

Innovation in Practice: The Introduction of a Fetal Fibronectin Test to Assist in the Diagnosis of Preterm Labour

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ABSTRACT

This paper reports on an innovation, within a maternity unit, to introduce a fetal fibronectin, point of care test, that will aid the clinician in correctly diagnosing preterm labour. In turn this will assist in developing an individual plan of care for each woman with suspected preterm labour, rather than treating each case with the same interventions regardless of subsequent outcomes.

Fetal fibronectin (fFN) is a complex adhesive glycoprotein which can be detected in the cervicovaginal secretions of women during pregnancy. Its concentration varies throughout pregnancy, detectable before 24 weeks of pregnancy the concentration then dips below the minimum detectable level up to 34 weeks of pregnancy, unless the woman is in preterm labour.

The fFN test was successfully introduced into clinical practice. Demonstrating that when used appropriately, on women with symptomatic suspected preterm labour, fFN testing can aid in accurate diagnosis and thereby avoid unnecessary, costly interventions.

KEY PHRASES

- The majority of women (80%) who present with the signs and symptoms of preterm labour will go on to deliver at, or after, 37 weeks gestation (Morgan et al 2007)
- Interventions and treatments for this group of women can therefore be unnecessary and costly.
- Fetal Fibronectin (fFN) is a complex adhesive glycoprotein which can be detected in the cervicovaginal secretions during pregnancy.
- A negative fFN test is 99.2% predictive that the woman will not deliver in the next 14 days (Honest.et al 2002)
- The introduction of a safe, simple fFN test can assist in correctly diagnosing true preterm labour, therefore avoiding unnecessary, costly interventions.

INTRODUCTION

Preterm birth is defined by the World Health Organisation as birth between 20 and 36 + 6/7 weeks of gestation (Berghella, Hayes, Visintine & Baxter, 2008) and is responsible for the majority of perinatal morbidity and mortality in the United Kingdom (Lu, Goldenberg, Cliver, Kreaden & Andrews, 2001).

Prior to the introduction of fFN testing the management of suspected preterm labour in this Trust was hospital inpatient admission, tocolytic therapy and selective in-utero transfers (Local Trust Guidelines, 2008). In approximately 20% of these admissions the woman will be found to be in labour and subsequently deliver a premature baby. The majority (80%) of women with the signs and symptoms of preterm labour will deliver at or after 37 weeks gestation. This means that many of the inpatient admissions, treatments and transfers, for suspected preterm labour are unnecessary and costly (Morgan, Goldenberg & Schulkin, 2007).

Previous practice was therefore expensive and highly disruptive to the woman and her family as it requires admission, observation with treatment and/or in-utero transfer of mother (Honest, Bachmann, Gupta, Kleijnen & Khan, 2002). It is therefore essential to identify as early as possible the 20% of women in true preterm labour, so that they can be treated appropriately, and the 80% that are not in preterm labour avoiding unnecessary intervention and cost.

AIM OF THE INNOVATION

The aim of this innovation was; to introduce a safe simple (fFN) test to assist in correctly diagnosing true preterm labour, which will;

- Enable clinicians to appropriately treat each woman (Grobman, Welshman & Calhoun, 2004).
- Reduce the risks associated with preterm. (Lu et al., 2001).
- Reduce unnecessary intervention. (Berghella et al, 2008).
- Minimise the hospital stay. (Ness, Visintine, Ricci & Berghella, 2007).
- Reduce anxiety in this group of women (Anderson, 2000).
- Reduce costs of treatment surrounding preterm labour (Grobman et al., 2004).

In symptomatic women who are fFN negative, the risk of delivery within 14 days is 0.8%, whereas the risk in fFN positive women is 14% (Honest et al., 2002). A Point of Care Test (POCT) for cervicovaginal fFN before steroids, tocolysis and in-utero transfer would reduce the in-utero transfer rate by approximately 50% without any significant adverse effect, as well as decreasing the unnecessary use of tocolysis and steroids (Honest et al., 2002). Cervicovaginal fFN can be assessed using a simple POCT and the aim of this innovation is to implement this safe and effective test into clinical practice.

