Preterm Labor Assessment Toolkit

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Preterm Labor Assessment Toolkit

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Introduction

There is substantial evidence in the literature of wide variation in the practices used to assess patients with symptoms of preterm labor, more than 75 percent of whom will deliver at term.[1,2,3] The March of Dimes offers a solution to this problem: the *Preterm Labor Assessment Toolkit (PLAT)*, a step-by-step guide for establishing a standardized clinical pathway for the assessment and disposition of women with suspected signs and symptoms of preterm labor. By addressing assessment of women with symptoms of preterm labor, we believe this toolkit complements recent publications from the American College of Obstetricians and Gynecologists (ACOG) related to: screening and management of asymptomatic women at risk of preterm birth; and management of women with confirmed preterm labor.

More than 75 percent of patients with symptoms of preterm labor will deliver at term.

Variation in assessment practices can result in avoidable complications for newborn babies. Standardization is thus a necessary response to preventable morbidities that may result in lifelong disabilities and chronic conditions. *PLAT* delineates an overarching standard that can be implemented at all levels of maternity care. This approach facilitates safe and timely triage and patient disposition, while minimizing potentially unnecessary interventions. It ensures that pregnancies at significant risk for preterm birth receive beneficial treatment in a timely manner, including antenatal corticosteroids and transport to a higher level of hospital care, when indicated, so that infants with very low birthweight (<1,500g [3.3 lbs.]) will receive appropriate care in the neonatal intensive care unit (NICU).

Implementation of a standardized protocol to identify those patients who are truly in labor will benefit *all women* who present in triage with suspected preterm labor. Hospitals providing all levels of care will be able to achieve the following five goals within a relatively brief time frame:

- Provide timely and appropriate interventions for preterm labor
- Optimize maternal-fetal safety
- Hospitalize only those patients at greatest risk for preterm delivery
- Promote effective and timely management to improve neonatal outcomes
- Avoid unnecessary treatment, interventions and medications

In 2013, the March of Dimes California Chapter, in collaboration with partners in California and across the country, revised the first edition of the *Preterm Labor Assessment Toolkit*. *PLAT* was developed in 2005 as a collaborative project of Sutter Medical Center, Sacramento and the March of Dimes California Chapter. This new edition incorporates advances in research and best practices, including feedback from providers who implemented *PLAT,* findings from 15 hospitals that participated in a pilot study, and insights gleaned during the first eight years of this project.

Following this introduction, *PLAT* is divided into five sections and also includes seven appendices:

1. **Overview** of preterm labor and discussion of key clinical issues.
2. One-page **Algorithm** (decision model), a **Protocol** and an **Order Set** for the assessment and disposition of women who present with signs and symptoms of preterm labor.
3. **Recommendations for Data Collection**, including suggested metrics and ICD-9, ICD-10, CPT, and HPCPS codes; pre- and post-implementation surveys and a sample chart audit tool.
4. **Implementation guidelines** for developing a standardized pathway for assessment and care as a quality improvement (QI) initiative. The guidelines present key components of change within a QI framework along with a standardized process (the MAP-IT quality improvement method) and a checklist for tracking the MAP-IT cycle.
5. Discussion of the integral role of **Patient Education and Home Care**. Includes home care instructions, a list of key patient education messages and information about patient education resources available from the March of Dimes in both Spanish and English.

Introduction

Appendices:

- Appendix A presents four **areas of evolving care** in the management of preterm labor including: care for women between 34 0/7 and 36 6/7 weeks of pregnancy; progesterone therapy for preterm birth prevention; use of tocolytics; and testing for preterm premature rupture of membranes or PPROM.
- Appendix B is a **decision tree and poster presentation** on the use of antenatal corticosteroids for fetal maturation at 24 to 34 weeks gestation.
- Appendix C includes web links to training in several **Competencies** that staff at some hospitals may need to develop.
- Appendix D is the **Evaluation Report** of the March of Dimes California Chapter's pilot study of *PLAT*.
- Appendix E presents **Case Studies** of two hospitals' experiences implementing *PLAT*.
- Appendix F is a **PowerPoint® presentation** that makes the case for standardizing preterm labor assessment and provides an overview of *PLAT*. It may be used for internal educational purposes by hospitals that adopt *PLAT*.
- Appendix G **acknowledges the experts** who collaborated on the first edition of *PLAT*.

The toolkit concludes with comprehensive **endnotes** to the research cited.

As providers, educators and advocates of maternal and child health, a formidable challenge lies ahead in our efforts to reduce the maternal-fetal complications associated with premature birth. The March of Dimes and our partners believe that standardized assessment of women with suspected preterm labor holds great promise for improving neonatal outcomes, reducing the lifelong burden of illness and disability in this population, and containing annual costs upwards of $26 billion.[4]

March of Dimes
October 2013

Introduction

Planning Notes:

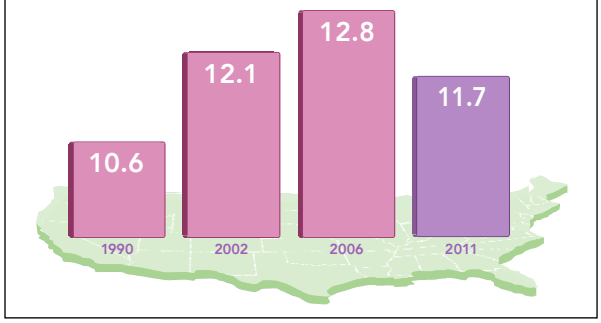
Overview

Preterm Labor Assessment and Clinical Disposition of Patients

In This Section

In 2011, approximately half a million babies were born too soon in the United States. Compared to babies born at or after 39 weeks, preterm babies are at greater risk of hospitalization, long-term health problems and infant death. In 2011, the rate of preterm birth in the United States was 11.7 percent (Figure 1).[5] This represents an 8.6 percent decrease since 2006, following a 20 percent increase since the early 1990s.[5,6] From this data, it is too early to know whether this downward trend will continue over time.

Figure 1: Preterm births, as percentage of all births, 1990 to 2011

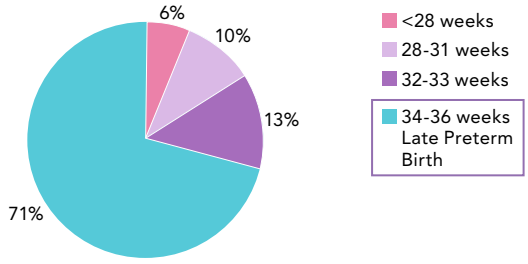


Source: National Center for Health Statistics, 1990 to 2011 final natality data

As shown in Figure 2, in 2011, 71 percent of preterm births occurred at or after 34 weeks of gestation (late preterm).[5] This represents an almost 9 percent decrease in the late preterm birth rate since 2006, following a 25 percent increase since the early 1990s.[7] Preterm birth is the leading cause of perinatal mortality and morbidity,* and presents a staggering economic burden to families, hospitals and public and private payers (Figure 3). In 2005, the Institute of Medicine estimated that the annual cost of preterm birth-related medical and educational expenses as well as the associated loss of productivity was more than $26 billion.[4]

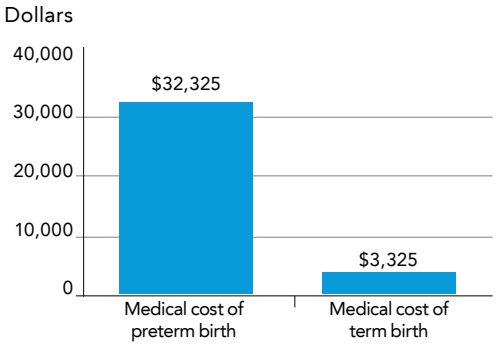
In 2006, the March of Dimes focused national attention on the enormous clinical and public health burden of preterm birth with passage of the PREEMIE Act (P.L. 109-450), which for the first time coordinated federal efforts to reduce premature birth. The *PREEMIE Reauthorization Act* represents a renewed commitment to our nation's efforts to reduce premature birth; expanding upon the original legislation to enhance research into the causes and prevention of preterm birth. Securing passage of the *PREEMIE Reauthorization Act* in the 113th Congress is a top federal advocacy priority for the March of Dimes.

Figure 2: Preterm birth by week of gestation, U.S., 2011



Source: National Center for Health Statistics, 2011 final natality data

Figure 3: Comparison of medical costs of preterm and term birth: U.S., 2005[8]



* *Preterm birth is associated with short- and long-term developmental delays, disability over the life course, and serious medical complications including cerebral palsy, sensory deficits, chronic lung disease, blindness, and hearing loss. (http://www.marchofdimes.com/baby/premature-babies.aspx, accessed July 23, 2013.)*

More than one-third of deaths during the first year of life are attributed to preterm-related causes. (http://www.prb.org/Articles/2009/prematurebirths.aspx, accessed August 6, 2013.) See also Honein MA, Kirby RS, Meyer RE, et al. for the National Birth Defects Prevention Network. The Association Between Major Birth Defects and Preterm Birth. Matern Child Health J. *2009;13:164–175.*

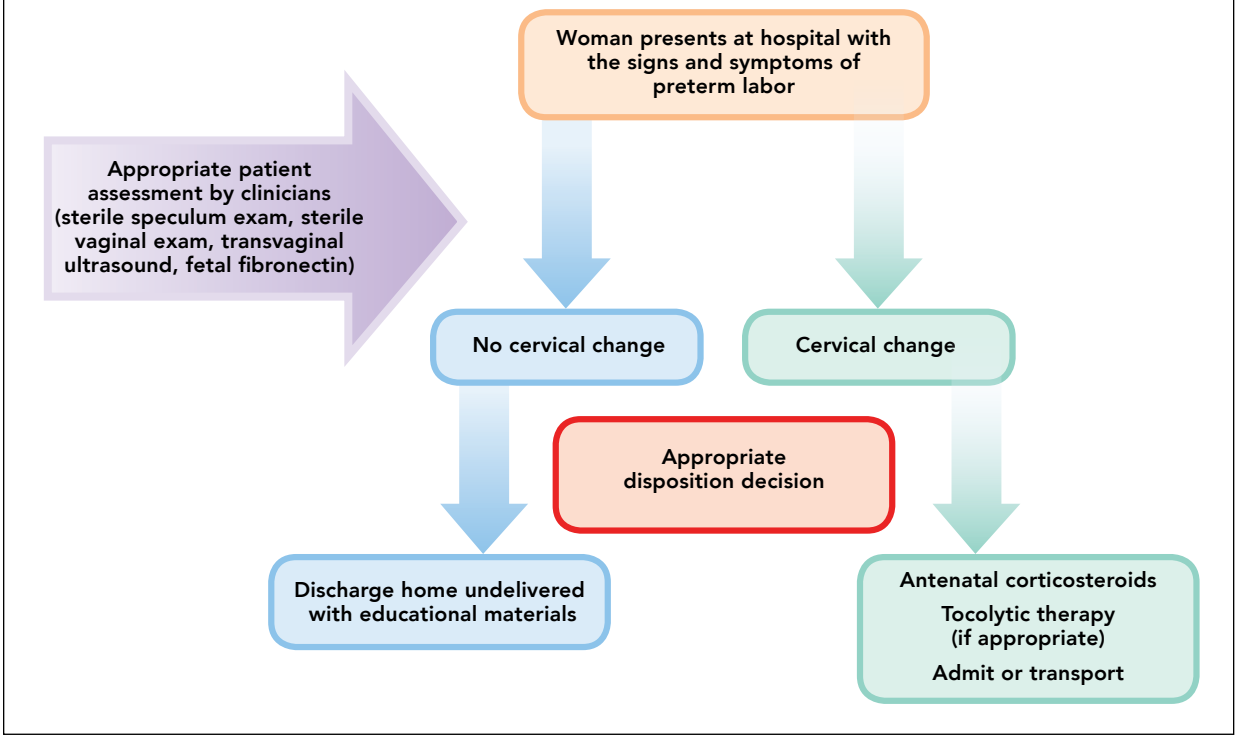
What Can We Do?

The Preterm Labor Assessment Toolkit (PLAT) specifically addresses the population of patients with suspected symptomatic preterm labor ≤36 6/7 weeks of completed gestation. The strategy combines clinical factors (e.g. gestational age, medical screening exam, and electronic fetal monitoring) in conjunction with screening tests to assess risk for symptomatic preterm birth. In doing so, we believe this toolkit complements recent ACOG publications related to the assessment of preterm birth risk in asymptomatic women as well as clinical management of women with confirmed preterm labor. This specific focus is warranted as approximately three-quarters of all preterm births occur spontaneously. Knowing when a woman is in preterm labor allows for timely decision making about possible transport to a higher level of care, administration of antenatal corticosteroids and/or tocolytics, and assembly of the high-risk team. While it may not be possible to decrease the rate of preterm birth for these patients, these interventions are well established to significantly improve neonatal outcomes. However, if a woman is found not to be in preterm labor, her practitioner can withhold unnecessary treatment and, instead, offer appropriate patient education and home care instructions.

Many conditions are associated with preterm birth and offer opportunities to improve outcomes. These include addressing maternal medical conditions and asymptomatic changes in cervical length. Evidence-based assessment and management for these subsets continues to evolve. For women at 34 0/7 to 36 6/7 weeks of pregnancy, assessment and management of preterm labor is controversial, as we discuss in Appendix A: Areas of Evolving Care. Figure 4 is a diagrammatic representation of a standardized pathway for preterm labor assessment for symptomatic women.[9]

The *Preterm Labor Assessment Toolkit (PLAT)* aims to ensure that cervical changes are uniformly assessed in women presenting with signs and symptoms of preterm labor. Uniform practice leads to appropriate disposition decisions. Throughout this document, references to hospital admission may, depending on circumstances, refer either to formal inpatient admission or to admission for short-term observation.

Figure 4: Pathway for standardized preterm labor assessment for symptomatic women



March of Dimes California Chapter, 2013

The March of Dimes California Chapter published the first edition of *PLAT* in partnership with Sutter Medical Center, Sacramento in 2005.[10] *PLAT* was developed in response to variation in practice and the absence of consistent standards for triaging women who present with signs and symptoms of preterm labor, noted in the literature as follows:

- IV hydration provides no benefit in managing preterm contractions during triage.[11]
- One dose of subcutaneous terbutaline does not improve pregnancy outcomes.[11]
- Patients with preterm contractions but no diagnosis of labor are over-treated, whereas those in active preterm labor are under-treated and deliver without receiving antenatal corticosteroids, which have been shown to improve outcomes.[1]
- Of women admitted for preterm labor, 50 percent to 80 percent are discharged and ultimately deliver at term.[12]
- Patients with negative fetal fibronectin test results who have ongoing, suspicious, mild symptoms continue to undergo unnecessary interventions such as admission and administration of tocolytics, corticosteroids and antibiotics that fail to increase the length of their babies' gestation.[13]
- Introduction of the fFN test into the standard triage process decreases antepartum admissions, costs per admission, length of stay, and use of tocolytics with no adverse impact on neonatal outcomes; and results in significant cost reduction in preterm labor management.[14]
- Overdiagnosis of preterm labor is common because the clinical criteria for diagnosis are inaccurate until labor is well-established. Two objective screens facilitate early detection: transvaginal ultrasound and the fFN test.[3]

Of women admitted for preterm labor, 50 percent to 80 percent are discharged and ultimately deliver at term.

The standardized pathway outlined in *PLAT* (Figure 4) allows for:

- Timely interventions
- Maintenance of maternal-fetal safety
- Hospitalization of only women at greatest risk for preterm delivery
- Effective and timely management to improve neonatal outcomes
- Avoidance of unnecessary treatment, interventions and medication

Prior to publication of *PLAT*, the potential of a programmatic or quality-improvement approach for reducing the number of unnecessary treatments and/or admissions for preterm labor had not been explored. While much had been written about evaluating individual patients' risk of preterm labor, a systems approach was absent.[15]

The current *PLAT* revision draws upon March of Dimes experience with implementation of the original *PLAT* in more than 40 California hospitals, as well as evolving best practices documented in the research literature. Findings from 15 hospitals are included in the *PLAT* Evaluation Report (see Appendix D). *PLAT* also provides guidance for the objective assessment of preterm birth risk, allowing improved performance on The Joint Commission's Third Perinatal Care Core Measure, which recommends administration of antenatal corticosteroids to patients at risk of preterm delivery at ≥24 and <32 weeks gestation.[16]

Standardization of Preterm Labor Evaluation

During the past decade, implementation of standardized protocols has significantly reduced adverse perinatal outcomes.[17,18,19,20] Elimination of elective delivery before 39 weeks is the endpoint that has received greatest attention in hospital-based, regional and statewide systems-change projects.[21,22,23,24] Policies and practices that have been developed and lessons learned in the course of implementing these projects suggest possible steps for standardizing preterm labor assessment.

Several studies have examined the implementation of standardized protocols to evaluate women with symptoms of preterm labor.[14,25,26,27] For example, in 2008, at Rochester Methodist Hospital of the Mayo Clinic, a standardized triage protocol patterned on March of Dimes *PLAT* reduced admissions of women with symptoms of preterm labor by 56 percent.[28] The study authors suggest that, on a national scale, this

reduced rate could result in estimated annual healthcare cost savings of $560 million. Furthermore, the study demonstrated the safety of standardized assessment. No adverse pregnancy outcomes occurred for the 201 patients who were evaluated (protocol specificity 96.4 percent [91.9 percent to 98.8 percent], negative predictive value [NPV] 99.2 percent [96 percent to 100 percent], and mean gestational age at delivery of 38 3/7 weeks), with an average interval of 8 weeks between preterm labor evaluation and delivery.

Assessing Signs and Symptoms of Preterm Labor

Changes in the uterus and cervix occur as pregnancy progresses to term. In preterm labor, cervical ripening and decidual activation occur earlier than uterine contractions and may be difficult to detect. Thus, per Iams, it is not uncommon that diagnosis of true preterm labor is established based on the high-threshold criteria of severe uterine contractions of six or more per hour, cervical dilation ≥3 cm, and 80 percent effacement accompanied either by vaginal bleeding or rupture of fetal membranes.[3] At this point, delivery may be inevitable, yielding insufficient time to prepare the fetus for premature birth.

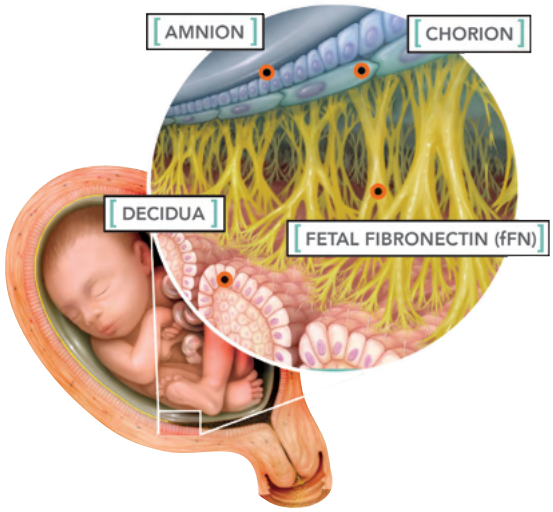
However, as a low-threshold criterion, uterine contractions alone are a poor positive predictor of true preterm labor. They will occur four or more times an hour in up to 1 in 4 pregnancies <32 weeks.[29] As a corollary, less than 40 percent of women diagnosed with preterm labor based solely on the high-threshold criterion of six or more uterine contractions per hour will deliver at term.[2,30]

Two specific and objective tools allow safe and cost-effective evaluation of triage patients who present with uterine contractions without cervical change (a low-threshold sign and symptom of preterm labor). These tools are the fetal fibronectin test and transvaginal ultrasound. In combination with a thorough patient history, medical screening exam and electronic fetal monitoring, the decision to admit, discharge or transport a patient to a higher level of care can generally be made in 4 hours or less.[26,27,28,31] However, for women at 34 0/7 to 36 6/7 weeks of pregnancy, diagnosis and management of preterm labor using these objective tools is less helpful. This is an evolving area of research for which definitive evaluation criteria have not yet been established. Further studies are needed before guidelines can be proposed.

The Fetal Fibronectin Test as an Assessment Tool

Fetal fibronectin (fFN) is a biomarker designed to screen for the risk of preterm labor ≤34 weeks of gestation. A protein related to cellular cohesiveness, fFN is concentrated at the membrane-decidua interface, as shown in Figure 5. During weeks 22 to 35 of a normal pregnancy, it is virtually undetectable in vaginal secretions below a threshold of 50 ng/ml, as illustrated in Figure 6. Disruption of the interface releases fFN, which can be detected via a rapid assay. Results can generally be reported back to the provider within 1 hour.

Figure 5: Fetal fibronectin is the "glue" at the maternal-fetal interface[32]



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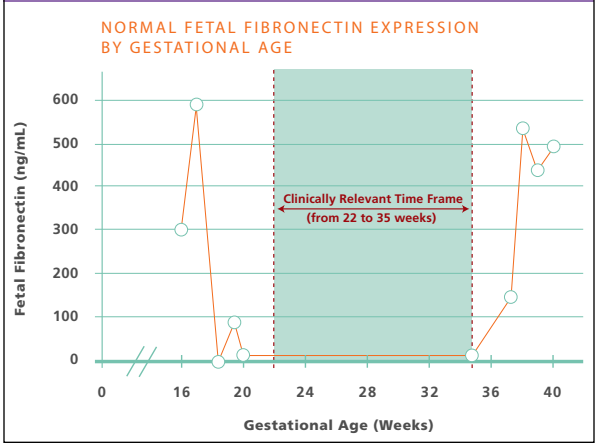
Disruption of the maternal-fetal interface causes the release of fibronectin into cervical/vaginal secretions. Fetal fibronectin appearance before 35 weeks is an indicator of increased preterm birth risk.

Figure 6: Expression of fetal fibronectin by gestational age[33]



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The fFN test yields a negative predictive value (NPV) within 7 to 14 days (95 percent to 99.5 percent NPV between 24 and 33 weeks), as Table 1 illustrates. The assay has a positive predictive value (PPV) of 13 percent to 40 percent for delivery within 14 days.[34,35,36,37] This wide range is an artifact of the diverse populations of women included in the study samples.

Table 1: Predictive value of fetal fibronectin assay within 7 to 14 days

fFN Result	Likelihood of delivery within 7 to 14 days
Negative	0.5 percent to 5.0 percent
Positive	13 percent to 40 percent

Thus, a woman who receives a negative fFN test result at 24 to 28 weeks gestation has a 0.5 percent to 5 percent chance of entering labor within the next 2 weeks (a 5 percent chance if obtained at 28 to 33 weeks gestation), while a positive fFN test result at 24 to 33 weeks gestation predicts a 13 percent to 40 percent chance of entering labor within the same time frame. This ability to detect increased risk of preterm birth in women with other criteria for preterm labor is useful, as it affords an opportunity for timely administration of antenatal corticosteroids (ACS), the single most effective intervention to improve health outcomes for premature infants born <34 weeks gestation. In addition, the fFN test's NPV permits decreased levels of medical intervention and avoids the risks and costs of overtreatment.[14,24,38]

At the time of this writing, obtaining a fFN specimen collection via speculum examination is the sole FDA-approved method of collection.[39] However, two alternative methods of nonspeculum fFN specimen collection have been reported.[40,41] In both studies, 95 percent to 96 percent agreement was found between blind nonspeculum vaginal swabbing and speculum examination. As of this writing, the fFN sample should be obtained *using an approved procedure*, and the *sample must be collected before a manual cervical exam is performed*.

The following limitations of the fFN test should be noted:

- The test has low sensitivity for women at less than 24 weeks gestation and more than 34 weeks gestation.
- The sample must be collected during a sterile speculum exam.
- Test results are invalid when:
  - There is evidence of vaginal bleeding.
  - Intercourse or sterile vaginal exam has occurred during the 24 hours prior to specimen collection.
  - The cervix is dilated ≥3 cm.
  - Fetal membranes are bulging or PPROM has occurred.
  - Open cervical and/or vaginal lesions are present.
- The positive predictive value of a positive fFN test alone is inadequate to be used exclusively to direct management in the setting of acute symptoms.[60]

Transvaginal Ultrasound as an Assessment Tool

Cervical length obtained by transvaginal ultrasound (TVU) in midgestation is a negative and positive predictor of preterm delivery. It is superior to digital assessment of cervical length during this period because the latter is subjective, limited to the external portion of the cervix and has high intraobserver variability.[42] When the cervix measures >25 mm in length by TVU, it has a NPV of >95 percent for preterm delivery before 32 gestational weeks.[43] For twin pregnancies at 20 to 24 weeks gestation, when length of the cervix is >25 mm by TVU, the NPV is >95 percent.[44] In combination with a fFN test result, TVU has been found to more accurately predict the likelihood of premature birth, but either screen alone also has been found to distinguish equally well between symptomatic patients at high and low risk for preterm delivery.[3,30]

A short cervix of clinical significance for true preterm labor is defined as <25 mm.[3] The likelihood of preterm delivery is gestational-age dependent. For example, a woman with a cervical length of 25 mm at 24 weeks who has had a prior preterm birth has a 9.9 percent risk of delivery before 32 weeks.[30]

Disposition decisions are based on findings from the general assessment and preterm labor assessment, including fFN, TVU and/or SVE results.

Developing competence in performing accurate TVU requires a steep learning curve. Not all obstetrics practices and hospitals have the requisite technical expertise available around the clock to perform the test accurately. For example, application of excessive probe pressure by an inexperienced operator may cause an open cervix to appear closed or normal.

TVU results are invalid as predictors of preterm birth:

- Before 15 gestational weeks and after 28 gestational weeks.
- When vaginal bleeding is present. (If TVU is performed in this scenario, it may provoke hemorrhage or increase the bleeding.)
- When the central placenta previa is bleeding. (When the central previa is **not** bleeding, TVU may be performed by an experienced operator who is aware of the patient's condition and mindful that the procedure may provoke bleeding.)
- When a woman's bladder is full, as the cervix may be deviated in relation to the volume of fullness. A full bladder may also compress the cervix between the probe and the bladder, causing the cervix to appear closed or falsely long. Most women find it painful to undergo the procedure with a full bladder and, hence, should empty their bladders beforehand.

Sterile Speculum Exam Capabilities

Cervicovaginal specimens may be collected during a sterile speculum examination (SSE). This also is an opportunity to inspect for cervicitis and umbilical cord or fetal prolapse and to assess cervical dilation and effacement.[45] In some states, the procedure may raise concerns about scope of practice for nurses or hospitals, although none arose during pilot testing in California.*

Sterile Vaginal Exam

When TVU and fFN are not available, sterile vaginal exam (SVE) also may provide significant clinical information.[46] For women presenting with signs and symptoms of preterm labor, SVE can be performed to assess cervical status and repeated (if cervical dilation is less than 2 cm) as needed at 2 hour intervals.

Disposition Decision

Disposition decisions — discharge with home care instructions and information about risk factors, if any, or admit/prepare for transport to a higher level of care — are based on findings from the general assessment and preterm labor assessment, including fFN, TVU, and/or SVE results. Table 2 presents possible results from preterm labor screening tests and associated care pathways for negative, positive and equivocal results.

** Nurses hold wide-ranging views about conducting this procedure. Anecdotal evidence suggests that nurses who perform SSEs consider it to be an extremely easy procedure and do not perceive it as outside the nursing scope of practice.*

Each state's Board of Nursing has the authority to define scope of practice within its jurisdiction. The following Advisory Opinion from the Wyoming Board of Nursing may be instructive. "It is within the scope of the Registered Professional Nurse to perform sterile speculum exams according to the following guidelines and the hospital's protocol: (1) The nurse must have the proper education and training and documented, demonstrated competency in the performance of sterile speculum procedures; and (2) There must be a follow-up by the licensed independent healthcare provider within twelve (12) hours following the speculum examination by the nurse regardless of the outcome of the test results." Sterile Speculum Exam to Determine Premature Rupture of Membranes—RN, Advisory Opinion Number: 06-165. Board Meeting Date: October 9-10, 2006. Wyoming Nurse Reporter *2007; 2(4):8.*

Table 2: Patient disposition based upon assessment for cervical change*[3,28,30,47,57,60]

Test Result	Antenatal Corticosteroids if 24 to 34 Weeks Gestation	Admit/ Prepare for Transport	Discharge
Cervical dilation of at least 2 cm by SVE, **and/or** Cervix ≤20 mm long by TVU between 20 and 28 weeks, **or** Repeat exam notes change in cervix (dilation and/or effacement)	Yes	Yes	No
Cervix 21-24 mm long by TVU between 20 and 28 weeks, **and/or** Positive fFN between 22 and 34 weeks	Consider administering	Consider admitting	Possible discharge, if no cervical change over 2-hour observation interval
Results of **ALL** factors assessed are negative (cervical dilation less than 2 cm by SVE, cervix ≥25 mm long by TVU, negative fFN)	No	No	Yes
SVE is the only means of cervical evaluation and neither fFN nor TVU are assessed: (A) Cervical dilation of less than 2 cm by SVE (B) Repeat SVE after two hours (C) **Cervical change** is detected at second SVE	Yes	Yes	No
SVE is the only means of cervical evaluation and neither fFN nor TVU are assessed: (A) Cervical dilation of less than 2 cm by SVE (B) Repeat SVE after two hours (C) **No cervical change** is detected at second SVE	No	No	Yes

**Individualized medical care directed by the provider should include consideration for patient history, gestational age and contraction pattern.*

For the vast majority of women seen in triage at less than 37 weeks gestation, the length of the cervix will be ≥25 mm by TVU and/or the fFN result will be negative. In general, these women can be discharged safely.[3,47,48] Once a woman has been discharged with home care instructions, it is prudent to schedule an outpatient visit within 1 week to follow possible signs and symptoms. A woman's risk of preterm labor may be reassessed when necessary.

Disposition of Women in Preterm Labor

Once a woman is diagnosed with significant risk factors for preterm birth, it may be beneficial to treat her with antenatal corticosteroids. Short-term tocolytics may also be considered (see Appendix A: Areas of Evolving Care). Transport to a higher level of care also may be indicated.

Antenatal corticosteroids (ACS): The American College of Obstetricians and Gynecologists recommends that women between 24 weeks and 34 weeks of pregnancy at risk of preterm delivery receive a single course of an antenatal corticosteroid such as dexamethasone or betamethasone.[49] If preterm birth does not occur within 2 weeks, a rescue course of ACS may be considered if the gestational age is <30 weeks and there is a continued risk of preterm delivery.[30] A maximum of two courses of ACS is recommended when clinically appropriate. While the effects of ACS on the mother may be minimal, women with diabetes may require close glycemic management.[50]

The vital public health impact of appropriate administration of ACS has led to its inclusion as a Joint Commission National Quality Core Measure of perinatal care.[16] According to the Vermont Oxford Network, only 74.5 percent of premature infants received ACS in 2008.[51] Yet ACS has been shown to reduce neonatal death by 30 percent; NICU admissions by 20 percent; and adverse outcomes—including respiratory distress syndrome, intraventricular hemorrhage, and necrotizing enterocolitis — by between 35 percent and 55 percent.[52] These rates suggest that standardized management can lead to significantly improved preterm birth outcomes and the importance of continuous monitoring using quality measures.

Level of Care: Between 10 percent and 20 percent of women who present with suspected signs and symptoms will deliver in 7 to 14 days.[3,30,48] When there is significant risk of preterm birth, transport to a higher level of care for delivery may optimize both maternal and infant outcomes.[25,55] For hospitals that offer higher levels of neonatal care, it is equally important to have a communication system in place in order to evaluate the capacity to care for an additional NICU admission. Having the appropriate medical team members available to attend high-risk deliveries results in the most timely assessment and management of a preterm infant. In some situations, particularly in the case of multiples, this may require bringing in additional multidisciplinary team members. Timely assessment of preterm labor will provide the greatest opportunity for the hospital to assemble the team whose care will result in the best possible outcome.

Fetuses transported in utero to a higher level of care have greater than 50 percent improvement in mortality risk compared with neonates transferred after delivery.

As part of its Perinatal and Reproductive Healthcare Endorsement Project, the National Quality Forum endorses delivery of very-low-birthweight infants (VLBW, <1500 g) at hospitals providing the appropriate level of care for the size of the infant. This measure underscores the significant impact patient disposition decisions may have on VLBW infants' health outcomes.[53] Fetuses transported *in utero* to a higher level of care have greater than 50 percent improvement in mortality risk compared with neonates transported after delivery.[54] A 2007 study of California births (n=48,237) between 1991 and 2000 found that infant mortality rates varied according to patient volume at the delivery hospital and the hospital's level of care.[55] Better neonatal outcomes were associated with hospitals with both higher volume (more than 100 VLBW infants per year) and higher level of care as compared with lower volumes and lower levels of care. Low-volume facilities with no NICU or a Level II NICU that cared for 100 or fewer VLBW infants were associated with significantly higher odds ratios for death ranging from 1.19 to 2.72. More than 80 percent of VLBW infants were born preterm. These data strongly suggest that maternal transport rather than neonatal transport is desirable.

Summary of Recommended Definitions for Levels of Neonatal Care, American Academy of Pediatrics[56]

Level I: Well-newborn nursery

- Provide neonatal resuscitation at every delivery
- Stabilize and provide care for stable 35 to 37-week infants
- Stabilize ill newborns and newborns <35 weeks gestation until transfer

Level II: Special care nursery

Level I and:

- Provide care for ≥32 weeks gestation and weighing ≥1500 g with physiologic immaturity, or problems anticipated to resolve rapidly, no need for immediate sub-specialty intervention
- Provide mechanical ventilation for <24 hours or continuous positive airway pressure or both
- Stabilize infants <32 weeks and <1500 g until transfer
- Provide convalescent care after intensive care

Level III: NICU

Level II and:

- Provide continuous life support and comprehensive care for infants <32 weeks and <1500g
- Provide advanced respiratory support, advanced imaging capability; prompt and available access to a full range of pediatric medical, surgical and imaging subspecialists

Level IV: Regional NICU

Level III and:

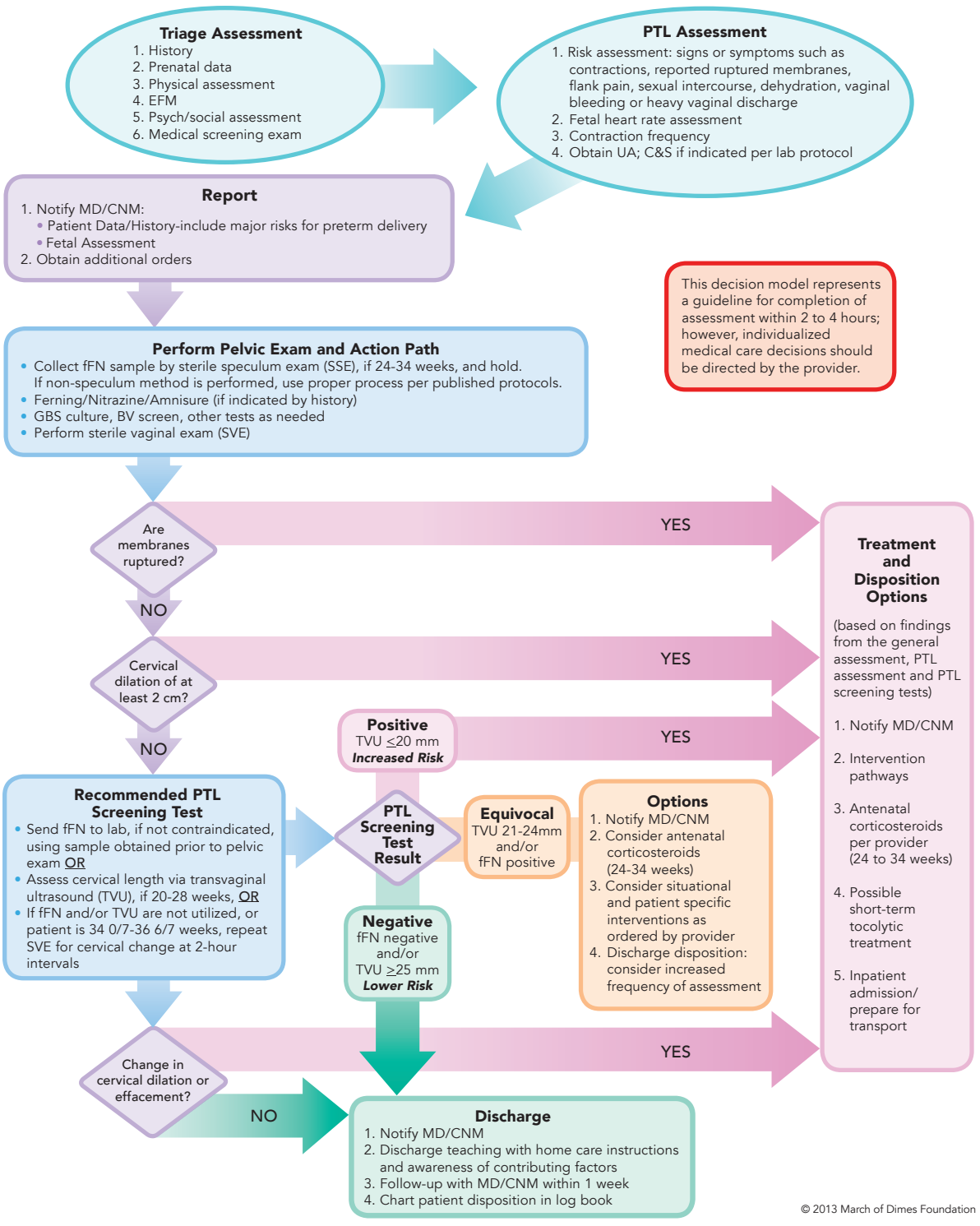
- Capability to provide surgical repair of complex congenital or postnatal conditions
- Provide on-site pediatric medical and surgical subspecialists, including pediatric anesthesiologists
- Facilitate transport and outreach education

Algorithm, Protocol and Order Set

In This Section

The *Preterm Labor Assessment Toolkit (PLAT)* specifically addresses the population of patients with suspected symptomatic preterm labor ≤36 6/7 weeks of completed gestation. The algorithm and protocol presented in this section combine clinical factors (e.g. gestational age, medical screening exam, and electronic fetal monitoring) with screening tests to assess risk for preterm birth. Knowing when a woman is in preterm labor allows for timely decision making about possible transport to a higher level of care, administration of corticosteroids and/or tocolytics, and assembly of the high-risk team.

Figure 7: Algorithm for preterm labor (PTL) triage assessment[3, 28, 30, 47, 57, 60]



Protocol For Care/Disposition of Women Presenting with Symptoms of Preterm Labor[3,28,30,47,57,60]

Purpose

To provide guidance and direction to nursing and medical staff in the identification, assessment and disposition of patients presenting with symptoms of preterm labor within 2 to 4 hours.

Level

Interdependent

Supportive Data

Preterm labor is the onset of regular uterine contractions that produce cervical change, effacement and/or dilation after fetal viability is established but before fetal maturity is achieved.

Preterm delivery is the primary cause of perinatal morbidity and mortality. Preterm labor must have all of the following components:

- Labor occurring between 20 and 36 6/7 weeks of pregnancy
- Regular uterine contractions, with or without ruptured membranes
- Evidence of cervical change (dilation and effacement) OR cervical dilation of at least 2 cm.

Data does not support the number of contractions that would lead to preterm birth. Hence, uterine contractions by themselves are NOT LABOR. This is best supported by data on home uterine activity monitoring, as well as data regarding the circadian rhythm of the uterus across gestation.

The early warning signs of preterm labor are often subtle and may be unrecognized until labor is advanced. Early detection and inhibition of preterm labor can potentially reduce perinatal morbidity and mortality. In addition, it is important to rule out preterm labor and avoid hospitalization, tocolysis and family disruptions, if possible.

Policy

Patients presenting with symptoms of preterm labor (contractions) will be cared for according to the following procedure/algorithm.

