Longitudinal Evaluation of the Patient Safety and Medical Liability Reform Demonstration Program

Demonstration Grants Final Evaluation Report

AHRQ
Agency for Healthcare Research and Quality

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Executive Summary

On September 9, 2009, President Obama directed the Secretary of the U.S. Department of Health and Human Services (HHS) to authorize demonstration projects to put "patient safety first," with the intent of reducing the occurrence of preventable injuries and deaths and ultimately stemming liability costs. In response, the Secretary launched the HHS Patient Safety and Medical Liability (PSML) initiative in October 2009. Funding was intended to address four goals: (1) putting patient safety first by reducing preventable injuries, (2) fostering better communication between doctors and patients, (3) ensuring fair and timely compensation for medical injuries while reducing malpractice litigation, and (4) reducing liability premiums.

Under the PSML initiative, the Agency for Healthcare Research and Quality (AHRQ) funded 7 demonstration grants totaling $19.7 million and 13 planning grants totaling $3.5 million. AHRQ commissioned James Bell Associates, Inc. (JBA), in partnership with RAND Corporation (RAND), to conduct an overarching, independent evaluation for this initiative. The seven demonstration projects were originally scheduled to run for 3 years beginning in late summer 2010. Many of the grantees requested and received no-cost extensions of varying lengths. All but one of the demonstration projects were completed by June 2014; the New York project received an extension and was completed in June 2015.

The demonstration grantees implemented complex, broad-ranging innovations in real-world settings, including hospitals and court rooms. Some projects featured novel approaches, while others implemented continuations, replications, or adaptations of existing models. All seven demonstration projects encountered challenges—some expected and others unexpected—that stretched project resources and required adjustments to implementation and evaluation expectations and strategies. Nevertheless, the projects had many accomplishments, such as developing and refining trainings, tools, products, and data collection instruments and contributing valuable learnings about what it takes to develop and sustain an operational patient safety and medical liability program.

This final evaluation report highlights the most substantive findings and lessons learned by the seven demonstration grantees.

Findings and Observations

In general, the seven demonstration projects focused on three main approaches to improving patient safety and reducing medical liability: (1) improving communication, (2) preventing harm through the use of best practices, and (3) exploring alternative methods of settling claims.

Improving communication. These grantees (New York State Unified Court System [NY], University of Illinois Medical Center at Chicago [UIC], University of Texas Health Science Center [UT], and University of Washington [UW]) pilot tested, replicated, and disseminated disclosure and resolution programs (DRPs). They helped to identify the conditions under which such programs can readily be adopted, as well as conditions under which their adoption becomes more difficult. Their findings are mostly descriptive.

Two projects (UT and UW) expanded our understanding of the potential role for patients and their family members in adverse event investigation and remediation. All projects in this category encountered a series of implementation and data collection challenges that the demonstration teams struggled to overcome. Consequently, only the UIC project, which started 4 years prior to the grant, was able to examine impact across multiple outcomes.

Preventing harm through the use of best practices. These grantees (Ascension Health, Fairview Health Services, and Massachusetts State Department of Public Health) showed that the implementation of specific evidence-based interventions (e.g., clinical bundles, team communication) may be associated with improvements in patient safety performance. Ascension and Fairview also offered suggestive findings that malpractice risk also may be reduced.

Exploring alternative methods of settling claims. One demonstration project (NY) sought to expedite the movement of malpractice cases through the claims process, increase the number of settlements, and, over time, lower malpractice costs and premiums through implementation of a judge-directed negotiation (JDN) program. This project's preliminary findings are both illustrative and suggestive regarding the kinds of cases selected to participate in the JDN, the handling and resolution of those cases, and the effect that JDN may have on time to settlement and settlement amount.

Table 1 below briefly summarizes the interventions studied and selected findings for each of the seven demonstration projects and presents a brief statement about our independent assessment of the findings. More detail about the individual projects (e.g., principal investigator, grant award amount, goals, methods, analyses, findings) and an expanded description of the findings, our independent assessment of the findings, and lessons learned follow in the full report and the individual grantee profiles in Appendix A.

Table 1. Selected Grantee-Reported Findings by Focus Area and Grantee Organization

Area of Focus	Grantee Organization	Intervention Studied	Summary of Selected Findings	Strength of the Evidence
Improving Communication	New York State Unified Court System (NY)	Communication and Resolution Program (disclosure and resolution program)	Data were collected on 125 communication and resolution program cases at the 5 participating hospitals in New York City. A small number of cases (20) progressed to a claim (6) or lawsuit (14) within 12 to 15 months after communication and resolution program completion. Eleven of the 20 cases with a claim or lawsuit involved substandard care and causation, and the hospital offered compensation in 3 of these 11 cases.	Grantee reports descriptive findings only; no statistical analysis is reported. No conclusions can be drawn about the impact of disclosure and resolution programs on outcomes.
	University of Illinois Medical Center at Chicago (UIC)	Seven Pillars (disclosure and resolution program)	In an extension of an existing program, UIC Medical Center showed improvements in malpractice outcomes and adverse event reporting, including reductions of approximately 42% in the number of claims, 51% in the costs per claim, and 47% in the number of lawsuits. A significant reduction was found in mean time to closure per claim (from 4 to 2.4 years). The project reported significant improvements in communication processes, including a 52% increase in incident reporting, 96% increase in peer reviews, and a 91% increase in patient consults. The self-insurance fund balance moved from a $30 million deficit to a $40 million surplus.	Grantees employed a relatively strong research design for assessing the impact of the Seven Pillars intervention at UIC medical center. Longitudinal data suggest significant impact of the intervention on both patient safety and malpractice outcomes.
		Replication of Seven Pillars	The impact of the Seven Pillars intervention at 10 replication sites is not known because of insufficient data.	No evidence.
	University of Texas Health Science Center (UT)	Disclosure and apology training	Clinical faculty from 6 UT hospitals who had participated in disclosure and apology training had significantly more positive attitudes about error disclosure, and they perceived disclosure of a medical error as less damaging to patient and peer trust in them than faculty who had not participated in disclosure and apology training.	It is difficult to assess the strength of the findings because it is not clear how some of the statistical comparisons were constructed. Low response rate to the survey limits the generalizability of findings.
		Development of an adverse event	Based on 62 interviews conducted using a debriefing method developed through the grant, patients and their	Qualitative, interview-based study. No quantitative

Area of Focus	Grantee Organization	Intervention Studied	Summary of Selected Findings	Strength of the Evidence
		debriefing method	families can provide critical information about adverse events that is not otherwise known to those analyzing the event.	statistical analysis is reported.
	University of Washington (UW)	Disclosure and apology coaching training	In an attitude survey, 33% of staff who participated in disclosure and apology coach training were enthusiastic about the training but lacked confidence that their organizational leaders had a shared vision around using error disclosure processes.	Grantee reports descriptive findings only; no statistical analysis is reported. No conclusions can be drawn about impact.
		Team communication training	The rates of communication-sensitive adverse events (CSAEs) were examined to assess the impact of communication training. The baseline rates were generally very low, with most CSAE improvements occurring in favoring intervention sites over comparison sites. An assessment of the differences between CSAEs before vs. after communication training is forthcoming.	Grantee reports baseline descriptive findings only; no statistical analysis is reported. No conclusions about impact can be drawn.
		Communication and resolution program	No conclusions can be drawn on the impact of the intervention on medical liability due to variability of tracking methods, and insufficient number of cases that advanced through the communication and resolution program.	No evidence.
Preventing Harm Through Best Practices	Ascension Health	Evidence-based obstetrics practice model	The project reported a 50% drop in injuries caused by difficulties in delivery due to shoulder dystocia (when the baby's shoulder becomes lodged behind the mother's pubic bone).	Confidence in findings is limited because of grantee's use of pre/post comparison design with no control sites. Findings are descriptive, but grantees report no statistical testing to determine significance of findings.
		Evidence-based obstetrics practice model	Six months following the end of the intervention, the 5 hospitals almost doubled their rate of reporting all adverse events in labor and delivery (increasing from 43 to 84 reports per 1,000 births).	Confidence in findings is limited because of grantee's use of pre/post comparison design with no control sites. Findings are descriptive, but grantees report no statistical

Area of Focus	Grantee Organization	Intervention Studied	Summary of Selected Findings	Strength of the Evidence
				testing to determine the significance of findings.
		Evidence-based obstetrics practice model	Three years after establishing the new guidelines, none of the 5 hospitals had any malpractice claims based on shoulder dystocia.	Conclusions are not supported by reported data.
	Fairview Health Services	Standardized processes, teamwork training, and performance feedback in perinatal units	Following the adoption of 3 standardized care processes by perinatal units, from 2010-2012, the proportion of deliveries with an adverse event decreased significantly for 14 participating hospitals and increased significantly for 8 comparison hospitals.	The grantee does not discuss why three of the four reported patient safety outcome measures studied failed to show significant effects from the intervention.
		Standardized processes, teamwork training, and performance feedback in perinatal units	A retrospective audit was conducted on 64 obstetric claims made against the participating hospitals. For births occurring from 2001-2012, the project reported a 19% reduction in frequency of obstetric claims per 10,000 deliveries. "Incurred" amounts (loss payments on closed claims and reserves set aside to pay pending claims) were significantly higher before the intervention ($17,908,000) than during the intervention period ($4,651,325).	Confidence in the findings is undermined by the use of a pre/post research design with no control groups. It is unclear whether the findings might have resulted from factors other than the intervention.
	Massachusetts State Department of Public Health	Clinical improvement processes within ambulatory care	Sixteen primary care practices that had participated in learning Webinars and received coaching and data feedback on improving clinical processes showed significant improvement in followup of abnormal test results. This was indicated by a 65% reduction in rates of abnormal lab results or high-risk referrals where there was no documented followup, and a 54% reduction in the rate of serious potential safety risk events where potential or actual harm could occur to the patient.	Confidence in the findings is undermined because the reported findings on the outcome measures represent an uncontrolled, pre/post comparison of those measures within the intervention settings.
		Clinical improvement processes within ambulatory care	Based on patient surveys, the primary care practices identified as "more engaged" in quality improvement activities showed significant improvement in 4 domains of patient experience (communication, coordination, patient-centered care, and office flow) than "less engaged"	The findings appear to be entirely descriptive in nature. No conclusions can be drawn about the impact of the intervention.

Area of Focus	Grantee Organization	Intervention Studied	Summary of Selected Findings	Strength of the Evidence
			intervention practices.	
Exploring Alternative Methods of Settling Claims	New York State Unified Court System (NY)	Judge-directed negotiation	Thirty-two of the 326 malpractice cases against the 5 participating hospitals completed the judge-directed negotiation (JDN). Of the 32 cases, 15 were settled and 17 were voluntarily dismissed. Across these cases, the median time between filing and disposition of the case was 189 days. For 12 cases settled during JDN conference, the median settlement was $237,000, and the median time from filing to disposition of the case was 8 days. For three cases settled outside of negotiations, the median settlement was $55,000, and the median time was 240 days.	At the end of the study, the grantee reports descriptive findings only; no statistical analysis is reported. No conclusions can be drawn about the impact of the intervention.

Detailed Findings

The seven demonstration projects focused on three broad approaches to improving patient safety and reducing medical liability: (1) improving communication, (2) preventing harm through the use of "best practices," and (3) exploring alternative methods of settling claims.

Improving Communication

Four demonstration grantees—New York State Unified Court System, University of Illinois Medical Center at Chicago, University of Texas, and University of Washington—provided training on error disclosure and implemented disclosure and resolution programs (DRPs) loosely based on a model developed at the University of Michigan Health System.[2] Under DRPs, health care professionals and institutions disclose adverse outcomes to patients and families; investigate and explain what happened; use that knowledge to improve patient safety and prevent the recurrence of such incidents; and, when appropriate, apologize and offer fair financial compensation. The goal of a DRP is to help physicians, risk managers, and other staff communicate with patients to acknowledge medical errors and to make early offers of compensation to avoid costly litigation.

New York State Unified Court System

This demonstration project was implemented through a partnership between the New York State Department of Public Health (the State regulatory agency responsible for patient safety) and the New York State Unified Court System (the court system operating in the five boroughs of New York City). The grantees engaged five of the city's largest teaching hospitals—which provide services to some of the most economically disadvantaged and medically underserved populations in the city—in two different interventions: a judge-directed negotiation program (to be described later in this report) and a disclosure and resolution program. Through the disclosure and resolution program, which the grantee called communication and resolution, this grant aimed to enhance the patient safety culture in participating hospitals, prevent and address adverse events affecting general surgery patients, prevent the filing of malpractice claims through disclosure and early offer, and, over time, lower malpractice costs and premiums.

Overall, the hospitals implemented the disclosure part of the model with some success but experienced greater difficulty in implementing the apology and compensation component. Among the reasons given for the lack of full implementation of the communication and resolution program model were concerns that New York law does not shield apologies from being admissible in a lawsuit, that hospital negotiation with unrepresented patients and families might be seen as coercive, and lingering fear that any discussion of compensation might encourage rather than discourage the filing of claims.

The grantee reported the following findings about the first 125 adverse events resolved through the communication and resolution program at the five participating hospitals:[3]

- An initial disclosure of an adverse event to the patient or family member was documented in 79 percent of cases (the remaining cases were discussed with the patient or family but were typically considered known complications rather than adverse events). Explanation

of the reason for harm was provided in 88 percent of cases, and expressions of sympathy (without an acknowledgement of responsibility) were made in 64 percent of cases. An apology acknowledging responsibility was given in only 13 percent of cases.

