The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes

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Objective. To determine whether a communication and resolution approach to patient harm is associated with changes in medical liability processes and outcomes.

Data Sources/Study Setting. Administrative, safety, and risk management data from the University of Illinois Hospital and Health Sciences System, from 2002 to 2014.

Study Design. Single health system, interrupted time series design. Using Mann–Whitney U tests and segmented regression models, we compared means and trends in incident reports, claims, event analyses, patient communication consults, legal fees, costs per claim, settlements, and self-insurance expenses before and after the implementation of the "Seven Pillars" communication and resolution intervention.

Data Collection Methods. Queried databases maintained by Department of Safety and Risk Management and the Department of Administrative Services at UIH. Extracted data from risk module of the Midas incident reporting system.

Principal Findings. The intervention nearly doubled the number of incident reports, halved the number of claims, and reduced legal fees and costs as well as total costs per claim, settlement amounts, and self-insurance costs.

Conclusions. A communication and optimal resolution (CANDOR) approach to adverse events was associated with long-lasting, clinically and financially significant changes in a large set of core medical liability process and outcome measures.

Key Words. Patient safety, medical liability, disclosure, communication, resolution

Improving patient safety and minimizing medical liability costs are important priorities for U.S. health care system reform (Kohn, Corrigan, and Donaldson 2000; Clinton and Obama 2006; Leape et al. 2009; Mello and Brennan 2009). It may be possible to achieve these goals by developing a culture of

transparency, effective communication, and early resolution following adverse events caused by inappropriate care or other factors.

According to the U.S. Agency for Healthcare Research and Quality, communication and optimal resolution (i.e., CANDOR) refers to "a process that health care institutions and practitioners can use to respond in a timely, thorough, and just way when unexpected events cause patient harm" (Agency for Healthcare Research and Quality 2016). A CANDOR program generally includes an integrated set of processes for event identification, system activation, response and disclosure, investigation and analysis, resolution and remediation, and care for care providers.

These programs have demonstrated that effective communication with patients and families in the immediate aftermath of patient harm, regardless of the cause of that harm, can lead to organizational learning, improved surrogate measures of patient safety, and reduction in medical liability (Boothman et al. 2009; Kachalia et al. 2010; Helmchen, Richards, and McDonald 2011; Mello et al. 2014a,b; Agency for Healthcare Research and Quality 2016). In CANDOR programs, health systems and medical liability insurers encourage communication of unanticipated outcomes to patients while seeking early resolution that may include offering an apology, an explanation, a commitment to learn and improve, an admission of liability, and where appropriate, reimbursement or compensation (Mello et al. 2014a,b).

The following sections describe how the University of Illinois Hospital and Health Sciences System (UIH) responded to its own local medical liability crisis by adopting a version of a CANDOR program known as the Seven Pillars (McDonald et al. 2010). The first section describes the historical context, and the following section describes the intervention.

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Catalyst for Change in Approach to Medical Liability

In 2001, a medical liability crisis erupted nationwide, leading to calls for transformation within the medical and legal communities (Thorpe 2004). Many regions across the United States faced rising medical malpractice premiums and large judgments. Insurance carriers began to exit the marketplace, further increasing upward pressure on malpractice premiums (Freudenheim 2001).

The UIH, located in a jurisdiction without limits personal injury liability payouts, Cook County, Illinois, was adversely affected by these events. In 2001, the excess insurance carrier that provided coverage to UIH for any loss greater than $3 million exited the marketplace. In 2002, excess carriers in Cook County would not provide financial coverage at any level less than $15 million per case. This caused a shortfall in the UIH self-insurance fund, with a potential $12 million gap on every case involving major harm. The result was a massive increase in the required annual contribution to the University's self-insurance fund that was needed to cover potential ongoing losses and to reduce the fund deficit of more than $30 million.

Responding to the Institute of Medicine's report of the large numbers of preventable patient deaths (Kohn, Corrigan, and Donaldson 2000) and the medical liability crisis in Illinois, UIH charged the office of the Chief Medical Officer with developing an alternative approach for managing the health system's patient safety, medical liability, and risk profile. The team explored programs from around the country, including those at the Lexington, KY Veterans Administration (Kraman and Hamm 1999) and the University of Michigan (Boothman et al. 2009). Further exploration into the impact of effective communication after unexpected outcomes on patient claims behavior was also conducted during this time (Hickson et al. 2002).

In September 2005, then Senators Clinton and Obama proposed the Medical Error Disclosure and Compensation (MEDiC) Act (Clinton and Obama 2006). Although it did not pass, the proposal brought the work of the University of Michigan to the forefront of the medical liability reform debate. As a result, UIH leadership granted permission to develop an alternative approach to patient safety and medical liability, and UIH initiated an intervention to increase transparency, early reporting and rapid investigation of unexpected adverse outcomes, learning and improvement, and full disclosure of inappropriate care with early resolution.

Development of the UIH Approach to CRP: The Seven Pillars

The UIH team conducted site visits with the early adopters of alternative dispute resolution and disclosure and early offer programs. The University of Michigan program (Boothman et al. 2009) inspired the model for the Seven Pillars approach (McDonald et al. 2010). A preliminary process model was developed and then revised based on feedback from patients and families who had been harmed by medical care. The Seven Pillars approach to responding to patient safety incidents was finalized after integrating this feedback (McDonald et al. 2010).

The approach consists of seven processes that are deployed in the wake of a patient harm event. The seven components are as follows: (1) incident reporting; (2) investigation while holding hospital bills and professional fees; (3) early communication with patient/family; (4) full disclosure, apology, and rapid remedy if appropriate; (5) system improvement; (6) data tracking and evaluation; and (7) education and training (McDonald et al. 2010). The driving hypothesis is that early and consistent communication with patients and/or family members after an adverse event will serve to maintain trust between the patient and the health system and yield improved learning, patient outcomes, and reduced medical liability (Hickson et al. 2007; Hickson and Entman 2008).

