Using the Preterm Labor Assessment Toolkit (PLAT): Strategies for Success

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Learning Objectives

- Identify the importance of standardization in perinatal health care
- Describe key components of the March of Dimes Preterm Labor Assessment Toolkit
- Describe strategies that can be used to improve the identification and management of preterm labor in order to improve preterm labor and birth outcomes.

What’s the Issue?

“Despite an increased focus on the quality and safety of care, the US Health Care system does not reliably deliver safe, high quality care for all women and infants.”

“In many cases a gap still exists between best evidence and routine practice”
Who Shares This Priority?

AWHONN

Make a Difference Together!

• Using standardized, process tools that are evidence based improve the “consistency” and quality of healthcare for mothers & infants?

• Identify and model the “Best Practices” that contribute to safety and quality improvements in perinatal outcomes?

• Better utilize hospital resources by reducing unnecessary admissions, interventions, and maternal transports?

Preterm Labor Assessment Toolkit
Preterm Labor Assessment Toolkit (PLAT) Goal

To improve perinatal health outcomes by establishing a standardized clinical pathway for the assessment and disposition of women with suspected signs and symptoms of preterm labor.

Objectives

• Define ‘Toolkit’
• Understand the scale and impact of preterm birth
• Understand how timely assessment can improve neonatal and long-term child health outcomes
• Understand how the March of Dimes Preterm Labor Assessment Toolkit improves quality of care through evidence-based, standardized pathways

PLAT Overview: What Is a “Toolkit”?

Toolkit: All-inclusive package to help facilitate improved clinical outcomes, excellent patient care and efficient resource allocation. (CPQCC.org)

PLAT: Package of resources you need to standardize preterm labor assessment at your hospital.

Core Contents of PLAT:
1. Overview: Preterm labor assessment and clinical disposition of patients
2. Algorithm, Protocol and Order Set
3. Data Collection: Suggested measures and data sources
4. Standardization of preterm labor assessment as a quality improvement project
5. Patient education and home care instructions
Preterm Birth in the United States

Preterm birth (<37 completed weeks)
- 11.7% of all 2011 live births
  - over 460,000 babies
Late preterm (34 to 36 weeks)
- 8.3% of live births
  - about 328,000 babies
Early preterm (<34 weeks)
- 3.4% of live births
  - about 134,000 babies

National Center for Health Statistics, 1990-2011 Final Natality Data, Data shown is % of live births

What Are the Consequences of Preterm Birth?

Health Impact
More than one-third of deaths during the first year of life are attributed to preterm birth-related causes.
Lifelong complications, including:
- cerebral palsy
- developmental delays
- chronic lung and vision problems

Economic Impact
Annually, preterm birth costs:
- An average of $52,000 per premature infant
- $26 billion for the U.S.
- Costs include health care, education and lost productivity


What Are the Causes of Preterm Birth?

- Spontaneous Preterm Labor 40-45%
- Preterm Premature Rupture of Membranes (PPROM) 30-35%
- Indicated 30-35%
Definition of Preterm Labor

Preterm labor occurs between 20 and 36 6/7 weeks of pregnancy. It is generally based on clinical criteria of:
- Regular uterine contractions with or without ruptured membranes accompanied by:
- Initial presentation with cervical dilation of at least 2 cm OR
- Change in cervical exam (dilation and/or effacement) on serial exams

Identifying women with preterm labor who ultimately give birth prematurely is difficult.
- Approximately 50% of women hospitalized for preterm labor actually deliver at term.


Risk Factors for Preterm Delivery

- Greatest risk
  - Previous preterm birth
  - Multiple gestation
  - Cervical or uterine anomalies
  - Presence of fFN between 22 and 34 weeks gestation
  - Cervix <25 mm long by TVU between 20 and 28 weeks

- Medical risks
  - Infections
  - Diabetes
  - Hypertension
  - Thrombophilias
  - Vaginal bleeding
  - Birth defects
  - IVF
  - Underweight or obesity
  - Short pregnancy interval

- Lifestyle and environmental risks
  - Late or no prenatal care
  - Cigarette smoking, drinking alcohol, drug use
  - Lack of social support
  - Stress
  - Long working hours with prolonged standing

- Other
  - African-Americans and American Indians
  - <17 or >35 years of age
  - Low socioeconomic status (SES)


Risk of Subsequent Preterm Delivery

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<thead>
<tr>
<th>First Delivery</th>
<th>Second Delivery</th>
<th>Risk of Subsequent Preterm Delivery</th>
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<td>Term</td>
<td>Term</td>
<td>9%</td>
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<td>Term</td>
<td>Preterm</td>
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<td>Term</td>
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<td>24%</td>
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<td>Preterm</td>
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Interventions That Do Not Reduce Risks of Preterm Birth

