$).[407] [evidence level 1b]

Another RCT (n = 321) compared different oxytocin infusion concentrations (20 iu/l versus 160 iu/l). The results showed that the lower concentration group had more need for additional uterotonics (39% vs. 19%, $p < 0.001$). There was no difference in the incidence of hypotension between the two groups.[408] [evidence level 1b]

One small RCT (n = 40) compared oxytocin to misoprostol orally and found no difference between the two uterotonics.[409] Misoprostol has not been found to be as effective as oxytocin for preventing postpartum haemorrhage after vaginal birth in large multicentred RCTs.[410] [evidence level 1b]

Another RCT (n = 60) compared prophylactic administration of intravenous oxytocin and intramyometrial prostaglandin and detected no difference in mean estimated blood loss between the two uterotonics.[411] [evidence level 1b]

Oxytocin (Syntocinon) has a short half life (4–10 minutes). Carbetocin is an oxytocin derivative which has a longer half life of 40 minutes.[412] Two published RCTs (n = 694 + n = 40) have compared 100 microgrammes carbetocin with an 8-hour oxytocin infusion.[413,414] The oxytocin regimen is not that recommended within this guideline. Only 1 RCT (n = 57) measured estimated blood loss and there was no difference detected between the groups.[413] [evidence level 1b] The other RCT reported surrogate measures such as need for additional oxytocic.[414] The RCTs were funded by the companies that produce carbetocin. Carbetocin is licensed in the UK but is yet to be launched. The basic NHS price is expected to be in the region of £12–15 per vial (information supplied by manufacturers) this compares to oxytocin which costs about £1.40 for a 5-iu or 10-iu vial.[353]

Excessive haemorrhage or uterine atony can occur at CS despite the use of prophylactic uterotonics. Haemorrhage is an important cause of maternal mortality. However it is outside the scope of this guideline to address the management of obstetric haemorrhage.

Recommendations

Number	Recommendation
80	Oxytocin 5 IU by slow intravenous injection should be used at CS to encourage contraction of the uterus and to decrease blood loss. [C] **[2004]**

Method of placental removal

Nine RCTs have studied the effect of method of placental removal. Three of these are included in a systematic review.[415] Eight of the RCTs considered blood loss and endometritis[416,417] and one RCT only looked at fetomaternal haemorrhage[418]. Feto-maternal transfusion does not appear increased by manual removal of the placenta (RR 0.37, 95% CI 0.13 to 1.07).[418] [evidence level 1b]

The methods of placental removal described in each of the RCTs are manual removal of the placenta compared to controlled cord traction or spontaneous separation of the placenta. In current UK practice, the controlled cord traction is used more frequently (73%) compared to manual removal of the placenta (25%).[306] [evidence level 3]

A meta-analysis of five of the RCT that reported data for endometritis was undertaken. The meta analysis showed an increased incidence of endometritis with manual removal of the placenta compared to spontaneous separation (RR 1.54, 95% CI 1.23 to 1.92) [evidence level 1a].The definition of endometritis was similar across the different RCTs (temperature of greater than 38° C, tender uterus, raised leucocyte count and offensive lochia). In four of the six RCTs all women received prophylactic antibiotics. In one RCT no antibiotics were given[417] [evidence level 1b] and in the other RCT there was variable use of antibiotics.[419] [evidence level 1b] All of these RCTs used routine administration of intra operative uterotonics.[417,419–422] [evidence level 1b]

Three RCTs reported blood loss as an outcome measure.[416,417,421] Meta-analysis of these RCTs showed no difference between manual removal and spontaneous separation of the placenta (SMD 0.62ml, 95% CI –1.17ml to 2.4 ml) [evidence level 1b].

Three RCTs reported on the effect of changing gloves after manual removal of the placenta and found no difference in the likelihood of post-CS endometritis (RR 1.1, 95% CI 0.75 to 1.47,[423]; RR of 1.0, 95% CI 0.79 to 1.3,[422] and RR 1.2, 95% CI 0.5 to 2.8).[419] [evidence level 1b].

Recommendations

Number	Recommendation
81	At CS, the placenta should be removed using controlled cord traction and not manual removal as this reduces the risk of endometritis. [A] **[2004]**

Exteriorisation of the uterus

A survey of current surgical practice in the UK reports that 69% of surgeons rarely exteriorise the uterus for repair at CS, 18% 'sometimes do so' and 13% usually exteriorise the uterus.[306] [evidence level 3] Four RCTs compare exteriorisation to intraperitoneal repair, two of the RCTs are included in a systematic review,[424] the other two RCTs were published after the systematic review.[425,426] All four RCTs report on blood loss and wound infection however this is measured differently across the trials (such as total units of blood transfused in each group, mean change in haematocrit per group, peri-operative change in haemoglobin and mean drop in haemoglobin between the two groups) Three RCTs detected no difference in blood loss between the groups.[427,428,425] [evidence level 1b] The fourth RCT detected a reduction in haemoglobin drop if the uterus is exteriorised (SMD 0.2 g/dl 95% CI 0.03 g/dl to 0.51 g/dl) however there was no difference in blood transfusion rates or surgeon's estimates of blood loss.[426] [evidence level 1b]

Two RCTs reported on the proportion of women in each group that had blood transfusion. The meta-analysis of this outcome showed no d ifference in rate of blood transfusion between the two groups (RR 1.17, 95% CI 0.43 to 3.19).[425,426] [evidence level 1b]

Three RCTs reported on wound infection. The meta-analysis showed no difference in wound infection between the two groups (RR 0.48 95% CI 0.18 to 1.29).[425–427] [evidence level 1b]

One RCT assessed nausea, vomiting, sensation of tugging and pain scores at the end of the procedure and found no difference between the two groups. All of the women had CS under regional anaesthesia. However two women in the exteriorised group had their epidural converted to general anaesthetic due t o pain.[426] [evidence level 1b] The other RCT reported intra operative nausea, vomiting and intra operative pain and found no difference in these outcomes between the groups. Daily pain scores were measured from day 1 to day 5 postoperatively. Pain scores were higher in the exteriorisation group on day 3. A postal questionnaire was used to assess pain scores and satisfaction with the CS experience at six weeks. No difference was found in mean satisfaction scores or persistent pain.[425] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

One- versus two-layer closure of uterus

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Closure of the peritoneum

Closure of the peritoneum (visceral and parietal) has formed part of standard surgical practice and aimed to restore anatomy, reapproximate the tissues and reduce infection by forming an anatomical barrier. Current UK practice reports that 66% of surgeons do not close the parietal peritoneum while 34% do close the parietal peritoneum.[306] [evidence level 3]

A systematic review comparing non-closure with closure of the peritoneum at CS includes four RCTs (n = 1194).[437] [evidence level 1a] Two RCTs compared closure to non-closure of both visceral and parietal peritoneum,[438,439] one RCT compared closure to non-closure of the visceral peritoneum only[440] and one RCT compared closure with non-closure of the parietal peritoneum only.[441] Overall, non-closure of the peritoneum saved operating time (weighted mean difference of 6.12 minutes, 95% CI –8.00 to –4.27) with no significant differences detected in postoperative morbidity, analgesic requirements or length of hospital stay [evidence level 1a].

Since the review 7 RCTs comparing closure of both visceral and parietal peritoneum with non-closure of peritoneum have been published.[441–447] [evidence level 1b] Four RCTs (n = 845 women) considered a wide range of morbidity measures as well as operating times.[442–445] All consistently found operating times to be less with non-closure of the peritoneum. Three RCTs found no difference in morbidity measures between the closure and non-closure groups.[442,444,445] One RCT suggested fewer postoperative complications.[443] Three RCTs assess the effect on postoperative pain.[441,446,447] [evidence level 1b] All three trials report no difference in postoperative pain (assessed using a visual analogue scoring (VAS),[441,446,447] decreased use of analgesia after 24 hours with non-closure[441] and increased maternal satisfaction.[447] None of the RCTs reported long term outcomes related to healing and scarring or implications for future surgery.

Recommendations

Number	Recommendation
84	Neither the visceral nor the parietal peritoneum should be sutured at CS because this reduces operating time and the need for postoperative analgesia, and improves maternal satisfaction. [A] **[2004]**

Closure of the abdominal wall

We did not identify any RCTs that looked at closure of rectus sheath at CS. A meta-analysis (15 RCTs) has evaluated methods of abdominal-wall closure for midline incisions in general surgical patients (n = 6566). The main outcome measures were incidence of hernias, wound dehiscence, wound infection, wound pain and suture sinus formation. Incisional hernias were less common with continuous slowly absorbable sutures compared with continuous rapidly absorbable suture or non absorbable suture. Wound pain and sinus formation was more common with non absorbable sutures.[448] [evidence level 1a]

A meta-analysis of RCTs comparing mass versus layered closure of midline incisions in general surgical patients found less incisional hernias and dehiscence to be less common with mass closures.[449] [evidence level 1a] Midline incisions are not commonly used for CS, however there is no direct evidence on this issue so for midline incisions at CS we have extrapolated the research evidence from general surgical trials. Further research is needed on this topic for transverse abdominal incisions.

Recommendations

Number	Recommendation
85	In the rare circumstances that a m idline abdominal incision is used at CS, mass closure with slowly absorbable continuous sutures should be used because this results in fewer incisional hernias and less dehiscence than layered closure. [B] **[2004]**

Number	Research recommendation
RR 34	RCTs are required to determine the effectiveness of mass closure compared to layered closure of the abdominal wall incision at CS particularly for transverse abdominal incisions.
RR 35	Research is required to assess the effect of the various surgical techniques for CS on future surgery such as repeat CS and the incidence of complications during future surgery such as hysterectomy and urogynaecological procedures.

Closure of subcutaneous tissue

Current practice in the UK for closure of the subcutaneous layer varies between obstetricians: 42% never close it; 21% always close; 8% only close if the layer is thin; 28% close if the layer is thick.[306] [evidence level 3]

Four RCTs have compared suturing of the subcutaneous tissue with no suturing at CS. Two RCTs randomised all women undergoing CS to suture or non-suture of the subcutaneous tissue space. One RCT found no difference in terms of wound infection or risk of wound separation.[450] [evidence level 1b] The other RCT reported suturing to be protective against wound separation (0.36, 95% CI 0.14 to 0.91) however the method of randomisation and hence the quality of the RCT is not clear.[451] [evidence level 1b]

Two further RCTs[452,453] (n = 76, n = 91) randomised women with at least 2 cm subcutaneous fat. Meta-analysis of these RCTs showed that closure of the subcutaneous space decreased the incidence of wound complications (RR 0.42, 95% CI 0.22 to 0.81). [evidence level 1a]

Recommendations

Number	Recommendation
86	Routine closure of the subcutaneous tissue space should not be used, unless the woman has more than 2 cm subcutaneous fat, because it does not reduce the incidence of wound infection. [A] **[2004]**

Use of superficial wound drains

Five RCTs (n = 1211) have compared the routine use of superficial wound drains in CS to their selective use.[452,454–457] [evidence level 1b] Each RCT measured slightly different parameters for the outcomes of infection and blood loss. There was no significant difference in wound infection, formation of haematoma, duration of hospital stay or need for analgesia between the groups.

One small RCT (n = 76) included women with more than 2cm of subcutaneous fat randomised into three groups. Group has suture closure of subcutaneous tissue, group 2 had a subcutaneous closed suction drain and group 3 the control group had neither.[452] Use of a subcutaneous drain was associated with reduced incidence of wound complications compared with controls (RR 10.2, 95% CI 1.4 to 72.9) and reduced incidence of wound infection or separation (RR 7.4, 1.0 to 54.8). This is a small trial and these findings could be due to chance.[452] [evidence level 1b]

We did not identify any evidence on the routine use of subrectus drains at CS.

Recommendations

Number	Recommendation
87	Superficial wound drains should not be used at CS because they do not decrease the incidence of wound infection or wound haematoma. [A] **[2004]**

Number	Research recommendation
RR 36	More RCTs are needed to determine the effect of wound drainage of postoperative morbidity especially in women more at risk of this outcome such as obese women.

Closure of the skin

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 37	More RCTs are needed to determine the effect of staples compared to subcuticular sutures for skin closure at CS on p ostoperative pain, cosmetic appearance and removal of sutures and staples.

Umbilical artery pH measurement

Umbilical artery pH, neonatal Apgar and n eonatal encephalopathy are the most reliable short term markers of poor longer term outcome such as neurodevelopment disability, cerebral palsy and perinatal death.[2] Guidelines on e lectronic fetal monitoring recommend that umbilical artery pH is assessed following unplanned CS[2] and paired umbilical artery and vein measurements are taken. [evidence level 4] This information can be used to review fetal wellbeing and to guide on-going care. It is can also be used for risk management and audit purposes.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Use of antibiotics

Infectious complications after birth are an important cause of maternal morbidity and can prolong length of hospital stay.[460] These include wound infection, postpartum endometritis and urinary tract infection.

Six RCTs (n = 2566) that compare planned CS to planned vaginal birth report on i nfection as a maternal morbidity outcome measure.[38–40,43,44,48] The incidence of infection was 6.4% for women in the planned CS group compared with 4.9% in the planned vaginal birth group. In the largest RCT the protocol suggested prophylactic antibiotics should be used at CS.[48] There was no information on the use of antibiotics in the other RCTs. No difference was detected in rate of infection between the two groups (pooled RR 1.29, 95% CI 0.97 to 1.72). [evidence level 1a]

Five RCTs comparing planned CS with planned vaginal birth reported on maternal puerperal pyrexia.[39–42,45] This was defined in one of the RCTs as temperature above 38°C.[42] Pyrexia can occur after any operative procedure and a low grade fever following a CS may not necessarily be a marker of infection. The pooled relative risk of puerperal pyrexia for women in the planned CS group was 1.96 (95% CI 1.36 to 2.84). [evidence level 1a]

Two cohort studies conducted in Israel[461] (n = 75,947) and the USA[462] (n = 33,251) examined the risk of infection according to mode of birth. In one study, the risk of infection was higher among women who had CS (7.9%) compared to those who had vaginal birth (1.8%) (RR 4.51 95% CI 4.00 to 5.09).[462] [evidence level 2b] The majority of infections were endometritis; wound infection among women who had CS. In the other cohort,[461] the incidence of postpartum endometritis among women who had CS was 2.6% compared to 0.2% among those who had vaginal births (RR 14.97, 95% CI 11.96 to 18.74).[461] [evidence level 2b] The incidence of wound infection following CS in this study was 4.0%.[461] The rates of wound infection were higher among women with gestational diabetes and those who had had previous CS.

In the UK 85% of surgeons usually administer prophylactic antibiotics, 12% do so if other factors are present and 3% rarely use them.[306] [evidence level 3]

One systematic review evaluates the use of antibiotic prophylaxis at CS on infectious complications.[463] This review included 81 RCTs (n = 11,957) of which 12 R CTs included women having planned CS (n = 2037), 23 RCTs included women having unplanned CS (n = 2132), 48 RCTs included women having either planned or unplanned CS (n = 6788). In most trials antibiotic prophylaxis was administered intravenously after clamping of the umbilical cord. Overall the use of prophylactic antibiotics with CS results in a reduction in the incidence of episodes of fever (RR 0.45, 95% CI 0.39 to 0.52), endometritis (RR 0.39, 95% CI 0.34 to 0.43), wound infection (RR 0.41, 95% CI 0.35 to 0.48), urinary tract infection (RR 0.54, 95% CI 0.46 to 0.64) and serious infection (RR 0.42, CI 0.28 to 0.65). [evidence level 1a]

Maternal side effects were not consistently collected across the RCTs. There were 3 possible episodes in the placebo group and 16 in the antibiotic group, such as phlebitis or rash at the intravenous infusion site. No serious drug reactions were reported. The effect on breast feeding and thrush in newborns being breastfed was not reported in any of the RCTs included in the systematic review.

Another systematic review[464] investigated the effectiveness of different antibiotic regimens. Fifty one RCTs were included. There is no advantage in using a multiple dose regimen compared with a single dose (OR 0.92, 95% CI 0.70 to 1.23). There was no difference in the efficacy of ampicillin compared with first generation cephalosporins (OR 1.27, 95% CI 0.84 to 1.93), nor was there any difference

between first generation compared with second or third generation cephalosporins (OR 1.21, 95% CI 0.97 to 1.51). [evidence level 1a]

Other methods to reduce infectious morbidity at CS have been investigated including RCTs on t he use of intra abdominal lavage with saline,[465] intrauterine lavage with antibiotics,[466] preoperative skin preparation[467] and vaginal preparation with povidone iodine[468] none of which showed a difference in infectious morbidity [evidence level 1b]. Pelvic irrigation with antibiotic solution[467] and the use of intravaginal metronidazole[469] did show some difference in infectious morbidity but the numbers were small. [evidence level 1b] We did not find any RCTs looking at the postoperative prophylactic use of antibiotics after CS.

Economic considerations for the use prophylactic antibiotics at CS

Where two antibiotics have the same efficacy, the less expensive antibiotic should be offered since there is no justification for the use of more expensive regimens. There is some economic evidence that a s ingle dose of antibiotic is as effective as two- and three-dose regimens[470] and since the efficacy is the same, the lower cost regimen should be offered.

An economic evaluation study undertaken in the United Kingdom in the late 1980s suggested that there might be significant savings from the use of prophylactic antibiotics.[471] This evaluation was based on a model that used post-CS wound infection rates of 8.4% and 50–70% reduction in odds of wound infection with the use of prophylactic antibiotics. Using these assumptions in an economic model, the estimated additional average cost of hospital postnatal care for women with wound infection (compared with women who had had CS and no wound infection) was £716. Introducing routine prophylaxis with antibiotics would reduce average costs of postnatal care by between £1,300 and £3,900 per 100 C S, depending on the cost of the antibiotic used and i ts effectiveness. This analysis supports the use of prophylactic antibiotics after CS since this strategy dominates a no antibiotic strategy (due to lower cost, greater effectiveness).

A cost-effectiveness analysis of the cost per post-CS infection averted has not been undertaken in a United Kingdom setting.

Timing of antibiotic administration

Introduction

Antibiotic prophylaxis at the time of a C S is proven to reduce post-operative maternal postnatal infective morbidity rates. Traditionally, antibiotics are not administered until after the umbilical cord is clamped so that the unborn baby is not unduly exposed to antibiotics administered to the mother, with potential adverse effects. This contrasts with the general timing of antibiotic administration for surgical site infection prophylaxis (see existing NICE guidance). This section examines whether administration of antibiotics before cord clamping is associated with lower maternal infective morbidity compared to administration post-clamping without imposing known additional risks to the neonate.

Review question

What is the effectiveness of antibiotics given prior to clamping of the cord compared to antibiotics given after clamping of the cord during a planned or unplanned caesarean section?

Existing NICE guidance

The Surgical site infection guideline (NICE, 2008) recommends that:

- Antibiotic prophylaxis should be given in clean-contaminated surgery (such as CS).
- Giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia should be considered or earlier for operations in which a tourniquet is used.
- Before giving antibiotic prophylaxis, the timing, pharmacokinetics (for example, the serum half-life) and nec essary infusion time of the antibiotic should be c onsidered. A repeat dose of antibiotic prophylaxis should be given when the operation is longer than the half-life of the antibiotic.
- Patients should be informed before the operation, whenever possible, if they will need antibiotic prophylaxis, and afterwards if they have been given antibiotics during their operation.

Overview of evidence

Six reports of RCTs were included in this review (Gordon et al., 1979; Sullivan, 2007; Thigpen et al., 2005; Wax et al., 1997; Nokiani, 2009; Yildirim, 2009).

Four studies were conducted in the USA (Gordon et al., 1979; Sullivan, 2007; Thigpen et al., 2005; Wax et al., 1997), one in Iran (Nokiani, 2009) and one in Turkey (Yildirim, 2009). Two of the American studies reported their participants to be high risk for subsequent infection (Sullivan, 2007; Thigpen et al., 2005). In total, 1503 women participated in these studies, with 805 receiving antibiotics prior to cord clamping and 6 98 receiving antibiotics after the cord was clamped. Two studies intentionally included women who were in labour and had unplanned CS (Thigpen et al., 2005; Wax et al., 1997), three studies included planned caesarean cases (Sullivan, 2007; Yildirim, 2009; Gordon et al., 1979) and the remaining study (Nokiani, 2009) included mostly women undergoing planned CS, although significantly more women in the post-clamping group had an intrapartum CS after the onset of labour, despite the investigators' efforts to recruit only participants undergoing planned CS.

One study examined the timing of a 1 g dose of intravenous (IV) ampicillin (Gordon et al., 1979) while the remaining studies examined the timing of cefazolin administered in a 1 g IV dose (Sullivan, 2007; Yildirim, 2009; Wax et al., 1997) or 2 g IV dose (Thigpen et al., 2005; Nokiani, 2009).

Six maternal and t hree neonatal outcomes were chosen by the GDG as being of priority to inform recommendations and the results for these are presented in Table 7.3.

Evidence profile

Table 7.3 GRADE findings comparing pre-clamp with post-clamp administration of antibiotics

Number of studies	Number of women/babies (%) or number of hours		Effect		Quality
	Pre cord-clamp antibiotics	Post cord-clamp antibiotics during CS	Relative (95% CI)	Absolute (95% CI)	
Overall/total maternal infectious morbidity					
5 studies (Gordon et al., 1979; Sullivan, 2007, Thigpen et al., 2005, Wax et al., 1997; Yildirim, 2009)	55/609 (9%)	84/607 (13.8%)	RR 0.65 (0.47 to 0.9)	48 fewer per 1000 (from 14 fewer to 73 fewer)	High
Maternal wound infection					
5 studies (Gordon et al., 1979; Sullivan, 2007, Thigpen et al., 2005, Wax et al., 1997; Yildirim, 2009)	18/609 (3%)	29/607 (4.8%)	RR 0.63 (0.35 to 1.11)	18 fewer per 1000 (from 31 fewer to 5 more)	Moderate
Surgical site opening					
1 study (Nokiani, 2009)	0/196 (0%)	1/91 (1.1%)	RR 0.16 (0.01 to 3.78)	9 fewer per 1000 (from 11 fewer to 31 more)	Low

Number of studies	Number of women/babies (%) or number of hours		Effect		Quality
	Pre cord-clamp antibiotics	Post cord-clamp antibiotics during CS	Relative (95% CI)	Absolute (95% CI)	
Total maternal fever					
1 study (Nokiani, 2009)	10/196 (5.1%)	3/91 (3.3%)	RR 1.55 (0.44 to 5.49)	18 more per 1000 (from 18 fewer to 148 more)	Low
Maternal urinary tract infection [UTI]					
3 studies (Gordon et al., 1979; Wax et al., 1997; Yildirim, 2009)	3/281 (1.1%)	6/276 (2.2%)	RR 0.55 (0.15 to 1.98)	10 fewer per 1000 (from 18 fewer to 21 more)	Moderate
Endometritis or endomyometritis					
5 studies[7] (Gordon et al., 1979; Sullivan, 2007, Thigpen et al., 2005, Wax et al., 1997; Yildirim, 2009)	24/609 (3.9%)	42/607 (6.9%)	RR 0.57 (0.35 to 0.92)	30 fewer per 1000 (from 6 fewer to 45 fewer)	High
Endometritis					
1 study (Nokiani, 2009)	0/196 (0%)	0/91 (0%)	not pooled	not pooled	Low
Maternal pneumonia or respiratory tract infection [RTI]					
2 studies (Wax et al., 1997; Yildirim 2009)	0/243 (0%)	0/236 (0%)	not pooled	not pooled	Low
Neonatal sepsis or infection					
4 studies (Sullivan, 2007, Thigpen et al., 2005, Wax et al., 1997; Yildirim, 2009)	37/588 (6.3%)	41/582 (7%)	RR 0.89 (0.58 to 1.35)	8 fewer per 1000 (from 30 fewer to 25 more)	Moderate
Neonatal sepsis					
1 study (Nokiani,2009)	4/196 (2%)	1/91 (1.1%)	RR 1.86 (0.21 to 16.38)	9 more per 1000 (from 9 fewer to	Low

Number of studies	Number of women/babies (%) or number of hours		Effect		Quality
	Pre cord-clamp antibiotics	Post cord-clamp antibiotics during CS	Relative (95% CI)	Absolute (95% CI)	
				169 more)	
Mean neonatal length of stay					
1 study (Sullivan, 2007)	6.6 ± 9.9 (n = 185)	8.5 ± 15.8 (n = 194)	NC	MD 1.9 hours shorter (4.54 shorter to 0.74 longer)	Moderate
Mean neonatal length of stay					
1 study (Nokiani, 2009)	2.99 ± 0.07 (n = 196)	2.99 ± 0.11 (n = 191)	NC	MD 0.0 hours (0.02 shorter to 0.02 longer)	Low
Mean neonatal intensive care unit [NICU] length of stay					
1 study (Sullivan, 2007)	14.2 ± 15.8 (n = 185)	19.7 ± 24.9 (n = 194)	NC	MD 5.50 shorter (9.68 shorter to 1.32 shorter)	Moderate
Mean NICU length of stay					
1 study (Yildirim, 2009)	8.25 ± 2.62 (n = 201)	5.66 ± 2.58 (n = 198)	NC	MD 2.59 longer (2.08 longer to 3.10 longer)	Moderate

CI confidence interval; MD mean difference; NC not calculable; RR risk ratio

Evidence statements

Maternal outcomes

Overall/total maternal infectious morbidity

A meta-analysis of five RCTs found that antibiotics given before cord-clamping reduces the incidence of total maternal infectious morbidity compared to antibiotics given after cord-clamping. This finding was statistically significant. The evidence for this outcome was of high quality.

Maternal wound infection

A meta-analysis of five RCTs did not find a statistically significant difference in the rate of maternal wound infection when antibiotics were given before cord-clamping when compared with occasions when the antibiotics were given after cord-clamping. The evidence for this outcome was of moderate quality.

Surgical site opening

One study (with a serious design limitation) did not find a statistically significant difference in incidence rates of surgical site opening when antibiotics were given before cord-clamping when compared with occasions when the antibiotics were given after cord-clamping, although only one observation in 281 women undergoing CS was reported. The evidence for this outcome was of low quality.

Total maternal fever

One RCT did not find a statistically significant difference in the incidence of total maternal fever according to timing of antibiotic administration. The evidence for this outcome was of low quality.

Maternal urinary tract infection

A meta-analysis of three RCTs did not find a statistically significant difference in the incidence of maternal urinary tract infection according to the timing of antibiotic administration. The evidence for this outcome was of moderate quality.

Endometritis or endomyometritis

A meta-analysis of five RCTs found that administration of antibiotics before cord-clamping reduces the incidence of endometritis or endomyometritis compared to antibiotics given after cord-clamping. This finding was statistically significant. The evidence for this outcome was of high quality. One study (with a serious design limitation) found no incidences of endometritis in 281 women undergoing CS. This finding was not statistically significant. The evidence for this outcome was of low quality.

Maternal pneumonia or respiratory tract infection (RTI)

Two RCTs examined the effects of timing of antibiotic prophylaxis on t he incidence of maternal pneumonia or RTI. No events were seen in either study (n = 479). The evidence for this outcome was of low quality.

Neonatal outcomes

Neonatal sepsis or infection

A meta-analysis of four RCTs did not find a statistically significant difference in the rate of neonatal infection or sepsis when antibiotics were given before cord-clamping compared with occasions when antibiotics were given after cord-clamping. The evidence for this outcome was of moderate quality. One study (with a serious design limitation) did not find a statistically significant difference in the rate of neonatal sepsis when antibiotics were given before cord-clamping compared with occasions when antibiotics were given after cord-clamping. The evidence for this outcome was of low quality.

Neonatal length of stay

Two RCTs did not find a statistically significant difference in the mean neonatal length of hospital stay when antibiotics were given before cord-clamping compared with occasions when antibiotics were given after cord-clamping. The evidence for this outcome was of moderate quality in the first study and low quality in the second study.

Neonatal intensive care unit (NICU) length of stay

One RCT found that administration of antibiotics after cord-clamping reduced the length of stay in a NICU compared to antibiotics administered prior to cord-clamping. This finding was statistically significant. One RCT found that administration of antibiotics before cord-clamping reduced the length of stay in a NICU compared to antibiotics administered after cord-clamping. This finding was statistically significant. The evidence for this outcome was of moderate quality.

Evidence to recommendations

Relative value placed on the outcomes considered

In developing the recommendations, it was necessary to consider the outcomes for both the woman and her baby. The GDG agreed that the most relevant outcomes to consider were measures such as sepsis which could be determined objectively. Antibiotics are given at CS to prevent maternal infection associated with surgery. Infection is reported in the literature in different ways: different types of infection may be reported in combination as an overall infection rate or different infections may be reported individually. Also, infection is reported using different definitions across studies; for example wound infection versus surgical site opening.

