



Caesarean section: Evidence Update March 2013

A summary of selected new evidence relevant to NICE
clinical guideline 132 'Caesarean section' (2011)



Evidence Update 35

Evidence Updates provide a summary of selected new evidence published since the literature search was last conducted for the accredited guidance they relate to. They reduce the need for individuals, managers and commissioners to search for new evidence. Evidence Updates highlight key points from the new evidence and provide a commentary describing its strengths and weaknesses. They also indicate whether the new evidence may have a potential impact on current guidance. For contextual information, this Evidence Update should be read in conjunction with the relevant clinical guideline, available from the NHS Evidence topic page for [caesarean section](#).

Evidence Updates do not replace current accredited guidance and do not provide formal practice recommendations.

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Contents

Introduction	4
Key points	5
1 Commentary on new evidence	7
1.1 Woman-centred care.....	7
1.2 Planned CS	8
1.3 Factors affecting likelihood of CS during intrapartum care	15
1.4 Procedural aspects of CS	15
1.5 Care of the baby born by CS.....	21
1.6 Care of the woman after CS.....	21
1.7 Recovery following CS	22
1.8 Pregnancy and childbirth after CS	22
2 New evidence uncertainties.....	25
Appendix A: Methodology.....	26
Appendix B: The Evidence Update Advisory Group and Evidence Update project team	28

Introduction

This Evidence Update identifies new evidence that is relevant to, and may have a potential impact on, the following reference guidance:


- ¹  [Caesarean section](#). NICE clinical guideline 132 (2011).

A search was conducted for new evidence from 25 May 2010 to 25 September 2012. A total of 2705 pieces of evidence were initially identified. Following removal of duplicates and a series of automated and manual sifts, 18 items were selected for the Evidence Update (see Appendix A for details of the evidence search and selection process). An [Evidence Update Advisory Group](#), comprising topic experts, reviewed the prioritised evidence and provided a commentary.

Although the process of updating NICE guidance is distinct from the process of an Evidence Update, the relevant NICE guidance development centres have been made aware of the new evidence, which will be considered when guidance is reviewed.

Other relevant NICE guidance

The focus of the Evidence Update is on the guidance stated above. However, overlap with other accredited guidance has been outlined as part of the Evidence Update process. Where relevant, this Evidence Update therefore makes reference to the following guidance:

- ¹  [Induction of labour](#). NICE clinical guideline 70 (2008).
- ² [Intraoperative blood cell salvage in obstetrics](#). NICE interventional procedure guidance 144 (2005).

Feedback

If you have any comments you would like to make on this Evidence Update, please email contactus@evidence.nhs.uk

¹ NICE-accredited guidance is denoted by the Accreditation Mark 

² Guidance published prior to NICE accreditation

Key points

The following table summarises what the Evidence Update Advisory Group (EUAG) decided were the key points for this Evidence Update. It also indicates the EUAG's opinion on whether the new evidence may have a potential impact on the current guidance listed in the introduction. For further details of the evidence behind these key points, please see the full commentaries.

The section headings used in the table below are taken from the guidance.

Evidence Updates do not replace current accredited guidance and do not provide formal practice recommendations.

Key point	Potential impact on guidance	
	Yes	No
Woman-centred care <ul style="list-style-type: none"> Evidence suggests that caesarean section (CS) increases the risk of severe acute maternal morbidity. 		✓
Planned CS <ul style="list-style-type: none"> Evidence suggests that medical complications at 3 months may not differ between planned vaginal delivery and planned CS in first pregnancy. Auditing using the Ten Group Classification System may result in reduced CS rates. Evidence from a small study suggests that the addition of MRI to ultrasound examination does not change delivery mode in patients at risk of placenta accreta, but further research is needed. Conservative management of placenta accreta, including use of prophylactic pelvic artery catheterisation, may preserve fertility. However further research is needed on methods for reducing maternal blood loss during surgery for morbidly adherent placenta. A small study suggests that blood cell salvage may be safe and effective in high-risk planned and unplanned CS. Data from randomised controlled trials is lacking on the outcomes of planned CS for non-medical reasons; therefore, there is a need for a systematic review of observational studies and synthesis of qualitative data. 		✓ ✓ ✓ ✓ ✓ ✓
Procedural aspects of CS <ul style="list-style-type: none"> A decision-to-delivery interval of 30 minutes for category 1 CS may be achievable and appropriate in clinical practice. An oxytocin infusion in addition to bolus oxytocin may reduce the need for additional uterotonic agents, but may not affect the frequency of major obstetric haemorrhage. In situ repair of the uterus may be associated with less pain and no increase in haemorrhage or infection compared with exteriorised repair of the uterus. 		✓ ✓ ✓

Key point	Potential impact on guidance	
	Yes	No
<ul style="list-style-type: none"> Incidence of maternal infection does not seem to be associated with choice of single versus double layers of sutures, closure or non-closure of the peritoneum, or use of a subrectus drain. However, locked single-layer closures may be associated with higher incidence of uterine rupture in repeat pregnancies compared with unlocked single layer or double layer closures. Further research of the outcomes associated with methods of internal closure in CS is needed. Rates of infection with skin closure by sutures may not differ significantly compared with staples, but staples may be more likely to result in skin separation. 	✓*	✓
Pregnancy and childbirth after CS <ul style="list-style-type: none"> Many maternal outcomes for planned repeat CS may be similar to those of planned vaginal birth after CS, but rates of death and serious outcomes may be higher in babies whose mothers planned vaginal birth after CS. Planned CS may be associated with less risk of uterine rupture compared with spontaneous labour without augmentation. Risk of uterine rupture may be increased if labour is induced. 		✓ ✓

* Evidence Updates are intended to increase awareness of new evidence and do not change the recommended practice as set out in current guidance. Decisions on how the new evidence may impact guidance will not be possible until the guidance is reviewed by NICE following its published processes and methods. For further details of this evidence in the context of current guidance, please see the full commentary.

1 Commentary on new evidence

These commentaries analyse the key references identified specifically for the Evidence Update. The commentaries focus on the 'key references' (those identified through the search process and prioritised by the EUAG for inclusion in the Evidence Update), which are identified in bold text. Supporting references provide context or additional information to the commentary. Section headings are taken from the guidance.

1.1 Woman-centred care

Planned caesarean section (CS) compared with planned vaginal delivery

[NICE CG132](#) recommends that the risks and benefits of CS and vaginal birth should be discussed with women, including the risks of placental problems with multiple CS. The guidance compares the risks of planned CS with planned vaginal birth for women with an uncomplicated pregnancy and no previous CS. Planned CS may reduce the risk of: perineal and abdominal pain during birth and 3 days postpartum, injury to vagina, early postpartum haemorrhage, and obstetric shock. Planned CS may increase the risk of: longer hospital stay, hysterectomy caused by postpartum haemorrhage, and cardiac arrest.

A Dutch prospective cohort study (n=2552) reported by [van Dillen et al. \(2010\)](#) was part of the Nationwide Study into Ethnic Determinants of Maternal Morbidity in the Netherlands (LEMMoN study), which assessed the risk of severe acute maternal morbidity (SAMM) related to mode of delivery.

SAMM was classified according to 5 categories: intensive care unit admission, uterine rupture, eclampsia, major obstetric haemorrhage, and miscellaneous. Deliveries were classified as vaginal delivery, planned CS, and unplanned CS. A further intention-to-treat analysis was performed for planned vaginal delivery (all vaginal deliveries plus unplanned CS) compared with planned CS. The risk of SAMM being related to mode of delivery was assessed in 2 subgroups: all SAMM inclusions and those possibly related to mode of delivery. In the second group all cases that were not clearly related to mode of delivery were excluded (n=1103), for example SAMM before delivery.

A total of 1479 (58%) women with SAMM had vaginal deliveries, and 1073 (42%) had CS: 565 planned and 508 unplanned. The overall incidence of SAMM was significantly higher for CS compared with vaginal delivery (odds ratio [OR]=4.2, 95% CI 3.9 to 4.6, p value not reported). The incidence of SAMM was 23 out of 1000 in the planned CS group compared with 6 out of 1000 in the planned vaginal delivery group (OR=3.9, 95% CI 3.5 to 4.3). The outcomes for maternal mortality (OR=4.0, 95% CI 1.9 to 8.2) and obstetric hysterectomy (OR=6.4, 95% CI 4.2 to 9.7) were also significantly in favour of planned vaginal delivery compared with planned CS. Of the 2552 participants with SAMM in the study, 19% (479) had CS in a previous pregnancy compared with 7% (25,621) of all deliveries in the Netherlands during the study period (OR=3.0, 95% CI 2.7 to 3.3).

