Preterm Labour (V.2)

The scope of this guideline is only for Singleton pregnancies

Guideline Readership
This guideline applies to all women presenting with potential or diagnosed preterm labour within the Heart of England Foundation Trust and to attending clinicians; obstetricians, midwives, specialist midwives and neonatal clinicians.

All care is tailored to individual patient needs, with an in-depth discussion of the intended risks and benefits of either undergoing or declining intervention or any procedure.

Guideline Objectives
To provide evidence based information to clinicians to deliver appropriate care to women with potential or diagnosed preterm labour.

Other Guidance
NICE (2015) Preterm labour and Birth. 20th November 2015 ng25 (NICE compliant)

Ratified Date: 29th June 2017
Launch Date: 11th July 2017
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Guideline Author: Malarselvi Mani and Shalini Patni: Consultant O&G
Acknowledgements; Dr P Simmons: consultant neonatologist (epicure- 2data)
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Management of Suspected preterm labour (PTL) 22 – 25+6 weeks gestation

Obtain history
(Refer to PT referral pathway for patients presenting at GHH between 23 to 30 weeks in singleton or <34 weeks if multiple pregnancy)
Abdominal palpation, speculum examination
Establish the fetal lie and presentation using ULTRASOUND.
Fetal fibronectin IFN (If IFN is negative – PTL is unlikely; if positive – treat as PTL)
FH monitoring, Steroids, tocolysis, In-utero transfer (IUT) where appropriate
Inform CONSULTANT

22 weeks to 22+6 weeks
*Prospective parents will be counselled by Midwife and the Obstetric team.
*Steroids and Magnesium are not indicated
*Babies at this gestation do not survive
*Babies will be offered ‘comfort care’ only
*Live-born babies must be seen by a Doctor from the Obstetric team while they are still alive, to allow the Death Certificate can be completed.

If the woman and her partner still have unresolved questions after counselling from the Obstetric Consultant then the Consultant Neonatologist may be asked to speak with them.

23 to 24+6 weeks
*(or woman presents between 22-24 weeks with significant uncertainty over dates)

If IFN negative & os closed – PTL unlikely, can be discharged advice and FU if required
If IFN positive or >3cm dilated – Likely PTL
*Offer steroids
*Obtain with Consultant in tocolysis & Magnesium Sulphate (MgSO4) for neuroprotection
*Inform Neonatal Unit (NNU)
*IUT where appropriate
*Prospective parents will initially be counselled by Midwives and the Obstetric team.
*When time allows, the Neonatal Consultant / Middle grade should also speak with parents
*If the baby is cephalic and in a good condition, the Neatal Team will attend delivery and established contractions
*Those who respond well to stabilisation attempts will be taken Neonatal Intensive Care Unit (NICU) for intensive care
*If positive fFN or >3cm dilated –

Women/Families who request that their baby is assessed at birth and stabilisation attempted
*Steroids, MgSO4 would be indicated
*The Neonatal Team will attend the delivery
*Live-born babies will be seen by an Obstetric doctor, to enable completion of death certificate

Women/Families who do not wish to have any attempts made to resuscitate their baby after birth
*Steroids & MgSO4 would not be indicated
*‘Comfort Care’ will be offered
*Live-born babies will be seen by an Obstetric doctor, to enable completion of death certificate

24 to 25+6 weeks
*If positive IFN or >3cm dilated
**Steroids, tocolysis are indicated this is an Obstetrician’s decision
**Discuss difficulty in monitoring IFN
**Discourage attempts to stabilise more mature babies in good condition
**Magnesium Sulphate if active labour defined as >4cm and established contractions
**Inform NNU, IUT if needed
**Prospective parents will initially be counselled by Midwives and the Obstetric team.
**When time allows, the Neonatal Consultant / Middle grade should also speak with parents
**Neonatal Team will attend delivery and established contractions
**Those who respond well to stabilisation attempts will be taken Neonatal Intensive Care Unit (NICU) for intensive care
**If IFN >3cm & os closed – PTL unlikely can be discharged advice and FU if required

Middlesex

**Appendix 1: Framework for multidisciplinary working at the thresholds of viability
Outcomes per gestational age refer to body of guideline

Please note: At Birmingham Heartlands (BHH) site, instead of the Quantitative Fetal fibronectin, we will now use the Qualitative Fetal fibronectin for a short period of time as part of the QUDIS Research Study. The set-up of the machine and the procedure to do the test will be exactly similar to one before.

The Qualitative test will give you a positive or negative result instead of a value. Positive will mean 50 or more and negative will mean <50. This will not have any effect or change in the management of the patients i.e if positive: follow them as >/= 50 and if negative follow them as <50. It will not affect the management of patients who do not wish to take part in the trial. If positive follow them as >50 and if negative follow them as <50.

