

POLICY DEVELOPMENT: PRACTICE IMPROVEMENT,
BLIND SWEEP FETAL FIBRONECTIN
COLLECTION

by

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DEDICATION

This dedication is for my mother who has always inspired me to be a nurse, my husband's endless support in my journey in continuing my education and my faithful dog Remi who kept me company while working on this project.

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I would like to thank all of those who have been involved with my project, especially my committee members. This project would not be possible without the guidance of my committee. A special thanks to Dr. Julie Ruff, Dr. Alice Running, Dr. Tracy Hellem and Dr. Leah Miller.

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ABSTRACT

Recognizing preterm labor can help guide the management of care of the mother and fetus between the obstetrician and registered nurse. A simple test called the rapid fetal fibronectin (fFN) can detect proteins that are indicators of preterm delivery. A trained registered nurse can perform this simple test, in which a swab is placed in the posterior fornix of the vagina. The March of Dimes has created a pathway for standardized preterm labor assessment developing a Preterm Labor Assessment Tool (PLAT) for hospitals to aid in the reduction preterm labor and deliveries. A positive fFN test allows for antenatal steroids and preparation for optimal neonatal care, whereas a negative fFN test allows for less intervention, avoidance of unnecessary medical treatment and hospitalization, and the provision of reassurance to both obstetrician and patient. The purpose of this project was to develop an evidence based policy that would guide and support practice improvements for the blind sweep fFN collection method. This evidence based protocol will allow trained registered nurses to perform a blind sweep fFN test without an obstetrician or residents' supervision. By performing the fFN tests on patients who present with preterm labor signs and symptoms, obstetricians will be able to recognize preterm labor assessment and initiate early treatment.

CHAPTER ONE – INTRODUCTION

Background

The United States preterm birth rate is among the highest of high-resource nations. (National Center for Health Statistics, 2018). Preterm birth (PTB) and its complications are the number one cause of infant mortality in the United States, approximately 380,000 infants are born prematurely each year. The preterm birth rate (the percent of babies born before 37 weeks each year) is 9.8 % in the United States; 1 in 10 babies are born prematurely. CNN Health (2009, reported the average cost of medical care for a premature or low birth-weight baby for its first year of life is about \$49,000, according to a new report from the March of Dimes Foundation.

Fetal fibronectin (fFN), a complex adhesive glycoprotein and biomarker for preterm delivery, can be detected in pregnant women who present with preterm labor (PTL) between 22-34 weeks gestational age. The fibronectin biomarker is highly associated with the risk of preterm delivery when present in cervicovaginal secretions. A simple test called the fFN test can be performed on pregnant women who present with signs and symptoms of preterm labor. The fFN test can help identify PTL in pregnant women and allow for timely and appropriate interventions as well as the prevention of unnecessary medical treatments, interventions, and medications.

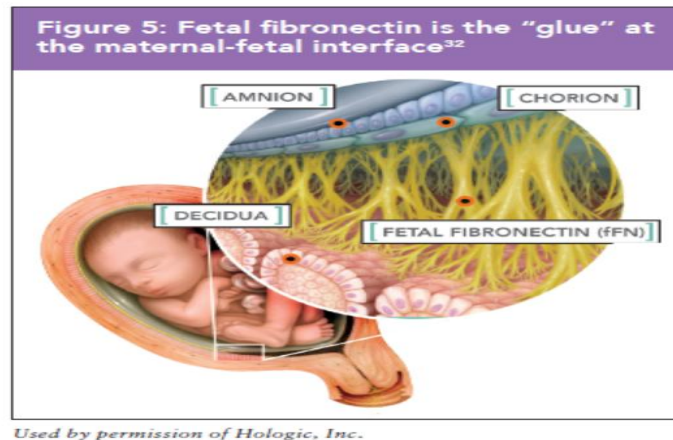
Role of fFN in Predicting Labor

The American College of Obstetricians and Gynecologists (2016), defines PTL as regular contractions resulting in cervical changes starting before 37 weeks of gestation.

Uterine contractions alone are not a good predictor of PTL. Imperceptible signs and symptoms, such as cervical ripening and decidual activation, occur earlier than uterine contractions, but can be difficult to detect. Uterine contractions can vary in strength and consistency and do not always result in cervical changes associated with PTL. Therefore, the industry recommendation to determine PTL is the combined use of the fFN test and transvaginal ultrasound. These are specific and objective tools that allow for the safe and effective evaluation of the patient who presents with contractions without cervical change (Hedriana et al., 2013).

Fetal fibronectin is a glue like substance that keeps the amniotic sac "glued" to the lining of the uterus (mayoclinic.org, 2018). The detection of the fFN protein can be used to screen for PTL. "A protein related to cellular cohesiveness, fFN is concentrated at the membrane-decidua interface (see Figure 1). During weeks 22-35 of a normal pregnancy, it is virtually undetectable. Disruption of the interface releases fFN, which can be detected via rapid assay" (Hedriana, Byrne, et al., 2013, p. 6).

Figure 1. Placental view of the various layers in the placenta and the placement of fFN.



Hedriana H, Byrne J, Campbell Bliss M, Kowalewski, L., Georges, M., Lombardo, V., Mason-Marti, P., Linden, R., Frye, D., Meyers, J. & Clark, S. (2013) *March of Dimes PTL assessment toolkit*. White Plains, NY: March of Dimes.

Similarly, when there is a disruption of the maternal-fetal interface, fFN is released into the cervical/vaginal secretions (Hedriana et al., 2013). Fetal fibronectin detected prior to 35 weeks gestational is an indicator of PTL. When fFN is released into cervical/vaginal secretions it can be detected by a rapid assay test. A rapid assay is a quantitative test that detects concentrations of fFN in cervicovaginal secretions. The fFN assay yields a negative predictive value within 7 to 14 days of 95-99 % between 24-33 weeks of gestation. The assay has a positive predictive value of 13-40 % for delivery within 14 days which could be an indicator for preterm delivery. Thus, a pregnant woman who receives a negative fFN test result has a 0.5-5 % chance of PTL within the next two weeks and a positive fFN test result predicts a 13-40 % chance of PTL.

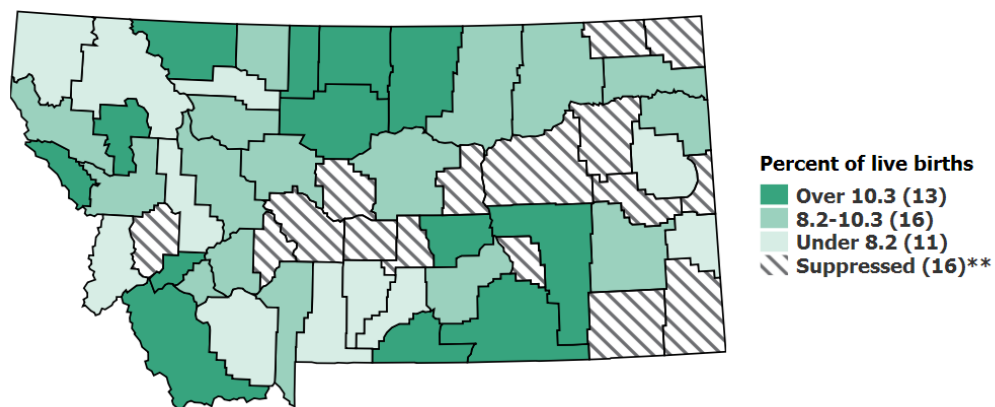
A positive test allows for timely and appropriate interventions such as the administration of antenatal steroids to further develop the infants' lungs. Antenatal steroids have been shown to reduce neonatal morbidities and it is recommended by

ACOG (2016) that all patients delivering between 24-34 weeks gestation age receive one full dose of steroids within seven days of precipitous delivery (Hedriana et al., 2013). Conversely, a fFN negative test allows for discharge and prevention of unnecessary and costly medical care.

Preterm Birth in Montana

The March of Dimes (2017) reported that PTB rate in the U.S. rose in 2015 for the first time in eight years. The cost for preterm births in Montana alone is estimated to be over 71 million dollars annually (The March of Dimes, 2013). Premature births are closely associated with cerebral palsy, mental impairment, vision deprivation, and permanent hearing loss among other deficiencies. In 2016, Montana's PTB rate was 8.7%. Missoula County's PTB rate was 7.5 % (Montana Public Health Data Source). Figure 2 is a map of preterm births per county in Montana.

Figure 2. Preterm birth rate in Montana < 37 weeks, 2012-2015 average.



