HCA Perinatal Safety Initiative

- Kathleen B. Weatherstone, M.D.
- Manager, Sunflower Neonatology Associates
- Director, Overland Park Regional and Centerpoint NICUs
HCA Perinatal Safety Initiative

• Started as a risk-management effort
• In 2001, 9% of malpractice claims against HCA were related to obstetrics
• 50% of all claims settled in excess of $1 million were OB-related
• Identified major problem in standardizing reading of fetal heart rate monitor tracings
HCA Perinatal Safety Initiative

- HCA partnered with the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) to train and certify all HCA labor and delivery nurses in their standardized competency course in fetal heart rate monitoring
- By the end of 2002, 5000 nurses were trained
- Need for physicians and nurses to improve communication around interpretation
- Developed course for both nursing and physicians
- Today, fetal heart rate monitoring is a standard competency for nurses and delivering physicians in labor and delivery units
Reduction in Obstetrical Claims: Standardizing Fetal Monitoring Competencies

- Partnered with professional nurses association to establish baseline training.
- Required training for Obstetric RNs.
- Empowered RNs to escalate monitoring issues.
- Developed advanced course for RNs and physicians.
- Established common language for discussing monitoring issues.

**Percent of Perinatal Claims that are Monitoring Related by Report Year**

- 2002: 30%
- 2003: 28%
- 2004: 16%
- 2005: 22%
- 2006: 22%
- 2007: 21%
HCA Perinatal Safety Initiative

• Universal bilirubin screening initiative
  – Partnered with CDC, JCAHO, AAP and others to promote bilirubin testing through the “Kernicterus Prevention Partnership Campaign”
  – By Feb 2005, HCA was first healthcare system in nation to voluntarily require all of its hospitals with birthing units to screen all newborns for elevated bilirubin

• Medication safety
  – Electronic Medication Administration Record (EMAR) project. All medication at bedside is barcoded, scanned prior to administration
Management of Hyperbilirubinemia and Prevention of Kernicterus

- All newborns tested for jaundice
- Follow-up with pediatrician within 2-4 days if elevated
- Educate parents and clinicians on the dangers, signs and symptoms of jaundice

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Births</th>
<th>&gt;2500 Grams</th>
<th>&gt;24.9 mg/dl to 30 mg/dl</th>
<th>30 mg/dl or Greater</th>
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<td>225219</td>
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<td>68</td>
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</tr>
<tr>
<td>2008</td>
<td>217021</td>
<td>193350</td>
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<td>*0</td>
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<tr>
<td>2009 YTD</td>
<td></td>
<td></td>
<td>13</td>
<td>*0</td>
</tr>
</tbody>
</table>

Collaborated with CDC and NIH to develop a national campaign around HCA initiative

* While hospitals had newborns with values greater than >30mg in 2007-2009, the babies were transferred in or had pathologic jaundice due to metabolic conditions that were unavoidable
HCA Perinatal Safety Initiative

Objectives

• Examine collaborative, evidence based strategies to establish multidisciplinary health care teams to promote the delivery of high quality and safe maternal newborn care in order to improve perinatal/neonatal outcomes

• Recognize the value provided by current and new technology for the assessment and management of perinatal and neonatal patients in order to improve patient safety and enhance the quality of health care provided to patients
HCA Perinatal Safety Initiative

Objectives

• Understand the importance of timely recognition of designated clinical conditions as well as the necessity of appropriate, research based intervention and management during the antepartum, intrapartum, postpartum and newborn periods

• Integrate goals and standards established by National Quality Organizations, Patient Safety Organizations and selected regulatory agencies into the clinical practice of health care providers responsible for the care of perinatal and neonatal patients
Symposium on Quality Improvement to Prevent Prematurity

- Oct 8 and 9, 2009, Arlington Virginia
- March of Dimes in collaboration with ACOG, AAP, Am College of Nurse-Midwives, and AWHONN
- Steve Clark, MD, Medical Director of Women and Newborn’s Service, HCA and Janet Meyers, RN, MBA, Director of Perinatal Safety Initiative, HCA
HCA Definition of Quality is Derived from IOM Report: “Crossing the Quality Chasm”