- A quarter (25%) of the 125 events were reported to the Risk Management or Quality Departments within 24 hours, half (50%) within 6 days, and three-quarters (75%) within 18 days, with only a short time elapsing between the first communication with patients and families about the event and the last communication (50% were concluded within 2 days). Overall, 75 percent of communications were concluded within 32 days.

- Of the 125 events, 30 were judged by communication and resolution program decisionmakers to involve all of the essential elements of a negligence claim: an injury, causation, and substandard care. For these 30, the responses deemed appropriate by communication and resolution program decisionmakers included compensation (9) and an offer to waive medical bills (12).

- A small proportion of communication and resolution program cases (20 of 125, or 16%) progressed to a claim or lawsuit. Twelve to 15 months after communication and resolution program completion, 14 of the 125 cases (11.2%) resulted in a filed lawsuit and six (4.8%) others resulted in a claim but no filed lawsuit. Three of these cases (2.4%) were settled with a release of liability. Eleven of the 20 cases with a claim or lawsuit involved substandard care and causation, and the hospital offered compensation in 3 of these 11 cases.

Evaluation Observations

The New York demonstration project was very ambitious, involving five hospitals undertaking a number of patient safety initiatives within the hospitals along with the implementation of the disclosure and resolution program. In fact, some participants worried that with so many related activities going on in the hospitals at the same time (both within and outside of the grant, including the Federal Partnership for Patients), it might prove difficult to attribute any change to the grant program. Participants were also concerned about the added burdens, such as project-related data collection, to already overworked risk management staff.

The project's reported findings are both illustrative and suggestive regarding the kinds of cases that were selected for the communication and resolution program, the handling and resolution of those cases, and the experience of the participating hospitals. However, these findings are descriptive rather than evaluative, and preliminary, representing only the first 125 adverse events referred into the communication and resolution program. It is too small a number to evaluate the impact of the communication and resolution program for the individual hospitals and, the grantee has not used statistical methods to assess and test the significance of outcomes. In sum, we would describe the findings as interesting and promising, but further research would be needed to rigorously investigate the magnitude of the effects generated by these communication and resolution programs on malpractice outcome measures and to determine the statistical significance of the effects. This view matches the concerns of grant participants that the timeline was much too short to enable the project to adequately track the impact of the intervention, especially on malpractice outcomes.

As articulated by one site visit participant, “changing the way hospitals function and the way clinicians think is like turning an iceberg around. It is slow, persistent, takes continued engagement of leadership. How we keep that focus is a challenge.” At least as far as the implementation of disclosure and resolution in these hospitals is concerned, these data suggest some culture change.

University of Illinois Medical Center at Chicago (UIC)

This demonstration project had three principal goals: (1) to continue to refine the Seven Pillars intervention at the University of Illinois academic medical center (UIC), (2) to continue collecting and analyzing data on the impact of Seven Pillars at UIC, and (3) to replicate the Seven Pillars intervention components at 10 diverse community hospitals in the greater Chicago area. Replication of the model is important because disclosure and resolution models have heretofore been developed and tested at self-insured academic medical centers, where the liability interests of the institution and the physicians are aligned. The outstanding research question is whether such a model will also work at community hospitals, where the hospitals, physicians, and their respective insurers often have divergent interests with respect to malpractice claims.

Seven Pillars, developed in 2006 at the UIC Medical Center (now part of the University of Illinois Hospital and Health Sciences System), is a comprehensive process for responding to patient harm events. The objective of Seven Pillars is to improve patient safety and mitigate medical liability risk through improved communication with patients and families, disclosure and early offer when patients suffer preventable harm, and learning from medical errors. The intervention includes seven key components: (1) patient safety incident reporting; (2) investigation and root cause analysis; (3) communication and disclosure; (4) apology and remediation; (5) patient safety and systems improvement; (6) system process and performance improvement; and (7) education and training, including “care for the caregiver” training. The 10 community hospitals were eager to be trained in Seven Pillars, as they had been exposed to the principles of the model via publications and prior dissemination efforts.

Because the grantee began implementing Seven Pillars at UIC in 2006, years before the demonstration project, longitudinal data are available from this project to examine the impact of Seven Pillars across multiple outcomes. The following findings were reported by the grantee on the impact of Seven Pillars at UIC:[4]

- A comparison of means of each outcome measure from the pre- to post-intervention period (5 years before the intervention and 7 years after) revealed significant increases in the mean quarterly number of adverse event reports, patient communication consults, and root-cause analysis reviews, as well as decreases in the mean quarterly number of malpractice claims, legal fees and expenses, settlement amounts, and total liability costs.

- Similar positive effects for the Seven Pillars intervention were found in supplemental analyses undertaken on a “per malpractice claim” basis (e.g., number of lawsuits per claim, and liability costs per claim were reduced).

- Self-insurance costs for malpractice coverage, which were increasing prior to the intervention, were decreasing afterward; likewise, the self-insurance fund balance, which was negative and decreasing prior to the intervention, moved from a $30 million deficit to a $40 million surplus.

The grantee provided no data on the impact of Seven Pillars at the 10 replication hospitals. Training and technical assistance were provided to each of the community hospitals, and a secure data repository was established for the participating hospitals to submit patient safety data. Obtaining data on risk management and liability outcomes proved to be the most challenging. The grantee received only a few months of risk management and liability data from some of the replication sites. Although the community hospital staff valued the training and technical assistance, the risk management staff were already busy prior to the implementation of Seven Pillars and took on additional burdens related to the intervention without the support of grant funding.

Evaluation Observations

As mentioned above, the outstanding research question that this demonstration intended to answer is whether the existing disclosure and resolution model is a good "fit" for community hospitals, and if not, what alterations might need to be made to make it a good fit. While the demonstration was successful in accumulating more evidence for the model in self-insured academic settings, the inability to replicate the results of Seven Pillars in the community hospitals leaves that important question unanswered. We know from the experience of the UIC project that it is possible to package the training and tools and to implement them in community hospital settings; however, without outcome findings on the intervention, we do not yet know whether Seven Pillars will work outside of the settings in which it was developed.

The demonstration findings concerning the implementation of the Seven Pillars intervention at the UIC Medical Center reflect a well-designed, thoughtful assessment of liability and safety outcomes. Although the grantee's evaluation of UIC outcomes did not use a control group for comparison, the use of an interrupted time series design helps to strengthen the inference that the observed differences are a result of the intervention rather than a larger trend affecting the experience of all hospitals in the community (e.g., adoption of new Joint Commission standards). The findings at UIC illustrate the impact that the Seven Pillars intervention is capable of having. We also know that the inability to replicate the results of Seven Pillars at the 10 community hospitals reflected a series of implementation and data collection challenges that the demonstration team struggled to overcome. This is not the only project that attempted to work with hospitals to implement disclosure and resolution programs and struggled to implement program components and data collection efforts without new staff (or dedicated staff time). The assumption that hospitals can establish these labor-intensive programs within existing resources may be flawed. Also flawed may be assumptions about their capacity to produce the kinds of data necessary for sophisticated evaluation efforts without specific funding to do so. Understanding the possible reasons for the partial implementation of Seven Pillars is critical to future replication work.

University of Texas (UT)

This project aimed to implement and evaluate a disclosure and resolution model in UT hospitals and to identify best practices using disclosure to improve patient safety, with a focus on incorporating patient and family input into efforts to understand why errors occur. Key activities were (1) developing and testing a tool for UT hospitals to use to assess "disclosure culture" and (2) using a structured interview guide for gathering information from patients and family members after an adverse event. Grant activities involved six health institutions (four medical schools, one cancer center, and one health science center) in the UT System.

Initially, the grantee intended to implement and evaluate disclosure and resolution programs in UT hospitals and provide training for hospital staff in disclosure and apology; however, the demonstration project was not designed to actually implement the programs. The implementation was left to the individual hospitals, and they did not succeed on their own. Participants in the site visits told us that the training provided through the grant was excellent, but it was merely the first step in raising consciousness of the issues. They found a one-time training to be insufficient for helping risk managers to develop disclosure programs on their own without resources already in place. Careful attention needs to be paid to the use of "train-the-trainer" models without followup support and ongoing technical assistance. The training did begin to stimulate culture change within the hospitals (as reported by site visit participants), and the grantee used project resources to develop tools to assess changes in attitudes over time. Although there are no findings to report on the impact of DRP, the grantee was able to share evaluative data on three key aspects of their efforts, described below.

Perceptions about error disclosure. One of the most important products from this project has been the development of a survey tool to collect data from hospital staff on their attitudes toward disclosure and resolution. A new 51-item survey was developed to examine the relationship between patient safety culture and error disclosure. Clinical faculty members from six UT hospitals were invited to complete the electronic survey before they participated in the disclosure and resolution training (2010) and at the end of the project (2013). Approximately 10 percent (497 of 5,000) of the clinical faculty completed the first survey, and 24 percent (1,217 of 5,000) of the clinical faculty completed the second survey.[5] Findings included the following:[5]

- Compared with faculty who had not participated in the disclosure training, faculty who participated in the training had significantly more positive attitudes about error disclosure and perceived disclosure as less damaging to patient and peer trust in them.

- Comparing results from the first to the second survey, respondents overall had more positive perceptions toward disclosing minor errors (increasing significantly in their positive scores from 33% to 52%).[a] Moreover, respondents overall had more positive perceptions toward disclosing serious errors (increasing significantly in their scores from 53% to 70%). This suggests that perceptions of error disclosure change in a positive direction after participation in error disclosure training.

[a] Percentage positive scores represent the percentage of participants who averaged at least a 4 (i.e., agree slightly) on their Likert-type responses to all of the items that measure a specific type of culture.

- The survey asked respondents about the error disclosure "trust" culture (that is, their perceptions about whether disclosing a medical error in their clinical area might damage patient trust [or peer trust] in their competence). Comparing results from the first to the second survey, there were no changes overall in respondents' perceptions about error disclosure "trust" culture in their organizations.

- Comparing results from the first to the second survey, there were significant improvements in respondents' overall perceptions about their organization's safety culture (scores increased from 50% to 63%) and teamwork culture (scores increased from 62% to 73%). This latter finding suggests that perceptions of an organization's safety culture and teamwork culture change in a positive direction after participating in error disclosure training.

Patient and family member experience of medical harm after adverse event.[6] Seventy-two patients and family members who had experienced harm after an adverse event were recruited to participate in structured interviews with the goal of creating a "debriefing tool" that could be used by UT hospitals and others. Most of these participants were not UT patients. Of those interviewed, most reported that they would like to participate in the hospital's adverse event analysis process and be asked for their perspective, but they disagreed about the ideal timing of that involvement, which might vary by individual and the nature and severity of the event. Further, patient and family member preferences varied on the ideal person to conduct a debriefing. Although all had experienced harm, most respondents had no intention of pursuing legal action but felt (in some cases) that litigation was the only reliable way to access information about what happened to them. About half of participants indicated they would prefer to engage in adverse event analysis through a structured interview format rather than, for example, attend a meeting with the hospital board, complete a survey or questionnaire, or initiate a report to the hospital or a higher authority (i.e., a medical board or State regulatory agency).

Malpractice claims.[7] The grantee aimed to establish a baseline level of legal claims and other malpractice outcomes and to develop an approach that could be used in the future to assess the effects of a uniformly implemented DRP on legal claims and outcomes over time within the UT system. Toward that end, the grantee examined five "snapshots" of malpractice claims over a period from 2001 to 2012. The five snapshots included all malpractice claims that closed within the system during the years 2001-2002; 2006-2007; 2009-2010; 2010-2011; and 2011-2012 for a total of 715 closed claims. Of the 715 claims reviewed, 148 (21%) resulted in a payment, with the remaining being closed without payment. All 148 payments were reached through settlement, none through trial.

These are baseline data. At this point, the grantee has no data on the effectiveness of the DRPs—the DRPs were not implemented as intended, and it would be too early to detect malpractice outcomes. What the grantee can do, however, is look at a contextual issue, which is the impact of malpractice reform in Texas on claiming behavior in the UT System. This contextual issue is important because future evaluations will need to be able to differentiate the impact of DRP from the impact of earlier, more traditional malpractice reforms (such as damage caps and changes to the statute of limitations) and from other environmental forces that may be affecting all hospitals in Texas (the "secular trend").

Overall, the number of claims, lawsuits, and paid claims in the UT System decreased after Texas enacted malpractice reform in 2003). An analysis comparing data before malpractice reform (2001–2002) and after malpractice reform (2009–2012) revealed the following:

- The proportion of claims resulting in settlements did not change significantly after malpractice reform was enacted, but the proportion of claims in which lawsuits were filed decreased significantly (54% vs. 31%; $p<.001$).

- The proportion of claims that were dismissed decreased significantly (34% vs. 22%; $p=.001$), while the proportion of claims that were closed due to an expired statute of limitations increased significantly (32% vs. 51%; $p<.001$).

- The average (mean) payments decreased significantly from $290,992 to $90,429 ($p<.001$).

- Settlements reached after malpractice reform were significantly more likely than those before malpractice reform to prohibit error disclosure in each of a variety of ways ($p<.001$). Across all years, in a subset of relevant settlement agreements (124), the great majority (89%) included nondisclosure agreements.

- The length of time from an event to a claim decreased (no doubt due to changes in the statute of limitations), but there was no significant change in the amount of time from claim to closure.

Evaluation Observations

The UT demonstration stood out from the others for its primary focus on patients and families and its various efforts to determine how and under what circumstances patients who had been harmed by medical error could contribute to efforts by hospitals to improve patient safety. Patients and their family members who participated in the development of the debriefing tool told the UT investigators what others have said before them: Litigation is sometimes undertaken as much to get information about what happened, and to get assurance that someone is addressing the problem so that no other patient is harmed in the same way, as it is to get compensation for injury. This is an important "lesson learned," and the efforts of this grantee to bring the perspective of the harmed patient to the center of the investigation of medical errors are a unique contribution that deserves follow-on work.

