

**Fetal Fibronectin Testing for the Diagnosis of Preterm
Labour: A Review of the Economics Literature and
Cost Analysis for Alberta**

Report prepared for the Alberta Health Technologies
Decision Process: Fetal Fibronectin Project

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Fetal fibronectin testing for the diagnosis of pre-term labour

1.0 Background

Preterm birth (PTB) is one of the biggest problems in modern obstetrics. Preterm birth is responsible for the majority of perinatal mortality and adverse long-term neurological outcomes. Preterm birth rates in Alberta are higher than the national rate, and both have been rising over time. In 2004, in Alberta almost 9% of live births were preterm. PTB can arise due to spontaneous labour with or without premature rupture of membranes, or it can be as a result of an intervention induced by fetal or maternal complications. For spontaneous preterm labour (PTL) without rupture of membranes, the majority of women presenting with symptoms will go on to deliver at term (over 80% deliver at term). Thus, the challenge in practise is to correctly identify those women who are in true preterm labour and will deliver preterm.

The objective of early diagnosis is transfer to an appropriate tertiary centre, administer corticosteroids to help maturation of immature neonatal lungs, perhaps administer antibiotics and possibly administer tocolytics to prolong pregnancy. Correct diagnosis means identifying which patients need these treatments and which do not. The fetal fibronectin (fFN) test is a diagnostic test that can be used to help diagnose PTL in women with signs and symptoms of labour, intact membranes and less than 3 cm cervical dilation. The signs and symptoms of preterm labour are regular uterine contractions, low abdominal cramping, low back pain, pelvic pressure or increased vaginal discharge. The positive predictive value of the test for delivery within 7 days is 20%, meaning that 20%

of women testing positive will go on to deliver within 7 days. The negative predictive value of the test for delivery within 7 days is 99%, meaning that 99% of women testing negative will not deliver within 7 days (Norman and Greer, 2005).

The primary advantage of the test is its simplicity of use and the strong negative predictive value. This potentially gives the ability to more accurately identify those women who are in true preterm labour, and who therefore need to be transferred and treated. Importantly, transfer and treatment can be avoided for those women determined not to be in true labour. This can save health care resources in transferring patients and in inpatient admissions for preterm labour, as well as provide peace of mind and enable women to remain in their community and homes.

2.0 Objectives

This report was prepared as part of the Alberta Health Technologies Decision Process review of fFN testing in Alberta. In addition to this report, the AFHMR Health Technology Assessment Unit prepared a report entitled “The role of the rapid fetal fibronectin assay in the management of suspected preterm labour” which contains details on the biological basis of the test, the mechanism of the test, and on diagnosis and management of PTL including the role of fFN, the regulatory status in Canada, unpublished Canadian studies of the impact of fFN (including the economic impact) and reviews published systematic reviews and health technology assessment studies. Therefore, these topics are not duplicated in this report.

The objectives of this report are as follows:

1. Review of the published literature examining economic impact of fFN test.
2. Describe population characteristics of Alberta women presenting with symptoms of PTL (number, age, socioeconomics, regional distribution).
3. Examine the cost implications of fetal fibronectin testing in Alberta.

Part I of this report contains the review and summary of the published literature on the economic impact of fFN testing. Part II of this report addresses the second and third objectives using administrative data.

Part I: The Economics of Fetal Fibronectin Testing for the Diagnosis of Preterm Labour: A Literature Review

3.0 Introduction

The purpose of Part I of this report is to summarize the available published evidence on the economic impact of fetal fibronectin testing for the diagnosis of preterm labour. As noted previously, there is also additional Canadian evidence which does not yet appear in the published literature. That unpublished evidence is not presented in this document, but is summarized in the AFHMR report prepared as part of the Fetal Fibronectin Health Technology project.

4.0 Methods

A review of the literature was conducted to identify relevant articles for this review. Relevant databases were searched as well as bibliographies of the selected papers. We selected studies for review which examined the impact of fetal fibronectin testing on hospital admission, length of stay, maternal transfers, use of tocolytics and corticosteroids as part of a comparative study of different strategies for the management of preterm labour, including fFN or not. The impact on quality of life, including maternal anxiety and stress was also considered. Details of the search strategy can be found in Appendix 1. In the following section, the results of the literature review are presented, and the evidence available from studies using non-experimental design approaches, including

decision modelling, and experimental (randomized controlled trial) designs is presented and critically reviewed.

5.0 Results of the Literature Review

Ten papers were selected for full review. The papers selected are identified and summarized in a Table in Appendix 2. The published literature on the economics of fetal fibronectin testing ranges from 1999 through 2005 and includes both non-experimental and experimental study designs (cohort studies pre- and post-introduction of fFN and also randomized controlled trials) and two decision-analytic modelling studies. The evidence comes from primarily out of the United States (seven studies), with a single study from each of Canada, New Zealand and Australia. Most of the published studies look at the impact of fFN testing at tertiary care hospitals only, with only two studies that considered referring hospitals as well (Giles *et al*, 2000, Joffe *et al*, 1999). Only the Giles *et al* study however, explicitly considered the effect on transfers; the Joffe *et al* study did not identify transfers but noted that patients were selected who presented to either physician's offices or the hospital.

5.1 *Non-experimental evidence*

The conclusion based on the non-experimental evidence is that the potential for changing the management of preterm labour and reducing admissions for threatened preterm labour promised by the high negative predictive value of fFN testing can be realized in practice.

The first studies came out of the U.S. and Australia (Joffe *et al* 1999, Giles *et al* 2000). Joffe *et al* 1999 was a pre-post fFN comparison of admissions, and tocolytic prescriptions as well as neonatal outcomes. Compared to baseline, there were significantly fewer admissions for PTL, fewer prescriptions written, fewer admissions per patient and shorter length of stay. There were no differences in neonatal outcomes (NICU admissions, length of stay, and days of ventilator support). This was one of the few studies which considered neonatal outcomes.

The Giles *et al* 2000 study was based upon an 18 month prospective audit of fFN use, and did not actually compare the fFN tested group with an untested historical control group – thus its estimates of cost savings are misleading. They compare the management of the fFN positive group and the fFN negative group and estimate costs savings of fFN for transfers based on an assumption that in the absence of fFN testing all patients who tested negative would have been transferred. This would overestimate the costs savings. This study was the only one that explicitly looked at transfers from rural hospitals to tertiary facilities, thus it is unfortunate that the study is flawed and renders the conclusions about transfer uncertain.

The only published Canadian evidence comes from Abenhaim *et al* 2005 which looked at the impact of fFN testing on hospital resource utilization at a university-associated tertiary care hospital in Montreal. A prospective cohort of 116 women presenting with preterm labour after fFN testing was available was compared with an historical cohort of women prior to the availability of fFN. There is little information given about the

selection of the historical cohort other than to say they were identified through a systematic review of all birthing centre triage visits, admissions and discharges – as was the cohort for the post-fFN period. Overall, in the post-fFN time period, there were lower admissions for PTL with eventual discharge undelivered, and there was a statistically significant 88% reduction in days hospitalized and lower total cost. The post-fFN study period did not begin until six months after its introduction to allow a learning period by clinicians in terms of the use and interpretation of the test. It is important to note that not all patients in the post-fFN period actually had an fFN test conducted – including some who were admitted and delivered preterm, and others who were discharged with alternate diagnoses. 47 fFN tests were done (out of 116 women) – the rest were diagnosed based on clinical criteria. If fFN tests had been done on all women, this may have impacted the results – highlighting the importance of an explicit fFN protocol to guide how the test can be incorporated into the management of PTL. It is also important to note that 25% of the fFN tests conducted were “inappropriate” (although half of these were for twin gestations, which other studies did not exclude) - these costs were included in the analyses, so again this highlights the importance of education around the appropriate use of the test as well as potentially greater gains to be made in cost savings.

The most recent study adopting a non-experimental design was conducted in New Zealand (Mussaad *et al* 2005). This is the only of these studies not to find a difference in spending on management for PTL. They did find a difference in the use of tocolytics and steroids, however this did not translate into cost savings. There was no difference in length of hospital stay. They also found no difference in neonatal outcomes (NICU

admissions, and invasive ventilation). However, this was a very small study with only 30 patients in the post-fFN group matched with 30 historical controls and there are issues around patient selection. They also considered the first 30 fFN tested patients so did not allow any time for a settling in period for familiarization with the test and how to interpret it. They specify that all patients testing positive are admitted which may not be an appropriate management strategy based on the poor positive predictive value of the fFN test. For all these reasons, the results of this study are not particularly robust.

5.2 Decision modelling approach

There were two studies which adopted a decision modelling approach to examine the potential impact of fFN testing. Decision models create a set of strategies which might be adopted, incorporate data from local sources as well as typically relying in large part on data from the literature, and examine the relative costs and effects of those different strategies.

The first published decision model was the Mozurkewich *et al* 2000 study. They consider six different strategies for the management of threatened pre-term labour (patient presents with regular contractions, between 24-34 weeks, with intact membranes and cervical dilation <3 cm). The strategies considered are (1) treat all with tocolytics and corticosteroids, (2) administer ‘traditional’ fFN test and in meantime treat all, discontinuing those who are negative, (3) administer cervical ultrasound (transvaginal or transperineal) and treat only with abnormal cervical length measurements, (4) administer ‘rapid’ fFN and treat those who are positive, (5) administer rapid fFN plus ultrasound and treat those with abnormal results on at least one, (6) treat none. They further consider an

additional 3 strategies – (7) treat all women with outpatient corticosteroids only, (8) corticosteroids to all, tocolytics only to those with positive rapid fFN test, and (9) corticosteroids to all, tocolytics only to those with abnormal cervical length. The majority of the data for the decision model was taken from the literature, and also from local institutional data (Michigan). The outcome focus was on respiratory distress syndrome (RDS) and neonatal death. They found that the cheapest strategy was the treat all with corticosteroids, the strategy with the lowest number of cases of RDS was the cervical length plus corticosteroids strategy, and the strategy with the fewest neonatal deaths was the same for treat all as cervical length plus corticosteroids (and almost the same for both fFN strategies). Compared with treating all women with threatened preterm labour, the authors conclude that risk assessment strategies using either fFN or cervical length assessment offer cost savings and prevent cases of respiratory distress syndrome and neonatal death. The addition of corticosteroids improves the clinical outcomes at lower costs.

The Sullivan *et al* 2001 adopted a decision-modelling approach to assess the question of the impact of fFN testing in reducing costs of managing PTL. They use local data on PTL from a U.S. hospital and data from the literature on fFN testing as estimates in their model. They compare three strategies fFN testing on all, examination alone and fFN testing only on those for whom clinical criteria suggest admission. They find that costs can be higher if fFN is done on all women, rather than on those for whom clinical criteria alone can not rule out PTL. The admission rates rise in the presence of fFN testing – they assume that all positive fFN patients would be admitted. Some of the estimates built into

the model are not based on any available evidence - in particular, the assumptions about the prevalence of a positive fFN assay in the context of the different strategies.

5.3 Experimental study design

The strongest study design to answer the question of the impact of fFN testing is an experimental design - that is, randomized controlled study design. There are four reported randomized controlled trials, all conducted in the U.S. at tertiary care hospitals: three have been published (Grobman *et al* 2004, Lowe *et al* 2004, Plaut *et al*, 2003) and an additional one is published in abstract form (Nguyen *et al* 2002). The findings from these studies are mixed. They do not, in general, provide strong evidence that fFN testing reduces health care utilization: the Grobman *et al*, 2004 study of 100 randomized patients concludes that fFN testing did not reduce the health resource utilization, the Lowe *et al*, 2004 study of 100 randomized patients found no significant difference between groups in terms of administration of drugs, length of stay in labour and delivery, admissions and length of stay in the antepartum ward using standard analytic techniques but do find evidence of a shorter length of stay using a hazard model approach, and the Nguyen *et al* 2002 study of 77 randomized patients conclude that fFN testing increased time spent in triage and hospital charges. The Plaut *et al*, 2003 study randomized 100 patients and found no difference in length of stay in general, however they did note a 40% decrease in hospital stay for those women who were observed longer than six hours.

The Nguyen *et al* 2002 study has not been published in full, therefore it is not possible to fully assess the adequacy of this evidence. There is insufficient evidence provided about the study design, including the management of patients in the no fFN group. They

indicate that *all* patients with a positive fFN result underwent further observation. This appears to be an inappropriate use of the test. In addition, while the triage times were statistically significantly different but it is not clear that an 18 minute difference is meaningful from a policy perspective.

The Plaut *et al* 2003 RCT originally planned to focus on transfers to tertiary care hospitals, but stopped their study early due to lack of enrolment. No reasons are provided for the difficulty in enrolling patients – fFN testing was not available outside the study protocol. The authors report an analysis of length of stay. While overall length of stay was not significantly different between the group who had fFN test results available and the group that did not, there was a 40% decrease in hospital stay for the group at higher risk of PTL (i.e., those who had longer periods of observation). No fFN protocol was developed and implemented as part of the trial, but the authors argue that they “...attempted to mimic the real world, where physicians are educated about a test and then try to incorporate it in their practice.”

