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Smoothing Patient Flow in the ICU

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Smoothing patient flow is cost-effective and delivers predictable staffing needs, allowing in turn for predictable, improved care. It also allows a rational assessment of resources and need, so that planned expansion of resources can be undertaken if growth and need have truly exceeded present capacity.

—Ryckman et al., page 542



Methods, Tools, and Strategies

A Comprehensive Perinatal Patient Safety Program to Reduce Preventable Adverse Outcomes and Costs of Liability Claims

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Safe care for mothers and infants during labor and birth is the goal of all clinicians and health care systems. Strategies to achieve this goal, such as operational and clinical practices based on professional guidelines/standards and best available evidence, must be well-designed and supported with sufficient resources and committed system leadership. We report details and achievements of a successful comprehensive perinatal patient safety program initiated by Catholic Healthcare Partners (CHP) in Cincinnati, with a focus on the 16 perinatal units surveyed between 2003 and 2007.

Background

CHP is a religious health care system with 32 hospitals, 16 of which have a perinatal service, responsible for approximately 17,700 births annually. The CHP mission of providing excellent care for mothers and infants, along with increasing costs of obstetrical liability claims, was the genesis of the program. A foundational philosophy from corporate leaders serves as the program core: "National guidelines and standards and current evidence will be the basis and underlying principles of perinatal care at all CHP hospitals."

As the program has evolved and professional liability claims have decreased, the primary focus has changed from loss reduction to patient safety and quality improvement. The board of directors is continually updated on progress and has taken a keen interest in ensuring success. Administrative leaders at each hospital are aware that this program is a high priority for the executive leadership team of the CHP system and as such are motivated to support program implementation. A member of the executive team serves as a sponsor for the program.

Program Components

INITIAL EDUCATION EFFORTS

Under the direction of the corporate director of loss prevention [C.C.K.], the perinatal initiative began in 1999 with annual educational offerings by a variety of perinatal clinical experts [including K.R.S., G.E.K.], which key members of the perina-

Article-at-a-Glance

Background: To achieve the goal of safe care for mothers and infants during labor and birth, Catholic Healthcare Partners (CHP; Cincinnati) conducted on-site risk assessments at the 16 hospitals with perinatal units in 2004–2005, with follow-up visits in 2006 through 2008.

On-Site Risk Assessments: In addition to assessing overall organizational risk, the assessments provided each hospital a gap analysis demonstrating up-to-date and out-dated practices and strategies and resources necessary to make all practices consistent with current evidence and national guidelines and standards.

Critical Aspects of Clinical Care: Review of claims and near-miss data indicate that fetal assessment, labor induction, and second-stage labor care comprise the majority of risk of perinatal harm. Therefore, these clinical areas were the focus of strategies to promote safety. To promote consistency in knowledge and practice, in 2004 a variety of strategies were recommended, including interdisciplinary fetal monitoring education and routine medical record reviews to monitor ongoing adherence to appropriate practice and documentation.

Outcomes: Success in implementing essential structural and process components of the perinatal patient safety program have resulted in improvement from 2003 to 2008 in specific outcomes for the 16 perinatal units surveyed, including reduction of perinatal harm, number of claims, and costs of claims.

Future Directions: The program continues to evolve with modifications as needed as more evidence becomes available to guide best perinatal practices and new guidelines/standards are published. A patient safety program guided and supported by a health care system can result in safer clinical environments in individual hospitals and in decreased risk of preventable perinatal harm and liability costs.

tal leadership team in each hospital were invited to attend. These sessions were intended to provide information regarding best perinatal practices on the basis of current evidence and national guidelines/standards promulgated by professional organizations. In addition, risk reduction strategies for specific practices known to increase the likelihood of perinatal injury and harm were presented. As others have discovered, simple provision of information and education does not always readily translate into changes in clinical behavior.

ON-SITE RISK ASSESSMENTS

To move the corporate goals further, beginning in 2003, CHP engaged perinatal safety consultants [K.R.S., G.E.K.] to conduct in-depth perinatal risk assessments of all CHP hospitals providing perinatal services. These assessment visits were scheduled in advance and took place throughout 2004 and 2005. The primary goals of the assessments were to evaluate whether existing operations and clinical practices were (1) consistent with the principles of patient safety, high reliability, and perinatal teamwork; (2) based on scientific evidence; and (3) consistent with published guidelines and standards for practice from professional and other health care organizations.* In addition to assessing overall organizational risk, the process provided each hospital a gap analysis demonstrating which practices were up to date, which practices were outdated, and importantly, strategies and resources necessary to move all practices to be consistent with current evidence and national guidelines and standards (Table 1, page 567, shows a list of sample items included in a gap analysis).