The UT demonstration findings focus primarily on specific tools and interventions that were developed by the UT team in the context of its broader effort to develop and implement a disclosure and resolution model among UT hospitals. The project provides results on a disclosure culture survey for physicians, before and after the administration of disclosure training. The survey results superficially indicate that disclosure training has a positive impact on disclosure culture. Furthermore, the results provide some additional support for describing and validating the survey instrument, which potentially could be a useful tool for other hospitals seeking to undertake DRP interventions in the future. The patient and family member interviews, by contrast, involve a qualitative approach to investigating patient and family perspectives on disclosure and event analysis processes. The results are interesting and potentially useful for the

design of patient-centered debriefing and event-analysis processes in the future. Although worthwhile in their own right, neither of these project components speaks to the original intent of the UT team to field a DRP intervention in multiple hospitals and to investigate the impact of that intervention on malpractice claiming and other outcome measures. No data are available concerning the latter, although the grantee undertook a baseline analysis describing the impact of malpractice reform on UT closed claims. This analysis includes a series of comparisons of UT hospital claims before and after the introduction of malpractice reforms in Texas; however, the grantee did not explain what statistical methods were used to generate these findings. Based on what the researchers did describe, it is not possible to determine whether these reported changes are impacts of the reforms or are related to other changes that might have occurred in participating hospitals over the same time period.

University of Washington (UW)

This project formed a statewide initiative (The HealthPact) to serve as a vehicle for informing and sustaining the project's goals. It comprised stakeholders from across the State interested in enhancing communication and accountability in health care delivery. An important focus of this project was to measure and track patient safety events that are especially sensitive to communication breakdowns. The grantee implemented three interventions aimed at improving communication to prevent and respond to medical errors: (1) team communication training, with the goal of establishing trainers at 10 sites to provide site-specific team communication training; (2) error disclosure training, with the goal of establishing coaches at the same 10 sites to provide guidance to providers and risk management staff on using error disclosure processes; and (3) disclosure and resolution programs (which the grantee called Communication and Resolution Programs), with the goal of developing a collaborative communication and resolution program in an "open" system (environments where multiple insurers are involved in addressing adverse events). The communication and resolution program was launched at five health care institutions: three hospitals within a single hospital system and two multispecialty physician clinics.

Unfortunately, the project was unable to implement the communication and resolution program across the five facilities within the 3-year grant period. Some sites did begin implementation, but risk and claims managers tended to use the communication and resolution program selectively and did not track cases as directed. As a result, the grantee was able to collect data on only 30 communication and resolution program cases, an insufficient number for drawing any conclusions about the effect of the communication and resolution program on liability. Although we do not have findings to report on the implementation of the communication and resolution program, the grantee was able to share evaluative data on two key aspects of its efforts, described below.

Perceptions about error disclosure training.[8] In qualitative interviews with organizational leaders, respondents remarked on the ongoing need for organizational support, raised questions about the amount of training and available resources to sustain the budget for training, and voiced concern about management of errors. Training evaluations, which were completed by 159 of the 251 (63%) trainees, revealed that the training was well received, with ratings for each item and

subscale being high. The results from an attitude survey[b], completed by 85 of the 251 (40%) trainees, showed that respondents were enthusiastic about the training but lacked confidence that their organizational leaders had a shared vision and perspectives around using new error disclosure processes. The Disclosure Culture Scale[c] revealed respondents' general agreement that there was organizational support for disclosure of error to patients, but their responses were less in agreement about whether adequate training on disclosure was provided or whether retaliation, loss of trust, or damaged reputations were concerns.

Communication-sensitive adverse events (CSAEs).[9] the term "CSAE" was coined by the UW project and defined as "an adverse clinical event for which a lack of adequate communication may have been a contributing factor"[9] (p. 6). To assess the impact of communication training on the identification of and response to CSAEs, the grantee plans to conduct a comparison of the rates of CSAEs at participating sites and control sites. At the time of the grantee's final report, only baseline data on CSAEs were available. Data from two State databases were obtained to conduct retrospective analyses—administrative data from the Comprehensive Hospital Abstract Reporting System (CHARS) and clinical registry data from the Surgical Care and Outcomes Assessment Program (SCOAP). For the baseline period of 2009–2011, CHARS data included 4 of the intervention sites and 93 comparison sites, and SCOAP data included the same 4 intervention sites as well as 48 comparison sites. The CHARS dataset contained 1,684,916 unique patients, including 211,593 who experienced a CSAE. The SCOAP dataset contained 51,537 unique patients, including 5,004 who experienced a CSAE. The baseline rates for individual CSAEs were generally very low (<0.001% for CHARS and <1% for SCOAP), with most rate ratios favoring intervention hospitals over comparison sites at baseline. An assessment of the differences between CSAEs over time (before vs. after implementation of the communication training) is forthcoming.

Evaluation Observations

The UW demonstration was extremely ambitious in its project aims. It was an enormous undertaking to establish HealthPact and engage the right stakeholders. Once the project started encountering challenges with implementing the communication and resolution program, the group's focus narrowed considerably to supporting communication and resolution program and promoting patient-centered accountability in systems that involve more than one insurer. Patient advocates associated with HealthPact led the way to expanding participant understanding of the immense distance between the health care system's current response to medical injury and patient and family needs.

The project trained a large number of clinicians; for the team communication training, 71 participants fulfilled the Master TeamSTEPPS® training, 69 participants completed the train-the-trainer module, and over 1,300 providers completed the front-line clinician training. Almost 400 disclosure and apology coaches were trained. The grantee learned a lot from conducting trainings, including recognizing the need to move to a "train-the-trainer" model. This approach required sites to identify a "champion" and a "change team" and to send them to UW for

[b] The attitude survey, developed by the grantee, assessed attitudes about the error disclosure coaching training.
[c] The Disclosure Culture Scale, a new instrument developed by the grantee, assessed respondent beliefs regarding their organization's stage of integration and acceptance of error disclosure recommendations and standards promoted in the study.

additional training. This modification was a significant expansion of the scope of the project that put enormous stress on grantee faculty and support staff as well as the sites.

As mentioned above, the UW demonstration project ran into difficulties in implementing the planned communication and resolution program intervention across the State. Perhaps the biggest challenge was that each participating site differed in the degree to which its organizational culture, policies, and practices were aligned with the key elements of the communication and resolution program. (This was true in each of the demonstration projects in the PSML initiative that attempted to implement DRP.) Each host organization also had a different level of commitment by organizational leaders, which was reflected in a different level of resource allocation (e.g., risk and claims staff dedicated to data collection). Additionally, when it was time to use the communication and resolution program, sites tended to be reticent about being the first to use the new process. Risk and claims managers (being risk adverse) preferred to learn from initial experimentation by others. Some risk and claims managers also preferred to wait for an "ideal" case (one without high stakes but one significant enough to warrant the effort). Physicians were also hesitant to participate in the communication and resolution program, their main concern being possible punitive action by the State board of medicine. The UW grantee concluded that "operating communication and resolution programs in which two or more insurers must collaborate to resolve cases is highly challenging and likely requires several preconditions not present for our sites, including a commitment from physicians to collaborate with facilities to resolve incidents, mechanisms for quickly transmitting information to remote insurers, tolerance for missteps in early attempts at collaboration, and clear protocols for joint investigations and resolutions"[9] (p. 18).

The findings from the baseline assessment of CSAEs are descriptive, rather than evaluative, and are preliminary. We offer no comment on assessment methodology for the communication and resolution program because the grantee did not ultimately conduct such assessments.

Improving Communication—Lessons Learned

Building robust disclosure and resolution programs involves challenges for both implementation and evaluation. In principle, DRPs operate to ensure better disclosure and communication between providers and patients in the aftermath of an adverse event, with positive downstream effects on malpractice outcomes and patient safety culture. In practice, however, these programs can be challenging to establish, especially within the existing resources of host institutions. It is notable that grant resources tended to go toward the development of tools and training and not to operations. An assumption was made that DRP could be supported by hospitals within existing risk management resources, but the experience of these projects suggests that assumption may be faulty. One disadvantage that the four demonstration projects shared—unlike their predecessors (like University of Michigan)—was that they were "outsiders" (of a sort) trying to convince hospitals to implement and evaluate the impact of DRP, rather than "insiders" developing a home-grown approach to disclosure and resolution. From their combined experience, it seems critical to implementation that institutional cultural change take place. Fortunately, these four grantees have much to share about what that change looks like.

The experience of these projects can teach us a lot about what went right (e.g., support from engaged and motivated institutional leadership, building on existing patient safety initiatives,

committed and purposeful project leadership), what can go wrong, and how future replications might avoid these problems. Review of future proposals to support DRP implementation might include specific attention to whether participating hospitals (and other host organizations) have an adequate budget provided by the grant or other sources and dedicated staffing to implement the DRPs described in the proposals. In addition, the review might assess whether timelines are sufficient for bringing the project to scale prior to the start of data collection.

While we learned a lot from the experience of these four demonstrations, one critical question posed in at least two of the applications remains unanswered: Is the DRP model suitable for non-academic, non-self-insured hospitals? Early demonstrations of DRP (including those at the University of Michigan, Stanford, and the UIC hospital within the PSML portfolio) have illustrated the promise of the DRP model but also many of the difficulties involved in exporting a DRP to community hospital settings. Within the PSML portfolio, the UW project also experienced these difficulties in its attempt to negotiate a plan for implementation that would bring together a large group of stakeholders across the State. This challenge exists because the non-academic hospital setting involves an elaborate web of risk relationships among physicians, hospitals, malpractice insurers, and patients, as well as "risk shifting" behavior among these parties. In this environment, the incentives to litigate or settle malpractice claims are not aligned across the parties involved. Because of the failure of any of the demonstration projects to replicate in non-academic settings despite plans to do so, this important policy question remains unanswered. Although there is accumulating evidence (some of it strong evidence) that DRPs can positively affect both patient safety and malpractice outcomes, there is no evidence to date as to the outcomes that could be reasonably expected from implementation across a broad range of hospital types (such as academic and non-academic, urban and rural, within integrated health systems and stand-alone hospitals, those that employ physicians and other health professionals and those that do not).

From a research standpoint, tracking the impact of a DRP requires good data on malpractice and safety outcomes, including measures related to mediating factors such as changes in institutional processes and patient safety culture. Capturing meaningful claims data, in particular, may require several years due to the malpractice "claims tail" (i.e., malpractice claims frequently take 5 years from the occurrence of an adverse event to surface and/or resolve). As a result, any effort to assess the outcomes associated with a DRP is likely to require ongoing support on the part of a host institution and 6 to 10 years of data collection.

Preventing Harm Through Best Practices

Three grantees—Ascension Health, Fairview Health Services, and the Massachusetts State Department of Public Health—aimed to prevent medical errors and poor health outcomes while reducing malpractice lawsuits by implementing "best practices." Two projects (Ascension Health and Fairview Health Services) focused on spreading clinical best practices for safety interventions to hospital-based perinatal units and obstetrics departments. One project (Massachusetts State Department of Public Health) focused on increasing the efficiency and efficacy of high-risk clinical and communication processes in a group of outpatient primary care practices.

Ascension Health

This project focused on ways to improve the quality of perinatal care delivery and the management of adverse perinatal events in five geographically dispersed hospitals. The impetus for this project was twofold: Previous perinatal safety projects undertaken by Ascension Health had shown some success in reducing preventable injuries, but these projects had been disseminated somewhat unevenly and their impact was leveling off, and the organization had a desire to continue identifying new safety interventions in the perinatal area. For the current project, a uniform, evidence-based obstetrics practice protocol was established for dealing with shoulder dystocia[d]. Use of a uniform practice protocol is based on the idea that eliminating variation in adherence to clinical guidelines during perinatal emergencies will translate to improved patient safety. Key project tasks included creating broad-based physician engagement and adoption of all elements of the previously tested perinatal safety initiative and adding a comprehensive team approach to labor and delivery management that incorporates a shoulder dystocia management program. This project also involved developing, implementing, and evaluating error disclosure through a coordinated communication intervention with patients and the care team. Other elements of the intervention included training labor and delivery clinicians on electronic fetal monitoring, teamwork and communication, and documentation of unintended events. The project team used the principles and practices of a High-Reliability Organization (HRO) to facilitate adoption and spread of the intervention. This package of interventions was intended to reduce the number of malpractice lawsuits, consequently decreasing the annual malpractice funding expense for obstetrics. This grantee's findings are described below.

Shoulder dystocia management.[10] Following the adoption of the new protocol to prevent shoulder dystocia, 99 percent of deliveries involving shoulder dystocia had a head-to-body delivery within 3 minutes, a finding sustained for 2 years after implementation of the new protocol.

Event reporting.[11] Six months following the end of the intervention, the five participating hospitals demonstrated improvement in event reporting, nearly doubling their rate of reporting for all unexpected medical events in labor and delivery per 1,000 births (43 vs. 84 per 1,000 births; $p<.01$).

Harm.[11] Six months following the end of the intervention, the project demonstrated reduction in harm at the five participating hospitals, decreasing the rate of high-risk malpractice events for shoulder dystocia per 1,000 births by half (14 vs. 7 per 1,000 births; $p<.01$). Further, incidents of shoulder dystocia decreased 50 percent.

