Clinical Excellence Series

Eliminating Birth Trauma at Ascension Health

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This article is the fifth of a series, which charts the journey of one health care system, Ascension Health, toward the clinical transformation of inpatient care and no preventable injuries or deaths.

As previously described, Ascension Health, the largest Catholic and largest nonprofit health care system in the United States, articulated a call to action to provide "Healthcare That Works, Healthcare That Is Safe, and Healthcare That Leaves No One Behind."[1,2] This article reports on three alpha sites' experiences in addressing one of Ascension Health's eight priorities—perinatal safety.

In February 2004, the Seton Family of Hospitals, Austin, Texas (Seton) and St. Mary's Hospital for Women and Children, Evansville, Indiana (St. Mary's) began their efforts to eliminate birth trauma. Seton, a multihospital network with four hospitals providing obstetrical services, had 9,050 live births in 2004, and St. Mary's, a 480-bed community hospital, had 2,081 live births. In December 2004, Our Lady of Lourdes Memorial Hospital, Binghamton, New York (Lourdes), a 267-bed hospital with 1,201 live births in 2004, was added as the third site.

According to the Agency for Healthcare Research and Quality (AHRQ), the rate of birth trauma per 1,000 live births was 7.358 in 2001.[3] Birth trauma is emotionally devastating to families. Fortunately, it occurs with a relatively low frequency; however, the long-term cost to providers, families, and society is reflected in the enormous burden of litigation costs associated with these injuries. The scale of litigation and the emotional cost to providers have led to a dramatic escalation in cesarean section (C-section) delivery rates and the widespread

Article-at-a-Glance

Background: Ascension Health identified perinatal safety as one of eight priorities for action in a systemwide effort to achieve zero preventable injuries and deaths by July 2008.

Implementation: Three alpha sites developed and implemented transformational practices aimed at eliminating preventable birth trauma. Standardized order sets linked to all major areas of obstetrical care were either updated or developed and then tested and incorporated into the work flow of the labor and delivery units. Best practices were shared via team meetings and conference calls. Each site created systems to ensure that evidence-based practices were reliably followed for high-risk conditions associated with perinatal harm, that robust strategies for communication were adopted, and that collaborative practice was promoted among caregivers.

Results: By June 2006, all facilities achieved birth trauma rates that were at or near zero in conjunction with the implementation of these practices.

Discussion: Three alpha sites of differing size, patient demographics, and available resources, using a combined uniform and facility-specific approach, achieved a significant reduction in the incidence of birth trauma. Yet each site adopted unique site-specific processes designed to enhance practice on the basis of unit or institutional culture, market challenge, and/or the prospect for success.

Table 1. Elective Induction Bundle

- Assessment of gestational age (ensuring that gestational age is ≥ 39 weeks)
- Monitoring fetal heart rate for reassurance
- Pelvic assessment
- Monitoring and management of hyperstimulation

Table 2. Augmentation Bundle

- Estimated fetal weight
- Monitoring fetal heart rate for reassurance
- Pelvic assessment
- Monitoring and management of hyperstimulation

decision made by many physicians to discontinue the practice of delivering babies.[4]

Ascension Health recognized that reducing the rate of birth trauma could contribute to its goal of zero preventable injuries and deaths. Together, the three alpha teams adopted principles common to the "high-reliability organization"[5] with the intent of developing transformational processes to reach Ascension Health's goal by July 2008. In keeping with widely accepted standards, the alpha sites set the Agency for Healthcare Research and Quality's Birth Trauma–Injury to Neonate (Patient Safety Indicator [PSI] 17) as the standard for defining birth trauma.[6]

An analysis of the evidence-based literature reveals that most neonatal injuries are potentially avoidable with recognition and anticipation of known risk factors. Common issues responsible for the majority of preventable perinatal harm and obstetrical liabilities include the following[7]:

- Failure to recognize fetal distress/non-reassuring fetal status
- Failure to effect a timely cesarean birth
- Failure to properly resuscitate a depressed baby
- Inappropriate use of oxytocin/misoprostol
- Inappropriate use of vacuum/forceps

Suboptimal outcomes are also seen when there is poor communication among caregivers, failure of the provider to respond when needed, and/or failure to initiate the chain of command when there is clinical disagreement.[8]

Each alpha site developed a multifaceted approach to enhancing perinatal safety in an effort to develop and test transformational practices. A communication tool known as SBAR (***S***ituation, ***B***ackground, ***A***ssessment, ***R***ecommendation) was customized for perinatal use.[9] Following a collaborative learning session involving all three sites, a common interpretational format for fetal heart monitoring was adopted from National Institute of Child Health and Human Development (NICHD) guidelines for electronic fetal monitoring (EFM),[10] which were endorsed by the American College of Obstetrics and Gynecology (ACOG)[11] and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN).[12] Department and staff meetings, both formal and informal, were restructured to accommodate joint nurse–physician EFM strip interpretation and emphasized communication using SBAR.

