3centres Collaboration
Cervical Shortening
Cervical Insufficiency

Clinical Practice Guidelines 2011
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AIM

This guideline aims to offer advice to care providers on the assessment and management of women with a diagnosis of cervical shortening and/or cervical insufficiency.

While preterm birth may be the final outcome for a woman with a shortened cervix, management of preterm birth per se is not the focus of this guideline. 3Centres has developed another guideline addressing preterm labour and birth (See www.3centres.com.au/preterm_labour)

SEARCH AND APPRAISAL

The following methods of search and appraisal were used: An Ovid platform database selection was made using Medline, Embase, Cochrane databases, for evidence published in English from the year 1998 onwards.

Professional body websites were also used: American College of Obstetricians and Gynecologists (ACOG), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal College of Obstetricians and Gynaecologists (RCOG), Society of Obstetricians and Gynaecologists of Canada (SOGC).

Other websites accessed: National Health and Medical Research Council (NHMRC), National Institute for Health and Clinical Excellence (NICE) and BMJ Best practice.

Where international guideline groups have cited levels of evidence, these have been referred to in the summary boxes at the conclusion of each section. Also see Appendix 4. Evidence tables.

Search terms used were: cervical insufficiency, cervical shortening, threatened preterm labour, cervical incompetence, cerclage, tocolytic(s), preterm birth, progesterone, prostagstational, cervical length

In the compilation of these recommendations, international guidelines and the results of systematic reviews were used to compare facets of care. Contemporary reviews and recommendations from professional bodies were also used. Individual randomized controlled trials were used if they provided a high level of evidence, as determined by the NHMRC evidence level grading criteria.¹

In addition, a survey was circulated to the Women’s Hospitals Australasia (WHA) members to ascertain the routine practice among leading hospital clinicians for the care and management of women with cervical shortening. Seventy surveys were distributed and eleven replies were received, representing a 15.7% response rate. (Appendix 1)

Following an iterative consultation process among key stakeholders from the three tertiary centres, a consensus of opinion was gained in most instances. In cases of conflicting points of view, a variance process was initiated whereby the Co-Chairs of the 3centres Collaboration made the final decision.


Please refer to the website for updates to this guideline. www.3centres.com.au
INTRODUCTION

One of the challenges facing health care providers is the diagnosis and subsequent management of a woman with a shortened cervix.

While there are many publications relating to the diagnosis and management of women with a shortened cervix, there is a paucity of high level evidence, such as randomised control trials, to support and guide clinical practice. In particular, there are several concerns with the current evidence that contribute to uncertainty about best management strategies:

- There is no uniform definition of a short cervix and cervical length varies with gestation.
- Women are often not stratified into high risk or low risk/no previous risk factors.
- While there is an association between a shortened cervix and preterm labour and birth, most women with a short cervix do not experience a preterm birth and most preterm births are not thought to be primarily due to a cervical problem.

It is hoped that this guideline will assist clinicians in the care of women who have been identified as having a short cervix, whether or not they have a prior history of preterm birth or pregnancy loss, thus reducing variation in clinical practice and improving pregnancy outcomes.

It is further anticipated that the guideline will highlight the considerable uncertainties that remain in the provision of care for women with a short cervix.

The 3centres Collaboration encourages further research to better understand cervical shortening and predict pregnancy outcomes, with a view to developing improved aetiology-directed interventions.

CERVICAL LENGTH MEASUREMENT

Measurement of cervical length by transvaginal ultrasound (TVU) is considered to be safe in pregnancy and has been shown to be well tolerated by women.2

The Australian Society of Ultrasound in Medicine (ASUM) recommends that all women having a mid-trimester ultrasound scan should have their cervical length measured.3 ASUM does not provide the evidence to support this recommendation. Indeed, there is no evidence that routine cervical length measurement in all women improves pregnancy outcomes.4 Nonetheless, clinicians should be aware that as cervical lengths are increasingly being reported, it is more likely that they will be required to interpret cervical length measurements.

Cervical length changes throughout pregnancy, progressively shortening towards term. Thus, average cervical length is dependant upon the gestation at which it is measured.

Over the past decade or so there have been numerous studies reporting cervical length at varying gestations, in differing populations. The majority of published data report cervical length at 22-25 weeks gestation. At this gestation, the median (50th centile) cervical length in singleton pregnancies equates to approximately 35mm.5 Other threshold values for clinical decision making at 24 weeks gestation correspond to: 30mm = 25th centile, 25mm = 10th centile, 20mm = 5th centile.

In Australia the majority of women have their mid-trimester ultrasound examination performed at 18-20 weeks gestation. There are no published population data on cervical length at this gestation.

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Cervical length is most accurately measured by transvaginal ultrasound and only after the woman has emptied her bladder. The cervix is measured with the ultrasound probe directed into the anterior fornix of the vagina. Pressure on the cervix may artificially increase the length and should be avoided. The cervix is measured in the sagittal view from the internal os to the external os. The measurement may be taken in a straight line or a curved line. The cervix should be assessed over several minutes and the shortest measurement reported. Cervical length measured in this manner is highly reproducible.

In addition to measuring length, some authors have described the use of provocation tests to induce funnelling, such as fundal pressure, coughing, standing or Valsalva manoeuvre during assessment of the cervical length. There is no evidence that such tests improve the utility of cervical length as a predictor of pregnancy outcome when compared to cervical measurement without provocation. In the absence of such evidence, cervical provocation tests cannot be recommended for clinical practice.

A variety of terms have been used to describe the cervix further, such as “funnelling”, “beaking” or “wedging”. These terms have been used with no clear definition, or distinction between them when during ultrasound, there is the invagination of the membranes and amniotic fluid into the proximal end of the endocervical canal. This invagination will continue as the cervix shortens and dilates. If the membranes remain intact there may be a large portion ballooning out into the vagina, known as “hourglass membranes”. The presence of funnelling with a shortened cervix is considered an ominous sign, associated with an increased risk of preterm birth.

### SUMMARY - CERVICAL LENGTH MEASUREMENT

- ASUM recommends all pregnant women should have a cervical length measurement, although there is no evidence that this improves pregnancy outcomes.
- TVU is safe, reproducible and acceptable to women and is the preferred method of assessing cervical length. Evidence SOGC II-B
- Cervical length progressively shortens throughout pregnancy.
- Terms such as funnelling, beaking and wedging have become interchangeable, with no clear distinction between them. The presence of funnelling is an ominous sign associated with an increased risk of preterm birth.
- Provocation tests such as fundal pressure etc, are not recommended.
- The presence of a shortened cervix in those at high risk for a preterm birth, have an even greater risk of preterm birth. Evidence RANZCOG 2008

### DEFINITIONS

**Short cervix**

Recognising the association between cervical shortening and risk of spontaneous preterm birth, the discovery of a short cervix may change the care offered to an individual woman.