The GDG chose overall infectious morbidity as the most useful outcome to inform recommendations. Results were compiled into an ov erall rate where this was possible. The GDG acknowledged that different infections would contribute to this overall score in each study. The GDG also thought it was important to consider the rates of particular types of maternal infection and identified five maternal outcomes relating to these (see Evidence profile above).

The GDG considered confirmed estimates of neonatal infection to be the most informative neonatal outcome. The proxy estimate of neonatal length of stay in intensive care was also used, although it was acknowledged that this outcome is less useful as it is also affected by other factors such as hospital policy.

Trade-off between clinical benefit and harms

The GDG agreed that prevention of maternal infection was the most important outcome when considering timing of antibiotic administration but that it was important to take into consideration potential harmful effects on the neonate. The group agreed that the strongest and clearest evidence showed that there was a reduction in maternal morbidity when antibiotics were administered prior to an incision being made. Furthermore, the GDG members felt from their clinical experience that the benefits of administering antibiotics prior to incision would be even more pronounced in women with a longer incision-to-delivery time (such as obese women) as their chance of being exposed to infection is greater.

The evidence for neonates was more equivocal and the GDG did not feel able to discern an effect of the timing of antibiotics on benefits or harms for neonates. The evidence showed no difference in rates of neonatal infection between the early administration and later administration groups. In addition, the GDG recognised that while administering antibiotics prior to incision would expose the baby to the antibiotic, in breastfed babies antibiotics would be passed to the baby anyway, regardless of the timing of their administration. While two RCTs showed a reduction in neonatal intensive care length of stay for the delayed administration group, this difference was not apparent in two other trials and the GDG felt the effects of confounding variables on this outcome meant it was less valid as an indicator of neonatal wellbeing compared with overall infection rates.

Trade-off between net health benefits and resource use

Although no formal cost effectiveness modelling was carried out for this question, the GDG noted that with relatively strong evidence for a reduction in maternal infections with pre-incision administration of antibiotics, and no clear evidence either way for an effect on neonatal outcomes, it was likely that pre-incision administration of antibiotics would be cost effective compared with administration after cord clamping.

Quality of evidence

The evidence considered in this review was of mixed quality. The GDG noted a particular problem with one study which included twice as many women with an unplanned CS in one arm of the study than the other (Nokiani F.A., 2009). They felt that this was likely to impact on the results and so did not feel that it was appropriate to use the study in developing recommendations.

The GDG also noted that in one study which reported on mean length of NICU stay, the antibiotics were infused for 45 m inutes prior to incision. As this practice would only be possible with planned CSs, the GDG did not feel that these results were generalisable.

Overall, the GDG felt that the evidence which showed a clear difference in outcomes (overall maternal infectious morbidity and rates of endometritis or endomyometritis) was of a good quality.

Other considerations

All of the evidence reviewed for this section related to cefazolin (five studies) and ampicillin (one study). The GDG was aware that despite the recommendations from the original guideline, these antibiotics are not commonly used in the UK. The GDG was also aware of findings from the ORACLE studies which looked at the use of antibiotics both in women with pre-labour rupture of membranes and in women thought to be in preterm labour. These studies found an increased risk of necrotising enterocolitis in babies in both groups if they were exposed in utero to co-amoxiclav. This risk did not vary between babies born to both groups of women and nor did it vary whether birth was while still being exposed to co-amoxiclav or whether the exposure had ceased. Given this increased risk, and given the neonate's chance of exposure to the antibiotic when giving prophylaxis before skin incision or cord-clamping, the GDG agreed that the use of co-amoxiclav should be di scouraged, particularly as there are a number of acceptable alternative antibiotics available.

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline

Thromboprophylaxis for CS

Pregnancy is a risk factor for thromboembolic disease. The reported incidence of pulmonary thromboembolism is 6 per 10,000 maternities, this varies according to risk factors such as maternal age, obesity, smoking.[472] Pulmonary embolism is the leading direct cause of maternal death in the UK (estimate mortality rate of 1.45 per 100,000 maternities).[95]

Thromboembolic disease is rare and is reported as an outcome measure in only one RCT of planned CS compared with planned vaginal birth, however, within this trial there were no ev ents in either group.[48]

A population-based cohort study evaluated the risk of thromboembolism by mode of birth (n = 1,003,489) (1987–1995).[473] The risk of pulmonary embolism was increased for women who had CS compared with those who had vaginal birth (unadjusted RR 3.8 95% CI 2.0 to 4.9). [evidence level 2b] Within this cohort it is not known how many women in this study would have received thromboprophylaxis.

A systematic review of thromboprophylaxis during pregnancy and the early postnatal period was identified.[474] [evidence level 1a] The review included eight RCTs (n = 649) of which only four studies address the issue of thromboprophylaxis for CS (n = 350). The interventions evaluated in these trials include hydroxyethyl starch, heparin and placebo. Thromboembolic events are relatively rare so that although no d ifferences were detected between the intervention and control groups this is probably because the trials are too small to evaluate these outcomes. There is a l arge RCT of thromboprophylaxis after CS in progress.[475] [evidence level 1b]

Currently available publications to guide practice on this issue recommend thromboprophylaxis for CS based on assessment of risk (such as unplanned versus planned CS, maternal age o ver 35 years, weight greater than 80 k g, medical complication). Recommended thromboprophylaxis includes hydration, early mobilisation, graduated elastic compression stockings and low-molecular-weight heparin.[476] [evidence level 4] Data from the NSCSA shows that in current practice, thromboprophylaxis is used in 89% of unplanned CS and 87% of planned CS.

Recommendations

Number	Recommendation
93	Women having a CS should be offered thromboprophylaxis because they are at increased risk of venous thromboembolism. The choice of method of prophylaxis (for example, graduated stockings, hydration, early mobilisation, low molecular weight heparin) should take into account risk of thromboembolic disease and follow existing guidelines. [D] **[2004]***

* See also the NICE guideline “Venous thromboembolism - reducing the risk” (NICE CG92, 2010)

Number	Research recommendation
RR 38	What is the most effective antibiotic to prevent maternal infectious morbidity post-CS when given prior to incision
RR 39	What is the physical, psychological and social impact of maternal infectious morbidity post-CS?

Need for further surgery (including hysterectomy)

Surgery immediately following birth can include manual removal of placenta, uterine curettage, and laparotomy (with or without hysterectomy). In the UK, the reported rate of peripartum hysterectomy is 6–7 per 10,000 deliveries.[477,478] In other well resourced countries the incidence (excluding elective hysterectomy) range from 4–15 per 10,000.[479–484] These rates vary according to parity, number of previous CS and other conditions e.g. placenta praevia. In one UK survey about 2% of women required further surgery.[485]

The need for dilatation and curettage was reported in one RCT (n = 2082) that compared planned CS with planned vaginal birth. Dilatation and curettage was reduced in the planned CS group (0.3%) compared to the planned vaginal birth group (0.4% RR 0.75, 95% CI 0.17 to 3.34).[48] [evidence level 1b]. Hysterectomy was reported in two RCTs.[44,48] In one RCT there were no events in either group.[48] In the other RCT[44] (n = 208), 1.1% of women in the planned CS group and none of the women in the planned vaginal birth group were reported to have this outcome.

One Australian cohort study (n = 29,488) evaluated need f or further surgery following childbirth.[486] The return to theatre rate for women who had a CS was 0.5% compared to 0.03% of women who had vaginal birth (unadjusted RR 17.53, 95% CI 9.37 to 32.1). [evidence level 2a] The main reason for further surgery in both groups was severe obstetric haemorrhage. 80% of women who had further surgery for haemorrhage following CS required a laparotomy compared to 27% of women who required surgery after vaginal birth for severe haemorrhage. The majority (73%) of women who had a vaginal birth with severe haemorrhage requiring surgery had uterine curettage.

Two cohort studies[482,484] conducted in the USA have compared rates of hysterectomy for women according to mode of birth. The rate of peripartum hysterectomy was higher among women who had CS (0.7 to 0.8%) compared with 0.01 to 0.02% among women who had vaginal birth (unadjusted RR 95.5, 95% CI 67.7 to 136.9;[482] unadjusted RR 43.97 95% CI 22.52 to 85.85).[484] The RR adjusted for placenta praevia was reported to be 10.8 (95% CI 7.6 to 15.4).[482] [evidence level 2a] In one of these studies, 19% cases of peripartum hysterectomy were in women who were in their first pregnancy. Data on rates of peripartum hysterectomy following primary CS were not reported in either of these studies.

Maternal satisfaction during CS

A number of practices have been suggested to improve women's satisfaction with CS birth. These include seeing the baby born via a l owered screen; music playing in theatre; silence at moment of birth in theatre so the mother's voice is the first the baby hears and lowering the lights at the moment of birth. We did not identify any RCT that evaluated the effectiveness of these changes in practice. Although no papers discuss the use of music during CS one experimental study (n = 65) describes the use of medical resonant music therapy as preoperative preparation for CS compared with women who received sedatives. The experimental group receiving music therapy had lower cortisol levels and noted better sleep and less need for analgesics postoperatively.[487] [evidence level 2b]

Case reports[488] [evidence level 3] and case series[489] [evidence level 3] report positive maternal attitudes towards music during labour in terms of pain relief and satisfaction. A non systematic review of literature on the efficacy of music therapy for premature infants suggest that music is associated with reduced length of hospital stay, improved weight gain and oxygen saturation level.[490] [evidence level 3]

A number of studies relate to hearing 'mother's voice' were identified. One (n = 10 babies) experiment showed that neonates were 'more likely to work' to produce their mother's voice than other female voices[491] [evidence level 3] and another experimental study (40 neonates) found that neonates responded more to their mother's voice than other female voices even when there was no postnatal experience of the mother's voice.[492] [evidence level 3]

No other published evidence was found on other changes in practice to improve woman's satisfaction of CS birth. Personal communication from consumer groups suggest that this is an area that warrants further research due to woman's perceptions of the benefit of these practices.[493]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 40	More evaluation of interventions such as seeing baby born via a lowered screen; music playing in theatre; silence in theatre so mother's voice is the first baby hears and lowering the lights in theatre during CS are needed.

8 Care of the baby born by caesarean section

The perinatal mortality rate in England and Wales is 7.9 per 1000 total births.[79] The effect of caesarean section (CS) on baby outcome is not a simple reciprocal relationship.[494,495] Perinatal mortality rate can decline in the presence of a low and stable CS rate or remain stable while the CS rate increases.[494,496] [evidence level 4] A cohort study (n = 11,702) reported neonatal mortality. No difference was detected in neonatal mortality between vaginal birth and CS however the study is underpowered to evaluate this outcome (risk ratio [RR] 1.09, 95% confidence interval [CI] 0.14 to 8.38).[497] [evidence level 2b]

8.1 Presence of paediatrician at CS

One cohort study reported of infants delivered by CS (using regional anaesthesia) were more likely to have a 1 m inute Apgar of less than 4, (6.3%) compared with infants delivered vaginally (1.3%. RR 3.04 95% CI 1.80 to 5.13).[497] [evidence level 2b] Two descriptive studies list CS as one of the situations that require a paediatrician to be present at birth.[498,499] [evidence level 3] A series of 460 deliveries showed that there was higher incidence of neonatal resuscitation with planned CS deliveries compared to vaginal births. Similar results were found in two other studies as well.[500,501] Of the 59 “emergency” CS, 24 were for fetal distress of which 12 needed resuscitation. There is no difference in the need for resuscitation between babies with cephalic presentation born by CS (1.8%) and vaginal birth (2.7%) with no evidence of fetal distress.[502] [evidence level 3]

A large observational study from the USA (n = 3940) reported that infants born by CS with general anaesthesia are at an increased risk of having 1- and 5-minute Apgar scores of less than 7 when compared with those born by CS with regional anaesthesia (1-minute Apgar less than 7 R R 3.13, 95% CI 2.5 to 3.88. 5-minute Apgar RR 3.6, 95% CI 1.81 to 7.00) and the need for resuscitation (RR 2.02, 95% CI 1.39 to 2.9)[317] [evidence level 3].These findings are consistent with those in the NSCSA.[290]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

8.2 Neonatal encephalopathy and cerebral palsy

There are a number of causes of cerebral palsy and probably only about 10% are related to intra partum events.[503] The majority of neurological pathologies causing cerebral palsy occur as a result of multi factorial and mostly unpreventable reasons during either fetal development or the neonatal period.[504,503] It is therefore not surprising that ecological studies do not show an association between high CS rates and low cerebral palsy rates.[505] [evidence level 3] The impact of CS on cerebral palsy was assessed in a systematic review. The review identified 10 studies none of which found a difference in the rates of cerebral palsy, abnormal neurological development between children born by

CS or vaginal birth. The studies were in groups at "high risk" of these outcomes (such as preterm birth, breech).[505] [evidence level 3]

Another cohort study considers the effect of CS on severe neurological morbidity including cerebral palsy.[100] There was an increased risk of severe neurological morbidity in those delivered by CS (unadjusted RR 1.81, 95% CI 1.56 to 2.11). [evidence level 2b] A case–control study compared 164 babies with neonatal encephalopathy compared with 400 babies that did not have neonatal encephalopathy (controls). Babies that had neonatal encephalopathy were more likely to have had instrumental vaginal delivery (OR 2.34, 95% CI 1.16 to 4.70), "emergency" CS (OR 2.17, 95% CI 1.01 to 4.64) and less likely to have had "elective" CS (OR 0.17, 95% CI 0.05 to 0.56).[506] [evidence level 3]

Recommendations

Number	Research recommendation
RR 41	Further evaluation of the long and short term risks and benefits of CS compared with vaginal birth for babies is required.

8.3 Birth injuries

The benefits of CS for specific groups such as term breech, or preterm birth are discussed in Chapter 5. The evidence on the comparative risk of birth injuries in term singleton cephalic infants is limited to one large audit of birth records looking at mode of birth and intracranial injury[507] and one case–control study looking at brachial plexus injuries.[508]

In the audit,[583,340] live born singleton infants born to nulliparous women, weighing between 2500 g and 4000 g over a two year period were studied. Breech presentations were excluded. Neonates were grouped according to mode of birth. The incidence of intracranial haemorrhages was 0.01% in the 'CS during labour' group compared to 0.05% in the 'spontaneous' vaginal birth group (OR 2.1, 95% CI 1.6 to 2.7). It was 0.04% in the 'CS before labour' group (OR 0.7, 95% CI 0.4 to 1.3).[507] [evidence level 3]

The case–control study compared all modes of birth including assisted vaginal deliveries[508] for risk of brachial plexus injury in 106 cases of Erb's palsy and 382 controls. No difference between CS and vaginal birth could be found for brachial plexus injuries once controlled for birth weight and presentation (OR 0.5, 95% CI 0.1 to 1.9). [evidence level 3]

8.4 Thermal care for babies born by CS

Descriptive studies report that babies born by CS have lower body temperatures[509,510] [evidence level 3]. Standard care includes a warm environment for the newborn. We did not identify any studies that address the specific requirements for thermal care for babies born by CS. One RCT showed that fathers can effectively achieve heat conservation in healthy newborn infants.[511] [evidence level 1b] Skin-to-skin contact for women and their newborn babies is addressed in Section 8.5.

Recommendations

Number	Recommendation
96	Babies born by CS are more likely to have a lower temperature, and thermal care should be in accordance with good practice for thermal care of the newborn baby. [GPP] **[2004]**

Number	Research recommendation
RR 42	Research is required to establish the thermal care requirements for babies born by CS.

8.5 Maternal contact (skin-to-skin)

A systematic review was identified that looked at early skin-to-skin contact for women and t heir healthy babies.[512] Sixteen RCTs and on e quasi-randomised trial were included (n = 806). Two of these RCTs included women having CS. The methodological quality of 12 of the included RCTs was poor. Overall, early skin-to-skin contact was associated with higher rates and longer duration of breastfeeding (OR 2.15, 95% CI 1.10 to 4.22. WMD 41.99, 95% CI 13.97 to 70.0) reduced infant crying (OR 21.89, 95% CI 5.2 to 92.3) and higher score summary score of maternal affection. There were no apparent negative effects. One RCT included only women having CS and used three different instruments to evaluate the impact of early contact (within 12 hours of birth) on maternal perceptions of their infant, mothering skills and maternal behaviour. They found significant differences between the groups that had early versus late or limited (after 12 hours) contact and found early skin-to-skin contact to be of benefit. However, these differences were less marked one month after birth.[513] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

8.6 Breastfeeding

At least 70% of women express a pr eference for a birth that would give them the best start to breastfeeding.[4] The RCTs that compare planned vaginal birth with planned CS include only women with small, preterm or term breech babies. Three RCTs[40,42,514] measure uptake of breastfeeding either as rates of breastfeeding at discharge from hospital or as “any attempt at breastfeeding”.[40,42,514] Overall, no difference was detected between the two groups (Pooled RR 0.94, 95% CI 0.89 to 1.00). [evidence level 1a].

One RCT[514] also surveyed women at three months to ask if breastfeeding had been initiated at any time and if they were currently breastfeeding. At three months no difference in breastfeeding rates was detected between the groups. (Planned CS group 68%, planned vaginal birth group 70% RR 0.98, 95% CI 0.92 to 1.05). [evidence level 1b]

In the non intention to treat analysis, 73–77% of women who had a vaginal birth and 65–67% of those who had CS, had breastfed at three months after birth.[514]

Six relevant population studies were identified.[515–520] These included diverse populations from several countries including one from the UK.[515] In this latter study (n = 202), breastfeeding rates were 76% among those who delivered vaginally and 39% among those who had a CS. [evidence level 2a] Rates of breastfeeding vary markedly between countries from around 30% in Hong Kong[518] to more than 90% in Scandinavia.[519,520] [evidence level 2a] In all studies rates of initiation of breastfeeding were higher in women who had had a vaginal birth compared to those having a CS. Two of the studies[517,519] followed women up f or 3 m onths, and o ne[519] followed women up f or 6 m onths. There

was no difference in breastfeeding rates according to mode of birth at either 3 or 6 months. [evidence level 2a]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

9 Care of the woman after caesarean section

Common complications and the estimated frequency with which they occur are shown in Table 4.5.

High dependency unit/intensive therapy unit admission

Maternal mortality is rare. In the UK it is 11.4/100,000 maternities,[95] [evidence level 3] the direct maternal mortality rate from all causes is 1/20,000 maternities. The mortality rate for women who have vaginal deliveries is 16.9/million compared to 82.3 per million for women who have caesarean section (CS) (risk ratio [RR] 4.9, 95% confidence interval [CI] 2.96 to 7.97).[95] However it was not possible to determine the proportion of the increased risk that is attributable to antecedent conditions or the procedure itself. The incidence of severe morbidity for women giving birth has been reported to be 12 per 1000 deliveries.[292] A small proportion of women (0.1–0.9%) develop complications of pregnancy that require admission to an Intensive Therapy Unit (ITU)[521]. High dependency unit (HDU)/ITU admission was not reported as an outcome in any of the randomised controlled trials (RCTs).

In the NSCSA, 10% of women who had CS required special care postoperatively within a high dependency unit, 3.5% of these women were transferred to an intensive care unit.[4] [evidence level 3]

Table 9.1 shows the proportion of women who had CS and required admission to an intensive care unit according to the reason for the CS.

We identified one case control study that examined risk factors associated with intensive care unit admission during hospital stay for childbirth among women in USA between 1984 and 1997 (n = 2046).[522] The overall rate of admission to an intensive care unit (ICU) was 0.13%. The odds of admission to ICU was significantly higher for women who had CS compared with those who had vaginal birth, after adjustment for socio demographic factors (age and ethnicity) and type of hospital (OR 9.0, 95% CI 7.24 to 11.16). [evidence level 3] However it is not possible to disentangle the effect of CS from the reasons for CS when interpreting these results. A UK study that evaluated the risk of severe obstetric morbidity has not been included here because the comparison groups are between women who had unplanned CS to women who had either planned CS or vaginal births.[292] [evidence level 3]

Table 9.1 Admission to intensive care unit (ICU) according to reason for CS (n = 29,349)

Reason for CS	Admission to ICU (%)	OR (95% CI)
Breech	0.2	1.00
Placenta praevia, actively bleeding	2.5	16.6 (5.3 to 52.2)
Placenta praevia, not actively bleeding	1.1	7.0 (2.2 to 22.1)
Placental abruption	1.1	7.2 (1.7 to 30.4)
Pre-eclampsia/eclampsia/HELLP	1.9	12.4 (4.3 to 35.5)
Maternal medical disease	2.7	17.8 (6.4 to 49.2)
Uterine rupture	6.4	43.3 (9.9 to 189.5)

Recommendations

Number	Recommendation
99	Healthcare professionals caring for women after CS should be aware that, although it is rare for women to need intensive care following childbirth, this occurs more frequently after CS (about 9 per 1000). [B] **[2004]**

9.1 Routine monitoring after CS

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

9.2 Pain management after CS

In the UK, intrathecal analgesia, patient controlled analgesia, local anaesthetic wound infiltration and nonsteroidal anti-inflammatory agents are commonly used for analgesia post-CS.

Intrathecal analgesia

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Non-steroidal anti-inflammatory analgesia

Non-steroidal anti-inflammatory drugs (NSAIDs) are used together with other modalities of pain relief after CS mainly to reduce the need for morphine based analgesics. We considered evidence on NSAID preparations available in the UK.

Two RCTs looked at the analgesic sparing effect of rectal NSAIDs suppository (diclofenac) administered immediately post-CS. In one RCT (n = 50) there was no difference in the VAS scores but the time to request for first analgesia was prolonged with rectal NSAID from 13 hours 45 minutes in the placebo group to 18 hours 58 minutes in the study group ($p < 0.03$).[542] [evidence level 1b] The other RCT (n = 45) used the amount of PCEA as an outcome measure as well as VAS scores of pain. Women who received the rectal NSAID used less PCEA local anaesthetic solution (52.8 ml) compared to the control group (74 ml). There was no difference in VAS pain scores.[543] [evidence level 1b]

Another RCT (n = 50) administered the NSAID (75 mg diclofenac) intramuscularly to women who were using morphine based PCA post-CS. The women who had the NSAID consumed less morphine via the PCA than the control group (mean at 18 h ours post-CS was 61.4 mg compared with 91.4 mg).[544] [evidence level 1b]

Complications following regional anaesthesia

In England and Wales 77% of unplanned and 91% of planned CS are performed with regional anaesthetic (spinal or epidural).[4] [evidence level 3] Information on anaesthetic complications in the UK is not routinely collected other than serious complications resulting in mortality.[95] A prospective multi disciplinary audit in the UK reported that epidural analgesia contributes to a neurological complication in 1/13,007 women.[545] [evidence level 3] The National Obstetric Anaesthetic Database reported incidence of headache ranged from 1.1% to 1.9% between all anaesthetic techniques and increased to 11% for women receiving multiple regional anaesthetics.[546] [evidence level 3] Unpublished data from a U K audit of 517,455 deliveries including 135,546 epidurals for analgesia and anaesthesia described complications rates associated with regional anaesthesia. 1/5000 (0.02%) epidural catheters are sited in the epidural vein; 1/3000 (0.034%) are sited in the intrathecal space; total spinal block occurs in 1/20,000 (0.005%) epidurals and 1/4000 (0.025%) subdural bleeds occur.[547] [evidence level 3]

An audit of epidural related complications from Australia reports rates of complications for regional anaesthesia as follows: need for re insertion of epidural catheter 4.7%; hypotension after epidural for CS 28%; inadequate block 1.7%; conversion to general anaesthetic 0.5%. Serious complications are relatively rare: unexpected high block 0.07%; high block requiring intubation 0.02% respiratory

depression 0.06% and local anaesthetic toxicity 0.04%.[548] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

Number	Research recommendation
RR 43	Further research is needed to determine the effect of wound infiltration with local anaesthetic at CS on the need for post-CS analgesia.

9.3 Early eating and drinking after CS

A systematic review compared early with delayed oral fluids and food after CS and included 6 RCTs. Three RCTs were limited to CS with regional anaesthesia; the other 3 RCTs included both regional and general anaesthesia. The intervention groups varied (either allowing immediate access to fluids and food within 6–8 hours if the woman was hungry or thirsty). The comparison groups delayed oral intake for a m inimum of 12 ho urs to 24 hours, or to the presence of bowel sounds and graduated intake. Early eating and drinking was associated with reduced time to return of bowel sounds (1 RCT, n = 118; weighted mean difference of –4.3 hours, 95% CI –6.78 hours to –1.82 hours) and reduced postoperative hospital stay (2 RCTs, n = 220). There was no difference between the intervention and control groups with respect to nausea, vomiting, abdominal distension, time to bowel action, paralytic ileus and number of analgesic doses.[549] [evidence level 1a]

Recommendations

Number	Recommendation
107	Women who are recovering well after CS and who do not have complications can eat and drink when they feel hungry or thirsty. [A] **[2004]**

9.4 Urinary catheter removal after CS

Urinary bladder catheters are commonly used during CS to prevent damage to the bladder during surgery. The effect of urinary bladder catheterisation at CS on has been described in a prospective survey (n = 8402) as a risk factor for postpartum urinary retention.[550] [evidence level 3] Evidence to determine timing of removal of the urinary catheter and the value of routine indwelling catheterisation is currently under review.[551] We identified two RCTs on t his topic. One RCT compared immediate catheter removal to removal of an i ndwelling catheter the next day in women who had a C S under general anaesthetic (n = 107). They report no d ifference in incidence of urinary tract infection (RR 1.64, 95% CI 0.80 to 3.34) but more instances of urinary retention with intermittent catheterisation

(39% vs. 0%).[552] [evidence level 1b] A small RCT compared urinary retention after CS with a general anaesthetic to urinary retention after CS with an epidural anaesthetic and found no difference.[553] [evidence level 1b]

Another RCT (n = 78) compared removal of the urinary bladder catheter immediately post-operatively with removal the next day in women undergoing gynaecological (pelvic) surgery, 29 who had C S. They found no difference in the incidence of urinary tract infection, urinary retention or fever but the method of randomisation is unclear and data given in the paper is incomplete.[554] [evidence level]

Recommendations

Number	Recommendation
108	Removal of the urinary bladder catheter should be carried out once a woman is mobile after a regional anaesthetic and not sooner than 12 hours after the last epidural 'top up' dose. [D] **[2004]**

9.5 Respiratory physiotherapy after CS

One RCT (n = 120) has evaluated the effect of respiratory physiotherapy after CS under general anaesthesia. The RCT did not detect a difference between the intervention group who had post-CS respiratory physiotherapy and the control group for coughing, phlegm, body temperature, chest palpation and auscultation.[555] [evidence level 1b]

Recommendations

Number	Recommendation
109	Routine respiratory physiotherapy does not need to be offered to women after a CS under general anaesthesia, because it does not improve respiratory outcomes such as coughing, phlegm, body temperature, chest palpation and auscultatory changes. [A] **[2004]**

Number	Research recommendation
RR 44	Research is needed to establish the effect of non-respiratory physiotherapy for women following CS on post-CS recovery.

9.6 Debriefing for women after CS

A longitudinal study, based in Australia suggests that a high level of obstetric intervention during childbirth, such as unplanned CS is associated with the development of acute traumatic symptoms in women postnatally.[556] [evidence level 3] Midwife led debriefing has been proposed to be of value in reducing the incidence of depression and anxiety after birth. A systematic review (11 RCTs) evaluating the effect of psychological debriefing on the prevention of post traumatic stress disorder (PTSD) in the general population reported that single session individual debriefing did not affect the incidence of PTSD at 3 to 5 months (6 RCT, n = 387, OR 1.22, 95% CI 0.60 to 2.46) and increased the likelihood of long term PTSD (after one year 2 RCTs, n = 238, OR 2.04, 95% CI 0.92 to 4.53).[557] [evidence level 1a] Only two of the included studies were in an obstetric setting.[558,559] Of these two trials, one was UK based (n = 129) and included primigravid women who had a normal vaginal birth.

Women who received midwife debriefing were less likely to have high anxiety and depression scores after birth than women who did not (anxiety score OR 13.5, 95% CI 0.41 to 56.9; depression OR 8.5, 95% CI 2.8 to 30.9).[559] [evidence level 1b] The second RCT was from Australia (n = 1041) looked at the effect of midwife-led debriefing on maternal depression after operative childbirth. No difference was detected in depression scores (OR 1.24, 95% CI 0.87 to 1.77) or in the proportion of women who reported that depression had been a pr oblem at six months after the birth (OR1.37, 95% CI 1.00, 1.86)[558] [evidence level 1b]

Subsequently a f urther two RCTs have been published. One RCT (n = 103) tested opportunity to debrief at an initial postnatal interview (less than 72 hours postpartum) and 4–6 weeks postpartum to usual care. The RCT reported a high baseline prevalence of post-traumatic stress disorder (9.6% of women at 4 to 6 weeks postpartum). No difference was detected in the prevalence of symptom profile for PTSD immediately following debriefing or at 3 m onths. (RR 1.06, 95% CI 0.61 to 1.84). This is RCT is underpowered to detect a 2% difference in prevalence of symptoms of post-traumatic stress disorder.[560] [evidence level 1b] A recently published RCT (n = 1745) compared a midwife debriefing session within 72 hours of birth to usual care. No differences were detected between the groups for either stress disorders or depression (assessed EPDS and report of depressive illness).[561] [evidence level 1b]

Recommendations

Number	Recommendation
	The recommendation for this review has been amended and updated following a new (2011) review. The new recommendation can be found in section 11.2

Number	Research recommendation
RR 45	More RCT evidence is required to determine the effect of midwifery-led debriefing following CS.