Equipment

- Fetal monitor
- Blood pressure cuff
- Stethoscope
- Thermometer
- Sterile speculum
- Lab materials for fetal fibronectin (fFN) test, fern test, nitrazine test, Amnisure® and Group B Beta Strep (GBS) culture

Procedure

When patient presents to Labor and Delivery:

1. Place the patient in the triage or labor room for evaluation and reassure her and family by careful explanation of all procedures.
2. The registered nurse will ask the patient about the following issues and review the prenatal record to determine:
   - Best gestational age of fetus by assessing dating criteria
   - Previous preterm labor/delivery (weeks gestation/birthweight)
   - Recent history of urinary tract or any other genito-urinary infections
   - Multiple pregnancy or hydramnios
   - Uterine bleeding
   - Uterine abnormalities
   - Incompetent cervix
   - PPROM
   - Low socioeconomic status
   - Nutritional status/weight gain
   - <18 years or >40 years of age
   - Use of any form of tobacco
   - Alcohol or substance abuse
   - Domestic violence
   - Current employment/work activity
   - Any current stressor (economic, physical or emotional)

Assessment/Supportive Care

3. Identify patient in preterm labor expediently:
   a. Document prenatal history and patient's presenting symptoms.
   b. Assess for signs and symptoms of vaginal and urinary infection.
   c. Assess for signs and symptoms of PPROM or vaginal bleeding.
   d. Identify if sexual intercourse occurred within past 24 hours.
   e. Obtain and monitor vital signs.
   f. Monitor fetal heart rate and uterine activity by EFM.
   g. Manually palpate abdomen to ascertain strength of contractions.
   h. Assess hydration level/nutritional status.
4. Consider obtaining urine sample for evidence of dehydration and/or infection. Order urine C&S, if indicated by laboratory parameters.
5. Place patient in lateral recumbent position.
6. Notify provider to provide report after obtaining baseline data. Ask if fFN test, fern test, GBS culture, wet mount and/or BV screen are to be obtained prior to sterile vaginal exam (SVE). ***DO NOT perform an SVE exam prior to fFN testing. An SVE can cause a false positive fFN test.***
7. Obtain specimen or samples by sterile speculum exam (SSE)

OR

If non-speculum collection method is performed for the fFN test,

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

NOTE: This is the only method prescribed by the manufacturer pending FDA approval.

8. Do SVE if ordered unless contraindicated (i.e., vaginal bleeding, PPROM, vulvar herpes lesions). If unable to assess for cervical change by fFN or TVU, do SVE to assess cervix digitally. (A 2-hour interval is recommended.) The same individual should perform SVEs, if possible, for the most accurate assessment of cervical change. Serial SVEs may be performed more than once at 2-hour intervals if a symptomatic patient is clinically stable and has major risks for preterm delivery, e.g., prior preterm delivery before 34 weeks or current estimated gestational age (EGA) of less than or equal to 32 weeks.
9. May orally hydrate per patient comfort. If evidence of dehydration, infuse ordered IV fluid for 2 hours unless contraindicated, i.e., heart disease, severe renal failure or high-order multiple gestation.
10. Monitor uterine activity and fetal heart rate continuously or as ordered by provider.
11. Notify provider to discuss patient disposition (admit or transfer) if patient has PPROM.
12. Refer to and follow the Preterm Labor Triage Algorithm to guide patient care during triage and patient disposition decision (admit, discharge or transfer).

Disposition Options (based on findings from the general assessment, PTL assessment and PTL screening tests; for patients with intact membranes)

13. Cervical dilation of at least 2 cm by SVE

    AND/OR

    Cervix ≤20 mm long by TVU between 20 and 28 weeks gestation:
    a. Notify provider.
    b. Administer antenatal corticosteroids, if between 24 and 34 weeks gestation.
    c. Initiate short-term tocolytic therapy, if ordered by provider.
    d. Admit as inpatient/prepare for transport.
    e. Activate intervention pathways (e.g., cerclage, vaginal progesterone), if appropriate.
14. Cervix 21-24 mm long by TVU between 20 and 28 weeks gestation

    AND/OR

    Positive fFN between 22 and 34 weeks gestation
    a. Notify provider.
    b. Consider antenatal corticosteroids, if between 24 and 34 weeks.
    c. Consider situational and patient specific interventions as ordered by provider.
    d. Discharge disposition after adequate assessment for cervical change: Consider increased frequency of assessment.

15. Results of ALL factors assessed are negative (cervical dilation of less than 2 cm by SVE, cervix ≥25 mm long by TVU, negative fFN):
    a. Notify provider.
    b. Teach patient home care instructions; make aware of risk factors, if any. (See take-home education/ instructional materials.)
    c. Make follow-up medical appointment in one week.
    d. Discharge if ordered by provider.
16. Cervical dilation of less than 2 cm by SVE only (neither fFN **nor** TVU available):
    a. Wait 2 hours and repeat SVE. (Serial SVEs may be performed more than once at 2-hour intervals if a symptomatic patient is clinically stable and has major risks for preterm delivery, e.g., prior preterm delivery before 34 weeks or current EGA of less than or equal to 32 weeks.)
    b. Cervical change:
        i. Notify provider.
        ii. Begin antenatal corticosteroids if between 24 and 34 weeks gestation.
        iii. Initiate short-term tocolytic therapy if ordered by provider.
        iv. Consider admission as inpatient/preparation for transport.
    c. No cervical change:
        i. Notify provider.
        ii. Teach patient home care instructions; make aware of risk factors, if any. (See take-home education/instructional materials.)
        iii. Make follow-up medical appointment in 1 week.
        iv. Discharge if ordered by provider.

Reportable Conditions

17. Report promptly to provider:
    a. Increased frequency, duration and/or intensity of uterine contractions
    b. Spontaneous rupture of membranes
    c. Increasing amounts of vaginal discharge and/or bleeding
    d. Alterations in maternal vital signs or non-reassuring FHR pattern
    e. Signs/symptoms of UTI
    f. Positive fFN test results
    g. Transvaginal cervical length measurement

Documentation

18. Document the following in the medical record:
    a. Assessments and interventions
    b. Uterine contraction and FHR every 30 minutes while contracting
    c. Provider orders
    d. Medications given
    e. Lab results
    f. Patient disposition (admit, discharge, transfer) as dictated by hospital policies and procedures
    g. Patient education on preterm labor
    h. Patient Home Care Instructions, if discharged

Adapted from the 2005 Preterm Labor Assessment Toolkit developed by Sutter Medical Center, Sacramento under a grant provided by the March of Dimes California Chapter.

Form 1: Preterm Labor Assessment Order Set

Preterm Labor Assessment Order Set

Date: _____ Time: _____

Preterm labor assessment orders as follows:

1. ☐ Admit patient to OB for observation.

2. ☐ Implement Protocol for Care/Disposition of Women Presenting with Symptoms of Preterm Labor.

3. ☐ Obtain and send clean catch urine specimen for UA and complete C&S, if indicated.

4. ☐ Perform sterile speculum exam to collect fFN specimen (before the SVE), Fern test specimen and cultures, if indicated.

fFN test for patients:

- 24 through 34 weeks GA
- Without ROM
- Not actively bleeding
- No sexual intercourse during past 24 hours

5. ☐ Obtain a transvaginal ultrasound for cervical length if between 20 and 28 weeks gestation (if TVU available).

6. ☐ Perform a sterile vaginal exam to determine cervical status.

7. ☐ Send fFN specimen to lab if patient <3 cm dilated and no evidence of PPROM.

8. ☐ Monitor continuously using EFM.

9. ☐ Other: _____

_____

_____

_____

_____

_____

Provider Signature: _____

Planning Notes:

Data Collection

Suggested Measures and Data Sources

In This Section

The standardization of clinical practice has a demonstrated impact on patient outcomes, safety and resource utilization. Clinicians who implement *PLAT* may wish to collect and analyze specific metrics to determine the extent to which hospital policies and procedural changes are being followed, patient outcomes are improved through uniform assessment and triage, and costs are reduced. Outcome measures include:

- Number of patients who presented with suspected preterm labor
- Number of patients assessed using *PLAT*
- Length of patient stay in clinic or on service
- Percentage of patients who received a fFN test or TVU
- Percentage of patients who received antenatal corticosteroids at the appropriate time

Data can be collected and extracted pre- and post-implementation of the toolkit in order to understand the impact of standardization on relevant variables. Several metrics may be analyzed together to identify changes over time. Codes for diagnostic procedures in the algorithm, including treatment with antenatal corticosteroids, are listed in Table 3. Timely evaluation of preterm labor patients allows for administration of antenatal corticosteroids to patients determined to be in preterm labor. The Joint Commission's Perinatal Care Measure PC-03 recommends that a full course of corticosteroids be given to women ≥24 and <32 gestational weeks who are at risk of preterm delivery.[16]

Timely evaluation of preterm labor patients allows for administration of antenatal corticosteroids to patients determined to be in preterm labor. The Joint Commission's voluntary Perinatal Care Measure PC-03 recommends that a full course of corticosteroids be given to women between 24 and 32 gestational weeks who are at risk of preterm delivery.

Table 3: Assessment measures and ICD-9/ICD-10/CPT/HPCPS Codes	
Measures	**Codes**
Presentation for Preterm Labor	*ICD-9 codes for presentation for preterm labor*
	644.00 Threatened premature labor, unspecified as to episode of care
	644.03 Threatened premature labor antepartum
	644.10 Other threatened labor, unspecified as to episode of care
	644.13 Other threatened labor antepartum
	644.20 Early onset of delivery, unspecified as to episode of care
	644.21 Early onset of delivery with or without antepartum condition
	ICD-10 codes for presentation for preterm labor
	O60.00 Threatened premature labor, unspecified trimester
	O60.02 Threatened premature labor, second trimester
	O60.03 Threatened premature labor, third trimester
	O47.00 False labor before 37 completed weeks of gestation, unspecified trimester
	O47.02 False labor before 37 completed weeks of gestation, second trimester
	O47.03 False labor before 37 completed weeks of gestation, third trimester
	O47.1 False labor at or after 37 completed weeks of gestation
	O47.09 False labor, unspecified
	O60.10 Preterm labor with preterm delivery, unspecified trimester
	O60.12 Preterm labor second trimester with preterm delivery second trimester
	O60.13 Preterm labor second trimester with preterm delivery third trimester
	O60.14 Preterm labor third trimester with preterm delivery third trimester
	O60.2 Term delivery with preterm labor
	O60.20 Term delivery with preterm labor, unspecified trimester
	O60.22 Term delivery with preterm labor, second trimester
	O60.23 Term delivery with preterm labor, third trimester
Fetal Fibronectin	*CPT Code for Fetal Fibronectin*
	82731 Fetal fibronectin, cervicovaginal secretions, semi-quantitative
Transvaginal Ultrasound	*CPT Code for Transvaginal Ultrasound*
	76817 Transvaginal ultrasound - Obstetrical
Antenatal Steroid	*ICD–9 and HCPCS (Healthcare Procedure Coding System) codes for administration of antenatal steroids*
	90782 Administration of injection (SQ or IM)
	J0704 Betamethasone injection

Table 4 outlines triage scenarios for patients with a chief complaint of contractions prior to 37 weeks and data collection measures to help guide a hospital in determining progress in standardizing preterm labor assessment, and improving patient safety and outcomes over time. Cost reductions also may be evaluated.

Table 4: Patient scenarios and measures for statistical evaluation

Patient Scenario	Measures for Statistical Evaluation
Patients triaged in L&D, determined not to be in PTL, sent home undelivered, and later delivered at term	**Evaluated and Sent Home** • Total number of patients • Length of stay until discharge (in hours) • Documented preterm labor assessment—fFN, TVU and/or serial SVE showing no cervical change • Antenatal corticosteroids and tocolytics NOT administered • Time to subsequent visit/triage • Number of repeat visits until admission and delivery
Patients triaged in L&D, determined not to be in PTL, sent home, and later delivered preterm	**Sent Home and Later Delivered Preterm** • Total number of patients • Documented preterm labor assessment – fFN, TVU and/or serial SVE showing no cervical change • Length of stay until discharge (in hours) • Antenatal corticosteroids and tocolytics NOT administered • Time to subsequent visit/triage • Number of repeat visits until admission and delivery • Outcome: Date and time of delivery, gestational age at time of delivery, birthweight, NICU admission
Patients triaged in L&D, determined to be in PTL, and admitted but later sent home undelivered; delivered on a subsequent admission	**Admitted and Later Sent Home Undelivered** • Total number of patients • Documented preterm labor assessment – fFN, TVU and/or serial SVE showing cervical change • Percent of positive fFN patients or TVU findings ≤20 mm • Antenatal corticosteroids administered only after assessment • Tocolytics administered only after assessment • Length of stay until discharge • Number of return visits without delivery • Number of weeks from first presentation to date of delivery • Outcome: Date and time of delivery, birthweight, gestational age at time of delivery, NICU admission
Patients triaged in L&D, determined to be in PTL, admitted, and delivered preterm on this admission	**Admitted and Delivered** • Total number of patients • Documented preterm labor assessment – fFN, TVU and/or serial SVE showing cervical change • Percent of positive fFN patients or TVU findings ≤20 mm • Antenatal corticosteroids administered • Tocolytics administered • Length of stay until delivery (in hours) • Number delivered within 24 hours • Number delivered >24 hours following admission • Number of patients augmented following admission • Outcome: Gestational age at time of delivery, birthweight, NICU admission

Pre- and Post-Implementation Surveys

The California Chapter of the March of Dimes developed the Pre- and Post-Implementation Survey (see Figures 8 and 9) to help hospitals gather qualitative data before and after implementing the Toolkit. The pre-survey assesses knowledge, behavior and practices to assist hospitals in developing their implementation plans. The post-implementation survey can be administered after a full rollout of the Toolkit to assess change. To download copies of the surveys, visit **www.prematurityprevention.org**

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

Standardization of Preterm Labor Assessment Pre-Implementation Survey

Name/Title: _____ City: _____

Hospital Name: _____ Date Completed: _____

1. Does this hospital have a Preterm Labor (PTL) Assessment Protocol?
   - ☐ Yes (Proceed to Question #2.)
   - ☐ No (Proceed to Question #4.)
2. Does the protocol include a definition of preterm labor?
   - ☐ Yes (Proceed to Question #3.)
   - ☐ No (Proceed to Question #4.)
3. Does the definition include: *(Check all that apply.)*
   - ☐ Number of contractions/hour
   - ☐ Cervical dilation
   - ☐ Cervical effacement
   - ☐ All of the above
4. 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
5. 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.)
6. 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.)
7. 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.)
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: _____
9. 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
10. 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.
11. 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
12. Are the RNs on your L&D unit currently performing sterile speculum exams?
    - ☐ Yes
    - ☐ No
13. 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
14. 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.)
15. At what gestational age would the PTL patient be transferred? *(Select one)*
    - ☐ <32 weeks gestation
    - ☐ <34 weeks gestation
    - ☐ <36 weeks gestation
16. What is the average number of PTL patient transports/year for your hospital?
    - ☐ <5
    - ☐ Between 5 and 10
    - ☐ >10
17. What issues or needs around preterm labor assessment could the *Preterm Labor Assessment Toolkit* address at your hospital?

    _____

    _____

    _____

    _____

Figure 9: Standardization of preterm labor assessment post-implementation survey

Standardization of Preterm Labor Assessment Post-Implementation Survey

Name/Title: _____ City: _____

Hospital Name: _____ Date Completed: _____

1. How long has this hospital had a preterm labor assessment protocol in place based on the *Preterm Labor Assessment Toolkit (PLAT)*?
- ☐ 1 month
- ☐ 2 months
- ☐ 3 months
- ☐ 4 months
- ☐ 5 months
- ☐ 6 months or more

2. Does the protocol include a definition of preterm labor?
- ☐ Yes (Proceed to Question #3.)
- ☐ No (Proceed to Question #4.)

3. Does the definition include: (*Check all that apply.*)
- ☐ Number of contractions/hour
- ☐ Cervical dilation
- ☐ Cervical effacement
- ☐ All of the above

4. Since the introduction of *PLAT*, is there a sense of increased consistency among practitioners in the assessment of women presenting with the signs and symptoms of preterm labor?
- ☐ Yes
- ☐ No
- ☐ Unsure

5. Are the RNs on your L&D unit currently performing sterile speculum exams on every woman presenting with signs and symptoms of preterm labor?
- ☐ Yes
- ☐ No *(If no, please explain the practice at your hospital.)*

_____

_____

_____

6. Is it currently the practice at this hospital to use the fFN test to assist in the disposition of women presenting with the signs and symptoms of preterm labor?
- ☐ Yes (Proceed to Question #7.)
- ☐ No *(Why not? Check all that apply.)*
  - ☐ No buy-in from practitioners
  - ☐ Collection issues
  - ☐ Expensive technology
  - ☐ Our lab does not offer this test
  - ☐ Other _____

(Proceed to Question #8.)

7. Which of the following best describes the use of the fFN test at this hospital?
- ☐ All practitioners use fFN
- ☐ Most practitioners use fFN
- ☐ Some practitioners use fFN

8. 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
- ☐ Cervical length ≥25 mm per transvaginal ultrasound
- ☐ Contractions stop
- ☐ Negative fFN result
- ☐ Practices vary greatly by practitioner

9. Which factors lead practitioners to admit and/or transport patients who come to this hospital with signs and symptoms of preterm labor? *(Check all that apply)*
- ☐ Cervical change
- ☐ Cervical length per transvaginal ultrasound
- ☐ Contractions
- ☐ Positive fFN result
- ☐ Practices vary greatly by practitioner

10. Have your maternal transport practices changed since the implementation of *PLAT*?
- ☐ Yes ☐ No

Please explain: _____

_____

_____

11. What has been the most important use or benefit of *PLAT* at your hospital? _____

_____

_____

12. Were there any unexpected benefits from the process of implementing *PLAT*?
- ☐ Yes ☐ No

Please explain: _____

_____

_____

13. What challenges/barriers have you faced to the implementation of *PLAT* at your hospital? *(Check all that apply.)*
- ☐ Physician buy-in
- ☐ Collection of chart audit data *(Please describe.)*

_____

- ☐ Working with the lab *(Please describe.)*

_____

- ☐ Too time-intensive for staff
- ☐ Other *(Please describe.)*

_____

_____

Preterm Labor Assessment Chart Audit Tool

The California Chapter of the March of Dimes developed a chart audit tool to help hospitals analyze their preterm labor assessment protocols, procedures and patient outcomes. A baseline, pre-implementation chart audit may be conducted prior to rollout of the toolkit to identify key issues and barriers that can be anticipated and managed. During the first year of the rollout, a post-implementation chart audit can be conducted to evaluate the extent to which assessment is being implemented according to prescribed standards. Experience has demonstrated that some change will be evident within the first 3 months, but full implementation of and adherence to revised protocols may take up to 1 year. Assessing protocol deviation will help evaluate changes in clinicians' practice behaviors. To download a copy of the pre- and post-implementation chart audit tool and instructions for use, visit **www.prematurityprevention.org**

Figure 10: Preterm labor assessment chart audit tool

Preterm Labor Assessment Chart Audit Tool

Charts below represent: ___ *Pre*-PLAT Implementation ___ *Post*-PLAT Implementation

Hospital Name: ______________________

Name of Auditor: ______________________

Date of Audit: ______________________

Patient ID number	Date presenting at hospital with preterm labor signs and symptoms	Time presenting at hospital with preterm labor signs and symptoms	EDC	Gest age	SSE performed first Y / N	fFN collected if 24-34 weeks Y / N or N/A Results obtained Y / N If yes, indicate (+) or (-)	Membranes ruptured Y / N	Was status of membranes confirmed? Y / N If yes, circle how below: **F, N,** and/or **A** Ferning (F) or Nitrazine (N) or AmniSure (A)	Transvag. Ultrasound if 20-28 weeks Y / N or N/A If yes, indicate cervical length	First SVE performed Y / N If yes, cervix ≥2 cm dilated or ≥80% effaced Y / N	Repeat SVE performed Y / N Time elapsed since first SVE was performed (write in hours & minutes) Cervical change Y / N	Disposition Admitted (A) Discharged home undelivered (D) or Transported to higher level of care (T) Circle **A, D** or **T** and indicate Date/Time of disposition **order**	Tocolized **during assess. period** Y / N	Antenatal Steroids begun **during assess. period** Y / N or N/A	If discharged home undelivered, education materials provided on signs and symptoms of preterm labor Y / N or N/A	If admitted, eventually discharged home undelivered Y / N If **Yes**, indicate Date/Time of discharge If **No**, leave Date/Time blank	If known, indicate Date/Time of delivery If unknown, leave blank	**If Mother Admitted & Delivered**	
																		Infant admitted to your NICU Y / N	Infant transported Y / N If yes, indicate Date/Time of transport
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______
					Y / N	Collected: Y / N or N/A Results: Y / N If yes, + / -	Y / N	Y / N F / N / A	Y / N or N/A If yes, cervical length: ______	Y / N Cervix ≥2 cm or ≥80%: Y / N	Y / N Time elapsed: ______ Change: Y / N	A / D / T Date: ______ Time: ______	Y / N	Y / N or N/A	Y / N or N/A	Y / N Date: ______ Time: ______	Date: ______ Time: ______	Y / N	Y / N Date: ______ Time: ______

**30 preterm labor assessment charts should be represented in audit, or 100% in a 3 month period (whichever is less).*

Standardization of Preterm Labor Assessment as a Quality Improvement Project

In This Section

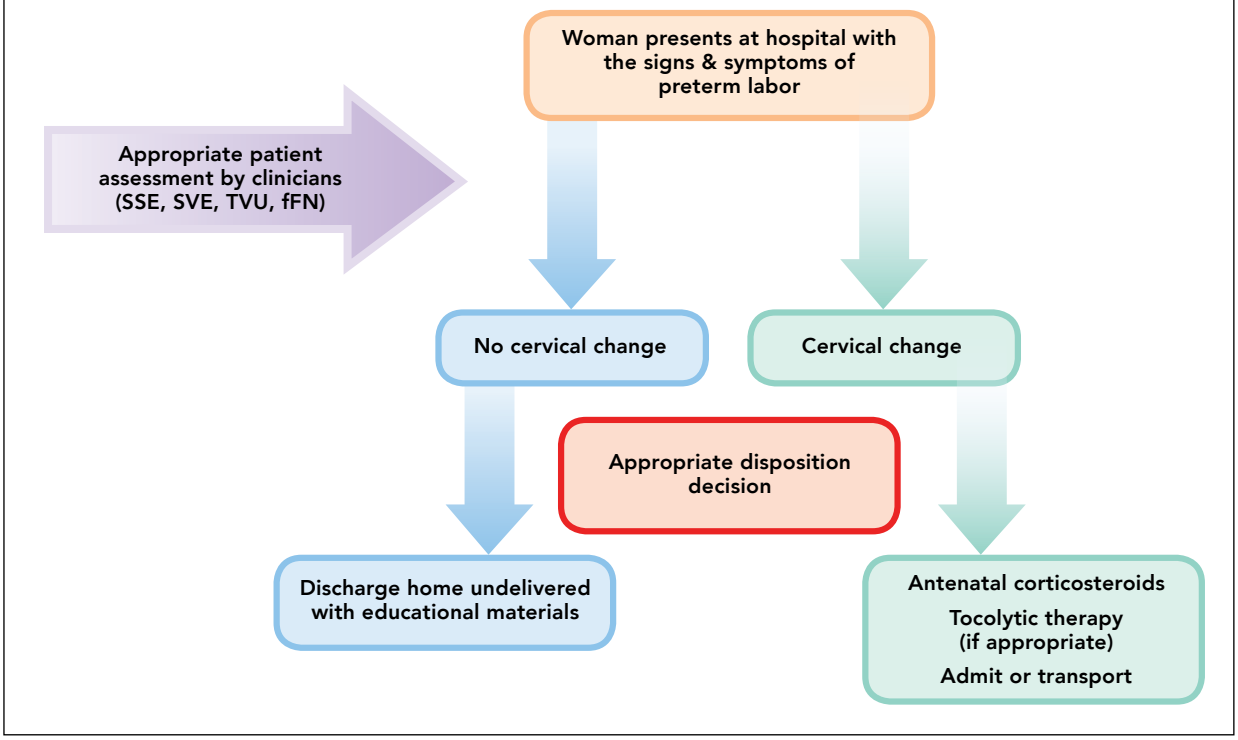
Seven components of change, as delineated in **Table 5**, underpin standardized patient assessment and clinical disposition as represented in the Preterm Labor Assessment Algorithm. The Pathway for Standardized Preterm Labor Patient Assessment is illustrated in **Figure 11.**[9] Hospitals may choose to address preterm labor assessment as a quality improvement (QI) project, as the Toolkit was developed to support systems change initiatives.

Many quality improvement methodologies have been developed. One approach, the **M**obilize, **A**ssess, **P**lan, **I**mplement, **T**rack (MAP-IT) cycle, can be utilized to drive preterm labor assessment. Steps in the MAP-IT cycle are listed chronologically in **Figure 12.**[58] A checklist to assist institutions with initiating and tracking these steps is presented in **Table 6.**

Table 5: Key Change Components

- Physician and nurse champions
- Support from key hospital leadership
- Hospital policies and protocols that standardize preterm labor assessment
- Laboratory and radiology equipment, i.e., Group B Beta-streptococcus screen, fern test, fFN collection and testing, and transvaginal ultrasound
- Order sets
- Preterm labor patient education materials and home care instructions
- Maternal transport process

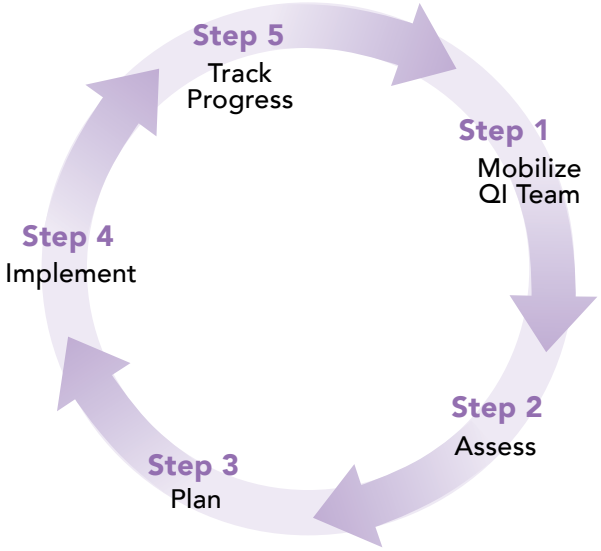
Figure 11: Pathway for standardized preterm labor assessment for symptomatic women



March of Dimes California Chapter, 2013

MAP-IT Cycle and Steps

Figure 12: MAP-IT cycle and steps



Step 1: Mobilize QI Team

- Identify and recruit physician, nurse-midwife and nurse champions to lead initiative. Identify data collection champion to support tracking and evaluation. Identify key hospital administrators to support rollout and widespread acceptance of practice/policy changes.

Step 2: Assess

- Assess current preterm labor assessment knowledge, practice, policy, protocols and order set using baseline chart audit or other data source and the Pre-Implementation Survey.
- Identify the time and process required for internal approval of new policy and protocol.
- Determine availability of in-house fFN and/or transvaginal ultrasound and sterile speculum exam capability 24/7.
- Assess existing process and agreement for maternal transport to a higher level of care.
- Identify clinical staff training needs and barriers to full implementation.
- Review current patient education/home care instructions on the signs and symptoms of preterm labor.

Step 3: Plan

- Revise/develop the department's preterm labor patient assessment protocol, order set, patient education and home care instructions. Secure departmental approval.
- Identify and address laboratory and radiology resource and equipment needs.
- Develop data collection and evaluation strategies.
- Establish target start date for rollout of new preterm labor assessment protocol.

Step 4: Implement

- Convene department meetings and conduct trainings to secure support to standardize patient assessment of preterm labor and implement new protocol.

Step 5: Track Progress

- Analyze data on adherence to new protocol and report results to clinical staff.
- Review and re-educate, if necessary, to ensure patient assessment pathway is being followed.

Adapted with permission from MAP-IT: A Guide To Using Healthy People 2020 in Your Community. U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. Healthy People 2020. Washington, D.C.

Table 6: Checklist to track and implement MAP-IT cycle

Preterm Labor Assessment Standardization Implementation Checklist

Mobilize QI Team

- ☐ Secure Hospital Leadership:
  - ○ Physician Champion: _____
  - ○ Nurse/CNM Champion: _____
  - ○ Evaluation/Data Collection Support: _____
  - ○ Hospital Administrators (e.g., CEO, COO, VP of Women's and Children's Services)
  - ○ Other (e.g., QI Director, Lab Director, etc.): _____

Implement Activities

- ☐ Explore possibility of preterm labor assessment becoming a hospital QI initiative.
- ☐ Ensure maternal transport process and agreements are in place.
- ☐ MD/RN staff education needs identified.
- ☐ Preterm Labor Assessment Protocol revised and approvals complete. Date: ___/___/___
- ☐ Order Set updated and integrated. Date: ___/___/___
- ☐ Laboratory and radiology equipment and resource needs identified and met.
- ☐ Education events carried out (grand rounds, department meetings, trainings). Date: ___/___/___
- ☐ Nursing competencies completed (sterile speculum exam, fFN specimen collection).
- ☐ Preterm labor patient education materials selected and available to distribute.

Data Collection

- ☐ Outline evaluation plan to improve preterm labor assessment, clinical decisions, patient outcomes and cost savings (utilizing data collection sources or audit tools).
  - ○ Complete Pre-Implementation Survey. Date: ___/___/___
  - ○ Collect Pre-Implementation data. Date: ___/___/___
- ☐ Post-Implementation data collection to measure change. Date: ___/___/___
- ☐ Complete Post-Implementation Survey after rollout to assess change process. Date: ___/___/___

Preterm Labor Assessment Toolkit Start Date (all implementation activities complete): ___/___/___

Planning Notes:

Patient Education and Home Care Instructions

In This Section

For many patients, triage visits to assess possible symptoms of preterm labor may be the first opportunity for meaningful education on this vital issue. Conveying information and answering patients' questions are integral components of the preterm labor assessment visit.

Just as *preterm birth has reached epidemic proportions*, so, too, there is an *epidemic of misinformation* about preterm birth. Particularly striking is the gap in knowledge that a full-term pregnancy is 40 weeks and that maturation and growth takes place during the final weeks of pregnancy, when significant brain, lung and liver development occur.

A survey of insured women who recently gave birth found that only 25.2% of women defined full term as 39 to 40 weeks.[59] But, more importantly, 92.4% of women reported that giving birth before 39 weeks was safe.[59] Thus, it appears that the vast majority of new, and therefore expectant, mothers have only a minimal understanding of the critical importance of the last weeks of pregnancy to their babies' lifelong health.

A recent study found that 75 percent of women who recently gave birth believed full term is reached before 39 weeks of gestation, and 92 percent reported that giving birth before 39 weeks was safe.

March of Dimes educational materials listed at the end of this section can help increase your patients' understanding of the risks associated with preterm birth and enable them to take action in the event they experience signs and symptoms of preterm labor.

Patient Education Talking Points

- Preterm labor is labor that occurs before 37 completed weeks of pregnancy. Babies born too early may have serious health problems or need to stay in the hospital longer than babies born on time.
- Even if you do everything right, you can still have preterm labor.
- If you believe you are in preterm labor, call your health care provider or go directly to the hospital.
- Contractions are not necessarily an indicator of preterm labor. It's normal for your uterus to contract at times during pregnancy. This may happen when you first lie down, after sex, or after you walk up and down stairs. It is not normal to have regular, frequent contractions before your baby is due. If you feel a contraction every 10 minutes or more often during 1 hour (more than five contractions in an hour), then your uterus is contracting too much. Call your health care provider.
- Learning the signs of preterm labor may help keep your baby from being born too early:
  - Contractions that make your belly tighten up like a fist every 10 minutes or more often
  - Change in the color of your vaginal discharge or bleeding from your vagina
  - The feeling that your baby is pushing down, which is called pelvic pressure
  - Low, dull backache
  - Cramps that feel like your period
  - Belly cramps with or without diarrhea
- If you experience the signs of preterm labor, your health care provider can do a simple exam and non-invasive tests to see if you're having preterm labor.
- If you are in preterm labor, you may be given medication to delay contractions. If your provider thinks you may deliver early, you may be given a medication, called a corticosteroid, to help your baby's lungs develop and an antibiotic to prevent infection in your baby, if needed. This can help prevent serious health complications in your baby.
- If you have been sent home from the hospital because there was no evidence that you are in labor, make an appointment with your doctor in 1 week or call your doctor's office to discuss what you felt and why you thought you were in preterm labor.

Patient Education Resources Available from March of Dimes

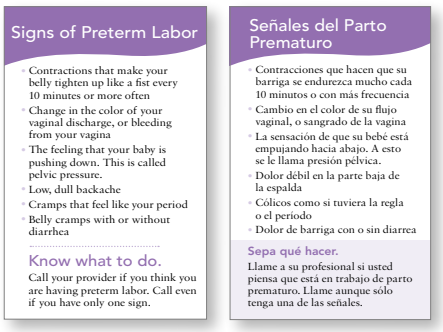
Patient education is a critical component of managing preterm labor. Your patients will benefit from a variety of fact sheets, wallet cards, DVDs and brochures that reinforce your key messages. Most resources are available in English and Spanish and can be shared with family members and friends. Mothers-to-be will want to read and review them up until their final weeks of pregnancy.

Signs of Preterm Labor/Señales del parto prematuro (flyer)

Use this flyer to educate women about the signs and symptoms of preterm labor and what they should do if preterm labor occurs.

Signs of Preterm Labor/Señales del parto prematuro (wallet card)

This is a great reminder for pregnant women about the signs of preterm labor and what to do if they occur.



Premature Birth: Reducing Your Risk/El nacimiento prematuro: Reduzca su riesgo (DVD)

Several 2- to 3-minute video vignettes educate women on how to reduce their risk of having a premature birth. Topics include signs of preterm labor, the importance of 39 weeks in scheduling birth, progesterone treatment, risk reduction, and risk reduction associated with fertility treatment. These are perfect for office waiting rooms or a closed-circuit TV system. The on-demand version includes broadcast rights for the life of the DVD (one location only).

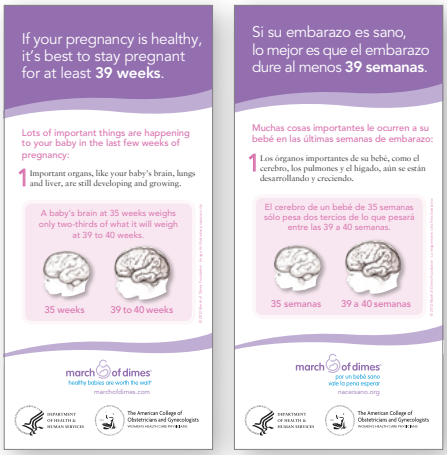
Preterm Labor/El parto prematuro (bilingual booklet)

This teaches women about preterm labor and its warning signs and risk factors. It also describes contractions and possible testing for preterm labor. Content is 7 pages in each language.

To order call 1-800-367-6630 or visit **marchofdimes.com/catalog.**

Brain Development Flyer/ Folleto del desarrollo cerebral

This flyer tells women why, if their pregnancy is healthy, getting to 39 weeks of pregnancy is best for their baby's development. Includes images of the difference in a baby's brain development at 35 and 39 weeks.



Late Preterm Brain Development Card/Tarjeta del desarrollo cerebral — prematuro casi a término (teaching tool)

A perfect teaching tool for providers to use with pregnant women, this laminated card illustrates the differences in brain development at 35 and 39 to 40 weeks of pregnancy. Teaching points on the back give facts about the importance of going full term if your pregnancy is healthy. The card is sized to fit in a lab coat pocket. Recommended for use with *Why The Last Weeks of Pregnancy Count*.

To order call 1-800-367-6630 or visit **marchofdimes.com/catalog.**

T-shirt Poster/ Afiche con el mensaje en camiseta (poster)

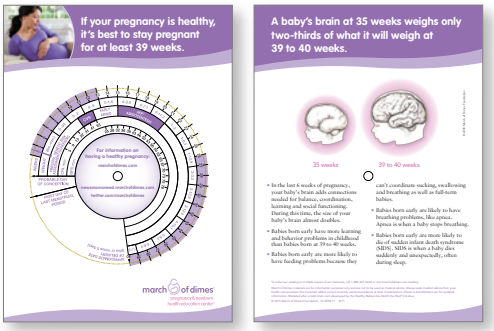
This reminds women about the importance of the last few weeks of pregnancy in a baby's development and encourages women with a healthy pregnancy to wait for labor to begin on its own.

Brain Development Poster/ Afiche del desarrollo cerebral

Lots of important things are happening to a baby in the last few weeks of pregnancy. This poster tells women why, if their pregnancy is healthy, getting to 39 weeks of pregnancy is best for their baby. It includes images of the difference in a baby's brain development at 35 and 39 weeks.

39-week Pregnancy Wheel

The wheel helps determine conception date, when a pregnancy test shows positive and when prenatal testing is appropriate. The back of the card features images of the difference in a baby's brain development at 35 and 39 weeks.



Why the Last Weeks of Pregnancy Count/Por qué son importantes las últimas semanas del embarazo (bilingual brochure)

This describes the baby's growth and development in the last few weeks of pregnancy and includes questions a woman can ask her provider about scheduling delivery. Recommended for use with the *Late Preterm Brain Development Card*. Content is 11 pages in each language.

Preterm Birth (fact sheet)

Print fact sheets right from your desktop or have the files sent directly to your print vendor. Purchase one of our Print Your Own titles and receive a printable PDF file via email. All Print Your Own fact sheets are sold in units of 50. Fact sheets print double sided 8½ inches by 11 inches. Download the free LockLizard plug-in to view PDF. Instructions included with order.

Thinking About Pregnancy After a Premature Birth/El embarazo después de haber tenido un bebé prematuro (13 page booklet)

For women who have had a premature baby and are concerned about having another, this includes information on risk factors for premature birth and treatments available to help them stay pregnant longer. Content is 13 pages in each language.

Prenatal Care/Cuidado prenatal (bilingual booklet)

This teaches women why prenatal care is an important part of having a healthy pregnancy. It describes a prenatal care schedule and what to expect at prenatal care checkups, including prenatal tests. Also it discusses exercise during pregnancy, the importance of identifying health problems that might affect pregnancy, and how to know when labor begins. It includes a brief discussion of preterm labor. Content is 28 pages in each language.

Form 2: Home Care Instructions for Women at Risk for Preterm Labor

Home Care Instructions for Women at Risk for Preterm Labor

Your health care provider has determined that you can be sent home from the hospital. It is important that you make an appointment with your health care provider in 1 week, or call, to discuss your signs and symptoms and hospital visit.

Basic instructions are listed below.

Call your health care provider or the hospital immediately if:

- Your baby stops moving.
- Your bag of water breaks.
- You have more than _____ contractions in 1 hour.
- You have any bleeding from your vagina.
- You have a low, dull backache. The pain may be felt in your lower back, or move to your sides or front.
- You have a fever higher than 100.4 F.

The hospital number to call is:

_____

Activity

Many women have more contractions when they are active. This is normal, and there is no proof that restricting your activity, including sexual intercourse, will reduce your risk for preterm birth. However, your health care provider may choose to limit your activity and recommends the following activity level for you:

☐ **Limited activities**	Most of the time you should lie down on your side. You may be up during the day for short periods of time (less than 30 minutes). No heavy work or lifting is permitted. Someone else needs to do the laundry and cleaning.
☐ **Extended activities**	You may be up during the day but you must lie down at least once in the morning and once in the afternoon for about 2 hours. No laundry, cleaning, heavy work, gardening or lifting is permitted. You may need to be off of work outside the home.
☐ **No activity restrictions**	You may resume your normal activities.

For all activity levels, if you begin to have contractions, you should stop what you are doing immediately and lie down on your side.
Drink 2 to 3 glasses of water or juice, monitor your contractions and call your health care provider or the hospital.

Turn over to learn the warning signs of preterm labor.