In collaboration with the Institute for Healthcare Improvement (IHI), two new perinatal "bundles" were developed for the use of oxytocin in elective induction (Table 1, above) and augmentation of labor (Table 2, above). A bundle is "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."[9] Bundle science theory requires the creation of a framework for focusing performance on selected best practices. This is meant to ensure attentiveness to clinical process and that the methodology has been validated for that purpose.[13]

To guarantee that all elements of both bundles were dependably addressed to ensure the safest use of oxytocin, standardized order sets and documentation forms with check boxes and "fill-in" blanks were created. These were meant to serve as forcing functions aimed at "making it easy to do the right thing."

Implementation

Each alpha site began its individual perinatal safety efforts in February 2004, following the establishment of an interdisciplinary team. Membership included senior administrators, multiple physician specialties, nursing, risk management, quality leaders, and other key staff members.

Elective Induction Bundle Compliance at St. Mary's Hospital for Women and Children, February 27, 2005–February 16, 2006

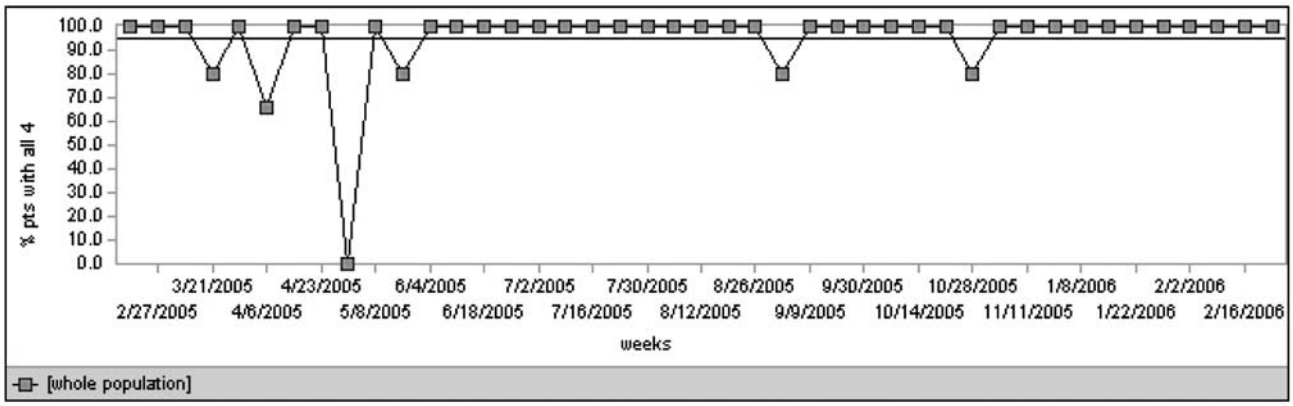


Figure 1. *The percentages of time all four aspects of the elective induction bundle (standard project measure) were in place are shown.*

The three sites' goal was to create a change package of clinical processes that would be medically sound, would reflect best practice, and could generate positive and reproducible outcomes in the effort to eliminate all preventable injury and death to neonates by July 2008. In the absence of published systematized processes that could reliably achieve such an outcome, attention first centered on the five recurring clinical areas responsible for the majority of preventable perinatal harm.[7]

At all three sites, highly standardized order sets linked to all major areas of obstetrical care were either updated or developed and then tested and incorporated into the work flow of the labor and delivery (L&D) units. Best practices were shared via team meetings and conference calls.

The AHRQ PSI 17 definition[6] was used to assess birth trauma rates, and data were collected and posted monthly. The initial identification for each birth trauma was made via hospital coding data as well as from "real-time" unit reports. Each birth trauma was subsequently validated by chart review.

In conjunction with expert consultants from the IHI, oxytocin bundle compliance was assessed by retrospective review of five charts per week or 20 charts per month, all randomly selected, for both elective inductions and for augmentations. The technique used for random selection varied among sites, depending on patient volume and the frequency of oxytocin use. The larger sites (Seton, St. Mary's) used a "simple random sample" (selection entirely by chance) process or alternatively, a sample taken from a standard patient population (for example, the first five relevant patient charts each week). Lourdes' smaller site included virtually all patients who received oxytocin during the month in question in the analysis. All sites also used one of the following two methods for assessing bundle compliance[14]:

- Standard project measure, which identifies the percentage of time all four aspects of the bundle were in place. In this instance, a chart was not considered compliant unless all four elements of the bundle were addressed and executed (Figure 1, above).
- Composite measure, which identifies the percentage of time all aggregate components were in place. By this method, the compliance rate was measured as the total number of components successfully executed divided by the total number of components measured (Figure 2, page 18).

