Prematurity prevention for women/birthing people at high risk of spontaneous preterm labour

University Hospitals of Leicester NHS Trust

Trust ref: C4/2020

Contents

Perinatal Excellence to Improve Outcomes for Premature Birth

A bundle of perinatal interventions that will contribute to a reduction in brain injury and mortality across UHL by optimising:

PERIPrem

NHS University Hospitals of Leicester NHS Trust

1 Right place of Birth

Mothers presenting with signs of labour <32 weeks gestation should be directed to LRI.

2 Antenatal Steroids

Mothers who give birth <34 weeks gestation should receive a full course of antenatal steroids.

Maximum benefit is achieved if administered between 24 hours and 7 days prior to delivery (timed from second dose).

3 Antenatal Magnesium Sulphate

Mothers who give birth <30 weeks gestation should receive antenatal Magnesium Sulphate for fetal neuroprotection.

4 Antibiotic Prophylaxis

All women in confirmed preterm labour should receive antibiotic prophylaxis against Group B Streptococcus.

5 Early Breastmilk

Babies born <34 weeks gestation benefit from receiving mother's breastmilk within 6 hours of birth.

We are aiming to improve continuation of breastfeeding.

6 Optimal Cord Management (OCM)

Delayed cord clamping for at least one minute improves survival rates in preterm infants.

A member of the neonatal team should be present to assess the baby prior to cord clamping to support this.

7 Thermal Care

Babies born at <34 weeks gestation should have a temperature measured on admission to Neonatal Unit within 1 hour of birth, which is in range of 36.5-37.5°C.

8 Respiratory Management

For babies who need invasive ventilation, use synchronised volume-targeted ventilation (VTV) as the primary mode of respiratory support.

9 Caffeine

We give caffeine routinely to babies <30 weeks gestation and those who are symptomatic of apnoea of prematurity at <34 weeks gestation. This is continued until they are more mature (around 33-34 weeks).

10 Probiotics

Babies (<32 weeks gestation or <1500g birth weight) should be commenced on probiotics once the baby has been on minimal enteral feeds for 24 hours.

Supporting compliance with the bundle for all eligible mothers and their babies born at less than 34 weeks gestation to improve the optimisation and stabilisation of the preterm infant.

1. Introduction and who the guideline applies to:

This guideline is intended for use by midwives and obstetricians who are planning antenatal care for women/birthing people at UHL. Note that it refers to women/birthing people at risk of spontaneous preterm birth. It excludes women/birthing people at risk of indicated preterm birth due to maternal or fetal factors (such as pre-eclampsia or fetal growth restriction).

Related UHL Documents:

Preterm Labour Guidance in the Absence of PPROM UHL Obstetric Guideline
Booking Process and Risk Assessment UHL Obstetric Guideline
Aspirin in Pregnancy UHL Obstetric Guideline
Antenatal and Intrapartum Management of Twin Pregnancy
Smoking Cessation for Pregnant Smokers and Partners UHL Obstetric Guideline

Background:

The risk of spontaneous preterm birth (<37 weeks gestation) is approximately 7%. The majority of those births will be to women/birthing people with previously low risk pregnancies. However, it is possible to identify risk factors either at the time of booking for antenatal care, or that occur during the pregnancy, that indicate an increased risk of spontaneous preterm birth. Intervention during the pregnancy in these women/birthing people may decrease their risk of preterm birth or may improve the condition and prognosis of the preterm baby when it is born.

Abbreviations:

UHL	University Hospitals of Leicester	PPROM	Pre-term Premature Rupture of Membranes
LRI	Leicester Royal Infirmary	LLETZ	Large Loop Excision of the Transformation Zone
LGH	Leicester General Hospital	BV	Bacterial Vaginosis
PPC	Premature Prevention Clinic	MgSO4	Magnesium Sulfate
		CO	Carbon Monoxide

2. Assessment and management of women/birthing people at high risk of spontaneous preterm birth

2.1 Pre-existing risk factors for spontaneous preterm birth.

The following groups of women/birthing people are at increased risk of preterm birth and should be identified at booking:

HIGH RISK	INTERMEDIATE RISK
Preterm birth ≤34 weeks in the preceding pregnancy	Previous caesarean at full dilation
Preterm prelabour rupture of the membranes	LLETZ >15mm depth or > 1 LLETZ

(PPROM) at ≤34 weeks in the preceding pregnancy	procedure or cone biopsy.
2nd trimester miscarriage at 16-23 weeks in the preceding pregnancy	Connective tissue disorders (such as Ehler Danlos)
Trachelectomy for previous cervical cancer	
Congenital uterine anomaly	
Intrauterine adhesions (Ashermans)	
Previous cervical cerclage	

All women/birthing people should be made aware of symptoms of preterm labour and PPROM and be informed of who to ring to seek help and advice. Those at higher risk of preterm labour should be informed they are higher risk of preterm birth.

Preterm birth ≤34 weeks in the preceding pregnancy

The history should be reviewed. If the previous preterm birth was iatrogenic (e.g. Caesarean or induction of labour for a fetal or maternal indication), then the care should be targeted at preventing the underlying cause (such as pre-eclampsia or growth restriction) rather than referral to PPC.
Women/birthing people with one prior spontaneous preterm birth have a 15-20% chance of a preterm birth in their current pregnancy. The majority of recurrences are within 2 weeks gestation of the previous preterm birth. A term birth following the preterm birth reduces the risk significantly, almost back to the background population risk.

Preterm prelabour rupture of the membranes (PPROM) at ≤34 weeks in the preceding pregnancy

As for the previous group, a subsequent term birth reduces the risk of a preterm birth in the current pregnancy.

2nd trimester miscarriage at 16-23 weeks in the preceding pregnancy

The history should be carefully reviewed to identify the initiating event of the miscarriage. If the miscarriage was an intrauterine fetal death that occurred with intact membranes prior to the onset of labour, care should be targeted at identifying placental causes of miscarriage rather than PPC referral.