For more information go to **marchofdimes.com**

Home Care Instructions (continued)

Warning signs of preterm labor

It is normal for your uterus to contract now and then during pregnancy. Preterm labor is when you have frequent contractions, as described below, along with the opening of your cervix before the 37th completed week of pregnancy. Warning signs that you might be having preterm labor are:

- Contractions that make your belly tighten up like a fist every 10 minutes or more often.
- Cramps that feel like your period.
- Low, dull backache.
- The feeling that your baby is pushing down. This is called pelvic pressure.
- Belly cramps with or without diarrhea.
- Change in the color of your vaginal discharge.
- General feeling that "something is not right."
- Bleeding from your vagina.

If you have any of these signs and symptoms or are unsure, call your health care provider.

• **Baby movements and contractions**	Lie on your side for 1 hour. Place your hands near your belly button. Count the times your baby moves or kicks. If the baby does not move at least ____ times in ____ hour(s), **call your health care provider.** At the same time, feel your belly for tightening. Remember, contractions do not have to hurt. **If you have ____ contractions or more in 1 hour, call your health care provider.**
• **Sexual relations**	Do not have any sex until your health care provider says it is okay. Having sex or orgasm may cause uterine contractions.
• **Diet**	You still need to eat well for your and your baby's health. Pick foods that are high in iron, calcium and fiber, such as red meat, cheese and bran muffins.
• **Fluids**	Women who get dehydrated sometimes have more uterine contractions. Drink six to eight 8-ounce glasses of fluid a day. Water, non-fat or 1 percent milk and fruit juice are good choices. If you have diabetes, do not drink juice.
• **Stool softeners**	Constipation (hard stools) is a common problem. The stool softener is to prevent constipation. If you get constipated, drink lots of water and eat foods with fiber. You also can call your health care provider for help with constipation.
• **Other**	_____ _____ _____

For more information go to **marchofdimes.com**

Appendices

In This Section

In this appendix we discuss four areas of evolving care in the management of women with signs and symptoms of preterm labor:

I. Assessment and management of women between 34 0/7 and 36 6/7 weeks of pregnancy
II. Progesterone to improve birth outcomes
III. Tocolytic agents
IV. Management of women with preterm premature rupture of membranes (PPROM)

I. Assessment and Management of Women Between 34 0/7 and 36 6/7 Weeks of Pregnancy

Assessment and management of women presenting with signs and symptoms of preterm labor between 34 0/7 and 36 6/7 weeks of pregnancy is a clinical challenge as clear guidelines have not yet been developed. The objective screening tests, transvaginal ultrasound and fetal fibronectin, are not indicated for this group.[3,30,48] Therefore, these patients should be assessed for cervical change by serial vaginal examination.

Women between 34 0/7 and 36 6/7 weeks of pregnancy should be assessed for cervical change by serial vaginal exam.

Based on current literature, women in this group are not candidates for antenatal corticosteroid (ACS) treatment, thus tocolytic use to support such treatment is not indicated (with the possible exception of preparing a woman in preterm labor for transport to a higher level of care).[60] Studies on the use of ACS in this time frame continue, but have not progressed to the point of recommended practice.[61] Therefore, during the late preterm period, we recommend that providers consider assessing these patients on a case-by-case basis via twice-weekly telephone calls with a weekly pelvic exam to monitor possible cervical changes.[30,46,62,63]

II. Progesterone to Improve Birth Outcomes

Recent publications cite the benefits of progesterone therapy to reduce rates of preterm birth in asymptomatic women who are at increased risk due to history and/or short cervix identified by TVU. **Intramuscular progesterone** at a recommended dose of 250 mg/week has been found to decrease *repeat* preterm delivery, thus reducing infant complications in this population, including intra-ventricular hemorrhage, necrotizing enterocolitis, NICU admissions and the need for supplemental oxygen therapy.[64] However, intramuscular progesterone has not consistently been shown to benefit women with multiple gestations.[3,44]

Vaginal progesterone (with cerclage in some cases) may be administered daily by women with a cervical length of 10 to 25 mm identified by transvaginal ultrasound examination between 16 to 24 weeks gestation. The recommended dose is 90 mg vaginal progesterone gel or a 200 mg micronized progesterone capsule until 37 weeks to reduce the risk of preterm birth, thus improving neonatal outcomes.[64,65,66,67]

III. Tocolytic Agents

Tocolytic agents have the goal of arresting or inhibiting uterine contractility, thereby prolonging gestation for up to 48 hours. This additional time permits administration of corticosteroids and maternal transport to a facility with a neonatal intensive care unit, if indicated. Maintenance tocolysis has been shown to be "ineffective for preventing preterm birth and improving neonatal outcomes" and therefore, is not recommended. [30,60]

While several tocolytics have been studied, including beta-mimetics, magnesium sulfate, calcium channel blockers, and NSAIDS,[30,44] no clear, long-term agent to arrest preterm labor has been identified.[60] All tocolytic use in the United States is off label, since Ritodrine (a beta-mimetic), was removed from the market by the manufacturer in 1993.[68]

In addition, in 2011, the Food and Drug Administration (FDA) added a "black box" warning to another beta-mimetic drug, terbutaline sulfate, because of the potential for serious maternal heart problems and death. Per ACOG Practice Bulletin 127, Management of Preterm Labor, "The FDA posted warnings specifically cautioning against the use of maintenance oral terbutaline during pregnancy. Because of the lack of efficacy and potential maternal risk, the FDA states that oral terbutaline should not be used at all to treat preterm labor. Injectable terbutaline may be used only in an inpatient, monitored setting but should not be used for longer than 48-72 hours."[60]

Studies of the effectiveness of different therapies to delay delivery until term have reported conflicting results, with each agent demonstrating only limited benefit.± Iams and Berghella suggest that the failure of tocolytics to reduce the incidence of preterm birth in clinical trials and practice is not the result of inadequate dosage and/or ineffective drugs but, instead, provides evidence that uterine contractions are late manifestations of preterm parturition.[30]

Combining tocolytic drugs potentially increases maternal morbidity and should be done with caution. The choice of therapy should be determined by physician preference, taking into account maternal condition, gestational age and a drug's ability to stop myometrial contractions acutely, as well as its potential side effects and maternal-fetal safety profile.[69]

Tocolytics should be used only to manage the acute phase of preterm labor.

Tocolytics can, in some cases, delay delivery for a brief period of time, but they do not reliably reduce or prevent preterm birth or affect neonatal outcomes. They should be used only to manage the acute phase of preterm labor. Once labor is arrested, therapy can be discontinued and then restarted if an acute episode recurs.[30] Prolonged use of any tocolytic drug may potentially increase maternal-fetal risk without offering a clear benefit.

While magnesium sulfate has traditionally been administered as a tocolytic, evidence suggests that it also can confer benefit to neonates by reducing the risk of cerebral palsy.[70,71] As noted in a joint clinical opinion from ACOG and the Society for Maternal-Fetal Medicine, several randomized controlled trials have examined the effect of magnesium sulfate treatment on neuroprotection and preterm births. While "none of the individual studies found a benefit with regard to their primary outcome," meta-analysis "suggests that magnesium sulfate given before anticipated early preterm birth reduces the risk of cerebral palsy in surviving infants."[71]

Different administration and dosing schedules were used in the largest trials, creating a challenge for clinicians who wish to follow established practice. To this end, Reeves et al. provide an algorithm for selecting maternal candidates and administering therapy.[70] This much-needed protocol fills a gap until evidence emerges from clinical trials for the development of inclusion criteria, treatment regimens, concurrent tocolysis and maternal monitoring.

IV. Preterm Premature Rupture of Membranes (PPROM)

PPROM is a risk factor for preterm labor and delivery.[45] Table 7 presents the common tests utilized to make a diagnosis. In some cases, it is necessary to additionally verify PPROM by measuring amniotic fluid volume using transabdominal ultrasound.[45]

Table 7: Comparison of performance metrics (%) for AmniSure, fern test and nitrazine test[72]

(n=25)	AmniSure®	Fern Test	Nitrazine Test
Sensitivity	93.3	73.3	86.7
Specificity	100	100	70.0
Positive Predictive Value	100	100	81.3
Negative Predictive Value	90.9	71.4	77.8
Accuracy	96.0	84.0	80.0

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± *A 2010 metaanalysis of 26 trials of tocolytic agents (n=2,179) found no difference between nifedipine and magnesium sulfate in tocolytic efficacy. However, nifedipine was associated with a reduction in the risk of delivery within 7 days when treatment was initiated before 34 weeks gestation, and a reduction in serious neonatal complications in comparison with beta-mimetic agents. Nifedipine also was associated with fewer maternal adverse events than both beta-mimetics and magnesium sulfate. (Conde-Agudelo A, Romero R, Kusanovic JP. Nifedipine in the management of preterm labor: A systematic review and metaanalysis. Am J Obstet Gynecol. 2011;204:134.e1-20.)*

Appendix B – Use of Antenatal Corticosteroids for Fetal Maturation at 24 to 34 Weeks Gestation

The American College of Obstetricians and Gynecologists recommends treatment with a single course of antenatal corticosteroids (ACS) for women between 24 and 34 weeks of pregnancy at risk of preterm delivery. If preterm birth is anticipated between 34 and 39 weeks gestation with lung immaturity documented by amniotic fluid, a course of ACS may be considered. Figure 13 presents a guideline for care; however, individualized medical care is directed by the physician.

Figure 13: Decision tree for use of ACS for fetal maturation at 24 to 34 weeks gestation

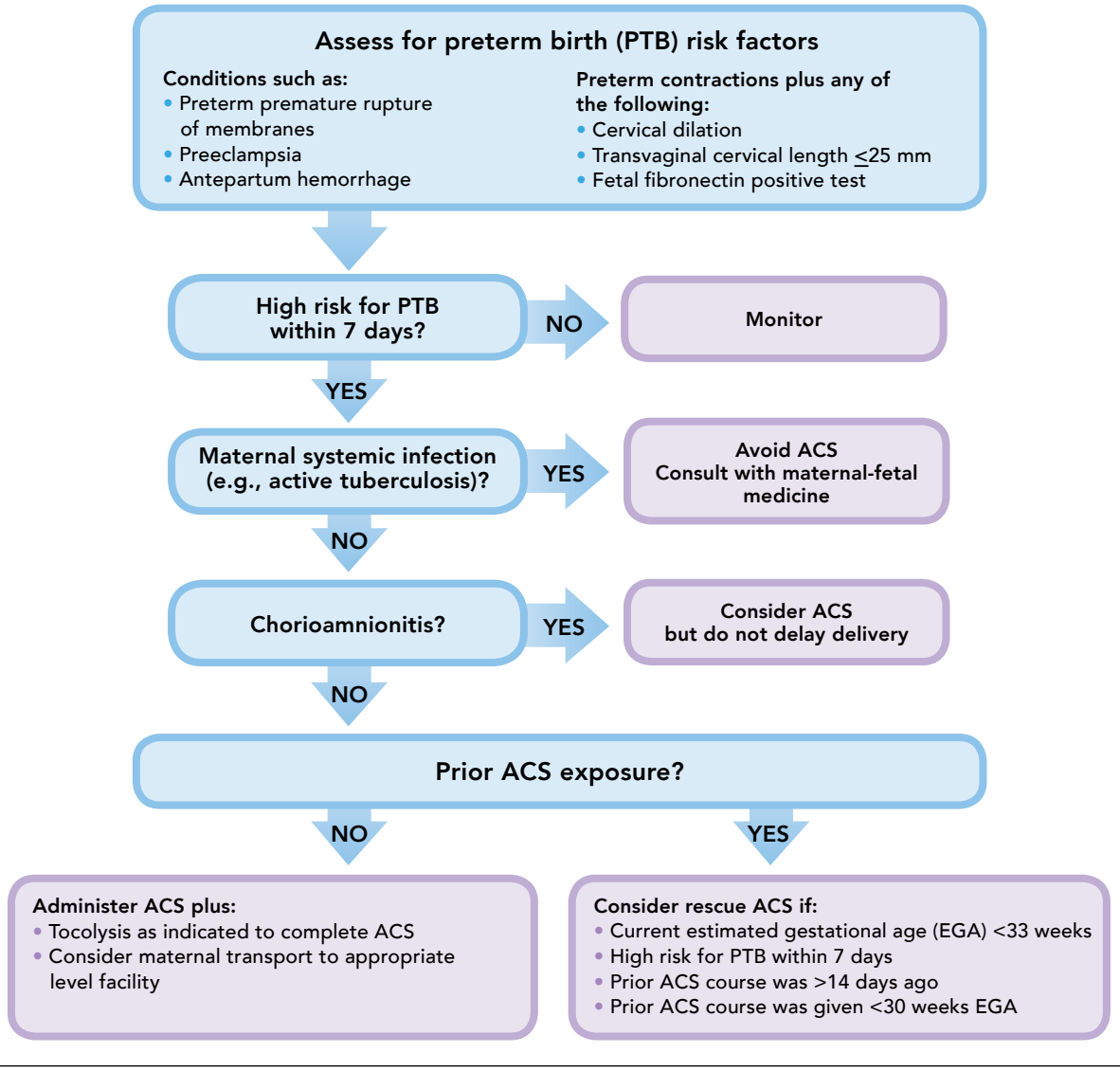

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Figure 14: Perinatal core measure: Antenatal steroid performance improvement following a premature birth risk assessment decision model and perinatal QI toolkit

SANTA CLARA VALLEY MEDICAL CENTER

Perinatal Core Measure: Antenatal Steroid Performance Improvement Following a Premature Birth Risk Assessment Decision Model and Perinatal QI Toolkit

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Maternal Child Health Group: [a]Obstetrics & Gynecology/Maternal Fetal Medicine and [b]Pediatrics/Neonatology
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Santa Clara Valley Medical Center, San Jose, Calif.

SUMMARY

Given the recognized health benefits for premature infants, improved ACS performance provides long-term value for children and families. In this era, when hospital performance data are subject to greater public access and payer scrutiny, opportunities to gain tangible improvements in performance outcomes provide value for all stakeholders.

We report antenatal corticosteroids (ACS) performance at Santa Clara Valley Medical Center (SCVMC), a large public hospital that is a regional, tertiary-level, perinatal center. Improvements in ACS performance are reported after a collaborative quality improvement (QI) effort that included implementing a clinical antenatal ACS management decision model as well as data system process improvement using the California Perinatal Quality Care Collaborative (CPQCC) Antenatal Corticosteroid Therapy Toolkit, a statewide perinatal QI toolkit.

BACKGROUND

As obstetricians, we are challenged with improving maternal and child health outcomes, even with potentially unavoidable adverse events such as premature birth (PTB). The premature neonate derives greater benefit from antenatal corticosteroids (ACS) than from any single intervention prior to or after birth. Despite longstanding recommendations, we frequently miss opportunities to give ACS to women with identifiable PTB risk factors. For this reason, ACS use has emerged as a core safety measure that is closely monitored at the local, state, and national levels by The Joint Commission (TJC), LeapFrog Group and others.

We used CPQCC network definitions with the ACS measure defined as the percent of delivered premature infants (401-1500 grams and 24 6/7 to 33 6/7 weeks) whose mothers received ACS.

CASE STUDY

A QI initiative was implemented at our institution in 2006 after benchmarking ACS performance in 2005. This involved specific actions that targeted clinical care and documentation.

Targeted clinical improvements

The SCVMC OB triage unit is high volume with over 10,000 patient visits per year. Services are provided by OB/Gyn physicians and Labor and Delivery nurses employed by the hospital.

OB triage clinical care was revised to use evidence-based standardized assessment for published ACOG criteria and consistent with the *Preterm Labor Assessment Toolkit*. An evidence-based decision model and order set to administer ACS to candidates between 24 and 34 weeks gestation, when appropriate, were then implemented.

For women with symptomatic contractions, the decision model used clinical findings and fetal fibronectin (fFN) to determine management. Women meeting premature birth risk criteria, including fFN positive test, received an initial course of ACS. Women who did not meet PTB risk criteria, e.g., stable cervix with negative fFN, did not receive ACS and were not admitted, even with persistent uterine activity.

Targeted documentation improvements

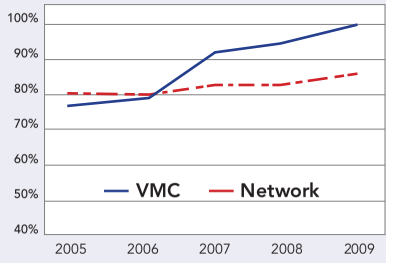
QI activities also included using the California Perinatal Quality Care Collaborative Antenatal Corticosteroid Therapy Toolkit to improve processes of documentation and data collection. Many reports in the literature cite challenges in the reliability of reported health measures due to gaps between actual clinical performance and data collection reporting systems.

RESULTS

During SCVMC's five-year study period (2005-2009), there were 27,737 births and 60,015 total OB triage evaluations for all indications. For this period, the % ACS in 302 infants (89% of whom were inborn) at our center was compared to 28,593 (76% inborn) infants reported to the CPQCC network.

We found that standardized management (including the PTB risk assessment decision model) to determine ACS administration and the QI toolkit were associated with significant improvement in ACS performance between 2005 baseline and 2009 (77.1% vs 100%, $p<0.01$).

Percent Antenatal Steroids, 2005 to 2009, Infants 401 to 1500 grams and 24/0 to 33/6 weeks Gestation, VMC compared to all CPQCC Centers



CONCLUSIONS

This program demonstrated that hospitals that successfully implement quality improvement initiatives **can** improve the performance of Perinatal Core Measure ACS administration by using both 1) evidence- based decision models to standardize clinical management and 2) perinatal QI toolkits that improve data collection/reporting.

REFERENCE

California Perinatal Quality Care Collaborative Antenatal Corticosteroid Therapy Toolkit.

http://www.cpqcc.org/quality_improvement/qi_toolkits/antenatal_corticosteroid_therapy_rev_october_2009

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Resources for developing competencies in a number of areas that will help your institution implement *PLAT* are available online. These include:

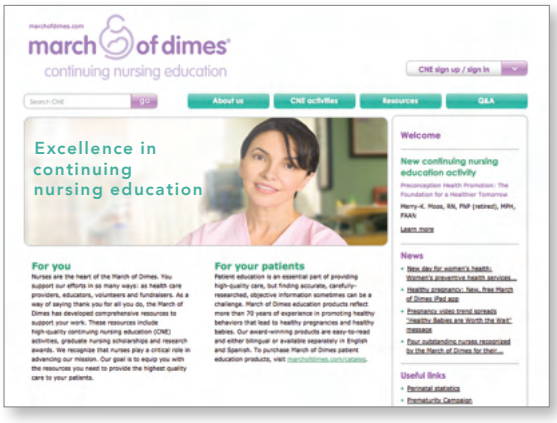
- **Speculum Examination Training (SSE):** The American College of Nurse-Midwives offers a web-cast focused on SSE training for registered nurses. This is a free, continuing education credit program designed to teach basic skills to intrapartum nurses. See **midwife.org/Intrapartum-Sterile-Speculum-Examination**

  To download an example of a **sterile speculum examination competency checklist**, visit **prematurityprevention.org**

- **Group B Streptococcus (GBS) Specimen Collection[73]:** Procedures for collecting and processing clinical specimens for group B streptococcal culture and performing susceptibility testing to clindamycin and erythromycin are described here: **cdc.gov/groupbstrep/index.html**

- **Intrapartum Nursing Management of Preterm Labor:** (5.0 contact hours) Designed for registered nurses who provide triage, stabilization and intrapartum care for women at risk for preterm birth due to preterm labor or preterm premature rupture of membranes. Reviews evidence-based practices for optimizing the health of infants born prematurely and for supporting the health of women and families facing threatened preterm birth. Controversies and emerging evidence regarding management of threatened preterm birth are discussed, as are guidelines for nursing and medical interventions and interdisciplinary management.

  – Free to read; $15 test fee
  – **marchofdimes.com/nursing**



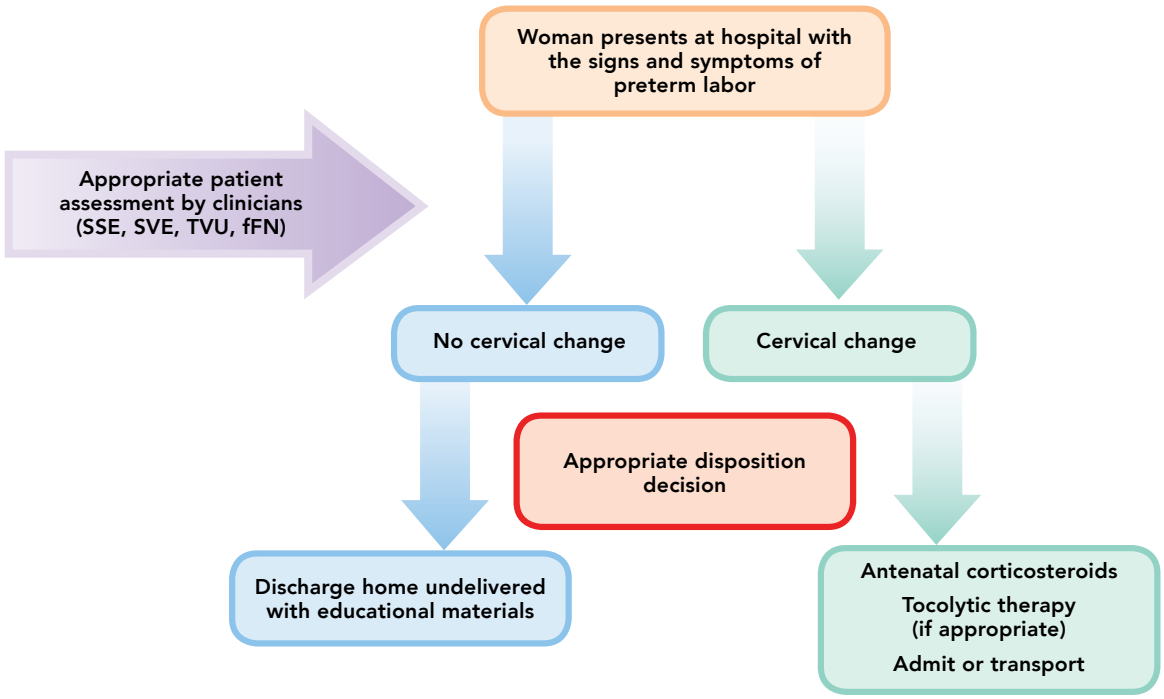
- **Transvaginal Ultrasound Assessment of the Cervix and Prediction of Spontaneous Preterm Birth:** This article is designed for physicians and ultrasound technicians wishing to learn more about transvaginal ultrasound techniques. **uptodate.com (search for transvaginal ultrasound assessment)** Available to subscribers of Uptodate.com only.

The *PLAT* Evaluation

Research Question

The March of Dimes California Chapter conducted a pilot evaluation of *PLAT* during the period 2008 to 2011. The principal research question that drove the evaluation was: *Could PLAT implementation improve patient assessment, resulting in appropriate disposition decisions?* The pathway for patient assessment is shown in Figure 15.[9]

Figure 15: Pathway for standardized preterm labor assessment for symptomatic women



March of Dimes California Chapter, 2013

Hypothesis and Methods

In 2008, the March of Dimes California Chapter hired an external evaluator to lead the evaluation and formed an evaluation committee to provide input on evaluation instruments, procedures and data interpretation. The committee included March of Dimes staff, the external evaluation team and additional volunteers and partners. The evaluation tested the hypothesis that following *PLAT* implementation, 90 percent of preterm labor assessment procedures would comply with the *PLAT* protocol. The principal data source was pre- and post-implementation medical chart review using an audit tool. (A revised version of this tool, reflecting lessons learned from the tool's use in the evaluation, is available for download at prematurityprevention.org.)

Fifteen hospitals in California that were implementing *PLAT* provided the data used to evaluate clinicians' patient assessment behaviors. A profile of the participating hospitals is presented in Table 8. Staff at each hospital abstracted data from up to 30 triage encounters or 100 percent of triage encounters during a 3-month period, whichever was less, both before and after *PLAT* implementation.

Table 8: Profile of 15 evaluation hospitals

Total births/year	29,500
Range of births/year	300 to 3,500
Setting	5 rural, 8 urban, 2 university
Level of care	6 Level I, 2 Level II, 5 Level III, 2 Level IV

The medical chart data were used to assess clinician behaviors at eight decision points that define *PLAT* compliance. These decision points are:

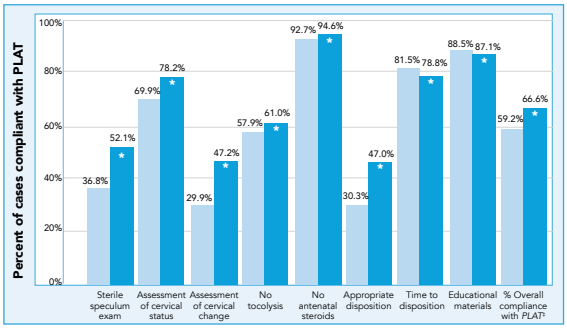
1. **Sterile speculum examination**
   To determine status of cervix and amniotic membranes.
2. **Assessment of cervical status**
   To determine degree of cervical dilation and effacement.
3. **Assessment of cervical change**
   To determine change in cervical dilation, effacement, consistency and position.
4. **No tocolysis use prior to completion of assessment**
   Treatment for preterm labor is not initiated until assessment is complete and preterm labor diagnosis is made.
5. **No antenatal steroid use prior to completion of assessment**
   Treatment for preterm labor is not initiated until assessment is complete and preterm labor diagnosis is made.
6. **Appropriate disposition decision**
   Decision to discharge, transport or admit is based on completed cervical change assessment. It should be noted that there may be other factors not addressed by *PLAT* that are relevant to making the appropriate disposition decision for a specific patient who presents with signs or symptoms of preterm labor. As addressed in the *PLAT* evaluation, however, disposition decision was coded as "appropriate" or "inappropriate" only in relation to completed cervical change assessment per *PLAT*. It should be noted that this study did not distinguish admits from transfers in determining the appropriate disposition decision. Distinguishing whether admit or transfer was the appropriate action was not feasible for several reasons, including level-designation issues in California.
7. **Time to disposition**
   Time from patient presentation at hospital to disposition decision is less than 5 hours to allow for timely interventions for women in true preterm labor or timely rule-out of preterm labor and discharge for those who are not.
8. **Provision of educational materials**
   Patients who are discharged home are provided with educational materials describing the signs and symptoms of preterm labor and when to call the provider and/or return to the hospital.

After each site's pre-implementation data were collected, the external evaluator provided a brief report back to the site that summarized the site's own data and aggregate data from all project sites for which data were available. The report included frequency data on patients with and without ruptured membranes, use of tocolysis and corticosteroids during assessment, disposition decision, and deliveries (for admits only). Average time to disposition, overall and by disposition decision was also provided. In addition, the report included a summary of the percentage of cases that were compliant with each of the eight *PLAT* decision points. A project staff member discussed the findings with the site, including areas of strength and areas for improvement. A similar report was provided to each site at post-implementation, along with a graph comparing the site's compliance with each decision point before and after *PLAT* implementation. A project staff member again discussed the findings with the site.

Results

The evaluation found that overall compliance with the *PLAT* protocol increased significantly from 59.2 percent at pre-implementation to 66.6 percent at post-implementation (Figure 16). Compliance increased from pre- to post-implementation for six of the eight decision points (see Figures 16 and 17). The four decision points for which the increases were statistically significant were implementation of sterile speculum exam, assessment of cervical status, assessment of cervical change and appropriate disposition decision.

Figure 16: Compliance with *PLAT* decision points pre- and post-implementation



* Change from pre- to post-implementation is statistically significant, p<0.05
‡ % compliance with PLAT = Avg # of decision points followed/Total # of applicable decision points

Figure 17: Compliance with *PLAT* decision points pre- and post-implementation

	N	Excluded	Pre (%)	Post (%)	% Change
Sterile speculum exam	825	5	36.8	52.1	41.6*
Assessment of cervical status	827	3	69.9	78.2	11.9*
Assessment of cervical change	818	12	29.9	47.2	57.9*
No tocolysis	816	14	57.9	61.0	5.4
No antenatal steroids	817	13	92.7	94.6	2.0
Appropriate disposition	806	24	30.3	47.0	55.1*
Time to disposition	827	3	81.5	78.8	-3.3
Educational materials	709	121	88.5	87.1	-1.6

* Change from pre to post is statistically significant, p < 0.05
"Excluded" includes missing and N/A
Change in the positive direction is the desired outcome

A breakdown of disposition decision into admitted/transferred cases vs. discharged home undelivered cases showed that disposition decisions based on a complete cervical change assessment increased for both groups but reached statistical significance only among patients sent home undelivered (see Figure 18). With a larger sample, the change in disposition based on completed cervical change assessment for admits/transfers might have also reached statistical significance.

Figure 18: Disposition decision based on completed cervical change assessment

	N	Excluded	Pre (%)	Post (%)
Disposition				
Admits/Transfers	87	13[α]	4.2	6.3*
Sent home undelivered	719	10[α]	26.1	40.8*
Unknown	–	1[‡]	–	–
TOTAL	**806**	**24**	**30.3**	**47.1**

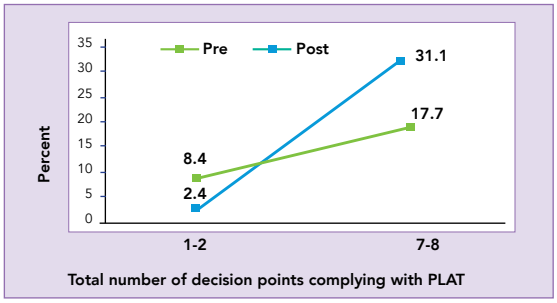
* Change from pre to post is statistically significant with p<0.05
α Cervical change assessment not reported or N/A
‡ Medical record met criteria for inclusion but disposition not reported
Change in the positive direction is the desired outcome.

The decision point data also indicated that from pre- to post-implementation, compliance with *not initiating treatment for preterm labor prior to assessment completion* increased for both tocolysis and antenatal corticosteroids (see Figures 16 and 17). However, these increases in compliance were not statistically significant. At both timepoints, a large minority of patients was treated with tocolysis during preterm labor assessment.

Distribution of educational materials to patients discharged home undelivered was close to 90 percent at both pre- and post-implementation and showed a very slight decrease over time. Compliance with *PLAT* also decreased slightly for time to disposition. However, neither change was statistically significant (see Figures 16 and 17). The lengthier assessment time following *PLAT* implementation may have resulted from clinicians' attention to carefully working through the *PLAT* protocol.

Additional analyses showed that over time, there was a statistically significant *decrease* in the number of cases that complied with only 1 to 2 decision points and a statistically significant *increase* in the number of cases that complied with 7 to 8 decision points (see Figure 19). However, the hypothesis that 90 percent of charts would comply with *PLAT* was not realized. Moreover, at post-implementation, compliance with the most fundamental elements of the preterm labor assessment process, including assessment of cervical status and cervical change, had risen to only 78.2 percent and 47.2 percent respectively, with an appropriate disposition decision being made in only a minority — 47.0 percent — of cases examined (Figures 16 and 17). However, a 50 percent improvement in assessment of cervical change and appropriate disposition decisions is an indicator of progress.

Figure 19: Total decision points complying with *PLAT*



Change from pre to post is statistically significant for 1-2 decision points and for 7-8 decision points, p<0.05

Surveys and phone meetings with hospital site representatives indicated that factors that limited success included clinician reluctance to perform a sterile speculum exam for all patients; perceived expense of using fetal fibronectin testing; incomplete cervical change assessment, which in turn affected disposition decision compliance; and physician insistence on initiation of treatment for preterm labor, i.e., antenatal corticosteroids and tocolytics, prior to completion of assessment. Additionally, in considering the results, it is important to keep in mind that the change-over-time data represent only the first 3 months after implementation. As clinicians become familiar with the procedures, it is expected that compliance will increase.

To date, one of the 15 pilot study hospitals has also provided 9-month follow-up data on decision point compliance, and the findings are quite promising. The most notable increases at 9 months post-implementation were use of the sterile speculum exam (with a post compliance of 96.6 percent), assessment of cervical status (with a post compliance of 100 percent), assessment of cervical change (with a post compliance of 96.6 percent), and appropriate disposition (with a post compliance of 96.0 percent).

Lessons Learned

The evaluation provided insight on both facilitators and barriers to *PLAT* implementation. Examples of key facilitators and barriers that were identified by the evaluation sites and by project staff are provided in Table 9.

Table 9: Facilitators and barriers to *PLAT* implementation

Facilitators	Barriers
• Passionate MD, RN, and data champions • Baseline data report to support need for new policy, procedure and/or standard • Making the process a quality improvement project • Collaboration with Regional Perinatal Programs of California: Facilitated ongoing relationships with hospitals and promoted common goal of improving quality of care and compliance with standards • Holding meetings and/or trainings for physicians and nurses together to achieve buy-in on all sides and generate excitement about changes • *PLAT* Hospital Network: Forum for sharing best practices, troubleshooting and encouraging peer support	• General trust in fetal monitoring to assess preterm labor • Nurses not prepared or comfortable to perform SSE • Perceived expense of using fetal fibronectin testing vs. cost of hospital stay • Physician insistence on tocolytic or antenatal steroid treatment prior to completion of assessment • Competing quality improvement priorities • Limited staff time and other resources • Staff changes in nursing leadership, resulting in process delays

The *PLAT* evaluation also yielded additional lessons on how to better support hospitals, use results to teach providers and drive change, and refine *PLAT* content and measurement instruments. Key lessons learned by hospitals during *PLAT* implementation include:

- Labor can be missed when fetal monitoring of uterine activity is the only form of assessment.
- Hospital change processes take time. Hospital leaders must often balance many change processes simultaneously.
- Provision of baseline data reports to sites can help move change forward. By seeing data illustrating their areas of strength and weakness, site staff can focus their energies on specific areas for improvement.

The evaluation found that the increase in overall clinician compliance with the PLAT protocol was statistically significant.

Barstow Community Hospital

Barstow, California

Case Study

Standardizing the assessment of women presenting with signs and symptoms of preterm labor

Background

Barstow Community Hospital (BCH) is a for-profit, rural hospital that delivers approximately 300 babies per year. BCH opened a new all private room 30-bed facility in October 2012. The hospital has a well-baby nursery and transports about 20 mothers and 15 babies a year to higher levels of care. High-risk specialists are not available in-house; however, patients are referred to an outpatient perinatologist nearby, and the hospital consults with the closest tertiary center regularly. BCH is the only hospital within a 30 to 150 mile radius, with no other hospital located between Barstow and Las Vegas, Nevada. Barstow Community Hospital serves a population that often presents with high-risk conditions and inadequate prenatal care.

Key facilitators to PLAT implementation include having passionate physician, nursing and data champions and making the process a quality improvement project.

In 2008, the Obstetrics (OB) Manager resolved to address the issue of long delays in obtaining fetal fibronectin (fFN) test results, which were outsourced for processing at another hospital. Waiting 24 hours for test results led to variation in practice and unnecessary treatment. The OB Manager and obstetricians viewed implementation of the March of Dimes *Preterm Labor Assessment Toolkit (PLAT)* as an opportunity to bring fFN testing in-house and create a uniform, well-defined plan for assessing women presenting with the signs of preterm labor.

The OB Manager acted as the champion for the project. Utilizing the tools outlined in *PLAT*, she collaborated with departmental physicians to revamp existing preterm labor policy, procedures and physician order sets to include a definition of preterm labor. Performing a sterile speculum exam was identified as the essential first step in assessing every patient. In addition, she aligned BCH policy with that of the nearest tertiary center to ensure continuity of care when patients are transferred out. She also worked with the March of Dimes and the hospital lab director to bring fFN testing capabilities to the hospital.

Nursing staff and physician education were conducted at the same time. Both groups came together for a presentation delivered by a respected perinatologist from the tertiary center. During the presentation, nurses and physicians were excited by the opportunity to implement a standardized protocol that would ensure that everyone was using the most effective tools available to assess and diagnose women presenting with signs of preterm labor. A department physician provided "back to basics" training for all nursing staff on sterile speculum exams to ensure that everyone would conduct the exam in the exact manner demonstrated. To support implementation of the new policy, staff members were asked to read and sign the new policy. In addition, a board was posted in the unit communicating results of chart audits that measured adherence to the new policy.

A key step in the new policy rollout was bringing the fFN test in-house. The OB Manager worked diligently over the course of 7 months to present a cost analysis to the hospital's administrators. Her analysis demonstrated the savings gained by sending a patient home after obtaining negative fFN results within 1 hour (from the in-house lab) and thus avoiding the cost of IVs, tocolytics and unnecessary long hospitalizations while awaiting fFN results.

Using a quality improvement model, the OB Manager conducted a baseline chart audit followed by 3-month and 9-month post-implementation chart audits to assess practice change. Results were shared with nursing staff and physicians through meetings, one-on-one discussions and a communication board posted in the unit. This ongoing feedback facilitated institutionalization of the practice changes. In addition, the OB Manager wrote thank-you notes to staff and held a "success party" to celebrate the improvements demonstrated through chart audits.

Key Steps

- Establish policy and procedures and develop physician order sets that:
  - Explicitly define preterm labor
  - Utilize sterile speculum exam as the initial assessment strategy to determine cervical status
  - Move fetal fibronectin test to in-house lab processing
- Ensure that a maternal transport process is in place.
- Convene a meeting and educational session for nurses and physicians jointly to achieve buy-in by all sides and generate excitement about changes.
- Make the case for bringing fFN processing in-house so that test results are turned around within 1 hour, allowing for timely and appropriate disposition decisions.
- Establish preterm labor assessment as a quality improvement project using the fFN test as a quality indicator. Through chart audits the hospital can evaluate whether or not all patients who should have received the fFN test based on presentation and eligibility criteria received it.
- Share results of regular chart audits to demonstrate progress and identify areas for improvement to help motivate the department. Also, share results with individual nurses who may need additional training or reinforcement on policies or competencies such as performing sterile speculum exams.
- Distribute March of Dimes patient education materials to every patient sent home to support patients' understanding of preterm labor signs and symptoms and clarify when to return to the hospital or schedule an office visit with their provider.

Performing a sterile speculum exam was identified as the essential first step in assessing every patient.

Barriers and Solutions

Barrier: Locum tenens physicians were not always aware of the new *PLAT* processes.

Solution: Nurses were well trained in the new protocol and physician order set. They followed the steps consistently, including performing sterile speculum exams and collecting fFN tests. Their consistency conveyed the message to locum tenens physicians that this was the expected standard. Over time, the new policy was accepted.

Barrier: The hospital received support from the nearest tertiary center, which provided neonatal transport. As is common in the obstetric community, a maternal transport agreement was not officially in place. This created a challenging situation when BCH staff and physicians were required to travel by ambulance with women in advanced labor who required a higher level of care. As a result, the majority of these women were delivered at BCH and a neonatal transport team from the tertiary center took care of and transported babies requiring higher levels of care. Thus, due to logistics, less emphasis was placed on maternal transport and greater emphasis on neonatal transport.