The Seven Pillars intervention includes incident reporting that triggers a rapid response system. The rapid response system seeks, concurrently, to provide support to the patient and family, to investigate the event, and to provide ongoing support to the caregivers (Scott et al. 2010) involved in the event. Communication with patients and families occurs within 15–30 minutes after notification of the event and continues throughout the investigation period. Event investigations are conducted rapidly.

Once consensus has been reached as to the facts, including potential factors leading to the event and possible breaches of the standard of care, a patient or family meeting is convened to discuss the findings of the event analysis, including, in appropriate cases, the admission of mistakes along with an apology and a discussion of appropriate resolution, including the promise to waive or reimburse patients for all hospital and professional fees and the costs of future care associated with the preventable harm.

Information collected from the time of the report through the event analysis, full explanation, apology, and resolution is used to improve hospital processes and embedded into ongoing health professional educational efforts, thereby linking the outcomes into a cycle of continuous improvement.

Financial resolution recommendations are developed outside the control of the Department of Safety and Risk Management and within the context of a medical malpractice action group with broad stakeholder engagement, including clinical departments, patient safety, claims management, legal, business, and finance. The University of Illinois Board of Trustees makes the final decision regarding financial resolution.

Licensed professionals involved in cases associated with financial resolution were reported to the National Practitioner Data Bank and the Illinois Department of Financial and Professional Regulation, consistent with federal and state regulations. As part of the peer support or "care-for-the-caregiver" program (Scott et al. 2009, 2010), attempts were made to support professionals throughout this regulatory response process.

The Seven Pillars approach was presented to and approved by the UIH leadership, including the Office of Legal Counsel and the Office of Business and Financial Services in March of 2006. The program was presented to and approved by the College of Medicine's Medical Service Plan [MSP], representing the several hundred physicians practicing at UIH. The MSP agreed to provide financial incentives to departments participating in the program.

Following full approval by the administrative and clinical arms of the health system, communication skills training for stakeholders was conducted by Gerald Hickson and James Pichert from the Vanderbilt Center for Patient and Professional Advocacy. Following the communication training, the program went live on April 1, 2006. The first major case, involving a financial resolution of more than $1 million, took place in June 2006. Program updates, including process improvements following event analyses, were presented quarterly to University leadership and the Executive Committee of the MSP.

Two processes encouraged physician incident reporting. For attending physicians, the departmental share of yearly malpractice premium was based upon a formula that included a substantial financial penalty (>$10,000) for patient adverse events that resulted in a claim without a prior report having been received by the Department of Safety and Risk Management. In addition, graduate medical education program directors established the expectation that resident physicians would submit incident reports. This resulted in a substantial increase in reporting, communication with patients and families, and learning from patient safety events (Jericho et al. 2010).

The Department of Safety and Risk Management began to ensure proper feedback to reporters, and it frequently took visible actions in response to reports. The program also launched a care-for-the-caregiver program, whereby clinicians discovered they would reliably receive peer

support after unexpected outcomes, and this seemed to increase the trust between the clinicians and the Department of Safety and Risk Management.

Study Objective

The purpose of this investigation was to determine whether a CANDOR intervention based on the Seven Pillars approach to adverse events was associated with measurable improvements on a targeted set of safety, communication process, and liability outcomes.

Hypotheses

We expected the intervention to be associated with an *increase* in incident reports, patient communication consults, and event analyses, and a *decrease* in claims, lawsuits, legal fees and expenses, settlement amounts, total liability costs, time to closure, and self-insurance funding needs.

STUDY DATA AND METHODS

Design

We used an interrupted time series design within one organization (UIH), using itself as a historical control (Cook and Campbell 1979a,b; Gillings, Makuc, and Siegel 1981; Weinberg et al. 2001; Wagner et al. 2002). In this type of design, outcomes are repeatedly measured over time, and the analysis assesses changes in the outcome before and after an "interruption." In some cases, the interruption in the time series is the result of natural experiments or policy changes (Wagner et al. 2002) and in others, like ours, it is a planned intervention (Weinberg et al. 2001).

Analyses of interrupted time series (ITS) designs focus on both the absolute level of an outcome at a given point in time (typically immediately before and after the intervention) and on the trend in the outcome during a specific period before and after the intervention. We analyzed outcomes for 5 years prior and 7 years after our intervention. The design allowed us to assess the time course of the effect of our interventions on each outcome (immediate or delayed), the persistence of these effects, their magnitude, and their direction.

Setting

UIH consists of the University of Illinois Hospital, its medical center, and more than 20 affiliated outpatient locations. Nearly all of the physicians who work with UIH are University employees and are provided liability coverage from the same University self-insurance plan.

Data

We obtained study data by querying databases maintained by the Department of Safety and Risk Management and the Department of Administrative Services at UIH. The main dataset was extracted from the risk module of the Midas incident reporting system, for calendar years 2000–2013, although not every outcome spans that entire time period. The study was approved by the Institutional Review Board at UIC.

Outcome Definitions

We analyzed quarterly (and sometimes annual) trends in incident reports, patient communication consults, event analyses, claims, lawsuits, legal fees and expenses, settlement amounts, total liability costs, time to closure, and self-insurance funding needs and balances. Some outcomes were analyzed on the basis of both cumulative quarterly total and per claim quarterly means (defined as the cumulative total divided by the total number of claims).

   Incident reports are reports received by the Safety and Risk Management Department describing actual harm, near misses, and unsafe conditions. A *patient communication consult* is a support service available to facilitate health care providers in effective and honest communication about adverse events and outcomes to patients and families. When a patient communication consult is requested, a trained member of the risk management or medical staff comes to the aid of a front-line clinician to assist with difficult conversations with a patient or family. An *event analysis* is the evaluation of all factors leading to an event. In the Seven Pillars program, individual performance is evaluated by peers in order to enhance the quality of their work or to determine the reasonableness of care. Reason's unsafe acts algorithm was employed as part of a structured approach to determination of individual accountability (Reason 1997).