The Grobman *et al* 2004 study focussed on whether fFN testing changed physician behaviour and resultant health care costs. The fFN test had not been used in their hospital setting prior to the study, and was only available within study protocol during the study. The fFN swab was conducted following cervical exam for all patients who met the inclusion/exclusion criteria but then patients were randomized into two groups: one where the attending physician had the results available and one where they did not (the swabs were frozen and analyzed as a batch later). Since the attending physicians were not

familiar with using fFN in practice, an educational intervention was provided as well alongside the trial: prior to the study a letter explaining the characteristics of the test was sent to admitting obstetricians. Also when fFN test results were provided to physicians, they were reminded of the meaning of the results with the delivery of a standardized reminder. No evaluation of the effectiveness of the educational intervention was conducted.

The Grobman *et al* study found no difference in time spent in labour and delivery for initial evaluation, frequency of tocolysis or corticosteroids, admissions or readmission post-discharge. Sub-group analysis was conducted by time to assess whether there was a learning curve in terms of altering behaviour – they found no difference, however the study was not powered for this analysis. This study fails to find a difference in behaviour. It is unclear whether these admitted obstetricians are already doing a very good job on correctly identifying PTL and thus there was not room for much improvement or alternatively whether the educational intervention failed to adequately inform clinicians how to use the fFN test results in supplementing their clinical judgement. The authors conclude that further evidence is needed and “perhaps, for example, a standardized clinical pathway may need to be implemented if the value of these tools is to be realized optimally.”

The Lowe *et al* 2004 study looked at the impact of fFN testing on length of hospital stay and preterm labour interventions in the context of a tertiary care hospital in the U.S. Their inclusion criteria allowed twin gestations and included greater cervical dilation than

other studies for multiparous women. They included women who had already been started on tocolytics or other therapies prior to transfer to the tertiary care facility in their study, but do not report on the percentages in each arm, so it is difficult to interpret their results on drug use. Overall, the results of this RCT did not find any difference in the two groups in terms of time spent in labour and delivery, admission to the antepartum unit, length of stay on the antepartum ward, use of tocolysis, steroids and antibiotics. However, using Cox proportional hazards model, and adjusting for previous preterm birth, cervical dilation and gestational age, they did find that fFN women had a shorter stay in labour and delivery. The authors did not report on any testing that the assumptions of that model were met, however, it is of note that this study found this difference using a different method of analysis than the standard unadjusted difference in means between two groups. This raises the question of why these adjustments were not made in other studies, as well, and what the implications may be for their conclusions.

In summary, the evidence from RCTs is mixed. Generally, little evidence supporting the potential of fFN to change management of PTL, and reduce unnecessary treatment, was provided. However, two studies, Plaut *et al* 2003 and Lowe *et al* 2004 did report reduction in length of stay for some women. It is possible that the inability to detect any change in behaviour in some studies, was due in part, to the lack of a effective educational intervention and the lack of an implemented fFN testing protocol – thus physicians did not incorporate the fFN test results to change their management of preterm labour.

6.0 Conclusions

The following summarize the conclusions of the review of the literature:

- Based on its high negative predictive value, fFN testing has theoretical potential to reduce health care utilization and unnecessary treatment by more accurately identifying women who are not in true preterm labour.
- The potential of fFN testing has been shown in non-experimental studies, but given the study design, the change in behaviour may be due to factors that influenced changing practice patterns, other than the introduction of the fFN test.
- The potential to reduce health care utilization and unnecessary treatment has not been confirmed, for the most part, in the experimental (RCT) studies that have been conducted. These RCTs did not incorporate explicit protocols for positive and negative fFN management, nor did they incorporate demonstrated educational interventions. Knowledge translation is a key component of these RCTs however this was not fully addressed by any of the trials. This may explain the limited impact of fFN testing in terms of change in behaviour managing PTL.
- Both the non-experimental and experimental evidence has flaws, which affect the robustness of their conclusions.
- The literature supports the importance of establishing a protocol for the use of fFN results in the management of PTL, education both initially and on an ongoing basis is required and audit is necessary to ensure the potential is realized. "...if physicians are reluctant to abandon interventions in the setting of a negative test

result and begin to use increased interventions after a positive test (which has a low predictive value), the number of medical and social resources that are consumed will actually increase after the use of the test.” Grobman *et al*, 2004.

- There is a suggestion that using fFN testing is most useful in the context where clinical criteria would warrant admission (Plaut *et al*, Sullivan *et al*, Abenhaim *et al*). For those whom clinical criteria rules out PTL there is little benefit; there is particular benefit for those at ‘high-risk”, *i.e.*, those who would be admitted on clinical criteria.
- The published literature considers the impact of fFN testing available in referral tertiary hospitals where admissions (or transfer) for care for PTL would occur. The impact of fFN testing outside these settings has not been examined in the published literature.
- None of the studies considered the impact of fFN testing on quality of life, and in particular maternal stress and anxiety. A study looking at using fFN testing to predict preterm delivery in non-symptomatic high risk women (Shennan *et al* 2005) found that a positive fFN result was associated with statistically and clinically significantly higher levels of anxiety. However, this is not likely applicable to the use of the test in women experiencing signs and symptoms of PTL who are already experiencing high levels of anxiety.

Part II: Analysis of cost implications of fFN testing for Alberta

7.0 Introduction

The objectives of Part II of this report are to describe the population characteristics of Alberta women presenting with symptoms of PTL as well as to examine the cost implications of fetal fibronectin testing in Alberta. The objectives of this study are addressed by an analysis of administrative data from Alberta Health and Wellness.

8.0 Data extraction strategy from Alberta Health databases

We identified all individuals in the inpatient or ambulatory care databases with a diagnosis of O42.xxx, O47.xxx, O75.xxx or O60.001 or grouping to CMG 599 or CMG 619. (See Appendix 3) We received demographic information and information on all inpatient, ambulatory care and physician services received during the first encounter and following that until fiscal year end. (See Data requirements summary in Appendix 4). We have received data year 2004/2005, and also data year 2002/2003¹. In 2004/2005, fFn testing had already been implemented in the Calgary Health Region and in addition during the period June 15, 2004 through Feb 15, 2005 a pilot study using the fFN test was being conducted at the Royal Alex.

¹ Fiscal year 2002/2003 has been received as of March 3, 2006, but is not included in this report. Note, additional analyses for 2002/3 are not included in the primary analysis. However, where relevant this data will be referred to.

The initial data extraction strategy involved a broad inclusion strategy. Our initial analysis will focus on three sub samples of women: those women with a diagnosis of O47003 (threatened preterm labour <37 weeks gestation), or O75803 (preterm labour with delivery delayed by therapy, antepartum condition) or O60000 (preterm birth). We will further exclude those women whose gestational age at the time of diagnosis was >35 weeks, and who had ruptured membranes (O42xxx) since the fFN test is not appropriately used in these women.

9.0 Population Characteristics of women presenting with threatened preterm labour

The following descriptive information is provided on the sub-sample of women who present with symptoms of preterm labour and have an inpatient or outpatient encounter with a coding of O47003. There were 1962 such women. We then exclude those from whom we could not confirm when they gave birth (171 women), who had ruptured membranes (144), who were at gestational week above 35 at first visit (297), who had missing age of the mother and missing gestational age (5). We also excluded 99 women who had an outpatient assessment for threatened preterm labour but did not have an inpatient assessment – presumably these women were ruled out as being in true preterm labour in the outpatient setting and thus fFN testing was not relevant. We ended up with a sub-sample of 1247 women. This includes 212 women who were at gestational week 35 at their first visit. The project charter suggested that these women are part of the target population although the Society of Obstetricians and Gynaecologists of Canada's

special report on Preterm labour refers to women less than 34 weeks gestation as the target population.

We will also present similar information about a second sub-sample of women who had a diagnosis of O60000 (PTB) but without having had a diagnosis coded O47000, as these women are also women who presented to the system with signs of PTL. Because they actually progressed to give birth, they may not have had a coding of threatened labour although at their initial presentation they would have been considered in threatened labour until the diagnosis was confirmed. These women will also be considered as potential patients on whom the fFN test might be conducted. There were 2734 of these patients. Those who had ruptured membranes were excluded (911), as were those who had had a previous admission for threatened PTL and were captured in the previous sub-sample (294), and those who were at greater than gestational week 35 at the visit (651) and those for whom there was no age/region of residence information (2). This sub-sample does include 247 patients at gestational week 35. This final sub-sample consists of 844 women.

Finally, we consider the sub-group of women with a diagnosis of O75803 (preterm labour, delivery delayed by therapy). There were 696 such women. After excluding those for whom we could not confirm date of birth (76), those with ruptured membranes (41), outpatient assessment without inpatient admission (5), no gestational age or mother's registry information (5), those already included in the other two sub samples (273) those with gestational age greater than 35 at first visit (154). We also included in

this group 149 patients from the O47.003 sub sample who had an outpatient admission for O47.003, but never had an inpatient admission for O47.003. This resulted in a final sub sample of 291, including 11 at gestational week 35.

9.1 Number of women

In 2004/2005 there were 1247 women diagnosed with threatened PTL in either an outpatient or inpatient setting. In 2004, there were 40,581 births in the province so this represents approximately 3% of births. There were also 846 preterm births in women who never had an episode of threatened PTL, and another 280 with a diagnosis of preterm labour delayed by therapy. In total, there were 2396 women who would have initially presented to the system with symptoms of PTL. This represents 5.9% of births in 2004.²

In the 1247 women diagnosed with threatened PTL, 359 of them have an inpatient admission for threatened PTL. There are 394 inpatient admissions in this group. Of the 888 patients with an outpatient admission for threatened PTL only, for all but one there is an eventual birth related inpatient admission. 238 of these women had additional inpatient admissions prior to the birth admission – 139 of these were for 075.803 and as noted these women we included in that sub-sample. The remainder of these admissions were for other complications such as gestational hypertension, cervical incompetence, hemorrhage, or other diseases complicating pregnancy.

² There were 40,581 births in Alberta in 2004-2005 (Source: Alberta Perinatal Health Program).

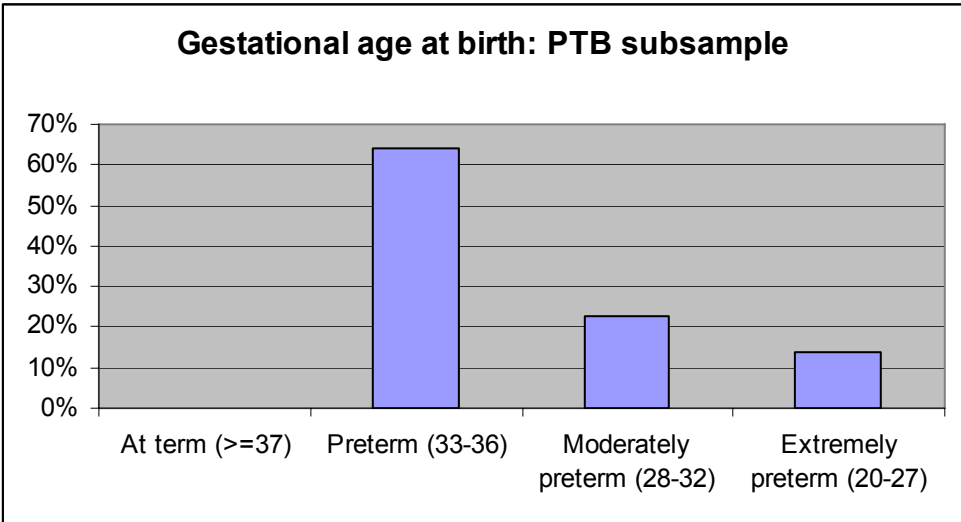
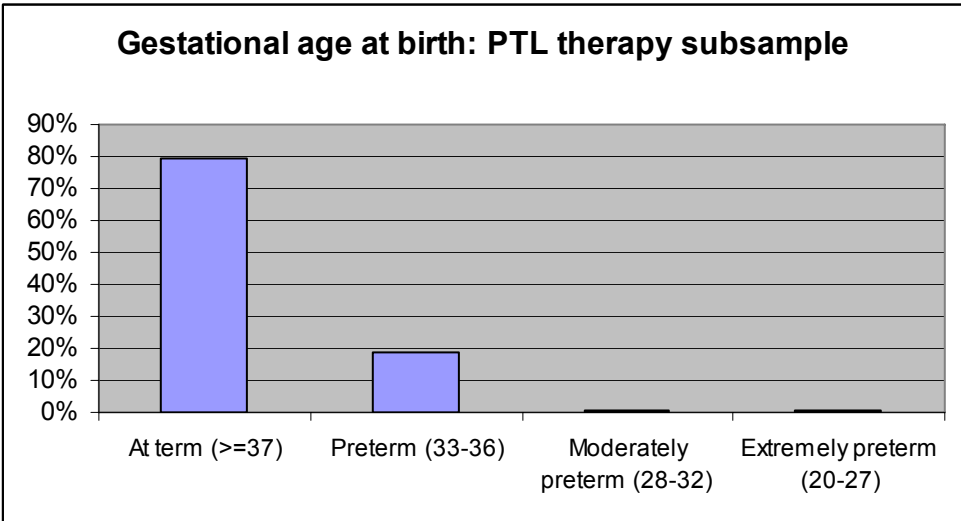
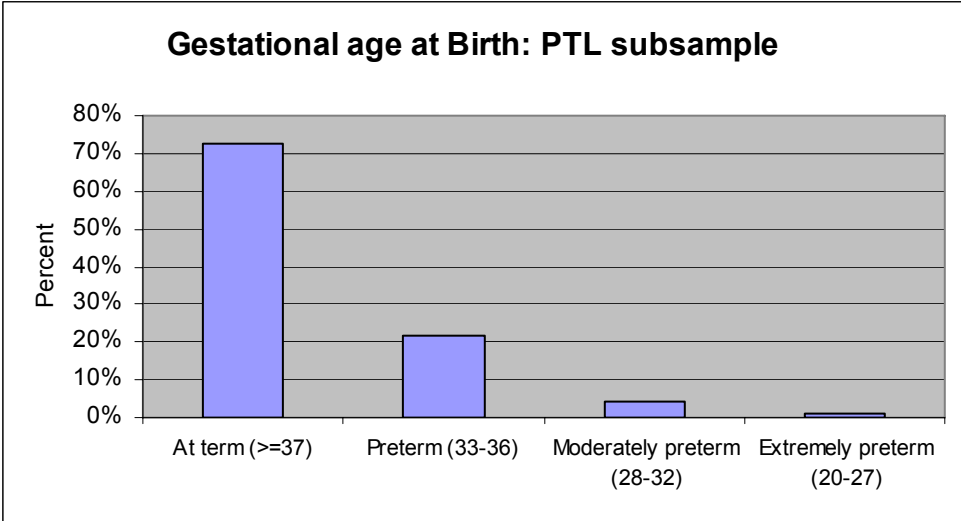
In the 844 women with a PTB diagnosis, there are 846 inpatient admissions. There are two women who have two preterm births during the one year period of our data.

