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PATIENT SAFETY & MEDICAL LIABILITY

Decreasing Malpractice Claims by Reducing Preventable Perinatal Harm

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Objective. To evaluate the association of improved patient safety practices with medical malpractice claims and costs in the perinatal units of acute care hospitals.

Data Sources. Malpractice and harm data from participating hospitals; litigation records and medical malpractice claims data from American Excess Insurance Exchange, RRG, whose data are managed by Premier Insurance Management Services, Inc. (owned by Premier Inc., a health care improvement company).

Study Design. A quasi-experimental prospective design to compare baseline and postintervention data. Statistical significance tests for differences were performed using chi-square, Wilcoxon signed-rank test, and *t*-test.

Data Collection. Claims data were collected and evaluated by experienced senior claims managers through on-site claim audits to evaluate claim frequency, severity, and financial information. Data were provided to the analyzing institution through confidentiality contracts.

Principal Findings. There is a significant reduction in the number of perinatal malpractice claims paid, losses paid, and indemnity payments (43.9 percent, 77.6 percent, and 84.6 percent, respectively) following interventions to improve perinatal patient safety and reduce perinatal harm. This compares with no significant reductions in the nonperinatal claims in the same hospitals during the same time period.

Conclusions. The number of perinatal malpractice claims and dollar amount of claims payments decreased significantly in the participating hospitals, while there was no significant decrease in nonperinatal malpractice claims activity in the same hospitals.

Key Words. Perinatal malpractice claims, patient safety, perinatal outcomes, care bundles, *in situ* simulation training

There is a recognized link between perinatal harm, malpractice claims, and malpractice payments. However, few studies have quantified this relationship and even fewer studies have undertaken efforts to improve perinatal patient safety in order to reduce preventable patient harm and assess the impact on

the level of malpractice litigation. Labor and delivery pose substantial risk for harm to mothers and newborns, with perinatal complications reported from 3 to 10.7 percent of all deliveries ranging from minor lacerations to major injury (Mann et al. 2006; Nielsen et al. 2007; Kozhimannil et al. 2013; Goffman et al. 2014; New Jersey Hospital Association Institute for Quality & Patient Safety 2014). At least 1.5 percent of hospitalized obstetrical patients experience a sentinel event (MANA 2009) and obstetrics is high risk for medical malpractice claims. The rate of malpractice claims filed for perinatal harms is reported at 5.64 per 10,000 births (AON Risk Solutions, 2013) and almost 90 percent of obstetricians have been sued while practicing (Strunk 2012). The cost of medical liability insurance for obstetricians is typically the highest or second highest of medical specialties in all U.S. states (CRICO Strategies 2013).

The purpose of the present study was to examine the relationship between improved patient safety practices and liability claims and costs in the perinatal units of acute care hospitals.

METHODS

This study is part of a larger quasi-experimental, prospective quality improvement collaborative (QIC) project 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 clinical education regarding best practices 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. 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

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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 consulting. The Phase 2 intervention introduced intensive *in situ* simulation training at each hospital, while continuing all Phase 1 activities.

We hypothesized that the evidence-based care bundles will facilitate the delivery of standardized care practices for deliveries occurring at the participating hospitals. This is consistent with expert opinion that delivery of standardized, evidence-based care bundles may result in a decrease in the incidence of adverse birth outcomes and thus perinatal patient harm (Knox, Simpson, and Garite 1999; Simpson, Kortz, and Knox 2009). As unintended patient harm is a major contributor to malpractice claims, reducing perinatal harm should thus also reduce the incidence of malpractice claims, the number of successful malpractice claims, and accompanying expenditures (Clark et al. 2008).

We used a train-the-trainer method to sequentially train a team from each hospital, which in turn trained all staff at their respective perinatal units. The interdisciplinary trainer team from each hospital, comprised of an obstetrician and an obstetrical 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, as the data partner, obtained IRB approval from a hospital outside of the study group.

