Standard Operating Procedure for the use of the Fetal Fibronectin in detecting preterm labour

Author/Owner	**Senior Midwife/ Practice Educator Midwife/ Maternity Guideline Group**	
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1.0 Introduction

This Standard Operating Procedure provides a framework for care delivery and promotes a clear and uniform approach to the use of Fetal Fibronectin in the diagnosis of pre-term labour when the membranes are intact.

2.0 Objective

To ensure women who present with suspected pre-term labour with intact membranes receive the appropriate diagnostic tests.

To ensure testing is undertaken in accordance with the manufacturer's recommendations, thus validating the result.

3.0 Scope

This guideline applies to all medical and midwifery staff working on the maternity unit.

4.0 Management/ Procedure

Fetal fibronectin (fFN) is a protein that is detected in cervicovaginal secretions throughout pregnancy. Between 22 and 35 weeks, these levels should be relatively low. Concentrations of fetal fibronectin ≥50ng/ml between 22-35 weeks gestation are associated with an increased risk of preterm delivery (Peebles 2014). Processing the fetal fibronectin test will provide a numerical level, which can determine the risk of delivery.

The use of the fetal fibronectin test should:

- reduce the need for tocolysis
- reduce the need for steroids
- reduce unnecessary in utero transfer
- reduce unnecessary hospital admission

4.1 Contraindications for fetal fibronectin:

- Moderate/ heavy bleeding
- Ruptured membranes
- Recent sexual intercourse (within 24 hours)
- Recent cervical manipulation e.g. digital vaginal or speculum examination
- High Vaginal Swab (HVS) taken prior to fetal fibronectin sample

4.2 Procedure

1. Undertake a clinical assessment of the woman including relevant history. If preterm labour is suspected between 22+0 and 34+6 weeks gestation, a fetal fibronectin test may be appropriate to determine the likelihood of delivery.
2. Perform a speculum examination to identify the cervix **using water as a lubricant.**
3. Lightly rotate the swab (supplied in the pack) across the posterior fornix of the vagina for 10 seconds.
4. Remove swab and place in the test tube. Gently mix the swab in the buffer solution for another 10 seconds. If the test is to be used immediately, remove the swab.

   NB: The swab can also be broken at the shaft and secured in the test tube if needing to be used at a later time. Specimens not tested within 8 hours of collection should be refrigerated and tested within 3 days.
5. Use the analysing machine to obtain a quantitative value
6. Enter User ID (Surname and initial) and press Next.
7. Enter Rapid fFN 10Q Cassette Lot number and press Next.
8. Enter Patient ID and press Next.
9. Insert the Rapid fFN 10Q Cassette and press Next.
10. Pipette 0.2ml from the sample collected in the buffer solution into the designated Cassette. Press Start Test.
11. The fFN concentration will be displayed and printed within 10 minutes.
12. Use the QUiPP app to calculate birth prediction. Please refer to the preterm labour guideline for further information

4.3 Act on the results as follows:

4.3.1 Positive result:

- A symptomatic woman with a positive swab has an increased chance of having a preterm birth
- If fetal fibronectin testing is positive (concentration more than 50 ng/ml), view the woman as being in preterm labour and offer treatment.

*****Refer to appendix one for management according to the Fibronectin level*****

4.3.2 Negative result:

- If fetal fibronectin testing is negative (concentration 50 ng/ml or less), explain to the woman that it is unlikely that she is in preterm labour
- It is reasonable to withhold tocolysis and steroids if the Ffn swab is negative.
    - Instead women should be observed for four hours OR until the results of other investigations have been obtained
- 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
- Analgesia should be prescribed if required
- Inform and discuss with the woman and her partner, that her risk of delivering in the next 10 days is 1%
- Educate on the signs and symptoms of preterm labour
- Arrange antenatal follow up within two weeks with the woman's consultant or the on-call consultant if she was previously under midwifery led care

4.3.3 Invalid result:

This means that either too little or too much buffer solution has been added to the cassette. The analysis can be repeated using the same buffer solution and a second cassette ensuring that the person running the test is familiar with the TLiQ system.