APPRAISAL OF THE FETAL FIBRONECTIN LITERATURE

The highest level of literature found in this appraisal was a 2008 Cochrane Systematic Review by Berghella et al; this was appraised using Critical Appraisal Skills Programme (CASP). The criteria used for considering studies

for inclusion in the systematic review were published randomized controlled trials; the participants were pregnant women between the gestational ages of 22 to 34 weeks, who were screened for fFN, when presenting with the signs and symptoms of preterm labour.

Although 13 trials were identified by Berghella et al (2008) only 5 were eligible for inclusion because in the remaining 8 only women with positive results were included, this excluded women with a negative result and therefore was thought to bias the trial. Although only trials with both positive and negative results were included in the review, the focus of the Berghella et al systematic review (2008) was to assess the effectiveness of management, based on the knowledge of positive fFN test results. Thus he ignored the value of the negative result, losing the opportunity to widen the scope of the review to demonstrate the usefulness of the negative result in the clinical field. The focus of this literature review and of the innovation is in predicting the symptomatic woman that will **not** go on to deliver prematurely. The more important result, to this innovation, is the negative fFN and the effect that this has on preventing unnecessary interventions (Peaceman et al, 1997). It was difficult, therefore, to make any meaningful comparisons between the trials and the proposed innovation as the women with negative results were not followed up in the trials. The systematic review did nevertheless demonstrate sound evidence of the accuracy of the fFN test, and its relevance to predicting delivery in women presenting with suspected preterm labour, thereby clearly establishing the need for the implementation of this innovation. There was also no mention in the literature reviewed of the incident of false positive fFN

tests, this potential problem will be looked at carefully when evaluating the introduction of fFN tests in this innovation.

IMPLEMENTATION

Managing the implementation of this innovation proved more complex than first anticipated as it involved organisational, individual and team change. Any innovation should be driven by senior leadership (Clarke, 2008) with commitment to providing adequate resources. It is especially important here as changing practice requires a change in organisational culture and attitudes and this is unlikely to be achieved if senior leadership is not involved (Clarke, 2008). Engaging the Lead Consultant of Delivery Suite, General Manager and Head of Midwifery was essential to the success of this innovation. It would not only secure the necessary finances, but would also give credence to the test itself and the value of change in clinical practice. Involvement of senior management was achieved by all members of the team presenting the literature search and initial financial projection. The importance of this support cannot be underestimated as leadership actions, such as supporting the innovation, strongly influence peoples beliefs (Blackwood, 2006).

When forming the implementation team the aim was to keep the membership numbers to a minimum (Cohen & Bailey, 1997) as the more people in a team, the more difficult it is to communicate quickly and effectively, to achieve consensus and coordinate activity. This team would need to steer and coordinate, as well as review the process and evaluate the outcomes. The team members were initially selected by the team leader approaching individuals in

the appropriate areas. After the first month interest in the project was such that midwives, doctors and students volunteered to be involved, strengthening the support for the innovation. The original SWOT Analysis completed at the inception of the innovation was looked at again and expanded (Table 1.1).

Table 1.1.
SWOT Analysis 2

<p>STRENGTHS</p> <ul style="list-style-type: none"> • Simple Point of Care Test • No extra invasion to women • Negative result 99.3% predictive 	<p>WEAKNESSES</p> <ul style="list-style-type: none"> • Unknown false positive % • Finding time for training • Non compliance of staff
<p>OPPORTUNITIES</p> <ul style="list-style-type: none"> • Improved experience for women • Intervention reduced • Intervention focused on most high risk cases • Reduction in costly treatment 	<p>THREATS</p> <ul style="list-style-type: none"> • Approval by POCT committee • Securing finance • Multi-disciplinary teams variability in using test

From this targets were identified and the innovation was divided into five areas with individual members of the team volunteering to be responsible to drive forward one area. These were;

- Business case and securing finance
- Sourcing the test.
- Presenting to the POCT committee
- Writing guideline/policy
- Training

Over arching all of these and the responsibility of all members of the team was communication of the innovation to the multi-disciplinary team.

