5-2018

PRETERM LABOR ASSESSMENT TOOLKIT IMPLEMENTATION

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PRETERM LABOR ASSESSMENT TOOLKIT IMPLEMENTATION

By

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SCHOLARLY PROJECT

Submitted to
Northern Michigan University
In partial fulfillment of the requirements
For the degree of

DOCTOR OF NURSING PRACTICE

School of Nursing

May 2018

SIGNATURE APPROVAL FORM

PRETERM LABOR ASSESSMENT TOOLKIT IMPLEMENTATION

This DNP Scholarly Project by Mandi Mae Wilkins is recommended for approval by the student's Faculty Chair, Committee and Department Head in the School of Nursing.

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First Reader Date

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Department Head Date

ABSTRACT

PRETERM LABOR ASSESSMENT TOOLKIT IMPLEMENTATION

Mandi Mae Wilkins

Every year 10% of babies in the United States are born premature. Prematurity is the leading cause of infant mortality. Standardized preterm labor (PTL) assessment protocols reduced preterm birth rates, decreased costs, and resulted in more timely diagnoses and prevented the overtreatment of pregnant women who were not experiencing true preterm labor. At a Midwestern, Level II trauma hospital with regional neonatal intensive care unit and 700 annual deliveries, a Preterm Labor Assessment Toolkit (PLAT) was implemented and pre- and post-data garnered. The toolkit contained a provider algorithm and an order set for triaging preterm labor (PTL) patients. Beginning in fall 2015, a chart audit from a convenience sample of 91 coded threatened PTL patients between 24 and 36.6 weeks' gestation occurred. Post-implementation data was collected after two years on 90 patients with the same criteria. Key measures outlined and compared included disposition to decision times, frequency of sterile speculum and vaginal exams, fetal fibronectin collection, cervical length measurements, and the use of antenatal steroids and tocolytic therapies. In comparison to pre-implementation results, post-implementation findings showed increased numbers of sterile speculum exams, fetal fibronectin collection, and cervical length measurements. In the sample study, the disposition to decision time was cut in half and no patients delivered preterm after implementation of the PLAT protocol.

Keywords: Evidence-based, standardized protocol, preterm birth, quality improvement.

DEDICATION

This scholarly project is dedicated to my father, who always believed in me and said I could do anything in life, the support team who helped me stay steadfast through the hoops, and my husband Michael Wilkins, my sister Brandi McCrum, and a friend and colleague, Patti Greethurst.

ACKNOWLEDGMENTS

I wish to thank my preterm labor project partner Erika Osier RN; my project chair Professor Dr. Jane Campbell; project consultant Maternal Fetal Medicine Specialist Dr. Michael Ruma; and project readers, professors Michelle Johnson RN, and Dr. Kristi Robinia.

PREFACE

Hologic Company, the producer of fetal fibronectin, provided a grant allowing Erika Osier and I to host a Preterm Labor Toolkit Event held July 11, 2016 at Northern Michigan University. The company also provided monetary means for us to present at Henry Ford Hospital and share our research data. Finally, Hologic Company is assisting us in the publication of a white paper where our case study will be showcased in the Fetal Fibronectin Handbook.

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SYMBOLS AND ABBREVIATIONS

AS ..... Antenal Corticosteroids

CL .....Cervical Length

fFN…... ..... Fetal Fibronectin

MOD ..... March of Dimes

PLAT .....Preterm Labor Assessment Toolkit

PTL ..... Preterm Labor

TVUS .....Transvaginal Ultrasound

Preterm Labor Assessment Toolkit Implementation

Chapter One

Clinical Problem

The WHO (World Health Organization) reported over 15 million premature babies are born across the globe each year (2015). Preterm birth is defined as babies born alive at or before 36.6 weeks' gestation of pregnancy, and are further classified as extremely preterm prior to 28 weeks, very preterm between 28 to 32 weeks, and moderate to late preterm between 32 to 37 weeks (WHO, 2015). The WHO (2015) stated 75% of preterm births were preventable with current diagnostic and cost-effective interventions. The March of Dimes (MOD) found one in 10 deliveries are preterm in the United States (MOD, 2016). Preterm birth remains constant as one of the leading causes of infant mortality.