Good Hope Hospital will continue to use the Quantitative Fetal Fibronectin Test and is unaffected by the QUDIS trial.
Obtain history-
(Refer to Preterm referral pathway for patients presenting at GHH between 23
to 30 weeks in singleton or <34 weeks if multiple pregnancy)
Abdominal, speculum examination
Establish the fetal lie and presentation using ULTRASOUND.
Fetal fibronectin (fFN) (If fFN negative – PTL is unlikely, if fFN positive – treat as PTL)
FH monitoring, Steroids, tocolysis, In-utero transfer (IUT) where appropriate
INFORM CONSULTANT

26+0 to 29+6 weeks
If fFN positive >3cm dilated –
- Steroids & Tocolytics
- Administer MgSO4 if established labour
- Continuous fetal heart (FH) monitoring if labour established (Consultant’s discretion)
- Offer caesarean section (CS) if not cephalic
- Inform Neonatal Unit (NNU) & In-utero transfer (IUT) where appropriate
If fFN negative <3cm dilated & os closed – PTL unlikely, can be discharged with advice and FU if required

30 to 34+0 weeks
If fFN positive >3cm dilated –
- Steroids & Tocolytics
- Continuous FH monitoring if labour established
- Offer caesarean section (CS) if not cephalic
- Inform NNU & IUT where appropriate
If fFN negative & os closed – PTL unlikely, can be discharged with advice and follow up if required
If fFN not available - consider Transvaginal Scan (TVS) for Cervical length
- if >15mm – PTL in the next 48 hours is unlikely
- if <15mm – treat as PTL

34+1 to 36+6 weeks
- Consider steroids till 35+6 weeks and further if associated FGR, discuss with consultant.
- Continuous FH monitoring if labour established
- Offer CS if not cephalic
- Inform NNU & IUT where appropriate (until 34+6 weeks)

TVS for Cervical length
- if >15mm – PTL in the next 48 hours is unlikely
- if <15mm – PTL

NB: TVS should only be performed by healthcare professionals who have the training and experience to do the Cervical length measurement
DO NOT use TVS & fFN in combination to diagnose PTL
2. Executive Summary & Overview

Preterm delivery (PTD) is defined as delivery before 37 weeks' gestation and after 24 completed weeks of gestation (corresponding to an average fetal weight of 500 g). Perinatal morbidity and mortality for infants born without congenital abnormalities is primarily dependent on gestation. The earlier the PTD, the greater the morbidity related to prematurity, which includes cerebral palsy, neuro-developmental delay, blindness, deafness and chronic lung disease.

Preterm birth is the single biggest cause of neonatal mortality and morbidity in the UK. Over 52,000 babies (around 7.3% of live births) in England and Wales in 2012 were born preterm – that is, before 37+0 weeks of pregnancy. There has been no decline in the preterm birth rate in the UK over the last 10 years. Babies born preterm have high rates of early, late and post neonatal mortality, and the risk of mortality increases as gestational age at birth decreases. Babies who survive have increased rates of disability. Recent UK studies comparing cohorts born in 1995 and 2006 have shown improved rates of survival (from 40% to 53%) for extreme preterm births (born between 22 and 26 weeks). Rates of disability in survivors were largely unchanged over this time period. The Preterm Delivery rate at HEFT is between 7.5 to 8% since 2010.

Around 75% of women delivering preterm do so after preterm labour, which may or may not be preceded by preterm pre-labour rupture of membranes. The remaining women delivering preterm have an elective preterm birth when this is thought to be in the fetal or maternal interest; for example, because of extreme growth retardation in the baby or maternal conditions such as pre-eclampsia.

Survival rates at preterm gestations

The chances of survival of a preterm baby are highly dependent on gestation. Survival is rare before 24 weeks. Premature babies of 24 and 25 weeks of gestation are at high risk for death or significant disability, with 26 weeks being the earliest time when a good outcome is more likely than not. Gestations of 27 and 28 weeks are generally associated with more than 90% survival with more than 90% of survivors having no significant disability. Survival and disability rates at 34 weeks and beyond are similar to those at term. Table 1 and 2 summarise the data from the Epicure 2 study.

<table>
<thead>
<tr>
<th>Table 1 Outcomes for babies alive at the onset of their mother's labour</th>
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<tbody>
<tr>
<td>EPICURE 2 (English births in 2006)</td>
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<tr>
<td>N° Babies Alive at Labour Onset</td>
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<tr>
<td>N° Babies Still born</td>
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<tr>
<td>N° Babies Born Alive</td>
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<tr>
<td>N° Babies who die on labour suite</td>
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<tr>
<td>N° Babies Admitted to NNU</td>
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<tr>
<td>N° Babies who Die in NNU</td>
</tr>
<tr>
<td>N° Babies Discharged home</td>
</tr>
<tr>
<td>Number affected by Disability at 3 years of age (from the initial 100)</td>
</tr>
<tr>
<td>Severe</td>
</tr>
<tr>
<td>Moderate disability</td>
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<tr>
<td>Disability Free</td>
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</tbody>
</table>
3. Body of Guideline

Management of preterm labour guided by gestation:

Less than 23 weeks gestation

The management of cases of threatened preterm labour at less than 23 weeks should take place in a consultant unit. It is vital that patients are given accurate information and have realistic expectations of the management of their baby. Babies born before 23 weeks will not be admitted to a neonatal unit (NNU) and will be given comfort care with emotional support to the family during the difficult process of miscarriage (if the baby is born with no signs of life) or neonatal death and bereavement. Emotional support during bereavement is best delivered locally (Refer to Bereavement pathways for further guidance as necessary).

More than 23 weeks of gestation

The current area of uncertainty in extreme prematurity is 23 weeks gestation. This covers 23+0 to 23+6 weeks gestation as calculated from the final due date following an early dating scan. The majority of babies given full neonatal intensive care following birth at this gestation will either die or will have significant and serious disability. Optimal management of these cases involves individualised care, taking into account all relevant factors. A full and frank discussion with the parents must be undertaken if delivery at 23 weeks is anticipated. If after careful counselling by an experienced neonatologist/paediatrician, despite full understanding of the likely outcomes, the parents are still keen to pursue active and intensive management care should be provided in a maternity unit that has level 3 neonatal facilities. Therefore, if the woman is at Good Hope Hospital (GHH) she should be transferred to Birmingham Heartlands Hospital (BHH) if a neonatal cot is available. If no cots are available she should
be transferred to an alternative maternity unit that has level 3 neonatal care facilities, preferably within the network (refer to transfer procedure for further guidance).