** Suppressed due to missing data or insufficient numbers.

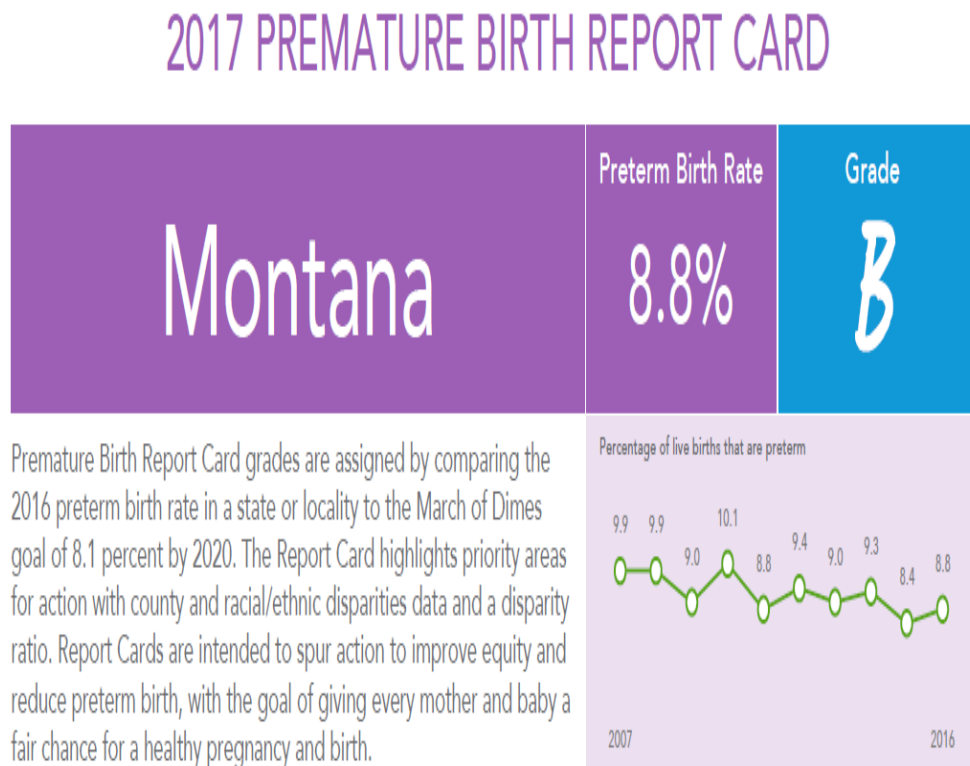
March of Dimes. National center for health statistics, final natality data. (2018).

Retrieved from; marchofdimes.org

Identifying a problem in preterm births, starting in 2006, The March of Dimes focused national attention on clinical preterm education in the hope of educating health care workers, obstetricians, and patients to decrease preterm births. Figure 3 demonstrates Montana's 2017 premature birth report card from the March of Dimes.

To assess each state, The March of Dimes has developed a report card that grades how well each state is doing with the prevention of PTB. Grades are determined by the March of Dimes based on PTB rates from National Center for Health Statistics, (2017). In 2017, Montana received a grade of “B” with a PTB rate of 8.8% (Figure 3).

Figure 3. Montana's report card grade from the March of Dimes



March of Dimes. Montana's report card grade from the March of Dimes. (2018). Retrieved from; marchofdimes.org

During this time a system-wide initiative was developed to improve PTL outcomes on a national level. The March of Dimes PTL Assessment Tool (PLAT) was introduced to help standardize the care of pregnant women presenting with the signs and symptoms of PTL. The PLAT focuses on the population of patients with suspected symptomatic PTL $\leq 36\frac{6}{7}$ weeks of gestation. An important step in the PLAT algorithm assessment is the collection of an fFN sample.

As a result of the PLAT algorithm initiated by the March of Dimes, there has been a significant reduction of adverse perinatal outcomes. The standardization of PTL evaluation and implementation of standardized protocols has been key in this reduction. As a result of this success, the Rochester Methodist Hospital for Mayo Clinic implemented a standardized triage protocol patterned on the PLAT and reduced the admission of pregnant women with PTL signs and symptoms by 56%. On a national scale, utilizing a standard approach to women who are at risk for PTL could result in an estimated \$560 million annual healthcare cost savings (Hedriana et al., 2013).

Local Problem

Assessing women for preterm labor comes with some risk and the need for skilled technicians. During the assessment an obstetrician typically performs an fFN test with the use of a speculum. Speculum examinations can be invasive and registered nurses (RNs) usually cannot collect an fFN specimen unless they are trained. Alternatively, there is a method of collection known as the blind sweep collection method. The blind sweep collection method is considered as effective as the standard speculum examination

method (Farag, Mohammed, Elliathy & Salama, 2015). Blind vaginal sweep collection of fFN is not considered to be as invasive as it does not require a speculum. Additionally, this collection method may be completed by a registered nurse (RN).

The policy for detecting preterm labor at a small hospital in north west Montana fell short of the current recommendations. Nurses were not able to collect fFN tests due to the use of a speculum and the lack of a policy for a blind sweep collection method. Therefore, fFN tests were not being performed routinely on patients who present with possible PTL. Furthermore, hospital nurses were not familiar with the procedure and initially were not comfortable in performing a blind sweep fFN collection.

Summary of Problem

Early recognition of preterm labor can reduce unnecessary hospital admissions, decrease hospital length of stay and guide patient care to an appropriate level of care. Testing for fibronectin is a safe, evidence based, low cost, way to determine PTL that can be conducted by nurses. At a local hospital in Montana, there is no current policy outlining the effectiveness of, and procedure for fFN testing. A policy would guide and support the blind sweep method performed by nurses in order to collect a specimen for fFN.

Goal Statement

The goal of this thesis was to propose and implement an evidence-based policy to the local hospital advisory board which would train RN's to perform the blind sweep fFN

test on pregnant women presenting with signs of PTL. This goal was met by creating a hospital policy that is evidence based identifying the blind sweep collection procedure for fFN. Secondly, for this thesis, the policy was presented to hospital administration and obtained approval for implementation. The desired outcome of this new policy and procedure is to increase the number of fFN tests performed thus improving PTL management along with standardizing of care for patients presenting with signs and symptoms of PTL. Given the amount of time required for a policy and procedure change, the results of implementation will not be included in this project.

Theoretical Framework

Change in human behavior is difficult, for this reason a change theory is appropriate for this thesis. The theory of change by Kurt Lewin, who is considered the father of social psychology acted as a guide for this project. Lewin's theory of change focuses on a three-stage model known as the unfreeze-moving-refreeze model (Mitchell, 2013).

According to Lewin's theory of change, implementing new nursing practices can be challenging for improvement in healthcare delivery. Presenting change to staff in a well thought out and planned manner can increase the likelihood and scope of a project.

There are many ways of implementing change. However, planned change, which is a purposeful, calculated collaborative effort to bring about improvements with the assistance of a change agent, is the most commonly adopted (Mitchell, 2013, pg.32).

Lewin identified three stages through which change agents must proceed before change becomes part of a system. Unfreezing is when change is needed, moving is when change is initiated, and refreezing is when equilibrium is established . Unfreezing focuses on the driving forces for change and preparation for the desired outcome. Whereas refreezing makes changes permanent and establishes new ways of operating, while rewarding the desired outcomes (Mitchell, 2013).

Using Lewin's change model as a guide, unfreezing occurred when the current research supported an evidence based practice of collecting fFN using the blind sweep method. The nursing staff were initially uncertain and doubtful about performing a blind sweep fFN test. Change processes are at risk of failing because organizations do not always succeed in communicating and explaining the need for change to their employees. "Time and communication are the two keys to the changes occurring successfully. People need time to understand the changes, they also need to feel highly connected to the organization throughout the transition period" (Mitchell, 2013., p. 32).

Moving, or the second stage outline by Lewin was the practice of creating an evidence-based policy and educating the hospital staff to the new procedure. By explaining the benefits and convenience of a blind sweep fFN test to the nursing staff and obstetricians, the need for change was acknowledged and supported.

Finally, resolving the uncertainty of the staff and the provision of a blind sweep fFN policy will aid in the change of practice. This final stage according to Lewin will be the refreezing of behavior change. If this new process is accepted by unit then the desired outcome would be moving into the refreezing stage solidifying the change. Eventually,

the staff will feel confident and comfortable with the new process of collecting an fFN test.

CHAPTER TWO – REVIEW OF LITERATURE.

Review of Literature

An extensive review of current literature was performed to support this thesis. Multiple databases were used in the literature search including the Cumulative Index of Nursing and Allied Health Literature (CINAHL), The Cochrane Library, PubMed, ScienceDirect, and Google Scholar. The following phrases and key words were used in the search process; *fFN*, *blind vaginal fFN collection method*, *comparison of speculum and non-speculum collection of fFN*, *PTL*, *predicting PTL with fFN*, and *cost analysis of fFN test*.

The initial search of literature did not garner sufficient results, therefore the search criteria were expanded to include *collection methods of fetal fibronectin*. Approximately, 25 articles were used to compile the final literature review that related to fibronectin, speculum exams, blind sweep procedures, preterm labor and preterm birth. Most of the current literature pertained to fFN testing and its reliability to predict PTL using the speculum exam. There is little debate that, fibronectin is a reliable standard to test for PTL. Interestingly, the method to collect the specimen is less clear, and slower to be adopted as industry standard. The literature review that follows includes a discussion about rates of preterm birth, fFN and its role in predicting PTL, collection methods and cost analysis. Details regarding these findings will be discussed.