In the 291 women with a diagnosis of preterm labour with delivery delayed by therapy, there are 280 inpatient admissions. There are 11 women with an outpatient admission, but no inpatient admission for this diagnosis.

9.2 Gestational age at birth

Women with threatened PTL presented for the first time between gestational week 12 and 35, with the average gestational age being 31 weeks. The average gestational age at birth was 37 weeks. 73% of these women went on to give birth at term (≥ 37 weeks), and 27% gave birth preterm. 22% of them were born between preterm between 33-36 weeks, 4% moderately preterm between 28-32 weeks and 1% were extremely preterm between 20-27 weeks. Similarly, in the sub-sample of women with preterm labour delayed by therapy, 80% delivered at term, 19% delivered between 33-36 weeks, and 1% each were moderately or extremely preterm.

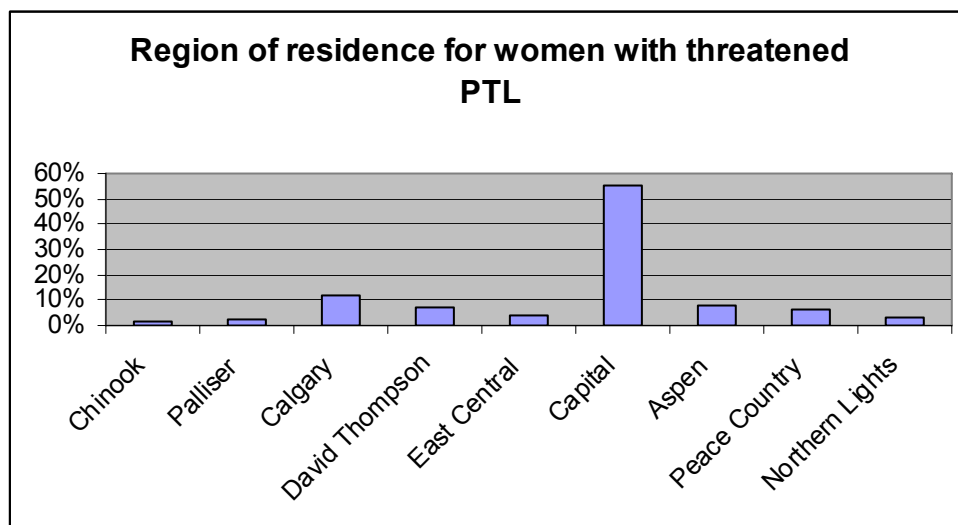
In the PTB sub-sample, the average gestational age was 32 weeks. 64% were preterm between 33-36, 22% were moderately preterm between 28-32 weeks and 14% were extremely preterm between 20-27 weeks.



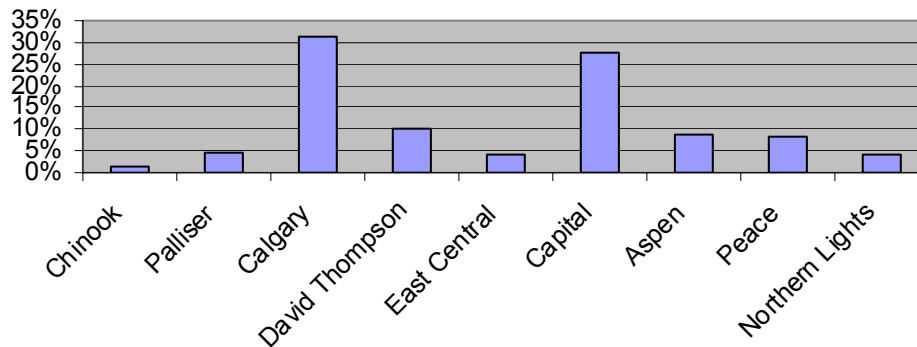
9.3 Regional distribution

For the 1247 women with threatened preterm labour, over 50% of them were from Capital Health Region and only 11% were from the Calgary Health Region. However, when you look at only the 394 women with inpatient admissions for threatened preterm labour, we see 31% in Calgary and 28% in Edmonton. This is in comparison to Calgary accounting for 36% of all live births and 38% of all preterm births, while Capital accounts for 29% of all births and 31% of preterm births in 2003 (Alberta Reproductive Health Report, 2005 Tables update). There are far more women in Capital who have an outpatient assessment for threatened preterm labour, however roughly the same number of women in the two regions who have admissions for threatened preterm labour.

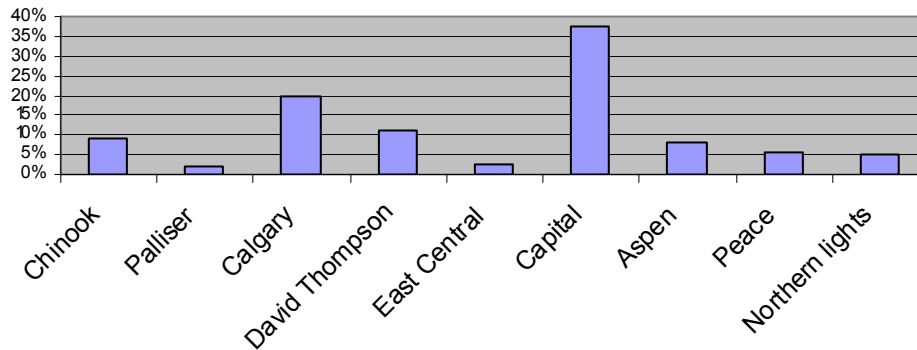
For the group of women experiencing PTB without a previous PTL admission, Calgary accounts for 44% and Capital accounts for 27%. We can also see that for the sub sample with the diagnosis of PTL delayed by therapy, Calgary accounts for 20% and Capital accounts for 37%.



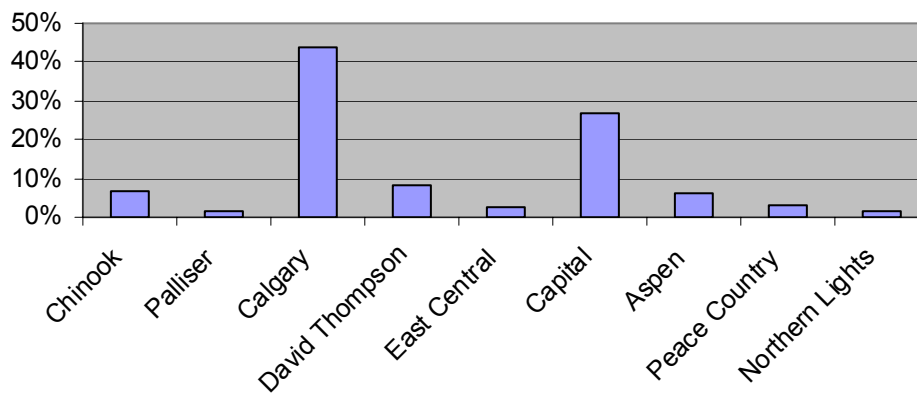
Region of residence for women with threatened PTL inpatient admissions



Region of residence for women with PTL delayed by therapy



Region of residence for women with PTB



9.4 Age Structure

The average age of women presenting with PTL was 27, with the youngest being 15 and the oldest being 44. The average maternal age for all births in Alberta in 2003 was 29. Thus, this sub-sample of women presenting with PTL is a younger group. The group of women with PTL delayed by therapy are similar with an average age of 27. In both groups, there was no difference in the maternal age for those who went on to give birth at term, versus those who did not. For the PTL sub-group, average maternal age by region is shown below.

Average Maternal age by region of residency
(PTL sub-sample)

RHA	Age (years)
Chinook Regional Health Authority	24.6
Palliser Health Region	28.3
Calgary Health Region	27.7
David Thompson Regional Health Authority	25.8
East Central Health	27.3
Capital Health	28.0
Aspen Regional Health Authority	25.1
Peace Country Health	25.4
Northern Lights Health Region	26.5

The average age of women in the PTB sub-sample is 30 years, with the youngest being 14 and the oldest being 46. These women are slightly older than the average maternal age for all births in Alberta.

9.5 Socioeconomic Structure

The indicator of socioeconomic status available in the data is whether the mother is aboriginal, receives health care premium support or is on welfare. In the sub sample of women presenting with PTL, 10% are aboriginal, 16% receive premium support and 9% are on welfare. The sub sample with PTL delayed by therapy is very similar. The aboriginal and people income support groups are overrepresented in this sub sample of women compared with the female population between 13 and 50, or with distribution of children under the age of 1. In particular, those on welfare which is 9% of the women with threatened PTL, but account for only 3% of childbearing women and 3.5% of children less than one. Also 10% of the women with threatened PTL are aboriginal compared to 4% and 6% of the childbearing women and children under 1 respectively.

The group of women with PTB more closely mimic the population of childbearing women or of children under age 1, but are still over represented in the aboriginal, premium support of welfare groups. This disparity is more evident though in the group of women with threatened preterm labour.

Women Presenting with Preterm Labour 2004/2005

SES	Count	% Distribution
0	823	65.5%
A	131	10.4%
S	195	15.5%
W	108	8.6%
Total	1257	100.0%

Women with Preterm Birth 2004/2005

SES	Count	% Distribution
0	645	76.2%
A	72	8.5%
S	83	9.8%
W	46	5.4%
Total	846	100.0%

Female Population, Age >= 13 and <=50, Alberta, March 31, 2005

SES	Active Population Count (in 000's)	% Distribution
0	751.8	81.5%
A	37.1	4.0%
S	106.5	11.5%
W	27.0	2.9%
Total	922.4	100.0%

Source: Population Registry File 2004/2005

Female and Male Population, Age < 1, Alberta, March 31, 2005

SES	Active Population Count (in 000's)	% Distribution
0	31.3	77.3%
A	2.5	6.2%
S	5.3	13.1%
W	1.4	3.5%
Total	40.5	100.0%

Source: Population Registry File 2004/2005

10.0 Cost implications

10.1 Costs of fFN testing

As per the AHFMR fFN report, based on communication with the manufacturer³:

Specimen Collection Devices, consisting of a plastic tube with buffer, cap and swab are at no charge. Dating on the product is 4 years at room temperature. It is possible to break the specimen collection kits into individual units for small testing sites.

Test cartridges for fFN testing are in boxes of 24 and are \$97.27 per determination and have an 18-month dating from manufacture. It is possible to break the specimen collection kits into individual units for small testing sites.

The Tli IQ instrument system and printer which consists of all hardware components to run an fFN assay on site. For hospitals >1000 births/year, the hardware components are supplied at no charge. For hospitals <1000 births /year, the equipment is available on a rent-to-own basis for a 24 month payment of \$111 for 24 months or purchased for \$2668. Currently, all service, replacement and training costs are included.

These prices include all quality control of both the test cartridges and the Tli IQ.

³ This updates the costing information available in the Alberta Health Technologies Decision Process, Fetal Fibronectin Project Charter. The per determination cost is US\$100, and the instrument system is US\$2400. This has been converted to Canadian dollars at a rate of \$1.11.

10.2 Potential number of tests

Using administrative data on the number of admissions related to preterm labour symptoms, we can estimate the potential number of fFN tests that might be conducted if it were available. We have considered two different populations of patients as potentially eligible for the fFN test, and also considered the possibility that is available in different types of hospitals.