Significant cervical surgery

All women/birthing people with a cold knife cone biopsy are at high risk of preterm birth.
Women/birthing people with a history of trachelectomy (who usually have a cerclage already *in situ*) are at high risk of preterm birth, especially PPROM.
Women/birthing people with LLETZ or colposcopy should have their notes reviewed carefully. If the dimensions of the tissue removed at LLETZ is available, then that should be used to guide care. The smallest figure of the 3 dimensions of the biopsy will be the depth. If the woman/birthing person has had more than one LLETZ, the total depth of cervix removed should be calculated and used. Punch biopsies of the cervix can be discounted from the

calculation. A LLETZ of >15mm and cone biopsy would be considered an intermediate risk. A trachelectomy would be high risk.

If no dimensions are available, or if the notes state 'colposcopy' only, then a more detailed history should be taken to establish whether any tissue was removed. A pragmatic decision regarding offering investigations during pregnancy should then be made based on the information obtained.

Previous cervical cerclage

The history of the previous pregnancy and indication for the previous cerclage should be reviewed. A previous cerclage is not an absolute indication for cervical cerclage in the current pregnancy. Management options in the current pregnancy include serial cervical length scans, or elective cervical cerclage.

Congenital uterine anomaly

Women/birthing people with a congenital uterine anomaly are at increased risk of preterm birth. The exact nature of the anomaly is not well delineated in most women/ – the majority are described as 'bicornuate'. The underlying cause of the increase in preterm births in these women/birthing people is unclear. It may be due to reduced uterine capacity, or due to a structural cervical problem. There is an increased risk of associated anomalies, and these should also be considered. Approximately 30% will have an associated renal anomaly, and consideration should be given to a renal ultrasound scan if one has never been performed. Some women/birthing people will have 2 cervical canals, and some may have a vaginal septum which may obstruct labour. They are also at risk of malpresentation.

Previous 2nd stage Caesarean section

This has recently been described to increase the risk of preterm birth in the next pregnancy, especially early preterm birth/late miscarriage. Women with a previous 2nd stage Caesarean section have an approximately 28% increased risk of birth at <34 weeks gestation. The studies supporting this have small numbers [a]. This may be due to the disruption of the annular muscle fibres of the cervix by an inadvertently low uterine incision, or by the passage of the surgeons hand alongside the fetal head. Information regarding the previous 2nd stage caesarean section should be explored at booking by using enquiring questions such as, "Were you confirmed as fully dilated? Were you pushing? Was a ventouse/forceps delivery attempted?"

Intrauterine adhesions (Ashermans)
Intrauterine adhesions are thought to lead to preterm birth due to reduced capacity of the uterus. The potential abnormal placentation can also lead to growth restriction.

This list is not exhaustive. There may be women/birthing people who do not fit these criteria who will benefit from additional targeted antenatal care. Women/birthing people with a previous 2nd trimester miscarriage or neonatal death due to prematurity should be considered for referral even if they have had a term baby since their loss. Similarly, women/birthing people with more than one preterm birth may require referral even if the last baby was at term. Care needs to be individualised.

2.2 Antenatal care

Women/birthing people at high risk of spontaneous preterm birth should have targeted antenatal care aimed at minimising their risk of prematurity and optimising the condition of the baby.

There are a number of risk factors that may be recognised at booking for antenatal care, which identify women/birthing people who are at increased risk of a preterm delivery. These women/birthing people should be referred for consultant-led antenatal care which is aimed at reducing the risk of preterm birth. This care may be at the Prematurity Prevention Clinic (PPC) at LRI or LGH.

2.3 Screening and assessment

Urine tract infection and asymptomatic bacteriuria also increase the risk of preterm birth. Women/birthing people identified as being at high risk of preterm birth should have their MSU sent at booking reviewed. Positive MSUs that have been treated should be followed up with a sample to indicate infection has resolved.

They should be offered cervical length scans for screening. The timing and frequency of screening should be targeted according to the past history of the woman/birthing person. The earlier the previous preterm birth, the more preterm births that she has had, or the larger the cervical biopsy taken, the higher the risk and the closer the surveillance that should be undertaken.

Cervical length measurement should be undertaken by transvaginal ultrasound with an empty bladder. The shortest of 3 measurements is taken, with fundal pressure applied for 30 seconds to identify any dynamic cervical change. Funnelling of the internal os is not an independent risk factor; its presence is usually associated with a shorter cervical length.

The screening schedule currently in use in the Prematurity Prevention Clinic is outlined in Appendix 1.

2.4 Interventions

A short cervix predicts an increased risk of preterm birth, as illustrated in Appendix 2. Cervix <25mm is considered short, with cervix <15mm very short. Women/birthing people with significant shortening of the cervix over a short space of time may also be included in this group, even if the cervix remains above 25mm.

Women/birthing people with a cervical length <25mm should have intervention discussed to reduce the risk of subsequent preterm birth and optimise the condition of the baby.

Treatment strategies that may be considered include:

<u>Cervical cerclage</u>

This is insertion of a suture transvaginal either high (Shirodkar) or low (McDonald), usually performed under spinal anaesthetic. There is evidence that insertion of cerclage in women/birthing people at high risk of preterm birth, who have been identified as having a short cervix, reduces the risk of preterm birth. The procedure may be difficult (or occasionally impossible) if there has been significant cervical surgery in the past.

See Appendix 3 and 4 for Cerclage.

Progesterone treatment

There is conflicting evidence on the benefit of progesterone treatment. However, NICE recommend it as a treatment option for high-risk women/birthing people with a short cervix.[b] Currently progesterone is offered in the form of Cyclogest 200mg nocte up to 34 weeks gestation. It is also considered for use in women/birthing people having rescue cerclage and for patient request.

If women/birthing people attend having been starting on cyclogest for early pregnancy bleeding, then a individualised care plan needs to be created. Often the dose can be dropped to once daily dosing or stopped.