The method used to eliminate elective inductions before 39 weeks also varied depending on the site. Some of the sites instituted a "hard stop" methodology, in which staff would not allow inductions before that gestational age to be scheduled unless the medical indication was documented. Physicians who disagreed with this approach were referred to an appropriate physician or staff leader according to the chain of command. Other sites did not attempt to eliminate scheduling up front but

Augmentation Bundle Compliance at Our Lady of Lourdes Memorial Hospital, March 14, 2005–February 28, 2006

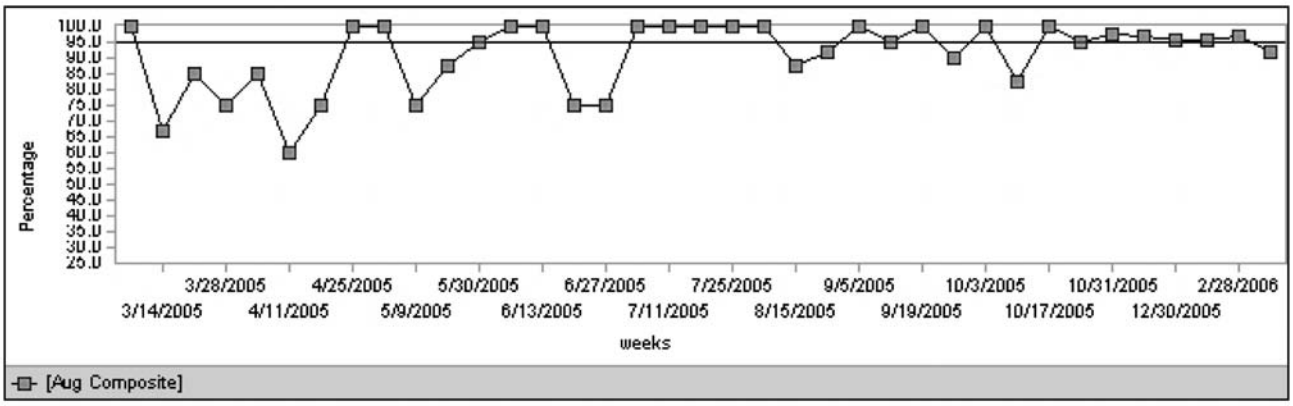


Figure 2. *The percentage of time all aggregate components were in place (composite measure) are shown.*

performed retrospective review and took action utilizing physician "report cards" and/or peer review.

At all three sites, oxytocin could not be started until assessment of the fetal heart monitor tracing for reassurance was documented, for which NICHD nomenclature was adopted. In addition, according to ACOG, "The presence of fetal heart rate accelerations generally ensures that the fetus is not acidemic and provides reassurance of fetal status."[11(p. 1457)]

By definition, "pelvic assessment" involved an examination that included measurement of degree of dilation and effacement, the station, cervical position and consistency, and fetal presentation. To be considered compliant, it had to be performed and documented before oxytocin was initiated.

Monitoring and managing hyperstimulation was intended to monitor the patient for the presence of this finding and to respond appropriately. For all sites, hyperstimulation was defined as follows: (1) a persistent pattern of more than five contractions occurring during a 10-minute period, (2) contractions lasting 2 minutes or more, or (3) contractions of normal duration occurring within 1 minute of each other that may or may not have included nonreassuring fetal heart measurements.[15]

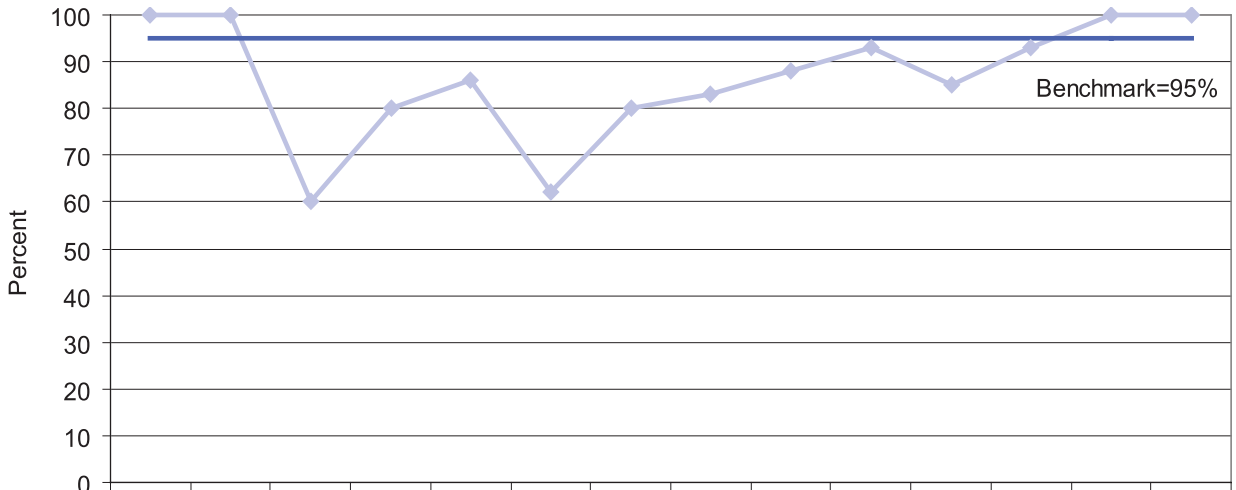
Each site took a broad-based approach to achieve the desired transformational processes. The L&D process was mapped from start to finish, and the areas of highest potential risk were identified by using the Failure Mode and Effects Analysis (FMEA) technique.[16] The analysis revealed that variation in practice and deviation from consistent adherence to ACOG guidelines were two major causes of failure. To address these findings, the alpha sites determined that best practices called for the following:

- Ensuring that operative devices (that is, forceps and vacuum) were used according to ACOG guidelines[17] (implemented at Seton and St. Mary's)
- Ensuring that elective labor induction was confined to fetuses of gestational age ≥ 39 weeks[18] (implemented at Seton and Lourdes)
- Ensuring that effective communication and collaborative practice occurred between staff and providers in recognizing fetal distress (implemented at all three sites)

Site-Specific Areas of Concern

Each site focused on other selected areas of concern specific to the organization. Seton incorporated the "Live Case Study" process for direct observation[19] of L&D unit function by other Seton facilities and created an infrastructure for simulation of obstetrical emergencies using high-fidelity mannequins. St. Mary's implemented an aggressive education campaign in conjunction with formal shoulder dystocia drills for all staff in the L&D suite as a result of two birth trauma injuries that accompanied a total of 15 vacuum deliveries in 2004. Lourdes focused on communication (SBAR), education, and a culture

Elective Inductions for Gestational Age ≥ 39 Weeks at Our Lady of Lourdes Memorial Hospital, February 1, 2005–March 31, 2006



	Feb-05	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	Mar-06
Gestational Age ≥ 39 weeks	100	100	60	80	86	62	80	83	88	93	85	93	100	100
Number of Patients	4	3	10	5	7	8	5	6	8	14	13	14	5	10
Benchmark=95%	95	95	95	95	95	95	95	95	95	95	95	95	95	95

Figure 3. *The prevalence of elective induction before 39 weeks dropped significantly at Lourdes Memorial Hospital (as shown) and the other two alpha sites. For example, for August 2005, 80% of elective inductions were conducted at ≥ 39 weeks; that is, 20% were conducted earlier. Data collected for the following quarter (April 1, 2006–June 30, 2006) demonstrated a small backward trend (data not shown).*

shift to collaboration among all care providers.[11] Recognizing the role nurse–physician communication played in ensuring fetal and maternal safety, Lourdes initiated collaborative learning[20] through formal and informal meetings to instruct all caregivers in EFM definitions, interpretation, and interventions.

Results

All three sites achieved consistently high levels of compliance with both bundles. Compliance with the elective induction bundle was challenging because of the element of restricting elective inductions to gestational age ≥ 39 weeks (example, Figure 1). Compliance with the augmentation bundle, while also challenging because of the requirement to ensure documentation of estimated fetal weight (EFW), was also accomplished (example, Figure 2).

Overall, the prevalence of elective induction before 39 weeks dropped significantly at all sites. Lourdes reached the goal of no elective inductions before 39 weeks by March 2006 (Figure 3, above). Data collected for the following quarter demonstrated a small backward trend (data not shown), leading to corrective action that included direct intervention with the physicians involved. St. Mary's experienced a decrease of elective inductions from 27% in 2005 to 14% by June 2006. In the four units associated with the Seton network, this practice was effectively eliminated (Figure 4, page 20).

The focus on selective site-based initiatives also yielded beneficial results. Seton's effort to standardize use of assistive operative devices led to a "ten to the minus two"[21] performance in ensuring that no more than three "pop offs" occurred when a vacuum was applied, that combined use of vacuum and forceps did not occur, and that application of vacuum devices was not carried out before 36 weeks gestation. By the end of fiscal year 2006, Seton accomplished a significant reduction (36%) in operative vaginal deliveries from a frequency of 7.4% to 4.7% ($p < .001$, confidence interval [CI] = 95%; Figure 5, page 21).

St. Mary's shoulder dystocia education campaign and drills resulted in zero birth traumas in conjunction with the 37 shoulder dystocia cases between January 2005

Reduction of Elective Inductions Before 39 Weeks at the Seton Family of Hospitals, July 1, 2004–March 31, 2006

