The Military Health System's

PARTNERSHIP FOR PATIENTS CAMPAIGN

SAFE CARE SAVES LIVES

Implementation Guide for Obstetrical Adverse Events

June 17, 2013

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

PARTNERSHIP FOR PATIENTS

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1 Contents

Obstetrical Harm Burden of Illness

- Obstetrical adverse events currently occur in approximately 9 percent of all U.S. deliveries.
- Elective delivery – vaginal or cesarean sections before 39 weeks gestation result in higher rates of adverse respiratory outcomes, mechanical ventilation, sepsis and hypoglycemia for newborns.
- A review of medical malpractice claims reveals that the use of oxytocin to stimulate labor is involved in more than 50 percent of the situations that result in birth trauma.
- Partnership for Patients literature estimates that 30 percent of obstetrical adverse events are preventable.

Sources:

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http://www.ihi.org/knowledge/Pages/IHIWhitePapers/IdealizedDesignofPerinatalCareWhitePaper.aspx

1. Introduction

This implementation guide was created to support the Partnership for Patients, a national initiative sponsored by the Department of Health and Human Services to reduce harm in health care facilities. Military Health System leadership has pledged its support to the PfP, and has made a commitment to specific, identified aims. Improving the quality and safety of health care in all Department of Defense facilities will only be possible with universal support at every level in the MHS.

This guide is one of 10 harm-specific guides designed to assist you as you implement identified evidence-based practices to improve patient care. Common to all guides are resources that support efforts to educate the health care team by providing MHS-selected EBPs and quality improvement strategies.

In addition, implementation strategies and tools relevant to all harm categories are included in a guide titled —Practical Applications for Process Improvement and Change Management. This guide supports efforts to equip the health care team with rapid-cycle process improvement methods and engage the health care team with change management strategies.

The four components of Rapid Cycle Improvement are Plan, Do, Study, and Act:

Plan – What are you trying to accomplish? What is the ideal state? What is the current state? What plan or strategy will provide improvement to the gaps identified between the ideal and the current? Understand the plan and the purpose.

Do – Test the improvement in your case the implementation, document problems, observations, lessons learned.

Study – what went well, what didn't go well? Utilize qualitative analysis. Why did it go well or not go well?

Act – Do you adopt the plan (standardize it), adapt the plan (modify and try again), or abandon the plan (begin the cycle again). [8]

This Implementation guide for Obstetrical Adverse Events is designed to support your MTF as you implement identified Obstetrical evidence-based practices to improve patient care.

2. Obstetrical Adverse Event Prevention Evidenced-Based Practices

2.1 Background Information

Perinatal events have a lifelong impact for mothers, infants and their families. While most pregnancies result in the safe delivery of a healthy baby without harm to either the mother or child, obstetrical events can have an impact during the perinatal period. The Institute of Medicine defines an adverse event as an injury resulting from medical care rather than the patient's underlying medical condition.[1] In obstetrics, adverse events include harm to either the mother or infant. Our goal is to prevent the preventable; minimize unexplained variability while clinically defending the unpreventable with clinical explanation of necessary variability to allow for the appropriate application of consistent evidence-based practice.

2.2 Risk factors

Raising awareness of perinatal safety and establishing evidence-based care guidelines has helped make progress towards improving perinatal outcomes. The MHS is tracking the following individual perinatal risk factors:

1. Elective term delivery (greater than 37 weeks but prior to 39 weeks gestation without medical indications)
2. Obstetrical trauma, third or fourth degree lacerations with or without instruments, based on the Agency for Healthcare Research and Quality Patient Safety Indicator
3. Safe use of the high alert drug Oxytocin, using the Institute for Healthcare Improvement bundles for use of Oxytocin in elective inductions and oxytocin augmentations of labor

2.3 Evidence-Based Practice Guidelines

A care bundle is a set of evidence-based interventions when used together with reliable implementation and team collaboration may improve certain patient outcomes. The MHS-endorsed the use of IHI Perinatal bundles are based on the IHI safe medication practices for patients receiving oxytocin, and documentation of care during induction and augmentation of labor. Bundles themselves as tools to track practice do not improve outcomes; the ability of the team to reliably implement every bundle element for all patients, unless medically contraindicated, can advance care to achieve the improved outcomes. To reduce incidence of neonatal injury by appropriate use of the high alert medication, Oxytocin, in Obstetrics, the IHI created care bundles. The use of the IHI bundles has not been proven to improve maternal or neonatal outcomes.