Two primary methods for obtaining fFN are supported by the literature. Most commonly a speculum collection of fFN is obtained when a speculum is inserted into the

vagina by an obstetrician and a sample of cervicovaginal secretions is obtained under direct visualization of the vaginal cavity. The alternative method for collection of fFN is the blind vaginal sweep. This is performed by inserting a finger in the vagina, depressing downward and inserting a polyester swab along the finger to allow for collection of secretions in the posterior fornix.

Preterm Birth

Preterm birth is defined as childbirth occurring at less than 37 completed week or 259 days of gestation. It is a major determinant of neonatal mortality and morbidity and has long-term adverse consequences for health (Beck et al., 2010). Infants born prematurely are at higher risks of cerebral palsy, sensory deficits, learning disabilities, respiratory issues and death. "Worldwide spontaneous preterm birth before 37 weeks gestation occurs in around 11.1% of all live births. It is the second most common direct etiological factor of child health before the age of five" (Farag et al., 2015., p. 1009). Despite extensive research and intervention, the incidence of PTB is increasing in many countries. The rate of PTB in the U.S. is 12%, higher than many other developed countries. Preterm births cost an excess of \$12 billion in health care costs annually in the United States (March of Dimes, 2013). Preterm birth is considered one of the most common and costly obstetrical indications for hospital admissions accounting for appropriately 33% of hospital admissions to a perinatal unit (Boots et al., 2014).

Fibronectin and Its Role in Predicting PTL

Fibronectin, which is a complex adhesive glycoprotein, can be detected in pregnant women who present with PTL between 22-34 weeks gestational age. An article by Farag and colleagues (2015), reported that fFN is a well validated biomarker that can be used to identify PTL. Fibronectin is one of the best predictors of PTB. Fibronectin measures resides in its negative predictive value which allows for medical treatment on an outpatient basis and avoids unnecessary medical costs and interventions. (Farag et al., 2015).

An fFN test assesses the risk of PTL by measuring the levels of fFN in cervicovaginal secretions. Levels measuring 50 ng/mL or greater at or after 22 weeks have been associated with an increased risk of spontaneous preterm birth; "in fact, fFN is one of the best predictors of PTB in all populations studied so far, including low and high-risk for delivery of pregnant women without PTL, twins, and pregnant women in PTL" (Berghella, Hayes, Visintine, & Baxter, 2007., p. 3).

The evidence supporting the use of fFN to identify patients at risk for PTL was strong. Pointing & Tomlin (2011) reported the use of the fFN test to determine which pregnant women may go into PTL within the next 14 days. A negative fFN test can prevent unnecessary intervention for women suspected of PTL. Pregnant women who had a negative fFN could be managed on an outpatient basis reducing inpatient hospital costs and unnecessary medical care. Karamisheva et al. (2015) in a prospective, longitudinal study found that fFN had an excellent negative predictive value of 97% of predicting PTL; "a negative fFN test is 99.2% predictive that the woman will not deliver in the next

14 days. The introduction of a safe, simple fFN test can assist in correctly diagnosing true PTL, avoiding unnecessary, costly interventions" (Pointing & Tomlin, 2011., p. 31).

Due to both lack of staff availability and staff training, the fFN test is currently underutilized in hospitals. In a prospective cohort study, Abenhaim, Morin, and Benjamin, (2005) looked at pregnant women who presented with PTL signs and symptoms when fFN testing was available compared with an historical cohort of pregnant women presenting before fFN was available. The researchers included pregnant women between 24-34 weeks gestation. The authors concluded the availability of fFN testing was associated with a reduction in hospital admissions up to 90%, length of hospital stay, and overall hospital costs in the management of threatened PTL.

The evidence is clear that, standardization of care can reduce unnecessary hospital admissions of pregnant women who present with PTL. The American College of Obstetricians and Gynecologist (ACOG) Committee on Patient Safety and Quality Improvement (2016) has called for the development of clinical guidelines and the standardization of practice to improve patient outcomes. They aim to accomplish this by introducing checklists and protocols to reduce PTL. The American College of Nurse is in agreement, midwives state; "evidence-based methods of identifying pregnant women at risk for premature labor, including ongoing risk assessment at each visit, screening pregnant women with premature labor contractions using fFN testing and screening with cervical length measurements techniques should be accessible in all practice settings" (McCue & Torbenson, 2017., p. 62).

Collection Methods

The current published research supports both speculum and clean sweep collection methods as safe and reliable to test for fFN. Research results that follow provide similar findings when comparing speculum and finger sweep methods.

Current recommendations by the FDA include the use of a speculum for the collection of the fFN test. However, this can have negative consequences; the speculum requirement can prohibit the test since an obstetrician must be readily available to perform the speculum exam. Additionally, contamination can occur if not performed correctly decreasing the test validity. A nurse who is not trained to perform the test and/or a sterile vaginal exam done prior to collection of the fFN increase probability of contamination.

Contrary to the current recommendation several studies have concluded the blind sweep technique just as effective as the speculum exam. A study done by Roman et al., (2005), assessed the accuracy between the collection of an fFN sample without the use of a speculum a cohort of patients were followed with serial fFN testing . All patients were considered to be high risk for premature labor. A total of 1,396 fFN tests from 416 pregnancies were performed with the blind sweep technique.

Findings detailed in this study indicated that sampling for fFN via the blind sweep sampling technique carries similar negative predictive values and specificities for spontaneous preterm birth as speculum-directed in asymptomatic, high risk woman" (Roman et al., 2005, p. 5).

A similar study by Stafford & Dildy (2005) confirmed these findings. They examined the use of the standard fFN cut-off of 50ng/ml. They found excellent agreement between

cervicovaginal fFN concentrations collected with and without speculum. An additional study by Garite, Lucah, William, Bobritchi, and Lapointe (2005) confirmed the same findings.

In agreement, Stafford et al. (2008) found that there is strong evidence supporting equality of fFN results obtained by speculum and non-speculum methods. In support of these findings, two separate prospective studies were performed with the same findings; these studies demonstrated that the digital direct and blind nonspeculum collection method provide very similar quantitative fFN concentrations as well as excellent agreement with qualitative fFN results when compared with the speculum method" (Stafford et al., 2008., p.131).

A more current and larger study by Farag et al., (2015) compared the accuracy of the vaginal swab in the diagnosis of PTL and prediction of subsequent occurrence of PTB. This prospective study was completed in a large hospital in Egypt where there are approximately 18,000 deliveries a year. Pregnant women presenting with threatened premature labor between the gestation weeks of 24-34 weeks were recruited for the comparison of the accuracy of blind vaginal and cervicovaginal fFN collection methods to predict PTB. Two different swabs and samples were collected. One swab was collected from the blind sweep technique, and the other was collected using a speculum. Qualitative and quantitative assessment of fFN was completed using enzyme-linked immunosorbent assay (ELISA) used to detect fFN. Agreement was found between the two sample methods. Both swabs gave the same result in 45 pregnant women (90%) and gave different results in five pregnant women (10%).

Therefore, it appears the clean sweep method is just as reliable and consistent in collecting fFN than the speculum method. Interestingly, no current research has been published supporting these same findings. In summary, the data suggest that speculum placement may not be necessary for the collection of fFN. A blind sweep technique appears to produce the same quality outcome. The benefit for this method is that it is simpler thus there is less room for error and it does not require an obstetrician to complete the exam (Farag et al., 2015). See Table 1 for a summary of studies investigating the two methods of collection.

Table 1. Studies on blind specimen collection for fFN testing

Table 4 Studies on blind specimen collection for fFN testing					
	Coleman <i>et al.</i> , 1998 ¹²	Kalchbrenner <i>et al.</i> , 1999 ¹³	Roman <i>et al.</i> , 2005 ¹¹	Stafford <i>et al.</i> , 2008 ¹⁴	Present study 2014
Study design	Cohort study. Women with symptoms of threatened PTL. <i>n</i> = 121. GA = 24–34 weeks. Two sequential vaginal fFN swabs were obtained (with and without a speculum). Qualitative only. Double blinded.	Abstract presented at the ACOG 47th Annual clinical meeting.	Historical cohort study. Asymptomatic women with risk factors of PTB. <i>n</i> = 416. GA = 22–32 weeks. One fFN swab was obtained (without a speculum). Quantitative and qualitative. Not blinded.	Two prospective studies.† Women presenting to ER and requiring speculum. <i>n</i> = 169 and 31. GA = 22–43 weeks. Two sequential vaginal fFN swabs were obtained (with and without a speculum). Quantitative and qualitative. Not mentioned.	Prospective study. Women with symptoms of threatened PTL. <i>n</i> = 50. GA = 24–34 weeks. Two sequential vaginal fFN swabs were obtained (with and without a speculum). Quantitative and qualitative. Double blinded.
Results	Substantial association between samples obtained with and without a speculum $\kappa = 0.65$ (95%CI: 0.44–0.87).	Strong correlation between non-speculum and speculum collection methods.	For delivery <34 weeks, blind fFN swab had sensitivity of 44.7%, specificity of 88.4%, PPV of 27.9%, and NPV of 94.1%.	More than 95% agreement with $\kappa > 0.85$ in both studies. Comparison of intensity showed that both collection methods detected similar amounts of fFN.	Significant moderate negative correlation between fFN measured in both blind vaginal ($r = -0.502$; $P < 0.05$) and cervicovaginal swabs ($r = -0.607$; $P < 0.05$) and sampling–delivery interval was found.
Points of weakness	Qualitative only	Article no longer available.	Did not compare with speculum method. Retrospective, not blinded, heterogeneous group of patients.	Two non-speculum collection methods. Clinical outcomes were not recorded. Majority of studied women were at term.	Small sample size

†Two similar studies, except for a difference in the non-speculum collection technique and the handling before testing. ACOG, American College of Obstetricians and Gynecologists; CI, confidence interval; ER, emergency room; fFN, fetal fibronectin; GA, gestational age; κ , Cohen's kappa coefficient; NPV, negative predictive value; PPV, positive predictive value; PTB, preterm birth; PTL, preterm labor.