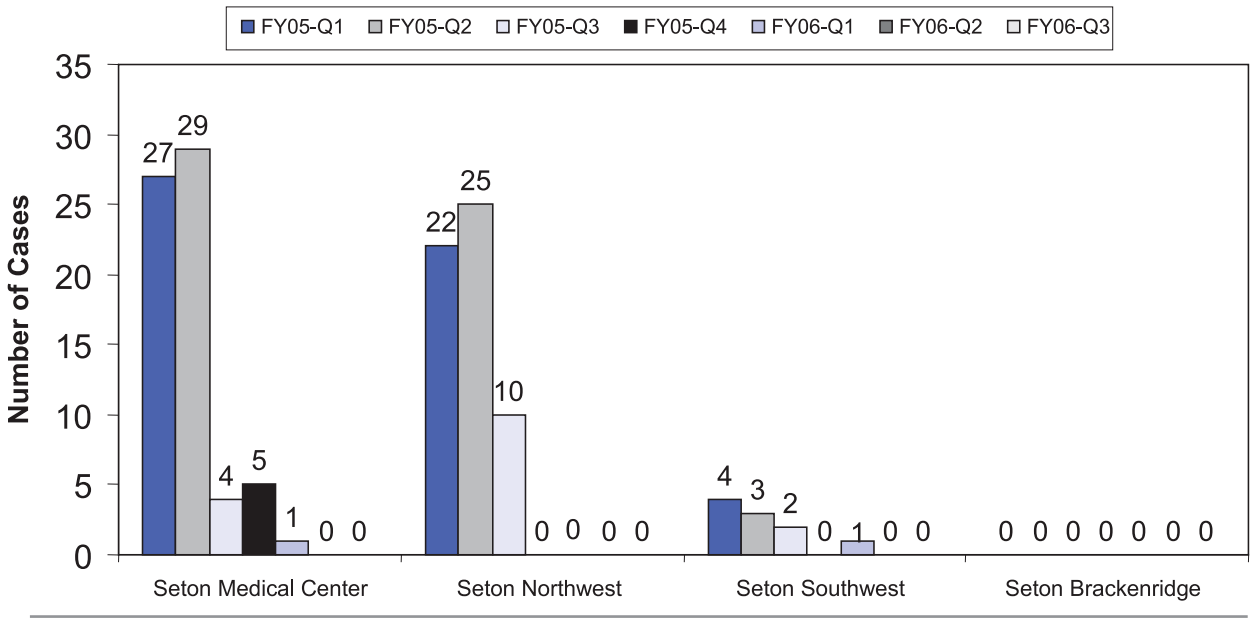


Figure 4. *Elective induction before 39 weeks was effectively eliminated at the four units associated with the Seton network. The number of number of elective inductions remained at zero through the end of fiscal year (FY) 2006 (April 1, 2006–June 30, 2006; data not shown).*

and June 2006. Lourdes' communication (SBAR) program related to EFM interpretation achieved 100% participation among available caregivers in a joint physician–nurse conference held during 2006. Communication and teamwork became central to the continuing success of Lourdes' high-reliability perinatal service. Lourdes was the first of the three sites to accomplish nurse-physician collaborative education with EFM.

The collective result of all practices implemented was a substantial reduction in the incidence of birth trauma at all sites (Figure 6, page 22). By the end of fiscal year 2006, Seton experienced an 85% reduction in its birth trauma incidence, from a frequency of 2 per 1,000 (or 0.2%) for fiscal years 2003 and 2004 to 0.3 per 1,000 (or 0.03%) for fiscal years 2005 and 2006 ($p < .001$, CI = 95%). St. Mary's achieved zero birth traumas for the last 18 months of the study through June 2006, and Lourdes observed two incidents during a 12-month period through June 2006.

Discussion

Although birth trauma to the neonate occurs with a relatively low frequency,[3] it poses a tragic state of affairs for the affected patient and his or her family. The long-term cost of birth trauma to providers and society also is reflected in the enormous burden of litigation cost associated with injuries of this sort. Thus, any change in clinical practice that contributes to the reduction or elimination of birth trauma can only have a salutary impact on patients, family, and providers alike.

To a large extent, the approach to eliminate birth trauma was similar at all three alpha sites. At each site, an interdisciplinary team provided the initial vision. Senior leadership and physician champions helped to remove organizational barriers as the nursing team worked to operationalize the changes in the daily work. Quality leaders were responsible for measurement of predetermined indicators. Evidence-based practices were identified and actively promoted. Desired outcomes were identified prospectively, and accumulated data were regularly shared with staff and obstetricians.

All three sites adopted and employed the induction and augmentation bundles that drove clinical processes around the best practice use of oxytocin. The three sites developed and used a customized version of the SBAR

Operative Vaginal Delivery Rates (Using Vacuum or Forceps) at the Seton Family of Hospitals (Combined), July 1, 2000–March 31, 2006