During this implementation the MHS will use the IHI bundles for Oxytocin use in Elective inductions and Augmentation of labor. If no improvement in clinical outcomes, a different set of process and outcome measures will be implemented and the use of these specific bundles will be discontinued. In order to achieve a high level of reliability, teamwork and communication is an essential ingredient to ensure success.

2.3.1 Evidence-Based Practice Guidelines –Elective Early-term Delivery

Preterm birth is birth before 37 completed weeks of gestation. It is the leading cause of neonatal death in the United States and places infants at risk for lifelong disabilities, such as cerebral palsy, blindness, and physical and neurological impairment. [2]

Compared with term infants, late preterm infants are at increased risk for mortality and numerous morbidities (Table 1.3). A large study of national vital statistics data shows infants born in the late preterm period, compared to term infants, were six times more likely to die in the first week of life, and three times more likely to die in the first year of life.[3]

Furthermore, late preterm infants have an increased risk for rehospitalization following initial hospital discharge after birth and for sudden infant death syndrome (SIDS). They are more likely than term infants to need early intervention and special education; they have a higher risk of serious behavior and learning problems, cerebral palsy and intellectual disability; and they are at increased risk for mental illness and long-term disability as adults. [4,5,6]

MHS Action Plan: MTF will review of all NON-medically indicated elective deliveries between 37 and 39 completed weeks of gestation. [7]

2.3.2 Evidence-Based Practice Guidelines-Perineal Trauma

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 neonatal injury such as scalp lacerations, retinal hemorrhages, cephalohematomas, subgaleal hemorrhages, intracranial hemorrhages, hyperbilirubinemia and/or maternal trauma.[8] ACOG advises against the use of

sequential instruments except under conditions in which it may not be possible to perform an immediate cesarean section. [9]

MHS Action Plan: MTFs will review of all 3rd and 4th degree lacerations. [9]

2.3.3 Evidence-Based Practice Guidelines-IHI Bundles Oxytocin use for Elective Inductions and Labor Augmentation

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 six claims in 2006. Several IHI Perinatal Improvement Community teams, who have continuously participated in the Community for more than 3 years, have developed a highly reliable system and have self-reported the same results to IHI. [8]

1. Assess gestational age (ensures 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. In the event of an adverse outcome, plaintiff's attorneys may use non-compliance with this current guideline as an indicator of poor care.[10]

MHS Action Plan: GESTATIONAL AGE is 39 weeks or greater. Gestational age is documented prior to initiation of oxytocin. Appropriate dating criteria includes first trimester ultrasound, LMP or other established criteria. [11]

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. Category II fetal heart rate would make the induction medically indicated NOT elective.

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 academic and provides reassurance of fetal status. [12]

Because the positive predictive value of reassuring fetal assessment is high (greater than 99 percent), it is vital that definitions are accepted and used by all members of the care team.[9]

Fetal monitor strip MUST be reviewed. The reviewer looks for numbers of incidence of tachysystole, at notes (flow sheets, notes) for documentation of tachysystole, for treatment (oxytocin dose change (decrease or off), use of tocolytic (terbutaline), internal monitors (placement or recalibration), and/or palpation in addition to external uterine monitoring. [13]

FETAL STATUS: Assess and document PRIOR to initiation of oxytocin and DURING administration.

- Fetal Heart category I based on NICHD September 2008 Tier Recommendations
- Fetal Heart category II would make the induction MEDICALLY indicated not Elective. Do not count this in the IHI bundle
- NICHD Classification I for elective induction
- NICHD classification I & II for Augmentation

MHS Action Plan: Review EFM strip in conjunction with documentation.

3. Document pelvic examination.

The provider should perform and document pelvic examination to determine dilation, effacement, station, cervical position and consistency, 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 induction is best attempted at that time. Contemporary assessment of the pelvis and cervix is needed prior to proceeding with induction of labor. [9]

PELVIC EXAM: Documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency; clinical pelvimetry (adequate, sufficient or proven to number of pounds/grams) and an assessment of the fetal presentation.

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. [14]

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.[9]

MHS Action Plan: Monitor tachysystole events

TACHYSYSTOLE: Recognized and managed throughout the administration of oxytocin. Definition: Greater than five contractions in 10 minutes, averaged over a 30-minute window. If present, it is recognized, (documented) and treated.[12]

Fetal monitor strip MUST be reviewed. The reviewer looks for numbers of incidence of tachysystole. The reviewer looks at notes or flow sheets for documentation of tachysystole. The reviewer looks for treatment (oxytocin dose change (decrease or off), use of tocolytic (terbutaline), internal monitors (placement or re calibration), palpation in addition to external uterine monitoring.

