Reference Number: UHBOBS215 **Version Number:** 1	**Date of Next Review:5/06/ 2023** **Previous Trust/LHB Reference Number:** *N/A*

Preterm Labour and PPROM

Prevention, Diagnosis and Management
Including the Diagnosis and Management of Preterm Prelabour Rupture of Membranes (PPROM)
And Detailing the Management of Women with Suspected or Confirmed COVID-19 presenting with Preterm Labour and/or PPROM.

Introduction and Aim

8% of all births will occur before 37 completed weeks of gestation. 70% of these are spontaneous following either the onset of spontaneous contractions or following preterm prelabour rupture of membranes (PPROM). Preterm birth is the biggest cause of neonatal morbidity and mortality in the UK[1].

Most women who present with symptoms of threatened preterm labour will go on to deliver at term, even in the absence of intervention. It is therefore essential to recognise those women who are at the highest risk in order to target interventions to those who will benefit the most, whilst minimising unnecessary treatment in women who do not need it.

Executive Summary

Change in Practice	Comment	Document Links
Risk stratification of women at increased risk of Preterm Birth	Details high and intermediate risk factors for preterm birth	Table 1 High Risk Criteria for Preterm Birth Table 2 Intermediate Risk Criteria for Preterm Birth
OBS55 Clinic	Referral pathway for women at high or intermediate risk of preterm birth.	Appendix 1: Referral Form for OBS 55 Clinic
Cervical Length Scanning	Indications and protocol for performing cervical length scanning.	**2.4.1** How to measure the Cervix and Interpret Results
Cervical Cerclage	Indications and process for cervical cerclage.	**2.5** Cervical Cerclage
Fetal fibronectin	Guidance for the use and interpretation of fetal fibronectin for the diagnosis of preterm labour. Note: if COVID-19 is suspected or confirmed, Actim Partus should be used instead.	Figure 2 Diagnosis of Preterm Labour in Women with INTACT Membranes and NO Suspicion of COVID-19
Actim Partus	Guidance for the use and interpretation of Actim Partus for the diagnosis of preterm labour in women with suspected or confirmed COVID-19.	Figure 3 Diagnosis of Preterm Labour in Women with INTACT Membranes and Suspected or Confirmed COVID-19

Actim PROM	Guidance on the use and interpretation of Actim PROM for the diagnosis of PRETERM (<37 weeks) prolonged rupture of membranes (PPROM). Note: if over 37 weeks, refer to Term SROM guideline.	Figure 4 Diagnosis and Management of Prelabour Rupture of Membranes
Management of Preterm Labour	New flowchart outlining guidance on the management of preterm labour.	Figure 5 Management of Preterm Labour
Tocolysis	Advice on the indication, use and dosage of tocolysis in the management of preterm labour.	**5.3** Tocolytics for Preterm Labour/ Threatened Preterm Labour
Magnesium Sulphate	Guidance on the use and dose of magnesium sulphate for fetal neuroprotection.	**5.6** Magnesium Sulphate for Fetal Neuroprotection
Management of PPROM	Flowchart outlining suggested management of PPROM	Figure 4 Diagnosis and Management of Prelabour Rupture of Membranes
Intrauterine Transfers	Documentation required for intrauterine transfer, and the management thereof.	**9.2** Appendix 2: All Wales Intrauterine Transfer Communication Form
Counselling in Extreme Preterm Birth	New BAPM guidance for counselling parents in extreme preterm (<27 weeks) birth/ PPROM.	**6** Counselling Parents on Neonatal Outcomes in Extreme Preterm Birth <27 weeks gestation
Extreme Preterm Integrated Care Pathway	Documentation that should be completed for all preterm births <27 weeks gestation.	**9.3** Appendix 3: Extreme Preterm Integrated Care Pathway

Objectives

- *Measures to identify women at high risk of preterm birth and reduce that risk.*
- *Guidance on the diagnosis of preterm labour and threatened preterm labour.*
- *Guidance on the diagnosis and management of preterm prolonged rupture of membranes (PPROM).*
- *Guidance on the management of preterm labour and threatened preterm labour.*
- *Standardising the documentation and management of extreme preterm using the Extreme Preterm Integrated Pathway.*

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts.

Equality Health Impact Assessment	*An Equality Health Impact Assessment (EHIA) has been completed.*

Documents to read alongside this Procedure	*British Association of Perinatal Medicine* Framework for Practice for the Perinatal Management of Extreme Preterm Birth before 27 weeks of gestation.
Approved by	*Maternity Professional Forum.* *Maternity Quality and Safety Forum.*

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Disclaimer

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Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	*27 May 2020*	*05/06/2020*	***New Document*** *Replacing Premature Labour and Management (November 2014) and Premature Labour and Premature Rupture of Membranes (May 2014)*

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2 Preventing Preterm Birth

2.1 Specialised Antenatal Care

Specialised antenatal care for women at high risk of preterm births reduces the number of preterm births, and specialist clinical teams are recommended to deliver this care[2,3].

Trans-vaginal cervical length scans have been found to be a reasonable predictor of preterm delivery in women at high risk of spontaneous preterm birth[4]. There is a consistent association between cervical length below the 10 percentile (25 mm) and spontaneous preterm birth[5].

Cervical cerclage[6] and progesterone[7] have been found to reduce the risk of preterm birth in women with risk factors and a short cervix.

Women at high risk of preterm birth should be offered the following: -

- Patient-centered antenatal care and support
- Transvaginal Cervical length screening
- Management of the short cervix (Cerclage or Progesterone)

Care for women at a high risk of preterm birth is offered in either the Tuesday morning Rainbow Clinic at UHL or in the Thursday morning antenatal clinic in UHW, depending on Obstetric history.

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2.2 Referral Criteria for Women at Risk of Preterm Birth

In women with high risk criteria, referral should be sent at the booking appointment with the community midwife.

2.2.1 High Risk Criteria

High risk of preterm birth – referral criteria	
Previous spontaneous PTB < 34 weeks	Child alive and well: refer to OBS 55 NND: refer to Rainbow Clinic
One or more spontaneous mid-trimester losses 16-24 weeks	Refer to Rainbow Clinic
Previous preterm pre labour rupture of membranes <34/40	Refer to OBS 55 using form at the first booking appointment.
Previous cervical cerclage (Stitch)	Successful outcome: Refer to OBS 55 using form at the first booking appointment.

	Failed cerclage: URGENT referral to OBS 55 **
Known uterine variant (i.e. unicornuate, bicornuate uterus or uterine septum).	Refer to OBS 55 using form at the first booking appointment.
2 or more LETZ (loop excision transformation zone) or Knife cone biopsy	Refer to OBS 55 using form at the first booking appointment.
Trachelectomy (for cervical cancer) **	URGENT referral to OBS 55 using form at the first booking appointment.

Table 1 High Risk Criteria for Preterm Birth

** Women with a previous failed cerclage or a trachelectomy have a very high risk of preterm birth and may benefit from early elective cerclage[8].

A woman with a previous failed Transvaginal cerclage will generally be advised to have an interpregnancy-sited trans abdominal cerclage.

Urgently refer *to Thursday OBS 55 Clinic* ***and****/or discuss with a Consultant Obstetrician.*

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2.2.2 Intermediate Risk Criteria

Intermediate risk of preterm birth	
Previous full dilatation caesarean section *	Refer to OBS 55 using form at the first booking appointment.
One previous LETZ*	Directly book OBS 55 Alternate FRI PM for single scan at 20 weeks.

Table 2 Intermediate Risk Criteria for Preterm Birth

*If abnormal smear +/- colposcopy and biopsy only, no need for scan. If women have had a TERM DELIVERY after the risk factor event, the risk of preterm birth is LOW and no need for cervical length scans.

- *If transvaginal scan shows cervical length ≥ 25mm then return to routine care.*
- *If transvaginal scan shows cervical length <25mm urgently discuss with Consultant Obstetrician on call and follow NICE guidance.*

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2.3 Management at OBS 55 Clinic

Women will be seen for first visit at approximately 16 weeks gestation.

- A full history will be taken and risk of preterm birth assessed.
- Smoking cessation and dietary advice will be offered.
- An individualised plan for Transvaginal cervical surveillance will be made – usually fortnightly surveillance until 24 weeks gestation. Fetal Fibronectin testing may be appropriate in some women to give a quantifiable risk of pre-term birth. This will be part of an individualised plan.
    - Women will be asked to consent for their details being entered into the preterm clinical network database.
- ***If cervix remains ≥ 25mm*** *then the woman will be* ***discharged*** *from clinic at 24 weeks to consultant care as appropriate. A note will be made in the Obstetric management plan in the clinical notes.*

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2.4 Management of Women with Cervical Length <25mm

- **If cervical length is < 25mm** at any time then the risk of preterm labour before 35 weeks is approximately 55%[9]. Discuss management with a Consultant Obstetrician and/or refer to Thursday Obs 55 Clinic
- Cervical cerclage may be offered depending on previous risk factors, rate of cervical change and clinical picture.
- Progesterone vaginal / rectal pessary (cyclogest) 400mg BD until 34 weeks may be given to women who decline cerclage when medical team feel it is indicated following short cervix on USS[1].
- **If** the cervix is open then woman should be admitted. Screen for infection (LVS, MSSU, CRP and WCC) and discuss with a Consultant Obstetrician urgently regarding potential cerclage placement and further management.

Women will be followed up in the Thursday Obs 55 clinic.

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2.4.1 How to measure the Cervix and Interpret Results

1. Cervical length measurement should only be obtained by transvaginal scan. Verbal consent is required and a chaperone. The cervix should fill approximately 75% of screen. The bladder should be empty, and the anterior and posterior lips of cervix should be of equal width in the image. The cervical length should be recorded as the straight length between internal and external os (thick black arrow). The dotted arrow is the funnel length, which **should not be included** in the cervical length measurement. The examination should be performed over 3-5 minutes, and 3 measurements taken within 10% of each other. The 'shortest best' measurement should be reported.

2. If cervix is 25mm or more this is reassuring.
3. If cervix is less than 25mm it is short and specialist management should be offered.

