Fetal Fibronectin Policy

Hutt Maternity Policies provide guidance for the midwives and medical staff working in Hutt Maternity Services. Please discuss policies relevant to your care with your Lead Maternity Carer.

Purpose
Fetal Fibronectin testing kits are used to detect the presence of Fetal Fibronectin (fFN) in the vaginal secretions of women presenting with suspected preterm labour between 24+0 and 34+6 weeks gestation. The presence or absence of fetal fibronectin can help predict a woman’s risk of going into labour. A negative fFN result means that it is extremely unlikely that the woman will deliver in the next 7 days (only 1 in 125 will do so). A negative fFN can help avoid the inconvenience of hospital admission or transfer to a tertiary unit and can allow us to be more judicious in our use of both antenatal maternal steroid therapy for fetal lung maturation and tocolysis.

Scope
This policy will involve:
- Delivery Suite Midwives
- Lead Maternity Care Providers (LMC)
- Medical personal

Roles & responsibilities
The required sample will be obtained by the delivery suite midwife/the LMC/or the on-call obstetric team prior to further digital assessment of the vagina but following instruction from the Obstetrician on call. The sample may only be taken if the practitioner has attended appropriate training in the obtaining of a sample.

Definition
Fetal Fibronectin (fFN) - is a high molecular weight glycoprotein produced by chorioamniotic membrane and trophoblastic cells. It is thought to function as a biological glue, maintaining the integrity of the chorio-decidual interface.
In normal pregnancy fFN is rarely detected in cervico vaginal fluid in the second and third trimesters. However, fFN is present in cervico vaginal fluid of about 20-30% of women in preterm labour. It is hypothesised that disruption at the choriodecidual interface by inflammatory processes releases fFN into the cervicovaginal fluid.

Prerequisites

Inclusion Criteria
Threatened preterm labour where:
- steroid +/- tocolysis administration is indicated
- 24+0 to 34+0 weeks gestation
• Fetus is alive and viable
• Cervix is dilated <3 cm and > 1 cm length
• No complications that warrant early delivery are present
• Discussed with specialist obstetrician

Exclusion Criteria
• Threatened preterm labour where:
  ▪ Rupture of membranes confirmed on speculum examination
  ▪ Visible vaginal bleeding*
  ▪ Vaginal sexual intercourse in last 24 hours*
  ▪ Digital vaginal examination in last 24 hours*
  ▪ Cervix is dilated > 3cm or < 1 cm long.
  ▪ Indication to expedite delivery
  ▪ Placenta praevia

*Test can still be undertaken if planning steroids and tocolysis. A negative result is a true result. A positive result maybe a false positive, but will not alter planned management.

Note: It is currently unclear whether cervical cerclage may indirectly alter the reliability of the test and it would therefore seem appropriate that this high risk situation is regarded as a relative contraindication to fetal fibronectin testing.

Policy
Any women between 24 and 35 weeks gestation complaining of or observed to have recurring uterine activity which is thought to represent a realistic risk of premature delivery such that our usual management would have included hospital admission, administration of steroids, tocolytics and ultrasound scan is deemed eligible.

Fetal wellbeing should be demonstrated by fetal heart monitoring. If there are no concerns, fibronectin testing may be appropriate. If the fetal heart rate is non reassuring and vaginal examination would help determine management, no attempt should be made to delay appropriate clinical management in order to perform the swab.

The above exclusion criteria are noted. No vaginal examination is undertaken prior to a speculum examination at which time a swab for fFN testing is collected.

The usual cervical and vaginal swabs for chlamydia, ureaplasma/mycoplasma and high vaginal swab are taken during the same examination, but after collection of the fibronectin sampling.

The specimen is collected with the swab provided and sealed. This may be collected while it is determined whether to send it for testing as it may not be obvious whether to test or not initially.

The consultant obstetrician overseeing the care should be contacted to consider if testing is appropriate as the processing of the swab is expensive.
**Collection**
The specimen should be obtained from the posterior fornix of the vagina or ectocervical region of the external cervical os during a speculum examination using only warm water as lubricant.

The Dacron swab provided in the Specimen collection kit is inserted into the vagina and lightly rotated for a minimum of 10 seconds to fully absorb secretions from the area described above.

Collect the specimen first before any other type of cervical examination.

Remove swab and insert the tip into test tube with buffer. Mix vigorously in the buffer for 10 – 15 seconds. Discard applicator.

Insert test strip (dip area) into the buffer for exactly 10 (ten) minutes.

Remove test strip and read results.

Complete audit form located with the fFN test kits.

**Precautions**
- Specimen collection for fFN must be undertaken prior to collection of culture specimens.
- Specimen collection must be obtained prior to digital cervical exam or vaginal probe ultrasound exam as any physical manipulation of the cervix may cause release of fetal fibronectin from the membranes, thus resulting in a false positive test result.
- Patients could be tested if the patient reports having had intercourse within 24 hours prior to collection time. The risk is of a false positive result as a result of exposure to semen. However, a negative test result is a true negative.
- Use warm water only as a lubricant for the sterilised speculum examination. Do not use lubricants, soaps or disinfectants before or during specimen collection. The presence of lubricants or creams may interfere with the test.
- Use only the Dacron swab and plastic tube containing liquid in the Adeza specimen collection tube. Do not use cotton swabs or glass tubes to collect or store test.

**Results**
The result obtained may be used to guide clinical management in the following way:

*A positive result* - Means there is a risk of premature delivery within the next 7 days and depending upon the clinical scenario, admission or transfer to a Level 3 unit and the administration of maternal steroids +/- tocolytics may be appropriate.

*A negative result* - Means there is a very low likelihood of delivery in the next 7 days. Management must be based on the clinical scenario, but consideration should be given to early discharge home and not administering steroids or tocolytics.
Follow-up
Women with a negative result who are discharged home should be given advice to return if situation deteriorates. Arrange follow-up with antenatal clinic or LMC as appropriate.

References

Related documents
Pre-term labour policy
Nefidipine tocolysis policy

Further information / assistance
Fetal Fibronectin Test Collection Guide

Informed Consent
The right of a consumer to make an informed choice and give informed consent, including the right to refuse medical treatment, is enshrined in law and in the Code of Health and Disability Consumers’ Rights in New Zealand. This means that a woman can choose to decline treatment, referral to another practitioner, or transfer of clinical responsibility. If this occurs follow the process map on page 18 of the Referral Guidelines (Ministry of Health, 2012).
Management of woman with threatened preterm labour

- Woman at risk of delivery 24+0 to 34+6 weeks, singleton pregnancy, no cerclage, no fetal compromise

  - No vaginal exam or intercourse in the past 24 hours

  - Speculum exam
    - No PROM
    - No APH
    - Cervix < 3cm
    - Obtain fetal fibronectin swab
    - Take usual cervical/vaginal swabs

  - Digital vaginal exam

    - Cervix ≥ 3cm dilated or fully effaced
      - Discard fetal fibronectin swab
      - Admit
      - Administer tocolysis
      - Administer steroids as per protocol

    - Cervix ≤ 3cm dilated and >1cm long
      - Consult with obstetrician
      - Submit fetal fibronectin specimen for testing
      - Fetal fibronectin test POSITIVE
        - Discharge home with advice to return if situation deteriorates or admit to ward for observation
        - Arrange follow up with antenatal clinic or LMC within 2 days
      - Fetal fibronectin test NEGATIVE