ACOG states that the following do not appear to reduce the risk of preterm birth and should not be routinely recommended for women with signs and symptoms suggestive of preterm labor:

- Bedrest
- Hydration
- Pelvic rest

Interventions That Do Reduce Risks Associated with Preterm Birth

Preventing preterm birth:

- Progesterone for asymptomatic women with preterm birth risk factors (e.g., prior preterm birth and/or short cervical length measured by TVU)
- Cerclage (for a limited number of special situations)

Preparing for preterm birth can improve outcomes:

- Antenatal corticosteroids
- Short-term tocolytic agents
- Transport to a tertiary care facility

Why This Matters: Benefits of Antenatal Corticosteroids (ACS) Between 24 and 34 Weeks

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<thead>
<tr>
<th>Antenatal corticosteroids led to reduction in:</th>
<th>~ 30%</th>
<th>~ 35%</th>
<th>~ 50%</th>
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<td>Early systemic infections</td>
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ACS Use

The Joint Commission Perinatal Care Core Measure-03 Antenatal Steroids

• Patients at risk of preterm delivery at 24 to 32 weeks gestation receiving antenatal steroids prior to delivering preterm newborns.

ACOG

• “The most beneficial intervention for patients in true preterm labor is the administration of corticosteroids.”
• Recommended between 24 weeks and 34 weeks gestation when risk of preterm delivery is within 7 days.

Performance on Antenatal Steroid Measure

| 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%

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

Contractions: A Diagnostic Challenge

• The assessment of preterm delivery risk based solely on symptoms and physical examination may be inaccurate.
• Uterine contractions alone are a poor positive predictor of true preterm labor.
• Contractions will occur four or more times an hour in up to 25% 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.

Management of Preterm Contractions

Hospital triage units tend to be inconsistent, with high variation in assessment and management of women with symptoms of preterm labor.

Treatment of 239 women presenting with preterm contractions at a network of 11 Wisconsin non-level III hospitals.

Findings:
- The average gestational age was 31.9 weeks.
- Only 17% of patients had any cervical changes with contractions.
- Over-treated low-risk patients:
  - 76% of those without cervical changes received short-term tocolytics.
- Under-treated high-risk patients:
  - Only 33% of those who delivered <34 weeks gestation received ACS.


If Contractions Are Confusing, What Can We Do?

Without standardization:
- Ineffective use of available tools and interventions.
- 50 to 80% of women admitted for preterm labor are discharged and ultimately deliver at term.

With standardization:
- Reduced antepartum admissions and length of stay.
- Reduced tocolytics.
- Increased antenatal steroid use.
- Cost savings.

Standardized assessment improves accurate diagnosis of preterm labor.


Preterm Labor Assessment for Symptomatic Women
Standardized Pathway for Improving Outcomes

Value of Standardized Assessment

• Identifying those patients in true labor will benefit all women who present in triage with signs and symptoms of suspected preterm labor
• Hospitals providing all levels of care will achieve the following outcomes within a relatively brief timeframe:
  - Timely and appropriate interventions
  - Optimal maternal-fetal safety
  - Hospitalization of only those patients at greatest risk for preterm delivery
  - Effective transport of preterm labor patients to higher, more appropriate levels of care
  - Avoidance of unnecessary treatments, interventions and medications

Tools to Standardize Assessment

Standardized assessment to diagnose preterm labor:
• Consistent definition by clinical criteria as regular uterine contractions accompanied by presentation with cervical dilation of at least 2 cm or a change in cervical exam (dilation and/or effacement) on serial exam.

Standardized assessment of risk factors associated with preterm birth:
• Consistent use of objective information to assess symptomatic women who do not meet the clinical criteria for preterm labor noted above.
• Examples include prior preterm birth as well as risk assessment via Transvaginal Ultrasound (TVU) and Fetal Fibronectin test (fFN).
Transvaginal Ultrasound (TVU)

Cervical length was measured at 24 weeks.

Preterm Delivery <35 Weeks

Probability of Preterm Delivery (%)


TVU — Technical Challenges

Accurate transvaginal ultrasound requires appropriate training and technique

Correct technique with "abnormal" finding

Incorrect technique results in "normal" finding 17 seconds later

TVU — Contraindications and Limitations

- Invalid <15 weeks and >28 weeks
- Steep learning curve — inability to recognize landmarks
- Vaginal bleeding (some instances)
- Central placenta previa
- Excessive probe pressure
- Filled maternal bladder
- Limited access to appropriate TVU equipment and trained staff in some hospitals

Used with permission from Andrea Jelks, MD, Santa Clara Valley Medical Center

Used with permission from James Byrne, MD Santa Clara Valley Medical Center
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 (weeks) at time of measurement

<table>
<thead>
<tr>
<th>Week of pregnancy</th>
<th>Cervical length, mm</th>
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<tr>
<td>0</td>
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<td>2</td>
<td>14</td>
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<td>16</td>
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Fetal fibronectin (fFN) Test

- Fetal fibronectin (fFN) is a biomarker screen associated with preterm birth
- In normal pregnancies between 22 to 35 weeks gestation, fFN is generally undetectable in cervico-vaginal secretions
- A positive fFN is associated with increased risk (13%-40%) of delivery within 14 days
- A negative fFN is associated with low risk (0.5%-5%) of delivery within 14 days
- The data of Positive Predictive Value and Negative Predictive Value can assist with risk assessment and provider decision-making regarding risk-appropriate care

fFN — Contraindications and Limitations

- Invalid <24 weeks and >34 weeks
- Sterile speculum exam (SSE) collection is the only FDA-approved collection method
- Vaginal bleeding
- Prior intercourse and/or sterile vaginal exam (SVE) in the last 24 hours
- Cervix ≥3 cm dilated
- Bulging fetal membranes/PPROM
- Open cervical and/or vaginal lesions
Summary

- The scale and impact of preterm birth are significant.
- Timely assessment of women with preterm labor symptoms can improve neonatal and long-term child health outcomes by targeting risk-appropriate interventions in those at risk for preterm labor.
- The March of Dimes Preterm Labor Assessment Toolkit improves quality of care through evidence-based, standardized pathways that:
  - Standardize assessment to help diagnose women in preterm labor using clinical criteria and
  - Standardize assessment of risk factors associated with preterm birth for those women who do not meet clinical criteria for preterm labor.
Step 1: Assessment/Supportive Care

1. Place the patient in the triage or labor room for evaluation, which should be completed in 2 to 4 hours.
2. Reassure the patient and her family with careful explanation of all procedures.
3. The registered nurse will review the prenatal record and inquire about previous preterm deliveries.
4. Obtain objective data:
   - External monitor for contractions and fetal heart pattern
   - Routine labs
   - SSE: assess for ruptured membranes, obtain fFN (if ordered)
   - SVE: assess cervical status
   - Preterm labor screen: TVU and/or fFN test
5. Inform OB provider

Step 2: Disposition
Option A — Preterm Labor is Identified

If regular uterine contractions are accompanied by:
   a) Initial SVE with cervical dilation of at least 2 cm AND/OR
   b) Short cervix ≤20 mm long by TVU between 20 and 28 weeks OR
   c) Repeat SVE notes change in cervix (dilation and/or effacement)

Then:
1. Notify provider
2. Administer antenatal corticosteroids if between 24 and 34 weeks gestation
3. Initiate short-term tocolytic therapy, if ordered by provider
4. Admit as inpatient/prepare for transport
5. Activate intervention pathways (e.g., cerclage, vaginal progesterone), if appropriate

Step 2: Disposition
Option B — Preterm Birth Risk Factors

If regular uterine contractions are accompanied by:
   a) Cervix 21-24 mm long by TVU between 20 and 28 weeks gestation
   b) Positive fFN between 22 and 34 weeks gestation

Then:
1. Notify provider
2. Consider antenatal corticosteroids (if between 24 and 34 weeks gestation)
3. Consider situational and patient-specific interventions as ordered by provider
4. Discharge disposition after adequate assessment for cervical change:
   Consider increased frequency of assessment
Step 2: Disposition
Option C — Low Risk of Preterm Labor

If regular uterine contractions and results of ALL factors assessed are negative (cervical dilation of less than 2 cm by SVE, no cervical change at two hours, cervix ≥25 mm long by TVU, negative fFN):

Then:
1. Notify provider
2. Teach patient home care instructions; make aware of risk factors, if any
3. Make follow-up medical appointment in one week
4. Discharge, if ordered by provider

*Assumes intact membranes.

Step 2: Disposition
Option D — fFN & TVU Unavailable

If cervical dilation is less than 2 cm by SVE only (neither fFN nor TVU available):

Recommend serial SVE to assess for cervical change:
1. Wait 2 hours and repeat SVE. Serial SVE may be performed more than once at 2-hour intervals if the 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) ≤32 weeks
2. If cervical change, then:
   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. Consider admission as inpatient/preparation for transport
3. If no cervical change, then:
   A. Notify provider
   B. Teach patient home care instructions; make aware of risk factors, if any
   C. Make follow-up medical appointment in one week
   D. Discharge if ordered by provider