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 four to five specific behavioral interventions. 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; Riley et al. 2011; 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 labor were based on consensus recommendations to reduce variation in these care processes (Cherouny et al. 2005).

Teamwork Training. We used didactic content and *in situ* simulation (ISS) to support the creation of highly reliable teams at intervention hospitals. Both training modalities were based on a condensed TeamSTEPPS™ curriculum (Miller et al. 2008; Riley et al. 2011), which focused on four behaviors associated with the majority of team and communication failures during perinatal emergency events: situational awareness; standard language of Situation, Background, Assessment, Recommendation; closed loop communication; and a shared mental model (Miller et al. 2008; Riley et al. 2010; Institute for Healthcare Improvement 2012). 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 ISS strategy, shown to be a superior training modality for improving teamwork (The Joint Commission 2006; Jewell and McGiffert 2009; Sorra et al. 2009; Riley et al. 2011), 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 ISS training was provided. Five simulation scenarios were developed: postpartum hemorrhage, uterine rupture, abruption, shoulder dystocia, and resuscitation of the hypovolemic newborn. Each ISS training consisted of three phases: (1) a briefing to set the stage, (2) the simulation experience, and (3) a facilitated debriefing. Videotapes 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 ISS training was then provided to labor and delivery, neonatal, operating room, anesthesia, lab, blood bank, respiratory therapy, and ancillary staff over the course of a year.

Clinical Education and Performance Feedback. Education was provided regarding best practices 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® (Institute for Healthcare Improvement 2012). In addition, five medical providers 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 = 121 of 130) of the clinical staff successfully completed the advanced training, including 89 percent (n = 57 of 65) of the physicians and 97 percent (n = 63 of 65) of the registered nurses. There was no cost to the hospital or the participants for the licensure.

Performance feedback was provided to all teams using 60 monthly webinars, routine conference calls, and e-mails to benchmark their progress. Topics included 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.

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).

HOSPITAL SELECTION AND SETTING

In 2008, an invitation was sent to 16 health care systems insured by AEIX which operated 67 hospitals providing obstetrical services. Each system was invited to nominate one hospital to become involved in the Premier Perinatal Safety Initiative. Thirteen systems accepted this invitation with funding provided by AEIX to cover the participation costs. In addition, three health care systems elected to enroll a second hospital at their own expense. The research team was not involved in the final selection of the selected hospitals. Of the 16

hospitals participating in Phase 1, 13 continued through Phase 2. We report findings for those 13 hospitals. Compared to the 13 continuing hospitals, the three hospitals that were excluded had slightly lower adverse event outcome measures. One of the participating hospitals closed their obstetrical unit; another hospital discontinued participation due to competing priorities for staff time and resources; and the third hospital was excluded because of a 2.5-fold drop in delivery volume from baseline to intervention periods. We do not have claims data for these three hospitals.

The 13 hospitals in this study are located in 10 states. Seven hospitals had nonacademic status while six were academic centers. Academic teaching status was defined by presence of a residency program. Four hospitals had small birth volume, seven hospitals had medium birth volume, and two hospitals had large birth volume (Small from 1,000 to 2,499, Medium from 2,500 to 5,000, and Large over 5,000). All participating hospitals had a perinatal unit consisting of physicians, nurses, and ancillary support personnel eligible to participate in the study interventions and an interdisciplinary team to lead the work in their institutions.

VARIABLES

The outcome variables consist of five metrics: two metrics related to harm reduction and three measures related to malpractice activity. We reported the reduction of harm metrics elsewhere (Riley, McCullough, and Dinh 2015). In this study, we examine trends in lawsuit claims related to maternal and neonatal injury. We define a claim as a lawsuit or a formal demand for compensation due to an alleged error arising out of treatment of a patient. We examine only those lawsuits that were filed; no potential claims were considered, because hospitals vary in identification and reporting of adverse events which may become claims. Claims that did not concern inborn labor and delivery events or that did not involve neonates over 2,000 grams were separated from those that did concern labor and delivery events.

