Implementation of fetal fibronectin testing: admissions, maternal interventions and costs at one year

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Summary:

Fetal fibronectin testing (fFN) has a high negative predictive value for preterm delivery, but it has a cost implication. This two stage prospective study evaluated the real patient costs and clinical impact of introducing the fFN test in women presenting acutely with threatened preterm labour in a tertiary UK obstetric hospital.

Introduction of the fFN test for women with threatened preterm labour reduced antenatal admissions and *in utero* transfers, and reduced steroid treatment and tocolysis, even at one year after implementation. The total number of bed days for women with threatened preterm labour who did not deliver during admission fell from 132 days (mean 8.8 days) to 25 days (mean 3.6 days). The mean cost of admission per woman before introduction of the fFN test was £1,032 (95% CI £880 to £1184); after it was £339 (95% CI £261 to £417). In this small single centre study, the introduction of the test produced a cost saving of £693 per woman (95% CI, £464 to £922) which over 12 months potentially saves £74,844 (95% CI £50,112 to £99,576). Further studies are needed to formally evaluate the cost-effectiveness of the fFN test and its impact on clinical decision-making in large populations.

Key words: fetal fibronectin, preterm birth, costs

Introduction:

Current antenatal management of women in threatened preterm labour relies on timely administration of maternal antenatal steroids, tocolysis to delay delivery until fetal lung maturity is reached and in utero transfer to a unit with appropriate level neonatal intensive care. Based on clinical judgement alone however, fewer than 50% of all women admitted with threatened preterm labour actually deliver their baby during that admission (Lockwood et al., 1991). Better diagnosis could avoid unnecessary admissions, *in utero* transfer, and treatment with steroids and costly tocolytic drugs.

Fetal fibronectin (fFN) is a glycoprotein and biochemical marker which is detectable in a woman's cervicovaginal secretions throughout pregnancy, with low levels between 22 and 35 weeks of gestation. fFN concentrations ≥50ng/ml at this time indicate a greater risk of preterm birth in women presenting with threatened preterm labour (Peaceman et al., 1997). Using a 50ng/ml cut-off, the fFN test has a negative predictive value (NPV) of 99.2%, and a positive predictive value (PPV) >40% for delivery within 14 days. 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 (Honest et al., 2002).

Introduction of the fFN test to the UK and the rest of Europe has been slow in comparison to other countries such as Australia (Giles et al., 2000), New Zealand (Groom et al., 2006), the United States (Plaut et al., 2003, Swamy et al., 2005, Incerti et al., 2007) and Canada (Giles et al., 2000, MacDonald et al., 2007). In these countries where the impact of *in utero* transfer is high due to their large distances, implementation of the fFN test has been shown to reduce *in utero* transfers and medical costs. Economic analyses of the test have used assumptions to model the data rather than use

real-life clinical data sources (Honest et al., 2002). A reduction in costs may not be immediately evident (Musaad et al., 2005) and there are concerns that increasing clinician reliance on the test with overuse in women presenting with abdominal pain may reduce potential cost savings long term. No studies have investigated whether the initial cost savings continue long term after implementation. In addition the cost savings might depend on whether a unit tocolyses with Atosiban (£339 for a course) or cheaper unlicenced alternatives such as nifedipine. An alternative to the fFN test is sonographic measurement of cervical length (CL), where CL <15 mm indicates a higher chance of preterm birth in symptomatic women (Tsoi et al., 2006). In most UK hospitals however, accurate sonography is not available after hours or on weekends, when many women with threatened preterm labour present to hospital.

In our tertiary obstetric hospital, we hypothesized that introduction of the fFN test would safely reduce in-patient admissions, in utero transfer, administration of steroids and tocolytics and importantly would result in long lasting cost saving. We quantified the impact of antenatal preterm admissions on the hospital before the test in all women presenting acutely with threatened preterm labour. After introduction of the fFN test we evaluated the performance of the test ten weeks and at one year after implementation in women with the same presentation. Finally we calculated the cost savings in the departmental budget one year after implementation.

Materials and Methods:

University College London Hospital (UCLH) is a tertiary referral centre with 5200 deliveries per annum supported by an on-site level 3 neonatal intensive care unit. It is the main referral unit for the North Central London

Perinatal Network (NCLPN). The practice at UCLH before April 2009 was to admit all women presenting acutely to Labour Ward and the day case Maternal Fetal Assessment Unit (MFAU) in threatened preterm labour for observation, plus a course of maternal steroids and tocolysis (Atosiban). All admissions, prescriptions of steroids and tocolytics were based on clinical judgement alone as to the likelihood of imminent delivery. Women underwent clinical examination, cardiotocography and were observed on the labour ward for up to 4 hours. Women thought to be at high risk of spontaneous preterm birth were admitted to hospital for at least 24 hours observation.