5.0 Roles and responsibilities

5.1 Midwives

To provide the best evidence-based care for women in accordance with appropriate guidance from diagnosis to delivery. To identify and manage preterm labour as part of a multi-disciplinary team.

5.2 Obstetricians

To provide the best-evidenced care for women in accordance with appropriate guidance from diagnosis of condition to delivery.
To identify and manage preterm labour as part of a multi-disciplinary team.

6.0 Associated documents and references

Barnsley Hospital NHS Foundation Trust (2021) Guideline for women in preterm labour (including labour at a low gestational age).

Hologic (2016). Quantitative Fetal Fibronectin: let the numbers tell her story.
NHS Clinical network: Predictive testing in pregnant women with threatened preterm labour: A best practice toolkit

NHS England (2019) Saving Babies Lives v2. A care bundle for reducing perinatal mortality.
NICE (2019). Preterm Labour and Birth. NICE Guideline NG25. London.

Peebles, D. (2014) Fetal fibronectin testing in women with threatened preterm labour: *A best practice toolkit*. [online] Available at: https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2019/11/Fetal-fibronectin-testing-in-women-with-threatened-preterm-labour_-A-best-practice-toolkit.pdf

PReCePT (2014). Reducing cerebral palsy through improving uptake of magnesium sulphate in preterm deliveries (online). https://www.ahsnnetwork.com/case-study/precept-reducing-cerebral-palsy-through-improving-uptake-of-magnesium-sulphate-in-preterm-deliveries

7.0 Training and resources

Training will be delivered as outlined in the Maternity Training Needs Analysis. This is updated on an annual basis.

8.0 Monitoring and audit

Any adverse incidents relating to the Standing Operating Procedure for the use of the Fetal Fibronectin in detecting pre-term labour will be monitored via the incident reporting system. Any problems will be actioned via the case review and root cause analysis action plans. The action plans are monitored by the risk midwife to ensure that improvements in care are made. The trends and any root cause analysis are discussed at the monthly risk meetings to ensure that appropriate action has been taken to maintain safety.

The Standing Operating Procedure for the use of the Fetal Fibronectin in detecting pre-term labour will be audited in line with the annual audit programme, as agreed by the CBU. The audit action plan will be reviewed at the monthly risk management meetings on a quarterly basis and monitored by the risk midwife to ensure that improvements in care are made.

9.0 Equality and Diversity

The Trust is committed to an environment that promotes equality and embraces diversity in its performance as an employer and service provider. It will adhere to legal and performance requirements and will mainstream equality, diversity and inclusion principles through its policies, procedures and processes. This procedure should be implemented with due regard to this commitment.

To ensure that the implementation of this procedure does not have an adverse impact in response to the requirements of the Equality Act 2010 this policy has been screened for relevance during the policy development process and a full equality impact assessment is conducted where necessary prior to consultation. The Trust will take remedial action when necessary to address any unexpected or unwarranted disparities and monitor practice to ensure that this policy is fairly implemented.

This procedure can be made available in alternative formats on request including large print, Braille, moon, audio, and different languages. To arrange this please refer to the Trust translation and interpretation policy in the first instance.

The Trust will endeavor to make reasonable adjustments to accommodate any employee/patient with particular equality, diversity and inclusion requirements in implementing this procedure. This may include accessibility of meeting/appointment venues, providing translation, arranging an interpreter to attend appointments/meetings, extending policy timeframes to enable translation to be undertaken, or assistance with formulating any written statements.

9.1 Recording and Monitoring of Equality & Diversity

This section is mandatory for all Trust Approved Documents and must include the statement below:

The Trust understands the business case for equality, diversity and inclusion and will make sure that this is translated into practice. Accordingly, all pprocedures will be monitored to ensure their effectiveness.

