



Royal College of
Obstetricians &
Gynaecologists

Cervical Cerclage

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1. Purpose and scope

Since the 1960s, the use of cerclage has expanded to include the management of women considered to be at high risk of mid-trimester loss and spontaneous preterm birth by virtue of factors such as multiple pregnancy, uterine anomalies, a history of cervical trauma (e.g. conisation or operations requiring forced dilatation of the cervical canal) and cervical shortening seen on sonographic examination. However, the use and efficacy of cerclage in these different groups is highly controversial since there is contradiction in the results of individual studies and meta-analyses.

Cerclage remains a commonly performed prophylactic intervention used by most obstetricians despite the absence of a well-defined population for whom there is clear evidence of benefit. Furthermore, there is little consensus on the optimal cerclage technique and timing of suture placement. The role of amniocentesis before emergency (rescue) cerclage insertion and the optimal management following insertion are also poorly defined. Complications are not well documented and often difficult to separate from risks inherent to the underlying condition. The purpose of this guideline is to review the literature and provide evidence-based guidance on the use of cerclage.

2. Background

Prematurity is the leading cause of perinatal death and disability. Preterm birth before 37⁺⁰ weeks of gestation accounted for 7.6% of all live births in England and Wales in 2005. Although preterm birth is defined as delivery before 37⁺⁰ weeks of gestation, the majority of prematurity-related adverse outcomes relate to birth before 33⁺⁰ weeks of gestation. Mortality increases from about 2% for infants born at 32 weeks of gestation to more than 90% for those born at 23 weeks of gestation.¹ Two-thirds of preterm births are the consequence of spontaneous preterm labour and/or preterm prelabour rupture of membranes (PPROM). The rate of spontaneous preterm birth continues to rise globally despite efforts to the contrary, and interventions aimed at reducing preterm birth have been largely disappointing.

Cervical cerclage was first performed in 1902 in women with a history of mid-trimester abortion or spontaneous preterm birth suggestive of cervical 'incompetence', with the aim of preventing recurrent loss. Cervical incompetence is an imprecise clinical diagnosis frequently applied to women with such a history where it is assumed that the cervix is weak and unable to remain closed during the pregnancy. However, recent evidence suggests that rather than being a dichotomous variable, cervical 'competence' is likely to be a continuum influenced by factors related not solely to the intrinsic structure of the cervix but also to processes driving premature effacement and dilatation. While cerclage may provide a degree of structural support to a 'weak' cervix, its role in maintaining the cervical length and the endocervical mucus plug as a mechanical barrier to ascending infection may be more important.

All decisions about cerclage are difficult and should be made with senior involvement. A doctor with the necessary skills and expertise to perform cerclage should carry out the procedure.



3. Identification and assessment of evidence

This RCOG guideline was developed in accordance with standard methodology for producing RCOG Green-top Guidelines.²⁻⁴ The Cochrane Library (including the Cochrane Database of Systematic Reviews), DARE, EMBASE, TRIP, Medline and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. The search was restricted to articles published between 1980 and November 2008. The databases were searched using the relevant MeSH terms, including all subheadings, and this was combined with a keyword search. Search words included 'cervical cerclage', 'cervical suture',

'midtrimester miscarriage', 'McDonald cerclage', 'Shirodkar cerclage', 'infection and cerclage', 'tocolytics and cerclage' and 'inflammatory mediators and cerclage', and the search was limited to humans and the English language. The National Library for Health and the National Guidelines Clearing House were also searched for relevant guidelines and reviews.

4. Definitions

Previous terminology (prophylactic, elective, emergency, urgent, rescue) of cervical sutures (cerclage) can be ambiguous. More appropriate nomenclature based on indication for cervical suture is recommended. The terms below are increasingly used in the scientific literature.

History-indicated cerclage

Insertion of a cerclage as a result of factors in a woman's obstetric or gynaecological history which increase the risk of spontaneous second-trimester loss or preterm delivery. A history-indicated suture is performed as a prophylactic measure in asymptomatic women and normally inserted electively at 12–14 weeks of gestation.

Ultrasound-indicated cerclage

Insertion of a cerclage as a therapeutic measure in cases of cervical length shortening seen on transvaginal ultrasound. Ultrasound-indicated cerclage is performed on asymptomatic women who do not have exposed fetal membranes in the vagina. Sonographic assessment of the cervix is usually performed between 14 and 24 weeks of gestation.

Rescue cerclage

Insertion of cerclage as a salvage measure in the case of premature cervical dilatation with exposed fetal membranes in the vagina. This may be discovered by ultrasound examination of the cervix or as a result of a speculum/physical examination performed for symptoms such as vaginal discharge, bleeding or 'sensation of pressure'.

Transvaginal cerclage (McDonald)

A transvaginal purse-string suture placed at the cervicovaginal junction, without bladder mobilisation.⁵

High transvaginal cerclage (Shirodkar)

A transvaginal purse-string suture placed following bladder mobilisation, to allow insertion above the level of the cardinal ligaments.⁶

Transabdominal cerclage

A suture performed via a laparotomy or laparoscopy, placing the suture at the cervicoisthmic junction.⁷

Occlusion cerclage

Occlusion of the external os by placement of continuous non-absorbable suture. The theory behind the potential benefit of occlusion cerclage is retention of the mucus plug.⁸

5. History-indicated cerclage

5.1 When should a history-indicated cerclage be offered?

History-indicated cerclage should be offered to women with three or more previous preterm births and/or second-trimester losses.

B

History-indicated cerclage should not be routinely offered to women with two or fewer previous preterm births and/or second-trimester losses.

B

Characteristics of the previous adverse event, such as painless dilatation of the cervix or rupture of the membranes before the onset of contractions, or additional risk factors, such as cervical surgery, are not helpful in the decision to place a history-indicated cerclage.

✓

There is insufficient evidence to recommend the use of prepregnancy diagnostic techniques aimed at diagnosing ‘cervical weakness’ in women with a history of preterm birth and/or second-trimester loss in the decision to place a history-indicated cerclage. Such techniques include assessment of cervical resistance index, hystero-graphy or insertion of cervical dilators.