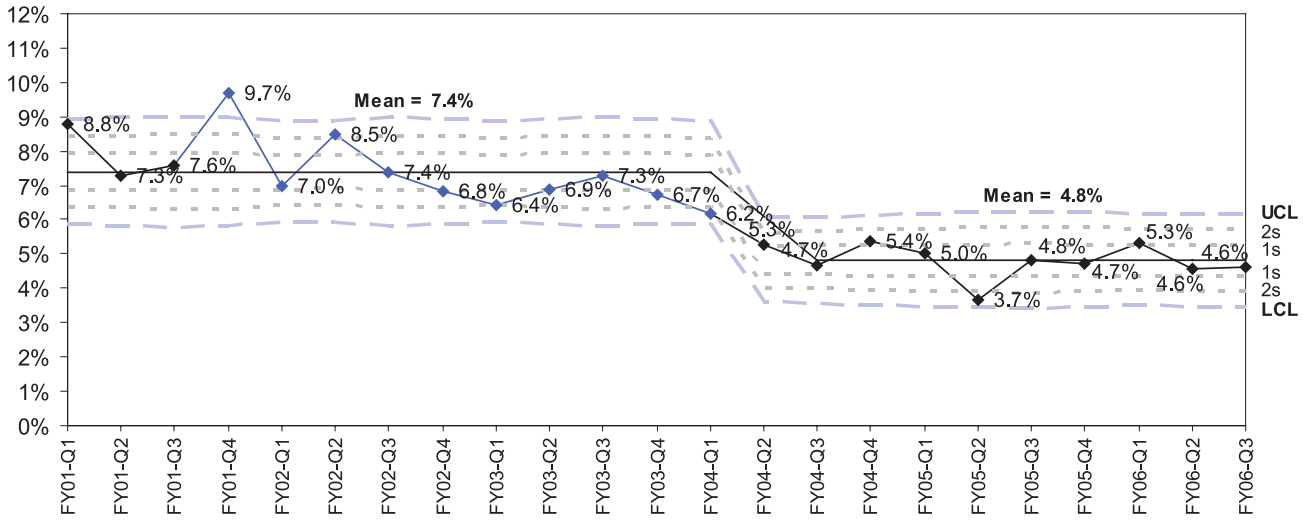


Figure 5. *By the end of fiscal year (FY) 2006, Seton accomplished a significant reduction (36%) in operative vaginal deliveries from a frequency of 7.4% to 4.8%. For FY06-Q4 (4th quarter; April 1, 2006–June 30, 2006), the mean operative vaginal rate was 4.1% (data not shown). UCL, upper control limit; LCL, lower control limit; s, sigma.*

tool to facilitate communication on the L&D unit, introduced processes aimed at eliminating iatrogenic prematurity by discouraging/preventing elective induction before 39 weeks of gestation, and reinforced appropriate use of assistive operative devices. Each facility actively engaged in the adoption of a common interpretational construct for EFM and engaged in education programs to advance the perinatal safety initiative. A culture of collaboration displaced, to a large degree, the traditional structure of autonomy and hierarchy that previously marked all units. Perhaps the hallmark of this project lay in the demonstration that the simultaneous blending of standardization of practice with highly reliable communication and collaboration strategies can drive substantive clinical process change and better clinical outcomes.

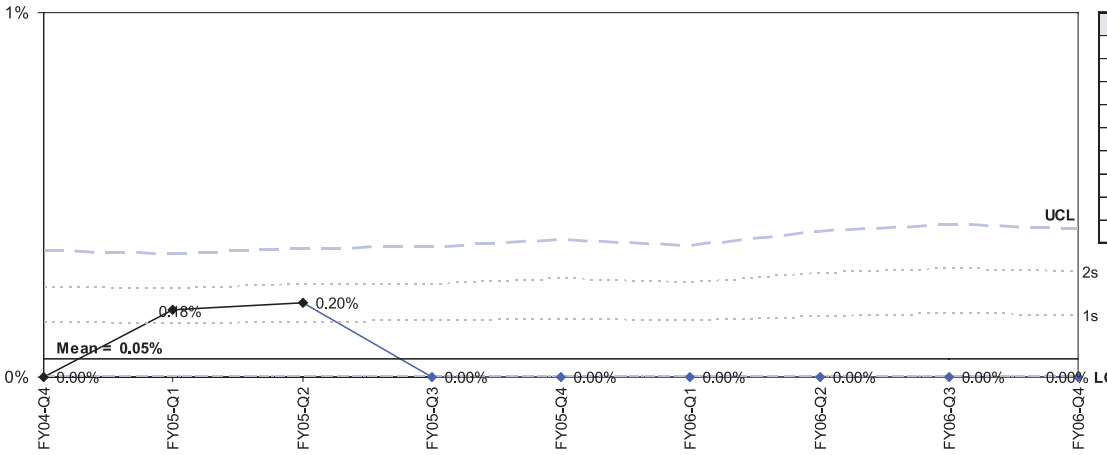
Although there was a great deal of consistency in each site's approach, each site adopted unique site-specific processes designed to enhance practice on the basis of unit or institutional culture, market challenge, and/or the prospect for success. As part of a consensus reached between staff and physicians at Seton, inductions for gestational age less than 39 weeks were not scheduled in the absence of an acceptable medical indication. In conjunction with established best practice, vacuum device use was not allowed before 36 weeks gestation or after three pop-offs had occurred during the delivery process. Combined use of vacuum and forceps was also deemed to be unacceptable practice.

On the basis of its own different circumstances, St. Mary's adopted an alternative approach to elective inductions. Physician and nursing team members made a proposal to the other hospital in the community to work together to improve the well-being of neonates. All physician groups deliver babies at both hospitals; therefore the expectation was that both hospitals would benefit from collaborative efforts to support best practices. Chart reviews were conducted monthly to ensure adherence to the documentation and practice changes that were made as a result of the initiative. All statistics were posted in the physicians' and nurses' lounges and discussed at obstetrics section, team, and nursing meetings, thus increasing dialogue for further improvements in patient care. Nurses and physicians became vested in promoting and sustaining the positive changes that led to the decrease in birth traumas.