SAMM was possibly related to mode of delivery in 1449 cases (57%): 1049 (72%) with vaginal delivery and 400 (28%) with CS. Of CS deliveries, 158 (40%) were planned and 242 (60.5%) were unplanned. The incidence of SAMM possibly related to CS was 7.5 out of 1000 compared with 3.5 out of 1000 for vaginal delivery (OR=2.2, 95% CI 1.9 to 2.5). The incidence of SAMM possibly related to planned CS was 6.4 out of 1000 compared with 3.9 out of 1000 for planned vaginal delivery (OR=1.7, 95% CI 1.4 to 2.0).

The authors stated that some of the decisions for excluding deliveries in which SAMM was not clearly related to mode of delivery may be contentious. Also, study bias by indication could not be totally excluded, although the selected groups reflected actual practice.

The results are broadly consistent with [NICE CG132](#) in showing that CS is associated with higher risk of maternal morbidity than vaginal birth, and are unlikely to impact on [NICE CG132](#).

Key reference

van Dillen J, Zwart JJ, Schutte J et al. (2010) [Severe acute maternal mortality and mode of delivery in the Netherlands](#). *Acta Obstetrica et Gynecologica Scandinavica* 89: 1460–5

1.2 Planned CS

[NICE CG132](#) recommends that pregnant women with a singleton breech presentation at term, for whom external cephalic version is contraindicated or has been unsuccessful, should be offered CS because it reduces perinatal mortality and neonatal morbidity. The guidance also suggests that when a woman requests a CS, explore, discuss and record the specific reasons for the request.

A Swedish prospective cohort study reported by [Larsson et al. \(2011\)](#) compared maternal outcomes in healthy women who were giving birth to their first child, after planned CS (n=247) or planned vaginal delivery (n=294). Medical outcomes were compared at 3 months, including the risk of infection and excess blood loss. Women with primiparous normal pregnancy and BMI less than 30 kg/m² were recruited at between 37 and 39 weeks' gestation. The CS group included breech presentation (n=132) and maternal request (n=115).

Details of the mode of delivery, duration of hospital stay, Apgar score, presumed infections and health and condition of the newborn baby were obtained from medical records. Participants were sent a questionnaire on sociodemographic background and health after their inclusion in the study, and sent another 3 months after delivery about complications in the postpartum period (completion rates were 82–95%). Prophylactic antibiotics were administered to women who underwent CS in labour. After CS, blood loss was estimated jointly by the obstetrician and anaesthetic nurse. The content of drainage bottles was measured and recorded. After vaginal delivery, blood loss was estimated visually by the midwife. If estimating blood loss was difficult, or if the visual estimate of blood loss exceeded 500 ml, then pads, swabs and diapers were weighed.

Three women planning CS had vaginal deliveries and 45 women in the planned vaginal delivery group had CS. Epidural analgesia was used in 49% of women who had a vaginal delivery (143 out of 294), and in 12% (34 out of 294) labour was induced. Most planned deliveries by CS were performed using spinal anaesthesia. In each group, 10 women had CS under general anaesthesia.

There were no differences in estimated blood loss, rate of blood transfusions, or rate of infections between the planned CS or planned vaginal delivery groups. Mean blood loss did not differ significantly between groups (p=0.32). No significant differences were noted in rates of infection at 3-month follow-up.

Two days after delivery, 100% of women in the planned CS group and 67% in the planned vaginal delivery group needed analgesia (p<0.001). Women in the planned CS group had more abdominal pain and women in the planned vaginal delivery group had more perineal pain (both p<0.001). At 3 month follow-up there were no significant differences in reported pain of any kind (data not reported).

Limitations stated by the authors included that visual estimation of blood loss is unreliable, and that the complication rate for planned vaginal delivery was higher than previously reported. The authors acknowledged that because they reported findings by intended mode of delivery and not by actual delivery mode, the complication rates are higher than in previously reported studies. They also noted that the small size of the study meant unusual complications may have been overlooked.

The results of this study suggest that there is no difference between planned vaginal delivery and planned CS in first pregnancy in terms of medical complications after 3 months. This study did not cover the outcomes of actual vaginal birth or CS and so is unlikely to have an impact on [NICE CG132](#).

Key reference

Larsson C, Saltvedt S, Wiklund I et al. (2011) [Planned vaginal delivery versus planned caesarean section: short-term medical outcome analyzed according to intended mode of delivery](#). *Journal of Obstetrics and Gynaecology Canada* 33: 796–802

Reducing CS rates

[NICE CG132](#) does not contain any recommendations on classifying perinatal care or reducing rates of CS.

A Chilean prospective interrupted time series study (n=4813) reported by [Scarella et al. \(2011\)](#) evaluated whether the introduction of the 'medical audit cycle' reduced CS rate without increasing maternal or fetal risk using the Ten Group Classification System (TGCS).

All pregnant women presenting to a single hospital in spontaneous labour were included. All newborn babies weighing under 500 g and deliveries by private doctors were excluded. The TGCS was used to identify the main contributors to the CS rate. Group 5 of the TGCS was divided into 2, separating those with 1 prior CS (group 5a) from those with more than 1 (group 5b). Data were obtained from the woman's health record and crosschecked with the labour ward book and entered into a clinical record to ensure that each woman was correctly classified according to the TGCS. The hospital adverse events committee reported all cases of neonatal asphyxia and 5-minute Apgar scores below 7.

The study was subdivided into 3 periods. A basal period of 3 months, when the TGCS was implemented, to identify the main contributors to the overall CS rate so that efforts could be made to reduce the rates of CS in these groups of interest. This was followed by an intervention period of 9 months in which strategies were introduced to reduce the rate of CS in these groups. The TGCS was audited monthly and the changes in TGCS and CS rate were distributed to all staff. Every 3 months staff meetings were held; changes in CS rates according to TGCS were reported alongside rates of 5 minute Apgar scores below 7. Staff were also ranked according to the CS rates on their shift in the groups of interest. In a post-intervention period of 9 months the intervention ceased and only the follow-up data were registered according to the TGCS, without reporting the information to staff.

During the basal period 231 of 627 labours (37%) resulted in CS. The 4 TGCS groups of interest with the greatest contribution to the overall CS rates were: group 1, women in spontaneous labour with single births who had not previously given birth, with cephalic presentation at 37 weeks or more; group 2a, the same as group 1, but with induced labour; group 5a, women who had previous births with 1 previous CS, with a single cephalic presentation at 37 weeks' gestation or more; and group 10, all single cephalic babies, at 36 weeks' gestation or less. These groups accounted for 57% of the total CS population.

The overall CS rate reduced to 27% in the intervention period and was 32% in the post-intervention period. CS rates in the groups of interest reduced from 39% in the basal period to 27% in the intervention period, and rose again to 33% in the post-intervention period. The post-intervention CS rates were lower than the basal CS rates for both the groups of interest (relative risk [RR]=0.85, 95% CI 0.72 to 0.99) and all women (RR=0.86, 95% CI 0.76 to 0.97).

The authors reported that they were unable to establish which components of the intervention produced the change in CS rates. There was also no comparator group to evaluate other factors that may have produced any change. Finally, an interrupted time series evaluation has potential bias in that it cannot control for all variables, such as seasonal variation.

The results indicate that auditing using the TGCS may result in reduced CS rates. However, because there are no current recommendations for classifying perinatal care or reducing rates of CS, it is unlikely to have an impact on [NICE CG132](#).

Further information on how the TGCS can be used as part of a multidisciplinary quality assurance programme was discussed by [Robson et al. \(2012\)](#).

Key reference

Scarella A, Chamy V, Sepúlveda M et al. (2011) [Medical audit using the Ten Group Classification System and its impact on the caesarean section rate](#). *European Journal of Obstetrics & Gynecology and Reproductive Biology* 154: 136–140

Supporting reference

Robson M, Hartigan L, Murphy M (2012) [Methods of achieving and maintaining an appropriate caesarean section rate](#). *Best Practice & Research Clinical Obstetrics & Gynaecology* 27: 297–308

Magnetic resonance imaging (MRI) for morbidly adherent placenta

[NICE CG132](#) recommends that if a colour-flow Doppler ultrasound scan result suggests morbidly adherent placenta discuss with the woman the improved accuracy of MRI in addition to ultrasound to help diagnose morbidly adherent placenta and clarify the degree of invasion. An explanation of what to expect during an MRI procedure should be given detailing that current experience suggests that MRI is safe, but that there is a lack of evidence about any long-term risks to the baby. MRI should be offered if acceptable to the woman.

A retrospective review of clinical data was performed by [McLean et al. \(2011\)](#) to evaluate whether MRI after ultrasound for women with or at risk of placenta accreta (n=139) had an effect on rates of CS with immediate hysterectomy. Women who had placenta accreta confirmed by ultrasound or documented operative diagnosis, or at least 1 risk factor for placenta accreta were included. Risk factors included: 2 or more prior CS, placenta praevia, age 35 years or older, or more than 4 prior births.