Shoulder dystocia-related claims. In 2009, prior to the intervention, the rate of obstetric malpractice claims at the five participating hospitals ranged from 1.5 to 5.4 per 1,000 births. In 2013, 2 years after establishing the new protocol, none of the five hospitals had malpractice claims based on shoulder dystocia.[10] As a result of these safety improvements, some of the

[d] Shoulder dystocia is a labor complication that occurs when a baby's shoulder is lodged behind the mother's pubic bone after the baby's head has emerged, preventing the baby from passing through. Because severe consequences can occur when the baby is stuck for more than 3 minutes, it is important to release the shoulder quickly after the head emerges.

money that had been saved for malpractice claims was diverted to support implementation of the intervention at 42 additional Ascension Health hospitals[11].

Evaluation Observations

This project accomplished what many other PSML demonstration projects did not—it created institutional cultural change that was necessary for the package of interventions to take root and be sustained past the grant period. Ascension Health's High-Reliability Organization culture seemed to facilitate the uptake of both the new shoulder dystocia protocol and new adverse event reporting procedures. Moreover, acknowledging the specific culture of each demonstration site, the project team collaboratively developed the protocol, training, and maintenance plan with stakeholders at each hospital. Allowing the demonstration sites to work through implementation and data collection processes was critical given their diverse experiences with evidence-based guidelines and research. It also increased buy-in and follow-through. Similarly, initiating a "real-time" review of unexpected events through the DRP was very uncomfortable at first. Typically, risk managers review claims by themselves long after an event occurs; having a team review the claim together with the physician lead, nurse lead, and risk manager in real time was a cultural change that was closely monitored through regular phone calls with the project team and representatives from the demonstration sites. Open communication was encouraged when problems arose.

Compared with the other projects that offered training, Ascension trained a high percentage of clinicians. During the rollout of the training, the project team heard from participants that the training was valuable, but that it needed to be relevant and accessible. The project team adjusted the original 7-hour training requirement to create an individual learning path for each physician that fit with his or her level of decisionmaking. As a result, all 76 clinicians serving on an Obstetrics Event Response Team in each of the 5 participating hospitals received training on implementation of the high-reliability root cause analysis and quick-response model. In the same hospitals, 93 percent of 302 clinicians completed all the trainings offered on disclosure and resolution and documentation.[11]

The project's outcome findings related to reducing harm and high-risk malpractice claims are suggestive, but the research design the grantee used and the data analysis it reports make the findings difficult to interpret. In particular, the reported findings appear to be based on a simple pre/post comparison on several outcome measures in hospitals that implemented a new risk-reduction model without any control hospitals. The grantee did not address the possibility that factors other than the introduction of the new care model (e.g., adoption of different evidence-based guidelines in the labor and delivery units) might have contributed to the observed pre/post differences. Also, the outcome measures reported are not well described, and the measure of "high-risk malpractice events" in particular is not explained. Taken in total, and given the research design, analytic approach, and measures, we do not have strong confidence in the reported findings.

Fairview Health Services

The PSML grant supported Phase II of the Premier Patient Safety Initiative study (2011–2012), which built on the success of Phase I (2008–2010), conducted prior to the PSML initiative.

Although improvements in bundle compliance[e] were achieved in Phase I, the study period was presumed to be too short to achieve 90 percent or higher compliance. It was believed that additional time and effort were needed to achieve high-reliability performance. Phase II aimed to restart the Phase I program and create high-reliability teams and standardized care processes in the perinatal units of 14 of the 16 Phase I acute care hospitals. The grantee anticipated that increasing team communication skills around patient care bundle implementation would lead to improving compliance for these patient care bundles, which would lead to a reduction in harm and the associated malpractice claims and costs. Interdisciplinary teams were trained in teamwork concepts and management of critical labor and delivery events through a combination of in-situ simulation and TeamSTEPPS® training. The project implemented the same three patient care bundles from Phase I: elective induction (a procedure used to stimulate labor before it begins on its own, for a nonmedical reason), augmentation (a medical intervention used to stimulate contractions when labor has started on its own but is not progressing), and vacuum extraction (the use of a suctioning device attached to the baby's head to ease the baby down the birth canal). The grantee reported the results below.

Bundle compliance.[12] Based on chart review, the use of the three patient care bundles increased from the rates established during Phase I. In Phase II, between Quarter 3 of 2010 and Quarter 4 of 2012, average compliance increased from 54 percent to 70 percent for the vacuum extraction bundle, 74 percent to 86 percent for the augmentation bundle, and 87 percent to 88 percent for the elective induction bundle. Participating hospitals improved overall compliance with all the patient care bundles from 72 percent to 81 percent during this time.

Harm and clinical measures. The grantee reported findings on four composite scores that measure perinatal adverse events: the Adverse Outcome Index (AOI), the Weighted Adverse Outcome Score (WAOS), the Severity Index (SI), and the AHRQ Patient Safety Index (PSI) 17-birth trauma score. All of these scores, which are defined in the grantee profile in Appendix A, represent measures of events that are potentially modifiable through improved teamwork.

- When examining the differences between the intervention and control hospitals, from Quarter 2 of 2010 through Quarter 4 of 2012, the proportion of deliveries with an adverse event (as measured by the AOI) decreased for the 14 participating hospitals and increased for the 8 comparison hospitals (p=.025). Differences between the intervention and comparison hospitals were not detected for three other adverse event scores (WAOS, SI, and PSI 17).[12]

- When examining only the intervention hospitals, from Quarter 1 of 2006 through Quarter 4 of 2012, the proportion of deliveries with an adverse event (as measured by the AOI) decreased 14.4 percent (p=.032). There were no significant decreases in the other measures of harm (WAOS, SI, and the PSI 17).[14]

Malpractice claims. Two years into the intervention, a retrospective audit was conducted on 64 obstetric claims made against the 14 intervention hospitals. For the births occurring from 2001 (before Phase I) through 2012 (through Phase II), the project reported a 19% reduction in

[e] A bundle is a defined set of evidence-based interventions that have been demonstrated to improve patient outcomes when performed collectively and reliably.[13]

frequency of obstetric claims per 10,000 deliveries (2.1 to 1.7 per 10,000 deliveries). "Incurred" amounts (loss payments on closed claims and reserves set aside to pay pending claims) were significantly higher before the intervention at $17,908,000 compared with incurred amounts on claims for births during the intervention period at $4,651,325.[12]

Evaluation Observations

The Fairview Health Services project benefitted from the work completed prior to the PSML demonstration project, given that the 14 intervention hospitals participated in Phase I, during which many of the implementation startup issues had been addressed and the project protocols had been refined. Additionally, the participating hospital teams were familiar with the data collection and transmission processes. The demonstration did, however, face challenges with achieving the desired 100% compliance rate with the bundles due to competing demands of provider attention, a lack of active physician champions who were able to change peer behavior, and turnover of personnel. Team communication training was considered to be an important aspect of implementation; however, participation in training varied greatly by hospital, ranging from an estimated 10 percent to 93 percent of clinicians, with a median attendance of 50 percent of clinicians per participating hospital.[12]

Although the project findings reported by the grantee are suggestive of both patient safety and medical malpractice effects associated with the multisite perinatal care intervention, the strength of those findings is limited by concerns about the research design. Broadly, the design of the Fairview evaluation involved pre/post tracking of patient safety outcomes (adverse event measures) at 14 intervention hospitals and malpractice outcomes at 13 intervention hospitals over a period of 7 years (for the adverse event measures) and 4 years (for the malpractice measures). Although control hospitals were included in the study, many of the final analyses conducted by the Fairview team did not involve data collected from these control hospitals. As a result, it is difficult to draw conclusions from the evaluation, because it is unclear whether the observed findings are the result of the intervention or other factors that may have been influencing the intervention hospitals at the same time. This problem (pre/post comparisons without controls for all measures) broadly applies to many of the reported findings.

With regard to perinatal safety outcomes specifically, the Fairview researchers investigated the impact of their intervention on four different measures of adverse outcomes. The researchers detected a significant change in only one of the four measures (AOI) following the intervention. They did not address this finding or explain why three of the four outcome measures were apparently unaffected by the intervention, although they did note in their final report that the measures of harm selected by the project might not be amenable to improvement at the level aspired to by the project.

With regard to malpractice outcomes, the grantee had access to more years of claims data due to its participation in Phase I of this study, allowing for a longitudinal analysis of project findings. Given this advantage, it is not clear why the grantee did not include the control hospitals in the final claims analyses. Ultimately, the Fairview researchers found that the intervention was associated with statistically significant reductions in several measures of malpractice claims and costs at participating hospitals. However, the meaningfulness of these findings is qualified both by the uncontrolled pre/post research design and the small absolute number of claims observed

during the study. Taken in sum, and given these methodological concerns, we believe that the outcome findings reported by the grantee should be interpreted with caution.

Massachusetts State Department of Public Health

The Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and Satisfaction (PROMISES) project is an extension of the work done by researchers from the Harvard Malpractice Study team. This group published groundbreaking findings demonstrating that preventable harm in hospitalized patients was much more common than previously known and that malpractice suits often fail to identify seven of every eight cases when preventable harm occurred.[15] PROMISES broadened the focus to outpatient primary care practices, where most health care is delivered and where the majority of malpractice claims now originate. The project aimed to determine whether implementation of one or more quality improvement (QI) activities in a group of 16 outpatient primary care practices would improve safety and reduce medical malpractice risk. Its focus was on specific areas of care management that contribute to a large proportion of medical errors in ambulatory settings: (1) the management of laboratory test results, (2) the management of referrals (for example, to specialists), (3) medication management, and (4) communication among care providers and with patients. Providers and staff from the intervention practices participated in learning Webinars and received data feedback and customized coaching by Improvement Advisors in the in the use of QI methods (PDSA cycles) for improving workflow and efficiency. Some grantee-reported outcomes from its evaluation are described below.

Safety practices.[16] Chart reviews were conducted by the grantee at each of the intervention sites before and after the intervention to capture objective information about how abnormal lab results, referrals, and medications were handled. Up to 100 charts were reviewed at each of the 16 intervention sites. The project team recorded all occurrences of abnormal records for the intervention's targeted labs or any high-risk referrals where there was no documented followup. From the beginning of the project to the end, chart reviews showed the following:

- The prevalence of four measures of "abnormal" laboratory test followups significantly decreased after the practices participated in the intervention. Specifically, there were decreases in instances when results were not in the chart (2.2% to 0.8%), when the action plan was not documented in the chart (20.4% to 14.4%), when a patient was not notified of a test result (20.8% to 15.0%), and when an action plan was not completed (19.3% to. 10.8%).

- The rates of potential safety risks[f] associated with abnormal lab results significantly decreased after the practices participated in the intervention. Specifically, the rate of potential safety risks decreased from 155 per 1,000 patients to 54 per 1,000 patients, which is a 65 percent reduction in rates of abnormal lab results or high-risk referrals where there was no documented followup in the chart.

[f] Potential patient safety risks are defined as the number of abnormal laboratory test results or referrals for which there was no documentation of clinician followup including acknowledgement, patient notification, an action or treatment plan, or evidence of a completed plan.

- The rates of *serious* potential safety risks[g] associated with abnormal lab results significantly decreased after the practices participated in the intervention. Specifically, the rate of *serious* potential safety risk decreased from 28 per 1,000 patients to 13 per 1,000 patients, which is a 54 percent reduction in events where potential or actual harm was found and there was no documented followup in the chart.

Patient perceptions and attitudes.[17] Based on patient surveys administered at the beginning of the project and again at the end, there were no significant differences in how patients perceived their experience at the 16 intervention sites versus the 9 control sites. Among only the intervention sites, patients had different attitudes about the sites identified by the Improvement Advisors as "more engaged" in the project's improvement activities versus the sites identified as "less engaged." Patients rated the more engaged intervention sites as significantly more positive when it came to practice communication, practice leadership, and test result management.

Staff perceptions and attitudes.[16] Approximately 61 percent (292) of all practice staff members completed the first survey before the initiation of improvement activities, and 60 percent (287) of all practice staff members completed the second survey at the end of the project.

- Overall, from the first to the second survey, staff at intervention sites rated their experience with their practice as showing greater improvement compared with staff at control sites across all 11 domains (access to service and care, medication management, referral management, test result management, malpractice concerns, patient-focused care, quality and risk management, practice communication, work environment, teamwork, and practice leadership).

- From the first to the second survey, there were no significant differences between the average staff ratings of the intervention sites and the control sites in terms of the three high-risk domains targeted by the PROMISES intervention (malpractice concerns, patient-focused care, and teamwork).

- Among intervention sites, staff ratings from the "more engaged" sites showed improvement from the first to the second survey in their ratings on three domains—practice communication ($p<.001$), practice leadership ($p<.05$), and test result management ($p<.05$)—compared with ratings from staff associated with the "less engaged" intervention sites.

Evaluation Observations

The PROMISES demonstration was unique in that it implemented its intervention in outpatient practice settings. This involved conducting a lot of field work and spending time getting to know staff and operations at 16 individual primary care practices. PROMISES experienced delays in getting practices up and running, which affected implementation as well as evaluation measurement. The project team came to appreciate the different levels of innovation readiness of

[g] Serious potential safety risks are defined as those events where the project team, when looking for abnormal laboratory test results or referrals for which there was no documentation of clinician followup, found potential or actual harm (i.e., if not treated, harm that would place the patient at risk of death or potential to cause persistent deterioration of life function).

the practices. Moreover, the Improvement Advisors found it challenging to provide meaningful assistance for all levels of practices. In general, it was a challenge to engage and sustain the attention of busy practices; practices are overwhelmed with many competing demands (e.g., meaningful use, other QI projects), they are chronically understaffed (100% of the practices experienced turnover in leadership positions), and many practices could not automate data collection and had to put "workarounds" in place to improve work processes. The project has helped to identify the conditions under which such evidence-based programs can readily be adopted in primary care practices, as well as conditions under which their adoption becomes more difficult.