Three randomised controlled trials (RCTs) have been conducted comparing history-indicated cerclage with expectant management.⁹⁻¹¹ The largest trial, coordinated by the Medical Research Council and Royal College of Obstetricians and Gynaecologists, was an international multicentre trial which recruited 1292 women whose obstetrician was uncertain as to whether a cerclage would be of benefit (71% of the study population had a history of second-trimester loss or preterm birth before 37 weeks of gestation). Randomisation allocated 647 women to cerclage and 645 to no cerclage.¹¹ Overall, there were fewer deliveries before 33 weeks of gestation in the cerclage group compared with the controls (13% versus 17%; RR 0.75; 95% CI 0.58-0.98), which was compatible with the prevention of one delivery before 33 weeks of gestation for every 25 cerclage insertions. There was no significant difference between the two groups in fetal/neonatal outcome (total numbers of miscarriages, stillbirths and deaths following live birth 55 [8.5%] in the cerclage group compared with 68 [10.5%] in the control group; OR 0.79; 95% CI 0.54-1.14). However, two of the eight infant deaths in the cerclage group were ascribed to conditions subsequent to preterm birth, compared with seven of the 14 in the control group. There were insufficient data to allow any conclusions to be drawn as to whether women were more likely to benefit if the previous loss had features suggestive of cervical incompetence (e.g. painless cervical dilatation or rupture of the membranes before the onset of contractions). Of six prespecified subgroup analyses, only women with a history of three or more pregnancies ending before 37 weeks of gestation ($n = 104$) benefitted from cerclage, which halved the incidence of preterm delivery before 33 weeks of gestation (15% versus 32%, $P < 0.05$). No effect was observed in those with only one (delivery before 33 weeks of gestation in the cerclage group 14% versus 17% in the expectant group) or two previous early deliveries (delivery before 33 weeks of gestation in the cerclage group 12% versus 14% in the expectant group), previous cervical surgery or first-trimester loss/uterine anomaly; however, the authors concluded that the relatively small numbers in each group limited the reliability of these results.

One further trial of 506 women considered at moderate risk of cervical incompetence, based on a scoring system to assess risk factors, randomised 268 to a McDonald cerclage and 238 to a policy of no cerclage. Women with prior second-trimester losses of a live fetus were excluded. There was no significant difference in preterm delivery (6.7% in the cerclage group versus 5.5% in the expectant group), although those with cerclage were more likely to be admitted to hospital and receive tocolytics.⁹ A third trial recruited 194 women who had had at least two previous preterm deliveries before 37 weeks of gestation (or one or more preterm delivery before 34 weeks of gestation); 96 women were randomised to McDonald cerclage and 98 to expectant management. There was no difference in outcome, with 34% delivering before 37 weeks of gestation in the cerclage group and 34% in the no cerclage group.¹⁰

Evidence level 1+

No studies provide sufficient data to examine the influence of additional risk factors such as cervical surgery or the characteristics of the previous delivery/miscarriage on the effect of history-indicated cerclage.

The studies that have examined the use of prepregnancy techniques (e.g. hystero-graphy, cervical resistance indices, insertion of cervical dilators) to assess cervical weakness were observational and not designed to test the hypothesis that their use optimised the selection of women for history-indicated cerclage.^{12,13} The largest study of cervical resistance indices (force required to dilate the cervix to 8 mm) reported that 175 women with a history of mid-trimester loss had a lower cervical resistance index than 123 parous women with no such history ($P < 0.001$). However, in this study all women with a history of low cervical resistance index had a suture inserted, with a successful pregnancy outcome in 75%. This rate is no higher than that expected with expectant management¹¹ and the absence of a control group makes it inappropriate to draw any evidence-based conclusions on the usefulness of this technique.¹⁵

6. Ultrasound-indicated cerclage

6.1 When should an ultrasound-indicated cerclage be offered?

6.1.1 Women with a singleton pregnancy and no history of spontaneous mid-trimester loss or preterm birth

The insertion of an ultrasound-indicated cerclage is not recommended in women without a history of spontaneous preterm delivery or second-trimester loss who have an incidentally identified short cervix of 25 mm or less.

B

To et al. screened 47 123 women at 22–24 weeks of gestation using transvaginal ultrasound to measure cervical length. In 470 women (1%), the cervix was 15 mm or less. Of these women, 253 (54%) agreed to participate in a randomised study comparing Shirodkar cerclage ($n = 127$) with expectant management ($n = 126$). The incidence of preterm delivery before 33 weeks of gestation was similar in both groups, at 22% (28 of 127) in the cerclage group versus 26% (33 of 126) in the control group (RR 0.84; 95% CI 0.54–1.3; $P = 0.44$), with no significant differences in perinatal or maternal morbidity or mortality.¹⁴

Evidence level 1++

This was further confirmed in an individual patient data (IPD) meta-analysis of four RCTs of cerclage versus expectant management in women with a short cervix (in which women from the previously discussed RCT were included). This meta-analysis reported no overall evidence of benefit of cerclage in women with cervical length less than 25 mm who had no other risk factors for spontaneous preterm birth.¹⁵

6.1.2 Women with a singleton pregnancy and a history of spontaneous mid-trimester loss or preterm birth

Women with a history of one or more spontaneous mid-trimester losses or preterm births who are undergoing transvaginal sonographic surveillance of cervical length should be offered an ultrasound-indicated cerclage if the cervix is 25 mm or less and before 24 weeks of gestation.

A

An ultrasound-indicated cerclage is not recommended for funnelling of the cervix (dilatation of the internal os on ultrasound) in the absence of cervical shortening to 25 mm or less.