- **Safe:** Avoiding injuries to patients from the care that is intended to help.
- **Effective:** Providing services based on scientific knowledge to all who could benefit and refraining from providing services not likely to benefit
- **Patient Centered:** Providing care that is respectful and responsive to individual patient preferences, needs and values and assuring that patient values guide all clinical decisions
- **Timely:** Reducing waits and sometimes harmful delays for both those who receive care and those who give care.
- **Efficient:** Avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equitable:** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location or socio-economic status.
Bundle of Obstetrical Improvement Strategies to Reduce Claims Experience

Goal: Decrease adverse outcomes

- Standard approaches to high risk maternal/neonatal conditions
- Improved Emergency Cesarean response time
- Improved clinician competency in fetal monitoring
- Established a common language for staff to use in communicating concerns
- Standard approaches for managing high risk maternal medications

Result: HCA claims experience below industry benchmarks for 4 years
Principles of High Reliability Organizations

TIMING OF ELECTIVE DELIVERY

Steven L. Clark, MD
Medical Director Women and Newborn’s Service
Hospital Corporation of America

Webcast supported by the March of Dimes
“We are confident that this higher level of care cannot be achieved by further stressing current systems of care. The current care system cannot do the job. Trying harder will not work. Changing systems of care will.”

The Institute of Medicine - Crossing the Quality Chasm
Figure 2. Percentage of infants born preterm and born low birthweight: United States, 1990, 1995, 2000, and 2004

†Preliminary data.

NOTE: Due to changes in data collection from implementation of the 2003 revision of the U.S. Standard Certificate of Live Birth, there may be small discontinuities in rates of primary cesarean delivery and VBAC in 2003 and 2004; see "Technical Notes."
IN THE IOM REPORT, SYSTEMS FLAWS WERE MORE IMPORTANT THAN INCOMPETENT PRACTITIONERS
THE HCA SYSTEMS APPROACH

Based upon 5 principles

• Uniform process = improved outcome/ Process variation = poor outcome. Physician autonomy is an antiquated and generally dangerous concept.
• Every member of the team is empowered and obligated to stop dangerous care
• Cesarean delivery is a process, not an outcome endpoint
• Litigation is best reduced by reducing adverse outcomes and improving documentation, not by attempting to make bad care more defensible
• Effective peer review is, with few exceptions, non-existent and needs to be overhauled.
Oxytocin was recently added to the Institute for Safe Medical Practices list of high risk medications which “bear a heightened risk of harm” and which warrant “special safeguards to reduce the risk of error”

