



How-to Guide: Prevent Obstetrical Adverse Events

Prevent obstetrical adverse events by implementing the components of care recommended in this guide.

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Introduction

What is the Institute for Healthcare Improvement?

The Institute for Healthcare Improvement (IHI) is a not-for-profit organization leading the improvement of health care throughout the world. IHI helps accelerate change by cultivating promising concepts for improving patient care and turning those ideas into action. Thousands of health care providers participate in IHI's groundbreaking work.

What is a How-to Guide?

IHI's How-to Guides address specific health care interventions hospitals and/or entire health systems can pursue to improve the quality of health care. These interventions align with several national initiatives of the Institute of Medicine (IOM), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Joint Commission (JC), Centers for Disease Control and Prevention (CDC), as well as the Department of Health and Human Services' "Partnership for Patients" initiative.

IHI Perinatal Improvement Community

The content of this How-to Guide has been developed through the work of faculty and participants in the IHI Perinatal Improvement Community. Since 2005, the Community has provided results-focused improvement opportunities to teams with a wide range of content and improvement experience. The aim of the Community is to create a perinatal unit that reliably delivers care with a goal of zero preventable injury. The Community's content focuses on four key areas to eliminate harm to mothers and their children: leadership support, reliability science, effective teamwork, and patient- and family-centered philosophies and science.

The Case for Preventing Obstetrical Adverse Events

In the United States there are over four million births each year. Although many births may seem uneventful and normal, national data portrays a different scenario. According to national data from 2008, 94% of births listed some type of pregnancy complication.¹ Not only are complications costly to the mother and the family, they are also costly to the system of health care, increasing both the maternal and the neonatal costs of care. For example:

- Stays with pregnancy-related complications tended to be longer (2.9 days for non-delivery stays and 2.7 days for delivery stays) than delivery stays without complications (1.9 days).
- Maternal stays with complications were about 50% more costly (\$4,100 for non-delivery stays and \$3,900 for delivery stays) than delivery stays without complications (\$2,600).
- Maternal stays with pregnancy and delivery-related complications accounted for \$17.4 billion, or nearly 5% of total hospital costs in the United States.¹

In addition to pregnancy complications, adverse events (harm) also occur while the mother is in the hospital. IHI defines an adverse event as *any noxious or unintended event occurring in association with medical care*.² For some events and by this definition, pregnancy complications may also be identified as an adverse event. Many of the adverse events that occur are the result of system failures, not individual failures. It is now known that by creating a more reliable system of care we will be able to prevent, mitigate, and identify opportunities to prevent harm.³

In 2004, IHI developed two perinatal care “bundles” — the Elective Induction Bundle and the Augmentation Bundle — and tested these bundles in the IHI Idealized Design of Perinatal Care project.³ “Bundles” are a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually. Experience from the use of bundles in other clinical areas, such as care of the ventilated patient, has shown that reliably

¹ Elixhauser A, Wier LM. *Complicating Conditions of Pregnancy and Childbirth, 2008*. HCUP Statistical Brief #113. May 2011. Rockville, MD: Agency for Healthcare Research and Quality. Available at: <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb113.pdf>.

² Griffin FA, Resar RK. *IHI Global Trigger Tool for Measuring Adverse Events (Second Edition)*. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2009. Available at: <http://www.ihl.org/knowledge/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx>.

³ Cherouny PH, Federico FA, Haraden C, Leavitt Gullo S, Resar R. *Idealized Design of Perinatal Care*. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2005. Available at: <http://www.ihl.org/knowledge/Pages/IHIWhitePapers/IdealizedDesignofPerinatalCareWhitePaper.aspx>.

applying these evidence-based interventions can dramatically improve outcomes.⁴ This innovative work led to the hypothesis that the use of bundles in the delivery of perinatal care would have a similar effect.

IHI has found that reliable design reduces unintended variation and perinatal harm. Examples of outcome improvements include: reduction in harm to less than 5% (as defined by the [IHI Perinatal Trigger Tool](#)⁵); a reduction in babies transferred to an elevated level of care; improved teamwork and communication; and the elimination of elective deliveries prior to confirmation of fetal maturity by current standards, which usually requires gestational age greater than or equal to 39 weeks.

Bundles themselves do not improve outcomes; the ability of the team to reliably implement every bundle element for all patients, unless medically contraindicated, advances care to achieve the improved outcomes. In order to achieve a high level of reliability, teamwork and communication is an essential ingredient to ensure success.

The most important idea underlying bundles is the “all-or-none” concept: a team gets credit for implementing the bundle only if every bundle element is delivered for each patient, unless medically contraindicated. This goal serves as a change catalyst that moves a team toward a design in which all elements of the bundle will be successfully delivered (defined as delivered to the patient).⁶ Providing care in the usual manner will not accomplish this level of reliable design. The “all-or-none” measurement criterion also provides a different perspective on care delivery: the view of the patient.

Most organizations and clinicians assume that policy and procedure result in high compliance. Similar to findings using the IHI Ventilator Bundle, when clinicians collected their initial data using the IHI Perinatal Bundles, they were surprised at the low levels of all-or-none compliance. Many obstetrical units reported 10% to 20% compliance at best. Participants and faculty in the IHI Perinatal Improvement Community, the next phase of the Idealized Design work, were thus motivated to change processes in their obstetrical units to improve their reliability rates. It is important to note that measuring compliance with each bundle element, as well as all-or-none compliance, is the first step in building a reliable system. It both allows teams to find their most problematic areas and helps build will for improvement by acknowledging the low number of patients who receive all the care they need and deserve.⁷

⁴ Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012. Available at: <http://www.ihi.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>.

⁵ IHI Perinatal Trigger Tool. Cambridge, MA: Institute for Healthcare Improvement. Available at: <http://www.ihi.org/knowledge/Pages/Tools/PerinatalTriggerTool.aspx>.

⁶ Nolan T, Resar R, Haraden C, Griffin FA. *Improving the Reliability of Health Care*. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2004. Available at: <http://www.ihi.org/knowledge/Pages/IHIWhitePapers/ImprovingtheReliabilityofHealthCare.aspx>.

⁷ Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012. Available at: <http://www.ihi.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>.

Potential Impact

Admission for childbirth is the number one reason for admission to the hospital in the United States. As noted previously, there are significant cost implications to obstetrical complications and adverse events.⁸ The health care dollar implication is significant when looking at the numbers in aggregate. However, the cost to the patient — mother or neonate — is difficult to calculate when looking at psychological or physical injury from the immediate or long-term perspective.

The goal of Idealized Design of Perinatal Care is to achieve a new level of safer, more effective care and to improve the outcomes of mothers and neonates. Once the appropriate structure and process have been reliably implemented and outcomes have improved, the risk of medical malpractice has been shown to decrease. In 2008, Clark et al. published the results from the Hospital Corporation of America's (HCA) work. According to the authors, in the HCA system with over 200 hospitals nationwide, "obstetric malpractice claims currently rank behind 'accidents on hospital grounds' in terms of litigation loss and cost." They believe that "fewer adverse perinatal outcomes lead to less litigation" and reported a "downward trend from 14 claims per 10,000 births in 1998 to 6 claims in 2006."⁹ Several IHI Perinatal Improvement Community teams, who have continuously participated in the Community for over three years, have developed a highly reliable system and have self-reported the same results to IHI.

A study published by authors from Yale-New Haven also cited the following conclusion: "a systematic strategy to decrease obstetric adverse events can have a significant impact on patient safety."¹⁰

⁸ Elixhauser A, Wier LM. *Complicating Conditions of Pregnancy and Childbirth*, 2008. HCUP Statistical Brief #113. May 2011. Rockville, MD: Agency for Healthcare Research and Quality. Available at: <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb113.pdf>.

⁹ Clark SL, Belfort MA, Byrum SL, et al. Improved outcomes, fewer cesarean deliveries, and reduced litigation: Results of a new paradigm in patient safety. *Am J Obstet Gynecol*. 2008; Aug;199(2):105.e1-7.

¹⁰ Pettker CM, Thung SF, Norwitz ER, et al. Impact of a comprehensive patient safety strategy on obstetric adverse events. *Am J Obstet Gynecol*. 2009; 200:492.e1-492.e8.

Essential Elements of Prevention of Obstetrical Adverse Events

Introduction to Safe Use of Oxytocin and the IHI Oxytocin Bundles

The rate of labor induction in the United States has more than doubled since the late 1990s, with close to 25% of pregnant women undergoing scheduled induction. The most commonly used drug for induction is oxytocin.¹¹ The method for administering this commonly used drug is a source of disagreement between nurses and doctors. Sources of disagreement include what is a safe dose; what is the safe frequency and intensity of contractions; when should oxytocin be used; whether a given hospital should have a standardized concentration; and how oxytocin should be administered. Furthermore, the drug is strongly associated with medical malpractice claims in the US and abroad.¹²

The IHI Oxytocin Bundles have evolved over the seven years since they were initially developed. Two significant events occurred that helped to reduce discussion and clinical controversy. First, in 2007, the Institute for Safe Medication Practices (ISMP) added oxytocin to its list of high-alert medications.¹³ Second, in 2008, the Eunice Kennedy Shriver National Institute for Child Health and Human Development sponsored a workshop focused on fetal heart rate monitoring. The result of this workshop was an updated nomenclature to describe fetal heart patterns and classifications, and the definitions of uterine contraction patterns. The revised nomenclature and definitions were simultaneously adopted by the American Congress of Obstetricians and Gynecologists (ACOG) and Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and published as the standard of care in the fall of 2008.¹⁴

According to the ISMP, high-alert medications are *medications that bear a heightened risk of causing significant patient harm when used in error*.¹³ Because the effects of these errors can be devastating to the patient — in the case of labor induction there are two patients at risk — the ISMP recommends the use of the following strategies to improve safety of high-alert medications:

- Improve access to information about the drug;
- Limit access;
- Appropriately label the medication;

¹¹ ACOG Practice Bulletin No. 107: Induction of labor. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2009 Aug;114(2 Pt 1):386-397.