MRI was performed on 29% (n=40) of women, with 40% (16 of 40) diagnosed as negative and 60% positive for placenta accreta (24 of 40). Of 6 women who had a vaginal delivery, 4 had negative imaging examinations for placenta accreta, but were included in the study group because of their additional risk factors. Two of the 4 negative ultrasound examinations were true negatives with spontaneous vaginal deliveries, and the other 2 were false negatives resulting in hysterectomies because of postpartum bleeding and placenta accreta. The remaining 2 women had abnormal ultrasound, followed by MRI. One MRI suggested possible accreta, but the woman had spontaneous vaginal delivery. The final woman had an ultrasound suspecting accreta that was upgraded on MRI to probable percreta, but the woman had an uncomplicated vaginal delivery.

CS was performed in 84 women, and 79 of those (94%) had a normal operative diagnosis; the other 5 women had placenta accreta. Of these, ultrasound positively diagnosed 3, diagnosed 1 as placenta praevia and 1 as normal placenta. Only 1 woman had ultrasound followed by an MRI, both of which diagnosed increta.

CS with immediate hysterectomy was performed in 49 women and ultrasound failed to diagnose 2 women who had an operating room diagnosis of placenta percreta. Ultrasound diagnosed placenta praevia in 12 women, which was confirmed in surgery in only 2 women. Of the other 10 women, 7 had MRI showing placenta accreta, and 1 MRI showed praevia but the operative diagnosis was percreta. MRI downgraded disease severity for a further 8 women, 4 were incorrectly downgraded to placenta praevia, and 4 women had placenta accreta confirmed in surgery.

The final operative diagnosis was highly correlated with both ultrasound and MRI diagnosis ($p > 0.0001$) and either scan was significantly associated with CS and immediate hysterectomy

($p \leq 0.005$). Positive imaging diagnoses were also significantly associated with higher transfusion requirements ($p \leq 0.005$). For all categories there was no significant difference regardless of incremental imaging ($p > 0.3$).

The authors noted that the results from ultrasound and MRI and the operative and final diagnoses were not independent variables so they could not assess sensitivity, specificity or positive predictive value of ultrasound and MRI.

Additional limitations of the study stated by the authors include the absence of a blinded reinterpretation of each woman's ultrasound and MRI or a pathological confirmation of the final diagnosis. The number of MRIs was smaller than the number of ultrasounds so the study may have been underpowered to detect an effect from the addition of MRI. The study duration was 13 years so the technology and experience of imagers may have developed in this time. The population was from a high risk obstetric centre so may be biased towards more complex cases.

The results of this study suggest that the addition of MRI to ultrasound examination does not change delivery mode in patients at risk of placenta accreta. Although this is inconsistent with [NICE CG132](#) the results are unlikely to change guidance because of the limitations of the evidence.

Key reference

McLean La, Heilbrun ME, Eller AG et al. (2011) [Assessing the role of magnetic resonance imaging in the management of gravid patients at risk for placenta accreta](#). *Academic Radiology* 18: 1175–80

Conservative management of placenta accreta

[NICE CG132](#) does not have specific recommendations for the management of placenta accreta, but recommends that all hospitals should have a locally agreed protocol for managing morbidly adherent placenta that sets out how care should be provided.

A French retrospective cohort study by [Provansal et al. \(2010\)](#) evaluated the fertility and obstetric outcomes after conservative management of placenta accreta ($n=46$) in 2 tertiary maternity centres. All women with placenta accreta confirmed by 1 or more of the following were included: absence of a plane of cleavage between the placenta and myometrium; impossibility of or incomplete manual removal of placenta or evidence of placental retention; heavy bleeding from the implantation site after forcible placental removal during CS; absence of decidua or presence of smooth muscle fibres in contact with placental villi. Women who had initial radical surgery or life-threatening haemorrhage were excluded, as were all women who underwent attempted extraction or separation of the placenta from the uterus. Fertility was assessed only for women who had conservative management with all or part of the placenta left in the uterus.

Conservative treatment involved monitoring for spontaneous resorption, but may have involved removing parts of the placenta that spontaneously separated from the uterus, with the intention of reducing the size of the placenta. If heavy haemorrhaging occurred after conservative treatment, a secondary hysterectomy was performed. Supplementary treatment included: arterial vascular ligation ($n=14$), uterine sutures ($n=2$), embolisation of the uterine arteries ($n=14$), or administration of either uterotonic agents ($n=40$) or methotrexate ($n=7$). Data were collected retrospectively from the women's medical records or charts, and from a follow-up telephone survey, which recorded time to resumption of menstrual periods, desire for pregnancy, and outcomes of any future pregnancies.

The placenta was left partially in situ in 65% ($n=30$), and completely in situ for 35% ($n=16$). The final diagnosis was confirmed in only 17 women (37%), either by histology or by a clinical diagnosis of placenta percreta ($n=10$). Twenty women had a planned CS, 23 had unplanned CS and 3 had spontaneous vaginal delivery. Conservative management was unsuccessful for 6 women, all of whom needed hysterectomy, 3 within 24 hours, and 3 after 24 hours.

Of the 40 women successfully managed conservatively, 5 were lost to follow-up (median follow-up=65 months, range 18–156 months). Menstrual function was irregular in 11 of the 35 women who completed follow-up (31%). All women resumed a menstrual cycle after a median of 130 days (range 48–176 days) and none had amenorrhoea. Eight women with placenta still in situ underwent hysteroscopy because of irregular menses (n=1), ultrasound findings (n=5), or routinely (n=2), at a median of 186 days (range 120–270 days). Hysteroscopy was normal in 3 women, and showed persistent trophoblastic residue in 5 women. This was associated with uterine synechiae in 2 women.

Of the 35 women followed-up, 21 did not want further pregnancies during the study period. Of the 14 women who wanted further pregnancies, 12 had at least 1 more, with 15 pregnancies occurring in total. Two of the 12 women (17%) with a subsequent pregnancy had new dysmenorrhoea after the conservative management of their placenta accreta. Six pregnancies did not last beyond the first trimester (5 spontaneous abortions and 1 planned termination). Eight pregnancies were normal until term and 1 was complicated by intrauterine growth restriction. Three women had spontaneous vaginal deliveries and 6 had CS. Two women had a recurrence of placenta accreta, one of whom had a hysterectomy, and the other was managed conservatively.

Limitations of the study expressed by the authors were that because the placenta was left in place, confirmation of placenta accreta was not possible in most cases. The high morbidity results expressed here may also explain the low number of women who wanted further pregnancies. The retrospective design of the study also limits the interpretation of results in comparison with randomised controlled design.

This study suggests that conservative management of placenta accreta may preserve fertility. Because [NICE CG132](#) does not have specific recommendations for the management of placenta accreta this study is unlikely to have an impact on guidance.

Key reference

Provansal M, Courbiere B, Agostini A et al. (2010) [Fertility and obstetric outcome after conservative management of placenta accreta](#). *International Journal of Gynecology & Obstetrics* 109: 147–50

Prophylactic pelvic artery catheterisation

[NICE CG132](#) has no recommendations about interventions to reduce postpartum haemorrhage in women with suspected morbidly adherent placenta. The [full version of NICE CG132](#) states that balloon catheters can be used to reduce the need for cross-matched blood, but that there is variation in practice and a lack of evidence to support their use in the management of morbidly adherent placenta. An Israeli retrospective study by [Sivan et al. \(2010\)](#) evaluated prophylactic pelvic artery catheterisation, balloon occlusion and embolisation before CS in women with ultrasound findings consistent with, or significant clinical risk factors for, placenta accreta (n=30). Risk factors were defined as previous CS, and the presence of placenta praevia diagnosed in transvaginal ultrasound scan. All women underwent planned CS with prophylactic, fluoroscopic-guided, pelvic artery catheterisation of internal iliac arteries. The rates of intraoperative and postoperative complications, and maternal outcome were recorded.

Before surgery, the women were examined and counselled by a multidisciplinary team that included an obstetrician, an anaesthetist, an invasive radiologist and a neonatologist, and were given prophylactic antibiotics. The first 8 catheterisations were done through left brachial approach, with the tip of the catheter left in the aorta to be advanced into the internal iliac artery for embolisation if needed. The subsequent 22 catheterisations were through the bilateral femoral contralateral approach with the tip of the catheter left in the internal iliac artery. The catheters were then fixed and the patient taken immediately for CS under general anaesthetic.

After delivery, occlusion balloons were inflated (in those with femoral approach) with 2 ml of mixed saline with contrast material. Manual extraction of the placenta was attempted in all cases. Balloons were deflated and embolisation was done only in those cases where bleeding was considered to be 'massive'. Prepared precut gel foam particles were injected during embolisation under fluoroscopic imaging to the anterior division of the internal iliac artery. Haemostatic control was also used, including haemostatic sutures and intrauterine balloon with prostaglandin F2-alpha infusion.