Cost Analysis

Performing blind sweep fFN collection on pregnant women who present to labor and delivery units with signs and symptoms of PTL can be a cost-saving effort. Preterm birth costs employers in excess of \$12 billion in health care costs, according to statistics from the March of Dimes (2013). Additionally, a 90% reduction in maternal transports has been reported as a direct result of fFN testing (Giles, Bisits, Knox, Madsen & Smith, 2000., p.1).

A systematic review and cost analysis was performed using the rapid fFN test. According to Deshpande et al, (2013) accurate detection of PTB decreases unnecessary use of resources;

The main potential role is likely to be reducing health-care resource usage by identifying pregnant women not requiring intervention. Evidence from randomized control trials suggests that fFN does not increase adverse outcomes and may reduce resource use (Deshpande et al., 2013., p. 2).

Similarly, a retrospective 12-month observational study of patients with signs and symptoms of PTL was conducted at the Mayo Clinic. All the patients were evaluated via triage per a standardized protocol combined with fFN assay and cervical length measurements by ultrasound. There was a 56% reduction in hospital admissions compared to the prior year and an estimated annual savings of \$39,000.00.

“Implementation of a standardized protocol for evaluation of PTL reduces the rate of unnecessary hospital admissions for observation with consequent significant reduction in expense” (Rose, McWeeney, Brost, Davies & Watson, 2010., p. 2).

Of the pregnant women who present for evaluation of PTL, only 10% deliver preterm, highlighting the imprecise nature of correlating signs and symptoms with true

labor. This results in unnecessary hospitalization and medical interventions (McCue & Torbenson, 2017). McCue and Torbenson concluded the fFN test is easy to administer, non-invasive, and has no related side-effects.

The negative predictive value of fFN is high, with a negative test associated with a <1% chance of giving birth in the next two weeks. The test itself is objective, and its benefits with respect to cost, and decreased health care utilization are well documented (McCue & Torbenson, 2017., p. 62).

CHAPTER THREE – METHODS

Ethical Review

This thesis was found “exempt” by the Montana State University Institutional Review Board after it was determined this was not a research study, no data nor subjects were involved in the thesis. The thesis did not meet the defined criteria of research nor were protections of public or individual rights required.

Sample/Setting

This thesis took place at a small 80 bed rural hospital with 1200 employees located in Western Montana. Within the hospital there is an Obstetrics department which included Labor and Delivery, Post-Partum and an Intensive Care Nursery. Approximately 1200 births take place at this hospital yearly (communitymed.org).

Project Development

Assessment of Current Practice

In order to meet the thesis goal, the initial step was to gather a baseline for current practice obtaining fFN in women with PTL symptoms. As discussed earlier in the review of literature, the fFN test is not currently used in all hospitals due to lack of staff training and availability of trained staff members. At the time of this thesis, fFN tests were collected by an obstetrician using the speculum exam. Nurses in the labor and delivery department were not trained to perform speculum exams, therefore fFN tests were not

consistently performed with patients who present with PTL signs and symptoms. If a patient presented in the middle of the night and an obstetrician is not “in-house” the test was not collected.

The initial step of this project was to introduce and educate the staff and obstetricians of the labor and delivery unit at the hospital to the blind sweep technique. The blind sweep collection method was presented to the Labor and Delivery RNs at a staff meeting in March 2018. RNs were given information regarding standardization of care for PTL patients along with educational material discussing the blind sweep fFN collection method. The obstetricians were given information regarding the blind sweep fFN by the maternal fetal medicine physicians during their monthly meeting in March.

Initial evaluation of current practice was done through discussion with stakeholders and a pre-implementation assessment survey provided to the department nurses. Prior to educating the department staff, Obstetricians and RNs were individually interviewed regarding their knowledge about alternative collection methods of fFN in the labor and delivery unit. RNs were asked if the unit had a fFN policy, what the current practice was in the hospital when using fFN to assist in the PTL assessment, how often practitioners in the hospital use the fFN test as part of their PTL triage assessment, if a RN blind sweep fFN policy was implemented would more practitioners utilize the test as a part of their PTL assessment, and was there consistency among the practitioners at the hospital in the assessment and disposition of the women presenting with signs and symptoms of PTL?

The obstetricians were individually asked if they used fFN to assist with diagnosis of PTL and if the answer was no, why? Also, the obstetricians were asked if they were familiar with the blind sweep fFN collection method and if a policy was developed would they utilize the fFN test more often?

During these discussions there appeared to be a variety of responses when asked how often and when a fFN test was collected. For instance, one Obstetrician may collect an fFN test on a patient who presents with PTL at 24 weeks gestation while another Obstetrician will not collect a fFN depending on their preference. These findings were confirmed by the March of Dimes standardized preterm labor assessment pre-implementation survey. Additionally, a review of the current policies and procedures revealed the hospital did not have a policy for triage of the preterm patient and collection of fFN. Therefore, a common problem/complaint was identified, the unit did not have a policy and procedure that supported the blind sweep collection method. fFN collection was not a standard or routine test ordered for pregnant women who presented with signs and symptoms of PTL. This became the focus of the staff education and subsequent policy created to address the issue.

Planning and Evaluation

When RNs and obstetricians were asked why they did not perform or order a blind sweep fFN tests, the main response was that facility did not have a policy for the procedure. A gap between education and the lack of a policy was recognized and the need for a policy was identified. The blind sweep collection method was discussed with the obstetrical educator (OBE) along with the need for a new policy to help standardize

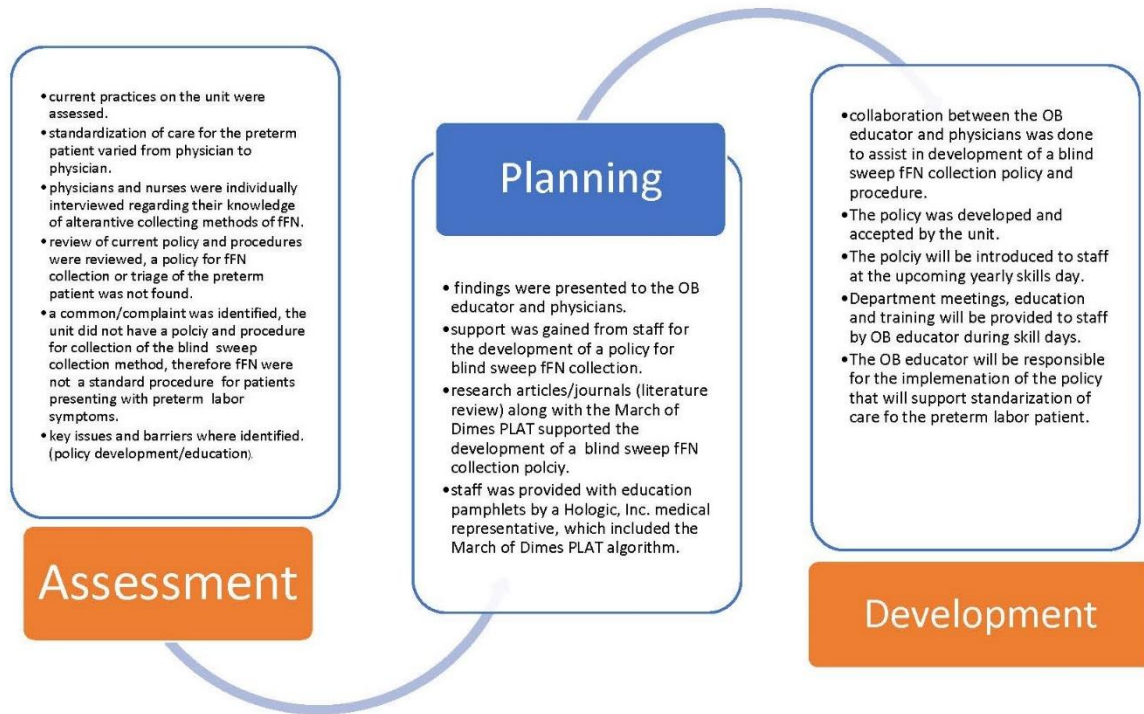
the care of the PTL patient. The OBE was provided with research articles/journals along with the algorithm for PLAT. Support was garnered from obstetricians and RNs to develop a policy that will guide the blind sweep collection method. Key players, including nursing staff and obstetricians were identified and involved in the decision-making process to introduce a policy that would allow trained RNs to collect fFN via the blind sweep technique.