   We defined a *claim* as a request, either written or verbal, for financial compensation related to a patient harm event. We did not count as claims:

potentially compensable events, tendered lawsuits, or when medical staff were named as respondents in discovery.

Legal fees were defined as payments to attorneys or para-professionals for hourly work. Legal expenses were defined as all legal costs excluding legal fees, such as filing fees, expert witness expenses, travel, phone, postage, copying, etc. *Settlement amount* was defined as the total amount paid to settle a claim. *Total liability costs* were defined as the sum of settlements, legal fees, and legal expenses. All dollar values were adjusted for inflation to be equivalent to 2013 dollars using the annual Consumer Price Index (Urban) from the U.S. Department of Labor (Bureau of Labor Statistics: U.S. Department of Labor 2014).

Self-insurance is a method of managing risk by setting aside a pool of money to be used if an unexpected loss occurs. The *self-insurance fund* is a fund controlled and managed by the University in which money is held in reserve for paying estimated and ongoing indemnity and legal costs.

Self-insurance balance is the difference between the current dollars in the fund and all current estimated expenses for all current and actual claims and lawsuits and those that may arise in the future related to any care that has been rendered up until to the date of calculating the balance.

Self-insurance funding needed is the money needed by the self-insurance fund to cover the estimated payouts for the coming year. At UIH, not only did it need to cover the estimated payouts for each coming year but also to begin to close the deficit in the fund that occurred when St. Paul Insurance left the market.

Outcomes pertaining to lawsuits, legal fees and expenses, and settlement amounts were based on closed claims only. There is a 2-year statute of limitations in Illinois. Observational data ended December 31, 2013, so counts of lawsuits pertained only to incidents occurring before December 31, 2011.

To account for variation in the volume or intensity of clinical services being provided at UIH, we normalized outcomes by dividing by number of patient encounters in the inpatient and outpatient settings. Results are reported in terms of outcomes per 100,000 encounters. We considered alternative normalization methods, such as normalizing by relative value units, but these measures changed significantly over our observation period. In a similar analysis, Kachalia et al. (2010) normalized by 100,000 encounters.

Analysis Plan

We computed descriptive statistics for the main dataset of risk management incidents. We then compared the pre- and postintervention means for each

outcome using nonparametric tests (the normal approximation to the Mann–Whitney *U* test). Next, we analyzed ITS data using segmented linear regression with terms for time (representing the preintervention trend), intervention (representing the change in level of the outcome from immediately prior to immediately after the intervention), and time after intervention (representing the difference in time trend between pre- and postintervention periods (Cook and Campbell 1979a; Wagner et al. 2002). We used SAS 9.4 for all statistical analyses. We used PROC GENMOD for dollar outcomes and PROC AUTOREG for other outcomes.

RESULTS

Descriptive Statistics

The main dataset consisted of 764 claims-related incidents, 127 of which involved UIH physicians working off-site at other hospitals. For the analyses below, we only included the 637 on-site claims-related incidents, of which 257 were nonlawsuit claims, 207 were lawsuits, 156 were potentially compensable events, and 17 were cases where UIC was named as a respondent in discovery (see Table 1). In the analysis and discussion below, lawsuits and nonlawsuit claims are referred to collectively as "claims." As of December 31, 2013, 367 of the 637 total claims-related incidents were closed claims (167 lawsuits and 200 nonlawsuit claims).

Comparison of Preintervention and Postintervention Means

Comparing the entire preintervention period to the entire postintervention period, we observed significant postintervention changes in mean quarterly

Table 1: Characteristics of Medical Malpractice Incidents at UI Health, 2000–2013

Legal Type	Open (n = 133)	Closed (n = 504)	Total (n = 637)
Claim			
Nonlawsuit	57 (42.9)	200 (39.7)	257 (40.4)
Lawsuit	40 (30.1)	167 (33.1)	207 (32.5)
Potentially compensable event	36 (27.1)	120 (23.8)	156 (24.5)
Respondent in discovery	0 (0)	17 (3.4)	17 (2.7)

Note. Column percentages are in parentheses, summing to 100% vertically. See text for definition of event types.

number of incident reports (pre = 394.8, post = 837.6, $z = -5.1$, $p < .0001$), patient communication consults (pre = 0.2, post = 9.6, $z = -6.5$, $p < .0001$), event analyses (pre = 0.7, post = 19.6, $z = -6.4$, $p < .0001$), claims (pre = 8.8, post = 5.1, $z = 3.4$, $p = .0004$), and lawsuits (pre = 4.5, post = 2.4, $z = -3.7$, $p = .0002$). We also observed significant decreases in mean quarterly legal fees and expenses (pre = \$554,221, post = \$98,017, $z = -4.2$, $p < .0001$), settlement amounts (pre = \$3,379,561, post = \$1,670,979, $z = -2.8$, $p = .005$), and total liability costs (pre = \$3,933,781, post = \$1,768,996, $z = -3.3$, $p = .001$) (see Table 2).

In addition to examining these outcomes on a cumulative quarterly basis, we examined many on a per claim basis for each quarter (e.g., mean settlement amount per claim per quarter). Quarterly lawsuits per claim decreased significantly (0.58 vs. 0.39, $z = -2.0$, $p < .05$), as did legal fees and expenses per claim, settlement amounts per claim, and total liability costs per claim (see Table 2 for details). Mean time to closure decreased significantly from 4.0 to 2.4 years ($z = -4.0$, $p < .0001$).

In the pre-post comparison of means, total funding needed for self-insurance and the self-insurance trust fund balance did not change significantly.