Intrauterine balloons were inserted through the uterine incision during CS. When bleeding was sufficiently controlled, the balloons were inflated and prostaglandin F2-alpha infusion was started. Hysterectomy was indicated if bleeding was uncontrolled despite interventions including haemostatic sutures and internal iliac artery ligation. Catheters were removed 2 hours after surgery and all women were reviewed by an invasive radiologist for catheterisation-related complications, and by an obstetrician.

All participants had at least 1 previous CS. During surgery, morbidly adherent placenta was identified in 25 women (83%): 13 women had placenta percreta and 12 had placenta increta or placenta accreta. Embolisation was performed on 23 women (77%).

In 2 women ligation of the internal iliac artery failed and hysterectomy was performed. Estimated blood loss in these 2 cases was 2000 ml and 9000 ml. Median estimated blood loss was 2000 ml (range 500–900 ml), and a median of 4 units of blood (range 0–15 ml) were transfused. Median blood loss and surgery did not differ depending on port of entry, number of previous CS, or whether the woman had placenta increta, accreta or percreta.

Two women were observed in intensive care for 24 hours and the rest were transferred to the delivery ward immediately after surgery. Disseminated intravascular coagulation was diagnosed by the surgeons in 6 women (24%), with 2 (8%) having hysterectomies. Major post-operative complications were a vesicouterine fistula and a tubo-ovarian abscess. Other complications included fever (50%) and pulmonary congestion (10%). There were no major catheter-related complications. Minor catheter-related complications (17%) included subcutaneous haematoma (n=2), and transient leg ischaemia (n=3), which resolved spontaneously. Median postoperative hospital stay was 5.5 days (range 4 to 28 days). Three women went on to have further term CS deliveries.

The authors noted that the lack of a control group was a major limitation of this study. Another limitation was the unavoidable lack of pathological confirmation of the diagnosis in all cases that the uterus was preserved.

The results of this study provide limited evidence for the safe and effective use of prophylactic pelvic artery catheterisation in women with placenta accreta, but the sample size was small. This study is unlikely to have an impact on [NICE CG132](#) because further research is needed, in line with a research recommendation in the [full version of NICE CG132](#), on the effectiveness of treatments for reducing morbidity associated with maternal blood loss during surgery for morbidly adherent placenta.

Key reference

Sivan E, Spira M, Achiron R et al. (2010) [Prophylactic pelvic artery catheterization and embolization in women with placenta accrete: can it prevent caesarean hysterectomy?](#) *American Journal of Perinatology* 27 455–61

Blood cell salvage

NICE interventional procedures guidance ([IPG144](#)) recommends that, although intraoperative blood cell salvage is an efficacious technique for blood replacement, there are theoretical safety concerns when it is used in obstetric practice. Therefore, data collection is important

and clinicians should report all complications to the [Medicines and Healthcare products Regulatory Agency](#).

A retrospective study of case records by [Sullivan et al. \(2011\)](#) reviewed the effectiveness of blood cell salvage used during both planned and unplanned CS (n=107). Blood-cell salvage equipment was prepared before surgery for 102 women who were deemed at high risk of haemorrhage, such as having placenta praevia, multiple repeat operations, or antepartum haemorrhage. There were also 5 women who had severe bleeding and cell salvage was set up during unplanned CS. Salvaged blood was reinfused only when the collection of fluid was more than 800 ml.

Blood lost during surgery was collected in an isolated suction system and was prepared and reinfused as soon as possible both during and after surgery. A separate suction system was used for amniotic fluid. Anticoagulant was drip-fed into the operative field and allowed to mix with shed maternal blood before being sucked into a sterile reservoir. The mixture was filtered to remove larger clots and debris. Swab washing was used if possible to increase the reinfusion quantity. Once enough blood was collected (usually 800 ml) it was centrifuged, washed, then reconstituted and suspended in saline ready for reinfusion. Reinfusion was completed within 6 hours of prescription by the anaesthetist.

Of the 107 women, 36 (34%) had salvaged blood reinfused. The remaining 71 (66%) did not have sufficient blood loss to collect and reinfuse. Of the 31 women who were prepared for cell salvage preoperatively, 10 had unplanned CS. Only 6 of the 31 women who were prepared for cell salvage preoperatively needed banked blood. The mean volume of blood lost from the 36 women was 1275 ml (planned mean=830 ml, unplanned mean=1897 ml). The proportion of reinfused salvaged blood was higher in the planned group (28%) compared with the unplanned group (15%). This was because of the higher volume of blood lost and loss of blood before cell salvage was set up in the unplanned group. The mean volume of blood and fluid lost was 4000 ml in women who had cell salvage set up during the procedure compared with 835 ml in those who had cell salvage set up in advance.

The results of this small study provide limited support for the use of cell salvage in high-risk planned and unplanned CS. These results are unlikely to affect recommendations in [NICE CG132](#) or [NICE IPG144](#).

Key reference

[Sullivan JV, Crouch ME, Stoken G et al. \(2011\) Blood cell salvage during cesarean delivery. International Journal of Gynaecology and Obstetrics 115: 161–3](#)

CS for non-medical reasons

[NICE CG132](#) recommends that if a woman requests a CS when there is no other indication; discuss the overall risks and benefits of CS compared with vaginal birth. If necessary, a discussion should be held with other members of the obstetric team (including the obstetrician, midwife and anaesthetist) if necessary to explore the reasons for the request, and ensure the woman has accurate information. If after discussion and offer of support (including perinatal mental health support for women with anxiety about childbirth), a vaginal birth is still not an acceptable option, offer a planned CS.

A Cochrane review by [Lavender et al. \(2012\)](#) evaluated the effects of planned CS versus planned vaginal birth in women with no clear clinical indication for CS. All randomised controlled trials (RCTs) containing pregnant women in their first pregnancy, with cephalic presentation at term, with no medical indication for CS were to be included. The primary outcomes were: serious maternal morbidity or death; serious neonatal morbidity or perinatal death, excluding fatal malformations; and maternal postnatal depression.

No RCTs could be used to base practice recommendations on. The authors suggested that consequently there is a need for a systematic review of observational studies and synthesis of qualitative data. Because no RCTs compared planned vaginal birth with planned CS this review is unlikely to have an impact on [NICE CG132](#).

Key reference

Lavender T, Hofmeyr GJ, Neilson JP et al. [Caesarean section for non-medical reasons at term](#). Cochrane Database of Systematic Reviews 2012, issue 3: CD004660

1.3 [Factors affecting likelihood of CS during intrapartum care](#)

No new key evidence was found for this section.

1.4 [Procedural aspects of CS](#)

Decision-to-delivery audit times

[NICE CG132](#) recommends using the following decision-to-delivery intervals to audit the overall performance of an obstetric unit: 30 minutes for category 1 CS, both 30 and 75 minutes for category 2 CS. Category 1 CS is when there is immediate threat to the life of the woman or fetus, and category 2 CS is when there is maternal or fetal compromise that is not immediately life-threatening.

A prospective, observational cohort study reported by [Pearson et al. \(2011\)](#) evaluated the current target decision-to-delivery intervals for unplanned CS. The primary objective was to assess the impact of decision-to-delivery intervals on neonatal condition in women undergoing CS for unplanned indications (59 category 1 and 532 category 2). Data relating to category of delivery and indication was taken from clinical records. If more than 1 indication was listed, investigators decided which to enter as primary indication. A diagnosis of acidosis was made if the cord arterial pH was 7.10 or less and the base excess was less than -12 mmol/litre. A diagnosis of asphyxia was defined as a 5 minute Apgar score less than 7. Apart from the authors, clinical staff were unaware of the audit to reduce bias and altered clinical behaviour.

Decision-to-delivery intervals were recorded for all category 1 and 487 of 532 category 2 deliveries (91%). Category 1 deliveries were achieved within a significantly shorter decision-to-delivery interval (median=23 minutes, interquartile range [IQR] 19–37 minutes) than intrapartum category 2 deliveries (median=58 minutes, IQR 36–82 minutes, $p<0.0001$), and 68% were achieved within 30 minutes of decision. For category 2 CS, delivery was achieved within 75 minutes in 66% and 180 minutes in 93%. Category 2 deliveries were more likely to be within the 75 minute target if the primary indication was fetal distress during labour (median 55 minutes, IQR 41–75 minutes).

The decision-to-delivery interval for babies born with acidosis (median=28 minutes, IQR 18–52 minutes) was significantly shorter than for babies born without acidosis (median=57 minutes, IQR 33–84, $p=0.0025$). For category 1, deliveries within the target time did not reduce the odds of acidosis (OR=1.70, 95% confidence interval [CI] 0.34 to 8.55). The decision-to-delivery interval for babies born with asphyxia (median=59 minutes, IQR 40–82 minutes) was not significantly different compared with the 523 babies born without asphyxia (median=57 minutes, IQR 33–84 minutes, $p=0.37$).