There is no evidence of benefit for steroids or tocolysis at less than 24+0 weeks gestation. However, steroids can be considered between 23 to 23+6 weeks after discussing with the neonatal consultant in individual cases. The final decision should be made by the Consultant Obstetrician, in close discussion with the prospective parents.

Management at 34 and 35 weeks gestation – Provision of neonatal care locally

The vast majority of premature babies who are 34 and 35 weeks of gestation will have good outcomes and will be low risk for high dependency including intensive care. Unless there are exceptional circumstances pregnant women after 34 weeks gestation should be managed locally at place of admission either at BHH and GHH. It is anticipated that the decision for in utero transfer at 35 weeks and over will be an exceptionally rare event.

Risk factors for preterm labour

- Previous preterm labour
- Multiple pregnancy
- Genital tract infections, bacterial vaginosis (BV) is associated with increased risk of preterm labour/preterm birth (refer to Bacterial infections & Sepsis in pregnancy guideline for further management)
- Urinary tract infections (UTI)
- Assisted conception
- Preterm prelabour rupture of membranes (P-PROM) refer to SROM guideline
- Surgical procedures involving the cervix, cervical trauma
- Uterine anomalies
- Fetal anomalies
- Polyhydramnios / Oligohydramnios
- Vaginal bleeding
- Severe systemic maternal illness
- Chronic maternal medical conditions
- Acute maternal conditions (severe pre-eclampsia, antepartum haemorrhage)

Risk reduction

a. Antenatal education/health promotion

- Undertake a comprehensive review of all previous pregnancies as the greatest risk factor is previous preterm birth
- Counsel women about modifiable risk factors such as smoking cessation
- Management of underlying chronic diseases i.e. diabetes, hypertension
- Provide lifestyle advice i.e. balanced diet, advice regarding exercise and stress management
- Refer to preterm pregnancy clinic (PPC) if indicated (refer to PPC guideline for referral criteria)

b. Genital tract infections (refer to Bacterial infections & Sepsis in pregnancy guideline for further management)

- If a woman is presenting with an abnormal vaginal discharge, a vaginal swab should be taken for culture and sensitivity (MC&S)
• In women with abnormal flora - Bacterial vaginosis and Mixed anaerobes on Low vaginal/high vaginal (LVS/HVS) swab; treatment with antibiotics may reduce the risk of preterm birth
• Treat Bacterial vaginosis and Mixed anaerobes on LVS/HVS with Clindamycin cream per vagina (PV)

c. Bacteriuria
• Asymptomatic bacteriuria has been associated with risk of preterm labour, a midstream specimen of urine (MSU) should be taken for screening at booking
• Urinary tract infection (UTI) is associated with threatened preterm labour, women presenting with symptoms should be screened and antibiotics prescribed if a UTI is confirmed. Please follow up the results of the Midstream urine.

d. Cervical length measurement / vaginal progesterone / Cervical cerclage where appropriate as per the preterm prevention clinical (PPC) guideline.

Maternal Assessment

a. Telephone Triage
Refer to Appendix 1 for management
It is mandatory that staff receiving such a phone call make contact with the other unit and not ask women to make a call to the other unit she has been advised to go to.

b. Assessment on admission
Refer to Appendix 2 for management
Examination and investigations should be performed to rule out possible causes of preterm labour and/or ruptured membranes. Maternal infections, chorioamnionitis, placental abruption, preeclampsia, fetal anomalies, polyhydramnios and trauma must all be considered.

  • Pregnant women with suspected miscarriage, preterm labour/ abdominal pain after 16 weeks gestation should be assessed in the maternity unit, not in the emergency department (A&E/ED)
  • All women in threatened preterm labour should be assessed by an Obstetric ST2 or above.
  • Gestation should be calculated from dating scan
  • The hand-held antenatal records/ electronic maternity record should be reviewed at the time of presentation to check past obstetric, medical and surgical history
  • During assessment consider all causes of abdominal pain i.e. obstetric, medical and surgical
  • In all cases an underlying cause such as infection or placental abruption should be sought
  • Undertake a full set of modified obstetric early warning score (MEoWS) observations
  • Urinalysis and consider sending a MSU to exclude UTI
  • Abdominal palpation to assess uterine tone, contractions, fetal size (fundal height) and presentation
  • Take full blood count (FBC), C-reactive protein (CRP) and group and save (G&S)
Sterile speculum examination to:
- Confirm/exclude rupture of membranes
- Visualise the cervix
- Assess liquor (e.g. clear, meconium stained, blood stained)
- Collect vaginal swab and Midstream urine (MSU) for microscopy culture and sensitivity (MC&S)
- Perform Quantitative Fetal fibronectin test (fFN)

If a speculum examination is not undertaken a low vaginal swab should be taken.

Vaginal examination (VE) to assess cervical dilatation unless contraindicated by ruptured membranes or suspected placenta praevia.

Note: A VE must not be carried out prior to an fFN test.

Fetal Fibronectin (fFN)
For this trust the quantitative Fetal Fibronectin (fFN) test is preferred because of its ability to provide a quantifiable test result that better informs management over and above other tests that only provide a ‘positive’ or ‘negative’ result (e.g. non-quantitative fFN/Quickcheck or Actim Partus).

However

Please note: Instead of the Quantitative Fetal fibronectin, we will now use the Qualitative Fetal fetal fibronectin for a short period of time as part of the QUIDS Research Study.

The set-up of the machine and the procedure to do the test will be exactly similar to one before.

The Qualitative test will give you a positive or negative result instead of a value. Positive will mean 50 or more and negative will mean <50.

This will not have any effect or change in the management of the patients ie if positive: follow them as >/= 50 and if negative follow them as <50.

The flow chart 1 has been amended to reflect this change. It will not affect the management of patients who do not wish to take part in the trial.

If positive follow them as >50 and if negative follow them as <50.

Good Hope Hospital will continue to use the Quantitative Fetal Fibronectin Test and is unaffected by the QUIDS trial.
The fFN test can be used in women with Multiple Pregnancy.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Consideration</th>
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<tbody>
<tr>
<td><strong>Context</strong></td>
<td><strong>Fetal fibronectin (fFN) is a glycoprotein thought to promote adhesion between the fetal chorion and maternal decidua. It is normally present in low concentrations in the cervicovaginal secretions between 18 and 34–36 weeks gestation, rising as term approaches</strong></td>
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<tr>
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<td>• Elevated levels of fFN (typically greater than 50 ng/mL) in cervicovaginal secretions after 22 weeks gestation are associated with an increased risk of preterm birth (PTB)</td>
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<tr>
<td></td>
<td>• A negative fetal fibronectin (fFN) is associated with a 99.5% negative predictive value for PTB within 7 days and 99.2% in the next 14 days</td>
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<td>• Quantitative fetal fibronectin testing may improve assessment of overall risk, reduce unnecessary transfer and ultimately reduce longer term costs</td>
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<tr>
<td><strong>Indications</strong></td>
<td><strong>Symptomatic preterm labour between 23+0 and 34+0 weeks gestation, and</strong></td>
</tr>
<tr>
<td></td>
<td>• Intact membranes, and</td>
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<td></td>
<td>• Cervical dilatation less than or equal to 3 cm</td>
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<tr>
<td><strong>Contraindications</strong></td>
<td><strong>Gestational age &lt;23 weeks or &gt;34 completed weeks</strong></td>
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<tr>
<td></td>
<td>• Cervical dilatation more than 3 cm</td>
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<td></td>
<td>• Ruptured membranes</td>
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<td></td>
<td>• Moderate to severe vaginal bleeding</td>
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<td></td>
<td>• Sexual intercourse or vaginal examination within the previous 24 hours</td>
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<td></td>
<td>• Presence of soaps, gels, lubricants or disinfectants</td>
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<tr>
<td><strong>Quantitative fFN Testing</strong></td>
<td>Quantitative fFN testing can:</td>
</tr>
<tr>
<td></td>
<td>• Quantify the likelihood of PTB</td>
</tr>
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<td></td>
<td>• Assist with risk assessment and planning</td>
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<td></td>
<td>• Avoid unnecessary interventions</td>
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<tr>
<td></td>
<td>• Identify women for targeted interventions</td>
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<tr>
<td></td>
<td>• Provide reassurance to health care providers and the woman</td>
</tr>
<tr>
<td>fFN &lt;50ng/mL (negative)</td>
<td>• Unlikely that patient is in Preterm Labour</td>
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<td></td>
<td>• Think about alternate diagnosis</td>
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<td></td>
<td>• Discuss about the benefits and risks of going home compared with admission</td>
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<td></td>
<td>• Discharge home if:</td>
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<tr>
<td></td>
<td>i. Maternal vital signs within normal parameters</td>
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<td></td>
<td>ii. Normal fetal heart/CTG relevant to gestational age</td>
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<tr>
<td></td>
<td>iii. No signs of chorioamnionitis</td>
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<td></td>
<td>iv. Contractions infrequent / irregular</td>
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<tr>
<td></td>
<td>v. No / minimal cervical change</td>
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<td>• Provide the woman with information that:</td>
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<tr>
<td></td>
<td>i. Aids her recognition of the signs and symptoms of preterm labour</td>
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<td></td>
<td>ii. Provides instruction about when to seek clinical advice</td>
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<tr>
<td>fFN &gt;50ng/mL (positive)</td>
<td>• Admit</td>
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<tr>
<td></td>
<td>• Treat with tocolysis to allow steroid administration, magnesium sulphate for fetal neuroprotection or in-utero transfer</td>
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</tbody>
</table>
Method – PRIOR TO DIGITAL EXAMINATION PERFORM fFN TEST

1. Specimen must be collected using speculum PRIOR to digital examination or collection of culture specimens
2. Sterile speculum using water only as lubricant
3. Use the swab in the collection kit. Rotate the sterile applicator tip of the swab provided across the **posterior fornix** (not endocervix) of the vagina for **10 seconds** (no less) to absorb cervicovaginal secretions.
4. Remove the swab from the patient and immerse the tip in the buffer. Break the shaft at the score.
5. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube.
6. Write the patient’s name and hospital number on the specimen transport tube label
7. From the main menu select 1- TEST PATIENT
8. Enter user ID (Name: press key repeatedly until correct letter appears on the screen) and press ENTER
9. Enter the last two digits of the cassette lot (on cassette pouch) and press ENTER
10. Enter the patient’s PID number and press ENTER
11. Remove the cassette from its pouch and insert it into the analyzer and press ENTER
12. The analyzer will check that the cassette is inserted properly.
13. The instrument will beep repeatedly and the display will read ADD SAMPLE AND IMMEDIATELY PRESS ENTER
14. Add 200 mcL (using a 1mL syringe) of the patient’s sample and press ENTER
15. The analyzer will begin a 7 minute incubation countdown, following which the analyzer will begin analysis of the cassette.
16. When testing is complete, the system will display and print the result
17. Result will be given in ng/mL and should be interpreted and managed accordingly

**Cervical length**

Transvaginal ultrasound of cervical length (TVCL) can aid in assessing the risk of PTB if QfFN is not available.