Analysis of Segmented Regression

Table 3 summarizes the results of segmented regression analyses of the study outcomes.

Figures 1–8 illustrate the magnitude, time course, and direction of the changes in process and outcome measures during the pre- and postintervention period for selected outcomes. Additional figures are available in an online Appendix. Segmented regression analysis of these time series data tested the overall time trend (across the entire observation period), the instantaneous effect of the intervention (i.e., the difference between the quarter immediately prior to and immediately after the intervention), and the effect of the intervention on the time trend for each outcome. The last of these measures, testing the change in trend pre versus post, will typically be of greatest interest.

Incident Reports. Figure 1 shows a significant decrease in the number of incident reports ($b = -132.20$, $p < .0001$) immediately after the rollout of the new reporting system, followed by a significant and long-lasting positive change in the reporting trend, compared to the preintervention period ($b = 35.84$,

Table 2: Pre- and Postintervention Means for Selected Outcomes

Outcome	Preintervention Mean (SD)	No. Quarters	Postintervention Mean (SD)	No. Quarters	Z	p-value Mann–Whitney U Test
Incident reports*	394.8 (52.9)	25	837.6 (338.7)	31	−5.1	<.0001
Patient consults*	0.20 (0.6)	25	9.6 (4.7)	31	−6.5	<.0001
Event analyses*	0.7 (1.2)	25	19.6 (11.2)	31	−6.4	<.0001
Claims*	8.8 (3.9)	25	5.1 (3.3)	30	3.4	.0007
Lawsuits*	4.5 (2.0)	25	2.4 (1.6)	23	3.7	.0002
Legal fees and expenses* ($)†	$554,221 ($687,339)	25	$98,017 ($180,110)	23	−4.2	<.0001
Settlement amount* ($)†	$3,379,561 ($3,290,139)	25	$1,670,979 ($3,889,852)	23	−2.8	.005
Total Liability Cost*†	$3,933,781 ($3,580,458)	25	$1,768,996 ($4,042,765)	23	−3.3	.001
Lawsuits per claim	0.58 (0.32)	25	0.39 (0.23)	23	−2.0	0.05
Legal fees and expenses per claim ($)†	$82,367.3 ($124,439)	25	$20,738.9 ($35,224.6)	23	−3.5	.0004
Settlement amount per claim ($)†	$455,263 ($442,515)	25	$277,513 ($577,079)	23	−2.4	.01
Total Liability Cost per claim†	$537,630 ($504,544)	25	$298,252 ($599,847)	23	−2.8	.005
Time to closure (years)	4.0 (1.3)	25	2.4 (1.3)	23	−4.0	<.0001
Self-insurance fund ($)†	Mean (SD)	Years	Mean (SD)	Years		Mann–Whitney U Test
Total funding needed	$27,911,318 ($9,375,609)	7	$37,953,061 ($6,826,901)	9	−1.8	.07
Trust fund balance	−14,637,045 (17,151,734)	7	−7,282,020 (27,546,299)	9	−0.21	.83

Notes. *Quarterly, per 100,000 patient encounters.
†All dollar amounts are inflation-adjusted to 2013 dollars using the consumer price index.

Table 3: Segmented Regression Analysis of Interrupted Time Series for Selected Outcomes

Outcome	Independent Variable						
	Time		Intervention		Time after Intervention		
	Estimate (SE)	Pr>|t|	Estimate (SE)	Pr>|t|	Estimate (SE)	Pr>|t|	R-square
Incident reports*	0.01 (2.82)	0.99	−132.20 (51.75)	<.0001	35.84 (3.64)	0.004	0.91
Patient consults*	0.15 (0.16)	0.35	6.38 (2.77)	0.03	−0.14 (0.22)	0.51	0.33
Event analyses*	0.11 (0.24)	0.67	3.49 (3.85)	0.37	0.78 (0.34)	0.03	0.54
Claims*	0.27 (0.08)	0.002	−2.54 (1.57)	0.11	−.55 (0.10)	<.0001	0.51
Lawsuits*	−0.14 (0.04)	.003	1.54 (0.88)	0.09	−0.03 (0.06)	0.64	0.50
Legal fees and expenses* ($)†	−0.004 (0.06)	0.95	1.22 (1.20)	0.31	−0.26 (0.08)	0.002	
Settlement amount* ($)†	−0.004 (0.06)	0.95	1.09 (1.18)	0.36	−0.24 (0.08)	0.004	
Total liability cost*†	−0.01 (0.05)	0.77	1.14 (0.93)	0.22	−0.23 (0.07)	0.0004	.60
Lawsuits per claim	−0.03 (0.005)	<.0001	0.41 (0.12)	0.001	0.02 (0.01)	0.04	
Legal fees and expenses per claim ($)†	−0.10 (0.04)	0.02	3.30 (1.20)	0.006	−0.28 (0.09)	0.002	
Settlement amount per claim ($)†	−0.04 (0.06)	0.54	1.488 (1.15)	0.20	−0.15 (0.08)	0.06	
Total Liability Cost per claim†	−0.05 (0.05)	0.33	1.56 (0.93)	0.09	−0.15 (0.07)	0.02	
Time to closure (years)	−0.14 (0.02)	<.0001	1.65 (0.51)	0.002	0.02 (0.04)	0.62	0.68
Self-insurance fund ($)†							
Total funding needed	3,939,070 (831,106)	0.0005	2,180,126 (4,595,781)	0.64	−5,912,737 (1,006,519)	<.0001	0.68
Trust fund balance	−4,287,939 (2,765,836)	0.15	−11,084,649 (15,294,291)	0.48	13,185,796 (3,349,594)	0.002	

Notes. *Quarterly, per 100,000 patient encounters.
†All dollar amounts are inflation-adjusted to 2013 dollars using the consumer price index.