This list includes only 11 other medications
A protocol for use of oxytocin

Roger K. Freeman, MD; Mike Nageotte, MD

Induction or augmentation of labor with oxytocin occurs frequently in modern obstetric practice. With induction of labor in certain centers approaching 40% of patients and augmentation of labor being more the rule than the exception, it appears that oxytocin is now utilized in the majority of laboring patients. Despite this fact, there is less than consensus regarding the best nursing and physician practices with respect to the safe use and efficacy of this potentially dangerous drug. In this month’s issue, Clark and colleagues report on a simple checklist protocol for the use of oxytocin in labor. As they astutely point out, variations in management that are lauded by many practitioners as “individualization” based on medical judgment and experience do not necessarily equate to best practice in clinical settings. One prominent example of this that is well known to obstetric care providers is the fact that cesarean delivery rates for similar indications have remarkably high variation both between and within institutions. These differences appear to be more related to the individual healthcare provider, the patient specific socioeconomic group, the type of insurance, or teaching versus nonteaching hospital than to any specific clinical patient characteristics. In a similar fashion, there are multiple protocols for oxytocin administration, including “Low Dose,” “High Dose,” “Active Management of Labor,” patterns. In their pilot program, both “pre-oxytocin” and “oxytocin in use” checklists were recorded in a prospective fashion by nursing personnel both prior to initiation of oxytocin and then every 30 minutes while oxytocin was being infused. Despite understandable clinical concerns expressed by caregivers prior to study initiation, this approach actually resulted in no change in either the duration of time from institution of oxytocin infusion until delivery or in the overall cesarean delivery rate. The mean maximum oxytocin infusion rate was significantly reduced. Furthermore, there appeared to be improved newborn outcomes with significantly fewer adverse results following protocol implementation. The multiple small differences in outcome measurements that favored the “conservative” check list group may well be significant with larger numbers. In fact, when this approach was subsequently applied to all Hospital Corporations of America hospitals, there was a significant reversal of the preceding year over year rise in cesarean delivery rates. It would be interesting if the authors have access to the same outcome data that were evaluated in their initial program to determine if a statistically significant improvement in neonatal outcomes could be demonstrated across the some 220,000 births in the year with the conservative check list compared to the preceding year.
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Oxytocin is a synthetic octapeptide currently used in a majority of all births in the United States. In the past 2 decades, the near-universal use of controlled infusion devices and electronic fetal heart rate and uterine contraction monitoring instruments has made oxytocin safer than it once was. Nevertheless, oxytocin remains the drug most commonly associated with preventable adverse events during childbirth.

Oxytocin is also frequently implicated in professional liability claims and thus poses a dual concern for individual clinicians and the organizations in which they practice. Approximately half of all paid obstetric litigation claims involve allegations of oxytocin misuse.

Recently, oxytocin was added to the list of high-alert medications designated by the Institute for Safe Medication Practices (ISMP), a distinction reserved for drugs that are highly effective, highly lethal, or both.

Oxytocin is the drug most commonly associated with preventable adverse perinatal outcomes and was recently added by the Institute for Safe Medication Practices to a small list of medications “bearing a heightened risk of harm,” which may “require special safeguards to reduce the risk of error.” Current recommendations for the administration of this drug are vague with respect to indications, timing, dosage, and monitoring of maternal and fetal effects. A review of available clinical and pharmacologic data suggests that specific, evidence-based guidelines for the intrapartum administration of oxytocin may be derived from available data. If implemented, such practices may reduce the likelihood of patient harm. These suggested guidelines focus on limited elective administration of oxytocin, consideration of strategies that have been shown to decrease the need for indicated oxytocin use, reliance on low-dose oxytocin regimens, adherence to specific semiquantitative definitions of adequate and inadequate labor, and an acceptance that once adequate uterine activity has been achieved, more time rather than more oxytocin is generally preferable. The use of conservative, specific protocols for monitoring the effects of oxytocin on mother and fetus is likely not only to improve outcomes but also reduce conflict between members of the obstetric team. Implementation of these guidelines would seem appropriate in a culture increasingly focused on patient safety.

**Key words:** adverse perinatal outcomes, evidence-based guidelines, labor, monitoring protocols, oxytocin

Cite this article as: Clark SL, Simpson KP, Knox GE, et al. Oxytocin: new perspectives on an old drug.
Maternal death in the 21st century: causes, prevention, and relationship to cesarean delivery

Steven L. Clark, MD; Michael A. Belfort, MD; Gary A. Dildy, MD; Melissa A. Herbst, MD; Janet A. Meyers, RN; Gary D. Hankins, MD

OBJECTIVE: We sought to examine etiology and preventability of maternal death and the causal relationship of cesarean delivery to maternal death in a series of approximately 1.5 million deliveries between 2000 and 2006.

STUDY DESIGN: This was a retrospective medical records extraction of data from all maternal deaths in this time period, augmented when necessary by interviews with involved health care providers. Cause of death, preventability, and causal relationship to mode of delivery were examined.