To quantify the cost and impact of preterm antenatal admissions on the hospital before introduction of the fFN test, we audited all admissions to UCLH between 22 and 34+6 weeks of gestation for 2 months (January-February 2009). To ensure complete case ascertainment we audited all women who presented acutely in the Labour Ward and in the day case Maternal Fetal Assessment Unit (MFAU) at UCLH. Women presenting to other parts of the hospital, for example Accident & Emergency, would always be referred to LW or MFAU and were not admitted directly to the Antenatal Ward. Clinical staff completed an audit proforma when a woman presented and was admitted to the Antenatal Ward. To ensure complete case assessment the logbooks for Labour Ward and MFAU admissions were checked daily and compared with proformas completed prospectively. The study team checked the Antenatal and Postnatal Wards daily to ensure complete case ascertainment.

Data on presenting symptoms, vaginal examination findings, diagnosis, all investigations performed (including fFN test, ultrasound scans, blood tests and microbiology), all treatments (including analgesia, antibiotics, tocolytics), length of stay and *in utero* transfers were collected prospectively and

confirmed using the electronic inpatient bed-state. The pregnancy outcome was determined from the case notes. Women whose cervix was found to be ≥3cm dilated on vaginal examination were diagnosed to be in established preterm labour. Threatened preterm labour was diagnosed when women presented with painful uterine contractions and the cervical dilatation was <3cm.

An automated qualitative fFN test, TLi_{IQ} (Hologic, USA) was introduced to the unit in March 2009 supported by a training programme for healthcare staff. The unit's threatened preterm labour guideline was revised to incorporate the fFN test into the algorithm, which was then disseminated to other hospitals in the NCLPN. The use of and the predictive performance of the fFN test was audited in the first 10 weeks of the test and results were disseminated to all medical and midwifery staff to support implementation of the test.

Ten months after introduction of the test (January – February 2010) and one year after the initial audit of antenatal preterm admissions, we re-audited all antenatal preterm admissions to UCLH between 22 and 34+6 weeks. To ensure complete case ascertainment we again audited all women who presented acutely in the Labour Ward and in the day case Maternal Fetal Assessment Unit (MFAU) at UCLH. Audit proformas, admission logbooks and wards were checked daily as described earlier. The fFN machine was prospectively checked daily for test usage to ensure that no tests were missed out. Over the year following fFN implementation the performance of the test was monitored daily. We calculated the impact and costs of care. The predictive performance of the fFN test in women with threatened preterm labour was monitored over the entire year. Between the two audit time periods, mid-trimester cervical length sonography at the time of the anomaly

scan was introduced for all women booked at UCLH as a screening test for increased risk of spontaneous preterm birth. All women with an incidental finding of a cervical length ≤25mm were referred for a consultant obstetric opinion in the UCLH Preterm Birth clinic.

The costs of all assessments and all treatments that every woman underwent before and after implementation of fFN testing were derived. We used cost data available from the Primary Care Trust (cost of 24 hour admission to the hospital, £420), UCLH pharmacy (£339 per atosiban tocolysis, £5 for equipment per infusion, £5 for steroid injection, £10 for analgesia; costs included intravenous access, infusion fluids, syringes and needles), UCLH pathology services (full blood count, FBC £10; Group and Save £20; mid stream urine (MSU) culture £20; high vaginal swab (HVS) for culture, £25; costs included syringes and needles, blood bottles and swabs), UCLH obstetric ultrasound scan (£70) and the London Ambulance Service (in utero transfer cost, £100). The costs are indicated, in **Table 3** and were measured in 2012 UK£. Discounting of costs was unnecessary, because all costs per patient were incurred within a single year. Since all women underwent cardiotocography, blood pressure measurement, MSU dipstick and review by a midwife and a doctor during their initial presentation to hospital, we have not included these costs. To calculate patient costs we split patient admissions into two groups dependent on whether the woman received tocolysis (defined as a Full admission) or did not receive tocolysis (defined as a Minor admission, **Table 3**). A Minor admission included the hospital admission, any laboratory investigations that were performed on the woman, a fetal ultrasound scan after admission if clinically indicated, and the use of analgesia and steroids as required. Full admission included items provided in Minor admission and the use of tocolysis and *in utero* transfer as required.