The Centers for Disease Control (CDC) (2017) accounted preterm births are the greatest cause of infant death, with most demises occurring in babies born at less than 32 weeks' gestation. As preterm babies survive, this vulnerable population faces many dangerous and costly health challenges, including respiratory issues from underdeveloped lungs, feeding difficulties, cerebral palsy, intellectual disabilities, and vision or hearing impairments (CDC, 2017). Data from the past decade in the Institute of Medicine Committee on Understanding Premature Birth and Assuring Healthy Outcomes (2007) estimated at minimum, the cost of preterm birth in the United States is $26 billion dollars with the average cost at $50,000 for each baby.

According to the Michigan Department of Health and Human Services (MDHHS), seven out of every 1,000 babies born won't live to blow out candles on their

first birthday cake (2012). Of these deaths, the Michigan Infant Mortality Reduction Plan (MIMRP) found 25% related to premature birth (2012). To address the high infant mortality rate, the Michigan Department of Community Health (MDCH) collaborated with the March of Dimes (MOD) and the Michigan Hospital Association (MHA) to create the MIMRP. The plan aligns with existing policies and health initiatives such as Healthy Babies are Worth the Wait, a campaign promoted to waiting 39 weeks for cesareans or inductions (MDHHS, 2012). Strategies encompassed waiting for full term deliveries, providing progesterone to at-risk mothers, and providing better access to care and decreasing health disparities. One significant area not addressed in the state plan was correctly identifying mothers in preterm labor, allowing for the delay or prevention of preterm births.

Diagnosing and treating threatened PTL (preterm labor) is imperative in preventing preterm birth, and in preventing unnecessary and costly interventions to patients. No standardization in care exists in Michigan nor in the United States for the assessment of threatened PTL patients. Differences in assessment practices result in adverse outcomes and/or preventable complications for both mothers and babies. A patient presenting with PTL can go to one hospital for observation and monitoring, whereas another hospital may use a precise protocol to diagnose PTL. In these cases, if not diagnosed accurately these women are subjected to numerous costly interventions, including transfers via ambulance, admission and observation, IV fluids, fetal monitoring, antenatal corticosteroids, and magnesium therapy. Although some instances of preterm birth are unavoidable, studies show up to 75% of mothers presenting in threatened PTL go on to deliver healthy babies at term (March of Dimes, 2016).

Adopting a PTL assessment protocol can decrease preterm birth rates, improve outcomes for mothers and babies, and save patients, hospitals, and taxpayers economically. Standardization of care for preterm labor patients has been very successful in numerous hospitals across the United States through implementation of protocols such as the Preterm Labor Toolkit (PLAT), which was advocated for by the March of Dimes at the time of this research (2016). PLAT consists of an algorithm and protocol of care measures based on presenting symptoms and health status of the preterm labor patient. The evidence-based protocol allows a guide for care providers to implement interventions and diagnostic testing such as sterile speculum exams, fetal fibronectin collection, and cervical length measurements. At minimum, adoption of fetal fibronectin testing and cervical length measurements of the protocol require consideration, as these were identified as predictors associated with impending preterm birth (Bolt et al., 2011).

The purpose of this project and clinical research was to improve healthcare outcomes within the upper peninsula of Michigan by standardizing care for preterm labor patients. The goal for implementation of this standardized care model was to decrease patient transfers from outlying facilities, increase cost savings, and improve overall patient outcomes for the region.

The Donabedian (1988) theoretical framework for quality of care was a conducive guide for this project. Addressing quality in this theory occurred by reviewing how well care was performed, if there were positive outcomes, and monetary effectiveness (Donabedian, 1988). Statistics of the adherence to the standard protocol, outcomes of patients including delivered or undelivered status, disposition to decision times, and cost

savings for decreased length of stays and transfers from outlying facilities were all examined in this project.

The PLAT set forth a standardized algorithm for providers based on patient assessment data and specific premade order sets allowing for care interventions (see Appendix A). Donabedian (1988) placed suppositions in the quality of care into three categories: structure, process, and outcome. Structure is indicative of the setting in which care ensues. The project was conducted at a Level III trauma hospital with regional NICU and resources to implement all components of PLAT. The process represented the care provided or standardized preterm labor protocols instituted in this case. Finally, for the Donabedian model, the outcome designated effects of care implemented on the population, identified in this study as preterm labor patients and their offspring.