However, there are no uniform criteria defining a “short cervix”, and the inverse relationship between cervical length and risk of preterm birth is likely to be a continuum. The most frequently

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6 Antguaco TL et al, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® assessment of gravid cervix. American College of Radiology (ACR); 2008. 5p
used definition of a shortened cervix is one that measures less than 25mm (10th centile) on a TVU scan at 20–24 weeks gestation. By definition, approximately 8-10% of women will have a cervical length of <25mm at 23 weeks gestation.9

There is no evidence that targeting interventions by a cervical length of <25mm is associated with improved pregnancy outcomes. However, there is recent evidence that using a cervical length of <20mm (5th centile), whether in women with no previous history of preterm birth or pregnancy loss or in women with an obstetric/medical history suggestive of a high risk of preterm birth, may allow directed care that might improve pregnancy outcomes.10 For this reason 3Centres recommend using a cervical length ≤20mm at 18-22 weeks gestation to define a threshold where specific care may then be considered.

In addition to cervical length per se, clinicians are encouraged to consider other factors that may put the woman at high risk for spontaneous preterm birth such as the number of fetuses, the presence of infection, obstetric history, the presence or absence of symptoms, rate of change of cervical length and gestational age at which the cervical length was obtained. (The earlier in gestation the shortening is detected, the higher the risk of preterm birth)

Cervical insufficiency

Cervical insufficiency is thought to be due to a congenital or acquired (e.g. by previous surgery) structural weakness of the cervix.

The term “cervical incompetence” is considered pejorative and insensitive. It is recommended that this term is no longer used.

Typically, women with cervical insufficiency present with painless, cervical shortening and dilation in mid-pregnancy, which is sometimes associated with an increased, watery vaginal discharge, and/or increasing pressure symptoms.

Cervical insufficiency is associated with an increased risk of mid-trimester pregnancy loss or preterm birth and this guideline also aims to direct future care for those women with a past diagnosis of cervical insufficiency that has led to a pregnancy loss.

### SUMMARY SHORT CERVIX DEFINITION

**Short cervix**

- Cervical length of 20mm or less on TVU at 18-22 weeks gestation.
- Cervical shortening is usually painless, may be accompanied by a watery vaginal discharge or be asymptomatic.

**Cervical insufficiency**

- Structural weakness of the cervix associated with an increased risk of mid-trimester loss.

### CERVICAL LENGTH AND RISK OF PRETERM BIRTH

There is a strong inverse relationship between cervical length in mid-pregnancy and the risk of preterm birth. Measurement of cervical length provides an accurate prediction of that risk. This relationship is particularly enhanced in women at high risk of preterm birth, such as those with a previous pregnancy loss or cervical surgery. In essence, the shorter the cervix and the earlier the

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Please refer to the website for updates to this guideline. [www.3centres.com.au](http://www.3centres.com.au) 6.
gestation, the higher the risk of preterm birth - a risk that is exacerbated if other risk factors are present. 

For example, in a large (nearly 40,000 women) population-based prospective multicentre study: 1% of women had a cervix <15mm and 35% of these women gave birth before 32 weeks; 20% of women had a cervix 16-25mm and 10% of these women gave birth before 32 weeks. 

Similarly, in another large study, 2% of women had a cervical length ≤ 15 mm at 23 weeks; these women accounted for 90% and 60% of those experiencing a preterm birth at ≤ 28 and ≤ 32 weeks, respectively. 

If a shortened cervix is observed on ultrasound scan at 18-22 weeks gestation, women should be able to have an extensive discussion about the risks of preterm birth with a senior obstetrician and/or a neonatologist. Written information should also be provided.

**Short cervix in a general, low-risk population**

In a low-risk population without recognised risk factors, the incidence of preterm birth before 35 weeks gestation when cervical length was <25mm measured at 24 weeks gestation, has been reported in one paper as 3% in a population of 2107 women studied.

**Short cervix in a high-risk population**

In addition to cervical length, an individual woman’s medical and pregnancy history and ethnic origin may also identify her at high risk of spontaneous preterm birth.

The following table, derived from a population of high-risk women, is a further illustration of the predictive value of cervical length and the risk of preterm birth. It may be useful when discussing ongoing management options with women.

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<th>Length of cervix (mm)</th>
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Table 2. Predicted probability of preterm delivery before week 28, by cervical length (mm) and time of measurement (week of pregnancy) in a high-risk population. Adapted from: Berghella et al 2007

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SUMMARY – CERVICAL LENGTH AND THE RISK OF PRETERM BIRTH

- The finding of a short cervix on routine mid pregnancy ultrasound increases the risk of preterm birth.
- The earlier in pregnancy the short cervix is found, the greater the risk of preterm birth.
- The risk of preterm birth is further heightened if risk factors are present.
- Women should be able to have an extensive discussion about the risks of preterm birth with a senior obstetrician and/or a neonatologist.

MANAGEMENT OPTIONS - GENERAL

Conservative management
In the absence of specific evidence, in certain circumstances clinicians, in consultation with the woman, may reasonably choose conservative management as the initial preferred option. See population specific options.

Cervical surveillance
As above and due to the heterogeneity of many research studies, cervical surveillance by transvaginal ultrasound serial scans, may be the option of choice. See population specific options.

Progesterone
In recent years there has been renewed interest in the use of prophylactic progesterone in women at high-risk of preterm birth. A number of randomized clinical trials have been completed that address different populations of women. However, the optimal dose, route of administration, and gestational age at which to commence and cease progesterone therapy remains inconclusive at present. A number of other clinical trials are on-going that may assist in informing future practice. See population specific options for 3centres recommendations.

Cervical cerclage
There have been various terms used to describe cervical cerclage such as prophylactic, therapeutic or emergency. These terms are now considered ambiguous and therefore for the purpose of this guideline, we have used the definitions of cervical sutures as suggested by the Royal college of Obstetricians and Gynaecologists in May 2011 as follows: ¹⁴

History-indicated cerclage
Insertion of a cerclage as a result of factors in a woman’s obstetric or gynaecological history, which increases the risk of spontaneous second-trimester loss or preterm delivery. A history-indicated suture is performed as a prophylactic measure in an asymptomatic woman 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’.

The decision to place a rescue cerclage should be individualised and is dependant upon the gestation at presentation. 3centres recommends caution when considering inserting a rescue cerclage at later gestations as there is insufficient evidence to recommend this practice. An experienced obstetrician should be involved in this decision-making.