The work of the PROMISES demonstration is noteworthy for having proposed the strongest research design of the seven PSML demonstration sites, involving a prospective randomized controlled trial (RCT) to assess the impact of a statewide collaborative safety intervention in ambulatory care. An RCT is a strong research design; it involves intervention sites and similar control sites that do not participate directly in the intervention. This allows investigators to answer the "effectiveness" question because they can directly analyze the impact of the intervention over time while controlling for many unrelated effects that are observed at the control sites.

Unfortunately, the PROMISES demonstration ultimately did not follow through on the initial plan to conduct an RCT since the grantee spent much of its resources engaging practices to participate, leaving insufficient resources to conduct chart reviews at the control sites. Instead, the project's reported findings on the outcome measures represent an uncontrolled, pre/post comparison of those measures within the intervention settings. This is a weaker research design than an RCT, diminishing our confidence that the observed findings (particularly on safety risks) were actually caused by the PROMISES interventions. In sum, we would say that this project produced an interesting and suggestive set of findings concerning a package of patient safety interventions in the ambulatory care setting. However, these findings do not directly address the impact of the demonstration on malpractice risk, and the main findings the grantee has reported regarding patient safety risks are correlational rather than causal.

Preventing Harm Through Best Practices—Lessons Learned

The projects that implemented evidence-based guidelines, with careful attention to training teams on communication processes and skills specific to those evidence-based guidelines, appear to be promising models for inpatient and outpatient settings that are seeking to prevent harm to patients. We learned a lot from the three projects (Ascension Health, Fairview Health Services, and Massachusetts State Department of Public Health), especially what it takes to seed, nurture, measure, and sustain improvements in patient safety processes. All three projects incorporated the input of stakeholders from the local settings (e.g., obstetrical units and risk management departments, primary care practices) from startup through project completion. They used site champions to inform the project about the local conditions and assist with identifying barriers and facilitators to implementation. The project leaders were inclusive of the patient's perspective, as two of the three projects interviewed patients during the intervention to solicit their specific viewpoints. The three projects modeled approaches that emphasize flexibility and customization of the evidence-based intervention and data collection processes to meet site-specific needs and circumstances. They encouraged participants to raise issues and have open

dialogue, working together to resolve problems. All three projects had resourceful, committed leaders at the helm. From our interactions during site visits, it appeared that these team members worked well together and were unified in operationalizing the project's goals and approach. Their background in the research that supports the evidence-based guidelines and their working knowledge of quality improvement processes were also valued by the sites. Clearly, much has been learned from the project teams and their approach to seeding and sustaining standardized patient care processes under this PSML initiative.

Exploring Alternate Methods of Settling Claims

To improve dispute resolution after a malpractice claim has been filed, one demonstration project conducted by the New York State Unified Court System worked with five academic medical centers in the City of New York to send their malpractice claims through a novel program known as "judge-directed" negotiation (JDN).[18]

New York State Unified Court System

In 2004, the Honorable Douglas McKeon, Administrative Judge of the Civil Division of the New York State Supreme Court, Bronx County, pioneered a new approach for malpractice cases involving New York City's 11 public hospitals (under the auspices of the Health and Hospitals Corporation [HHC]). Anecdotally, the JDN program has been credited with decreasing the number of claims against HHC and annual medical malpractice costs by as much as $50 million a year since the program's inception, reducing HHC's indemnity costs from $190 million in 2003 to $144 million in 2008. HHC currently settles about 95 percent of its cases in chambers. For the demonstration program, an expanded and enhanced JDN program was implemented to expedite the movement of cases through the claims process, increase the number of settlements, and, over time, lower malpractice costs and premiums for its five participating hospitals across New York City boroughs. The grant also provided funding for a formal evaluation of JDN to document the program's effect on claims, time to settlement, and medical malpractice costs for the five participating hospitals.

Between September 2011 and May 2015, 716 cases entered JDN and 165 reached a final disposition. Data analysis is ongoing, but the grantee reported the following preliminary descriptive findings based on the 326 cases that entered into JDN by the end of the original grant period:[19]

- Of the 326 cases, most (more than 80%) involved serious, permanent harm or death.
- Of the 32 cases with a final disposition, 15 were settled and 17 were voluntarily dismissed. Across these cases, the median time between filing and disposition of the case was 189 days.
    - Based on anecdotal data provided by the grantee, JDN cases are being resolved in a shorter timeframe compared with the historical median for cases in the Manhattan courts (718 days), Brooklyn courts (952 days), and Bronx courts (1,266 days).

- For 12 cases settled during JDN conference, the median settlement was $237,000, and the median time from filing to disposition of the case was 8 days. For three cases settled outside of conference, the median settlement was $55,000, and the median time was 240 days.
    - Based on anecdotal data provided by the grantee, JDN cases are being settled for similar amounts as compared with the historical median for cases in Manhattan courts ($223,750), for slightly lower amounts compared with the historical median for cases in Brooklyn courts ($255,000), and for lower amounts than the historical median for cases in Bronx courts ($350,000).

- Preliminary findings from the attorney surveys are encouraging: 90 percent of respondents thought the JDN program had reduced litigation costs for their case, 80 percent thought the JDN was a positive contribution to case resolution, and 90 percent were satisfied or very satisfied overall.

Evaluation Observations

As mentioned previously, the demonstration project in New York was multifaceted. It was originally designed with the idea that patient safety interventions in hospitals would reduce adverse events and thus claims. The thinking was that the DRPs would be utilized by the hospitals to disclose adverse events, and the investigations would lead to certain decisions, including providing compensation without the need for litigation. But if the cases were filed, the JDN program would bring them to a quick resolution (either with payment if the hospital was at fault or closure without payment if not). In practice, the hospitals were much more interested in participating in the expansion of the JDN program than they were in building DRPs.

The New York demonstration provides a descriptive summary of 326 cases that were processed through the JDN during the demonstration period. The findings are both illustrative and suggestive regarding the kinds of cases that were selected to participate in the JDN program and the handling and resolution of those cases. Previously reported results by the New York demonstration team have included the observation (based on anecdotal data) that cases passing through the JDN were resolved, on average, in less than half the time of a comparison group of baseline New York medical liability cases, although we have no information on which to judge the comparability of those cases. In sum, we would describe the findings from the New York demonstration as promising, but further research would be needed to rigorously investigate the magnitude of the effects generated by this program on malpractice outcome measures and to determine the statistical significance of any effects.

Exploring Alternate Methods of Settling Claims—Lessons Learned

JDN appears to be a promising model. The New York project was given a 2-year no-cost extension to allow for the collection of data on additional JDN cases. These data should be available within a year. Two concerns were raised by the implementation of JDN in New York: (1) whether any judge could be “taught” the necessary negotiation skills, and (2) whether this model might be an efficient approach to dispute resolution outside of large urban areas with a high number of high-cost cases. The first question has been at least partially addressed by the experience of the New York demonstration—five additional judges were trained and became part

of the JDN program over the course of the 3 years of implementation. The second question is unaddressed at this time; should the followup analyses currently underway establish a strong relationship with malpractice outcomes, the question is worth further exploration by AHRQ

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Evaluation Issues

Several broad observations around evaluation issues emerged in our 5-year evaluation of the PSML demonstration projects. These issues touch on impact, measurement, and policy.

Efforts to link the issues of patient safety and malpractice liability through the PSML demonstration projects are complex and highly varied.

Applicants for the PSML demonstration grants were required to address both patient safety and medical malpractice outcomes in an effort by AHRQ to make a positive impact in both areas. However, AHRQ's original request for applications did not specifically describe how these two pieces were supposed to fit together in the projects, and the demonstrations varied considerably in how they sought to bridge the issues.

A few of the projects implemented both clinical interventions (e.g., best practices in obstetrics) and malpractice interventions (e.g., DRPs) within the same institutions without there being a clear connection between the two elements. Some of the projects focused on malpractice interventions with the assumption that these might feed back into hospital-based root cause analysis or other quality improvement processes in ways that could improve patient safety. Others implemented patient safety interventions that plausibly might reduce the occurrence of adverse events and thus stem the flow of subsequent claims.

Of the seven demonstration projects, four (Ascension Health, Fairview Health Services, New York State Unified Court System, and University of Illinois Medical Center at Chicago) attempted to closely explore a causal link between patient safety interventions and subsequent malpractice outcomes, and the strength of findings from these four projects is limited by weaknesses in their research designs. It is also important to acknowledge that practical impediments (e.g., insufficient time for relevant data collection, insufficient numbers of cases to examine statistical effects) made it very difficult for the demonstration projects to undertake this kind of analysis. In sum, seeking to quantify a direct patient safety–malpractice link may not be the most appropriate benchmark for reflecting on the impact of the demonstration projects, given what most of them were actually set up to do.

There is no single, most relevant set of measures for capturing PSML outcomes across diverse studies.

Malpractice and patient safety have a complex relationship that may not be easily or simply reducible to a single set of outcome measures. AHRQ's initial plan to require the PSML demonstration sites to collect Common Formats data on adverse event reporting, for example, was ultimately not enforced by the Agency, in part because of the questionable relevance of those data across all seven demonstration projects. When project leaders were asked what they believed the single most relevant and appropriate outcome measure might be, as applied to their

demonstration project, two Principal Investigators answered "time to resolution of [malpractice] claims." This is noteworthy for several reasons: (1) it is a relevant and material criterion for some PSML projects but not others, (2) it does not attempt to tie patient safety and malpractice together, and (3) it cannot be generated during a 3-year grant period using the existing administrative datasets that AHRQ had originally hoped would be the main source data for evaluating the PSML initiative.

Basic evaluation challenges are intrinsic to the PSML portfolio.

Building on the preceding discussion, one of our chief observations from the first year of the PSML evaluation was that limits on data were likely to thwart efforts to assess the impact of the PSML projects in a consistent way. Among the threshold challenges identified was the problem of the malpractice "claims tail" (i.e., that malpractice claims frequently take years from the occurrence of an adverse event to surface and/or resolve). Time lags and idiosyncrasies in data gathered by the PSML projects, inapplicability or intractability of existing national patient safety and malpractice datasets, and substantive variation in the interventions across projects made it difficult for many of the PSML projects to document direct patient safety or claims-based outcomes, much less to do so through consistent measures and data across the seven projects. Here again, we are not suggesting that projects have not attempted or achieved useful outcomes, merely that a more idiographic approach to evaluating the projects and to identifying relevant outcomes and data may be necessary.

Meanwhile, national data pipelines on patient safety and malpractice outcomes are limited and involve considerable lag time, suggesting another target of opportunity for AHRQ and policymakers going forward. Better national data, particularly on malpractice litigation and early disclosure and settlement activities, will be a precursor for any future efforts to assess regional and national performance. Recent changes to the National Practitioner Data Base (NPDB) have made it even less useful for evaluation going forward. Therefore, future large-scale initiatives that build on the PSML experience and target malpractice outcomes will need to be funded for longer grant periods (6–10 years), allowing for the maturation of the "tail" of claims data and the assessment of the impact on malpractice outcomes. AHRQ and other funders will also need to pay closer attention to the quality of the study designs as well as the grantees' ability to collect data to ensure that the evidence generated can support policymaking.

Contributions to Patient Safety and Medical Liability

Taken in sum, what can the health care and policy communities learn from the PSML initiative? Clearly, the PSML demonstration projects generated a series of tools, training modules and curricula, program models, evaluation instruments, products, and other materials, and many of these have the potential to spur or assist in the replication of PSML interventions elsewhere and in the development of additional innovations. Moreover, preliminary findings from several of the PSML demonstration projects suggest positive (and in other cases, promising) outcomes associated with some facet of the interventions, either in terms of patient safety performance, malpractice risk/claiming, or both. An equally important aspect of the learning generated by the PSML demonstration projects involves the barriers and challenges encountered, as well as the facilitators that enabled progress, as much as any of the research findings and products generated by the projects. Put another way, the reasons why the PSML demonstrations were difficult to

carry out may be at least as instructive to future efforts in this arena as are the tools and documented successes of the portfolio itself.

In this vein, it is important to recognize that the initial plans for the PSML portfolio (dating back to AHRQ's original request for proposals and request for applications) implicitly assumed that (1) all the PSML projects would tie patient safety and malpractice liability together in basically similar ways in their interventions, such that common performance metrics could and would apply across projects; (2) national data resources for both patient safety and malpractice outcome variables would be available and appropriate for the projects to draw upon for use in the evaluation; and (3) the 3-year grant period would allow sufficient time for grantees to implement the demonstration projects and collect and analyze data on all relevant outcomes. None of these initial assumptions were realized in practice. Partly in consequence, results across the PSML portfolio cannot easily be reduced to a simple "box score." Further, such a measure would not be the best way to understand what these seven demonstration projects actually did or to summarize what was learned from them.

While some of the initial expectations were unrealized and formal outcomes data and analysis from the PSML projects are limited, the projects have nevertheless contributed many useful and important learnings to the field's knowledge base. For example, several of the PSML projects have done useful piloting, replication, and dissemination work on DRPs. The projects have helped to identify the conditions under which such programs can readily be adopted, as well as conditions under which their adoption becomes more difficult. The projects have demonstrated that under optimal conditions, DRPs can produce measurable, positive impacts on a series of patient safety and liability outcome measures. They also have demonstrated that under suboptimal conditions, DRPs can be quite difficult to implement, different stakeholder groups may have understandably different perspectives regarding the attractiveness and risk implications of DRP, and the early offer (or "resolution") component of DRPs tends to be more difficult to carry out than the disclosure (or "communication") component.