Arabin Pessary

The use of Arabin cervical pessary was found to be more effective than cerclage in the prolongation of pregnancy in a multifactorial research in Spain. It proved that, in women/birthing people with cervical length <25 mm in 18–22 weeks of pregnancy, the use of pessary decreased premature birth in 34 weeks of gestation by 88% and also decreased neonate complications.
Larger studies are needed to further determine its efficacy. Women/birthing people who do not want or they cannot undergo cervical cerclage, particularly for women/birthing people with decreased cervical length after 24 weeks of gestation can have Arabin pessary. No negative association between early preterm labour and pessary have been found.
Arabin pessary can therefore be used as an alternative to cerclage till 24 weeks gestation and can be discussed for use till 28 weeks. Elective removal of pessary should be booked for 35 – 36 + 6 weeks gestation at prematurity prevention clinic.
See Appendix 5 for more information.

Conservative management and review in 1-2 weeks

If the cervical length is changing very little, consideration could be given to review in 1-2 weeks. Take into account the gestation when planning this as an option, as other treatments (especially cerclage) may be relatively contraindicated at later gestations.

None of these treatment strategies has been demonstrated to be superior to the others, and all may be considered and discussed. The woman's/birthing persons past obstetric history, and the gestation at the time of scan, should be taken into consideration. Inclusion in a clinical trial may also be an option.

Transabdominal cerclage
Women/birthing people who have had trachelectomy often come with an abdominal cerclage in situ. If a cerclage has failed previously, consideration for a transabdominal cerclage may be required, the Consultant specialising in prematurity prevention should liaise with Leeds Teaching hospitals NHS Trust.

2.5 Management from 22/40Women/birthing people with a short cervix from 22 weeks onwards should be offered additional testing to further establish their risk of preterm birth.

Babies may be resuscitated and receive neonatal intensive care from 23 weeks onwards (rarely from 22 weeks). If the cervix is <25mm from this gestation onwards, consideration should be given to using additional testing to more accurately establish the risk of delivery. Quantitative fibronectin testing may enable a more accurate risk to be calculated by combining it with the cervical length using the QUIPP app. If we perform Quantitative fibronectin testing [d] on women/birthing people with cervix <25mm at 23 weeks or more, the decision to give steroids or admit would have to be on an individual basis depending on the clinical history, cervical length, rate of change of cervix, other symptoms etc. Risk of delivery of 5% within 7 days should prompt a discussion with the women/birthing people and the neonatal team regarding wishes for neonatal intervention; if they delivered at this gestation.

If quantitative fibronectin is unavailable, use Actim Partus.

If the predictive testing indicates further increased risk of preterm birth:

- Advise the woman/birthing person of the signs of preterm labour/PPROM.
- Consider admission to the antenatal ward (take into account distance to the hospital, potential language/communication difficulties, past obstetric history).
- Consider administration of antenatal steroids for fetal lung maturation. Note however that there is little/no benefit to steroids that are administered more than 7 days prior to delivery. Steroids administered even within 24 hours of delivery provide significant benefit to the baby. Therefore, waiting until symptoms develop is a reasonable option, with careful safety net advice on early presentation to Maternity Assessment Unit if the woman/birthing person has any concerns.
- If symptomatic for preterm birth, refer to management of preterm birth guideline for MgSO4 and antibiotics.

2.6 Management of infection

Women/birthing people at high risk of preterm birth who are identified with urine infection should be offered appropriate antibiotic treatment. MSU should be reviewed from booking. If MSU at booking is negative and urine dip is negative at appointment and asymptomatic, no further MSU needs to be sent. If +ve urine dip then send MSU.

Urinary tract infection and asymptomatic bacteruria are both associated with an increased incidence of pyelonephritis and increased risk of preterm birth. Treatment should be offered in accordance with the antibiotic sensitivities of the bacteria identified and the UHL antibiotic prescribing guideline.

Routine screening for bacterial vaginosis is not undertaken, as the evidence is limited. If the women/birthing people report vaginal discharge, clinical assessment can be undertaken and consideration of vaginal swabs.

2.7 Aspirin

Assess all women/birthing people at booking to determine if a prescription of aspirin is appropriate. This is generally prescribed when preterm birth is associated with placental disease based upon her personalised risk assessment. The dose is 150 mg once at night-time until 36/40.

See Aspirin in pregnancy UHL Guideline

2.8 Smoking

Assess smoking status at booking and at every contact, make efforts for the pregnancy to be smoke free by 16 weeks.

Smoking doubles the risk of preterm delivery and therefore all women/birthing people should be asked about smoking, and cessation advice and/or referral should be provided. Women/birthing people who have experienced a previous preterm birth, who stopped smoking early in the pregnancy, modify their risk back to that of a non- smoker. If smoking cessation is delayed until the third trimester this modifiable benefit is lost.

All women/birthing people should have CO levels done at each contact.

Whenever CO testing is offered, it should be followed up by an enquiry about smoking status with the CO result recorded. Then instigate an opt-out referral for women/birthing people who have an elevated CO level (4ppm or above) who identify themselves as smokers or have quit within the last two weeks by a local tobacco dependence treatment advisor.

2.9 Multiple pregnancy

Risk assessment and management in multiple pregnancy should comply with NICE guidance and antenatal management of multiple pregnancy UHL Guideline

Women/birthing people with multiple pregnancy will not be seen in the prematurity prevention clinic routinely. They can be referred with a multiple pregnancy when they have other preterm risk factors. Care should be individualised as there is little or no evidence to support interventions.

2.10 Awareness of BAPM toolkit and Neonatal input

Staff to be aware of the Antenatal Optimisation for Preterm Infants less than 34 weeks A Quality Improvement Toolkit October 2020. Inform parents of the PERIPREM passport if signs of preterm labour. See Appendix 7 To allow opportunity to discuss preterm delivery with the neonatologist.