9.7 Length of hospital stay and readmission to hospital

Length of hospital stay after childbirth is declining; recent routine national statistics for England[562] suggest that women who have a spontaneous vaginal delivery spend on average 1 day in hospital, women who have an instrumental delivery spend 1 or 2 days in hospital and women who have a CS spend 3 or 4 days in hospital.

In one RCT[48] that compared planned CS with planned vaginal birth, the median length of hospital stay for women in the planned CS group was 4 days (5th centile 1.7 days, 95th centile 7.4 days). For women in the planned vaginal birth group it was 2.8 days (0.8, 6.9 days). The median length of stay reported in this RCT[48] is compatible with routine maternity statistics for the U.K. In 3 RCTs[38,39,42] the length of hospital stay was reported as either greater or less than 10 days. On pooling these results, the relative risk of length of hospital stay greater than 10 days for women in the planned CS group was 1.27 (95% CI 0.35 to 4.65). [evidence level 1a]

Readmission to hospital

Infection and bleeding constitute the main reasons for readmission to hospital following birth.[563] Two surveys of women in the postpartum period have estimated about 3% are readmitted to hospital for reasons related to their own health.[563,564]

Readmission to hospital was not included as an outcome measure in the RCTs of planned CS versus planned vaginal birth.

One prospective cohort study in Australia[564] examined rates of readmission to hospital within 8 weeks of birth. A higher proportion of women who had CS (5.3%) reported readmission to hospital compared to women who had vaginal birth (2.2%) (OR 2.46, 95% CI 1.11 to 5.43). [evidence level 2b] Similar findings were reported in a retrospective cohort study conducted in Washington USA[565] (n = 256,795). The age adj usted relative risk for rehospitalisation among women who had CS compared to those who had vaginal birth was increased (RR 1.8, 95% CI 1.6 to 1.9). [evidence level 2b]

Discharge from hospital after CS usually occurs on day 3.[562] [evidence level 3] A systematic review of early post natal discharge from hospital included eight RCTs but only two RCTs included women who had caesarean births, one of which is ongoing.[566] [evidence level 1a] The RCT (n = 61) randomised women having CS to either early hospital discharge and home follow up or usual hospital discharge (requires the woman to be ambulatory, voiding, tolerating a normal diet, passing flatus, normal uterine involution, afebrile for 24 hours, uncomplicated wound healing, removal of skin sutures or stapes and an adequate blood count). Women in the intervention group were discharged when they met the same criteria other than afebrile for 24 hours and staple or suture removal. They report no difference in maternal or infant rehospitalisations, maternal affect or overall maternal functional status. Women in the early discharge group were more satisfied with care and had a 29% reduction in health care requests.[567] [evidence level 1b]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

10 Recovery following caesarean section

Postnatal advice for women who have had a caesarean section (CS) includes general and specific advice. Specific advice includes advice on CS wound care, analgesia at home, when to resume normal activities such as driving, exercise and sexual intercourse and the provision of detailed information on possible risks associated with CS birth and possible complications. Information on the risk and benefits of CS should have been discussed prior to CS however they should be reiterated again. It is outside the scope of this guideline to consider general post natal advice. General advice has been developed and published as part of randomised controlled trial (RCT) (IMPaCT study).[568] [evidence level 3]

Pain

Antenatally about 60% women express a preference for a birth that is as pain free as possible and for a quick recovery.[4] Assessment of pain during the immediate postoperative period is not reported in any of the RCTs .One RCT (n = 1596) report on abdominal, perineal and back pain at three months after birth.[514] [evidence level 1b] Four cohort studies involving a total of 4749 women in Australia,[564,569] USA[570] and Scotland[563] reported on pain between 2 weeks to 18 months after birth.

Three months after delivery women who had planned CS were more likely to report pain in the abdomen (RR 1.76, 95% CI 1.24 to 2.50), and pain deep inside the abdomen (risk ratio [RR] 1.89, 95% confidence interval [CI] 1.29 to 2.79) than women who had planned vaginal birth at three months after birth. Not surprisingly perineal pain is reduced in women who have planned CS (RR 0.32, 95% CI 0.18 to 0.58).[514] [evidence level 1b] At three months after birth there is also no difference in reports of back pain (RR 0.93, 95% CI 0.71 to 1.22).[514] [evidence level 1b] Back pain is common, 22% to 50% of women surveyed report having back pain at either 8, 16 or 24 weeks after birth. Mode of birth has not been found to affect rates of back pain.[563,564,569] [evidence level 2b]

In cohort studies 60% of women who had a CS (either planned CS or CS in labour), reported having wound pain at 24 weeks after birth,[563,564] [evidence level 2b]

There is little direct evidence to guide prescribing practice of analgesia after discharge from hospital for women who have had a CS with no c omplications. Current guidelines on p ost-CS wound care suggest that for mild post-CS pain paracetamol (1000 mg four times daily) should be prescribed, for moderate pain co-codamol (1 to 2 tablets four times daily) and for severe pain co-codamol with added ibuprofen (500 mg twice daily).[568] [evidence level 3]

Wound care

General CS wound care advice for women includes encouraging women to take prescribed analgesia, to complete antibiotics if prescribed, to wear loose comfortable clothes and cotton underwear, to bath or shower daily, to gently clean and dry the wound well (flannels or washcloths should be f reshly laundered) and only apply dressings if advised by the doctor or midwife.[568] [evidence level 3]

Infection

Evidence from cohort studies report an increased risk of postpartum endometritis among women who had CS compared to those who had spontaneous vaginal birth (RR 4.51, 95% CI 4.00 to 5.09).[462] [evidence level 2b] For this reason prophylactic antibiotics are prescribed during CS.[463] [evidence level 1a] Overall the impact of CS on risk of infection when antibiotics are used is less clear. No difference was detected in rates of infection between women randomised to have planned CS (6.4%) and planned vaginal birth (4.9%) (RR 1.29, 95% CI 0.97 to 1.72).[48] [evidence level 1a]

Midwives and doctors involved in post natal care of women who have had a CS should retain a high index of suspicion for wound infection, urinary tract infection and endometritis; they should ask the woman about wellbeing and in particular any signs of fever; assess the wound for signs of infection, separation or dehiscence; discuss pain relief requirements and plan to remove sutures or clips when appropriate.[568] [evidence level 3]

Urinary symptoms

Urinary symptoms in women who have had a CS are commonly due to urinary tract infection, but can be due to stress incontinence or rarely due to urinary tract injury.

Pregnancy and childbirth are established risk factors for urinary incontinence. Urinary incontinence is the involuntary loss of urine that becomes a social or hygienic problem.[571] [evidence level 4] Women who have had a C S may have urinary incontinence but the risk of incontinence following CS is reduced compared to women who have had a vaginal birth. (3 months following birth planned CS 4.5%, planned vaginal birth 7.3% (RR, 95% CI 0.62 0.41 to 0.93).[514] [evidence level 1b] Five cohorts also report an increased risk of urinary incontinence among women who have vaginal deliveries compared to those who have CS.[572–576] [evidence level 2b]. One cohort (n = 149) did not detect any difference in urinary incontinence at 9 weeks by mode of birth.[577] [evidence level 2b] Risk of incontinence increases following pregnancy (10% in the nulliparous women, 16% after CS and 21% after vaginal birth)[574] [evidence level 2b]

The estimated incidence of bladder injury in women delivered by CS is 0.1% and 0.003% in women delivered vaginally (RR 36.59, 95% CI 10.43 to 128.38). Ureteric injury occurred in 0.03% of women who had CS and in 0.001% women who had vaginal birth (RR 25.22, 95% CI 2.63 to 243.50).[578] [evidence level 3] In other studies the frequency is reported to range between 16 per million to 1%.[579,578,580,581] Risk factors include repeat CS and peripartum hysterectomy.[580,582,583] [evidence level 3] Two RCTs include bladder/bowel/ureteric injury as an outcome measure.[44,48] There were no events in either group in one RCT,[48] while in the other 1 of the 93 women in the planned CS group, and none of the 115 women in the planned vaginal birth group suffered this morbidity measure.[44] [evidence level 1b]

Faecal incontinence

Faecal or anal incontinence has been defined as the involuntary leakage of solid or liquid faeces or gas.[584] One RCT (n = 1596) asked women about symptoms of incontinence of faeces and flatus three months following birth. No difference was detected between the groups. (Incontinence of faeces 0.8% planned CS 1.5% planned vaginal birth group RR 0.54, 95% CI 0.18 to 1.62. Incontinence of flatus 10.7% planned CS, 9.7% planned vaginal birth RR 1.10, 95% CI 0.79 to 1.54).[514] [evidence level 1b] Non-intention-to-treat analysis was also not different.

Four cohort studies evaluated faecal or anal incontinence according to mode of birth. In two of these studies[584,585] no difference was detected in the prevalence of faecal incontinence among women who had CS and those who had vaginal birth. In the other two studies[586,587] none of the women who had CS were reported to have faecal incontinence. The prevalence of faecal incontinence among women who had vaginal deliveries in these studies ranged from 1% to 23%.

Resuming activities

In one cohort study (n = 971) the extent to which bodily pain interfered with usual activities was measured 8 w eeks after birth. Women who had C S were more likely to have bodily pain which interfered with usual activity.[570] [evidence level 2b] At six months pain limited physical activity among women who had either CS or assisted vaginal birth when compared with women who had spontaneous vaginal birth after birth. [evidence level 2b]

The Association of Chartered Physiotherapists in Women's Health (ACPWH) suggests that women who have had a C S should wait 8 t o 10 weeks before commencing vigorous exercise. We did not identify any other guidance on exercise after a CS.[588] [evidence level 4]

The Driver and Vehicle Licensing Agency (DVLA) in their guide for medical practitioners as to current medical standards of fitness to drive do not specifically provide guidance on driving after CS. They provide a g eneral statement on dr iving after any surgery that suggests that drivers wishing to drive

after surgery 'should establish with their own doctors when it is safe to do so'. They add that decisions regarding return to driving should consider recovery from the surgical procedure itself, recovery from the anaesthesia, distracting effect from the pain of the surgery and any resultant physical restrictions. [evidence level 4]

Sexual intercourse

A study of women in their first pregnancy reported the pre-pregnancy prevalence of sexual problems to be 38%. Sexual morbidity increased in the first three months after birth to 83%, declining to 64% at 6 months after birth.[589] [evidence level 2b]

Sexual function after birth has been as sessed in one RCT[514] and 4 c ohort studies. The measures used to assess this included resumption of sexual activity after birth[514,590] and dyspareunia following birth.[514,589,591] One RCT evaluated sexual function at 3 m onths after birth and did not detect any difference between the two groups in the proportion of women who reported (i) not having sex since the birth (RR 1.12, 95% CI 0.89 to 1.42) or (ii) having pain during sex on the most recent occasion (RR 1.03, 95% CI 0.91 to 1.16).[514] [evidence level 1b]

One cohort study (n = 971) included women in their first pregnancy. No difference was detected between women who had CS and those who had vaginal birth (assisted or unassisted).[570] [evidence level 2b] A smaller study from the USA (n = 66) did not detect any difference in dyspareunia at 2–8 weeks postpartum between women who had CS and those who had vaginal birth.[591] [evidence level 2b] The third study reported that one month after birth women who had CS were more likely to have resumed intercourse than women who delivered vaginally.[590] [evidence level 2b] The fourth study reported that dyspareunia was associated with vaginal deliveries and previous experience of dyspareunia in the first 3 months after birth. At six months there was no difference detected in rates of dyspareunia according to mode of birth[589] [evidence level 2b]

Breastfeeding

Rates of initiation of breastfeeding are higher among women who had vaginal birth compared with those who had CS. However, by three to six months after birth there is no difference in breast feeding rates between the two groups.[514] [evidence level 1b]

Postnatal depression

The incidence of postnatal depression is estimated to be 13%.[592,593] Self report measures tend to yield higher estimates of postpartum depression than interview-based methods.[593] [evidence level 2b] Depression following childbirth has been assessed by various scales including the Edinburgh Postnatal Depression Scale (EPDS),[592] the Profile of Mood States (POMS),[594] the Beck Depression Inventory, the Zung Depression Scale and the Center for Epidemiological studies Depression scale.[593]

One RCT measured postnatal depression, at 6 weeks[48] (n = 2086) and 3 months[514] (n = 1596). Early postpartum depression occurred in 0.3% of women in the CS group and none in the planned vaginal birth group. It is therefore not possible to estimate a relative risk measure for this outcome. At 3 months no di fference was detected in postnatal depression as defined by the Edinburgh Postnatal Depression scale (EPDS) between the groups (RR 0.93, 95% CI 0.70 to 1.24). [evidence level 1b]

Six observational studies have evaluated post natal depression and mode of birth. These studies were conducted in Scotland,[563] Australia,[592,594,595] USA[596] and Finland.[597] A variety of methods have been used to assess postnatal depression and the length of follow up varies between 2 weeks to 18 months. Two studies[563,594] report a higher prevalence of postnatal depression among women who had a CS in the first two weeks after birth compared to those who had a vaginal birth. However, after 8 weeks postpartum, no difference was detected in the prevalence of postnatal depression between the two groups. [evidence level 2b]

Post-traumatic stress disorder

None of the RCTs on p lanned mode of birth have evaluated the impact of this on post-traumatic stress disorder. Two cohort studies from Sweden examined the prevalence of post-traumatic stress disorder between 1 month and 2 years postpartum. No difference was detected in the prevalence of post-traumatic stress disorder between women who had CS and vaginal birth. Compared with women

who had vaginal birth, a higher proportion of women who had “emergency” CS (OR 6.3, 95% CI 2.0 to 20.2) and those who had assisted vaginal birth (OR 4.8, 95% CI 1.5 to 15.2) had post-traumatic stress disorder at 1–2 years after birth.[598,599] [evidence level 2b]

Maternal satisfaction

One RCT asked women at three months after birth about their likes and dislikes regarding the childbirth experience.[514] More women in the planned CS group indicated that they liked being able to schedule their birth (RR 1.99, 95% CI 1.66 to 2.40), liked that the childbirth experience was not very painful (RR 1.18, 95% CI 1.05 to 1.31) and felt reassured about their infant’s health (RR 1.13, 95% CI 1.06 to 1.20). However, fewer women in the planned CS group indicated that they ‘liked that birth was natural’ (RR 0.17, 95% CI 0.14 to 0.22), ‘liked actively participating in the birth’ (RR 0.37, 95% CI 0.31 to 0.44) and ‘liked that recovering from the childbirth experience was not difficult’ (RR 0.84, 95% CI 0.77 to 0.92). A similar proportion of women in both groups indicated that they ‘liked the method of birth that they had ha d’ or ‘felt reassured about their own health’. The proportion of women that reported that ‘there was nothing they liked about their childbirth experience’ was also similar in both groups. No difference was detected between the two groups with regards to either ‘ease in caring for their new infant’ or ‘adjusting to being a new mother’. Similar trends were seen for these outcomes in the non intention to treat analysis. [evidence level 1b]

One cross sectional study[600] surveyed women within a week of birth in Dublin, Ireland. The CS rate in this study was 10%. 91% of women who had vaginal birth compared with 33% of those who had CS reported that they would like a similar mode of birth for future pregnancies. [evidence level 3]

Prolapse

The prevalence of genital prolapse around the menopause has been estimated at 5%. In a c ase control study (n = 21,449) women attending menopause clinics were examined for uterine prolapse. Previous CS was associated with a 40% reduction in the risk of developing uterine prolapse (OR 0.6, 95% CI 0.5 to 0.8).[601] [evidence level 3] Another case control in the USA found that women who underwent surgery for uterovaginal prolapse were less likely to have had a CS.[602] [evidence level 3]

Recommendations

This section was updated and replaced in 2020. Please see the NICE website for the updated guideline.

[*] For more recent recommendations on wound care see ‘Surgical site infection’ (NICE clinical guideline 74).

11 Pregnancy and childbirth after caesarean section

11.1 Implications of caesarean section for future pregnancies

Infertility

Infertility is defined as failure to conceive within 1–2 years of unprotected sexual intercourse. Most studies however have measured birth interval, reflecting future live birth rates and not rates of conception. These studies may not have been able to adjust for confounding factors such as use of contraception.

We found one systematic review[603] which included 8 cohort studies in Northern Europe and USA and one further cohort study[164] conducted in England which had addressed this question. Follow-up period in most studies ranged between 3.5 to 6 years, however one study had a follow up period between 1–19 years. Register information or interviews examined outcomes of at least one pregnancy, at least one live birth, all pregnancies, all live births, and fecundity. Almost all studies report that fewer women having a caesarean section (CS) will subsequently have children/or will have less children, due to a combination of a lessened desire for, or an incapability of having children. There is a 46% increase in the risk of having no more children five years after primary CS (risk ratio [RR] 1.46, 95% confidence interval [CI] 1.07 to 1.99).[164] [evidence level 2b]

Sterilisation rates were higher after a C S in 3 s tudies. The increased risk ranged between 6% and 23%.[604] [evidence level 2b]

Placenta praevia

We identified three recent cohort studies and an earlier systematic review. The incidence of placenta praevia in these studies ranges from 0.2%[605] to 0.5%[606,607] for women with a previous vaginal birth and 0.4%[605] to 0.8%[607] for women with a previous CS. These studies report a 30% to 60% increase in risk of placenta praevia in subsequent pregnancies for women who had had a previous CS compared to those who had had vaginal deliveries. Three case series[608–610] have reported on the incidence of placenta praevia and placenta accreta in women who have had previous CS. Overall the incidence of placenta accreta is estimated to be 1 in 2500 pregnancies, however, there is no comparative data for the incidence in women who have not had previous CS.

The incidence of placenta praevia ranges from 0.2% to 0.5% for women with a previous vaginal birth and 0.4% to 0.8% for women with a previous CS. [evidence level 2b].

Stillbirth

A large retrospective cohort study in Scotland (n = 120,633) investigated the association between previous CS and risk of stillbirth in subsequent pregnancies. The risk of antepartum stillbirth among women who had no previous CS was 2 per 1000 compared to 4 per 1000 among women who had a previous CS (hazard ratio 1.64, 95% CI 1.17 to 2.30). The risk of unexplained stillbirth associated with previous CS differed with gestational age, the excess risk was apparent from 34 weeks (hazard ratio 2.23, 95% CI 1.48 to 3.36).[611] [evidence level 2b]

11.2 Pregnancy and childbirth after CS

Introduction

A recent study of 146 NHS trusts in England (Bragg et al., 2010) found that one in four women had a CS. The rise in primary CS rates has led to an increased proportion of women of reproductive age with a scarred uterus. Thus, the issue of the most appropriate mode of delivery following a CS continues to be the subject of research and debate.

This section presents the best available evidence to facilitate antenatal counselling and decision making when planning the mode of birth following one or more previous CSs.

Review question

What are the risks and benefits of planned caesarean section compared with planned vaginal birth for both women and babies in women who have had a previous caesarean section?

Overview of evidence

Four studies were included in this review (Guise et al., 2010; Cahill et al., 2010; Tahseen & Griffiths, 2010; Law et al., 2010).

Of the four studies, one is a systematic review (Guise et al., 2010), one was conducted in the USA (Cahill et al., 2010), one in the UK (Tahseen & Griffiths, 2010) and one in Hong Kong (Law et al., 2010). One study is a large, rigorous systematic review of observational studies (Guise et al., 2010). One study (Tahseen & Griffiths, 2010) performed a systematic review of observational studies of success rates and adverse maternal and neonatal outcomes of vaginal birth after one or two CSs and repeat CSs.

One study (Cahill et al., 2010) reported maternal morbidity in women with three or more prior caesarean births who attempt a vaginal birth (VBAC).

One study (Law et al., 2010) reported maternal psychological status among women with one previous caesarean birth who were randomised to planned vaginal birth or planned CS.

Evidence profile

One evidence profile summarises maternal outcomes from one s ystematic review plus one randomised trial of the risks and be nefits of “elective” repeat CSs [ERCS] compared with trial of labour [TOL] (Guise et al., 2010, Law et al., 2010). One evidence profile summarises neonatal outcomes from one systematic review of the risks and benefits of ERCS compared with TOL (Guise et al., 2010). Three evidence profiles report maternal complications associated with repeat CS as reported by the same systematic review (Guise et al., 2010). One evidence profile reports maternal outcomes of vaginal birth or planned CS after two previous CSs compared with vaginal birth or planned CS after one previous CS (Tahseen & Griffiths, 2010). Maternal morbidity in women who plan vaginal birth after three or more prior CSs is detailed in one evidence profile reporting findings from one observational study (Cahill et al., 2010). All included studies were observational studies. Therefore, using the GRADE system, the quality of the evidence was moderate, low or very low for all studies.

Maternal outcomes

All of the data included in Table 11.1 have been taken from one systematic review and one randomised trial and details outcomes for women who have had one previous CS. The number in the first column indicates the number of studies within the review that contribute data to that outcome.

Table 11.1 GRADE summary of findings comparing planned CS with planned vaginal birth in women with a previous CS (maternal outcomes)

Number of studies	Number of women		Effect		Quality
	Planned CS	Planned vaginal birth	Relative (95% CI)	Absolute (95% CI)	
Maternal mortality (term)					
4 studies (Guise et al., 2010)	17/225,239 (7.5 per 100,000)	3/156,690 (1.9 per 100,000)	RR 3.94 (1.20 to 12.5)[a]	Absolute risk difference: 5.6 more deaths per 100,000 (from 1.2 more to 10.4 more)	Moderate
Maternal mortality (any gestational age)					
12 studies (Guise et al., 2010)	19/229,635 (8.2 per 100,000)	5/167,220 (3.0 per 100,000)	RR 2.76 (1.07 to 7.14)[a]	Absolute risk difference: 5.3 more deaths per 100,000 (from 0.4 more to 10.3 more)	Moderate
Uterine rupture (term)					
2 studies (Guise et al., 2010)	4/18,195 (0.22 per 1000)	118/16,250 (7.26 per 1000)	RR 0.03 (0.011 to 0.082)[a]	Absolute risk difference: 7.04 fewer per 1000 (from 8.5 fewer to 5.8 fewer)[a]	Very low
Uterine rupture (any gestational age)					
4 studies (Guise et al., 2010)	6/26,535 (0.22 per 1000)	148/20,717 (7.14 per 1000)	RR 0.031 (0.014 to 0.070)[a]	Absolute risk difference: 7 fewer per 1000[a] Adjusted risk difference: 5.1 fewer per 1000[a] (from 2.3 fewer to 11.2 fewer)	Very low

2011 Update

Number of studies	Number of women		Effect		Quality
	Planned CS	Planned vaginal birth	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion (term)					
4 studies (Guise et al., 2010)	607/227,960 (2.6 per 1000)	547/156,690 (3.5 per 1000)	RR 0.76 (0.67 to 0.85)[a]	Absolute risk difference: 0.9 fewer per 1000[a] Adjusted risk difference: 1.4 fewer per 1000 (from 0.7 fewer to 2.2 fewer)	Very low
Blood transfusion (any gestational age)					
9 studies (Guise et al., 2010)	712/233,884 (3 per 1000)	641/167,423 (3.8 per 1000)	RR 0.795 (0.714 to 0.884)[a]	Absolute risk difference: 0.8 fewer per 1000 (from 1.16 fewer to 0.41 fewer)[a]	Very low
Hysterectomy (term)					
3 studies (Guise et al., 2010)	248/227,479 (1.09 per 1000)	174/155,763 (1.11 per 1000)	RR 0.97 (0.80 to 1.18)[a]	Absolute risk difference: 0.02 fewer per 1000 (from 0.24 fewer t0 0.18 more)[a]	Very low
Hysterectomy (any gestational age)					
8 studies (Guise et al., 2010)	280/234,349 (1.19 per 1000)	197/167,710 (1.17 per 1000)	RR 1.01 (0.84 to 1.22)[a]	Absolute risk difference: 0.02 more per 1000 (from 0.19 fewer to 0.23 more)[a]	Very low
Infection: endometritis, chorioamnionitis, wound and other postpartum infections (any gestational age)					
10 studies (Guise et al., 2010)	32 per 1000	46 per 1000	Not calculable (NC)	Absolute risk difference: 14 fewer per 1000[a]	Very low
Length of hospital stay (any gestational age)					
8 studies (Guise et al., 2010)	Mean 3.92 days	Mean 2.55 days	NC	MD 1.37 higher	Very low

Number of studies	Number of women		Effect		Quality
	Planned CS	Planned vaginal birth	Relative (95% CI)	Absolute (95% CI)	
Edinburgh Postnatal Depression Scale (6 months postpartum)					
1 study (Law et.al., 2010)	Median 0.0 (inter-quartile range 0.0–4.0)	Median 0.5 (inter-quartile range) 0.0–4.0)	NC	*P* = 0.766	Low
Beck Depression Inventory (6 months postpartum)					
1 study (Law et.al., 2010)	Median 1.5 (inter-quartile range 0.0–4.8)	Median 1.0 (inter-quartile range 0.0–4.3)	NC	*P* = 0.929	Low
Client Satisfaction Questionnaire (6 months postpartum)					
1 study (Law et.al., 2010)	Median 24.0 (inter-quartile range 22.0–25.0)	Median 23.0 (inter-quartile range 22.0–25.0)	NC	*P* = 0.433	Low

[a] Calculated by NCC-WCH technical team

CI confidence interval; MD mean difference; NC not calculable; RR risk ratio

Repeat CS

Narrative discussions of maternal complications associated with multiple CSs were reported in one systematic review (Guise et al., 2010). All participants gave birth by CS. The number of studies contributing to the outcome in question is reported in the first column of the table. For Tables 11.2 to 11.4 just one study from within the systematic review (not the same study) contributed data to each outcome. All included studies involved women giving birth at any gestation.

Table 11.2 GRADE summary of findings for repeat CS (one prior CS compared with two prior CSs)

Number of studies	Number of women		Effect		Quality
	1 prior CS	2 prior CSs	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion rates					
1 study (Guise et al., 2010)	427/23,579 (1.8%)	202/7,902 (2.6%)	0.70 (0.60 to 0.83)[a]	Absolute risk difference: 7 fewer per 1000 (from 11 fewer to 3 fewer)[a]	Low
Infection rates (endometritis)					
1 study (Guise et al., 2010)	404/14,808 (2.7%)	178/6,324 (2.8%)	0.96 (0.81 to 1.16)[a]	Absolute risk difference: 1 fewer per 1000 (from 5 fewer to 3 more)	Low

Number of studies	Number of women		Effect		Quality
	1 prior CS	2 prior CSs	Relative (95% CI)	Absolute (95% CI)	
Wound complication (infection and wound dehiscence)					
1 study (Guise et al., 2010)	165/15,808 (1.0%)	107/5,324 (2.0%)	0.55 (0.43 to 0.70)[a]	Absolute risk difference 10 fewer per 1000 (from 13 fewer to 5 fewer)*	Low
Surgical (bladder) injuries rates					
1 study (Guise et al., 2010)	15/15,808 (0.1%)	18/6,324 (0.3%)	0.33 (0.17 to 0.65)	Absolute risk difference: 3 fewer per 1000 (from 3 fewer to 3 fewer)	Low

[a] Calculated by NCC-WCH technical team

CI confidence interval

Table 11.3 GRADE summary of findings for repeat CS (one prior CS compared with two or more prior CSs)

Number of studies	Number of women		Effect		Quality
	1 prior CS	≥ 2 prior CSs	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion rates					
1 study (Guise et al., 2010)	16/491 (3.3%)	22/277 (7.9%)	0.41 (0.22 to 0.76)[a]	Absolute risk difference: 46 fewer per 1000 (from 56 fewer to 14 fewer)	Low
Hysterectomy rates					
1 study (Guise et al., 2010)	1/491 (0.20%)	3/277 (1.08%)	0.18 (0.03 to 1.30)[a]	Absolute risk difference: 9 fewer per 1000 (from 29 fewer to 2 more)	Low

[a] Calculated by NCC-WCH technical team

CI confidence interval

Table 11.4 GRADE summary of findings for repeat CS (one prior CS compared with three prior CSs)

Number of studies	Number of women		Effect		Quality
	1 prior CS	3 prior CSs	Relative (95% CI)	Absolute (95% CI)	
Surgical (bladder) injuries rates (any gestational age)					
1 study (Guise et al., 2010)	15/15,808 (0.09%)	17/1452 (1.2%)	0.08 (0.04 to 0.15)	Absolute risk difference: 11 fewer per 1000 (from 17 fewer to 6 fewer)[a]	Low
Infection (endometritis) (any gestational age)					
1 study (Guise et al., 2010)	404/15,808 (2.5%)	43/1452 (3.0%)	0.86 (0.63 to 1.17)	Absolute risk difference: 5 fewer per 1000 (from 14 fewer to 4 more)[a]	Low
Wound complication (infection and wound dehiscence)					
1 study (Guise et al., 2010)	165/15,808 (1.0%)	22/1452 (1.5%)	0.68 (0.44 to 1.06)[a]	Absolute risk difference: 5 fewer per 1000 (from 12 fewer to 1 more)[a]	Low

[a] Calculated by NCC-WCH technical team

CI confidence interval

Vaginal birth attempt following two or more CS

All of the data included in this section have been taken from two studies (Cahill et al., 2010; Tahseen & Griffiths, 2010) that reported maternal morbidity in women who attempted VBAC. The range of successful VBACs was 74% to 80% in one observational study (Cahill et al., 2010) and 72% to 76% in the other study (Tahseen & Griffiths, 2010). For the systematic review (Tahseen & Griffiths, 2010) the number of studies reported in the first columns of Tables 11.5 and 11.6 corresponds to the number of included studies contributing findings to each reported outcome.