Chapter Two

Literature Review

An extensive literature review was conducted for this project. Search tools included the Cochrane Library and resources cited from the March of Dimes Preterm Labor Assessment Toolkit. A search through the Cochrane Library with key words *preterm labor assessment* yielded 534 results, which was narrowed down to seven by *choosing pregnancy*, *childbirth*, and *prevention* subtitles with a back date from 2008. Results were narrowed to four articles. Pertinent key articles represented in current literature regarding standardization of preterm labor, fetal fibronectin, and cervical length measurement were garnered.

Preterm labor and birth place a strain both on the economy and on patients emotionally. Examined in research were the phenomenon and cause of preterm labor, while providers tracked risk factors for individual patients and treatment accordingly. A standardized approach to utilizing the pathophysiology behind PTL and monopolizing on clues set forth by the human body was attained with current diagnostics and protocols.

Rose (2010) was a cornerstone article for this project and consisted of a 12-month retrospective observational study at the Mayo Clinic. A protocol similar to the Preterm Labor Assessment Toolkit was implemented to standardize care of threatened preterm labor patients. In outcome data for the Rose (2010) study, only three women delivered within 7 days, out of 201 patients; and the hospital admission rate decreased by over half in that year, resulting in an annual cost savings of $40,000.

A study by Lucovnik, Chambliss, and Garfield (2013) tracked unnecessary treatment costs by conducting a chart audit on 12 months' worth of data from

hospitalizations for preterm labor at less than 34 weeks' gestation. Lucovnik et al. (2013) found hospital costs to be just over one million dollars to manage care for patients who went on to deliver full term, with the mean patient cost at just over $20,000. The study concluded futile interventions contributed to the explosion of health care costs and were preventable through the use of current diagnostic tests and standardized protocols (Lucovnik, Chambliss, & Garfield, 2013).

Diagnostic tests beneficial in diagnosing preterm labor include (fFN) collection and cervical length measurements. Fetal fibronectin is a glycoprotein secreted by chorionic membranes that adhere membranes to the underlying maternal decidua and indicate preterm labor if found in cervco-vaginal secretions between 24 weeks' and 34 weeks' gestation. The fFn test has been in practice for the past 2 decades. Peaceman et al. (1997) found the test carries a negative predictive value of 99% that a woman will not deliver within 2 weeks of a negative fFN test.

The Iyer et al. (2012) study conducted by Brigham Women's and Children's Hospital found the implementation and use of fFN alone decreased the hospital's unnecessary PTL admissions that resulted in a one million dollar a year cost savings. Results from a Cochrane systematic review by Bergella (2008) examined five-controlled studies of nearly 500 pregnant women and found a lack of sufficient evidence to support or negate the use of the fFN for diagnosing women with PTL. More recently, Blackwell et al. (2017) completed a retrospective cohort study and analysis using information from a large insurance claims database containing nearly 23,000 patient charts. Results of the study found the number of patients who delivered preterm within 3 days of discharge of OB triage was lower in women who received fFN screening (Blackwell et al., 2017).

Blackwell et al. (2017) noted of their sample, 20% of patients delivered preterm within 3 days of discharge, and of those patients, only 4% were evaluated with fFN.

Cervical length measurements via ultrasound are another diagnostic tool utilized for threatened preterm labor patients. A review conducted by Slager and Lynne (2012) revealed gestational age is a predictor of preterm labor and subsequent birth. Slager and Lynne (2012) found women with cervixes less than 25mm had nearly a 45% risk of giving birth within the following 7 days. In contrast, Berghella, Baxter, and Henrix (2013) provided an additional review of literature and noted a lack of sufficient evidence to recommend routine CL screening in pregnancy.

As utilized in the PLAT algorithm for this study, evidence based research shows that combining the use of the fFN test and CL measurement provides the most accurate diagnosis. DeFranco, Lewis, and Odibo (2013) stressed the importance of concurrently using the fFN test and CL measurement in a systematic research analysis and explained the combined effect had a negative predictive value of 93%. McCue and Torbenson (2017) revealed fFN elicited cost savings by ruling out patients with false labor, and when used concurrently, the positive predictive value increased to 45%. A cost-effectiveness study on these two diagnostic tests was conducted by Van Baaren et al. (2013) in The Netherlands. Results of the study, found by triaging PTL patients with a CL measurement less than threshold and combining fFN testing, indicated accrued savings were between $3 and $14 million (EUR) annually on the unnecessary treatment of women not in true PTL.