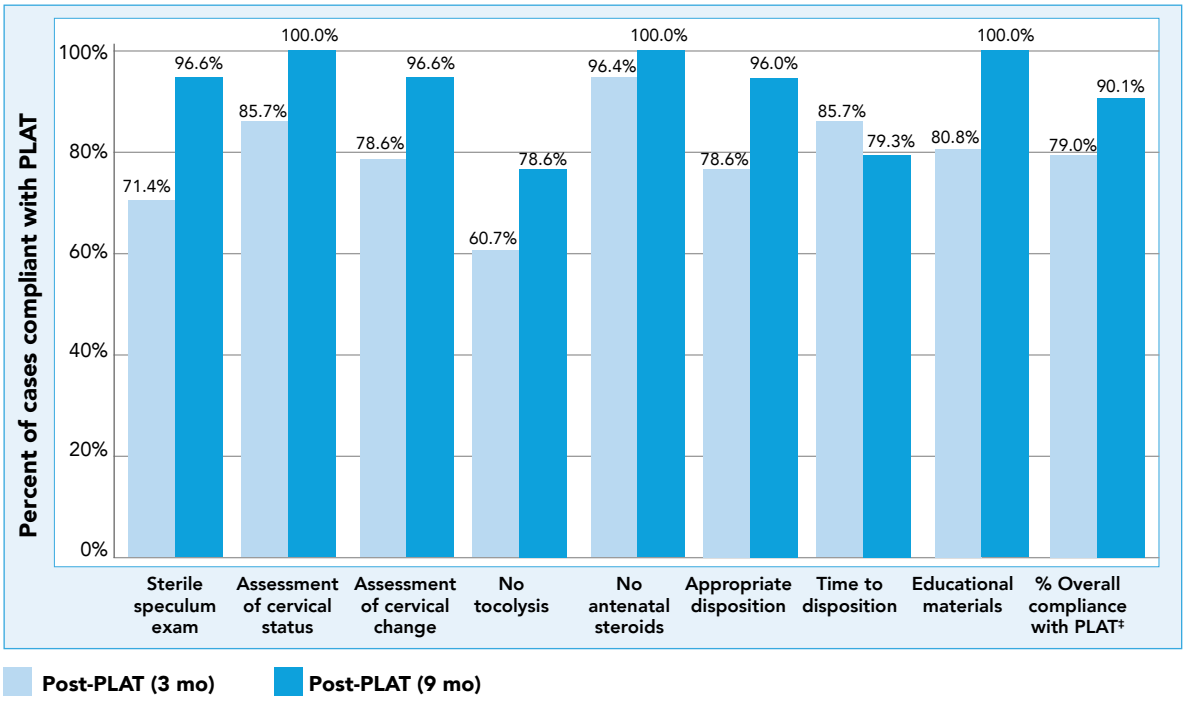
Solution: Following *PLAT* afforded greater opportunity to identify women in preterm labor earlier and provided time to prepare for maternal transport. At the same time, a maternal transport agreement was established with a second regional center offering maternal transport services.

Outcomes

BCH participated in the March of Dimes California Chapter pilot evaluation to assess the impact of *PLAT* on clinician assessment behaviors. BCH conducted chart audits of 30 triage encounters prior to implementation and at 3 and 9 months following *PLAT* implementation. Patient data were used to evaluate clinician behaviors at eight decision points that define *PLAT* compliance. (For more information about the pilot evaluation study, including a description of the decision points and results for 15 hospitals, see Appendix D: March of Dimes Pilot Study Evaluation Report.)

As shown in Figure 20, compliance with the *PLAT* protocol at BCH increased from pre- to post-implementation for seven of the eight decision points. The most notable increases from pre-implementation to 9 months post-implementation are use of the sterile speculum exam (with a post compliance of 96.6 percent), assessment of cervical status (with a post compliance of 100 percent), assessment of cervical change (with a post compliance of 96.6 percent), and appropriate disposition (with a post compliance of 96.0 percent).

Figure 20: Compliance with *PLAT* decision points post-implementation at Barstow Community Hospital



‡ % compliance with PLAT = Avg # of decision points followed/total # of applicable decision points

Lessons Learned

- Using the QI model, collecting and analyzing chart audit data provided positive reinforcement to support behavioral change. The reports showing improvement served as an incentive to the department to sustain changes.
- Implementation of the sterile speculum exam for all patients was the key to making a practice change.
- Development and implementation of a standard physician order set allowed a clearly defined triage and assessment plan to be followed for all patients.
- Anecdotally, patient satisfaction with the triage experience increased because patients felt that "more was being done" for them when a sterile speculum exam and fFN test were performed and educational materials were provided. They reported feeling safer and more confident when they were discharged home.
- Collaboration with the Regional Perinatal Programs of California (RPPC) was key to successful implementation and evaluation. (The state of California funds the RPPC system to support hospitals that undertake perinatal quality improvement initiatives. RPPC program directors are responsible for working with hospitals in defined regions.)

Front Line Experiences

- "A couple of months after implementing our new policy, I had a patient present at 23 to 24 weeks gestation. She had some intermittent cramping but she did not exhibit or report great discomfort. The monitor did not pick up any contractions nor could I palpate any contractions. Before the new protocol, I would have watched her for an hour on the monitor and sent her home per common practice. But this time, I followed the protocol steps and when I performed the sterile speculum exam, I could see that her bag of waters was bulging, and she was 2 to 3 cm dilated. I immediately called the closest tertiary hospital, and their transport team was able to arrive before the baby was born. This experience changed my thinking and convinced me of the importance of assessing *every* woman using a standard procedure. We don't want to miss anyone." –*OB Manager*

Following PLAT afforded greater opportunity to identify women in preterm labor earlier and provided time to prepare for maternal transport.

- Another nurse had an *aha!* moment when she discovered that a patient whom she determined was dilating preterm had been evaluated the previous day prior to implementation of *PLAT*. This patient delivered that day at BCH, and the baby was later transported to the regional NICU. The nurse wondered if *PLAT* protocol had been followed, could the patient have been diagnosed more quickly, allowing transport of the mother to a higher level of care?

For more information about the Barstow Community Hospital project, contact:

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University of California Davis Medical Center

Sacramento, California

Case Study

Standardizing the assessment of women presenting with signs and symptoms of preterm labor

Background

University of California Davis Medical Center (UCDMC) is a non-profit, 645-bed teaching hospital that delivers approximately 2,400 babies per year. Serving a 33-county, 65,000-square-mile area, this tertiary-care center with a Level III NICU accepts transports from the northern part of the state. In-house, high-risk specialists are available 24 hours a day. UCDMC is the only hospital in Sacramento with a laborist.

In 2010, the Labor and Delivery Department began a targeted effort to increase efficiency and decrease the time required to rule out preterm labor. The March of Dimes *Preterm Labor Assessment Toolkit (PLAT)* was selected as the basis for developing a protocol with a clear assessment pathway to shorten time to discharge for women who were not in preterm labor.

An OB/GYN chief resident acted as champion of the project with support from the Medical Director of Maternity Services, other medical residents and triage nurses. Utilizing tools outlined in *PLAT*, the project champion created algorithms and protocols that established assessment steps and tools, including transvaginal ultrasound (TVU) and fetal fibronectin (fFN).

The project champion presented the new process to the department. Residents received didactic and hands-on training, as they were primarily responsible for conducting triage assessment. They implemented two significant changes to the hospital's triage process — performing initial sterile speculum exams and collecting fFN samples on all patients (unless a contraindication was present) and increasing utilization of TVU. (Residents were trained to perform the exam.) To support implementation, the new algorithm and protocol were posted on departmental bulletin boards and in triage.

The project champion conducted baseline and 3-month post-implementation chart audits to assess practice change. Results were shared with nursing staff and physicians during meetings. This ongoing feedback facilitated institutionalization of the practice changes.

Key Steps

- Establish a preterm labor assessment algorithm and protocol that:
  - Includes clear, well-defined steps to ensure timely triage and disposition
  - Utilizes sterile speculum exams as the initial assessment so that cervical status is determined and a fFN sample is collected for every patient
- Share results of regular chart audits to show progress, motivate the department and build confidence in the new protocol.

Collecting and analyzing chart audit data was a positive reinforcement to support practice change.

Outcomes

UCDMC participated in the March of Dimes California Chapter pilot evaluation to assess the impact of *PLAT* on clinician assessment behaviors. UCDMC conducted chart audits of 30 triage encounters prior to and again at 3 months following *PLAT* implementation. Medical chart data were used to evaluate clinician behaviors on eight decision points that define *PLAT* compliance. (For more information about the pilot evaluation study, including description of the decision points and the results for 15 hospitals, see Appendix D: March of Dimes Pilot Study Evaluation Report.)

As shown in Figure 21, UCDMC outcomes substantially improved after *PLAT* implementation. Compliance with the *PLAT* protocol increased significantly overall from 75.0 percent to 91.2 percent. It also increased from pre- to post-implementation for six of the eight decision points with one additional decision point remaining consistent at 100 percent compliance. Statistically significant increases from pre- to post-implementation were documented for use of the sterile speculum exam (69.0 percent to 100 percent), assessment of cervical change (57.7 percent to 100 percent), and appropriate disposition (68.0 percent to 96.2 percent). Additionally, UCDMC experienced a statistically significant decrease in average time to disposition for preterm labor assessment triage (5.0 to 3.4 hours; data not shown in figure), which was also a desired outcome. Lastly, there was a statistically significant reduction in tocolysis use during the assessment period among women who were sent home undelivered (13.8 percent to 0.0 percent; data not shown in figure).

Lessons Learned

- Collecting and analyzing chart audit data was a positive reinforcement to support practice change. Reports showing positive improvement provided incentive to the department to sustain changes.
- Implementation of the sterile speculum exam and fetal fibronectin test collection for all patients were key to making practice changes.
- Development and implementation of the standardized algorithm allowed for creation of a clearly defined triage and assessment plan for all patients.
- Buy-in from the chief residents facilitated continued support for and reinforcement of changes in residents' assessment practices.

For more information about the UC Davis Medical Center Project, contact:

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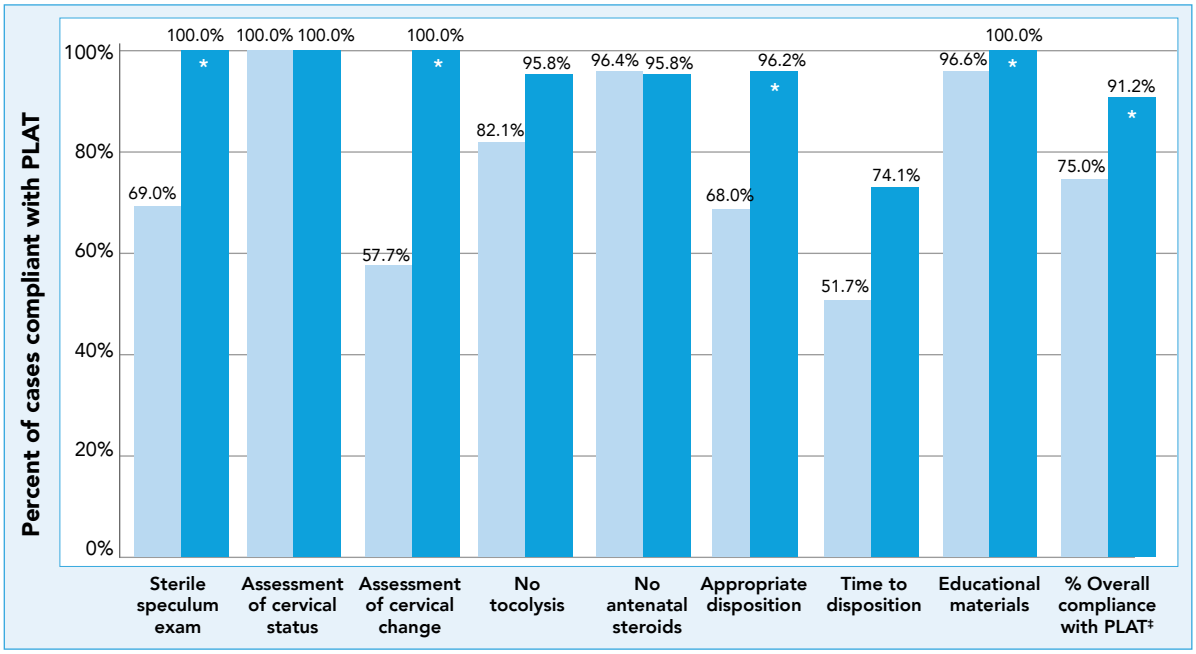
Figure 21: Compliance with *PLAT* decision points pre- and post-implementation at UC Davis Medical Center



‡ % compliance with PLAT = Avg # of decision points followed/Total # of applicable decision points
*Statistically significant change from pre-implementation to post ($p<0.05$)

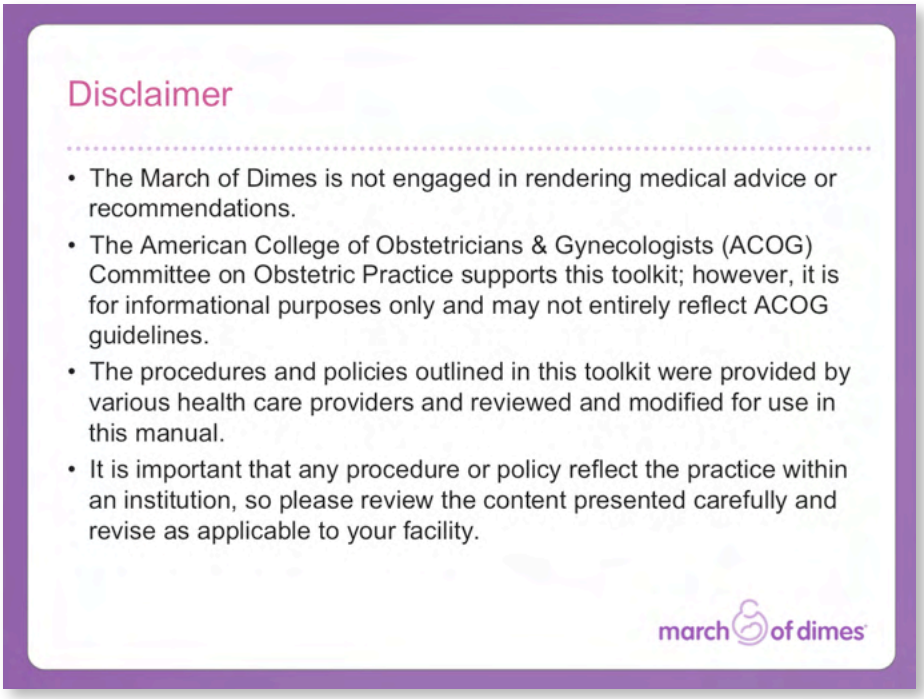
Presentation 1

Note to presenter:

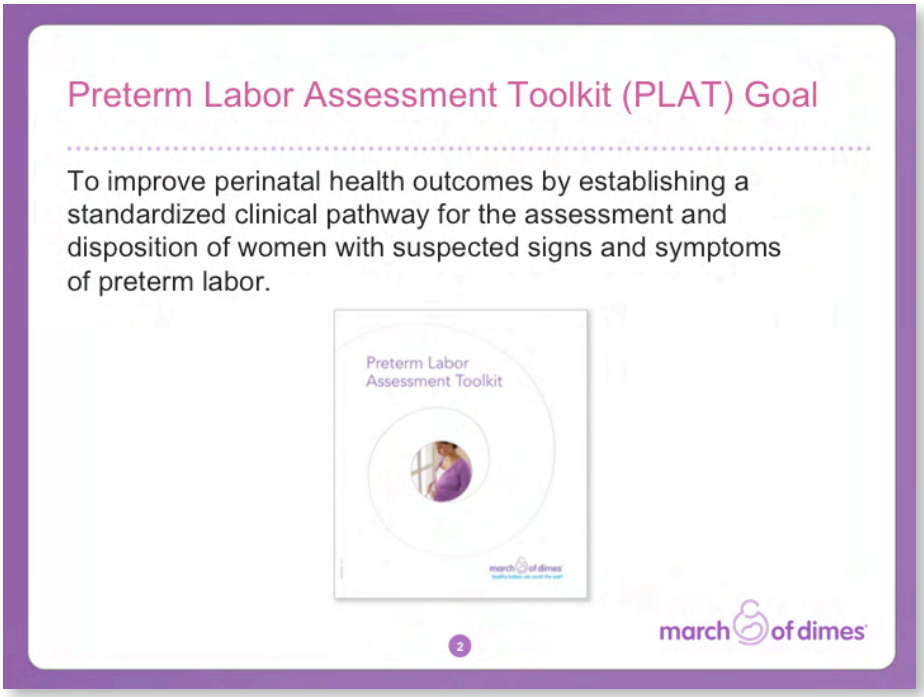
The goal of this two-part slide deck is to support hospital clinicians in understanding the importance of standardizing preterm labor assessment and the steps to take to drive change in assessing patients presenting with signs and symptoms of preterm labor.

This slide deck can be tailored to meet the needs of the audience. When adapting the slide deck, the following guidelines must be followed:

- The slide deck is copyrighted by March of Dimes Foundation. Slides contained in this deck should not be changed or amended.
- Additional slides can be added, but new slides must not contain the March of Dimes logo or copyright.



It is mandatory that the content of the disclaimer slide be presented to the audience.

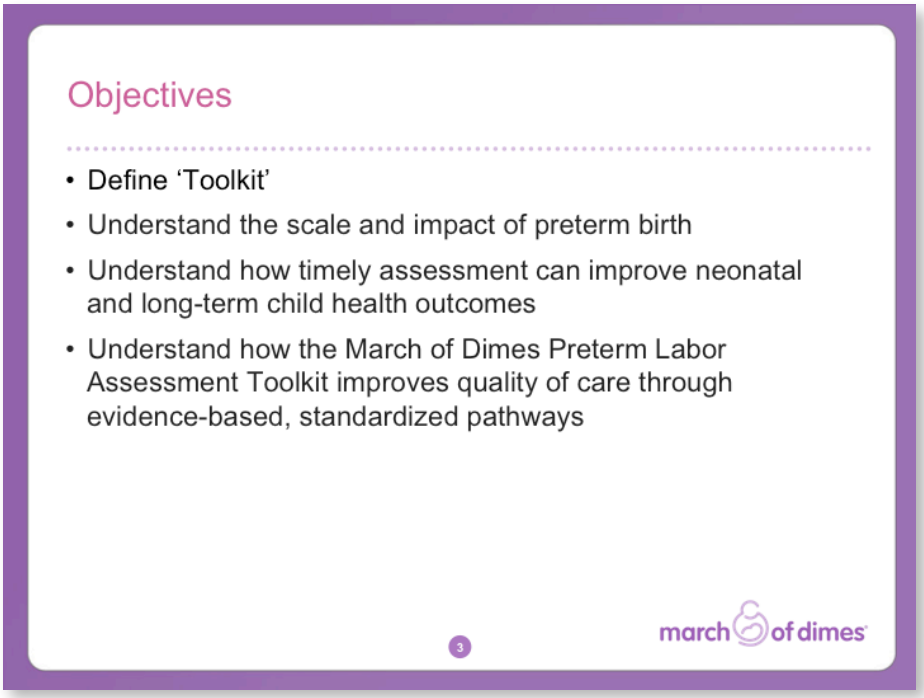


The March of Dimes *Preterm Labor Assessment Toolkit* was developed to support clinical staff at hospitals with accomplishing this goal in a step-by-step manner.

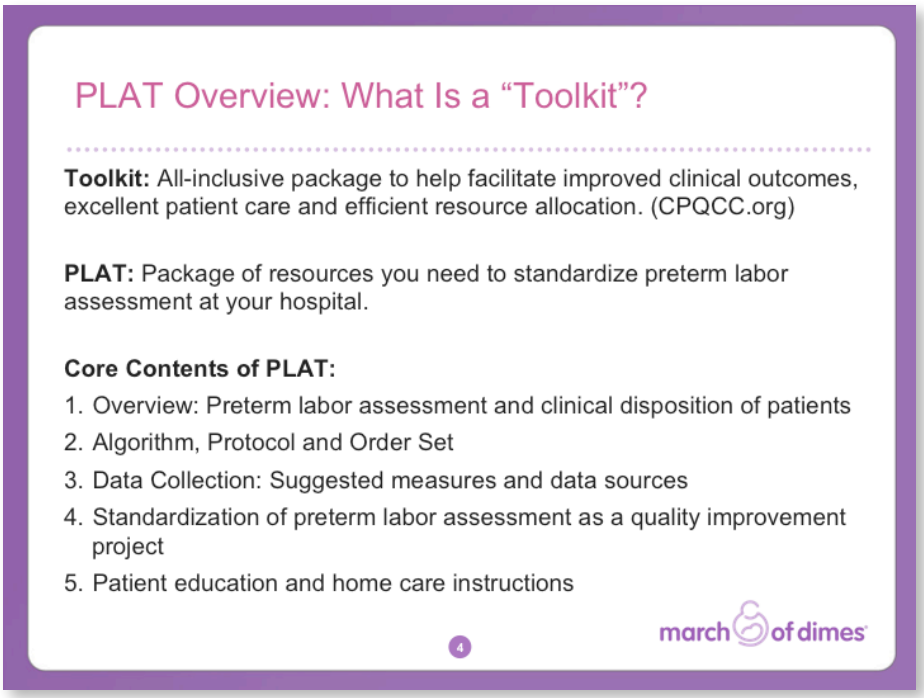
By addressing assessment of women with symptoms of preterm labor, we believe this toolkit complements recent publications from the American College of Obstetricians and Gynecologists (ACOG) related to:

a) screening and management of asymptomatic women at risk of preterm labor **and**

b) management of women with confirmed preterm labor.

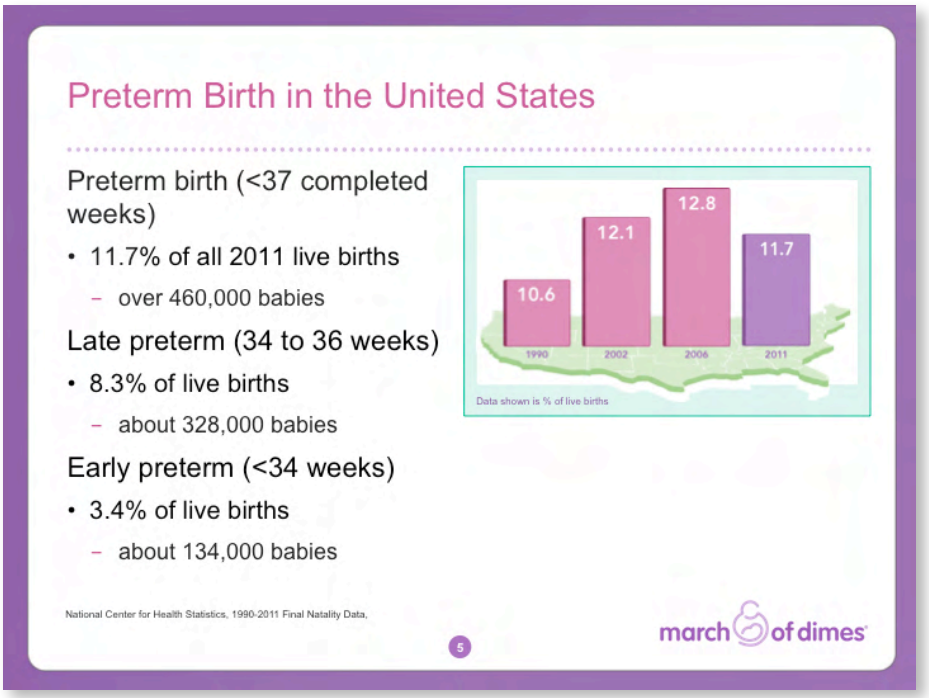


Learning objectives for this presentation.



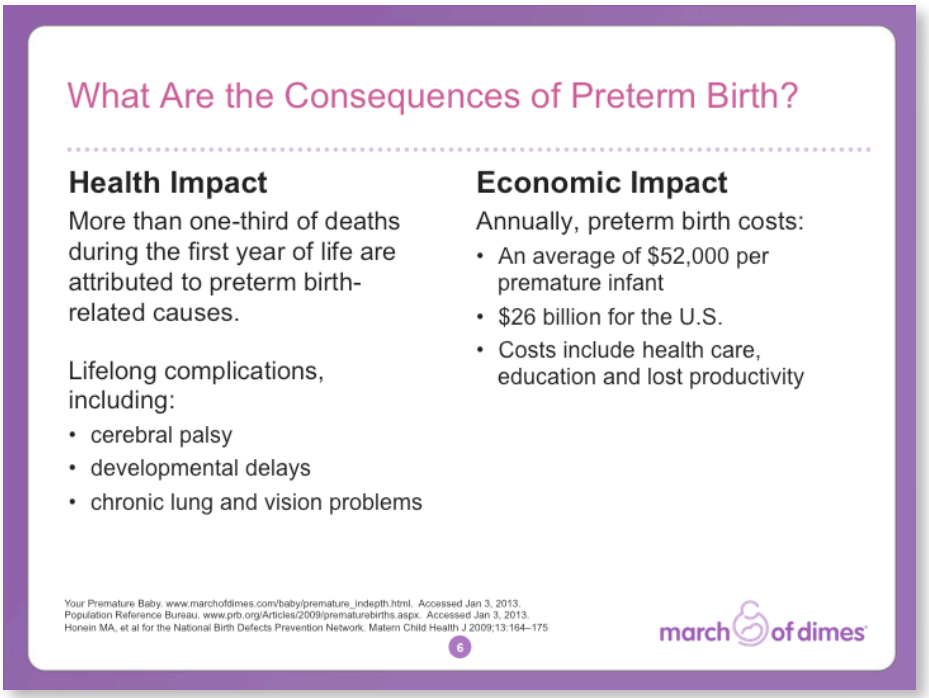
PLAT supports local providers and hospitals by providing practical tools and resources to implement improvements in care.

The toolkit includes materials such as protocols and order sets that are intended to be customized to meet a hospital's specific needs. This approach benefits local providers and hospitals who would otherwise face the burden of developing these materials themselves.



The scale of preterm birth:

- Approximately 4 million babies are born each year in the United States.
- 11.7% are born prematurely. This represents a 8.6 percent decrease since 2006, following a 20 percent increase since the early 1990s (see graph on slide).
- The U.S. preterm birth rate is higher than that of most other developed countries.
- Improving outcomes in early preterm birth (<34 weeks) is the sub-group of added emphasis for society and medical professionals due to the significant morbidities, mortality, and health care costs associated with these vulnerable children.

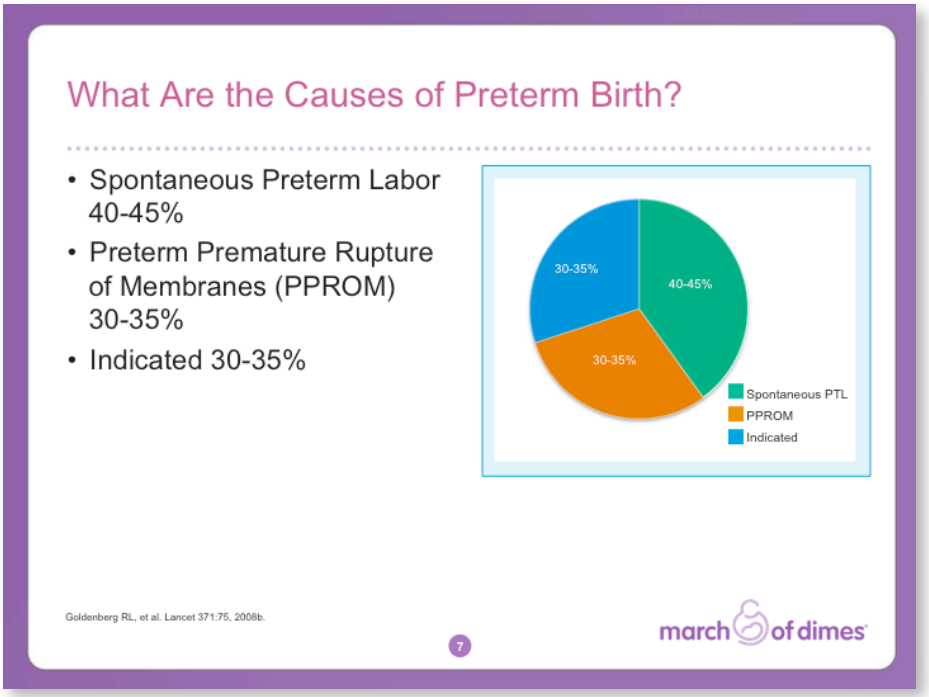


The impact of preterm birth:

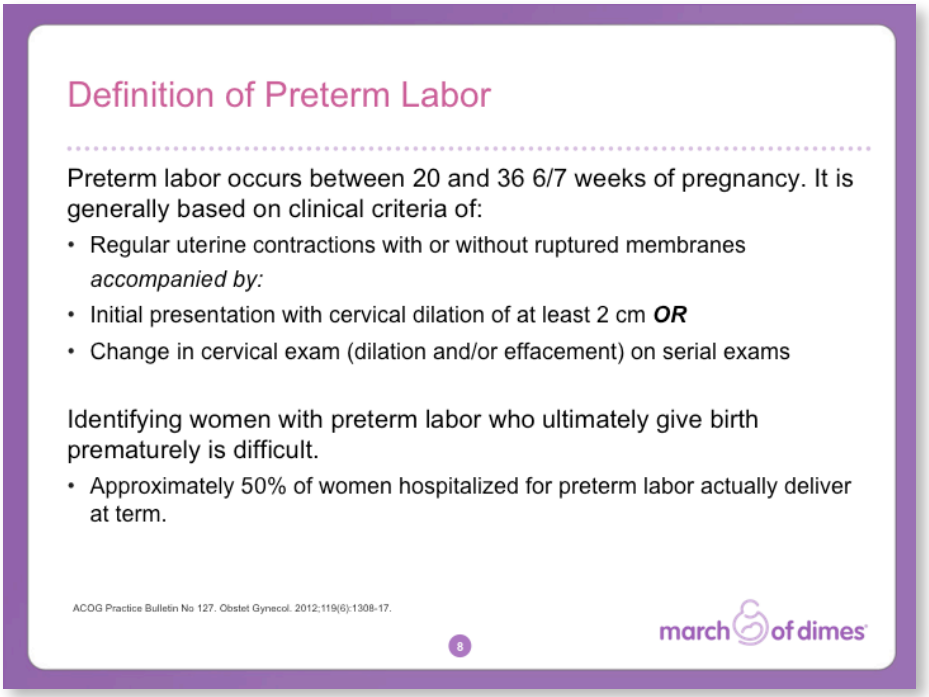
- Babies born prematurely, compared to babies born at or after 37 weeks, are at greater risk of hospitalization, long-term health problems and death.
- Since prevention of preterm birth remains elusive, we can significantly improve neonatal outcomes by timely preparation for preterm birth, such as administration of antenatal corticosteroids, initiating short-term tocolytic therapy, and admitting or transporting mothers to a higher level of care before delivery.

Additional References:

1. Kramer MS, Demissie K, Yang H, Platt RW, Sauvé R, Liston R for the Fetal and Infant Health Study Group of the Canadian Perinatal Surveillance System. The contribution of mild and moderate preterm birth to infant mortality. *JAMA*. 2000;284:843-849.
2. Callaghan WM, MacDorman MF, Rasmussen SA, Qin C, Lackritz EM. The contribution of preterm birth to infant mortality rates in the United States. Pediatrics. 2006;118:1566-1573.
3. Institute of Medicine. Preterm birth: causes, consequences, and prevention. 2006. Available at: http://www.iom.edu/CMS/3740/25471/35813.aspx. Accessed November 29, 2012.
4. Swamy GK, Ostbye T, Skaerven R. Association of preterm birth with long-term survival, reproduction, and next-generation preterm birth. *JAMA*. 2008;299:1429-1436.



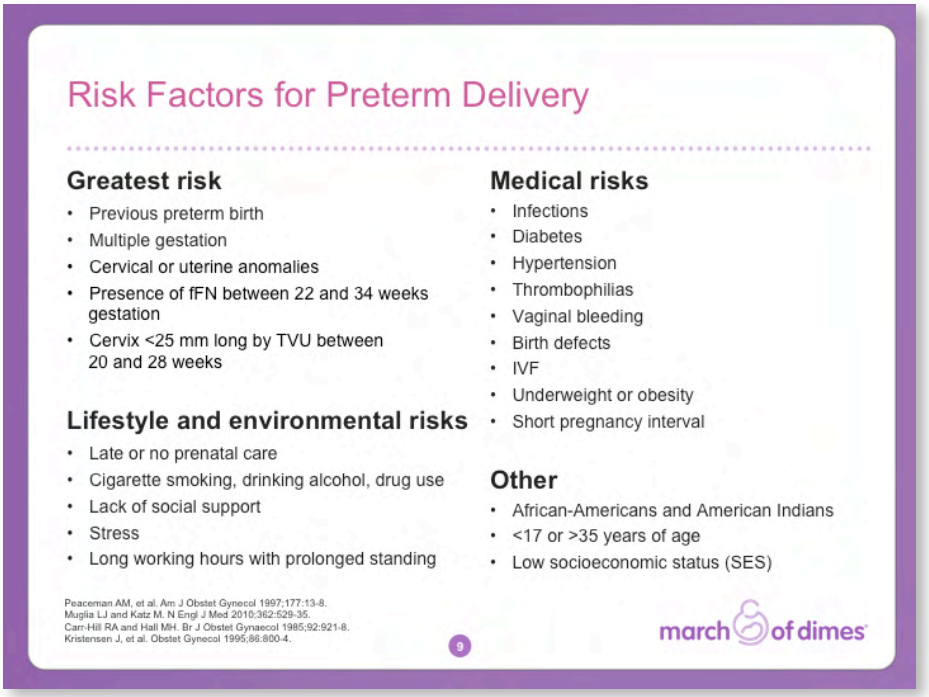
- Spontaneous preterm labor is the single largest cause of preterm birth (40%-45%). Its symptoms may include vaginal bleeding with an increase in vaginal mucous discharge for 2 days or more with or without uterine contractions.
- Many women have symptoms of preterm labor for more than 2 days prior to delivery, allowing time for interventions that can improve outcomes for the baby:
  - Implementation of risk-appropriate care for BOTH mother and baby, such as notification of the NICU team or maternal transport to a higher level of care
  - Administration of antenatal corticosteroids
- In this graph, indicated (30-35%) includes elective preterm deliveries.
  - Tighter protocols for the timing of elective inductions and C-sections could eliminate most of these iatrogenic preterm birth cases. (Download the *Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age; Quality Improvement Toolkit* at prematurityprevention.org)



- ACOG Practice Bulletin 127, June 2012 uses the clinical criteria listed on this slide to define preterm labor.
- Hospitals adopting a standardized definition of preterm labor aid in consistent assessment of women presenting with signs and symptoms of preterm labor.
- One acknowledged challenge is the difficulty identifying women with preterm labor who will ultimately give birth prematurely. As noted in ACOG Practice Bulletin No 127, "The assessment of preterm delivery risk based on symptoms and physical examination alone is inaccurate." (See references below). As a result, preterm delivery will not occur in 50% of women hospitalized with preterm labor.

Additional References:

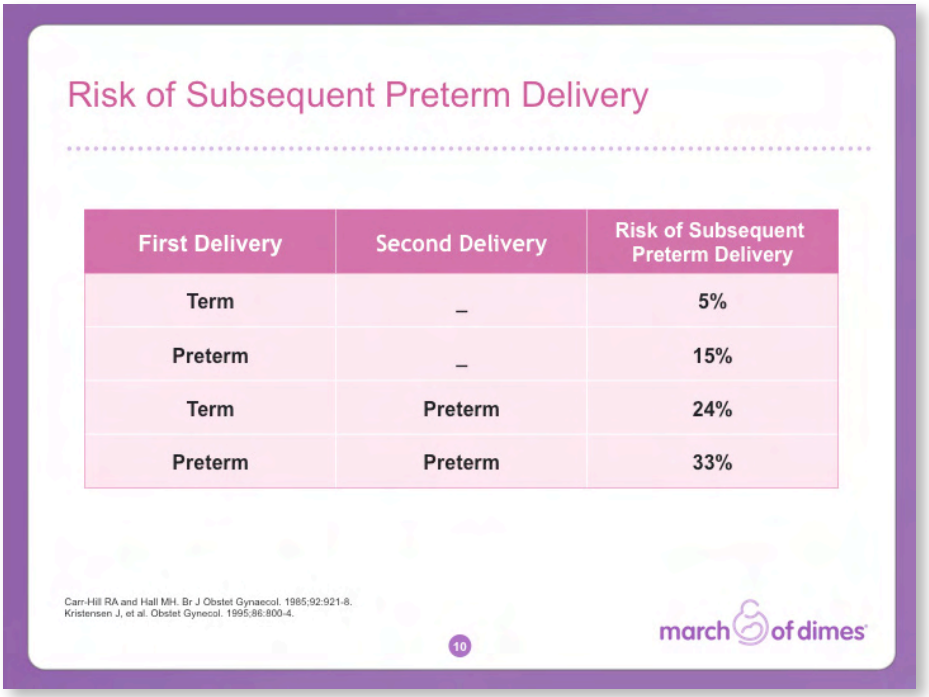
1. Peaceman AM, Andrews WW, Thorp JM, Cliver SP, Lukes A, Iams JD, et al. Fetal fibronectin as a predictor of preterm birth in patients with symptoms: a multicenter trial. Am J Obstet Gynecol 1997;177:13–8.
2. Main DM, Gabbe SG, Richardson D, Strong S. Can preterm deliveries be prevented? Am J Obstet Gynecol 1985;51:892–8.
3. Dyson DC, Crites YM, Ray DA, Armstrong MA. Prevention of preterm birth in high-risk patients: the role of education and provider contact versus home uterine monitoring. Am J Obstet Gynecol 1991;164:756–62.



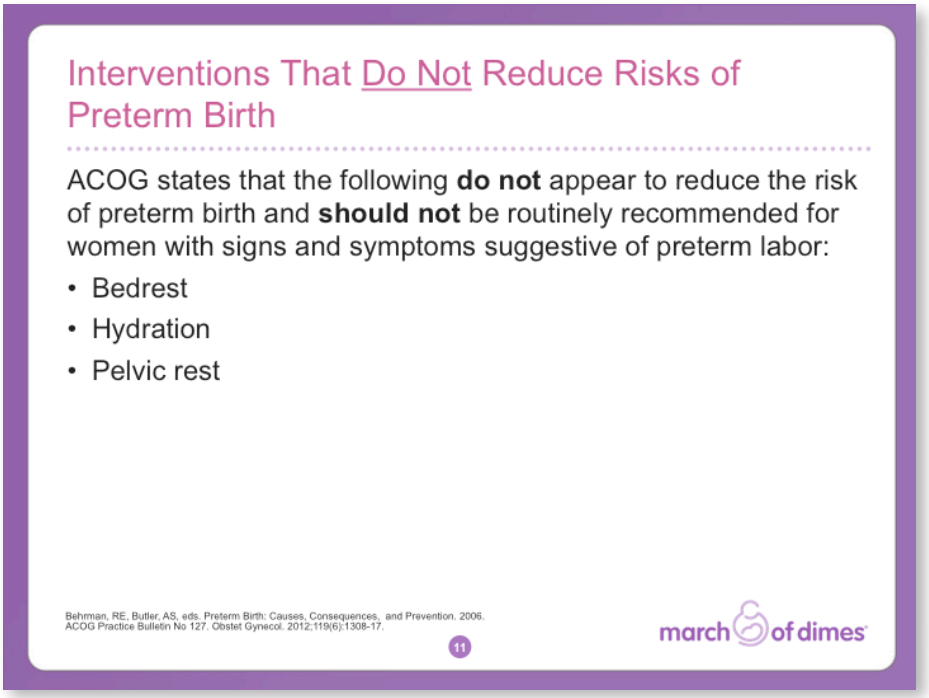
- This slide lists the most common risk factors for preterm delivery.
  - Previous preterm birth is the most significant predictor of a subsequent preterm delivery.
  - The presence of fetal fibronectin (fFN) or a short cervix on Transvaginal Ultrasound (TVU) have been associated with preterm birth.
  - Many of these risk factors, such as age or ethnic group, are inherent and cannot be modified. Other risk factors, such as smoking and concurrent medical conditions, can be improved through appropriate interventions.
- If assessing preterm delivery risk based on symptoms and physical examination alone is often inaccurate, then which additional factors are associated with preterm birth?
- Even if preventing preterm birth is not possible, the ability to identify those women most at risk for preterm labor may improve neonatal outcomes by allowing timely interventions such as antenatal corticosteroids.