Cerclage type
There are two types of transvaginal cerclage, Shirodkar and McDonald. The Shirodkar technique involves reflecting vaginal skin allowing placement of the suture high up around the cervix, as close as possible to the level of the internal cervical os. The McDonald ‘purse string’ technique involves inserting the suture around the intravaginal portion of the cervix, without reflection of vaginal skin, and is technically simpler to perform. Currently, there is no evidence to recommend one type of suture over the other.
Cervical cerclage may be placed under a regional or general anaesthetic.
Transabdominal cerclage, either by laparoscopy or laparotomy, is an option if a previous transvaginal cervical cerclage has failed or it is not technically possible. Laparoscopic placement of a cerclage can be performed pre-pregnancy or in early pregnancy. Both transabdominal cerclage options require a general anaesthetic. The fetus is later delivered by caesarean section.
Clinicians should decide which technique to use, based on their experience and expertise, and on the woman’s history.

Cerclage complications
Commonly cited but with little or no evidence, complications of cervical cerclage are said to include bleeding from suture placement, infection, preterm pre-labour rupture of membranes (PPROM). Suture displacement secondary to uterine contractions may also occur. Also, with the use of a general anaesthetic for any procedure, there are potential anaesthetic risks to consider.

There is insufficient evidence to guide practice when a woman has preterm pre-labour rupture of membranes (PPROM) and a cervical cerclage in situ. The results from an on-going multi-centre trial will help to guide future practice. Until the results from that trial have been published, most common clinical practice is to remove a cervical suture if a woman presents with PPROM. However, 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.

Transvaginal cerclage should be removed in late pregnancy to allow a normal vaginal birth. There is limited evidence to guide the timing of removal but it is most common to remove a suture at or after 36-37 weeks gestation. Women should be counselled that there is about a 10% chance of spontaneous labour in the 48 hours following cerclage removal. Routine induction of labour at the time of cerclage removal cannot be recommended. The suture must be removed at any gestation in the presence of established labour or chorioamnionitis.

The role of perioperative antibiotics associated with cerclage placement.
There is no evidence to guide practice regarding the use of prophylactic perioperative antibiotics at the time of cerclage.

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15 Removal-v-retention of cerclage in preterm, pre-labor rupture of membranes. ClinicalTrials.gov identifier: NCT00201656
Until there is evidence that such therapy is associated with more good than harm, the use of prophylactic antibiotic therapy is not recommended.

**The role of Indomethacin/tocolytics following cerclage placement**

In two studies the use of indomethacin following ultrasound indicated placement of cerclage did not demonstrate a reduction in preterm birth when compared to those receiving cerclage alone. The routine use of indomethacin is not recommended until future research can guide practice.\(^{16,17}\) There have been no randomized studies to show that the routine use of any tocolytic therapy after cerclage placement is effective. Therefore, routine tocolytic therapy following cerclage placement cannot be recommended.

**Rest**

Many clinicians have recommended hospitalisation and bed-rest for women with a shortened cervix. However, there is no evidence that bedrest improves pregnancy outcomes in these women. Bed rest and/or hospitalisation is not recommended for any population group unless individual circumstances dictate it so.\(^{18,19}\)

**POPULATION SPECIFIC MANAGEMENT OPTIONS**

**GENERAL POPULATION LOW-RISK WOMEN**

It is important to be able to advise and provide appropriate care for low-risk women who have no previously known risk factors and have an incidental finding of a shortened cervix on a routine TVU scan. The number of these women may be increasing due to the widespread use of high quality ultrasound and use of the transvaginal route.

**Conservative management:**

There is insufficient evidence to recommend routine transvaginal serial ultrasound assessment of cervical length in women with no risk factors.\(^4\) Ultrasound screening lacks the discriminatory power to be used effectively in a low risk population. However, in the case of a routine ultrasound study of the fetal and maternal anatomy, cervical length may often be included in the assessment. When cervical length is <25mm before 24 weeks gestation, it would be considered as being shortened.

In women with a cervical length of between 20-25mm, there is insufficient evidence to support any specific intervention. In this situation, an experienced clinician should review the ultrasound findings and discuss the findings with the woman, advising that her risk of spontaneous preterm birth is less than 5%. Some clinicians may choose to repeat TVU length measurement 1-2 weeks later, although there is no evidence to support such practice. Admission of a woman with cervix 20-25mm to hospital cannot be recommended. There is no evidence that hospitalisation or bed-rest reduces the risk of preterm birth in these women.

**Progesterone:**

There is limited evidence examining the effectiveness of vaginal progesterone solely in a low-risk population of women, with an incidental finding of a short cervix.


\(^{17}\) Visintine J., Airoldi J., and Berghella V. Indomethacin administration at the time of ultrasound- indicated cerclage: is there an association with a reduction in spontaneous preterm birth? American Journal Of Obstetrics And Gynecology, 198(6), 06 2008.


\(^{19}\) Sosa C, Althabe F, Belizan J, and Bergel E. Bed rest in singleton pregnancies for preventing preterm birth. Cochrane database of systematic reviews (Online), (1), 2004.
In one trial that included low and high-risk women, the authors concluded that in women whose cervix was <15mm, the administration of 200mg of vaginal progesterone daily from 24 – 34 weeks gestation, reduced their risk of preterm birth by 44% (19% in the placebo group, 34% in the progesterone group). This was not associated with a significant improvement in neonatal outcome.\textsuperscript{20}

A multicentre, randomised, double-blind, placebo controlled trial, in a mixed population (low risk and high risk), 458 women with a shortened cervix (10-20 mm) at 19 - 24 weeks gestation, were administered 90mg of vaginal progesterone gel. In women without a history of preterm birth (84% of the population), vaginal progesterone administration was associated with a significant reduction (almost 50%) in the rate of preterm birth before 33 weeks, (7.6% vs 15.3%). Within the whole treatment group, overall there was a 45% reduction in the rate of preterm birth before 33 weeks gestation, and improved neonatal outcomes.\textsuperscript{20}

3centres Collaboration recommends offering vaginal progesterone 90-200mg to women who are shown to have a cervix <20mm at 18-22 weeks gestation. On average, this would be expected to halve their risk of preterm birth.

Alternatively, the offer of vaginal progesterone (200mg capsule nocte) is recommended to women who are shown to have a cervix <15mm at 20-25 weeks gestation. On average, this would expect to reduce their risk of preterm birth at <34 weeks by 44\% \textsuperscript{20}

Cervical cerclage:
There is no evidence to show that the insertion of an ultrasound indicated cerclage in women in whom the diagnosis of a short cervix is an incidental finding, improves pregnancy outcome. Accordingly, cervical cerclage is not recommended for women who have an incidental finding of a short cervix.\textsuperscript{21}

Rest:
There is no evidence that bedrest improves pregnancy outcomes in women who have the incidental finding of a short cervix. Bed rest and/or hospitalization is not recommended.\textsuperscript{18,19,22}

### SUMMARY: GENERAL POPULATION LOW RISK WOMEN

- **Conservative management.** Cervix 20-25mm - Consider repeat at TVU 1-2 weeks.
- **Progesterone research.** Cervix <20mm, 90mg daily 19-24 weeks until 37 weeks (Hassan 2011)  
  Cervix < 15mm, 200mg progesterone 24-34 weeks until 36 weeks. (Fonseca 2007)

3centres recommend either of these progesterone options, using 200mg if 90mg or 100mg is unavailable

### HIGH-RISK WOMEN – ASYMPTOMATIC

Women at high-risk of preterm birth are those where there is often a history of multiple cervical dilatations,\textsuperscript{23} other cervical trauma, surgical intervention such as a cone biopsy or obstetric trauma, uterine malformations, multiple pregnancy, ethnicity, low BMI or most commonly, previous pregnancy loss in the second or early third trimester, where there is no fetal cause for the pregnancy loss.\textsuperscript{24}


\textsuperscript{22} Fox NS Does hospitalization prevent preterm delivery in the patient with a short cervix Am J Perinat 2007; 24: 49-53


The risk factors for cervical shortening leading to preterm birth should be evaluated at the first antenatal visit. Because cervical shortening may lead to preterm birth, the risks of preterm birth should be discussed with all high-risk women. The outcome of all discussions needs to be clearly documented.