Chapter Three

Methodology

In October 2015, the March of Dimes Preterm Labor Assessment Toolkit was implemented at a Level III hospital in the upper peninsula of Michigan, with a regional NICU having 700 annual deliveries. Institutional Review Board approval was obtained for the project (see Appendix B). The regional hospital cares for all area high risk obstetrical patients and receives transfers from outlying facilities on a regular basis (see Appendix C). A majority of these patients are eventually discharged home undelivered after receiving multiple costly interventions and a 1 to 2 day hospital stay.

The PLAT algorithm was initiated to standardize care, improve patient outcomes with shorter disposition to decision times, and enable cost-effectiveness in treating threatened preterm labor patients for the hospital. Provider buy in was obtained via informational meetings and staff education was executed. Specific order sets were put in place for PTL patients, including having fFN at the top of the set for alerting providers to obtain this key measure first. fFN must be collected prior to a sterile vaginal exam with gel that can give false positive results, and be obtained via cervical secretions therefore requiring a sterile speculum exam.

The algorithm (see Appendix A) utilized a specific protocol for triaging PTL patients based on gestational age and presenting condition. If adhered to, any patients with no amniotic rupture that were between 24 and 34 weeks gestation had a fetal fibronectin obtained via a sterile speculum exam. In addition, a sterile vaginal exam would be performed to ensure the patient was not dilated past 2 cm. Finally, a transvaginal ultrasound would then be conducted to measure the cervical length. If found

to be greater than 25 mm and the fetal fibronectin negative with no cervical dilation >2cm, than patients were placed in a low risk category for PTB and could be discharged home. If patients were found to be at a high risk for PTB, than appropriate interventions were given including tocolytics to relax the uterus from contracting and corticosteroid therapy to improve lung maturity.

The retrospective cohort study compared a convenience sample of 90 preterm labor patients in the 2 years prior to implementation, with a convenience sample of 91 patients in the 2 years following implementation. Patient selection occurred using ICD 9 and ICD 10 codes indicating threatened preterm labor and individuals were between gestational ages of 24 and 36.6 weeks, respectively. Charts were analyzed and anonymous patient data were input into the March of Dimes PLAT Chart Audit Tool.

Data included specific outcome measures and clinical decision points of the PLAT algorithm and protocol. Nominal and scale statistics comprised:

- Gestational Age
- Sterile Speculum Exam
- fFN Collection
- Transvaginal US for CL
- Disposition: admitted or discharged
- Time to disposition
- Tocolysis Administration
- Antenatal Steroid Administration
- Cost Savings (nursing hours/fetal monitoring)

Findings from these specific data for both pre-implementation data and post-implementation data were compared. Statistical analyses occurred using SPSS Statistics 2017 software to ascertain the significance of different diagnostic tests, including fFn, and transvaginal ultrasound. Transfer patient data were analyzed for frequency, length of stay, and overall outcomes of delivery or discharge. A major basis for analyzing data was the disposition to decision, or triage times after implementation of the protocol.

Chapter Four

Project Analysis

In reviewing results of the study and reflecting on the guidance of the Donabedian Model (see Figure 1), findings were positive in effect of the implementation of a standardized protocol. The structure or algorithm allowed for triage time from disposition to decision to reduce by 50%, saving both time and resources. Clinical decision points and diagnostics completed in the process increased by 10% in post-implementation data to allow more competence in decision-making. By utilizing the protocol, the overall outcome was this regional obstetrical unit became more efficient in diagnosing and treating preterm labor, meeting the goal to improve patient outcomes and decrease unnecessary costs.

Results

Compared in the study were 2 years' pre-implementation with 2 years' post-implementation data from the implementation of the PLAT with standardized algorithm for the treatment of PTL patients. The sample of patients included women of childbearing age who resided in the upper peninsula of Michigan, a rural underserved area of roughly 300,000 residents. Patients in the sample size were between 24 and 36.6 weeks' gestational age (GA), with the average GA at 32 weeks. Criteria for the sample included patients identified with ICD-9 and ICD-10 codes for preterm labor or threatened preterm labor.