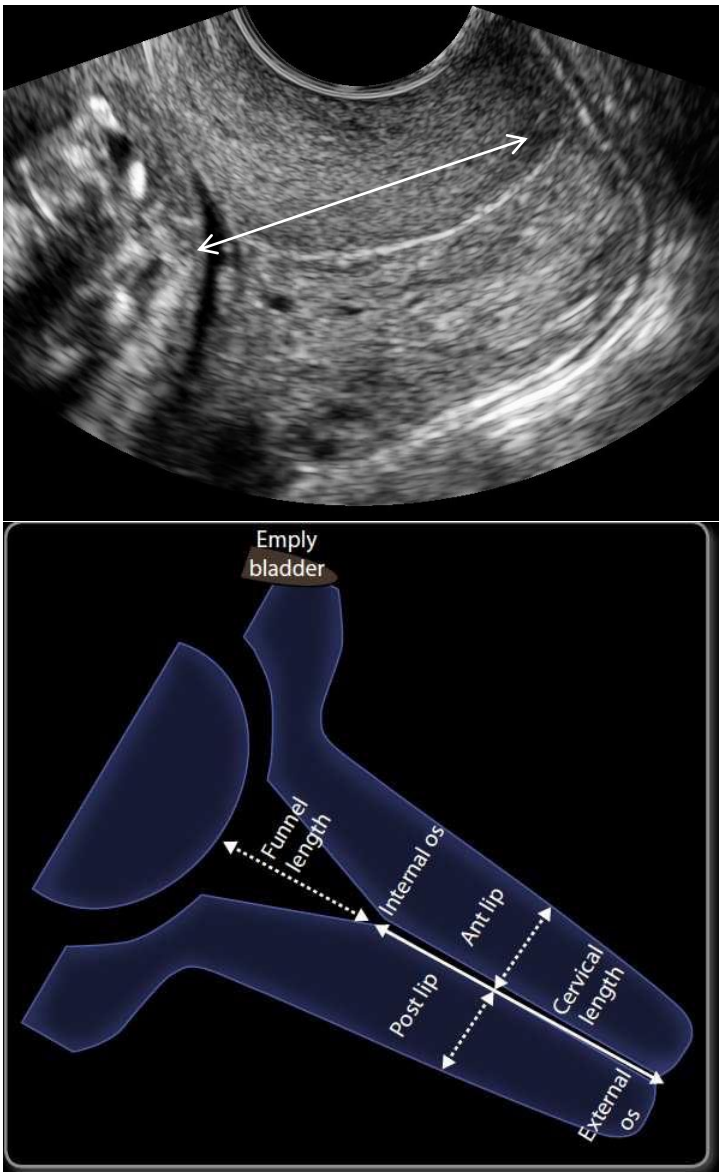

Figure 1 How to Measure Cervical Length on Transvaginal Ultrasound

CLEAR : Cervical Length Education and Review Programme

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2.5 Cervical Cerclage

If cervical cerclage is indicated it should be booked on the Theatre man elective list for delivery suite. The consultant on for that day should be informed.

- Perform HVS in clinic prior to suture placement.
- Provide information about cerclage (RCOG patient information leaflet) and C-Stich (Randomised controlled trial of braided vs. monofilament suture).
- Cerclage is performed in theatre, under **regional or general anaesthetic.**
- Antibiotics and Tocolysis are **not** routinely given.
- Women will be **followed up** in one of the OBS 55 / Rainbow consultant-led clinics.

- Routine cervical length scans should not be arranged following cerclage, but may be requested if findings would influence management or, in exceptional circumstances, for reassurance of the woman.

2.5.1 Removal of Cervical Cerclage

Suture removal should be arranged on labour ward at 37 weeks (needs noting in diary but does not need to be booked on theatre man unless it was a Shirodkar cerclage, which would require removal in theatre under regional anaesthesia).

2.5.2 Preterm Rupture of Membranes with Cervical Suture in Situ

If the woman presents in preterm labour or with a spontaneous rupture of membranes the suture **should be removed ASAP** to prevent cervical injury and infection respectively. In cases of extreme prematurity (< 28 weeks) then it may be preferable to leave the suture long enough to gain steroid maturity (consider giving at 12 hourly intervals). Decision to be made by Consultant-on-call.

After delivery any woman who has attended the OBS 55 clinic should have her notes forwarded to Lynne Morgan for noting of outcomes (and for European Preterm Birth registry/ Preterm Network Database, if consented to this).

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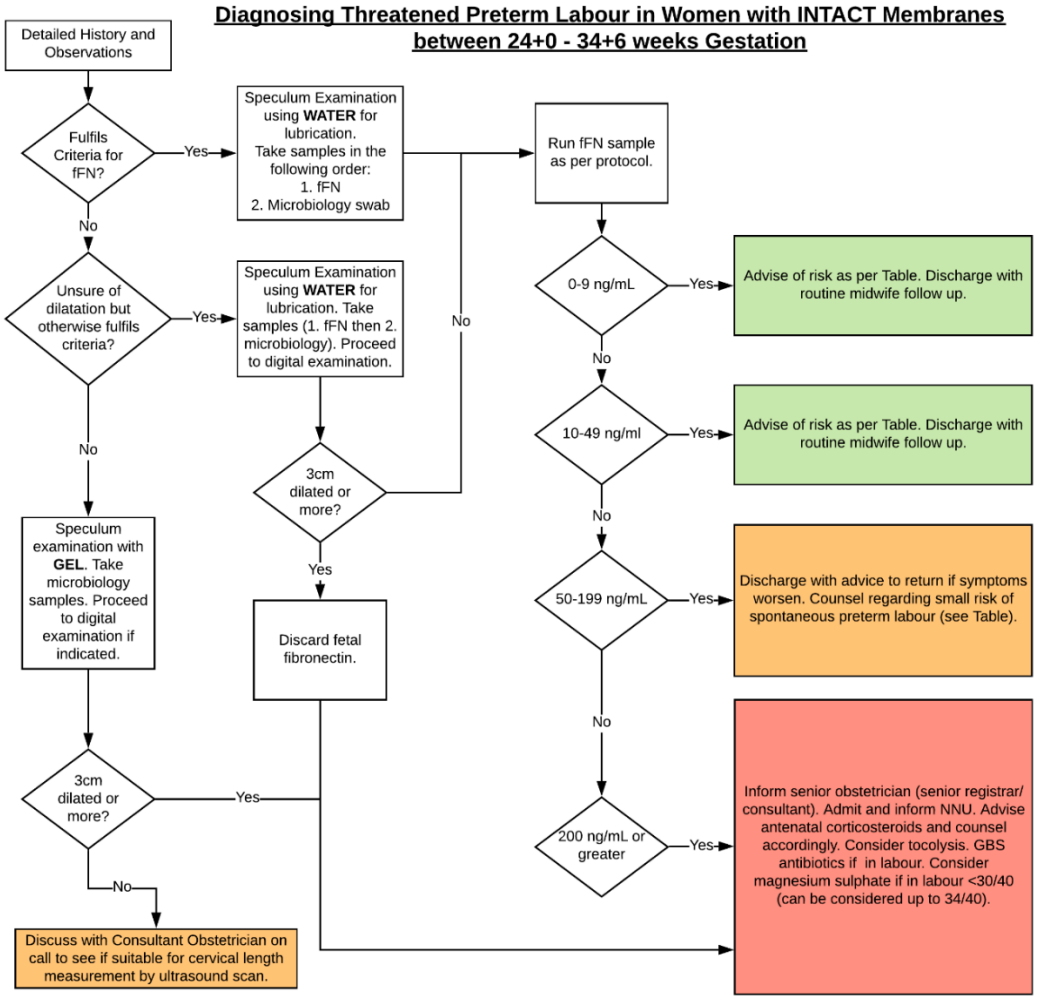
3 Diagnosis of Threatened Preterm Labour in Women with Intact Membranes

3.1 Flowchart for the Diagnosis of Preterm Labour in Women with INTACT Membranes and Asymptomatic for COVID-19



Criteria for using fFN

- Signs and symptoms of preterm labour.
- Between 24 weeks and 34+6 weeks gestation.
- Intact membranes.
- Cervix <3cm dilated.

Contraindications to fFN

- Ruptured membranes.
- Cervix 3cm dilated or more.
- Any contraindications to tocolysis.
- Presence of cervical cerclage.
- Moderate/severe vaginal bleeding (may give false positive result).
- Sexual intercourse or vaginal examination within the last 24 hours.

fFN Value ng/mL	% who will deliver within 2 weeks	% who will deliver <34/40
0-9	<2	<2
10-49	<2	8
50-199	8	12
200-499	29	33
>500	46	75

Figure 2 Diagnosis of Preterm Labour in Women with INTACT Membranes and NO Suspicion of COVID-19

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3.2 Flowchart for the Diagnosis of Preterm Labour in Women with Confirmed or Suspected COVID-19

Due to the requirement for isolation of both patients and potentially infected samples, fetal fibronectin testing will not be available for use in women with suspected or confirmed COVID-19. The only facilities for testing fetal fibronectin samples is on the Obstetric Assessment Unit. Samples taken from women with suspected or confirmed COVID-19 **must not** be taken out of the restricted 'red zone' areas. Instead, an Actim Partus test should be performed in line with the following flowchart.

See SOP for the Use of Actim Partus in Suspected Preterm Labour in Patients with Suspected or Confirmed COVID-19 Infection for more information.