Six babies died: 2 because of extreme prematurity; 3 had serious congenital abnormalities; and 1 because of severe acidosis and asphyxia (delivered within target time). Five of the surviving neonates had neurological impairment, 2 of whom had conditions unrelated to birth events. The other 3 had conditions thought to be related to perinatal ischaemia and were category 2 deliveries within target.

The authors noted that the higher acidosis seen with shorter times to delivery may be due to selection bias, in that clinicians act more quickly in cases of greater urgency. The authors noted the limitation that the allocation to CS categories has considerable heterogeneity and they suggest that consensus is needed.

The authors concluded that the 30 minute target for category 1 deliveries is appropriate, but suggested splitting category 2 deliveries into a 75 minute target for concerns about fetal health or placental bleeding, and a 180 minute target for other category 2 indications. This evidence is broadly supportive of [NICE CG132](#) and so is unlikely to have an impact on the guidance.

Key reference

Pearson GA, Kelly B, Russell R et al. (2011) [Target decision to delivery intervals for emergency caesarean section based on neonatal outcomes and three year follow up](#). *European Journal of Obstetrics & Gynecology and Reproductive Biology* 159: 276–81

Use of uterotonics

[NICE CG132](#) recommends that oxytocin 5 IU by slow intravenous injection should be used at CS to encourage contraction of the uterus and to decrease blood loss.

A double-blind placebo-controlled RCT reported by [Sheehan et al. \(2011\)](#) assessed the effects of adding an oxytocin infusion to bolus oxytocin in terms of blood loss at planned CS (the Elective Caesarean Section Syntocinon [oxytocin] Infusion Trial, n=2069).

Women were randomly assigned to receive either an intravenous oxytocin 5 IU bolus plus oxytocin 40 IU infusion over 4 hours (n=1033) or oxytocin 5 IU bolus plus placebo infusion over 4 hours (n=1025). The primary outcomes were major obstetric haemorrhage (>1000 ml) and use of an additional uterotonic agent. Blood loss was estimated by calculating the difference between the preoperative and postoperative packed cell volume.

Healthy women at term (>36 weeks) with single pregnancies having planned CS were included. Exclusion criteria were: placenta praevia, thrombocytopenia, coagulopathies, previous major obstetric haemorrhage (>1000 ml), known fibroids, and current anticoagulant treatment. Women who were aged under 18 years were also excluded and clinicians could additionally exclude women if major haemorrhage was expected.

Surgical and anaesthetic standards were standardised: all women underwent spinal anaesthesia; and controlled cord traction was specified for delivery of the placenta after administration of the oxytocin bolus. A 2-layer closure of the uterine incision, and avoiding externalisation of the uterus for suturing unless clinically indicated were also specified. If the uterus remained atonic then the clinician could use an additional uterotonic agent. Deviations from the standard protocol were recorded.

Major obstetric haemorrhage did not differ significantly between the bolus plus infusion group (158 of 1007, 15.7%) and the bolus plus placebo group (159 of 994, 16%, adjusted OR=0.98, 95% CI 0.77 to 1.25, p=0.86). However, when results were stratified by the experience of the obstetrician: for junior obstetricians, adding the oxytocin infusion to the bolus resulted in a lower rate of major obstetric haemorrhage (17.3%) compared with bolus plus placebo (22.2%, OR 0.57, 95% CI 0.35 to 0.92, p=0.02); for senior obstetricians, rates of haemorrhage were lower than those of junior doctors, but the rate of major obstetric haemorrhage was higher in the oxytocin infusion plus bolus group (14.4%) than in the bolus plus placebo group (11.9%, no statistical comparison reported). Women in the bolus plus infusion group (126 of 1033, 12.2%) were less likely to need an additional uterotonic agent than those in the bolus plus placebo group (189 of 1025, 18.4%, adjusted OR=0.61, 95% CI 0.48 to 0.78, p<0.001).

A limitation stated by the authors was that they could have included a third comparison group that reflected current US clinical practice (use of a placebo bolus with an oxytocin infusion),

but this approach would have deviated from hospital protocols. Also, because clinicians intervene if uterine atony occurs, the use of an additional uterotonic agent could have been considered as an important outcome in itself.

The study results suggest that the addition of an oxytocin infusion to oxytocin bolus may reduce the need for additional uterotonic agents, but may not affect the frequency of major obstetric haemorrhage. Therefore, this evidence is unlikely to have an impact on [NICE CG132](#).

Key reference

Sheehan SR, Montgomery AA, Carey M et al. (2011) [Oxytocin bolus versus oxytocin bolus and infusion for control of blood loss at elective caesarean: double blind, placebo controlled, randomised trial](#). *BMJ* 343: 276–81

Repair of the uterus

[NICE CG132](#) recommends that intraperitoneal repair of the uterus at CS should be undertaken. Exteriorisation of the uterus is not recommended because it is associated with more pain and does not improve operative outcomes such as haemorrhage and infection.

A Turkish prospective randomised trial reported by [Doğanay et al. \(2010\)](#) compared uterine repair performed in situ with extra-abdominal repair following CS. The primary outcome was intraoperative blood loss, measured as the difference in the woman's haemoglobin levels before and after CS. Secondary outcomes included: time to return of bowel sound, rates of uterine atony, intraoperative complications, additional use of postoperative analgesia, endometritis, and wound infection.

Women with pregnancies of at least 36 weeks' gestation were randomly assigned to intraperitoneal (group 1, n=2462) or exteriorised uterine repair (group 2, n=2463). Indications for CS included fetal distress, dystocia, breech presentation, and maternal preference. Exclusion criteria included: high-risk pregnancy, third trimester bleeding, chorioamnionitis, more than 12 hours of membrane rupture, intrapartum antibiotic use, more than 1 previous CS, and a history of abdominal surgery other than 1 previous CS.

After spinal anaesthesia was administered, the skin was scrubbed with chlorhexidine and povidone-iodine solution. A Pfannenstiel incision was made, followed by a transverse lower segment uterine incision. The umbilical cord was clamped and prophylactic antibiotics were given intravenously. External uterine massage and gentle traction of the umbilical cord were used to aid placental delivery. Following placental delivery, the uterus was closed in a continuous single layer using a synthetic absorbable braided suture. Finally, 20 IU of oxytocin was added to an infusion of 5% dextrose to prevent uterine atony. For postoperative analgesia, all patients were administered tenoxicam 20 mg intravenously, followed by an oral analgesic 4 times daily, until no longer needed. An intravenous infusion of dextrose was administered for 24 hours; liquids and soft foods were allowed only after the first intestinal sounds.

The difference between preoperative and postoperative haemoglobin levels were similar between groups, with a reduction in haemoglobin of 1.2 g/dl (standard deviation [SD]±0.4 g/dl) for intraperitoneal uterine repair and 1.1 g/dl (SD±0.7 g/dl, p=0.21) for exteriorised uterine repair. The mean operation time was significantly shorter for intraperitoneal repair (36.8 minutes, SD±4.2 minutes) than for exteriorised repair (44.6 minutes, SD±3.7 minutes, p=0.001). Uterine atony developed in 96 women (4%) who had intraperitoneal repair and 226 women (9%) who had exteriorised repair (p=0.001). Four women with uterine atony in the exteriorised repair group had hysterectomies.

No differences in bowel, bladder or ureteral injury were noted, but 11 women who underwent exteriorised repair had an ovarian vein rupture, compared with none in the intraperitoneal

repair group ($p=0.001$). Additional analgesia was needed by 17% of women who had intraperitoneal repair, and 35% of those who had exteriorised repair ($p=0.002$). Bowel function returned within 12 hours of CS in 74% of women in the intraperitoneal group and 46% of those in the exteriorised repair group ($p=0.001$). No significant difference in rates of endometritis were seen (14.7% for extraperitoneal repair vs 18.1% for exteriorised repair, $p=0.06$); but less women in the intraperitoneal group (4.6%) than in the exteriorised group had wound infection (11.5%, $p=0.003$).

The authors did not discuss possible limitations of their study. However the results that exteriorised repair of the uterus is associated with more pain, and does not improve rates of haemorrhage or infection are consistent with [NICE CG132](#).

Key reference

Doğanay M, Tonguc EA, Var T et al. (2010) [Effects of method of uterine repair on surgical outcome of cesarean delivery](#). *International Journal of Gynecology & Obstetrics* 111: 175–8

Internal closure techniques in CS

[NICE CG132](#) recommends that the uterine incision should be sutured with 2 layers, except within a research context because the effectiveness and safety of single layer closure of the uterine incision is uncertain. The guidance also recommends that 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. Superficial wound drains should not be used because they do not decrease the incidence of wound infection or wound haematoma, but no recommendations were made about the use of subrectus drains.