Figure 1:   Quarterly Incident Reports per 100,000 Encounters at UIH, 2000–2014
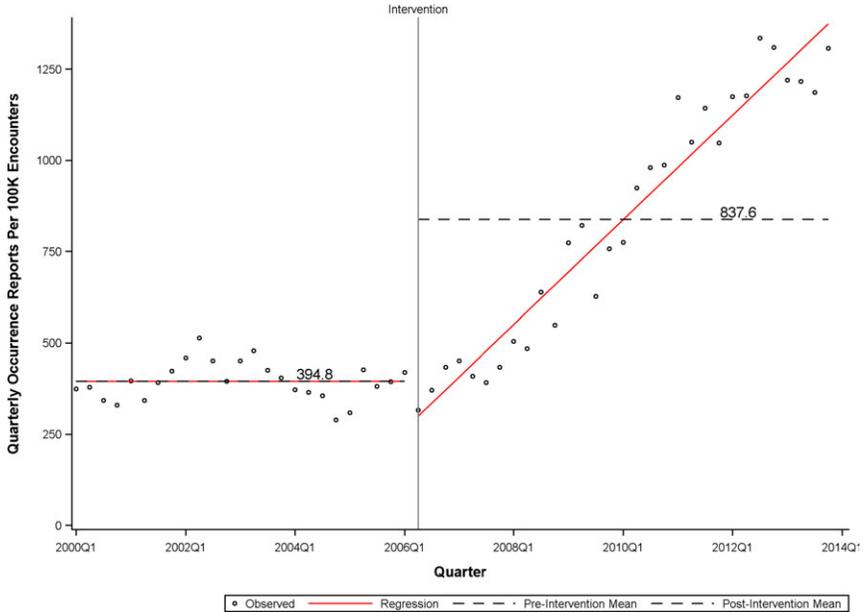
$p = .004$). Incident reports increased by roughly 36 reports per quarter for the 7-year postintervention observation period.

Patient Communication Consults. There was an immediate postintervention increase in communication consults ($b = 6.38$, $p = .03$) with no significant overall time trend or change in the postintervention time trend.

Event Analyses. Figure 2 shows a significant increase in the postintervention time trend for quarterly number of event analyses postintervention ($b = 0.78$, $p = .03$), with no change in the immediate pre-post comparison and no significant overall effect of time.

Claims. Figure 3 shows a significant declining trend in quarterly claims during the time after the intervention, compared to the preintervention trend ($b = −0.55$, $p < .0001$).

Figure 2:   Quarterly Event Analyses per 100,000 Encounters at UIH, 2000–
2014
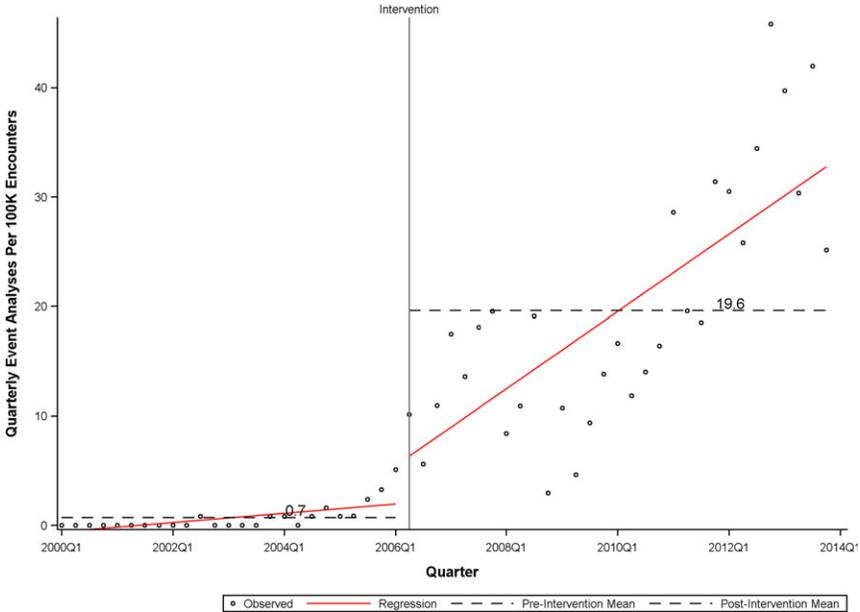
Lawsuits. The number of lawsuits per quarter decreased significantly during the entire time period ($b = -0.14$, $p = .003$), with no significant effect of the intervention (see Figure 4).

Legal Fees and Expenses. There was a significant decreasing trend in quarterly legal fees and expenses during the postintervention period ($b = -0.26$, $p = .002$).

Settlement Costs and Total Liability Costs. Quarterly settlement costs decreased significantly during the postintervention period ($b = -0.24$, $p = .004$), as did total liability costs, that is, the sum of settlement costs and legal fees and expenses ($b = -0.23$, $p = .0004$, see Figure 5).

Quarterly Lawsuits per Claim. The number of lawsuits per claim declined significantly over the entire observation period ($b = -0.03$, p < .0001). Lawsuits