¹² Miller LA. Oxytocin, excessive uterine activity, and patient safety: Time for a collaborative approach. *Perinat Neonat Nurs*. 2009; 23(1):59-68.

¹³ ISMP's List of High-Alert Medications. Institute for Safe Medication Practices. Available at: <http://ismp.org/Tools/highalertmedications.pdf>.

¹⁴ ACOG Practice Bulletin No. 106: Intrapartum fetal heart rate monitoring: Nomenclature, interpretation, and general management principles. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2009 Jul;114(1):192-202.

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- Standardize the ordering, storage, preparation, and administration; and
- Employ redundancies or double checks in the process of care.

Of particular importance to the use of oxytocin was the updated terminology from the American Congress of Obstetricians and Gynecologists to describe uterine activity.¹⁵

- *Normal*: Five contractions or less in ten minutes averaged over a 30-minute window
- *Tachysystole*: More than five contractions in a 10-minute window and averaged over 30 minutes

Additionally, a practice standard described by ACOG states that whenever a patient is receiving oxytocin during the intrapartum period, a qualified obstetrician who can perform an immediate cesarean section must be available should the need arise. (See “IHI Perinatal Improvement Community Bundle Sequencing” on page 17.)

¹⁵ Miller LA. Oxytocin, excessive uterine activity, and patient safety: Time for a collaborative approach. *Perinat Neonat Nurs*. 2009; 23(1):59-68.

1. IHI Elective Induction Bundle (Oxytocin)

Review of medical malpractice claims reveals that oxytocin, which stimulates uterine contractions and induces labor, is involved in more than 50% of the situations leading to birth trauma. To minimize the opportunity for harm, it is necessary to understand the pharmacology of the drug and its impact on the fetus. With this knowledge, protocols should exist to guide its appropriate use.

The IHI Elective Induction Bundle (Oxytocin) has four elements that must be considered when using oxytocin to induce labor:

1. Assess gestational age (ensure fetal maturity, which generally equates to gestational age greater than or equal to 39 weeks).
2. Recognize and manage fetal heart rate status (NICHD Category I).
3. Conduct a pelvic assessment.
4. Recognize and manage tachysystole.

[Note that bundle elements 2, 3, and 4 are ongoing as long as oxytocin is administered.]

These four bundle elements were selected by expert faculty who helped IHI develop the bundle and are based on recommendations for care supported by standard setting organizations, including ACOG and AWHONN, and referenced in the Guidelines for Perinatal Care.¹⁶

IHI Elective Induction Bundle (Oxytocin) Elements

1. Assess gestational age (ensure fetal maturity, which generally equates to gestational age greater than or equal to 39 weeks).

Before the elective induction of labor is initiated, fetal maturity must be confirmed. In practice, this means it must be determined that the fetus has a **gestational age of greater than or equal to 39 weeks**. This determination must be documented according to agreed upon standards within the organization in compliance with recommendations established by ACOG. Although babies are electively delivered before 39 weeks of gestational age up to one-third of the time, ACOG guidelines and other research report that the likelihood of harm to the baby from elective delivery is greater before 39 completed weeks. The March of Dimes (MOD) has published new scientific information that also shows brain growth for the fetus at 35 weeks is only two-thirds of what it will be at 40 weeks.¹⁷ In the event of an adverse outcome, plaintiffs' attorneys may use non-compliance with this current guideline as an indicator of poor care.

¹⁶ Ong S. Guidelines for perinatal care, 6th edition. *The Obstetrician & Gynaecologist*. 2008 Jul;10(3):207.

¹⁷ Get ready for labor: Why at least 39 weeks is best for your baby. Available at: http://www.marchofdimes.com/pregnancy/getready_atleast39weeks.html.

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What changes can we make that will result in improvement?

- Implement the ACOG criteria for the accurate determination of gestational age as the organizational standard.
- Require verification that criteria are met prior to every booking of an elective delivery or scheduled cesarean by requiring the prenatal record.
- Use a checklist of gestational age determination criteria to aid in verification.
- Use standardized guidelines supported by the medical staff, with a clear escalation policy when recognition reveals gestation dating is not accurate. The escalation policy's intent is to ensure accurate dating to avoid unintended sequelae related to elective delivery.
- Engage prenatal office staff in the process so that there is understanding of the reasons for the organizational standard, the need for the prenatal record, and clear communication of criteria.
- Engage patients in the process early in the pregnancy by collaborating in the establishment of confirmation of the estimated due date. (See IHI/Childbirth Connection tool.¹⁸)
- Review all cases of deliveries occurring prior to 39 weeks of gestation. This review can serve to improve criteria and definition, as well as to identify opportunities for further education and improvement.
- Educate staff and new obstetrical care providers regarding indications and criteria during their initial training, as well as during ongoing educational programs (such as for annual competencies).
- Collect data on all (medical) deliveries occurring in the gestational age group of 37.0 through 38.6 weeks and provide this data to the medical staff. It is important to collect further data by *indicator* for delivery so the organization is able to study the reasons and appropriateness for delivery occurring in this gestational age group. Although the Joint Commission and Leapfrog provide medical reasons for delivery prior to 39 established weeks, it is important to also understand the local factors contributing to reasons why deliveries occur in this specific age range in a particular organization. Learning from the different indicators that medically support delivery will allow additional opportunities for improvement in the care of women who are required to deliver in this gestational age group.

¹⁸ “Which Due Date Should I Use?” Worksheet. Childbirth Connection and the Institute for Healthcare Improvement. Available at: http://childbirthconnection.org/pdfs/Which_Due_Date_Should_I_Use.pdf.

2. Recognize and manage fetal heart rate status (NICHD Category I).

Prior to the administration of oxytocin for an elective induction, monitoring fetal heart rate for well-being is determined using the National Institute for Child Health and Human Development (NICHD) terminology (establishment of the Category I criteria). Additionally, clinicians need to *monitor fetal heart rate and the effects of uterine stimulants on the fetus throughout the entire process of labor*, and ensure the availability of a physician capable of performing an emergency cesarean section should it be necessary.

For the first time, two major governing organizations, ACOG and AWHONN, have accepted the definitions of fetal monitoring developed by the NICHD. This adoption is based on the goal of using a standard terminology to describe fetal heart rate monitoring and then developing an agreed upon action plan to ensure compliance with this bundle element. According to ACOG, “the presence of fetal heart rate accelerations generally ensures that the fetus is not acidemic and provides reassurance of fetal status.”¹⁹ Because the positive predictive value of reassuring fetal assessment is high (greater than 99%), it is vital that definitions are accepted and used by all members of the care team.

What changes can we make that will result in improvement?

The goal is to *prevent* fetal compromise by administering oxytocin when it is indicated and provided in a safe manner.

- Use multidisciplinary education and a structured algorithm in order to train staff to *identify* or recognize failures in oxytocin administration. The algorithm is designed to mitigate oxytocin administration failures to prevent harm.
- Adopt a standardized fetal monitoring educational program for both medical and nursing staff, and develop credentialing standards to be supported by the organization.
- Provide ongoing education in the form of fetal monitoring case reviews that are multidisciplinary in focus; include formal (e.g., grand rounds, case reviews) and informal reviews (e.g., fetal monitoring reviews at the nurses station).
- Incorporate NICHD terminology in all documentation of fetal heart rate status.
- Adopt fetal heart rate management algorithms (see example on page 13) based on the three-tiered NICHD Fetal Heart Rate Status Categories (defined on page 12), with clear action plans to guide the multidisciplinary team to respond appropriately for each category. These action plans will prevent the failure-to-rescue outcomes that occur when left to individual care plans.

¹⁹ ACOG Practice Bulletin No. 62: Intrapartum fetal heart rate monitoring. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2005 May;105(5 Pt 1):1161-1169.