C

An RCT of ultrasound-indicated cerclage involving 302 women with singleton pregnancies with a history of spontaneous preterm birth between 17⁺⁰ and 33⁺⁶ weeks of gestation, who were found to have a cervical length of less than 25 mm detected during serial sonographic examinations between 16⁺⁰ and 21⁺⁶ weeks of gestation, reported that when compared with expectant management, cerclage reduced preivable birth (at less than 24⁺⁰ weeks of gestation: 6.1% versus 14%; $P = 0.03$) and perinatal death (8.8% versus 16%; $P = 0.046$) but did not prevent birth at less than 35 weeks of gestation (32% versus 42%; OR = 0.67; 95% CI 0.42–1.07) unless cervical length was less than 15 mm (OR 0.23; 95% CI 0.08–0.66).¹⁶

Evidence level 1++

Similar results were reported from a meta-analysis that included 607 pregnancies from four RCTs of ultrasound-indicated cerclage.¹⁵ This study reported that in the subgroup of women with singleton pregnancies with a history of preterm second-trimester loss (16–23 weeks of gestation) or birth before 36 weeks of gestation, when compared with expectant management, cerclage resulted in a significant reduction in delivery before 35 weeks of gestation (RR 0.57; 95% CI 0.33–0.99 and RR 0.61; 95% CI 0.40–0.92, respectively), which was of a similar magnitude to the reduction observed in the previous study.¹⁶

There are no studies evaluating ultrasound-indicated cerclage performed solely on the presence of funnelling. However, studies have demonstrated that funnelling is a function of cervical shortening and does not appear to independently add to the risk of preterm birth associated with cervical length.^{17,18}

Evidence
level 2++

6.2 Who should be offered serial sonographic surveillance ± ultrasound-indicated cerclage?

Women with a history of spontaneous second-trimester loss or preterm delivery who have not undergone a history-indicated cerclage may be offered serial sonographic surveillance, as there is evidence to suggest that those who experience cervical shortening are at an increased risk of subsequent second-trimester loss/preterm birth and may benefit from ultrasound-indicated cerclage (see 6.1), while those whose cervix remains long have a low risk of second-trimester loss/premature delivery.

B

Women should be informed that expectant management is a reasonable alternative since there is a lack of direct evidence to support serial sonographic surveillance over expectant management. Furthermore, the majority of women with a history of second-trimester loss/preterm delivery will deliver after 33 weeks of gestation.

D

In studies where serial sonographic surveillance of cervical length has been carried out in women with a history of second-trimester loss and/or spontaneous preterm delivery, between 40% and 70% of women maintain a cervical length of more than 25 mm before 24^{±0} weeks of gestation.^{11,16,19-21} In three of these studies which reported the outcome of pregnancy in those who maintained a cervical length of more than 25 mm and hence did not receive cerclage, more than 90% of women delivered after 34 weeks of gestation. This suggests that serial sonographic surveillance may differentiate between women with a prior second-trimester loss/preterm birth who might benefit from cerclage and women who do not need intervention.

Evidence
level 2+

In the Medical Research Council/RCOG randomised study, women with a history of one, two or three or more previous second-trimester losses or spontaneous preterm births had an 83%, 86% and 68% chance, respectively, of delivery after 33 weeks of gestation when managed expectantly.¹¹ Given that there are no randomised studies directly comparing a policy of serial sonographic surveillance ± ultrasound-indicated cerclage with expectant management in women with a history of one or more spontaneous preterm births/mid-trimester losses, and given the significant chance of delivery after 33 weeks of gestation in such women, expectant management is a reasonable alternative.

Evidence
level 4

7. Can cervical cerclage be recommended in any other groups considered at increased risk of spontaneous preterm delivery?

7.1 Multiple pregnancies

The insertion of a history- or ultrasound-indicated cerclage in women with multiple pregnancies is not recommended, as there is some evidence to suggest it may be detrimental and associated with an increase in preterm delivery and pregnancy loss.

B

In a meta-analysis, subgroup examination of 39 twin pregnancies demonstrated a doubling in delivery rates before 35 weeks of gestation with the use of ultrasound-indicated cerclage compared with expectant management in women with a cervical length less than 25 mm (RR 2.15; 95% CI 1.15-4.01).¹⁵ Insertion of cerclage may also be associated with increased perinatal mortality, although this was not statistically significant (RR 2.66; 95% CI 0.83-8.54).

Evidence
level 1++

A prospective cohort study of 147 twin pregnancies identified 37 women with cervical length less than 25 mm between 18 and 26 weeks of gestation, of whom 21 underwent insertion of McDonald cerclage and 12 did not.²² Insertion of cervical cerclage was not associated with any significant improvement in preterm delivery at 34 weeks of gestation or less (42.9% in the cerclage group versus 50% in the non-cerclage group). Small numbers and lack of randomised design limit the conclusions that can be drawn from this study. Furthermore, those women who underwent cerclage had a significantly shorter mean cervical length compared with those who did not.

Evidence level 2++

There is only one RCT of history-indicated cerclage in twin pregnancies. This study examined the effect of cerclage ($n = 25$) versus no cerclage ($n = 23$) in twins conceived following ovulation induction, and demonstrated that cerclage was not effective in prolonging gestation or improving fetal outcome.²³

Several studies of cervical cerclage have included a subgroup of multiple pregnancies; however, they were of insufficient number to enable conclusions to be drawn regarding the effect of cerclage in preventing preterm birth. In an IPD meta-analysis,²⁴ data for multiple gestations were available in 66 mothers from three randomised studies.^{11,25,26} The use of cervical cerclage in multiple gestations was associated with a substantial increase in pregnancy loss or death before discharge from hospital (OR 5.88; 95% CI 1.14–30.19); however, the results should be interpreted with caution owing to the relatively small number of women included.

Evidence level 1+

7.2 Uterine anomalies and cervical trauma

History- or ultrasound-indicated cerclage cannot be recommended in other high-risk groups such as women with müllerian anomalies, previous cervical surgery (cone biopsy, large loop excision of the transformation zone or destructive procedures such as laser ablation or diathermy) or multiple dilatation and evacuation.

B

The existing published studies are either inadequately controlled or include insufficient numbers to be able to make evidence-based recommendations in the vast majority of the groups mentioned above. In the IPD meta-analysis of ultrasound-indicated cerclage,¹⁵ subgroup analysis of those women with a history of cone biopsy ($n = 64$) or more than one dilatation and evacuation ($n = 131$) showed no difference in preterm birth before 35 weeks of gestation in the cerclage group compared with the expectantly managed group (RR 1.18; 95% CI 0.57–2.45 and RR 0.91; 95% CI 0.57–1.47, respectively); however, the authors concluded that that the results should be interpreted with caution owing to the small numbers of women. There were insufficient women with müllerian anomalies or diethylstilbestrol exposure to perform subgroup analyses.