Table 11.5 GRADE summary of findings for planned VBAC after two prior CSs compared with planned repeat CS after two prior CSs

Number of studies	Number of women		Effect		Quality
	Planned vaginal birth 2 prior CSs	Planned repeat CS 2 prior CSs	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion					
6 studies (Tahseen & Griffiths, 2010)	47/2,292 (2.1%)	172/10,277 (1.7%)	RR 1.22 (0.89 to 1.68)	Absolute risk difference: 4 more per 1000 (from 2 fewer to 11 more)[a]	Very low
Febrile morbidity					
6 studies (Tahseen & Griffiths, 2010)	192/2,678 (7.2%)	630/9,858 (6.4%)	RR 1.12 (0.95 to 1.3)	Absolute risk difference: 8 more per 1000 (from 3 fewer to 19 more)[a]	Very low
Hysterectomy					
7 studies (Tahseen & Griffiths, 2010)	9/1,747 (0.5%)	51/8,009 (0.6%)	RR 0.80 (0.40 to 1.61)	Absolute risk difference: 1 fewer per 1000 (from 4 fewer to 4 more)	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; RR risk ratio; VBAC vaginal birth after caesarean section

Table 11.6 GRADE summary of findings for planned VBAC after three or more prior CSs compared with planned repeat CS after three or more prior CSs

Number of studies	Number of women		Effect		Quality
	Planned vaginal birth ≥ 3 prior CS	Planned repeat CS ≥ 3 prior CS	Relative (95% CI)	Absolute (95% CI)	
Blood transfusion					
1 study (Cahill et al., 2010)	2/89 (2.2%)	17/771 (2.2%)	RR 1.02 (0.24 to 4.43)	Absolute risk difference: 0.4 more per 1000 (from 21 fewer to 56 more)[a]	Very low
Fever					
1 study (Cahill et al., 2010)	14/89 (15.7%)	121/771 (15.7%)	RR 1.00 (0.60 to 1.67)	Absolute risk difference: 0.3 more per 1000 (from 67 fewer to 93 more)[a]	Very low
Bladder injury rates					
1 study (Cahill et al., 2010)	0/89	12/771 (1.6%)	Not calculable (NC)	Absolute risk difference: 15 fewer per 1000 (from 27 fewer to 25 more)[a]	Very low
Surgical injury rates					
1 study (Cahill et al., 2010)	0/89	7/771 (0.9%)	NC	Absolute risk difference: 9 fewer per 1000 (from 18 fewer to 32 more)[a]	Very low
Uterine rupture					
1 study (Cahill et al., 2010)	0/89	0/771	NC	NC	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; NC not calculable; RR risk ratio; VBAC vaginal birth after caesarean section

Neonatal outcomes

All of the data included in Table 11.7 have been taken from one s ystematic review (Guise et al., 2010). The number in the first column indicates the number of studies from that review which report on those outcomes.

Table 11.7 GRADE summary of findings comparing planned CS with planned vaginal birth in women with a previous CS (neonatal outcomes)

Number of studies	Number of neonates		Effect		Quality
	Planned CS	Planned vaginal birth	Relative (95% CI)	Absolute (95% CI)	
Perinatal mortality (term)					
5 studies (Guise et al., 2010)	46/35,686 (0.12%)	72/41,213 (0.17%)	RR 0.73 (0.51 to 1.06)[a]	Absolute risk difference: 0.46 less deaths per 1000 Calculated risk difference: 0.41 (from 1.0 fewer to 0.1 more)	Very low
Neonatal mortality (term)					
6 studies (Guise et al., 2010)	40/63,843 (0.06%)	51/44,485 (0.11%)	RR 0.546 (0.36 to 0.82)[a]	Absolute risk difference: 0.52 fewer deaths per 1000 (from 0.92 fewer to 0.17 fewer)[a]	Very low
Bag and mask ventilation (term)					
3 studies (Guise et al., 2010)	62/976 (6.3%)	183/1134 (16.1%)	RR 0.39 (0.30 to 0.52)[a]	Absolute risk difference: 98 fewer per 1000 (Calculated risk difference: 25 fewer per 1000 [from 7.7 fewer to 50 fewer])[a]	Very low
Transient Tachypnea (term)					
3 studies (Guise et al., 2010)	190/1476 (12.9%)	427/3451 (12.4%)	RR 1.04 (0.88 to 1.21)[a]	Absolute risk difference: 5 more per 1000 (Calculated risk difference: 8.3 more per 1000 [from 33 fewer to 17 more])	Very low

[a] Calculated by NCC-WCH technical team

CI confidence interval; RR risk ratio

No pooled data was reported in the systematic review (Guise et al., 2010) for neonatal intensive care unit [NICU] admission, hypoxic-ischemic encephalopathy (HIE) and neonates' Apgar score. There were narrative discussions for these outcomes which are summarised here.

There was evidence that the rate of NICU admission was higher in neonates born by planned repeat CS compared with neonates born following planned vaginal birth (eight studies, low quality, pooled data not reported).

There was very low quality evidence from three studies that reported lower rates of HIE among neonates born by planned repeat CS compared with neonates born following planned vaginal birth (pooled data not reported) .

There was low quality evidence from four studies that found no difference in the proportion of babies with an Apgar score of 7 or below at 5 minutes in neonates born by planned repeat CS compared with neonates born following a planned vaginal birth (pooled data not reported).

Evidence statements

Maternal outcomes following one CS

The evidence for all outcomes other than maternal mortality was of very low quality.

Maternal mortality

One systematic review found that the maternal mortality rate was higher in women who had undergone planned repeat CS at term compared with women who had undergone a planned vaginal birth at term. This finding was statistically significant. The evidence for this outcome was of moderate quality.

One systematic review found that the mortality rate was significantly higher in women who had undergone planned repeat CS at any gestational age compared with women who had undergone a planned vaginal birth at any gestational age. This finding was statistically significant. The evidence for this outcome was of moderate quality.

Uterine rupture

One systematic review found that the rate of uterine rupture was lower among women with planned repeat CS at term compared with women who had undergone a planned vaginal birth at term. This finding was statistically significant.

One systematic review found that the rate of uterine rupture was lower among women with planned repeat CS at any gestational age compared with women who had undergone a planned vaginal birth at any gestational age. This finding was statistically significant.

Blood transfusion

One systematic review found that the rate of blood transfusion was lower among women who had a planned repeat CS at term when compared with women who had undergone a planned vaginal birth at term. This finding was statistically significant.

One systematic review found that the rate of blood transfusion was lower among women who had a planned repeat CS at any gestational age when compared with women who had undergone a planned vaginal birth at any gestational age. This finding was statistically significant.

Hysterectomy

One systematic review did not find a statistically significant difference in the rates of hysterectomy among women who had a planned CS at term compared with women who had undergone a planned vaginal birth at term.

One systematic review did not find a statistically significant difference in the rates of hysterectomy among women who had a planned CS at any gestational age compared with women who had undergone a planned vaginal birth at any gestational age.

Infection (endometritis)

One systematic review found that the rate of infection was lower among women with planned repeat CS when compared with women who had a planned vaginal birth. However, the paper did not provide enough data to determine if this difference was statistically significant.

Length of hospital stay

One systematic review found that the mean length of hospital stay was longer among women with planned repeat CS when compared with women who had a planned vaginal birth. However, the paper did not provide enough data to determine if this difference was statistically significant.

Postnatal depression

One randomised trial did not find a statistically significant difference in the rates of postnatal depression 6 months postpartum among women who had a planned CS compared with women who had a pl anned vaginal birth using the Edinburgh Postnatal Depression Scale and Beck Depression Inventory scales..

Client satisfaction

One randomised trial did not find a statistically significant difference in the rates of client satisfaction 6 months postpartum among women who had a planned CS compared with women who had a planned vaginal birth using Client Satisfaction Questionnaires scores.

Repeat caesarean sections

No pooled data was reported in the systematic review (Guise et al., 2010) for maternal complications associated with repeat CS. There were narrative discussions of each included study for the following outcomes:

One prior CS compared with two prior CSs

The evidence for all outcomes was of low quality.

Blood transfusion

One study found that the rate of blood transfusion was lower among women giving birth by CS following one prior CS compared with women who had undergone two prior CSs at any gestational age. This finding was statistically significant.

Infection (endometritis)

One study did not find a statistically significant difference in infection rates in women giving birth by CS following one prior CS compared with women who had undergone two prior CSs at any gestational age.

Wound complication

One study found that the wound complication rate was lower among women giving birth by CS following one prior CS compared with women who had undergone two prior CSs at any gestational age. This finding was statistically significant.

Surgical injuries

One study found that the rate of surgical injuries was lower among women giving birth by CS following one prior CS at any gestational age when compared with women who had two prior CSs. This finding was statistically significant.

One prior CS compared with two or more prior CSs

The evidence for both outcomes was of low quality.

Blood transfusion

One study found that fewer women giving birth by CS following one prior CS at any gestational age required a blood transfusion when compared with women who had two or more prior CSs. This finding was statistically significant.

Hysterectomy

One study did not find a statistically significant difference in the rate of hysterectomy among women giving birth by CS following one prior CS at any gestational age when compared with women who had two or more prior CSs.

One prior CS compared with three prior CSs

The evidence for all outcomes was of low quality.

Surgical injuries

One study found that the rate of surgical injuries was lower among women giving birth by CS following one prior CS at any gestational age when compared with women who had three prior CSs. This finding was statistically significant.

Infection (endometritis)

One study did not find a statistically significant difference in the infection rates among women giving birth by CS following one prior CS compared with women who had undergone three prior CSs at any gestational age.

Wound complication

One study did not find a statistically significant difference in the wound complication rates among women giving birth by CS following one prior CS compared with women who had undergone three prior CSs at any gestational age.

Planned VBAC after two prior CSs versus planned repeat CS after two prior CSs

The evidence for all outcomes was of very low quality.

Blood transfusion

One systematic review did not find a statistically significant difference in the rate of blood transfusions among women who planned a vaginal birth following two prior CSs compared with women who had a planned CS following two prior CSs.

Febrile morbidity

One systematic review did not find a statistically significant difference in the rate of febrile morbidity among women who planned a vaginal birth following two prior CSs compared with women who had a planned CS following two prior CSs.

Hysterectomy

One systematic review did not find a statistically significant difference in the rate of hysterectomy in women who planned a vaginal birth following two prior CSs compared with women who had a planned CS following two prior CSs.

Planned VBAC after three or more prior CSs versus planned repeat CS after three or more prior CSs

The evidence for all outcomes was of very low quality.

Blood transfusion

One study did not find a statistically significant difference in the blood transfusion rates among women who planned a vaginal birth following three or more prior CSs compared with women who had a planned CS following three or more prior CSs.

Fever

One study did not find a statistically significant difference in fever rates in women who planned a vaginal birth following three or more prior CSs compared with women who had a planned CS following three or more prior CSs.

Bladder injury

One study did not find a statistically significant difference in the rate of bladder injuries among women who planned a vaginal birth following three or more prior CSs compared with women who had a planned CS following three or more prior CSs.

Surgical injury

One study did not find a statistically significant difference in the rate of surgical injuries among women who planned a vaginal birth following three or more prior CSs compared with women who had a planned CS following three or more prior CSs.

Uterine rupture

One study did not find a statistically significant difference in the rate of uterine rupture in women who planned a vaginal birth following three or more prior CSs compared with women who had a planned CS following three or more prior CSs.

Neonatal outcomes

The evidence for all outcomes was of very low quality.

Perinatal mortality

One systematic review did not find a statistically significant difference in the perinatal mortality rate among infants born to women who planned a repeat CS at term compared with infants born at term to women who planned a vaginal birth.

Neonatal mortality

One systematic review found that the neonatal mortality rate was lower for infants born at term to women who planned a r epeat CS compared with infants born at term to women who planned a vaginal birth. This finding was statistically significant.

Bag and mask ventilation

One systematic review found that the use of bag an d mask ventilation was lower among neonates born at term to women who planned a repeat CS compared with neonates born at term to women who planned a vaginal birth. This finding was statistically significant.

Transient tachypnea

One systematic review did not find a s tatistically significant difference in the incidence of neonatal transient tachypnoea between neonates born to women who planned a repeat CS and those born at term to women who planned a vaginal birth.

Health economics

A model was developed to compare the cost effectiveness of VBAC versus a planned CS in women with one previous CS and with no plans for further children. A summary of this analysis is provided below (see Chapter 13 for further details).

In addition to the costs of birth, the model also estimated 'downstream' costs and quality adjusted life years (QALYs) based on the risk of adverse events for each planned mode of birth. The base case analysis considered only the outcomes that were reported in the review undertaken for this guideline to determine the risks and benefits for both women and babies of planned CS compared with planned vaginal birth in women who have had a previous CS. Secondary analyses also used outcomes that were only reported in the review which compared the risk and benefits of planned CS compared with planned vaginal birth. However, it should be r ecognised that these risks are likely to be underestimated for this population and that the relative risk for these adverse outcomes may also be different in this population.

The results tended to show that VBAC was more likely to be cost effective, although this was a borderline finding and considerable uncertainty remains, especially with respect to all the outcomes that may differ between the different modes of planned birth in this population.

Evidence to recommendations

Relative value placed on outcomes considered

It was noted that findings from studies of babies born at term were very similar to those that included babies born at any gestational age. This was thought to reflect the relatively low numbers of preterm babies included in the studies involving all gestational ages. The extra statistical power afforded by the larger numbers where studies of all gestational ages have been included meant the GDG was happy to consider this evidence when making recommendations.

Maternal mortality is clearly a vitally important outcome at an individual level, but in terms of informing decision making for a whole population, the very low numbers of deaths reported in the studies (absolute numbers range from 1.9 to 7.5 per 100,000) mean this outcome does not necessarily drive the recommendations made. Other important outcomes, including uterine rupture and neonatal mortality, were more common, although still rare, meaning that although differences between study groups were statistically significant, the low incidence meant that they were also considered less clinically significant in terms of driving clinical practice and advice to women. In the context of low actual risk, then absolute risk will be a more important consideration than relative risk.

The reported neonatal outcomes of bag and mask ventilation and transient tachypnoea were felt to be of limited value as it was not possible to determine how these outcomes related to ongoing health problems or disability.

Trade-off between clinical benefits and harms

Mortality-related outcomes are very rare. However, the GDG noted that for women planning birth following one previous CS, maternal mortality is statistically significantly higher for women planning a repeat CS while neonatal mortality is statistically significantly higher for women planning a vaginal birth. Perinatal mortality is not statistically different between the two groups.

The GDG agreed that although it is right to give women all available information when planning mode of birth, the important thing to emphasise to women planning birth after one previous CS is that serious adverse outcomes, including maternal and neonatal mortality, uterine rupture, need for blood transfusion and h ysterectomy, are rare, no matter whether women choose a planned repeat CS or VBAC.

The GDG noted that the relative risk of adverse outcomes may vary from woman to woman depending upon her obstetric history, including reasons for previous CS(s) and whether or not a woman has previously given birth vaginally. These individual considerations need to be taken into account when discussing mode of birth following one or more previous CSs.

When considering increasing numbers of previous CSs, the evidence showed no difference between planned vaginal birth and planned CS in rates of blood transfusion, fever and hysterectomy after two prior CSs. However, with an increasing number of CSs, there is an increasing risk of need for blood transfusion, wound complications and injuries to the bladder, regardless of the mode of birth.

Trade-off between net health benefits and resource use

An economic model developed for this guideline to compare the cost effectiveness of planned CS versus planned vaginal birth in women who have had a pr evious CS did not strongly suggest a preferred mode of birth. As a result, this model would, given the current state of evidence, support a recommendation allowing women to choose their preferred method of birth in consultation with the healthcare professionals responsible for her care. Considerations about any future pregnancies may be an important factor in the decisions made, given the increased risks in, for example, incidence of placenta praevia and morbidly adherent placenta, which are associated with repeat CSs.

Quality of evidence

The evidence for outcomes following one previous CS was drawn from one l arge meta-analysis of observational studies and one randomised controlled trial (RCT), and ranged from moderate to very low. The large sample sizes reported for the meta-analysis meant the GDG felt more confident in the validity of the findings regarding rare outcomes.

The evidence examining outcomes following more than one previous CS is of low and very low quality. While evidence comparing outcomes for women having a CS following one, two or more previous CSs is interesting and can be used to provide general information about increasing risks following two or more CSs, it does not help a w oman decide the level of risk associated with her choice of mode of birth in the current pregnancy. However, this information is helpful for decision making about future births. The evidence comparing outcomes for women choosing a planned vaginal birth compared with those choosing a pl anned CS after two or more previous CSs is useful in this respect as this reflects the choice women have. Unfortunately, this evidence is of very low quality, thus lowering the validity of the reported findings.

No good quality evidence was available for women planning birth following five or more previous CSs.

Other considerations

The GDG noted that many women leave hospital following a caesarean birth without understanding the implications for planning future pregnancies and births. It was felt that it is important to provide this information to women and their partners so that they can have an accurate picture of what this means for them when planning their family, including options for future modes of birth. The GDG agreed that there is a benefit to providing this information to women and their partners prior to leaving the hospital because the medical records are easily available to refer to. As a result, the GDG recommended that this discussion take place with women after the CS. However, the GDG also recognised that some

women may prefer to have this discussion at a later date, so highlighted that this discussion can be deferred. Due to the large amount of information women and t heir partners receive during the immediate postnatal period, this information should be provided both verbally and in written formats. It is important to emphasise to women that, regardless of future choice of mode of birth, poor outcomes are very rare.

Recommendations

Number	Recommendation
119	When advising about the mode of birth after a previous CS consider: • maternal preferences and priorities • the risks and benefits of repeat CS • the risks and benefits of planned vaginal birth after CS, including the risk of unplanned CS. **[new 2011]**
120	Inform women who have had up to and including four CS that the risk of fever, bladder injuries and surgical injuries does not vary with planned mode of birth and that the risk of uterine rupture, although higher for planned vaginal birth, is rare. **[new 2011]**
121	Offer women planning a vaginal birth who have had a previous CS: • electronic fetal monitoring during labour • care during labour in a unit where there is immediate access to CS and on-site blood transfusion services. [GPP] **[2011]**
122	During induction of labour, women who have had a previous CS should be monitored closely, with access to electronic fetal monitoring and with immediate access to CS, because they are at increased risk of uterine rupture. [GPP] **[2004]**
123	Pregnant women with both previous CS and a previous vaginal birth should be informed that they have an increased likelihood of achieving a vaginal birth than women who have had a previous CS but no previous vaginal birth. [B] **[2004]**
124	While women are in hospital after having a CS, give them the opportunity to discuss with healthcare professionals the reasons for the CS and pr ovide both verbal and printed information about birth options for any future pregnancies. If the woman prefers, provide this at a later date. **[new 2011]**

For recommendations on methods of induction for women who have had a previous CS, see the Induction of labour guideline (NICE, 2008)

Number	Research recommendation
RR 46	A comparison of the long term psychological and physical outcomes between women who have chosen and/or been advised towards a VBAC or a planned repeat CS.
RR 47	An evaluation of the effectiveness of continuity of carer on the proportion of women planning and achieving a VBAC, and the short and long term psychological and physical outcomes of women following a planned VBAC.

2011 Update

2011

2011 Update

12 Auditable standards

Table 12.1 Suggested audit criteria

Criterion	Exception	Definition of terms
Making the decision		
Was there a documented discussion on benefits and risks of caesarean section and vaginal birth specific to the woman and her pregnancy?		
If the woman requested a caesarean section was there a documented discussion on t he specific reasons for the request?		
Carrying out the procedure		Regional anaesthesia – spinal or epidural anaesthesia
Was the caesarean section carried out using a regional anaesthesia?		
Did the woman receive prophylactic antibiotics?		
Did the woman receive prophylactic antibiotics before skin incision?		
Were antacids given before regional or general anesthesia?		
Were drugs such as H2 receptor antagonists or proton pump inhibitors given before regional or general anesthesia?		
Were antiemetics given before regional or general anesthesia?		
If a planned caesarean section was carried out, was this after 39 weeks?	Specific clinical indications	
Reducing the likelihood of CS	Women in labour, women with a uterine scar or abnormality, fetal compromise, ruptured membranes, vaginal bleeding and medical conditions	
If the woman had an uncomplicated singleton breech pregnancy at 36 weeks gestation, was there a documented offer of exteranl cephalic version?		
Did the woman have continuous support during labour from women with or without prior training?		
If the woman had an uncomplicated pregnancy beyond 41 weeks, was there a documented offer of induction of labour?		
If the woman had spontaneous labour with an uncomplicated singleton pregnancy at term, was a partogram with a 4-hour action		Partogram – graphic representation of labour progress

line used?	
Was there documented involvement of a consultant obstetrician in the decision making for caesarean section?	Women not having a CS
If caesarean section was undertaken for abnormal fetal heart rate pattern in suspected fetal acidosis, was fetal blood sampling undertaken?	Severely abnormal fetal heart rate pattern Contraindications to fetal blood sampling

An electronic audit tool is available to help organisations to collect and record the data in respect of these audit criteria. In addition, clinical audit tools containing audit criteria and data collection tools have been developed in respect of four topics which are key priorities in the updated guidance: morbidly adherent placenta, mother-to-child transmission of HIV, maternal request for CS and timing of antibiotic administration.

13 Health economics

13.1 Introduction

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

The GDG prioritised the clinical questions where it was thought that economic considerations would be particularly important in formulating recommendations. For this guideline the areas prioritised for economic analysis were:

- diagnosis of morbidly adherent placenta (see Section 5.6 for summary and Section 13.2 for full details)
- maternal request for CS (see Section 5.9 for summary and Section 13.3 for full details)
- vaginal birth after CS (see Section 11.2 for summary and Section 13.4 for full details).

13.2 Cost effectiveness of diagnosis of morbidly adherent placenta

Introduction

In women who have had a previous CS there is an increased risk of placenta praevia and this risk increases with the number of previous CSs (Clark et al., 1985). In turn, women with placenta praevia from a previous CS are at risk of a morbidly adherent placenta. Although this risk is small, it increases with the number of previous CSs (Silver et al., 2006). In addition to an increased maternal mortality risk, a morbidly adherent placenta also can lead to excessive blood loss, the need for a hysterectomy and surgical complications.

Practice for the diagnosis of a m orbidly adherent placenta is not consistent across England and Wales. Furthermore, there is uncertainty about the accuracy of imaging techniques used to diagnose a morbidly adherent placenta and about whether a diagnosis using these imaging techniques leads to improved outcomes. As a r esult, this was considered an important issue for the update of the guideline.

A systematic review of the literature did not identify any papers addressing the cost effectiveness of diagnostic imaging for morbidly adherent placenta. Therefore, a new model was developed for the purposes of this guideline.

Method

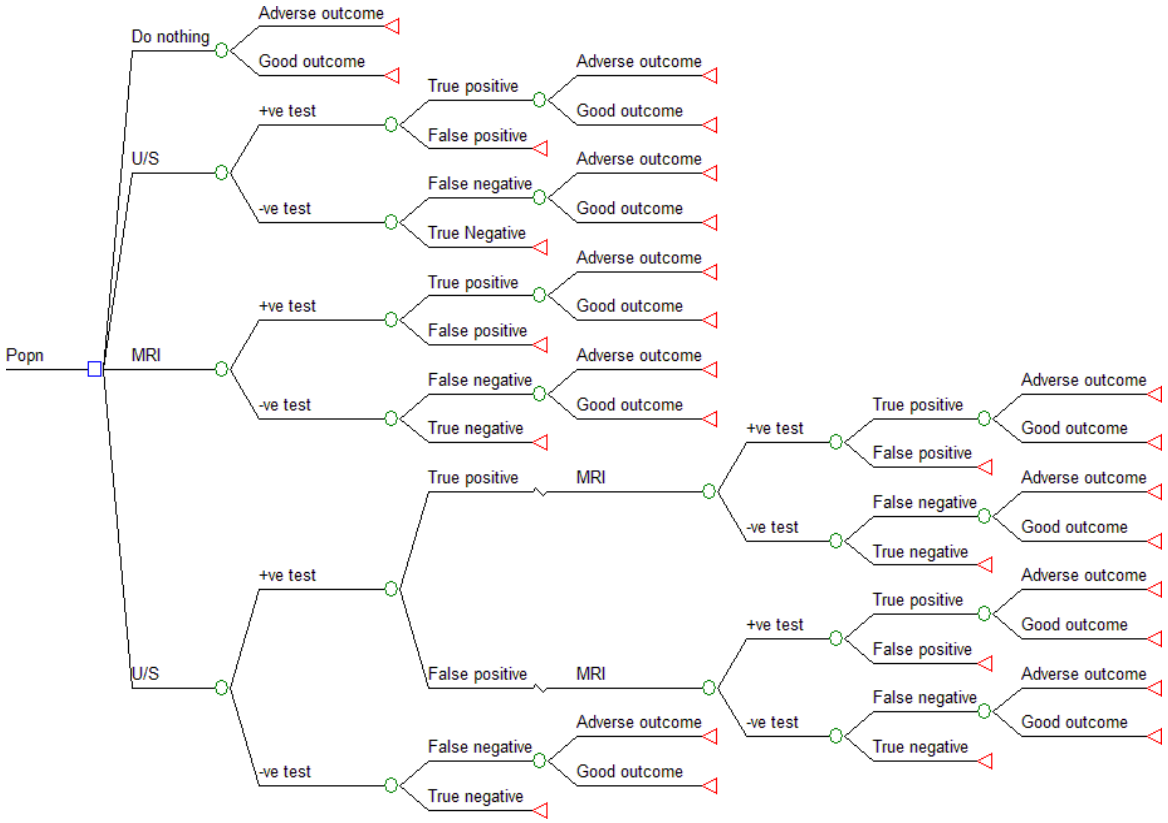
A decision analytic model was developed in Microsoft Excel® to compare the cost effectiveness of the following diagnostic strategies for morbidly adherent placenta:

- none
- ultrasound
- magnetic resonance imaging (MRI)
- ultrasound followed by MRI in ultrasound test positives.

The basic structure of the model is illustrated in Figure 13.1. In assessing the cost effectiveness of these diagnostic strategies it is important not to overlook treatment as the two are highly interdependent. For example, a very effective and inexpensive treatment may not ultimately be cost effective if the costs of identifying patients who could benefit are prohibitively high. Similarly, a very accurate and cheap diagnostic test may not be worth doing if it has no bearing on patient outcomes.

The clinical review did not identify any evidence of the relationship between a diagnosis of morbidly adherent placenta and patient outcomes. Nevertheless, the GDG thought there were likely to be advantages in terms of 'being prepared'. These advantages could be in terms of 'downstream' cost savings and possible improved outcomes for mother and baby. In addition, the GDG considered there was a benefit to the mother in being prepared for some of the likely outcomes of her pregnancy and birth. In the absence of evidence to quantify these benefits, this model adopts a 'what-if' approach to determine the thresholds for cost effectiveness.

Figure 13.1 Decision tree for different diagnostic strategies to identify morbidly adherent placenta



This analysis was undertaken from the perspective of the National Health Service (NHS) and personal social services which is in accordance with NICE guidelines methodology (NICE, 2009). Costs and benefits are compared using standard methods of incremental analysis of costs and benefits. Costs were based on 2009/10 prices. A number of sensitivity analyses were undertaken to assess the importance of parameter uncertainty within the model.