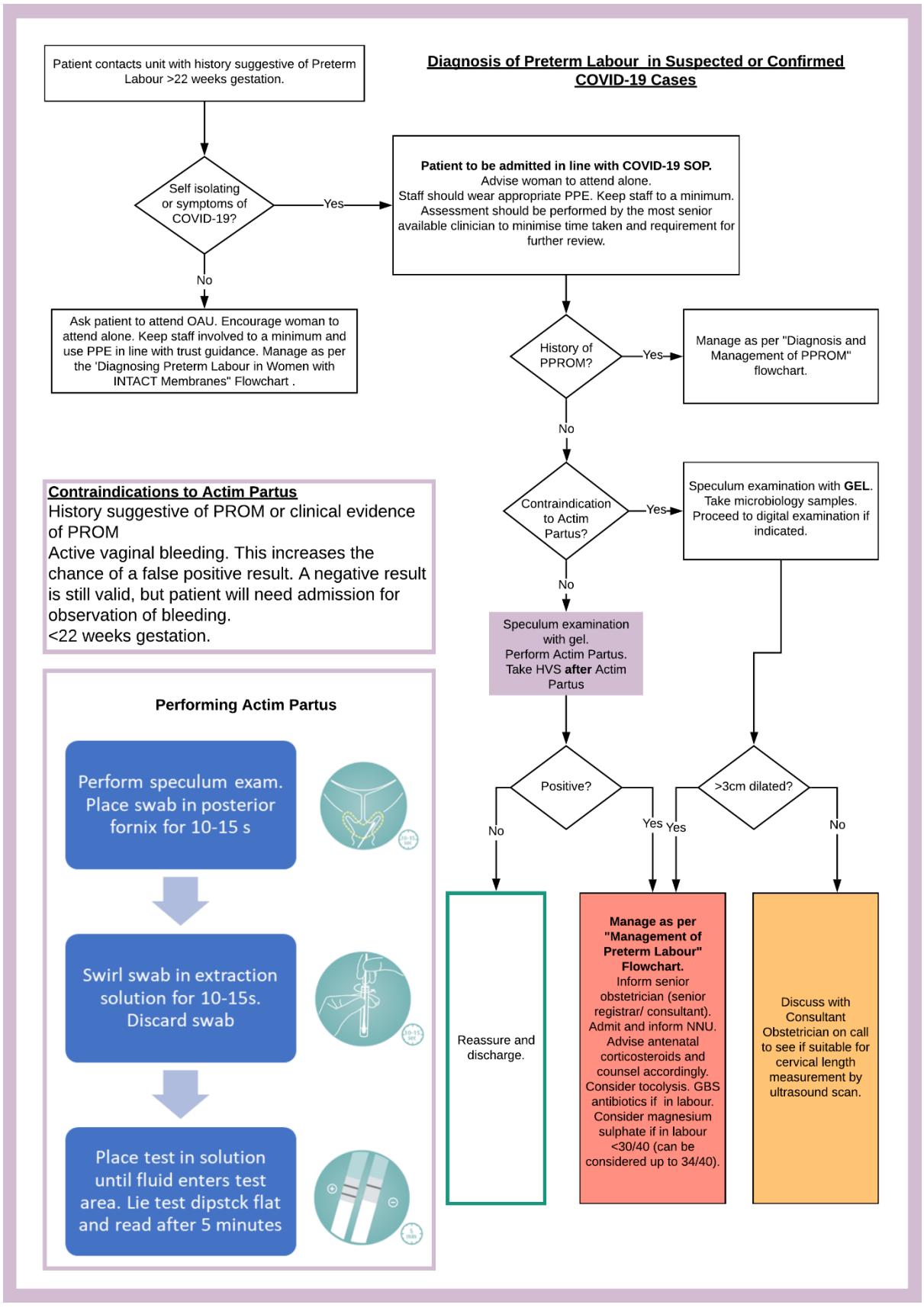

Figure 3 Diagnosis of Preterm Labour in Women with INTACT Membranes and Suspected or Confirmed COVID-19

3.3 Diagnosis of Preterm Labour

8% of all births will occur before 37 completed weeks of gestation. 70% of these are spontaneous following either the onset of spontaneous contractions or following preterm prelabour rupture of membranes (PPROM). Preterm birth is the biggest cause of neonatal morbidity and mortality in the UK[1].

A majority of women who present with symptoms of threatened preterm labour will go on to deliver at term, even in the absence of intervention. It is therefore essential to recognise those women who are at the highest risk in order to target interventions to those who will benefit the most, whilst minimising unnecessary treatment in women who do not need it.

3.3.1 History, Assessment and Examination

3.3.1.1 History

A detailed history should be taken. When taking the history, risk factors for preterm labour (Table 1) should be taken into account.

3.3.1.2 Assessment

Carry out an initial assessment of any woman who may be in labour[10]:

Initial observations of the woman:

- Review the antenatal notes (including all antenatal screening results) and discuss these with the woman
- Ask her about the length, strength and frequency of the contractions
- Ask about any pain that she is experiencing and discuss the options for pain relief
- Record her pulse, BP and temperature and perform a urinalysis
- Record if she has any vaginal loss

Initial observations of the unborn baby:

- Ask about the baby's movements over the last 24 hours
- Palpate the abdomen to determine the fundal height, the baby's lie, presentation, position, engagement of the presenting part, and the frequency and duration of any contractions
- Auscultate the fetal heart for at least 1 minute immediately after the contraction

3.3.1.3 Examination

Offer a speculum examination to assess for any vaginal loss and for cervical dilatation (do not use any lubricating gel if you plan to take a sample for fFN). If she fulfils the criteria for fetal fibronectin to be tested, then the sample should be taken at this point. Once the fFN sample has been obtained consider a microbiology swab depending on the context. If the extent of cervical dilatation cannot be assessed on speculum, a digital vaginal examination may be required. If this is the case, then take the fFN sample before performing a digital examination and discard the sample if she is then found to be ≥3cm dilated.

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3.3.2 Fetal Fibronectin (fFN)

3.3.2.1 What is Fetal Fibronectin?

Fetal Fibronectin (fFN) is a glycoprotein that is produced by fetal cells and acts almost like a biological adhesive between the chorion and the decidua. Any local inflammatory, infectious or mechanical damage may result in fFN "leaking" into the vagina. The concentration of fFN in the cervicovaginal fluid is relative to the risk of spontaneous preterm labour.

3.3.2.2 Criteria and Contraindications for using Fetal Fibronectin

Criteria for using fFN	Contraindications to fFN
• Signs and symptoms of preterm labour between 24 weeks and 34+6 weeks of gestation • Intact membranes • Cervix < 3cm dilated	• Ruptured membranes • Cervix ≥3cm dilated • Any contraindication to tocolysis • A symptomatic patient with a cervical cerclage • Moderate/severe vaginal bleeding (may give false positive result). • Sexual intercourse or vaginal examination within the last 24 hours ○ If fFN is done in this situation then a result of <200ng/mL can still be interpreted as a valid negative result. A result >200ng/mL may be either a true or a false positive and cannot be relied upon – in this context the sample should be repeated ≥24 hours after the most recent examination.

Table 3 Criteria and Contraindications for the Use of Fetal Fibronectin

3.3.2.3 Method for Carrying Out Fetal Fibronectin Test[11]

1. **Specimens should be taken BEFORE any culture specimens or digital vaginal examination is performed.**
2. Perform a speculum examination using **only water as a lubricant.**
3. Lightly rotate the swab across the posterior fornix for 10 seconds to absorb secretions.
4. Immerse the tip of the swab into the buffer solution provided. Swirl the swab in the solution for at least 10 seconds.
5. If you will be testing the sample immediately, the swab can now be discarded. If there will be a delay in testing, then snap the swab shaft using the top of the tube and replace tube cap until it clicks (NB the shaft of the swab must be aligned with the hole in the base of the cap). If the sample is stored at room temperature it must be tested within 8 hours.
6. Ensure that the patient's details are on the test tube.
7. Select 'Test Patient' on the analyser and enter patient details.
8. Enter Rapid fFN Cassette Lot Number.
9. Insert Rapid fFN cassette into analyser and pipette 0.2ml of the buffer solution into the well of the cassette before pressing Start.
10. When complete (approximately 10 minutes), the system will display the result and will print them on a sticky label.
11. Ensure that the results label is attached to the patient's notes.
12. The results will be given in ng/mL. The result should be interpreted and managed in accordance with the table below. The figures below can be used to help counsel the patient.

3.3.2.4 Spontaneous Preterm Birth Rate within fFN Levels.

fFN Value ng/mL	% who will deliver within 2 weeks	% who will deliver <34/40	Suggested Management
0-9	<2	<2	Discharge with routine midwife follow up
10-49	<2	8	Discharge with routine midwife follow up
50-199	8	12	Discharge with advice to return if symptoms worsen Counsel regarding small risk of spontaneous preterm labour
200-499	29	33	Admit and inform NNU Advise antenatal corticosteroids and counsel accordingly Tocolysis GBS antibiotics if in labour Magnesium Sulphate if in labour and <30/40 (can be considered up to 34/40) (see below for full management guidelines)
>500	46	75	Admit and inform NNU Advise antenatal corticosteroids and counsel accordingly Tocolysis GBS antibiotics if in labour Magnesium Sulphate if in labour and <30/40 (can be considered up to 34/40) (see below for full management guidelines)

Table 4 Spontaneous Preterm Birth Rate According to Fetal Fibronectin Level

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3.3.3 QUIPP App

There is an excellent free mobile app called '**QUIPP**' which will generate an individualised risk based on the patient's history, cervical length (if available) and fFN result. This will allow for more tailored counselling.

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3.3.4 Transvaginal Cervical Length Scanning

If a patient is not suitable for Fetal Fibronectin testing i.e. if she has had recent intercourse, recent vaginal examination or has blood in the vagina (but NOT if this is an active APH), AND is symptomatic, discuss with the Consultant Obstetrician on call as to whether she would be suitable for cervical length measurement by ultrasound scan.

If the cervical length is ≤15mm she should be managed in the same way as a patient who has a FFN >500 ng/mL (see Table 4).

3.3.4.1 Arranging Transvaginal Cervical Length Scans

These should be performed on Labour Ward by an on-call obstetrician who is trained and experienced in transcervical scanning. The portable bedside ultrasound scanner can be used.

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4 Preterm Prelabour Rupture of Membranes (PPROM)

4.1 Flowchart for the Diagnosis and Management of PPROM

See SOP for the Use of Actim PROM in Suspected Prelabour Rupture of Membranes in Patients with Suspected or Confirmed COVID-19 Infection for more information.