3. Education and training:

None

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Factors identified at booking and attended PPC	Perinatal review of premature births/records	Dunkerton	12 monthly	Mat governance

	PPC attendance			
Fibronectin usage and outcomes in asymptomatic in clinic	Audit of outcomes after fibronectin and QUiPP app use	Dunkerton	12monthly	Mat Governance
Fibronectin usage in symptomatic women	Audit of outcomes after fibronectin and QUiPP app use	Dunkerton	12 monthly	Mat governance

5. Supporting References:

a. Watson HA, Carter J et al. (2017). Full dilation caesarean section: a risk factor for recurrent second-trimester loss and preterm birth. AOGS.96: 1100-1105
b. NICE Guideline No 25. (2015 Updated June 2022). Preterm labour and birth. Available at:https://www.nice.org.uk/guidance/ng25/resources/preterm-labour-and-birth-pdf-1837333576645
c. Panagiotis Tsikouras et al. (2018). Comparative Evaluation of Arabin Pessary and Cervical Cerclage for the Prevention of Preterm Labor in Asymptomatic Women with High Risk Factors Int. J. Environ. Res. Public Health: 15: 791.
d. Honest Honest, Lucas M Bachmann, Janesh K Gupta, Jos Kleijnen, Khalid S Khan. (2012). Accuracy of cervicovaginal fetal fibronectin test in predicting risk of spontaneous preterm birth: systematic review Vol 325. 1-10.
e. Chapman D.K.; Bartlett J.; Powell J.; Carter N. (2016). Bacterial Vaginosis Screening and Treatment in Pregnant Women. Journal of Midwifery and Women's Health; vol. 61 (no. 5); p. 628-631.
f. Saving Babies' lives Crae Bundle. Version Three. (2023). NHS England. https://www.england.nhs.uk/wp-content/uploads/2023/05/PRN00614-Saving-babies-lives-version-three-a-care-bundle-for-reducing-perinatal-mortality.pdf

6. Key Words

Arabin Pessary, Ashermans, Cervical cerclage, McDonald, PPROM, PPC, QUIPP app, Quantitative Fibronectin, Shirodkar

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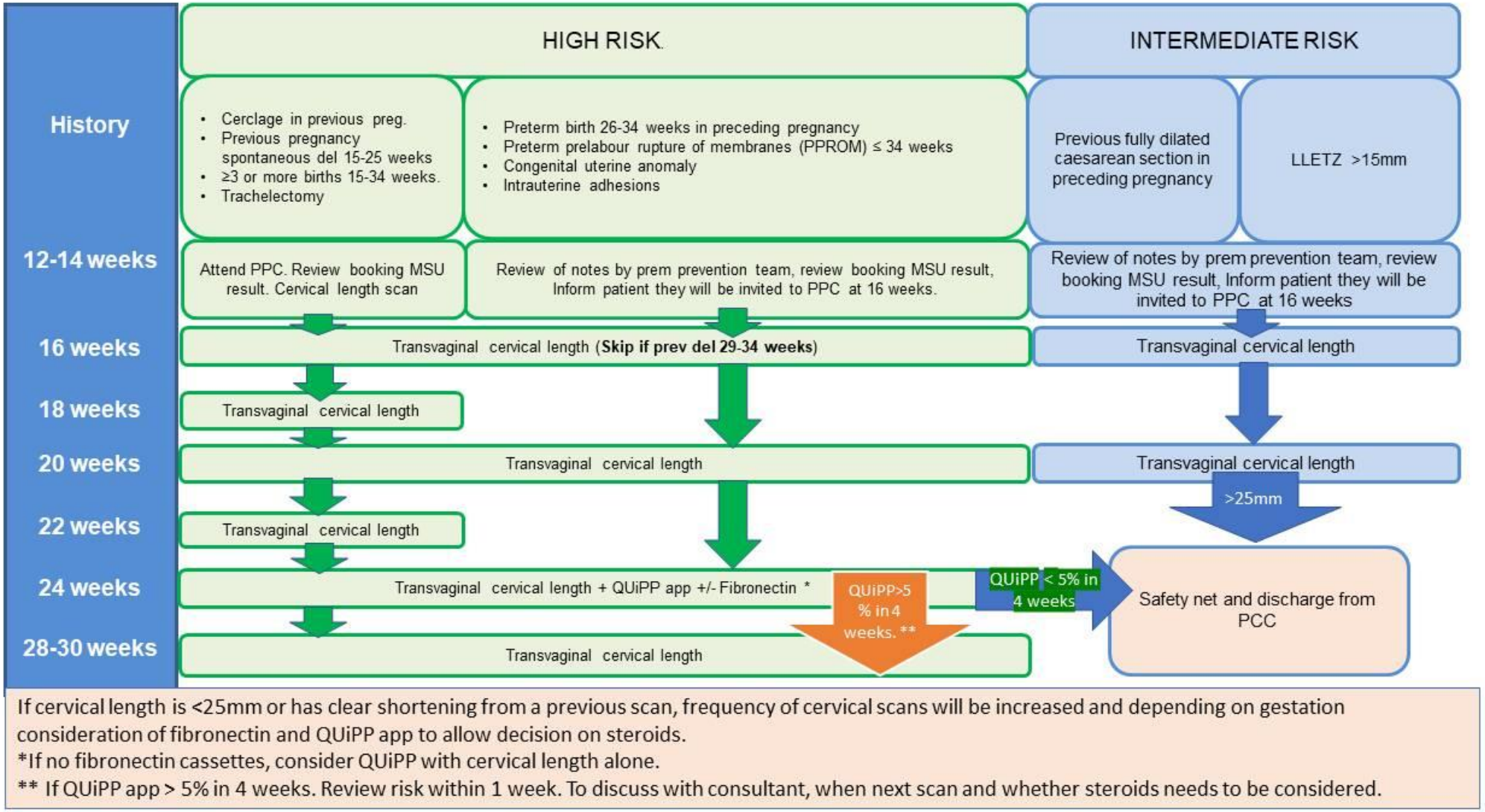
The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