Model inputs

The default model input values are shown in Tables 13.1 to 13.3. Based on GDG opinion, the costs of 'being prepared' following a diagnosis of morbidly adherent placenta would typically be two hours of a consultant anaesthetist's time and hav ing four units of cross-matched blood available. Diagnostic accuracy data was taken from the literature that was retrieved as part of the systematic review that was undertaken for the guideline.

The use of 'adverse outcome' in this context of the model is purposefully vague, given that it is not known to what extent having a diagnosis and 'being prepared' leads to better outcomes. However, it is intended to capture the idea that treatment, which in this case is 'being prepared', could mitigate any adverse outcomes relative to a state of not being prepared.

The probabilities of an ad verse outcome, with and without 'being prepared', are illustrative values. These values are used to provide a 'what-if' with respect to treatment effectiveness. The QALY loss associated with an adverse outcome and the costs associated with an 'adverse outcome' are set to zero in the model's default setting, but the impact of relaxing this assumption on model outcomes can readily be observed.

Table 13.1 Unit costs for model to compare cost effectiveness of different diagnostic strategies for identifying morbidly adherent placenta

Item	Value	Source	Notes
Ultrasound	£55	NHS Reference Costs 2009-10	Outpatient Currency code RA23Z Scan < 20 minutes
MRI	£175	NHS Reference Costs 2009-10	Outpatient Currency code RA01Z
Being prepared	£800	http://www.hta.ac.uk/fullmono/mon1044.pdf	Unit of blood £111.16 x 4 Matching £23.24
		Curtis 2009	2 hours of anaesthetist's time £332 Based on medical consultant and including qualification costs
'adverse outcome'	£0	n/a	Can be varied as part of a 'what-if' analysis

MRI magnetic resonance imaging

Table 13.2 Probabilities for model to compare cost effectiveness of different diagnostic strategies for identifying morbidly adherent placenta

Item	Value	Source	Notes
Prevalence	3%	Silver et al., 2006	In women with placenta praevia, the risk for placenta accreta was 3% for first repeat caesarean deliveries
Adverse outcome|prepared	10%	n/a	illustrative value
Adverse outcome|not prepared	40%	n/a	illustrative value
Ultrasound sensitivity	92%	Shih et al., 2009	US colour Doppler
Ultrasound specificity	68%	Shih et al., 2009	US colour Doppler
MRI sensitivity	100%	Masselli et al., 2008	
MRI specificity	100%	Masselli et al., 2008	

MRI magnetic resonance imaging

Table 13.3 Outcomes and valuation of outcomes to determine cost effectiveness

Item	Value	Source	Notes
Willingness to pay for a QALY	£20,000	NICE guideline manual (2009)	
QALY loss adverse outcome	0.00	n/a	Can be varied as part of a 'what-if' analysis

QALY quality adjusted life year

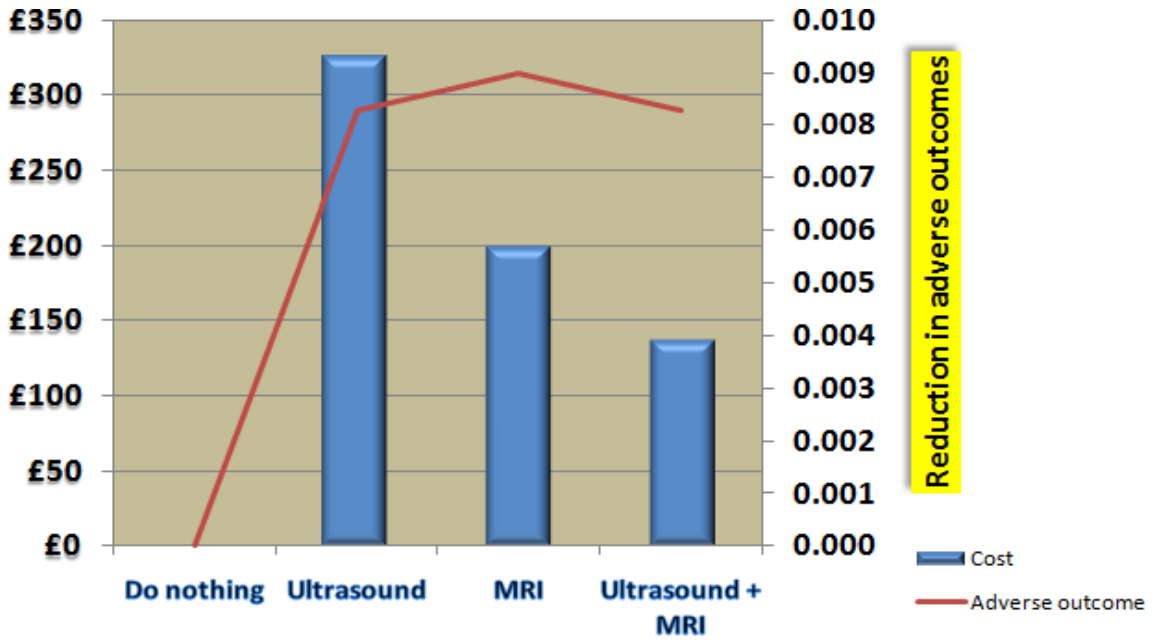
Results

The results using the base case inputs are shown in Table 13.4 and Figure 13.2. It m ust be remembered that there is an e lement of 'what-if' in these results, with some of the inputs being hypothetical illustrative values. These results show the diagnostic costs of the respective strategies and do not consider any 'downstream' savings that might arise as a result of being prepared or any health gains to the mother and baby.

Table 13.4 Results for base case analysis

Strategy	Cost	Incremental cost
Do nothing	£0	£0
Ultrasound plus MRI	£136	£136
MRI	£199	£63
Ultrasound	£325	£126

Figure 13.2 Results with base case values

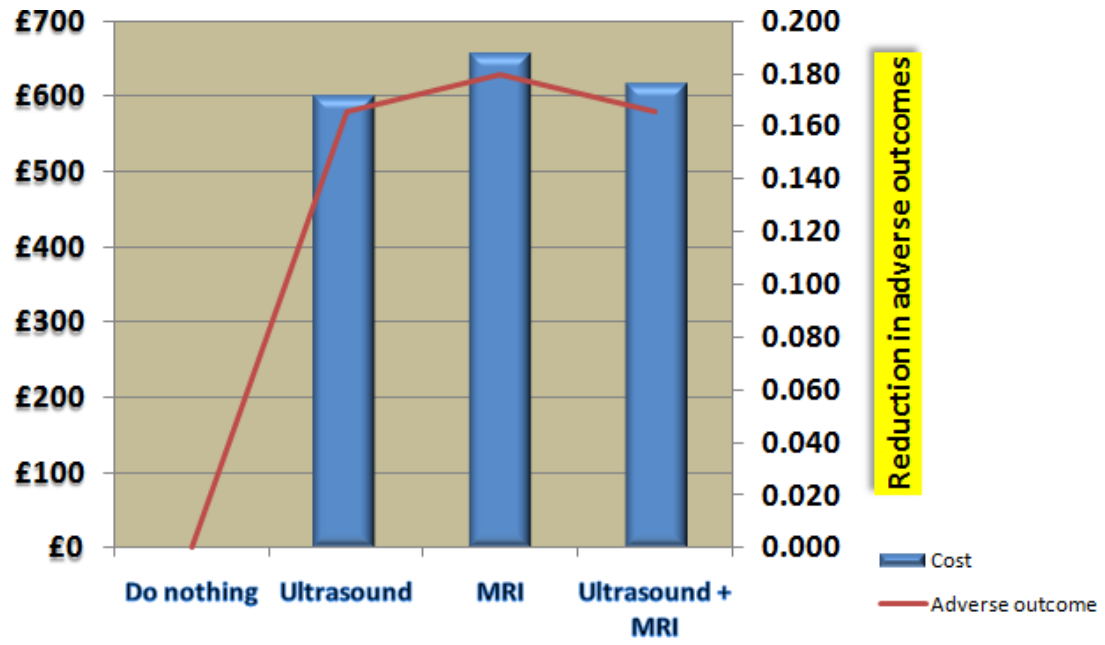


Sensitivity analysis

Changing prevalence

There is less uncertainty surrounding the prevalence of morbidly adherent placenta than there is for other parameter values. However, showing the impact of a different prevalence gives insights into the drivers of the model's results. Figure 13.3 shows the results for a pr evalence of 60% holding other model values constant at their base case values.

Figure 13.3 Results with prevalence set to a hypothetical 60%



Assuming that an 'adverse outcome' has cost implications

Here two 'what-ifs' are explored: first, if the 'downstream' costs of an adverse outcome are assumed to be £5000; and second, if those costs were assumed to be £30,000. The results of these scenarios are shown in Figures 13.4 and 13.5 respectively.

Figure 13.4 Results with 'adverse outcomes' set to £5000

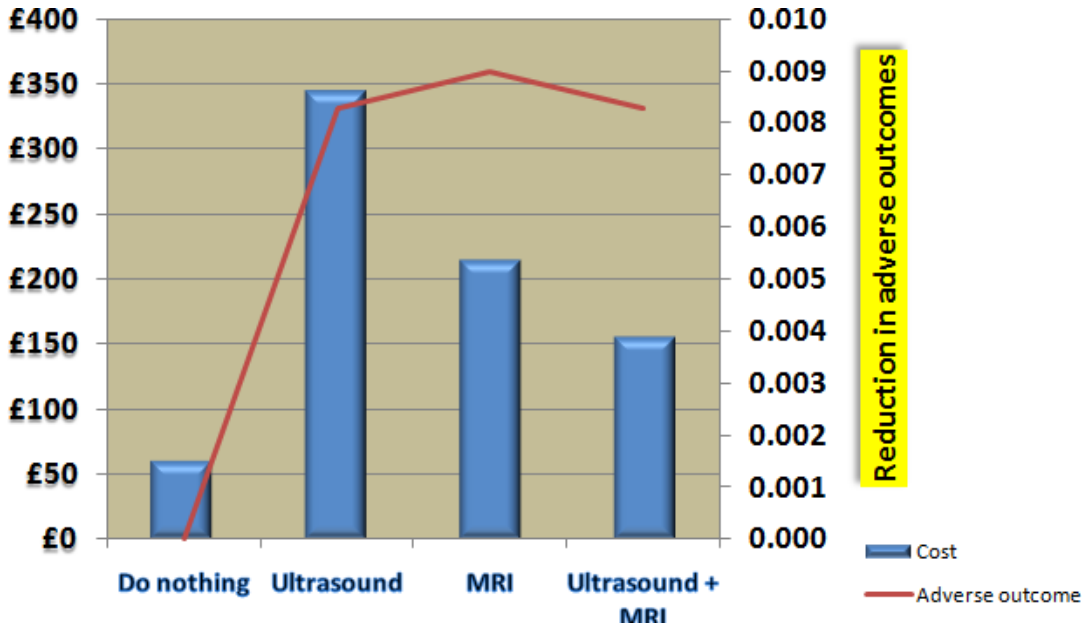
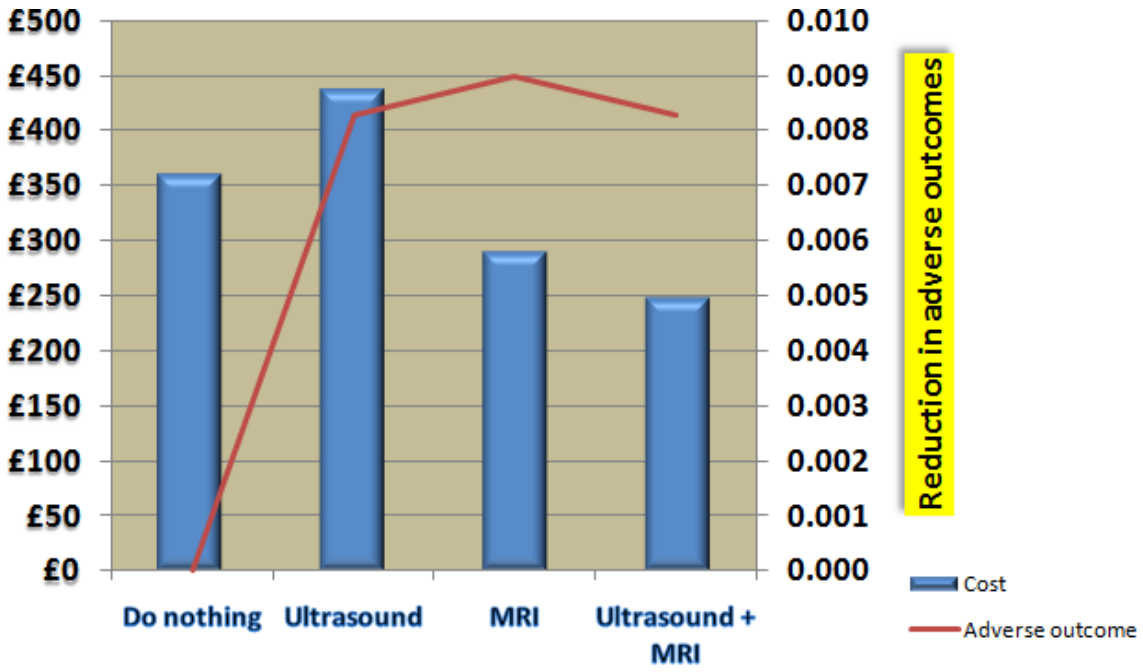


Figure 13.5 Results with 'adverse outcomes' set to £30,000



Assuming an 'adverse outcome' has QALY implications

In this analysis we assess the cost effectiveness assuming that averting 'adverse outcomes' has a QALY gain for the mother and/or baby. All other inputs in the model are held constant at their base case level, including the assumption that there are no 'downstream' costs associated with an adverse outcome. Table 13.5 shows the results for a QALY loss per adverse outcome of 0.02 and Table 13.6 shows the results when a much greater QALY loss of 5.00 is assumed.

Table 13.5 Results with QALY loss from "adverse outcomes" set to 0.02

Strategy	Cost	Incremental cost	QALY	Incremental QALY	ICER
Do nothing	£0	-		-	-
Ultrasound plus MRI	£136	£136	0.00011	0.00011	£822,645
MRI	£199	£63	0.00012	0.00001	£4,359,028
Ultrasound	£325	£126	0.00011	-0.00001	Dominated

QALY quality adjusted life year; ICER incremental cost effectiveness ratio

Given the reported incremental cost, a strategy of ultrasound plus MRI would have to generate 0.0068 QALYs per pregnancy for this to be cost effective relative to 'do nothing'. Similarly, MRI alone would have to produce an additional 0.0031 QALYs per woman compared do ultrasound plus MRI in order to be considered cost effective relative to that strategy.

Table 13.6 Results with QALY loss from 'adverse outcomes' set to 5.0

Strategy	Cost	Incremental cost	QALY	Incremental QALY	ICER
Do nothing	£0	-		-	-
Ultrasound plus MRI	£136	£136	0.0276	0.0276	£3291
	£199	£63	0.0300	0.0024	£17,436
MRI					
Ultrasound	£325	£126	0.0276	-0.0024	Dominated

QALY quality adjusted life year; ICER incremental cost effectiveness ratio

A threshold analysis was undertaken which showed that the QALY gain would have to be 0.8 or greater for ultrasound plus MRI to be cost effective relative to 'do nothing'. A further threshold analysis found that MRI alone would be the most cost-effective strategy, at a willingness to pay threshold of £20,000 per QALY, if the QALY loss associated with an 'adverse outcome' was 4.4. However, these threshold results are for when other model inputs are held constant at their base case value.

Two-way sensitivity analysis varying the QALY loss and cost of an 'adverse outcome'

Two very important unknowns in the model are the QALY loss from an 'adverse outcome' and the 'downstream' costs arising from this loss. In this analysis the QALY loss from an 'adverse outcome' is varied between 0.0 and 10.0 and the 'downstream' cost of an 'adverse outcome' is varied between £0 and £10,000. Figure 13.6 shows the thresholds at which a s trategy of ultrasound plus MRI is cost effective relative to 'do nothing' for different QALY and 'downstream' cost combinations. Figure 13.7 shows the thresholds for determining the cost effectiveness of MRI alone relative to ultrasound plus MRI.

Figure 13.6 Cost effectiveness thresholds for ultrasound plus MRI relative to 'do nothing'

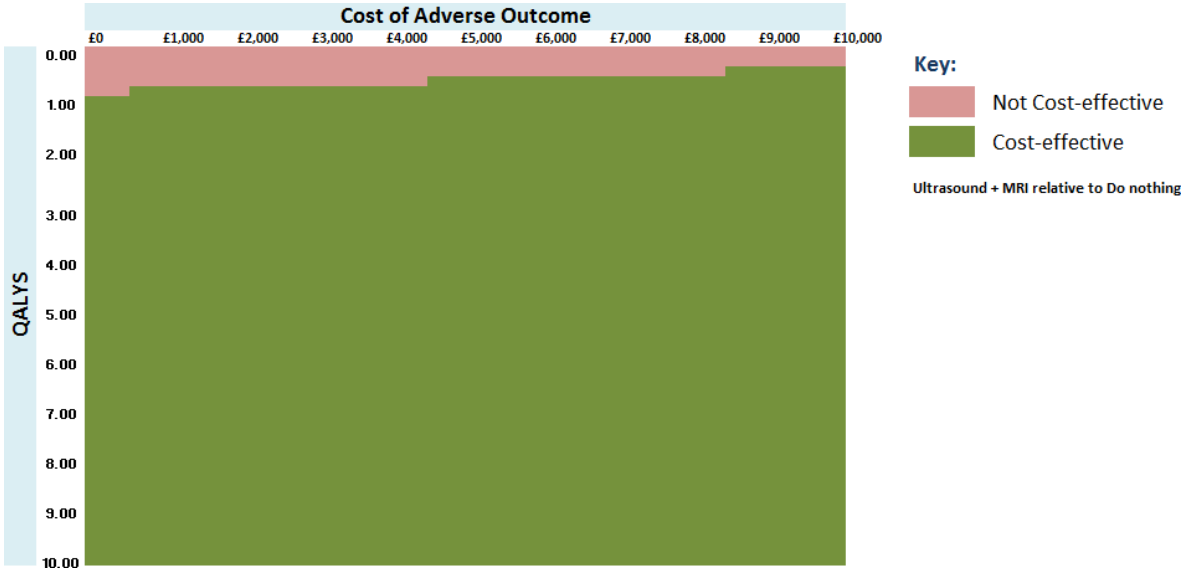
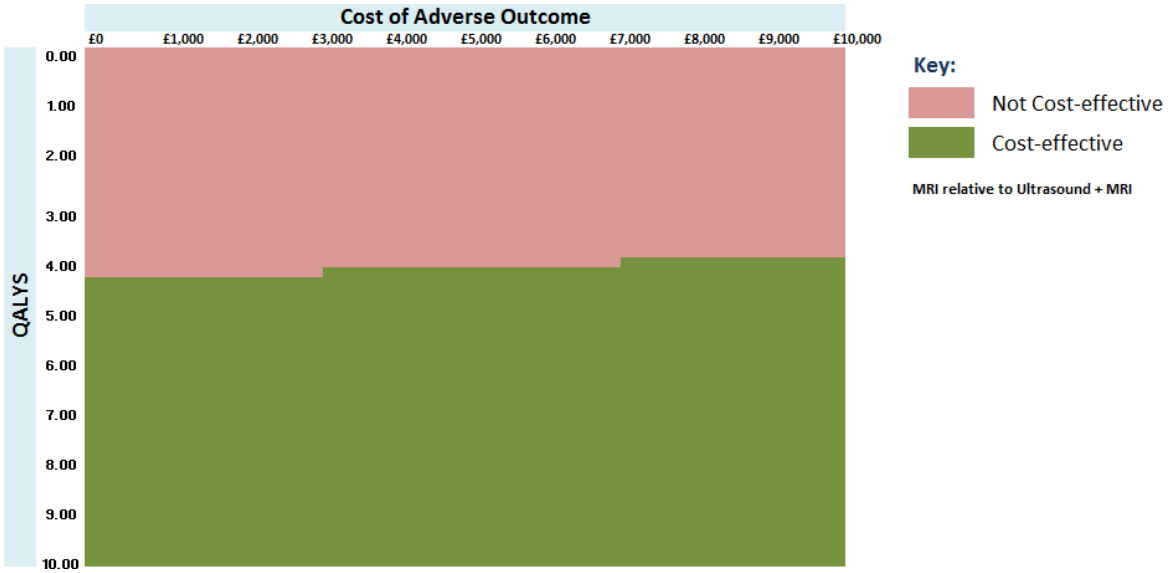


Figure 13.7 Cost effectiveness thresholds for MRI relative to ultrasound plus MRI



Two-way sensitivity analysis varying the QALY loss and cost of an 'adverse outcome' assuming a lower effectiveness from 'being prepared'

In the previous analysis, the effectiveness of 'being prepared' was assumed to be t hat used in the base-case analysis. However, there is a lack of evidence as to whether 'being prepared' does lead to such a r eduction in 'adverse outcomes'. In this analysis we assume that the risk of an 'adverse outcome' in a case of morbidly adherent placenta is 20% if not prepared compared with a risk of 10% if prepared. In other words, we assume here that correctly identifying cases has a smaller benefit in terms of averting 'adverse outcomes'. The 'downstream' cost of an 'adverse outcome' is varied between £0 and £100,000 and the QALY loss from an 'adverse outcome' is varied between 0.0 and 25.0. This analysis for ultrasound plus MRI relative to 'do nothing' is displayed in Figure 13.8 and for MRI alone relative to ultrasound plus MRI in Figure 13.9.

Figure 13.8 Cost effectiveness thresholds for ultrasound plus MRI relative to 'do nothing' assuming that the risk of an 'adverse outcome' when not prepared is 20%

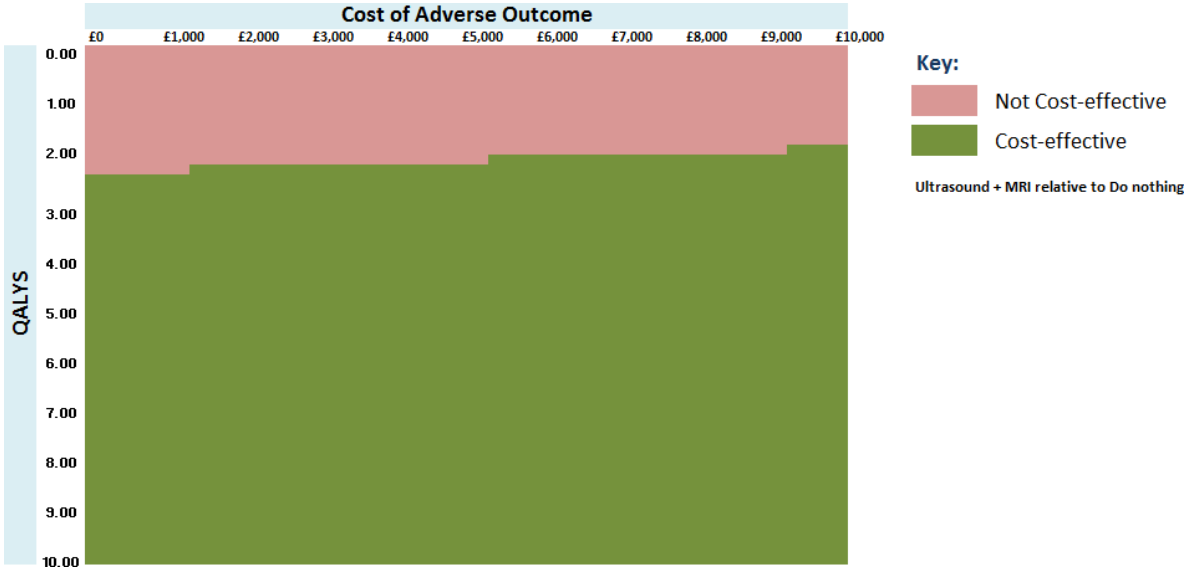
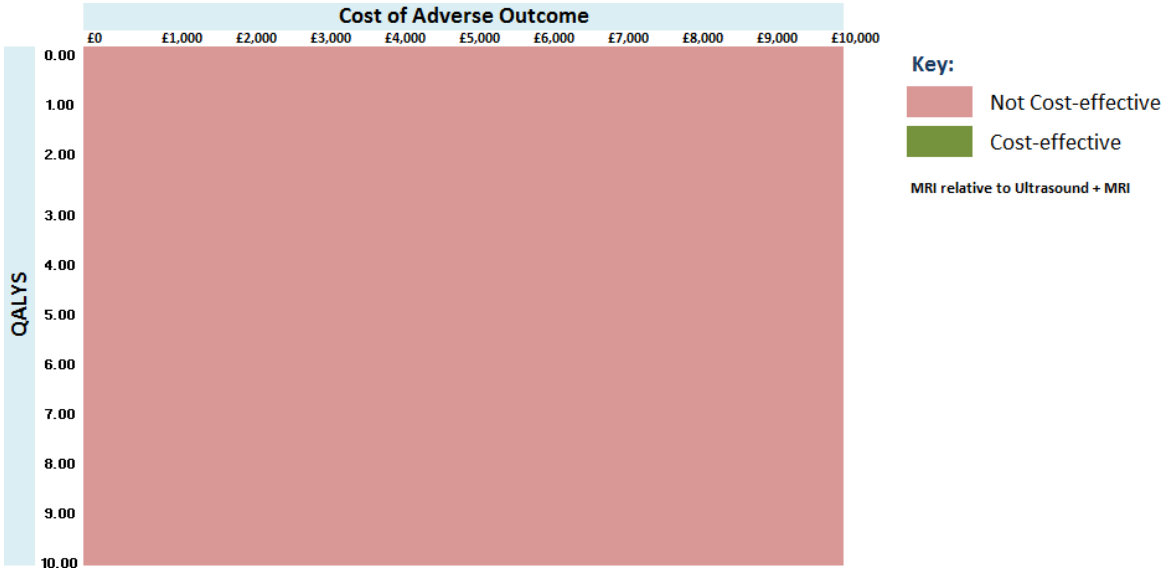


Figure 13.9 Cost effectiveness thresholds for MRI relative to ultrasound plus MRI assuming that the risk of an 'adverse outcome' when not prepared is 20%



Discussion

Caution needs to be exercised in interpreting the results of this analysis given the 'what-if' approach. Nevertheless, it does give some insights into the cost effectiveness of different diagnostic strategies for morbidly adherent placenta. First, there is good evidence on the prevalence of morbidly adherent placenta in women with placenta praevia. The prevalence is quite low and therefore the false positive rate is likely to be an i mportant determinant of cost effectiveness. As a r esult, the strategy of ultrasound was dominated in most of the above analyses. This was because it had a relatively high false positive rate, which meant lower diagnostic costs were more than offset by higher 'preparedness' costs, and i ts lower sensitivity meant that fewer 'adverse outcomes' were prevented than in other diagnostic strategies. Only when the prevalence was set to an unrealistically high level did ultrasound alone become the cheapest diagnostic strategy.

The results also suggest a potential advantage of the sequential ultrasound plus MRI strategy compared to MRI alone. By testing ultrasound positives with MRI to confirm the diagnosis, the false positives are removed. The additional costs of the MRI test are more than offset by the reduction in unnecessary 'preparedness'. On the other hand, the actual number of MRI tests undertaken is much less than occurs with a strategy based on MRI alone: because of the substantial difference in costs between an ultrasound and MRI, this means that the sequential strategy has markedly lower diagnostic costs, even if the absolute number of tests undertaken is higher. Furthermore, although true positives are missed because of the lower sensitivity of ultrasound compared to MRI, the low prevalence and the fact that the ultrasound detects 92% of cases means that the absolute difference in missed cases is very small. Therefore, for MRI alone to be cost effective, 'being prepared' would have to substantially reduce the risk of 'adverse outcomes' and/or there would have to be large QALY losses and 'downstream' costs associated with 'adverse outcomes' in order to make the higher costs worthwhile. This is well illustrated in Figures 13.7 and 13.9.

Figures 13.8 and 13.10 show that a much lower QALY gain and 'downstream' saving is necessary for ultrasound plus MRI to be considered cost effective relative to 'do nothing'. Of course, this is predicated on the point estimates of test accuracy used in the model being a good approximation of their 'true' value. Sensitivity analysis was not undertaken on d iagnostic test parameters as these inputs had at least some evidential basis and this was considered very much a second order level of uncertainty compared to the effectiveness of 'being prepared', the QALY loss and 'downstream' costs of 'adverse outcomes'. Were the diagnostic accuracy values found to be substantially different then the 'what-if' results would all differ. Nevertheless, it should be remembered that the 'what-if' analyses do have some uncertainty associated within them for this reason.