Classification of the NICHD Fetal Heart Rate (FHR) Status Categories

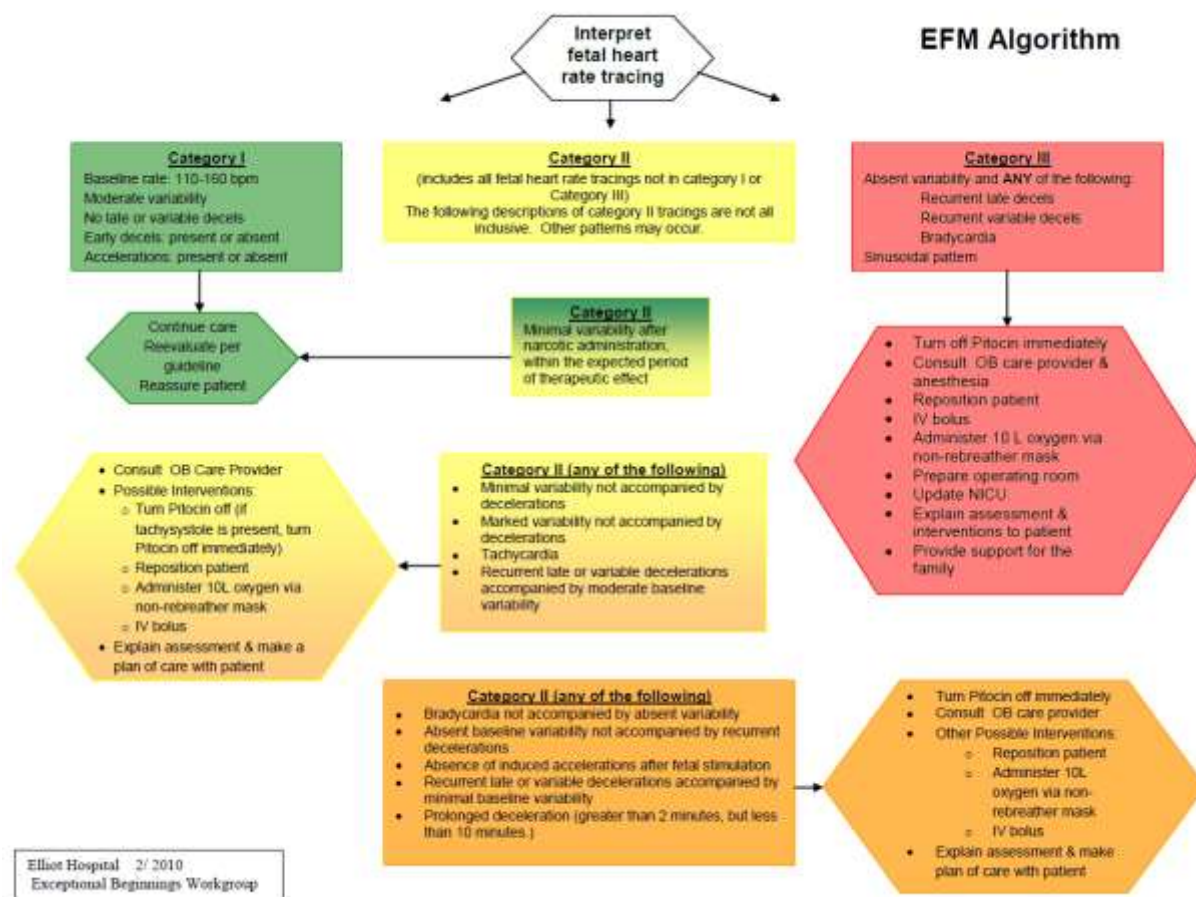
Category I FHR tracings are normal. Category I FHR tracings are strongly predictive of normal fetal acid-base status at the time of observation. Category I FHR tracings may be monitored in a routine manner and no specific action is required.

Category II FHR tracings are indeterminate. Category II FHR tracings are not predictive of abnormal fetal acid-base status, yet presently there is not adequate evidence to classify these as Category I or Category III. Category II FHR tracings require evaluation and continued surveillance and reevaluation, taking into account the entire associated clinical circumstances. In some circumstances, either ancillary tests to ensure fetal well-being or intrauterine resuscitative measures may be used with Category II tracings.

Category III FHR tracings are abnormal. Category III tracings are associated with abnormal fetal acid–base status at the time of observation. Category III FHR tracings require prompt evaluation. Depending on the clinical situation, efforts to expeditiously resolve the abnormal FHR pattern may include, but are not limited to, provision of maternal oxygen, change in maternal position, discontinuation of labor stimulation, treatment of maternal hypotension, and treatment of tachysystole with FHR changes. If a Category III tracing does not resolve with these measures, delivery should be undertaken.²⁰

²⁰ ACOG Practice Bulletin No. 106: Intrapartum fetal heart rate monitoring: Nomenclature, interpretation, and general management principles. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2009 Jul;114(1):192-202.

Example Electronic Fetal Monitoring (EFM) Algorithm



Source: Elliot Hospital, Manchester, New Hampshire

3. Document pelvic examination and use Bishop Score.

The provider should perform and document pelvic examination to determine dilation, effacement, station, cervical position and consistency (Bishop Score), fetal presentation, and adequacy of the maternal pelvis. The results of this examination will confirm the patient success as a candidate for induction and assist in determining whether or not induction is best attempted at that time. Contemporary assessment of the pelvis and cervix is needed prior to proceeding with induction of labor.

What changes can we make that will result in improvement?

- At the individual hospital level, discuss which Bishop Scoring system you will use and define.
- Require Bishop Score documentation prior to the initiation of oxytocin.
- At the department level, determine and discuss compliance with the pelvic exam prior to the initiation of oxytocin by an obstetrical care provider as required by ACOG criteria; communicate determination to all stakeholders.

4. Recognize and manage tachysystole.

Finally, because it is a frequent and potentially consequential occurrence during induced labor, tachysystole must be identified using a standard definition and documented. A corresponding plan for a consensus response to the tachysystole must also be made. The overall goal is to monitor for tachysystole and respond appropriately. The definition of tachysystole has been adopted and standardized as part of the 2008 NICHD update and is published in that document, as described below.

Characteristics of uterine contractions:

- The terms hyperstimulation and hypercontractility are not defined and should be abandoned.
- Tachysystole should always be qualified as to the presence or absence of associated FHR decelerations.
- The term tachysystole applies to both spontaneous and stimulated labor. The clinical response to tachysystole may differ depending on whether contractions are spontaneous or stimulated.²¹

What changes can we make that will result in improvement?

- At the individual hospital level, discuss in a multidisciplinary meeting the adoption of the NICHD/ACOG definition for tachysystole.
- At the individual hospital level, standardize the recognition and management of tachysystole by developing algorithms and a standard order set.
- Educate all staff and ensure staff and obstetrical care providers are aligned in support of the algorithm and criteria. Encourage feedback after testing the algorithm with patients who are undergoing elective medical induction.
- Provide informed consent to the patient regarding the risks and benefits of the use of the drug oxytocin for induction of labor.

²¹ ACOG Practice Bulletin No. 106: Intrapartum fetal heart rate monitoring: Nomenclature, interpretation, and general management principles. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2009 Jul;114(1):192-202.

- Standardize protocols for administering oxytocin to a minimum of one low dose protocol and one high dose protocol that are also linked to the documentation system.
- Provide case reviews and real-time feedback to nursing and obstetrical care providers on compliance rates with the appropriate tachysystole recognition and management system. For example, huddle hourly at the nursing station to review the fetal monitoring pattern of any patient receiving oxytocin.
- Develop an escalation policy to standardize the response to any opt out situations by any provider administering oxytocin.
- Collect data on the use of terbutaline and emergency cesareans performed as a result of the overuse of oxytocin.

2. IHI Augmentation Bundle (Oxytocin)

Augmentation of labor is a coordinated effort to enhance uterine contractions for a woman who is already in labor. One reason to augment labor is inadequate contractions in terms of strength or frequency, resulting in inadequate progress of labor. Oxytocin is used to augment uterine contractions.

The IHI Augmentation Bundle (Oxytocin) has four elements:

- Estimate fetal weight.
- Recognize and manage fetal heart rate status (exclusion of NICHD Category III).
- Conduct pelvic assessment.
- Recognize and manage tachysystole (same definition as in the Elective Induction Bundle).

Estimation of fetal weight replaces gestational age in this bundle. Since cephalopelvic disproportion may prevent the progression of labor, estimated fetal weight assessment is used to exclude fetal weight as a cause. It is also important to know the size of the fetus to determine whether a continued attempt at vaginal delivery is appropriate when faced with a labor abnormality. Monitoring for fetal reassurance and for uterine tachysystole and the teams' subsequent responses to both have the same implications as in the Elective Induction Bundle. Again, pelvic assessment should be performed and documented by pelvic examination before the augmentation is initiated.

The Oxytocin Bundles (Elective Induction and Augmentation) have continued to evolve over time, resulting in two implementation levels. The Elective Induction and Augmentation Bundles are the first level of implementation for reliable execution. In 2010, a second more advanced tier was added to the bundles. Below is a description of all the bundles currently being used by the IHI Perinatal Improvement Community, with the exception of the Vacuum Bundle, which is described separately below.

What changes can we make that will result in improvement?

- At the individual department level, determine and define how and by whom the estimated fetal weight will be determined.
- Define how documentation of the estimated fetal weight (EFM) will occur, which may include the estimate in grams or pounds and/or the use of terminology such as SGA/AGA/LGA.
- At the individual department level, discuss any additional actions that the team needs to take or be aware of when the EFW is greater than 4,500 grams. Have a communication plan whenever it is determined that the fetus may be at risk for shoulder dystocia and use this plan as a critical component of a pre-procedure briefing.
- As a team, agree on the definition of labor and when augmentation is appropriate.