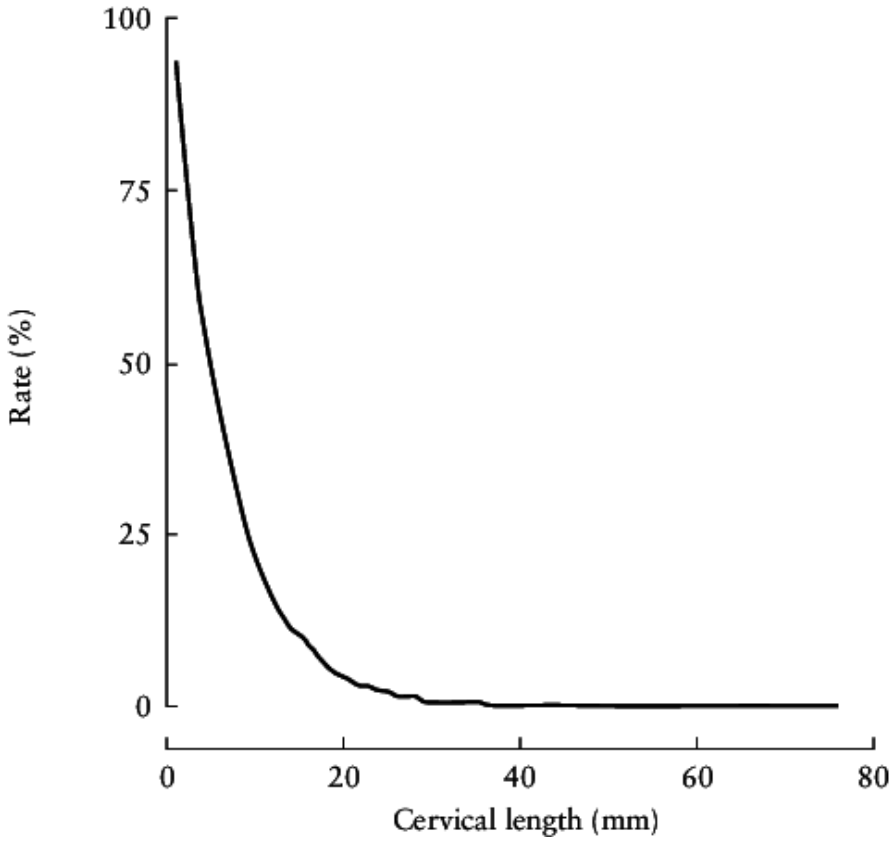
CONTACT AND REVIEW DETAILS			
Guideline Lead (Name and Title) Authors: Penny McParland – Consultant Humera Ansar- Consultant, Natasha Archer – Consultant and Anu Shajpal - Obstetrician			**Executive Lead** Chief Medical Officer
Details of Changes made during review:			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
December 2022	**2**	**S Dunkerton**	**Information regarding previous caesarean section and confirmed second stage added to list of pre-existing factors for high risk management.** **Aspirin administration to be discontinues at 36/40 in line with Aspirin guidance** **Smoking status should be confirmed at every contact as per smoking cessation guidance.** **Antenatal screening schedule made clearer**
October 2023	**3**	**S Dunkerton**	**Pre-existing risk factors for preterm birth now clarified as high risk and intermediate risk.** **Amendments to risk factors made;** 2nd trimester miscarriage at 16-23 weeks in the preceding pregnancy – previously 15-23 weeks New specification re- LLETZ >15mm depth or > 1 LLETZ procedure or cone biopsy. Added Connective tissue disorders (such as Ehler Danlos) & Intrauterine adhesions (Ashermans) **Management from 22/40Women/birthing people with a short cervix from 22 weeks (previously from 23 weeks) onwards should be offered additional testing to further establish their risk of preterm birth.** Removed Actim Partus & Partosure from management plan. Risk of delivery of 5% within 7 days (previously >10% within 7 days should lead to consider steroids) should prompt a discussion with the women/birthing people and the neonatal team **AN Schedule updated in line with changes**

Appendix 1 Clinic Schedule

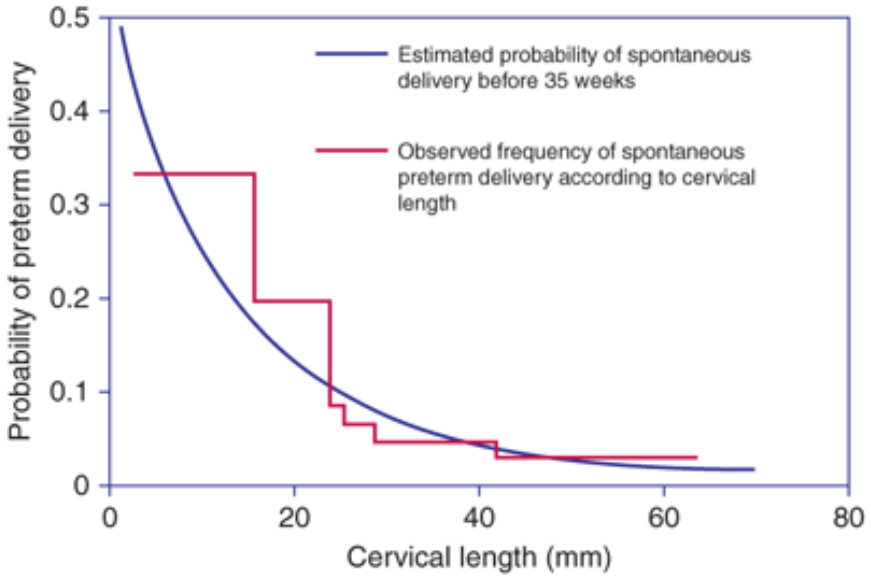


If cervical length is <25mm or has clear shortening from a previous scan, frequency of cervical scans will be increased and depending on gestation consideration of fibronectin and QUiPP app to allow decision on steroids.
*If no fibronectin cassettes, consider QUiPP with cervical length alone.
** If QUiPP app > 5% in 4 weeks. Review risk within 1 week. To discuss with consultant, when next scan and whether steroids needs to be considered.

Appendix 2: Prediction of preterm birth



From To MS et al. Cervical length and funnelling at 23 weeks gestation in the prediction of early spontaneous preterm delivery. Ultrasound Obstet Gynecol 2001; 18: 200-203



From Iams et al. The length of the cervix and the risk of spontaneous premature delivery. NEJM 1996; 334: 567-573

Appendix 3: Cervical cerclage

Cervical cerclage was described by McDonald in 1947 and by Shirodkar in 1955, to reduce the risk of late miscarriage or preterm birth. The only randomised trial on its use concluded that it had an important beneficial effect in only 1 in 25 cases where it was used, reducing the preterm birth rate in the study from 17% to 13%. The interaction between cervical function and infection is not well understood, and probably represents a continuum rather than an absolute all or nothing effect (the concept of the 'incompetent' cervix).
Evidence for the use of cerclage remains very limited, and most of the guidance around it is based on 'good practice' rather than true evidence.