Table 1 shows the three malpractice liability variables, measures, and data sources for the study.

Data Collection

The data for this study come from litigation records from AEIX, obtained through special arrangement for the purposes of this study. The medical

malpractice claims data for this study were available through confidentiality contracts with Premier Insurance Management Services, Inc. (PIMS). The claims data were collected and evaluated by experienced Senior Claims Managers from PIMS through on-site claim audits to evaluate claim frequency, severity, and financial information.

Because of the potential delay in filing claims and adjudicating the claims settlements, it is possible that all the claims from injuries incurred during this study are not yet filed, or settled, at the time of data analysis. Previous studies have shown an average lag of 1.2 years between an incident and claim filing, with over 85 percent of claims filed within 3 years from date of incident, and a lag of 1.8–2.4 years from claim filing to claim closure (Kim 2007; Gimm 2010; Seabury et al. 2013). To account for the possible effect of claims lag in this study, we only analyzed data from 2006 to 2009, allowing at least a 5-year period for claims to be filed and adjudicated. Claims from 2006 to 2007 constitute the study's baseline period (prior to the intervention); claims from 2008 to 2009 constitute the study's intervention period.

Data Analysis

Data on the date of injury, claim amount, and result of the claim were analyzed to compare participating hospitals from the baseline period (2006–2007) to the intervention period (2008–2009). All dollar amounts were converted to constant 2009 dollars using the consumer price index (U.S. Department of Labor Bureau of Labor Statistics 2015). We compared baseline versus intervention claim incidence and payment amounts for perinatal-related claims within each hospital. Next, we analyzed perinatal-related claims pre- versus postintervention versus nonperinatal-related claims pre- versus postintervention for intervention hospitals. The main outcome of interest was the differential change in perinatal-related versus nonperinatal claims, pre- versus postintervention. Three time periods are considered when analyzing medical malpractice claims: the date of injury, the date a claim is made, and the date at which a claim is paid or closed. In Table 1, Variable 1 refers to claims made for injuries which occurred during the 4-year study period within 5 years of injury. Variable 2 refers to all of the claims paid for injuries during the 4 year study period within 5 years following the year of injury. As randomization is not a feasible study design for this research question, our analytic approach helps to control for changes in overall historical claim patterns within each hospital. Variable 3 refers to the dollar amount paid for claims for injuries during the 4 years of the study period and closed within 5 years following the

Table 1: Malpractice Variables, Outcome Measures, and Data Source

Malpractice Liability Outcomes	*Outcome Measure*	*Data Source*
Number of claims made: Claims filed for injuries during 1/1/06–12/31/09 (reported within 5 years following year of injury)	Number	Claims file audit
Number of claims paid: Claims paid for lawsuits for injuries occurring 1/1/06–12/31/09 (within 5 years of injury)	Number	Claims file audit
Total losses paid: Dollar value of all malpractice payments 1/1/06–12/31/09	Dollars	Claims file audit
Total indemnity paid: Dollar value of indemnity (liability) losses paid 1/1/06–12/31/09	Dollars	Claims file audit
Total legal defense costs: Dollar value of costs for legal defense related to malpractice cases 1/1/06–12/31/09	Dollars	Claims file audit

year of injury. Variables 4 and 5 refer to the total indemnity (i.e., liability) payments and legal defense costs for malpractice claims, respectively.

We tested for significant changes in outcome measures shown in Table 1 using several statistical methods. Specifically, differences in incidence of malpractice claims made, claims paid, and liability spending were examined using paired *t*-tests (to test for significant changes in each hospital's mean outcome values pre- vs. postintervention), and Wilcoxon signed-rank tests (to test for significant changes in each hospital's median outcome values). Given that liability payments for perinatal-related claims can be rare but especially costly, excluding outliers is not appropriate. We present both mean values and median values in order to include the impact of these rare but large payments (using mean values) and mitigate the impact of exceptionally outsized payments (using median values).