Potential number of tests done if all admissions for women in the various sub-sample groups are included:

- 394 inpatient admissions for women with threatened PTL diagnosis
 - 846 inpatient admissions for women with PTB diagnosis
 - Note – this is likely an overestimate as for some of these patients it may be obvious early that the symptoms of labour are progressing and an fFN test would not be done.
 - 280 inpatient admissions for women with PTL delayed by therapy
- Potential number of tests: 1520

Another possibility is that fFN testing is only done at Level II or Level III hospitals where treatment for possible preterm birth would be provided. The Level III hospitals are Foothills hospital in CHR and Royal Alexandra in Capital. The Level II hospitals are Lethbridge Regional in Chinook, Rockyview and Peter Lougheed in Calgary, Red Deer General in David Thompson, Misericordia and Grey Nuns in Capital, Queen Elizabeth II in Peace. For the purposes of this analysis, we have also included Medicine Hat

Regional Health Centre in Palliser. In this case, the number of potential tests is as follows:

- 321 admissions for threatened PTL
- 819 for PTB
- 265 for PTL delayed by therapy
 - Potential number of tests: 1405

10.3 Variable costs of fFN testing

This section considers the variable cost of the fFN test cartridges. The laboratory costs for processing are not included. There are two different scenarios considered in terms of the number of fFN tests that might be performed (see table below). The first (Scenario 1) is to assume that one test per inpatient admission would be performed and consider each of our three sub samples (those with PTL, those with PTL delayed by therapy and those with PTB) as the population on whom the test would be done. The variable cost of testing at \$100 per test, then would range between \$38,324 and \$147,850.

The other clinically relevant scenario is that the fFN test is only available at Levels II and III hospitals. If a woman is suspected of being in preterm labour then she would be transferred and admitted to one of these facilities depending on her gestational week of her pregnancy. If in both Level II and III hospitals, the cost of testing ranges between \$31,224 and \$136,664.

Variable cost of fFN testing

Scenarios	Number of tests	Variable costs of testing (\$97.27 per test)
<i>fFN testing in all facilities</i>		
PTL only (394)	394	\$38,324
above + PTL delay by tx (280)	674	\$65,560
above + PTB (846)	1520	\$147,850
<i>fFN test at Level II and III hospitals</i>		
PTL only (321)	321	\$31,224
above + PTL delay by tx(586)	586	\$57,000
above + PTB (819)	1405	\$136,664

10.4 Fixed costs

If only implemented in Levels II and III hospitals, there would be no fixed costs because the fFN hardware costs for hospitals with greater than 1000 births is provided at no charge.

If implemented in all hospitals: there are 62 Level I hospitals where births occurred in 2004. The total hardware costs, at \$2668 per, would thus be \$162,748.

10.5 Length of Stay

The average length of stay (LOS) for threatened PTL was 2.01 days, ranging between 1 and 69. Excluding two outliers (LOS > 30 days), the average LOS for admissions related to threatened PTL was 1.77.

The average length of stay for PTL delayed by therapy was 3.44 days, ranging between 1 and 48. Excluding outliers, the average LOS was 2.87.

The average length of stay related to preterm birth is 5.33 days, ranging between 1 and 50 days.

Recall that fFN testing had been implemented in the Calgary Health Region during the time period covered by this data. In the Calgary Health Region, the average length of stay for threatened PTL is 1.82 days. In the Capital Health Region, the average length of stay is 2.69. Not including the Royal Alex, the average length of stay in Capital is 3.5. The average length of stay for threatened preterm labour is shorter in the Calgary Health Region during this period (when fFN testing is being done) than in Capital. This should be interpreted with some caution, as there may be differences in the case-mix or other influencing factors between these two Health regions not related to fFN testing. Comparing LOS in the two regions in the 2003/2004 data shows that the LOS in Capital was also higher than Calgary without fFN testing, and that in both cases LOS fell over time. The rate of decline was larger in Calgary which may be associated with the availability of fFN testing, although this association can not be confirmed with this data.

Also, during the data year 2004/2005, Capital Health region was undertaking a pilot study of fFN testing at the Royal Alexandra. The fFN pilot study was going on during June 15, 2004 through February 15, 2005. The average length of stay during the fFN pilot study at Royal Alex was 1.85 days (excluding two outliers who had LOS of 30 and

69 days for which there were complicating factors determining the LOS). During the non-fFN availability at the Royal Alex, the average LOS was 2.91. Thus, the average LOS at the same hospital was a day shorter when the fFN test was available.

10.6 Average Costs for threatened PTL

9.6.1 Inpatient admission

The provincial average cost was \$669 per inpatient admission day.

9.6.2 Physician billing

The average physician billing was \$108 per inpatient admission day.

9.6.3 Potential costs avoided from LOS reductions

Consider the scenario of putting fFN testing into Level III and II hospitals only. There are 1405 admissions, including 819 for PTB. Using the information on average LOS at the Royal Alexandra as an indicator, we will assume that fFN testing reduces overall length of stay by 1 day. This is a conservative estimate – for example, the Calgary study showed a greater reduction in length of stay for specific admissions (see the AHFMR fFN report). Excluding those admissions that include PTB, this would result in a potential to decrease LOS then for 586 admission days. The hospitals in the CHR already have fFN testing – thus based on the number of admissions we assume that each would have lasted an additional day, and thus that there would have been an additional 194 admission days. These are admission days avoided which have an opportunity cost of \$150,554. In Capital Health, there is a potential for a reduction of 301 admission days. This represents a savings valued at \$233,576. In the other Level II hospitals outside of Capital and Calgary, there are a potential for a reduction of LOS for 91 admission days. However, the

average LOS for these admissions is already very close to 1, so we conservatively estimate that only half will have a 1 day reduction. This results in LOS reduction valued at \$35,308. Thus, the total potential costs avoided due to LOS reductions is \$419,428.

If instead we consider the scenario where fFN testing is available in all hospitals, the same LOS reductions as noted above would still be applicable. In addition, there would be any potential LOS reductions from the availability of the test in Level I hospitals. There are 115 admission days, including 27 for PTB in Level I hospitals. Thus, there are 88 admissions that could potentially have an LOS reduction. If we assume a 1 day reduction, the value of the LOS reduction is \$68,288. However, again the average LOS for these is very close to one so a conservative estimate with only half of the admissions having 1 day reduction would result in a cost savings for LOS reduction of \$34,144. This results in total potential costs avoided due to LOS reductions in this scenario of \$419,428 if no additional LOS reductions in the Level I hospitals are possible or between \$453,572 to \$487,716 if some reductions are possible.

10.7 Ambulance Transfers

10.7.1 Numbers of Transfers between facilities

There were 64 ambulance transfers in this group of women with threatened PTL associated with admissions for threatened PTL. Of these, only 1 resulted in birth. There were an additional 42 transfers between facilities that did not involve the use of an ambulance. Presumably, the patients arranged their own transportation in these cases. Of these 5 resulted in birth.

Looking at the 64 ambulance transfers only, there were 53 that were by ground ambulance, 4 by air ambulance, and 7 by combined air and ground ambulance.

All four of the air ambulance transfers are to the Royal Alexandra in Capital Health Region. Three of these are from Aspen Regional Health Authority, and one is from Peace.

Looking at the combination transfers, 6 of them involve transfers between regions and 1 represents a transfer within the Northern Lights health region. The between region transfers are as follows: There was one transfer from Palliser to Calgary Health Region, two from Aspen to Capital, one each from Northern Lights and Peace to Capital, and one from Capital back to Peace. The first case was a transfer to Foothills from Palliser for an admission that resulted in birth – therefore is an unavoidable transfer. The latter case is a woman who was transferred to Royal Alex from Peace River via ground ambulance (but not coded for PTL) and then transferred back to Peace River by combined air/ground ambulance and discharged. She gave birth a month later at 40 weeks gestational age, in Peace River. These two cases are removed from consideration.

For the ground ambulance transfers, 17 of the 53 were between health regions. Some of these ground ambulance transfers would be unavoidable because they came from the community. Removing the ‘unavoidable’ ground ambulance transfers, there are 38 ground ambulance trips.

Ambulance Transfers (for threatened PTL subgroup)

Inter-regional Transfers					
From RHA	To RHA	Air	Ground	Combo	Comments
Palliser	Calgary		1	1*	unavoidable
David Thompson	Calgary		2		
Northern Lights	Capital		1	1	
East Central	Capital		4		
Aspen	Capital	3	7	2	
Peace	Capital		1	1	
David Thompson	Capital		1		
Capital	Peace	1		1*	unavoidable
Total inter-regional		4	17	6	
Intra-regional Transfers					
		Air	Ground	Combo	
Calgary			8		4 unavoidable
Capital			15		2 unavoidable
Northern Lights			2	1	all unavoidable
Aspen			2		2 unavoidable
Chinook			3		all unavoidable
Palliser			2		one unavoidable
Peace			1		one unavoidable
David Thompson			3		one unavoidable
Total intra-regional		0	36	1	
Total trips		4	53	7	64
Total avoidable		4	38	4	48

10.7.2 Total ambulance Transfers

We also looked at all air or combined ambulance transfers in the entire data set not just for the PTL sub-sample. There were 200 of these. For 57 of them, the gestational week was >35 thus fFN testing is not applicable. There were 55 trips with a gestational age <35 and these were examined – they were all for preterm births, thus would not be avoidable transfers. For the remaining 88 of them, the gestational age was missing requiring additional investigation. Looking more closely at the missing GA trips, it turns out there

are 8 avoidable air transfers, and 9-13 avoidable combination air/ground transfers. (See Appendix 5 for details).

10.7.3 Costs of ambulance transfers

Average air ambulance cost: \$3644

Average ground ambulance cost: \$450-500 (from IHE Provincial Cost List)

10.7.4 Cost savings from avoided ambulance transfers

Using the information from the analysis of PTL transfers only:⁴

- 8 avoidable air/combined ambulance trips - \$29,152 savings
- 42 ground ambulance/combined trips – \$21,000 savings

Using the more complete information from the detailed examination of at all air/combination transfers, there were 8 potentially avoidable air transfers and 9-13 potentially avoidable air/ground combination transfers:

- \$77,491 - \$87,781 in potentially avoidable costs.

11.0 Overall cost implications

Putting all the information on the cost implications from the previous sections together, we consider the costs of fFN testing, including both variable and fixed, and then offset these with the costs avoided from the value of LOS reductions and avoided ambulance transfers to consider the overall cost implications. Note that the bulk of the costs avoided are in reduced LOS – thus do not represent dollars released, but do address capacity issues. See Appendix 6 for detailed calculations.

⁴ This does not include the PTL delayed by therapy sub-group, and this is conservative.

For the base case (scenario 2) with testing at Levels II and III hospitals:

- Net costs avoided are \$280,596
 - The bulk of this savings are realized in Capital and Calgary
- Assumes no air ambulance transfers prevented
- This includes one ground ambulance transfer prevented
- This assumes doing the fFN test on all admissions which results in PTB – this is likely an overestimate and thus the net savings are conservative.

Consider also scenario 1 (test in all facilities):

- Overall cost implications range from an overall cost avoidance of \$207,330 to \$307,118.
 - Adding testing to Level I facilities as well means overall savings are reduced in all but the least conservative sub-scenario compared with Scenario 2 (see Appendix 6).
- This assumes all air/combined ambulance transfers avoided are allocated to this Scenario.
- The sub-scenarios vary in terms of the assumed amount of the ambulance transfers. This assumes ground ambulance transfers range between \$21,000 based on using the information from the PTL transfers only plus an assumed \$42,000 to account for if all PTL and PTL delayed by therapy were included (ground ambulance transfers for *all* patients have not been

examined in detail, only the PTL subgroup). Air transfers avoided range between \$77,500 and 88,000).

- This assumes doing the fFN test on all admissions which results in PTB – this is likely an overestimate and thus the net savings are conservative.
- The sub-scenarios vary in terms of the potential for admission day reductions outside the Level II and III hospitals. There are an additional 115 admissions in 36 Level I facilities in this fiscal year – including 27 admissions for PTB. The average number of admissions per facility is 2.75, with a range between 1 and 14. Given that the average LOS is already less than 2 days, it could reasonably be assumed these are not reduced any further. (Scenario 1a, 1b) Further, given that these patients are not being transferred to higher level facilities one could assume that they are being correctly diagnosed in their home facilities. Alternately, you could assume there is a 1 day reduction, or more conservatively that 50% of admissions have a 1 day reduction.

These detailed cost calculations consider the impact of fFN testing in a one year horizon only, and assume that the fixed costs of purchasing the equipment are all borne in year 1. However, it is important to note as well that in Year 2, the net savings would then be increased in Scenario 1 by the amount of the fixed costs: thus adding \$162,748 to each of the net cost savings in Scenarios 1a-1f. Assuming no change in the number of tests and admission days, this would mean that fFN testing in the Level I facilities would result in

additional system savings in year 2 for all the sub-scenarios (ranging between \$89,482 and \$189,270).

Alternately, looking at a two year horizon and assuming that the equipment is leased on a 48 month basis the fixed costs would be equally split between the two years, and in all but the sub-scenarios, there are additional system savings in both years of between \$8,108 and \$107,896.

12.0 Conclusions

There are a few limitations and caveats to note regarding this analysis based upon administrative data. First, the number of tests and reductions in admissions is estimated using administrative data, thus the actual numbers of both are not known. A conservative approach was taken both in terms of the number of tests (we included admissions for PTB in estimating potential number of tests) and also in estimating possible length of stay reductions. It is important to note that only Alberta residents only are included in the data analysis, thus out of province admissions to the tertiary care facilities are not accounted for. In this analysis, the impact of fFN testing only considers reduced length of stay, and there is no way to account for the important impact of reductions in unnecessary treatments (not just costs of these treatments, but the benefits associated with women not receiving these drugs unnecessarily). Out of pocket costs of families are not included, and in addition the anxiety and stresses associated with the experience of preterm labour, and how this may be impacted by fFN testing, are not accounted for. The impact of fFN testing in Level I facilities is speculative as there is little information available in the literature to base projected impact upon.