Other PSML projects focused on documenting the impact of a combined package of safety, communications, and training interventions in high-risk clinical settings (particularly around obstetrics practice) and the potential for improving both clinical and malpractice outcomes as a result. These projects showed that the implementation of specific patient safety interventions (and/or the standardization of clinical care through "best practices") may indeed be associated with corresponding improvements in patient safety performance, and with at least suggestive findings that malpractice risk may be positively affected as well. That said, these projects also demonstrate that the relevant measures of patient safety outcome may be fairly specific to the clinical settings being studied; by extension, any related malpractice effects may need to be aggregated across settings and across time to be detectable.

It bears repeating that the wealth of toolkits, surveys, training modules, and other materials constructed and validated by the demonstration projects during the grant period represent some of the most important products resulting from the PSML initiative. Several projects developed Web sites that house intervention materials developed through their PSML demonstration grant. For example, the UW HealthPact Web site (http://www.healthpact.org/) offers HealthPact materials used for team communication training, disclosure coach training, and the

Communication and Resolution Program (e.g., implementation, training, and evaluation material). Other projects developed dissemination materials based on their experiences with the demonstration. One example is PROMISES, which created a four-page document and companion video that provides guidelines for outpatient primary care practice staff on how to communicate with patients after an error has occurred and has caused the patient harm. The tool, "When Things Go Wrong in the Ambulatory Setting," contains "tips and suggested language for communicating with the patient, and responses to frequently asked questions about how to communicate, provide an apology, and offer needed emotional support" (http://www.macrmi.info/blog/valuable-tool-when-things-go-wrong-ambulatory-setting-guideline-communication-and-resolution-outpatient-practices/#sthash.jLyop6cm.dpuf). Demonstration projects also developed tools related to the patient experience. As previously described, the UT project constructed the patient-centered interview tool, IMproving Post-event Analysis and Communication Together (IMPACT) for eliciting patient and family perspectives on their harmful events. The Ascension Health project created a video on high reliability principles and the effects of disclosure, with highlights from parents of an infant injured from birth trauma. It relays the story of a family whose child was injured during labor and delivery at an Ascension Health hospital and how the organization responded to the family and involved staff members. A description of tools and other products developed by the PSML demonstration projects are described in the grantee profiles (Appendix A).

Finally, several of the PSML demonstration projects fundamentally sought to influence one or more elements of institutional culture (i.e., collective attitudes, practices, beliefs). Across projects, the nature of the "culture" focus varied. In some, for example, the focus was on error disclosure culture and factors that contribute to better uptake and fidelity in disclosure practice. In other projects, patient safety culture in clinical settings was emphasized. Regardless, "culture" was an interesting focus for intervention in several respects: (1) it is a mediating variable that does not directly translate into either patient safety or malpractice outcomes, (2) it nevertheless has the theoretical potential to influence both of these outcomes, and (3) the best way to measure it may depend on the goals of each specific PSML demonstration project. The experience of these projects in changing and measuring patient safety-related culture has relevance not only to the impact of the PSML portfolio but also more broadly to the design and assessment of future interventions in the patient safety and malpractice policy space.

Lessons Learned From Implementation Challenges

What key lessons can be gleaned from the implementation challenges encountered by the PSML grantees? Perhaps first among these involves the time window that is likely to be needed in any future implementation and evaluation effort examining malpractice claiming effects. As we describe above, and in several of our previous evaluation reports to AHRQ, malpractice claiming and adjudication can often take 5 or more years from initial claim to resolution. As a result, it is fundamentally unrealistic to implement new clinical or policy interventions for patient safety that will impact meaningfully on malpractice claims within a 3-year timeframe. Realistically, 6 to 10 years might be needed for undertaking this kind of activity and for rigorously documenting its impact. Acknowledging and accommodating the "real-world" timeframes in the planning and design of follow-on PSML efforts would be a major step forward.

A second lesson involves recognizing the multifaceted relationship between patient safety and medical malpractice: PSML projects may need to target a specific element of that relationship to be directly comparable with one another. For example, one theoretical connection between patient safety and malpractice involves improving patient safety outcomes by reducing preventable injuries in hospitals. In principle, doing so may also reduce malpractice claiming. This is one plausible way to intervene in the PSML environment, and it has a corresponding set of implications for the types of interventions that might be fielded and for the performance data that would need to be collected to rigorously assess outcomes. By contrast, an entirely different set of PSML interventions might be designed around reducing malpractice claiming directly, as through disclosure and resolution efforts, on the assumption that a less litigious malpractice climate would then help to stimulate more effective root cause analysis and patient safety improvement efforts. These interventions, too, are intuitively reasonable, but they are also qualitatively different, and different kinds of performance data are needed to assess them. Practically speaking, each type of intervention that might be undertaken as a PSML activity involves a specific underlying conceptual relationship between patient safety and medical malpractice, and each entails correspondingly different data collection and analytic approaches to evaluate it. For future initiatives under the PSML portfolio, it would be desirable to articulate the policy focus and research aim more clearly at the outset, so that the potential for an "apples-to-apples" comparison of findings is improved or the potential for an "apples-to-oranges" comparison of findings across interventions is better recognized and planned for from the beginning.

A third lesson is that currently available national data resources are poorly aligned to support future PSML initiatives, particularly so on the malpractice claims side. As we have discussed previously at some length, the National Practitioner Data Base has serious weaknesses when it comes to using claims data for assessing the impact of PSML projects.[1] Perhaps the most important of these for national evaluations is the fact that NDPB claims data are only geocoded at the State level in the public-use data file and therefore cannot readily be linked to specific hospitals and other host organizations in connection with PSML interventions.

For hospital systems and other health care entities that undertake PSML-style interventions in the future, one of the basic planning steps involves considering the outcome metrics to track and the data to generate that will be useful and appropriate in context. The upside is that some relevant performance metrics for at least some types of PSML projects may be relatively easy to track locally and are not dependent on these national data pipelines to collect (e.g., numbers of claims and/or time to resolution of claims in the context of a DRP intervention).

Followup to the PSML Demonstration Projects

To extend the reach and impact of the PSML initiative, AHRQ has already launched two additional projects under the PSML umbrella.

The first project, the Safety Program for Perinatal Care, is working with labor and delivery units at 50 participating hospitals to implement perinatal safety interventions that were fielded and tested in two of the PSML demonstration projects. The interventions include safely managing labor-inducing medications and shoulder dystocia (when delivering the baby is difficult because

the shoulder is lodged behind the mother's pubic bone). These and other interventions are bundled in evidence-based clinical tools and resources. Together with interdisciplinary team training and in-situ simulation, the Safety Program for Perinatal Care creates a comprehensive unit-based approach for labor and delivery. Physicians, nurses, and other clinicians at the 50 participating hospitals are receiving training and technical assistance from experts, and the intention is for the 50 hospitals to participate in data collection activities that measure changes in organizational safety culture and clinical safety outcomes.

In the second project, a comprehensive disclosure and resolution program (Communication and Optimal Resolution [CANDOR]) resource toolkit is being developed and implemented in 14 participating hospitals. Informed by several of the PSML demonstration projects (including UIC, NY, and UW), each hospital can customize the toolkit based on its needs in several core areas, including: adverse event reporting, process improvement, communication and disclosure, care for the caregiver, and resolution. An intra-project evaluation is assessing the usability of the tools, as well as each hospital's ability to implement the CANDOR process.

Recommendations for AHRQ's Next Steps

Commit resources to a longer-term effort to address the intersection of patient safety and medical liability.

AHRQ was asked by the Secretary of HHS to use its authority under 42 USC 299a(a) to support the President's PSML initiative as part of its Patient Safety Portfolio. AHRQ has provided leadership over the past 5 years to this effort. The current portfolio of PSML demonstration and planning grants can reasonably be viewed as the first and formative step in a longer-term effort to build models and national capacity for tracking and evaluating new policies and programs on medical liability and patient safety. The President directed the Agency to "move forward on a range of ideas about how to put patient safety first …," and these first pilot projects did just that. They were investigator-initiated models—a "let every flower bloom" approach to model development. Given the dearth of evidence on program models, this approach made sense. Grantees learned as they implemented, and the field has benefited from the experience of the current PSML portfolio, including better understanding of the implementation challenges and facilitators, the relevant types and potential sources of performance data, as well as now having access to preliminary data on promising models, which should heavily influence efforts going forward.

A reasonable next step for AHRQ to take is to incorporate what was learned through the PSML demonstration and planning grants with the learnings from the subsequent projects (Safety Program for Perinatal Care and CANDOR) to identify the most promising models for a much more rigorous "road test" in multiple host organizations around the country. In a second stage of the PSML initiative, we recommend that AHRQ consider sponsoring a true multi-site demonstration program within which multiple host organizations would implement the same model program, albeit under different local conditions. In this demonstration, a particular focus should be placed on (1) planning for, monitoring, and troubleshooting implementation of the chosen program model; (2) creating a realistic timeline for the grants that allows for full program implementation before data collection begins; (3) designing an overarching evaluation that will yield high-quality evidence of effectiveness and implementing that evaluation design across

sites; and (4) choosing investigators and host organizations that have demonstrated a capacity for longitudinal data collection.

Proactively address data challenges in future PSML initiatives.

After completing an inventory of data systems and measures in the first year of the PSML evaluation, we identified a series of major challenges to using existing secondary data systems to assess the impact of the PSML demonstration projects. For the future, two implications follow. First, the field may need more investment and national infrastructure development to improve common datasets and measures relating to PSML outcomes, particularly around malpractice claiming. Second, at least in the near term, future PSML demonstration projects are likely to continue collecting their own primary data, based on thoughtful decisions upfront about the most relevant and useful outcome measures. In fact, a number of the PSML demonstration projects invested substantial resources to create data collection instruments that can be repurposed for future initiatives (e.g., the REDCAP data collection instruments used in the New York project for both DRPs and the JDN program). One problem the various sites faced, though, was that investigators were building "Cadillac" data collection systems that simply could not be sustained after the grant ended. Researchers working with clinicians and risk managers need to reduce the burden of such data collection so that monitoring can be sustained in "real-world" host organizations after the grant period is over.

Support studies to test additional "best practices" for their impact on reducing malpractice exposure.

Two of the PSML demonstration projects (Ascension and Fairview) focused on reducing variation in care by implementing evidence-based guidelines and processes to improve clinical practice in labor and delivery. Another project (PROMISES) focused on specific areas of care management (such as the management of abnormal test results) that contribute to a large proportion of medical errors in ambulatory settings. Much of the development of these types of quality improvement efforts, including the development of TeamSTEPPS® training protocols, specific patient care bundles, checklists, and other tools, has originated with AHRQ and with AHRQ-funded investigators. Future work in this area would be a natural extension of AHRQ's existing efforts to disseminate and encourage the uptake of models (such as the development and implementation of bundles) aimed at reducing variation in care and improving patient safety across the country. Under an extended PSML portfolio, investigators could be encouraged to focus on risks that contribute to large numbers of medical errors and to investigate the effects of remediating interventions on malpractice as well as clinical outcomes.

Fund more exploratory work examining the role of patients and families in the investigation and remediation of patient safety problems.

The UT and UW demonstration projects explored the questions, "What should be the role (if any) for patients and their family members in adverse event reporting, investigation, and remediation? What can patients and family members (potentially) add to the information that hospitals and ambulatory practices already gather in root cause analysis and other investigatory processes? What (if anything) is unique about the contribution the patient voice can make to a 'learning organization'? Can patients participate in root cause analysis and/or processes of quality improvement (such as LEAN) and, if so, how?" These are all intriguing questions that

have been raised, but not answered, by the work of these grantees. More work in this area is needed.

Consider adding a "disclosure culture" module to the AHRQ patient safety culture survey.

The UT project developed and conducted preliminary psychometric testing of a module on disclosure culture that could be integrated into any existing patient safety culture survey. Given that AHRQ's survey is broadly used in the field, to advocate the addition of a disclosure culture module would raise consciousness of disclosure issues and begin to change the conversation nationally.

Include in the AHRQ Clearinghouse all of the tools, training packages, and products developed by the PSML demonstration grantees.

As we have noted earlier in this report, possibly the most important impact of this initiative will come from the various tools, training packages, program models, videos, slide decks, publications, and other products produced by the grantees for their own programs. Wide dissemination of these products by AHRQ is in keeping with the goals of the initiative—to enhance the diffusion of program-related interventions beyond the specific projects.

Conclusion

President Obama's purpose was to stimulate the development of a range of innovative ideas that put "patient safety first and let doctors focus on practicing medicine." The legacy of the PSML initiative is that it accomplished the goal of addressing the challenges of the current medical liability system taking a nontraditional approach. All parties involved in malpractice reform generally agree that doctors are troubled by—and patients and family members are not well served by—the current medical liability system. Evaluations of policy interventions (like damage caps, changes to the statute of limitations, and limits on attorney's fees) have produced only equivocal findings; some studies suggest a positive impact on claims and costs, but others raise questions about basic fairness (e.g., if such changes cause injured parties to be unable to seek due compensation because they cannot find a lawyer).

The PSML initiative took a decidedly different approach. Instead of seeking legislative changes, it empowered States and health care organizations to think "outside the box" about solutions that would reduce preventable injuries, foster better communication between doctors and patients, and award compensation to injured patients in a timely and efficient manner.