RESULTS: Ninety-five maternal deaths occurred in 1,461,270 pregnancies (6.5 per 100,000 pregnancies.) Leading causes of death were complications of preeclampsia, pulmonary thromboembolism, amniotic fluid embolism, obstetric hemorrhage, and cardiac disease. Only 1 death was seen from placenta accreta. Twenty-seven deaths (28%) were deemed preventable (17 by actions of health care personnel and 10 by actions of non-health care personnel). The rate of maternal death causally related to mode of delivery was 0.2 per 100,000 for vaginal birth and 2.2 per 100,000 for cesarean delivery, suggesting that the number of annual deaths resulting causally from cesarean delivery in the United States is about 20.

CONCLUSION: Most maternal deaths are not preventable. Preventable deaths are equally likely to result from actions by nonmedical persons as from provider error. Given the diversity of causes of maternal death, no systematic reduction in maternal death rate in the United States can be expected unless all women undergoing cesarean delivery receive thromboembolism prophylaxis. Such a policy would be expected to eliminate any statistical difference in death rates caused by cesarean and vaginal delivery.

Key words: cesarean delivery, maternal death, quality of care

OBSTETRICS

Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety

Steven L. Clark, MD; Michael A. Belfort, MD, PhD; Spencer L. Byrum, LCDR (ret.) USCG; Janet A. Meyers, RN; Jonathan B. Perlin, MD, PhD

The Hospital Corporation of America (HCA) is the nation’s largest private health care delivery system, providing approximately 220,000 deliveries annually in 120 facilities in 21 states. Representing approximately 5% of all births in the United States, we describe here our assessment and approaches to 4 major challenges in contemporary obstetric practice and the initial results of these initiatives. Notably, and as part of a concerted effort to incorporate the features of high-reliability organizations into HCA’s obstetrical services, these interventions have been associated with improved perinatal outcomes, a reduced primary cesarean delivery rate, and lower maternal and fetal injury, with reduced litigation, as measured by halving of the number of claims and a nearly 70% decrease in error rates compared to the short-term trend have not been readily forth-

In a health care delivery system with an annual delivery rate of approximately 220,000, a comprehensive redesign of patient safety process was undertaken based on the following principles: (1) uniform processes and procedure result in an improved quality; (2) every member of the obstetric team should be required to halt any process that is deemed to be dangerous; (3) cesarean delivery is best viewed as a process alternative, not an outcome or quality endpoint; (4) malpractice loss is best avoided by reduction in adverse outcomes and the development of unambiguous practice guidelines; and (5) effective peer review is essential to quality medical practice yet may be impossible to achieve at a local level in some departments. Since the inception of this program, we have seen improvements in patient outcomes, a dramatic decline in litigation claims, and a reduction in the primary cesarean delivery rate.

Key words: litigation, patient outcomes, patient safety, quality medical practice

Hospital Corporation of America (220,000 deliveries annually)
Frequency Trends
Reported Claims Per 10,000 Births

Accident Year


HCA
Figure 5. Percentage of preterm births: United States, 1990, 2004, and 2005

<table>
<thead>
<tr>
<th>Year</th>
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<th>34-36 weeks</th>
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<td>1.4</td>
<td>1.9</td>
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<td>2005</td>
<td>12.7</td>
<td>9.1</td>
<td>1.6</td>
<td>2.0</td>
</tr>
</tbody>
</table>

*1 Based on preliminary data.
SOURCE: CDC/NCHS, National Vital Statistics System*
THE POINT

• Elective “term” deliveries have gotten out of hand
• As a profession, we have become sloppy and regularly violate the standard of care set by our professional organization (ACOG)
• This practice is causing neonatal morbidity and contributing to the increasing cesarean delivery rate
THE REASONS

• Patient convenience
• Physician convenience/lifestyle
• Outdated terminology
• “Normalization of deviance”
Terminology

- Term = 37-42 weeks
- Preterm = < 37 weeks
- Postterm = > 42 weeks

Classifications developed in an era in which dates were always uncertain, and timing of delivery was largely a matter of chance.