Implementation

The policy was created using the most current recommendations and guidelines for PTL supported by ACOG , The Association of Pregnant Women's Health, Obstetric and Neonatal RNs (AWHONN) and the March of Dimes. The policy and subsequent staff education was supported by evidence from Cochran reviews, prospective studies, and diagnostic meta-analysis.

Collaboration between the OBE and the obstetricians was formed to assist in the development of a blind sweep fFN collection policy and procedure. With the guidance from hospital obstetricians and a thesis committee member, Dr. Leah Miller, a policy was developed which safely guides and supports the use of the blind sweep collection method for the collection of the fFN. Figure 4 outlines the process described above.

Figure 4. Policy development process



Collection Process

The policy and procedure were written following the most current recommendations. The full policy can be found in Appendix A. Presently, criteria for patients who would benefit from the fFN test are pregnant women between 24-34 weeks gestation presenting with the signs and symptoms of PTL such as regular contractions, greater than six per hour, pelvic pressure, back pain, pelvic pain, cramping, pressure, feeling of fullness, vaginal bleeding and/or increase or change in vaginal discharge. Limitations for the collection a fFN test are a low sensitivity for pregnant women who are less than 24 weeks gestation and more than 34 weeks gestation, the test cannot be performed if the patient has moderate to heavy vaginal bleeding, has had recent

intercourse, sterile vaginal examination, cervical dilations of ≥ 3 centimeters, bulging fetal membranes, or premature rupture of membranes (Hedriana et al., 2013).

The test is collected by placing the index finger through the vaginal opening and depressing the posterior vaginal wall and sliding the polyester swab along the fingers until resistance is met and/or the posterior fornix is reached. The swab is left in place for 10-30 seconds, removed, placed in the appropriate specimen container and sent to a lab for testing. Specimens collected but not tested within eight hours of collection may be stored in a refrigerated area for three days. The hospital currently uses a rapid fFN specimen collection kit. This kit will continue to be used for the blind sweep fFN collection method. Figures 5 and 6 depict the specimen kit along with the collection method.

Figure 5. Specimen collection kit. Hologic, Inc. (2015)

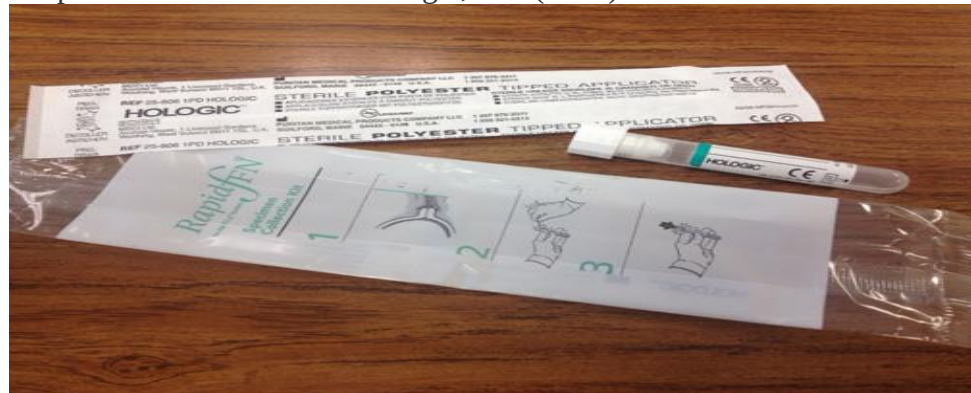
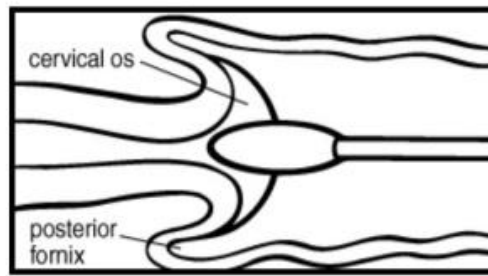


Figure 6. Specimen collection for fFN testing

Specimen Collection for fFN Testing



- Lightly rotate swab across either the posterior fornix of the vagina or the ectocervical region of the external cervical os for 10 seconds.

Hologic, Inc. (2015) Specimen collection kit

March of Dimes PTL Assessment Toolkit

Hospitals can decrease negative PTL outcomes by standardizing their triage assessments of pregnant women presenting with PTL signs and symptoms with the use of March of Dimes PLAT.

The value of standardized assessment will help identify those patients in true labor and will benefit all pregnant women who present in triage with signs and signs and symptoms of suspected PTL. Hospitals providing all levels of care will achieve timely and appropriate interventions, optimal maternal safety, hospitalization of only those patients at greatest risk for preterm delivery, effective transport of PTL patients to higher, more appropriate levels of care and avoidance of unnecessary treatments, interventions and medications (Hedriana et al. 2013., pg. 79).

The March of Dimes' (2013) Preterm labor assessment tool (PLAT) enables the standardized identification of pregnant women in PTL. The PLAT reliability ensures

timely and appropriate interventions for improved neonatal outcomes. Improvement of the timing of antenatal steroid administration within seven days is expected to provide the highest reduction in neonatal morbidity. The PLAT is also designed to decrease unnecessary interventions and medical treatments when PTB occurs. Appendix B and C are the standardized PTL assessment and PLAT algorithm by the March of Dimes for symptomatic pregnant women.

In summary, a gap in hospital policy and staff education was identified in this thesis. Stakeholders in the hospital setting including obstetricians, nurses, and administration were brought in to support a policy and procedure creation. Stakeholders assisted in policy and procedure development for fFN collection (Appendix A). This policy and procedure was created using the current guidelines published by industry experts. A standardized tool and algorithm was followed to ensure the policy and procedure met the highest standards of safety.

CHAPTER FOUR – OUTCOMES/RESULTS

Outcomes

The new policy was reviewed by the OBE and approved for practice by the maternal fetal medicine obstetricians in fall 2018. As part of the implementation, the OBE will present the new policy at the yearly labor and delivery skills day in late November or December 2018 then move towards implementation after RNs complete skills day competency.

Additionally, while not part of the thesis goal due to time constraints, the policy will educate, train, and measure outcomes for the management of PTL at the hospital where the policy and procedure was implemented. Assessment of maternal and fetal outcomes as well as financial effects would be suggested as part of the outcome measures.

Ultimately, while beyond the goal of this thesis, the plan is to disseminate this policy by having the staff educator of the labor and delivery unit present this policy to smaller regional Montana hospitals. Rural hospitals are at an increased risk for PTL/delivery complications due to a lack of resources to care for the patient and baby if delivery is imminent. If rural hospitals are able to perform the blind sweep fFN test, the obstetrician may have more time to make decisions to transport the laboring patient to a hospital with a higher level of care and to administer steroids if needed based upon the fFN result.

Results

During the inquiry phase a PTL assessment Pre-Implementation Survey (Appendix D) was completed by nine RNs in the labor and delivery unit at the hospital in the spring of 2018. The results of the survey showed there was inconsistency in how each obstetrician managed patients with signs and symptoms of PTL. Eight of nine RNs reported the hospital did not have a premature labor protocol. When asked why obstetricians do not use the fFN test in assessment of symptomatic premature labor patients, RNs reported obstetrician preference, lack of policy, no buy in from obstetricians, collection issues, and not enough education. These findings were confirmed when speaking with obstetricians who work in the department.

As a result of the interview and survey findings, a Policy and Procedure was created for patients presenting with PTL (Appendix A). This policy and procedure were developed for the hospital labor and delivery unit to help standardize the triage assessment of PTL patients.

Barriers

Throughout the process of developing a policy and procedure for the blind sweep fFN collection method, a few barriers were encountered. Initially, not all obstetricians were receptive to RN's collecting fFN specimens using the blind sweep method. Obstetricians questioned whether the test was necessary and how the results would change the plan of care for the patient presenting with signs and symptoms of PTL. The option of performing a blind sweep fFN test, especially during the night or if an

obstetrician or resident is not available, was discussed with the obstetricians by the OBE. Additionally, obstetricians were provided with the current literature pertaining to blind sweep safety and efficacy. After discussing and explaining the importance of the fFN test and standardization of care with the obstetricians, they were in agreement with the new process.

Similarly, the nursing staff voiced concerns regarding feelings of comfort performing the test due to limited staff, education, and lack of a policy for collection of the fFN test. Nurses were also educated on and provided literature regarding the safety and efficacy of blind sweep fFN collection. The RNs were more receptive to the new process once the procedure to collect a blind fFN test along with an explanation of the simplicity was provided. Additionally, the OBE provided a skills station and competency checklist as part of the new policy and procedure that delivered additional education for the RNs.