1. Elective cervical cerclage should be placed before 17 weeks gestation, after confirmation of gestational age by ultrasound scan.

The RCOG Green Top guideline (now archived) and the NICE Preterm Labour and Birth guideline suggest that a prior history of 3 preterm births is an indication for elective cerclage. It would seem reasonable to offer cerclage to women/birthing people with a history of 2 prior late miscarriages/preterm births at <28 weeks gestation where cervical function is likely to have played a causative role.
Previous cervical cerclage is not an absolute indication for repeat cerclage. Serial ultrasound assessment of the cervix is an option, and many women/birthing people will not require repeat cerclage. However, it is acknowledged that dependent on their history and circumstances, many women/birthing people with a previous cerclage will wish to have a repeat elective cerclage.
The obstetric and medical history should be considered when deciding to insert an elective cerclage. Prior ultrasound assessment of gestational age should occur prior to insertion. If trisomy screening is being undertaken at 11-14 weeks gestation, then it would be good practice to ensure the result of this is normal prior to cerclage insertion.

2. Women/birthing people with a cervical length of <25mm at ≤ 24 weeks should be considered for cervical cerclage.

There is evidence that insertion of cerclage in women/birthing people at prior high risk of preterm birth (e.g. previous preterm birth or cervical surgery) with a cervical length of <25mm at ≤ 24 weeks reduces the risk of preterm birth. Alternative treatment options may also be considered including treatment with progesterone or inclusion in a clinical trial. It would be good practice for ultrasound-indicated cerclage to be inserted within 7 days of the scan. Cerclage inserted at 19 weeks gestation or greater should be preceded by anomaly scan to ensure normal fetal anatomy prior to insertion.

3. Women/birthing people undergoing cerclage should receive perioperative antibiotics

There is very little evidence to guide the operative procedure. Good practice points would include:

- Cerclage technique should be decided by the operating surgeon (McDonald vs Shirodkar). There is no evidence regarding the best technique. There are theoretical advantages to the Shirodkar technique (higher cerclage, better length of cervix, burial of suture material).
- Suture material should be at the preference of the operating surgeon (braided vs monofilament) or may be dictated by participation in clinical trial.

- Insertion should normally be performed under regional anaesthesia due to the reduced maternal and fetal risks associated with this compared to general anaesthesia.
- Perioperative antibiotic cover should be administered (usually 1.5g IV cefuroxime and 500mg IV metronidazole)
- Postoperative tocolysis/analgesia with a single dose of 100mg indomethacin per rectum should be given (if there are no maternal contraindications to NSAID use).
- Foley catheter may be required until the regional block has worn off.
- Women/birthing people who have Shirodkar cerclage inserted should be advised regarding the possible passage per vaginum of the vaginal wall suture material (which may be alarming and may be confused with the cerclage)

4. Clinic follow up with assessment of cervical length should be offered after insertion

This should be approximately 2-4 weeks after insertion.

5. Women/birthing people who present at 16-24 weeks with bulging membranes should be considered for 'Emergency' cerclage. The decision to place an emergency suture should be individualised, taking the parents' views carefully into account. The balance is between a useful prolongation of pregnancy with its reduced neonatal morbidity and mortality, against the possibility of prolonged severe neonatal morbidity in a baby that might otherwise die. The woman's/birthing person's decision should be aided by a senior obstetrician

Care should be taken to assess for evidence of intrauterine infection. Account should be taken of the clinical history and gestational age. It would be unusual to insert cerclage beyond 24 weeks gestation.
Assessment for infection should include maternal observations and measurement of white cell count and C-reactive protein.

Contraindications include-

- Active preterm labour,
- clinical evidence of chorioamnionitis
- values of >20 for both CRP and WCC are relative contraindications to the insertion of cerclage.
- Continued vaginal bleeding
- PPROM
- Evidence of fetal compromise
- Lethal fetal defect
- Fetal death

Advanced dilatation of the cervix (more than4cm) or membrane prolapse beyond the external os appears to be associated with a high chance of cerclage failure
Even with apparent clinical exclusion of infection, approximately 30% of women/birthing people will deliver within 2 weeks of rescue cerclage. Dependent on gestation, this may result in a surviving extremely preterm infant with disability. A 'good' outcome may be prolongation for 8 weeks, which is still likely to be a very preterm baby. These risks should be discussed as part of the consent process for insertion of a Emergency cerclage.

Consideration should be given to administration of antibiotics around the time of insertion, up to 24 hours intravenous antibiotics may be given. Consider giving oral antibiotics for 5 days and progesterone vaginal pessary 200 mg at night till 34 weeks. Routine postoperative WCC and CRP is not required unless symptomatic. (The CRP will rise in the postoperative period due to tissue handling and dissection).
Cerclage inserted at 19 weeks gestation or greater should be preceded by anomaly scan to ensure normal fetal anatomy prior to insertion.

6. Women/birthing people with cerclage in situ who have clinical evidence of infection should have the cerclage removed.

Assessment of the whole clinical picture should be made, to include previous obstetric history, gestational age, maternal observations (especially temperature, pulse and respiratory rate), maternal white cell count and C-reactive protein.
Unscheduled cerclage removal because of maternal infection should be a consultant decision.
Cerclage removal should not be undertaken based on investigation results only (WCC and CRP) in the absence of clinical signs.

7. Women/birthing people with cerclage in situ who present with PPROM should have the cerclage removed.

The presence of suture material in the vagina after PPROM has occurred increases the risk of maternal sepsis. The cerclage should therefore be removed if PPROM is confirmed. If there is no clinical evidence of infection the removal may be deferred for 24 hours to allow for fetal lung maturation with steroids (consider the gestation when planning this).