A meta-analysis by [Roberge et al. \(2011\)](#) evaluated the association between use of single-layer or 2-layer closure of the uterus after CS and risk of uterine rupture during a trial of labour in a subsequent pregnancy. Because of a lack of RCTs, observational studies were included if they scored at least 5 points on the Newcastle-Ottawa Scale. All included studies compared single-layer with double-layer closure of the myometrium in women who had no more than 1 CS. The primary outcome was uterine rupture, defined as a complete separation of the uterine scar with disruption of the visceral peritoneum or rupture of the bladder, needing an emergency intervention.

Data from 9 studies were included, consisting of 1 RCT, 6 cohort studies, and 2 case-control studies ($n=5810$) with all studies containing data on uterine rupture during a trial of labour. The specific technique for single-layer closure (locked vs unlocked and continuous vs interrupted) could be identified for most studies, but many studies reported that there was no local standard for double-layer closure.

The difference in risk of uterine rupture between previous single-layer closure of the uterus was not significantly higher compared with double-layer closure (OR=1.71, 95% CI 0.66 to 4.44, $p=0.27$). Sensitivity analysis did not find heterogeneity or significant differences due to study design, trial size, or whether the trial of labour was before or after 2002. However, a locked single-layer closure was associated with an increased risk of uterine rupture compared with a double-layer closure (OR=4.96, 95% CI 2.58 to 9.52, $p>0.001$). An unlocked single-layer closure was not associated with an increased risk of uterine rupture (OR=0.49, 95% CI 0.21 to 1.16, $p=0.1$). There was significant heterogeneity across studies ($p<0.0002$), which was mainly attributable to the 2 types of single-layer closure (locked vs unlocked).

Several limitations were stated by the authors. Most of the included studies were retrospective and only 1 RCT provided long-term follow-up data, which were available for a limited number of women. The authors suggested that closure techniques may have varied within some hospitals. Information on the suture type (locked or unlocked) for the first or second layer of a double-layer closure was usually not available. No study compared locked compared with unlocked single-layer sutures. It was also not possible to evaluate the

presence of publication bias because the number of studies was too small. Other factors, such as suture material, inclusion or exclusion of decidua in the uterine suture, and certain risk factors for uterine rupture, including fetal macrosomia, labour dystocia, and labour induction, were not considered.

The CAESAR RCT reported by the [CAESAR study collaborative group \(2010\)](#) assessed 3 pairs of alternative CS techniques in a 2x2x2 design: single-layer closure (n=1505) versus double-layer closure (n=1506) of the uterine incision; closure (n=1512) versus non-closure (n=1515) of the pelvic peritoneum; and liberal (n=1413) versus restricted (n=1414) use of a subrectus sheath drain. Women older than 16 years having a first CS were included if it was planned through the lower uterine segment and had no clear indication for any particular surgical technique to be used. All other aspects of the CS procedure were at the discretion of the surgeon as long as approaches were consistent across allocated groups.

The primary outcome was maternal infectious morbidity, defined as having 1 or more of the following: antibiotic use for maternal febrile morbidity (temperature > 39°C on any occasion or > 38°C on two or more successive days) during the postnatal hospital stay, endometritis, or wound infection treated with antibiotics. Inpatient data were collected from the hospital notes. Women completed a questionnaire 6 weeks after CS delivery and recorded whether antibiotics or additional analgesia had been prescribed during the postnatal period and for what reason.

After randomisation but before CS, 2 women withdrew consent and 30 had a vaginal delivery, so these women were excluded from the intention-to-treat analysis. The risk of maternal infectious morbidity was similar between groups (16–18%). For each pair of interventions there were no significant differences between the arms of the trial and the primary outcome. When the study outcomes were analysed according to the 8 groups there were no significant differences between the groups for any outcomes. Twelve serious adverse events were reported, spread equally among arms.

Subgroup analysis showed evidence of an association between closure of the peritoneum and use of a subrectus sheath drain (p=0.006). Women allocated to liberal use of a subrectus sheath drain had a higher risk of maternal infectious morbidity associated with non-closure of the pelvic peritoneum (21%) compared with closure (15%). Women allocated to restricted use of a subrectus sheath drain had a lower risk of maternal infectious mortality with non-closure of the peritoneum (16%) compared with closure of the peritoneum (18%). Compliance with allocation in most groups was more than 90%, but was only 63% in the liberal use of subrectus sheath group, mainly because of good haemostasis; there was no evidence that compliance had an effect on any outcome.

A limitation of the study stated by the authors was lower than anticipated recruitment and the study had to be closed prematurely. However, they stated that the power for detecting the main effects of the trial should not have been affected, but the power to detect interactions was low.

The study by the Caesar collaborative group (2010) suggests that levels of postoperative maternal infection do not seem to be affected by the choice of single versus double layers of sutures, closure or non-closure of pelvic peritoneum, or use of a subrectus drain. These findings are unlikely to affect recommendations in NICE CG132 because further research into the safety and effectiveness of these surgical techniques is needed. The meta-analysis by Roberge et al. (2011) suggests that locked, but not unlocked single-layer closures may be associated with a higher risk of uterine rupture in a subsequent pregnancy compared with double-layer closure, which is consistent with [NICE CG132](#). This study also suggested that unlocked single-layer closure may have a rate of uterine rupture in future pregnancy similar to that of double-layer closure, but further research is needed to confirm these findings.

Key references

Roberge S, Chaillet N, Boutin A et al. (2011) [Single- versus double-layer closure of the hysterotomy incision during cesarean delivery and risk of uterine rupture](#). *International Journal of Gynecology & Obstetrics* 115: 5–10

CAESAR study collaborative group (2010) [Caesarean section surgical techniques: a randomised factorial trial \(CAESAR\)](#). *BJOG: An International Journal of Obstetrics and Gynaecology* 117: 1366–76

Skin closure after CS

[NICE CG132](#) recommends that obstetricians should be aware that the effects of different suture materials or methods of skin closure at CS are not certain.

A meta-analysis by [Tuuli et al. \(2011\)](#) evaluated whether staples or subcuticular sutures were associated with a higher risk of wound complications when used for transverse skin incisions following CS. RCTs and prospective cohort studies that compared outcomes of transverse CS wounds closed with staples or subcuticular sutures were included. Retrospective cohort studies, case-control studies and reports, and studies that did not provide sufficient information on population characteristics, surgical procedures, or outcomes, and those involving vertical skin incisions were excluded.

The primary outcome was wound complication, defined as the occurrence of wound infection or separation. Secondary outcomes included operation time, pain, cosmetic appearance and patient satisfaction. Qualitative synthesis was performed on 3 of the secondary outcomes and overall conclusions were made ('staples superior', sutures superior', or 'equivalent') when differences in scales for measuring outcomes made quantitative meta-analysis difficult. An overall conclusion was based on the number of studies supporting the superiority of a chosen method.

Six studies met the inclusion criteria (5 RCTs and 1 prospective cohort study) with a total of 803 wounds closed with staples and 684 closed with subcuticular sutures. All RCTs were of 'fairly good' quality when assessed by Physiotherapy Evidence Database scale scoring 8–9 out of 11, but the prospective cohort study was of poor quality, scoring 5 out of 11. Four studies evaluated both components of the primary outcome; 2 studies reported on wound infection, but not separation.

The meta-analysis indicated that staple closure was associated with a twofold higher risk of either wound infection or separation (13.4%) compared with sutures (6.6%, OR=2.06, 95% CI 1.43 to 2.98). The associated number needed to harm was 16. When the rates of wound infection were compared there was no significant difference between sutures and staples (OR=1.41, 95% CI 0.92 to 2.17), but staple closure was associated with a significantly higher risk of wound separation (OR=4.24, 95% CI 2.16 to 8.34). The estimated time saved by staple closure ranged from 3.3 to 9.3 minutes (4 studies). The 2 closure techniques were judged to be equivalent with regard to postoperative pain (3 RCTs), cosmetic outcome (3 RCTs), and patient satisfaction (5 RCTs).

The authors noted several limitations: not all studies reported wound infection and wound separation as outcomes, and the definitions of wound infection varied from infections needing antibiotic treatment or drainage, to superficial infections. Other wound complications, such as seromas and haematomas were not reported in most studies and were not included in this analysis. The lack of blinding in some studies could have introduced bias and the use of different suture types could have also affected outcomes. Confounding by other factors was also possible, such as obesity, skin preparation, emergency of procedure, preoperative antibiotics, and subcutaneous tissue closure.

An updated Cochrane review by [Mackeen et al. \(2012\)](#) also compared the effects of skin closure techniques and materials on maternal and operative outcomes after CS. Only RCT comparisons of skin closure techniques in CS were considered. The primary outcome was

wound infection, which included surgical site infection and cellulitis requiring antibiotics. The primary comparison was absorbable subcuticular sutures compared with non-absorbable staples. Trials in which 30% of participants were not closed by the method to which they were allocated were excluded. Data from 8 studies were included in the meta-analysis, an increase of 7 trials compared with the original Cochrane review on this topic ([Alderdice et al. 2003](#)) that was included in the evidence review in developing [NICE CG132](#).