There is insufficient evidence on which to base strong recommendations for the management of women at high risk of cervical shortening and preterm birth. In discussion with the woman, clinicians may choose from three broad approaches to management, singularly or in combination. Care for each woman is individualised, dependent upon her gestation, history and circumstances, and on the considerations of an experienced clinician.

**Cervical surveillance:**

If cervical length surveillance is the preferred management option for high-risk women, then serial TVU scans should be offered, starting at about 16 weeks gestation, or earlier if indicated by the woman’s history and risk factors. It may also be appropriate that the frequency of antenatal visits is increased to allow timely review of the ultrasound results.

There is no agreed optimum frequency of cervical scanning. In general, it is recommended that cervical ultrasounds should be performed every week to every four weeks. However, the frequency of ultrasound scanning is dictated by the gestation, cervical length, and rate of change, pre-existing risk factors or if there is a change in the clinical picture. A woman with changing symptomatology, increasing pelvic pressure or mucoid discharge, may require more frequent scans. The benefit of cervical surveillance is that it is a non-invasive option.

If changes are observed on ultrasound surveillance then the next step(s) in management should be discussed with the woman.

**Progesterone:**

Systematic reviews from a number of randomised trials have shown that progesterone reduces the risk of preterm birth in high-risk women, who have had a previous, spontaneous preterm birth.

In the population of women at high risk for preterm birth who currently have a normal cervical length, two trials have demonstrated that the use of prophylactic progesterone reduced their incidence of preterm labour and birth.

In the first trial, a daily dose of 100mg of vaginal progesterone in women with a history of preterm birth, administered between 24–34 weeks gestation, showed that progesterone administration was associated with delayed cervical shortening as pregnancy progressed, a lower rate of preterm birth, a lower frequency of newborn admission to the intensive care unit and a shorter length of neonatal stay.

More recently, a secondary analysis of another randomized controlled trial suggested that the use of progesterone is effective in prolonging pregnancy of women with a history of spontaneous preterm birth <34 weeks gestation. Women were given progesterone (17-alpha hydroxyprogesterone

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25 ACOG Practice bulletin No. 48 Cervical Insufficiency. Obstetrics and Gynecology, Volume 102, No. 5, November 2003, pp. 1091-1099(9)
caproate) from 15-20\textsuperscript{4} weeks gestation until 36 weeks gestation.\textsuperscript{29} (17-alpha hydroxyprogesterone caproate is not currently available for use in Australia.)

If it is decided that vaginal progesterone is indicated, then until further evidence is available to guide otherwise, 3Centres recommends the use of 90-200mg vaginal progesterone suppository daily until 34 weeks gestation.

**Cervical cerclage:**

It has been suggested that using serial ultrasound to identify cervical changes in women thought to be at high of preterm birth because of previous pregnancy losses, and thereby better target cervical cerclage rather than routine cerclage in all such women may reduce cerclage rates and result in similar pregnancy outcomes as cerclage placement on the basis of history alone.\textsuperscript{30,31} Thus, the use of cervical surveillance for identifying cerclage candidates may usefully reduce the number of cerclages inserted.

A history indicated cerclage is inserted in asymptomatic women who are at risk of mid-pregnancy loss and/or very preterm birth based on previous obstetric risk factors (>2 previous PTB) where the attending clinician(s) believe that cervical insufficiency was a major contributor to the loss.\textsuperscript{34}

The suture is placed prior to any cervical change, typically at 13-16 weeks gestation, once the risk of early miscarriage has passed. Insertion at 14 weeks also allows completion of first trimester aneuploidy testing, if desired, prior to cervical cerclage.

**Rest:**

Clinicians often recommend additional rest in the belief that it reduces the gravitational challenge on the cervix, particularly where physical exertion (prolonged standing, long occupational hours, heavy lifting etc) may increase the likelihood of preterm birth. However there is no evidence that bed-rest is beneficial for a woman at risk of preterm labour, and so cannot not be recommended.\textsuperscript{18,19}

### HIGH-RISK WOMEN - ASYMPTOMATIC

**Risk factors include:**

- Spontaneous mid trimester loss without identifiable cause. (3+ losses RCOG 2011)
- Multiple cervical procedures: Cone biopsies, LLETZ, surgical dilatations.
- Congenital uterine abnormality.
- Multiple pregnancies.
- Cervical trauma.

**Evidence:** ACOG 2003

### MANAGEMENT OPTIONS SINGULARLY OR IN COMBINATION

2. History indicated cerclage. Placed 12-14 weeks. Small risk of: trauma, anaesthetic risks, bleeding, PPROM
3. Remove: ≥36 weeks or sooner in cases of infection or labour. Evidence RCOG 2011
4. Vaginal progesterone 90-200mg daily, 24-34 weeks. (Excl. multiple pregnancy)

### HIGH-RISK WOMEN WITH A SHORT CERVIX

This group of high-risk women are found to have a shortened cervix during surveillance.


The management options to be considered and discussed with an individual woman who has been shown to have a shortened cervix will depend on the clinical situation, including other signs or symptoms of labour or chorioamnionitis, the number of fetuses in utero, other high-risk factors, cervical length and gestational age at which the cervical length was obtained. The management options detailed in this guideline relate to the woman with a singleton pregnancy who is not in labour and who does not have chorioamnionitis.

**Continued cervical surveillance:**

As per cervical surveillance option above for high-risk women - asymptomatic. However, without some form of intervention, the risk of fetal loss is high in this group of women and therefore it is not likely to be the preferred option.

**Progesterone:**

In addition to the use of progesterone in a mixed population of high and low risk women, there are two more trials that focused on those high-risk women who presented with a shortened cervix.