Figure 3:   Quarterly Claims per 100,000 Encounters at UIH, 2000–2014
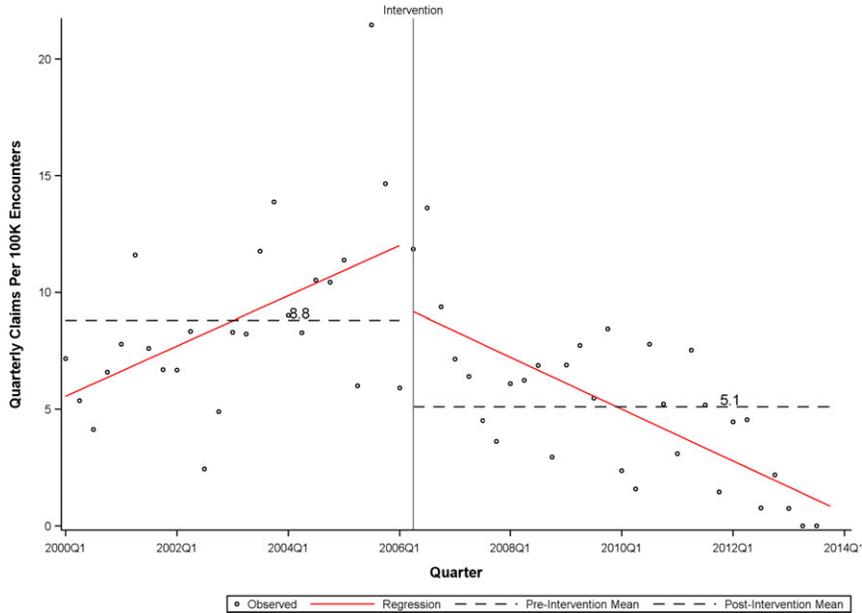
per claim increased significantly immediately after implementation of the program (p = .001), and there was a small but significant decrease in the slope of the time trend after the intervention (b = 0.02, p = .04), meaning that the rate of decline in lawsuits per claim slowed during the postimplementation period.

Quarterly Legal Fees and Expenses per Claim. On a per claim basis, legal fees and expenses declined over the entire observation period (b = −0.10, p = .02) and rose slightly immediately after the intervention (b = 3.30, p = .006). Compared to the rate of decline during the preintervention period, the rate of decline increased in the postintervention period (b = −0.28, p = .002). That is, per claim legal fees and expenses declined more rapidly in the postintervention period than they did in the preintervention period.

Quarterly Settlement Amounts per Claim. There were no statistically significant differences in settlement amounts per claim over the observation period, although the difference in trend approached significance (b = −0.15. p = .06),

Figure 4:   Quarterly Lawsuits per 100,000 Encounters at UIH, 2000–2011
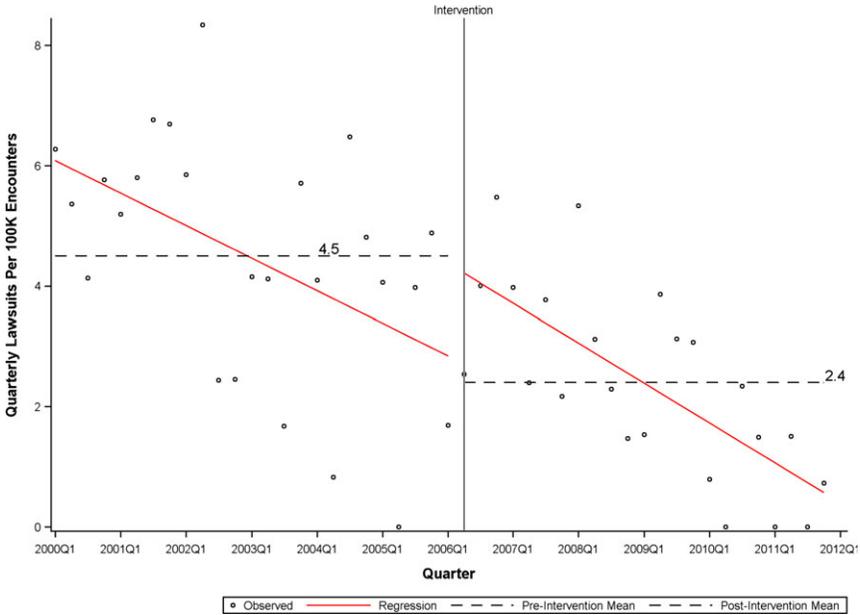

with the postintervention rate of decline in per claim settlement costs tending to be steeper than the preintervention trend.

Quarterly Total Liability Costs per Claim. The rate of decline in total liability costs per claim was significantly steeper during the postintervention period compared to the preintervention period ($b = -0.15$, $p = .02$).

Self-Insurance Funding Needed. The total amount of funding needed for the self-insurance fund showed a significantly increasing trend across the entire observation period ($b = 3,939,070$, $p = .0005$, see Figure 6). There was no change immediately after the intervention. The slope of the postintervention trend was significantly different (and in the opposite direction) from the preintervention trend ($b = -5,912,737$, $p < .0001$). Although self-insurance funding needs increased during the preintervention period, they decreased during the postintervention period (see Figure 6).

Figure 5:   Quarterly Total Liability Costs at UIH, 2000–2012
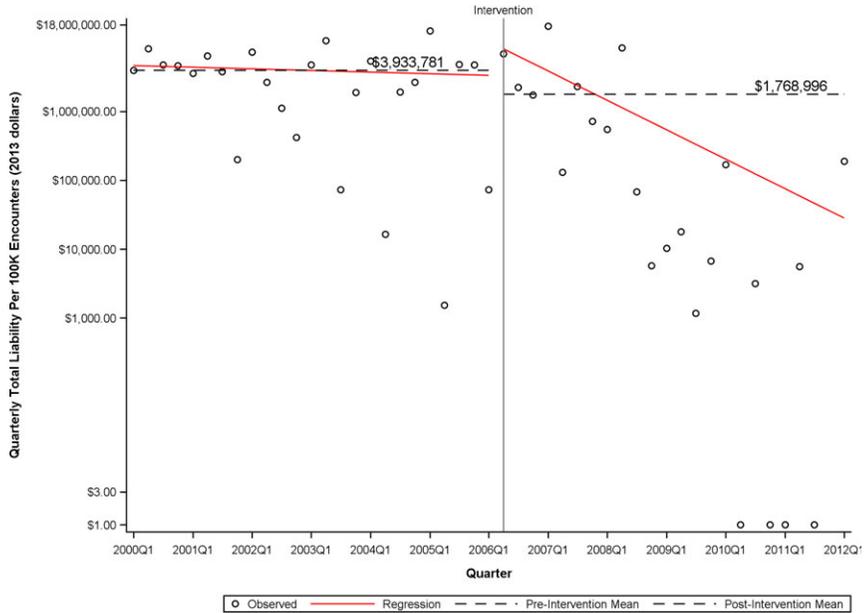
Self-Insurance Fund Balance. Figure 7 shows that that the balance in the self-insurance fund was negative and decreasing during the preintervention period. In the postintervention period, the trend reversed, a difference that was statistically significant ($b = 13{,}185{,}796$, $p = .002$).