Based on the analysis of the administrative data, the following conclusions regarding the population of women in Alberta with signs of PTL:

- The number of women presenting with signs of PTL represent approximately 6% of all births in Alberta.
- The majority of these do not progress to PTB.
- Threatened PTL disproportionately affects more disadvantaged groups.

The following conclusions regarding the impact of fFN can be drawn:

- There are shorter average LOS for threatened PTL when fFN is available than when it is not.
- There were 43 ground ambulance transfers between hospitals that could have been avoided – of these the majority are within regions, and only 19 involve between region transfers.
- An examination of air/combined transfers reveals a small number of potentially avoidable transfers: 8 air transfer and 9-13 combination transfers (out of a total of 200).
- Implementing fFN testing in Level II and III hospitals involves net cost “savings” to the system, primarily driven by cost avoidance from reduced LOS.
- Implementing fFN testing in Level I hospitals involves additional system savings, when a two year time horizon is considered. However, there is little evidence in the literature on the use of fFN testing in these types of facilities, therefore these conclusions should be further researched.

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APPENDIX 1

SEARCH STRATEGIES

Premature Labour Economics Literature Search

MEDLINE (OVID 1966 to October Week 2 2005)

Cochrane Central Register of Controlled Trials (OVID 4th Quarter 2005)

1. fibronectins or receptors, fibronectin[MeSH exploded terms]
2. labour, premature[MeSH exploded]
3. (preterm or premature) ADJ2 (labour or labour or birth or deliver*)[Text Words]
4. 2 or 3
5. 1 and 4
6. (fetal or foetal) ADJ2 fibronectin*[Text Words]
7. 5 or 6
8. labour, premature/economics[MeSH exploded]
9. costs and cost analysis or economics[MeSH exploded terms]
10. cost or costs or cost effective* or economic*[Text Words]
11. 9 or 10
12. 4 or 7
13. 11 and 12
14. 8 or 13
15. limit 14 to English language
16. labour, premature/diagnosis[MeSH Major exploded]
17. limit 1 to review articles
18. Canada[MeSH exploded]
19. Canada or Canadian or British Columbia* or Alberta* or Saskatchewan* or Manitoba* or Ontario* or Quebec* or Nova Scotia or New Brunswick or Newfoundland or Prince Edward island or PEI[Text Words]
20. 3 or 4
21. 1 and 5
22. trend* or history or historical or utilization or utilisation[Text Words]
23. 1 and 7
24. labour, premature/history[MeSH exploded]
25. 2 or 6 or 8 or 9
26. limit 10 to human and English language

EMBASE (OVID 1980 to 2005 Week 42)

1. fibronectin or fibronectin binding protein or fibronectin receptor[EMBASE exploded terms]
2. premature labour[EMBASE exploded term]
3. (preterm or premature) ADJ2 (labour or labour or birth or deliver*)[Text Words]
4. 2 or 3
5. 1 and 4
6. (fetal or foetal) ADJ2 fibronectin*[Text Words]
7. 5 or 6
8. economic evaluation or economic aspect[EMBASE exploded terms]
9. cost or costs or cost effective* or economic*[Text Words]
10. 8 or 9
11. 4 or 7
12. 10 and 11
13. limit 12 to English language
14. premature labour/diagnosis[EMBASE Major exploded term]

15. limit 1 to reviews
16. Canada[EMBASE exploded]
17. Canada or Canadian or British Columbia* or Alberta* or Saskatchewan* or Manitoba* or Ontario* or Quebec* or Nova Scotia or New Brunswick or Newfoundland or Prince Edward island or PEI[Text Words]
18. 3 or 4
19. 1 and 5
20. trend* or history or historical or utilization or utilisation[Text Words]
21. 1 and 7
22. 2 or 6 or 8
23. limit 9 to human and English language

CINAHL (OVID 1982 to October Week 2 2005)

1. fibronectins[CINAHL exploded term]
2. labour, premature[CINAHL exploded term]
3. (preterm or premature) ADJ2 (labour or labour or birth or deliver*)[Text Words]
4. 2 or 3
5. 1 and 4
6. (fetal or foetal) ADJ2 fibronectin*[Text Words]
7. 5 or 6
8. labour, premature/economics[CINAHL exploded]
9. economics or costs and cost analysis[CINAHL exploded terms]
10. cost or costs or cost effective* or economic*[Text Words]
11. 9 or 10
12. 4 or 7
13. 11 and 12
14. 13 or 8
15. limit 14 to English language
16. labour, premature/diagnosis[CINAHL Major exploded term]
17. limit 2 to review articles
18. Canada[CINAHL exploded term]
19. Canada or Canadian or British Columbia* or Alberta* or Saskatchewan* or Manitoba* or Ontario* or Quebec* or Nova Scotia or New Brunswick or Newfoundland or Prince Edward island or PEI[Text Words]
20. 3 or 4
21. 1 and 5
22. trend* or history or historical or utilization or utilisation[Text Words]
23. 1 and 7
24. labour, premature/history, trends[CINAHL exploded terms]
25. 2 or 6 or 8 or 9
26. limit 10 to human and English language

Cochrane Database of Systematic Reviews (OVID 3rd Quarter 2005)

1. (preterm or premature) ADJ2 (labour or labour or birth or deliver*)[Keywords/Text Words]
2. (fetal or foetal) ADJ2 fibronectin*[Keywords/Text Words]
3. cost or costs or cost effective* or economic*[Keywords/Text Words]
4. 1 or 2
5. 3 and 4
6. (preterm or premature) ADJ2 (labour or labour or birth or deliver*)[Keywords/Text Words]
7. diagnose\$ or test\$ or predict\$ or detect\$ or screen\$ or marker\$[Keywords/Text Words]

NHS Economic Evaluation Database (University of York CRD) Health Technology Assessment Database (University of York CRD)

DARE Database of Abstracts of Reviews of Effects (University of York CRD)

1. fibronectins or receptors, fibronectin[Subject terms]
2. labour, premature[Subject term]
3. (preterm or premature) AND (labour or labour or birth or deliver*)[Text Words]
4. 2 or 3
5. 1 and 4
6. (fetal or foetal) AND fibronectin*[Text Words]
7. costs and cost analysis or economics[Subject terms]
8. cost or costs or cost effective* or economic*[Text Words]
9. 7 or 8
10. 4 or 5
11. 9 and 10
12. 6 or 11 labour, premature[Subject term]
13. diagnose\$ or test\$ or predict\$ or detect\$ or screen\$ or marker\$[Text Words]
14. 1 and 2

EconLit (EBSCO 1969 to present)

Biological Abstracts (ERL WebSPIRS 1980 to August 2005)

ProQuest Dissertations and Theses

Canadian Research Index (Microlog)

KUUC Knowledge Utilization Database (University of Laval)

1. (preterm or premature) AND (labour or labour or birth or deliver*)[Keywords/Text Words]
2. (fetal or foetal) ADJ2 fibronectin*[Keywords/Text Words]
3. cost or costs or cost effective* or economic*[Keywords/Text Words]
4. 1 or 2
5. 3 and 4(preterm or premature) AND (labour or labour or birth or deliver*)[Keywords/Text Words]
6. diagnose\$ or test\$ or predict\$ or detect\$ or screen\$ or marker\$[Text Words]
7. 1 and 2

Grey literature web sites search terms (see attached list of web sites)

1. (preterm or premature) AND (labour or labour or birth or deliver*)[Text Words]
2. (fetal or foetal) ADJ2 fibronectin*[Text Words]
3. cost or costs or cost effective* or economic*[Text Words]
4. 1 or 2
5. 3 and 4(preterm or premature) AND (labour or labour or birth or deliver*)[Text Words]
6. diagnose\$ or test\$ or predict\$ or detect\$ or screen\$ or marker\$[Text Words]
7. 1 and 2
8. Canada or Canadian or British Columbia* or Alberta* or Saskatchewan* or Manitoba* or Ontario* or Quebec* or Nova Scotia or New Brunswick or Newfoundland or Prince Edward island or PEI[Text Words]
9. 3 and 4
10. trend* or history or historical or utilization or utilisation[Text Words]
11. 3 and 6
12. 5 or 7

NOTES:

- a) denotes truncation
- b) ADJ denotes adjacency
- c) denotes truncation
- d) ADJ denotes adjacency

Preterm Labour Literature Search Web Sites

Note: Government web sites not searched as these will be covered elsewhere

Canadian Web Sites

Alberta Heritage Foundation for Medical Research
www.ahfmr.ab.ca

Canadian Coordinating Office for Health Technology Assessment
www.ccohta.ca/default.cfm

Canadian Health Services Research Foundation
www.chsrf.ca

Canadian Institutes of Health Research
www.cihr-irsc.gc.ca

Canadian Nurses Association
www.cna-nurses.ca/cna

Centre for Health Services and Policy Research, UBC
www.chspr.ubc.ca

Manitoba Centre for Health Policy
www.umanitoba.ca/centres/mchp/lmchp.htm

Canadian Healthcare Association
<http://www.cha.ca/>

Canadian Institute of Health Research:
<http://secure.cihi.ca/cihiweb/>

Canadian Medical Association
<http://www.cma.ca>

Canadian College of Health Services Executives
<http://www.cchse.org/>

Health Quality Council (Saskatchewan)
<http://www.hqc.sk.ca>

Institute for Clinical Evaluative Science
<http://www.ices.on.ca/>

Institute of Health Economics
<http://www.ihe.ca>

McGill University Health Centre. Health Technology Unit
<http://www.mcgill.ca/tau>

Australia/New Zealand

New Zealand Health Information Service

<http://www.nzhis.govt.nz>

Centre for Health Economics (Monash University)

<http://www.buseco.monash.edu.au/centres/che/>

Centre for Health Program Evaluation (Monash University)

<http://www.chpe.buse.co.monash.edu.au>

Australian Policy Online

www.apo.org.au

Centre for Health Economics Research and Evaluation

www.chere.uts.edu.au

Monash Institute of Health Services Research

<http://203.94.147.62/index.asp>

UK Web sites

Centre for Health Economics (University of York)

<http://www.york.ac.uk/inst/che>

Centre for Reviews and Dissemination, University of York (UK)

<http://www.york.ac.uk/inst/crd/welcome.htm>

Kings Fund

<http://www.kingsfund.org.uk>

UK National Research Register

<http://www.nrr.nhs.uk/>

National Coordinating Centre for Health Technology Assessment

www.nchta.org/index.htm

UK National Institute for Clinical Excellence

www.nice.org.uk

US Web sites

Health Policy Institute (Georgetown University)

<http://www.georgetown.edu/research/ihcrp/index.html>

RAND Organization

<http://www.rand.org>

U.S. Agency for Healthcare Research and Quality
<http://www.ahrp.gov>

U.S. Office of the Surgeon General (US)
<http://www.surgeongeneral.gov>

Milbank Memorial Fund
www.milbank.org

National Bureau of Economic Research
www.nber.org

National Institutes of Health
www.nih.gov

Social Science Research Network
www.ssrn.com/index.html

U.S. General Accounting Office
www.gao.gov

International Websites

World Health Organization
www.who.int/en/

International Health Policy Library
www.policylibrary.com/health

European Centre for Health Policy
www.who.dk/echp

APPENDIX 2

SUMMARY TABLES FOR ECONOMICS ARTICLES

<p>Abenhaim HA, Morin L, Benjamin A. Does availability of fetal fibronectin testing in the management of threatened preterm labour affect the utilization of hospital resources? <i>Journal of Obstetrics & Gynaecology Canada: JOGC 2005; 27(7):689-694.</i></p>	
Overall conclusion	Availability of fFN associated with a reduction in hospital admissions, length of stay and overall hospital costs in the management of threatened PTL.
Aim	“To examine how the availability of fetal fibronectin testing affects the utilization of hospital resources”
Setting	Canada, Royal Victoria Hospital, a university-associated tertiary care hospital in Montreal.
Design	Prospective cohort of women presenting with possible PTL when fFN testing was available, compared with a historical cohort of women prior to availability of fFN. Inclusion: singleton pregnancies, presenting between 24-34 weeks gestation with signs and symptoms of PTL.
Methods	<p>Comparison of rates, duration and costs of hospitalization for the two cohorts of women, with and without available fFN testing. Comparison was made during a 20 week study period. For fFN group, this was six months after test became available.</p> <p>Subjects for both cohorts identified by review of birthing centre triage visits, admissions and discharges. fFN test results taken from fFN testing log book.</p> <p>Initial clinical evaluation same in both cohorts.</p> <p><u>fFN protocol:</u> Testing was not performed in women with multiple pregnancy, ruptured membranes, vaginal bleeding, history of recent intercourse, recent digital examination. Specimens obtained as per manufacturer instructions, discarded if PTL were clinically confirmed (cervix dilated > 3cm) or ruled out (cervix closed and uneffaced and contractions ceased). fFN results available within 30 minutes (implying point of care availability).</p> <p>Management decisions were based on initial clinical evaluation and fFN test when indicated. Final decisions regarding discharge for fFN negative made by attending physician.</p> <p>Patients were either (1) admitted and discharged undelivered (PTL), (2) delivered after admission (PTB), or (3) discharged.</p>
Results	<p>Characteristics of two cohorts were comparable in terms of number of subjects, and distribution of gestational age at presentation.</p> <p>12 inappropriate tests were done: 6 for twin pregnancies, two for inappropriate gestational age, and four for ‘reassurance’ of mother presenting with diagnoses other than PTL.</p> <p>Authors point out that more women received “active management” (testing or admission) in study period (29+24 = 53) than baseline period (0+37). They characterize this as more “unnecessary” testing.</p> <p>Outcomes: lower admission rate for PTL with eventual discharge undelivered in fFN group. Significantly lower days hospitalized (5.2 vs. 0.6), lower cost of admission, lower total cost.</p>
Critical comments	<p>Of note is the fact that 25% of fFN tests were “inappropriate”. The authors did include these costs in their analysis. However, they note the need for continued monitoring and education around appropriate use.</p> <p>They excluded costs of subjects that delivered during admission – but these numbers weren’t significantly different in the two groups.</p> <p>Good that they waited to examine impact after a settling in period.</p> <p>It is important to note that not ALL patients in fFN available period were tested (only 35 of 116), the rest were admitted or discharged based on clinical criteria. <u>If ALL had the test, it may not have been cheaper.</u></p> <p>They authors point out...”the importance of reviewing and evaluating the use of fFN testing in the labour and delivery ward to maintain quality assurance and to ensure that clinical practices are current and evidence-based.”</p> <p>No neonatal outcomes considered.</p>