IHI Perinatal Improvement Community Bundle Sequencing			
Elective Induction Bundle (Initial-Oxytocin)		Augmentation Bundle (Initial-Oxytocin)	IHI Oxytocin Bundles (2004)
<ul style="list-style-type: none"> Gestational age (GA) >39 weeks Pelvic assessment Recognition and management of tachysystole Recognition and management of fetal heart rate (FHR) Status (NICHD Category I-Normal) 		<ul style="list-style-type: none"> Estimated fetal weight (EFW) documented Pelvic assessment Recognition and management of tachysystole Recognition and management of FHR status (Exclusion of NICHD Category III) 	<p>Basic Oxytocin Bundles: Defined as patient who receives oxytocin for elective induction or augmentation. Focus on eliminating elective delivery prior to 39 weeks and reliable execution of component indicators.</p>
Advanced Elective Induction Bundle	Advanced Indicated Induction Bundle	Advanced Augmentation Bundle	IHI Advanced Bundles (2010)
<p>Defined: Patient without a medical indication for delivery between 39 and 40+6 weeks gestational age</p> <ul style="list-style-type: none"> GA >39 weeks Pelvic assessment: Favorable Bishop Score* (locally defined) Recognition and management of complications of induction method (including tachysystole) Recognition and management of FHR Status (NICHD Category I-Normal) 	<p>Defined: Patient with a medical indication for induction</p> <ul style="list-style-type: none"> Acceptable medical indication for labor induction documented (locally defined) Pelvic assessment Recognition and management of complications of induction method (including tachysystole) Recognition and management of FHR Status (Exclusion of NICHD Category III) 	<p>Defined:</p> <ul style="list-style-type: none"> EFW documented Pelvic assessment Recognition and management of tachysystole Recognition and management of FHR Status (NICHD Category I-Normal) (Exclusion of NICHD Category III) <p>(May include amniotomy, nipple stimulation, acupuncture, and oxytocin)</p>	<ul style="list-style-type: none"> Accept 39 weeks as minimal GA for elective delivery Focus moves to pharmacologic or mechanical initiation of labor — no longer focused on (just) oxytocin Evidence-based gestational dating is core** <hr/> <p>Vacuum Bundle (2008)</p>
<p>* Generally defined as a Bishop Score ≥ 9 on the 13-point scale, prior to cervical maturation, which indicates the patient has the same cesarean section rate as the spontaneously laboring patient. Modifications of the Bishop Score based on current literature is acceptable, for instance, adding points for multiparous patients, etc.</p> <p>** First day of last menstrual period (LMP) should be:</p> <ol style="list-style-type: none"> 1) accurately known and documented 2) in a patient with regular menstrual cycles (28-30 days) 3) one who has not recently come off hormonal contraception <p>If all conditions are not met, the gestational dating should be established by ultrasound, preferably between 6 and 12 weeks, by multiple crown rump length measurements that are recorded for review as needed (Yolk sac or gestational sac measurement is not acceptable for accurate dating). If the patient is beyond 12 weeks, an ultrasound prior to 20 weeks with multiple biometric measurements (BPD, HC, AC, bone length) is preferable after 14 weeks as there is a loss of accuracy in gestational dating between 12 and 14 weeks by all methods.</p> <p>If all conditions are met, and the ultrasound performed in the first trimester is within 7 days (or if the first ultrasound is performed in the second trimester prior to 20 weeks is within 10 days) of the accurately known LMP in the regularly cycling patient not recently off hormonal contraception, the LMP dating can be used. It is always acceptable to use the first trimester ultrasound dating if performed in a quality ultrasound setting that includes quality review. Pregnancies resulting from in vitro fertilization should be dated based on the date of fertilization (as the ovulation date) or the age of the embryos in days at transfer from fertilization date.</p> <p>Once established, the gestational dating should not be changed. However, it is important to consider the error of gestational dating for clinical management issues. For instance, one might consider beginning post dates fetal assessment in the patient who is 41 weeks by accurate LMP dating whose gestational dating is established by a first trimester ultrasound which was 6 or 7 days earlier than the menstrual dating.</p>			
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3. IHI Vacuum Bundle

We have described the inappropriate use of oxytocin and developed the IHI Oxytocin Bundles (Elective Induction Bundle and Augmentation Bundle) to mitigate two of the conditions that contribute to birth trauma: inappropriate use of oxytocin and inadequate assessment of the fetus. A third bundle was developed to mitigate the birth trauma associated with operative vaginal deliveries. National statistics on operative vaginal birth indicate that the incidence may be somewhere between 10-15% of all deliveries.²²

Operative vaginal deliveries pose a significant risk to both the mother and fetus during delivery. Significant variation in the frequency of operative vaginal delivery has been observed by provider and institution. In order to reduce variation in the response and treatment from the health care team, IHI developed the Vacuum Bundle. Some of the IHI Perinatal Improvement Community teams have also adopted many of the components in the use of forceps or combined the elements for an operative delivery bundle.

As in all obstetric interventions, it is always important to weigh the consequences of the intervention against the consequences of other care options, such as continued observation. Some of the consequences of vacuum or forceps use are scalp lacerations, retinal hemorrhages, cephalohematomas, subgaleal hemorrhages, intracranial hemorrhages, hyperbilirubinemia, and maternal trauma. ACOG advises against the use of sequential instruments except under conditions in which it may not be possible to perform an immediate cesarean section.

Table 1. Effect of Delivery on Neonatal Injury

Delivery Method	Death	Intracranial Hemorrhage	Other*
Spontaneous vaginal delivery	1/5,000	1/1,900	1/216
Cesarean delivery during labor	1/1,250	1/952	1/71
Cesarean delivery after vacuum/forceps	N/R	1/333	1/38
Cesarean delivery with no labor	1/1,250	1/2,040	1/105
Vacuum alone	1/3,333	1/860	1/122
Forceps alone	1/2,000	1/664	1/76
Vacuum and forceps	1/1,666	1/280	1/58
Abbreviation: N/R indicates not reported.			
*Facial nerve/brachial plexus injury, convulsions, central nervous system depression, mechanical ventilation			
From: Towner D, Castro MA, Eby-Wilkens E, Gilbert WM. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. <i>N Engl J Med.</i> 1999;341:1709-1714.			

The components of the Vacuum Bundle were designed with a focus on alternatives to vacuum delivery and the safe and appropriate use of the device. The bundle is a reliability tool designed for a multidisciplinary team to perform the procedure on appropriate patients as safely as possible.

²² ACOG Practice Bulletin No. 17: Operative vaginal delivery. American College of Obstetricians and Gynecologists; 2000.

Vacuum Bundle Elements

1. Consider alternative labor strategies.

This bundle element addresses strategies during the second stage of labor and should be considered once the patient is fully dilated. Alternatives may include resting the patient with no urge to push (passive descent); specific strategies for the patient with an epidural; and pushing and breathing techniques (such as pushing with every other contraction).

2. Prepare patient by discussing and documenting informed consent.

Overall, the incidence of serious complications with the use of the vacuum extractor is 5%.²³ Therefore, it is important that the patient is aware of the possible outcomes with the use of this intervention. During a prenatal care office visit, the patient should be presented with the risk and benefits of vacuum use and the provider should ensure that informed consent is documented.

3. Know high probability of success with EFW, fetal position, and station.

ACOG reports that a randomized study identified three factors associated with the development of shoulder dystocia: use of vacuum device, time required for delivery, and birth weight. They also report in Practice Bulletin No. 17 that data from a California study identifies the highest risk of fetal injury occurs when both the vacuum and forceps are used during a delivery or when a vaginal operative attempt is followed by cesarean delivery.²³ In light of this data, knowing the EFW, fetal position, and station will help to achieve a high probability of success.

4. Determine maximum vacuum device application time and pop-offs.

A local team should establish parameters for maximum vacuum device application time and pop-offs based on the type of equipment used at the facility and the corresponding manufacturer recommendations for the available equipment. The practice and use of vacuum devices should be designed to enable staff to communicate effectively during the procedure regarding these parameters.

5. Make a contingency strategy, including a cesarean and resuscitation team.

It is recommended that a pre-briefing huddle be part of the strategy for using the vacuum device to ensure that the operating room and nursery staff is immediately available should the use of the vacuum fail, thereby avoiding delay in care or rescue.

²³ ACOG Practice Bulletin No. 17: Operative vaginal delivery. American College of Obstetricians and Gynecologists; 2000.

What changes can we make that will result in improvement?

- Include strategies for effective monitoring and ongoing care of both patients — mother and neonate — involved in the use of the vacuum.
- Adopt the AWHONN Second Stage of Labor Algorithm to standardize the nursing care of the patient in the second stage of labor.²⁴
- Brief the pre-procedure team prior to the administration of the vacuum for delivery so all team members are aware of the care plan. The team should be prepared to mitigate any possible complications, including acknowledgement of where the delivery should occur — i.e., in the labor or cesarean room — and the availability of personnel able to perform a cesarean delivery and infant resuscitation, if necessary.
- Standardize equipment available on the unit in order to appropriately and reliably train all individuals in its use in order to be fully prepared.
- Develop and implement credentialing standards for medical staff in the use of vacuums.
- Review all deliveries where the vacuum is used. Because the number of deliveries utilizing the vacuum are predominantly small, identify areas for improvement and provide feedback to the department. It has been shown that use of vacuum equipment is often not documented or communicated to staff and providers caring for the infant, especially when used as part of a scheduled cesarean delivery.
- Identify the neonate as high risk whether or not an injury is visible. Ensure appropriate handover and reliable communication of vacuum equipment usage to the parents and the pediatric provider.
- Identify and mitigate any clinical changes in the neonate as the result of vacuum application through continued surveillance of the neonate and partnership with parents.

²⁴ *Nursing Care and Management of the Second Stage of Labor: Evidence-Based Clinical Practice Guideline, 2nd Edition*. Washington, DC: Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN); 2007.

Reliable Design Strategy

The IHI Perinatal Team initially developed the IHI Elective Induction and Augmentation Bundles (Oxytocin Bundles) based on data that demonstrated oxytocin administration was not reliable and was linked to medical malpractice cases. Since many women receive oxytocin during labor, the team chose this drug as its starting point for improving safety. Despite hospitals having policies and guidelines in place, results showed that the process of oxytocin administration was autonomous and often dependent on nurse and physician personal preference and experience, rather than on standardization. It is essential that all clinical personnel understand reliable design and the IHI bundle methodology; reading the IHI white paper “[Using Care Bundles to Improve Health Care Quality](#)” is strongly recommended.²⁵ Excerpts from the white paper follow.

Bundle Design

When designing care bundles, the following design guidelines have proved helpful:

Bundle Design Guidelines
<ul style="list-style-type: none"> • The bundle has three to five interventions (elements), with strong clinician agreement. • Each bundle element is relatively independent. • The bundle is used with a defined patient population in one location. • The multidisciplinary care team develops the bundle. • Bundle elements should be descriptive rather than prescriptive, to allow for local customization and appropriate clinical judgment. • Compliance with bundles is measured using all-or-none measurement, with a goal of 95 percent or greater.