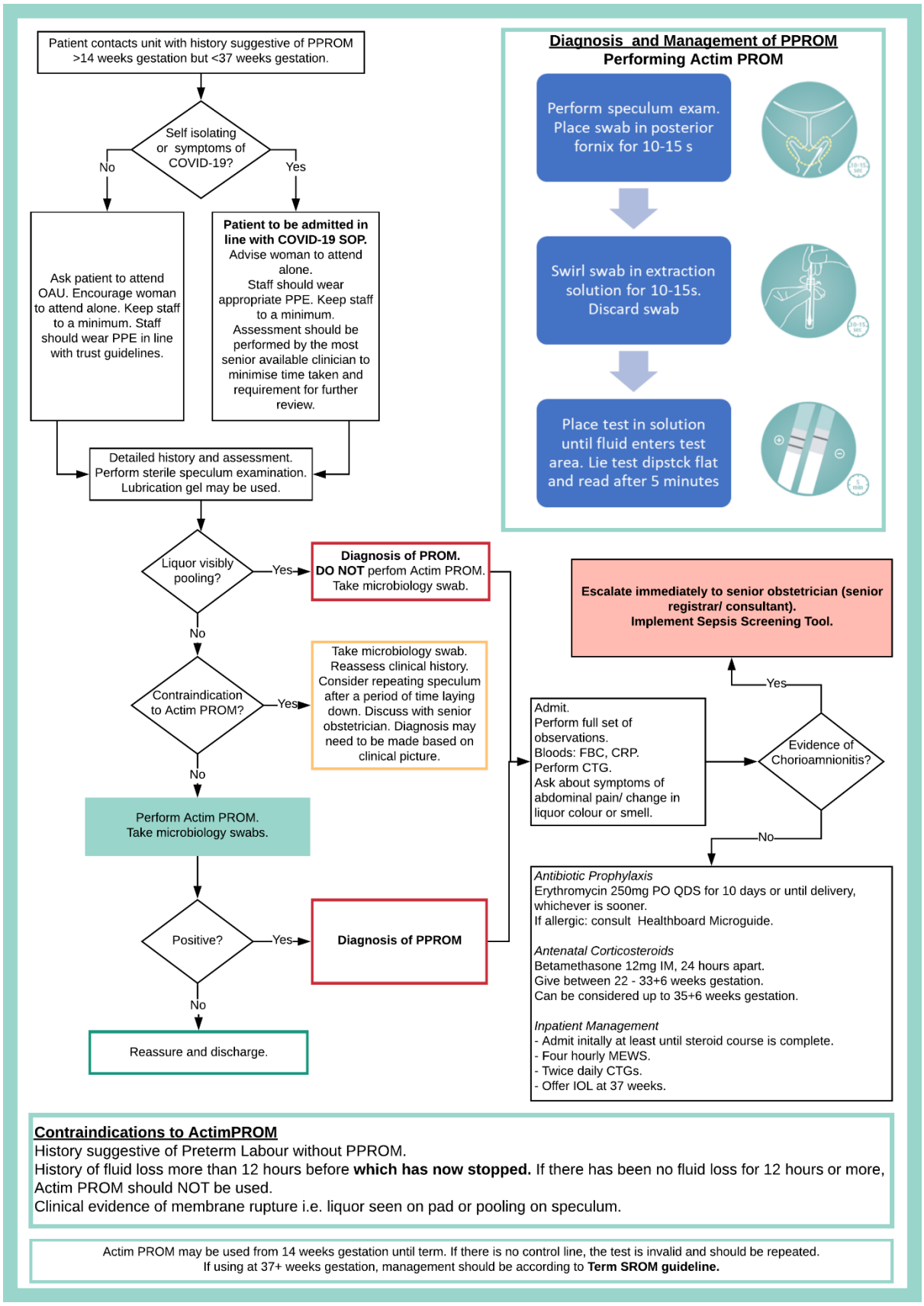

Figure 4 Diagnosis and Management of Prelabour Rupture of Membranes

4.2 Diagnosis of PPROM

Preterm prelabour rupture of membranes (PPROM) complicates up to 3% of pregnancies and is associated with 30–40% of preterm births. PPROM can result in significant neonatal morbidity and mortality, primarily from prematurity, sepsis, cord prolapse and pulmonary hypoplasia. In addition, there are risks associated with chorioamnionitis and placental abruption. The median latency after PPROM is 7 days and tends to shorten as the gestational age at PPROM advances.

The 'gold standard' for diagnosing PPROM is to take a detailed history and perform a sterile speculum examination[12]. A pool of liquor in the vagina is diagnostic and no further testing is needed. However clinical assessment alone may be equivocal in 10-20% of cases. Therefore, if pooling is NOT seen or if examination findings are equivocal then Actim PROM should be used.

4.2.1 Actim PROM

4.2.1.1 What is Actim PROM?

Actim PROM is a vaginal swab that detects insulin-like growth factor binding protein-1 (IGFBP-1) which is found in amniotic fluid. It can be used at any gestation.

It has excellent sensitivity (97-100%)[13,14] and specificity (95-100%) meaning that a patient can be confidently discharged back to their normal antenatal care without the need for further visits or investigations. Conversely it should also reduce the number of women in whom PPROM is missed.

It is important to be aware that the sensitivity of this test will be significantly lower in the case of 'micro-leaks' where more than 12 hours has elapsed since liquor was first noted to be draining.

4.2.1.2 Criteria and Contraindications for using Actim PROM

Criteria for using Actim PROM	Contraindications for using Actim PROM
• History of SROM within the last 12 hours, but **NO** evidence of liquor on speculum examination • Any gestation • Can be used in the presence of blood, semen, infection, lubricant	• Evidence of SROM on examination • History of threatened preterm labour **WITHOUT** any history of PPROM • Loss of fluid over 12 hours ago, with no further loss since

Table 5 Criteria and Contraindications for the Use of Actim PROM

4.2.1.3 Method for Carrying Out Actim PROM[15]

1. Hold the swab in the vagina for 10-15 seconds. Ideally this should be done as a high vagina swab at the time of speculum examination. This allows for visual assessment of any liquor draining and may negate the need for testing. The sample can also be obtained from a low vaginal swab left in situ for 10-15 seconds but this should **ONLY** occur if the patient declines a speculum examination.
2. Place the swab in the Specimen Extraction Solution and swirl around vigorously for 10-15 seconds.
3. Discard the swab.
4. Place the yellow dip area of the dipstick into the solution and hold it there until you see the liquid enter the result area.

5. Remove the dipstick from the solution and place in a horizontal position.
6. Interpret the results:

POSITIVE RESULT: **- 2 blue lines.** Can be read as soon as 2 lines are visible.

- Treat as PPROM

NEGATIVE RESULT: **- 1 blue line.** Should be confirmed at 5 minutes.

- PPROM excluded. Discharge if no other concerns. Return to her regular antenatal care.

INVALID RESULT: **- No line**. Test should be repeated.

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4.3 Management of PPROM

4.3.1 Antibiotic Prophylaxis

Following the diagnosis of PPROM oral erythromycin should be given 250mg QDS for 10 days (if allergic see Healthboard Microguide) or until the woman is in established labour, whichever is sooner.

4.3.2 Antenatal Corticosteroids

Women who have PPROM between 22+0 and 33+6weeks' gestation should be offered corticosteroids. Steroids can be considered up to 35+6weeks' gestation.

4.3.3 Identifying Infection

A combination of clinical assessment (pulse, blood pressure, temperature and symptoms), maternal blood tests (C-reactive protein and white cell count) and fetal heart rate (CTG) should be used to diagnose chorioamnionitis in women with PPROM; these parameters should not be used in isolation.

The white cell count will rise 24 hours following administration of corticosteroids and should return to baseline 3 days following administration.

4.3.4 Ongoing Management

The optimal method of monitoring to predict adverse fetal outcome after PPROM has not been determined. If delivery seems imminent, then in-patient care is indicated to prepare the woman for birth (including, if relevant, the administration of intravenous magnesium sulphate). The decision to offer outpatient care to women with PPROM, following a period of in-patient care, should be made on an individual basis. Factors including past obstetric history, support at home and distance from the hospital should be taken into account in discussion with the woman about her preferences, and markers of delivery latency should be assessed (the presence of antepartum haemorrhage, amniotic fluid volume, gestational age at which PPROM occurs and clinical and laboratory markers of infection).When considering the gestational age at which PPROM occurs, delivery latency remains relatively constant from 24+0 to 28+0 weeks gestation at 8–10 days (median) and then decreases to 5 days (median) at 31+0 weeks. Women with clinically diagnosed PPROM who have reduced amniotic fluid volumes on ultrasound are more likely to give birth within 7 days from membrane rupture.

A retrospective cohort study of women with PPROM who had planned home care, found that membrane rupture occurring before 26+0weeks, non-cephalic presentation and

oligohydramnios were associated with an increased risk of 'complication' (defined as fetal death, placental abruption, umbilical cord prolapse, delivery outside of hospital and neonatal death). The authors concluded that hospital-based care should be recommended to women who have all three of these features.

4.3.4.1 Timing of Delivery

Women whose pregnancy is complicated by PPROM after 24+0 weeks gestation and who have no contraindications to continuing the pregnancy should be offered expectant management until 37+0 weeks; timing of birth should be discussed with each woman on an individual basis with careful consideration of patient preference and ongoing clinical assessment.

For those with evidence of GBS colonisation in the current pregnancy or in previous pregnancies, the perinatal risks associated with preterm delivery at less than 34 +0 weeks of gestation are likely to outweigh the risk of perinatal infection. For those at more than 34 +0 weeks of gestation it may be beneficial to expedite delivery if a woman is a known GBS carrier.

4.3.4.2 Inpatient Management

When cared for as an inpatient, women with PPROM should have their vital signs, including pulse, blood pressure, respiratory rate and temperature, recorded on an obstetric early warning chart. This should be done once every 4 hours. CTG should be performed twice daily. They should also be observed for clinical symptoms and signs of infection.

4.3.4.3 Outpatient Management

When cared for as an outpatient, women should be advised of the symptoms of chorioamnionitis and be reviewed 1-2 times per week until delivery in the DAU or OAU. Each review should include blood tests (Full blood count and C-reactive protein), clinical recordings and fetal heart rate monitoring. If the woman has any concerns, she should attend the hospital immediately.

Frequency of outpatient review should be decided by the discharging consultant. An antenatal clinic appointment should be arranged for within 1 week of discharge to make an ongoing plan of antenatal care and decision regarding timing of delivery.

4.3.4.4 Fetal Monitoring

Fetal growth should be assessed on ultrasound scan fortnightly and amniotic fluid and umbilical artery Doppler studies weekly.

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5 Management of Preterm Labour