Figures 13.5 and 13.6 suggest that the model output is not that sensitive to the costs of an ‘adverse outcome’. This is principally due to the low prevalence of morbidly adherent placenta. Nevertheless, even at low prevalence, Tables 13.5 and 13.6 suggest that the QALY gained from an av erted ‘adverse outcome’ is likely to be an important determinant of cost effectiveness. Clearly, any QALY gain also depends on the effectiveness of ‘being prepared’ in averting ’adverse outcomes’.

Conclusion

An absence of evidence on a number of key parameters means that firm conclusions about the cost effectiveness of different diagnostic strategies cannot be reached from this model. However, the model does use a ‘what-if’ approach to show the scenarios in which different strategies would be cost effective. Clearly, if ‘being prepared’ confers no benefit to mother and child, then no diagnostic strategy is likely to be cost effective unless society places a very high value on providing information to the woman. At this stage there is no evidence to quantify the extent to which ‘being prepared’ does improve outcomes, but the expert and consensus opinion of the GDG members is that some improvement in outcomes is likely to result from ‘being prepared’.

However, even if ‘being prepared’ does confer a benefit, that is a necessary but not sufficient condition for diagnosis to be cost effective. In addition, the benefit must be worth the additional costs involved in which case adverted ‘adverse outcomes’ must also yield a s ufficiently large QALY gain and/or ‘downstream’ saving. Again, this is an unknown, but although current UK practice varies, it does involve diagnostic strategies to diagnose morbidly adherent placenta. Furthermore, it is plausible to anticipate that there would be some QALY gain and ‘downstream’ saving from averting ‘adverse outcomes’. Therefore, the GDG recommendation of the ultrasound plus MRI strategy seems reasonable based on this analysis.

Ultrasound alone is likely to be dominated because of the high false positive rate associated with a test specificity of 68%. On the other hand, MRI alone is more expensive than a sequential test strategy and sensitivity analysis suggested large treatment effect sizes, QALY losses and ‘downstream’ savings from ‘adverse outcomes’ would be necessary to justify the additional diagnostic and ‘preparedness’ costs. Furthermore, there could be capacity constraints in recommending this strategy and therefore such a recommendation would be difficult to justify in the absence of good cost effectiveness evidence. On the other hand, much smaller benefit from diagnosis is required for ultrasound plus MRI to be cost effective relative to no diagnosis. Therefore, while further evidence is required, a recommendation of ultrasound plus MRI seems to make pragmatic sense given current practice, GDG opinion and the insights available from this ‘what-if’ modelling approach.

13.3 Cost effectiveness of planned vaginal birth versus maternal request caesarean section

Introduction

Many developed countries have experienced rising rates of caesarean section. In England, CS rates have increased from 9.0% in 1980 to 24.6% in 2008–09 (Bragg et al., 2010). While some of the change is likely to be explained by changes in the case-mix of women giving birth (increasing maternal age at first pregnancy, for example) and improvements in technology making the operation safer, there is also evidence of a dr amatic increase in CS rates among women with no i ndicated medical risk (Zupancic, 2008).

A number of commentators have expressed concern about the economic implications of these trends and the issue is potentially an important one given scarce resources (Zupancic, 2008; Druzin and El-Sayed, 2006). Data from NHS Reference Costs shows that CS is generally more expensive than vaginal birth. This is consistent with other cost comparisons of different modes of birth (Allen et al., 2005; Druzin and El-Sayed, 2006). Furthermore, CS is not without risk and it is frequently suggested that it leads to worse maternal and infant outcomes in the current pregnancy and in any subsequent pregnancies. If CS typically has higher costs and worse outcomes, then CS without any indicated medical risk may indicate an inefficient use of resources. In this case, it might be reasonably argued that maternal request for CS in the absence of medical indication should not be routinely granted in a publicly funded healthcare system, with the opportunity costs implied.

However, there are others who have argued that the cost effectiveness issue is perhaps not as straightforward. First, comparisons of planned CS and planned vaginal birth often do not exclude those with an obstetric indication for CS. Such comparisons are therefore not done on a like-for-like basis and it is, of course, to be expected that the subset with indications for CS are likely to experience more complications and concomitant costs, as they are inherently higher risk pregnancies. Second, unplanned CS is more expensive than 'elective' caesarean and this is a relatively common occurrence for planned vaginal birth but unusual when CS is planned. Furthermore, unplanned CS has the worst maternal and infant outcomes of all modes of birth. Normal vaginal birth is not risk free and some adverse outcomes, such as urinary incontinence, occur more frequently in women who give birth vaginally (Thom & Rortveit, 2010).

A literature search identified two primary research papers which evaluated the cost effectiveness of maternal request CS (Xu et al., 2010; Culligan et al., 2005), although there were a number of other studies comparing costs. One US study (Xu et al., 2010) used a Monte Carlo simulation decision model to compare the cost effectiveness of maternal request CS with a trial of labour (TOL) in primigravid women without a medical or obstetric indication for CS. In particular, the authors stated that they wanted to consider the lifetime management of pelvic floor disorders. The model was restricted to women having a single lifetime birth (accounting for 21.6% of parous women in the USA) and did not consider any impact that the mode of birth for the primigravid pregnancy may have on subsequent pregnancies. In addition to pelvic floor complications, the analysis also included other maternal and perinatal mortalities. Costs were calculated using a societal perspective. This study did not reveal a clearly preferred mode of birth based on cost effectiveness analysis, although the authors reported that when compared to a t rial of labour, the probability of maternal request CS being cost effective was 82% using a societal willingness to pay for a QALY threshold of $50,000.

Another US study (Culligan et al., 2005) used a decision analysis to evaluate planned CS to prevent anal incontinence and brachial plexus injuries associated with macrosomia. A population at risk of a macrosomic baby was identified using an ultrasound at a gestational age of 39 weeks. The authors argued that such a policy would be cost effective, producing cost savings and net QALY gains.

Neither of these studies alone or in combination was deemed adequate to make recommendations for the NHS. First, one of the studies (Culligan et al., 2005) focuses on a population with an obstetric indication and in that sense is not relevant to the question being addressed. Second, both are US studies and it is well recognised that treatment costs differ between the UK and the USA, often substantially. Third, while one study (Xu et al., 2010) was based on published literature, the evidence was not clearly retrieved in a systematic view and, unlike this guideline, reviewed outcomes were not based on planned mode of birth. Nor did the study adopt a health service cost perspective which might have been consistent with the NHS and personal social services perspective recommended in the NICE guidelines manual (NICE, 2009).

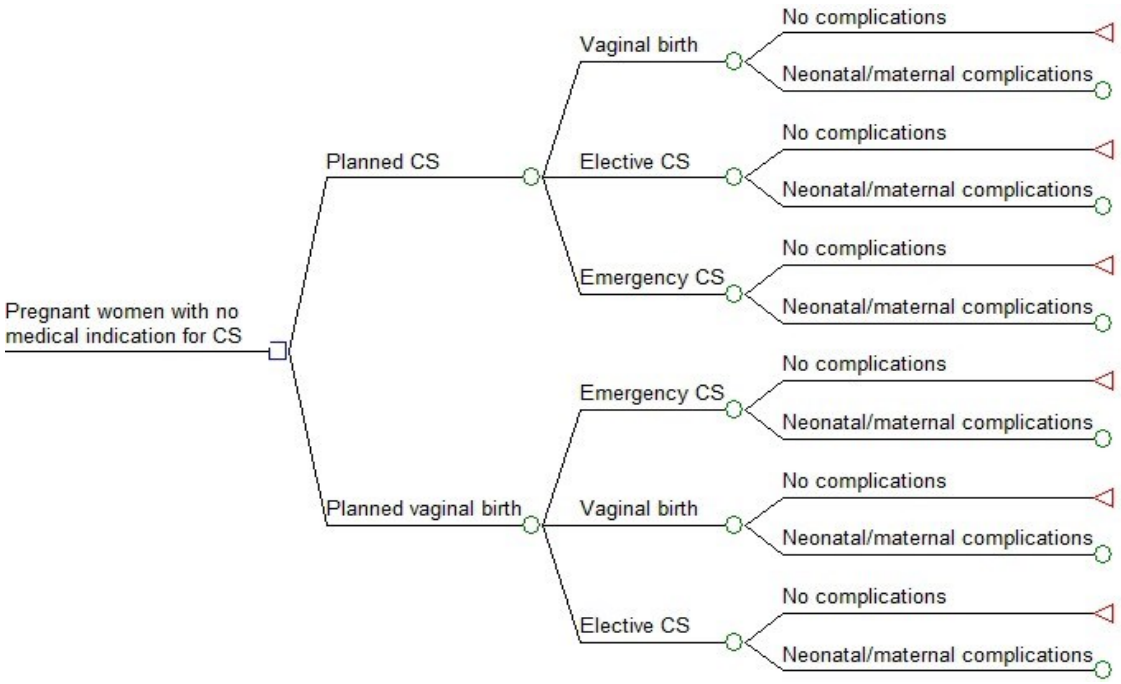
Therefore a model was developed for this guideline to assess the cost effectiveness of planned vaginal birth versus planned CS in primiparous women without an obstetric indication for CS.

Method

A cost utility analysis was undertaken using a decision analytic model developed in Microsoft Excel® to compare the cost effectiveness of planned vaginal birth versus planned CS in England and Wales. The population modelled was women without any obstetric indication for CS and not having had a previous CS. The intention is that the population does not differ systematically by mode of birth if vaginal birth is not contraindicated for women having planned CS.

The basic structure of the model is illustrated in Figure 13.10. As well as considering the costs of modes of birth, we also aim to evaluate the 'downstream' impact on costs and health-related quality of life arising from adverse events.

Figure 13.10 The decision tree for comparison of planned vaginal birth with maternal request CS



This analysis was undertaken from the perspective of the NHS and personal social services which is in accordance with NICE guidelines methodology (NICE, 2009). Costs and benefits are compared using standard methods of incremental analysis of costs and benefits. Costs were based on 2009/10 prices. A number of sensitivity analyses were undertaken to assess the impact that changes in the base case assumptions would have on the model's results.

The cost of method of birth

The cost of actual vaginal birth, planned CS and unplanned CS was calculated using NHS Reference Costs 2009/10. Data on the number of cases were used to calculate a mean weighted cost for each mode of birth. The weighted mean costs were £1512 for a vaginal birth, £2369 for a planned CS and £3042 for an unplanned CS as shown in Tables 13.7 to 13.9. However, the costs of a planned mode of birth will depend on the actual mode of birth: see Table 13.10. For example, it is estimated that 10% of planned vaginal births will result in an unplanned CS.

A weighted mean cost for each planned mode of birth is then derived according to the relative proportion of different modes of birth occurring for each planned method: see Table 13.11. The costs of CS will be based on all women having CS, including those with an obstetric indication. This may influence both the weights applied to different types of CS delivery and their costs. However, good quality UK cost data for CS performed solely on the basis of maternal request is not currently available.

Table 13.7 Vaginal birth costs

Category	Birth details	Cases	Cost	Weighted cost
Elective inpatient	Normal birth with complications (CC)	158	£1558	£0.51
Elective inpatient	Normal birth without CC	1101	£1151	£2.61
Elective inpatient	Normal birth with epidural with CC	13	£1827	£0.05
Elective inpatient	Normal birth with epidural without CC	51	£1260	£0.13

Category	Birth details	Cases	Cost	Weighted cost
Elective inpatient	Normal delivery with induction with CC	740	£2109	£3.22
Elective inpatient	Normal birth with induction without cc	2503	£1306	£6.74
Elective inpatient	Normal birth with postpartum surgical intervention	173	£1964	£0.70
Elective inpatient	Assisted birth with CC	29	£2366	£0.14
Elective inpatient	Assisted birth without CC	58	£1374	£0.16
Elective inpatient	Assisted birth with epidural with CC	28	£2376	£0.14
Elective inpatient	Assisted birth with epidural without CC	54	£1421	£0.16
Elective inpatient	Assisted delivery with induction with CC	314	£2307	£1.49
Elective inpatient	Assisted birth with induction without CC	445	£1631	£1.50
Elective inpatient	Assisted birth with postpartum surgical intervention	119	£2374	£0.58
Non-elective (long stay)	Normal birth with complications (CC)	18,298	£2138	£80.62
Non-elective (long stay)	Normal birth without CC	63,195	£1624	£211.49
Non-elective (long stay)	Normal birth with epidural with CC	2258	£2280	£10.61
Non-elective (long stay)	Normal birth with epidural without CC	5307	£1745	£19.08
Non-elective (long stay)	Normal birth with induction with CC	29,101	£2496	£149.68
Non-elective (long stay)	Normal birth with induction without cc	56,705	£1831	£213.96
Non-elective (long stay)	Normal birth with postpartum surgical intervention	12,114	£2272	£56.72
Non-elective (long stay)	Assisted birth with CC	3781	£2449	£19.08
Non-elective (long stay)	Assisted birth without CC	7012	£1864	£26.93
Non-elective (long stay)	Assisted birth with epidural with CC	3137	£2491	£16.10
Non-elective (long stay)	Assisted birth with epidural without CC	4874	£2088	£20.97
Non-elective (long stay)	Assisted birth with induction with CC	15,496	£2683	£85.68
Non-elective (long stay)	Assisted birth with induction without CC	19,401	£2168	£86.68
Non-elective (long stay)	Assisted birth with postpartum surgical intervention	6202	£2618	£33.46
Non-elective (short stay)	Normal birth with complications (CC)	14,594	£977	£29.38
Non-elective (short stay)	Normal birth without CC	126,917	£908	£237.48
Non-elective (short stay)	Normal birth with epidural with CC	942	£1031	£2.00
Non-elective (short stay)	Normal birth with epidural without CC	5195	£977	£10.46
Non-elective (short stay)	Normal birth with induction with CC	9503	£1070	£20.95
Non-elective (short stay)	Normal birth with induction without CC	50,040	£989	£101.98
Non-elective (short stay)	Normal birth with postpartum surgical intervention	4890	£1203	£12.12
Non-elective (short stay)	Assisted birth with CC	1486	£1128	£3.45
Non-elective (short stay)	Assisted birth without CC	5889	£1060	£12.86

Category	Birth details	Cases	Cost	Weighted cost
Non-elective (short stay)	Assisted birth with epidural with CC	768	£1249	£1.98
Non-elective (short stay)	Assisted birth with epidural without CC	2355	£1159	£5.62
Non-elective (short stay)	Assisted birth with induction with CC	2282	£1219	£5.73
Non-elective (short stay)	Assisted birth with induction without CC	6609	£1138	£15.50
Non-elective (short stay)	Assisted birth with postpartum surgical intervention	1067	£1345	£2.96
Day	Normal birth with complications (CC)	5	£1484	£0.02
Day	Normal birth without CC	25	£980	£0.05
Day	Normal birth with induction with CC	3	£1074	£0.01
Day	Normal birth with induction without cc	10	£1350	£0.03
Day	Normal birth with postpartum surgical intervention	3	£1072	£0.01
Day	Assisted birth with CC	3	£1656	£0.01
Day	Assisted birth without CC	12	£914	£0.02
	Assisted birth with induction without CC	2	£2287	£0.01
Total		**485,267**		**£1512**

Table 13.8 Planned caesarean section (CS) costs

Category	Delivery details	Cases	Cost	Weighted cost
Elective	Planned lower uterine CS	1897	£1822	£58.23
Non-elective (long stay)	Planned lower uterine CS	54,206	£2441	£2209.09
Non-elective (short stay)	Planned lower uterine CS	3249	£1488	£81.45
Day case	Planned lower uterine CS	7	£2011	£0.24
Total		**59,359**		**£2369**

Table 13.9 Unplanned caesarean section (CS) costs

Category	Delivery details	Cases	Cost	Weighted cost
Elective	Emergency or upper uterine CS	1005	£2979	£34.11
Non-elective (long stay)	Emergency or upper uterine CS	84,286	£3088	£2965.19
Non-elective (short stay)	Emergency or upper uterine CS	2475	£1496	£42.18
Day case	Emergency or upper uterine CS	11	£2535	£0.32
Total		**87,777**		**£3042**

Table 13.10 Proportion of actual modes of birth for planned vaginal and caesarean section (CS) birth

Planned method	Actual method	%	Source
Vaginal	Vaginal	85	NHS Reference Costs 2009/10*
Vaginal	Unplanned CS	15	NHS Reference Costs 2009/10*
CS	Vaginal	2	Caesarean Section Guideline 2004
CS	Unplanned CS	2	Caesarean Section Guideline 2004
CS	CS	96	Caesarean Section Guideline 2004

Table 13.11 Weighted mean cost of birth by planned mode of birth

Planned method	Weighted mean cost	Notes
Vaginal	£1741	(0.85 x £1512) + (0.15 x £3042)
CS	£2365	(0.02 x £1512) + (0.02 x £3042) + (0.96 x £2369)

Downstream costs

If the evaluation was restricted solely to birth costs, then the true opportunity cost of choosing one mode of birth over another is likely to be misreported, given that there are a number of adverse maternal and neonatal outcomes associated with birth. This analysis estimates 'downstream' costs associated with adverse outcomes by using the clinical review of the risks of planned vaginal birth and planned CS undertaken for this guideline. The outcomes are limited to those for which there was reported data in the review, which focused on outcome by planned, as opposed to actual, mode of birth. For some of these outcomes, results from more than one study were presented. However, it wasn't reasonable to pool results from these studies and in such cases the model used the risk from the largest study. While this provides a consistent approach, it doesn't necessarily mean that the bigger study estimated the true risk more accurately. Sensitivity analysis could be used to test whether using estimates based on other studies made important changes to the model outcome.

The cost of each adverse outcome is shown in Table 13.12. A weighted mean cost associated with adverse outcomes can then be calculated based on the risk of that outcome, as shown in Table 13.13. These costs are then added to the planned birth cost to give the total estimated cost of planned vaginal birth and planned CS.

In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-years-of-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect. Furthermore, to the economy as a whole, litigation costs and compensation for harm are "transfer payments" rather than "costs", as they primarily result in a redistribution of income and wealth rather than the use of finite resources.

* It is assumed that a planned vaginal birth can only result in an actual vaginal delivery or emergency CS. Therefore, we assume that 59,359 births (see Table 13.18) were planned CS and that these accounted for 96% of planned CS births (Caesarean Section Guideline 2004), giving an estimate of 61,832 planned CSs in total. From the Caesarean Section Guideline 2004 we assume that 2% of planned CSs result in an emergency section (0.02 x 61,382 = 1228) and that 2% of planned CSs result in an actual vaginal delivery (1228). From Tables 13.7 we therefore estimate the number of actual vaginal deliveries that were planned (485,267 – 1228 = 484,039) and from Table 13.9 the number of planned vaginal deliveries resulting in emergency CS (87,777 – 1228 = 86,549)

Table 13.12 The costs of adverse birth outcomes*

Outcome	Cost	Source	Notes
Maternal death	£0	Assumption	It is assumed that these costs would be included within birth costs
Injury to bladder, ureter, genital tract	£504	NHS Reference Costs 2009/10	HRG Currency Code LB15D/E Bladder minor procedures
Hysterectomy	£2999	NHS Reference Costs 2009/10	HRG Currency Code MA07C/D Upper genital tract major procedures
Deep vein thrombosis (DVT)	£686	NHS Reference Costs 2009/10	HRG Currency Code QZ20Z
Blood transfusion	£863	Varney et al., 2003	£635 for red blood cells transfusion at 2000/01 prices. Updated using HCHS Index (Curtis, 2009)
Early postpartum haemorrhage (PPH)	£0	Assumption	It is assumed that these costs would be included within birth costs
Infection (wound and post partum)	£0	Assumption	It is assumed that these costs would be included within birth costs
Anaesthetic complication	£0	Assumption	It is assumed that these costs would be included within birth costs
Uterine rupture	£0	Assumption	It is assumed that these costs would be included within birth costs
Intraoperation trauma	£0	Assumption	It is assumed that these costs would be included within birth costs
Assisted ventilations or intubations	£1962	NHS Reference Costs 2009/10	HRG Currency Code DZ27A/B/C Respiratory failure with intubation
Acute renal failure	£3120	NHS Reference Costs 2009/10	HRG Currency Code PA38D Renal disease with renal failure with length of stay 1 day or more
Cardiac arrest	£1207	NHS Reference Costs 2009/10	HRG Currency Code EB05Z
Obstetric shock	£1297	NHS Reference Costs 2009/10	HRG Currency Code EB03I Heart failure or shock

* Costs based on NHS Reference Costs are generally a weighted average of all costs given for a particular currency code. It is weighted by the cases or 'Activity' levels shown in the NHS Reference costs

Outcome	Cost	Source	Notes
Neonatal mortality	£1150	NHS Reference Costs 2009/10	HRG Currency Code PB01Z Major neonatal diagnoses
Hypoxic-ischemic encephalopathy (HIE) (central nervous system [CNS] depression, seizures, pH < 7)	£1150	NHS Reference Costs 2009/10	HRG Currency Code PB02Z Major neonatal diagnoses
Intracranial haemorrhage	£1150	NHS Reference Costs 2009/10	HRG Currency Code PB02Z Major neonatal diagnoses
Neonatal respiratory morbidity composite of respiratory morbidity	£1150	NHS Reference Costs 2009/10	HRG Currency Code PB02Z Major neonatal diagnoses
Neonatal intensive care unit (NICU) admission	£1087	NHS Reference Costs 2009/10	HRG Currency Code XA01Z Neonatal critical care intensive care

Table 13.13 The weighted cost of adverse outcomes by planned mode of birth

Outcome	Cost	Vaginal birth risk	Weighted vaginal cost	CS risk	Weighted CS cost
Maternal death	£0	0.00002	£0	0.00000	£0.00
Injury to bladder, ureter, genital tract	£504	0.00984	£4.96	0.00000	£0.00
Hysterectomy	£2999	0.00016	£0.48	0.00058	£1.74
DVT	£686	0.00027	£0.19	0.00060	£0.41
Blood transfusion	£863	0.00065	£0.56	0.00024	£0.21
Early PPH	£0	0.06198	£0.00	0.03883	£0.00
Infection (wound and post partum)	£0	0.00211	£0.00	0.00601	£0.00
Anaesthetic complication	£0	0.00209	£0.00	0.00528	£0.00
Uterine rupture	£0	0.00029	£0.00	0.00015	£0.00
Intraoperation trauma	£0	0.00288	£0.00	0.00139	£0.00
Assisted ventilations or intubations	£1962	0.00006	£0.12	0.00013	£0.26
Acute renal failure	£3120	0.00015	£0.47	0.00004	£0.12
Cardiac arrest	£1207	0.00039	£0.47	0.00190	£2.29
Obstetric shock	£1297	0.00019	£0.25	0.00006	£0.08
Neonatal mortality	£1150	0.00071	£0.82	0.00173	£1.99
HIE (CNS depression, seizures, pH < 7)	£1150	0.00234	£2.69	0.00191	£2.20
Intracranial haemorrhage	£1150	0.00026	£0.30	0.00000	£0.00
Neonatal respiratory morbidity composite of respiratory morbidity	£1150	0.11528	£132.57	0.12046	£138.53
NICU admission	£1087	0.06308	£68.57	0.13889	£150.97
Total			**£212.45**		**£298.80**

CNS central nervous system; DVT deep vein thrombosis; HIE Hypoxic-ischemic encephalopathy; NICU neonatal intensive care unit; PPH postpartum haemorrhage

QALYs

Cost effectiveness is determined by effects as well as costs and t his requires estimation of any differences between planned modes of birth in terms of health-related quality of life. A health state utility for a particular outcome is estimated and combined with the duration in this state to estimate a quality adjusted life year (QALY); NICE's preferred outcome measure for economic evaluation. All QALYs are discounted at an annual rate of 3.5% in accordance with NICE guidance.

Table 13.14 shows the estimated QALYs allocated to each adverse pregnancy outcome, using only those outcomes for which data was reported in the clinical review. Then, using the clinical review undertaken for this guideline, the risks of these adverse outcomes for each mode of birth can be used to calculate a weighted QALY loss associated with each planned mode of birth: see Table 13.15.

No QALY was assigned to the actual mode of birth, although there are studies which have done so (Xu et al., 2010; Vandenbussche et al., 1999; Turner et al., 2008). This was because duration in this birth 'state' is short and t he concomitant QALY loss would be ne gligible. Similarly, the base case QALY loss for many of the adverse pregnancy outcomes are set to zero, because although there may be an important health state utility loss associated with that outcome, the duration of that loss is likely to be short, in which case there will only be a very small associated QALY loss.

Table 13.14 The QALY loss of adverse birth outcomes

Outcome	QALY loss	Notes
Maternal death	24.80	This is based on the 53 years remaining life expectancy of a mother (ONS, 2011) giving birth at an age of 29.4 years, the mean maternal age at birth (ONS, 2010). It assumes remaining years are lived in full health.
Injury to bladder, ureter, genital tract	0.00	
Hysterectomy	9.79	This is based on a utility loss of 0.395 (Xu et al., 2010) which is assumed to be lifelong and is therefore calculated for the remaining 53 years life expectancy of a mother in the same way as maternal death.
DVT	0.00	
Blood transfusion	0.00	
Early PPH	0.00	
Infection (wound and postpartum)	0.00	
Anaesthetic complication	0.00	
Uterine rupture	0.00	
Intraoperation trauma	0.00	
Assisted ventilations or intubations	0.00	
Acute renal failure	0.00	
Cardiac arrest	0.00	
Obstetric shock	0.00	
Neonatal mortality	27.68	This is based on a l ife expectancy of 80 years at birth (ONS, 2011) and assumes remaining years are lived in full health.
HIE (CNS depression, seizures, pH < 7)	4.43	This is based on a l ife expectancy of 80 years at birth (ONS, 2011) and using mild cerebral palsy as a proxy to estimate health state utility loss. We assume a health state utility loss of 0.16 (Heintz et al., 2008).

Outcome	QALY loss	Notes
Intracranial haemorrhage	0.00	
Neonatal respiratory morbidity composite of respiratory morbidity	0.00	
NICU admission	0.00	

CNS central nervous system; DVT deep vein thrombosis; HIE Hypoxic-ischemic encephalopathy; NICU neonatal intensive care unit; ONS Office for National Statistics; PPH postpartum haemorrhage; QALY quality adjusted life year

Table 13.15 The weighted QALY loss of adverse outcomes by planned mode of birth

Outcome	QALY loss	Vaginal risk	Weighted vaginal QALY loss	CS risk	Weighted CS QALY loss
Maternal death	24.80	0.00002	0.00050	0.00000	0.00000
Injury to bladder, ureter, genital tract	0.00	0.00984	0.00000	0.00000	0.00000
Hysterectomy	9.79	0.00016	0.00157	0.00058	0.00568
DVT	0.00	0.00027	0.00000	0.00060	0.00000
Blood transfusion	0.00	0.00065	0.00000	0.00024	0.00000
Early PPH	0.00	0.06198	0.00000	0.03883	0.00000
Infection (wound and post partum)	0.00	0.00211	0.00000	0.00601	0.00000
Anaesthetic complication	0.00	0.00209	0.00000	0.00528	0.00000
Uterine rupture	0.00	0.00029	0.00000	0.00015	0.00000
Intraoperation trauma	0.00	0.00288	0.00000	0.00139	0.00000
Assisted ventilations or intubations	0.00	0.00006	0.00000	0.00013	0.00000
Acute renal failure	0.00	0.00015	0.00000	0.00004	0.00000
Cardiac arrest	0.00	0.00039	0.00000	0.00190	0.00000
Obstetric shock	0.00	0.00019	0.00000	0.00006	0.00000
Neonatal mortality	27.68	0.00071	0.01965	0.00173	0.04789
HIE (CNS depression, seizures, pH < 7)	4.43	0.00234	0.01037	0.00191	0.00846
Intracranial haemorrhage	0.00	0.00026	0.00000	0.00000	0.00000
Neonatal respiratory morbidity composite of respiratory morbidity	0.00	0.11528	0.00000	0.12046	0.00000
NICU admission	0.00	0.06308	0.00000	0.13889	0.00000
Total			**0.03209**		**0.06203**

CNS central nervous system; DVT deep vein thrombosis; HIE Hypoxic-ischemic encephalopathy; NICU neonatal intensive care unit; PPH postpartum haemorrhage; QALY quality adjusted life year

Conceptually it might be considered easier to compare incremental QALY gains rather than QALY losses. Therefore, the weighted QALY losses from adverse maternal and neonatal outcomes are subtracted from the lifetime QALY of mother and i nfant* in the absence of any adverse outcomes.† These are based on the remaining life expectancy of the mother (47 years) and the life expectancy at birth of the infant (80 years) estimated from Office of National Statistics (ONS) interim life tables. It is assumed that remaining life years are lived in full health and that QALYs are discounted using an annual discount rate of 3.5% (NICE, 2009). The QALYs associated with planned vaginal birth and planned CS are given in Table 13.16.