Many different stakeholders would be involved in the implementation of this innovation, who work in two very different area's, the Maternity Assessment Centre (MAC) and Delivery Suite (DS). The teams focus was, in keeping with the Trusts philosophy, to make patient safety and quality of care strategic priorities. Therefore obtaining the right test was imperative to the success of the innovation (Peaceman et al., 1997). The test chosen by the majority of the team had all the quality assurance that would be required by the POCT committee. As well as being simple to use, the company would also provide a training and audit package to assist the team in these areas. The literature was also very 'user friendly' and would be a useful aid in the training and preparation of local guidelines for the use of the test.

The test was then presented to and approved by the Point of Care Test Committee and needed to conform to the POCT policy. To facilitate writing a local guideline to underpin the introduction of the fFN test the team contacted six other Trusts who had already introduced the test. Appreciation of the importance of sharing information (Lynch, 2006) proved invaluable as problems that they had encountered during the implementation of fFN testing in their areas was highlighted. Advice was given by the fFN leads in each Trust on the writing of the guideline and the content of the training programme. The finished guideline is a sound reflection of the best available evidence for safe effective practice in this area and a testament to inter-Trust sharing. Clinical champions were appointed to increase wider motivation to

succeed by maintaining the enthusiasm for the project in the clinical area, throughout the 24 hour period (Stuart, 2003), as women can present at anytime in preterm labour, this would ensure that the test did not become a Monday to Friday, 9 to 5 innovation.

The first problem encountered was a clinical one. The swab must be taken before any other examination is performed, so that the accuracy of the test is not compromised by other products such as lubricants, used during vaginal examination. Therefore the swab could not be taken as an after thought, when the practitioner was reminded by the midwifery team. This problem was minimised through constant reminders from the implementation team and the clinical champions in the initial stages until the test became established. It was noted though that the midwifery team took more of a lead in the innovation, often having to remind the medical staff that the criteria for taking the test had been met and reminding them of the guideline. This can be explained, in some part, by the rapid turnover of junior medical staff (four monthly rotations for General Practitioner Trainees) and the seniority of the MAC and DS Coordinators. Yet a midwife taking the lead, in instructing junior doctors, as demonstrated in this innovation, has been part of Maternity Units hierarchy for years (Cartwright 1979).

The second problem was the need to compete with the day to day clinical work which meant that the vision of this innovation needed to be communicated frequently. This was solved by attendance of the team at multi-disciplinary handover's between shifts, enabling the testing to be discussed three times a day. At the same time results were fed back, any problems

highlighted and most importantly any member of staff that had not been trained could be identified. Communicating in this way had the added bonus of 'creating short term wins' (Kotter, 1995) as when results were fed back to the multi-disciplinary team in this way, women who had benefited from a negative fFN test, by being reassured and sent home were highlighted. Success stories like these reinforced the usefulness of the test and the vision of the innovation.

EVALUATION

The fetal fibronectin test was a completely new concept in this Trust therefore the level of knowledge regarding what fFN is and its uses at the start of this innovation was minimal to non-existent. A lot of new information needed to be delivered and understood by the multi-disciplinary team in a short space of time. Evaluation of the effectiveness of the dissemination of information was by feedback from staff once the training had been completed (Stuart, 2003). A simple form indicating their level of knowledge prior to training and following the session was filled in. This confirmed that 100% of staff felt their knowledge had increased following the training. Feedback from the team members at the end of the three month period was very positive and the enthusiasm for the project remained high.

Introducing this test as a POCT rather than a laboratory based test has meant rapid results were received by the clinical team (Grobman et al., 2004). The machine and printer were provided and maintained free from the company. The value of the internal quality control of the device, that determined it was

technically performing correctly, was confirmed by the reliability of the results obtained. The device proved to be very user friendly. All clinicians completed a feedback sheet at the end of the data collection period to audit the POCT. 100% reported that no problems were found with the device or printer. Also reported was the ease of the daily quality control test and the clear printout that was received containing results, date and time. The results were obtained within 20 minutes of the swab being taken; therefore rapid decisions could be made on plans of care reducing the overall anxiety of the women (Kirkham, 2004).