5.1 Flowchart for the Management of Preterm Labour

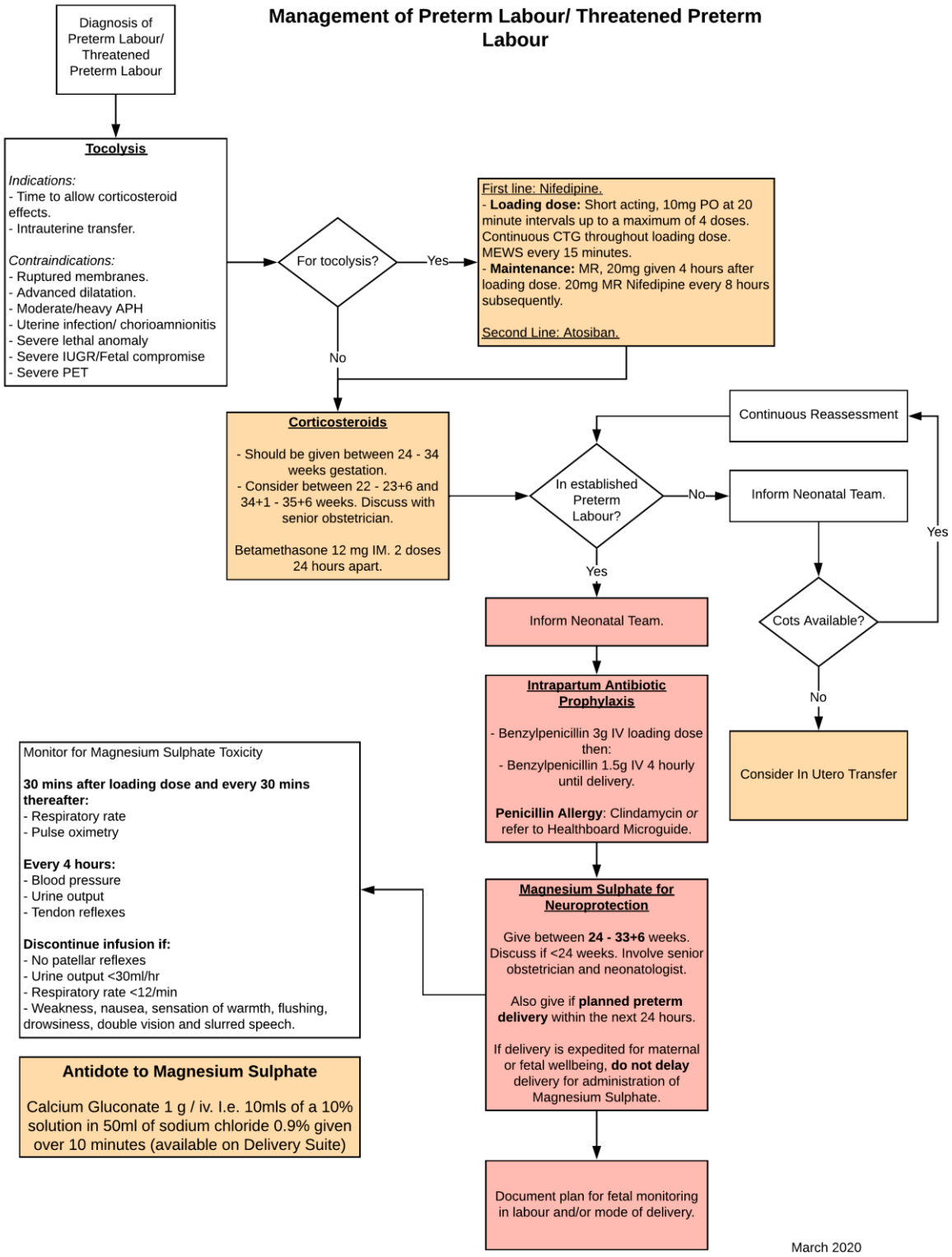

Figure 5 Management of Preterm Labour

5.2 Place of management

< 17/40 Transfer to Gyanaecology ward

≥ 17/40 Transfer to Maternity

If unsure of gestational age, Neonatologist should attend birth to assess and resuscitate if appropriate.

5.3 Tocolytics for Preterm Labour/ Threatened Preterm Labour

It is reasonable not to use tocolytic drugs, as there is no clear evidence that they improve outcome. Tocolytics should only be used if the few days gained will be put to good use. The main indications for tocolysis are:

- Corticosteroid administration (ideally tocolytics should be used if needed until 24 hours after the administration of the second steroid dose)
- In-utero transfer

Tocolytics should be offered to women between 24 and 33+6 weeks gestation who have intact membranes and are in suspected or diagnosed preterm labour. Use of tocolytics (and steroids) before 24/40 should be discussed with the Obstetric Consultant and Neonatal team.

Nifedipine and Atosiban have comparable efficacy. Nifedipine is used as first line. Betaminetics (eg – Terbutaline) should NOT be used for tocolysis in this context.

5.3.1 Contraindications to Tocolysis

- Ruptured membranes
- Advanced dilatation
- Moderate/heavy APH
- Uterine infection
- Severe lethal anomaly
- Severe IUGR/Fetal compromise
- Severe PET

5.3.2 Nifedipine (First Line)

Loading: Oral Nifedipine tablet 10mg on four occasions 20 minutes apart (ie – 10mg orally at 0, 20, 40 and 60 minutes);

OR, at 20 minute intervals until contractions stop, up to a maximum of 4 doses.

NB: Short acting nifedipine is associated with a sudden drop in blood pressure. Maternal observations should be done every 15 minutes throughout loading dose, and continuous CTG should be applied.

Maintenance: Oral Nifedipine modified release (MR) tablet 20mg, given 4 hours after loading dose. This is followed by Nifedipine MR 20mg 8 hourly for 48 hours or until a clinician directs for it to be stopped.

5.3.3 Atosiban (Second Line)

Atosiban should only be used if Nifedipine is contraindicated (severe maternal cardiopulmonary compromise), or intolerance to Nifedipine. Two vial sizes are available (0.9ml for initial bolus and 5ml vials for preparation of infusion).

Atosiban is administered as follows:

Loading: Intravenous bolus of one 0.9ml vial injection over 1 minute (one vial = 6.75mg)

Maintenance: Given as an IV infusion as follows:

5ml vials are used to set up the infusion. Any of the following solution can be used – 100ml bag is required.

- 0.9% w/v normal sodium chloride solution
- Ringer's lactate solution
- 5%w/v dextrose solution

1. Remove and discard 10ml of dilution solution from 100ml infusion bag. This should be replaced by 10ml Atisoban (2 x 5ml vials) to make 100ml of infusion solution.
2. Set up an IV infusion which runs initially at **24ml/hour** (18mg/hour) **for 3 hours.**
3. Reduce this to **8ml/hour** (6mg/hour) for up to a further **45 hours** (Total duration no more than 48 hours). Replacement bags should be prepared as required so that the infusion can be continued uninterrupted. If bags of different volume are used, the dilution calculation should be adjusted accordingly to achieve the same concentration. Use infusions within 24 hours after preparation.

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5.4 Corticosteroids

A single course of antenatal corticosteroids should be recommended for threatened preterm delivery between 24 and 34 weeks gestational age. It should also be considered between 34 and 35+6 weeks giving consideration to the ratio of risk to benefit. If unsure, these cases should be discussed with a senior Obstetrician.

Women between 22-23^{+6} weeks of gestation presenting with preterm labour or PPROM should be reviewed by a senior obstetrician (ideally consultant) and a senior neonatal clinician to make a decision regarding the management plan at delivery, as detailed in Section 6. This should be taken into account when considering antenatal corticosteroids in this group.

An attempt should be made to accurately predict preterm delivery, before starting a course of corticosteroids.

5.4.1 Corticosteroid Regime

Betamethasone 12mg IM, two doses 24 hours apart.

If Betamethasone is not available, Dexamethasone is given 6mg IM, for four doses, 12 hours apart.

5.4.2 Counselling Patients Regarding Corticosteroids

Benefits[16]**:**

- Reduction in perinatal mortality by 28%

- Fetal lung maturation (with reduction in Respiratory Distress Syndrome (RDS) of 34%)
- Reduction in intraventricular haemorrhage of 45%
- Reduction in necrotising enterocolitis (RR0.50, 95% CI 0.32 – 0.78)

Potential Risks:

Evidence for long term outcomes in children and adults exposed to antenatal corticosteroids is limited, but numerous systematic reviews and meta-analyses addressing this issue have reported no difference in serious long-term outcomes in childhood or adulthood. Concerns regarding low birthweight were raised following two RCTs[1] and animal studies. A 2017 Cochrane review[16] of 30 RCTs no difference for most childhood and adult outcomes (including neurodevelopmental outcomes, adult diabetes prevalence and childhood and adult weight), and no difference in maternal outcomes including risk of chorioamnionitis, endometritis and maternal death. There was no difference in birth weight adjusted for gestational age at delivery.

There is clear evidence for the benefits of antenatal corticosteroids, and they may be considered as safe for both mother and baby.

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5.5 Intrapartum Antibiotic Prophylaxis

Intrapartum antibiotics should be recommended for all women in confirmed preterm labour[17]. This is because the risk of vertical transmission of GBS infection is higher in preterm infants and the mortality from neonatal GBS infection is 10 times higher than at term. Women should be given antibiotic prophylaxis as recommended on the Healthboard Microguide.

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5.6 Magnesium Sulphate for Fetal Neuroprotection

Antenatal Magnesium Sulphate therapy given to women at risk of preterm birth within the next 24 hours reduces the risk of cerebral palsy and the rate of substantial gross motor dysfunction in their children.

Magnesium sulphate should be considered in women who are in established preterm labour or having a planned preterm delivery within 24-hours between 24-29^{+6} weeks of gestation[1]. It should be considered between 30-33^{+6} weeks of gestation for the same indications.

Women between 22-23^{+6} weeks of gestation presenting with preterm labour or PPROM should be reviewed by a senior obstetrician (ideally consultant) and a senior neonatal clinician to make a decision regarding the management plan at delivery, as detailed in Section 6. This should be taken into account when considering magnesium sulphate in this group.

When delivery needs to be expedited for reasons of maternal or fetal wellbeing then delivery should not be delayed solely for magnesium sulphate administration. Magnesium sulphate infusions should not be used during antenatal transfer. Magnesium sulphate when given solely

for protection against cerebral palsy is discontinued after delivery. There is insufficient evidence that a repeat course of antenatal magnesium sulphate for fetal neuroprotection should be administered.

5.6.1 Instructions for Administration of Magnesium Sulphate

5.6.1.1 Ready to Administer Syringes

When possible use the ready to administer syringes that are supplied by Pharmacy. These are stored between 15°C and 25°C in the treatment room on delivery suite.

Loading Dose 4g in 20ml (20%) via a syringe pump:

The 30ml syringe containing 20mls of the loading dose is to be attached to a syringe pump and administered at a rate of 60ml/hour, i.e. 4gm will be given over a 20 minute period **or** 240mls/hour if given over 5 minutes in the case of an eclamptic fit.

Maintenance infusion 10g in 50ml (20%) via a syringe pump:

The 60ml syringe containing 50mls of the maintenance dose is to be attached to a syringe pump and administered on completion of loading dose; set rate at 5ml/hour which equates to 1gm/hour.

5.6.1.2 Alternate Preparation

If the ready to administer syringes are unavailable, please see instructions below in red for alternate preparation. When prepared in this way the magnesium sulphate will be added to a bag of sodium chloride and given via an infusion pump.

Loading dose 4g in 50mls via an infusion pump:

When a pre-prepared syringe is unavailable remove 8mls of sodium chloride 0.9% from a 50ml bag of sodium chloride 0.9% and add 8mls of Magnesium Sulphate injection 50% (This produces 4g in 50mls). The 50ml bag is to be attached to a giving set and administered at a rate of 150ml/hour, i.e. 4gm will be given over a 20-minute period or 600mls/hour if given over 5 minutes in the case of an eclamptic fit.

Maintenance dose 40g in 500mls via an infusion pump:

When a pre-prepared syringe is unavailable remove 80mls of sodium chloride 0.9% from a 500ml bag of sodium chloride 0.9% and add 80mls of Magnesium Sulphate injection 50% (This produces 40g in 500mls). The 500ml bag to be attached to a giving set and administered on completion of loading dose set rate at 12.5ml/hour which equals to 1gm/hour.