Table 1

Results of study on maternal admissions and triage time

Results

	Maternal Admissions[a]	Disposition to decision time[b]
Pre-implementation (n=90)	9	5 hrs
Post-implementation (n=91)	2	2.6 hrs

[a]Maternal transfer patients not included
[b]P-value 0.013

Of 181 patients evaluated, 11 in the pre-implementation group delivered preterm, and zero patients in the post-implementation group delivered preterm at that visit. After implementation of the protocol, the average time in triage from disposition to decision was decreased by nearly half from 5 hours post-implementation to 2.6 hours pre-implementation (95% confidence interval [CI], Pvalue= 0.013). This resulted in a calculated estimated savings of $340,000 in triage costs in the post-implementation sample.

Compared to pre-implementation data and removing transfer patients who were automatically admitted, results showed maternal hospital admissions decreased by 78% (nine versus two patients). A length of stay for admission with preterm labor was on average 3 days long. This reduction in admissions brought about savings of approximately $150,000 in the post-implementation sample.

Table 2

Cost Savings

Cost-Savings

Item	Cost	Savings
1 Hour in Triage	$2600	$330,000
3 night LOS OB Unit	$22,800	$150,000

All clinical decision points increased with the use of the standardized algorithm. Sterile speculum exams with fFN collection in the post-implantation group increased by nearly 20%. Transvaginal ultrasounds doubled, adding to the level of competency and assurance in positive predictive value of the diagnosis. Tocolysis increased by 10% and AS increased in patients admitted.

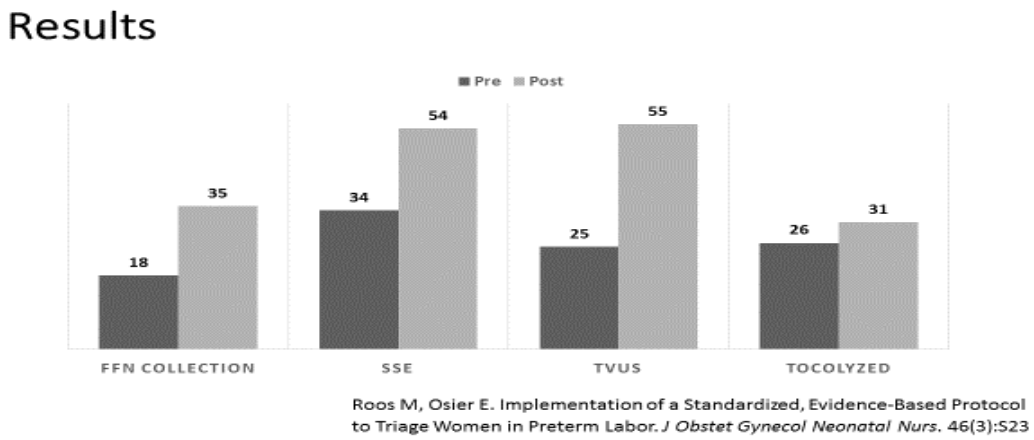

Figure 1. Results of descriptive data in percentages

Transfer patient outcomes improved with 29 patient transfers sent home undelivered in the post-implementation study sample, compared to the pre-implementation sample where six patient transfers (out of 22) delivered preterm. Transfer patients in the area can be problematic for the regional unit as these patients utilize resources including transportation via ambulance, costly interventions, and automatic admission. At UPHS Marquette, the average outpatient cost is $3,000, whereas a transfer patient admission can cost as much as $17,000 after a 3-night stay with medical interventions. The hospital is currently identifying ways to decrease unnecessary transfers by instituting the PLAT protocol or at minimum the fFN collection at outlying sending facilities.

Conclusion

This was the first study with the focus on evaluating the effectiveness of a standardized algorithm for triaging preterm labor patients in the upper peninsula of Michigan. Examined in the retrospective study were 90 pre-implementation preterm labor patient charts in the 2 years preceding with 91 post-implementation charts in the 2 years after initiation of the protocol. The use of an evidence-based standardized algorithm in triaging PTL patients was effective in both improving patient outcomes and in decreasing costs. Hospital admissions decreased by 78%, which resulted in an estimated $150,000 cost savings. The time of disposition to decision, or time in triage, decreased from approximately 5 hours to 2.6 hours. This accounted for an estimated $340,000 in cost savings. When coupled with admission savings, the result was nearly $500,000 in savings for the hospital over a 2-year period in only a small sample of patients.