- **TVCL must be performed by a credentialed clinician**
- **Lack of local capability to perform TVCL is not a reason for transfer**

If the clinical assessment suggests that the woman is in suspected preterm labour and she is 30+0 weeks pregnant or more consider transvaginal ultrasound measurement of cervical length as a diagnostic test to determine likelihood of birth within 48 hours. Act on the results as follows:

- if cervical length is more than 15 mm, explain to the woman that it is unlikely that she is in preterm labour and:
  - think about alternative diagnoses
  - discuss with her the benefits and risks of going home compared with continued monitoring and treatment in hospital
  - advise her that if she does decide to go home, she should return if symptoms suggestive of preterm labour persist or recur

**If cervical length is 15 mm or less, view the woman as being in diagnosed preterm labour and offer treatment.**

If a woman in suspected preterm labour who is 30+0 weeks pregnant or more does not have transvaginal ultrasound measurement of cervical length or fetal fibronectin testing to exclude preterm labour, offer treatment consistent with her being in diagnosed preterm labour.
Do not use transvaginal ultrasound measurement of cervical length AND fetal fibronectin testing in combination to diagnose preterm labour.

Ultrasound scans should be performed by healthcare professionals with training in, and experience of, transvaginal ultrasound measurement of cervical length.

Diagnosing preterm prelabour rupture of membranes (P-PROM) – refer to SROM Guideline

**Maternal Corticosteroids**

There is strong evidence that maternal steroids reduce the incidence and severity of respiratory distress syndrome (RDS), significant reduction in rates of neonatal death, intraventricular haemorrhage and are safe for the mother (RCOG Green –top Guideline, October 2010) and should be given when there is a high risk of preterm birth. The recommended gestation range for giving maternal steroids is 24 to 35+6 weeks.

Steroids may be used before this gestation (23 to 23+6) at the individual instigation of Consultant Obstetrician taking all clinical aspects into consideration.

**Dose:**

**Dexamethasone 9.9mg intramuscular (IM) and prescribe a second dose in 12 – 24 hours or Betamethasone 12mg IM and prescribe second dose in 12 - 24 hours.**

The 2nd dose of steroids should be administered 24 hours after the first dose, but can be given between 12 and 24 hours if circumstances dictate this to be more practical.

Do not routinely offer repeat courses of maternal corticosteroids, but take into account:

- the interval and the gestational age since the end of last course particularly if the first dose was given prior to 26 weeks gestation and another obstetric indication has risen.
- A repeat course of steroid must be a Consultant decision

**Tocolysis in preterm labour**

“It is reasonable not to use tocolytic drugs, as there is no clear evidence that they improve outcome. However, tocolysis should be considered if the few days gained would be put to good use, such as completing a course of corticosteroids, or in utero transfer” (February 2011 RCOG Green –top guideline no 44).

Before tocolysis is commenced the consultant obstetrician must be informed of the patient’s condition. **Tocolysis is only used for a maximum of 48 hours to allow time for maximal fetal lung maturation under the action of exogenously administered corticosteroids.**

The evidence supporting the use of tocolysis is presumed to be of benefit to the fetus. Delaying of the delivery process for sufficient time for steroids to take effect may produce benefits greater than that of using no tocolysis. Tocolysis should not be used in the case of equivocal cervical findings without a fFN test being performed. Any condition where tocolysis is considered and the patient is not a candidate for fFN needs prior consultation with the Consultant obstetrician.
Candidates for tocolysis are as listed below;

a) 23+0 - 34 weeks gestation
b) Intact membranes though ruptured membranes may be considered under extreme clinical conditions e.g. previous perinatal losses at premature ages.
c) No listed maternal or fetal contraindication as below

Contraindications to the use of any tocolytic agents:

a) Placental Abruption, Significant haemorrhage, i.e. not just from cervical dilation
b) Sepsis, Chorioamnionitis
c) Fetal distress
d) Maternal condition which precludes delaying delivery
e) Lethal fetal anomalies
f) Intrauterine Death (IUD)

Options for Tocolysis

Nifedipine – modified release (NOT CAPSULES) is the first drug of choice. If Nifedipine is contraindicated, offer Atosiban (Intravenous only) for tocolysis. Do not offer Betamimetics for tocolysis

Nifedipine - is a calcium channel blocker. A Consultant Obstetrician MUST recommend its use. Patient must have IV access if Nifedipine is given.

Specific contraindications

a) Maternal blood pressure > 140/90 (this may be changed with Consultant approval)
b) Cardiac disease
c) Maternal hypotension BP < 100/60
d) Patients on Magnesium Sulphate for Severe PET / eclampsia
e) Known hypersensitivity to Nifedipine

Initial dose 20 mgs modified release (MR) orally followed by 10-20mg three times daily adjusted according to uterine activity for up to 48 hours. Review of the fetal and maternal condition may lead to cessation of the drug 24 hours after initial dose. If any change in the clinical condition occurs contact the Registrar or Consultant. Total dose of >60mg/24hours should be avoided due to four fold increase of side effects. (RCOG Guideline 1b, February 2011).