Additional References:

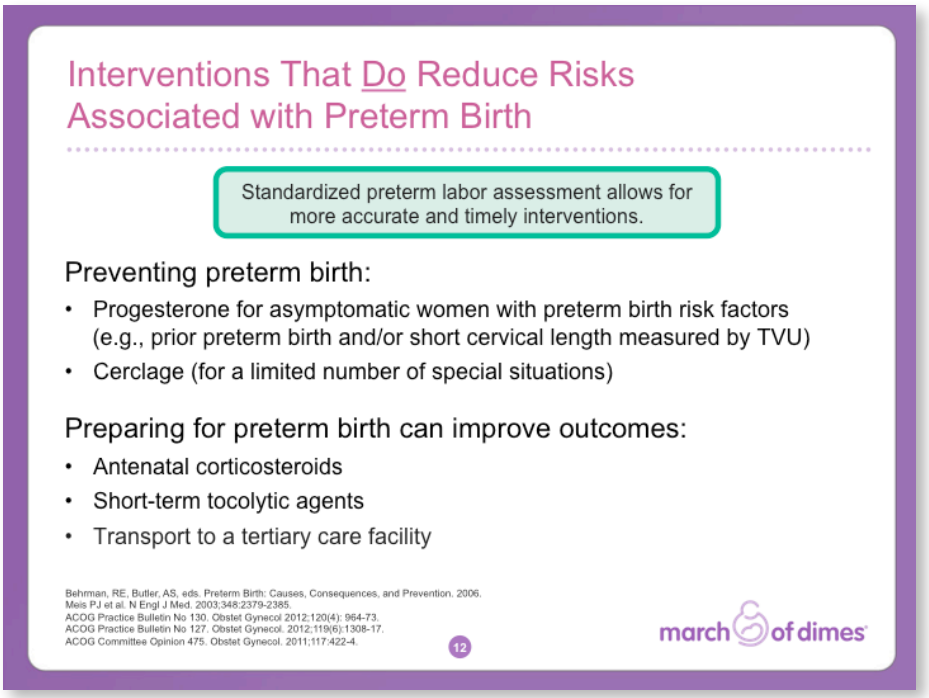
1. ACOG Practice Bulletin No 127. Obstet Gynecol. 2012;119(6):1308-17
2. Berghella V, Baxter JK, Hendrix NW. Cervical assessment by ultrasound for preventing preterm delivery. Cochrane Database of Systematic Reviews 2009, Issue 3. Art.:CD007235
3. Berghella V, Hayes E, Visintine J, Baxter JK. Fetal fibronectin testing for reducing the risk of preterm birth. Cochrane Database of Systematic Reviews 2008, Issue 4. Art:CD006843
4. Swamy GK, Simhan HN, Gammill HS, Heine RP. Clinical utility of fetal fibronectin for predicting preterm birth. J Reprod Med 2005;50:851-6
5. Ness A, Visintine J, Ricci E, Berghella V. Does knowledge of cervical length and fetal fibronectin affect management of women with threatened preterm labor? A randomized trial. Am J Obstet Gynecol 2007;197:426.e1–7



- Prior preterm birth is an important risk factor.
- This slide illustrates the increased probability of a subsequent preterm birth based on the history of previous preterm birth.



- Many historical recommendations are not beneficial.
- Interventions such as severe restrictions on lifestyle (e.g., pelvic rest and bedrest) for women with signs and symptoms suggestive of preterm labor are of uncertain effectiveness.
- Their potential harms (e.g., thrombosis from statis in the lower extremities) or negative impacts (e.g., loss of employment) should not be underestimated.
- ACOG states that bedrest, hydration and pelvic rest (abstention from intercourse and orgasm) have not been shown to be effective for the prevention of preterm birth and should not be routinely recommended.



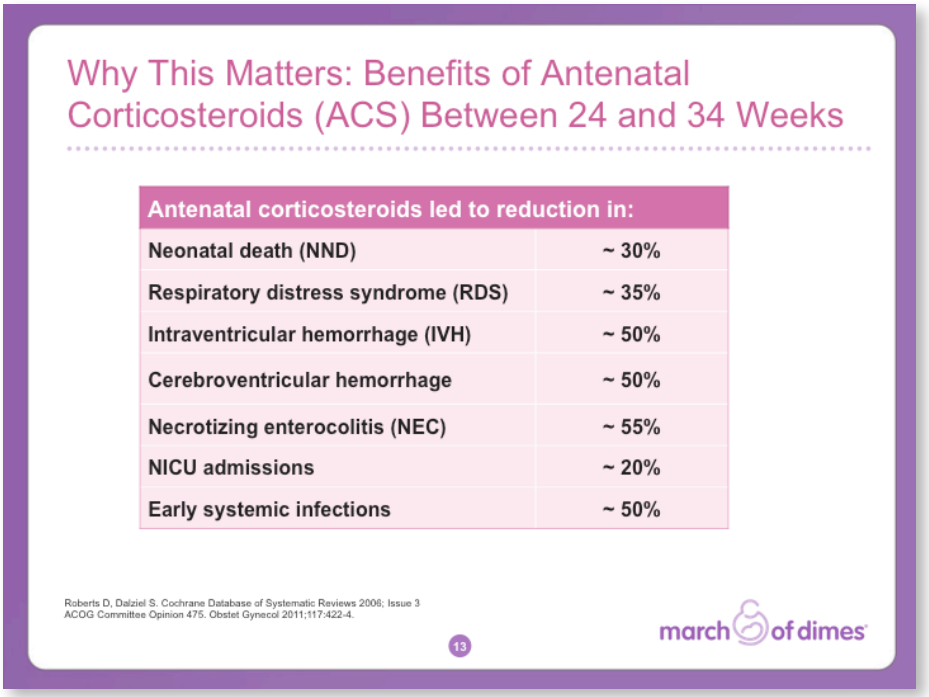
A KEY SLIDE

Interventions that can prevent preterm birth:

- Progesterone administration has been shown to be effective in reducing the risk of preterm birth in specific populations:
  - Intramuscular progesterone to asymptomatic women with a history of spontaneous preterm birth
  - Vaginal progesterone to asymptomatic women at high risk of preterm labor due to a transvaginal ultrasound of a very short cervix (< 20 mm) before or at 24 weeks gestation
- Prophylactic cervical cerclage also has been reported to reduce the rate of preterm birth in special situations.

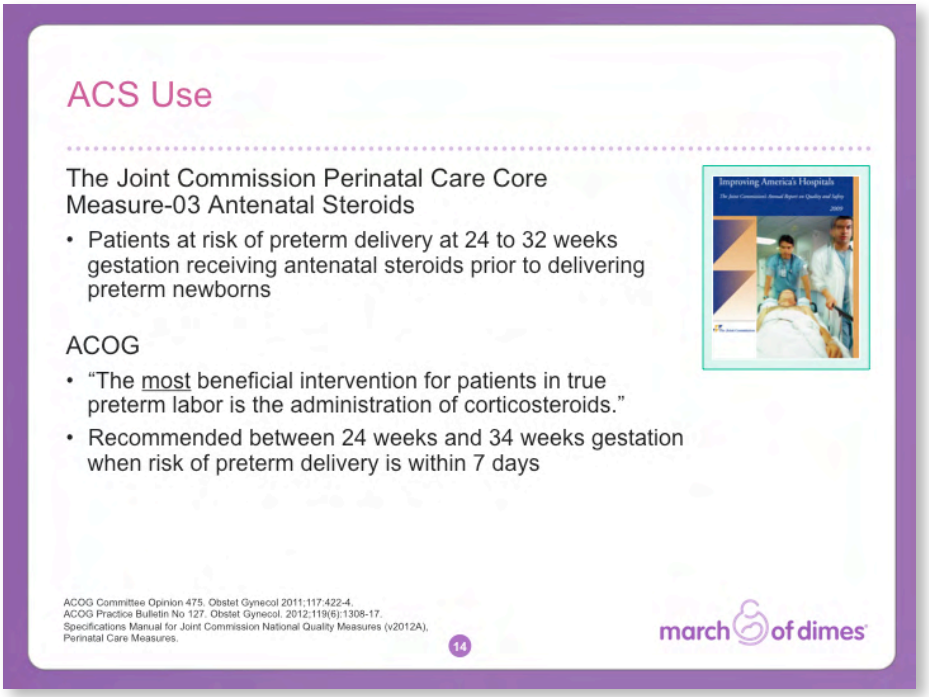
Interventions that prepare at-risk women for preterm delivery can improve outcomes:

- Per ACOG, antenatal corticosteroids are "the most beneficial intervention for patients in true preterm labor", significantly reducing mortality and morbidities for infants born prematurely, particularly those born prior to 32 weeks gestation. Antenatal steroids are recommended between 24 weeks and 34 weeks gestation when there is risk of preterm delivery within 7 days.
- Short-term tocolytic drugs may prolong gestation long enough to administer corticosteroids, assemble the neonatal team, or allow transport to a facility with a neonatal intensive care unit.
- Magnesium sulfate has been shown to be effective in reducing the severity and risk of cerebral palsy if administered when birth is anticipated before 32 weeks gestation (ACOG Practice Bulletin 127).



KEY POINT: ACS use in appropriate patients significantly reduces prematurity-related mortality as well as every known major morbidity.

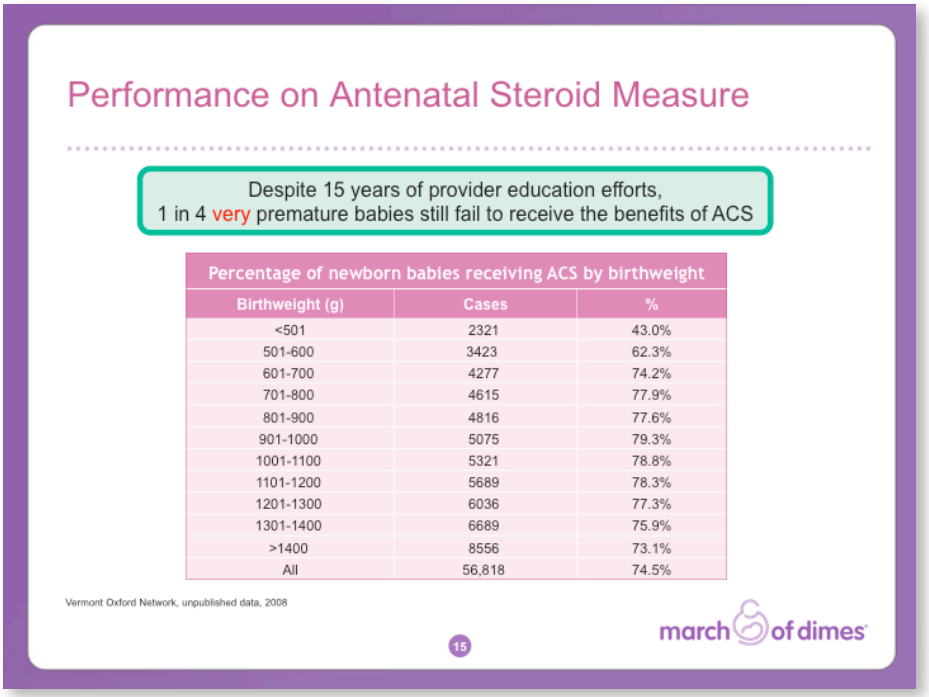
- The benefit of identifying and treating women at high risk of preterm delivery is clear, as demonstrated by this metaanalysis of 21 studies (3,885 women and 4,269 infants; published by the Cochrane Database). The data in this table illustrate significantly improved outcomes for babies whose mothers received ACS prior to delivery.
- Based on well-established value, ACOG recommends antenatal corticosteriods between 24 weeks and 34 weeks gestation when there is risk of preterm delivery within 7 days.
- Standardized assessment and management of preterm labor symptoms can improve identification of those women who are most likely to benefit from ACS treatment.



KEY POINT: National efforts are seeking to improve the appropriate utilization of ACS following nearly 20 years of provider education efforts since the NIH Consensus Statement, "Effect of corticosteroids for fetal maturation on perinatal outcomes" was published in 1994.

Recent national actions include:

- The Joint Commission added Antenatal Steroids as a perinatal care core measure that will be reported by hospitals as an indicator of quality of care.
- ACOG Committee Opinion 475 in 2011 made clear recommendations related to antenatal corticosteroids:
  - A single course of corticosteroids is recommended for pregnant women between 24 weeks of gestation and 34 weeks of gestation who are at risk of preterm delivery within 7 days.
  - A single course of repeat antenatal corticosteroids should be considered in women whose prior course of antenatal corticosteroids was administered at least 7 days previously and who remain at risk of preterm delivery before 34 weeks of gestation.
- While the effects of ACS on the mother may be minimal, women with diabetes may require close glycemic management.



Performance on Antenatal Steroid Measure

Despite 15 years of provider education efforts,
1 in 4 very premature babies still fail to receive the benefits of ACS

Percentage of newborn babies receiving ACS by birthweight

Birthweight (g)	Cases	%
<501	2321	43.0%
501-600	3423	62.3%
601-700	4277	74.2%
701-800	4615	77.9%
801-900	4816	77.6%
901-1000	5075	79.3%
1001-1100	5321	78.8%
1101-1200	5689	78.3%
1201-1300	6036	77.3%
1301-1400	6689	75.9%
>1400	8556	73.1%
All	56,818	74.5%

Vermont Oxford Network, unpublished data, 2008

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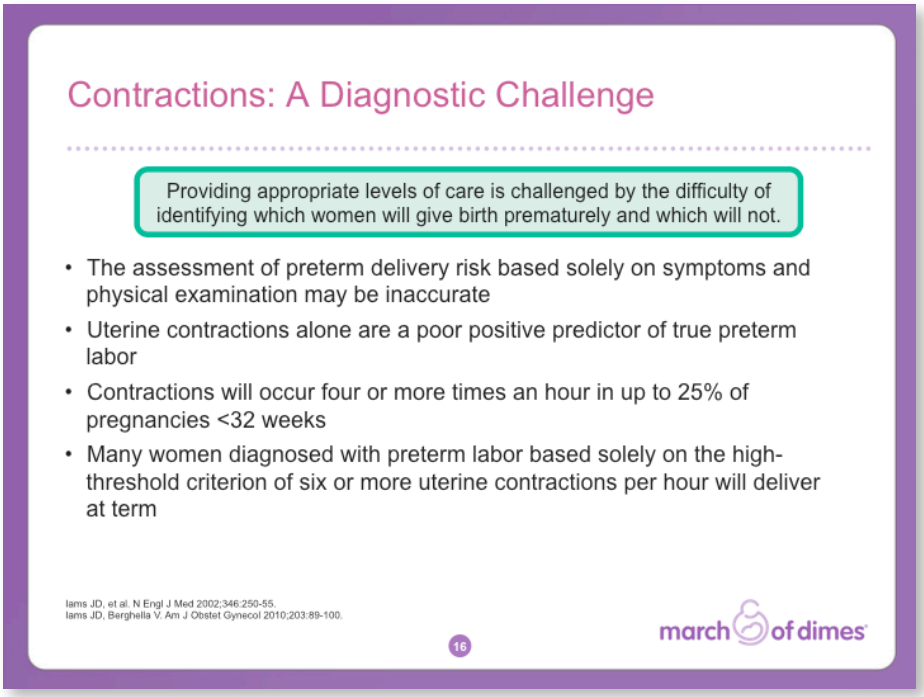
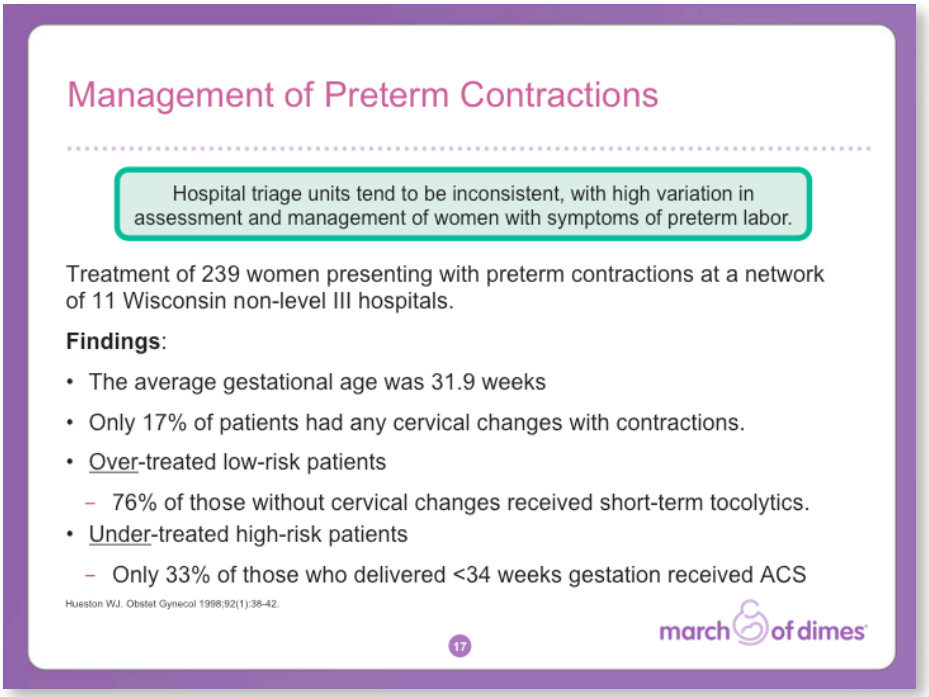
march of dimes

- Despite these long-term efforts to improve care delivery, as noted on the previous slide, antenatal corticosteroids remain underutilized even in the most at-risk populations.
- As illustrated by this data reported by Vermont Oxford Network of high-level NICU facilities, only 74.5% of very premature infants received antenatal steroids. This rate of non-utilization is consistent with data reported from multiple other care collaboratives across the USA.
- **KEY POINT:** Currently, 1 in 4 very premature babies fail to receive the benefits of antenatal steroids. Therefore, there are significant opportunities improve utilization of antenatal steroids and thus improve newborn outcomes.



KEY POINT: There are clear challenges to providing appropriate interventions, such as ACS, due to the difficulty identifying women with preterm labor who will ultimately give birth prematurely.

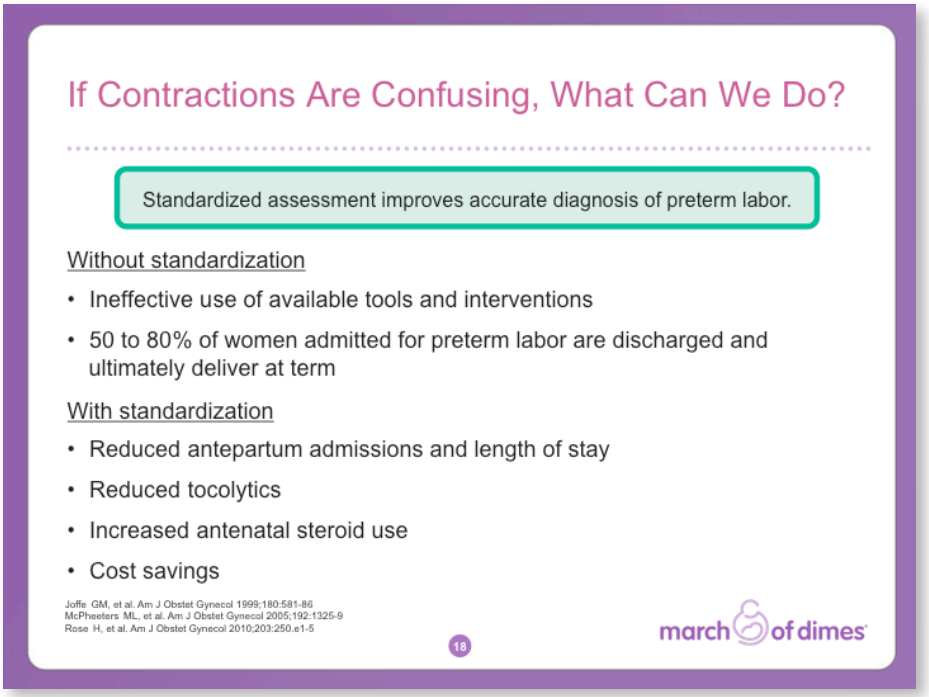
- Uterine contractions pose a challenge. As noted in ACOG Practice Bulletin No 127, "the assessment of preterm delivery risk based on symptoms and physical examination alone is inaccurate."
  - Changes in the uterus and cervix occur as pregnancy progresses to term.
  - In preterm labor, cervical ripening and decidual activation occur earlier than uterine contractions and may be difficult to detect.
  - Thus, per Iams (2003) it is not uncommon that diagnosis of preterm labor is established based on the high-threshold criteria of severe uterine contractions of six or more per hour, cervical dilation ≥3 cm, and 80 percent effacement accompanied either by vaginal bleeding or rupture of fetal membranes.
  - At this point, delivery may be inevitable, yielding insufficient time to prepare the fetus for premature birth.
- As a low-threshold criterion, uterine contractions alone are a poor positive predictor of true preterm labor. They will occur four or more times an hour in up to 25 percent of pregnancies >32 weeks.
- Many women diagnosed with preterm labor based solely on the high-threshold criterion of six or more uterine contractions per hour will deliver at term.



- This slide demonstrates some of the limitations providers face when using preterm contractions and variable assessment as a basis for predicting which women are at risk for preterm labor.
- It is reported that hospital triage units are inconsistent, with high variation in assessment and management of women with symptoms of preterm labor.
- In this study by Hueston, care provided by obstetricians, family practice physicians and residents at community hospitals in a large network was reviewed retrospectively.
- Findings include:

1. Over-treatment: High utilization of tocolytics in women at low risk.
   - Many women (76%) who did not have cervical change were nonetheless admitted to receive tocolytics. The majority delivered at term.
2. Under-treatment: Low utilization of antenatal steroids in women at high risk.
   - A very low percentage (only 33%) of women who delivered preterm received antenatal corticosteroids, meaning 67% of premature infants did not benefit from steroids in this study.

KEY POINT: The failure to consistently utilize antenatal corticosteroids in patients at risk for preterm birth represents a significant missed opportunity to improve neonatal outcomes.



KEY POINT: Given the 'real life' challenges of triage assessment, as noted in the previous slide, *PLAT* seeks to assist providers and hospitals in providing standardized assessment of women at risk for preterm labor, which allows for timely decision-making and interventions.

- Pregnancies identified as increased risk for preterm birth can receive higher levels of care such as antenatal corticosteroids, tocolytics, and/or admission/maternal transport.
- Pregnancies identified as decreased risk for preterm birth (including the majority of women with preterm labor symptoms) can receive more limited interventions that are risk-appropriate, such as increased surveillance as an outpatient.
- Standardized assessment is crucial, as wide variations in the assessment of preterm labor symptoms result in disparities in health outcomes.

Additional References:

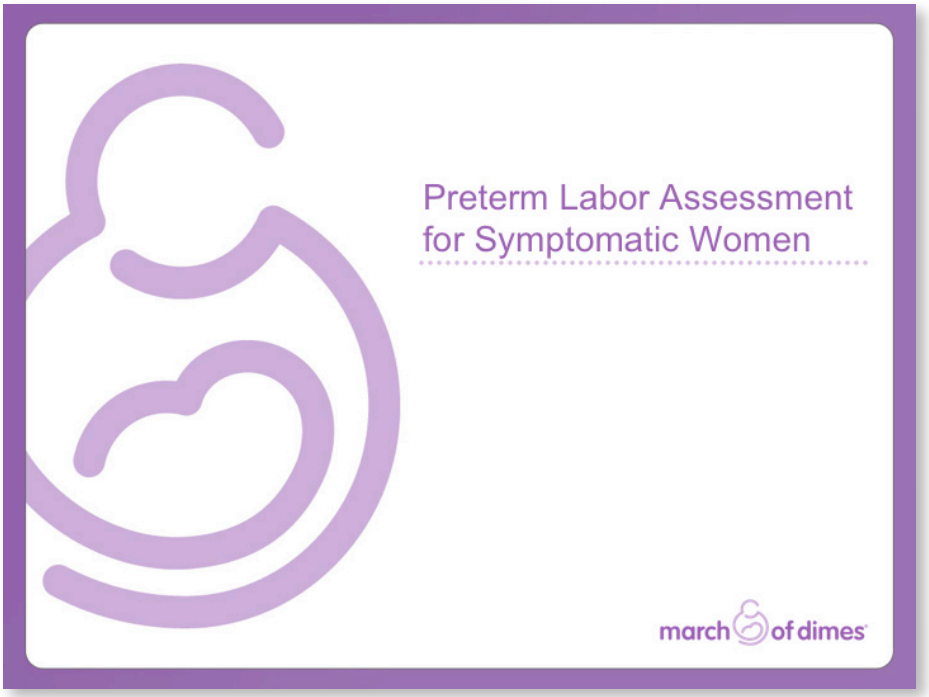
1. Joffe et al. *Am J Obstet Gynecol.* 1999;180:581-86

Standardization resulted in: an 11% decrease in antepartum admissions; 20% decrease in length of stay; 15% reduction in tocolytic prescriptions; 1.2% increase in antenatal steroid use. One hospital experienced a total L&D cost savings of $416,120 a year instituting a standardized triage assessment less the cost of fFN implementation and testing.

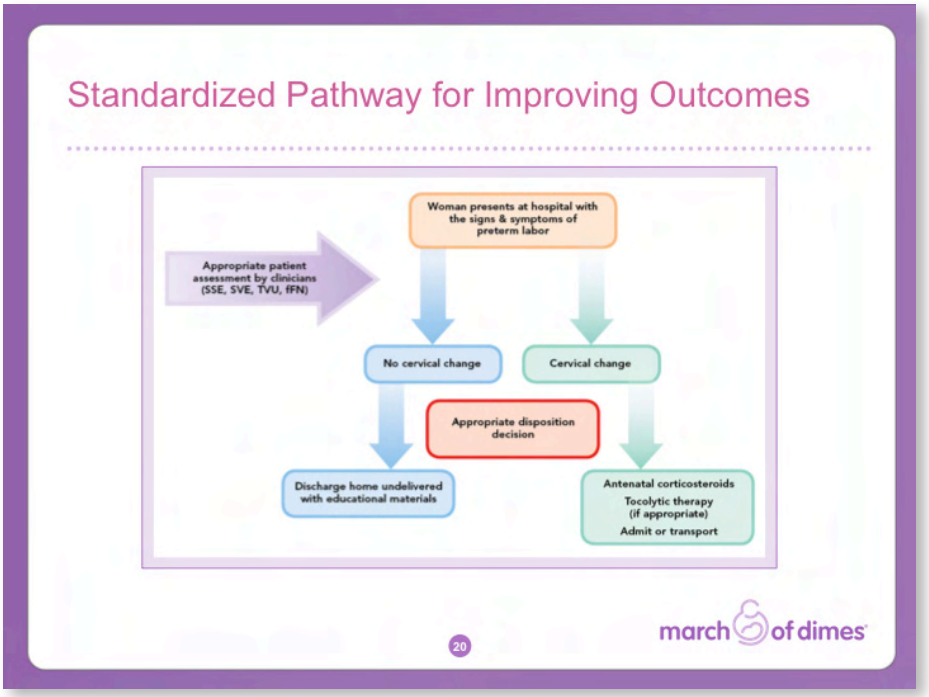
2. Rose et al. *Am J Obstet Gynecol.* 2010;203:250.e1-5

Standardizing triage demonstrated an algorithm NPV of 99.2% (96% to 100%) with a mean gestational age at delivery after assessment of 38 weeks, 3 days and an average interval between assessment and delivery of 57.4 days, resulting in a 56% reduction in admission rates. On a national scale, a reduction by 56% in antepartum admissions for preterm labor would result in an estimated cost savings of $560 million annually (based on the estimated cost of a 48-hour hospitalization for patients ultimately discharged undelivered).

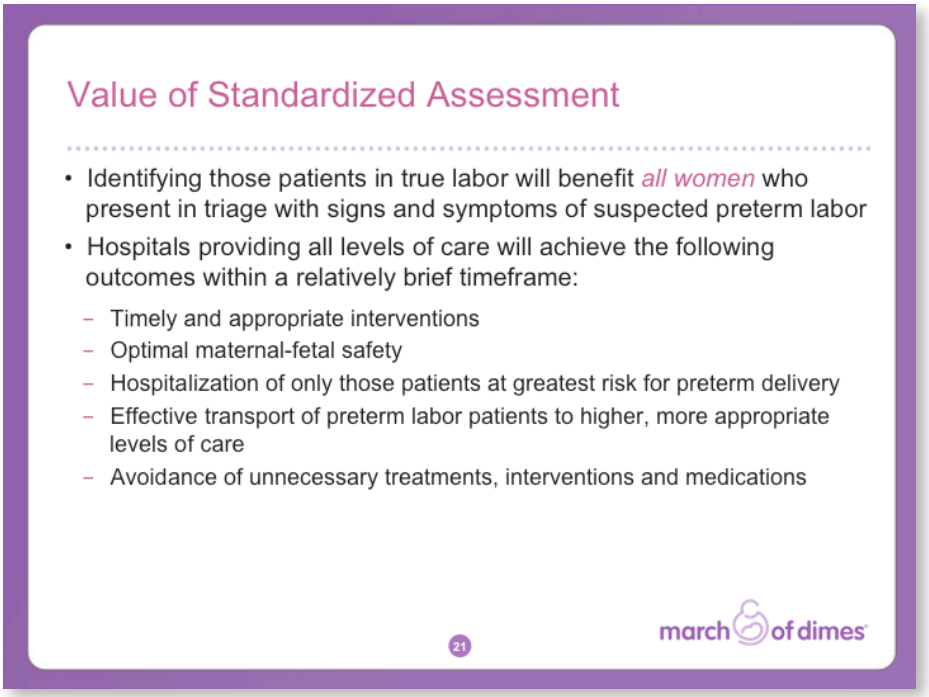
Appendix F – Implementation of the Preterm Labor Assessment Toolkit: A PowerPoint® Presentation



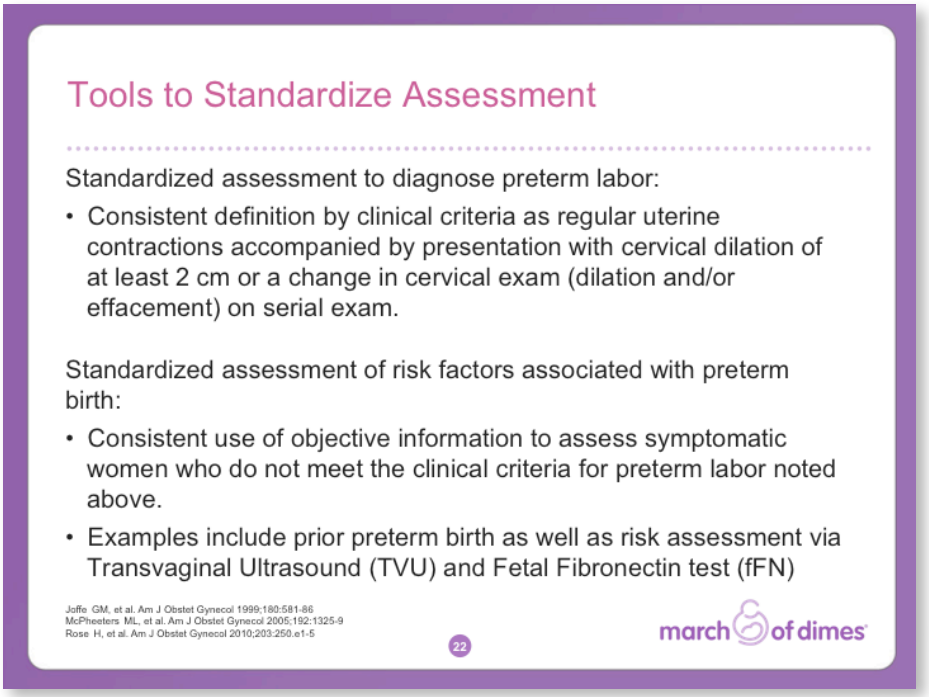
- Given the impact of preterm labor on maternal child health, as well as the challenges with diagnosis, *PLAT* seeks to assist providers and hospitals in standardizing assessment of women at risk for preterm labor, as this allows for timely decision-making and interventions.
- Additionally, *PLAT* seeks to assist hospitals in reducing unnecessary interventions and treatments when preterm birth is unlikely.



- March of Dimes Preterm Labor Assessment Toolkit (*PLAT*) aims to ensure that cervical changes are uniformly assessed in women presenting with signs and symptoms of preterm labor. Uniform practices lead to appropriate disposition decisions.
- The algorithm, protocol and tools outlined in *PLAT* drive change in assessment behaviors (purple arrow), resulting in appropriate disposition decisions (red box). These, in turn, lead to improved outcomes.

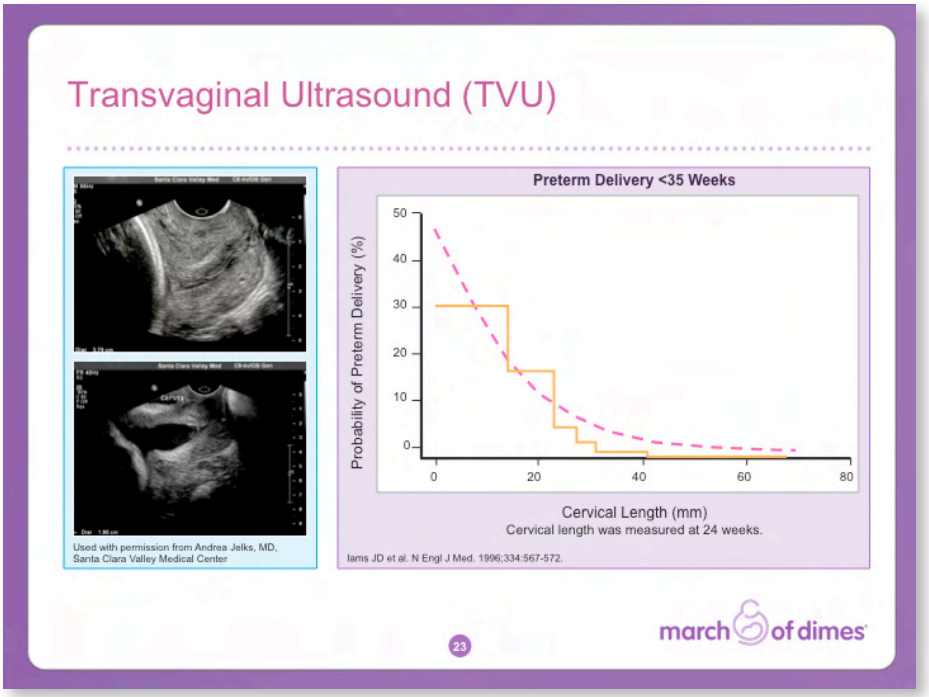


- During the past decade, implementation of standardized protocols has significantly reduced adverse perinatal outcomes.
- Elimination of elective delivery before 39 weeks is the endpoint that has received greatest attention in hospital-based, regional and statewide systems-change projects. Policies and procedures that have been developed and lessons learned in the course of implementing these projects suggest possible steps for reducing the incidence of preterm birth.
- Prior to publication of *PLAT* in 2005, the potential of a programmatic or quality improvement approach for reducing the volume of unnecessary treatment and/or admissions for preterm labor had not been explored. While much had been written about evaluating an individual patient's risk of preterm labor, a systems approach was absent.
- The current *PLAT* revision draws upon March of Dimes experience with implementation of the original *PLAT* in 40 California hospitals with varying levels of care, as well as evolving best practices as documented in the research literature. The goals of *PLAT* are presented in this slide.
- Additionally, *PLAT* also can be used to incorporate The Joint Commission's Third Perinatal Care Core Measure, administration of antenatal corticosteroids to women at risk for preterm labor.



KEY POINT: *PLAT* assists providers and hospitals in providing standardized assessment of women with symptoms of preterm labor and assessment of possible risks for preterm birth, which allows for timely decision-making and interventions.

- *PLAT* facilitates provider decisions to admit, discharge or transport a patient to a higher level of care. This can occur promptly, within 2 to 4 hours, depending on patient status and local resources.
- First, women should have a standardized assessment to diagnose preterm labor using the clinical criteria described by ACOG.
- Second, for women who do not meet the clinical criteria for PTL noted above, standardized assessment for risk factors associated with preterm birth increases the opportunity for risk-appropriate interventions.
- This assessment for risk of preterm birth includes a thorough patient history including prior preterm birth, medical screening exam and electronic fetal monitoring. Risk assessment is facilitated by two objective evaluation tools: transvaginal ultrasound (TVU) and fetal fibronectin testing (fFN).



KEY POINT: Cervical length, measured by Transvaginal Ultrasound (TVU), is a biomarker for risk assessment.

- As a negative predictor of preterm delivery: TVU cervical length greater than 25 to 30 mm is widely considered to be low likelihood of preterm birth.
- As a positive predictor of preterm delivery: TVU with "short" cervical length ≤20 mm is widely considered to be high risk for preterm birth.

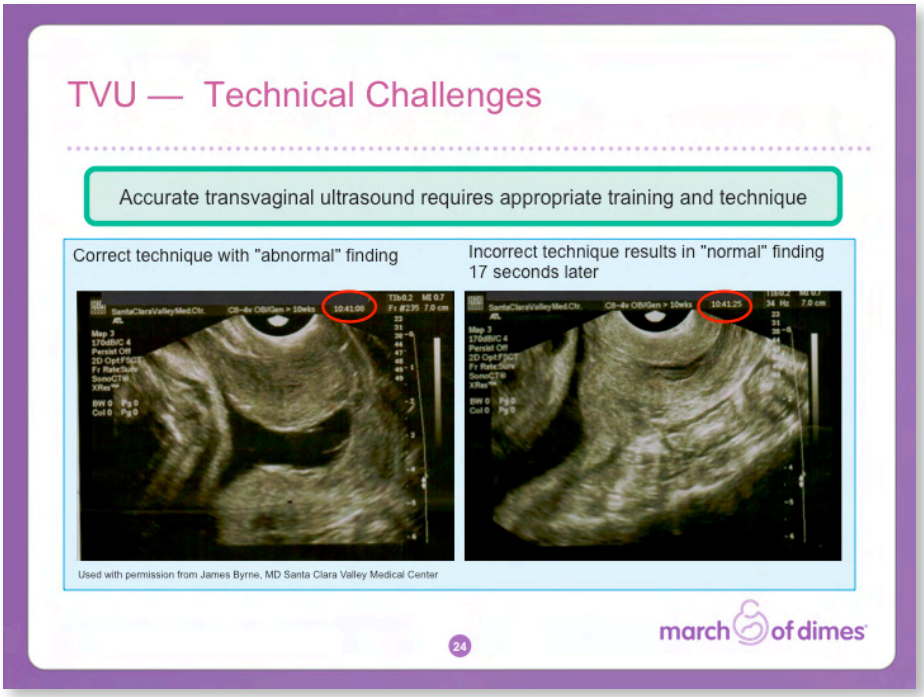
IMAGES: The top image on the left illustrates a normal cervix measures by TVU; the distance from internal os to external os is 37 mm. The bottom image illustrates a short cervix of 19 mm with evidence of funneling.

GRAPH: (Iams JD, Goldenberg RL, Meis PJ, et al, and the NICHD MFMU Network. The length of the cervix and the risk of spontaneous premature delivery. N Engl J Med. 1996;334:567-572.)

- This graph is from the landmark work by Iams and colleagues, illustrating the relationship of cervical length to risk of preterm birth in asymptomatic patients. Iams et al conducted a multicenter study to measure the length of the cervix and examine the relation of this measurement to the risk of spontaneous preterm birth. They examined 2915 women at 24 weeks gestation and then again at approximately 28 weeks (n=2531); the women were outpatients without signs of preterm labor.
- The graph shows the estimated probability of spontaneous preterm birth before 35 weeks gestation from the logistic-regression analysis (dashed line) and the observed frequency of spontaneous preterm birth (solid line) according to cervical length measured at 24 weeks.
- The probability of spontaneous preterm birth increased with decreasing cervical length.