Patient outcomes improved reflective with less time in triage by a disposition and diagnosis made quicker with standardized evidence-based diagnostic testing, allowing for peace of mind. Of patients admitted for preterm labor in post-implementation data, all were discharged home undelivered from that visit. This included transfer patients sent from outlying facilities who were automatic admissions with 3-day stays.

Hospitals across the United States can synthesize research included in this study and others such as the Rose (2010) study at the Mayo Clinic. Outcomes of both studies provided strong evidence a standardized algorithm for triaging PTL patients improves patient outcomes and decreases unnecessary costs to hospitals. Preterm births are the number one cause of infant deaths across the United States and the world. Consistent implementation of evidence-based protocols such as PLAT can improve patient outcomes for this population.

It is imperative all healthcare agencies have collaboration, commitments, and cooperation from administration, physicians, multidiscipline teams, and nurses to implement standardized algorithms for improved patient outcomes and to become more fiscally responsible in accruing unnecessary healthcare costs. Next steps should address implementing a national standardized algorithm that tailored to facilities based on their resources. Strategies to attain this would involve the comprehensive approach and advocacy of dedicated individuals to highlight benefits from the latest research such as this study to national audiences, including government health committees. In the future, hospitals across the United States should adopt and personalize a standardized algorithm to triage preterm labor patients efficiently for improved patient outcomes.

Limitations to the study included the convenience sample of patients. A limitation in this study was patients were coded with specific ICD-9 and 10 codes for preterm and threatened preterm labor. The limitation identified in data collection was that some patients were coded incorrectly and were not preterm labor patients; such patients were removed from the study. Another limitation to the convenience sample was transfer patients. Due to the automatic admission and nature of treatment, transfer patients skewed data from admissions. To garner a true admission percentage, transfer patients were excluded from the number of admissions.

A final limitation to the study was that transvaginal ultrasounds increased two-fold and this had the potential to decrease cost savings. Transvaginal ultrasounds can cost $1,000-$3,000. Even with this limitation, savings to the hospital were identified and rather remarkable at nearly half a million dollars in 2 years on a fraction of patients triaged. The clinical measure of transvaginal ultrasound with cervical length allowed overall for a more definitive diagnosis and discharge sooner for patients, which may offset the extra cost.

Aside from study limitations, results of this research provided positive assurance in the effectiveness of a standardized algorithm for PTL patient triage moving forward. The outcome for patients to have peace of mind with swifter diagnoses and either discharge or admission and treatment is imperative. Future studies can assess and measure this qualitative data behind standardized protocols from the patient's point of view and experience.

After implementation of the standardized PTL algorithm, patients were triaged faster and subsequently discharged sooner receiving fewer unnecessary costly interventions if not high risk for PTB. Patients identified in PTL received treatment earlier to have better outcomes by stopping or slowing the progression of labor and allowing antenatal corticosteroid (AS) treatment. The correct timing of AS within 1 week of delivery was key to their benefit in allowing for fetal lung maturity. Results from a study conducted by Adams, Kinzler, Chavez, and Vintzileos (2015) revealed 80% of the time patients receive AS at suboptimal timing. Utilizing evidence-based standardized algorithms, such as PLAT, increased the potential to improve the timing of AS and the outcomes for preterm babies.

In the post-implementation group, no preterm deliveries were noted at hospital visits and all admitted patients were discharged home undelivered. Studies such as Rose (2010) tracked patients sent home undelivered to assess if they went on to deliver at term. This was efficient in analyzing the true outcomes of these mothers. In future studies, end outcomes of the PTL patients can be measured to assess the validity of the standardization further. For this study, in the immediate triage visit, optimal outcomes were found including decreased disposition to decision times and less maternal admissions with resultant increased cost savings. Although preterm birth at times can be inevitable, in cases where a standardized protocol is followed to diagnose and treat, improved outcomes are possible in this population.