Unfortunately, the quantitative results on the impact of the innovations reported here are equivocal as well. Some evaluations show an impact on patient safety and malpractice outcomes, but our confidence in these findings is limited by concerns about the underlying study designs. Nevertheless, the learnings from the PSML demonstration projects are immense and provide clear direction for AHRQ and the Nation to continue on the path initiated by the President. Much work has been done, and more work remains.

Appendix A: Grantee Profiles

New York State Unified Court System

Title: The NYS Medical Liability Reform & Patient Safety Demonstration Project
Award Number: R18 HS19505-01
Principal Investigator: The Honorable Judy Harris Kluger, J.D. **Award:** $2,999,787
Period of Performance: 7/01/10–6/30/15

Goals

Through initiatives to promote safety culture, a communication and resolution program (CRP), and an expanded and enhanced judge-directed negotiation (JDN) program, this grant aimed to enhance the patient safety culture in participating hospitals, prevent and address adverse events, prevent the filing of cases through disclosure and early offer, expedite the movement of cases through the claims process, increase the number of settlements, and, over time, lower malpractice costs and premiums.

Although the project received a no-cost extension through June 30, 2015, the five hospitals ceased project participation on June 30, 2013.

Methods

The grantee implemented three program components in five medium and large academic medical centers in New York City. These five hospitals provide care to some of the city's most economically disadvantaged and medically underserved populations.

The first component was hospital-based initiatives to promote a culture of patient safety. The grant required that each of the hospitals focus its attention on developing a culture of patient safety by, at a minimum, (1) conducting the AHRQ patient culture survey at the beginning and at the end of the grant, (2) enhancing adverse event reporting and response, and (3) providing communication training to general surgical staff using either TeamSTEPPS® or a similar type of training package. (TeamSTEPPS®—Team Strategies and Tools to Enhance Performance and Patient Safety—is an evidence-based teamwork system developed by AHRQ and the Department of Defense's Patient Safety Program to improve communication among health care providers.) Each hospital used a variety of patient safety-related initiatives and interventions tailored to its own organization. Some examples of specific interventions include a refined surgical safety universal protocol, a practice guideline for managing obese surgical patients, and improvements in adverse event reporting systems. The grantee estimates that 5,000 hospital staff across the participating institutions received TeamSTEPPS® training.

The second component was a communication and resolution program (CRP) in the general surgery departments at each site. Staff at all five sites received disclosure training developed in consultation with the Greater New York Hospital Association and the Madison Consulting Group that included presentation of didactic material, role-playing, and small-group exercises. Different hospitals had different types of staff attend the training (e.g., surgeons, other clinicians,

risk managers, quality and patient services staff). Reportedly, participant reaction to the training was overwhelmingly positive. A 6-month follow-up satisfaction survey of training participants revealed that they found the skills they learned helpful and used them in practice. According to the grantee's final report, the training continues to be provided to hospital staff by their malpractice insurer.

Each of the hospitals worked with the Department of Health staff to diagram how an adverse event involving severe harm would be managed, including the process they planned to use to make decisions about when to make a disclosure, the staff who would make it, and the process by which an offer and resolution would follow. Based on the University of Michigan Health System model (Boothman, Blackwell, Campbell, et al., 2009), the CRPs involved prompt reporting of the adverse event to the hospital, full disclosure to the patient/family, a timely investigation, an explanation of investigation findings and an appropriate apology to the patient/family, and an effort to learn about patient safety. In addition, when providers failed to meet the standard of care, CRPs were to seek to achieve a resolution by offering compensation without requiring families to sue. The project provided customized training in disclosure skills to clinicians at each site.

The third component of the grant was the enhanced judge-directed negotiation (JDN) program, which was modeled after a program developed in 2004 by the Honorable Douglas McKeon, New York State Supreme Court 12th Judicial District, Bronx County. Judge McKeon continues to provide leadership to the program. The JDN program aimed to prevent protracted legal battles and reduce the legal costs and frustration for providers and patients who pursue malpractice claims through the traditional court system. As a result of the grant, all malpractice lawsuits against the five participating hospitals were directed to a special program of judge-directed settlement negotiations. Under this model, a judge with experience in medical malpractice cases and training in clinical issues and negotiation skills presides over the malpractice lawsuit from the filing of the case to the end or until a trial is scheduled. The judge convenes the parties "early and often" to discuss the case and help broker an expedited and equitable settlement. The judge facilitates negotiations but does not attempt to impose a settlement or a settlement amount. The plaintiff may move ahead with trial if the parties do not agree on a settlement after a period of negotiation. One significant advantage of this approach to malpractice liability reform is that it does not require any change to the law.

With grant funding, the JDN program was expanded to include courts in Brooklyn and Manhattan, where additional training increased the number of judges to five. A full-time nurse-attorney was hired to provide input when the judge or lawyers needed clinical information, to keep notes on the cases and their disposition, and to enter data for the evaluation.

Analysis

Communication and resolution program. CRP process and outcomes were measured using structured data on CRP events entered by hospital staff, insurer data on the aggregate numbers of claims processed during the intervention period, surveys of participating physicians (for each case, the physician most involved in the case received a 15-item survey), and interviews with hospital administrators about their experiences with the CRP program. Over 22 months, starting

in September 2011, data were collected on 125 CRP events. Surveys were received from 70 of the 123 physicians who received one.

Enhanced judge-directed negotiation program. The evaluation of the JDN program had two components. The first was a litigant satisfaction survey, in which opposing attorneys were asked to complete an online survey about how the JDN affected overall outcomes. The second evaluation component assessed the effect of the JDN on the resolution of cases. The focus was primarily on the time to disposition, percent of cases settled, and the stage at which cases were settled. It should be noted that the final analysis of data is not complete, as the grant project was extended through June 2015 in order to allow time for additional data collection and analysis.

From the beginning of the grantee's data collection in September 2011 to the submission of its final report, 326 cases had entered the JDN and 32 had reached a final disposition. At the time of the final report, the grantee had received 16 responses from the 31 attorney surveys sent. The findings on the JDN presented below reflect the data analysis at the time of the grantee's final report.

Findings

Communication and resolution program. Findings regarding the CRP implementation are below:

- Of the 125 CRP events, the greatest proportion resulted in temporary but severe harm (68.8%). Cases next often involved death (15.2%) and permanent but not severe harm (7.2%). In more than half of cases, patients required altered medical management (56.8%) and a prolonged hospital stay (52.0%), with 11.2 percent of injured patients acquiring a disability. The most common clinical events were unintended laceration or puncture (18.4%) and anastomotic leak/enterotomy (16.8%).
- Overall, the hospitals implemented the key steps of the CRP. An initial disclosure was documented in 92 percent of CRP cases. Communication that an adverse event occurred was documented in 79 percent of cases, with explanations of the reasons for harm (88%) and "apologies of sympathy" (64%). An apology acknowledging responsibility was given in only 13 percent of cases.
- A quarter (25%) of the events assessed were reported to Risk Management or Quality within 24 hours, half (50%) within 6 days, and three-quarters (75%) within 18 days, with only a short time elapsing between the first communication with patients and families about the event and the last communication (50% were concluded within 2 days). Overall, 75 percent of communications were concluded within 32 days.
- Of the 125 events, 30 were judged to involve "all of the essential elements of a negligence claim: an injury, causation, and substandard care" (Mello, 2015, p. 8). For these 30, the responses deemed appropriate included compensation (9) and an offer to waive medical bills (12).
- Very few CRP cases (20) progressed to a claim or lawsuit. Twelve to 15 months after CRP completion, 14 of the 125 cases (11.2%) resulted in a filed lawsuit and six (4.8%) others resulted in a claim but no filed lawsuit. Three of these cases (2.4%) were settled with a release of claims. Eleven of the 20 cases with a claim or lawsuit involved

substandard care and causation, and the hospital offered compensation in 3 of these 11 cases.

- Physicians, nearly all of whom (98%) were surgeons, generally lacked awareness of the CRP. Most were not knowledgeable of the compensation given to the patient or the amount of time needed to resolve the case. However, physicians rated the CRP positively. On a scale of 1 to 100, physicians gave positive ratings regarding disclosure conversations with the patient/family, the assistance they received in preparing for the disclosure conversation, their interactions with CRP representatives (when they had them), and their treatment by CRP representatives (medians of 85.5, 87.0, 89.5, and 75.0, respectively). Respondents were less positive about the likelihood that the program helped them avoid a lawsuit (median of 50.0).
- The CRP process shed light on the causes of harm. In cases involving violations of the standard of care, the leading human factors contributing to errors were communication problems among providers (17 cases, 56.7%) and inattention (13 cases, 43.3%). In these cases with substandard care, most (86.7%) involved a failure of an individual provider, and half (50%) involved a system failure.

The grantee encountered a host of barriers to implementation of CRP, including risk management workload, malpractice insurer reticence (because of fear that disclosure would increase claims), and institutional resistance (hospitals unwilling to negotiate directly with patients and families). Further, because New York lacks legislation supporting disclosure and resolution, the tort system is very polarized, making it difficult to garner enthusiasm for early resolution.

The grantee also noted that the disclosure side of the CRP was implemented much more successfully than the compensation/resolution side. In most cases in which there was deviation from the standard of care, compensation was not pursued. However, the project was successful in changing the culture and mindset around communication.

Enhanced judge-directed negotiation program. From the beginning of the grantee's data collection in September 2011 to the preparation of this report in late May 2015, 716 cases had entered the JDN and 165 had reached a final disposition. The grantee had received 98 responses from the 211 attorney surveys sent. (Surveys were sent when the JDN process was completed, even if a final disposition had not yet been reached. Some surveys had not yet been sent at the time of this report.).

When the grantee submitted a final report at the end of the original grant period, it provided the following interim data analysis although enrollment into the JDN was ongoing. The final analysis of data is not complete, because the JDN program continued to accrue cases through April 2015.

- Of the 326 cases that had entered the JDN by the end of the original grant period, most (more than 80%) involved serious, permanent harm or death.
- Of the 32 cases with a final disposition at that point, 15 were settled and 17 were voluntarily dismissed. Across these cases, the median time between filing and disposition of the case was 189 days.

- For 12 cases settled during conference, the median settlement was $237,000, and the median time from filing to disposition of the case was 8 days. For three cases settled outside of conference, the median settlement was $55,000, and the median time was 240 days.
- It appeared to judges that the participants in JDN cases were "highly engaged and working hard to reach resolution." According to the grantee, several factors appeared to have promoted settlement: having early dialogue, a "high-exposure" case, and agreement on key facts. Unrealistic plaintiff expectations appear to have hindered settlement.
- Preliminary findings from the attorney surveys received to date were encouraging: 90 percent of respondents thought the JDN program had reduced their case's litigation costs, 80 percent thought the JDN was a positive contribution to case resolution, and 90 percent were satisfied or very satisfied overall.

Participating hospitals were more enthusiastic about participating in the JDN program than they were in implementing the CRP or the patient safety initiatives. From early in the project, involved stakeholders showed their interest in alternatives to taking claims to trial. Attorneys on both sides—for the plaintiff and defense—could see the value. The New York court system is committed to the JDN program and has continued the program past the end of the grant period using internal court funding. Hospitals that did not participate in the grant have asked to join the program, particularly hospitals in the City and outer boroughs, where there are high malpractice costs and a high concentration of cases.

Selected Publications and Presentations Developed by Grantee

Publications and Manuscripts:

Mello MM. The medical liability climate: The calm between storms is the time for reforms. Bill of Health Blog, Harvard Law School/Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics. Oct. 31, 2014. Available at http://blogs.law.harvard.edu/billofhealth/2014/10/31/the-medical-liability-climate-the-calm-between-storms-is-the-time-for-reforms/

Mello MM, Greenberg Y, Senecal SK, et al. Case outcomes in a communication-and-resolution program in New York hospitals. Manuscript submitted for publication. 2015.

Mello MM, Senecal SK, Kuznetsov Y, et al. Implementing hospital-based communication-and-resolution programs: Lessons learned in New York City. Health Aff. 2014;33(1):30-38. PMID: 24395932.

Mello MM, Studdert DS, Kachalia A. The medical liability climate and prospects for reform. JAMA. 2014;312(20):2146-2155.

Sage WM, Gallagher TH, Armstrong S, et al. How policy makers can smooth the way for communication-and-resolution programs. Health Aff (Millwood). 2014;33(1):11-19. PMID: 24395930.

Presentations:

Cohn J. Offer and disclosure programs, the New York model. American College of Surgeons, 2012 Medical Liability Reform Summit; 2012 Oct 19; Washington, DC.

Cohn J. New approaches to medical liability reform, the role of the state: Can government help states to embrace patient safety and reduce medical liability costs? National Academy for State Health Policy, 24th Annual State Health Policy Conference, New Directions in State Health Policy; 2011 Oct 5; Kansas City, MO.

Cohn J, Senecal S. Poster: The New York patient safety/medical liability reform demonstration project. Agency for Healthcare Research and Quality, 2012 Annual Conference, Moving Ahead: Leveraging Knowledge and Action to Improve Healthcare Quality, Medical Liability Reform and Patient Safety Initiative; 2012 Sep 10; Bethesda, MD.

Kluger JH. Innovative medical liability reform in action. American Medical Association, State Legislative Strategy Conference; 2012 Jan 5-7; Tucson, AZ.

Kluger JH. Innovations in addressing medical malpractice claims, Part I. Judge American Health Lawyers Association; 2012 May 4.

Kluger JH. Litigation Section of the CBMA and the Academy of Medicine of Cleveland and Northern Ohio, Medical Malpractice Issues for Attorneys and Physicians, Medical Specialty Court Initiatives. 2012 Apr 17; Cleveland, OH.