The bundle has three to five interventions (elements), with strong clinician agreement.

The goal of the bundle approach is to pull together the short list of interventions and treatments that are *already recommended* and that are generally accepted in national guidelines and by local consensus of clinicians as being appropriate care for the population of focus. Including only those elements that most clinicians accept as being applicable to most patients in the population allows the team to move forward with improvement, rather than spend time debating the validity of the elements. Moreover, as the number

²⁵ Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012. Available at: <http://www.ihl.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>.

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of bundle elements increases, it becomes geometrically more difficult to achieve high compliance with the all-or-none measure. Since the intent is neither to create a comprehensive care protocol nor to include elements that vary in their applicability to individual patients, three to five bundle elements is most successful.

Each bundle element is relatively independent.

The bundle is designed so that if one of the elements of care is not implemented for a patient, it should not affect whether other bundle elements are implemented. For example, in the IHI Central Line Bundle, if the central line insertion site was not cleansed with chlorhexidine (one of the bundle elements), the remaining four Central Line Bundle elements still could be implemented.

The bundle is used with a defined patient population in one location.

The bundle is most successfully applied to a discrete patient population in a defined location — for example, patients on ventilators in the ICU. Care teams physically working together in the same location with a defined patient population allows for strategies to achieve all-or-none bundle compliance that are not always transferable when multiple teams across locations are involved.

For example, the bundle approach was tested in an IHI Collaborative on perioperative safety, using the surgical site infection (SSI) prevention measures from the Surgical Care Improvement Project (SCIP). These measures cross multiple geographic areas — the preoperative holding area, the operating room, postanesthesia care, and the postoperative ward — and occur at different times in the perioperative process. There were often at least four different teams involved, one or more from each geographic area, that rarely came in contact with each other. Although teams were able to improve the individual elements of care that occurred in their respective areas, the bundle approach was less successful — that is, participants found it difficult to develop strategies that applied to all team members towards moving the all-or-none measure for SSI.

If a particular type of harm (e.g., sepsis) occurs in more than one location, develop a bundle for each location and design good handoffs. For example, there are two IHI Sepsis Bundles — one for management of septic patients in the emergency department, and another for management of septic patients in the ICU.

The multidisciplinary care team develops the bundle.

Communication and teamwork are fundamental to the success of a bundle. Having bundles developed by care teams with members from many disciplines will improve the likelihood of the bundle's acceptance and success.

Bundle elements should be descriptive rather than prescriptive, to allow for local customization and appropriate clinical judgment.

As noted previously, it is essential that bundle elements have the consensus of local clinicians. In some cases, the science or generally accepted opinion may support a general care element, but the care element could be implemented in several ways or have varying interpretations. For example, the deep vein thrombosis and peptic ulcer disease prophylaxis elements of the IHI Ventilator Bundle do not specify the type of prophylaxis. Local clinicians will determine the appropriate form for their patient population and care setting. Bundle elements must be applied sensibly; they should never be forced when clinically inappropriate, and there should always be an “opt out” choice. All exceptions should be documented in the patient record so that all members of the care team are aware of the rationale.

Compliance with bundles is measured using all-or-none measurement, with a goal of 95 percent or greater.

Compliance with bundles is measured by documentation of adherence to all elements of the bundle using a simple “yes” or “no.” If all elements have been accomplished, or if an element was documented as medically contraindicated (with the goal that all care team members know the rationale for exceptions, which may change over time), the bundle is counted as complete for that patient. If any of the elements are absent in the documentation, the bundle is incomplete (no “partial credit” is given).

Bundles are designed around specific elements of care received by a patient; thus the patient should be the denominator for each bundle element. We do *not* recommend including general processes that are not patient interventions (for example, hand hygiene or contact precautions, which are measured as compliance by observed opportunity of caregiver interaction; or room cleaning, which is measured daily), as this may lead to a mixed measure that is difficult to track. The percent of all-or-none compliance for a bundle always focuses on a patient population (e.g., the percentage of patients on ventilators in the ICU who received all bundle elements, or had documentation of contraindications). This all-or-none measurement approach for bundles focuses attention on the importance of delivering all elements of the bundle to the patient, unless medically contraindicated.

Theory of Change: Why Do Bundles Produce Better Outcomes?

Changes to care, those changes are extensions of a theory of how they will work to improve care. Theory can be broadly described as a proposed explanation for an observed phenomenon derived using a scientific method. For implementation of bundles, the “theory of change” is essentially the answer to the question, “Why do bundles of care, when systematically and reliably applied, produce better outcomes for patients?”

We found that using bundles and all-or-none measurement change the way care is provided in important ways.

1. Bundles change the assumption that evidence-based care is being delivered reliably.

If each of five bundle elements is delivered at 90 percent reliability, then the bundle is delivered at 59 percent reliability, as bundle reliability is the product of each element’s reliability (90% x 90% x 90% x 90% x 90%). Typically, most clinicians assume that the bundle elements are being reliably performed on their patients. However, when they collect their initial data, they are surprised at the low levels of all-or-none bundle compliance, with some ICUs finding reliability levels of 10 to 20 percent.

2. Bundles promote awareness that the entire care team must work together in a system designed for reliability.

Teams that have achieved high levels of bundle compliance and concomitant improved outcomes did so through working as a team in new ways. Critical elements of bundle success include using specific daily goals developed by the team and patient, multidisciplinary rounds where the bundle elements are discussed and checked, and debriefs at the end of the day to reflect on compliance and to plan ongoing improvements.

3. Bundles promote the use of improvement methods to redesign care processes.

Organizations and the clinical teams within them are all different. How they learn to apply the bundle reliably is something that they must discover by systematically applying an improvement method. Teams can use many methods to improve process reliability and outcomes. In the original bundle development work, teams used the Model for Improvement,²⁶ which begins with three questions:

- *What are we trying to accomplish?*

The aim of using bundles is to reduce harm and improve care for the patient through improving the reliability of care processes.

²⁶ Langley GL, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* (2nd edition). San Francisco: Jossey-Bass Publishers; 2009.

- *How will we know the change is an improvement?*

Two measures will indicate if changes are leading to improvement: all-or-none bundle compliance and improved patient outcomes.

- *What changes can we make that will result in improvement?*

Several changes are listed above — daily goals, multidisciplinary rounds, and debriefing; in addition, effective changes include the use of huddles, checklists, standardization, and co-location of resources (e.g., the central line equipment cart).

Teams then test the changes using the Plan-Do-Study-Act (PDSA) cycle iteratively to learn and refine the changes until they are able to produce reliable processes that lead to improved outcomes.

Forming the Team

IHI recommends a multidisciplinary team approach to improvements in patient care. Improvement teams should be heterogeneous in make-up, but homogeneous in mindset. The value of bringing diverse personnel together is that all members of the care team are given a stake in the outcome and work to achieve the same goal.

All the stakeholders in the process must be included in order to gain the buy-in and cooperation of all parties. For example, teams without nurses are bound to fail. Teams led by nurses may be successful, but often lack leverage; physicians must also be part of the team.

Some suggestions to attract and retain excellent improvement team members include using data to define and solve the problem; finding champions within the hospital who are of sufficiently high profile and visibility to lend the effort immediate credibility; and working with those who want to work on the project rather than trying to convince those who do not.

The team needs encouragement and commitment from an authority who actively works in the patient care areas where this work is being done. Identifying a champion increases a team's motivation to succeed. When measures are not improving fast enough, the champion re-addresses the problems with all clinical staff, including physicians, and helps to keep everybody on track toward the aims and goals.

Eventually, the changes that are introduced become established. At some point, however, changes in the field such as new evidence will require revisiting the processes that have been developed. Identifying a "process owner," a figure that is responsible for the functioning of the process now and in the future, helps to maintain the long-term integrity of the effort.

Setting Aims

Improvement requires setting aims. An organization will not improve without a clear and firm intention to do so. The aim should be time-specific and measurable; it should also define the specific population of patients that will be affected. Agreeing on the aim is crucial; so is allocating the people and resources necessary to accomplish the aim. The following is an example of an appropriate aim:

Increase Augmentation Bundle and Elective Induction Bundle compliance by 50% by June 30, 2012, and achieve a 95% compliance rate with these bundles by December 2012. Increase Vacuum Bundle compliance by 50% by December 2012. By December 2012, our perinatal harm rate will remain below 5% (as measured by the IHI Perinatal Trigger Tool).

Teams are more successful when they have unambiguous, focused aims. Setting numerical goals clarifies the aim, helps to create tension for change, directs measurement, and focuses initial changes. Once the aim has been set, the team needs to be careful not to back away from it deliberately or "drift" away from it unconsciously.

Using the Model for Improvement

In order to move this work forward, IHI recommends using the Model for Improvement. Developed by Associates in Process Improvement, the Model for Improvement is a simple yet powerful tool for accelerating improvement that has been used successfully by hundreds of health care organizations to improve many different health care processes and outcomes.

The model has two parts:

- Three fundamental questions that guide improvement teams to: 1) set clear aims, 2) establish measures that will tell if changes are leading to improvement, and 3) identify changes that are likely to lead to improvement.
- The Plan-Do-Study-Act (PDSA) cycle to conduct small-scale tests of change in real work settings by planning a test, trying it, observing the results, and acting on what is learned. This is the scientific method, used for action-oriented learning.

Implementation: After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team can implement the change on a broader scale. For example, begin by testing the algorithm with one nurse on one patient to ensure it is appropriate to use during labor augmentation.