Time to Closure. Figure 8 shows that time to closure for closed claims decreased steadily over the entire observation period ($b = -0.14$, $p < .0001$). There was a significant increase in time to closure immediately after the intervention ($b = 1.65$, $p = .002$). Time to closure continued to decline during the postintervention period, but the rate of decline did not differ from the preintervention period ($b = 0.02$, $p = .62$).

DISCUSSION

The purpose of this investigation was to determine whether a communication and optimal resolution (i.e., CANDOR) approach to adverse events would be associated with measurable changes in medical liability processes and

Figure 6:   Self-Insurance Total Funding Needed, 2000–2015
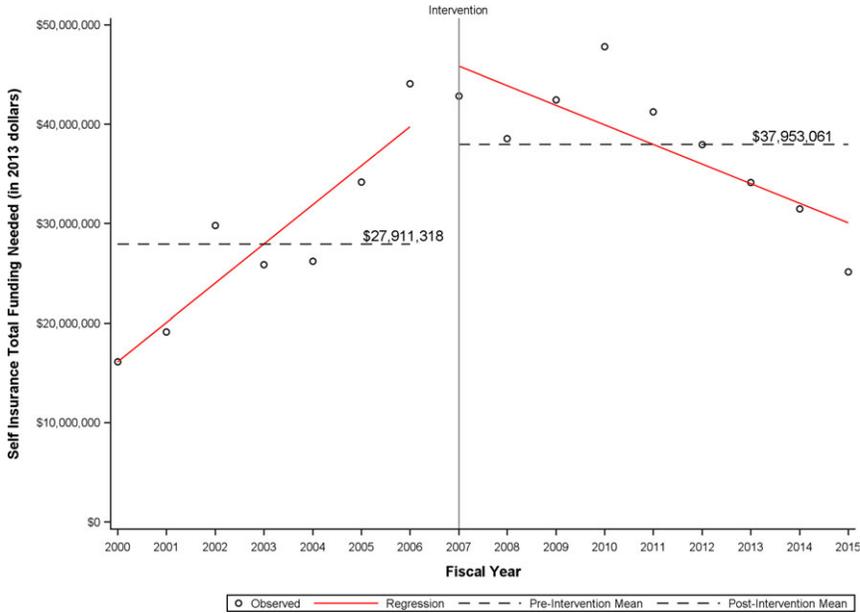
outcomes. The data show an association between the intervention and the majority of outcomes. In the segmented regression analyses of ITS data, the observed pre- versus post-changes in time trends were both practically and statistically significant and in the predicted and desirable direction. Incident reports, event analyses, and patient communication consults became more common. Claims were less common, settlement costs, and legal fees and expenses went down, both overall and on a per claims basis. Annual contributions to the self-insurance fund declined dramatically, and the self-insurance fund moved from a $30 million deficit to a $40 million surplus.

Unexpected Findings

Two results were not consistent with our hypotheses about the beneficial effects of the intervention. These concerned lawsuits and time to closure, both of which went down dramatically over the period of observation, but the postintervention rates of decline were not greater during than those observed in the preintervention period, so the declines could not be attributed to the intervention.

Figure 7: Self-Insurance Balance (Deficit/Surplus), 2000–2015
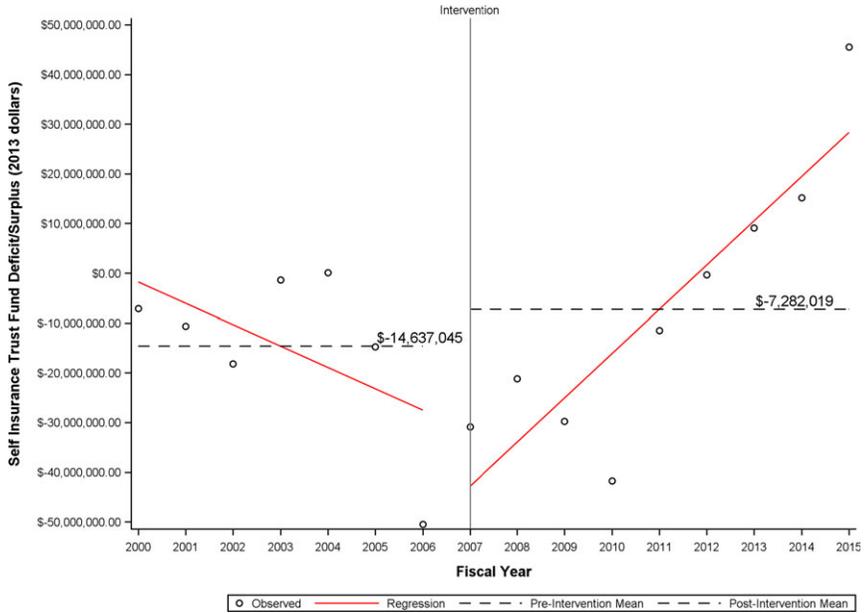
Lawsuits per Claim. We expected that rate of lawsuits per claim would decrease after the intervention. As it happened, there was a brief postimplementation increase in lawsuits per claim, and a slight reduction in the rate of decrease in lawsuits per claim over the entire postintervention period. These were unexpected findings, and we can only speculate about their cause. From inspection of Figures 3 and 4, it is clear that, in the year or two after the intervention began, the quarterly number of claims declined at a more rapid rate than the quarterly number of lawsuits. As a result, the ratio of lawsuits to claims increased during that period.