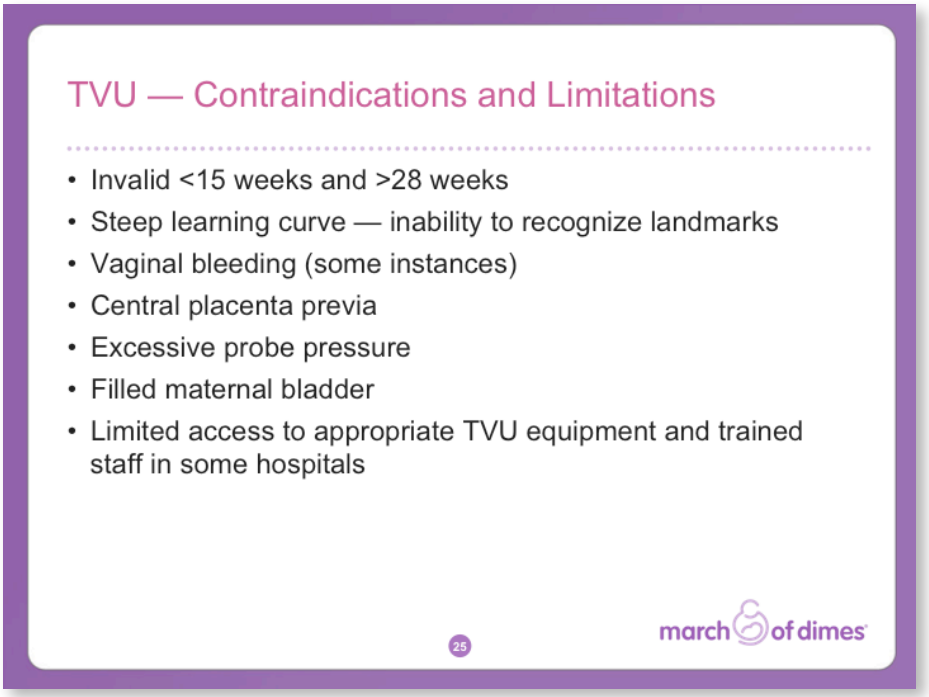
Additional References:

1. ACOG Practice Bulletin No 130. *Obstet Gynecol.* 2012; 120(4): 964-73.
2. Hibbard JU et al. *J Perinatol.* 2000;20:161-165.
3. In women with contractions, a cervical length less than 15 mm was associated with a 37%-47% chance of delivering within 7 days. (Tsoi E et al. *Ultrasound Obstet Gynecol.* 2003:21(6):552-555; Fuchs I et al. *Ultrasound Obstet Gynecol.* 2004:24(5):554-557.)
4. With a cervical length greater than 30 mm preterm birth is highly unlikely. (Schmitz T et al. *Am J Obstet Gynecol.* 2006;194:138-143.)

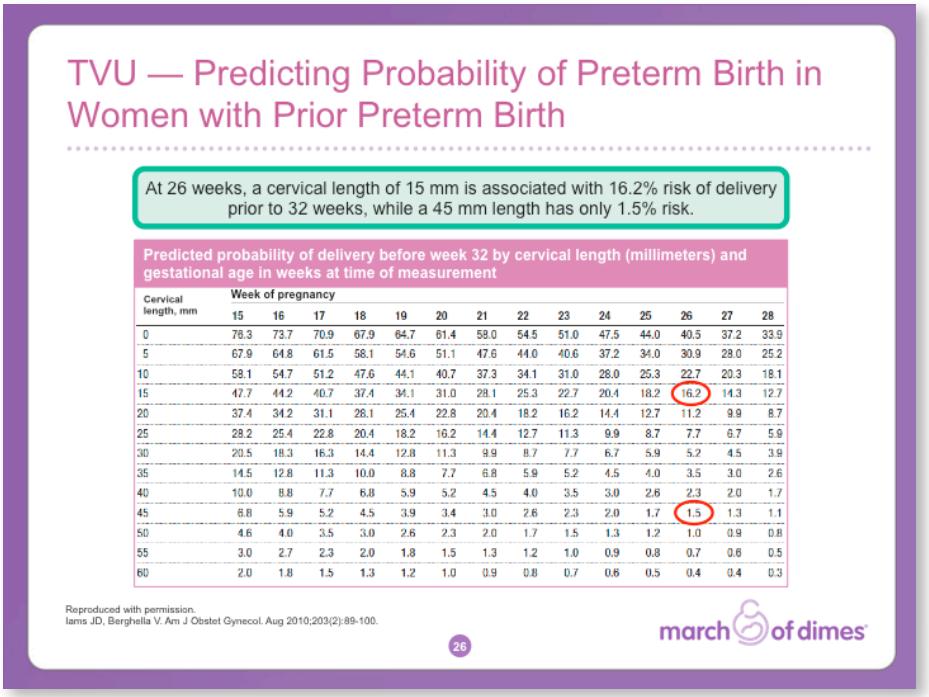


KEY POINT: While transvaginal cervical length is a well-validated screen to predict preterm birth, providers must also be aware of the need for appropriate training and technique to correctly interpret TVU. Many incorrectly assume that this is a relatively "simple" transvaginal ultrasound.

- Failure to perform the TVU properly can result in incorrect assessment. For example, excess pressure on the probe on a dilated cervix can lead to pressing the cervix closed.
- Take a closer look at the scan images in this slide:
  - Both images were obtained during one TVU assessment of a woman who was at 25 weeks gestation.
  - The image on the left that appears to be an "abnormal" scan is accurate, including the dilation of internal os, significant funneling, and short cervix.
  - The image on the right that appears to be "normal" scan is inaccurate. While the image conveys a closed cervix and normal length, this image was in fact obtained only 17 seconds after the "abnormal" image. This resulted from excess pressure with the ultrasound probe against the cervix.
  - In this case, the excess pressure was intentionally applied to illustrate that TVU technical skills are crucial.



- TVU is not a valid test for patients less than 15 weeks gestational age as the lower uterine segment may not be fully developed, and the internal os cannot be well visualized. After 28 weeks, changes in cervical length may be physiologic and better determined by direct examination of the cervix using SVE.
- To properly image the cervix and measure accurately, the ultrasound operator must be familiar with certain landmarks and be able to observe them.
- Vaginal bleeding, if present, needs prior assessment to determine the probable cause prior to introducing the vaginal transducer into the vaginal vault.
- Central placenta previa, if actively bleeding, may contraindicate placement of the vaginal transducer into the vaginal vault. Undue trauma to the cervix may provoke bleeding.
- Excessive probe pressure and over-filled maternal bladder can interfere with the interpretation of cervical length as shown on the previous slide.
- Not all OB practices or hospitals have the technical expertise available or access to TVU 24/7, which can limit diagnosis and treatment options.



TVU — Predicting Probability of Preterm Birth in Women with Prior Preterm Birth

At 26 weeks, a cervical length of 15 mm is associated with 16.2% risk of delivery prior to 32 weeks, while a 45 mm length has only 1.5% risk.

Predicted probability of delivery before week 32 by cervical length (millimeters) and gestational age in weeks at time of measurement

Cervical length, mm	Week of pregnancy													
	15	16	17	18	19	20	21	22	23	24	25	26	27	28
0	76.3	73.7	70.9	67.9	64.7	61.4	58.0	54.5	51.0	47.5	44.0	40.5	37.2	33.9
5	67.9	64.8	61.5	58.1	54.6	51.1	47.6	44.0	40.6	37.2	34.0	30.9	28.0	25.2
10	58.1	54.7	51.2	47.6	44.1	40.7	37.3	34.1	31.0	28.0	25.3	22.7	20.3	18.1
15	47.7	44.2	40.7	37.4	34.1	31.0	28.1	25.3	22.7	20.4	18.2	16.2	14.3	12.7
20	37.4	34.2	31.1	28.1	25.4	22.8	20.4	18.2	16.2	14.4	12.7	11.2	9.9	8.7
25	28.2	25.4	22.8	20.4	18.2	16.2	14.4	12.7	11.3	9.9	8.7	7.7	6.7	5.9
30	20.5	18.3	16.3	14.4	12.8	11.3	9.9	8.7	7.7	6.7	5.9	5.2	4.5	3.9
35	14.5	12.8	11.3	10.0	8.8	7.7	6.8	5.9	5.2	4.5	4.0	3.5	3.0	2.6
40	10.0	8.8	7.7	6.8	5.9	5.2	4.5	4.0	3.5	3.0	2.6	2.3	2.0	1.7
45	6.8	5.9	5.2	4.5	3.9	3.4	3.0	2.6	2.3	2.0	1.7	1.5	1.3	1.1
50	4.6	4.0	3.5	3.0	2.6	2.3	2.0	1.7	1.5	1.3	1.2	1.0	0.9	0.8
55	3.0	2.7	2.3	2.0	1.8	1.5	1.3	1.2	1.0	0.9	0.8	0.7	0.6	0.5
60	2.0	1.8	1.5	1.3	1.2	1.0	0.9	0.8	0.7	0.6	0.5	0.4	0.4	0.3

Reproduced with permission.
Iams JD, Berghella V. Am J Obstet Gynecol. Aug 2010;203(2):89-100.

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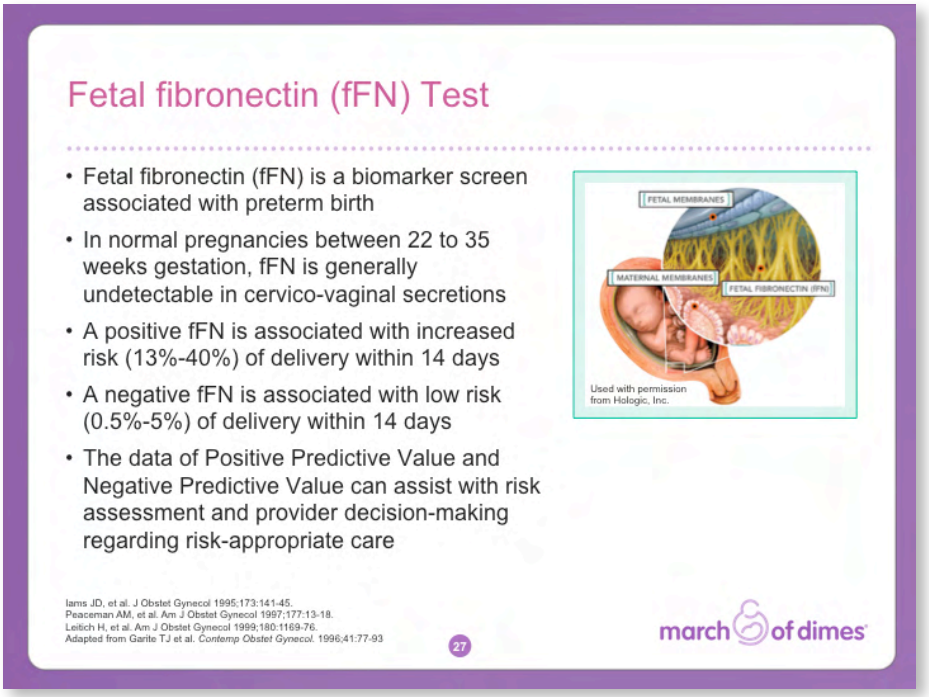
march of dimes

KEY POINT: TVU can provide valuable information to guide risk assessment for preterm birth.

- Data on this table indicates TVU measurement associated with probability of preterm birth at or before 32 weeks for women with prior preterm birth. Weeks 15 to 28 are listed across the X axis of the table; cervical length, in millimeters, is identified along the Y axis. (Iams JD, Berghella V. Am J Obstet Gynecol. Aug 2010;203[2]:89-100.)

For example, at 26 weeks gestation, the two numbers circled in red represent the preterm birth risk associated with two different TVU measurements:

- Increased risk: TVU cervical length of 15 mm is associated with a 16.2% risk of delivery prior to 32 weeks.
- Decreased risk: TVU cervical length of 45 mm is associated with only 1.5% risk of delivery prior to 32 weeks.
- This 16.2% level of increased risk of preterm birth can facilitate decision-making regarding interventions such as steroids. The use of similar risk levels to guide interventions is well accepted in Ob/Gyn.
- For example, there is recent discussion regarding the potential benefit of daily vaginal progesterone to reduce the rate of preterm birth. This is based on information that asymptomatic women with a short cervical length on TVU between 16 and 24 weeks gestation have an approximately 16% risk of preterm birth at less than 33 weeks gestation if not treated. (ACOG Practice Bulletin No 130. Obstet Gynecol 2012;120(4): 964-73.)



KEY POINT: Fetal fibronectin can provide valuable risk assessment information related to preterm birth.

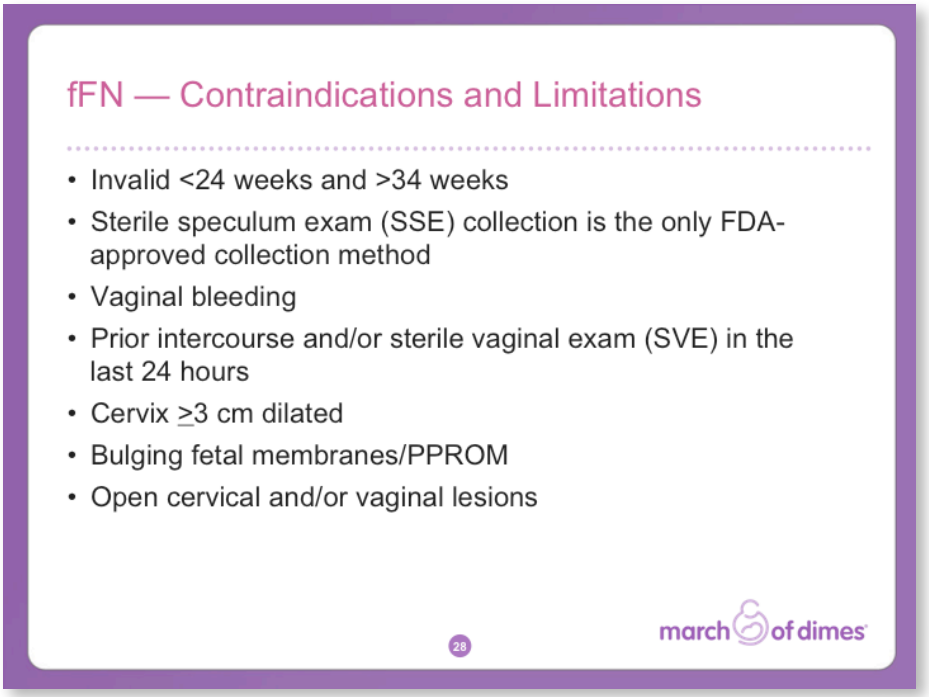
Fetal fibronectin (fFN) is a biomarker screen associated with risk of preterm labor ≤34 weeks of gestation.

- A protein related to cellular cohesiveness, fFN is concentrated at the membrane-decidua interface. During weeks 22 to 35 of a normal pregnancy, it is virtually undetectable in vaginal secretions below a threshold of 50 ng/ml.
- Disruption of the interface releases fFN, which can be detected via an assay that permits results to be reported back to the provider within 1 hour.

Risk assessment by fFN:

- Increased risk: A positive fFN has a positive predictive value (PPV) of 13 percent to 40 percent for delivery within 14 days, indicating increased risk of preterm birth. Note that this range of reported PPVs is an artifact of the diverse populations of women included in the various studies.
- Decreased risk: A negative fFN has a negative predictive value (NPV) of 95 percent to 99.5 percent, between 24 and 33 weeks, for delivery within 7 to 14 days, indicating decreased risk of preterm birth.

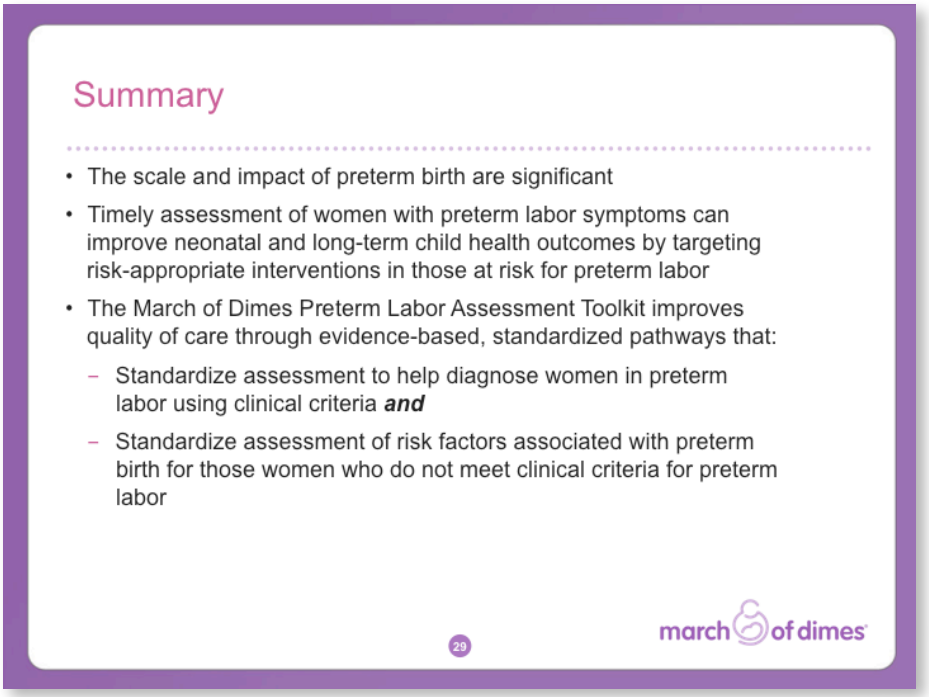
Similar to risk assessment using TVU measurement of the cervix, the fFN PPV and NPV can assist risk assessment and facilitate decision-making regarding risk-appropriate interventions that seek to optimize maternal-newborn care.



Limitations of Fetal fibronectin (fFN) Test

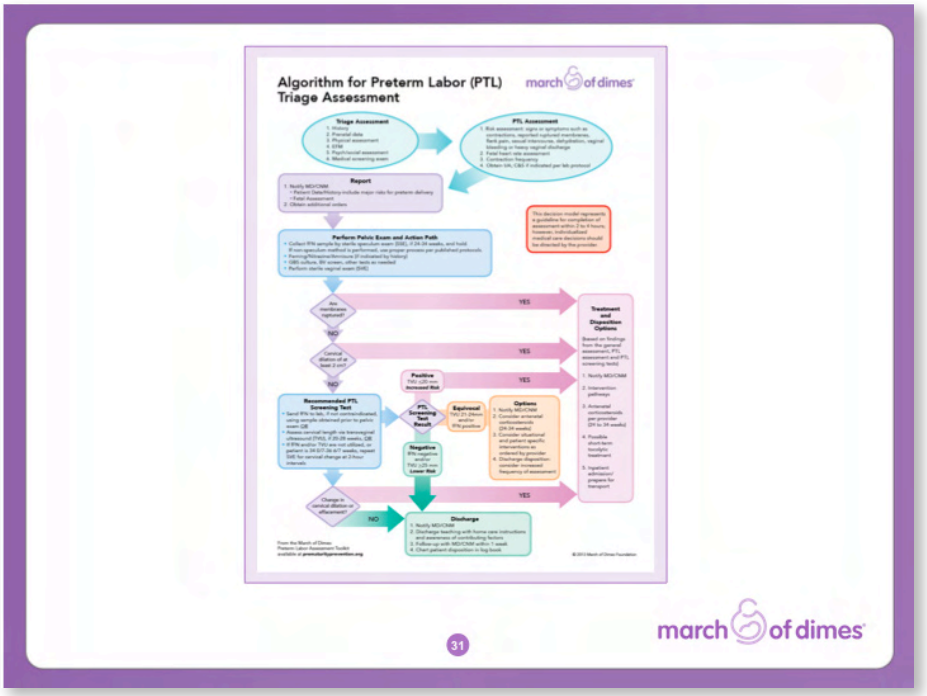
- Not a valid test for patients less than 24 weeks gestation or patients over 34 weeks gestation.
- Samples should not be collected in the setting of vaginal bleeding, prior intercourse and/or SVE within last 24 hours, cervix >3 cm dilated, bulging membranes, PPROM or open cervical/vaginal lesions.

Note that as of February 2013, fFN collection via speculum exam is the sole FDA-approved method of collection. Institutions with policies and procedures for non-speculum collection of fFN should follow published methods (e.g., Roman AS, Koklanaris N, Roshan D, et al. "Blind" vaginal fetal fibronectin as a predictor of spontaneous preterm birth. Obstet Gynecol 2005;105:285-289; Stafford IP, Garite TJ, Dildy GA, et al. A comparison of speculum and nonspeculum collection of cervicovaginal specimens for fetal fibronectin testing. *Am J Obstet Gynecol* 2008;199:131.e1-131.e4.)



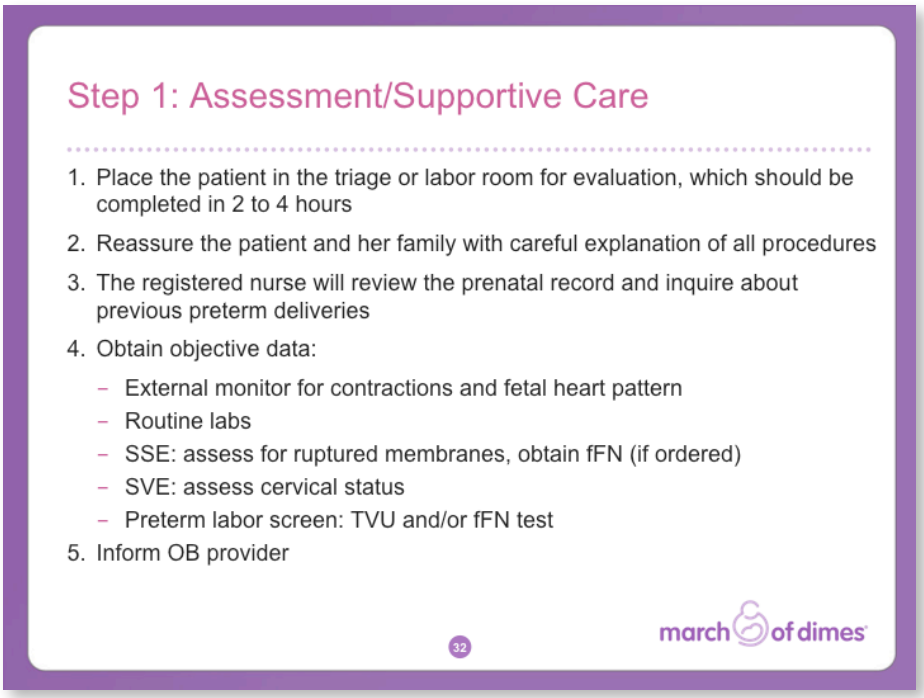
- This is a summary of main points prior to transition to detailed slides on the Toolkit and Algorithm.
- March of Dimes Preterm Labor Assessment Toolkit (*PLAT*) aims to assist providers and hospitals in providing standardized assessment of women with symptoms of preterm labor and possible risk for preterm birth, as this allows for timely decision-making and interventions.

Implementation and evaluation of *PLAT* in hospitals throughout California from 2005 to 2012 informed the revision of *PLAT* in 2013.

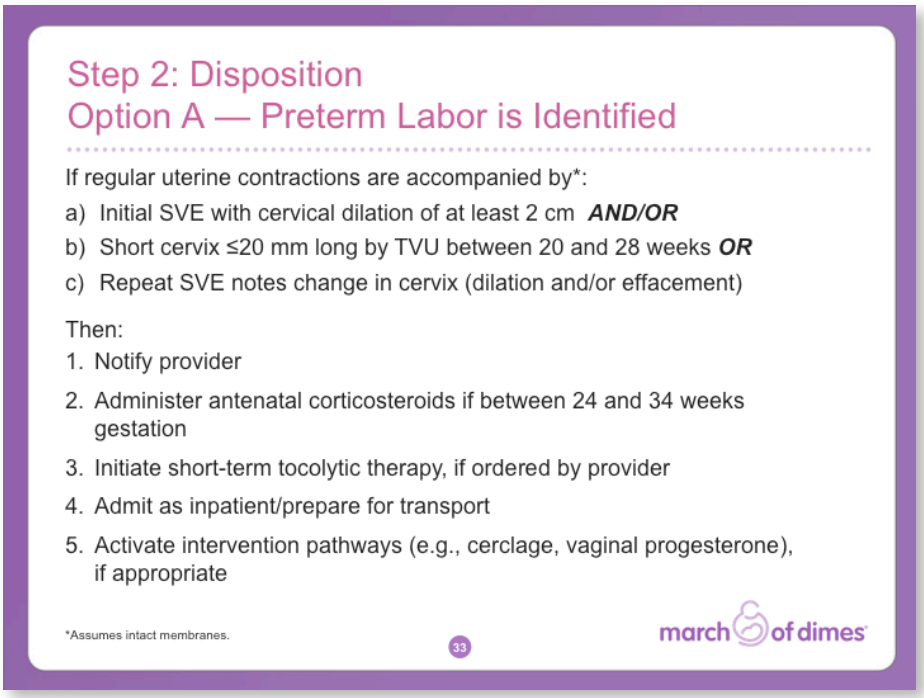


A prompt assessment of women with signs or symptoms of preterm labor is essential. Following a standardized approach will result in timely patient assessment, management decisions and appropriate interventions.

This is the assessment algorithm, the core of *PLAT*. Some hospitals have elected to enlarge the algorithm and post it in their triage rooms for easy reference. The next five slides will walk you through the algorithm and protocol.



Upon presentation in triage with signs and symptoms of preterm labor, the patient will be evaluated expediently, per hospital policy and procedures. Using *PLAT*, a disposition should be arrived at within 2 to 4 hours. Once objective data have been provided, the results should be acted upon with confidence.



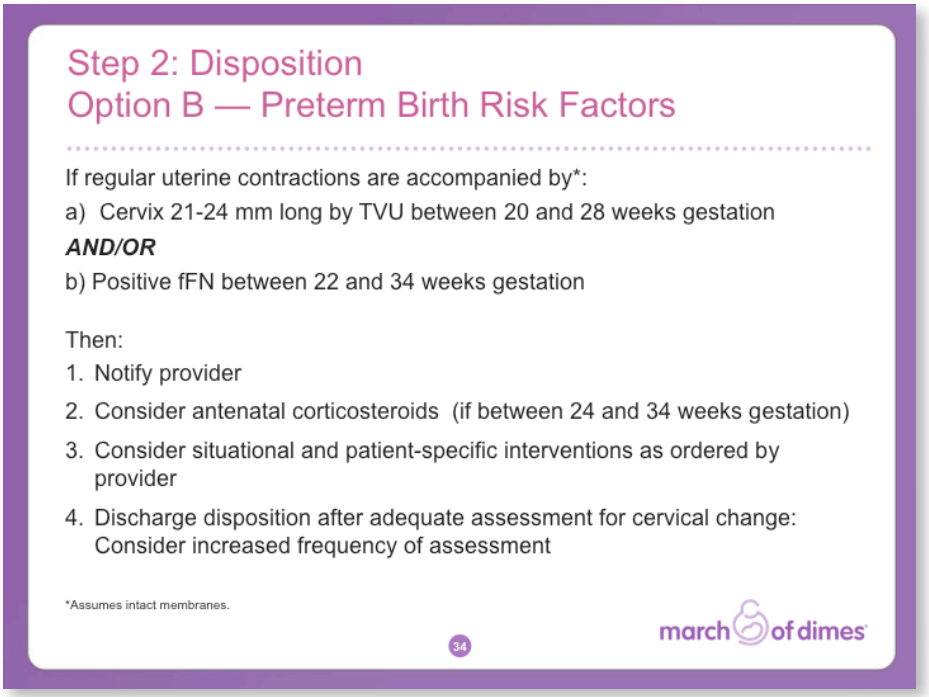
When preterm labor is identified by clinical criteria or a very short cervix, then a sequence of care pathways is promptly activated.

PLAT recommends activating the positive care pathway based on contractions accompanied by:

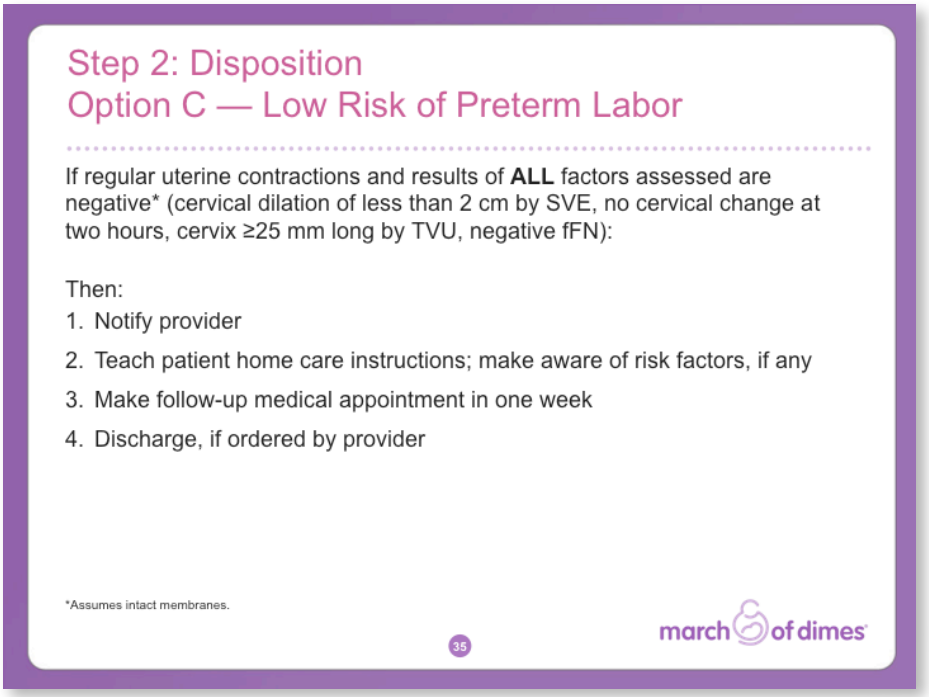
a) Initial exam on presentation with cervical dilation of at least 2 cm ***AND/OR***

b) Cervix ≤20 mm long by TVU between 20 and 28 weeks ***OR***

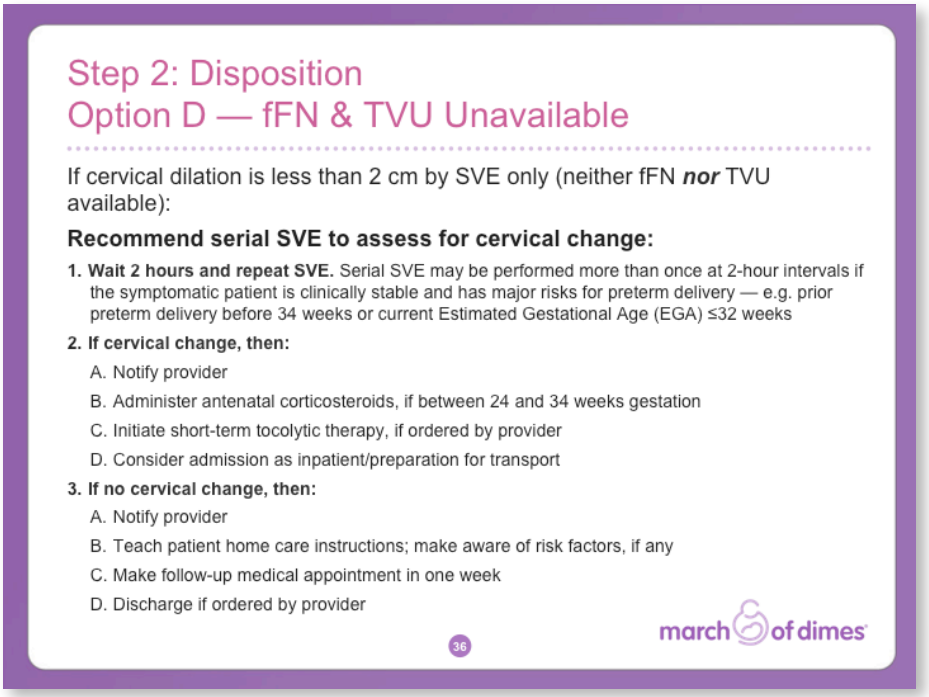
c) Repeat Sterile Vaginal Exam notes a change in cervical status (either dilation and/or effacement)



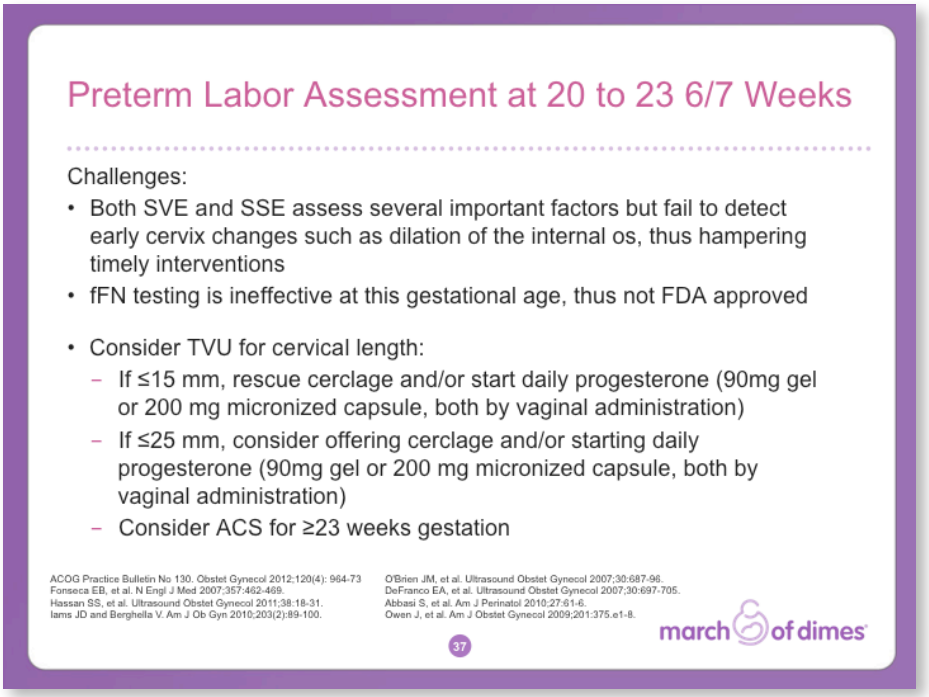
- For women who do not meet the clinical criteria for preterm labor noted in the prior slide, standardized assessment for risk factors associated with preterm birth allows consideration of risk-appropriate interventions.
- Examples of risk factors associated with preterm birth include prior preterm birth, short cervical length identified by transvaginal ultrasound and/or presence of fetal fibronectin.
- When risk factors for preterm birth are identified, a second sequence of care pathways and reassessment can be activated.
- This model is based on the favorable risk-to-benefit ratio of interventions such as antenatal corticosteroids and increased frequency of assessment for the development of preterm labor diagnostic criteria.
- To address a common question: When screening tests results conflict with each other (e.g., one test is positive while the second test is negative), then consider the patient as being at increased risk for preterm labor, even though a false positive is possible.



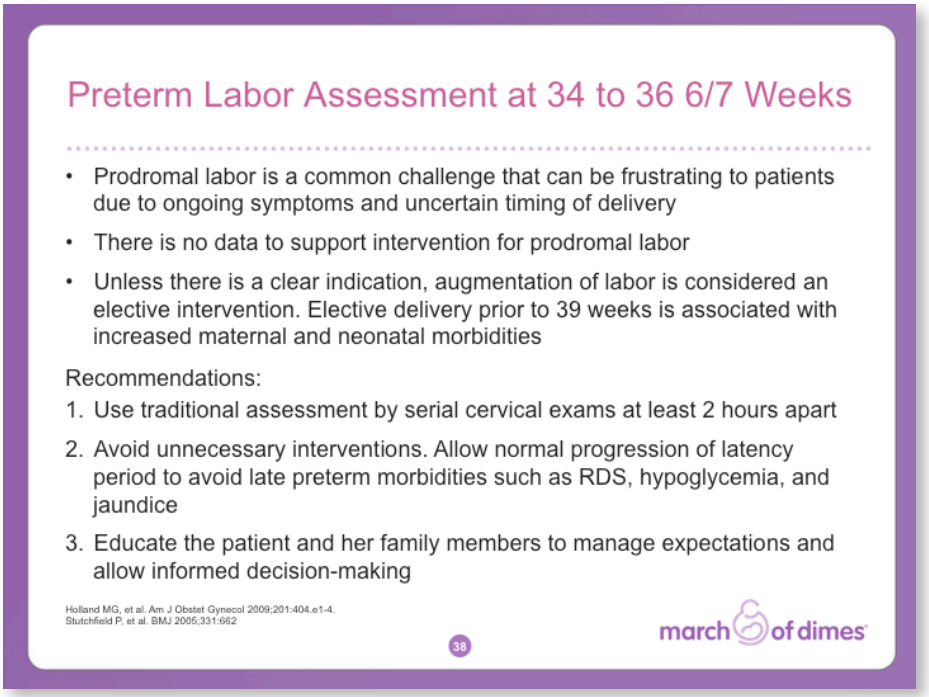
- When negative test results are obtained, a risk-appropriate care pathway is activated.
- A standardized approach will result in discharging patients with confidence and provides an opportunity for education.
  - Provide patient education materials and home care instructions (see toolkit for samples).
  - Follow-up of these patients within one week is important to assess and monitor preterm birth risk factors, as a negative screen has limitations.



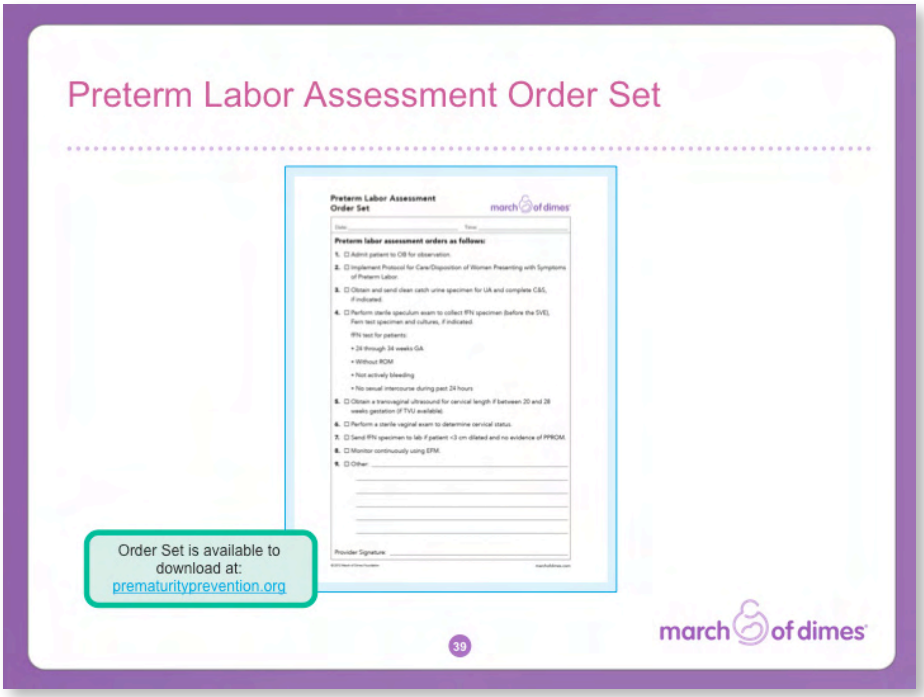
- If the evaluation of preterm labor symptoms is limited to monitoring uterine contractions and performing a physical exam, then it is important to repeat SVE in 2 hours to ascertain that no cervical change has occurred **prior to considering discharge.**
- A standardized approach will result in discharging patients with confidence and provides an opportunity for education.
  - Provide patient education and home care instructions (see toolkit for samples).
  - Follow-up of these patients within one week is equally important to assess and monitor preterm birth risk factors, as a negative exam has limitations.
- If there is perceived cervical change that meets the diagnostic criteria for preterm labor, timely interventions should be set in motion immediately. The decision to admit or transport should be made within 2 to 4 hours.