Side effects:
1. Headache
2. Flushing
3. Palpitations
4. Nausea and vomiting
5. Hypotension

Maternal and fetal observations

Established Preterm Labour

Whilst the mother is still actively contracting (more than 3 contractions in 30 minutes) continuous maternal observations should be performed every hour for blood pressure, pulse and temperature. If greater than 26 weeks gestation CTG monitoring should be employed.
Non established Pre-term Labour
When the contractions have reduced to less than 3 in 30 minutes, continuous CTG monitoring is no longer necessary. Listen to the fetal heart every hour. Once contractions have ceased completely then listen to the fetal heart every 4 hours. This will allow the mother to rest etc. Maternal observations should be performed every 4 hours.

Atosiban (Tractocile®)
Atosiban should only be used where there are contraindications to Nifedipine.

Contra-indications to the use of Atosiban include allergy to the drug and any obstetric condition that precludes the use of the any tocolytic agent.

Intravenous (IV) access is necessary with a 16 gauge (grey) cannula. Atosiban comes in two preparations, a vial containing 0.9mls equivalent to 6.75 mgs of Atosiban and a 5 ml vial containing 37.5 mgs of Atosiban. Two regimens are given below for the administration of Atosiban, one using syringe drivers and the other volumatics to administer the drug. Where possible the use of syringe drivers is preferable in order to reduce the fluid input administered.

Dosage for Atosiban
6.75mg as a bolus dose over 1 minute
Infusion 18mg/ hour for 3 hours
Infusion 6mg per hour for a maximum of 45 hours

Discontinue if:
a) The patient is having a significant adverse reaction to the drug
b) Immediate delivery of the fetus is indicated
c) Uterine contractions have stopped for 12 hours
d) There has been a total dose of 48 hours of treatment

If Atosiban is to be recommenced then the dosage regime needs to commence from the bolus dose again, but should still not be continued for more than 48 hours.

Syringe driver regimen:
a) Add one 5ml vial of Atosiban (7.5ml/ml) to 45ml of Sodium Chloride 0.9% and set the syringe driver to run at 24ml/hour (18mg/hour), but do not commence infusion
b) Draw up the IV bolus, 0.9ml from the Atosiban vial and administer over 1 min
c) Commence the syringe driver immediately after the bolus dose has been administered. This infusion will last for 2 hours.
d) Make up a second syringe as above and run for 1 hour at 24ml/hour and then decrease the rate to 8ml/hour (6mg/hour)
e) This infusion is continued at this rate until the Atosiban is discontinued

Loading dose volumatic:
Give the 0.9ml vial diluted with 5 mls of water for injection or Sodium Chloride 0.9% over 1 minute. This is the loading dose to quickly achieve the necessary maternal blood levels of the drug.
Maintenance dose volumatic:
The maintenance dose is in two stages:
1. remove 10 mls of Sodium Chloride 0.9% from a 100mls bag. Then add two 5 mls vials of Atosiban to the remaining 90 mls of Sodium Chloride 0.9% (giving 75mg of Atosiban in 100 mls of Sodium Chloride 0.9%).

Start the initial infusion for the first three hours at 24 mls per hour. This will deliver 18 mgs per hour of Atosiban.

2. After 3 hours reduce the infusion rate to 8 mls per hour or 6 mgs per hour of Atosiban

**Maximum time for administration is 48 hours.**

Maternal and fetal observations whilst tocolysis is the same as for Nifedipine

**Magnesium Sulphate (MgSO4) for fetal neuroprotection** - refer to relevant guideline for management

**Management of Suspected Chorioamnionitis** - refer to Bacterial infections and Sepsis in pregnancy guideline for management

**In-utero transfer of mothers** - refer to Transfer procedure for maternity further management

**REMEMBER: In-utero transfer is a Consultant-to-Consultant transfer and you are only deputised to facilitate it**

**Fetal monitoring** - refer to Antenatal and Intrapartum fetal monitoring guidelines for further management

**Monitoring options:** cardiotocography (CTG) and intermittent auscultation. 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)
- There is an absence of evidence that using CTG improves the outcomes of preterm labour for the woman or the baby compared with intermittent auscultation.

Involve a senior obstetrician in discussions about whether and how to monitor the fetal heart rate for women who are between 23+0 and 25+6 weeks pregnant. Cases at 24-25 weeks gestation are particularly difficult and the decision regarding management and fetal monitoring should be made by the Consultant Obstetrician.

**Actions:**
- Undertake an ultrasounds scan to assess fetal growth, liquor volume and Doppler studies where possible
- At this gestation the expectation is that continuous electronic fetal monitoring will not be used. It is important that the woman understands the limitations of continuous fetal monitoring at this gestation and the implications of intervention
- If continuous electronic fetal monitoring is used this **must** be a Consultant obstetric decision (refer to Intrapartum fetal monitoring guideline).
**Be aware that:**
- there is limited evidence about the usefulness of specific features to suggest hypoxia or acidosis in preterm babies
- the available evidence is broadly consistent with that for babies born at term
- A normal CTG trace is normal/reassuring and indicates that the baby is coping well with labour, but a non-reassuring/abnormal trace does not necessarily indicate that fetal hypoxia or acidosis is present.