Spread: After successful implementation of a change or package of changes for a pilot population or an entire unit, the team can spread the changes to other parts of the organization or to other organizations.

You can learn more about the [Model for Improvement](http://www.ihi.org) on www.ihi.org.



PDSA Worksheet

CYCLE: 1

DATE: 1/10/12

Project: Safe administration of oxytocin – Augmentation Bundle

Objective for this PDSA cycle: Determine the ease of use of a tachysystole algorithm.

Plan: With one nurse and one patient, test the algorithm to ensure it is appropriate to use during labor augmentation.

Questions: Will the algorithm allow the nurse to manage the patient's labor and minimize the need to interrupt care?

Predictions: Using the algorithm will standardize the response to the recognition of tachysystole and decrease the number of interruptions to care (e.g., phone calls and dosage changes).

Plan for change or test — who, what, when, where:

Day labor nurse will use the tachysystole algorithm with one augmentation patient today for eight hours with Dr. ____'s patient.

Plan for collection of data — who, what, when, where:

Nurse will use algorithm during the course of oxytocin administration for labor augmentation. Use data collection tool developed to collect information on whether the algorithm was easy to use (yes or no).

Team leader will interview nurse at end of her eight hours to review data collection and any qualitative feedback.

Do: Initiate the plan to use the algorithm for one eight-hour shift with one nurse and one patient.

Study: Did the algorithm work effectively? Was it easy to use? Do any changes need to be made before more testing with other patients/nurses/physicians?

Act: If no changes, plan to test on Day Two with three patients (if possible) and include testing on shifts other than day shift (i.e., test under a variety of conditions).

Getting Started

Hospitals will not successfully implement all the preventative elements or eliminate all obstetrical adverse events overnight. If you do, chances are that you are doing something suboptimally. A successful program involves careful planning, testing to determine if the process is successful, making modifications as needed, re-testing, and careful implementation.

- Select the improvement team and determine if you will test with one group of patients (a segment) or all.
- Assess the current process. Are you measuring any of the bundle components? Is there a process in place for daily review of patients on oxytocin? If not, work with staff to begin preparing for changes.
- Organize an educational program. Teaching the core principles of the Model for Improvement to the staff will open many people's minds to the process of change.
- Introduce the evidence and rationale for all bundle components.

First Test of Change

Once an improvement team has prepared the way for change by studying the current process and applying the Model for Improvement principles and theory, the next step is to begin testing elements to prevent obstetrical adverse events at your institution.

- Begin by developing one standard order set for the administration of oxytocin on all patients. Choosing patients electively induced (and thus pre-scheduled) as the first patient segment allows you to plan ahead for patients, nurses, and obstetrical care providers involved in the process.
- Work with each nurse who cares for the patient to be sure they are able to follow the orders and respond accordingly when tachysystole or fetal heart changes; indicate a response is needed.
- Ensure that the approach can be carried over from shift to shift to eliminate gaps in teaching and utilization.
- Gather feedback and incorporate suggestions for improvement.
- Engage the improvement team in additional PDSA cycles to refine the process and make it more reliable.

Measurement

Measure compliance with each of the key components of the IHI Oxytocin Bundles and Vacuum Bundle. Document whether each component of care was provided or contraindicated; these are “process measures.” While improvements in individual measures indicate the processes surrounding those care elements have improved, improvement in actual patient outcomes requires improvement in all component measures.

IHI recommends the use of some or all of the following measures, as appropriate, to track your progress. In selecting your measures, consider the following:

- Whenever possible, use measures you are already collecting for other programs.
- Evaluate your choice of measures in terms of the usefulness of the final results and the resources required to obtain them; try to maximize the former while minimizing the latter.
- Try to include both process and outcome measures in your measurement scheme.
- You may use different measures or modify the measures described below to make them more appropriate and/or useful to your particular setting. However, be aware that modifying measures may limit the comparability of your results to others’.
- Posting measure results within your hospital is a great way to keep teams motivated and aware of progress. Try to include measures that teams will find meaningful and exciting.

Process Measures

Process Measure 1: Augmentation Bundle (Oxytocin) Compliance

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Initial Weekly Process Measures	AB.01.b Augmentation Bundle Compliance (Oxytocin)	<p>N: Total number of charts that have all four components of the Augmentation Bundle (Oxytocin) in place and documented for the sample*</p> <p>D: Total number of the sampled charts (5 charts)</p> <p>*This is an "all or nothing" indicator. If any of the five elements of the bundle are not documented, do not count the patient in the numerator.</p>	<p>Every week for four weeks of the month, select a random sample of 5 charts of patients who have delivered and received oxytocin for augmentation of labor. Review the 5 charts for the four components of the Augmentation Bundle:</p> <ul style="list-style-type: none"> • Documentation of estimated fetal weight (EFW) • Pelvic assessment • Recognition and management of tachysystole • Recognition and management of Fetal Heart Rate (FHR) Status (Exclusion of NICHD Category III) <p>For the numerator, add the total number of charts that have all four components of the Augmentation Bundle completed and documented for the sample (5 charts).</p> <p>*If even one element of the bundle is missing, the case is not in compliance with the bundle. For example, if 3 of the 5 patients have all four bundle elements completed, then there is 60% (3 divided by 5) compliance with the Augmentation Bundle.</p>	90% or greater

See Appendix for Augmentation Bundle Composite and sampling tools for data collection.

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Process Measure 2: Elective Induction Bundle (Oxytocin) Compliance

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Initial Monthly Process Measures	EIB.O1.b Elective Induction Bundle Compliance (Oxytocin)	<p>N: Total number of charts that have all four components of the Elective Induction Bundle in place and documented for the sample*</p> <p>D: Total number of the sampled charts (5 charts)</p> <p>*This is an "all or nothing" indicator. If any of the elements of the bundle are not documented, do not count the patient in the numerator.</p>	<p>Every week for four weeks of the month, select a random sample of 5 charts of patients who have delivered and received oxytocin for elective induction of labor. Review the 5 charts for the four components of the Elective Induction Bundle:</p> <ul style="list-style-type: none"> • Gestational age >39 weeks • Pelvic assessment • Recognition and management of tachysystole • Recognition and management of Fetal Heart Rate (FHR) Status (NICHD Category I - normal) <p>For the numerator, add the total number of charts that have all four components of the Elective Induction Bundle completed and documented for the sample (5 charts).</p> <p>*If even one element of the bundle is missing, the case is not in compliance with the bundle. For example, if 3 of the 5 patients have all four bundle elements completed, then there is 60% (3 divided by 5) compliance with the Elective Induction Bundle.</p>	90% or greater

See Appendix for Elective Induction Composite and sampling tools for data collection.

Process Measure 3: Vacuum Bundle Compliance

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Advanced Weekly Process Measures	VB.01.b Vacuum Bundle Compliance	<p>N: Total number of patient charts that have all five components of the Vacuum Bundle in place and documented for the sample*</p> <p>D: Total number of the sampled charts (5 charts)</p> <p>*This is an "all or nothing" indicator. If any of the five elements of the bundle are not documented, do not count the patient in the numerator.</p>	<p>Every week for four weeks of the month, select a random sample of 5 charts of patients who have delivered. Review the 5 charts for the five components of the Vacuum Bundle:</p> <ul style="list-style-type: none"> • Consider alternative labor strategies • Prepare patient by discussing and documenting informed consent • Know high probability of success with EFM, fetal position, and station • Determine maximum vacuum device application time and pop-offs • Make a contingency strategy, including a cesarean and resuscitation team <p>For the numerator, add the total number of charts that have all five components of the Vacuum Bundle in place and documented for the sample (5 charts).</p> <p>*If even one element of the bundle is missing, the case is not in compliance with the bundle. For example, if 3 of the 5 patients have all five bundle elements completed, then there is 60% (3 divided by 5) compliance with the Vacuum Bundle.</p>	95% or greater

See Appendix for Vacuum Bundle Composite and sampling tools for data collection.

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Process Measure 4: Gestational Age Reliability

Note: IHI is the only organization focusing on this component.

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Optional "Test" Process Measures	GAR.01 Gestational Age Reliability	N: Number of patients from the denominator with documentation of optimal criteria* D: Number of patients scheduled for delivery (per week or per month)	Develop a consistent process for schedule of delivery and documentation of optimal criteria for gestational age reliability. On the last day of the week or month, count the total number of patients schedule for delivery. This is the denominator (D). From denominator (D), count the number of patients with documentation of optimal criteria.* *Optimal Criteria: a) Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater. b) Fetal heart tones have been documented as present for 30 weeks by Doppler. Ultra-sonography (electronic hand-held doppler fetoscope ultrasonography, not doppler ultrasound on an ultrasound machine). c) It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test result.	100%

See Appendix for data collection tool.

Outcome Measures

Outcome measures are also essential and should be collected in addition to the process measures for each of the key components of any of the IHI bundles. Outcome measures offer evidence that changes are actually having an impact at the system level.²⁷

Aligning your measures with those used for national programs or required reporting, such as the CDC and/or state requirements, will ease the burden of measurement.

Outcome Measure 1: Perinatal Harm — Rate of Adverse Events with Harm

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Monthly Outcome Measures	H.O1 Perinatal Harm: Rate of Adverse Events with Harm	N: Total number of adverse events in harm Categories E through I (in sample) D: Total live term births 37 weeks or above (in sample)	Every month, select a random sample of at least 20 coded and complete couplet records (mom and baby). Review the records using the IHI Perinatal Trigger Tool looking for triggers. Investigate each trigger further to determine if an adverse event with harm (Categories E through I) did in fact occur. Insert numerator (total number of identified adverse events with harm (Categories E through I) and denominator (total live term births 37 weeks or above in sample) See IHI Global Trigger Tool See Perinatal Chart Review Tool	5 or less per 100 live births

²⁷ Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2012. Available at: <http://www.ihi.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>.