An unanticipated success of the innovation was the involvement of student midwives and medical students. Both these groups were enthusiastic from the start, therefore becoming involved early on. The clinical setting provides unique learning experiences for students, which if managed proactively can be a positive growing episode (Stuart, 2003). Being involved in the implementation of an innovation and following the change process was an experience that the students had not been exposed to. Two of the student midwives reflected on their experience and shared their reflection with their peers at University. This meant that the innovation was taken to a much wider audience than was anticipated, as the group came from many surrounding Trust's, this offers the possibility of spreading good practice further within the profession.

CLINICAL OUTCOMES

In terms of clinical outcome the success of the innovation, was to identify women who presenting with the signs and symptoms of preterm labour would deliver prematurely. Use of the fFN test was to determine which of these women were not likely to deliver in the next 14 days. This would in turn prevent unnecessary intervention and reduce anxiety (Kirkham, 2004) and allow appropriate intervention for the women who were likely to deliver, thus also saving on financial resources. As this was not a primary research project, clinical audit was used to evaluate the effectiveness of the test itself. Each test was recorded not only in the woman's records but also in a project book. This information was then entered on to a data base specifically set up for the project.

During the data collection time, 1/1/09 to 31/3/09, 32 tests were performed. The number of women presenting with threatened preterm labour each year is approximately 398 (Local Annual Maternity Statistics, 07/08) therefore it would be expected that approximately 100 women would present during the data collection time with symptoms, in fact 91 presented. Of these women a large proportion would be excluded from having the test. This is for three reasons;

- The test was not appropriate in women with symptoms of cervical dilatation >3cm, bleeding per vagina (PV), spontaneous rupture of membranes (SRM) (Ness et al, 2007). These women will inevitably go on to deliver prematurely (Chandiramani & Shennan, 2006).

- The fFN test sample must be collected before the performance of any activities or procedures which might disrupt the cervix e.g. coitus, digital examination, vaginal ultra sound (Stafford et al., 2008)
- Tests result would be invalid if the swab was contaminated by any lubricants, soaps or disinfectants (Stafford et al., 2008).

At the start of the innovation it was difficult to predict how big the excluded group might be as it depended on so many variables. In particular the accurate giving and taking of the woman's history (Grobman et al., 2004). This was discussed at the weekly implementation team meeting and an estimate, based on clinical experience, was thought to be approximately 30% of all women presenting would be excluded from the test. In fact following the data collection the group proved to be disappointingly large at 48% (Figure 1.2).

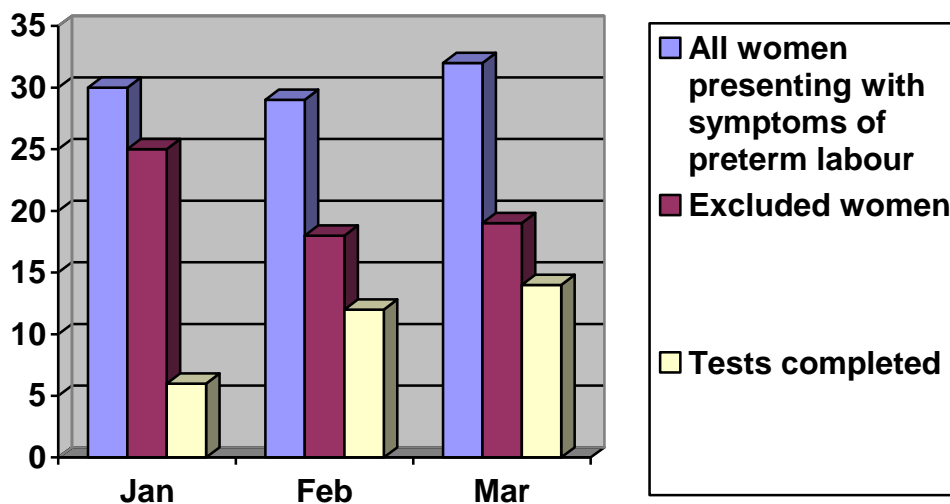


Figure 1.2.
Uptake of tests.