After introduction of fFN, a Minor or Full admission was as described above, but also included the cost of the fFN test when performed. In addition, we calculated the cost for women who only had the fFN test after its introduction and who were not admitted (fFN only, **Table 3**); this cost also included the cost of tests or treatments that the women underwent as part of their care during their hospital consultation, such as for example FBC, MSU, HVS and analgesia. For each cost component, for example a bed day, test, scan or prescription, the total number incurred before or after implementation of the fFN test was calculated from the individual patient audit data results to derive the resource use data. Then the unit costs were multiplied by the resource use data for each cost component and averaged by the number of women in each cohort, either before or after implementation of the fFN test. The mean cost component per patient was then summed to calculate a final mean cost per woman for the January to February 2009 cohort before fFN implementation and for the January to February 2010 cohort after fFN implementation.

Results:

Before the introduction of the fFN test, there were 69 preterm antenatal admissions (22 – 34+6 weeks of gestation) over two months (January – February 2009). The majority of admissions were of singleton gestation (n=60), with some twins (n=7) and one triplet pregnancy. The most common reason for admission was for threatened preterm labour, (18/69, 26.1%, **Table 1**). There were 7 women who had an *in-utero* transfer into UCLH, of whom 2 had threatened preterm labour; 5 of the transfers were from within the NCLPN. There were 2 women who had an *in- utero* transfer out of UCLH, 1 for threatened preterm labour who subsequently delivered at term. Delivery outcomes of women admitted with threatened preterm labour are shown in **Table 2**. Of 18 women admitted with threatened preterm labour, only 16.7% (n=3) delivered during their admission (median 8 days from admission to delivery, range 3-13 days, total 24 bed days). Tocolysis (Atosiban) was administered to 27.7% (n=5). Over three-quarters of the women admitted with threatened preterm labour did not deliver in that admission (15/18, 83.3%). The median time from admission to discharge for these women who did not deliver was 2 days (range 1 to 48 days, total 132 bed days). The average cost of admission per woman during this two month period was £1,032 (95% CI £880 to £1184, **Table 3**).

As part of implementation, the use and performance of the fFN test in our unit was evaluated ten weeks after its introduction. Over this time, 94 tests were carried out in 76 women with performance characteristics as shown: NPV 100% and PPV 43.8% for delivery within 2 weeks of the test, sensitivity 100%, specificity 89.4%. Results of the audit were disseminated to all clinical staff and midwives.

Ten months after the introduction of the fFN test we conducted a re-audit of all antenatal preterm admissions over a 2 month period (January and February 2010). There were 79 preterm admissions (22 – 35 weeks of gestation, **Table 1)**. The majority of admissions were of singleton gestation (n=65), with some twins (n=14). The most common reasons for admission were for maternal medical problems, followed by preterm prelabour rupture of membranes. There were two women admitted for an incidental finding of a short CL<25mm at their anomaly scan. Only 11 women (13.9%) were admitted for threatened preterm labour, and 4 (36.3%) delivered during their admission (**Table 2**). The median time from admission to delivery was 3 days (range 1-18 days, total 29 bed days). The median time from admission to discharge for those who did not deliver was 3 days (range 1-8 days, total 25 bed days). Only 1 woman admitted received tocolysis; she did not deliver during her admission and 7 women received steroids; none delivered during their admission. Of the women admitted with threatened preterm labour, 6 had a fFN test, of which 4 were positive. fFN was not performed in 5 women in threatened preterm labour due to contraindications to the test (cervical dilatation more than 3 cm, recent sexual intercourse and moderate or heavy vaginal bleeding). The average cost of admission per woman was £333 (95% CI £255 to £411**, Table 3**).

The use and performance of the fFN test was evaluated during the re-audit period (January to February 2010) to reassess test performance. In 41 fFN tests conducted the characteristics were as follows: NPV 97% and PPV 33% for delivery within 2 weeks of the test, sensitivity 100%, specificity 90%. For the year following fFN implementation the NPV for spontaneous preterm birth within 2 weeks of the test was 99.2%% (March 2009 to March 2010).

Comparing the mean cost per woman before (£1,032, 95% CI £880 to £1184) and after the introduction of fFN £333, 95% CI £255 to £411) resulted in a cost saving of £699 (95% CI £469 to £929) per woman (**Table 3**).

