Impact of a comprehensive patient safety strategy on obstetric adverse events

Christian M. Pettker, MD; Stephen F. Thung, MD; Errol R. Norwitz, MD, PhD; Catalin S. Buhimschi, MD; Cheryl A. Raab, RNC; Joshua A. Copel, MD; Edward Kuczynski, MA; Charles J. Lockwood, MD; Edmund F. Funai, MD

OBJECTIVE: We implemented a comprehensive strategy to track and reduce adverse events.

STUDY DESIGN: We incrementally introduced multiple patient safety interventions from September 2004 through November 2006 at a university-based obstetrics service. This initiative included outside expert review, protocol standardization, the creation of a patient safety nurse position and patient safety committee, and training in team skills and fetal heart monitoring interpretation. We prospectively tracked 10 obstetrics-specific outcomes. The Adverse Outcomes Index, an expression of the number of deliveries with at least 1 of the 10 adverse outcomes per total deliveries, was analyzed for trend.

RESULTS: Our interventions significantly reduced the Adverse Outcomes Index (linear regression, \( r^2 = 0.50; P = .01 \)) (overall mean, 2.50%). Concurrent with these improvements, we saw clinically significant improvements in safety climate as measured by validated safety attitude surveys.

CONCLUSION: A systematic strategy to decrease obstetric adverse events can have a significant impact on patient safety.

Key words: crew resource management, medical errors, obstetric adverse outcomes, patient safety

In September 1999, the Institute of Medicine (Washington, DC) assessed the prevalence and impact of medical errors in the United States, estimating that a staggering 44,000-98,000 patients die each year as a result of medical errors.1 Concluding that a majority of medical errors are caused by correctable faults, this report was a “call to arms” to deliver care more safely. Since then, improvements in safety have been documented in cardiology,2 critical care,3 and anesthesia,4 although there is a relative paucity of literature regarding monitoring and preventing obstetric adverse events. This is notable given that childbirth accounts for 4 million hospitalizations each year, ranking second only to cardiovascular disease, and obstetrics is considered to be in a liability crisis.5 The individual impact of an obstetric adverse outcome is considerable: 2 patients are often injured (mother and neonate) and neonatal insult may result in significant long-term consequences for families, including the effort and cost of lifelong care. In obstetrics, good outcomes are expected while adverse outcomes are often considered unavoidable because trends and causes may be difficult to discern without a formal tracking program.

With the hypothesis that a multifaceted approach to enhance the overall safety climate would reduce the rate of adverse outcomes, we partnered with our hospital (Yale-New Haven Hospital [YNHH], New Haven, CT) and our malpractice carrier (MCIC Vermont Inc, New York, NY) (Appendix A) to assess and improve our safety climate. The goal of this program was to improve patient safety, decrease patient injury, and decrease liability losses through a program that identified and initiated specific risk-reduction clinical practices and created a comprehensive culture of safety.

From the Department of Obstetrics, Gynecology, and Reproductive Science, Yale University School of Medicine (Drs Pettker, Thung, Norwitz, Buhimschi, Copel, Lockwood, and Funai and Mr Kuczynski), and Yale–New Haven Hospital (Ms Raab), New Haven, CT.

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Correspondence: Christian M. Pettker, MD, Department of Obstetrics, Gynecology, and Reproductive Sciences, Yale University School of Medicine, 333 Cedar St., PO Box 208063, New Haven, CT 06520-8063.

christian.pettker@yale.edu.

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Introduction of a patient safety program
This program was initiated as a quality assessment and improvement activity and consisted of an initial independent assessment of the service, followed by a series of interventions.

Outside expert review
We began with a review of our obstetric services by 2 independent consultants (a maternal-fetal medicine physician and a nurse specialist/leader), both experts in perinatal risk assessment and management and unaffiliated with Yale University or Yale-New Haven Hospital. Their review consisted of a 3-day visit (December 2002) to assess organizational risk and patient safety issues. They interviewed staff from all professional categories (physicians, nursing, administration) and used a triangulation method to resolve differences in perspectives, reporting only those findings repeated in at least 2 of 3 domains. They also reviewed hospital policies and protocols and compared them with national standards. The review and recommendations—focused on principles of patient safety, evidence-based practice, and consistency with the standards of professional and governing bodies—provided an outline with specific observations and recommendations for improvement. General weaknesses were found in: (1) a lack of institutional guidelines (eg, for misoprostol inductions and oxytocin administration); (2) ineffective communication practices; (3) poor knowledge of chain of command; and (4) the absence of a quality assurance mechanism.

Protocols and guidelines
In response to this review, we developed a series of protocols and guidelines delineating practice standards. These protocols were directed at the organization of patient care (eg, admission criteria to different units and appropriate disposition of high-risk cases) and practices considered at greatest risk for mismanagement and highest yield for correction (eg, induction criteria and administration of oxytocin, prostaglandin, and magnesium sulfate). These protocols and guidelines aimed to codify and standardize existing practices (eg, clarify the appropriate dosing of oxytocin). Some protocols were in place before the consultant review; formal revision and implementation of these began in the first quarter of 2004. Further protocols and policies—37 in total (Appendix B)—have been developed by our patient safety committee (see below) since that time.

Obstetric safety nurse
To assist in data collection and facilitate planned interventions, we created the position of patient safety nurse in June 2004. This position has been described in detail previously. This nurse’s main responsibility was to provide a formal method of evaluating clinical care and outcomes for our obstetrics services. To identify cases complicated by adverse outcomes and system weaknesses, the nurse led our anonymous event reporting system and on a daily basis reviewed triage, labor, and neonatal logs; met with charge nurses; and attended resident morning report. This nurse’s methods of case ascertainment were consistent throughout the period of this project. This nurse then initiated investigations into adverse and sentinel events through root-cause analysis, presenting a quality assurance document for review by the patient safety committee. Beginning in September 2004, data were collected prospectively—on an occurrence basis—for an adverse event database of prespecified outcomes measures (maternal death, maternal ICU admission, maternal return to operating department, in-hospital fetal demise >24 weeks, term 5-minute Apgar score <7, umbilical cord pH <7.0, postpartum hemorrhage resulting in hysterectomy/transfusion/uterine artery ligation/uterine artery embolization, shoulder dystocia, uterine rupture or dehiscence, fetal traumatic birth injury, or unexpected term admission to newborn ICU). Assessments were reported to the patient safety committee, local hospital leaders, and MCIC Vermont, Inc obstetric leadership. In addition, this nurse initiated and directed our programs in team training and electronic fetal monitoring (EFM) certification.

Anonymous event reporting
We activated a computerized tool for anonymous event reporting (Peminic Inc, Princeton, NJ), allowing any member of the hospital staff to anonymously report medication errors, device-related events, falls, or other events that in the opinion of the staff member may have caused harm to a patient or visitor. Our patient safety nurse directed its application specifically to reporting obstetric events in July 2004 and continually educated staff on its use.

The obstetric hospitalist—Yale On-Call Attending
The role of the Yale On-Call Attending (OCA) and the description of YOCA duties were initiated in July 2003 (expanded August 2005) to provide a consistent system of inpatient coverage and resident supervision. Before YOCA, community physicians provided substantial resident coverage, including supervision of the care of resident clinic patients. However, these supervisory responsibilities were not clearly delineated and could vary by provider. Initially, the YOCA was a type of obstetric hospitalist (or laborist) covering all inpatients within the resident and university practices. An expansion of this role occurred in August 2005, so that the YOCA has responsibility for the quality of care of the entire obstetric service by providing services to patients within the university practices and emergency backup and consultation for all community physicians. In-house on-call attending services are provided 24 hours a day, 7 days a week by the members of our maternal-fetal medicine section.

Obstetric patient safety committee
This committee was formed in the fall of 2005 to define and track adverse events. With the assistance of the patient safety nurse, specific events were reviewed on a case-by-case basis. Based on these reviews, the committee addressed needs for protocols and policies. Examples of interventions included a shoulder dystocia documentation form, relabeling of magnesium and oxytocin intravenous fluids, and a standardized form for labor progress documentation.
Safety attitude survey/questionnaire
We implemented the Safety Attitudes Questionnaire (SAQ), a tool adapted from the aviation field and used for the assessment of health care employee perception of teamwork and safety. A SAQ specific to obstetrics has been developed and validated by Sexton et al.13,14 This anonymous survey helps detect perceived systemic weaknesses and differences of opinion over time or between employee groups (eg, staff, nursing, physicians) that result from being trained in contrasting styles. The survey consists of a series of statements to which the respondent is able to answer with agreement or disagreement, using a 5-point Likert scale. Differences of ≥ 10%, over time or between groups, are considered clinically significant; overall scores showing 80% agreement that the teamwork climate is favorable are considered the target for change. The questionnaire was distributed to all medical staff and employees involved in obstetric care initially in April through May 2004 and repeated in May 2006 and September 2007 to assess the progress of the patient safety initiative.

Team training
Our initial safety review highlighted weaknesses in the coordination and communication of the various members of the obstetric teams (eg, nurses, obstetricians, anesthesiologists, neonatologists, and administration and ancillary services). This is a common finding in health care: physicians, midwives, nurses, and staff train in isolated silos, with differing languages and contrasting perspectives, yet are expected to work in teams.1 We initiated a team training program based on crew resource management programs initiated and tested by the airline and defense industries in July 2005.15 Similar interventions have helped improve teamwork—although not necessarily outcomes—in medicine and obstetrics.16-19 Led by our patient safety nurse, these 4-hour seminars included videos, lectures, and role playing, and always integrated a mix of individuals within the obstetric team. Attendees were familiarized with the concept of the shared mental model for communication: an organized way for team members to conceptualize how a team works and to predict and understand how their team members will behave to improve overall team performance.20,21 Other specific concepts and techniques covered included structured communication/debriefing techniques (situation, background, assessment, recommendation),22 communication key words (“concerned,” “uncomfortable,” “scared”),23 the 2-challenge rule (a quick conflict resolution technique where a team member may question an action 2 times and, if a sufficient answer is not provided, may halt that action),24 the chain of command, and elements of an effective hand off of care.25 Completion of the seminars was a condition for employment and/or clinical privileges. The target group of 289 people completed team training at the end of October 2006; this represented the entire complement of physicians and nurses as well as a majority of the ancillary staff.

EFM certification
To standardize EFM interpretation, our patient safety nurse initiated an institutional education program that included dissemination and review of National Institute of Child Health and Human Development (NICHD) guidelines,26 review of tracings, allocation of study guides,27,28 and voluntary review sessions. This training culminated in an examination offered by National Certification Corp (http://www.nccnet.org; Chicago, IL), a nonprofit group that offers training and testing of fetal monitoring standards based on the 1997 NICHD criteria. All medical staff and employees responsible for fetal monitoring interpretation (resident and attending obstetricians, midwives, and labor room and antepartum nurses) were obligated to take this examination within 1 year of employment and pass within 18 months. The first series of examinations were offered in January through February 2006, and the target group of 211 individuals completed testing at the end of November 2006. During the study period there were no significant hospital-based patient safety initiatives that included the obstetrics service. Data collection was performed for surveillance purposes and was incorporated into a research protocol as a secondary effort. A waiver of consent was obtained from the Human Investigations Committee at Yale University School of Medicine, which, after review, designated this a quality improvement activity and not human subjects research. This project was performed in conjunction with our liability insurance carrier, MCIC Vermont, Inc, which provided financial support for our patient safety nurse. MCIC Vermont, Inc is a risk retention group, which provides medical professional and general liability insurance coverage to its academic medical center shareholders, their various affiliated entities, employees, and physicians.

Evaluation of the patient safety program
The effectiveness of these initiatives was assessed through the comparison of individual and composite adverse events over time. These events were compiled on a monthly basis from September 2004 through August 2007, when an initial analysis on the data was performed and submitted for presentation in a preliminary report. We determined a 3-year duration for this work was appropriate to provide adequate time for the training and testing initiatives and time for development and maturing of the culture of safety. Cases were collected as described above (see “Obstetric safety nurse” section); after case identification, the patient safety nurse (C.A.R.) reviewed the medical chart, created a summary narrative that was reviewed by the principal investigator (E.F.F.), and then presented the finalized findings to the safety committee. On this review, cases were classified only according to their worst outcome.

For the purposes of this report, cases underwent a second review for validation and coding by a second physician (C.M.P.). During this audit the original outcomes of interest listed above (see “Obstetric safety nurse” section) were modified to correspond to those of other published reports (Table), as a consensus of obstetric adverse events (Adverse
lacerations were ascertained retrospectively through review of our birth logs that record the types of lacerations for each delivery. This review also accounted for all applicable outcome categories for each patient; 1 patient could have multiple adverse events and all of these were recorded.

Compliance to the various initiatives was not officially tracked, although the patient safety nurse performed routine chart audits and addressed issues of compliance directly with the involved units and caregivers.

The main outcome of interest was the quarterly composite adverse event rate, expressed as the number of deliveries (mothers) with associated adverse events per total deliveries for that 3-month period. A multiple gestation was considered as a single delivery. The individual events comprising the composite event total are listed in Table 1 and are the basis of the obstetric AOI proposed by Mann et al.29 Fetal traumatic birth injury includes any injury deemed directly related to the obstetric care or birth event (eg, head trauma, fracture, neurologic injury such as Erb palsy, hemorrhage, or laceration). Unexpected admissions to our neonatal care unit and perinatal deaths include only cases where a preexisting antepartum maternal (eg, Rh isoimmunization) or fetal (eg, prematurity or anomaly) complication independent of the delivery was not present.

Beyond the components of the AOI, we also assessed other process variables (aspects of care related to quality, such as cesarean delivery and episiotomy rates) and reviewed each case of shoulder dystocia. Finally, we assessed results for our EFM training and changes in workplace safety perception based on the SAQ during the study period.

**Statistical analysis**

Data were analyzed by pregnancy, with multiple gestations classified as 1 delivery. Simple linear regression was used to evaluate the significance of the trend in quarterly AOI, cesarean delivery rate, and episiotomy rate. Student t test (2-tailed) and χ² testing was performed where appropriate. A P value of < .05 was considered significant. All analysis was performed with software (SPSS 16.0; SPSS Inc, Chicago, IL).

**RESULTS**

A total of 13,622 deliveries occurred in the 36-month period from September 2004 through August 2007, with a mean quarterly delivery number of 1135 (SD, ± 59). The mean quarterly AOI during this period was 2.50% (SD, ± 0.72%; range, 1.55-3.75%). When calculated monthly, mean AOI was 2.49% (SD, ± 0.86%; range, 0.75-4.58%). The change in the quarterly AOI during the study time period is shown in Figure 1; a statistically significant decrease in the AOI was seen during the study period (r² = 0.50, P = .011). This trend was still significant when the AOI was calculated on a monthly basis (r² = 0.33, P < .001). The mean quarterly AOI for the first half of the initiative (2.90 ± 0.64%) was also significantly different than that for the second half (2.09 ± 0.57%) (Student t test, P = .04).
Variations in most individual patient safety markers presented in Table 1 could not be meaningfully assessed because of their rare occurrence rates, although there was no statistically significant change. For the most common marker, third- and fourth-degree lacerations (quarterly mean, 18; SD, ± 4.2), there was no statistically significant change over time \( (r^2 = 0.11, P = .30) \). No outcome of the AOI was seen to increase over time. With respect to major obstetric quality measures not included in the AOI, our mean cesarean delivery rate was 35.1% (SD, ± 2.1%) and episiotomy rate was 10.9% (SD, ± 1.5%). Of note, the cesarean delivery rate showed a significant increase over time \( (r^2 = 0.50, P = .01) \) and the episiotomy rate showed a significant decrease over time \( (r^2 = 0.50, P = .01) \) (Figure 2). We had a total of 81 episodes of shoulder dystocia, with a rate of 5.95/1000 deliveries (SD, ± 2.3); there was no statistically significant change in this rate over time.

During 2006, our overall pass rate for EFM certification was 97% (213/219). Six persons failed the first time, with 1 failing a second time, requiring transfer off the antepartum service. All providers taking the examination in 2007 \( (n = 38) \) passed on the first attempt. No physicians or midwives failed the examination on the first attempt.

From 2004 through 2007, the percentage of respondents reporting a “good teamwork climate” and a “good safety climate,” as assessed by the SAQ, improved from 38.5% to 55.4% and 33.3% to 55.4%, respectively. During this same time period, perceptions among nurses and physicians of a “good teamwork climate” improved from 16.4% to 88.7% and 39.5% to 72.2%, respectively. These changes are considered clinically significant by those who designed the questionnaire.11

**COMMENT**

There exist few published models for the reduction of obstetric adverse outcomes. One limited example is the Institute of Healthcare Improvement’s *Idealized Design of Perinatal Care*, which presents 2 perinatal care bundles proposed as policies for the induction and augmentation of labor.30 Moreover, there is no standard for assessing the rates of adverse events in perinatal care. Some triggers (meant to capture events for further review) and outcome measures have been proposed, although none have been adopted universally.29,31 We report a novel way to describe a diverse array of patient safety interventions, with evidence of success at reducing adverse events, using an adverse outcomes assessment tool (the AOI). Our initial composite adverse event rate was comparable with, if not lower than, previous reports.31

We believe a combination of evidence-based standardization, enhancements in communication, and a dedicated patient safety nurse are the integral components of this effort. We are unaware of any models that would easily identify which, if any, individual interventions had the greatest impact and which were of no value at all. The project may have been enhanced by a more programmatic and stepwise introduction of our interventions, although this would have increased the time required for implementation. Our objective was not to conduct a randomized trial—although we agree that may be the gold standard—but rather, timely quality improvement. In fact, as recently suggested by Berwick,32 the type of study design we describe may arguably be the most feasible, if not most appropriate, for studying the “complex, unstable, [and] nonlinear social change” characterized by quality improvement initiatives. A clinical trial would require suspending all other quality improvement activities for our service during a substantial period of time; this would not be practical in today’s setting of stringent government oversight and high patient expectations. A rigorous application of methods of ascertainment and a thoughtful approach to meaningful interventions to influence behavior and culture can nonetheless yield important and valid results. The reporting of such methods and results is critical for comprehensive nationwide improvement in patient safety.

Because this is a descriptive report it may be inherently prone to bias. Our case- and event-identification methods may not have identified all adverse outcomes. However, these were collected prospectively on an occurrence basis and the methodology was unchanged over time. Importantly, our results were not affected by the biases inherent in reliance on coding or discharge diagnosis data. In addition, we are unable to control for confounding factors in the practice environment such as changes in staff or work hours, or improvements in other educa-
tional or skills sets, that were not a part of this project. Although we endeavored to give a comprehensive accounting of all substantive changes to our service during the reporting period, we may have failed to include some other important change that affected safety. Furthermore, we did not track compliance to the guidelines and protocols, although we believe adherence improved over time as we created a culture that promoted their integration. It is additionally worth noting that we did not implement any initiatives related to the cesarean delivery or episiotomy rate, which did show changes.

Our work adopted the AOI as the measure for tracking adverse events and validates its use and adoption for other studies. We also tracked other outcomes and safety measures not included in the AOI such as shoulder dystocia, cesarean delivery, and episiotomy rates. The incidence of shoulder dystocia at our institution falls at the lower range of national estimates (0.6-1.5%) and we were unable to demonstrate any significant change over time. Generally, cases of shoulder dystocia are not considered predictable. The value of monitoring these events may lie as a process measure, in assessing the quality of documentation and the conduct of appropriate emergency responses.

We noted a significant increase in cesarean delivery rate during the period of our initiative, potentially confounding the statistically significant decrease in adverse events. This study design cannot determine whether or how this change affected the overall change in AOI. Our rate of increase (1.7 percentage points annually) mirrors the national trend in cesarean rate (1.5 percentage point annual increase from 2000-2005). Surveys have indicated that physicians feel pressured to increase their cesarean rates and lower their vaginal birth after cesarean rates in response to mounting professional liability insurance costs; this is also supported by vital statistics analysis demonstrating an increase in primary cesarean rate associated with increasing liability premiums in Illinois. Further, the national decline in vaginal birth after cesarean has impacted overall cesarean rates. Although there are few studies, we are not aware of any published work demonstrating that obstetric care in the United States is appreciably safer since the cesarean rate began its latest increase in 1997. As a result, we believe that our own increase in cesarean rate is more likely related to the forces affecting national trends and did not materially contribute to our results. We cannot conclude whether this should be considered an improvement or a step backward.

We also note a significant decrease in episiotomy rate during the 3 years of the study. Overall, our episiotomy rate was 10.9%, which is low compared with the national rate (in 2005) of 19% and is likely influenced by a significant intra-partum midwifery presence at Yale. None of our initiatives, including our protocols and guidelines, was meant to specifically address the rate or practice of episiotomy. We speculate that our episiotomy rate decreased as our institution became more familiar with the accumulating evidence regarding the appropriate use of and indications for episiotomy. Given that episiotomy is a major risk factor for the most frequent outcome of the AOI, and is frequently overused, we believe it is a valuable indicator for tracking. Despite the decrease in episiotomy rate, there was no change in our third- and fourth-degree laceration rate, and thus we do not feel the change in episiotomy rate significantly impacted our overall AOI improvement.

We acknowledge that our comprehensive approach may not be applicable in all settings. YNHH is a large academic center with sufficient resources to support many simultaneous interventions, some of which are relatively costly. Our malpractice liability carrier supported the cost of the outside expert review, our patient safety nurse, her initial training in crew resource management training education, the SAQ, and the EFM examination. Initial costs of the program are estimated at $210,000, with ongoing yearly costs of $150,000. This investment is dwarfed by the average payment ($500,000-1,900,000) for just 1 obstetric liability claim.

Our efforts at performance improvement are still nascent, and we acknowledge that our service is still subject to adverse outcomes. We believe that continued application of these and similar strategies can have a further impact on safety. More work is necessary to establish benchmarks and best practices for obstetric care. This report is one of the early steps in this process.

APPENDIX
Appendix A

MCIC Vermont, Inc is a risk retention group that provides medical professional and general liability insurance coverage to its academic medical center shareholders, their various affiliated entities, employees, and physicians. The shareholders of MCIC Vermont, Inc are New York-Presbyterian Hospital (New York, NY), Cornell University (New York, NY), Columbia University (New York, NY), The University of Rochester/Strong Memorial Hospital (Rochester, NY), The Johns Hopkins Hospital and The Johns Hopkins University (Baltimore, MD), and Yale–New Haven Hospital and Yale University (New Haven, CT). Additional affiliated hospitals include Bridgeport Hospital (Bridgeport, CT), Greenwich Hospital (Greenwich, CT), Howard County General Hospital (Columbia, MD), Highland Hospital (Rochester, NY), and Johns Hopkins Bayview Medical Center (Baltimore, MD).
APPENDIX B
Yale–New Haven Hospital, New Haven, CT, obstetric protocols and guidelines

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*HIV, human immunodeficiency virus.*