Monitoring information will be collated, analysed and published on an annual basis as part of Equality Delivery System. The monitoring will cover the nine protected characteristics and will meet statutory employment duties under the Equality Act 2010. Where adverse impact is identified through the monitoring process the Trust will investigate and take corrective action to mitigate and prevent any negative impact

Appendix 1 Management of Women According to Fibronectin Level

Results and actions: Fetal Fibronectin								
fFn Value	**Risk of delivery within two weeks (%)**	**Risk of delivery before 34 weeks (%)**	**Management guidelines**	**Steroids**	**Admit**	**Tocolysis**	**$MgSO_4$**	**Follow up**
0-9	1.8	1.5	Discharge with routine midwife follow up	No	No	No	No	No
10-49	1.6	8.2	Discharge with routine midwife follow up	No	No	No	No	Yes- Midwife
50-199	7.7	11.5	Discharge with routine midwife follow up	No	No	No	No	Yes- Midwife
200-499	29	33	Admit Give Dexamethasone 12mg IM 12 hours apart Tocolysis $MgSO_4$ for neuroprotection of the newborn In women with renal compromise, serum magnesium monitoring is recommended	Yes	Yes	Yes	Yes, if in labour	Yes, Obstetrician in 1 week
≥ 500	46	75	Admit Give Dexamethasone 12mg IM 12 hours apart Tocolysis $MgSO_4$ for neuroprotection of the newborn In women with renal compromise, serum magnesium monitoring is recommended					

Additional information to aid in the management of threatened preterm labour- Interpretation of fFN results

Risk of Delivery[1]

fFN Level	N (%)	≤ 7 days	≤ 14 days	≤ 34 weeks
<10 ng/ml	170 (57%)	1%	1.8%	1.5%
10 - 49 ng/ml	62 (21%)	0%	1.6%	8.2%
50 - 199 ng/ml	41 (14%)	0%	7.7%	11.5%
200 - 499 ng/ml	14 (5%)	14%	29%	33%
≥500 ng/ml	13 (4%)	38%	46%	75%

Appendix 2

Glossary of terms

fFN – Fetal fibronectin

Appendix 3
Maintain a record of the document history, reviews and key changes made (including versions and dates)

Version	Date	Comments	Author

Review Process Prior to Ratification:

Name of Group/Department/Committee	Date
Reviewed by Maternity Guideline Group	04/02/2021
Reviewed at Women's Business and Governance meeting	19/02/2021
Approved by CBU 3 Overarching Governance Meeting	26/05/2021
Approved at Medicines Management Committee (if document relates to medicines)	N/A

Trust Approved Documents (policies, clinical guidelines and procedures)

Approval Form

Please complete the following information and attach to your document when submitting a policy, clinical guideline or procedure for approval.

Document type (policy, clinical guideline or procedure)	Guideline
Document title	Standard Operating Procedure for the use of the Fetal Fibronectin in detecting preterm labour
Document author (Job title and team)	Senior Midwife/ Practice Educator Midwife/ Maternity Guideline Group
New or reviewed document	New
List staff groups/departments consulted with during document development	Consultant obstetricians, lead midwives, senior midwives
Approval recommended by (meeting and dates):	Reviewed by Maternity Guideline Group 04/02/2021 Reviewed at Women's Business and Governance meeting 19/02/2021 Approved by CBU 3 Overarching Governance Meeting 26/05/2021
Date of next review (maximum 3 years)	26/05/2024
Key words for search criteria on intranet (max 10 words)	Fetal fibronectin, Preterm labour, Premature labour
Key messages for staff (consider changes from previous versions and any impact on patient safety)	
I confirm that this is the FINAL version of this document	**Name: Charlotte Cole** **Designation: Practice Educator Midwife**

FOR COMPLETION BY THE CLINICAL GOVERNANCE TEAM

Approved by (group/committee): CBU3 Governance **Date approved: 26/05/2021** **Date Clinical Governance Administrator informed of approval: 03/06/2021** **Date uploaded to Trust Approved Documents page: 08/06/2021**