The first, in 2007 (De Franco et al), was a secondary analysis of a previously reported trial. The authors concluded that women at high-risk for a preterm birth who had a short cervix, should be offered progesterone 90mg daily if their cervix measured <28mm.\(^\text{32}\)

Secondly, the O’Brien et al trial in 2009 reported that by offering high-risk women whose cervix was <25mm 90mg of progesterone daily, this will significantly preserve the cervical length.\(^\text{33}\)

The optimum dose and timing of progesterone remains to be determined. Until further evidence is available to better guide practice, 3Centres recommends the use of 90mg-200mg progesterone daily, or 200mg nocte until 36 weeks gestation.

**Cervical cerclage:**

A trial of ultrasound indicated cerclage in women with a history of preterm loss between 17 and 37 weeks gestation and cervical length <25mm detected at 16-22 weeks gestation, concluded that cerclage prevented preterm birth <24 weeks gestation when compared to expectant management 6.1% versus 14%; \(P = 0.03\) and perinatal death (8.8% versus 16%; \(P = 0.05\) but did not prevent birth at less than 35 weeks of gestation (32% versus 42%; \(OR = 0.67; 95\% \text{ CI } 0.42–1.07\)) unless cervical length was less than 15 mm (\(OR 0.23; 95\% \text{ CI } 0.08–0.66\)).\(^\text{34}\) Further, the results from a meta analysis of four RCT’s reviewing cerclage, showed that the intervention seemed to have a similar effect regardless of the degree of cervical shortening, including cervical lengths of 16–24 mm, as well as cervical lengths of <15.9mm.\(^\text{35}\)

If cerclage is the preferred management option in a woman who has had one or more mid-trimester losses, 3Centres recommend that it be placed at <22 weeks gestation and only if the cervix has reached ≤25mm.

---


Rest:
There is no evidence that bed-rest is beneficial for a woman at risk of preterm labour and so cannot be recommended. 18,19

WOMEN WITH MULTIPLE GESTATION
While women with a multiple pregnancy are considered high-risk for preterm labour and birth, there is insufficient evidence to support the recommendations for cervical cerclage as per the previous categories. 34,36

Similarly, the use of prophylactic vaginal progesterone in women with a multiple pregnancy has not been shown to improve outcomes. Progesterone cannot be recommended for women with a multiple pregnancy. 37,38

HIGH-RISK WOMEN WITH A SHORT CERVIX
High-risk women found to have a shortened cervix during surveillance.

MANAGEMENT OPTIONS SINGULARLY OR IN COMBINATION

- Continued cervical surveillance. (High risk of preterm birth)
- Ultrasound indicated cerclage. CL ≤25mm
- Rescue cerclage if cervical dilatation has occurred at ≤22 weeks gestation.
- Progesterone: 90mg daily if cervix < 20mm (Hassan 2011) [100mg or 200mg if 90mg is unavailable.] Or 200mg nocte if cervix <15mm (Fonseca 2007)
- Reduced activity (Little evidence)
- There is insufficient evidence to recommend cerclage or progesterone in women with multiple gestation

FETAL FIBRONECTIN TEST (fFN)
Occasionally a woman may present with a shortened cervix who is contracting. The treating clinician needs to ascertain whether this is an incidental finding of a shortened cervix or a short cervix that has effaced as part of preterm labour and if risk factors are present.

A negative fFN test has a very high negative predictive value: 99% of women with a negative result will not proceed to give birth in the following 7 days.

In one study in a high-risk pregnancy, the use of cervical length measurements in combination with fFN testing regardless of risk factors, concluded that a short cervix predicted a subsequent positive fetal fibronectin result, and a positive fetal fibronectin result predicted subsequent cervical shortening. 39 Therefore the use of fFN test in the presence of a short cervix might assist with further management.

Factors that may affect the fFN test results: Any cervical manipulation within the previous 24 hours, such as coitus, digital vaginal examination and TVU examination may affect the result. However, this should not dissuade the clinician from performing the test, even in the face of a positive result due to extraneous factors. Fetal fibronectin is also found in blood and semen, and these may cause false positive results however, negative results in any of these settings can still be considered reliable.

Dependant upon her gestation, if the woman is not already in a level 6 (tertiary) care setting, is symptomatic with a positive fFN result, it is advisable that the clinician consult with the Perinatal Emergency Services (PERS) for further assistance. (See below- Location of care)

Table 3. Fetal fibronectin test

<table>
<thead>
<tr>
<th>Indications</th>
<th>Symptomatic preterm labour. 24 – 34 weeks gestation. Intact membranes. Cervical shortening in a high-risk population, Cervical dilation &lt; 3cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factors that may affect the result</td>
<td>Ruptured membranes Evidence of vaginal bleeding Cervical cerclage in situ Also consider: Use of vaginal lubricants, coitus within last 24 hours, digital VE.</td>
</tr>
<tr>
<td>Procedure</td>
<td>Sterile speculum Sterile water as a lubricant Obtain from the posterior fornix Adhere to test kit manufacturers instructions.</td>
</tr>
<tr>
<td>A positive result</td>
<td>Admit, offer analgesia if required. Consider tocolysis and corticosteroids. N.B. False positive may be due to coitus, VE, TVU.</td>
</tr>
<tr>
<td>A negative result</td>
<td>Low risk of birth in 7 days. False negative may be due to use of vaginal lubricants or antiseptic solutions.</td>
</tr>
</tbody>
</table>

LOCATION OF CARE

The location of care will be dependent upon risk factors, gestation, planned management and the hospital facilities. At the extremes of gestation (less than 23 weeks and greater than 32-37 weeks), in consultation with specialists at a level 6 (tertiary) hospital, it may be suggested that the on-going management of women with a shortened cervix could be provided from a local level 4/5 hospital.

Women who present with a shortened cervix between 23-32 weeks gestation, may be managed in consultation with clinicians at a Level 6 (tertiary level) hospital.

When management has been instituted and the woman is clinically stable, ongoing management as an outpatient can be considered. If outpatient management is offered, women should be provided with clear follow-up arrangements and twenty-four hour access to obstetric services.

LOCATION OF CARE

- Gestations <23 weeks or >32 weeks: Possibly managed at a local hospital after level 6 hospital (tertiary) consultant advice.
- Gestations 23-32 weeks: Managed in consultation with a level 6 hospital.
- If managed as an outpatient, robust follow-up plans should be made and 24 hour obstetric care should be available.
- Consider available evidence and circumstances of the woman.

3centres Collaboration consensus agreement
POST PREGNANCY LOSS

All women who have had a second or third trimester pregnancy loss or preterm delivery due to cervical shortening should be offered a follow up postnatal consultation with a senior obstetrician. This would usually be organised for about six weeks postpartum. Discussion about the management of future pregnancies is important.

Information regarding the pregnancy, cause of cervical shortening and delivery should be provided to the general practitioner, as well as a plan for future pregnancies.