Table 13.16 Combined maternal/infant QALY by planned mode of birth

Planned mode of birth	QALY
Vaginal	51.448
Caesarean section	51.418

QALY quality adjusted life year

Results

The results are shown in Table 13.17. The base case result suggests that the birth cost of a planned vaginal birth is £700 cheaper than a planned CS. For an annual birth rate of 706,000 (ONS) this might suggest that approximately £4.9 million could be saved for every one percentage point reduction in CS rate, providing that the change occurred in a population similar to that used in this model.

Table 13.17 Results of base case analysis

Planned mode of birth	Birth cost	Adverse outcomes cost	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER
Vaginal	£1,741	£212	£1,954	-	51.448	0.030	Dominant
Caesarean section	£2,365	£299	£2,664	£710	51.418	-	Dominated

ICER incremental cost effectiveness ratio; QALY quality adjusted life year

However, beyond the immediate term it is more complicated than this. Using the base case model inputs, the results show that the savings might be even greater when adverse outcomes are considered, although uncertainty surrounds the point estimates of risks on w hich these costs are based. Furthermore, there are other adverse outcomes not included within the clinical review which, if included, could possibly yield a different result.

Due to the relative infrequency of adverse outcomes having a major QALY loss, there is only a small difference in QALYs between the two modes of birth in the base case analysis. Here, it slightly favoured planned vaginal birth primarily because of a c onsiderably lower neonatal mortality rate. Planned vaginal birth is said to be dominant, being cheaper and yielding a higher QALY.

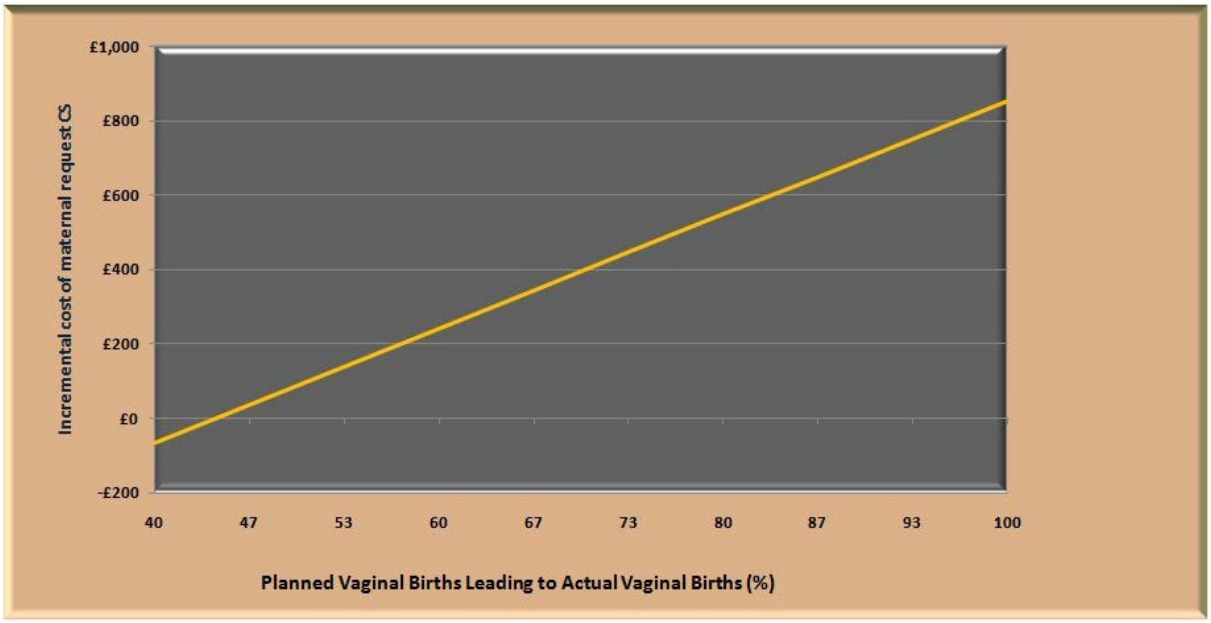
Sensitivity analysis

Varying actual vaginal birth rate from planned vaginal birth

In the one-way sensitivity analysis shown in Figure 13.11, we see how the actual vaginal birth rate determines the incremental costs of maternal request CS. Figure 13.11 shows that if the actual rate of vaginal birth for planned vaginal birth fell to 44% or below, then maternal request CS would become the cheapest birth option when only the immediate birth costs are considered. However, the current CS rate in England is 24.6% (Department of Health, 2009) and therefore, given that a large proportion of these will have a medical or obstetric indication, the lower bound of planned vaginal births which result in actual vaginal birth must be at least 75.4%.

* Singleton pregnancies are assumed
† Total lifetime QALY of healthy mother and infant: 24.80 + 27.68 = 52.48

Figure 13.11 Incremental costs of maternal request caesarean section varying the percentage of planned vaginal births leading to actual vaginal birth



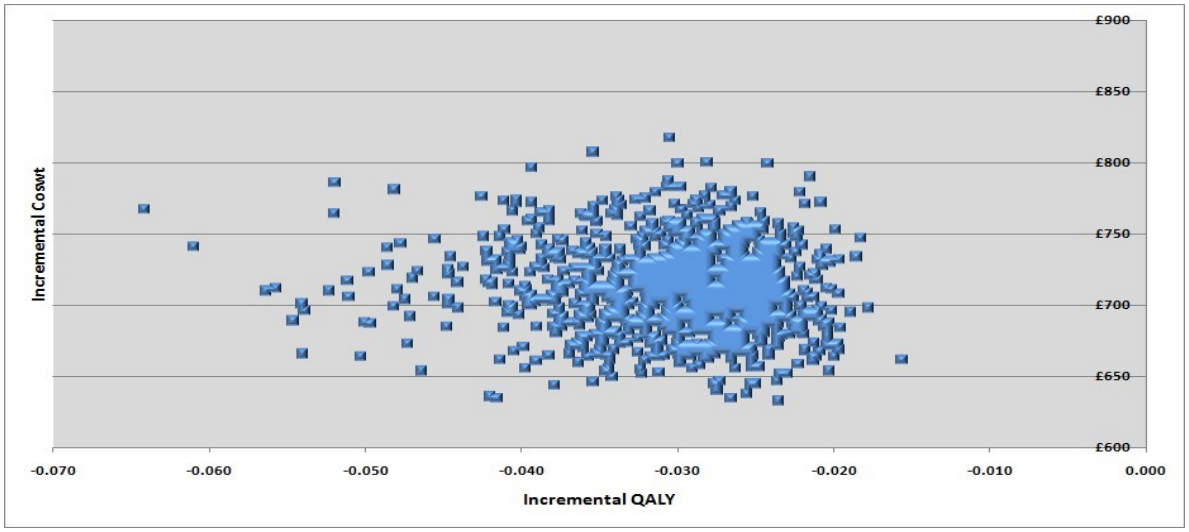
Probabilistic sensitivity analysis

The base case analysis is deterministic, using point estimates for the model's input parameters. However, it is usual practice in economic evaluation to address uncertainty in point estimate values through the use of sensitivity analysis. Where there are many input parameters, probabilistic sensitivity analysis is usually recommended to address uncertainty.

In the probabilistic analysis undertaken here, 1000 Monte Carlo simulations were run with the risks of adverse outcomes, included in the review reported for this guideline, sampled from a beta probability distribution, with the alpha parameter for each distribution given by the number of events and the beta parameter as the number of non-events. All other model inputs are fixed at their base case value, although the model allows the probabilistic analyses to be run with different values for these inputs. The results are shown in Figure 13.12.

In this analysis, maternal request CS had a higher incremental cost and a lower incremental QALY, suggesting that planned vaginal birth dominated maternal request CS with a probability of 100%.

Figure 13.12 Probabilistic sensitivity analysis of incremental costs and incremental QALYs of maternal request caesarean section



Introducing urinary incontinence as an adverse outcome

The base case analysis and sensitivity analyses above focused solely on adverse outcomes that were included in the review, a review which focused on reported outcomes according to the planned mode of birth. However, other studies have compared adverse outcomes by actual mode of birth and this was the approach in the previous version of this guideline. In these studies there are an increased number of reported adverse outcomes, particularly relating to a woman's pelvic floor. The model has been set up to allow analyses which include these additional adverse outcomes:

- iatrogenic surgical injury
- perineal and abdominal pain (4 months postpartum)
- pulmonary embolism
- faecal incontinence
- postnatal depression
- dyspareunia
- urinary incontinence.

In the default case, the risks, costs and QALY loss of all these adverse outcomes is set to zero but these assumptions can all be varied as part of a sensitivity analysis.

Here we explore the impact of introducing urinary incontinence to the analysis. Model inputs for this purpose were extrapolated from Xu et al.(2010).

Cost of stress urinary incontinence

Xu et al. (2010) assumes that only 61% of those with stress urinary incontinence seek health care. For those that do, an annual cost of £375 in routine care is assumed.[*,†] Assuming a life expectancy of 80 years and an age at birth of 29 years, these costs would continue for 50 years. It is additionally assumed that there is a di agnostic cost of £150 a nd that 18.2% of patients with stress urinary incontinence will have surgery at an age of 54 years at a cost of £6202. Discounting future costs at an annual 3.5% discount rate as recommended by NICE, the cost of stress urinary incontinence is estimated as shown in Table 13.18.

Table 13.18 Estimated costs of stress urinary incontinence

Care/intervention	Estimated cost
Routine care	£9163 x 0.61 = £5589
Diagnosis	£150 x 0.61 = £92
Surgery	£6202 x 0.182 = £1129
Total	**£6810**

QALY loss from urinary incontinence

Xu et al. (2010) reports a health state utility of 0.81 for stress urinary incontinence and 0.87 after successful surgery. We assume here that this represents a health state utility loss of 0.19 and 0.13 respectively. We follow Xu et al. in assuming that the 39% of women with stress urinary incontinence who do not seek health care suffer no lack of utility. It is assumed that 18.2% of women with stress urinary incontinence will have surgery and that it will be successful in 81.3% of these patients.

[*] This is likely to include private expenditure which wouldn't be counted using the NICE reference case
[†] http://www.expedia.co.uk/pub/agent.dll - accessed 21/01/2011 exhange rate $1 = £0.629683

Thus, the discounted QALY loss from stress urinary incontinence is calculated as:

Not seeking health care: 0.39 x 0 = 0.00 QALYs

No surgery: $(0.61 - 0.182) \times \sum_{n=0}^{50} (0.19 \div 1.035n) = 1.99$ QALYs

Unsuccessful surgery: $0.034 \times \sum_{n=0}^{50} (0.19 \div 1.035n) = 0.16$ QALYs

'Cure': $0.148 \times (\sum_{n=0}^{24} (0.19 \div 1.035n) + \sum_{n=25}^{50} (0.13 \div 1.035n)) = 0.62$ QALYs

This gives a total QALY loss of 2.77 QALYs.

Urinary incontinence risk

In its base case analysis, Xu et al. (2010) assumes that the probability of a w oman experiencing stress urinary incontinence is 19.9% for a s pontaneous vaginal birth, 21.8% for an i nstrumental vaginal birth, 11.5% for an unplanned CS and 10.0% for a CS on maternal request. Therefore, for the purposes of this sensitivity analysis, we can calculate the urinary incontinence risk for each mode of birth. The calculations are shown below and the results of this sensitivity analysis are shown in Table 13.19.

Planned vaginal

Using NHS Reference Costs 2009/10 activity data, normal birth accounts for 83.2% of vaginal births with the remaining 16.8% being assisted.

Weighted risk of actual vaginal birth: (0.832 x 0.90 x 0.199) + (0.168 x 0.90 x 0.218) = 0.182

Weighted risk of an unplanned CS: (0.10 x 0.115) = 0.0115

This gives a planned vaginal stress urinary incontinence risk of 0.194.

Maternal request caesarean section

Weighted risk of actual vaginal: (0.832 x 0.02 x 0.199) + (0.168 x 0.02 x 0.218) = 0.004

Weighted risk of an unplanned caesarean section: (0.02 x 0.115) = 0.002

Weighted risk of planned caesarean section: (0.96 x 0.10) = 0.096

This gives a maternal request CS stress urinary incontinence risk of 0.102.

Table 13.19 Results when urinary incontinence is included as an adverse outcome

Planned mode of birth	Birth cost	Adverse outcomes cost	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER
Vaginal	£1741	£1534	£3275	-	51.911	-	-
Caesarean section	£2365	£993	£3359	£84	52.135	0.224	£373 per QALY

ICER incremental cost effectiveness ratio; QALY quality adjusted life year

Including urinary incontinence greatly reduces the incremental costs of a maternal request CS, because the 'downstream' costs of a pl anned vaginal birth increase more due t o the higher risk of stress urinary incontinence with vaginal birth. Similarly, the greater reduction in health-related quality of life arising in women having a planned vaginal birth from stress urinary incontinence now leads to CS on maternal request having a higher QALY. An incremental cost-effectiveness ratio of £373 per QALY would suggest that a maternal request CS could be considered a cost-effective alternative to planned vaginal birth.

Discussion

The results presented in this analysis do not definitively determine the relative cost effectiveness of maternal request CS as opposed to planned vaginal birth. In terms of the immediate costs of birth, this model, using the most comprehensive and detailed NHS Reference Costs yet produced for modes of birth, does suggest that a planned vaginal birth is cheaper. The base case analysis suggests that the NHS could save in the region of £4.9 million in birth costs for every percentage point reduction in CS, at least if the reduction occurred in women with similar obstetric and medical characteristics to the model population. It is possible that the differential of £700 is over-stated, as the cost data for CS does also include CS where there was a medical or obstetric indication. As shown in the sensitivity analysis varying the proportion of planned vaginal births leading to actual births, the immediate costs of planned vaginal birth are likely to remain cheaper even if the base case proportion of actual vaginal births was over-stated.

The base case and pr obabilistic sensitivity analysis both suggested that planned vaginal birth was more cost effective and cheaper than maternal request CS. In a publicly funded health service, such a result can be used to justify a d ecision not to make CS available purely on g rounds of maternal request. In these analyses, planned vaginal birth was also cheaper in terms of the 'downstream' costs associated with adverse outcomes. Here the adverse outcomes were limited to those included in the review produced for this guideline, which in turn was based on studies reporting adverse outcomes based on pl anned mode of birth rather than actual mode of birth, although the former, if studied sufficiently, should implicitly capture the effects of actual birth. In addition to the cheaper costs of planned vaginal birth, the cost effectiveness was also driven by a smaller loss of QALYs with planned vaginal birth. The drivers of this are the increased relative risk of hysterectomy and neonatal mortality with maternal request CS. In the base case model, a planned vaginal birth had a hi gher maternal mortality than a maternal request CS, although higher maternal mortality for CS generally is often reported (Harper et al., 2003). Furthermore, one of the studies included in the clinical review undertaken for this guideline (Deneux-Tharaux, 2006a) reported higher maternal mortality for planned CS. We did not use the data from this study as where outcomes were reported in more than one study, our method was to use the largest study. However, if higher maternal mortality with planned CS is assumed, this simply strengthens the cost effectiveness conclusion of the base case analysis.

However, the risk could also have been evaluated by actual mode of birth rather than the planned mode of birth, as was the case with the previous version of this guideline. In such studies women are often reported at being at greater risk of urinary incontinence following vaginal birth, as was also reported in the previous version of this guideline. To address this issue, a sensitivity analysis was undertaken in which urinary incontinence was introduced as an adverse outcome. The model inputs for this adverse outcome were taken from or extrapolated from a s tudy by Xu et al. (2010) which suggested that if society was willing to pay $50,000 per QALY then there was an 82% probability that maternal request CS was cost effective for a primigravid woman without medical or obstetric indication and having only one childbirth in her lifetime. In this sensitivity analysis, the model suggested that maternal request CS would be cost effective even if remaining slightly more expensive as a result of the lower QALY loss arising from reduced rates of stress urinary incontinence. Clearly, there are other adverse outcomes besides urinary incontinence which were not reported in the clinical review for this guideline but which may also have a bearing on the cost effectiveness of the different modes of birth.

However, the Xu et al. (2010) study may also have its limitations, especially in the context of England and Wales. Costs differ substantially between the US and England and Wales. The costs they report, which include productivity losses, are different from those that would be used by an evaluation employing NICE methodology. Furthermore, while their parameter estimates were obtained from the published literature, there is no indication to suggest that these were retrieved in a systematic way. There are a num ber of studies which have contested the extent to which CS is protective against urinary stress incontinence, especially across the entire childbearing population (Nygaard, 2006). Others have acknowledged an increased short-term occurrence with vaginal birth but claim that severe symptoms do not differ by mode of birth (Press et al., 2007). To fully model the effect of stress urinary incontinence is incredibly complicated if it is accepted that there are differences by mode of birth. It essentially involves having a model for a complete disease pathway broken down by disease severity. Conservative and medical treatment alternatives exist for stress urinary incontinence and these are not included within the Xu et al. (2010) model.

Conclusion

This model suggests that the immediate birth costs are lower for planned vaginal delivery than they are for maternal request CS. However, the model does not conclusively demonstrate the cost effectiveness of one mode of birth over the other. Using the adverse outcomes data only included in the review produced for this guideline, planned vaginal birth does appear more cost effective but its cost effectiveness relative to maternal request CS is likely to be reduced to some extent if adverse outcomes such as urinary incontinence are included within the model.

Given these results, there is no strong health economic evidence which would lead to a revision of previously issued NICE guidance.

13.4 Cost effectiveness of vaginal birth after caesarean (VBAC) – one previous CS with no plans for further children

Introduction

The current guidance of the American College of Obstetricians and Gynaecologists is that, 'Attempting a vaginal birth after cesarean (VBAC) is a safe and appropriate choice for most women who have had a prior cesarean delivery, including for some women who have had two previous cesareans'. (ACOG, 2010)

In women having had a pr evious CS there are risks associated with both a trial of labour and with repeat CS. The greatest risk of adverse maternal outcomes occurs in a failed trial of labour. However, successful VBAC has the fewest complications and therefore the failure rate for trial of labour is likely to be an important determinant of the overall comparative risks of a trial of labour and repeat CS.

The previous CS guideline concluded that the cost effectiveness of a t rial of labour compared to a planned CS couldn't be 'categorically determined' with the results sensitive to the rates of adverse events.

Method

A cost utility analysis was undertaken using a decision analytic model developed in Microsoft Excel® to compare the cost effectiveness of VBAC versus planned CS in England and Wales in woman having one previous CS and with no plans for further children. As well as considering the costs of birth, we also aim to evaluate the 'downstream' impact on costs and health-related quality of life arising from adverse events.

This analysis was undertaken from the perspective of the NHS and personal social services which is in accordance with NICE guidelines methodology (NICE, 2009). Costs and benefits are compared using standard methods of incremental analysis of costs and benefits. Costs were based on 2009/10 prices. A number of sensitivity analyses were undertaken to assess the impact that changes in the base case assumptions would have on the model's results.

The cost of birth

The costs are the same as used in the model comparing the cost effectiveness of planned vaginal birth versus maternal request CS (see Section 13.3). As in the maternal request model, the cost of a planned birth depends on the actual mode of birth. For a planned VBAC the values are taken from the National Sentinel Caesarean Section Audit (Thomas J and Paranjothy S, 2001) which indicated that a trial of labour after CS had a 64% success rate. For a planned CS the rates for the different actual modes of birth are the same as used in the maternal request model. The default values for the actual birth method by planned method are shown in Table 13.20.

Table 13.20 Proportion of actual modes of birth for planned vaginal and caesarean section (CS) birth

Planned method	Actual method	%	Source
Vaginal	Vaginal	64	NSCSA (2001)
Vaginal	Unplanned CS	36	NSCSA (2001)
CS	Vaginal	2	As maternal request model (see Section 13.2)
CS	Unplanned CS	2	As maternal request model (see Section 13.2)
CS	CS	96	As maternal request model (see Section 13.2)

Downstream costs

In addition to the costs of birth this analysis estimates 'downstream' costs associated with adverse outcomes by utilising the clinical review of VBAC undertaken for this guideline. The outcomes are limited to those for which there was reported data in the review, which focused on outcome by planned, as opposed to actual, mode of birth. Most of the costs for these adverse outcomes were reported in Section 13.2. The additional cost for this analysis is shown in Table 13.21.

The GDG said that transient tachypnea would typically involve an admission to a neonatal intensive care unit and it was costed on this basis. The clinical review also reported bag and mask ventilation as an outcome but the GDG considered that the costs of this would be negligible. A weighted mean cost associated with adverse outcomes can then be calculated based on the risk of that outcome, as shown in Table 13.22. These costs are then added to the planned birth cost to give the total estimated cost of planned vaginal birth and planned CS.

Table 13.21 The costs of adverse birth outcomes[a]

Outcome	Cost	Source	Notes
Transient tachypnea	£1087	NHS Reference Costs 2009/10	HRG Currency Code XA01Z Neonatal critical care intensive care

[a] Costs based on NHS Reference Costs are generally a weighted average of all costs given for a particular currency code. It is weighted by the cases or 'Activity' levels shown in the NHS Reference costs

Table 13.22 The weighted cost of adverse outcomes by planned birth type

Outcome	Cost	Vaginal birth risk	Weighted vaginal cost	CS risk	Weighted CS cost
Maternal death	£0	0.00002	£0	0.00008	£0.00
Hysterectomy	£2999	0.00117	£3.51	0.00119	£3.57
Blood transfusion	£863	0.00383	£3.31	0.00304	£2.62
Infection (wound and post partum)	£0	0.04600	£0.00	0.03200	£0.00
Uterine rupture	£0	0.00714	£0.00	0.00023	£0.00
Neonatal mortality	£1150	0.00115	£1.32	0.00063	£0.72
Transient tachypnea	£1087	0.12373	£134.49	0.12873	£139.93
Total			**£142.63**		**£146.84**

QALYs

A QALY loss was estimated for maternal death, neonatal mortality and hysterectomy. The values for these outcomes are shown in Section 13.2. All QALYs are discounted at an annual rate of 3.5% in accordance with NICE guidance.

Using the clinical review undertaken for this guideline, the risks of these adverse outcomes for each birth type were used to calculate a weighted QALY loss associated with each planned birth type as shown in Table 13.23.

Table 13.23 The weighted QALY loss of adverse outcomes by planned birth type

Outcome	Cost	Vaginal birth risk	Weighted Vaginal cost	CS risk	Weighted CS cost
Maternal death	24.80	0.00002	0.00050	0.00008	0.00198
Hysterectomy	9.59	0.00117	0.01122	0.00119	0.01141
Blood transfusion	0.00	0.00383	0.00000	0.00304	0.00000
Infection (wound and post partum)	0.00	0.04600	0.00000	0.03200	0.00000
Uterine rupture	0.00	0.00714	0.00000	0.00023	0.00000
Neonatal mortality	27.68	0.00115	0.03183	0.00063	0.01744
Transient tachypnea	0.00	0.12373	0.00000	0.12873	0.00000
Total			**0.04355**		**0.03083**

Conceptually it might be considered easier to compare incremental QALY gains rather than QALY losses. Therefore, the weighted QALY losses from adverse maternal and neonatal outcomes are subtracted from the lifetime QALY of mother and i nfant* in the absence of any adverse outcomes†. These are based on the 53 years remaining life expectancy of the mother and the 80 years life expectancy at birth of the infant (ONS, 2011). It is assumed that remaining life years are lived in full health and that QALYs are discounted using an annual discount rate of 3.5% (NICE, 2009). The QALYs associated with planned vaginal birth and planned CS is given in Table 13.24.

Table 13.24 Combined maternal/infant QALY by planned mode of birth

Planned mode of birth	QALY
Vaginal	52.437
Caesarean section	52.449

* Singleton pregnancies are assumed
† Total lifetime QALY of healthy mother and infant: 23.70 + 27.68 = 51.38

Results

The results are shown in Table 13.25. The base case result suggests that the birth cost of a planned VBAC is £307 cheaper than a planned CS. However, the base case also suggests that planned CS has a higher QALY and the corresponding ICER of £24,141 indicates that planned CS can be considered borderline cost effective relative to VBAC using the NICE advisory threshold of £20,000 to £30,000 per QALY, especially given the level of uncertainty surrounding long-term downstream costs and QALYs.

Table 13.25 Results of base case analysis

Planned mode of birth	Birth cost	Adverse outcomes cost	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER
Vaginal	£2063	£143	£2205	-	52.437	-	-
CS	£2365	£147	£2512	£307	52.449	0.012	£24,141

ICER incremental cost effectiveness ratio; QALY quality adjusted life year

Sensitivity analysis

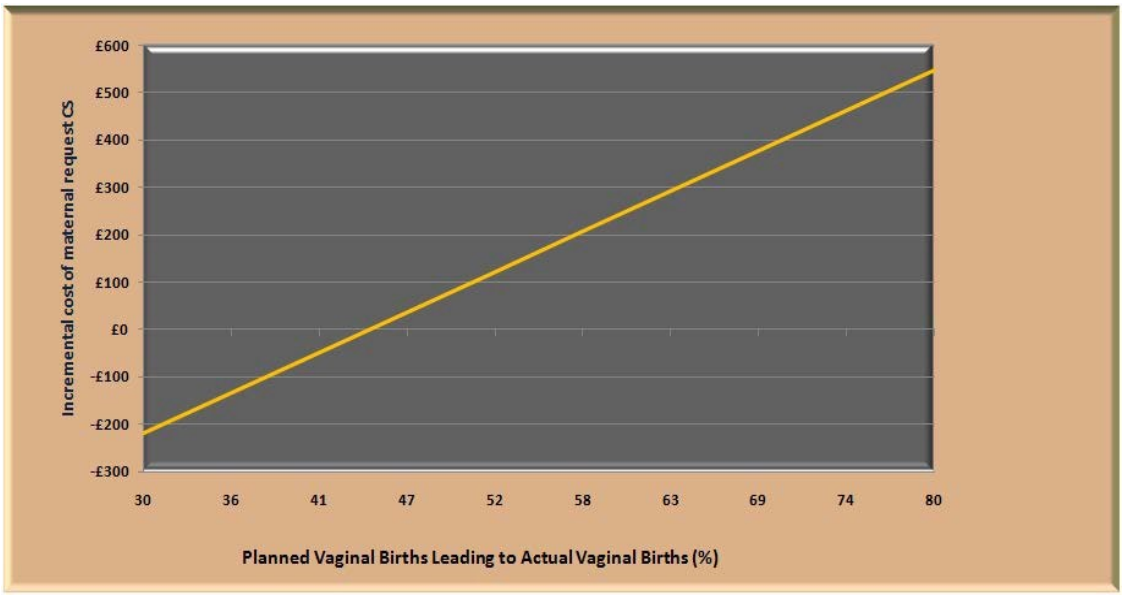
Including data from review of maternal request for CS

In this analysis, data were included for other adverse outcomes reported as part of the review for maternal request CS, but not the VBAC review. This suggested that a planned CS had an ICER of £30,513 relative to VBAC, which would only still be considered to be borderline cost effective if the upper limit of the NICE willingness to pay threshold of £30,000 per QALY was being used.

Varying actual vaginal birth rate from planned VBAC (including data from maternal request CS review)

In the one-way sensitivity analysis shown in Figure 13.13, we see how the actual vaginal birth rate determines the incremental costs of a planned CS relative to VBAC. Figure 13.13 shows that if the actual rate of vaginal birth for planned vaginal birth fell to approximately 45% or below, then planned CS would become the cheapest birth option when only the immediate birth costs are considered.