We surmise that this occurred because the program was initially more effective at preventing claims than preventing lawsuits. This was likely due to the use of the Patient Communication Consult Service (PCCS), which engaged with patients and families soon after adverse events, provided information, explanation, and sometimes remedies, and thereby eliminated the motivation for filing a claim (Golann 2011). The PCCS was designed to prevent patients and families from needing to file a claim in order to get answers to their questions about the adverse event. One factor impacting lawsuit filing in Illinois may have been the lack of a prelitigation "cooling off" period, as

Figure 8:   Quarterly Mean Time to Closure per Claim at UIH, 2000–2011
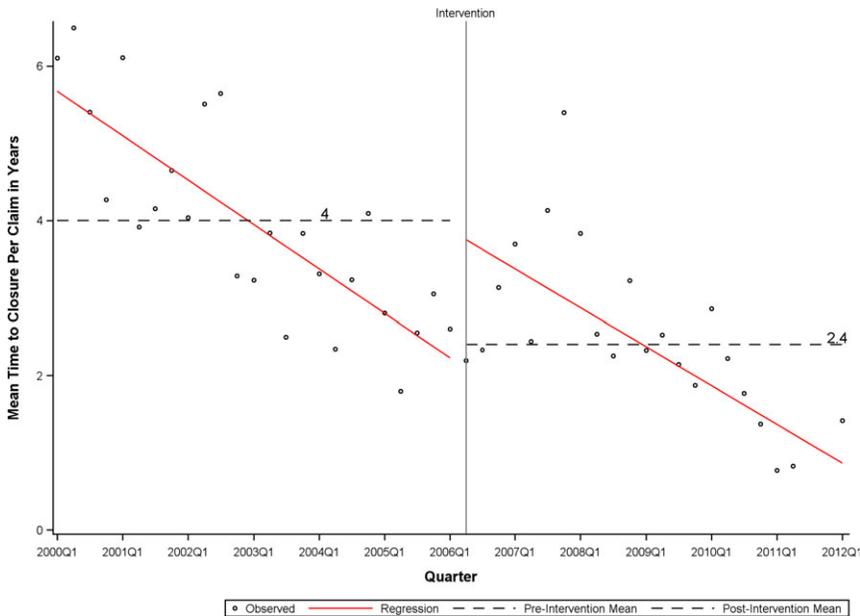
provided in Michigan and Massachusetts, during which patient and family concerns can be addressed and resolved prior to litigation.

    In spite of the brief, postintervention increase in lawsuits per claim, the number was still significantly lower in the postintervention period than in the preperiod (0.58 vs. 0.39, $p < .05$), as were claims, legal fees and expenses, settlement costs, and total liability costs.

Time to Closure. We hypothesized that time to closure would go down after the intervention. Instead, it increased slightly immediately after the intervention, before returning to its preintervention declining trend. But as with the unexpected increase in lawsuits per claim, it is important to note that the time to closure was still significantly lower in the postintervention period than it was in the preintervention period (4.0 years pre vs. 2.4 years post, $p < .0001$). So although there was a brief postintervention increase in time to closure, the intervention did not substantially alter the longer term trend toward shorter times to closure. One possible explanation is that Illinois Tort Reform, passed in late 2005, prompted a delay in closure while

plaintiffs awaited an expected determination of the unconstitutionality of the reform that ultimately occurred at the circuit court level in November, 2007 (Circuit Court of Cook County 2007) and was affirmed by the Illinois Supreme Court. This might explain the initial increase in time to closure in the early postintervention period.

In spite of dire predictions to the contrary (Studdert et al. 2007), both the current findings and those published previously (Kachalia et al. 2010) indicate that telling the truth to patients and families and offering early resolution after adverse events does not produce any significant negative liability consequences.

Overall, when viewed in terms of both the absolute level and trends in important outcomes, the Seven Pillars CANDOR intervention achieved its main goals.

Limitations

This investigation was carried out in only one health system, a self-insured, academic medical center with an employed medical staff. Results observed may or may not be generalizable to systems with open medical staffs of physicians insured by multiple providers. The current study lacked a direct measure of patient harm, making it impossible to determine whether the observed decline in malpractice claims was due to fewer patients being harmed or to adverse events being resolved without recourse to claims. The study was not a randomized trial. However, it did use an ITS design, which is generally regarded as a strong, nonrandomized design. The ITS makes it possible to distinguish between changes attributable to secular trends that precede the intervention (e.g., in this study, the decline in lawsuits and in time to settlement), and changes that are attributable to the intervention because they coincide with the intervention and have no other apparent explanation. The design would have been even stronger had we had one or more control health systems, enabling us to do a difference-in-differences analysis, or if we had been able to identify instrumental variables to control for unmeasured confounders.

CONCLUSION

We conclude that a communication and optimal resolution (CANDOR) approach to adverse events, one which emphasizes a culture of transparency,

honest communication following patient harm, including full disclosure of inappropriate care following preventable harm, learning and improvement, and prompt settlement when harm results from unreasonable care, was associated with increases in the frequency of incident reports, event analyses, and postevent communication consults, and reductions in claims, legal fees, legal expenses, costs per claim, settlement costs, and self-insurance costs. These results were of a clinically and financially significant magnitude and persisted for more than 7 years after the initial intervention.

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SUPPORTING INFORMATION

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

Appendix SA1: Author Matrix.

Figure S1. Quarterly Communication Consults per 100,000 Encounters at UIH 2000–2014.

Figure S2. Quarterly Lawsuits per Claim at UIH, 2000–2011.