RESULTS

A total of 185,373 births from 13 intervention hospitals are represented in this study. We report only a 4-year period of the study in order to create a 5-year time lag from date of injury. Table 2 shows there was a total of 125 claims made resulting from birth injuries during this time period with 25 claims (0.01 percent of deliveries; 20 percent of claims) resulting in payments at a total cost of $27.3 million incurred in settling these cases. Legal defense costs account for 15 percent of total claims cost. There are approximately 6.7 claims filed for

Table 2: Descriptive Statistics for Participating Hospitals (2006–2009)

	Total	*Annual*	*Per 10,000 Deliveries*
Total number of deliveries	185,373	46,343	–
Total number of perinatal claims made	125	31	6.7
Total number of perinatal claims paid	25	6	1.3
Total amount of losses paid for perinatal cases	$27,266,019	$6,816,505	$1,470,870
Total indemnity losses paid for perinatal cases	$23,151,569	$5,787,892	$1,248,920
Total legal defense costs for perinatal cases	$4,114,449	$1,028,612	$221,960

every 10,000 deliveries and approximately 1.3 claims paid for every 10,000 deliveries.

We next examine the OB malpractice claims in contrast to all the claims from these hospitals during the same time period. Table 3 indicates that OB claims represent 9 percent of all malpractice claims paid at all 13 hospitals, but 24 percent of the total malpractice costs and 27 percent of legal defense costs.

Table 4 standardizes the lawsuits and losses per 10,000 deliveries in order to assess the relationship of the perinatal patient safety interventions with malpractice claims. Significant reductions in the median financial losses occur from the baseline to intervention period ($385,980 median decrease in total losses per 10,000 deliveries) driven by a total median reduction of indemnity loss of $363,440 per 10,000 deliveries.

We further examine the impact of the intervention by comparing the level of OB malpractice claims activity with all malpractice claims activity in the participating hospitals. In analyses not adjusted for delivery frequency, Table 5 indicates there is a significant reduction in the total number of OB claims paid, losses paid, and indemnity payments (43.9 percent, 77.6 percent, and 84.6 percent, respectively) compared with no significant reductions in the total non-OB claims in the same hospitals during the same time period.

Table 3: Descriptive Comparison of Perinatal Claims versus Total Claims for Participating Hospitals (2006–2009)

	Total—All Claims	*Perinatal Claims*	*Nonperinatal Claims*	*Perinatal Share of Total*
Total number of claims made	1,047	129	918	12.3%
Total number of claims paid	280	25	255	9%
Total amount of losses paid	$114,840,207	$27,266,019	$87,574,188	24%
Total indemnity losses paid	$99,693,277	$23,151,569	$76,541,708	23%
Total legal defense costs	$15,146,934	$4,114,449	$11,032,485	27%

Table 4: Baseline versus Intervention Period Malpractice Liability Activity for Obstetrics-Related Claims at Participating Hospitals (2006–2009)

			Baseline to Intervention Change			
	Baseline: 2006–2007 (SE)	*Intervention: 2008–2009 (SE)*	*Mean† (SE)*	*p-Value*	*Median Hospital‡*	*p-Value*
Average annual deliveries	3,603	3,527	−152	.032	−146	.133
OB claims made per 10,000 deliveries	6.3 (8.2)	4.9 (4.9)	−1.4 (1.1)	.107	−1.9	.291
OB claims paid per 10,000 deliveries	1.9 (1.6)	1.2 (2.3)	−0.7 (0.7)	.165	0.0	.377
Total amount of losses paid per 10,000 deliveries	$2,172,960 (2,759,570)	$957,870 (3,092,740)	($1,215,090) (1,227,290)	.171	($385,980)	.050*
Total amount of indemnity losses paid per 10,000 deliveries	$1,879,810 (2,539,790)	$726,120 (2,765,030)	($1,153,700) (1,156,680)	.169	($363,440)	.046*
Total legal defense costs per 10,000 deliveries	$293,140 (350,970)	$231,750 (440,770)	($61,390) (440,230)	.312	($22,340)	.505
Average amount of losses paid per OB claim paid	$1,224,246 (1,733,957)	$175,349 (375,453)	($1,048,898) (1,731,971)	.025*	($360,282)	.054

Notes. †Paired *t*-test used to assess significance level.
‡Wilcoxon signed-rank test used to assess significance level.
*Significant *p*-value.