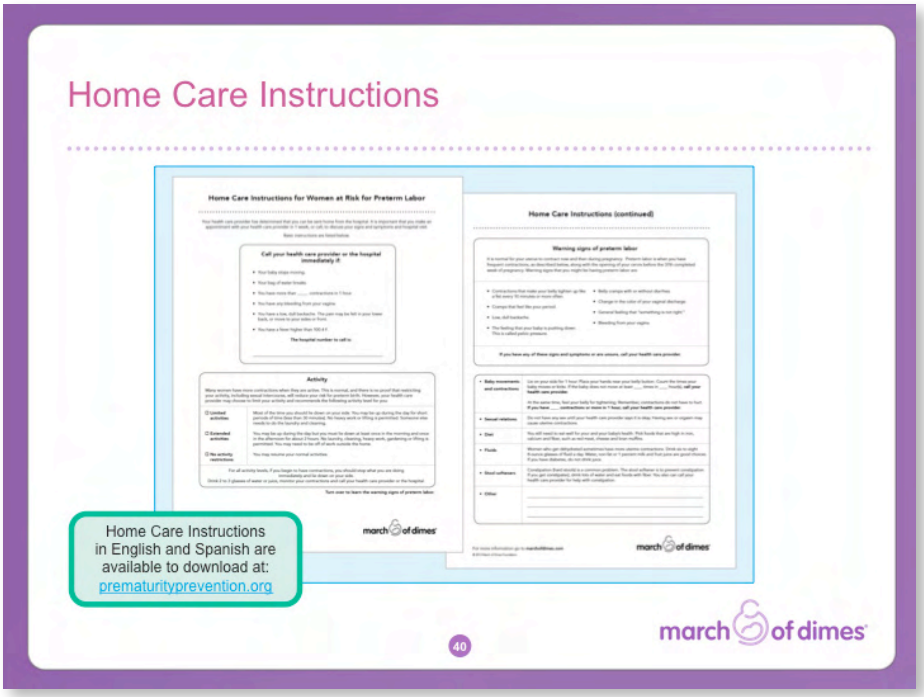
- Assessment of symptomatic preterm labor patients before the 24th week of pregnancy is challenging.
- If no complications are identified, serial SVEs may be conducted. However, cervical change may be a late symptom of preterm labor or cervical insufficiency. And fFN is not approved for this early gestational age.
- Therefore, before 24 gestational weeks, TVU is the best tool to assess whether a woman is at risk of preterm labor.
- If TVU findings are positive, several options are recommended, as noted on the slide.
- In addition, intramuscular progesterone 250 mg/week has been found to decrease the rate of repeat singleton preterm delivery. It has not been consistently shown to benefit multiple gestations.



- Assessment of symptomatic patients is challenging in terms of medical care, as well as managing patient expectations.
- Despite physical discomfort, prodromal contractions and early cervical change often do not progress into active labor.
- Ancillary tests such as fFN and TVU provide limited added value at these gestational ages.
- Assessment can begin with cervical examination. If no evidence of active labor, then serial SVE at least 2 hours apart may detect cervical change. If cervical change is detected but has not progressed to active labor, then obstetric intervention is not necessary.
- There is no data to support intervention for prodromal labor. Unless there is an obstetric indication, induction or augmentation of labor may be construed as elective interventions. Elective delivery prior to 39 weeks is associated with increased maternal and neonatal morbidities, as noted in many studies.
- It is recommended to allow the latency period to progress naturally, as there is a likelihood that cervical change may not progress beyond the initial assessment.
- Educating the patient and her family members helps to manage expectations and allow informed decision-making.
- Additional information is available in the toolkit.

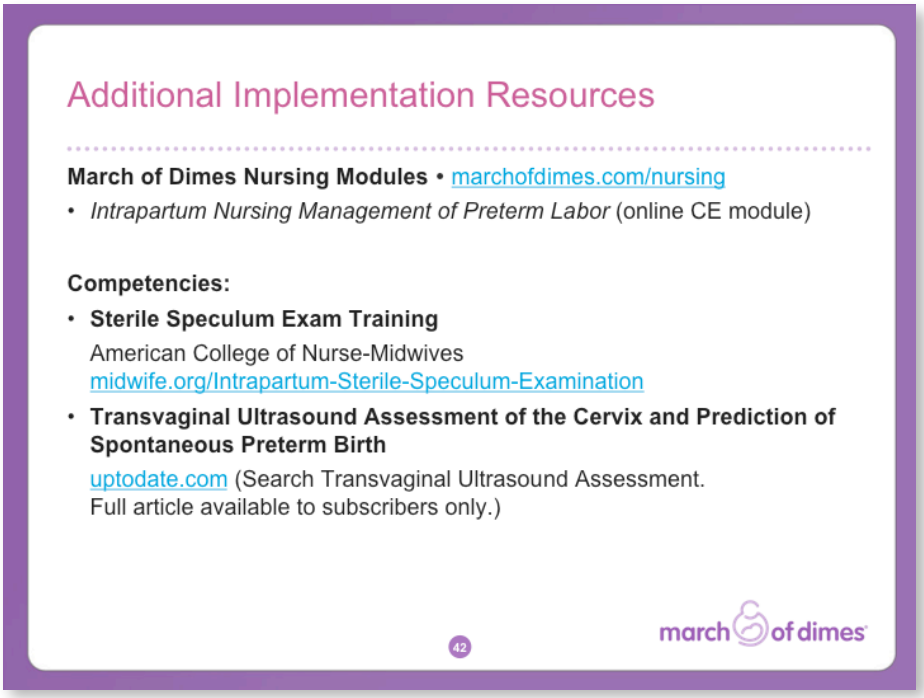


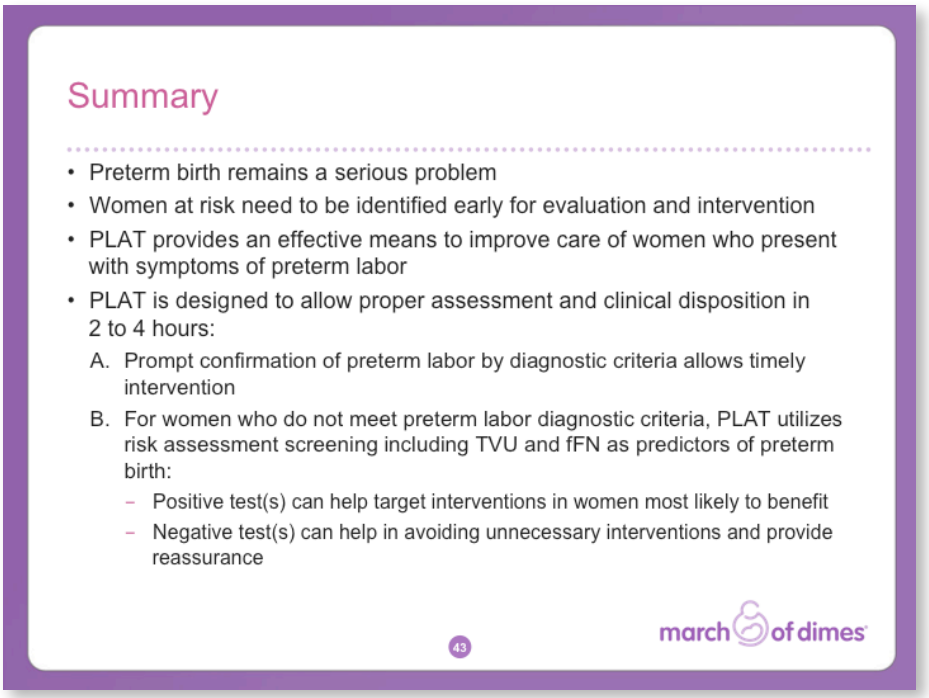
A sample Order Set is available in *PLAT* and may be downloaded from prematurityprevention.org for use at your facility.



- Sample home care instructions in English and Spanish for patients not in preterm labor are included in *PLAT* and can be downloaded from prematurityprevention.org.
- These home care instructions are not intended to discourage a patient from coming back to the hospital if signs and symptoms of preterm labor persist. Instead, they are designed to teach patients what to look for and when to call their health care provider.
- Instructions also direct patients to contact their regular health care provider to make an appointment in one week and discuss their signs and symptoms of preterm labor and their hospital assessment.

PLAT outlines March of Dimes patient education materials that are available for use by any facility. It is critical that each patient understand the importance of recognizing and reporting signs and symptoms of preterm labor. Early detection and diagnosis may provide just the time window needed for essential clinical interventions, such as antenatal corticosteroids, maternal transport to a higher level of care, or assembly of the high-risk team.





- To reiterate, given the impact of preterm labor on maternal child health, as well as the challenges with diagnosis, *PLAT* seeks to assist providers and hospitals in providing standardized assessment of women at risk for preterm labor as this allows for timely decision-making and interventions.
- One goal of *PLAT* is improve neonatal outcomes by identifying women at risk for preterm labor in order to allow opportunities for timely interventions and provide appropriate treatment when needed. A second goal is to reduce unnecessary intervention and treatment when preterm birth is unlikely.

External Reviewers

The 2013 PLAT Revision Steering Committee would like to thank the following reviewers for their insightful comments and support.

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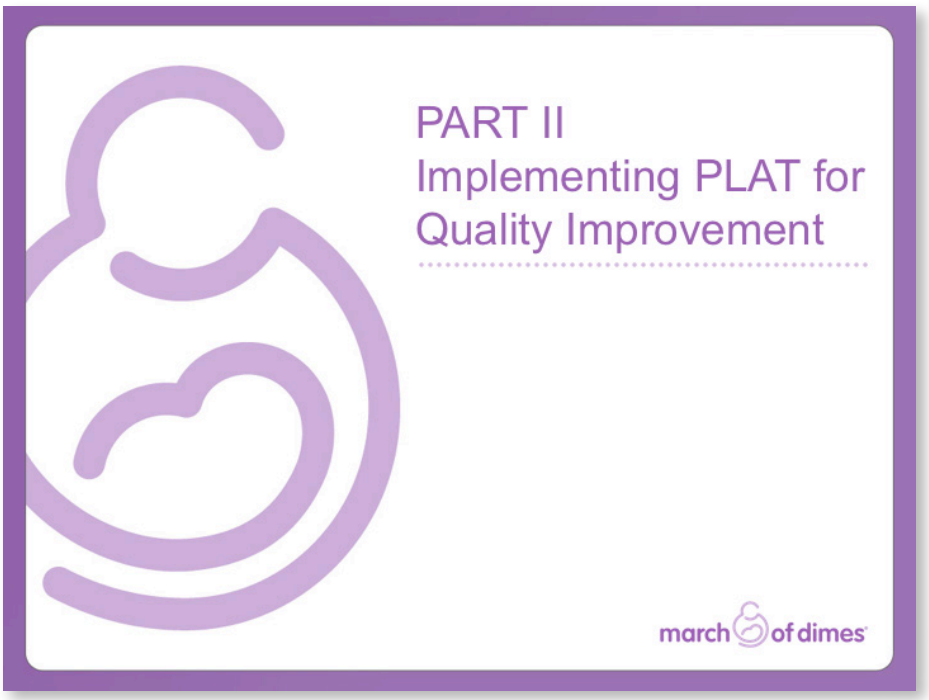
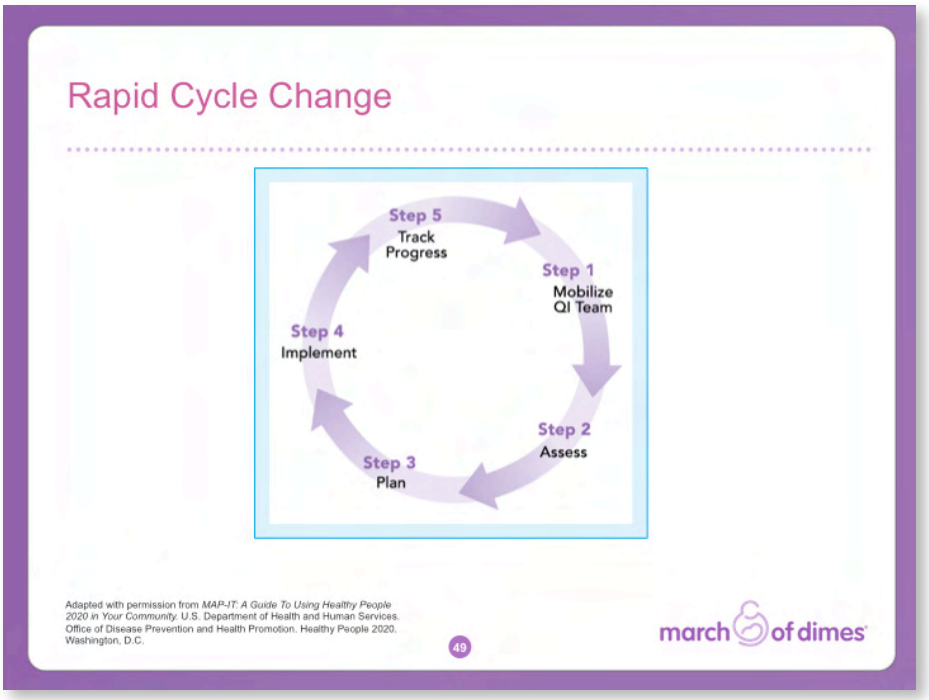
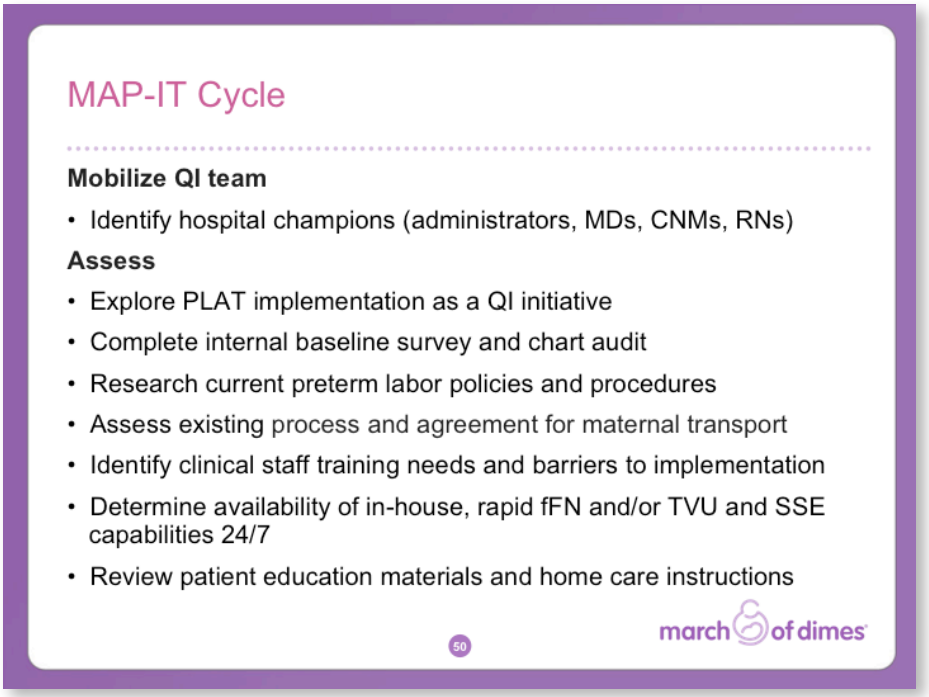


Presentation 2

The goal of Part 2 of the slide deck is to outline the steps that clinical staff can take to drive change and standardize assessment of patients presenting with signs and symptoms of preterm labor. This slide deck can be tailored to meet the needs, level and culture of the local hospital.



Hospitals may choose to address preterm labor assessment as a quality improvement project, as *PLAT* was developed to support systems change initiatives. Many quality improvement methodologies have been developed. One approach, the Mobilize, Assess, Plan, Implement, Track (MAP-IT) cycle, can be utilized to drive preterm labor assessment standardization. Steps in the MAP-IT cycle are listed chronologically in the toolkit. A hospital also may choose to use the PDSA approach or other quality improvement methodologies.



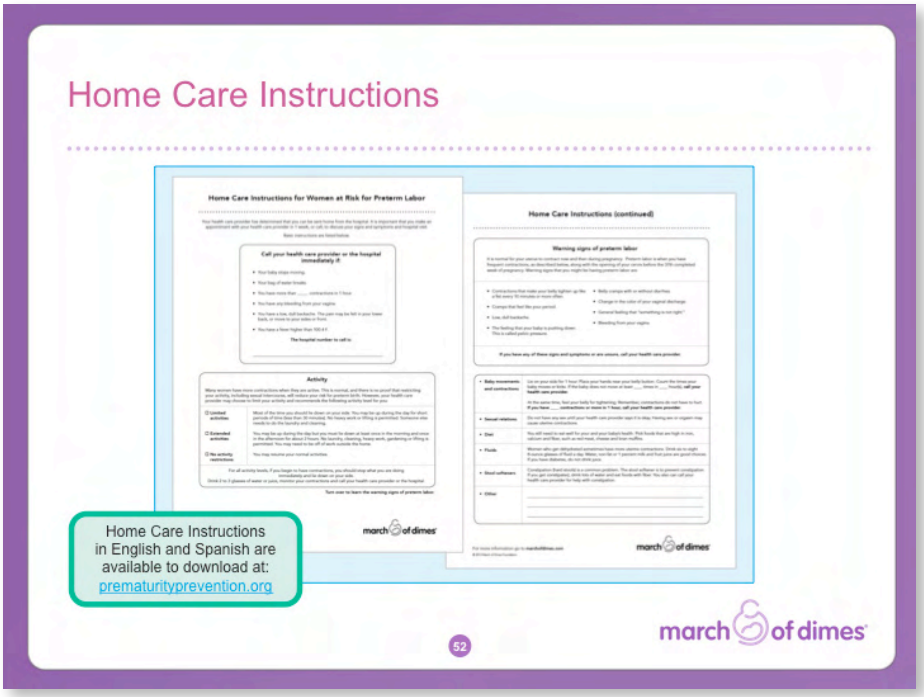
Mobilize

- To overcome barriers that may be institutionalized in a hospital's culture, an administrator, a physician and a nurse champion need to be identified as ambassadors for the initiative.

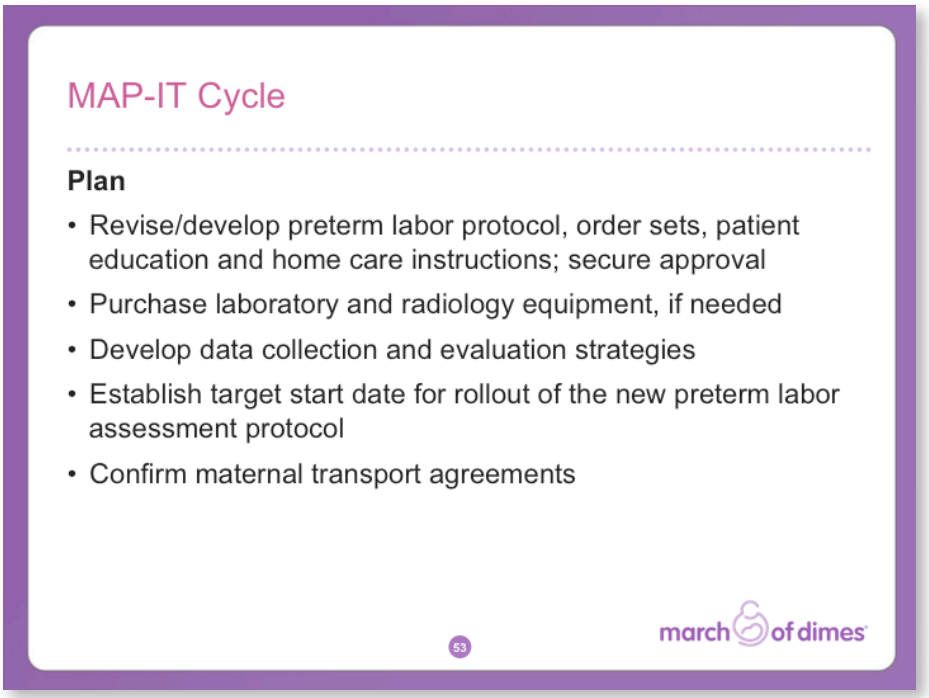
Assess

- Conducting a baseline survey will assist in identifying current practices and educational and equipment needs.
- A maternal transport process and agreements, if needed, must be in place before the initiative can be introduced as a quality improvement measure.
- Education needs are met by either grand rounds presentations or one or more town hall Q & A sessions. If the nursing staff is not skilled in performing sterile speculum exams, a link to web-based didactic education is included in *PLAT*, along with a link to skill certification checklists.
- Finally, perform a review of patient education materials and home care instructions and update if necessary.

PLAT outlines March of Dimes patient education materials that are available for use by any facility. It is critical that each patient understand the importance of recognizing and reporting signs and symptoms of preterm labor. Early detection and diagnosis may provide just the time window needed for essential clinical interventions such as antenatal corticosteroids, maternal transport to a higher level of care, or assembly of the high-risk team.

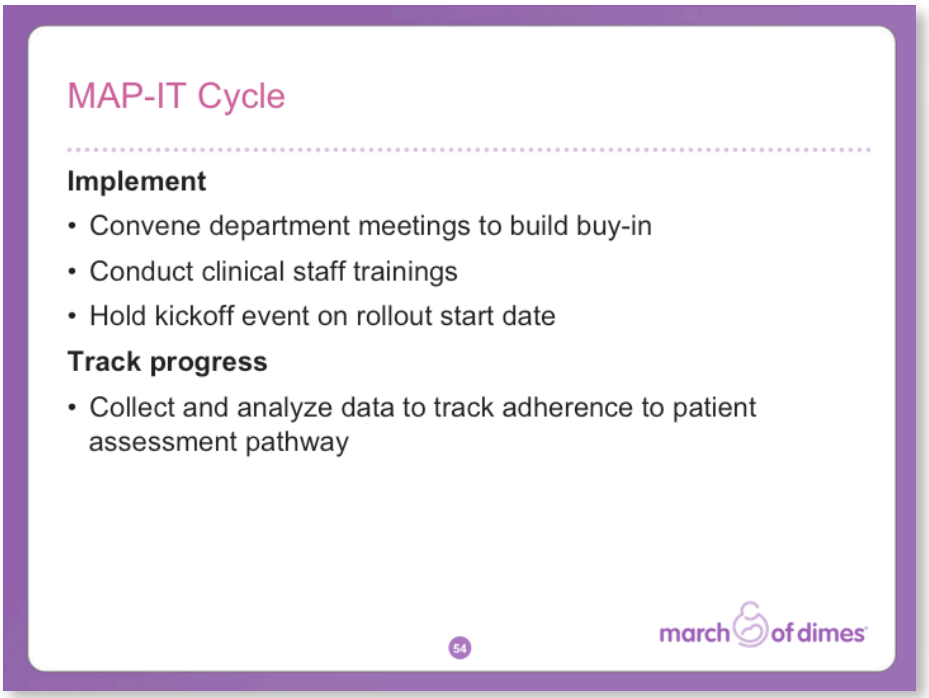


- Sample home care instructions in English and Spanish for patients not in preterm labor are included in *PLAT*, and can be downloaded from prematurityprevention.org.
- These home care instructions are not intended to discourage a patient from coming back to the hospital if signs and symptoms of preterm labor persist. Instead, they are designed to teach patients what to look for and when to call their health care provider.
- Instructions also direct the patient to contact their regular health care provider to make an appointment in 1 week and discuss their signs and symptoms of preterm labor and their hospital assessment.



Plan

- Samples of policies, procedures and orders are available in *PLAT* to assist hospitals with any needed modifications.
- Equipment needs refers to having an adequate number and size of speculums in the triage area, the availability of transvaginal ultrasound, and rapid fFN availability through the lab.

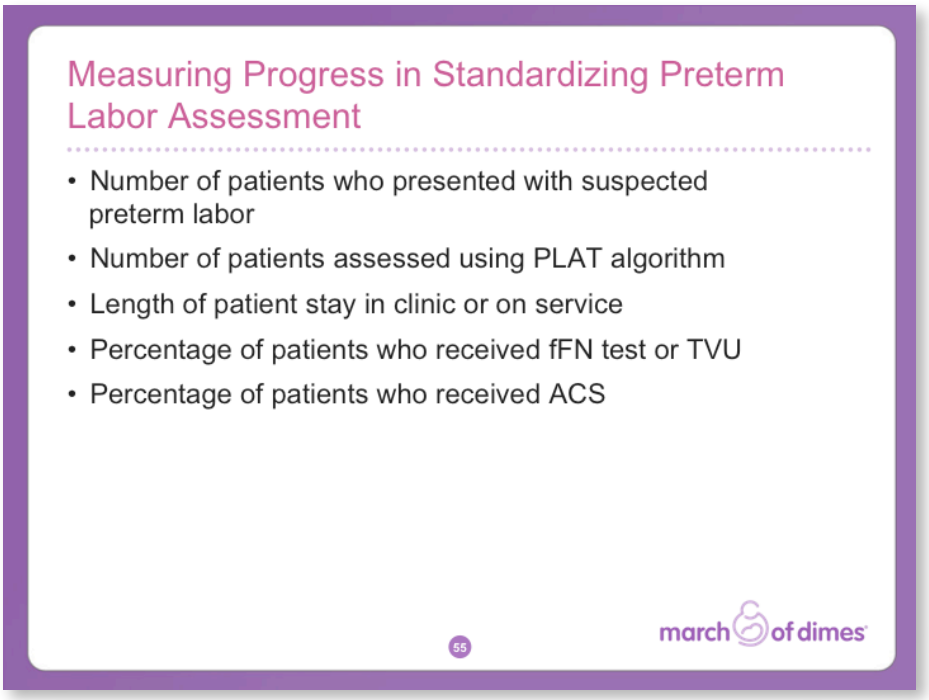


Implement

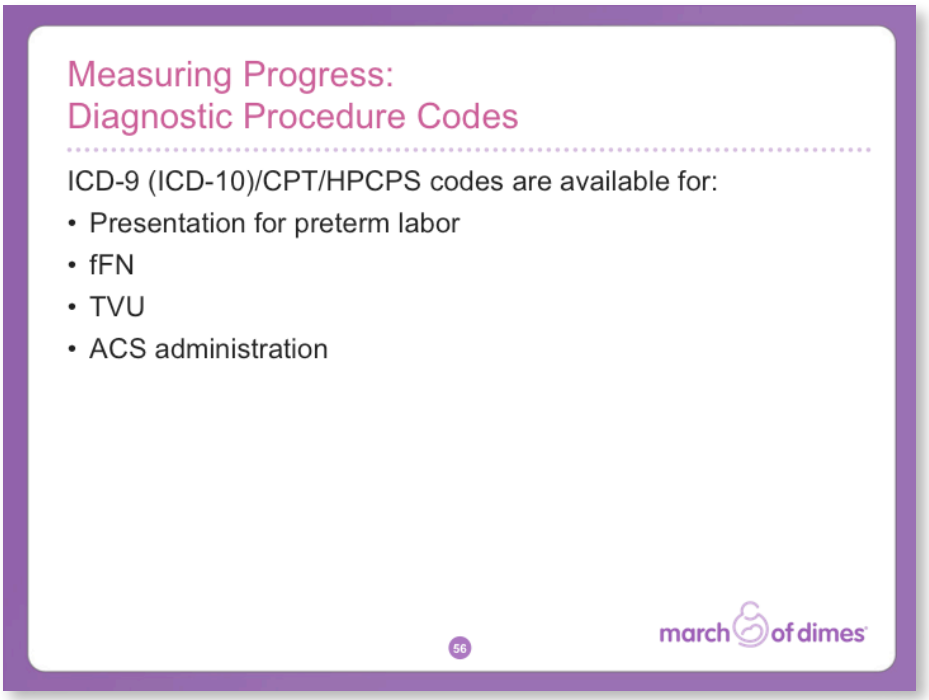
- To help establish consensus and buy-in, convene department meetings to discuss changes in protocol.

Track Progress

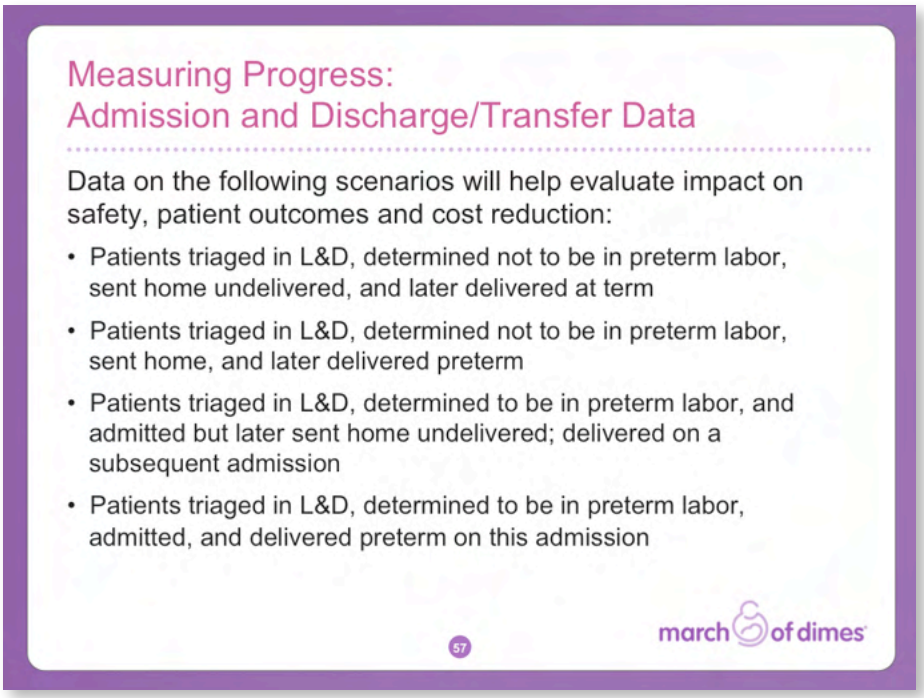
- Collect data to help inform progress in standardizing preterm labor assessment.



There are a variety of ways to measure progress. A facility's choice of metrics depends on the availability and ease of data collection. This slide lists five measures that may be evaluated. In the following slides, we identify more readily available data points that could be used to monitor departmental progress.



ICD-9 (ICD-10), CPT and/or HPCPS codes can be used to identify the number of patients presenting with the chief complaint of preterm labor. Other codes can help to determine the percentage of fetal fibronectin samples collected, TVU utilization and antenatal corticosteroid administration. These indicators will provide a broad-sweep picture of preterm labor assessment practices and can be used to compare before and after indicators and departmental adherence to the algorithm. Although they do not measure all aspects of the algorithm, changes in values over time will suggest changes in a department's practice.



If we take a closer look at these indicators, we can begin to evaluate the appropriateness of patient assessment and disposition decision-making. These metrics also will lead to the ability to determine potential as well as actual cost savings; for example, by comparing the total number of hospital days for mothers and babies before and after implementation of the initiative. Last, but certainly not least, quality improvement also can be evaluated by examining clinical outcomes for mothers and babies.

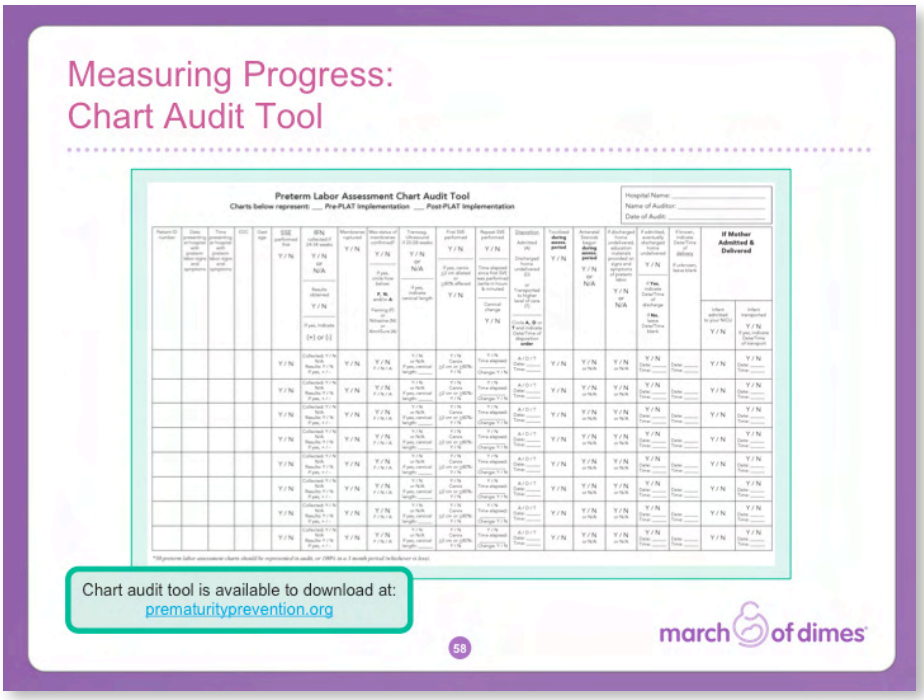
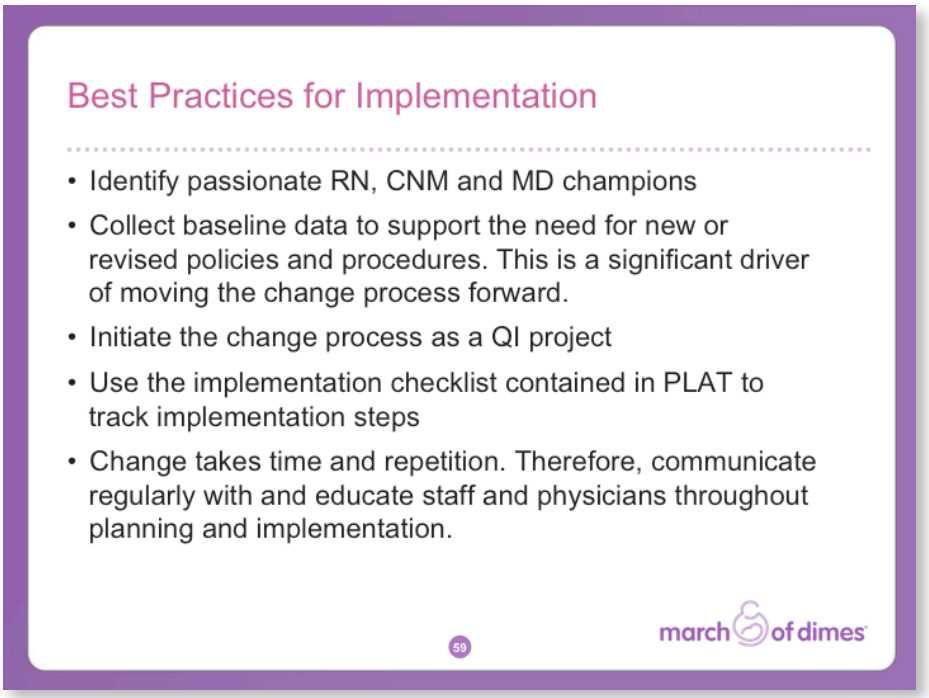
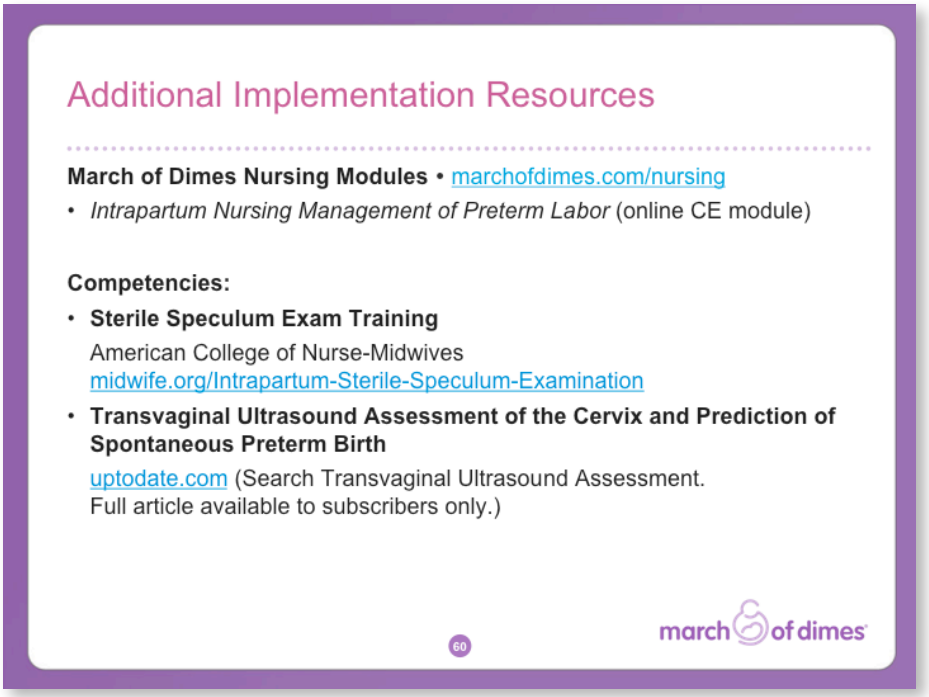


Chart audit affords the deepest dive into assessing practice by hospital department and/or individual practitioner. It also is the most time-consuming method of assessment. March of Dimes used this tool to assess departmental practice change and the effectiveness of *PLAT* during the pilot project evaluation. The chart audit tool can be downloaded at prematurityprevention.org.



- **Identify passionate nursing and physician champions.**
  Hospital leaders often must balance many QI projects or change processes at the same time. Therefore, it is essential to have committed champions to carry the initiative forward.
- **Collecting baseline data to support the need for new or revised policies and procedures is a significant contributor to moving the change process forward.**
  Baseline data help to demonstrate need and highlight problematic areas that may otherwise be hard to detect or pinpoint.
- **Initiate the change process as a quality improvement project.**
  Using metrics and measurement tools to track progress allows for the department, staff and physicians to see improvements.
- **Use a checklist to track progress.**
  An implementation checklist helps to keep the champions focused.
- **Allow for time and repetition.**
  Communicate with and educate staff and physicians often over the course of planning and implementing the initiative.