Appendix 4: Cervical cerclage removal

The majority of cerclages at UHL are Shirodkar cerclages which will usually require removal under regional block. A few will be McDonald cerclages which can usually be removed without anaesthetic in a Delivery Suite room. Check the operative notes to confirm the type of suture and the suture material used prior to both booking removal and prior to undertaking removal.

1. Booking removal of cerclage

- Book cerclage removal at antenatal clinic appointment at 28-30 weeks. Usually aim for removal at 36-37 weeks gestation. If delivery is to be by planned Caesarean then the cerclage can be removed at the end of the Caesarean (remember to put it on the theatre list and the consent form).
- If Shirodkar cerclage, examine in clinic to confirm regional block required (and write this on the theatre booking form). Only book for removal on Delivery Suite if both knots of the cerclage are easily palpable.
- If removal with regional block required, complete theatre booking form. The theatre team should try to book the removal on the theatre list of a consultant who regularly inserts cerclages (if one is available on the week required).
- If removal on Delivery Suite required (McDonald and some Shirodkars) then phone Delivery Suite to book. Ask the woman/birthing person to attend starved for 6 hours in case removal without anaesthetic fails.

2. Removal without anaesthetic on Delivery Suite

- Confirm cephalic presentation by scan first.
- Ensure equipment available – Cusco's speculum, scissors, long Spencer Wells forceps (2), good lighting.
- Offer Entonox.
- Perform VE prior to removing – check that knots easily palpable and identify location.
- Insert Cusco's speculum and visualise cerclage. Grasp with Spencer Wells. Identify both knots and cut below bottom knot to remove.
- Do not persist if woman/birthing person is in pain/distressed, or if removal is not possible within 10-15 minutes. Consider trying with regional block in theatre.

3. Removal of cerclage with regional block

- Confirm cephalic presentation by scan prior to taking to theatre.
- Once block is in, put woman's legs in lithotomy, clean and drape.
- Perform VE to determine whether suture is buried and how high it is.
- Use Sims speculum/vaginal wall retractors to visualise cervix.
- Grasp anterior and posterior lips of cervix with sponge holding forceps.
- If suture material is visible, grasp it with long Spencer Wells. Blunt and/or sharp dissection may be required to free the bottom knot. Only cut through the suture once the bottom knot is identified.

- If the suture is well buried, consider infiltration with xylocaine/adrenaline, incise over the knot, and dissect the knot free using McIndoe scissors. Divide below the bottom knot and remove.
- If vaginal wall dissection is required, then a single dose IV 1.5g cefuroxime and 500mg metronidazole should be given.
- Once suture is removed, inspect vaginal wall. Close any defect with Vicryl Rapide or equivalent.

4. If a Shirodkar suture is difficult to remove

- Do not persist for longer than 30 minutes without requesting help. If available, then Dr McParland should be requested to assist. If unavailable, then a second consultant who undertakes cerclage insertions should be requested (check the GAU and MAU duty consultants first to see if either of them would be appropriate).
- Cerclage removal should not take more than 60 minutes. If not achieved by this time then the procedure should be abandoned with full explanation to the woman/birthing person. Request a PPC consultant to review either in recovery/on the ward, or if none available book into the next PPC (even if fully booked).
- Antibiotic cover can be commenced for women/birthing people who the surgeon considered at high risk of infection, for example prolonged procedure time or risk of chorioamnionitis such as multiple manipulations of the internal cervix. In which case up to 24 hours of IV 1.5g cefuroxime TDS and 400mg PO Metronidazole TDS can be given. If signs of chorioamnionitis, to follow regimen on women's/birthing people's antimicrobial summary guideline.

Appendix 5: UHL Prem prevention Clinic Information

FAQs for Caring for women/birthing people with the ARABIN cervical pessary fitted

Q1. What are the side effects of the Arabin cervical pessary?

There are no known major or significant side effects. Vaginal discharge has been shown to increase in some, but not all, women/birthing people. All women/birthing people fitted with a pessary should be warned that increased vaginal discharge is a recognised side effect which is mostly watery in consistency.

Q2. When should I remove the Arabin Cervical pessary?

If the woman/birthing person does not experience PPROM or preterm labour, the pessary should be removed as per the protocol at 35-36+6 weeks.

In general, we would advise that you wait for definitive evidence of labour of PPROM before attempting to remove the pessary. Broadly speaking symptomatic women/birthing people with pessary should be managed in the same manner as women/birthing people with cerclage in situ. If there is clear evidence of PPROM the pessary should be removed to prevent chorioamnionitis and maternal sepsis. The pregnancy should then be managed as per local PPROM guidelines. Please be aware that heavy watery vaginal discharge can be confused with PPROM and the diagnosis of PPROM should be confirmed by a senior clinician before the pessary is removed.

All procedures that may be required to confirm or refute a diagnosis can be carried out with the pessary fitted i.e. transabdominal and transvaginal ultrasound, speculum examination, HVS, FBC/CRP. A speculum examination and PV examination can be safely performed to assess the position of the pessary and if the cervix is still closed. Transvaginal USS with the pessary in situ is likely to be even more informative. It is important to insert TV probe below the leading edge of the pessary to obtain adequate image of the cervical canal. Please refer to question 7 for further guidance on scanning with the pessary in situ.

Once the woman/birthing person is in labour with regular painful uterine contractions and obviously dilated external cervical os, remove the pessary.

If a woman/birthing person presents with deep vaginal pain or discomfort thought to be related to the pessary, she should be examined initially to ensure the pessary is in the correct position. If the pessary slips and sits on or traps the cervical tissue, this can cause for pain. The pessary should be readjusted (please see Q5), resized (if different size available) or if the patient is unable to tolerate the pessary, removed altogether after discussion with the patient. Depending on gestation and the indication an alternative treatment may be offered.

Q3. If the Arabin cervical pessary is removed or expelled can it be refitted?

If you remove the pessary during an episode of threatened PTL and the symptoms subside over the next 48hours, you could consider re-inserting the pessary. Although it is possible to clean and re- insert, we suggest that a new pessary is used. (NB: Used pessaries may be binned via the usual clinical waste disposal route).