Table 5: Changes in Baseline versus Intervention Period Malpractice Liability for Perinatal versus Nonperinatal-Related Claims at Participating Hospitals (2006–2009)

	Nonperinatal Claims				*Perinatal Claims*			
	Baseline: 2006–2007 (SE)	*Intervention: 2008–2009 (SE)*	*Percent Change*	*p-Value for Change*†	*Baseline: 2006–2007 (SE)*	*Intervention: 2008–2009 (SE)*	*Percent Change*	*p-Value for Change*†
Number of claims made (average per hospital)	43.54 (51.96)	37.00 (38.70)	−15.0%	.233	5.54 (9.73)	4.38 (7.05)	−20.9%	.214
Number of claims paid (average per hospital)	11.54 (10.78)	10.00 (7.91)	−13.3%	.219	1.23 (1.01)	0.69 (0.95)	−43.9%	.049*
Total amount of losses paid (average per hospital)	$4,639,164 (6,809,083)	$4,194,698 (5,849,142)	−9.6%	.367	$1,713,296 (2,710,887)	$384,090 (1,114,346)	−77.6%	.040*
Total amount of indemnity losses paid (average per hospital)	$4,031,426 (6,158,116)	$3,637,287 (5,647,905)	−9.8%	.375	$1,527,002 (2,563,152)	$235.888 (1,015,736)	−84.6%	.043*
Total legal defense costs (average per hospital)	$607,738 (711,448)	$557,411 (480,826)	−8.3%	.279	$186,293 (213,190)	$130,207 (231,920)	−30.1%	.153
Average amount per claim paid	$428,349 (478,919)	$1,260,960 (2,674,585)	194%	.149	$1,224,246 (1,733,957)	$175,349 (375,453)	−85.7%	.025*

Notes. †Significance tested using paired *t*-test.
*Significant *p*-value.

DISCUSSION

The findings from this study suggest that there is a significant decrease in malpractice claims activity following interventions to improve perinatal patient safety and reduce perinatal harm. Our results indicate that the total number of claims made against providers is 6.7 claims per 10,000 deliveries, which is slightly higher than the national rate of 5.64 per 10,000 births (AON Risk Solutions 2013). It is noteworthy that the rate of claims paid and the amount paid decreased substantially (perinatal claims paid dropped 37 percent from 1.9 per 10,000 deliveries to 1.2 per 10,000 deliveries; while the total amount of losses dropped 56 percent from $2,170,000 per 10,000 deliveries to $950,000 per 10,000 deliveries). Moreover, the number of perinatal claims made in this study did not change significantly over the study period. Equally noteworthy, there was no change in nonperinatal claims activity in the same hospitals between the baseline and intervention periods. While for perinatal claims, the average number of claims paid per hospital, the total average amount of losses paid per hospital, and the average amount of indemnity payments per hospital dropped precipitously (43.9 percent, 77.6 percent, and 84.6 percent, respectively) compared to no change in the overall claims activity in the same hospitals. Finally, the average amount paid per claim for nonperinatal claims did not change significantly while the average perinatal claims paid decreased significantly by 85.7 percent ($1,048,897).

The monetary amount of the perinatal malpractice claims paid in this study was reduced substantially, from $22,272,800 in the baseline period to $4,993,200 in the intervention period. To the extent that the nonperinatal claims paid did not change during the study period, the $17,279,600 decrease in perinatal claims paid may be associated with the intervention in this study.