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Outcome Measure 2: Time Between Elective Deliveries 39 Weeks

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Monthly Outcome Measures	TBED.TJC Time Between Elective Deliveries 39 Weeks (TJC PC.01)	Days: Number of days between patients with elective deliveries with ≥ 37 and < 39 weeks of gestation completed (TJC PC.01)	When events are relatively rare, the monthly statistic is a very small number or zero and it is hard to detect patterns of change. One useful approach is to track and display “time between” events. Instead of plotting the number of incidences each month, one would plot the time between incidences. Instructions for this type of data collection and analysis include entering data on the graph each time an event occurs.	As long as possible
	TBED.NQF Time Between Elective Deliveries 39 Weeks (optional) (NQF measure)	Days: Number of days between singletons electively delivered at ≥ 37 weeks of gestation completed (NQF measure)	<p>The IHI Perinatal Improvement Community uses monthly reporting, so this data is entered on the graph at least monthly — even if no event occurred. It is not unusual to have plotted your data and then detect another delivery. Revising your graph is then required.</p> <p>Create a process to capture data prospectively on 100% of patients in the pilot population. This measure may require revising run charts continuously.</p>	

Outcome Measure 3: Elective Delivery Rate Prior to 39 Weeks (TJC measure PC-01)

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Monthly Outcome Measures	ED.TJC Elective Delivery Rate Prior to 39 Weeks (TJC measure PC.01)	N: Number of patients from the denominator with elective deliveries D: Patients delivering newborns with ≥ 37 and < 39 weeks of gestation completed	On the last day of the month, identify your sample denominator. From this sample, count the number of patients with elective vaginal deliveries or elective cesarean sections at ≥ 37 and < 39 weeks of gestation completed (numerator) See Specifications Manual for Joint Commission National Quality Core Measures (2010A1)	0%
	ED.NQF Elective Delivery Rate Prior to 39 Weeks (optional) (NQF measure)	N: Number of babies from the denominator electively delivered prior to 39 completed weeks of gestation D: Number of singletons delivered at ≥ 37 completed weeks of gestation	On the last day of the month, identify your sample denominator. From this sample, count the number of babies electively delivered prior to 39 completed weeks of gestation (numerator). See NQF National Consensus for Perinatal Care 2008	0%

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Outcome Measure 4: Cesarean Rate for Low-risk First Birth Women (TJC Measure PC-02)

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Monthly Outcome Measures	CS.TJC Cesarean Rate for Low-risk First Birth Women (TJC measure PC.02)	N: Number of patients from the denominator with cesarean sections D: Number of nulliparous patients delivered of a live term singleton newborn in vertex presentation	On the last day of the month, identify your sample denominator. From this sample, count the number of patients with cesarean sections (numerator) <u>Specifications Manual for Joint Commission National Quality Core Measures (2010A1)</u>	
	CS.NQF Cesarean Rate for Low-risk First Birth Women (optional) (NQF measure)	N: Number of patients from the denominator that had a cesarean birth D: Number of live births at or beyond 37.0 weeks of gestation that are having their first delivery and are singleton (not twins or more) and vertex presentation (no breech or transverse positions)	On the last day of the month, identify your sample denominator (all live births at or beyond 37.0 weeks of gestation that are having their first delivery and are singleton [not twins or more] and vertex presentation [no breech or transverse positions]). <u>See NQF National Consensus for Perinatal Care 2008</u>	

Appendices

Additional resources for the elimination of elective deliveries prior to confirmation of fetal maturity (39 weeks)

- [California Maternal Quality Care Collaborative \(CMQCC\) : <39 Weeks Resources](#)
- [March of Dimes: Less Than 39 Weeks Toolkit](#)

Process Measure Composites and Data Collection Tools

Process Measure 1: Augmentation Bundle (Oxytocin) Composite

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Initial Weekly Process Measures	AB.01.a Augmentation Bundle Composite (Oxytocin)	<p>N: Total number of the four components of the Augmentation Bundle in place and documented for the sample (5 charts)*</p> <p>*Example Numerator: Chart 1 = 3 components Chart 2 = 4 components Chart 3 = 2 components Chart 4 = 4 components <u>Chart 5 = 3 components</u> Total = 16 components</p> <p>D: Total number of the four components of the Augmentation Bundle possible for the total sample (4 components x 5 charts = 20)</p>	<p>Every week for four weeks of the month, select a random sample of 5 charts of patients who have delivered and received oxytocin for augmentation of labor. Review the 5 charts for the four components of the Augmentation Bundle:</p> <ul style="list-style-type: none"> • Documentation of estimated fetal weight (EFW) • Pelvic assessment • Recognition and management of tachysystole • Recognition and management of FHR Status (Exclusion of NICHD Category III) <p>For the numerator, add the total number of the four components of the Augmentation Bundle in place and documented for the sample (5 charts).*</p> <p>The denominator is the total number of components (4) times the total number of charts reviewed in that month (20).</p> <p>When a rate of 95% is consistently achieved, convert to the Augmentation Bundle Compliance measure.</p> <p>See Augmentation Bundle Composite Data Collection Tool in Appendix.</p>	95% or greater

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Oxytocin- Augmentation Bundle Composite Data Collection Tool

Elements:

- **Estimated Fetal Weight (EFW):** _____ {gms or SGA/AGA/LGA}. Documented prior to initiation of oxytocin.
Team Definition: _____
- **Normal Fetal Heart Rate Status:** See NICHD September '08 Tier Recommendations. Assessed and documented prior to initiation of oxytocin *and* during administration.
Team Definition: _____
- **Pelvic Assessment:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency); clinical pelvimetry (acceptable is "adequate pelvis") and an assessment of the fetal presentation.
Team Definition: _____
- **Tachysystole:** Recognized and management throughout the administration of oxytocin. NICHD September '08 Definition- >5 contractions in 10 minutes, averaged over a 30 minute window. If present, it is recognized and treated.
Team Definition: _____

Instructions: Review 5 charts each week where oxytocin was used to augment labor.

N: Total number of individual components in place (5 charts X 4 elements= 20)

D: Total number of augmentation components possible in 5 charts reviewed (20)

Month _____ Week _____

Chart	EFW	Normal Fetal Status	Pelvic Examination	Tachysystole	Total
#1					
#2					
#3					
#4					
#5					
EX	yes	yes	yes	no	$\frac{3}{4} = 75\%$

→ When a rate of 95% or greater compliance is reached for at least _____ data points, move to the All or Nothing Measure (Augmentation Bundle).

Oxytocin- Augmentation Bundle Compliance

Data Collection Tool

Elements:

- **Estimated Fetal Weight (EFW):** _____ {gms or SGA/AGA/LGA}. Documented prior to initiation of oxytocin.
Team Definition: _____
- **Normal Fetal Heart Rate Status:** See NICHD September '08 Tier Recommendations. Assessed and documented prior to initiation of oxytocin *and* during administration.
Team Definition: _____
- **Pelvic Assessment:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency); clinical pelvimetry (acceptable is "adequate pelvis") and an assessment of the fetal presentation.
Team Definition: _____
- **Tachysystole:** Recognized and management throughout the administration of oxytocin. NICHD September '08 Definition- >5 contractions in 10 minutes, averaged over a 30 minute window. If present, it is recognized and treated.
Team Definition: _____

Instructions: Review 5 charts each week where oxytocin was used to augment labor.

N: Total number of charts that have **all** 4 components in place

D: Total number of charts reviewed (5 charts)

Month _____ Week _____

Chart	EFW	Normal Fetal Status	Pelvic Examination	Tachysystole	Total
#1					
#2					
#3					
#4					
#5					
EX	yes	yes	yes	no	$\frac{3}{4}=0\%$



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Process Measure 2: Elective Induction Bundle (Oxytocin) Composite

Category	Label & Description	Numerator (N) Denominator (D)	Collection Methodology	Goal
Initial Weekly Process Measures	EIB.O1.a Elective Induction Bundle Composite (Oxytocin)	<p>N: Total number of the four components of the Elective Induction Bundle in place and documented for the sample (5 charts)*</p> <p>*Example Numerator: Chart 1 = 3 components Chart 2 = 4 components Chart 3 = 2 components Chart 4 = 4 components <u>Chart 5 = 3 components</u> Total = 16 components</p> <p>D: Total number of the four components of the Elective Induction Bundle possible for the sample (4 components x 5 charts = 20)</p>	<p>Every week for four weeks of the month, select a random sample of 5 charts of patients who have delivered and received oxytocin for elective induction of labor. Review the 5 charts for the four components of the Elective Induction Bundle:</p> <ul style="list-style-type: none"> • Gestational age > 39 weeks • Pelvic assessment • Recognition and management of tachysystole • Recognition and management of FHR Status (NICHD Category I - normal) <p>For the numerator, add the total number of the four components of the Elective Induction Bundle in place and documented for the sample (5 charts). The denominator should be 20 each week.</p> <p>When a rate of 95% is consistently achieved, convert to the Elective Induction Bundle Compliance measure.</p> <p>See Elective Induction Composite Data Collection Tool in Appendix</p>	95% or greater

Oxytocin- Elective Induction Bundle Composite

Data Collection Tool

Elements:

- ☐ **Gestational Age 39 weeks or >.** Documented prior to initiation of oxytocin. Per ACOG definition in ACOG Practice Bulletin Number 107, August 2009 (Induction of Labor).

Team Definition _____

- ☐ **Normal Fetal Status:** See NICHD September '08 Tier Recommendations. Assessed and documented prior to initiation of oxytocin *and* during administration.

Team Definition _____

- ☐ **Pelvic Assessment:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency; Bishop's Score), clinical pelvimetry (acceptable is "adequate pelvis") and an assessment of the fetal presentation.

Team Definition _____

- ☐ **Tachysystole:** Recognized and management throughout the administration of oxytocin. NICHD September '08 Definition- >5 contractions in 10 minutes, averaged over a 30 minute window. If present, it is recognized and treated.

Team Definition: _____

Instructions: Review 5 charts each week where oxytocin was used to electively induce labor.

N: Total number of individual components in place (5 charts X 4 elements= 20)

D: Total number of elective induction components possible in 5 charts reviewed(20).

Month _____ Week _____

Chart	Gestational Age	Normal Fetal Status	Pelvic Assessment	Tachysystole	Total
#1					
#2					
#3					
#4					
#5					

→ When a rate of 95% or greater compliance is reached for at least _____ data points, move to the All or Nothing Measure (Oxytocin-Elective Induction Bundle).



Oxytocin- Elective Induction Bundle Compliance Data Collection Tool

Elements:

- ☐ **Gestational Age 39 weeks or >.** Documented prior to initiation of oxytocin. Per ACOG definition in ACOG Practice Bulletin Number 107, August 2009 (Induction of Labor).

Team Definition _____

- ☐ **Normal Fetal Status:** See NICHD September '08 Tier Recommendations. Assessed and documented prior to initiation of oxytocin *and* during administration.

Team Definition _____

- ☐ **Pelvic Assessment:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency; Bishop's Score), clinical pelvimetry (acceptable is "adequate pelvis") and an assessment of the fetal presentation.

Team Definition _____

- ☐ **Tachysystole:** Recognized and management throughout the administration of oxytocin. NICHD September '08 Definition - >5 contractions in 10 minutes, averaged over a 30 minute window. If present, it is recognized and treated.

Team Definition: _____

Instructions: Review 5 charts each week where oxytocin was used to electively induce labor.

N: Total number of charts that have all four components of the bundle in place and documented

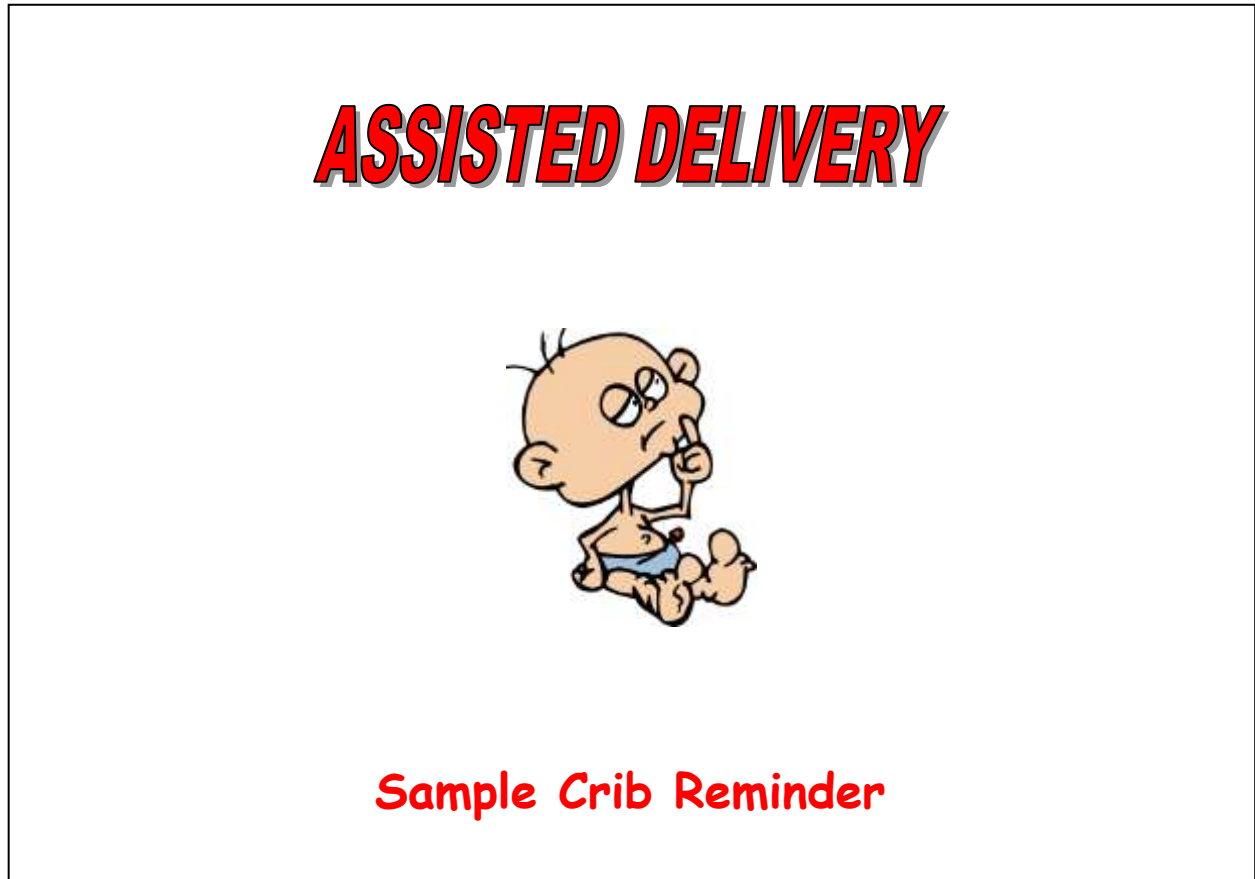
D: Total number of the sampled charts (5 charts)

Month _____ **Week** _____

Chart	Gestational Age	Normal Fetal Status	Pelvic Assessment	Tachysystole	Total
#1					
#2					
#3					
#4					
#5					
Example	yes	yes	no	no	2/4=0%



Sample Crib Reminder for Assisted Delivery



Other sites have used:

- Colored dot on crib card
- Laminated 4x6 card “Don’t forget to assess my head” or “vitals reminder”

Source: Iowa Health System Affiliate Neonatal Teams

Sample Neonatal Safety Improvement Charter



Timeline:
January 1, 2012 – December 31, 2012

IHS - Neonatal Safety Improvement Charter – Operative Delivery Monitor

Aim:

To improve the quality and safety of neonatal care delivered across the Iowa Health System for all operative (vacuum/forceps) delivered babies.

1. All affiliates will provide post operative delivery monitoring for 100% of neonates with operative delivery technology as measured by "Operative Delivery Minimum Neonatal Monitoring Guidelines".
2. IHS will achieve a 83.2% composite score by December 31, 2012.

Current State:

The application of vacuum technology is necessary in some deliveries, but has the potential to increase risk for outcome issues to mother and infant. Proper use of the technology decreases risk of harm to both mothers and infants. In 2009 the IHS Neonatal Team approved system-wide "Operative Delivery Minimum Neonatal Monitoring Guidelines" for any neonate delivered with the use of vacuum or forceps (vaginal or Caesarean). In 2010 an Operative Delivery Monitoring bundle was introduced to determine adherence to the minimum monitoring guidelines. Total composite score for 2010 began at 58% and ended the year at 89% with an overall 2010 Composite score of 78%. Total composite score for 2011 was 82% which exceeded the goal of 80%.

Focus/Boundaries:

The scope of this initiative begins with monitoring of any operative delivered neonate that had operative delivery technology (Vacuum/forceps) applied with either vaginal or Caesarean delivery through 48 hours after birth depending on discharge and stabilized neonate.

Measures:

Measures: Operative Deliveries Minimum guidelines for neonate monitoring.

Monitor/audit **all or minimum of 4** records/month for documentation of all guideline elements (includes vacuum/forceps use on both vaginal and C-section deliveries). Affiliates average from 1-20 vacuums/month. A review of a random 20% of records = maximum 4 records/month for review.

Source: Iowa Health System Affiliate Neonatal Teams

Sample Protocol for Group Consensus

Common Protocol for Iowa Health System Affiliate Perinatal Teams Group Consensus

Effective for: All neonates delivered by use of vacuum or forceps

1. Communicate information between nursing and provider caregivers and nurse-to-nurse handoffs about neonate's operative delivery.
2. Educate parent(s) regarding assessment of neonate after assisted delivery and report any change in status (i.e., poor feeding, changes in behavior, respiratory distress).
3. Monitoring guidelines:
 - a. Within first 30 minutes after initial stabilization at birth begin assessments hourly X 4
 - b. If clinical signs are evident, continue hourly assessment every hour for a minimum of 8
 - c. Continue assessment every 4 hours and PRN for 24 hours after birth depending on discharge
 - d. Continue assessment every 8 hours and PRN for 48 hours after birth depending on discharge
4. Assessment parameters to be included with each assessment:
 - a. Heart rate
 - b. Respiratory rate and effort — evaluate for any signs of respiratory distress
 - c. Head circumference
 - d. Head assessment — presence and status of edema, ecchymosis, scalp discoloration, and fontanel status (bulging or flat)
 - e. Skin color
 - f. Capillary refill time — petechiae, scleral and/or conjunctival hemorrhage, ecchymosis, or gingival bleeding
 - g. Pain
 - h. Level of consciousness (activity, sleep/awake state)
5. Blood pressure (right arm preferred) initially for baseline. Then repeat or increase frequency of BP assessment if abnormal or change in neonate status.
6. Consider additional monitoring with pulse oximeter if respiratory distress or color changes are noted.

Source: Iowa Health System Affiliate Neonatal Teams