5.6.2 Possible Side Effects

Maternal side effects are facial flushing, nausea and vomiting, sweating and injection site problems. Hypotension, tachycardia. Rarely, in those with neuromuscular disorders, can result in muscle weakness and paralysis. When given in conjunction with calcium channel antagonists, cardiovascular and neuromuscular effects may be exaggerated. There was no evidence of an effect on maternal death, cardiac respiratory arrest, pulmonary oedema, respiratory depression, severe postpartum haemorrhage or caesarean section rates.

5.6.3 Monitoring for Magnesium Sulphate Toxicity

30 minutes after loading dose and every 30 mins thereafter:

- Respiratory rate
- Pulse oximetry

At least every 4-hours

- Blood pressure
- Urine output via urometer: stop magnesium sulphate infusion if urine output is <0.5ml/kg/hr.
- Tendon reflexes

Discontinue infusion if

- No patellar reflexes
- Urine output <30ml/hour
- Respiratory rate <12/minute
- Weakness, nausea, sensation of warmth, flushing, drowsiness, double vision and slurred speech

5.6.4 Antidote to Magnesium Sulphate

Calcium Gluconate 1 g / iv. I.e. 10mls of a 10% solution in 50ml of sodium chloride 0.9% given over 10 minutes (available on Delivery Suite).

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5.7 Fetal Monitoring in Preterm Labour

Discuss with women in suspected, diagnosed or established preterm labour (and their family members or carers as appropriate):

- the purpose of fetal monitoring and what it involves
- the clinical decisions it informs at different gestational ages
- if appropriate, the option not to monitor the fetal heart rate (for example, at the threshold of viability)

These should be joint decisions made between the patient, the Obstetric team and the Neonatal team.

Involve a senior obstetrician in discussions about whether and how to monitor the fetal heart rate for women who are between 22+0 and 25+6 weeks pregnant. Please refer to the 'Management of Extreme Preterm Labour Integrated Care Pathway'.

DO NOT use a fetal scalp electrode for fetal heart rate monitoring if the woman is less than 34+0 weeks pregnant UNLESS all of the following apply:

- it is not possible to monitor the fetal heart rate using either external cardiotocography or intermittent auscultation
- it has been discussed with a senior obstetrician

- the benefits are likely to outweigh the potential risks
- the alternatives (immediate birth, intermittent ultrasound and no monitoring) have been discussed with the woman and are unacceptable to her

Discuss with the woman (and her family members or carers as appropriate) the possible use of a fetal scalp electrode between 34+0 and 36+6 weeks of pregnancy ONLY IF it is not possible to monitor the fetal heart rate using either external cardiotocography or intermittent auscultation.

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5.8 In Utero Transfer

If NICU does not have capacity, consider in utero transfer to another unit after assessment of maternal status. Decision to be made jointly by SpR & Band 7 midwife. If in doubt, contact the Consultant Obstetrician.

- The reason for transfer should be clearly explained to the family and clearly documented.
- It is essential that the counselling received and delivery plans are clearly communicated to the receiving hospital, so that there is continuity of management. An All Wales Intrauterine Transfer communication form (page 43) must be completed.
- In-utero transfer may not be possible (see below). In such cases the baby will need to be stabilised and transferred after delivery.
- All intrauterine transfers should be recorded on the database on S drive (to be done by the delivery suite co-ordinator).

5.8.1 Contraindications to In Utero Transfer

- Active labour.
- Maternal condition makes transfer unsafe (eg. Active APH, Severe PET).

If there is any doubt, the case should be discussed with the Consultant Obstetrician.

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5.9 Preterm Labour <26 weeks Gestation

This is an emergency and requires[18]:

- Experienced multidisciplinary perinatal staff to be involved.
- Good communication with parents, and between professionals.
- Documentation of discussion with parents.
- Appropriate counselling based on recent data (see Table 7 and Table 8).
- Every case of spontaneous preterm labour is a unique situation and treated individually.
- The parents' hopes and expectations need to be explored with honesty and compassion in a realistic way, drawing upon the available evidence. Communication and agreed plans must be documented in full and signed legibly. These plans may need to be revised frequently.
- Prior agreed management plan for the birth if time permits, particularly if <25/40 gestation, which should be fully documented.
- There should be an expectation of resuscitation at 24 weeks and beyond.

Documentation and management should be completed using the Extreme Preterm Integrated Care Pathway. (Page 44)

5.10 Mode of Delivery

Discuss the general benefits and risks of caesarean section and vaginal birth with women in suspected, diagnosed or established preterm labour and women with PPROM (and their family members or carers as appropriate).

Explain to women in suspected, diagnosed or established preterm labour and women with PPROM about the benefits and risks of caesarean section that are specific to gestational age. Highlight the difficulties associated with performing a caesarean section for a preterm birth, especially the increased likelihood of a vertical uterine incision and the implications of this for future pregnancies. Explain to women in suspected, diagnosed or established preterm labour that there are no known benefits or harms for the baby from caesarean section, but the evidence is very limited.

Consider caesarean section for women presenting in suspected, diagnosed or established preterm labour between 26^{+0} and 36^{+6} weeks of pregnancy with breech presentation.

5.10.1 Timing of Cord Clamping

The decision to delay cord clamping should be made at delivery and should depend on both the baby's and the mother's condition. The neonatal team can be involved in this decision at the time of delivery.

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5.11 In the Case of Intrapartum/ Neonatal Death

- The parents should be offered time alone with their baby.
- The parents should be offered the opportunity to discuss any concerns/questions at the time, and be aware of the possibility of a doctor being available for further discussion.
- The importance of post mortem examination should be discussed. They should be given the 'Information for Parents – Post-mortem examination of babies and children' booklet – see Trust's guidelines.
- X-rays, microbiological specimens, skin biopsy and chromosomal analysis may need to be considered.
- If the above are unacceptable to the family, photographs and/or external examination by a Geneticist may be useful and more acceptable.
- Parents will require further counselling from the obstetric team later (usually about 6 weeks) and paediatrician if appropriate.
- Medical illustration can take sensitive photographs for the parents.

5.11.1 Definitions/Classifications of Perinatal Death

Taken from MBRRACE-UK Perinatal Mortality Surveillance Report 2019[19]

Late fetal loss	A baby delivered between 22+0 and 23+6 weeks gestational age showing no signs of life, irrespective of when the death occurred.

Stillbirth	A baby delivered at or after 24+0 weeks gestational age showing no signs of life, irrespective of when the death occurred.
Antepartum stillbirth	A baby delivered at or after 24+0 weeks gestational age showing no signs of life and known to have died before the onset of care in labour.
Intrapartum stillbirth	A baby delivered at or after 24+0 weeks gestational age showing no signs of life and known to have been alive at the onset of care in labour.
Neonatal death	A liveborn baby (born at 20+0 weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available), who died before 28 completed days after birth.
Early neonatal death	A liveborn baby (born at 20+0 weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available) who died before 7 completed days after birth.
Late neonatal death	A liveborn baby (born at 20+0 weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available) who died after 7 completed days but before 28 completed days after birth.
Perinatal death	A stillbirth or early neonatal death.
Extended perinatal death	A stillbirth or neonatal death.
Termination of pregnancy	The deliberate ending of a pregnancy, normally carried out before the embryo or fetus is capable of independent life.

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6 Counselling Parents on Neonatal Outcomes in Extreme Preterm Birth <27 weeks gestation

Outcomes differ significantly based on gestational age at delivery. The British Association of Perinatal Medicine has produced a Framework for Practice for the Perinatal Management of Extreme Preterm Birth before 27 weeks of gestation.

Counselling should be performed by a senior neonatal clinician and a senior obstetrician, ideally in a multidisciplinary setting with midwifery and/or nurse support. This should be done at the earliest opportunity to offer parents time to process the information and make decisions. Follow up consultations may be appropriate to finalise management plans.

A decision should be made, in conjunction with the parents, regarding the type of care to provide to the baby at delivery. This will be either active (survival focused) care or palliative (comfort focused) care. The decision should be based on balanced information taking into account fetal and maternal risk factors (Figure 6) and clearly documented in the maternal notes. This decision should be regularly reviewed and changed if circumstances or risk factors change and may be influenced by the baby's condition at delivery. This should be explained to the parents and full discussion with them regarding the management options and what they entail should take place (Figure 7 Decision making around delivery, following risk assessment and after consultation with parents. BAPM 2019.Figure 7).

6.1 Assessing the risk in Extreme Preterm Birth <27 weeks of gestation[20]

6.1.1 Risk factors influencing outcome

These should be considered in order to refine the risk to the baby of extreme preterm birth, and should be reviewed regularly.

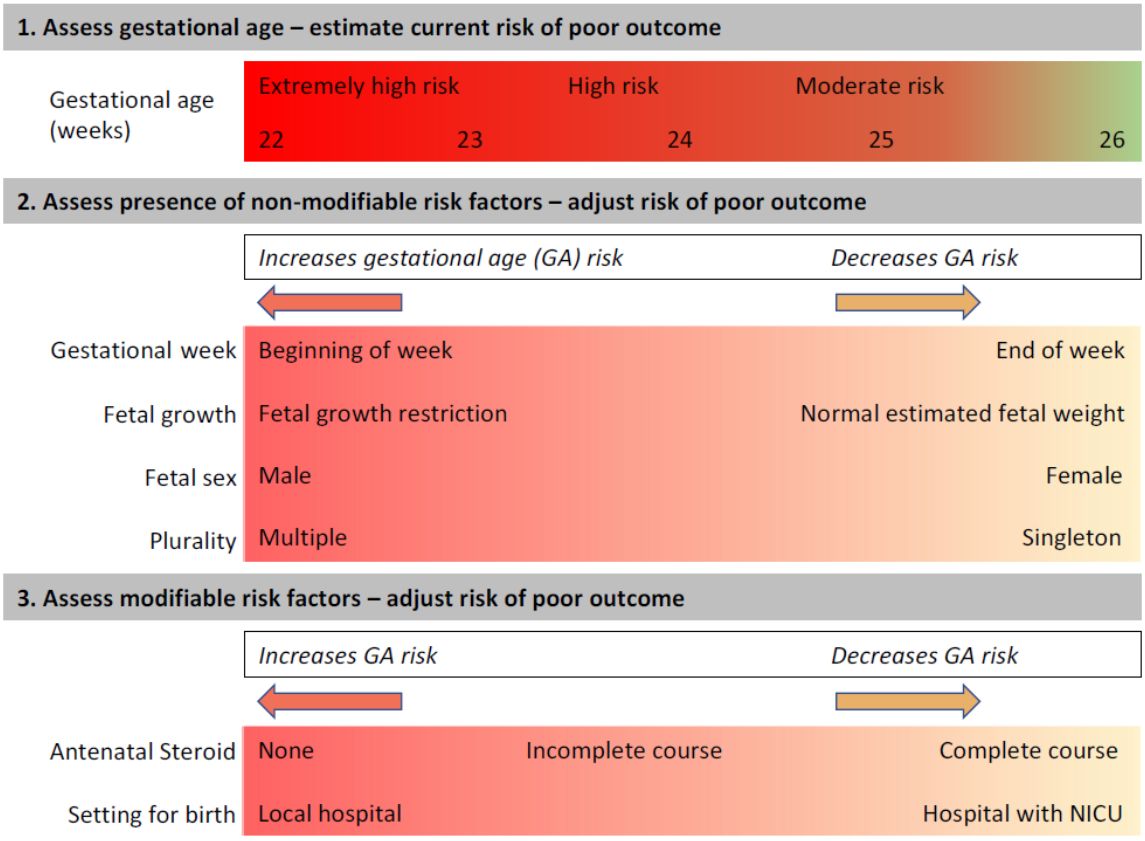

Figure 6 Visual tool for the Refinement of Risk. BAPM 2019.