Do these classifications make sense today?
CONSIDER:

• There is no physiologic basis for this demarcation
• Pulmonary maturity is a sliding scale reaching an apex at 39 weeks
• Fetal morbidity reaches a nadir at 39 weeks and increases progressively beyond 39 weeks
POTENTIAL CONSEQUENCES OF INAPPROPRIATE GROUPING

• Hesitation to intervene (with indications) at 36 weeks – “she is not yet term!”
• Lack of monitoring between 39-42 weeks – “she is not yet post term!”
• 37 week fetuses are considered as mature as 39 + week fetuses – “might as well get you delivered since you are at term!”
OBJECTIVE: To quantify adverse neonatal and maternal outcomes associated with elective term delivery at less than 39 completed weeks of gestation.

STUDY DESIGN: Prospective observational study conducted in 27 hospitals over the course of 3 months in 2007.

RESULTS: Of 17,794 deliveries, 14,955 (84%) occurred at 37 weeks or greater. Of term deliveries, 6562 (44%) were planned, rather than spontaneous. Among the planned deliveries, 4645 (71%) were purely elective; 17.8% of infants delivered electively without medical indication at 37-38 weeks and 8% of those delivered electively at 38-39 weeks required admission to a newborn special care unit for an average of 4.5 days, compared with 4.6% of infants delivered at 39 weeks or beyond \( (P < .001) \). Cesarean delivery rate in women undergoing induction of labor was not influenced by gestational age but was highly influenced by initial cervical dilatation and parity, ranging from 0% for parous women induced at 5 cm or greater to 50% for nulliparous women at 0 cm.

CONCLUSION: Elective delivery before 39 weeks' gestation is associated with significant neonatal morbidity. Initial cervical dilatation is highly correlated with cesarean delivery among women undergoing induction of labor in both nulliparous and parous women. Elective delivery before 39 completed weeks' gestation is inappropriate. Women contemplating elective induction at or beyond 39 weeks' gestation with an unfavorable cervix should be counseled regarding an increased rate of cesarean delivery.

Key words: elective delivery, induction of labor, repeat cesarean delivery
FOR WOMEN AT 39 WEEKS OR BEYOND WITH A FAVORABLE CERVIX, ELECTIVE INDUCTION CARRIES A CESAREAN RATE BELOW THAT SEEN IN THE GENERAL POPULATION WITH NO INCREASE IN NEONATAL MORBIDITY
ELECTIVE DELIVERY <39 WEEKS IS A NEW NQF QUALITY METRIC

Rate will affect hospital and physician reimbursement
THE POINT

• Elective “term” deliveries have gotten out of hand
• As a profession, we have become sloppy and regularly violate the standard of care set by our professional organization (ACOG)
• This practice is causing neonatal morbidity and contributing to the increasing cesarean delivery rate
• Let’s stop it before the government or insurance companies stop it for us!
Changes in Practice over the past 2 years: 2007 to 2009

• Same 27 facilities observed in the 2007 data
• Elective deliveries at >37 and 0 days decreased from 26.2% of all term deliveries in 2007 to 12.7% in 2009
• Similar decrease in total planned deliveries (elective and indicated combined): from 44% to 29%
• 56% decrease in elective delivery 37-38 weeks
• 52% decrease in elective delivery 38-39 weeks
• 16% decrease in NICU admissions among infants >37 weeks gestation

Steven Clark, MD
TERM DELIVERIES
HCA Pilot Facilities

Elective %

Elective + Indicated %

2007
2009

0 5 10 15 20 25 30 35 40 45

Elective %
Elective + Indicated
TERM NICU ADMISSIONS
HCA Pilot Facilities

NICU Admissions/10,000 Births

2007: 90
2009: 75
Financial Impact of Late Preterm Birth

- Retrospective study, 543,000 deliveries in California (Gilbert 2003). 5,788 34 week gestation infants
- Mean LOS and hospital costs were 5.9 days and $7200.
- Delay of delivery by 1 week: costs decreased to $4200
- 36-37 weeks: $2600 and $1700, whereas 38 weeks: $1100
Avoiding Iatrogenic Prematurity

Common public perception that “premature birth is a miracle rather than a risk”
(M. Buus-Frank, 2005)