It is estimated that perinatal injuries are involved in 43 percent of the total malpractice cases exceeding $5 million in loss payout (AON Risk Solutions 2013) with over half of the typical hospital's risk management budget spent in the labor and delivery area (Physician Insurers Association of America 2006). Moreover, maternal admissions with complications are about twice as costly as stays without complications, and admissions with pregnancy and delivery-related complications account for $17.4 billion in annual U.S. hospital costs (Elixhauser and Wier 2011).

Malpractice claims settlement expenses for obstetrics are enormous. An analysis of closed claims in Washington State showed labor and delivery claims against hospitals averaged $895,536 and defense expenses averaged

$93,402 (Kreidler 2013). Similarly, a 7-year analysis found the average loss paid by hospitals in Ohio for obstetric department claims was $881,104 (three times higher than all other losses), with defense costs averaging $107,672 (higher than all other departments) (Ohio Department of Insurance 2013); while a 5-year study by CRICO indicates that the indemnity cost of 476 closed claims was an average of $944,000, again 2.6 times higher than closed claims for all cases (CRICO Strategies 2015).

The findings from this study are relevant for two important reasons: (1) there is limited empirical evidence identifying methods to improve perinatal patient safety; and (2) with one exception, there are no studies that show the relationship between improved patient safety, reduced patient injury, and reduced malpractice claims. The exception is a retrospective study conducted at New York Presbyterian Hospital-Weill Cornell Medical Center, which indicated an association between a comprehensive obstetric patient safety program and decreased compensation payments (Grunebaum, Chervenak, and Skupski 2011). The findings in this study are also noteworthy in light of recent widespread concern about the lack of improvement in many clinical quality indicators, as well as the difficulty of sustaining QI initiatives over long periods of time (U.S. Department of Labor Bureau of Labor Statistics; White et al. 2005; Strunk 2012; Tallarico, Douglas, and Friess 2013). Among the group of hospitals in our study, certain perinatal liability measures decreased, even though other nonperinatal liability measures did not improve. This does not necessarily suggest a demonstration of the value of perinatal safety practices; however, it is suggestive that under some circumstances and in selected hospitals, adoption of perinatal safety measures may be associated with observable liability effects.

While the vast majority of U.S. births result in healthy infants and mothers, ongoing care of infants injured at birth places significant financial exposure on parents, care providers, insurance companies, and public agencies. A recent CRICO report found that 34 percent of perinatal-related closed malpractice cases involve one or more communication errors (CRICO Strategies 2015). Similarly, a study of liability claims found that the majority of preventable perinatal adverse events were associated with communication gaps between health care providers (White et al. 2005), an indicator that effective team-building and communication protocols can be effective in preventing perinatal harm. This study is the first prospectively designed study which contributes to a growing body of evidence that malpractice claims activity decreases following improvements in perinatal patient safety practices.

CONCLUSIONS

The purpose of this study was to examine whether the frequency and cost of malpractice claims is related to improved patient safety and reduced perinatal harm in hospital obstetrics units. Findings from the larger study indicated that a reduction in perinatal harm was associated with improved performance with standardized best practices and team training of obstetrical unit physicians and staff. The findings from this study indicate an average decrease of $1,048,000 per perinatal claim paid. The median dollar amount of perinatal claims paid also decreased significantly in the intervention period compared to the baseline period ($385,980 per 10,000 deliveries). The total amount of indemnity losses paid significantly decreased ($363,440 per 10,000 deliveries). While the number of perinatal malpractice claims and dollar amount of claim payments decreased significantly in the participating hospitals, there was no significant decrease in nonperinatal malpractice claims activity in the study hospitals.