The on-site assessments typically involve a two-day process including review of department meeting minutes, event reports, root cause analyses, policies, procedures, routine provider orders, and medical records, as well as interviews with administrators and focus groups of physicians, nurse midwives, and nurses. This on-site risk assessment methodology has been validated and modified on the basis of use in more than 200 hospitals and health care systems in the United States with which we [K.R.S., G.E.K.] have worked.

During the on-site risk assessment, 40 recent medical records, including their corresponding fetal monitoring strips,

are randomly selected from the birth log by the members of the perinatal team at each site. Ten medical records are reviewed in each the following categories: unplanned term cesarean birth, induction of term labor, term babies with Apgar scores of less than 7 at five minutes of life, and term babies admitted to the special care nursery or neonatal ICU. The medical record review process focuses on clinical practices during labor and birth known to increase risk of perinatal harm and professional liability.

For each case reviewed, corresponding fetal monitoring strips are compared to medical record documentation for determination of accuracy of fetal heart rate (FHR) pattern interpretation, communication of findings, and appropriateness and timeliness of interventions during indeterminate or abnormal FHR patterns, uterine tachysystole, and emergent cesarean birth. Care during cervical ripening, labor induction, second-stage labor, operative vaginal birth, and the newborn period are also reviewed. Perinatal team leaders, staff nurses, attending physicians, and nurse midwives are invited to attend and actively participate in the review process, which emphasizes system vulnerabilities and patterns of care rather than judgment of individual practitioners. At the conclusion of these educational sessions, the hospital is provided the tools and methodology with which to continue the process internally in the future. These tools and methodology include but are not limited to the following:

- Strategies to develop an interdisciplinary practice committee, review current evidence and guidelines/standards from professional organizations, and implement recommended practice changes¹

- Components of a clinically focused medical record review using fetal monitoring strips as the basis for validation of documentation and appropriate timely interventions²⁻⁴

- A medical record form for documentation of indications for elective birth^{5,6}

- Tools to measure fetal safety during labor,^{7,8} audit appropriate and timely treatment for oxytocin-induced uterine tachysystole,⁹ and evaluate care during second-stage labor⁶

Table 2 (page 568) provides a sample tool with which to evaluate second-stage labor care.

Traditionally, medical record reviews have focused on documentation rather than overall patterns and process of care with the fetal monitoring strip used as a guidepost. Therefore, most participants are surprised that their day-to-day care and operations are identified on the basis of the medical records reviewed. Feedback is generally positive, and most participants feel that they are able to conduct future reviews regularly on the basis of

* These organizations included the American College of Obstetricians and Gynecologists (ACOG); the American Academy of Pediatrics (AAP); the American Society of Anesthesiologists (ASA); the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN); the National Association of Neonatal Nurses (NANN); the Association of peri-Operative Registered Nurses (AORN); the American Association of Nurse Anesthetists (AANA); the American Society of Post-Anesthesia Nurses (ASPA), The Joint Commission; and the Institute for Safe Medication Practices (ISMP).