Discussion:

Our primary finding was that after introduction of fFN in a UK perinatal network level 3 hospital there was a sustained long-term reduction of in-patient admissions, costs of transfer and administration of steroids and tocolysis. The negative predictive value of the test was high even at one year after introduction, with an approximate 30% false positive result. The negative predictive value had the most effect in our unit, in allowing us to confidently discharge those women who were least likely to need intervention and delivery prematurely. For women who did deliver preterm during their admission, the admission to delivery interval fell from a median of 8 days to 3 days after introduction of the test, showing that as expected, implementation of the test selected women for admission who were most likely to deliver imminently. Prior to the introduction of the test the mean cost per woman was £1,032. Eighteen women were seen during the two month period. Over 12 months this translates into 108 women, with a total cost of £111,456. Following the introduction of the fFN test the saving was £693 (95% CI £464 to £922) per woman. If the annual number of 108 received the fFN test and were managed accordingly the total saving could be £74,844 (95% CI £50,112 to £99,576). Our economic analysis also demonstrates the significant cost saving that resulted even ten months after introduction of the test. The main cause of the saving was the decrease in the number of inpatient days followed by a lower use of tocolysis for women who were destined not to deliver. This is consistent with a systematic review with cost analysis of fetal

fibronectin based on modelled costs and unpublished data, which showed that admission rates had the largest effect on cost savings after introducing fetal fibronectin testing (Deshpande et al 2013). The reduction in tocolysis costs were less substantial and cost savings would be even lower in a unit that uses alternative unlicensed tocolytics.

The strength of this study is that it was a prospective, planned implementation incorporating fFN testing into a threatened preterm labour algorithm using real life costs. We audited all antenatal admissions before implementation to determine how much the diagnosis of threatened preterm labour contributed to our total admissions. The study was supported by inclusive training for both midwives and doctors and was communicated around the perinatal network. There were no adverse outcomes. The weaknesses of our study are that it was confined to one centre within the perinatal network and we reaudited over a relatively short duration. A longer time period will be required to monitor the effect of fFN testing on the whole network, as any new policy takes time to be implemented to full effect (Musaad et al., 2005). Future audits are planned across our perinatal network to study the effect of fFN testing on transfers within the network, steroid and tocolytic use.

Conclusions

One year after its introduction, use of the fFN test in a tertiary level maternity unit lead to a sustained reduction in the hospital costs associated with women presenting in threatened preterm labour. The test carries an initial cost when applied to this patient group. The cost-savings are substantial and are mainly associated with a reduction in inpatient stay.

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Declarations of Interest

ALD is an unpaid member of the Hologic European Perinatal Advisory Board. The other authors report no conflict of interest.

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Table 1: Primary reasons for preterm antenatal admission at 22 to 34+6 weeks of gestation

Primary diagnosis	Jan – Feb 2009	%	Jan – Feb 2010	%
Threatened preterm labour	18	26.1	11	13.9
Established preterm labour	2	2.9	3	3.8
PPROM	4	5.8	13	16.4
Maternal medical indication*	11	15.9	17	21.5
APH other than placenta praevia	8	11.6	8	10.1
Placenta praevia	5	7.2	2	2.5
Gestational hypertension	7	10.1	9	11.4
Fetal medicine indication∆	6	8.7	9	11.4
Fibroid-related pain	3	4.3	1	1.2
Incidental short cervix (<25mm)**	0	0	2	2.5
Not answered	**5**	**7.2**	**0**	**0**
Total number of admissions	**69**	**100%**	**79**	**100%**

*Maternal medical indications included management of diabetes, suspected pulmonary embolus, infections, systemic lupus erythematosus and headache
∆Fetal medicine indications included fetal growth restriction, and fetal structural abnormalities
APH: antepartum haemorrhage
Gestational hypertension includes PET: pre-eclampsia and PIH: pregnancy induced hypertension
PPROM: Preterm premature rupture of the membranes
**Note: Routine screening for cervical length at the 20 week anomaly scan was introduced between the two audit periods

Table 2: Antenatal preterm admissions (22 – 34+6 weeks of gestation) for threatened preterm labour and their management before and after introduction of the fFN test.