Evaluate fetal heart rate pattern AND documentation for occurrences of tachysystole and interventions. Number of occurrence should equal number of documented occurrence, and each occurrence should have an intervention.[9]

The IHI Augmentation Bundle (Oxytocin) consists of four elements:

- Estimate fetal weight
- Recognized and managed fetal heart rate status
  - (Exclusion of NICHD Category III)
- Conduct pelvic Assessment

- Recognized and managed tachysystole (same definition as in the Elective Induction Bundle)

Estimation of Fetal Weight: 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. [9]

Monitoring for fetal reassurance and for uterine tachysystole and the care 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.

- Estimated Fetal Weight (EFW): _____ {gms, lbs., or SGA/AGA/LGA} by palpation or ultrasound
- Small for Gestational Age (SGA)- full term infant with birth weight of 2500 grams or LESS Average for Gestational Age (AGA) full term infant is MORE than 2500 grams (about 5.5 lbs.) but LESS than 4000 gm. (about 8.75 lbs.)
- Large for Gestational Age (LGA) full term infant is MORE than 4000 gm. or 8.75 lbs.
- Document PRIOR to initiation of oxytocin.

Description	Data Source	Metric
IHI Perinatal Induction Bundle (use of Oxytocin) Observation / check list for bundle compliance	Medical record and fetal monitor review	Process Measure
IHI Perinatal Augmentation Bundle (use of Oxytocin) Observation/ check list for bundle compliance	Medical record and fetal monitor review	Process Measure
Joint Commission Perinatal Core Measure-01 (Elective Deliveries)	TJC ORYX	Process Measure

MHS Action Plan: IHI Tracking tool:

- MTFs will track five ELECTIVE Oxytocin inductions and record data on the IHI tracking Excel spreadsheet monthly.

- MTFs will track 20 Oxytocin augmentations (regardless of indication for augmentation) and track on the IHI tracking spreadsheet monthly.

MHS Action Plan: Patient outcome tool:

- MTF will track outcome measures on ALL reviewed charts:
  - ***Type of delivery***
    - Spontaneous Vaginal Delivery
    - Forceps
    - Vacuum
    - Cesarean
    - C/S after Trial Forceps
    - C/S after Trial Vacuum
  - ***Primary indication for delivery other than spontaneous Vaginal delivery***
  - ***Admission of neonate to other than full term (normal newborn) nursery*** - Indication for admission of neonate to special care or NICU

IHI Perinatal Elective Induction Bundle

1. Gestational age greater than or equal to 39 weeks
2. Recognition and management of tachysystole
3. Pelvic exam/assessment prior to administration of oxytocin
4. Reassuring fetal status/normal fetal status (using NICHD 3-Tier System)

Source:
IHI. Perinatal Elective Induction Safety.
http://app.ihi.org/imap/tool/#Process=cd6ce129-b442-49d6-b0d4-d160ec1f9528 Accessed 8/15/12.

IHI Perinatal Labor Augmentation Bundle

1. Documentation of estimated fetal weight
2. Recognition and management of tachysystole
3. Pelvic assessment
4. Reassuring fetal status / Normal fetal status (using NICHD 3-Tier System)

Source:
IHI. Perinatal Labor Augmentation Safety.
http://app.ihi.org/imap/tool/#Process=adf36aaa-63c5-4e2c-8c8d-e4ae8e9b29c4 Accessed 8/15/12.

3. MHS Performance Measures

In order to collect and interpret data that documents success in reducing the incidence of obstetrical adverse events, it is imperative that process and outcome measures be utilized. Data in the MHS is obtained through the review of medical records and coding of procedures and outcomes. Each MTF clinic or care delivery setting should be focused on consistent and frequent review of their internal data in addition to the cumulative rates seen in their Service and MHS.

The MHS has selected the following process and outcome measures to track performance.