Of the 6 studies evaluating the primary comparison, 5 RCTs were included in the meta-analysis by Tuuli et al. (2011) and their conclusions were similar. Wound infection rates did not differ significantly between absorbable sutures and non-absorbable staples (RR=0.85, 95% CI 0.43 to 1.71). These results did not differ when analysis was limited to the 5 studies in which Pfannenstiel incision was used (RR=0.41, 95% CI 0.12 to 1.36). There was significant heterogeneity between the subgroups in these analyses, suggesting that staples may have a different effect depending on the type of incision (vertical or Pfannenstiel). Incisions closed by staples were more likely to become separated (RR=3.82, 95% CI 2.05 to 7.12) and therefore need reclosing (RR=4.98, 95% CI 1.82 to 13.61). However, most studies did not define a minimum width for the definition of separation. No significant differences were seen for other secondary outcomes including pain and cosmetic outcome.

The authors stated that bias was low in 4 RCTs, but noted specific methodological concerns for 2 studies: 1 had a high attrition rate and the other had a high risk of bias. All authors were contacted to determine the number of women with wound complications, but only 1 could provide this information so some women with 2 infections may have been counted as 2 wound complications.

The meta-analyses by Mackeen et al. (2012) and Tuuli et al. (2011) both reported no significant difference in rates of infection between sutures and staples. Similarly, they both reported that staples were significantly more likely to cause skin separation. These studies also provide further information from RCTs on the lack of significant difference between staples and sutures on postoperative pain and cosmetic appearance, as requested in a research recommendation in the [full version of NICE CG132](#). Overall, these results suggest that sutures may be more effective than staples for skin closure and so may have a potential impact on [NICE CG132](#), although the details of any impact are outside the scope of the Evidence Update. Decisions on how the new evidence may impact guidance will not be possible until the guidance is reviewed by NICE following its published processes and methods.

Key references

Tuuli MG, Rampersad RM, Carbone JF et al. (2011) [Staples compared with subcuticular suture for skin closure after caesarean delivery: a systematic review and meta-analysis](#). *Obstetrics & Gynecology* 117: 682–90

Mackeen AD, Berghella V, Larsen M-L (2012) [Techniques and materials for skin closure in caesarean section](#). *Cochrane Database of Systematic Reviews* issue 9: CD003577

Supporting reference

Alderdice F, McKenna D, Dornan J (2003) [Techniques and materials for skin closure in caesarean section](#). *Cochrane Database of Systematic Reviews* issue 2: CD003577

1.5 Care of the baby born by CS

No new key evidence was found for this section.

1.6 Care of the woman after CS

No new key evidence was found for this section.

1.7 [Recovery following CS](#)

No new key evidence was found for this section.

1.8 [Pregnancy and childbirth after CS](#)

Vaginal birth after CS

[NICE CG132](#) recommends that 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.

An Australian prospective restricted cohort study reported by [Crowther et al. \(2012\)](#) consisted of a patient-preference cohort study, and a small nested randomised study. The aim of the trial was to compare the benefits and risks of a planned repeat CS (n=10 randomised, n=1098 preference) with a planned vaginal birth after CS (n=12 randomised, n=1237 preference).

The study included women who had a single prior CS and were pregnant with a live singleton in cephalic presentation, at 37 weeks gestation or more, and were considered suitable by their obstetrician for planned vaginal birth after CS. Exclusion criteria were: more than 1 CS; a vertical, inverted T or unknown CS incision; previous uterine rupture, surgery or perforation; multiple pregnancy; lethal congenital anomaly or fetal anomaly associated with mechanical difficulties at birth; or any contraindication to vaginal birth. Planned repeat CS was scheduled between 38 and 40 weeks: if a woman in the planned CS group entered labour before the scheduled procedure, a CS was considered to be unplanned. For women planning vaginal birth, clinicians agreed to follow the study protocol for intrapartum care. After study entry women planning vaginal birth awaited spontaneous onset of labour.

The primary outcome was a composite of death or serious outcome for the infant, defined as death after study entry or before hospital discharge, or serious morbidity. This was defined as 1 or more of: birth trauma; seizures at less than 24 hours age or needing 2 or more drugs to control; Apgar score less than 4 at 5 minutes; cord pH less than 7.0 or cord blood base deficit of 12 or more; stage 3 neonatal encephalopathy; admission to the neonatal intensive care unit for more than 4 days; severe neonatal lung disease; proven necrotising enterocolitis; and proven systemic infection in first 48 hours of life treated with antibiotics.

Of the women in the planned repeat CS group 98% delivered by CS and 2% by vaginal birth. In the planned vaginal birth after CS group 57% women had CS and 43% had vaginal birth. The risk of infant death before discharge or serious outcome was significantly reduced for infants born to women in the planned CS group compared with those in the planned vaginal birth group (RR=0.39, 95% CI 0.19 to 0.80, p=0.011). The number of CS needed to prevent 1 infant death in this group was 66 (95% CI 40 to 200).

When the individual components of the primary endpoint were examined there was a significant reduction in the risk of serious morbidity in infants born to the planned CS group compared with the vaginal birth group (RR=0.41, 95% CI 0.20 to 0.83, p=0.014). There were no significant differences between planned CS and planned vaginal birth for any of the other individual components of the primary outcome. No perinatal deaths occurred in the planned CS group, but unexplained 2 stillbirths occurred in the planned vaginal birth group.

Limitations stated by the authors were that few women consented to the randomised arm of the study because randomised trials are difficult when patients have strong treatment preferences. Unmeasured confounding may also have accounted for some of the findings in their study.

An Australian retrospective cohort study (n=21,389) reported by [Rozen et al. \(2011\)](#) assessed the outcomes of vaginal delivery after CS (TGCS group 5, n=423) compared with all cephalic singleton term births in women with no previous CS (TGCS groups 1–4, n=16,020). All multiple gestations, malpresentations, or premature births (TGCS groups 6–10) were excluded. Information was collected from medical records and women were stratified into the appropriate TGCS group after data collection. Primary outcomes were uterine rupture, post-partum haemorrhage, 3rd and 4th degree tears and neonatal morbidity (defined as admission to special care nursery or neonatal intensive care unit).

Most women in TGCS group 5 delivered by CS (80%) and most women in TGCS groups 1–4 delivered vaginally (83%). Post-partum haemorrhage following normal vaginal delivery was significantly higher for women in TGCS group 5 (16%) compared with those in TGCS groups 1–4 (11%, p=0.02). For women who had an instrumental vaginal delivery, post-partum haemorrhage was not significantly different for those in TGCS group 5 (30%) compared with those in TGCS groups 1–4 (29%, p=0.84). For women who had CS, those in TGCS group 5 had a lower rate of post-partum haemorrhage (26%) compared with those in TGCS groups 1–4 (37%, p<0.001).

The absolute number of 3rd and 4th degree tears was low. However, in women who had normal vaginal deliveries, there were significantly more tears in TGCS group 5 compared with TGCS groups 1–4 (1% vs 3% respectively, p=0.07), but this was not significant for instrumental vaginal delivery (6% vs 5% respectively, p=0.52). Admissions to the neonatal intensive care unit or special care nursery did not differ significantly for TGCS groups 1–4 compared with TGCS group 5 for normal vaginal deliveries (4% vs 4% respectively) or instrumental vaginal deliveries (8% vs 9% respectively, p=0.72). However, significant differences were noted for CS deliveries (12% vs 9%, p=0.01). Uterine rupture or dehiscence occurred in only 5 women overall (4 in TGCS group 5), but this low number resulted in insufficient power to detect statistical significance.

Limitations of the study stated by the authors were that the results need to be considered in the context of the TGCS classifications, which do not control for variables such as birth weight or whether CS was planned or unplanned. Another limitation was the retrospective nature of the analysis.

The results from Rozen et al. (2011) suggest that the risk of infant death before discharge or serious outcome for planned repeat CS is less than after planned vaginal birth after CS. However, the evidence from Crowther et al. (2012) suggested that many outcomes after vaginal birth after CS were not significantly different from those who had no previous CS. This evidence is unlikely to have an impact on [NICE CG132](#), which recommends discussing the risks and benefits of planned vaginal birth and of repeat CS.

Key references

[Crowther CA, Dodd JM, Hiller JE et al. \(2012\) Planned vaginal birth or elective repeat caesarean: patient preference restricted cohort with nested randomised trial. PLoS Medicine 9: e1001192](#)

[Rozen G, Ugoni AM, Sheehan PM \(2011\) A new perspective on VBAC: a retrospective cohort study. Women and Birth 24: 3–9](#)

Uterine rupture

[NICE CG132](#) recommends offering women planning a vaginal birth who have had a previous CS: electronic fetal monitoring during labour; and care during labour in a unit where there is immediate access to CS and on-site blood transfusion services, and notes that the risk of uterine rupture is higher for vaginal births after CS. [NICE CG70](#) recommends that if delivery is indicated, women who have had a previous CS may be offered induction, CS or expectant management on an individual basis, taking into account the woman's circumstances and wishes. At the time of publication of this Evidence Update vaginal PGE2 is either not

recommended or should not be used for this indication, depending on the preparation (gel, tablet or pessary). Informed consent should be obtained and documented. Current guidance recommends that intravenous oxytocin should not be used alone for induction of labour.