Preterm Labor Assessment at 20 to 23 6/7 Weeks

Challenges:
- Both SVE and SSE assess several important factors but fail to detect early cervix changes such as dilation of the internal os, thus hampering timely interventions
- fFN testing is ineffective at this gestational age, thus not FDA approved
- Consider TVU for cervical length:
  - If ≤15 mm, rescue cerclage and/or start daily progesterone (90mg gel or 200 mg micronized capsule, both by vaginal administration)
  - If ≤25 mm, consider offering cerclage and/or starting daily progesterone (90mg gel or 200 mg micronized capsule, both by vaginal administration)
  - Consider ACS for ≥23 weeks gestation

Preterm Labor Assessment at 34 to 36 6/7 Weeks

- Prodromal labor is a common challenge that can be frustrating to patients due to ongoing symptoms and uncertain timing of delivery.
- There is no data to support intervention for prodromal labor.
- Unless there is a clear indication, augmentation of labor is considered an elective intervention. Elective delivery prior to 39 weeks is associated with increased maternal and neonatal morbidities.

Recommendations:
1. Use traditional assessment by serial cervical exams at least 2 hours apart.
2. Avoid unnecessary interventions. Allow normal progression of latency period to avoid late preterm morbidities such as RDS, hypoglycemia, and jaundice.
3. Educate the patient and her family members to manage expectations and allow informed decision-making.

Preterm Labor Assessment Order Set

Order Set is available to download at: prematurityprevention.org

Home Care Instructions

Home Care Instructions in English and Spanish are available to download at: prematurityprevention.org
Patient Education Materials

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.)

PART II
Implementing PLAT for Quality Improvement
Rapid Cycle Change

MAP-IT Cycle

Mobilize QI team
- Identify hospital champions (administrators, MDs, CNMs, RNs)

Assess
- Explore PLAT implementation as a QI initiative
- Complete internal baseline survey and chart audit
- Research current preterm labor policies and procedures
- Assess existing process and agreement for maternal transport
- Identify clinical staff training needs and barriers to implementation
- Determine availability of in-house, rapid IFN and/or TVU and SSE capabilities 24/7
- Review patient education materials and home care instructions

MAP-IT Cycle

Plan
- Revise/develop preterm labor protocol, order sets, patient education and home care instructions; secure approval
- Purchase laboratory and radiology equipment, if needed
- Develop data collection and evaluation strategies
- Establish target start date for rollout of the new preterm labor assessment protocol
- Confirm maternal transport agreements
MAP-IT Cycle

**Implement**
- Convene department meetings to build buy-in
- Conduct clinical staff trainings
- Hold kickoff event on rollout start date

**Track progress**
- Collect and analyze data to track adherence to patient assessment pathway

Measuring Progress in Standardizing Preterm Labor Assessment

- Number of patients who presented with suspected preterm labor
- Number of patients assessed using PLAT algorithm
- Length of patient stay in clinic or on service
- Percentage of patients who received fFN test or TVU
- Percentage of patients who received ACS

Measuring Progress: Diagnostic Procedure Codes

ICD-9 (ICD-10)/CPT/HCPCS codes are available for:
- Presentation for preterm labor
- fFN
- TVU
- ACS administration
Measuring Progress: Admission and Discharge/Transfer Data

Data on the following scenarios will help evaluate impact on safety, patient outcomes and cost reduction:

• Patients triaged in L&D, determined not to be in preterm labor, sent home undelivered, and later delivered at term
• Patients triaged in L&D, determined not to be in preterm labor, sent home, and later delivered preterm
• Patients triaged in L&D, determined to be in preterm labor, admitted but later sent home undelivered; delivered on a subsequent admission
• Patients triaged in L&D, determined to be in preterm labor, admitted, and delivered preterm on this admission

Measuring Progress: Chart Audit Tool

Chart audit tool is available to download at: prematurityprevention.org

Best Practices for Implementation

• Identify passionate RN, CNM and MD champions
• Collect baseline data to support the need for new or revised policies and procedures. This is a significant driver of moving the change process forward.
• Initiate the change process as a QI project
• Use the implementation checklist contained in PLAT to track implementation steps
• Change takes time and repetition. Therefore, communicate regularly with and educate staff and physicians throughout planning and implementation.
Key Messages

- Compliance and change in clinician behavior and practice requires a commitment to improving both the process and the outcomes. Successful implementation requires both leadership and team collaboration.
- The use of a standard, evidence-based process to triage “threatened PTL” can reduce the costs associated with unnecessary admissions, interventions and maternal transports.
- The PLAT can be an effective tool to improve the timing of Antenatal Steroid administration & neonatal outcomes.
- All clinicians play a significant role in PLAT adoption.

Q & A

Download the PLAT & Other Resources at:

marchofdimes.org