EQUIVOCAL EVIDENCE OR UNLIKELY TO BE OF BENEFIT FOR PRACTICE

<table>
<thead>
<tr>
<th>Serial ultrasound of low risk women</th>
<th>Routine serial ultrasound for cervical length in low risk women is not recommended.</th>
<th>ACOG, RANZCOG, SOGC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple pregnancy</td>
<td>No benefit from cervical cerclage or progesterone in twin pregnancies where short cervical length was identified.</td>
<td>RANZCOG, Berghella, Norman</td>
</tr>
<tr>
<td>Bed rest</td>
<td>Given the known adverse affects associated with antenatal bed rest, this cannot be recommended for routine clinical practice.</td>
<td>Cochrane, RANZCOG, BMJ</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>There is no evidence of benefit of antibiotic therapy for preventing preterm birth in women with intact membranes.</td>
<td>Cochrane. Prophylactic antibiotics for inhibiting preterm labour with intact membranes. 2002. ACOG, BMJ-Best evidence</td>
</tr>
</tbody>
</table>

EVIDENCE IS LACKING AND FURTHER RESEARCH IS REQUIRED

<table>
<thead>
<tr>
<th>Tocolytics</th>
<th>Evidence to support their routine use after cerclage placement.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>Route of administration. Optimal doses. Gestational age to commence and cease treatment. Neonatal outcomes</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Prophylactic antibiotic therapy following cerclage placement</td>
</tr>
<tr>
<td>Serial scans after cerclage placement</td>
<td>The utility, benefits or harms of regular ultrasound scans following cerclage placement</td>
</tr>
</tbody>
</table>

ADDITIONAL REFERENCES

- ACOG Practice bulletin No. 48 Cervical Insufficiency. Obstetrics and Gynecology, Volume 102, Number 5, November 2003, pp. 1091-1099(9)

Please refer to the website for updates to this guideline. www.3centres.com.au
APPENDIX 1. SHORT CERVIX MANAGEMENT OPTIONS - FLOWCHART

<table>
<thead>
<tr>
<th>POPULATION GROUP</th>
<th>DESCRIPTION</th>
<th>MANAGEMENT OPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>General population - low risk women with a short cervix</td>
<td>Cervix &lt;20mm (Hassan 2011) Cervix &lt;15mm (Fonseca 2007) Cervix &lt;25mm (De Franco 2007)</td>
<td>Vaginal progesterone 90mg daily (Hassan 2011) [100mg-200mg if 90mg is unavailable] Vaginal progesterone 200mg nocte (Fonseca 2007) Or Vaginal progesterone 90mg daily (De Franco 2007) [100mg-200mg if 90mg is unavailable] Or Conservative management. Consider repeat TVU</td>
</tr>
</tbody>
</table>

| High-risk women | • Previous cerclage • Previous preterm births <21 <34 weeks • Multiple cervical dilatations • Multiple gestation* • Uterine malformations • Cervical surgery | Vaginal Progesterone 100mg daily (De Franco 2003) [100mg-200mg if 100mg is unavailable] History indicated cerclage 13-16 weeks (RCOG 2011) and/or Increased ultrasound surveillance (ACOG-Level B) |

| High-risk women with a short cervix | Cervix <20mm (Hassan 2011) Cervix <15mm (Fonseca 2007) Cervix <25mm (De Franco 2007) Cervix < 25mm (Grimes 2009) | Progesterone 90mg daily (Hassan 2011) Or Progesterone 200mg nocte (Fonseca 2007) Or Progesterone 90mg daily (De Franco 2007) Or Progesterone 90mg daily (Grimes 2009) etc. Recommendations are: Cervix <20mm 90-200mg daily Or Cervix <15mm 200mg nocte and/or Ultrasound indicated cerclage (RCOG 2011) and/or Increased ultrasound surveillance (ACOG-Level B) |

| | | Remove at 36-37 weeks (RCOG 2011) |

* Cerclage and progesterone not advised for multiple gestation
### APPENDIX 2. PROGESTERONE RESEARCH SUMMARY

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study type</th>
<th>Primary outcome</th>
<th>Sample size</th>
<th>When given</th>
<th>Route</th>
<th>Dose</th>
<th>CX length</th>
<th>Study gestation</th>
<th>Singleton, multiples or both</th>
<th>Population type</th>
<th>Effect / result</th>
</tr>
</thead>
<tbody>
<tr>
<td>da Fonseca et al 2003</td>
<td>RCT placebo controlled double Blind</td>
<td>Preterm birth &lt; 34 weeks</td>
<td>142</td>
<td>Daily</td>
<td>Vaginal suppository</td>
<td>100mg</td>
<td>24 - 34 weeks</td>
<td>Singleton</td>
<td>High-risk. ≥ 1 PTB, cerclage, uterine malformation</td>
<td>PTB 13.8% in progesterone group vs 28.5% in placebo group. P=0.03</td>
<td></td>
</tr>
<tr>
<td>Meiss et al 2003</td>
<td>Double blind placebo controlled</td>
<td>Birth &lt;37 weeks</td>
<td>463</td>
<td>Weekly</td>
<td>I.M. 17 alpha-hydroxyprogesterone</td>
<td>250mg</td>
<td>15-20 (^{+3}) weeks</td>
<td>Singleton</td>
<td>High-risk previous PTB</td>
<td>36.3% in the progesterone group vs 54.9% in the placebo group (P&lt;0.001). Reduction in neonatal morbidity and birth weight &gt;2500g</td>
<td></td>
</tr>
<tr>
<td>O’Brien et al 2007</td>
<td>Randomized, double-blind, multinational trial</td>
<td>Preterm birth ≤ 32 weeks</td>
<td>659</td>
<td>Daily</td>
<td>Vaginal gel</td>
<td>90mg</td>
<td>18-22 (^{+6}) from enrollment to 37 weeks or ROM or birth.</td>
<td>Singleton</td>
<td>High risk Previous PTB</td>
<td>Vaginal progesterone did not reduce the rate of preterm delivery (≤32 weeks) or decrease the frequency of neonatal morbidity and mortality.</td>
<td></td>
</tr>
<tr>
<td>Fonseca et al 2007</td>
<td>Multi-centre RCT placebo controlled Blinded</td>
<td>Preterm birth &lt; 34 weeks</td>
<td>250</td>
<td>Nocte</td>
<td>Vaginal capsules</td>
<td>200mg</td>
<td>&lt;15mm</td>
<td>Both. Included 24 women with twin</td>
<td>Mixed with Short cx &lt;15mm</td>
<td>19.2% in the progesterone group vs 34.4% in placebo group. (relative risk, 0.56; 95% confidence interval [CI], 0.36 to 0.86)</td>
<td></td>
</tr>
<tr>
<td>DeFrancesco et al 2007</td>
<td>Modified secondary analysis of RCT O’Brien 2007</td>
<td>Preterm birth ≤ 32 weeks</td>
<td>46</td>
<td>Daily</td>
<td>Vaginal gel</td>
<td>90mg</td>
<td>&lt;28mm ≤ 25mm</td>
<td>18-22 (^{+6}) weeks</td>
<td>Singleton</td>
<td>Mixed with short cx. (Previous PTB and cx ≤ 28mm + low-risk women with cx ≤25mm)</td>
<td>Women with cx ≤ 25mm: 0% progesterone group vs. 40% placebo group. Women with cx ≤ 28mm: 0% progesterone group vs. 29.6% placebo group. Reduced neonatal morbidity in both groups</td>
</tr>
<tr>
<td>O’Brien et al 2009</td>
<td>Modified secondary analysis of RCT O’Brien 2007</td>
<td>Preterm birth ≤ 32 weeks</td>
<td>104</td>
<td>Daily</td>
<td>Vaginal gel</td>
<td>90mg</td>
<td>&lt;25mm</td>
<td>From 28 weeks</td>
<td>Singleton</td>
<td>High risk Previous PTB + cx &lt;25mm</td>
<td>Progesterone administration was associated with delayed cervical shortening</td>
</tr>
<tr>
<td>Hassan et al 2011</td>
<td>Double blind placebo controlled, multi centre international</td>
<td>PTB &lt;33 weeks</td>
<td>465</td>
<td>Daily</td>
<td>Vaginal gel</td>
<td>90mg</td>
<td>10mm - 20mm</td>
<td>20-36 (^{+6}) weeks</td>
<td>Singleton</td>
<td>Mixed. (16% Previous PTB) Short cx 10-20mm</td>
<td>shortening</td>
</tr>
</tbody>
</table>