CHAPTER FIVE – DISCUSSION

Implementation Challenges/Successes

The biggest challenge with this project was locating adequate research data to build a strong literature review. There is an abundance of information on fFN testing and results, but not on the collection of the specimen or the comparison between the two methods. Limited information and research has been completed on the blind sweep fFN collection method.

The second challenge was the extended length of time required for policy approval from the hospital committee. Unfortunately, staff turmoil contributed to delay in policy approval. During the time of policy submission, the director of the unit resigned, the interim could not address policy change, and the OBE was on maternity leave. Additionally, time was lost due to submission of the policy and procedure change to the incorrect oversight committee. The policy was initially directed toward quality assurance for review, however this was not required because the policy was unit specific, rather than a hospital wide policy.

A strength of this project was the support from the March of Dimes. Over the past decade the March of Dimes has supported the implementation of standardized protocols to help reduce adverse perinatal outcomes. The March of Dimes has provided considerable funding and research to identify the strongest guidelines to prevent PTL. The introduction of a policy for performing the blind sweep fFN collection along with the

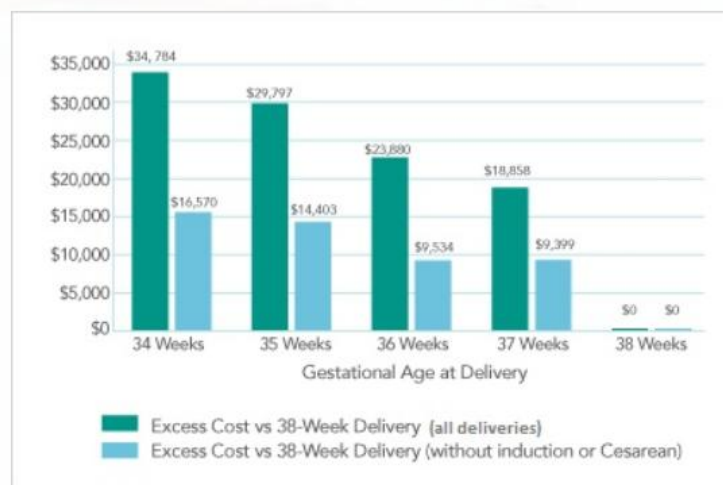
guidance of the March of Dimes PLAT aided in standardization of care for pregnant women in PTL at the hospital.

Cost Savings

As discussed in the literature review, performing a blind sweep fFN collection with pregnant women who present to labor and delivery units with the signs and symptoms of PTL can be a cost-saving effort (Desphande et al.,2013). Initiating a policy that will allow RNs to collect fFN tests via the blind sweep collection method could decrease hospitals costs regarding unnecessary medical admissions and unnecessary medical treatment. While no specific cost savings has been realized, Figure 7 demonstrates the costs and potential savings between term and preterm deliveries.

Figure 7. Excess cost of preterm delivery vs. cost of 38-week delivery

Excess Cost of Preterm Delivery versus Cost of 38-Week Delivery²



Gilbert, W. M., Nesbitt, T. S., & Danielsen, B. (2003). The cost of prematurity: quantification by gestational age and birth weight. *Obstetrics & Gynecology*, 102(3), 488-492.

Limitations

The limited current research articles supporting the use of the blind sweep fFN collection method is something to consider. Several referenced research articles report the need for larger studies and more research to determine how effective fFN is in preventing PTL (Roman et al., 2015).

Interestingly, the speculum collection method is currently the only FDA approved collection method. Hologic, Inc. is a large medical supply company and one of the main suppliers of the RapidfFN specimen collection kit. Recently a medical sales representative from Hologic, Inc. visited the unit at the hospital and reported the blind collection method is an option; however, it is not currently FDA approved. The medical sales representative referred back to the March of Dimes PLAT and how blind sweep or speculum collection is acceptable for the fFN. Knowing that medical companies are open to the blind sweep fFN collection method is encouraging and shows a need for more research and future studies.

Similarly, Ruma et al (2017) reported "a lack of agreement continues among obstetric professionals and societies on guidelines for standardization of the approach to the diagnosis and management of patients with signs and symptoms of PTL" (p. 356). This lack of consensus has likely resulted in poor identification of pregnant women who are at increased risk for PTB. A review of clinical guidelines and recommendations from a variety of studies regarding the use of fFN testing and transvaginal ultrasound found inconsistency among published guidelines, algorithms and studies on how to treat the signs and symptoms of PTL (Figure 8). However, each of these studies support the use of

fFN to determine PTL. Collaboration and agreement need to be addressed among healthcare obstetricians in order to provide standardized medical care to pregnant women with PTL signs and symptoms. "Healthcare providers, administrators, and payers must navigate conflicting recommendations and identify areas of agreement for this evaluation within their own setting"(Ruma, Bittner & Soh, 2017, p. 356). Additionally, larger randomized controlled trials would be helpful in establishing an industry standard for safety and consistency to identify women at risk of PTL.

Figure 8. Guidelines, Algorithms, and Evidence-Based Expert Opinion for fFN Testing

Source	Cervical Dilation	Contraction Frequency	Effacement	Cervical Length	fFN Test With TVU ^a
Professional Society Guidance					
ACOG Practice Bulletin 171 ¹ (2016)	No guidance	No guidance	No guidance	No guidance	"The positive predictive value of a positive fetal fibronectin test result or a short cervix alone is poor and should not be used exclusively to direct management in the setting of acute symptoms"
ACOG Practice Bulletin 130 ²⁸ (2012)	No guidance	No guidance	No guidance	No guidance	Does not recommend fFN use for screening in asymptomatic women
SMFM ¹⁹	No guidance	No guidance	No guidance	20-29 mm	"fFN seems to be most helpful for women with a 'borderline' TVU CL of 20 to 29 mm"
Expert Opinion					
Lockwood 2017 ¹⁴ (UpToDate)	<3 cm	≥4 in 20 min or ≥8 in 60 min	No guidance	20-30 mm	Yes
Published Algorithms					
Rose 2010 ¹³	<2 cm	≥4 /hr	<80%	16-29 mm	Yes
Ness 2007 ¹⁴	≤3 cm	≥6 /hr	<100%	20-29 mm	Yes
Iams 2003 (clinical + sonography data equivocal) ¹⁵	≤2 cm	Regular contractions ^b	<80%	20-30 mm	Yes
Iams 2003 (clinical + sonography data in conflict) ¹⁵	<3 cm and has changed	Regular contractions ^b	<80%	<35 mm	Yes

ACOG indicates American Congress of Obstetricians and Gynecologists; CL, cervical length; fFN, fetal fibronectin; PTL, preterm labor; SMFM, Society for Maternal Fetal Medicine; TVU, transvaginal ultrasound.

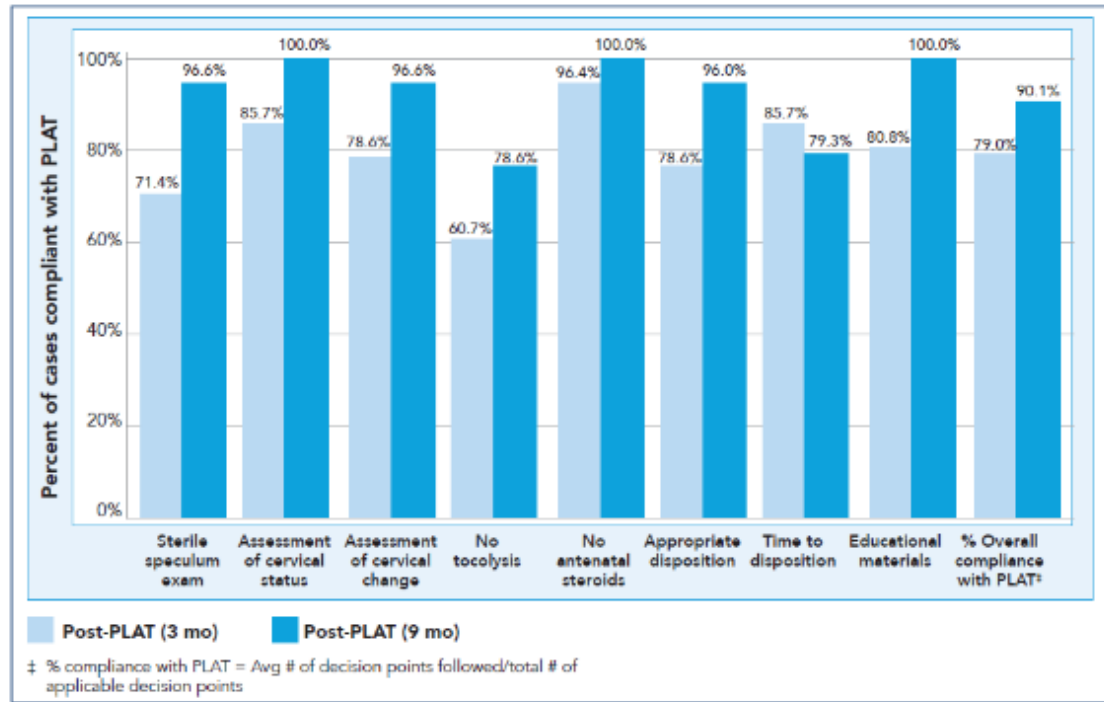
^afFN testing recommended for reported cervical length