Limitations

Medical malpractice claims data provide primarily a perspective on what has happened in the past. Insurers and quality improvement teams use it to help identify risk exposures in anticipation that the same errors could happen again. Insurers use prior loss data to forecast potential future losses. However, there are several issues which adversely impact the analytical use of the data. First, there are inherent problems in the legal system causing the outcome data to vary considerably under different state laws for similar injuries and fact patterns. These include considerable variation in time limits in which claims can be filed, as well as tort reform laws which govern evidence needed to prove legal fault and/or which place limits on the amount of damages which can be recovered. Some venues also have more liberal or conservative settlements and verdicts, depending on local culture and other demographics. In addition, there is a legal proximate cause required to be proven between any substandard care or negligence and the injury suffered, so that not every injury is legally compensable, even if caused by an adverse event.

Although the ideal study would have randomized sites to the intervention, the opportunity to randomize the groups was not available and a quasi-experimental design with a longitudinal analysis and a comparator group was used to assess the intervention effects in the larger study. All hospitals in this

study were members of AEIX. These results cannot be generalized to the universe of perinatal malpractice claims. Finally, because malpractice claims take years to file and resolve, data may not reflect conditions in the hospitals observed over the period of the study nor reflect ultimate financial outcomes for all years in time for this report. Our study does not explicitly control for potential variables that may also influence perinatal malpractice claims and costs, such as state regulations, other interventions occurring in sample hospitals, and regional patterns of treatment. This is not a multivariate study of administrative databases and we do not control for covariates with a large number of variables to control. By virtue of a prospective quasi-experimental design, we have limited this to a bivariate statistical analysis.

Additional biases limit the ability to effectively use claim data to make judgments about possible adverse events: (1) the mere fact a claim is filed does not indicate an error or injury occurred (60–80 percent of claims typically will resolve without loss payment); (2) health care providers may settle cases they believe are defensible to avoid potentially larger economic exposure from verdicts or to avoid the time and cost of litigation; and (3) patients may choose not to file claims against their health care providers even when they have been injured and are entitled to a legal recovery. Also, there was a high participation by the physicians and nurses to participate in the advanced online training fetal monitoring interpretation (94 percent). However, training was limited to 10 individuals at each location which could result in a larger portion of the relevant personnel receiving advanced training at the smaller facilities and thus a potential bias.

The intervention period reports findings over 2 years (2008–2009). While it is desirable to report a greater time period to monitor the impact of the interventions, we incorporated a minimum of a 5-year lag time to ensure that all claims were processed and adjudicated. The findings will be monitored in the future to extend the total years in the analysis of the intervention. In addition, three hospitals dropped from Phase 1 (the baseline phase) to Phase 2 (the intervention phase). We do not have claims data for these three hospitals. If these data were available, the results may be different from the findings that are reported. Finally, an important external factor occurred during the time period of this study. The 13 hospitals in this study were located in 10 states throughout the nation, and six of these states had or adopted tort reform during the time period of this study. It is possible that these tort reform initiatives effect the rate of claims made from the hospitals in this study. However, we compare the perinatal claims with all other claims from the same hospitals

during the same time period and we would expect that any influence of tort reform would extent to all malpractice claims in the hospital.

Perinatal claims pose some of the highest financial exposures when injuries include neurological impairment or brain damage, requiring long-term medical treatments, significant lost wages, and pain and suffering. These serious cases do not happen frequently, so they create a low-frequency but high-severity dataset. Typically, patients have 2 years from the date of injury to file a lawsuit, but minors have until they are 18 years old to file in many states. Studies have shown it can typically take 2–5 years after the claim is filed for the case to be investigated and resolved, with higher settlements often taking longer to achieve. Because of this long tail for a claim to be filed and resolved, metrics used for evaluating medical malpractice claims vary depending on the focus of the analysis. Closed claims are often utilized because they have resolved and have finalized data, but they may not be closed until several years after the injury occurred. The rate at which new claims are being filed may be an indicator of current improved quality of care, if analysis is based on the date of injury rather than date of claim filing. Claim results can be simply compared to baseline or to outside datasets from similar hospitals, if available.

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SUPPORTING INFORMATION

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

Appendix SA1: Author Matrix.