### APPENDIX 3. WHA SURVEY RESPONSES

Please refer to the website for updates to this guideline, [www.3centres.com.au](http://www.3centres.com.au)
<table>
<thead>
<tr>
<th>Questions</th>
<th>Hospital 1</th>
<th>Hospital 2</th>
<th>Hospital 3</th>
<th>Hospital 4</th>
<th>Hospital 5</th>
<th>Hospital 6</th>
<th>Hospital 7</th>
<th>Hospital 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>What ultrasonographic measurement constitutes a shortened cervix?</td>
<td>Usually we would consider a shortened cervix as &lt;2.5cm in second trimester.</td>
<td></td>
<td></td>
<td>25mm</td>
<td>Between 15 &amp; 24 weeks: 25mm or less</td>
<td>25mm</td>
<td>Probably &lt;2.5cm but I am more interested in progressive shortening in a patient with the right history, every 7 days</td>
<td>&lt;26mm</td>
</tr>
<tr>
<td>What is the frequency of cervical length assessment?</td>
<td>Frequency of cervical measurement may be 2-4 weekly</td>
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</tr>
<tr>
<td>What are the criteria for admission to hospital for women with a diagnosis of shortened cervix?</td>
<td>There are no criteria for admission for women with a diagnosis of shortened cervix. It would depend on clinician, gestational age, patients home location - many of our patients live rurally and therefore need admission if high chance of prem labour because of distance. No hospital policy on bed rest.</td>
<td></td>
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</tr>
<tr>
<td>What is your hospital’s policy on bed-rest for women with a diagnosis of shortened cervix?</td>
<td>No hospital policy but generally to avoid. Consider emergency cerclage No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>The use of antibiotics</td>
<td>Antibiotics would depend on swab results and possible history of bacterial vaginosis.</td>
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</tr>
<tr>
<td>Type -</td>
<td>often Erythromycin and Metronidazole</td>
<td></td>
<td></td>
<td></td>
<td>Erythromycin</td>
<td></td>
<td></td>
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<tr>
<td>Dose -</td>
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<td>Route -</td>
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<tr>
<td>Duration -</td>
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<td></td>
</tr>
<tr>
<td>When are steroids routinely given for fetal lung maturation?</td>
<td>Not routinely given</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Steroids would be given after viability (24 weeks) and consultant thought imminent risk of delivery. They may be used for example if significantly shortened cervix and high consequences of prem delivery -</td>
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<tr>
<td>Consider from 24 weeks onwards</td>
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<td></td>
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<tr>
<td>From 23/5 onwards</td>
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<td></td>
</tr>
<tr>
<td>If shortened cervix/threatened preterm labour/early delivery anticipated</td>
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<tr>
<td>&gt;22 +5 d. Intensive care offered after 23 w.</td>
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<tr>
<td>TPL/PREM LABOUR &lt; 34</td>
<td></td>
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</tr>
</tbody>
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<th>Hospital 7</th>
<th>Hospital 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you use Fetal fibronectin testing?</td>
<td>No, unfortunately</td>
<td>We use fetal fibronectin when deciding when to transfer prior to 30 weeks and if deciding whether to give steroids after this to women to 32-34 weeks. We use it in TPL regardless of cervical length. Sometimes we may use it with a shortened cervix but it would depend on the gestational age and if the woman had uterine activity etc.</td>
<td>Yes</td>
<td>No, but it would be useful</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Cerclage type used?</td>
<td>MacDonald</td>
<td>Cerclage is up to consultant. I use modified MacDonald.</td>
<td>McDonald with Mersilene tape (Modified McDonald's)</td>
<td>shirodkar</td>
<td>I use modified Shirodkar but others here use McDonald chorioamnionitis, APH, fetal abnormality etc</td>
<td>Shirodka suture nylon tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What are the Cerclage exclusion criteria?</td>
<td></td>
<td>Exclusion criteria depends on consultant. Generally- significant risk of infection, bleeding, 4 cm dilated cervix, Fetal anomaly, &gt;25-26 weeks and therefore reasonable progress if delivers, lack of maternal consent</td>
<td>Ruptured membranes, labour</td>
<td>Ruptured membranes, active infection, or bleeding</td>
<td>bulging membranes and thin cervix, technical difficulty</td>
<td>Est labours/ infection/ cervix dilated&gt;4cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the optimal gestation for cerclage insertion?</td>
<td>Cervical sutures are not used generally after 24 weeks and controversially between 20 and 24 weeks.</td>
<td>Obimal gestation for cerclage is 13-14 weeks. (exclusion of aneuploidy and first trimester miscarriage). But obviously if shortened cervix demonstrated later - when diagnosed.</td>
<td>13/40</td>
<td>after nuchal scan - 13-14 weeks</td>
<td>elective at 14 weeks after first trimester screening but mostly we are doing emergent sutures up to 22w</td>
<td>14 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you use: Progesterone</td>
<td>No</td>
<td>I think progesterone pessaries are the new treatment and the question is when to use them and for how long. They are expensive. They are only used as far as I know when the cervix measures less than 1.5 cm, and are continued to around 34 to 35 weeks.</td>
<td>Currently we are participating in the PROGRESS trial with regards to vaginal progesterone.</td>
<td>Only as part of PROGRESS</td>
<td>occasionally</td>
<td>Not yet awaiting the Progress trial</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>At what gestation -</td>
<td></td>
<td></td>
<td></td>
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</tr>
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<table>
<thead>
<tr>
<th>Questions</th>
<th>Hospital 1</th>
<th>Hospital 2</th>
<th>Hospital 3</th>
<th>Hospital 4</th>
<th>Hospital 5</th>
<th>Hospital 6</th>
<th>Hospital 7</th>
<th>Hospital 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose - With or without cerclage -</td>
<td>38 weeks</td>
<td>Not routinely</td>
<td>Cerclage is removed 36-37 weeks unless indicated earlier - SROM, infection etc.</td>
<td>36 weeks</td>
<td>36-37 weeks, or in labour</td>
<td>200mg either</td>
<td>38 weeks</td>
<td>nifedipine</td>
</tr>
<tr>
<td>Timing of cerclage removal?</td>
<td></td>
<td></td>
<td>Tocolysis - general policy is Nifedipine 20mg 1/2 hourly acutely for 3 doses. Maintenance is 10mg TDS. Terbutaline 500ug may also be actually used on occasion. Indomethacin 100mg supp may be used for 12-24 hours to cover cerclage or in acute rescue situations e.g. dilated cervix at 22 weeks.</td>
<td>36-37 weeks, or in labour</td>
<td>Yes</td>
<td>GTN Patch</td>
<td>Yes</td>
<td>nifedipine</td>
</tr>
<tr>
<td>Do you use Tocolysis?</td>
<td>38 weeks</td>
<td>Not routinely</td>
<td>Nifedipine started at cerclage then PRN for 24 hours</td>
<td>Yes</td>
<td>nifedipine</td>
<td></td>
<td>nifedipine</td>
<td>nifedipine</td>
</tr>
<tr>
<td>What drug -</td>
<td>Cerclage is removed 36-37 weeks unless indicated earlier - SROM, infection etc.</td>
<td>Tocolysis - general policy is Nifedipine 20mg 1/2 hourly acutely for 3 doses. Maintenance is 10mg TDS. Terbutaline 500ug may also be actually used on occasion. Indomethacin 100mg supp may be used for 12-24 hours to cover cerclage or in acute rescue situations e.g. dilated cervix at 22 weeks.</td>
<td>36-37 weeks, or in labour</td>
<td>Yes</td>
<td>GTN Patch</td>
<td>Yes</td>
<td>nifedipine</td>
<td></td>
</tr>
<tr>
<td>Dose - At what gestation -</td>
<td>Cerclage is removed 36-37 weeks unless indicated earlier - SROM, infection etc.</td>
<td>Tocolysis - general policy is Nifedipine 20mg 1/2 hourly acutely for 3 doses. Maintenance is 10mg TDS. Terbutaline 500ug may also be actually used on occasion. Indomethacin 100mg supp may be used for 12-24 hours to cover cerclage or in acute rescue situations e.g. dilated cervix at 22 weeks.</td>
<td>36-37 weeks, or in labour</td>
<td>Yes</td>
<td>GTN Patch</td>
<td>Yes</td>
<td>nifedipine</td>
<td></td>
</tr>
<tr>
<td>With or without cerclage -</td>
<td>Acute setting only other ???</td>
<td>Acute setting only other ???</td>
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</tbody>
</table>