Evidence level 1+

The Medical Research Council/RCOG study of history-indicated cerclage reported that in a subgroup analysis of women with a history of cone biopsy or cervical amputation ($n = 138$), there was no significant difference in delivery before 33⁺⁰ weeks of gestation in the cerclage group compared with the expectant group (19% versus 22%).¹¹

7.2.1 Radical trachelectomy

The decision to place a concomitant cerclage at radical trachelectomy should be individualised.

✓

There are several case series²⁷ reporting successful pregnancy outcomes with the use of concomitant cerclage placement at radical trachelectomy; however, the absence of a control group makes it impossible to provide evidence-based guidelines on the use of this technique.

Evidence level 3

8. Transabdominal cerclage

8.1 *When should a transabdominal cerclage be considered?*

In women with a previous failed transvaginal cerclage, insertion of a transabdominal cerclage may be considered, but this procedure may be associated with increased maternal morbidity.

D

Transabdominal cerclage can be performed preconceptually or in early pregnancy.

✓

A transabdominal cerclage is usually inserted following a failed vaginal cerclage or extensive cervical surgery. There are no randomised studies comparing the effectiveness of transabdominal cerclage with that of expectant management or transvaginal cerclage. The evidence is limited to a systematic review including 13 case series and one controlled non-randomised study of transabdominal versus transvaginal cerclage in women with a prior failed transvaginal cerclage. This systematic review reported a lower risk of perinatal death/delivery before 24 weeks of gestation (6% versus 12.5%) in those women who had undergone transabdominal cerclage ($n = 117$) compared with those who had a repeat insertion of transvaginal cerclage ($n = 40$).²⁸ However, there was a higher incidence (3.4% versus 0%) of serious operative complications (bleeding requiring transfusion, injury to bladder/bowel/uterine artery, anaesthesia problems). Davis et al., in their controlled non-randomised study in women with a prior failed transvaginal cerclage, reported that the incidence of delivery before 33 weeks of gestation was lower in the 40 women with a transabdominal suture compared with the 24 women with a transvaginal suture insertion (10% versus 38%; $P = 0.01$).²⁹

Evidence level 2/3

There are no studies directly comparing the insertion of a preconceptual transabdominal cerclage with insertion in early pregnancy. However, preconceptual insertion should be considered when possible because of the technical advantage of operating on the uterus of a woman who is not pregnant. Furthermore, there is no evidence that preconceptual transabdominal cerclage has any detrimental impact on fertility or management of early miscarriage. Abdominal cerclage can be safely left in place if a further pregnancy is a possibility.

8.2 *Should an abdominal cerclage be performed laparoscopically?*

There is no evidence to support a laparoscopic approach over laparotomy in the insertion of an abdominal cerclage.

D

One small study making a retrospective comparison in 19 women demonstrated a viable infant in nine of 12 women who received a laparoscopic procedure compared with five of seven who received an abdominal procedure.³⁰

Evidence level 3

8.3 *How should a delayed miscarriage or fetal death be managed in women with an abdominal cerclage?*

Management decisions in cases of delayed miscarriage or fetal death in women with an abdominal cerclage can be difficult and should be made with senior involvement. A doctor with the necessary skills and expertise to perform the procedure should carry out the procedure.

✓

Successful evacuation through the stitch by suction curettage or by dilatation and evacuation (up to 18 weeks of gestation) has been described; alternatively, the suture may be cut, usually via a posterior colpotomy. Failing this, a hysterotomy may be required or caesarean section may be necessary.

D

There are no studies evaluating the management of pregnancy termination in the event of fetal demise or the need to terminate a pregnancy. Success using the techniques described above has been reported by experienced clinicians.

Evidence level 4

9. Rescue cerclage

9.1 When should a rescue cerclage be considered?

The decision to place a rescue suture should be individualised, taking into account the gestation at presentation, as even with rescue cerclage the risks of severe preterm delivery and neonatal mortality and morbidity remain high. A senior obstetrician should be involved in making the decision.

D

Insertion of a rescue cerclage may delay delivery by a further 5 weeks on average compared with expectant management/bed rest alone. It may also be associated with a two-fold reduction in the chance of delivery before 34 weeks of gestation. However, there are only limited data to support an associated improvement in neonatal mortality or morbidity.

B

Advanced dilatation of the cervix (more than 4 cm) or membrane prolapse beyond the external os appears to be associated with a high chance of cerclage failure.

D

There has been one RCT evaluating 'rescue' cerclage and bed rest against bed rest alone.³¹ This trial included only 23 women (16 with singleton pregnancies and seven with twin pregnancies) who were confirmed to have cervical dilatation and prolapse of the membranes on speculum examination at a mean gestation of 22–23 weeks. No data are given on degree of cervical dilatation. All women, irrespective of random allocation, were hospitalised and on bed rest until 30 weeks of gestation and received 1 week of broad-spectrum antibiotics. In addition, those undergoing cerclage received perioperative indometacin. Eight of 13 women in the cerclage group required emergency removal of the suture for maternal or fetal reasons before 36 weeks of gestation. Women in the cerclage group delivered on average 4 weeks later than those in the bed rest group (mean interval between randomisation and delivery 54 days versus 20 days) and there was a significant reduction in delivery before 34 weeks of gestation (53% versus 100%; $P = 0.02$). There was a trend towards improvement in neonatal survival (56% versus 28%) and a significant reduction in compound neonatal morbidity (defined as neonatal admission to intensive care unit and/or neonatal death: 71% versus 100%; RR 1.6; 95% CI 1.1–2.3). The authors did not provide any data on the incidence of chorioamnionitis or neonatal morbidity.

Evidence level 1-

In a prospective non-randomised study of 46 asymptomatic low-risk women found to have a dilated cervix (mean 4 cm) with bulging membranes between 18 and 26 weeks of gestation (mean 22–23 weeks) during routine preterm delivery screening, the insertion of a rescue cerclage was associated with a mean prolongation of pregnancy of 8.8 weeks (range 0–17) compared with 3.1 weeks (range 0–11) in women who received bed rest alone.³² This prolongation resulted in a three-fold reduction in the number of births before 32 weeks of gestation (31% versus 94%; RR 0.33; 95% CI 0.19–0.57), a doubling in the number of live births (86% versus 41%) and an almost 40% improvement in neonatal survival (96% versus 57%; RR 0.59; 95% CI 0.0–0.76). No comparative data are provided regarding evidence of infection in the two groups.

The findings from one further prospective non-randomised study of 37 women with cervical dilatation of 4 cm or greater (mean 6 cm) between 20 and 27 weeks of gestation (mean 22–23 weeks) reported that the insertion of a rescue cerclage in 22 cases prolonged pregnancy for on average 4 weeks more than the 15 pregnancies managed with bed rest alone.³³ The mean age at delivery was 33 ± 4.4 weeks of gestation in the cerclage group and 28 ± 4.3 weeks of gestation in the bed rest group. There was no significant difference in perinatal survival (73% in the cerclage group versus 67% in the bed rest group). All women in this study received 48 hours of tocolytics (indometacin or ritodrine) and women in the cerclage group received 5 days of antibiotics and hospitalisation. Women in the bed rest group were hospitalised for the duration of their pregnancy. The rate of clinical chorioamnionitis was similar in the two groups (9% versus 13%), but no data were given on the neonatal infection rate.

Evidence level 2++

There is no clear evidence that the gestation at which the cerclage is inserted affects the magnitude of prolongation in gestation; however, consideration should be given to the fact that, in cases presenting before 20 weeks of gestation, insertion of a rescue cerclage is highly likely to result in a preterm delivery before 28 weeks of gestation. Furthermore, the decision to place a rescue cerclage beyond 24 weeks of gestation should be individualised and take into account the local gestational age of viability. Improvements in neonatal intensive care have advanced the gestational age of viability to 24 weeks of gestation in most developed countries and, given the potential risk of iatrogenic membrane rupture and subsequent preterm delivery, rescue cerclage can rarely be justified after this gestation.

Evidence
level 4

The aforementioned studies have not provided an analysis of prolongation of pregnancy in relation to cervical dilatation. However, several other uncontrolled studies have suggested that the presence of membrane prolapse beyond the external os and/or cervical dilatation greater than 4 cm are significant predictors of cerclage failure. In view of the absence of a control group in these studies, it is not clear whether this observation relates to treatment failure or a more advanced underlying process that makes this group of women inherently more likely to deliver.³⁴⁻³⁶

Evidence
level 3

10. What are the contraindications to cerclage insertion?

The contraindications to cerclage insertion are:

- active preterm labour
- clinical evidence of chorioamnionitis
- continuing vaginal bleeding
- PPRM
- evidence of fetal compromise
- lethal fetal defect
- fetal death.

11. What information should be given to women before cerclage insertion?

Before history- or ultrasound-indicated cerclage insertion, a woman should be given information about the potential complications, which should include the following:

Cerclage insertion is associated with a doubling in risk of maternal pyrexia but no apparent increase in chorioamnionitis.

B

Cerclage insertion is not associated with an increased risk of PPRM, induction of labour or caesarean section.

B

The insertion of a cervical suture is not associated with an increased risk of preterm delivery or second-trimester loss.

B

Before any type of cerclage insertion, women should be informed of the following:

There is a small risk of intraoperative bladder damage, cervical trauma, membrane rupture and bleeding during insertion of cervical cerclage.

D

Shirodkar cerclage usually requires anaesthesia for removal and therefore carries the risk of an additional anaesthetic.

✓

Cervical cerclage may be associated with a risk of cervical laceration/trauma if there is spontaneous labour with the suture in place.

D

Although women are often routinely informed of a number of potential complications associated with cerclage insertion, including PPRM, miscarriage, preterm labour, infection, bleeding and bladder or cervical damage, there is little published evidence to support this. None of the randomised studies of cervical cerclage has been designed or adequately powered to assess the risk of maternal morbidity and, to date, none of the larger studies of history- or ultrasound-indicated cerclage has reported an increase in PPRM, preterm delivery or second-trimester loss.^{11,16,25} Intraoperative complications including bladder damage, cervical trauma, membrane rupture and bleeding are reported but are rare (<1%).^{11,14,16}

Evidence level 1++

An IPD meta-analysis of seven randomised studies of cerclage insertion (combining data from studies of both history-indicated and ultrasound-indicated cerclage) found that cerclage was associated with an increased risk of maternal pyrexia (OR 2.35; 95% CI 1.37–4.05), but there was no evidence of increase in chorioamnionitis (OR 0.73; 95% CI 0.36–1.46), PPRM (OR 0.92; 95% CI 0.62–1.35), induction of labour or caesarean section (OR for spontaneous labour for no cerclage 0.81; 95% CI 0.65–1.02).²⁴

In a retrospective review of 251 cerclages (including 49 rescue and 202 history-indicated sutures) over a 7.5-year period, cervical laceration requiring suturing at the time of delivery was reported in 11% of Shirodkar and 14% of McDonald procedures, which was higher than that reported in 55 688 other deliveries occurring during the same period (2%). Although this was statistically significant ($P < 0.025$), this result is highly susceptible to reporting bias.

Evidence level 2

Several case series have reported high risks of membrane rupture and infection associated with rescue cerclage; however, the lack of a control group makes it difficult to separate the procedure-related risk from that inherent to the underlying condition.

12. Pre operative management

12.1 What investigations should be performed before insertion of cervical cerclage?

It is good practice to offer a first-trimester ultrasound scan and screening for aneuploidy before the insertion of a history-indicated suture to ensure both viability and the absence of lethal/major fetal abnormality. Before ultrasound-indicated or rescue cerclage, it is good practice to ensure an anomaly scan has been performed recently.



The use of routine maternal white cell count and C-reactive protein to detect subclinical chorioamnionitis before insertion of a rescue cerclage is not recommended. The decision to perform these tests should be based on the overall clinical picture, but in the absence of clinical signs of chorioamnionitis, the decision for rescue cerclage need not be delayed.



Although several studies have linked a raised maternal C-reactive protein level with histological evidence of chorioamnionitis in cases of preterm labour or PPRM, the sensitivity and specificity are considered to be too poor to be clinically useful.^{37,38} In an uncontrolled retrospective review of 17 cases of rescue cerclage, the authors reported that a preoperative C-reactive protein value below 4.0 mg/dl and a maternal white cell count less than 14 000/microlitre were associated with prolongation of pregnancy compared with women with values above these cut-offs. Interpretation of these results was confounded by the degree of cervical dilatation, such that those women with higher values also had more advanced cervical dilatation.

Evidence level 2

12.2 Should amniocentesis to detect infection be performed before rescue or ultrasound-indicated cerclage?

There is insufficient evidence to recommend routine amniocentesis before rescue or ultrasound-indicated cerclage as there are no clear data demonstrating that it improves outcome.



In selected cases where there is suspicion of intra-amniotic infection, amniocentesis may be performed to aid the decision about rescue cerclage, as the presence of infection is associated with a poor prognosis.

D

Amniocentesis before rescue cerclage does not appear to increase the risk of preterm delivery before 28 weeks of gestation.

D

Several studies have reported an association between poor pregnancy outcome and the presence of intra-amniotic infection/inflammation, diagnosed by amniocentesis, in women presenting with a dilated cervix, whether or not they undergo rescue cerclage.^{39,40} However, none of these studies was randomised and they are hence susceptible to selection bias, with the majority of women undergoing amniocentesis at the discretion of the individual physician. Rates of intra-amniotic infection vary from 13% to 51% depending on the criteria used to define a 'positive' result and the population selected.⁴¹⁻⁴³ Furthermore, the low specificity of amniocentesis could deny women cerclage who may have benefited from the procedure. The incidence of intra-amniotic infection in ultrasound-indicated cerclage is about 1-2%.

Evidence level 3

Airoldi et al.⁴¹ identified 122 women between 15⁺⁰ and 25⁺⁶ weeks of gestation with a dilated cervix (1-4 cm). Twenty-four (20%) of these had an amniocentesis performed. Following multivariate regression analysis, the authors concluded that an amniocentesis did not independently contribute to preterm birth before 28 weeks of gestation ($P = 0.90$).

Evidence level 2+

12.2.1 Is amnioreduction before rescue cerclage recommended?

There is an absence of data to either refute or support the use of amnioreduction before insertion of a rescue cerclage.

D

Several small studies have reported successful prolongation of pregnancy using amnioreduction before cerclage, but the absence of a valid control group makes it impossible to draw any evidence-based conclusion as to its contribution to the outcome.⁴⁴⁻⁴⁶

Evidence level 3

12.2.2 Should a latency period be observed between presentation and insertion of rescue or ultrasound-indicated cerclage?

There are no studies to support immediate versus delayed cerclage insertion in either rescue or ultrasound-indicated procedures, but as delay can only increase the risk of infection, immediate insertion is likely to supersede the benefits of waiting to see if infection manifests clinically.

✓

The interval between presentation and suture insertion varies between studies, with some authors advocating a period of observation to ensure that preterm labour, abruption and infection are excluded. Others argue that delayed insertion has the potential to increase the risk of ascending infection; however, no comparative studies of the two strategies exist.

12.2.3 Should routine genital tract screening for infection be carried out before cerclage insertion?

There is an absence of data to support genital tract screening before cerclage insertion.

✓

In the presence of a positive culture from a genital swab, a complete course of sensitive antimicrobial eradication therapy before cerclage insertion would be recommended.

✓

There are no studies evaluating the benefit of screening for genital tract infection before insertion of a cerclage.

13. Operative issues

13.1 *Should perioperative tocolysis be used for insertion of cerclage?*

There is no evidence to support the use of routine perioperative tocolysis in women undergoing insertion of cerclage.

D

In most of the existing randomised studies, the majority of women allocated cerclage also received perioperative tocolysis, most commonly indometacin. Consequently, there is no control group available for comparison. However, a retrospective cohort study involving 101 women who underwent ultrasound-indicated cerclage reported that the rate of preterm birth before 35 weeks of gestation was not significantly different in women who received indometacin for 48 hours following the procedure compared with those who did not (39% versus 34%).⁴⁷

Evidence level 2+

13.2 *Should perioperative antibiotics be given?*

The decision for antibiotic prophylaxis at the time of cerclage placement should be at the discretion of the operating team.

✓

There are no studies of perioperative antibiotic use in women undergoing cervical cerclage.

13.3 *What method of anaesthesia should be employed for the insertion of cerclage?*

The choice of anaesthesia should be at the discretion of the operating team.

✓

There are no studies comparing general with regional anaesthesia for insertion of cervical cerclage and hence the decision should be made on a case-by-case basis.

13.4 *Can cerclage be performed as a day-case procedure?*

Elective transvaginal cerclage can safely be performed as a day-case procedure.

C

Women undergoing ultrasound-indicated or rescue cerclage, given the higher risk of complications such as PPRM, early preterm delivery, miscarriage and infection, may benefit from at least a 24-hour postoperative period of observation in hospital. Cases should be managed on an individual basis.

✓

In women undergoing insertion of transabdominal cerclage via laparotomy, an inpatient stay of at least 48 hours is recommended.

✓

Golan et al. retrospectively compared 125 cases of elective outpatient cerclage with 101 cases of inpatient cerclage, during which women received complete bed rest in hospital for 48 hours postoperatively.⁴⁸ There was no significant difference in short-term complications or pregnancy outcome, but hospital stay was significantly shorter for those managed as planned day cases.

Evidence level 2+

13.5 *Which technique and material should be used?*

The choice of suture material should be at the discretion of the surgeon.

✓

The choice of transvaginal cerclage technique (Shirodkar versus McDonald) should be at the discretion of the surgeon.

D

There is no current evidence to support the placement of two purse-string sutures over a single suture.

C

There is no current evidence to support the placement of a cervical occlusion suture in addition to the primary cerclage.

✓

There is insufficient evidence to support any specific technique for cerclage insertion. In a secondary analysis of singleton pregnancy data from four randomised trials of cervical cerclage in women with a short cervix, there was no significant difference in the rate of delivery before 33 weeks of gestation in those with a McDonald cerclage compared with those with a Shirodkar suture, once adjusted for confounding factors (OR 0.55; 95% CI 0.2–1.3).⁴⁹ These results should be interpreted with caution since the study was not sufficiently powered to detect a statistically significant difference in this outcome.

Evidence level 2-

A retrospective analysis of 169 women having McDonald procedures and 82 women having Shirodkar procedures did not reveal any significant differences in fetal survival or major postoperative morbidity between the two techniques.⁵⁰ In a subgroup of women with one previous second-trimester loss, there was a significant increase in fetal survival in those with a high vaginal cerclage (100% versus 63%; $P < 0.05$). However, a similar effect was not observed in those with a previous preterm birth or those with more than one previous second-trimester loss.

Evidence level 3

In a small retrospective cohort study involving 150 women who had either an ultrasound-indicated ($n = 43$) or an elective ($n = 107$) cerclage, 112 were managed with a single purse-string suture and 38 with a double suture. There was no significant difference in preterm delivery or pregnancy loss. However, the study is limited by being retrospective and non-randomised and also underpowered to detect a significant difference in the primary outcomes.⁵¹

Evidence level 2-

There are no controlled studies on the use of a cervical occlusion suture in addition to the primary cerclage; however, this is the subject of a continuing randomised trial.⁸

14. Adjuvant management

14.1 Bed rest

Bed rest in women who have undergone cerclage should not be routinely recommended, but the decision should be individualised, taking into account the clinical circumstances and the potential adverse effects that bed rest could have on women and their families in addition to increased costs for the healthcare system.



There are no studies comparing bed rest with no bed rest in women undergoing cervical cerclage. A Cochrane review of bed rest in women at high risk of preterm delivery identified only one randomised cluster study of uncertain methodological quality. A comparison was made between 432 women prescribed bed rest and 834 women prescribed no intervention/placebo. Preterm birth before 37 weeks of gestation was similar in both groups (7.9% in the intervention group versus 8.5% in the control group; RR 0.92; 95% CI 0.62–1.37).⁵²

14.2 Sexual intercourse

Abstinence from sexual intercourse following cerclage insertion should not be routinely recommended.



There are no studies evaluating the effect of sexual intercourse on the risk of second-trimester loss or preterm delivery in women with cervical cerclage. Furthermore, there is no evidence that sexual intercourse in early pregnancy increases the risk of preterm delivery in women with a previous preterm birth. In a secondary analysis of an observational study of transvaginal sonographic examinations performed at 16–18 weeks of gestation on 187 women with singleton gestations with a prior spontaneous preterm birth before 32 weeks of gestation, women who reported infrequent sexual intercourse during early pregnancy had an incidence of recurrent spontaneous preterm birth of 28% compared with 38% in those women who reported some intercourse ($P = 0.35$).⁵³

14.3 Is there a role for post-cerclage serial sonographic surveillance of cervical length?

While routine serial sonographic measurement of the cervix is not recommended, it may be useful in individual cases following ultrasound-indicated cerclage to offer timely administration of steroids or in utero transfer.

D

Several studies have shown a significant increase in cervical length following the insertion of elective, ultrasound-indicated and rescue cerclage.⁵⁴⁻⁵⁷ A postoperative upper cervical length (closed cervix above the cerclage) of less than 10 mm before 28 weeks of gestation appears to provide the best prediction of subsequent preterm delivery before 36 weeks of gestation following the placement of an ultrasound-indicated cerclage.^{55,58}

14.4 Is there a role for repeat cerclage when cervical shortening is seen post-cerclage?

Placement of an ultrasound-indicated cerclage in the presence of cervical length shortening cannot be recommended as, compared with expectant management, it may be associated with an increase in both pregnancy loss and delivery before 35 weeks of gestation.

D

The decision to place a rescue cerclage following an elective or ultrasound-indicated cerclage should be made on an individual basis, taking into account the clinical circumstances.



In a retrospective cohort study involving 24 women with a history-indicated cerclage and subsequent cervical length shortening to less than 25 mm on ultrasound, 19 women were managed expectantly and five women underwent insertion of a reinforcing cerclage.⁵⁹ Repeat suture insertion was associated with a significantly earlier gestational age at delivery (21 versus 33 weeks of gestation; $P = 0.002$) and an increased miscarriage rate (80% versus 16%; $P = 0.01$). However, the selection criteria for choosing expectant management over repeat suture insertion were not defined and hence these results may be subject to bias.

Evidence level 2-

In a further retrospective cohort, Fox et al. followed 12 women with an elective cerclage who had cervical length shortening of more than 2 cm or prolapse of the membranes below the suture before 28 weeks of gestation, and who underwent between one and four repeat cerclage procedures.⁶⁰ The median gestation at delivery was 34 weeks (range 22-39), with 75% of women delivering before 37 weeks of gestation.

Evidence level 3

14.5 Is fetal fibronectin testing useful following insertion of a cervical cerclage?

Routine fetal fibronectin testing is not recommended post-cerclage. However, the high negative predictive value of fetal fibronectin testing for subsequent delivery at less than 30 weeks of gestation in asymptomatic high-risk women with a cerclage in place may provide reassurance to women and clinicians in individual cases. However, the increased false-positive rate of fetal fibronectin testing in such women makes the finding of a positive result less useful.

C

In a retrospective observational study involving 910 asymptomatic women at high risk of preterm birth, including 159 with a cervical cerclage in place, fetal fibronectin testing for the prediction of delivery before 30 weeks of gestation was shown to have a similar negative predictive value in both groups (over 98%) but a significantly lower specificity (77% versus 90%; $P < 0.001$) in those with a suture.⁶¹

Evidence level 2+

14.6 Should women receive supplemental progesterone following cerclage?

Routine use of progesterone supplementation following cerclage is not recommended.