Joffe GM, Jacques D, Bemis-Heys R, Burton R, Skram B, Shelburne P. Impact of the fetal fibronectin assay on admissions for preterm labor. American Journal of Obstetrics and Gynecology 1999; 180(3 PART 1):581-586.	
Overall conclusion	fFN use resulted in reduced PTL admissions, LOS, and prescriptions for tocolytics with no negative impact on neonatal outcomes.
Aim	“..to determine whether the introduction of routine fetal fibronectin bedside testing affected costs and transfer rates from referral district hospitals to a tertiary obstetric hospital, as well as direct admissions to a tertiary referral hospital”
Setting	Australia. Tertiary obstetric hospital as well as 9 referring district hospitals. Some fFN tests were done in physician’s offices.
Design	Prospective audit of fFN use in above settings, for 18 months (done alongside an RCT for a tocolytic). Compared to a baseline year pre-fFN. Inclusion: threatened preterm labour. 24-34 weeks gestational age, cervical dilation <5 cm Exclusion: vaginal bleeding, sexual intercourse, vaginal examination in previous 24 hrs.
Methods	fFN test done as per manufacturer instructions, test results within 24 hours (so not bedside version). Assay results available 24-48 hours. There was a specific management protocol with fFN in place. Looked at fFN testing to determine effect on maternal transfers, cost of transfers, and local preterm delivery rates and admissions to tertiary hospital.
Results	151 patients admitted (98 to referral hospitals, 53 to tertiary). No difference in maternal age or ethnicity of women, but fewer married and higher parity, in the pre- and post-fFN periods. There were significantly fewer patients admitted for PTL, length of stay and number of admissions per patient. Fewer patients received tocolytics and the costs for admissions were lower. There were no negative impacts on neonatal outcomes (admissions to NICU, NICU LOS, days of ventilator support per NICU admitted patient).
Critical comments	Results available 24-48 hours – could have seen better impact with point of care version of test. Due to design, can’t rule out fewer admissions due to fewer patients presenting with symptoms or changing practice patterns in preterm labour management over time.

Giles W, Bisits A, Knox M, Madsen G, Smith R. The effect of fetal fibronectin testing on admissions to a tertiary maternal-fetal medicine unit and cost savings. American Journal of Obstetrics & Gynecology 2000; 182(2):439-442.	
Overall conclusion	
Aim	“..to determine whether the introduction of routine fetal fibronectin bedside testing affected costs and transfer rates from referral district hospital to a tertiary obstetric hospital, as well as direct admissions to a tertiary referral hospital”
Setting	Australia. Referral district hospitals plus tertiary hospital.
Design	18 month prospective audit. No control comparison.
Methods	151 women who had the fFN test were studied. Cost savings in terms of transport costs for patients with a negative fFN result who weren't admitted or transferred were calculated.
Results	90% of women with fFN negative were not transferred from referral hospital. This was defined as an unnecessary transfer and cost savings calculated.
Critical comments	Looks only at reduced costs for fFN negative patients not admitted. (Assumes then they would ALL have been admitted in the absence of fFN – doesn't look for the reduction of admissions relative to management without fFN testing available). This also doesn't account for the potential for increased management costs of fFN positive patients. Very limited since no comparison group considered. No neonatal outcomes were considered.

Grobman WA, Welshman EE, Calhoun EA, Ramsey PS. Fetal fibronectin results did not reduce medical resource use for women with preterm uterine contractions. American Journal of Obstetrics and Gynecology 2004; 191, 235-40.	
Overall conclusion	fFN testing had NO EFFECT on use of medical resources (LOS, use of tocolysis and corticosteroids, admissions).
Aim	"...to assess whether the availability of fetal fibronectin results for women who undergo evaluation for preterm labour would affect physician resource use and health care costs."
Setting	U.S. tertiary care facility
Design	RCT (non-blinded), if eligible for fFN testing all tested, randomly allocated as to whether physician knew test results. Inclusion: 24-34 weeks gestation, singleton, uterine contractions (> 6 contractions per hour). Exclusion: vaginal bleeding, cerclage, nonintact membranes, >3cm dilation, vaginal exam or sexual intercourse within 24 hours. Also if already receiving treatment for preterm contractions. The fFN test had not been used in labour and delivery prior to study, and was only available within study protocol during the study.
Methods	Randomization occurred AFTER standardized evaluation, including fFN test followed by cervical exam. Swabs analyzed right away for "results available" group; frozen then analyzed as a batch for the "no results" group. fFN specimen collection as usual. No specific management protocol incorporated, see educational intervention below. For "results available" group, results communicated to attending physician by resident. Educational intervention to ensure attending physician "aware of test characteristics": <ul style="list-style-type: none"> • Before study, letter mailed to admitting OBs • When results given, the following statement always made: <i>"If a patient has a positive result, her risk of delivery in next 7 days is approximately 13%, if she has a negative result her risk of delivering is less than 1%. Your patient had a positive/negative test"</i>. All treatment decisions made by attending physician. Repeat PTL was maintained in original groups. "Results available" group could order a second test if >7 days post. Resource use data collected: <ul style="list-style-type: none"> • Number of hospital admissions • Number of hospital days • Hours on labour & delivery • Number of drug treatments Medical billing provided costs of this resource use. Patient related costs lost income, need to hire home assistance, lost time to usual activities, emotional impact. Sample size: 50 per group. Powered to detect a 20% cost difference.
Results	No difference in gestational age, cervical dilation, socioeconomic backgrounds, pregnancy outcomes. Predictive values of fFN similar to other studies: 8 positive results and 1 delivered within 1 week (PPV 12.5%), 5 delivered before 37 weeks (PPV 62.5%). 91 women had negative result and 3 delivered within one week (NPV 96.7%), 17 were delivered before 37 weeks (NPV 81.3%). No difference in: Time spent in labour and delivery for initial evaluation Frequency of tocolysis or corticosteroids Conversion to inpatient status Hospital readmission post-discharge Overall conclusion – no differences between the 2 groups with respect to any cost variable, including the primary outcome of the study (total costs). Conducted some sub-group analyses and did not find any indications of a difference by whether cervical dilation was present, by time (did it take time for them to learn how to do fFN?), or by patients on public aid vs. others.
Critical comments	Are these attending physicians "too good" already? That is, are they already doing a great job of identifying the right women to admit, and therefore not over prescribing etc? <ul style="list-style-type: none"> • Performed in a university hospital with 24-hour resident coverage and strict protocol for preterm labour management. No neonatal outcomes. Educational intervention not sufficient to affect behaviour?? <ul style="list-style-type: none"> • No assurance that the physicians understood the test. What is the impact of freezing the samples on the integrity of the results? Interesting quote: "...if physicians are reluctant to abandon interventions (such as bed rest) in the setting of a negative test result and begin to use increased interventions after a positive test (which has a low predictive value), the number of medical and social resources that are consumed actually will increase after the use of the test."

Lowe MP, Zimmerman B, Hansen W. Prospective randomized controlled trial of fetal fibronectin on preterm labour management in a tertiary care centre. American Journal of Obstetrics and Gynecology 2004; 190(2): 358-62.	
Overall conclusion	No difference in length of hospital stay and interventions. Some evidence of shorter length of stay in labour and delivery for fFN group.
Aim	“...to investigate the effect of the rapid fFN on the length of hospital stay and the use of preterm labour interventions.”
Setting	U.S. tertiary care center.
Design	RCT Women with signs and symptoms of PTL (uterine contractions and/or cervical change) examined at the labour and delivery unit, or those transferred there and already receiving tocolytics. Inclusion: GA between 23-34 weeks, > 16 years of age, cervical dilation <=3cm for primigravid women and <=4 cm for multiparous women. Exclusion: higher order (than twin) multifetal gestations, cerclage, preterm premature rupture of membranes, vaginal bleeding. Randomization stratified by GA.
Methods	fFN specimen collection usual as per manufacturer. Preterm labour management was left to the discretion of the treating physician. Women randomized to either: PTL management with fFN (as soon as criteria met) or PTL management without fFN. That is, women who had had a cervical ultrasound, transvaginal ultrasound or intercourse within the previous 24 hours were enrolled, but fFN test delayed.
Results	97 women were included (46 with fFN, 51 without). No difference in age, gravidity, parity, previous preterm birth, referring physician, multiple gestations, or GA at time of test. No difference in cervical dilation or effacement. No significant difference between groups in terms of: time spent in labour and delivery, admission to the antepartum unit, length of stay on the antepartum ward, use of tocolysis, betamethasone and antibiotics. No difference when the GA subgroups were analyzed. However, they also used a Cox proportional hazard model, with an adjustment for previous preterm birth, cervical dilation and GA which showed that women in the fFN group had a shorter length of stay in labour and delivery.
Critical comments	Only study to stratify by GA, but no power for GA subgroup analysis No test to ensure the assumptions of the Cox proportional hazard model were met. They do not report on how many women in each group had had drugs administered prior to referral which may confound the results. The authors suggest their sample size may have been too small to detect a smaller difference in length of stay. They powered based upon almost a 50% reduction. No neonatal outcomes.

Mozurkewich E, Naglie G, Krahn M, Hayashi R. Predicting preterm birth: a cost-effectiveness analysis. Am J Obstet Gynecol 2000;182(6): 1589-1598.	
Overall conclusion	Risk prediction strategies, including fetal fibronectin testing, may offer cost savings compared with treating all women with threatened PTL and may prevent similar numbers of cases of respiratory distress syndrome and neonatal deaths.
Aim	To compare the cost-effectiveness of 9 strategies for the management of threatened PTL
Setting	University hospital in Michigan, United States
Design	Decision analytic model of costs, cases of respiratory distress and neonatal deaths. Uses published meta-analyses data where possible, institutional data for costs.
Methods	9 different strategies are considered in the decision analysis: The strategies considered are (1) treat all with tocolytics and corticosteroids, (2) administer 'traditional' fFN test and in meantime treat all, discontinuing those who are negative, (3) administer cervical ultrasound (transvaginal or transperineal) and treat only with abnormal cervical length measurements, (4) administer 'rapid' fFN and treat those who are positive, (5) administer rapid fFN plus ultrasound and treat those with abnormal results on at least one, (6) treat none. They further consider an additional 3 strategies – (7) treat all women with outpatient corticosteroids only, (8) corticosteroids to all, tocolytics only to those with positive rapid fFN test, and (9) corticosteroids to all, tocolytics only to those with abnormal cervical length.
Results	Compared with treating all women with threatened preterm labour, the authors conclude that risk assessment strategies using either fFN or cervical length assessment offer cost savings and prevent cases of respiratory distress syndrome and neonatal death. The addition of corticosteroids improves the clinical outcomes at lower costs.
Critical comments	Traditional fFN no longer relevant, the rapid test is the only one available. The baseline comparator is "treat all" women – however, clinical management would not involve treating all women. Clinical judgement would determine who to treat (admit to hospital etc). This study does not carefully consider the entry criteria into the model.