Cases	**Jan-Feb 2009**	**Jan-Feb 2010**
Total number of preterm admissions	69	79
Threatened preterm labour admissions	18	11
In utero transfers in or out for threatened preterm labour	3	2
Cases of threatened preterm labour in which women did deliver		
Preterm births	3	4
Admission to delivery total number of bed days, (median length of stay)	24 days total, (8 days)	29 days total, (3 days)
Cases of threatened preterm labour in which women did not deliver		
Number of admissions	14	7
Admission to discharge total number of bed days, (median length of stay)	132 days total, (2 days)	25 days total, (3 days)
Maternal steroid treatment	11/14	7/7
Tocolysis treatment	5/14	1/7

Table 3: Total resource use and cost of patients presenting with threatened preterm labour before and after implementation of the fFN test.

Cost components and unit costs		Jan-Feb 2009 cohort before fFN implementation (N=69)				Jan-Feb 2010 cohort after fFN implementation (N=79)				
		Resource use data			Cost per patient, mean £ (95% CI)	Resource use data				Cost per patient, mean £ (95% CI)
Cost components	Unit costs, £	Full, count	Minor, count	Combined, count (mean, std. err.)		Full, count	Minor, count	fFN only	Combined, count (mean, std err.)	
Inpatient days*	420	72 days	84 days	156 days (2.26, 0.18)	950 (801 - 1099)	8 days	46 days	0 days	54 days (0.68, 0.09)	287 (211 - 364)
FBC	12	8 tests	10 tests	18 tests (0.26, 0.06)	3 (2 - 5)	1 test	10 tests	2 tests	13 tests (0.16, 0.04)	2 (1 - 3)
Group and Save	20	8 tests	10 tests	18 tests (0.26, 0.06)	5 (3 - 8)	1 test	10 tests	0 tests	11 tests (0.14, 0.04)	3 (1 - 4)
MSU	20	8 tests	10 tests	18 tests (0.26, 0.06)	5 (3 - 8)	1 test	10 tests	10 tests	21 tests (0.27, 0.06)	5 (3 - 8)
HVS	25	8 tests	10 tests	18 tests (0.26, 0.06)	7 (4 - 10)	1 test	10 tests	8 tests	19 tests (0.24, 0.06)	6 (3 - 9)
Ultrasound scan	70	6 scans	10 scans	16 scans (0.23, 0.06)	16 (8 - 24)	1 scan	9 scans	0 scans	10 scans (0.13, 0.04)	9 (3 - 14)
Atosiban	339	8 Rx	0 Rx	8 Rx (0.12, 0.04)	39 (12 - 67)	1 Rx	0 Rx	0 Rx	1 Rx (0.01, 0.01)	4 (-4 - 13)
Atosiban infusion equipment¶	5	8 Rx	0 Rx	8 Rx (0.12, 0.04)	1 (0 - 1)	1 Rx	0 Rx	0 Rx	1 Rx (0.01, 0.01)	0 (0 - 0)
Maternal steroid injection	5	8 Rx	6 Rx	14 Rx (0.20, 0.05)	1 (0 - 2)	1 Rx	10 Rx	0 Rx	11 Rx (0.14, 0.04)	1 (0 - 1)
In utero transfer	100	2 transfers	0 transfers	2 transfers (0.03, 0.02)	3 (-1 - 7)	0 transfers	1 transfers	0 transfers	1 transfer (0.01, 0.01)	1 (-1 - 4)
Analgesia	10	8 Rx	10 Rx	18 Rx (0.26, 0.06)	3 (1 - 4)	1 Rx	10 Rx	5 Rx	16 Rx (0.20, 0.05)	2 (1 - 3)
fFN test	35	0 tests	0 tests	0 tests (0.00, 0.00)	0 (0 - 0)	1 test	10 tests	31 tests	42 tests (0.53, 0.08)	19 (13 - 24)
Mean cost per woman, £					**1032 (880 - 1184)**					**339 (261 - 417)**

fFN = fetal fibronectin; FBC = full blood count; MSU = mid stream urine culture; HVS =high vaginal swab for culture; Full: full admission defined as hospital admission, laboratory investigations, a fetal ultrasound scan if clinically indicated, use of analgesia, steroids, tocolysis and *in utero* transfer if necessary; Minor: minor admission defined as hospital admission, laboratory investigations, a fetal ultrasound scan, use of analgesia, steroids and *in utero* transfer if necessary; Rx: prescription.

* Total inpatient days in full or minor admission group until discharge or delivery if delivered during admission

¶ Includes syringe pump, syringe and giving set