Lourdes approached the challenge of restricting elective inductions by seeking a culture change led by education about the bundles, followed by physician

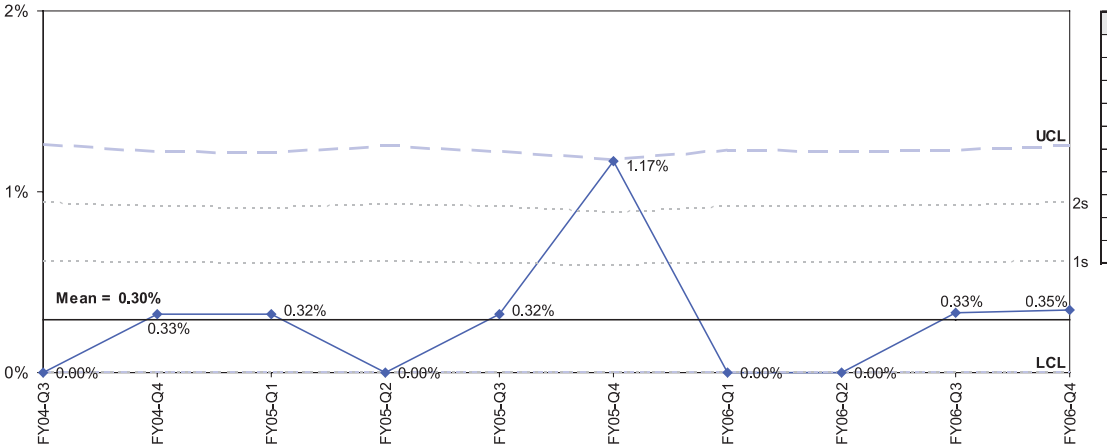
Birth Trauma Rates

St. Mary's Hospital for Women and Children, April 1, 2004–June 30, 2006



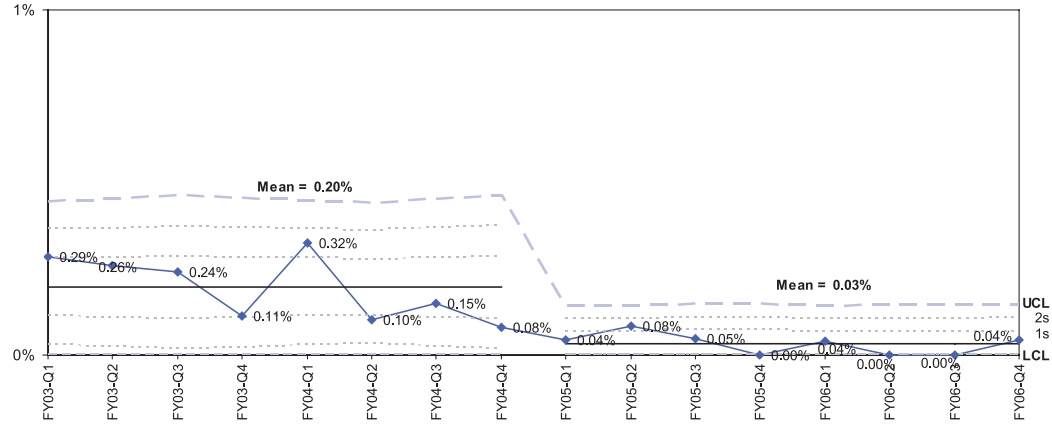
FY-Qtr	num/den
FY04-Q4	0 / 515
FY05-Q1	1 / 542
FY05-Q2	1 / 488
FY05-Q3	0 / 481
FY05-Q4	0 / 426
FY06-Q1	0 / 468
FY06-Q2	0 / 369
FY06-Q3	0 / 333
FY06-Q4	0 / 352

Our Lady of Lourdes Memorial Hospital, January 1, 2004–June 30, 2006



FY-Qtr	num/den
FY04-Q3	0 / 286
FY04-Q4	1 / 307
FY05-Q1	1 / 311
FY05-Q2	0 / 289
FY05-Q3	1 / 310
FY05-Q4	4 / 342
FY06-Q1	0 / 303
FY06-Q2	0 / 309
FY06-Q3	1 / 301
FY06-Q4	1 / 288

Seton Family of Hospitals, July 1, 2002–June 30, 2006



FY-Qtr	num/den	rate
FY03-Q1	8 / 2807	0.29%
FY03-Q2	7 / 2707	0.26%
FY03-Q3	6 / 2493	0.24%
FY03-Q4	3 / 2614	0.11%
FY04-Q1	9 / 2776	0.32%
FY04-Q2	3 / 2887	0.10%
FY04-Q3	4 / 2656	0.15%
FY04-Q4	2 / 2461	0.08%
FY05-Q1	1 / 2359	0.04%
FY05-Q2	2 / 2395	0.08%
FY05-Q3	1 / 2124	0.05%
FY05-Q4	0 / 2149	0.00%
FY06-Q1	1 / 2470	0.04%
FY06-Q2	0 / 2340	0.00%
FY06-Q3	0 / 2318	0.00%
FY06-Q4	1 / 2299	0.04%

Figure 6. *The collective result of all practices implemented was a substantial reduction in the incidence of birth trauma at all three alpha sites. FY, fiscal year; UCL, upper control limit; LCL, lower control limit; s, sigma.*