Description	Data Source	Metric
IHI Perinatal Induction Bundle Observation / check list for bundle compliance	Essentris	Process Measure
IHI Perinatal Augmentation Bundle Observation/ check list for bundle compliance	Essentris	Process Measure
PC-01 Elective Deliveries Numerator: Patients with elective deliveries to include ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for Medical induction of labor and/or Cesarean section while not in Active Labor or experiencing Spontaneous Rupture of Membranes Denominator: Patients delivering newborns with >= 37 and <39 weeks of gestation completed without medical indications	TJC ORYX	Process Measure

Description	Data Source	Metric
Obstetric Trauma Rate- Vaginal Delivery With Instrument **Numerator**: Discharges among cases meeting the inclusion and exclusion rules for the ICD-9-CM codes for 3rd and 4th degree obstetric trauma in any diagnosis field **Denominator:** All vaginal delivery discharges with any procedure code for instrument-assisted delivery	MHS PHP AHRQ PSI 18	Outcome Measure
Obstetric Trauma Rate- Vaginal Delivery Without Instrument **Numerator:** Discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9-CM codes for 3rd and 4th degree obstetric trauma in any diagnosis field **Denominator:** All vaginal delivery discharge patients	MHS PHP AHRQ PSI 19	Outcome Measure

The MHS' goal is to assist in clinical decision-making and practice to decrease the incidence of preventable adverse events in the perinatal population. The perinatal population is the largest population in both direct and purchased care delivered in the MHS. Our commitment to our families and their infants need to be the most consistent and evidence-driven. Collaborative support of these measures by all levels of care providers is imperative.

4. Collaborative statement

This implementation guide was created to support the Partnership for Patients, implemented in the Military Health System to decrease harm events in Obstetrics in the three specific areas.

1. Prevention of Early term delivery less than 39 weeks without medical indication.

2. Decrease incidence of perinatal lacerations (third and fourth degree) using the metrics for AHRQ Patient Safety indicators 18 & 19.

3. Safe use of the high alert medication Oxytocin for induction and augmentation of labor. Our leadership has pledged its support to the PfP to improve the quality and safety of health care in all Department of Defense facilities with universal support at every level in the MHS.

5. Summary

This guide is a resource to support efforts to educate the health care team by providing MHS-selected EBPs and quality improvement strategies.

The DoD Patient Safety Learning Center (PSLC) is a member-based Patient Safety Community of Interest. It enables connections among DoD, military and approved contractors who are engaged in patient safety activities. Members use the online space to access and share knowledge about patient safety, and collaborate on best practices across the Military Health System (MHS). In addition, members will be able to share files, access the Working Group meeting materials, as well as recordings and materials from Learning Circles and CoPs, access the results of the 2012 Culture Survey, and connect with groups such as Patient Safety Managers. To request to the PSLC complete the Access Request Form located at http://www.health.mil/dodpatientsafety/ProductsandServices/PSLC/PSLCAccess

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8. Appendix

Attachment A: Perinatal Induction Bundle - Compliance Form

IHI's Oxytocin-Induction Bundle Compliance

Data Collection Tool

Elements:

Gestational Age 39 weeks: 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 2008 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 2008 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.

- Numerator: Total number of charts that have **all four components** of the bundle in place and documented
- Denominator: 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%

Source: IHI Perinatal Induction Bundle Tool Compliance Form
http://www.ihi.org/knowledge/Pages/Tools/ElectiveInductionBundleDataCollectionTool.aspx Accessed 8/15/12.

Attachment B: Perinatal Augmentation Bundle - Compliance Form

IHI's 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 2008 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 2008 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.

- Numerator: Total number of charts that have all four components of the bundle in place and documented
- Denominator: Total number of charts reviewed (5 charts)

Month _____Week _____

Chart	EFW	Normal Fetal Status	Pelvic Examination	Tachysystole	Total
#1					
#2					
#3					
#4					
#5					
Example:	yes	yes	yes	no	3/4=0%

Source: IHI Perinatal Augmentation Bundle Tool Compliance Form
http://www.ihi.org/knowledge/Pages/Tools/AugmentationBundleDataCollectionTool.aspx Accessed 7/10/12.

9. SAFER Passages

SAFER Passages is a United States Air Force Service initiative directed by Col Merlin (Bardett) Faucett as a platform to review and educate Obstetrical staff on perineal preserving techniques. The SAFER Passages program highlights the following steps:

SAFER Passages reducing the risk of perineal trauma [15-27]

- Start perineal massage at 36 weeks
- Alleviate fear and anxiety
- Facilitate occiput anterior presentations
- Eliminate midline episiotomy
- Place a warm compress in late second stage
- Adduct the thighs at delivery — position 90 degrees or less