^bStates contraction frequency alone is insufficient to establish a diagnosis of PTL

American College of Obstetricians and Gynecologists. (2018). Guidelines, algorithms, and evidence-based expert opinion for fFN testing and PTL assessment. Retrieved from <https://www.acog.org/?IsMobileSet=false>

Finally, the goals of this thesis were to; write and implement an evidence-based policy at a local hospital which would train RN's to perform the blind sweep fFN test on pregnant women presenting with signs of PRL. This goal was met by creating an evidence-based policy which was approved by stakeholders and hospital administration. Unfortunately, due to time constraints outcomes and dissemination of this policy and procedure could not be assessed. A limitation to this thesis was the time constraint. The implementation phase was not completed due to the extensive time period needed to implement a policy. While outcomes could not be measured, The March of Dimes reported an increase of appropriate assessments by clinicians and an increase in standardization of practice after the implementation of PLAT (Figure 9) in hospitals throughout the U.S. There was an increase in disposition decisions based on completed cervical change assessment. The March of Dimes reported, on average, full compliance with the new protocol and procedure after three months (Hedriana et al., 2013). There is no reason to doubt the policy and procedure follow up assessment at the local hospital would demonstrate the same positive results.

Figure 9. Compliance with PLAT decision points pre- and post-implementation of 15 pilot hospitals.



American College of Obstetricians and Gynecologists. (2018). Compliance with PLAT decision points pre- and post-implementation of 15 pilot hospitals. Retrieved from <https://www.acog.org/?IsMobileSet=false>

Future Recommendations

The literature review revealed a few recommendations to strengthen the body of evidence related to fFN and collection methods. More randomized controlled designed studies with a focus on blind sweep fFN and its effectiveness on preventing PTL is recommended. Additionally, study of the effectiveness of the PLAT combined with the use of fFN testing after implementation and the changes in hospital admission rates is also recommended.

Additionally, the FDA only approvals of collection for fFN using the speculum route. Further research would support adding the blind sweep method as an approved format to obtain fFN. This would support the use of published protocols and guidelines.

Conclusion

As previously mentioned, the policy and procedure created as a result of this thesis was accepted by the local hospital and is in process to be implemented. Next it will be presented at the upcoming yearly skills day for the labor and delivery unit RNs. Because of this policy and procedure, each individual obstetrician will have the option to order a blind sweep fFN test based on the assessment of the patient. As shown in the literature review and the March of Dimes PLAT (2013), standardization of care for pregnant women who present with the signs and symptoms of PTL can help decrease unnecessary medical admissions and interventions, allow adequate time for steroid administration and transportation to an appropriate facility for patients presenting with signs and symptoms of PTL (Hedriana et al. 2013). Guidelines clearly support the use of fFN for early detection of PTL, while there is still some debate regarding the best collection method. The literature and evidence in this thesis support the use of fFN in detecting PTL using the blind sweep method. The newly approved policy and procedure fFN collection will increase the early detection of PTL, decrease unnecessary use of costly resources, and improve maternal fetal outcomes.

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APPENDICES

APPENDIX A

BLIND SWEEP FFN POLICY

Blind Sweep FFN Policy

OBJECTIVE: policy will guide trained RN in the use of blind sweep fFN collection method in cases of suspected PTL.

PURPOSE: blind sweep fFN collection method is used to detect the presence of fFN in vaginal secretions of pregnant women presenting to labor between the weeks of 22-34 weeks.

DEFINITION: a biomarker for preterm delivery, fFN is highly associated with the risk of preterm delivery when present in vaginal secretions. FFN is a glycoprotein located between the chorion and decidua that is absent or found only in low levels in cervicovaginal secretions between 22 and 34 weeks. A high level (>50ng/ml) of fFN in the cervicovaginal secretions at or after 22 weeks increases the risk of spontaneous preterm birth (PTB).

ROLES/RESPONSIBILITY: protocol will be followed by the labor and delivery RN under the guidance of the admitting obstetrician/midwife with training in the blind sweep fFN collection method.

INDICATION FOR TESTING

Threatened PTL where:

- Change in type of vaginal discharge (watery, mucus, or bloody)
- Increase in amount of discharge
- Pelvic or lower abdominal pressure
- Constant, low, dull backache
- Mild abdominal cramps, with or without diarrhea
- Regular or frequent contractions or uterine tightening
- 23-34 weeks gestation
- Fetus is alive and viable
- No complications that warrant early delivery
- Intended administration of antenatal steroids
- Intact membranes

EXCLUSIONS CRITERIA

- Cervical dilation >2 cm
- Ruptured membranes
- Twin gestation
- Moderate vaginal bleeding
- Vaginal exam
- Recent sexual intercourse

- Cervical cerclage
- Placenta previa
- Non reassuring fetal status

SPECIMEN COLLECTION PROCEDURE

STEP 1- Collect specimen prior to digital examination or manipulation of the cervix to avoid sample contamination.

STEP 2- Without using lubricant, carefully separate the labia and insert the sterile polyester swab directed towards the posterior fornix. Lightly rotate the swab in place for approximately 30 seconds to absorb cervicovaginal secretions.

STEP 3- Remove the swab and immerse tip in buffer. Break the shaft at the score even with the top of the tube.

STEP 4- Insert swab shaft into the hole inside the tube cap and push down lightly over the shaft, sealing the tube with a click. Ensure the shaft is inserted securely to avoid leakage. Label and send fFN sample to lab.

TEST RESULTS

Patient specimens having an absorbance greater than or equal to the absorbance of the positive reference caliber (containing 0.050mg/ml fFN) are defined as positive for the presence of fFN.

Negative fFN (negative predictive value-7 days=99.5%, 14 days=99.2%). Approximately 99.2% of pregnant women with signs and symptoms of PTL who have a negative test result will not deliver within the next 2 weeks. Less than 1% of pregnant women will deliver before 28 weeks if they have a negative fFN test result at 22–24 weeks.

Positive fFN (positive predictive value-7 days=12.7%, 14 days=16.7%). Over 40% of pregnant women with signs and symptoms of PTL who have a positive test result will deliver prematurely (before 37 weeks of gestation). At 22–24 weeks, a positive test result is associated with a 60-fold greater risk of premature delivery than a negative test.

Notify provider with fFN test results for orders.

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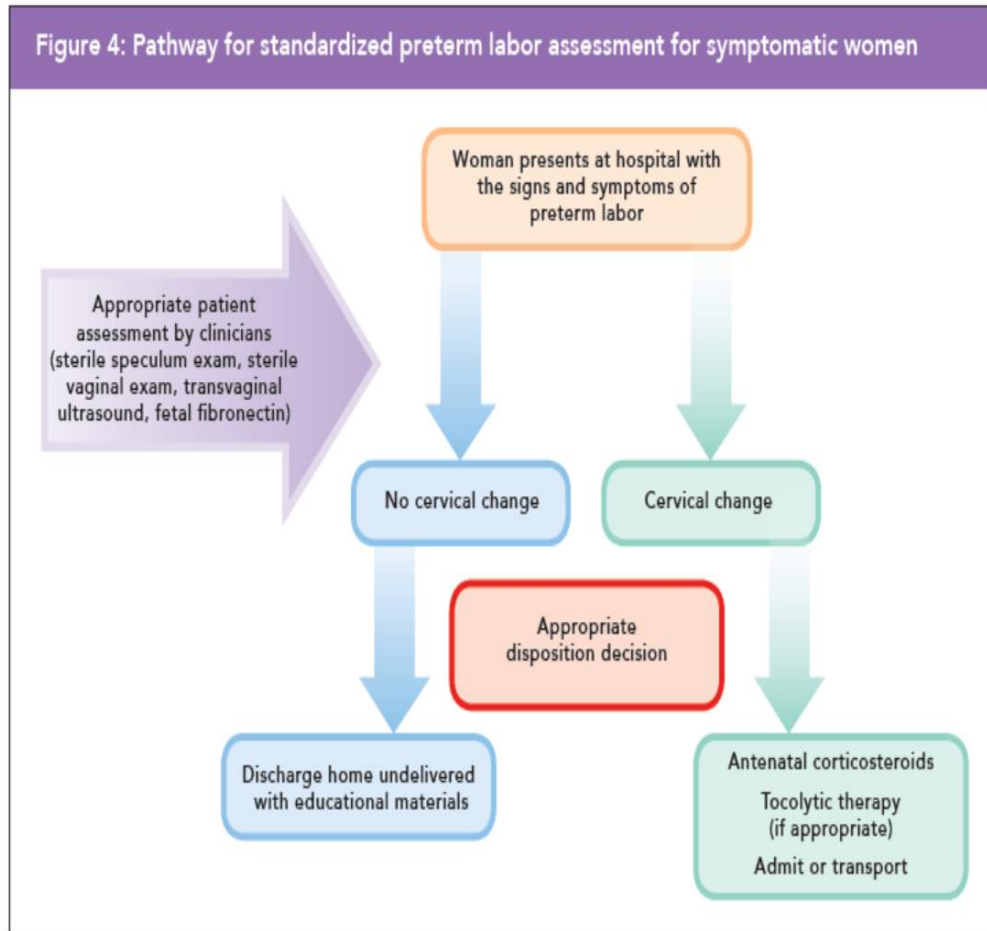
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APPENDIX B