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Appendix A

MOD Preterm Labor Algorithm

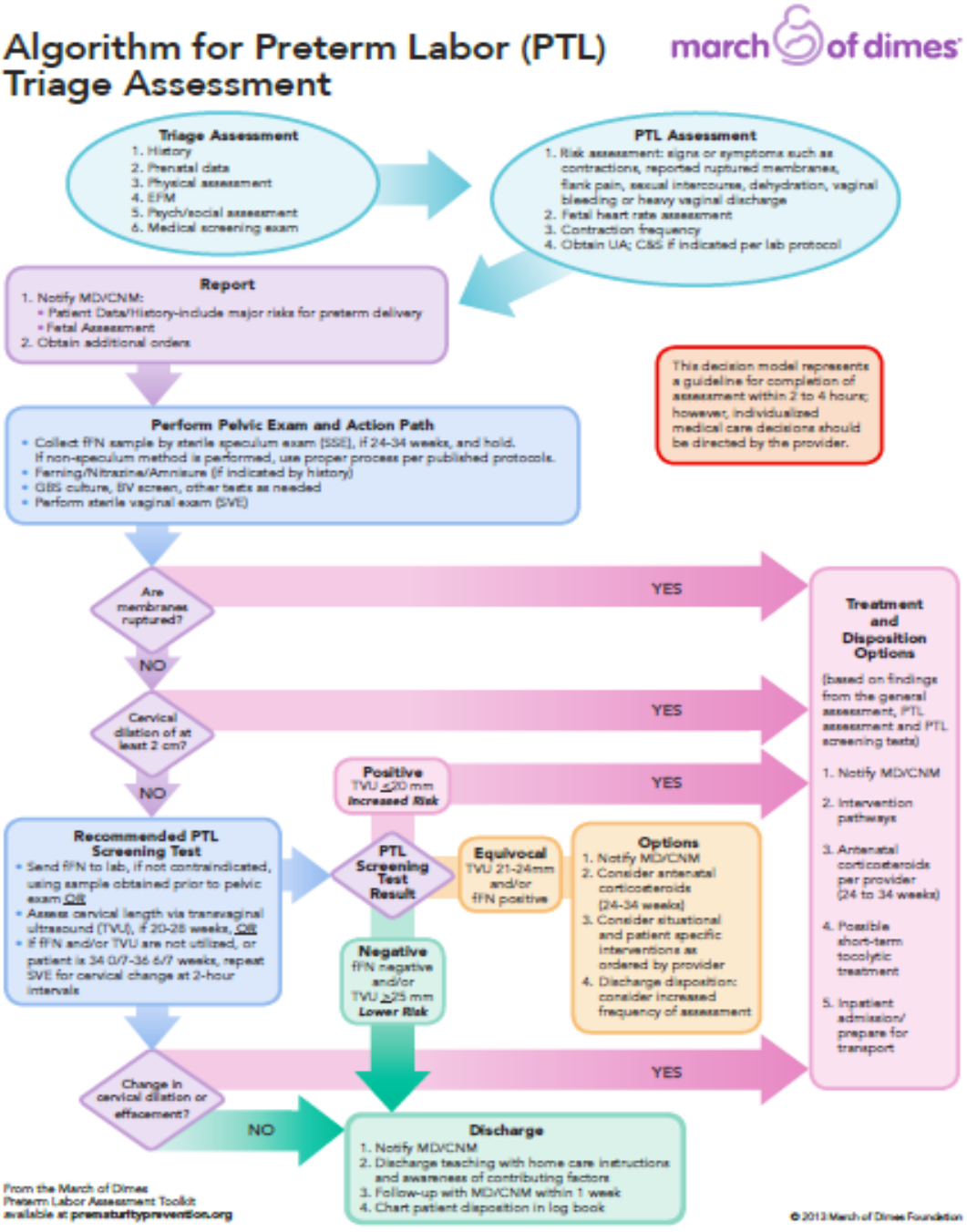
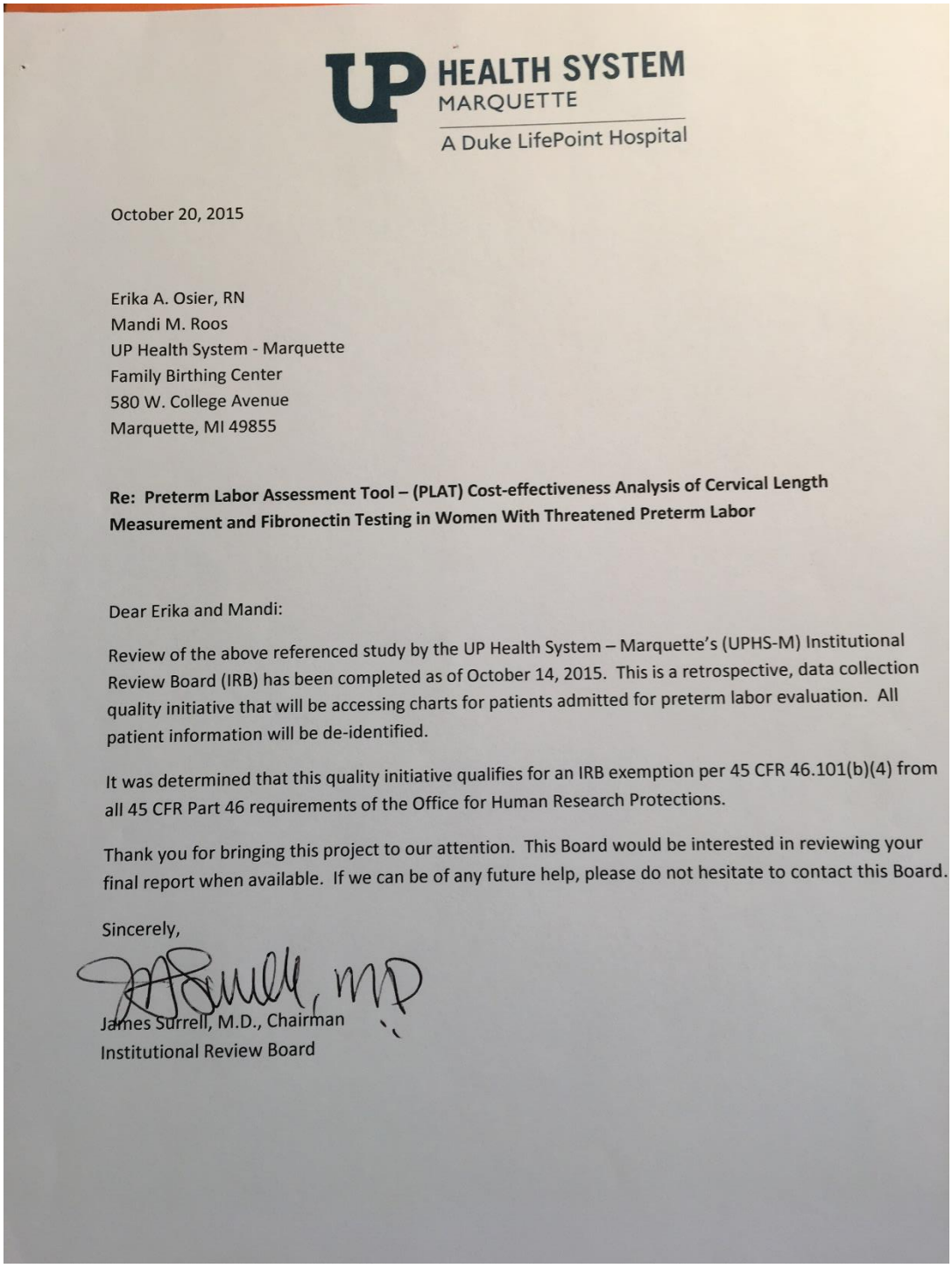