A partial explanation for this high figure was that the uptake of the test was lower than expected in the first month (20% compared to 41.3% and 43.7% in the following months). This was thought to be the clinicians not remembering to perform the test at the start of the examination, as communications

improved regarding the innovation then so did the uptake. The number of tests performed overall correlates with expectations reassuring the team that the test was being used appropriately.

The negative and positive results were entered on to the data base separately so that a clear picture could be seen regarding the outcomes. At the end of the data collection period the women's records were all recalled so that the treatment received and the outcomes could be added to the data base. The results of the tests were analysed separately (Figures 1.3 & 1.4). From this we could see how the result of the test correlated with the outcomes and whether clinical interventions were appropriate

Figure 1.3 Negative tests

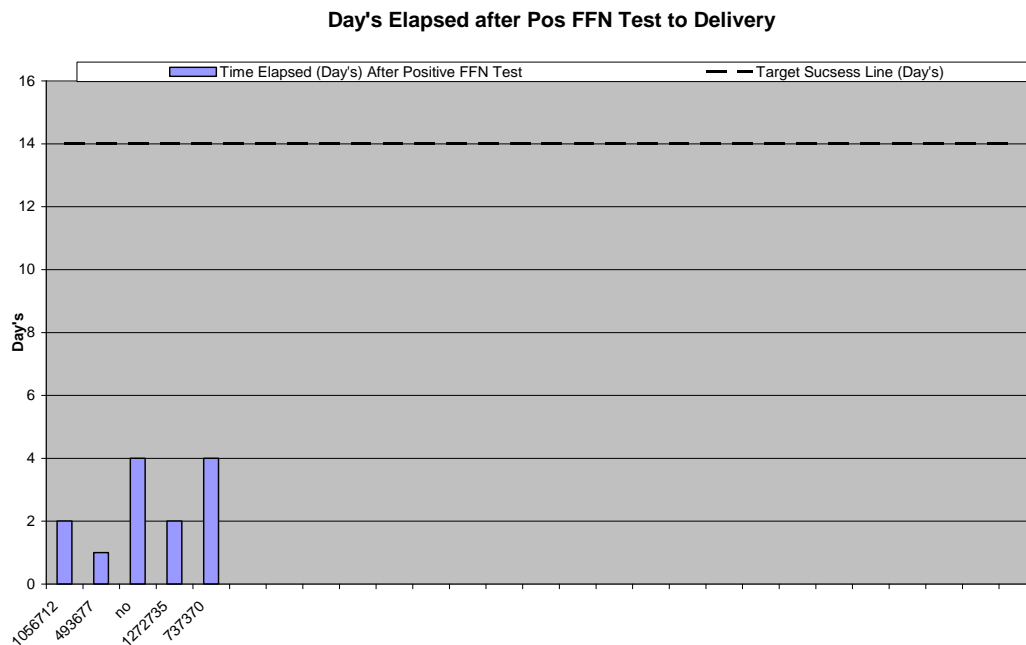


Figure 1.4. Positive tests

NEGATIVE TEST OUTCOMES

As can be seen in Figure 1.3 all the women with negative tests did not deliver within the 14 day period, which equates to 100% accuracy. Of the 27 negative tests obtained the clinical records were audited to ascertain what decisions had been made regarding a plan of care for each woman. Only 4 (14.8%) of the women who tested fFN negative were admitted for observation, of these only one was given steroids and none were given tocolytic therapy. The reasons for the admissions had been documented in all cases as abnormalities in the cardio tocograph recording (CTG) of the fetal heart. This meant that the women were admitted for reasons other than the suspected preterm labour; therefore the negative fFN test remained relevant.

The concern that there would be a high percentage of false positive results proved to be wrong. Out of the five positive tests obtained all delivered within 14 days, following treatment to delay delivery, so that time for corticosteroid therapy to work was achieved (Chandiramani & Shennan, 2006).

COST ANALYSIS

The cost of each test during the first three months was £35. This was a reduced rate (from £45) negotiated for the trial period and an increase in price would have to be taken into account when assessing whether the innovation would be cost affective in the future. Therefore the total cost of the 32 tests was £1120.

No tocolytic therapy (Atosiban) was used in any of the 27 negative tests. The cost of Atosiban treatment for one woman is £386 (information obtained from pharmacy budget information), saving £10,422.