Offer women in established preterm labour, but with no other risk factors, a choice of fetal heart rate monitoring using either:
- CTG using external ultrasound or
- intermittent auscultation.

**Fetal scalp electrode (FSE)**

Do not use an FSE 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 fetal heart rate using CTG or intermittent auscultation
- it has been discussed with a Consultant
- 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 FSE between 34+0 and 36+6 weeks of pregnancy if it is not possible to monitor the fetal heart rate using either external CTG or intermittent auscultation.

**Fetal blood sampling**

Do not carry out fetal blood sampling if the woman is less than 34+0 weeks pregnant.

Discuss with the woman the possible use of fetal blood sampling between 34+0 and 36+6 weeks gestation if the benefits are likely to outweigh the potential risks.

When offering fetal blood sampling, discuss this with the woman and advise her that if a blood sample cannot be obtained a caesarean section (CS) is likely.

**Mode of delivery**

Discuss the general benefits and risks of CS and vaginal birth with women in suspected, diagnosed or established preterm labour and women with preterm prolonged rupture of membranes (P-PROM) and their family members or carers as appropriate.

Explain to women in suspected, diagnosed or established preterm labour and women with P-PROM about the benefits and risks of CS that are specific to gestational age. In particular, highlight the difficulties associated with performing a CS for a preterm birth, especially the increased likelihood of a vertical uterine incision and the implications of this for future pregnancies especially if <26 weeks gestation.
Explain to women in suspected, diagnosed or established preterm labour that there are no known benefits or harms for the baby from CS, but the evidence is very limited.

Consider CS for women presenting in suspected, diagnosed or established preterm labour between 26+0 and 36+6 weeks gestation with breech presentation.

4. **Reason for development of the guideline**

Guideline development is to ensure a uniform and consistent approach, thus providing a safe multidisciplinary care framework throughout HEFT regarding the use of cell salvage in obstetric patients.

5. **Methodology**

Development of all guidelines adheres to a process of examining the best available evidence relevant to the topic, incorporating guidance and recommendations from national and international reports.

Finalised guidelines will ultimately be approved and ratified by the Obstetrics and Gynaecology Guideline Group and minuted as ratified.

6. **Implementation in HEFT & Community**

New/updated guidelines will be disseminated to all members of the multidisciplinary team, relevant to O&G, via trust email, audit meetings, team (ward) meetings, in-house training and any relevant workshops.

Electronic copies of the guideline will be available via the trust intranet and paper copies stored within designated clinical areas.

7. **Monitoring & Suggested Quality Standards**

Adherence and efficiency of clinical guideline will be monitored through regular clinical audit.

Following clinical audit of a guideline an addendum to change in clinical practice may be necessary. Any change to a clinical guideline requires that it must be ratified by the Obstetrics and Gynaecology Guideline Group locally.

Review dates will be set at a period of three years; however this set period can be overridden in light of new clinical evidence.

All unused/previous guidelines will be logged and archived electronically, and in paper format within the trust.

**Auditable Standards:**

a) All women in preterm labour or with a fetal fibronectin greater than or equal to 50ng/mL were given a course of antenatal corticosteroids

b) All women in preterm labour with a fetus at 24 to 30 weeks were given Mg So4

c) Documented involvement of a Consultant Obstetrician in the decision to commence a tocolytic drug

d) Number of babies born without exposure to antenatal corticosteroids

e) Documented evidence of counselling regarding fetal monitoring and Mode of Delivery in women who are in preterm labour < 26weeks
8. References
1. NICE guideline on Preterm labour and Birth, November 2015
5. Preterm labour, Tocolytic Drugs, RCOG Green Top guideline No:1B, April 2011.
6. Preterm Prelabour Rupture of membranes, RCOG Green Top Guideline No:44, November 2006 I Minor amendment October 2010
Appendices

Appendix 1 – Preterm pathway between GHH & BHH for women presenting by telephone ≤30 weeks gestation (Version 5)

Good Hope Hospital Preterm Pathway to Birmingham Heartlands Hospital for Women presenting

TELEPHONE 30 week’s gestation and less

The following women should be advised to attend BHH directly following a TELEPHONE CONSULTATION

- Singleton pregnancy between 23+0 and 30+0
- Twin pregnancies less than 34+0 weeks
- If presenting with any of the following symptoms:
  - Uterine contractions greater than 1 in 10 minutes occurring for more than 30 minutes
  - Fresh vaginal bleeding
  - Suspected preterm rupture of membranes
  - Abdominal pain

Special consideration should be given to singleton pregnancies less than 34+0 with a history of:
  - Preterm delivery or preterm rupture of membranes
  - Cervical suture

Exclusions

The following women can be assessed at GHH
  - Less than 23+0 weeks gestation
  - Decreased fetal movements
  - Unrelated medical conditions
  - Women who attend for monitoring e.g. Obstetric Cholestasis

Women meeting the above criteria ON TELEPHONE TRIAGE do not need obstetrician to obstetrician discussion/approval

Process for Transfer of Care

If the woman meets the above criteria she will be advised that she needs to attend the labour ward at BHH for assessment. The labour ward coordinator at GHH or senior midwife on MAC will speak to the labour ward coordinator at BHH to hand over the relevant history and presenting symptoms.