Table 1. Sample Items in Gap Analysis*

<p>Practices Consistent with Current Evidence and Guidelines and Standards from Professional Organizations</p>	<p>There is a person at every birth whose sole responsibility is the infant based on NRP guidelines.</p>
<p>Policies and procedures are generally well written and referenced to the appropriate guidelines and standards from professional organizations.</p>	<p>Neonatal resuscitation is conducted based on NRP guidelines.</p>
<p>There is an anonymous nonpunitive error reporting system.</p>	<p>There is established criteria for transfer of high-risk mothers and infants.</p>
<p>There is a good citizenship/professional behavior policy based on the definition of disruptive clinician behavior and recommended strategies for resolution by ACOG and The Joint Commission.</p>	<p>Practices That Could Benefit from Change to Be Consistent with Current Evidence and Guidelines/Standards from Professional Organizations and Promote Safer Care for Mothers and Babies</p>
<p>There is a standard policy and physician order set for oxytocin administration (start at 1 mU/min and increase by 1–2 mU/min based on labor progress and maternal-fetal status no more frequently than every 30 min; direct bedside provider evaluation is required for increases beyond 20 mU/min; IV solution with 30 units oxytocin in 500 mL for labor induction; IV solution with 20 units oxytocin in 1,000 mL for immediate postpartum; IV solutions prepared by pharmacy); documentation of fetal well-being via 30-min EFM strip occurs prior to initiation of oxytocin; ongoing assessment and documentation of fetal well-being occurs prior to every dosage increase.</p>	<p>Medical record documentation regarding FHR patterns is inconsistent with NICHD definitions.</p>
<p>There is an agreed-upon definition of uterine tachysystole based on ACOG/AWHONN (a contraction frequency of more than five in 10 min averaged over 30 min, a series of single contractions lasting two min or more, contractions of normal duration occurring within one min of each other); an indeterminate or abnormal FHR pattern or the woman's perception of pain is not included in the definition. There is an agreed-upon treatment plan for tachysystole linked to provider orders that does not require additional orders prior to implementation.</p>	<p>Based on medical record documentation, intrauterine resuscitation measures are not routinely being initiated during indeterminate or abnormal FHR patterns.</p>
<p>There is a standard policy for magnesium sulfate administration (IV loading dose administered in 4 gram [100 mL] or 6 gram [150 mL] solution; maintenance solution 20 grams in 500 mL; nurse double-checks for initial dose/pump setting and all dosage/pump changes; IV solutions prepared by the pharmacy; nurse staffing minimum of 1 to 1 at the bedside during first hour of infusion and 1 to 2 as condition is stabilized).</p>	<p>Fetal assessment does not routinely occur in the surgical suite prior to unplanned cesarean birth.</p>
<p>Anesthesia coverage is adequate to meet the needs of the service; emergent cesarean births are initiated in a timely manner; women in labor do not have to wait for epidural pain relief.</p>	<p>Elective births are occurring before 39 completed weeks of gestation.</p>
<p>There is a policy requiring full surgical team in-house during labor of women attempting VBAC; all aspects of VBAC care consistent with ACOG guidelines.</p>	<p>Oxytocin-induced uterine tachysystole is common.</p>
<p>* ACOG, American College of Obstetricians and Gynecologists; EFM, electronic fetal monitoring; IV, intravenous; AWHONN, Association of Women's Health, Obstetric, and Neonatal Nurses; FHR, fetal heart rate; VBAC, vaginal birth after cesarean; NRP, Neonatal Resuscitation Program; NICHD, National Institute of Child Health and Human Development; AAP, American Academy of Pediatrics.</p>	<p>Oxygen for intrauterine resuscitation is being administered concurrently with oxytocin.</p>
	<p>Misoprostol for cervical ripening is administered in doses higher than recommended.</p>
	<p>All women receiving Cervidil are not continuously monitored via EFM.</p>
	<p>Provider coached pushing during second stage labor or indeterminate or abnormal FHR patterns is routine.</p>
	<p>All women who present in labor without prenatal HIV results are not being offered rapid HIV screening.</p>
	<p>All babies who are circumcised are not provided anesthesia for the procedure.</p>
	<p>Nurse-to-patient ratios routinely exceed those recommended by AAP/ACOG/AWHONN.</p>

what they learned during the process and the tools they were provided during the site visit.

An oral summary of findings is presented at the end of the site visit, followed by a written summary with recommenda-

tions for practice changes as needed, supported by an extensive list of references and tools to facilitate change. Current evidence and guidelines/standards from the organizations listed earlier (footnote, page 556) serve as the basis for the recommended

Table 2. Sample Tool to Evaluate Second-Stage Labor Care*

Expected Aspects of Second-Stage Labor Care		
Aspects of Care	Results	
Pushing is delayed until urge to push (up to 2 hr for nulliparous women and up to 1 hr for multiparous women with regional anesthesia).	Yes	No
Encouragement to do whatever comes naturally while pushing (no encouragement of closed-glottis pushing, e.g., take a deep breath and hold it; no counting to 10 with each pushing effort)	Yes	No
Pushing efforts are limited to 3–4 per contraction.	Yes	No
If FHR is indeterminate or abnormal, pushing efforts are modified (pushing with every other or every third contraction to maintain stable FHR baseline and minimize FHR decelerations) or temporarily discontinued until FHR is normal.	Yes	No NA
Excessive uterine activity is treated in a timely manner or tachysystole† does not occur.	Yes	No
Pushing occurs in various positions such as semi-Fowlers, lateral, or squatting (no forcing the woman's legs against her abdomen; no pushing in the supine lithotomy position; pushing in stirrups is limited to immediately prior to birth).	Yes	No
Foley catheters are not in place during pushing.	Yes	No
Operative vaginal births are consistent with guidelines recommended by ACOG (2000),‡ FDA (1998),§ and vacuum manufacturer.	Yes	No NA
Compliance with all expected aspects of care	Yes	No

*FHR, fetal heart rate; NA, not applicable.