PATHWAY FOR STANDARDIZED PTL ASSESSMENT FOR
SYMPTOMATIC PREGNANT WOMEN

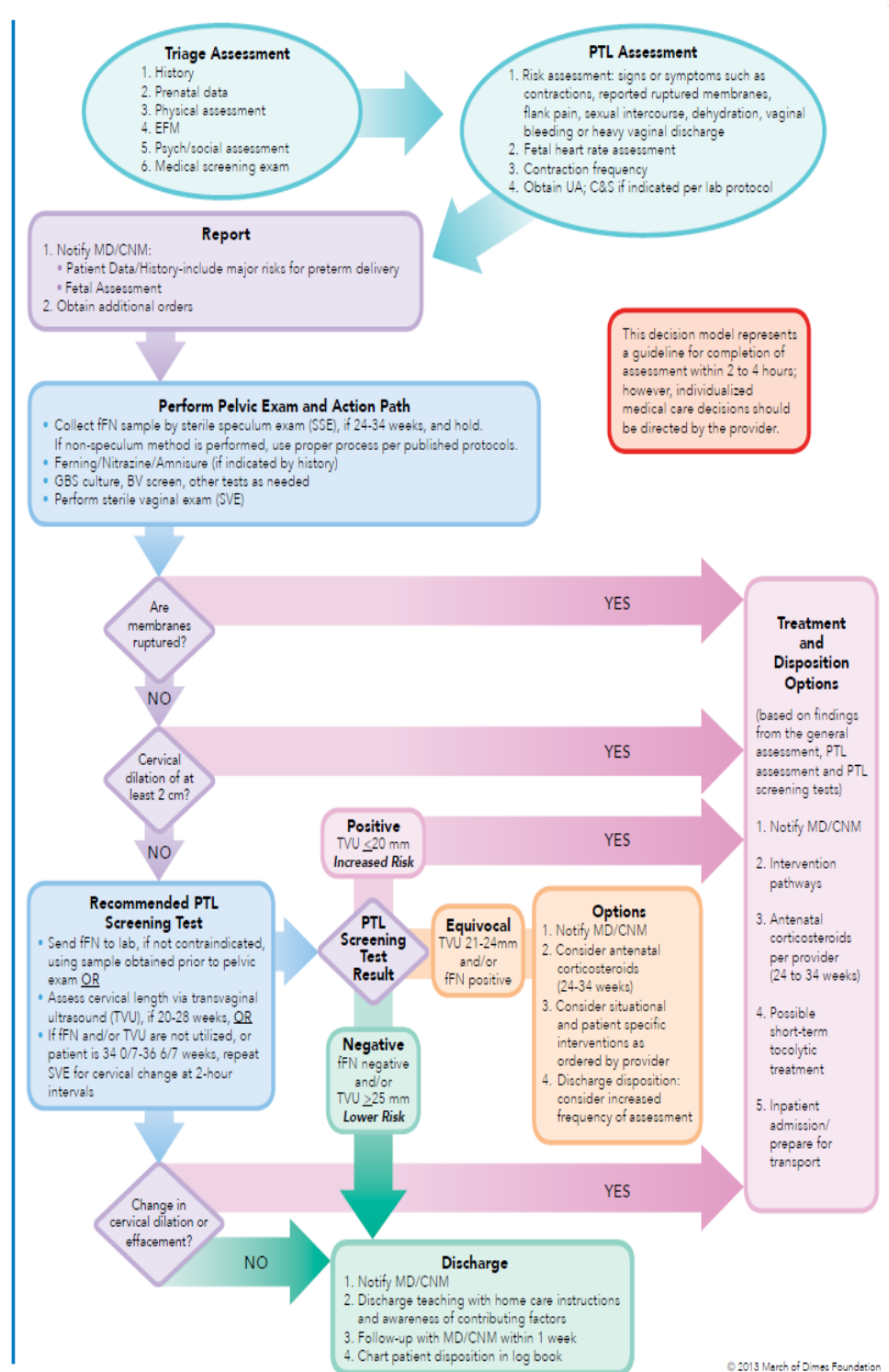


March of Dimes California Chapter, 2013

March of Dimes. Pathway for standardized preterm labor assessment for symptomatic women (2018), [retrieve from marchofdimes.org](https://marchofdimes.org)

APPENDIX C

ALGORITHM FOR PRETERM LABOR ASSESSMENT TOOLKIT
(PLAT) TRIAGE ASSESSMENT



March of Dimes. Algorithm for preterm labor assessment toolkit triage assessment (2018), retrieve from marchofdimes.org

APPENDIX D

STANDARDIZATION OF PRETERM LABOR ASSESSMENT
PRE-IMPLEMENTATION SURVEY

Figure 8: Standardization of preterm labor assessment pre-implementation survey

Standardization of Preterm Labor Assessment Pre-Implementation Survey 	
Name/Title: _____ Hospital Name: _____	
- Does this hospital have a Preterm Labor (PTL) Assessment Protocol? ☐ Yes (Proceed to Question #2.) ☐ No (Proceed to Question #4.) - Does the protocol include a definition of preterm labor? ☐ Yes (Proceed to Question #3.) ☐ No (Proceed to Question #4.) - Does the definition include: (Check all that apply.) ☐ Number of contractions/hour ☐ Cervical dilation ☐ Cervical effacement ☐ All of the above - On average, how long do practitioners observe a patient presenting to this hospital with signs and symptoms of preterm labor before disposition (admission, discharge or transport)? ☐ 0 to 2 hours ☐ Between 2 to 4 hours ☐ Between 4 to 8 hours ☐ Longer than 8 hours - Is it currently the practice at this hospital to use fetal fibronectin (fFN) to assist in the preterm labor patient disposition decision? ☐ Yes (Proceed to Question #6.) ☐ No (Proceed to Question #7.) - If yes, which of the following best describes the use at this hospital: a. ☐ All practitioners use fFN (Proceed to Question #9.) b. ☐ Most practitioners use fFN (Proceed to Question #8.) c. ☐ Some practitioners use fFN (Proceed to Question #8.) - If fFN testing was made available at this hospital, would practitioners use it to assist in the assessment/disposition of symptomatic PTL patients? ☐ Yes (Proceed to Question #9.) ☐ No (Proceed to Question #8.) - Why would practitioners not use the fFN test in the assessment/disposition of symptomatic PTL patients? (Check all that apply.) ☐ No buy-in from the practitioners ☐ Expensive technology ☐ Collection issues ☐ Other: _____ - Is there consistency amongst the practitioners at this hospital in the assessment and disposition (admit, discharge, transport) of women presenting with signs and symptoms of preterm labor? ☐ Yes ☐ No	- How do practitioners decide to send a patient home after she comes to this hospital with signs and symptoms of preterm labor? (Check all that apply.) ☐ No cervical change ☐ Contractions stop ☐ Negative fFN result ☐ Cervical length ≥ 25 mm per transvaginal ultrasound ☐ Practices vary greatly by practitioner. - What makes practitioners admit a patient who comes to this hospital with signs and symptoms of preterm labor? (Check all that apply.) ☐ Cervical change ☐ Contractions ☐ Positive fFN result ☐ Cervical length per transvaginal ultrasound ☐ Practices vary greatly by practitioner - Are the RNs on your L&D unit currently performing sterile speculum exams? ☐ Yes ☐ No - What is the average length of stay at this hospital for a preterm labor patient who is admitted as an inpatient and later discharged home undelivered? ☐ <4 days ☐ Between 4 to 6 days ☐ >6 days - Do practitioners at this hospital ever transfer your preterm labor patients to a higher level of care? ☐ Yes (Proceed to Question #15.) ☐ No (Proceed to Question #17.) - At what gestational age would the PTL patient be transferred? (Select one) ☐ <32 weeks gestation ☐ <34 weeks gestation ☐ <36 weeks gestation - What is the average number of PTL patient transports/year for your hospital? ☐ <5 ☐ Between 5 and 10 ☐ >10 - What issues or needs around preterm labor assessment could the <i>Preterm Labor Assessment Toolkit</i> address at your hospital? _____ _____ _____ _____

March of Dimes. Standardization of preterm labor assessment pre-implementation survey. (2018), retrieve from marchofdimes.org