Fetal fibronectin testing in women with threatened preterm labour: *A best practice toolkit*

NHS England

London Strategic Clinical Networks

Background and rationale

Aim

To optimise understanding and uptake of Fibronectin testing in women with threatened preterm labour in London.

This toolkit has been produced as part of the London Maternity SCN's strategy to identify areas of good practice in the network, and then to implement across all units to ensure equally good outcomes for women who are pregnant and their babies.

The remit for the toolkit is to present the principles underlying the use of fetal Fibronectin (fFN) testing rather than an exhaustive guideline; it is envisaged that all units will develop guidelines in line with these principles.

Current management of threatened preterm labour

Birth before 34 completed weeks of pregnancy is a significant cause of perinatal mortality and morbidity in the UK.

Current interventions that would be considered in a mother at high risk of imminent delivery of a premature baby include admission to hospital for monitoring, administration of steroids or tocolytic drugs to the mother and possible transfer to a specialist unit with appropriate staffing and expertise to most successfully care for a baby born at the extremes of viability. In particular, steroids and in utero transfer to a specialist unit have been associated with improved neonatal outcomes.

However, the management of women who present with threatened preterm labour, defined as uterine contractions but without cervical dilatation, is complicated by the fact that more than 50 per cent will eventually deliver at term. Intervening in this group, who are not destined to deliver preterm, will therefore result in unnecessary exposure of the fetus to steroids, unnecessary admission to hospital and possibly transfer to another unit.

Role of fetal Fibronectin testing

Fetal Fibronectin (fFN) is a glycoprotein which can be detected in a woman's cervicovaginal secretions throughout pregnancy, with low levels between 22 and 35 weeks of gestation.

Fetal Fibronectin concentrations greater than or equal to 50ng/ml between 22 and 35 weeks gestation are associated with an increased risk of preterm delivery. Using a 50ng/ml cut-off, the fFN test has a negative predictive value (NPV) of 99.2 per cent and a positive predictive value (PPV) greater than 40 per cent for delivery within 14 days in symptomatic women.

The risk of preterm delivery can be further stratified as fFN levels of less than 10ng/ml are associated with an even lower risk, whilst the highest risk of preterm delivery is seen with fFN levels of greater than 200ng/ml. The accuracy in predicting spontaneous preterm birth within 7-10 days of testing among women with symptoms of threatened preterm labour, before advanced cervical dilatation, has been confirmed in large studies[1-3].

The most useful aspect of these test characteristics is that a negative fFN test makes it highly unlikely that a woman's symptoms of preterm labour will result in delivery within the next 14 days (less than 1 per cent).

If clinicians respond to this information appropriately and do not admit or treat women who have contractions, without ruptured membranes or a history of preterm birth, and who have a negative fFN test, then a number of potential benefits may be realised:

Efficiencies resulting from

- Reduction in hospital admissions – Recent Health Technology Assessment (HTA) review suggests fFN testing is associated with cost savings when admissions are avoided[4].
- Reduction of in utero transfer rate (ambulance journeys)[5].
- Reduction in planning and administrative time for arranging transfer.
- Drug treatment – reduction in the use of tocolytics (eg Atosiban) and steroids.

Improved maternal experience by

- Avoiding unnecessary hospital admission.
- Avoiding ambulance transfer to an unfamiliar unit.
- Providing reassurance that preterm delivery is not imminent.

Improved service by

- Reducing the number of beds blocked by unnecessary admission and transfer. Currently, 47 per cent referrals to the Emergency Bed Service in London for in utero transfer are unsuccessful because there is no room; the median administrative time spent on these failed transfers is 340 minutes, involving discussions with between six and eight units[6].

Principles for the use of fFN testing in the London Maternity SCN

- Fibronectin is used in the management of women with threatened preterm labour and intact membranes.
- All network providers will have access to automated fetal Fibronectin analysis.
- Network providers will have local guidelines for the use of Fibronectin testing.
- A Fibronectin swab will be used to sample cervicovaginal fluid in the posterior fornix in all women with symptoms of preterm labour between 22 and 35 weeks gestation, with intact membranes and cervical dilatation less than 3 cm.
- The swab should be taken prior to digital examination.
- If the test is negative, the risk of preterm delivery within 10 days is 1 per cent. Steroids, tocolysis and in utero transfer are therefore not indicated.
- If the test is positive, the risk of preterm labour is increased and steroids, tocolysis and in utero transfer (if necessary) should be considered.
- Ruptured membranes, recent sexual intercourse, placenta praevia, abruption, heavy vaginal bleeding, cervical suture or recent cervical manipulation increase the risk of a false positive test.
- If the test is reported as invalid on two occasions, Fibronectin testing is contraindicated (eg digital exam performed) or Fibronectin is negative but the woman is still contracting, then trans-vaginal ultrasound can be used to measure cervical length. The risk of preterm labour is very low if the cervix is greater than 15 mm.
- In utero transfer because of perceived risk of preterm labour (in women with intact membranes) should not occur from network providers without prior Fibronectin analysis.

Education

The benefits associated with fFN testing, outlined above, will not be realised unless clinicians perform and interpret the test correctly. For instance, a recent HTA analysis found that cost savings were only achieved if clinicians did not admit women with a negative fFN test.

It is essential, therefore, that test implementation is more extensive than purchasing the swabs and point of care testing equipment.

All units will require a protocol that includes ongoing education about use and interpretation of findings.

Audit

Auditable standards include:

- The proportion of women presenting with threatened preterm labour tested for fFN.
- The proportion of women with threatened preterm labour and a negative fFN who received steroids, tocolysis, were admitted to hospital and/or were transferred to another unit.
- The proportion of women with threatened preterm labour and a positive fFN who received steroids, tocolysis, were admitted to hospital and/or were transferred to another unit.

Further reading

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