Please refer to the website for updates to this guideline. [www.3centres.com.au](http://www.3centres.com.au)
# APPENDIX 4 EVIDENCE TABLES

## National Health and Medical Research Council (NHMRC) evidence hierarchy

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention ¹</th>
<th>Diagnostic accuracy ²</th>
<th>Prognosis</th>
<th>Aetiology ³</th>
<th>Screening Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
</tr>
<tr>
<td>II</td>
<td>A randomised controlled trial</td>
<td>A study of test accuracy with: an independent, blinded comparison with a valid reference standard; among consecutive persons with a defined clinical presentation⁵</td>
<td>A prospective cohort study⁶</td>
<td>A prospective cohort study</td>
<td>A randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>A pseudorandomised controlled trial (i.e. alternate allocation or some other method)</td>
<td>A study of test accuracy with: an independent, blinded comparison with a valid reference standard; among non-consecutive persons with a defined clinical presentation⁵</td>
<td>All or none⁴</td>
<td>All or none⁴</td>
<td>A pseudorandomised controlled trial (i.e. alternate allocation or some other method)</td>
</tr>
</tbody>
</table>
| III-2 | A comparative study with concurrent controls:  
  - Non-randomised, experimental trial⁸  
  - Cohort study  
  - Case-control study  
  - Interrupted time series with a control group | A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence | Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial | A retrospective cohort study | A comparative study with concurrent controls:  
  - Non-randomised, experimental trial  
  - Cohort study  
  - Case-control study |
| III-3 | A comparative study without concurrent controls:  
  - Historical control study  
  - Two or more single arm study⁹  
  - Interrupted time series without a parallel control group | Diagnostic case-control study⁶ | A retrospective cohort study | A case-control study | A comparative study without concurrent controls:  
  - Historical control study  
  - Two or more single arm study |
| IV    | Case series with either post-test or pre-test/post-test outcomes | Study of diagnostic yield (no reference standard)¹¹ | Case series, or cohort study of persons at different stages of disease | A cross-sectional study or case series | Case series |

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American College of Obstetricians and Gynecologists (ACOG)
Practice Bulletins summarise current information on techniques and clinical management issues for the practice of obstetrics and gynaecology. Practice Bulletins are evidence-based documents, and recommendations are based on the available evidence.
The levels of evidence used are as follows:
Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:
Level A - Recommendations are based on good and consistent scientific evidence.
Level B - Recommendations are based on limited or inconsistent scientific evidence.
Level C - Recommendations are based primarily on consensus

Royal College of Obstetricians and Gynaecologists (RCOG)
Green-top Guidelines provide systematically developed recommendations, which assist clinicians and patients in making decisions about appropriate treatment for specific conditions. Green-top guidelines are concise documents, providing specific practice recommendations on focused areas of clinical practice. The Green-top guidelines are produced under the direction of the Guidelines and Audit Committee of the RCOG.
The levels of evidence used are as follows:
A Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.
B Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation.
C Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality.
✓ Good practice point. Recommended best practice based on the clinical experience of the guideline development group.

Classification of evidence levels
Ia Evidence obtained from meta-analysis of randomised controlled trials.
Ib Evidence obtained from at least one randomised controlled trial.
IIa Evidence obtained from at least one well designed controlled study without randomisation.
IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.
III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

The Society of Obstetricians and Gynaecologists of Canada (SOGC).
Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care
I: Evidence obtained from at least one properly randomized controlled trial
II-1: Evidence from well-designed controlled trials without randomization
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

A. There is good evidence to recommend the clinical preventive action
B. There is fair evidence to recommend the clinical preventive action
C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
D. There is fair evidence to recommend against the clinical preventive action
E. There is good evidence to recommend against the clinical preventive action
I. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.