6.1.2 Definition of Neonatal Risk in Extreme Preterm Birth[20]

Risk Category	Definition	Example	Management
Extremely High Risk	Babies with >90% chance of either dying or surviving with unacceptably severe impairment if active care is instigated.	a. Babies at 22_{+0} - 22_{+6} weeks of gestation with unfavourable risk factors b. some babies at 23_{+0} - 23_{+6} weeks of gestation with unfavourable risk factors, including severe fetal growth restriction c. (rarely) babies ≥ 24_{+0} weeks of gestation with significant unfavourable risk factors, including severe fetal growth restriction	Palliative (comfort focused) care would be in the best interests of the baby and life sustaining treatment should not be offered. There is no absolute indication for paediatric attendance at the birth although for individual families this may be helpful.
High Risk	Babies with a 50-90% chance of either dying or surviving with unacceptably severe impairment if	a. babies at 22_{+0} - 23_{+6} weeks of gestation with favourable risk factors b. some babies ≥ 24_{+0} weeks of gestation with unfavourable risk factors and/or co-morbidities	It is uncertain whether active (survival focused) management is in the best interests of the baby and their family. Parents should be counselled carefully and

	active care is instituted.		parental wishes should inform a joint decision to provide either active or palliative treatment. A senior neonatal clinician should attend the birth and supervise implementation of the agreed plan.
Moderate Risk	Babies with a <50% chance of either dying or surviving with unacceptably severe impairment if active care is instituted.	a. most babies ≥ 24_{+0} weeks of gestation b. some babies at 23_{+0} – 23_{+6} weeks of gestation with favourable risk factors.	Active management would be in the best interests of the baby. A senior neonatal clinician should attend the birth.

Table 6 BAPM definition of risk in extreme preterm birth infants and recommended management.

6.1.3 BAPM flowchart for management of extreme preterm babies based on risk category[20]

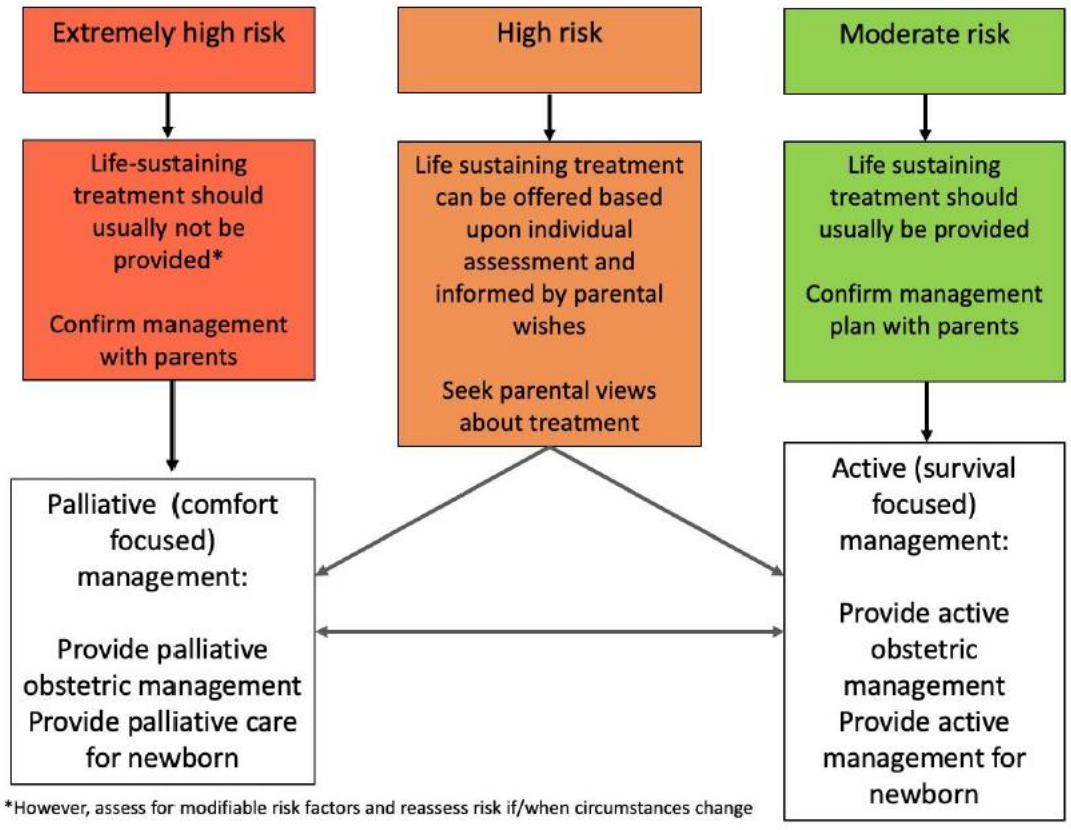

Figure 7 Decision making around delivery, following risk assessment and after consultation with parents. BAPM 2019.

6.1.4 Expected Neonatal Survival Rates with Extreme Preterm Birth[20]

	22 weeks	23 weeks	24 weeks	25 weeks	26 weeks
% of babies alive at start of labour that are born alive	63%	83%	92%	96%	98%
% of live births receiving active management	23%	88%	98%	100%	100%
% of live births that die in the delivery room before NNU admission	85%	26%	6%	4%	2%
% of babies receiving active care that survive until admission to NNU	65%	85%	96%	96%	98%
SURVIVAL TO 1 YEAR:					
Of those alive at onset of care in labour	**5%***	**28%**	**54%**	**71%**	**80%**
Of babies that received active management	**35%***	**38%**	**60%**	**74%**	**82%**
Of babies admitted to NICU	**54%***	**45%**	**63%**	**77%**	**84%**

Table 7 Expected Neonatal Survival Rates with Extreme Preterm Birth

6.1.5 Rates of Severe Impairment/Disability in Extreme Preterm Babies[21]

	22 weeks	23 weeks	24 weeks	25 weeks	26 weeks
Proportion of survivors that have severe impairment**	1 in 3	1 in 4	1 in 7	1 in 7	1 in 10

Table 8 Rates of Severe Impairment/ Disability in Extreme Preterm Babies

This includes any of: i) severe cognitive impairment with IQ < 55; ii) severe cerebral palsy; iii) blindness or profound hearing impairment. This does NOT include the babies with other milder forms of disability such as learning difficulties, mild cerebral palsy or behavioural problems. **This DOES NOT include other impairments/disabilities, which could be mental, physical or behavioural and are very difficult to quantify.

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8 Standard Operating Procedures (SOP)

8.1 SOP for the use of Actim Partus in Suspected Preterm Labour in Patients with Suspected or Confirmed COVID-19 Infection

	University Hospital of Wales	*Effective from: 01-01-2020*
Version Number & Date:	*Version 1. April 1,2020*	*Review date: 01-04-2021*
Previous version details	*Not applicable*	
Author: Monique Latibeaudiere **Designation:** Consultant Obstetrician and Gynaecologist		April 1, 2020

Background: Suspected pre-term labour is a common reason for presentation to the obstetric assessment unit; admission to hospital; medical treatment with corticosteroids and iatrogenic preterm birth. Symptoms of preterm labour are common, but most women are not at risk of preterm birth.

It is not clear whether COVID-19 increases the incidence of spontaneous preterm birth, although data is limited.

Women symptomatic of COVID-19 or who are self-isolating because of exposure to COVID-19 may present for assessment with a history suggestive of preterm labour.

These women should be assessed promptly, in line with maternity COVID=19 policy but it is paramount that accurate diagnosis is made to prevent unnecessary hospital admission or prolonged stay.

Actim-Partus is a reliable bedside test for use when preterm labour is suspected. It has a good negative predictive value and women in whom the test is negative may be safely discharged home and reassured that preterm birth is unlikely within the next 7-14 days.

Scope: This SOP applies to the care of women who present with a history suggestive of preterm labour after 22 completed weeks of pregnancy.

Why: Patients require timely and accurate diagnosis of preterm labour to ensure that appropriate multidisciplinary care can be arranged. Patients at low risk of preterm birth will avoid unnecessary admission and treatment. This protects patients and staff.

Where: Admission to the maternity unit will be as described in the COVID 19 SOP. The patient will be encouraged to attend for assessment alone. Staff attending to patient will be kept to a minimum and will wear appropriate PPE. If possible, the most senior staff should perform the assessment to limit the time taken.

What: Actim-PARTUS is a bedside test which detects the presence of phosphorylated Insulin-like Growth Factor Binding Protein – 1 (phosIGFBP-1) which is produced in the decidua. The presence of phosIGFBP-1 in the cervix may indicate an increased risk of preterm birth, but a negative result has a high negative predictive value (98%).

The test can be stored at room temperature.

It can be performed at any gestation after 22 weeks. Recent intercourse, slight vaginal bleeding, use of lubricants, presence of infection or use of hygienic products **are not** contraindications to its use.

Contraindications:

1. History suggestive of PROM or clinical evidence of PROM
2. Active vaginal bleeding. This increases the chance of a false positive result. A negative result is still valid, but patient will need admission for observation of bleeding.

How:

- Perform a sterile speculum examination, visualising the cervical os. If there is obvious amniotic fluid draining, DO NOT perform the test.
- Place the swab into the cervical os for 10-15 seconds.
- Remove the swab and place into the Specimen Extraction Solution and swirl for 10-15 seconds. Discard swab.
- Place the yellow end of the dipstick into Extraction solution and hold in place until the liquid is seen to enter the result area.
- Remove dipstick and place horizontally for 5 minutes. A positive result (2 blue lines) can be read at any time. A negative result (one blue line) can only be read at the end of 5 minutes. An absence of lines indicates a faulty test.