† Standard definition of tachysystole: more than 5 contractions in 10 min (averaged over 30 min), contractions lasting 2 min or more, or contractions of normal duration occurring within 1 min of each other; an indeterminate/abnormal FHR pattern or the woman's perception of pain not included in definition

‡ American College of Obstetricians and Gynecologists (ACOG): *Operative Vaginal Delivery*. Washington, DC: ACOG, 2000:

Indications when the fetal head is engaged and the cervix is fully dilated:

Prolonged second stage:
 Nulliparous women: lack of continuing progress for 3 hours with regional anesthesia or 2 hours without regional anesthesia
 Multiparous women: lack of continuing progress for 2 hours with regional anesthesia or 1 hour without regional anesthesia
 Suspicion of immediate or potential fetal compromise
 Shortening of the second stage for maternal benefit

§ Food and Drug Administration: *FDA Public Health Advisory: Need for CAUTION When Using Vacuum Assisted Delivery Devices*, May 21, 1998. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062295.htm> (last accessed Sep. 18, 2009):

For vacuum assisted birth: Rocking movements or torque should not be applied to the device; only steady traction in the line of the birth canal should be used and clinicians caring for the baby should be alerted that a vacuum device has been used so that they can adequately monitor the baby for the signs and symptoms of device-related injuries.

|| Manufacturer: Refer to specific manufacturer guidelines of device being used.

clinical practice changes. The written summary of findings is provided to the hospital's top administrators, perinatal leadership team members, and everyone who participated in the process.

An action plan from each hospital is expected within 60 days after receiving the written summary of findings. Follow-up on-site visits [by K.R.S., G.E.K.] occur within approximately 18 months to 3 years after the original visit to assess ongoing progress with implementation of the recommended practice and operational changes. In the case of the on-site visits summarized in this article, these follow-up on-site visits occurred in 2006 through 2008. Interim assessment of progress toward meeting the goals of the program between on-site visits ("virtual visits") are conducted via telephone with a member of the CHP executive committee as coordinator. Action plans, challenges, and barriers to full implementation of recommenda-

tions are discussed during these virtual visits. In addition to the action plan, the hospital's yearly completion of review regarding implementation of recommended policies, practices, and protocols was required. Selected aggregate data from these surveys are provided in Table 3 (page 570). Data on structure, process, and outcome measures are submitted each quarter to the system office. This information, along with comparison statistics based on national benchmark data, are shared among all facilities.

Two case studies of hospitals undergoing an on-site risk assessment are provided in Sidebar 1 (page 569).

Findings and Suggested Changes Based on Essential Criteria for Safe Perinatal Care¹⁰

PROFESSIONAL BEHAVIOR

Throughout the risk assessment process, rare but concerning

Sidebar 1. Case Studies

Case 1

The medical staff in one hospital were resistant to changing practice related to avoiding elective births before 39 completed weeks of gestation. They offered the following rationale: A few days really does not make a difference in newborn outcomes; women want to be induced early for comfort and planning; and at times the induction schedule is full during the 39th week, and an earlier date is the only option. However, they were concerned about labor inductions being scheduled "too" early, so members of the obstetrical department voted to use 38 3/7 weeks as the gestational age limit for elective labor induction.

Approximately six months later, in anticipation of the on-site risk assessment visit, members of the obstetrical department voted to move this limit to 38 5/7 weeks. Data were collected to monitor admission of infants with symptoms of iatrogenic prematurity to the neonatal intensive care unit (NICU). During the course of the next six months, a 50% reduction in the number of infants admitted to the NICU for symptoms of iatrogenic prematurity was noted. The obstetricians were reported to be surprised by this change in outcomes, and as a result, they decided to use 39 completed weeks of gestation as the limit for elective births, as recommended (American College of Obstetricians and Gynecologists: *Induction of Labor*. Washington, DC: American College of Obstetricians and Gynecologists, 2009.)

Case 2

In one hospital, medical record documentation did not reflect universally accurate interpretation of fetal heart rate (FHR) patterns or use of FHR definitions that were consistent with those recommended by the National Institute of Child Health and Human Development (National Institute of Child Health and Human Development: Electronic fetal heart rate monitoring: Research guidelines for interpretation. National Institute of Child Health and Human Development Research Planning Workshop. *Am J Obstet Gynecol* 177:1385–1390, Dec. 1997.) In addition, documentation regarding the same FHR patterns at times differed between nurses and physicians. In response to the review findings and based on CHP program recommendations, the perinatal leadership group at the hospital decided to require electronic fetal monitoring (EFM) certification for all members of the perinatal team. To promote success on the EFM certification examination, the perinatal team convened study groups and developed review courses offered on multiple days so all clinicians could attend. Flexibility in times for offering the certification exam allowed universal participation. On the basis of this advanced planning and a team effort, this hospital was the first in the CHP system to achieve 100% certification in EFM by all members of the perinatal team. All the clinicians were successful in passing the EFM certification exam on the first try and reported improvements in communication of FHR pattern data during labor (both orally and in the medical record) and perinatal teamwork.

reports of disruptive clinician behavior surfaced in a minority of the hospitals. When such behavior was noted, it was often linked to inappropriate clinical practices. The focus in the United States on disruptive behavior as a persistent threat to patient safety,^{11,12} followed by the American College of Obstetricians and Gynecologists (ACOG) committee opinion on disruptive behavior,¹³ served as a catalyst to our development in 2007 of a zero-tolerance policy systemwide and education regarding the policy for members of the leadership team and individual clinicians. The expectation that all professionals will conduct themselves in a professional manner at all times was widely disseminated and implemented across all facilities. Meaningful actionable follow-up was instituted for the minority of professionals whose behavior remained outside the expectations.

INTERDISCIPLINARY PERINATAL PRACTICE COMMITTEE

As the risk assessment process evolved, it became apparent that the perinatal leaders at each of the hospitals wanted to provide the best care possible but that in some cases they were lacking resources, such as lack of an established interdisciplinary perinatal practice committee; lack of a sufficient number of funded positions, such as perinatal clinical nurse specialists,

nurse educators, and medical directors; and/or a lack of sufficient education budgets (1) to ensure that up-to-date clinical information was readily available and (2) to take the lead on developing strategies for timely implementation of newly published guidelines and standards. As a first step, during the initial visits in 2004–2005 we asked each hospital to convene such a committee, one of the purposes of which was to provide a routine process to monitor publication of practice statements from professional organizations and regulatory agencies and include these publications as a standing agenda item.¹ To enhance the likelihood that clinical care would be consistent with the latest evidence and standards, the perinatal leadership team was encouraged to make plans for adoption within a reasonable time frame, with a discussion focusing on *how and when to implement* the recommended practice changes rather than *if* they would be adopted.

Each hospital was encouraged to budget positions for perinatal clinical nurse specialists and/or nurse educators and medical directors of the service. In addition, in 2004 CHP convened a group of expert perinatal clinicians, with representation from all CHP facilities, to participate in a Perinatal Clinical Advisory Team, which would meet on a quarterly basis to provide further guidance in achieving the program's goals.

Table 3. Perinatal Patient Safety Structures and Processes Comparison Data: Findings from Initial Risk Assessment and Status as of October 2007 for 16 Hospitals*

Structure or Process Measure	Initial Assessment n (%) Yes	October 2007 n (%) Yes	Positive Improvement % Change
Culture of Safety			
Interdisciplinary perinatal practice committee	7 (44)	16 (100)	+129
Physician-nurse co-chairs of interdisciplinary practice committee	4 (25)	16 (100)	+300
Regularly scheduled interdisciplinary case reviews	3 (19)	13 (81)	+333
Uniform criteria for selecting cases for review	5 (31)	14 (88)	+180
Anonymous nonpunitive error reporting system	14 (88)	16 (100)	+ 14
Good citizenship/professional behavior policy	12 (75)	16 (100)	+ 33
All members of the perinatal leadership team are members of their professional association	9 (56)	14 (88)	+ 56
Criteria for transfer of high-risk mothers and infants	12 (75)	16 (100)	+ 33
Nurse staffing based on AAP/ACOG/AWHONN guidelines	11 (69)	13 (81)	+ 18
Fetal Assessment			
Interdisciplinary fetal monitoring education	3 (19)	16 (100)	+433
Clinical algorithm for intrauterine resuscitation during indeterminate or abnormal FHR patterns	9 (56)	16 (100)	+ 78
Medical record documentation forms and electronic systems with cues for use of NICHD FHR definitions	3 (19)	13 (81)	+433
Routine medical record audits using fetal monitoring strips as part of the review	2 (13)	13 (81)	+550
Labor Induction			
Criteria for prioritizing labor inductions based on medical necessity	7 (44)	14 (88)	+100
Requirement for 39 completed weeks of gestation before elective births	4 (25)	16 (100)	+300
Standard policy and order set for oxytocin administration based on ACOG/AWHONN guidelines	3 (19)	14 (88)	+367
Standard policy and order set for misoprostol administration based on ACOG/AWHONN guidelines	7 (44)	14 (88)	+100
Agreed-upon definition of uterine tachysystole and expected interventions	4 (25)	16 (100)	+300
Other Labor Issues			
Nurses' role in epidural anesthesia based on AWHONN guidelines	8 (50)	16 (100)	+100
Standard policy for magnesium sulfate administration	10 (63)	14 (88)	+40
Policy requiring full surgical team in-house during labor of women attempting VBAC or no VBAC labor	9 (56)	16 (100)	+78
Protocol for second-stage labor care based on AWHONN guidelines	0 (0)	10 (63)	+625
Newborn Care			
Policy for prevention of perinatal group B streptococcus based on AAP/ACOG/CDC guidelines	10 (63)	16 (100)	+60
Policy for prevention of perinatal transmission of HIV based on ACOG/CDC guidelines	4 (25)	16 (100)	+300
Policy for treatment of neonatal hyperbilirubinemia and kernicterus prevention based on AAP/Joint Commission guidelines	11 (69)	16 (100)	+46
Policy requiring analgesia and anesthesia for all circumcisions	2 (13)	13 (81)	+550

* AAP, American Academy of Pediatrics; ACOG, American College of Obstetricians and Gynecologists; AWHONN, Association of Women's Health, Obstetric, and Neonatal Nurses; FHR, fetal heart rate; NICHD, National Institute of Child Health and Human Development; EFM, electronic fetal monitoring; VBAC, vaginal birth after cesarean; CDC, Centers for Disease Control and Prevention.

Updates on new publications regarding guidelines and standards and current evidence, interdisciplinary case review of near-miss or adverse outcomes, and strategies for implementing program components are the focus of the advisory team meetings. The advisory team suggests further directions of the peri-

natal safety program. At annual meetings, perinatal team members at each hospital are encouraged make presentations on specific areas of success, including their approach to implementation of recommended practices. This process helps team members across the CHP system to get to know and learn

from one another.

As an adjunct to its interdisciplinary perinatal practice committee, each hospital was provided a list of essential structures and processes that were vital to promoting perinatal patient safety. For some of these structures and processes, Table 3 provides data regarding initial status and status over time from the initiation of the project in 2003 to 2007 for the 16 perinatal units surveyed. Initially, wide variations existed among hospitals for many of the items listed; however, over time as the program developed, significant progress was made. CHP's goal is that all hospitals will have 100% of the fundamental structures and processes in place and fully operational.

CRITICAL ASPECTS OF CLINICAL CARE

Review of claims and near-miss data indicated that three aspects of clinical care comprise the majority of risk of perinatal harm—fetal assessment, labor induction, and second-stage labor care.¹⁰ Therefore, these clinical areas comprised the main focus of strategies to promote safety.

Fetal Assessment. Findings from the initial on-site risk assessments in 2004–2005 revealed variation in knowledge and practice regarding FHR pattern interpretation, intrauterine resuscitation, communication of abnormal fetal data, and expeditious cesarean birth for indeterminate or abnormal fetal status. All facilities had not yet adopted the definitions for FHR patterns suggested by the National Institute of Child Health and Human Development (NICHD).¹⁴ In many cases, the paper or electronic version of the medical record had not been updated to support use of the NICHD definitions. To promote consistency in knowledge and practice, in 2004 the following strategies were recommended:

- Interdisciplinary fetal monitoring education
- Certification of all members of the perinatal team in electronic fetal monitoring by the National Certification Corporation
- Revision of medical record documentation to include the NICHD FHR pattern definitions
- Development of standard intrauterine resuscitation protocols
- Regularly scheduled interdisciplinary case reviews, including the electronic fetal monitoring (EFM) strip
- Routine medical record reviews to monitor ongoing adherence to appropriate practice and documentation

To assist with the certification process, the CHP system sponsored regional certification review courses; provided multiple packets of study materials, including EFM textbooks, to each hospital; and covered the costs of the certification exams.

Labor Induction. At the initial assessment, lack of standardization of policies and routine orders for cervical ripening and labor induction was noted, with significant variation in practices. A commonly accepted definition of excessive uterine activity (typically referred to as hyperstimulation or tachysystole) was not available in most facilities to guide identification and treatment. As was occurring on the national level, elective labor inductions before 39 completed weeks of gestation were noted. Facilities were encouraged to develop plans to eliminate elective births before 39 completed weeks of gestation¹⁵ and to refer cases for quality review until this practice had been discontinued.

In some cases, multiple concentrations of oxytocin were used, along with many variations in the initial dose, rate increases, maximum rate, and intervals between rate increases. A standardized oxytocin policy and routine physician order set with dosage and intervals between dosage increases based on the cumulative body of evidence¹⁶ (start at 1 milliunit [mU]/min and increase by 1–2 mU/min no more frequently than every 30 minutes until contractions are every 2–3 minutes as long as the FHR pattern is normal) were introduced. A definition of excessive uterine activity included in ACOG recommendations^{17,18} (more than five contractions in 10 minutes averaged over 30 minutes, contractions lasting 2 minutes, or contractions of normal duration occurring within 1 minute of each other) that did not involve the patient's perception of pain or a delay in treatment until the FHR pattern was indeterminate or abnormal was included in the policy, along with a recommended protocol for treatment.

Second-Stage Labor Care. Medical record review during the initial on-site visits noted that the status at birth of some of the babies with low Apgar scores was related to prolonged periods of provider-coached second-stage labor pushing with recurrent FHR decelerations. Knowledge of evolving evidence regarding safe second-stage labor practices varied among the clinicians in each hospital. Many clinicians had been previously taught to continue coached pushing in this situation to expedite birth rather than let the baby recover in utero. A standardized second-stage labor protocol was suggested on the basis of current evidence and recommendations from ACOG¹⁹ and AWHONN,^{20,21} including the following:

1. Shortening the active pushing phase by delaying pushing for women with epidural anesthesia who do not feel the urge to push when they are completely dilated (up to 2 hours for nulliparous women and up to 1 hour for multiparous women)
2. Using an upright or semi-Fowler's position for pushing and avoiding forcing the woman's legs against her abdomen

3. Discouraging prolonged breath-holding (instead, instructing the woman to bear down and allow her to choose whether or not to hold her breath while pushing, for example, doing whatever comes naturally)

4. Discouraging more than three to four pushing efforts with each contraction and more than six–eight seconds of each pushing effort

5. Taking steps to maintain a normal FHR pattern while pushing

6. Pushing with every other or every third contraction or discontinuing pushing temporarily if necessary to avoid recurrent FHR decelerations

7. Repositioning as necessary for FHR decelerations

8. Avoiding uterine tachysystole

NEWBORN CARE

Several areas of newborn care were identified as areas for improvement during the first set of risk assessments. As such, standardized protocols based on ACOG and American Academy of Pediatrics guidelines and standards were recommended for circumcision care (including universal use of adequate anesthesia), prevention of perinatal group B streptococcus, prevention of newborn hyperbilirubinemia, prevention of perinatal transmission of HIV, and prevention of newborn abduction.

IN-HOUSE COVERAGE

In-house coverage for anesthesia, obstetric and neonatal care was a challenge because of the many small-volume services in CHP facilities. However, many facilities were ultimately able to secure budget support for in-house coverage for the perinatal service. Care for women undergoing a trial of labor after previous cesarean birth was eliminated in facilities that could not provide in-house surgical team coverage during this procedure. As an alternative, referral to nearby CHP facilities with this type of coverage was recommended.

Challenges

Some challenges specific to CHP's small-volume hospitals were encountered as the program was disseminated, including financial pressure creating resource limitations for implementation of recommendations, resistance to change ("the way we've always done it is working"), perceived threats to physician autonomy ("the system isn't going to tell me how to practice"; "standardization is cookbook medicine"), and lack of knowledge regarding some areas of clinical practice where evidence had evolved during the previous few years (for example,

NICHD (FHR) definitions, risks to babies born electively before 39 completed weeks of gestation, second-stage labor care). These challenges were similar to those facing other health care systems implementing patient safety programs and were not unexpected.

The traditional hierarchical model, in which physicians give orders and nurses are expected to follow those orders without question, was a major barrier, especially when combined with disruptive or nonprofessional behavior. Although completely contrary to what should be expected in high-reliability organizations (where everyone is encouraged and expected to speak up when he or she is concerned about safety), the hierarchical model still exists in many facilities in the United States. However, "there is no high reliable organization that develops guidelines for use in critical situations that are even remotely affected by concerns for preservation of pilot or operator autonomy."^{22(p. 105.e2)} Principles of high-reliability perinatal units were incorporated into the program, with critical components adopted from other industries.^{23,24}

Standardization of key clinical protocols, along with role modeling and education to empower nurses to voice concerns, and implementation of a systemwide professional behavior/good citizenship policy gradually resulted in changes in attitude and reduction in fear of retaliation if orders were questioned. However, more work needs to be done in the United States and elsewhere to promote acknowledgement of the *different but equal* contribution that each member of the perinatal team makes to the care process and ultimate outcomes. Some facilities have participated in team training exercises to facilitate change; all facilities have participated in interdisciplinary education regarding the latest evidence on the three key aspects of clinical care that are associated with the majority of perinatal patient harm.

Outcomes

Success in implementing essential structural and process components of the program, as detailed in Table 3, have resulted in improvement from 2003 to 2008 in specific outcomes for the 16 perinatal units surveyed, including reduction of perinatal harm, number of claims, and costs of claims. Birth trauma rates (Agency for Healthcare Research and Quality, Patient Safety Indicator 17²⁵) decreased from 5.0 to 0.17 per 1,000 births. The number of obstetrical occurrences (specified birth-related event or injury that may lead to a claim) decreased by 65%, from 7.2 to 2.5 per 1,000 births. The average costs per obstetrical claim decreased from \$1 million to < \$500,000. The number of new claims reported decreased by 48%.

These results are consistent with findings after implementation of a comparable comprehensive perinatal patient program [for which K.R.S. and G.E.K. also consulted] in other health care systems, where the composite rate of adverse perinatal events decreased from 3% to 1.25%, costs of claims decreased by 40%, and staff perception of the overall patient safety climate improved by 30% in 2.5 years.²⁶ Similar success with standardization of key clinical areas of care and adoption of high-reliability perinatal unit behaviors was reported by Clark et al.²² based on the Hospital Corporation of America (HCA) experience after their program was initiated in 2000. Since the HCA program began, the number of primary cesarean births decreased significantly, even while this rate was rising on the national level, and lower rates of maternal and fetal injury and decreased litigation were documented, as evidenced by a 50% reduction in claims and fivefold reduction in costs of claims.²² Likewise, a significant reduction in the rate of birth trauma,²⁷ even virtual elimination of preventable incidents,²⁸ has been reported by a hospital that conducted a safety program that included the identification of areas of perinatal clinical risk and standardization of related practices and protocols.

Because this was a descriptive study of a comprehensive multicomponent program evaluated during a five-year period using pre- and postimplementation data, we were unable to control for concurrent changes in leadership, personnel, and other hospital and health care system patient safety initiatives. Therefore, we may have inadvertently neglected to consider other important changes that may have contributed to the positive outcomes.

Future Directions

The program continues to evolve with modifications as needed as more evidence becomes available to guide best perinatal practices and as new guidelines/standards are published. Several additional hospitals with perinatal services have been acquired by CHP, and the perinatal patient safety program has also been implemented at those hospitals. The perinatal clinical advisory team has taken a leadership role in developing recommendations for future practice changes and strategies for realizing stated program goals. A critical aspect of success is the continued support from the board of directors and the message to administrators and clinicians that this program is an ongoing priority rather than a temporary patient safety initiative.

A patient safety program guided and supported by a health care system can result in safer clinical environments in individual hospitals and decreased risk of preventable perinatal harm and liability costs. Encouraging results from this program and

other perinatal patient safety programs may stimulate further development and more interest in participation, with the ultimate goal of providing the best possible care to mothers and infants. ■

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