An ante-natal in patient stay for a period of 72 hours is approximately £425.30 (information from Trust finance department). 23 women were not admitted following a negative test, saving £9,781.90.

The implementation of the innovation and the training was undertaken within the regular clinical shifts of the multi-disciplinary team. The training itself took 30 minutes and took place in the clinical field and therefore, though not measurable, was not a cost implication of any great amount. Although the staff were taken away from other duties for that short period no extra shifts were booked to cover this time away from the clinical area.

Cost of tests = £1120

Cost of intervention and admission if test not used = £20,203.90

Saving to Trust (Jan/Mar 09) = £19,083.90

Since the inception of the innovation subsequent data has been analysed and audits of results in the periods of July 09 to September 09 and again in January 10 to March 10 have confirmed the original findings.

CONCLUSION

This project was seen as a small change in a busy clinical area, but the amount of work that it would need to drive it forward was underestimated at the start. Getting the balance right between the short term goal of introducing

the test, and the long term goal of the education/training of the clinical staff, enabling them to take ownership and take forward the innovation, was difficult (Bridges, 2003). On reflection, the first month of data collection was disappointing, as previously noted this could have been prevented by more time being allocated to the initial training of staff and better communication of the purpose of the test.

Introducing a POCT into the clinical area also proved to be problematic, as it was much more time consuming than first anticipated and completely threw our carefully planned timetable adrift. This happened because none of the implementation team had any prior knowledge of the processes involved, therefore initially no extra time was factored in to compensate for this.

RECOMMENDATIONS FOR PRACTICE/FURTHER RESEARCH

Despite extensive research the incidence of preterm birth is increasing in many countries (Berghella et al., 2008). All members of the family in which preterm birth occurs feel the medical, social, psychological and financial effects (Lumley, 2004).

This innovation was driven by the need to accurately predict whether a woman with symptoms is indeed actually in preterm labour. To be able to do this means that the clinical team can either prevent unnecessary interventions or quickly put in place necessary interventions. This in turn reduces morbidity and mortality in mother, baby and the family (Grobman et al., 2004, Chandiramani & Shennan, 2006). To this end the fetal fibronectin test has

been demonstrated, by this project, to be a very useful point of care test, which enhances the decision making of the multi-disciplinary team.

The use of the fFN test in future practice could be expanded to include women with a high risk of preterm labour i.e. previous history or multiple pregnancies who are asymptomatic. At present these high risk women often spend a large part of their pregnancy as an inpatient for observation/rest 'just in case' they show signs of going into labour (Chandiramani & Shennan 2006). A test performed every month between 23 to 34 weeks gestation could indicate whether an asymptomatic woman was in danger of going into labour and provide more time for treatment to successfully prevent this occurring. As a simple POCT this could be performed at the local health centre, during routine antenatal clinics, therefore causing little disruption to the woman and her family (Kirkham, 2004).

Further research is required to determine whether the use of the fFN test on asymptomatic women would reduce the incidence of preterm delivery in high risk women. No trials were identified during the literature search on women without signs or symptoms of labour being routinely tested for the presence of fetal fibronectin. Women's choice and experience would also need to be measured, to determine how they feel about investigations and interventions surrounding preterm labour and delivery (Kirkham, 2004). Maternity care has moved on in recent years and now the more complicated notion of informed choice has replaced simple consent to treatment's (Kirkham, 2004). Evidence in the literature goes back as far as 1979 (Cartwright, 1979) to show that

women want to be consulted and informed regarding the treatments they receive during pregnancy and labour. Therefore measuring their experiences of an innovation such as this is an important part of the long term evaluation process (Kirkham, 2004).

This innovation in clinical practice has been of great benefit to the multi-disciplinary team, the maternity unit, the Trust and most importantly to the women and their families. The change process has not been without its problems, but these have been identified and solved in a positive way by the implementation team. Evaluation of the data to date is very positive and the aim of the innovation, to assist in correctly diagnosing true preterm labour, has been met. All stakeholders have shown ownership and commitment to the change which is now becoming embedded within the clinical practice of this maternity unit and has been cascaded throughout the Strategic Health Authority.

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