Musaad SMA, Melson CL, Boswell DR. Assessment of the impact of introducing fetal fibronectin assay in the management of preterm labour at Middlemore Hospital, New Zealand. Pathology 2005; 37(3):226-230.	
Overall conclusion	Total expenditure on patient management did not go down with fFN testing. Learning curve speculated – downward trend noted.
Aim	“To assess the impact of introducing the fFN assay on the diagnosis, length of hospital stay and cost of managing patients presenting with symptoms of premature labour in our hospital”
Setting	New Zealand.
Design	Observational, before and after fFN introduction, matched historical controls.
Methods	<p>The first 30 fFN tested patients were recruited and followed until delivery. “Management of preterm labour” compared with 30 matched historical controls. Indicators of this were:</p> <ul style="list-style-type: none"> cost savings (hospital days, medications and investigations) length of stay Rate of in utero transfers Delivery at gestations < 34 weeks Neonatal outcomes (admission to NICU, ventilation, death). <p>Inclusion criteria: GA 24-33 weeks, symptoms and signs of PTL, intact membranes, dilation < 3 cm, no cervical effacement (cervix > 1 cm long), no frank vaginal bleeding.</p> <p>Twin pregnancies included AND sexual intercourse in 24 hours prior did NOT exclude patients.</p> <p>fFN protocol: samples collected as per manufacturer instructions, used Rapid fFN Tli system, results available less than 12 hours.</p> <p>Previous PTL management strategy for patients 24-33 weeks gestation: start tocolysis, steroids, antibiotics. Many had an obstetric ultrasound.</p> <p>New protocol: if fFN positive admit and begin drug treatments, offered an ultrasound scan. If negative, discharge home with advice and follow-up.</p> <p>Cost data was taken from estimates submitted to Lab in support of introducing fFN testing (cost per day, cost of drugs, ultrasound and standard tests). NO detail given on the source of the original cost data. It indicates that calculations were made based on actual tests and interventions performed and the mean length of hospital stay.</p>
Results	<p>No difference in baseline characteristics of two groups (age, ethnicity, %twin gestations, gestational age.)</p> <p>Clinical variables: NO statistically significant difference in use of ultrasound, antibiotics, in utero transfer or median hospital days. Statistically significant difference in use of tocolysis and steroids.</p> <p>“Trend” towards lower median hospital stay in fFN group. There was a lot of variability in LOS.</p> <p>Control group: Median 2 days, Range 1-11, Mean(sd) 2.7 +/- 2.3.</p> <p>fFN: Median 1, range 1-6, Mean(sd) 1.97 +/-1.43.</p> <p>Costs variables: The control group has significantly lower costs for tests and interventions, but higher costs for hospital stay so that overall Total costs are not significantly different.</p> <p>However – there were 7 in the fFN group with long LOS due to other co-morbidities. The authors speculated this was driving costs and re-did the testing excluding these patients. In that case, total cost is still not statistically different but they indicate there is a ‘trend’ towards lower costs.</p> <p>There was no difference in GA at delivery, GA < 34 weeks, preterm delivery, and NICU admissions or ventilations.</p>
Critical comments	<p>Protocol violations: Sexual intercourse should be an exclusion criterion. (Can result in false positives). They had a 25% fFN positive rate, which is high.</p> <p>Very small numbers involved.</p> <p>Issues around patient selection – these patients with co-morbidities that would warrant hospitalization probably did not need fFN testing. They do not report same information about the control group.</p> <p>Unclear how control group was selected. It looks like it is all who are hospitalized versus a selection who presented with PTL. You would think some would be hospitalized and some sent home based on clinical indications. They do not report number of admissions, but 29 of 30 get steroids, so it appears that all were admitted.</p> <p>No neonatal outcomes</p> <p>More recent report of NZ study in presentation at conference.</p>

Nguyen TCQ, Toy EC, Baker B . The cost-effectiveness of fetal fibronectin testing in suspected preterm labor: a randomized trial [abstract]. Obstetrics & Gynecology 2002; 99(4 Suppl):97S, 2002.	
Overall conclusion	fFN testing associated with longer triage stays and higher hospital charges
Aim	“To compare the cost-effectiveness of vaginal fetal fibronectin testing versus observation in evaluating suspected preterm labour.
Setting	U.S.
Design	RCT Women between 24-35 weeks gestation with symptoms of PTL were recruited. Exclusion: abdominal trauma, bleeding, nonreassuring fetal heart tracing, history of tocolysis in the current pregnancy or recent digital exam or intercourse.
Methods	Protocol: prior to digital exam – a sterile speculum exam to assess for ruptured membranes AND fFN swab completed. If membranes intact and dilation < 3cm, women were randomized to either: “traditional observation” - swab discarded, observed with serial digital examinations. “fFN testing” If fFN negative – discharge home. If positive – further observation. Looked at time spend in triage and hospital charges.
Results	77 women enrolled – 35 in traditional group. 42 to fFN. Mean age, gravidity, parity, estimated gestational age, initial cervical dilation, and hospitalization and tocolysis rates were similar. fFN women spend more time in triage unit (3.3 versus 2.7 hours, p=0.05) and had higher hospital charges (\$452 vs. \$299, p=0.03)
Critical comments	Abstract only so ability to interpret is limited. This is not a cost-effectiveness study. Why history of tocolysis in current pregnancy excluded? Presumably to get only those presenting for first time with PTL. What is their triage process? The triage times are statistically significantly different, but is a 0.3 hour (18 minute) difference clinically meaningful? Were the results due to the apparently in appropriate use of positive fFN result - because all patients with positive results underwent further observation? Positive predictive value not good enough to merit this. No neonatal outcomes.

Plaut MM, Smith W, Kennedy K. Fetal fibronectin: the impact of a rapid test on the treatment of women with preterm labour symptoms. American Journal of Obstetrics and Gynecology 2003; 188(6): 1588-1593.	
Overall conclusion	Overall, no difference in length of stay. For high risk women, there was a significant reduction in length of stay.
Aim	"...to evaluate whether knowledge of the results of this rapid [fFN] test would decrease unnecessary interventions for patients with symptoms of preterm labour and perhaps to better identify that group of patients who might benefit from aggressive therapy that would include tocolysis, corticosteroids, and transfer to a tertiary care facility."
Setting	U.S., four community hospitals in Oregon/Washington (three used in analysis because one only enrolled one patient).
Design	RCT Inclusion: present with symptoms of PTL 24 -34 weeks 6 days. Exclusion: cervical manipulation (intercourse, vaginal examination or transvaginal ultrasound) within previous 24 hours, confirmed rupture of membranes, bleeding, dilation greater or equal to 3 cm, cervical cerclage, previous fFN testing within 2 weeks)
Methods	fFN protocol: usual as per manufacturer. Available only as part of study protocol. Test available in 1-2 hours. All women had the fFN test, and laboratory processed results – randomization took place at the laboratory where the lab personnel were given random instructions to either inform physician of results or inform physician the patient was in the no results group. Treatment decisions at the physician's discretion. Educational intervention to inform physician's about the test: 'standardized' educational materials distributed in conferences, as written materials, and as posters in labour and delivery areas. Study was powered for primary outcome of transport to tertiary care centres (n=500) but stopped prematurely for lack of enrolment. Analysis thus focussed on secondary outcomes, focussing on length of stay.
Results	100 patients (108 swabs) – 8 patients were entered into the study twice because they re-presented with PTL symptoms greater than 2 weeks after initial. NO difference in characteristics of study groups (gestational age, gestational age at delivery, known risk factors, twin gestations, fFN positive rate, parity). Hospital stay: length of stay (including observation plus admission) not significantly shorter in fFN results known group (6.8 versus 8.1, p=.35). However, for those observed more than six hours there was a statistically significant decrease in LOS from 37.8 to 22.7 (p=.04)
Critical comments	Treatment of readmissions? They did not follow costs up to birth. Educational intervention adequate? "One could argue that, because there was no required protocol for negative or positive tests in the group for whom the result was known, we may have seen no difference in some outcomes simply because physicians ignored the results of the test. Our study attempted to mimic the real world, where physicians are educated about a test then try to incorporate it into their practice." Study stopped early. In the end, they did not have sufficient power even for secondary analyses. The confidence intervals around estimates are large. 6 of 47 patients with negative fFN (results known) had aggressive therapy – this is indicative of potentially inappropriate interpretation of fFN results. For more difficult to diagnose patients (indicated by longer observation time), fFN testing did significantly reduce LOS by 40%. No neonatal outcomes.

Sullivan A, Hueppchen NA, Satin AJ. Cost effectiveness of bedside fetal fibronectin testing varies according to treatment algorithm. Journal of Maternal-Fetal Medicine 2001; 10(6):380-384.	
Overall conclusion	fFN testing on ALL patients presenting with PTL significantly increases costs; fFN testing after decision to admit based on clinical criteria may reduce the cost.
Aim	“To determine the cost-effectiveness of implementing fetal fibronectin testing in women with threatened preterm labour.”
Setting	U.S. hospital
Design	Decision analysis model of cost outcomes (hospital admission and fFN cost). Uses institutional data on threatened PTL, estimates from the literature.
Methods	Three strategies are compared in the decision analytic model: 1. fFN assay and examination 2. examination and fFN assay if decision to admit 3. examination only
Results	With varying prevalence of threatened preterm labour and varying admission rates, fFN testing on all patients will increase admissions and increase costs but fFN testing on only those who would be admitted will result in decreased admissions and lower costs.
Critical comments	No inclusions of cost of follow-up protocol for negative fFN assay patients or repeat episodes of PTL. Assumptions about rate of positive fFN in women who would be admitted by clinical criteria is not based on any evidence. No neonatal outcomes.

APPENDIX 3

Diagnosis codes used for initial selection of patients from AHW databases

O47003	False Lab <37 Comp Wks Gest/Antepart	FALSE LABOUR BEFORE 37 COMPLETED WEEKS OF GESTATION, ANTEPARTUM CONDITION OR COMPLICATION
O47103	False Lab >=37 Comp Wks Gest/Antepart	FALSE LABOUR AT OR AFTER 37 COMPLETED WEEKS OF GESTATION, ANTEPARTUM CONDITION OR COMPLICATION
O47903	False Labour Unspec/Antepartum	FALSE LABOUR, UNSPECIFIED, ANTEPARTUM CONDITION OR COMPLICATION
O75801	Preterm Labour W Del Delay Rx/Delivered	PRETERM LABOUR WITH DELIVERY DELAYED BY THERAPY, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
O75802	Preterm Labour W Del Delay Rx/Del W Comp	PRETERM LABOUR WITH DELIVERY DELAYED BY THERAPY, DELIVERED, WITH MENTION OF POSTPARTUM COMPLICATION
O75803	Preterm Labour W Del Delay Rx/Antepartum	PRETERM LABOUR WITH DELIVERY DELAYED BY THERAPY, ANTEPARTUM CONDITION OR COMPLICATION
O75804	Preterm Labour W Del Delay Rx/Postpartum	PRETERM LABOUR WITH DELIVERY DELAYED BY THERAPY, POSTPARTUM CONDITION OR COMPLICATION
O75809	Preterm Labour W Del Delay Rx/Unspec	PRETERM LABOUR WITH DELIVERY DELAYED BY THERAPY, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
O42011	Preterm Prm Lab 24 Hr/Delivered	PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
O42013	Preterm Prm Lab 24 Hrs/Antepartum	PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, ANTEPARTUM CONDITION OR COMPLICATION
O42019	Preterm Prm Lab 24 Hrs/Unspec	PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
O42021	Full Term Prm Lab 24 Hrs/Deliv	FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
O42023	Full Term Prm Lab 24 Hrs/Antepartum	FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, ANTEPARTUM CONDITION OR COMPLICATION
O42029	Full Term Prm Lab 24 Hrs/Unspec	FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE

- O42091 Prm Lab 24 Hrs Unspec/Deliv PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
- O42093 Prm Lab 24 Hours Unspec/Antepartum PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, ANTEPARTUM CONDITION OR COMPLICATION
- O42099 Prm Lab 24 Hrs Nos/Unspec PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR WITHIN 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O42111 Preterm Prm Lab Aft24 Hrs/Deliv PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
- O42113 Preterm Prm Lab Aft 24 Hrs/Antepartum PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, ANTEPARTUM CONDITION OR COMPLICATION
- O42119 Preterm Prm Lab Aft 24 Hrs/Unspec PRETERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O42121 Full Term Prm Lab Aft 24 Hrs/Deliv FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS. DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
- O42123 Full Term Prm Lab 24 Hrs/Antepartum FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, ANTEPARTUM CONDITION OR COMPLICATION
- O42129 Full Term Prm Lab Aft 24 Hrs/Unspec FULL TERM PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O42191 Prm Lab Aft 24 Hours Unspec/Deliv PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
- O42193 Prm Lab Aft 24 Hrs Unspec/Antepartum PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, ANTEPARTUM CONDITION OR COMPLICATION
- O42199 Prm Lab Aft 24 Hrs Nos/Unspec PREMATURE RUPTURE OF MEMBRANES, ONSET OF LABOUR AFTER 24 HOURS, UNSPECIFIED WHETHER PRETERM OR FULL TERM, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O42201 Prom Labour Delayed By Therapy/Deliv PREMATURE RUPTURE OF MEMBRANES, LABOUR DELAYED BY THERAPY, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION
- O42203 Prom Labour Delayed By Therapy/Antepartum PREMATURE RUPTURE OF MEMBRANES, LABOUR DELAYED BY THERAPY, ANTEPARTUM CONDITION OR COMPLICATION

- O42209 Prom Lab Delayed By Therapy/Unspec PREMATURE RUPTURE OF MEMBRANES, LABOUR DELAYED BY THERAPY, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O42909 Prom Nos/Unspecified PREMATURE RUPTURE OF MEMBRANES, UNSPECIFIED, UNSPECIFIED AS TO EPISODE OF CARE, OR NOT APPLICABLE
- O60001 ICD10CA Preterm Delivery/Delivered PRETERM DELIVERY, DELIVERED, WITH OR WITHOUT MENTION OF ANTEPARTUM CONDITION

CMG codes: 599 (Premature labour) or 619 (False Labour LOS < 3 Days (MNRH))

APPENDIX 4

Fetal Fibronectin Health Technology Project Data Requirements Summary

Data Year: 2004/2005

Methodology:

1. Identify all individuals in the inpatient database with a diagnosis of O42.XXX, O47.XXX, O75.XXX or O60.001 or grouping to CMG 599 or CMG 619.
Exclude: Records with Responsibility for Payment <> "01" (Provincial Government) and invalid PHNs.
2. Identify all individuals in the ambulatory care database with a diagnosis of O42.XXX, O47.XXX, O75.XXX or O60.001
Exclude: Records with Responsibility for Payment <> "01" (Provincial Government) and invalid PHNs.
3. For individuals identified, provide demographic information and information on all inpatient, ambulatory care and physician services received during the first encounter and following the first encounter until fiscal year end (as outlined below).