The RCOG guidance currently recommends that in women at high risk of preterm delivery, progesterone administration be restricted to clinical trials which aim to determine whether its use is associated with improved fetal, neonatal and/or infant outcome.⁶²

There are no comparative studies on the use of progesterone in woman who have undergone cerclage. In an RCT of ultrasound-indicated cerclage involving 302 women with singleton pregnancies and a history of spontaneous preterm birth between 17⁺⁰ and 33⁺⁶ weeks of gestation, an analysis of the woman's recorded intention to use supplemental progesterone did not appear to have any effect on delivery before 35⁺⁰ weeks of gestation (OR 0.97; 95% CI 0.6-1.6).¹⁶

15. When should the cerclage be removed?

A transvaginal cervical cerclage should be removed before labour, usually between 36⁺¹ and 37⁺⁰ weeks of gestation, unless delivery is by elective caesarean section, in which case suture removal could be delayed until this time.



In women presenting in established preterm labour, the cerclage should be removed to minimise potential trauma to the cervix.



There are no studies comparing elective removal of transvaginal cerclage with removal in labour. However, in the absence of preterm labour, elective removal at 36-37 weeks of gestation is advisable owing to the potential risk of cervical injury in labour and the minimal risk to a neonate born at this gestation.

A Shirodkar suture will usually require anaesthesia for removal.



There are no studies regarding the use of anaesthesia in the removal of a Shirodkar suture but, given that the technique involves burial of the suture, an anaesthetic is likely to be necessary for removal.

All women with a transabdominal cerclage require delivery by caesarean section, and the abdominal suture may be left in place following delivery.



There are no published studies on long-term outcome comparing a policy of removing a transabdominal cerclage to it remaining in place. However, if further pregnancies are contemplated, it is reasonable to recommend leaving the cerclage in place.

15.1 Should the cerclage be removed following PPRM?

In women with PPRM between 24 and 34 weeks of gestation and without evidence of infection or preterm labour, delayed removal of the cerclage for 48 hours can be considered, as it may result in sufficient latency that a course of prophylactic steroids for fetal lung maturation is completed and/or in utero transfer arranged.



Delayed suture removal until labour ensues or delivery is indicated is associated with an increased risk of maternal/fetal sepsis and is not recommended.



Given the risk of neonatal and/or maternal sepsis and the minimal benefit of 48 hours of latency in pregnancies with PPRM before 23 and after 34 weeks of gestation, delayed suture removal is unlikely to be advantageous in this situation.



Jenkins et al. retrospectively studied 62 women, approximately 50% of whom had an elective cerclage in place and the remainder a rescue cerclage in place, who had PPRM between 24 and 34 weeks of gestation but no signs of preterm labour or infection.⁶³ In 37 women there was

Evidence level 2+

immediate removal (less than 24 hours) of the suture and in 25 women removal was delayed (over 24 hours) based on clinician preference. The duration of latency from PPROM to delivery was significantly longer in the delayed-removal group (10.1 days versus 5.0 days; $P < 0.001$), but there was no significant difference in gestational age at delivery. Delayed removal was associated with significantly more women delivering more than 48 hours after presentation (96% versus 54%; $P < 0.001$) compared with immediate removal, accompanied by a trend towards lower neonatal mortality (4% versus 11%). There was no significant trend towards a higher rate of maternal infection (44% versus 22%) and neonatal sepsis (16% versus 5%) in the delayed-removal group. Prolongation of time to removal of cerclage to more than 48 hours in the delayed-removal group compared with the immediate group (206.8 ± 7.4 hours versus 5.4 ± 0.2 hours) may have contributed to the observed trend towards an increase in infectious complications. There was no obvious difference in outcome in those with a history-indicated, ultrasound-indicated or rescue cerclage.

Ludmir et al. retrospectively studied 30 women with an elective cerclage in place and PPROM between 24 and 32 weeks of gestation where all cases were managed expectantly but in 20 cases there was immediate removal of the suture and in 10 cases there was retention of the cerclage until delivery.⁶⁴ Significantly more women with retained cerclage had delivery delayed for at least 48 hours compared with women who had immediate cerclage removal (90% versus 50%), but there was no overall difference in gestation at delivery. Although there was no difference in the reported rate of chorioamnionitis prompting delivery in the retained cerclage versus the removed cerclage groups, there was a significantly higher neonatal mortality rate in the retained cerclage group (70% versus 10%), the majority of deaths in the former group being attributed to neonatal sepsis.

Both of these studies lack a randomised approach to the allocated management strategy and are hence subject to selection bias. Furthermore, there may be significant differences between the effects and complications associated with delayed removal in women with rescue, ultrasound-indicated and elective cerclage.

16. Suggested audit topics

- Number of women referred to a consultant obstetrician (or a specialist prematurity clinic) before 12 weeks of gestation as a proportion of those eligible for history-indicated cerclage.
- Review of the indications for cerclage in women having undergone a procedure in line with local protocol.
- Proportion of women receiving aneuploidy screening before history-indicated cerclage insertion.
- Pregnancy loss rate at less than 24 weeks of gestation and preterm delivery at 24–32 weeks of gestation following cervical cerclage insertion.

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APPENDIX

Clinical guidelines are 'systematically developed statements which assist clinicians and women in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No.1: *Development of RCOG Green-top Guidelines* (available on the RCOG website at <http://www.rcog.org.uk/guidelines>). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research might be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendations
1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias	A At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; or A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias	B A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias	C A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal	
2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal	
3 Non-analytical studies, e.g. case reports, case series	
4 Expert opinion	
	Good practice point  Recommended best practice based on the clinical experience of the guideline development group

This guideline was produced on behalf of the Guidelines Committee of the Royal College of Obstetricians and Gynaecologists by:

Professor AH Shennan FRCOG, London and Ms MS To MRCOG, London

and peer-reviewed by: BLISS (Babies Born too Soon, too Small, too Sick); RCOG Consumers' Forum; Royal College of Midwives; Mrs A Diyaf MRCOG, Nottingham; Ms LMM Duley FRCOG, Leeds; Mr RG Farquharson FRCOG, Liverpool; Ms SK Flint FRCOG, Tunbridge Wells; Mr KT Moriarty MRCOG, Warwickshire; Dr NC Smith FRCOG, Aberdeen.

The Guidelines Committee lead reviewers were: Mr M Griffiths FRCOG, Luton and Dr K Langford FRCOG, London.

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The final version is the responsibility of the Guidelines Committee of the RCOG.

The guidelines review process will commence in 2014 unless evidence requires earlier review.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available within the appropriate health services.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.