The woman should not be asked to phone BHH prior to attending
Appendix 2 – Preterm pathway to BHH for women presenting at GHH either on LW or A&E ≤30 weeks gestation (Version 4)

Good Hope Hospital Preterm Pathway to Birmingham Heartlands Hospital for Women Presenting at GHH either on the Labour Ward or A+E at 30 week’s gestation and less

The pathway below must be followed for women attending the Maternity Unit or A+E at GHH who present WITHOUT PRIOR TELEPHONE CONSULTATION

Singleton pregnancy between 23+0 and 30+6
Twin pregnancy less than 34+0 weeks

If presenting with any of the following symptoms the woman must be seen by a senior obstetrician (ST3 or above)

- Uterine contractions greater than 1 in 10 minutes occurring for more than 30 minutes
- Fresh vaginal bleeding
- Suspected preterm rupture of membranes
- Abdominal pain
- Singleton pregnancies less than 34+0 with a history of:
  - Preterm delivery or preterm rupture of membranes
  - Cervical suture

NOTE: If the woman presents in A+E she must be transferred to the labour ward for assessment

If following an obstetric review the woman needs to be transferred to BHH the following process must be followed

- The obstetrician or coordinator will liaise with the senior nurse on the NICU to establish whether a cot is available
- If a cot is available an in-utero transfer to BHH will be undertaken; there should be obstetrician to obstetrician AND coordinator to coordinator communication to share information and arrange the transfer
- If there are no cots available the consultant obstetrician on call will liaise with the consultant neonatologist on call at BHH to assess capacity
- If the neonatal consultant at BHH confirms that there is no capacity at BHH then an in-utero transfer to an alternative NICU must be arranged by GHH
Appendix3- Framework for Multi-Disciplinary Team working around the ‘Thresholds of Viability’

Decisions made concerning the management of ladies in labour at the threshold of viability and their babies are complex and can have life changing implications. It is essential that all team members have an understanding of the issues, so patients can be counselled appropriately. This Framework aims to outline the sort of treatments each team might offer, in these situations in order to aid discussions with parents; it does replace existing more detailed guidelines, outlining the specific treatments offered by each team.

**When a lady presents in labour at 22+6 weeks or less and gestation is clear from an early U/S scan**
- Prospective parents will be counselled by Midwives and the Obstetric team
- Steroids and Magnesium are not indicated for mother
- Babies at this gestation do not survive - The Neonatal Team will not attend the delivery
- Babies will be offered ‘comfort care’ only
- Live-born babies must be seen by a Doctor from the Obstetric Team while they are still alive, so later the Death Certificate can be completed

*If the lady and her partner still have unresolved questions after counselling from the Obstetric Consultant then the Consultant Neonatologist may be asked to speak with them.*

**When a lady presents in labour between 23+0 and 23+6 weeks and gestation is clear from an early U/S OR A lady presents at between 22 and 24 weeks AND there is significant uncertainty over dates**
- Prospective parents will initially be counselled by Midwives and the Obstetric team
- When time allows the Neonatal Consultant / Middle grade should also speak with parents
- A joint decision is then made which guides further individualised management:

**Some ladies will not want any attempts made to resuscitate their baby after birth**
- Steroids & magnesium would not be indicated
- The Neonatal Team would not attend the delivery
- Live born babies will receive comfort care after birth
- Live born babies will be seen by an Obstetric doctor, to enable death certificate completion

**Other ladies will request that their baby is assessed at birth and stabilisation attempted**
- Steroids and Magnesium may be indicated in these cases – Obstetrician’s decision
- The Neonatal Team will attend the delivery - the Baby will be weighed and assessed
- Babies <450g, those looking very immature or in poor condition will receive comfort care
- Attempts to stabilise more mature and babies in good condition will be made
- Those who respond well to stabilisation attempts will be taken NICU for intensive care
- Babies who do not respond to stabilisation will have care redirected to ‘comfort care’
When a lady presents 24+0 to 25+6 weeks and gestation is clear from an early U/S Scan

- Prospective parents will initially be counselled by Midwives and the Obstetric team
- When time allows, the Neonatal Consultant / Middle grade should also speak with parents
- Steroids and Magnesium are indicated – Obstetrician's decision
- Neonatal Team will attend delivery and attempt to stabilise the baby
- Those who respond well to stabilisation attempts will be taken NICU for intensive care
- Babies who do not respond to stabilisation will have care redirected to ‘comfort care’
## Meta Data

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### Related Policies/Topic/Driver

- Antenatal fetal monitoring & Intrapartum fetal monitoring
- Antibiotics in obstetrics
- Bacterial infections & Sepsis in pregnancy
- Care of the newborn at delivery
- Magnesium sulphate for fetal neuroprotection
- Modified early warning score (MEoWS)
- Preterm pregnancy clinic
- Transfer procedure

## Revision History

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<th>Date of Issue</th>
<th>Author(s)/Reviewer(s)</th>
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<tr>
<td>2</td>
<td>June 2017</td>
<td>Mani Malarselvi – Consultant O &amp; G Use of Qualitative Fibronectin as part of the QUIDS trial at BHH site in flow chart 1 and page 5 of the main body of the guideline. No change for GHH site.</td>
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<tr>
<td>1</td>
<td>July 2016</td>
<td>Malarselvi Mani – Consultant O&amp;G Shalini Patni – Consultant O&amp;G Acknowledgements; Dr P Simmons: consultant neonatologist (epicure-2data)</td>
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Reason for Issue:

New guideline (previous guidance from SWMNN)

Clinical Director: 

Signed: 

Name: Cathy Rhodes 

Date: 30th June 2017