An Australian retrospective cohort study reported by [Dekker et al. \(2010\)](#) aimed to quantify the risk of uterine rupture in women with 1 prior CS (n=29,008). The study was based on data from 1998 to 2000 and analysed only second singleton births with confirmed uterine rupture (n=48). Births were classified as: repeat CS without labour; spontaneous labour with augmentation with oxytocin; induction of labour with oxytocin only; induction with only prostaglandins; induction with both oxytocin and prostaglandins; and induction with neither oxytocin nor prostaglandins. Relative risks were calculated for the spontaneous labour without augmentation group compared with each of the other groups.

Cases of uterine rupture were identified from the International Classification of Diseases codes of the perinatal and hospital morbidity collections that were provided by hospitals to the state Departments of Health. Information from the case notes was requested on the onset of labour, whether labour was augmented or induced and the method used, method of birth, and details of the rupture to validate the data. The data were examined by a researcher and an obstetrician blinded to the labour status. Complete uterine rupture was defined as a rupture through the full thickness of the uterus with fetal parts or amniotic fluid in the abdominal cavity. Partial rupture was defined as a rupture through the full thickness of the uterus with ballooning of thin membrane but no fetal parts or amniotic fluid in the abdominal cavity.

Of the 48 confirmed uterine ruptures, 37 were complete ruptures. For complete ruptures placental abruption was the only variable showing increased risk of uterine rupture for each subgroup compared with women who had spontaneous labour without augmentation with oxytocin. The overall rate of vaginal birth in the vaginal birth after CS group was 54%.

When all subgroups were compared with spontaneous labour without augmentation with oxytocin, planned CS had the lowest risk of uterine rupture (OR=0.11, 95% CI 0.04 to 0.34) and complete uterine rupture (adjusted OR=0.04, 95% CI 0.01 to 0.30). The risk of uterine rupture was 3 to 5 times greater when labour was induced by any means. The highest risk of any uterine rupture was for oxytocin after spontaneous onset of labour (adjusted OR=9.99, 95% CI 4.71 to 21.21).

There are a number of limitations stated by the authors. Although the increased risk associated with oxytocin is clinically relevant it is based on 12 cases of complete uterine rupture. There may also be differences in groups of women who have a trial of labour, those who have no trial of labour, and those who have unplanned CS after a trial of labour. The data did not allow study of perinatal death, the effect of the length of inter-pregnancy interval, the reason for first CS, or details of induction dosages and rates of drug administrations.

The study suggests that planned CS may be associated with lower risk of uterine rupture compared with spontaneous labour without augmentation, and that inducing labour increases the risk of uterine rupture. This is generally consistent with the recommendation in [NICE CG132](#) that women planning vaginal birth after CS should be offered care during labour in a unit with immediate access to CS because of the possibility of uterine rupture.

Key reference

[Dekker GA, Chan A, Luke CG et al. \(2012\) Risk of uterine rupture in Australian women attempting vaginal birth after one prior caesarean section: a retrospective population-based cohort study. BJOG: An International Journal of Obstetrics and Gynaecology 117: 1358–65](#)

2 New evidence uncertainties

During the development of the Evidence Update, the following evidence uncertainties were identified for the NHS Evidence UK Database of Uncertainties about the Effects of Treatments (UK DUETs).

Planned CS

- [MRI scan in addition to ultrasound for diagnosis of placenta accreta in high risk patients, and likelihood of caesarean hysterectomy](#)
- [Red blood cell salvage during caesarean section for reduction of non-autologous blood transfusion](#)
- [Pelvic artery catheterisation and embolisation in women with placenta accreta undergoing caesarean section, for uterine conservation and reduced maternal morbidity](#)

Pregnancy and childbirth after CS

- [Planned repeat caesarean section at 39 weeks compared to vaginal birth after caesarean \(VBAC\)](#)

Further evidence uncertainties for caesarean section can be found in the [UK DUETs database](#) and in the [NICE research recommendations database](#).

UK DUETs was established to publish uncertainties about the effects of treatments that cannot currently be answered by referring to reliable up-to-date systematic reviews of existing research evidence.

Appendix A: Methodology

Scope

The scope of this Evidence Update is taken from the scope of the reference guidance:

- [Caesarean section](#). NICE clinical guideline 132 (2011)

Searches

The literature was searched to identify studies and reviews relevant to the scope. Searches were conducted of the following databases, covering the dates 25 May 2010 (the end of the search period of NICE clinical guideline 132) to 25 September 2012:

- CDSR (Cochrane Database of Systematic Reviews)
- CENTRAL (Cochrane Central Register of Controlled Trials)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- DARE (Database of Abstracts of Reviews of Effects)
- EMBASE (Excerpta Medica database)
- HTA (Health Technology Assessment) database
- MEDLINE (Medical Literature Analysis and Retrieval System Online)
- NHS EED (Economic Evaluation Database)
- PsycINFO

Table 1 provides details of the MEDLINE search strategy used, which was adapted to search the other databases listed above. The core population search strategy from the original guideline searches was used with the addition of the search term 'vaginal birth after cesarean' and its abbreviation 'VBAC', which was used in supplementary searches for the original guideline. The search strategy was used in conjunction with validated Scottish Intercollegiate Guidelines Network [search filters for RCTs, systematic reviews, and observational studies](#).

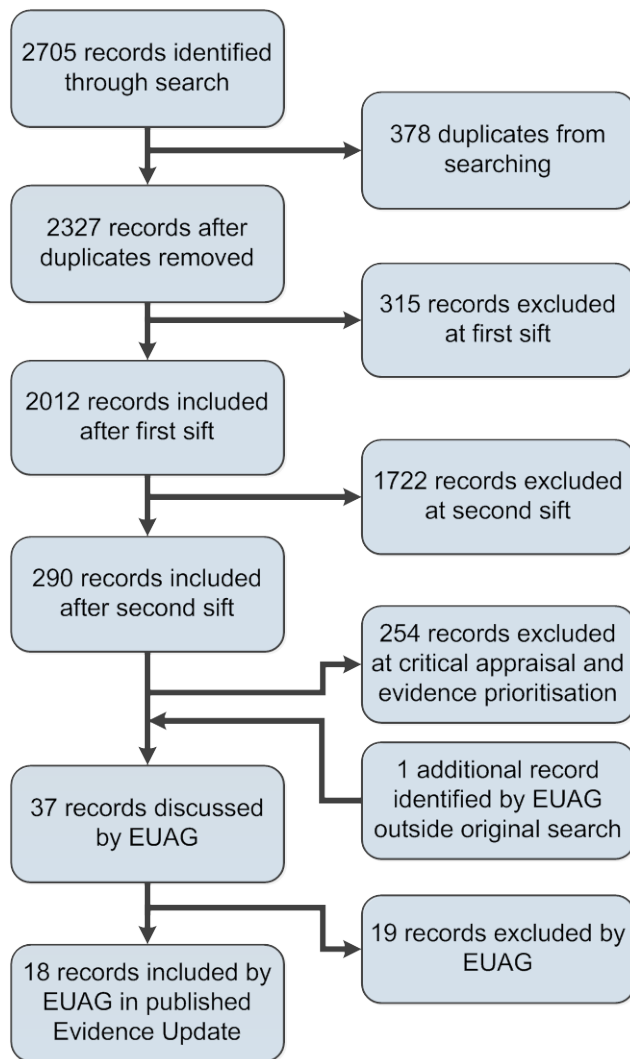
Figure 1 provides details of the evidence selection process. The long list of evidence excluded after review by the Chair of the EUAG, and the full search strategies, are available on request from contactus@evidence.nhs.uk

There is more information about [how NICE Evidence Updates are developed](#) on the NHS Evidence website.

Table 1 MEDLINE search strategy (adapted for individual databases)

1	exp cesarean section/	5	vaginal birth after cesarean/
2	(caesar#an\$ or cesar#an\$).ti,ab.	6	VBAC.ti,ab.
3	(deliver\$ adj3 abdom\$).ti,ab.	7	or/1-6
4	(c section\$ or c?section\$).ti,ab.		

Figure 1 Flow chart of the evidence selection process



EUAG – Evidence Update Advisory Group



Appendix B: The Evidence Update Advisory Group and Evidence Update project team

Evidence Update Advisory Group

The Evidence Update Advisory Group is a group of topic experts who review the prioritised evidence obtained from the literature search and provide the commentary for the Evidence Update.

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