Figure. March of Dimes Preterm Labor Assessment Toolkit Algorithm (2010)

Appendix B

IRB approval UP Health Systems Marquette



UP HEALTH SYSTEM
MARQUETTE
A Duke LifePoint Hospital

October 20, 2015

Erika A. Osier, RN
Mandi M. Roos
UP Health System - Marquette
Family Birthing Center
580 W. College Avenue
Marquette, MI 49855

Re: Preterm Labor Assessment Tool – (PLAT) Cost-effectiveness Analysis of Cervical Length Measurement and Fibronectin Testing in Women With Threatened Preterm Labor

Dear Erika and Mandi:

Review of the above referenced study by the UP Health System – Marquette's (UPHS-M) Institutional Review Board (IRB) has been completed as of October 14, 2015. This is a retrospective, data collection quality initiative that will be accessing charts for patients admitted for preterm labor evaluation. All patient information will be de-identified.

It was determined that this quality initiative qualifies for an IRB exemption per 45 CFR 46.101(b)(4) from all 45 CFR Part 46 requirements of the Office for Human Research Protections.

Thank you for bringing this project to our attention. This Board would be interested in reviewing your final report when available. If we can be of any future help, please do not hesitate to contact this Board.

Sincerely,

James Surrell, M.D., Chairman
Institutional Review Board

Appendix C

Name of Appendix

Figure. Upper Peninsula Regional Hospital and outlying critical care access facilities