Additional Implementation Resources
March of Dimes Nursing Modules • marchofdimes.com/nursing
• Intrapartum Nursing Management of Preterm Labor (online CE module)
Competencies:
• Sterile Speculum Exam Training
American College of Nurse-Midwives
midwife.org/Intrapartum-Sterile-Speculum-Examination
• Transvaginal Ultrasound Assessment of the Cervix and Prediction of Spontaneous Preterm Birth
uptodate.com (Search Transvaginal Ultrasound Assessment.
Full article available to subscribers only.)
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Case Studies
• Sutter Medical Center, Sacramento
• March of Dimes California Chapter
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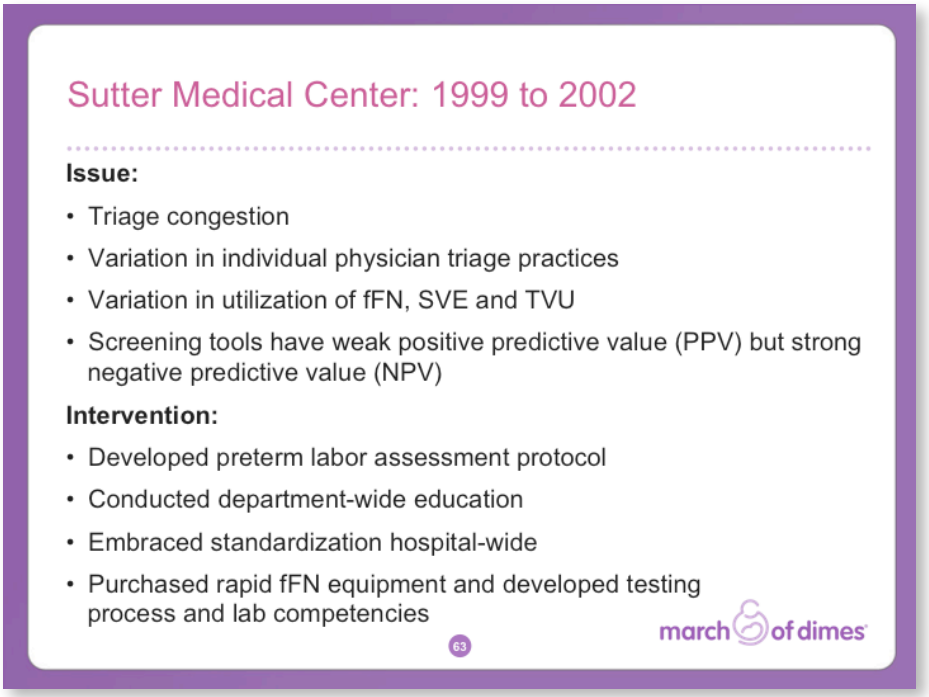
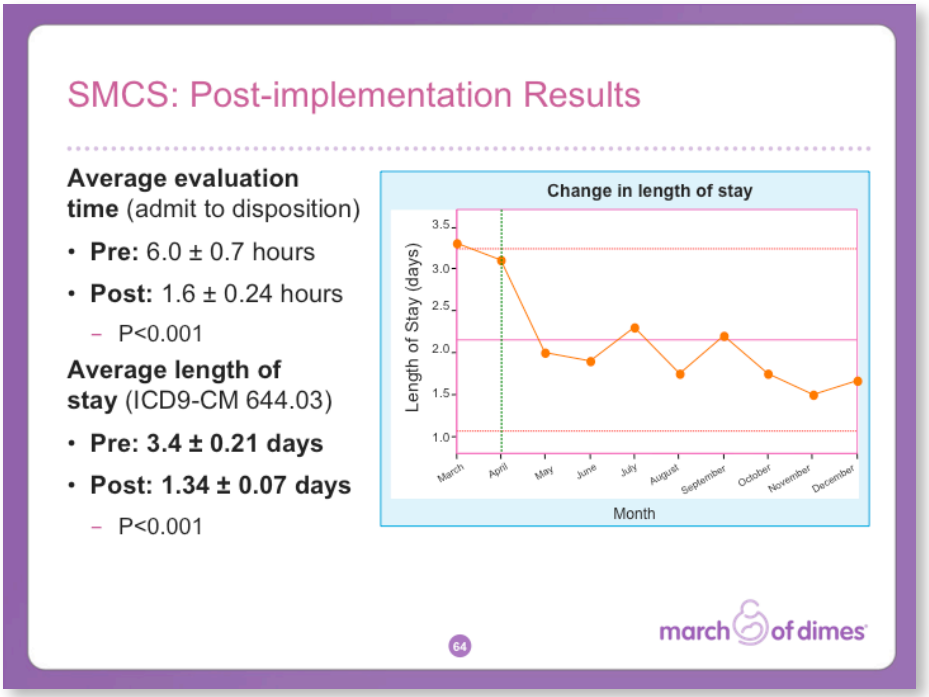
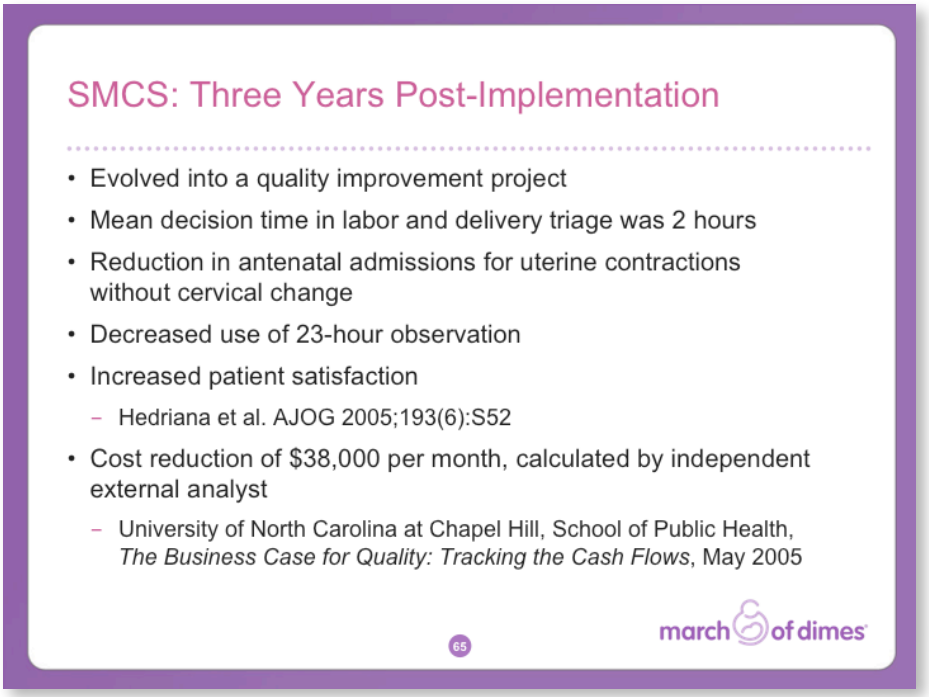
The Sutter Medical Center, Sacramento experience will be discussed in the next set of slides as a case study. Findings from Sutter Medical Center's experience led to the development of the first edition of the *Preterm Labor Assessment Toolkit*.



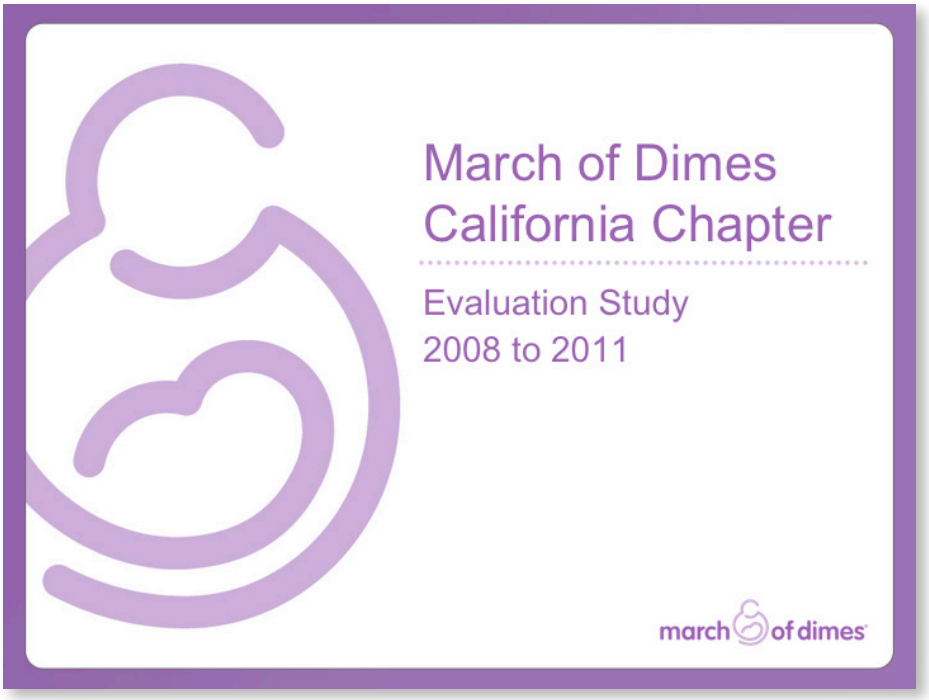
- Sutter Medical Center, Sacramento, the largest maternity hospital in Sacramento (handling 5,000 to 6,000 deliveries per year), had problems with congestion in its Labor & Delivery Unit, which includes: 3 triage beds, 6 labor beds, 14 LDRs and a 24 bed antepartum unit.
- In examining the problem, the OB department recognized wide variation in how its 36 providers, including four perinatologists, assessed preterm labor. Among the diagnostic tools used were serial vaginal exam, fetal fibronectin and, occasionally, transvaginal ultrasound. Nevertheless, this wide variability resulted in high consistency in ruling out preterm labor.
- The triage process in the labor and delivery unit was re-evaluated and compared with the process used by Intermountain Healthcare in Salt Lake City, including the use of fetal fibronectin.
- Based on Sutter's findings, a standardized process was developed to assess preterm labor symptoms. The change to assessment standardization included changing the culture within the department, one physician group at a time. Training of the nursing staff occurred simultaneously until the entire department embraced standardization.



- A standardized triage protocol was implemented in the OB department in March 2000, following a month of orientation and information dissemination. Standardization outcomes continued to improve with each subsequent month.
- The average time in triage decreased by more than 4 hours. Mean length of stay in the antenatal unit was reduced by 50%.



- For 3 years following implementation of standardization, the mean decision time remained at 2 hours. The 23-hour observation window in triage was eliminated, and disposition decisions were made after a maximum of 4 hours.
- Surveys showed an increase in patient satisfaction.
- Cost savings were not based on actual Sutter Medical Center data. Instead, an external analysis conducted by the University of North Carolina estimated a savings of $38,000 per month for the labor and delivery unit. (This estimate was derived from a cash-flow model that incorporated initial investment costs; cash inflows, i.e., payor reimbursement; and cash outflows, i.e., cost of tests.)


March of Dimes
California Chapter
Evaluation Study
2008 to 2011
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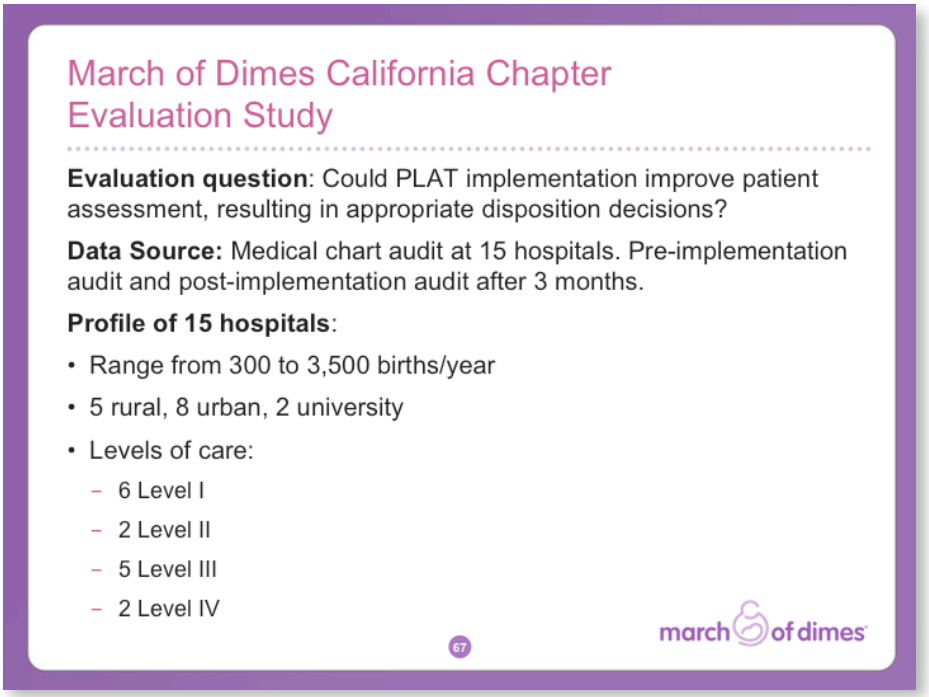
March of Dimes California Chapter
Evaluation Study
Evaluation question: Could PLAT implementation improve patient assessment, resulting in appropriate disposition decisions?
Data Source: Medical chart audit at 15 hospitals. Pre-implementation audit and post-implementation audit after 3 months.
Profile of 15 hospitals:
• Range from 300 to 3,500 births/year
• 5 rural, 8 urban, 2 university
• Levels of care:
– 6 Level I
– 2 Level II
– 5 Level III
– 2 Level IV
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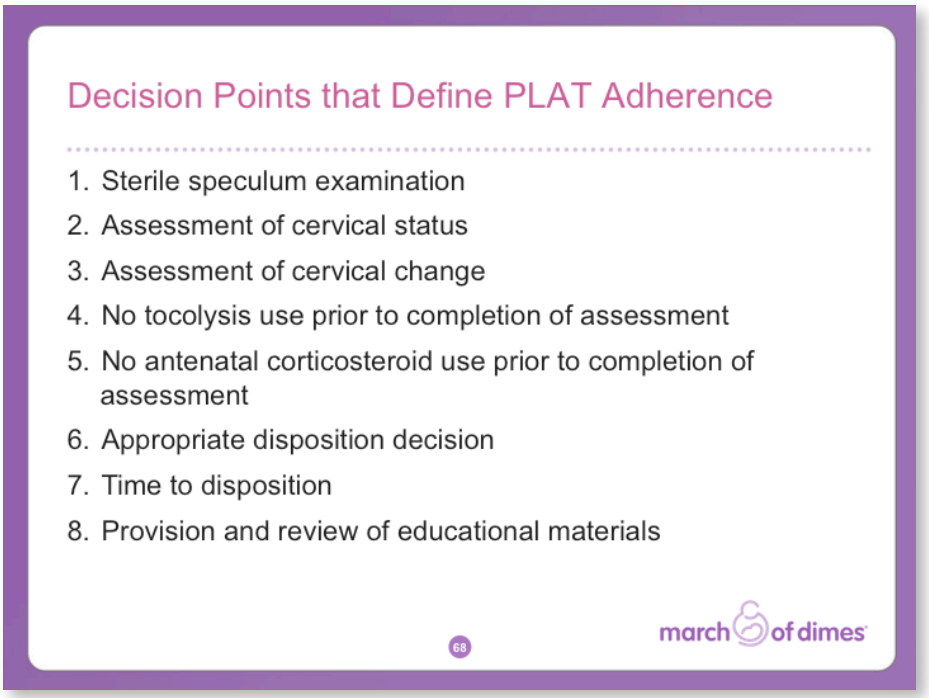
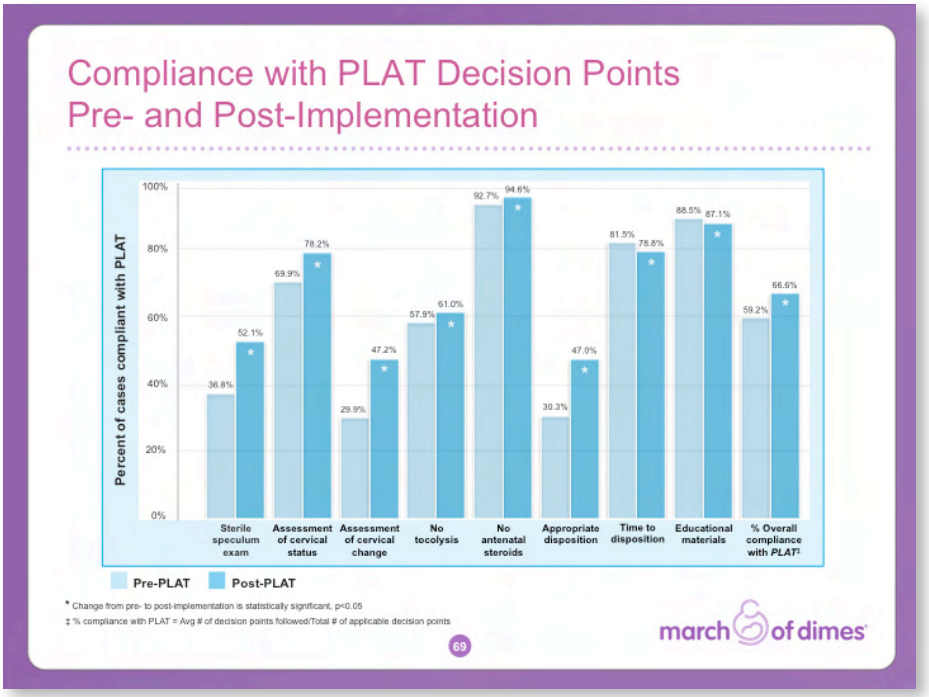


1. **Sterile speculum examination:** The purpose of this exam is to determine the status of the cervix and amniotic membranes.
2. **Assessment of cervical status:** The cervix is assessed to determine the degree of dilation and effacement.
3. **Assessment of cervical change:** The cervix is assessed to determine change in dilation, effacement, consistency and position.
4. **No tocolysis use prior to completion of assessment:** Treatment for preterm labor is not initiated until assessment is complete and the preterm labor diagnosis is made.
5. **No antenatal corticosteroid use prior to completion of assessment:** Treatment for preterm labor is not initiated until assessment is complete and the preterm labor diagnosis is made.
6. **Appropriate disposition decision:** Discharge, admit or transport decision is based on completed cervical change assessment.
7. **Time to disposition:** Time from patient presentation at hospital to disposition decision is less than 5 hours to allow for timely interventions for women in true preterm labor or timely rule-out of preterm labor and discharge for those who are not.
8. **Provide and review education materials:** Patients who are discharged home are provided with educational materials describing the signs and symptoms of preterm labor and when to call their provider and/or return to the hospital. These materials are reviewed with the patient to ensure that they are understood.



This graph shows the progress of the 15 pilot hospitals from pre- to post-implementation.

Results:

- Use of the various procedures that comprise the *PLAT* protocol increased after implementation for six key measures.
- There were statistically significant increases in adherence for:
  - Implementation of sterile speculum exam
  - Assessment of cervical status
  - Assessment of cervical change
  - Appropriate disposition decision
- Distribution of educational materials to patients discharged home undelivered was close to 90% at both pre- and post-*PLAT* implementation and declined very slightly over time.
- Time to disposition changed in a negative direction, but this finding was not statistically significant. The time increase may have resulted from additional time spent by clinicians in carefully working through the protocol. In other words, with the newly introduced protocol, more steps in the assessment process may have been completed.
- Treatment during the assessment period persisted, particularly with tocolytics.
- The data presented in this figure represent the first 3 months after implementation, the earliest stage in the learning curve. As the learning curve progresses, it is expected that overall adherence to *PLAT* will increase.

For speaker reference:

- "No tocolysis" and "no antenatal corticosteroids" refers to refraining from use of these agents prior to completion of the assessment.

Disposition Decision Based on Completed Cervical Change Assessment

	N	Excluded	Pre (%)	Post (%)
Disposition				
Admits/Transfers	87	13[α]	4.2	6.3*
Sent home undelivered	719	10[α]	26.1	40.8*
Unknown	-	1‡	-	-
TOTAL	**806**	**24**	**30.3**	**47.1**

*Change from pre to post is statistically significant with p<0.05
[α]Cervical change assessment not reported or N/A
‡Medical record met criteria for inclusion but disposition not reported
Change in the positive direction is the desired outcome.

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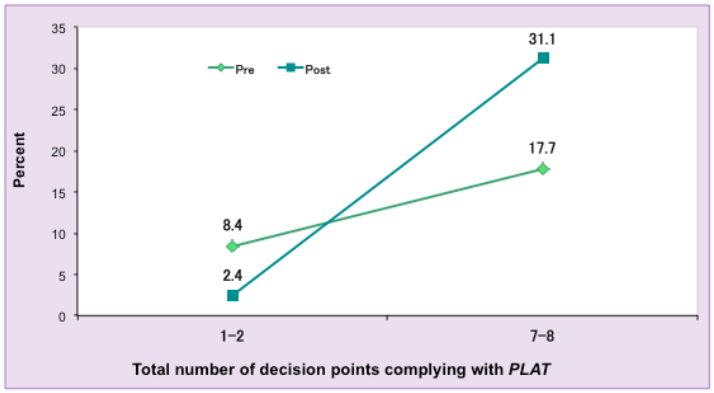
This table shows the change in *PLAT* compliance for disposition decision. There was an increase in disposition decisions based on completed cervical change assessment for patients who were admitted or transferred, and for patients sent home undelivered. However, the increase was statistically significant only for patients sent home undelivered. With a larger sample, the change in disposition based on completed cervical change assessment for admits/transfers might have reached statistical significance.

Total Decision Points Complying with PLAT



Change from pre to post is statistically significant for 1-2 decision points and for 7-8 decision points, p<0.05

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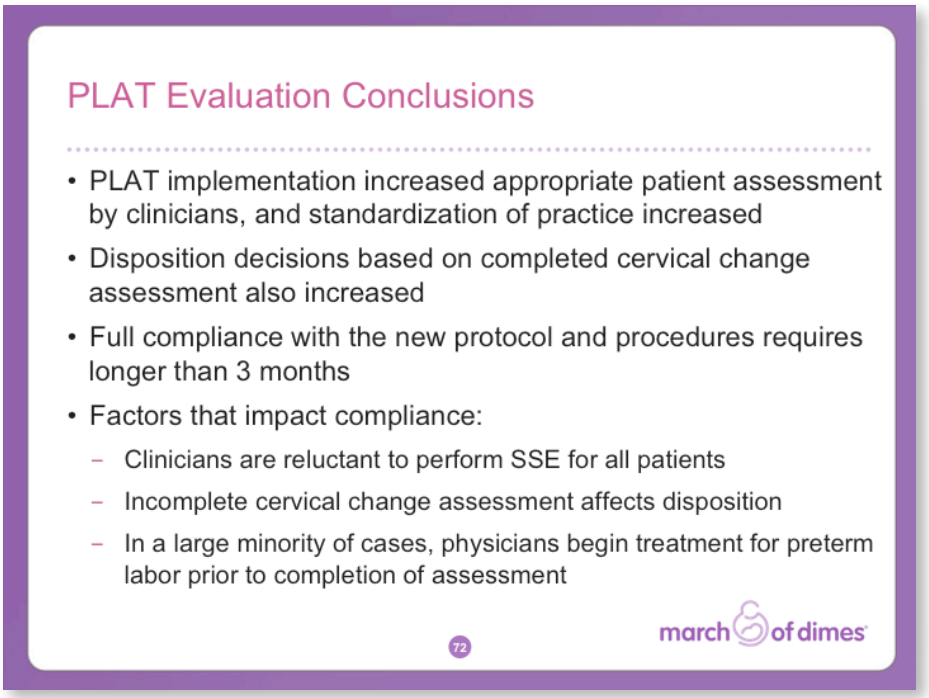
Statistically significant decrease for compliance with only 1 to 2 decision points total.

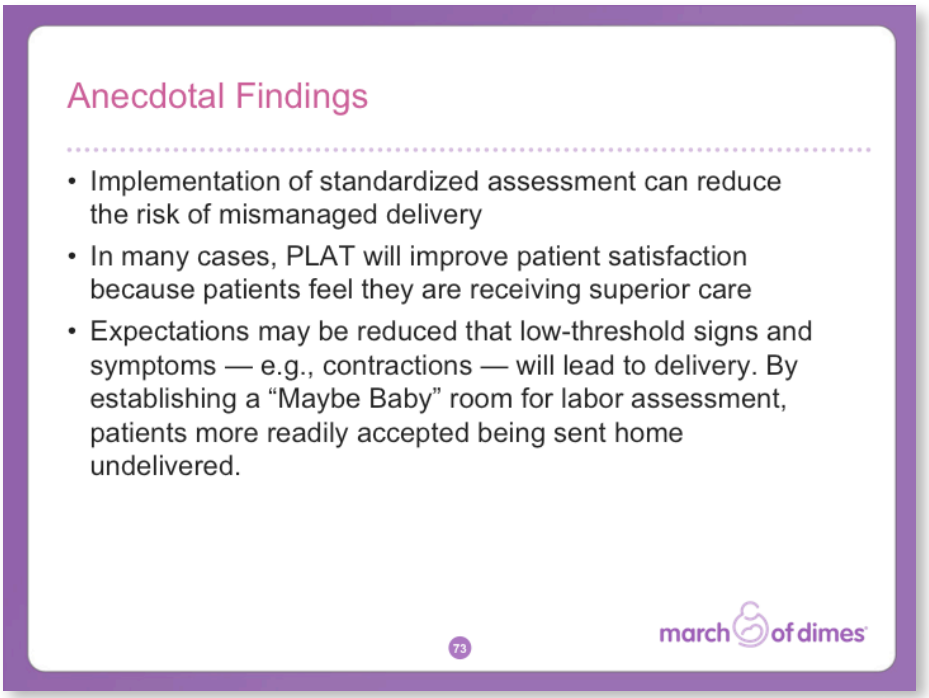
p < .0001 (pre 8.4% vs. post 2.4%)

Statistically significant increase for compliance with 7 to 8 decision points total.

p < .0001 (pre 17.7% vs. post 31.1%)

Again, the data presented in this figure represent the first 3 months after implementation, the earliest stage in the learning curve. As the learning curve progresses, it is expected that overall adherence to *PLAT* will increase.





- In triage, patients are typically placed on a fetal monitor, and if contractions don't appear on the monitor, they are sent home. However, the PLAT standardized assessment enables clinicians to identify symptoms and situations that might have been previously missed. For example, one hospital reported that a nurse followed the PLAT algorithm — even though the monitor indicated that the patient wasn't having contractions — and found a dilating cervix and a bulging bag of waters. This was discovered just in time to call in the neonatal transport team to be present for the delivery.
- Patients offer unsolicited comments stating they believe they are receiving better care.
- One hospital implemented an innovative "Maybe Baby" room. Language, combined with hospital layout, can have a profound impact on everyone's mindset.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The March of Dimes is grateful to the experts listed below who collaborated on the development of the first edition of the *Preterm Labor Assessment Toolkit* in 2005. Their early contributions to *PLAT* made this 2013 revised edition possible.

ACKNOWLEDGMENTS

The Preterm Labor Assessment Toolkit is a collaborative project between Sutter Medical Center, Sacramento and the March of Dimes California Chapter. This toolkit contains evidence based, consensus guidelines from healthcare professionals across California. The material is for information purposes only and does not constitute medical advice. The information and opinions expressed in this material are those of the authors and do not necessarily reflect the views of the March of Dimes. This project was made possible by a grant from the March of Dimes California Chapter and through an in-kind contribution from Sutter Medical Center, Sacramento. The following healthcare professionals have contributed their expertise toward the development of this project.

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Endnotes

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1. Hueston WJ. Preterm contractions in community settings: I. Treatment of preterm contractions. *Obstet Gynecol*. Jul 1998;92(1):38-42.
2. Hueston WJ. Preterm contractions in community settings: II. Predicting preterm birth in women with preterm contractions. *Obstet Gynecol*. Jul 1998;92(1):43-46.
3. Iams JD. Prediction and early detection of preterm labor. *Obstet Gynecol*. Feb 2003;101(2):402-412.
4. Behrman, RE, Butler, AS, eds. *Preterm Birth: Causes, Consequences, and Prevention*. 2007. http://www.iom.edu/Reports/2006/Preterm-Birth-Causes-Consequences-and-Prevention.aspx. Accessed August 6, 2013.
5. Martin JA, Hamilton BE, Ventura SJ, et al. Births: Final data for 2011. National vital statistics reports web release; vol 62 no 1. Hyattsville, MD: National Center for Health Statistics. 2013.
6. Your premature baby. http://www.marchofdimes.com/baby/premature-babies.aspx. Accessed August 6, 2013.
7. National Center for Health Statistics, final natality data. http://www.marchofdimes.com/peristats. Accessed August 12, 2013.
8. Costs of preterm birth: US, 2005. http://www.marchofdimes.com/peristats/ViewSubtopic.aspx?dv=ls&reg=99&top=3&stop=362&lev=1&slev=1&obj=1 Accessed September 19, 2013.
9. Pathway for standardized preterm labor assessment for symptomatic women. March of Dimes California Chapter. 2013.
10. March of Dimes California Chapter and Sutter Medical Center, Sacramento. *Preterm Labor Assessment Toolkit*. White Plains, NY: March of Dimes Birth Defects Foundation; 2005.
11. Guinn DA, Goepfert AR, Owen J, Brumfield C, Hauth JC. Management options in women with preterm uterine contractions: A randomized clinical trial. *Am J Obstet Gynecol*. Oct 1997;177(4):814-818.
12. McPheeters ML, Miller WC, Hartmann KE, et al. The epidemiology of threatened preterm labor: A prospective cohort study. *Am J Obstet Gynecol*. Apr 2005;192(4):1325-1329.
13. Pelaez LM, Fox NS, Chasen ST. Negative fetal fibronectin: Who is still treating for threatened preterm labor and does it help? *J Perinat Med*. 2008;36(3):202-205.
14. Joffe GM, Jacques D, Bemis-Heys R, Burton R, Skram B, Shelburne P. Impact of the fetal fibronectin assay on admissions for preterm labor. *Am J Obstet Gynecol*. Mar 1999;180(3 Pt 1):581-586.
15. The University of North Carolina School of Medicine at Chapel Hill developed an algorithm for triaging women with no risk factors who present with suspected symptoms of preterm labor. See Preterm labor 1 (no risk factors). 2002. http://mombaby.org/index.php?c=2&s=30. Accessed August 6, 2013.

16. The Joint Commission. Specifications manual for Joint Commission National Quality Measures, Perinatal Care (PC) Measures (Antenatal Steroids). http://jointcommission.org. Accessed February 8, 2013. Fifteen years earlier, in 1994, the National Institutes of Health recommended administration of a single course of antenatal corticosteroids for women at risk of preterm birth presenting between 24 and 34 weeks of gestation. See NIH Consensus Development Panel. "Effect of corticosteroids for fetal maturation on perinatal outcomes." *JAMA* 1995;273:413-418.

17. Clark S, Belfort M, Saade G, et al. Implementation of a conservative checklist-based protocol for oxytocin administration: Maternal and newborn outcomes. *Am J Obstet Gynecol*. Nov 2007;197(5):480.e1-5.

18. Pettker CM. Standardization of intrapartum management and impact on adverse outcomes. *Clin Obstet Gynecol*. Mar 2011;54(1):8-15.

19. Little GA, Horbar JD, Wachtel JS, Gluck PA, Muri JH. Evolution of quality improvement in perinatal care. In: Berns SD, ed. *Toward Improving the Outcome of Pregnancy III*. White Plains, NY: March of Dimes Foundation; 2010:10-18.

20. Berns SD, ed. *Toward Improving the Outcome of Pregnancy III*. White Plains, NY: March of Dimes Foundation; 2010.

21. Bieber E, Barfield WD, Dowling-Quarles S, Sparkman L, Blouin AS. Systems change along the continuum of perinatal care. In: Berns SD, ed. *Toward Improving the Outcome of Pregnancy III*. White Plains, NY: March of Dimes Foundation; 2010:112-22.

22. Oshiro BT, Henry E, Wilson J, Branch DW, Varner MW. Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system. *Obstet Gynecol*. Apr 2009;113(4):804-811.

23. Fisch JM, English D, Pedaline S, Brooks K, Simhan HN. Labor induction process improvement: A patient quality-of-care initiative. *Obstet Gynecol*. Apr 2009;113(4):797-803.

24. Donovan EF, Lannon C, Bailit J, Rose B, Iams JD, Byczkowski T. A statewide initiative to reduce inappropriate scheduled births at 36 0/7—38 6/7 weeks' gestation. *Am J Obstet Gynecol*. Mar 2010;202(3):243.e1-8.

25. Giles W, Bisits A, Knox M, Madsen G, Smith R. The effect of fetal fibronectin testing on admissions to a tertiary maternal-fetal medicine unit and cost savings. *Am J Obstet Gynecol*. Feb 2000;182(2):439-442.

26. Schmitz T, Maillard F, Bessard-Bacquaert S, et al. Selective use of fetal fibronectin detection after cervical length measurement to predict spontaneous preterm delivery in women with preterm labor. *Am J Obstet Gynecol*. Jan 2006;194(1):138-143.

27. Lowe MP, Zimmerman B, Hansen W. Prospective randomized controlled trial of fetal fibronectin on preterm labor management in a tertiary care center. *Am J Obstet Gynecol*. Feb 2004;190(2):358-362.

28. Rose CH, McWeeney DT, Brost BC, Davies NP, Watson WJ. Cost-effective standardization of preterm labor evaluation. *Am J Obstet Gynecol*. Sep 2010;203(3):250.e1-5.

29. Iams JD, Newman RB, Thom EA, et al. Frequency of uterine contractions and the risk of spontaneous preterm delivery. *N Engl J Med*. Jan 2002;346(4):250-255.

30. Iams JD, Berghella V. Care for women with prior preterm birth. *Am J Obstet Gynecol.* Aug 2010;203(2):89-100.

31. Hedriana HL, Bliss MC, Gilbert WM. Implementation of fetal fibronectin (fFN) testing in a large private practice hospital is safe and effective for the diagnosis and management of preterm labor (PTL). *Am J Obstet Gynecol* 2005;193(6):S52.

32. fFN (Fetal Fibronectin Test). http://www.ffntest.com/info/fetal_test/what_fetal.html. Accessed August 6, 2013.

33. Expression of fetal fibronectin by gestational age. http://www.ffntest.com/info/fetal_test/what_fetal.html. Accessed August 6, 2013.

34. Iams JD, Casal D, McGregor JA, et al. Fetal fibronectin improves the accuracy of diagnosis of preterm labor. *Am J Obstet Gynecol.* Jul 1995;173(1):141-145.

35. Peaceman AM, Andrews WW, Thorp JM, et al. Fetal fibronectin as a predictor of preterm birth in patients with symptoms: a multicenter trial. *Am J Obstet Gynecol.* Jul 1997;177(1):13-18.

36. Leitich H, Egarter C, Kaider A, Hohlagschwandtner M, Berghammer P, Husslein P. Cervicovaginal fetal fibronectin as a marker for preterm delivery: A meta-analysis. *Am J Obstet Gynecol.* May 1999;180(5):1169-1176.

37. Lopez RL, Francis JA, Garite TJ, Dubyak JM. Fetal fibronectin detection as a predictor of preterm birth in actual clinical practice. *Am J Obstet Gynecol.* May 2000;182(5):1103-1106.

38. Sullivan A, Hueppchen NA, Satin AJ. Cost effectiveness of bedside fetal fibronectin testing varies according to treatment algorithm. *J Matern Fetal Med.* Dec 2001;10(6):380-384.

39. Rapid Fetal Fibronectin Product Insert, Hologic Inc, 2009. http://www.ffntest.com/pdfs/rapid_ffn_product_insert_lettersize.pdf. Accessed August 6, 2013.

40. Roman AS, Koklanaris N, Paidas MJ, Mulholland J, Levitz M, Rebarber A. "Blind" vaginal fetal fibronectin as a predictor of spontaneous preterm delivery. *Obstet Gynecol.* Feb 2005;105(2):285-289.

41. Stafford IP, Garite TJ, Dildy GA, et al. A comparison of speculum and nonspeculum collection of cervicovaginal specimens for fetal fibronectin testing. *Am J Obstet Gynecol.* Aug 2008;199(2):131.e1-4.

42. Phelps JY, Higby K, Smyth MH, Ward JA, Arredondo F, Mayer AR. Accuracy and intraobserver variability of simulated cervical dilatation measurements. *Am J Obstet Gynecol.* Sep 1995;173(3 Pt 1):942-945.

43. Owen J, Szychowski JM, Hankins G, et al. Does midtrimester cervical length >25 mm predict preterm birth in high-risk women? *Am J Obstet Gynecol.* Oct 2010;203(4):393.e1-5.

44. Conde-Agudelo A, Romero R, Hassan SS, Yeo L. Transvaginal sonographic cervical length for the prediction of spontaneous preterm birth in twin pregnancies: A systematic review and metaanalysis. *Am J Obstet Gynecol.* Aug 2010;203(2):128.e1-12.

45. ACOG Committee on Practice Bulletins – Obstetrics. ACOG practice bulletin no. 80: premature rupture of membranes. *Obstet Gynecol.* Apr 2007;109(4): 1007-1019.

46. Newman RB, Goldenberg RL, Iams JD, et al. Preterm prediction study: Comparison of the cervical score and Bishop score for prediction of spontaneous preterm delivery. *Obstet Gynecol*. Sep 2008;112(3):508-515.

47. Iams JD, Creasy RK. *Preterm Labor and Delivery*. 5th ed. Philadelphia: Saunders; 2004.

48. Muglia LJ, Katz M. The enigma of spontaneous preterm birth. *N Engl J Med*. Feb 2010;362(6):529-535.

49. ACOG Committee on Obstetric Practice. ACOG committee opinion no. 475: antenatal corticosteroid therapy for fetal maturation. *Obstet Gynecol*. Feb 2011;117(2 Pt 1):422-424.

50. Myles TD. Steroids—plenty of benefits, but not without risk. *Obstet Gynecol*. Feb 2011;117(2 Pt 2):429-430.

51. Vermont Oxford Network, unpublished data.

52. Adapted based on Roberts D, Dalziel S. Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. *Cochrane Database of Systematic Reviews*. 2006, 3. Art. No. CD004454. DOI: 10.1002/14651858.CD004454.pub2.

53. National Quality Forum. Under 1500g infant not delivered at appropriate level of care. http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=308#k=0477. Accessed August 6, 2013.

54. Kennedy MB, Ruth DJ, Martin EJ. *Intrapartum management modules: A perinatal education program*. 4th ed. Philadelphia: Wolters Kluwer Health/Lippincott William & Wilkins; 2009.

55. Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birthweight infants. *N Engl J Med*. May 2007;356(21):2165-2175.

56. Committee on Fetus and Newborn. Levels of Neonatal Care. *Pediatrics*. Sept 2012;130(3):587-97.

57. Abrahams C, Katz M. A perspective on the diagnosis of preterm labor. *J Perinat Neonatal Nurs*. Jun 2002;16(1):1-11.

58. Adapted with permission from *MAP-IT: A Guide To Using Healthy People 2020 in Your Community*. U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. Healthy People 2020. Washington, D.C. Available at http://healthypeople.gov/2020/implementing/default.aspx Accessed August 6, 2013.

59. Goldenberg RL, McClure EM, Bhattacharya A, Groat TD, Stahl PJ. Women's perceptions regarding the safety of births at various gestational ages. *Obstet Gynecol*. Dec 2009;114(6):1254-1258.

60. ACOG Committee on Practice Bulletins - Obstetrics. ACOG practice bulletin no. 127: management of preterm labor. *Obstet Gynecol*. Jun 2012;119(6):1308-17.

61. ALPS (Antenatal Late Preterm: Randomized Placebo-Controlled Trial). https://mfmu.bsc.gwu.edu/research-projects. Accessed August 6, 2013.

62. Dyson DC, Danbe KH, Bamber JA, et al. Monitoring women at risk for preterm labor. *N Engl J Med*. Jan 1998;338(1):15-19.

63. Alexander S, Boulvain M, Ceysens G, Haelterman E, Zhang WH. Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour. *Cochrane Database Syst Rev*. 2010(6):CD005940. DOI: 10.1002/14651858.CD005940.pub2.

64. ACOG Committee on Practice Bulletins - Obstetrics. ACOG practice bulletin no. 130: prediction and prevention of preterm birth. *Obstet Gynecol*. Oct 2012;120(4):964-73.

65. DeFranco EA, O'Brien JM, Adair CD, et al. Vaginal progesterone is associated with a decrease in risk for early preterm birth and improved neonatal outcome in women with a short cervix: A secondary analysis from a randomized, doubleblind, placebo-controlled trial. *Ultrasound Obstet Gynecol*. Oct 2007;30(5):697-705.

66. Fonseca EB, Celik E, Parra M, Singh M, Nicolaides KH. Progesterone and the risk of preterm birth among women with a short cervix. *N Engl J Med*. Aug 2007;357(5):462-469.

67. Romero R, Nicolaides K, Conde-Agudelo A, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data. *Am J Obstet Gynecol* 2012; 206:124.e1-124.e19.

68. Blickstein I. *Multiple Pregnancy: Epidemiology, Gestation and Perinatal Outcome*. London: Taylor & Francis; 2005.

69. Caritis SN. Metaanalysis and labor inhibition therapy. *Am J Obstet Gynecol*. Feb 2011;204(2):95-96.

70. Reeves SA, Gibbs RS, Clark SL. Magnesium for fetal neuroprotection. *Am J Obstet Gynecol*. Mar 2011;204(3):202.e1-4.

71. ACOG committee opinion no. 455: magnesium sulfate before anticipated preterm birth for neuroprotection. *Obstet Gynecol*. Mar 2010;115(3):669-671.

72. Vischio V. AmniSure® ROM (Rupture of Membranes) Test. *Technically Speaking*. 2011;5(2). http://m.danburyhospital.org/en/sitecore/content/Home/About-Us/Publications/~/media/Files/Publications/Technically%20Speaking/Vol%205%20No2-2011.ashx. Accessed August 6, 2013.

73. Centers for Disease Control and Prevention. Prevention of perinatal group B streptococcal disease: Revised guidelines from the CDC. MMWR 2010; 59 (No.RR-10):1-36.

Planning Notes: