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PATIENT SAFETY & MEDICAL LIABILITY

Integrated Approach to Reduce Perinatal Adverse Events: Standardized Processes, Interdisciplinary Teamwork Training, and Performance Feedback

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Objective. To improve safety practices and reduce adverse events in perinatal units of acute care hospitals.

Data Sources. Primary data collected from perinatal units of 14 hospitals participating in the intervention between 2008 and 2012. Baseline secondary data collected from the same hospitals between 2006 and 2007.

Study Design. A prospective study involving 342,754 deliveries was conducted using a quality improvement collaborative that supported three primary interventions. Primary measures include adoption of three standardized care processes and four measures of outcomes.

Data Collection Methods. Chart audits were conducted to measure the implementation of standardized care processes. Outcome measures were collected and validated by the National Perinatal Information Center.

Principal Findings. The hospital perinatal units increased use of all three care processes, raising consolidated overall use from 38 to 81 percent between 2008 and 2012. The harms measured by the Adverse Outcome Index decreased 14 percent, and a run chart analysis revealed two special causes associated with the interventions.

Conclusions. This study demonstrates the ability of hospital perinatal staff to implement efforts to reduce perinatal harm using a quality improvement collaborative. Findings help inform the relationship between the use of standardized care processes, teamwork training, and improved perinatal outcomes, and suggest that a multiplicity of integrated strategies, rather than a single intervention, may be essential to achieve high reliability.

Key Words. High reliability, perinatal outcomes, quality improvement collaborative, standardized care processes, in situ simulation team training

Labor and delivery pose substantial risk for unintended harm to mothers and newborns. Perinatal complications are reported from 3 to 10.7 percent of all deliveries, ranging from catastrophic events, including maternal or infant death, to less severe conditions such as third- and fourth-degree perineal laceration (Mann et al. 2006; Nielsen et al. 2007; Kozhimannil et al. 2013; Goffman et al. 2014; New Jersey Hospital Association 2014). A number of approaches have been undertaken to improve perinatal safety, including (1) didactic training (Mann et al. 2006; Nielsen et al. 2007; Pratt et al. 2007); (2) simulation training (Miller et al. 2008; Fransen et al. 2012); (3) standardizing care (Cherouny et al. 2005; Mazza et al. 2007; Damon et al. 2013); or (4) a combination of these strategies (Ellis et al. 2008; Pettker et al. 2009; Guise et al. 2010; Phipps et al. 2012; Wagner et al. 2012; Goffman et al. 2014).

Communication breakdown and poor teamwork are major risks in perinatal units (Simpson and Knox 2003), associated with 70 percent of perinatal injury (The Joint Commission 2004) and increasing the risk of error 10-fold (Reason 1995) while accounting for approximately 55 percent of all active failures in a hospital setting (Riley et al. 2010a,b,c). Overall, it is estimated that 30 percent of obstetrical complications are preventable (Goffman et al. 2014), and growing evidence suggests that applying reliability principles to health care has the potential to reduce flaws in care processes and increase the consistency with which appropriate care is delivered leading to improved patient outcomes (Burke et al. 2004; Benneyan, Resar, and Scoville 2006; Riley et al. 2010a,b,c). These strategies are aimed toward achieving high reliability, defined as defect-free operations for long periods of time in a hazardous environment (Roberts 1990; Reinertsen and Clancy 2006).

This study reports the results of a quality improvement collaborative, called the Premier Perinatal Safety Initiative (PPSI), consisting of 14 hospitals

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in 12 states, to reduce perinatal harm. One intervention was implemented to reduce variation in perinatal care processes and two interventions were introduced to improve nontechnical skills, and the cognitive and interpersonal abilities that supplement technical clinical competency (Flin, O'Connor, and Crichton 2008).

MATERIALS AND METHODS

This 7-year study was a quasi-experimental, prospective quality improvement collaborative (QIC) consisting of a 5-year intervention period (January 1, 2008 to December 31, 2012) and a 2-year baseline period (January 1, 2006 to December 31, 2007) for which data were retrospectively collected. The project implemented three interventions: (1) standardization of evidence-based care; (2) interdisciplinary teamwork training; and (3) routine education with performance feedback. We utilized a 7-year horizon to evaluate the long-term impact of the interventions as well as to examine the interplay among diverse and unaffiliated hospitals. While rapid cycle projects are preferred in QICs, it has been the experience of the Institute for Healthcare Improvement that at least 18–24 months are required before culture change results in sustainable, reliable improvements in perinatal care and outcomes (Bisognano, Cherouny, and Gullo 2014). The intervention period entailed two phases: Phase 1 (January 1, 2008 to December 31, 2010) funded by American Excess Insurance Exchange (AEIX); and Phase 2 (January 1, 2011 to December 31, 2012) funded by the Agency for Healthcare Research and Quality (AHRQ). The Phase 1 intervention consisted of the initiation of evidence-based standardized care processes, didactic team training, monthly educational webinars, quarterly performance feedback, two all team in-person meetings, and periodic technical assistance coaching. Through this sequence, we engaged in continuous performance assessment, feedback, and tests of change using rapid cycle improvement. The Phase 2 intervention introduced intensive interdisciplinary in situ simulation training at each hospital, while continuing all Phase 1 activities. Figure 1 depicts the project timeline.

We instituted a set of technical and nontechnical interventions, similar to other complex interventions to improve care in real time in an applied clinical context (Pronovost et al. 2006, 2010; Bion et al. 2013). We expected that the application and maintenance of multiple interventions affecting the reliability of processes and individual cognitive and interpersonal skills over an

Figure 1: Premier Perinatal Safety Initiative Intervention Timeline

Notes. The timeline depicts the dates of meetings and intervention implementation that occurred during the 7-year project. On-site *in situ* simulation training occurred from January to June 2011.

extended time period would be necessary to produce sufficient behavior change to affect outcomes. All interventions except in situ simulation training extended over a 5-year period (2008–2012). The in situ simulation training occurred during year 4 (2011).

We used a train-the-trainer method to sequentially train a team from each hospital, which in turn trained staff at their respective perinatal units. The interdisciplinary trainer team from each hospital, comprised of a physician and a nurse, participated directly in all the interventions. The study was reviewed and ruled exempt by the University of Minnesota Institutional Review Board (IRB). Individual hospitals participating in the study processed IRB approval with their own IRBs as needed. The National Perinatal Information Center (NPIC), as the data partner, obtained IRB approval from a hospital outside of the study group.

Hospital Selection

In 2008, AEIX insured 90 hospitals in 19 health care systems. Sixteen of those health care systems had one or more hospitals providing obstetrical services; the other three systems had no obstetrical service line. An invitation to become involved in the PPSI was sent to these 16 health care systems, representing a total of 67 hospitals providing obstetrical services. Thirteen of the 16 systems accepted the offer, and each of the participating systems enrolled one hospital in the PPSI with funding by AEIX to cover costs of participation. In

addition, three health care systems elected to enroll a second hospital at their own expense. The health care systems selected the specific hospital(s) that participated in the study. The research team was not involved in the final selection of invited hospitals.

These 16 hospitals represent a range of birth volume, academic status, hospital size, and geographic location, creating a diverse mix of participants. Of the 16 hospitals participating in Phase 1, 14 continued through Phase 2. We report findings for those 14 hospitals. Compared to the 14 continuing hospitals, the two hospitals that were excluded had slightly lower adverse event outcome measures. One of the hospitals that withdrew from the study closed its obstetrical unit at the end of Phase 1. This decision was made by the hospital and was unrelated to their participation in this intervention. The other hospital team discontinued participation due to competing priorities for staff time and resources. The organization reported that it could not provide the needed staff time for the data collection (the hospital location, category, and number of deliveries are reported in the online appendix). Given this selection methodology, it is possible the 16 hospitals that volunteered for the study from the population of 67 hospitals may be more motivated to improve their obstetrical outcomes. This motivation could arise from concerns about quality, or from an existing culture of improvement. In any event, these hospitals may not be representative of the typical hospital in terms of motivation to improve.

Interventions

Standardized Care Processes. A care bundle is a set of evidence-based practices that have been demonstrated to improve patient outcomes when performed collectively and reliably. We introduced three standardized care processes: (1) elective induction bundle; (2) augmentation bundle; and (3) vacuum extraction bundle. Each bundle has 4–5 specific behavioral interventions (Table 1). The bundles share a common objective of standardizing processes and reducing practice variation. Originally developed by the Institute for Healthcare Improvement in 2005, the bundles have been applied in a number of perinatal care settings (Cherouny et al. 2005; Mazza et al. 2007; Institute for Healthcare Improvement 2012). When perinatal care bundles were initially developed a decade ago, the majority of birth trauma events were associated with oxytocin use, and the packages for elective induction and augmentation of

Table 1: Three Perinatal Care Bundles and Bundle Elements

<i>Elective Induction</i>	<i>Augmentation</i>	<i>Vacuum Extraction</i>
Gestational age ≥ 39 weeks	Documentation of estimated fetal weight	Alternative labor strategies considered
Or documented medical indication for induction if less than 39 weeks gestation	Normal fetal status	Informed consent discussed and documented
Normal fetal status prior to onset of oxytocin	Pelvic exam prior to onset of oxytocin	Estimated fetal weight, fetal position, and station known
Pelvic exam prior to onset of oxytocin	Recognition and management of tachysystole	Maximum application time and number of pop-offs predetermined
Recognition and management of tachysystole		Cesarean and resuscitation team available at delivery

labor were based on consensus recommendations to reduce variation in these care processes (Cherouny et al. 2005).

Consistency in the chart audit process was stressed with all teams. Each team developed different tools, such as forms or fields in their electronic medical records, for documentation of each bundle element. Each team assigned a key contact who was accountable for the data collection of the bundles for their respective team ensuring the audits were completed and the data entered into the online data reporting site for the project. The teams managed tachysystole two ways, by reviewing: (1) the fetal monitoring strips for the presence of tachysystole, or (2) the information entered by the nursing care provider on a tracking form for the bundle element.

Teamwork Training. We used didactic content and in situ simulation to support the creation of highly reliable teams at intervention hospitals. Both training modalities were based on a condensed TeamSTEPPS curriculum, derived from research (Miller et al. 2008), focused on four behavioral markers that identify high reliability team performance: (1) situation awareness; (2) closed-loop communication; (3) SBAR communication; and (4) shared mental model. These critical behaviors reflect the cumulative leadership performance of a critical incident team (Riley et al. 2008). This dual teamwork training strategy was structured to introduce learning, provide opportunities to practice the learning, and reinforce nontechnical team behaviors over an extended time. The didactic training was implemented in Phase 1 through face-to-face

meetings, monthly webinars, a 30-minute video, and a 2-hour presentation prior to the in situ simulation on-site training.

The in situ simulation strategy, shown to be a superior training modality for improving teamwork (The Joint Commission, 2006, 2007; Jewll and McGiffert 2009, Sorra et al. 2009), was introduced in a demonstration format during Phase 1. This was followed, in Phase 2, by a 3-day site visit to each perinatal unit where on-site in situ simulation training was provided. Five simulation scenarios were developed: postpartum hemorrhage, uterine rupture, abruption, shoulder dystocia, and resuscitation of the hypovolemic newborn. Each in situ simulation training consisted of three phases: (1) a briefing to set the stage; (2) the simulation experience; and (3) a facilitated debriefing. Video-tapes of the simulations were used during the debriefing for critical review and experiential learning. Using the train-the-trainer model for sustainability, the trainers at each hospital received extensive coaching and monitoring from two project team members (an obstetrician and an obstetrical nurse). The in situ simulation training was then provided to all labor and delivery, neonatal, operating room, anesthesia, lab, blood bank, respiratory therapy, and ancillary staff over the course of a year. Following the on-site train-the-trainer 3 days in situ simulation experiential training, each of the 14 sites conducted additional interdisciplinary in situ simulation offerings for 1 year. The goal of the study was to reach 100 percent participation of the staff. Each site had autonomy in conducting the simulations as well as choice in participation. Overall, 45.7 percent of clinical staff participated in at least one simulation (1,768 staff participating, including LNP, RN, and MD). Staff participation rates in the 14 hospitals ranged from 10 to 92 percent. For overall saturation, 9 percent of all departmental staff participated in at least two simulations, while 4 percent participated in at least three. Labor units were involved with 33 percent of the simulation scenarios, delivery teams were involved in 49 percent of the simulations, and neonatal (NICU) teams were involved with 18 percent of the scenarios. A phone audit with nursing leader of each site was done 1 year after the on-site in situ simulation train-the-trainer experiential education. Twelve hospitals (86 percent) reported scheduling conflicts and 11 hospitals (79 percent) reported physician buy-in to be key repetitive challenges to full simulation participation. Turnover of key personnel leading the in situ simulation effort was also reported with a 36 percent nurse manager turnover.

Education and Performance Feedback. Education was provided on a variety of contemporary teamwork and clinical topics including electronic fetal

monitoring (EFM). The EFM training included standardized language developed by the National Institute of Child Health and Human Development (Macones et al. 2008; American College of Obstetricians and Gynecologists 2010), using an institutional web-based education program Advanced Practice Strategies Advanced Fetal Monitoring & Assessment provided through Healthstream (Healthstream 2012). In addition, five physicians and five registered nurses responsible for fetal monitoring interpretation at each site were offered licenses to complete a more advanced online training with required competency test out. Overall 93 percent ($n = 130$ of 140) of the clinical staff successfully completed the advanced training, including 89 percent ($n = 62$ of 70) of the physicians and 97 percent ($n = 68$ of 70) of the registered nurses.

Performance feedback was provided to all teams using 60 monthly webinars, conference calls, and e-mails to benchmark their progress. Topics included overall compliance with the standardized processes (monthly), outcomes (quarterly), coaching to deal with change management barriers (ad hoc), and education regarding best practices (monthly), as well as an online website with numerous resources to support ongoing learning. These team webinars were also used to share learnings from other teams in the collaborative such as how to enhance bundle compliance, team communication, and resistance to change.

Quality Improvement Collaborative

We used a QIC to support the implementation of all three interventions. The QIC is a well-used approach by the health system to improve performance (Mittman 2004; Lindenauer 2008) and involves teams in a series of meetings to learn best practices from faculty knowledgeable about the content as well as quality improvement (Lindenauer 2008). QICs typically consist of interdisciplinary teams from numerous organizations willing to share experiences and to use quality improvement methods and techniques (Simon 2009).

Outcome Measures

We collected data on eight outcome measures selected from the National Perinatal Information Center database of coded discharge data submitted by hospitals. The eight measures were selected for their likely responsiveness to the intervention. Four measures (AHRQ PSI 1, 5, 7, and 16) were dropped from detailed analysis due to small numbers of

observations. Three of the four remaining outcome measures are related: Adverse Outcome Index (AOI), Weighted Adverse Outcome Score (WAOS), and Severity Index (SI). The three indices were formulated by consensus development conferences in the early 2000s (Mann et al. 2006). The AOI is the number of delivered mothers or infants with an adverse event, divided by the number of deliveries. Ten types of adverse events (e.g., uterine rupture, maternal blood transfusion) are included in the index. Although the AOI has been widely used, it has been subject to limited methodological scrutiny. Potential drawbacks of the AOI include being heavily influenced by high-volume adverse events and reliance on expertise of hospital coding and provider documentation (Foglia et al. 2015). The WAOS sums the weights for each of the adverse events that occurred and divides by the number of total deliveries. The SI sums the weights for each adverse event that occurred and divides by the number of patients that had an adverse event. The fourth outcome measure, AHRQ PSI 17-birth trauma, is a measure of a potential adverse event or complication experienced by a patient that could be prevented by system changes at the provider or organizational level (Agency for Healthcare Research and Quality 2013, 2014). We did not include PSI 18 and PSI 19, obstetrical trauma with and without instruments, for two reasons: (1) the predominant injuries reported for PSI 18 and PSI 19 are third- and fourth-degree perineal lacerations, both of which are already included in the AOI; and (2) there is considerable disagreement regarding laceration interpretation and coding issues associated with PSI 18 and PSI 19.

Data Collection

Care Bundles. The use of standardized processes (bundle compliance) was measured by chart audit using the IHI method (Cherouny et al. 2005). Data for the bundles were compiled in monthly retrospective chart audits by hospital staff, who audited 20 charts for each bundle per month. If fewer than 20 pertinent events occurred in a given month, all charts from that month were included. All items for bundle compliance were coded “yes” or “no,” with no credit for bundle compliance given unless all elements of the bundle were performed and documented. Each hospital uploaded all bundle metrics from the chart audits to an online bundle report module. A secure site was maintained by the research team and the data were uploaded for all three bundles each month along with birth log data. Bundle compliance rates were reported to

each perinatal team quarterly, including blinded performance relative to other intervention hospitals.

Outcome Measures. Each participating hospital collected monthly administrative data on all perinatal discharges for the 7-year period. Each quarter, the NPIC collected, processed, validated, and reported the outcome measures. Staff members at each hospital submitted data on births and adverse events electronically.

Statistical Methods. We used a run chart analysis to assess the process behavior of the standardized care bundles over the 7-year period. A run chart is a statistical process control technique that uses a time ordered sequence of consecutive observations to evaluate process behavior by identifying common cause variation and special cause variation. We also used run chart analysis to longitudinally analyze the AOI, WAOS, and SI in this study. Pre-post analyses using two-tailed *t*-tests were conducted for the outcome variables.

RESULTS

There were a total of 342,754 deliveries in the 14 hospitals, consisting of 107,472 births during the 2-year baseline period and 235,282 deliveries during the 5-year intervention period. Overall, a total of 1,883 (45.7 percent) perinatal staff at the 14 hospitals participated in the in situ simulation training; we did not record the number of staff participating in didactic training.

Standardized Processes

The use of the three standardized care processes, as well as the composite, across the 14 perinatal units is shown in Figure 2. The augmentation and induction care bundles were implemented Quarter 2-2008 through Quarter 4-2012, while the vacuum bundle was implemented Quarter 3-2008 through Quarter 4-2012. Use of the induction care bundle increased 113 percent (from 39 to 90 percent), with an increasing trend noted for the initial eight quarters, indicating special cause variation ($p < .003$) followed by common cause variation during the final 12 quarters, indicating a stable process. The augmentation

Figure 2: (a–d) Run Chart Analyses of Perinatal Care Bundles Compliance: (a) Composite, (b) Augmentation, (c) Induction, and (d) Vacuum

Notes. The compliance of the augmentation, vacuum, and induction standardized care bundles, as well as the composite compliance of all three bundles. Median compliance is noted in each graph, and periods of special cause are noted.

care bundle increased 377 percent (from 17 to 85 percent), with two long runs ($p < .003$). The vacuum bundle increased 900 percent (from 7 to 70 percent), with two long runs noted ($p < .003$). The composite standardized use of care

bundles increased 116 percent (from 37 to 80 percent), with two long runs ($p < .003$). The rate and magnitude of change, as well as overall performance levels, vary in each of the three care processes.

Outcomes

Table 2 shows a comparison of the baseline period with Phase 2 of the intervention for the four outcome measures. Overall, the AOI decreased 14.4 percent ($p = .032$), while there was no significant change in PSI 17, the WAOS, or SI. The run chart in Figure 3 shows the overall process behavior for the AOI over the 7 years (Quarter 1-2006 through Quarter 4-2012). Two occurrences of special cause are noted: (1) from Quarter 1-2006 to Quarter 1-2008 ($p < .003$) during the baseline period and (2) from Quarter 1-2010 to Quarter 4-2012 at the end of the project ($p < .003$). Common cause variation is observed between the two process shifts.

COMMENT

This prospective quasi-experimental study was conducted to improve performance of hospital obstetrical care and reduce preventable perinatal harm. The findings demonstrate the ability of hospital perinatal units to implement interventions over a sustained time period to reduce perinatal harm using a QIC.

The hospital perinatal unit staff substantially increased the use of standardized processes for each evidence-based care bundle. Of note are the differences between bundle compliance as well as the rate of change over time. While the vacuum extraction bundle moved the farthest, it had the lowest final compliance level of the three bundles. Full compliance with one or more

Table 2: Results of *T*-tests for Four Outcome Measures: Baseline Period Compared to Phase 2

<i>Measure</i>	<i>Baseline Period*</i> (2006–2007)	<i>Phase 2*</i> (2011–2012)	<i>Change (%)</i>	<i>p-value</i>
Adverse outcome index	0.055	0.047	−0.008 (−14.5)	.032
Weighted adverse outcome score	1.192	1.081	−0.111 (−9.3)	.100
Severity index	21.88	22.62	0.738 (3.4)	.460
Patient safety indicator 17	0.0019	0.0016	−0.0003 (−15.8)	.163

*Quarterly outcomes were averaged for each hospital, then averaged for all 14 hospitals.

Figure 3: Run Chart of the Composite Adverse Outcome Index of Fourteen Hospitals (January 2006–December 2012)

Notes. The run chart shows the effects of the interventions on the adverse outcome index. Intervention launches are indicated. Two periods of special cause are noted.

bundles was achieved by several perinatal units for one or more quarters, although none of the 14 perinatal units reached 100 percent bundle compliance in the same quarter. We also undertook extensive teamwork training using two training methods (didactic training and in situ simulation training) as well as common EFM interpretation and communication. The findings indicate that the AOI, an important measure of the incidence of perinatal harm, decreased 14 percent. The decrease in the AOI largely occurred only after the first quarter of 2011, at which point bundle compliance rates had all improved beyond their median rates, and at which time in situ simulation training was conducted. The AOI improvement logically could be related to either of those events, their combination, or some unmeasured event. It is possible that the in situ simulation training provided a necessary boost in commitment to decreasing adverse events, and that improved bundle compliance alone would not have produced the effect. While it is possible that the changes in our outcome measures could have been attained without these interventions, secular comparisons suggest otherwise. A population-based study in

British Columbia found no significant change in the AOI or WAOS over the 2004–2013 period, while the SI decreased significantly (Hutcheon et al. 2015). Likewise, nationwide data from the National Perinatal Information Center during the same period of this study indicate that AOI and WAOS increased during the same time period, while the SI remained unchanged. Similarly, PSI 17 incidence rates increased during the period 2009–2013 (Ledneva et al. 2015). To infer the causal relationships between the interventions and improved outcome, we follow the Pawson and Tilley (1997) CMO model, context + mechanisms = outcome, which has been promoted to accelerate the improvement of systems of care and clinical practice (Berwick 2008).

The interventions did not produce significant improvements in the other three outcome measures—the WAOS, SI, and AHRQ PSI 17-birth trauma. One potential interpretation of these seemingly heterogeneous intervention effects is that the outcome indexes measure separate concepts. For example, AOI measures the incidence of adverse perinatal outcomes in a population; WAOS measures the severity of total perinatal injury in an entire population; and SI measures the severity of perinatal injury in the subpopulation of patients who incur injury. Given that the AOI decreased significantly whereas the WAOS and SI did not, our findings suggest that the rate of perinatal harm decreased while the severity of harm, when injury did occur, remained unchanged. However, the lack of a reduction in total severity of injury could be interpreted that there was no change in the severity of injury for patients who were injured.

There is growing understanding that preventable perinatal injury is highly related to large variability in care processes and poor execution of non-technical skills (Simpson and Knox 2003; Salas, Gregory, and King 2011; Resar et al. 2012). The findings from the present study help inform the relationship between the use of standardized care processes, teamwork training, and improved perinatal outcomes. Process behavior is best understood by examining time ordered sequences in a key quality metric. Using a run chart analysis, our first statistically significant change in the AOI occurred when special cause variation lasting over 2 years (January 2006–March 2008) was followed by almost 3 years of common cause variation (September 2008–January 2011) immediately after the introduction of the standardized care processes. Such standardization of practices is the foremost building block to be addressed before other solutions to unsafe care are introduced (Amalberti et al. 2005).

It is likewise noteworthy that a second pattern of special cause occurred immediately after introduction of the in situ simulation training, suggesting

that nontechnical skills are also necessary to ensure safe patient care (Paisley, Baldwin, and Paterson-Brown 2001; Yule et al. 2008; Bisognano, Cherouny, and Gullo 2014). The second occurrence of special cause in the AOI run chart analysis occurred following the introduction of extensive in situ simulation training and also persisted almost 3 years, until the end of the study (March 2011–December 2012).

While the hospital staff in this study underwent extensive teamwork training over an extended time frame and dramatically increased the use of standardized care processes, it is not clear whether there is a threshold level at which point this care standardization impacted care outcomes. Most studies to improve perinatal outcomes are conducted in one hospital or system, implement a limited set of interventions, involve a small number of deliveries, and/or last a short duration. The findings from this study are especially relevant because of the large number of births (342,754) analyzed over a 7-year time frame using several interventions across 14 widely distributed hospitals, including both employed physicians and private hospital staff. Some perinatal events are so rare that examining a trend requires thousands of cases (Wagner et al. 2012), and the magnitude of this study enhances face validity of the findings.

Several precautions are in order when drawing conclusions regarding the causal relationship between the quality improvement interventions and change in performance (Bion et al. 2013). While findings from this study suggest training in technical and nontechnical interventions to improve patient safety combined with performance feedback resulted in a reduction in perinatal harm, this conclusion requires a nuanced interpretation. Although our discussion regarding industry trends indicates that these findings are not associated with any known secular trends, it is never the less possible these findings do reflect a secular trend. Next, these interventions were undertaken during a period of sustained activity on a national level to improve perinatal safety (Crofts et al. 2007; Clark et al. 2008; Draycott et al. 2008; Hansen and Arafeh 2012). Finally, the methodology applied in this study reflects a larger discussion currently underway in the science of improvement regarding the appropriateness of randomized controlled trials in contrast to other methods to accelerate improvement in clinical settings (Berwick 2008).

Limitations

The data for this analysis come from 14 hospitals who responded to an invitation to participate in a QIC to reduce perinatal harm. To establish causality,

an ideal study would randomly select participating sites and randomize them to intervention or control groups. Because of the potential that hospitals volunteering to participate were somehow different than those not volunteering to participate (e.g., differing levels of motivation to change or underlying leadership characteristics), we cannot establish a true causal link between the intervention and outcomes observed. However, the review of secular trends helps mitigate this potential threat to validity. We did not control for any related or competing interventions occurring in the perinatal units during this study. Another limitation of this study design was the inability to separate the effects of the multiple interventions on perinatal outcomes (standardized care processes, didactic, or in situ simulation training). The extent of in situ simulation training varied substantially in the participating hospitals. The in situ simulation participation data were collected retrospectively, and we do not have sufficient information regarding the uptake of the in situ simulation experience from the participants to assess this impact directly. It is unknown what amount of intervention with perinatal staff is necessary to produce desired outcomes. It is also unknown, given the lack of empirical data, the extent to which limited physician engagement, poor leadership, and turnover in nursing leadership plays in achieving and sustaining high reliability. During the course of this study, there was a 36 percent turnover of nurse managers. There is always a potential for leadership turnover to have a disruptive impact on perinatal unit performance. This potential impact was not addressed in the study. Finally, it is difficult to compare effectiveness of outcomes among studies because there is no commonly accepted time frame to measure adverse perinatal outcomes (Bailit 2007), and a variety of time intervals are used to report rates including monthly, quarterly, and annually. To address this concern, we used statistical process control analysis based on process shifts to assess change over time as reflected by special cause variation.

CONCLUSION

High reliability is especially necessary in perinatal units, where the consequences of errors are high, but the frequency of occurrence is low (Baker, Day, and Salas 2006). The findings from this study contribute to a slowly accumulating body of evidence regarding methods and approaches to reduce unintended perinatal injury. Perinatal teams work in complex systems where the best countermeasure to preventable harm consists of an

interdisciplinary team of experts (McIntyre and Salas 1995; Burke et al. 2004; Miller et al. 2008) using standardized care processes (Cherouny et al. 2005; The Joint Commission 2006; Jewll and McGiffert 2009; Resar et al. 2012) and supplemented by extensive teamwork training (Neily et al. 2010; Weaver et al. 2010; Shannon 2011; Resar et al. 2012) to improve the reliability of obstetrical work. These findings suggest that a multiplicity of integrated strategies, rather than a single intervention, may be essential to achieve high reliability. We propose the following recommendations for future research. First, assess the individual impact of the three interventions and their possible synergistic relationship. Second, consider teamwork training penetration (the percent of staff that participate in training) and saturation (the number of times that staff members train). Third, determine the extent of the uptake of the in situ simulation training from the participants and its impact on perinatal safety.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.
Table S1. Intervention ($n = 14$).