Primary Cesarean Delivery Rate at Seton Medical Center, Seton Family of Hospitals, January 1, 2004–March 31, 2006

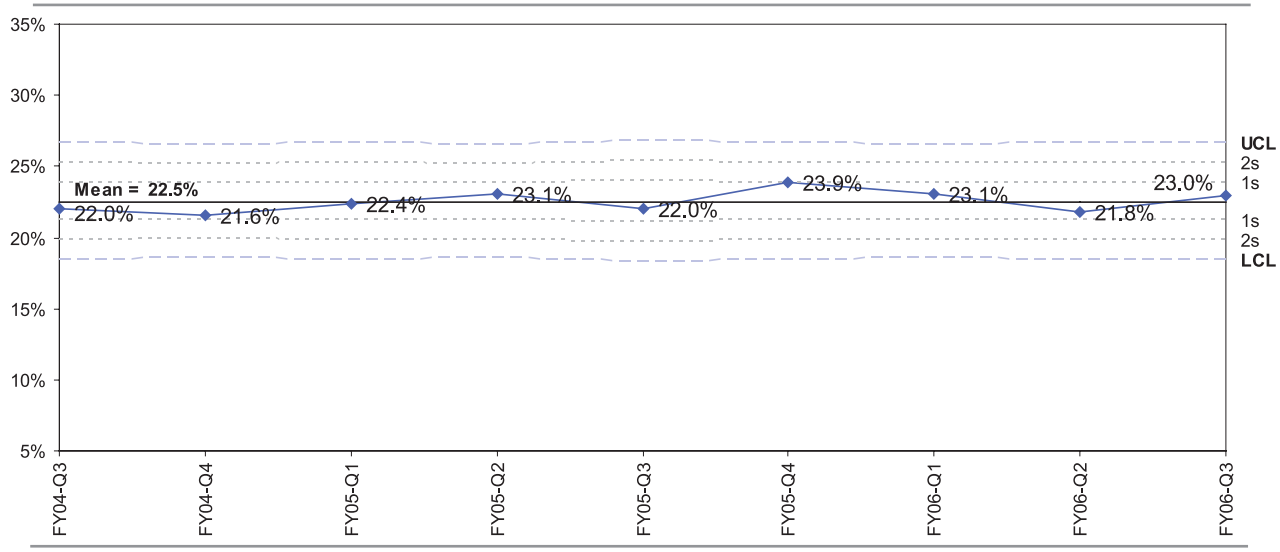


Figure 7. *The rate of primary cesarean section remained steady and in control at Seton Medical Center and the other alpha sites for the duration of the project. For fiscal year 2006, 4th quarter (FY06-Q4; April 1, 2006–June 30, 2006), the rate was 21.9% (data not shown). UCL, upper control limit; LCL, lower control limit; s, sigma.*

profiling. Beginning in January 2006, Lourdes posted data on the unit that showed overall hospital compliance with each element of the bundles and provided each provider a confidential report showing his or her individual compliance.

No improvement effort intended to transform care can assert success unless the source data are accepted as credible and verifiable. All three sites recognized the vital role of chart review in the validation of birth trauma cases even as many hospitals rely on coding sources that are largely financially driven to categorize clinical diagnoses and complications of care. In the case of this perinatal safety initiative, International Classification of Diseases, Clinical Modification (ICD-9-CM) coding systems do not allow for the differentiation of birth trauma sustained intrapartum and potentially separate adverse events that occur during the antepartum period. In addition, we found that ICD-9-CM 7679—"unspecified birth trauma"—can be a repository for highly variable injuries. This finding led the alpha sites to require that all reported birth traumas were validated during careful chart review by qualified personnel.

However, for the purposes of this project, the reduction in birth trauma seen at the alpha sites cannot be attributed to either this chart review or the heightened attention to coding. All facilities followed strict AHRQ guidelines[6] as the standard for measurement both for baseline data collected before the alpha project began and during the period of study.

Documentation for some elements of each bundle proved to be challenging. Providers were at first reluctant to document estimated fetal weight, contending in some cases that notation of gestational age should suffice. In addition, the lack of a uniformly accepted definition for hyperstimulation made compliance with that element of the bundles problematic and required site-based consensus before reliable documentation was ensured. Compliance called for recognition of a persistent hyperstimulation pattern, communication with the providers, and appropriate interventions.

One frequently voiced criticism was that any efforts made to reduce the frequency of operative delivery would directly result in an increase in the rate of primary C-section. Yet the alpha sites have not found this concern to be warranted. The national C-section rate has been increasing over time, which largely reflects the ACOG statement cautioning against vaginal birth after C-section[22] and maternal requests for

cesarean delivery.[23] An internal analysis of data collected from the three sites demonstrated that although the C-section rate *had* risen overall, the rate of *primary* C-sections remained steady and in control at the sites for the duration of the project (example, Figure 7, page 23).

Conclusion

Data from three health care systems representing six hospitals and more than 12,000 annual live births demonstrated a clear and convincing reduction in birth trauma during the course of the perinatal safety alpha effort. J

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