Q4. Can women/birthing people have sex with the Arabin cervical pessary fitted?

Women/birthing people and their partners can have sex with the pessary in situ. This advice should be tailored based on the individual clinical risk of preterm labour.

Q5. What do I do if the woman/birthing person reports the Arabin cervical pessary is uncomfortable?

Occasionally the pessary “slips” and rests on the cervix and it is painful for the woman/birthing person. Please do a PV examination to check that the pessary is correctly placed. The cervix should felt in the centre of the pessary with the pessary edge freely surrounding the cervix (i.e. you should run your finger around the smaller diameter hole without feeling any cervix under the lip of the pessary. This will ensure it is in the correct place.

However, if the cervix has effaced you may not feel any cervical tissue in the centre of the pessary with nothing to hold it in place. Do not remove the pessary just because the cervix is fully effaced. This should be done after you have clearly demonstrated the presence of a dilated external cervical os either by speculum or ideally by TV scan.

Q6. Should I do regular speculums to check the Arabin cervical pessary position?

No, it is not necessary to check the Arabin cercial pessary position, unless the woman/birthing person reports pain (as above). A speculum should be considered if the woman/birthing person has suspected PPROM, serious discomfort / regular painful contractions, or new onset discomfort or, PV bleeding (remove if signs of active labour). In the absence of PPROM and bleeding PV transvaginal scan is much more informative.

Q7. Can I do an ultrasound with the Arabin cervical pessary in situ?

A TV USS can be performed with an Arabin pessary in situ when to investigate discomfort or suspicion of threatened preterm labour/cervical dilatation. The vaginal probe needs to be directed initially towards the rectum at a 45 degree angle initially to come under the upper lip of the pessary and then angulated up towards the cervix.

A video which provides a helpful guide on the scan position can be found: https://www.youtube.com/watch?v=Vcm7AirceI0

During scanning look for funnelling /external os dilatation. Some women/birthing people may dilate virtually all of the cervix with no measurable cervical length (without delivering) for weeks. Consider admitting only women/birthing people with dilated external os or hourglass prolapsed of membranes in the vagina.

APPENDIX 6

Fibronectin swab of asymptomatic patient.

Please see UHL Preterm Labour in the absence of SROM for advice for fibronectin in the context of symptoms.

Please see video or written instructions below on how to take a swab.

Give appropriate information to the woman/birthing person about the test and obtain verbal consent.

• Sterile speculum examination by doctor without lubricant. Lubricant can interfere with fetal fibronectin assay – if fibronectin test is to be performed, take the sample prior to any digital vaginal assessment or TV scan

• A high vaginal swab should be performed at speculum examination when performing the fetal fibronectin test.

Step 1 Open the fetal fibronectin collection kit which contains a sterile polyester swab for specimen collection and a test tube containing buffer solution. Gently rotate the supplied swab across the posterior fornix of the vagina for 10 seconds toabsorb the cervicovaginal secretions.

Step 2 Remove swab and immerse tip in buffer. Gently mix the swab in the solution and remove the swab. Take the fFN sample (buffer solution) to the Rapid fFN 10Q Analyser on MAU. Note: A daily quality check of the 10Q analyser is carried out bythe health care assistant on Delivery Suite. A system pass or fail is then logged in the diary kept next to the analyser. This swab can be kept up to 24 hours before processing in the fridge or 12 hours at room temperature.

Step 3 Remove the Rapid fFN Cassette from the plastic box next to the analyser.

Step 4 Select TEST PATIENT from the Analyser Main Menu and enter the necessary information untilthe analyser prompts for cassette insertion.

Step 5 Insert the cassette into the analyser and press ENTER. The reference code on the cassette willappear on the analyser and this should match with the number on the test cassette.

Step 6 Pipette 0.2mls of patient sample buffer solution into the well of the Rapid fFN cassette and press ENTER. The analyser will complete the analysis of the fFN cassette in 10 minutes.

Appendix 7: Periprem Passport

Perinatal Excellence to Improve Outcomes for Premature Birth

A bundle of perinatal interventions that will contribute to a reduction in brain injury and mortality across UHL by optimising:

NHS University Hospitals of Leicester NHS Trust

1 Right place of Birth

Mothers presenting with signs of labour <32 weeks gestation should be directed to LRI.

2 Antenatal Steroids

Mothers who give birth <34 weeks gestation should receive a full course of antenatal steroids.

Maximum benefit is achieved if administered between 24 hours and 7 days prior to delivery (timed from second dose).

3 Antenatal Magnesium Sulphate

Mothers who give birth <30 weeks gestation should receive antenatal Magnesium Sulphate for fetal neuroprotection.

4 Antibiotic Prophylaxis

All women in confirmed preterm labour should receive antibiotic prophylaxis against Group B Streptococcus.

5 Early Breastmilk

Babies born <34 weeks gestation benefit from receiving mother's breastmilk within 6 hours of birth.

We are aiming to improve continuation of breastfeeding.

6 Optimal Cord Management (OCM)

Delayed cord clamping for at least one minute improves survival rates in preterm infants.

A member of the neonatal team should be present to assess the baby prior to cord clamping to support this.

7 Thermal Care

Babies born at <34 weeks gestation should have a temperature measured on admission to Neonatal Unit within 1 hour of birth, which is in range of 36.5-37.5°C.

8 Respiratory Management

For babies who need invasive ventilation, use synchronised volume-targeted ventilation (VTV) as the primary mode of respiratory support.

9 Caffeine

We give caffeine routinely to babies <30 weeks gestation and those who are symptomatic of apnoea of prematurity at <34 weeks gestation. This is continued until they are more mature (around 33-34 weeks).

10 Probiotics

Babies (<32 weeks gestation or <1500g birth weight) should be commenced on probiotics once the baby has been on minimal enteral feeds for 24 hours.

Supporting compliance with the bundle for all eligible mothers and their babies born at less than 34 weeks gestation to improve the optimisation and stabilisation of the preterm infant.