1. Population Registry Database (March 31st, 2005)

Record Count: 17,855

- Recipient Identifier (Randomly generated)
- Recipient Age
- Recipient Gender
- Recipient Health Region of Residence
- Recipient Postal Code (3 first digits only, will link to income level information from Census)
- Socioeconomic Status

2. Inpatient Database (2004/2005)

Record Count: 20,256

- Recipient Identifier (Randomly generated)
- Recipient Health Region of Residence at Service Date
- Recipient Age at Service Date
- Discharge Disposition
- Admission Date
- Discharge Date

- Length of Stay
- Facility Number
- Transfer To
- Transfer From
- Admit Via Ambulance
- Main Diagnosis
- Other Diagnoses (24 occurrences)
- Diagnosis Type
- Main Intervention
- Other Interventions (19 occurrences)
- Average Length of Stay
- Case Mix Group (CMG)
- Resource Intensity Weight (RIW)
- Main Patient Service
- Service Transfers (3 occurrences)
- Provider Service (8 occurrences)
- Responsibility for Payment
- Provider RHA
- Number of Previous Term Deliveries
- Number of Previous Pre-term Deliveries
- Gestational Age

3. Ambulatory Care Database (2004/2005)

Record Count: 48,217

- Recipient Identifier (Randomly generated)
- Recipient Health Region of Residence at Service Date
- Discharge Disposition
- Visit Start Date
- Visit End Date
- Facility Number
- MIS Functional Centre
- Transfer To
- Transfer From
- Admit Via Ambulance
- Main Diagnosis
- Other Diagnoses (9 occurrences)
- Main Intervention
- Other Interventions (9 occurrences)
- ACCS Group
- System Wide Relative Value
- Provider Type (5 occurrences)
- Doctor Service (5 occurrences)
- Responsibility for Payment
- Provider RHA

4. FFS Physician Database
Record Count: 248,689

- Recipient Identifier (Randomly generated)
- Recipient Health Region of Residence at Service Date
- Service Start Date
- Service End Date
- Provider Identifier
- Provider Discipline
- Provider Specialty
- Program Type
- Facility Number
- Functional Centre of Facility
- Diagnosis (3 occurrences)
- Service Code
- Amount Paid
- Service Health Region

APPENDIX 5

Information on all air and combined air/ground ambulance transfers

Examining the entire dataset, 200 air or combined air/ground ambulance transfers can be identified.

- For 57 trips in total (22 air, 35 combined), the woman's gestational week was greater than 35 therefore fFN is not applicable.
- For an additional 55 trips, there is a gestational age noted in the database:
 - 54 of these are for preterm birth, and are therefore unavoidable
 - 1 is for premature rupture of membranes, therefore fFN is not applicable
- For 88 trips (37 air, 51 combined), the gestational age is missing. These were examined in detail to determine the reason for the trip and also to infer the gestational age at the time of the trip based on the gestational age at birth.

Examining the 37 air ambulance trips:

- 3 were not for maternal diagnoses, 7 were maternal diagnoses but not PTL or fFN not applicable, 10 were for premature rupture of membranes, 2 were for diagnosis of PTL but gestational age greater than 37 weeks, 1 was for diagnosis of PTL and gestational age was < 37 but there were other complications, 3 were for diagnosis of PTL delayed by therapy but there were other complications. Thus, 26 of the trips are not avoidable.
- 4 trips were for diagnosis of PTL and 7 trips were for diagnosis of PTL delayed by therapy. Thus there are 11 potentially avoidable air transfers depending on the gestational age – these were examined in more detail.

From RHA	To RHA	Birth outcome	GA at Birth	RHA at Birth	Calculated GA at transfer	Avoidable?
Aspen	Capital	32 days later	39 weeks	Capital*	34.4	Potentially
Community	Northern Lights	5 days later	37 weeks	Northern Lights	36.3	No, from community, GA>35
Peace	Capital	37 days later	38 weeks	Capital*	32.7	Potentially
Aspen	Capital	48 days later	42 weeks	Capital*	35.1	Potentially GA = 35
David Thompson	Capital	32 days later	34 weeks	David Thompson	29.4	Potentially
Aspen	Capital	105 days later	40 weeks	Peace	24	Potentially
Peace	Capital	64 days later	40 weeks	Peace	30.9	Potentially
Aspen	Capital	32 days later	40 weeks	Aspen	35.4	Potentially (GA = 35)
Aspen	Capital	31 days later	37 weeks	Capital*	35.6	Not, original GA>35
Peace	Capital	33 days later	39 weeks	Peace	34.3	Potentially
Northern Lights	Capital	49 days later	38 weeks	Northern Lights	31	Potentially

* Note that for these three transfers to Capital, the birth ultimately occurred in Capital as well. For only one was there an additional ambulance transfer, the other two either remained in Capital for the remainder of their pregnancies or returned to Capital via personal transport for their births.

Of the 11 original air transfers examined in more detail, 2 can be removed as the gestational age at the time of the transfer was calculated (using the GA at birth) to be greater than 35 weeks.

➤ **9 avoidable air transfers, \$31, 896 in avoidable costs**

Examining the 51 combined air/ground transfers:

- 9 were for maternal diagnoses but not PTL or fFN not applicable, 6 were for premature rupture of membranes, 8 were for PTL > 37 weeks, 3 for PTL with complications, 4 for PTL delayed by therapy with complications. Thus 30 of these trips are not avoidable.
- 10 were for PTL, 11 for PTL delayed by therapy. Thus, there are 21 potentially avoidable trips to examine more closely.

From RHA	To RHA	Birth outcome	GA at Birth	RHA at Birth	Calculated GA at transfer	Avoidable?
Community	Northern Lights	Unknown	Unknown	Unknown	Unknown	No, from community
Community	Northern Lights	98 days later	41 weeks	Northern Lights	27	No, from community
Peace	Capital	37 days later	40	Capital*	35	Potentially
Palliser	Calgary	This trip	34	Calgary	34	No, birth
Aspen	Capital	40 days later	29	Capital*	33	Potentially
Community	Northern Lights	9 days later	37	Northern Lights	35	No, from community
Palliser	Calgary	This trip	32	Calgary	32	No, birth
Northern Lights	Capital	34 days later	29	Northern Lights	24	Potentially
Peace	Capital	Unknown	Unknown	Unknown	Unknown	Potentially, can not confirm GA
Community	Northern Lights	Unknown	Unknown	Unknown	Unknown	No, from community
Northern Lights	Capital	40 days later	28	Northern Lights	32	Potentially
Northern Lights	Capital	Unknown (as of 35 weeks later)				No, assume too early GA
Northern Lights	Capital	24 days later	37	Capital*	34	Potentially
Northern Lights	Capital	29 days later	38	Capital*	34	Potentially
?	Capital	25 days later	37	Peace	32	Potentially
Peace	Capital	87 days later	40	Peace	28	Potentially
Northern Lights	Capital	26 days later	37	Northern Lights	33	Potentially
?	Calgary	68 days later	41	Calgary*	32	Potentially

From RHA	To RHA	Birth outcome	GA at Birth	RHA at Birth	Calculated GA at transfer	Avoidable?
?	Capital	Not in data 23 weeks later				No, assume too early GA
Aspen	Capital	11 days later	35	Capital*	33	Potentially, birth within 14 days
Aspen	Capital	18 days later	37	Capital*	34	Potentially

*For 7 of these transfers, they ultimately gave birth in Capital or Calgary as well.

Of the 21 transfers examined in more detail, 7 can be removed as they either resulted in birth, were from the community or the gestational age at the time of transfer was calculated to be > 35 weeks.

Of the remaining, 11 are potentially avoidable. Two others are considered potentially avoidable as well – for one the GA can't be confirmed, and for the other birth did occur 14 days later so this person may have tested positive for fFN and been transferred anyways.

- **Between 11 and 13 combination ambulance trips are potentially avoidable, between \$45,595 - \$53,885.**

In total, there are between \$77,491 and \$87,781 in potential savings due to avoidable air or air/ground combined transfers.

APPENDIX 6

Detailed Cost Calculations

Detailed Cost Calculations - One Year Horizon

	NUMBER OF ADMISSIONS				
	Level II and III		Level II	Level I	
	CHR	Capital	Other region	All regions	
PTL	125	136	60	73	394
PTL delay tx	69	165	31	15	280
PTB	390	328	101	27	846
	584	629	192	115	1520

Scenario 2: fFN testing in Level II and III Hospitals

	2a	2b
<i>Costs of implementing fFN</i>		
Fixed costs	\$2,668	\$2,668
Variable costs	\$136,664	\$136,664
<i>Costs avoided</i>		
Ground transfers avoided	\$500	\$500
Air transfers avoided	\$0	\$0
LOS reductions	\$454,736	\$419,428
<i>Net cost avoidance</i>	\$315,904	\$280,596

In 2a, assume full potential LOS reduction for Level II hospitals outside Capital/Calgary

In 2b, assume 50% of admissions at Level II hospitals outside Capital/Calgary.

could see a LOS reduction b/c average LOS close to 1

Scenario 1: fFN testing in all facilities

	1a	1b	1c	1d	1e	1f
<i>Costs of implementing fFN</i>						
Fixed costs	\$162,748	\$162,748	\$162,748	\$162,748	\$162,748	\$162,748
Variable costs	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850
<i>Costs avoided</i>						
Ground transfers avoided	\$21,000	\$42,000	\$21,000	\$21,000	\$42,000	\$42,000
Air transfers avoided	\$77,500	\$88,000	\$77,500	\$77,500	\$88,000	\$88,000
LOS reductions	\$419,428	\$419,428	\$453,572	\$487,716	\$453,572	\$487,716
<i>Net cost avoidance</i>	\$207,330	\$238,830	\$241,474	\$275,618	\$272,974	\$307,118
<i>Change from Scenario 2b</i>	-\$73,266	-\$41,766	-\$39,122	-\$4,978	-\$7,622	\$26,522

1a assume lower amount for both transfers, no additional LOS reductions to Scenario 1b

1b assumes higher amount for both transfers, no additional LOS reductions to Scenario 1b

1c assumes lower amount for both transfers, additional LOS reduction on 50% of Level I admissions

1d assumes lower amount for both transfers, additional LOS reductions on all Level I admissions

1e assumes higher amount for both transfers, additional LOS reductions on 50% of Level 1 admissions

1f assumes higher amount for both transfers, additional LOS reductions on all Level I admissions

Year 2: Scenario 1 (fFN testing in all facilities), no fixed costs in Year 2

	1a	1b	1c	1d	1e	1f
<i>Costs of implementing fFN</i>						
Fixed costs						
Variable costs	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850
<i>Costs savings</i>						
Ground transfers avoided	\$21,000	\$42,000	\$21,000	\$21,000	\$42,000	\$42,000
Air transfers avoided	\$77,500	\$88,000	\$77,500	\$77,500	\$88,000	\$88,000
LOS reductions	\$419,428	\$419,428	\$453,572	\$487,716	\$453,572	\$487,716
<i>Net costs savings</i>	\$370,078	\$401,578	\$404,222	\$438,366	\$435,722	\$469,866
Change from Scenario 2b:		\$120,982	\$123,626	\$157,770	\$155,126	\$189,270

1a assume lower amount for both transfers, no additional LOS reductions to Scenario 1b
 1b assumes higher amount for both transfers, no additional LOS reductions to Scenario 1b
 1c assumes lower amount for both transfers, additional LOS reduction on 50% of Level I admissions
 1d assumes lower amount for both transfers, additional LOS reductions on all Level I admissions
 1e assumes higher amount for both transfers, additional LOS reductions on 50% of Level 1 admissions
 1f assumes higher amount for both transfers, additional LOS reductions on all Level I admissions

**Scenario 1 (fFN testing in all facilities)
 Per year, assuming fixed costs spread over two years**

	1a	1b	1c	1d	1e	1f
<i>Costs of implementing fFN</i>						
Fixed costs	\$81,374	\$81,374	\$81,374	\$81,374	\$81,374	\$81,374
Variable costs	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850	\$147,850
<i>Costs savings</i>						
Ground transfers avoided	\$21,000	\$42,000	\$21,000	\$21,000	\$42,000	\$42,000
Air transfers avoided	\$77,500	\$88,000	\$77,500	\$77,500	\$88,000	\$88,000
LOS reductions	\$419,428	\$419,428	\$453,572	\$487,716	\$453,572	\$487,716
<i>Net costs savings</i>	\$288,704	\$320,204	\$322,848	\$356,992	\$354,348	\$388,492
Change from Scenario 2b:	\$8,108	\$39,608	\$42,252	\$76,396	\$73,752	\$107,896

1a assume lower amount for both transfers, no additional LOS reductions to Scenario 1b
 1b assumes higher amount for both transfers, no additional LOS reductions to Scenario 1b
 1c assumes lower amount for both transfers, additional LOS reduction on 50% of Level I admissions
 1d assumes lower amount for both transfers, additional LOS reductions on all Level I admissions
 1e assumes higher amount for both transfers, additional LOS reductions on 50% of Level 1 admissions
 1f assumes higher amount for both transfers, additional LOS reductions on all Level I admissions