Figure 13.13 Incremental costs of maternal request caesarean section varying the percentage of planned vaginal births leading to actual vaginal birth

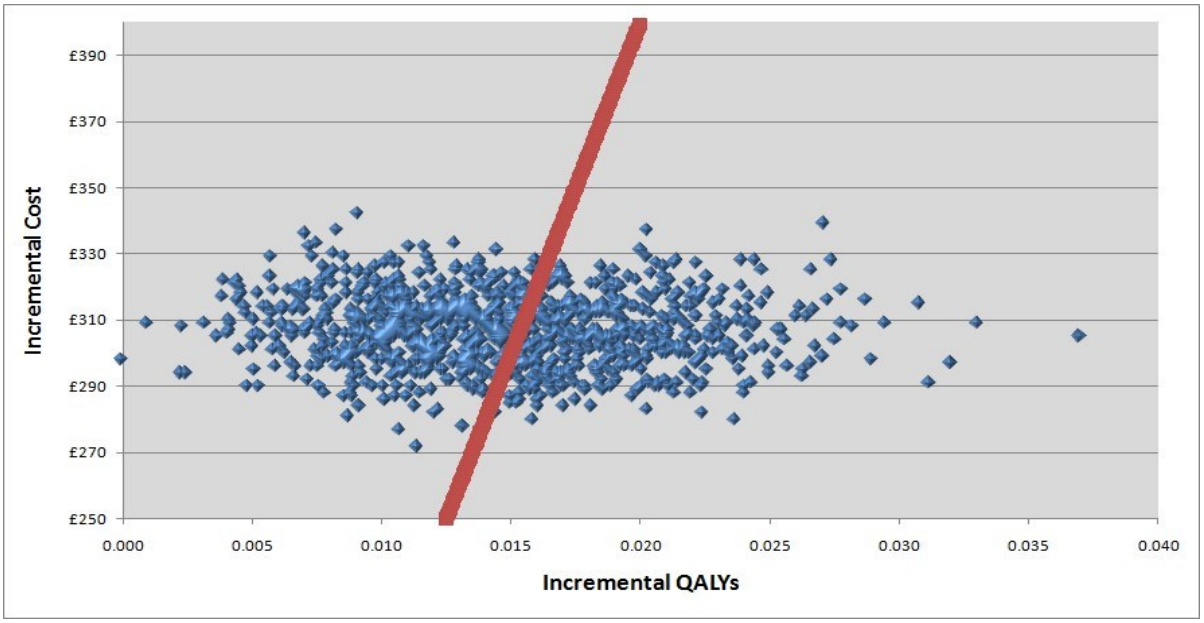


Probabilistic sensitivity analysis – VBAC review data

The base case analysis is deterministic using point estimates for the model's input parameters. However, it is usual practice in economic evaluation to address uncertainty in point estimate values through the use of sensitivity analysis. Where there are many input parameters, probabilistic sensitivity analysis is usually recommended to address uncertainty.

In the probabilistic analysis undertaken here, 1000 Monte Carlo simulations were run with the risks of adverse outcomes sampled from a bet a probability distribution, with the alpha parameter for each distribution given by the number of events and the beta parameter as the number of non-events. The risks were taken from those reported for the VBAC review undertaken for this guideline. All other model inputs are fixed at their base case value, although the model allows the probabilistic analyses to be run with different values for these inputs. The results are shown in Figure 13.14.

Figure 13.14 Probabilistic sensitivity analysis of incremental costs and incremental QALYs of planned caesarean section relative to VBAC

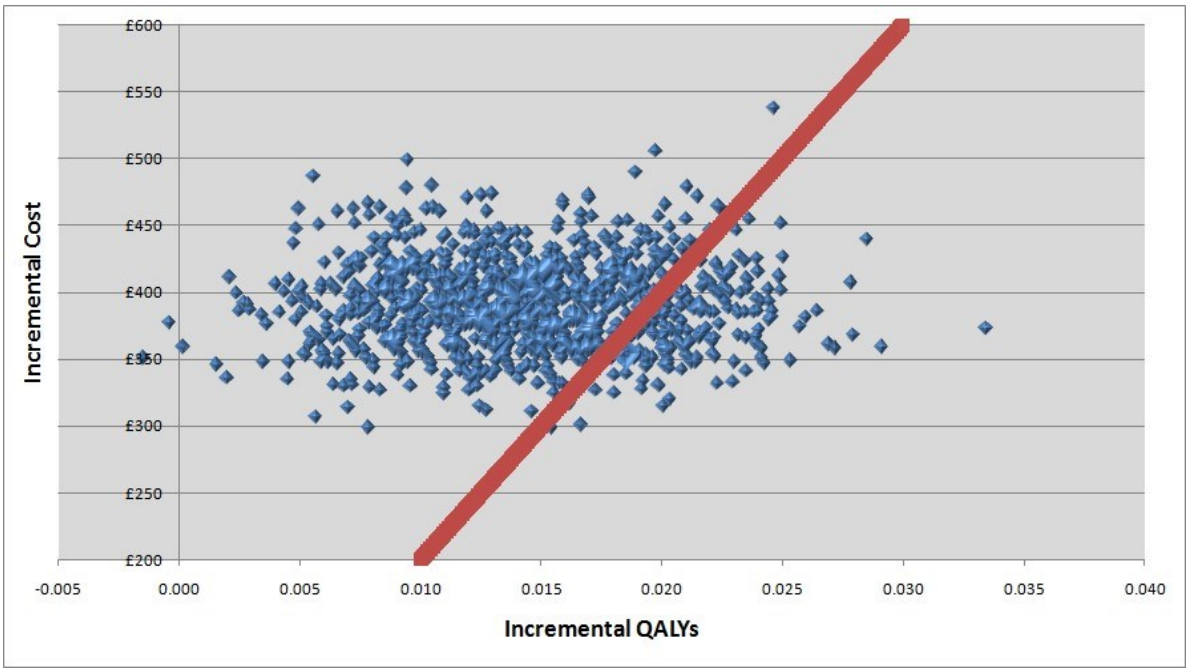


The red line indicates a £20,000 per QALY threshold. Points under this line are considered to be cost effective and points above are considered not to be cost effective. More simulations occur above the threshold, suggesting that there a better than a 50% chance that VBAC is cost effective relative to a planned CS. However, considerable uncertainty remains as a substantial minority of simulations show a planned CS as the more cost-effective option.

Probabilistic sensitivity analysis – VBAC and maternal request review data

This probabilistic sensitivity analysis additionally includes the risk reported in the maternal request model. The results are shown in Figure 13.15.

Figure 13.15 Probabilistic sensitivity analysis of incremental costs and incremental QALYs of planned caesarean section relative to VBAC



In this case there is a greater probability that VBAC is cost effective relative to a planned CS.

Discussion

The results presented in this cost effectiveness analysis do not provide strong evidence either way on the cost effectiveness of VBAC relative to CS in women who have had one previous birth. As with the maternal request model, not all important risks have necessarily been included within the model as inputs were limited to those reported in the clinical reviews undertaken for this guideline. Important adverse outcomes not included are those relating to the pelvic floor and to subsequent pregnancies, such as placenta praevia. This adds a further level of uncertainty to the equivocal cost effectiveness conclusions of this model. In addition, in the probabilistic sensitivity analysis that used data only reported in the maternal request review, it is likely that these risks will be higher in this population and the nature of this increased risk is likely to vary according to the planned mode of birth.

Conclusion

This model suggests that either VBAC or a planned CS can still be supported on cost effectiveness grounds for a woman's second birth. Women have the right to choose VBAC, but on the other hand any additional costs of a pl anned CS are relatively small and c an plausibly be justified in terms of additional benefit. Therefore, this model would support a woman being able to choose her preferred mode of birth in consultation with the healthcare professionals responsible for her care. Considerations about any future pregnancies may be an important factor in the decisions made.

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15 Abbreviations and glossary

15.1 Abbreviations

APH	antepartum haemorrhage
ART	antiretroviral therapy
CEMD	Confidential Enquiry into Maternal Deaths
CFM	colour-flow mapping
CI	confidence interval
CS	caesarean section
CSR	caesarean section rate
CTG	cardiotocograph
DDI	decision-to-delivery interval
DGH	district general hospital (non-teaching hospital)
DIC	disseminated intravascular coagulopathy
DVT	deep vein thrombosis
EFM	electronic fetal monitoring
ECV	external cephalic version
EL	evidence level
ERCS	elective repeat caesarean section
FBS	fetal blood sampling
FGR	fetal growth restriction
FHR	fetal heart rate
FIGO	International Federation of Gynecology and Obstetrics
FTP	“failure to progress” (in labour)
GDG	guideline development group
HAART	highly active antiretroviral therapy
HCV	hepatitis C virus
HDU	high dependency unit
HIE	hypoxic-ischemic encephalopathy
HIV	human immunodeficiency virus
HSV	herpes simplex virus
HTA	health technology assessment
ICER	incremental cost effectiveness ratio

ICU	intensive care unit
ITU	intensive therapy unit
IV	intravenous
LSHTM	London School of Hygiene and Tropical Medicine
MAP	morbidly adherent placenta
MRI	magnetic resonance imaging
MTCT	mother-to-child transmission
NCC-WCH	National Collaborating Centre for Women's and Children's Health
NCEPOD	National Confidential Enquiry into Perioperative Deaths
NICE	National Institute for Clinical Excellence
NICU	neonatal intensive care unit
NNT	number needed to treat
NSCSA	National Sentinel Caesarean Section Audit[4]
OR	odds ratio
PPH	postpartum haemorrhage
PPROM	prelabour preterm rupture of membranes
RCA	Royal College of Anaesthetists
RDS	Respiratory Distress Syndrome
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RR	risk ratio
RTI	respiratory tract infection
SCBU	special care baby unit
SGA	small for gestational age
SMD	standard mean deviation
SROM	spontaneous rupture of membranes
TOL	trial of labour
TTN	transient tachypnoea of the newborn
US	ultrasound
UTI	urinary tract infection
VBAC	vaginal birth after caesarean section
WHO	World Health Organization

15.2 Glossary

Absolute risk	Measures the probability of an event or outcome occurring (e.g. an adverse reaction to the drug being tested) in the group of people under study. Studies that compare two or more groups of patients may report results in terms of the Absolute Risk Reduction.
Absolute risk reduction (ARR)	The ARR is the difference in the risk of an event occurring between two groups of patients in a study – for example if 6% of patients die after receiving a new experimental drug and 10% of patients die after having the old drug treatment then the ARR is 10 – 6% = 4%. Thus by using the new drug instead of the old drug 4% of patients can be prevented from dying. Here the ARR measures the risk reduction associated with a new treatment. See also Absolute risk.
Allied health professionals	Healthcare professionals, other than doctors, midwives and nurse/midwife, directly involved in the provision of healthcare. Includes several groups such as physiotherapists, occupational therapists, dieticians, etc. (Formerly known as professions allied to medicine or PAMs.)
Applicability	The extent to which the results of a study or review can be applied to the target population for a clinical guideline.
Appraisal of evidence	Formal assessment of the quality of research evidence and its relevance to the clinical question or guideline under consideration, according to predetermined criteria.
Best available evidence	The strongest research evidence available to support a particular guideline recommendation.
Bias	Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias in research can make a treatment look better or worse than it really is. Bias can even make it look as if the treatment works when it actually doesn't. Bias can occur by chance or as a result of systematic errors in the design and execution of a study. Bias can occur at different stages in the research process, e.g. in the collection, analysis, interpretation, publication or review of research data. For examples see Selection bias, Performance bias, Information bias, Confounding, Publication bias.
Blinding or masking	The practice of keeping the investigators or subjects of a study ignorant of the group to which a subject has been assigned. For example, a clinical trial in which the participating patients or their doctors are unaware of whether they (the patients) are taking the experimental drug or a placebo (dummy treatment). The purpose of 'blinding' or 'masking' is to protect against bias. See also Double blind study, Single blind study, Triple blind study.
Bradycardia	Bradycardia is a baseline heart rate below the normal range. In the fetus, this is defined as a rate lower than 110 beats per minute.
Case–control study	A study that starts with the identification of a group of individuals sharing the same characteristics (e.g. people with a particular disease) and a suitable comparison (control) group (e.g. people without the disease). All subjects are then assessed with respect to things that happened to them in the past, e.g. things that might be related to getting the disease under investigation. Such studies are also called retrospective as they look back in time from the outcome to the possible causes.
Case series	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no c omparison (control) group of patients.

Causal relationship	Describes the relationship between two variables whenever it can be established that one causes the other. For example there is a causal relationship between a t reatment and a di sease if it can be shown that the treatment changes the course or outcome of the disease. Usually randomised controlled trials are needed to ascertain causality. Proving cause and effect is much more difficult than just showing an association between two variables. For example, if it happened that everyone who had eaten a particular food became sick, and everyone who avoided that food remained well, then the food would clearly be associated with the sickness. However, even if leftovers were found to be contaminated, it could not be proved that the food caused the sickness – unless all other possible causes (e.g. environmental factors) had been ruled out.
Clinical audit	A systematic process for setting and m onitoring standards of clinical care. Whereas 'guidelines' define what the best clinical practice should be, 'audit' investigates whether best practice is being carried out. Clinical audit can be described as a cycle or spiral. Within the cycle there are stages that follow a systematic process of establishing best practice, measuring care against specific criteria, taking action to improve care, and monitoring to sustain improvement. The spiral suggests that as the process continues, each cycle aspires to a higher level of quality.
Clinical effectiveness	The extent to which a s pecific treatment or intervention, when used under usual or everyday conditions, has a b eneficial effect on the course or outcome of disease compared to no treatment or other routine care. (Clinical trials that assess effectiveness are sometimes called management trials.) Clinical 'effectiveness' is not the same as efficacy.
Clinical governance	A framework through which NHS organisations are accountable for both continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Clinical impact	The effect that a guideline recommendation is likely to have on a t reatment, or treatment outcomes, of the target population.
Clinical question	This term is sometimes used in guideline development work to refer to the questions about treatment and care that are formulated in order to guide the search for research evidence. When a c linical question is formulated in a precise way, it is called a focused question.
Clinician	A health care professional providing patient care, e.g. doctor, nurse/midwife, physiotherapist.
Cochrane Collaboration	An international organisation in which people find, appraise and review specific types of studies called randomised controlled trials. The Cochrane Database of Systematic Reviews contains regularly updated reviews on a variety of health issues and is available electronically as part of the Cochrane Library.
Cochrane Library	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration). The Cochrane Library is available on CD-ROM and t he Internet.
Cohort study	An observational study that takes a group (cohort) of patients and follows their progress over time in order to measure outcomes such as disease or mortality rates and make comparisons according to the treatments or interventions that patients received. Thus within the study group, subgroups of patients are identified (from information collected about patients) and these groups are compared with respect to outcome, e.g. comparing mortality

	between one group that received a specific treatment and one group which did not (or between two groups that received different levels of treatment). Cohorts can be assembled in the present and followed into the future (a 'concurrent' or 'prospective' cohort study) or identified from past records and followed forward from that time up to the present (a 'historical' or 'retrospective' cohort study). Because patients are not randomly allocated to subgroups, these subgroups may be qu ite 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.
Co-morbidity	Co-existence of a disease or diseases in the people being studied in addition to the health problem that is the subject of the study.
Confidence interval	A way of expressing certainty about the findings from a study or group of studies, using statistical techniques. A confidence interval describes a range of possible effects (of a treatment or intervention) that are consistent with the results of a study or group of studies. A wide confidence interval indicates a lack of certainty or precision about the true size of the clinical effect and is seen in studies with too few patients. Where confidence intervals are narrow they indicate more precise estimates of effects and a larger sample of patients studied. It is usual to interpret a '95%' confidence interval as the range of effects within which we are 95% confident that the true effect lies.
Confounder or confounding factor	Something that influences a study and can contribute to misleading findings if it is not understood or appropriately dealt with. For example, if a gr oup 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 t o one gr oup being older than the other rather than due to the exercising. Age is the confounding factor here and the effect of exercising on heart disease cannot be assessed without adjusting for age differences in some way.
Consensus methods	A variety of techniques that aim to reach an agreement on a particular issue. Formal consensus methods include Delphi and nominal group techniques, and consensus development conferences. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic.
Consensus statement	A statement of the advised course of action in relation to a particular clinical topic, based on the collective views of a body of experts.
Considered judgement	The application of the collective knowledge of a guideline development group to a body of evidence, to assess its applicability to the target population and the strength of any recommendation that it would support. Consistency The extent to which the conclusions of a collection of studies used to support a guideline recommendation are in agreement with each other.
Control group	A group of patients recruited into a study that receives no t reatment, a treatment of known effect, or a pl acebo (dummy treatment) - in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Cost benefit analysis	A type of economic evaluation where both costs and benefits of health care treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost effectiveness	A type of economic evaluation that assesses the additional costs and benefits of doing something different. In cost effectiveness analysis, the costs and benefits of different treatments are compared. When a new treatment is compared with current care, its additional costs divided by its additional benefits is called the cost effectiveness ratio. Benefits are measured in natural units, for example, cost per additional heart attack prevented.

Cost utility analysis	A special form of cost effectiveness analysis where benefit is measured in quality adjusted life years. A treatment is assessed in terms of its ability to extend or improve the quality of life.
Cross-sectional study	The observation of a defined set of people at a single point in time or time period – a snapshot. (This type of study contrasts with a longitudinal study which follows a set of people over a period of time.)
Declaration of interest	A process by which members of a working group or committee 'declare' any personal or professional involvement with a company (or related to a technology) that might affect their objectivity e.g. if their position or department is funded by a pharmaceutical company.
Double blind study	A study in which neither the subject (patient) nor the observer (investigator/clinician) is aware of which treatment or intervention the subject is receiving. The purpose of blinding is to protect against bias.
Economic evaluation	Comparative analysis of alternative courses of action in terms of both their costs and consequences.
Efficacy	The extent to which a specific treatment or intervention, under ideally controlled conditions (e.g. in a l aboratory), has a beneficial effect on t he course or outcome of disease compared to no treatment or other routine care.
Elective	Name for clinical procedures that are regarded as advantageous to the patient but not urgent.
Epidemiology	Study of diseases within a population, covering the causes and means of prevention
Evidence based	The process of systematically finding, appraising, and using research findings as the basis for clinical decisions.
Evidence-based clinical practice	Evidence-based clinical practice involves making decisions about the care of individual patients based on the best research evidence available rather than basing decisions on personal opinions or common practice (which may not always be evidence based). Evidence-based clinical practice therefore involves integrating individual clinical expertise and patient preferences with the best available evidence from research
Evidence table	A table summarising the results of a collection of studies which, taken together, represent the evidence supporting a particular recommendation or series of recommendations in a guideline.
External validity	The degree to which the results of a study hold true in non-study situations, e.g. in routine clinical practice. May also be referred to as the generalisability of study results to non-study patients or populations.
Extrapolation	The application of research evidence based on studies of a specific population to another population with similar characteristics.
Forest plot	A graphical display of results from individual studies on a common scale, allowing visual comparison of results and examination of the degree of heterogeneity between studies.
Generalisability	The extent to which the results of a s tudy hold true for a popul ation of patients beyond those who participated in the research. See also External validity.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available.

Good practice point	Recommended good practice based on the expert experience of the guideline development group (and possibly incorporating the expertise of a wider reference group). A guideline development group may produce a 'Good practice point' (rather than an evidence based recommendation) on an important topic when there is a lack of research evidence.
Grade of recommendation	A code (e.g. A,B,C,D) linked to a guideline recommendation, indicating the strength of the evidence supporting that recommendation.
Grey literature	Reports that are unpublished or have limited distribution, and ar e not included in bibliographic retrieval systems.
Guideline	A systematically developed tool which describes aspects of a p atient's condition and t he care to be gi ven. A good guideline makes recommendations about treatment and care, based on the best research available, rather than opinion. It is used to assist clinician and patient decision-making about appropriate health care for specific clinical conditions.
Guideline recommendation	Course of action advised by the guideline development group on the basis of their assessment of the supporting evidence.
Health economics	A field of conventional economics which examines the benefits of health care interventions (e.g. medicines) compared with their financial costs.
Health technology	Health technologies include medicines, medical devices such as artificial hip joints, diagnostic techniques, surgical procedures, health promotion activities (e.g. the role of diet versus medicines in disease management) and other therapeutic interventions.
Health Technology Appraisal (HTA)	A health technology appraisal, as undertaken by NICE, is the process of determining the clinical and cost effectiveness of a health technology. NICE health technology appraisals are designed to provide patients, health professionals and managers with an aut horitative source of advice on new and existing health technologies.
HELLP	Abbreviation of haemolysis, elevated liver enzymes and low platelet count; a type of severe pre-eclampsia.
Heterogeneity	Or lack of homogeneity. The term is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different – in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up.
Hierarchy of evidence	An established hierarchy of study types, based on the degree of certainty that can be attributed to the conclusions that can be drawn from a well conducted study. Well-conducted randomised controlled trials (RCTs) are at the top of this hierarchy. (Several large statistically significant RCTs which are in agreement represent stronger evidence than say one small RCT.) Well-conducted studies of patients' views and e xperiences would appear at a lower level in the hierarchy of evidence.
Homogeneity	This means that the results of studies included in a s ystematic review or meta analysis are similar and there is no evidence of heterogeneity. Results are usually regarded as homogeneous when differences between studies could reasonably be expected to occur by chance. See also Consistency.

Information bias	Pertinent to all types of study and can be caused by inadequate questionnaires (e.g. difficult or biased questions), observer or interviewer errors (e.g. lack of blinding), response errors (e.g. lack of blinding if patients are aware of the treatment they receive) and measurement error (e.g. a faulty machine).
Intention to treat analysis	An analysis of a clinical trial where patients are analysed according to the group to which they were initially randomly allocated, regardless of whether or not they had dropped out, fully complied with the treatment, or crossed over and received the alternative treatment. Intention-to-treat analyses are favoured in assessments of clinical effectiveness as they mirror the non-compliance and treatment changes that are likely to occur when the treatment is used in practice.
Internal validity	Refers to the integrity of the study design.
Intervention	Healthcare action intended to benefit the patient, e.g. drug treatment, surgical procedure, psychological therapy, etc.
Level of evidence	A code (e.g. 1a, 1b) linked to an individual study, indicating where it fits into the hierarchy of evidence and how well it has adhered to recognised research principles.
Literature review	A process of collecting, reading and assessing the quality of published (and unpublished) articles on a given topic.
Meta analysis	Results from a collection of independent studies (investigating the same treatment) are pooled, using statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible e.g. because of differences in the study populations or in the outcomes measured, it may be i nappropriate or even misleading to statistically pool results in this way. See also Systematic review and Heterogeneity.
Methodological quality	The extent to which a study has conformed to recognised good practice in the design and execution of its research methods.
Morbidly adherent placenta	There are three grades of morbidly adherent placenta: accreta, increta and percreta. They are defined according to the depth of myometrial invasion. • accreta: chorionic villi are in contact with the myometrium (middle layer of the uterine wall) rather than being contained within the decidua (inner lining of the uterine wall during pregnancy) (approximately 80% of cases) • increta: extensive villous invasion into the myometrium (approximately 15% of cases) • percreta: villous invasion extends to (or through) the serosa (membrane covering the uterus) (approximately 5% of cases).
Multicentre study	A study where subjects were selected from different locations or populations, e.g. a c o-operative study between different hospitals; an i nternational collaboration involving patients from more than one country.
Necrotising enterocolitis	A condition in which sections of the intestine become inflamed and undergo necrosis (death of tissue). This can lead to perforation of the intestine.
Non-experimental study	A study based on subjects selected on the basis of their availability, with no attempt having been made to avoid problems of bias.
Number needed to treat (NNT)	This measures the impact of a treatment or intervention. It states how many patients need to be treated with the treatment in question in order to prevent an event which would otherwise occur. E.g. if the NNT = 4, then 4 patients would have to be treated to prevent one bad outcome. The closer the NNT is to 1, the better the treatment is. Analogous to the NNT is the Number Needed to Harm (NNH), which is the number of patients that would need to

	receive a treatment to cause one additional adverse event. e.g. if the NNH = 4, then 4 patients would have to be treated for one bad outcome to occur.
Objective measure	A measurement that follows a standardised procedure which is less open to subjective interpretation by potentially biased observers and s tudy participants.
Observational study	In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies.
Odds ratio	Odds are a way of representing probability, especially familiar for betting. In recent years odds ratios have become widely used in reports of clinical studies. They provide an estimate (usually with a confidence interval) for the effect of a treatment. Odds are used to convey the idea of 'risk' and an odds ratio of 1 bet ween two treatment groups would imply that the risks of an adverse outcome were the same in each group. For rare events the odds ratio and the relative risk (which uses actual risks and not odds) will be very similar. See also Relative risk, Risk ratio.
Outcome	The end result of care and treatment and/ or rehabilitation. In other words, the change in health, functional ability, symptoms or situation of a p erson, 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.
Peer review	Review of a s tudy, service or recommendations by those with similar interests and expertise to the people who produced the study findings or recommendations. Peer reviewers can include professional and/ or patient/ carer representatives.
Placenta accreta	See Morbidly adherent placenta
Placenta increta	See Morbidly adherent placenta
Placenta percreta	See Morbidly adherent placenta
Planned CS	A CS that is scheduled before the onset of labour.
Prognostic factor	Patient or disease characteristics, e.g. age or co-morbidity, which influence the course of the disease under study. In a randomised trial to compare two treatments, chance imbalances in variables (prognostic factors) that influence patient outcome are possible, especially if the size of the study is fairly small. In terms of analysis these prognostic factors become confounding factors.
Prospective study	A study in which people are entered into the research and then followed up over a per iod of time with future events recorded as they happen. This contrasts with studies that are retrospective.
P value	If a study is done to compare two treatments then the P value is the probability of obtaining the results of that study, or something more extreme, if there really was no difference between treatments. (The assumption that there really is no difference between treatments is called the 'null hypothesis'.) Suppose the p-value was p = 0.03. What this means is that if there really was no difference between treatments then there would only be a 3% chance of getting the kind of results obtained. Since this chance seems quite low we should question the validity of the assumption that there really is no difference between treatments. We would conclude that there probably is a difference between treatments. By convention, where the value of p is below 0.05 (i.e. less than 5%) the result is seen as statistically significant. Where the value of p is 0.001 or less, the result is seen as highly significant.

	p values just tell us whether an ef fect can be r egarded as statistically significant or not. In no way do they relate to how big the effect might be, for which we need the confidence interval.
Qualitative research	Qualitative research is used to explore and und erstand people's beliefs, experiences, attitudes, behaviour and i nteractions. It generates non-numerical data, e.g. a patient's description of their pain rather than a measure of pain. Qualitative research techniques such as focus groups and in depth interviews have been used in one-off projects commissioned by guideline development groups to find out more about the views and experiences of patients and carers.
Quantitative research	Research that generates numerical data or data that can be converted into numbers, for example clinical trials.
Random allocation or Randomisation	A method that uses the play of chance to assign participants to comparison groups in a research study, for example, by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual (or each unit in the case of cluster randomisation) being entered into a study has the same chance of receiving each of the possible interventions.
Randomised controlled trial	A study to test a s pecific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no t reatment. The two groups are followed up t o compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study.)
Relative risk	A summary measure which represents the ratio of the risk of a given event or outcome (e.g. an adverse reaction to the drug being tested) in one group of subjects compared to another group. When the 'risk' of the event is the same in the two groups the relative risk is 1. In a study comparing two treatments, a relative risk of 2 would indicate that patients receiving one of the treatments had twice the risk of an undesirable outcome than those receiving the other treatment. Relative risk is sometimes used as a synonym for risk ratio.
Reliability	Reliability refers to a method of measurement that consistently gives the same results. For example someone who has a high score on one occasion tends to have a high score if measured on another occasion very soon afterwards. With physical assessments it is possible for different clinicians to make independent assessments in quick succession – and if their assessments tend to agree then the method of assessment is said to be reliable.
Retrospective study	A retrospective study deals with the present/ past and does not involve studying future events. This contrasts with studies that are prospective. Review Summary of the main points and trends in the research literature on a specified topic. A review is considered non-systematic unless an extensive literature search has been carried out to ensure that all aspects of the topic are covered and an objective appraisal made of the quality of the studies.
Risk ratio	Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison (control) group. The term relative risk is sometimes used as a s ynonym of risk ratio.

Sample	A part of the study's target population from which the subjects of the study will be recruited. If subjects are drawn in an unbiased way from a particular population, the results can be generalised from the sample to the population as a whole. Sampling refers to the way participants are selected for inclusion in a study.
Selection bias	Selection bias has occurred if: a) the characteristics of the sample differ from those of the wider population from which the sample has been drawn OR b) there are systematic differences between comparison groups of patients in a study in terms of prognosis or responsiveness to treatment.
Selection criteria	Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.
Semi-structured interview	Structured interviews involve asking people pre-set questions. A semi-structured interview allows more flexibility than a structured interview. The interviewer asks a number of open-ended questions, following up ar eas of interest in response to the information given by the respondent.
Statistical power	The ability of a study to demonstrate an association or causal relationship between two variables, given that an association exists. For example, 80% power in a clinical trial means that the study has a 80% chance of ending up with a p value of less than 5% in a statistical test (i.e. a statistically significant treatment effect) if there really was an important difference (e.g. 10% versus 5% mortality) between treatments. If the statistical power of a study is low, the study results will be questionable (the study might have been too small to detect any differences). By convention, 80% is an acceptable level of power. See also p value.
Structured interview	A research technique where the interviewer controls the interview by adhering strictly to a questionnaire or interview schedule with pre-set questions.
Study population	People who have been identified as the subjects of a study.
Survey	A study in which information is systematically collected from people (usually from a sample within a defined population).
Systematic review	A review in which evidence from scientific studies has been i dentified, appraised and synthesised in a methodical way according to predetermined criteria. May or may not include a meta-analysis.
Target population	The people to whom guideline recommendations are intended to apply. Recommendations may be less valid if applied to a population with different characteristics from the participants in the research study – e.g. in terms of age, disease state, social background.
Validity	Assessment of how well a tool or instrument measures what it is intended to measure.