8.2 SOP for the Use of Actim PROM in Suspected Prelabour Rupture of Membranes in Patients with Suspected or Confirmed COVID-19 Infection

	University Hospital of Wales	*Effective from: 01-01-2020*
Version Number & Date:	*Version 1. April 1,2020*	*Review date: 01-04-2021*
Previous version details	*Not applicable*	
Author: Monique Latibeaudiere **Designation:** Consultant Obstetrician and Gynaecologist		April 1, 2020

Background: Suspected pre-labour rupture of membranes (PROM) is a common cause for presentation to the obstetric assessment unit; admission to hospital; medical treatment with corticosteroids and antibiotics and iatrogenic preterm birth. Novel coronavirus does not appear to increase the incidence of PROM, although data is limited. Women symptomatic of COVID-19 or who are self-isolating because of exposure to COVID-19 may present for assessment with a history suggestive of PROM.

These women should be assessed promptly, in line with maternity COVID-19 policy but it is paramount that accurate diagnosis is made to prevent unnecessary hospital admission or

prolonged stay. Actim-PROM is a sensitive and reliable diagnostic test for use when clinical findings of PROM are equivocal.

Scope: This SOP applies to the care of women who present with a history suggestive of rupture of membranes after 14 completed weeks of pregnancy.

Why: Patients will require clinical assessment to ensure timely and accurate diagnosis of PROM, and to avoid unnecessary admission and treatment. This assessment will be performed by trained clinical staff.

Where: Admission to the maternity unit will be as described in the COVID 19 SOP. She will be encouraged to attend for assessment alone. Staff attending to patient will be kept to a minimum and will wear appropriate PPE. If possible, the most senior staff should perform the assessment to limit the time taken.

What: Actim-PROM is a bedside test which detects the presence of Insulin-like Growth Factor Binding Protein – 1 (IGFBP-1) which is present in amniotic fluid.

The test can be stored at room temperature.

It can be performed at any gestation after 14 weeks. Recent intercourse, vaginal bleeding, use of lubricants, presence of infection or use of hygienic products **are not** contraindications to its use.

Contraindications:

1. History suggestive of preterm labour without PROM
2. History of fluid loss more than 12 hours prior which has now stopped
3. Clinical evidence of membrane rupture

How:

- Perform a sterile speculum examination, visualising the cervical os. If there is obvious amniotic fluid draining, DO NOT perform the test.
- Place the swab in the posterior fornix for 10-15 seconds.
- If speculum examination is declined, the test can be performed on a low vaginal swab left in situ for 10-15 seconds.
- Remove the swab and place into the Specimen Extraction Solution and swirl vigorously for 10-15 seconds. Discard swab.
- Place the yellow end of the dipstick into Extraction solution and hold in place until the liquid is seen to enter the result area.
- Remove dipstick and place horizontally for 5 minutes. A positive result (2 blue lines) can be read at any time. A negative result (one blue line) can only be read at the end of 5 minutes. An absence of lines indicates a faulty test.

9 Appendices

9.1 Appendix 1: Referral Form for OBS 55 Clinic

Please completed form and refer to clinic midwives.

Referrals will be triaged and women will be offered an appointment in the OBS 55 Clinic (Thursday am)

Patient name: **.....** **UNITNo:.....** **Date of Birth:.....** **Address:.....**	**Telephone number:.....**
Date of Referral:..... **Gestational age at referral.....** **(Please refer at booking)**	**Expected Date of Delivery:.....** **.....**
Past Obstetric History/Children/NND/Stillbirth.....	
Referral made by: Your name..... **Your telephone number/email address.....**	

High risk of preterm birth – please circle reason for referral	
Previous spontaneous PTB < 34 weeks	Child alive and well, refer to OBS 55 / NND refer to Rainbow Clinic
One or more spontaneous midtrimester losses 16-24 weeks	Refer to Rainbow Clinic
Previous preterm pre labour rupture of membranes <34/40	Refer to OBS 55 using form at booking
Previous cervical cerclage (Stitch)	Successful outcome - Refer to OBS 55 using form at booking Failed cerclage – URGENT referral to OBS 55 **
Known uterine variant (i.e. unicornuate, bicornuate uterus or uterine septum).	Refer to OBS 55 using form at booking
2 or more LETZ (loop excision transformation zone) or Knife cone biopsy	Refer to OBS 55 using form at booking
Trachelectomy (for cervical cancer)	URGENT referral to OBS 55 using form at booking
Intermediate risk of preterm birth	
Previous full dilatation caesarean section	Refer to OBS 55 using form at booking

If your reason for referring your patient does not appear in the list, please email the OBS 55 midwives.

9.2 Appendix 2: All Wales Intrauterine Transfer Communication Form

GIG CYMRU NHS WALES

ALL WALES INUTERO TRANSFER COMMUNICATION FORM

ADDRESSOGRAPH

	MATERNAL DETAILS	**FETAL DETAILS**
S ITUATION	**Gravida** ..... **Para** ..... **SROM** Y/N Date..... Time..... **Blood Group**..... Rh .....Antibodies..... **Medication**..... **Comments**	**EDD**..... **Gestation**..... **Multiple Pregnancy** Y/N No. of fetuses.....
B ACKGROUND	**Previous pre-term birth:** Y/N Details..... **Obstetric history**..... ..... **Medical history**..... ..... **Has Mother?** • Received health care treatments (inc IVF), in other countries outside Wales during last year? Y/N □ If yes, details of treatment..... Country..... • Had any infections/positive screening results during pregnancy? Y/N If yes, please specify.....	**Anomalies** Y/N Details..... .... **Safeguarding issues** Y/N Details..... ....
A SSESSMENT	**Pre-Term Labour Test:** Pos/ Neg fetal fibronectin/Actim partus **Vaginal Examination:** Date.....Time..... Findings..... ..... **Is Mother?** • Currently infected or colonised with organism/virus that is multiresistant or could cause harm to baby? Y/N/Unknown • If yes: Sensitivities of organism..... ..... • Currently on any antimicrobial treatment? Y/N • If yes, please specify..... ..... **HVS:** Y/N Date/s..... Sensitivities of isolates.....	**Fetal Compromise?** Y/N Comments..... ..... **Maternal Steroids?** Y/N Date..... Gest..... **USS** Date..... AC..... HC..... FL..... AFI..... Doppler..... EFW..... Comments.....

	Outstanding Microbiology results? Y/N Please specify.....	
RECOMMENDATION	**TRANSFER FROM:**	**TRANSFER TO:**
	Consultant Obstetrician	Consultant Obstetrician
	SPR:	DUTY SPR informed LW Coordinator informed Neonatal Unit informed ☐ ☐ **NB: All must be informed prior to transfer**
	Named midwife for transfer:	
	Person completing form: **NAME:** **DESIGNATION:** **SIGNATURE:**	

9.3 Appendix 3: Extreme Preterm Integrated Care Pathway

Extreme Preterm Delivery

Integrated Care Pathway

(22+0 to 24+6)

Mother's Name:	Patient identifier sticker here
Date of Birth:	
Hospital Number:	
NHS Number:	
Partner's name:	

All professionals utilising the care pathway to sign below

Professionals	Name and details	Date of involvement	Signature	Contact Number
Named Midwife				
Named Obstetrician				
Neonatal Consultant				
Obstetric trainee				
Neonatal trainee				

Please note: this pathway should be commenced when the obstetric and midwifery team, in collaboration with the family have agreed that the baby is at risk of being born preterm.

Initial Obstetric Discussion		
Date of assessment		
Estimate of gestational age today		
Basis for estimate of gestational age? (Was this a first trimester USS?)		
Number of fetuses		
Obstetric discussion led by	Print	Sign
People present		
	Other	

Assessment of fetal condition today		
No evidence of compromise		The information on this page must be reviewed weekly
Potentially compromised		
Compromised		
Maternal conditions contributing to potential outcome		

Antenatal corticosteroids		
Already given- DATE:	To be given	Deferred until……

Magnesium sulphate for neuroprotection		
Already given DATE:	To be given	Deferred until……

Antenatal monitoring		
No monitoring	Auscultation only	

Intrapartum monitoring		
No monitoring	Auscultation only	

Response to cord prolapse / prolonged bradycardia in the first stage of labour	
Not for caesarean section	For caesarean section

Notes

I understand and agree with the above plan of care.

Parent's signature……Date…….

Initial Neonatal Discussion		
Date of assessment		
Estimate of gestational age today		
Number of fetuses		
Neonatal discussion led by	Print	Sign
Job title		
People present		

Agreed delivery room care of baby	
For resuscitation	
For palliative care in delivery room	

Summary of neonatal discussion

The information on this page must be reviewed weekly

Plan for resuscitation	
All forms of resuscitation at all times	
Airway management but not UVC/drugs/Cardiac massage	
All forms of resuscitation unless there are no signs of life	
Not for resuscitation UNLESS there are signs of life	
Not for resuscitation EVEN if there are signs of life	

I understand and agree with the above plan of care.

Parent's signature……

NEONATAL REVIEWS

Review date		
Neonatal consultant/ trainee completing:		
Have parental views on delivery room management changed?	YES	NO

If YES to change in delivery room management please indicate the change below:

Plan for resuscitation	
All forms of resuscitation at all times	
Airway management but not UVC/drugs/Cardiac massage	
All forms of resuscitation unless there are no signs of life	
Not for resuscitation UNLESS there are signs of life	
Not for resuscitation EVEN if there are signs of life	
Notes	
I understand and agree with the above plan of care. **Parent's signature……**	

Review date		
Neonatal consultant/ trainee completing:		
Have parental views on delivery room management changed?	YES	NO

If YES to change in delivery room management please indicate the change below:

Plan for resuscitation	
All forms of resuscitation at all times	
Intubation and ventilation but not UVC/drugs/Cardiac massage	
All forms of resuscitation unless there are no signs of life	
Not for resuscitation UNLESS there are signs of life	
Not for resuscitation EVEN if there are signs of life	
Notes	

I understand and agree with the above plan of care.

Parent's signature……

OBSTETRIC REVIEWS

Review date		
Obstetrician / trainee completing		
Has the antenatal condition changed?	YES	NO
Have parental views on management changed?	YES	NO

Notes	
Print	**Sign**
I understand and agree with the above plan of care.	
Parent's signature……	

Review date		
Obstetrician / trainee completing		
Has the antenatal condition changed?	**YES**	**NO**
Have parental views on management changed?	**YES**	**NO**

Notes	
Print	**Sign**
I understand and agree with the above plan of care.	
Parent's signature……	

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