Kluger JH. Second meeting: The appropriateness of dimensions in health care, the judge directed negotiation program. 2011 Nov 11; Milan, Italy.

Mello MM. Medical liability reform: What's on (and off) the table now? Chicagoland Healthcare Risk Management Association Annual Meeting; 2010; Chicago, IL.

Mello MM. New directions in medical liability reform. Columbia Law School Health Law Colloquium; 2010; New York, NY.

Mello MM. Medical liability reform: What's on (and off) the table now? DuPage County Medical Society Annual Meeting; 2010; Oak Brook, IL.

Mello MM. New Directions in medical liability reform. Dana-Farber/Harvard Cancer Center Outcomes Research Program Seminar; 2010; Boston, MA.

Mello MM. Current directions in medical liability reform. Johns Hopkins Bloomberg School of Public Health; 2012; Baltimore, MD.

Mello MM. New directions in medical liability reform. Keynote Address, American College of Surgeons Medical Liability Summit; 2012; Washington, DC.

Mello MM. Hospital-led malpractice reform: Disclosure-and-offer programs in Massachusetts and beyond. Neurosurgery Grand Rounds, Massachusetts General Hospital; 2012; Boston, MA.

Mello MM. Disclosure of medical errors and medicolegal risk: Is it safe to be honest? Health Law Distinguished Speaker Series, Center for Health Law Studies, St. Louis University School of Law; 2012; St. Louis, MO.

Mello MM. Disclosure and resolution programs. Medical Malpractice Roundtable, University of Texas School of Law; 2013; Austin, TX.

Mello MM. Medical liability and accountability for safe care: Looking back, moving forward. Regis J. Fallon Lecture, Center for Health and the Social Sciences, University of Chicago; 2013; Chicago, IL.

Mello MM. Disclosure of medical errors: Is it safe to be honest? Ethics Grand Rounds, Dana Farber Cancer Institute; 2013; Boston, MA.

Mello MM. Next steps for communication and resolution programs. National Quality Colloquium Bootcamp; 2013; Washington, DC.

Mello MM. Disclosure and resolution programs as a quality improvement initiative. Third HealthPact Forum, 2013; Seattle, WA.

Mello MM. Implementing communication and resolution programs: Insights from early adopters. Georgia State University Center for Law, Health and Society Workshop; 2013; Atlanta, GA.

Mello MM. Implementing communication-and-resolution programs in hospitals. American Society for Healthcare Risk Management Annual Meeting; 2013; Austin, TX.

Mello MM. Managing medical liability risk through error disclosure and proactive compensation: Opportunities and challenges. Beth Israel Deaconess Medical Center Medicine Grand Rounds; 2014; Boston, MA.

Mello MM. Update on medical malpractice. Petrie-Flom Center Health Law Year in P/Review, Harvard Law School; 2014; Cambridge, MA.

Mello MM. Managing the risks of malpractice and error disclosure. Harvard Medical School Leadership Development for Physicians and Scientists Program; 2014; Boston, MA.

Mello MM. Hospitals' responses to medical errors: The role of alternative dispute resolution. Quinnipiac-Yale Dispute Resolution Workshop; 2014; Hamden, CT.

Mello MM. Operation and effects of communication-and-resolution programs in hospitals. Empirical Health Law Conference, Cornell University; 2014; Ithaca, NY.

Mello MM. New directions in medical malpractice reform. Deinard Memorial Lecture on Law and Medicine, University of Minnesota; 2014; Minneapolis, MN.

Mello MM. Can communication-and-resolution programs help hospitals avoid malpractice suits? American Association of Law Schools Annual Meeting; 2015; Washington, DC.

Mello MM. New directions in medical liability reform. Department of Health Policy and Administration Workshop, Gillings School of Public Health, University of North Carolina at Chapel Hill; 2015; Chapel Hill, NC.

Selected Other Products Developed by Grantee

- CRP training package for clinicians and JDN training for judges
- Litigation satisfaction surveys (provider, patient, and attorney)

Source Documents for This Grantee Profile

Boothman RC, Blackwell AC, Campbell DA, et al. A better approach to medical malpractice claims? The University of Michigan experience. J Health Life Sci Law. 2009 Jan;2(2):125-159. PMID: 19288891.

Kluger JH. Improving Communication With Patients—NY State Unified Court System. Final Progress Report. Prepared by New York State Unified Court System under grant number R18 HS19505. Prepared for the Agency for Healthcare Research and Quality. New York, NY; Jun 2014.

McKeon D. New York's innovative approach to medical malpractice. New Eng L Rev. 2011-2012;46(3):475.

Mello MM, Greenberg Y, Senecal SK, et al. Case outcomes in a communication-and-resolution program in New York hospitals. Manuscript submitted for publication. 2015.

University of Illinois at Chicago (UIC)

Title: The Seven Pillars: Crossing the Patient Safety-Medical Liability Chasm
Award Number: R18 HS19565-01
Principal Investigator: Timothy McDonald, M.D., J.D. **Award:** $2,998,083
Period of Performance: 7/01/10–6/30/14

Goals

This project is evaluating the effectiveness of a comprehensive process for responding to patient harm events known as the "Seven Pillars" that has been in place at the University of Illinois Medical Center at Chicago (now part of the University of Illinois Hospital and Health Sciences System, UIHHSS) since April 2006. The long-term objectives of the project are to improve patient safety and mitigate medical liability risk through (1) improved communication with patients and families, (2) disclosure and early offer when patients suffer preventable harm, and (3) learning from medical errors.

The intent of the project was to allow UIC to further refine the Seven Pillars, replicate the program from its academic hospital setting to 10 diverse community hospitals in the greater Chicago area, and measure the impact at these hospitals, as well as to collect and report additional data on the impact of Seven Pillars at UIC.

Methods

The key components of the Seven Pillars process include the following:

1. Patient safety incident reporting
2. Investigation and root cause analysis
3. Communication and disclosure
4. Apology and remediation
5. Patient safety and systems improvement
6. System process and performance improvement
7. Education and training

The 10 Chicago-area community hospitals were randomized into two groups (early and late implementers) for purposes of the evaluation. The grantee conducted baseline gap analysis (described below) to measure each hospital's implement readiness across various areas, and the initial training was intended to overcome the identified gaps. Three types of initial training were provided as part of the Seven Pillars implementation: (1) patient communication (crisis management and disclosure) training; (2) "care for the caregiver" training; and (3) resident training on reporting patient safety events. This initial set of trainings was complemented with follow-up training, "just-in-time" training, and as-needed training and consultation. The grantee noted that the roll-out of training was slower than expected, so that parts of the intervention were still being deployed in the five "early" implementing sites when the five "late" implementing sites came on board, one issue that may have made it difficult to differentiate outcomes between the two cohorts. The grantee also noted that some participating hospitals requested special

training on all Seven Pillars elements for their resident physicians. Although these trainings were outside the scope of the grant, the request was an encouraging indicator of a change in safety culture at these hospitals.

Seven Pillars was implemented in varying degrees at each of the 10 community hospitals. As expected, the Seven Pillars intervention was enhanced during the course of the demonstration in areas such as resident reporting, care for the caregiver, root cause analysis, and crisis management, with the enhancements being well received by the sites. Even in the third year of the grant, refinements to the training were ongoing. Several educational modules and tools were developed by the grantee, including training on data collection and a 40-hour CME-accredited program about Seven Pillars.

During the course of the grant, 7 of the 10 participating hospitals merged under a single corporate structure. Although the merger was initially a problem for implementation, the grantee noted, it ultimately facilitated dissemination of the model. Seven Pillars had a lot of support at the corporate level; and as a result, the grantee continued to work with the 7 hospitals initially included in the grant, as well as 13 or 14 other hospitals under the same corporate umbrella.

Analysis

For each of the participating community hospitals, the project team completed a baseline gap analysis using onsite meetings, focus groups, and key informant interviews to gather data from a range of individuals from frontline staff to executives and members of the board of directors. The gap analysis was intended to measure each hospital's readiness to implement the intervention across various areas. The grantee shared the findings of the baseline gap analysis with the community hospitals, then provided the initial training on Seven Pillars to overcome the identified gaps.

The evaluation plan for the grant included two assessments of the impact of the intervention at the participating community hospitals:

- Impact on patient safety process and outcome measures (e.g., number of adverse event reports, numbers of reported significant adverse events, patient safety culture, number and quality of disclosures)

- Impact on risk management and medical liability process and outcome measures (e.g., number of claims, time to settlement agreement, malpractice premiums, proportion of settlement received by patient or family).

The evaluation team planned to use an interrupted time series with a non-equivalent, no-treatment control group, so that five hospitals received the intervention first and the other five were initially the control sites, receiving the intervention at a later time.

The grantee also conducted an evaluation of the impact of Seven Pillars at UIC. The analysis involved an interrupted time series design with UIC, with itself as a historical control. Because the UIC site began implementation in 2006, sufficient data were available to examine the impact

of Seven Pillars on measures of patient safety process, outcomes measures (e.g., changes in physician practices), and risk/liability measures.

Findings

Replication site readiness. The gap analysis performed at each hospital proved useful to implementation. The grantee noted, for example, how corporate representatives for seven of the hospitals (those that merged during the course of the demonstration) identified as the result of the gap analysis the need for a Chief Medical Officer to implement Seven Pillars so they could establish a rapid response to patient harm that included physician engagement.

Impact of Seven Pillars at the replication sites. The grantee presents no data on the impact of Seven Pillars at the 10 community hospitals where the intervention was replicated in large part due to a failure to obtain the relevant data.

- **Patient safety process and outcome measures.** A secure data repository was established for the participating community hospitals to submit safety data, and data were collected through fall 2013; however, only 8 of the 10 sites regularly submitted data. Motivating the participating hospitals to supply data was a challenge. Because the research design called for a blinded analysis, the evaluation team could not complete the main analysis of impact of the intervention on the 10 hospitals until all data were received. To the best of our knowledge, UIC has not completed the proposed comparative analysis.

- **Risk management and medical liability measures.** Obtaining data on risk management and liability outcomes proved to be a challenge as well, and the grantee made adjustments to its plan for collecting these data. According to the final report, after many attempts to retrieve data on claims, payments, and other liability outcomes, and in consultation with a third party intermediary analysis team for the medical liability outcomes, the evaluation team determined that the only way they would be successful at retrieving any medical liability data from the community hospitals was to request hospital "loss-runs" for the pre- and postintervention periods. At last account, the evaluation team had received only a few months of such data.

  The grantee noted that, due to the short timeframe of the grant period, the analysis would not have resulted in statistical evidence on liability outcomes. The most important outcome that came to light through formal and informal measurements was the change in safety culture at the replication hospitals. This change may improve safety outcomes over time, but no specific data are available to support this claim.

Impact of Seven Pillars at UIC. The primary source of data was the UIHHSS incident reporting system, which was used to access records for 2000 to 2012. The analysis included 637 onsite incidents. The grantee first compared the means of each outcome measure during the period before the intervention to those after the intervention. A comparison of means from the pre- to post-intervention period revealed increases in mean quarterly number of incident reports ($p<.0001$), patient communication consults ($p<.0001$), and peer reviews ($p<.0001$) and decreases in mean quarterly number of claims ($p=.0005$), lawsuits ($p=.0003$), legal fees and expenses

(p=.003), settlement amounts (p=.005), and total liability costs (p=.001) (Lambert et al., 2014). Per claim examination reflects the same changes as the cumulative quarterly examination, with significant reduction in quarterly lawsuits per claim and legal fees and total liability costs per claim (p=.0005) (Lambert et al., 2014, p. 25). A significant reduction was also found in mean time to closure per claim (p<.0001). In addition, self-insurance costs, which were increasing prior to the intervention, were decreasing afterward; likewise, the self-insurance fund balance, which was negative and decreasing prior to the intervention, moved from a $30 million deficit to a $40 million surplus (Lambert et al., 2014, p. 22, 23, 50). According to the grantee, "Overall, when viewed in terms of both the absolute level and trends in important outcomes, the Seven Pillars intervention achieved its main goals" (Lambert et al., 2014, p. 24).

An analysis of the impact of Seven Pillars was also conducted on changes in physician practices (and service charges) related to patients presenting with chest pain, comparing practice at UIC to other non-federal general hospitals in the county that recorded at least 800 discharges per quarter. This analysis investigated the notion that a communication and resolution program may create a perceived reduction in the risk of lawsuits on the part of physicians, thus decreasing practices of defensive medicine (e.g., earlier discharge, fewer imaging studies and tests). The grantee accessed discharge records from January 2002 through December 2009 for patients admitted for chest pain. They compared 2,215 UIC records to 102,220 records from comparison hospitals selected through a propensity-score matching algorithm. The grantee found that UIC, compared with 43 other large and medium-sized hospitals in the same jurisdiction, achieved statistically significant reductions in the growth rate of charges for clinical laboratory and radiology services. However, the statistical models used did not directly test whether there was any reduction in the absolute level of charges for either clinical laboratory or radiology services in connection with the introduction of the Seven Pillars intervention. Further modeling and interpretive support is needed to answer that question.

Selected Publications and Presentations Developed by Grantee

Bell SK, Delbanco T, Anderson-Shaw L, et al. Accountability for medical error: Moving beyond blame to advocacy. Chest. 2011 Aug;140(2):519-526. PMID: 21813531.

Boike JR, Bortman JS, Radosta JM, et al. Patient safety event reporting expectation: Does it influence residents' attitudes and reporting behaviors? J Patient Saf. 2013 Jun;9(2):59-67. PMID: 23697981.

Helmchen LA. A cure for defensive medicine? The effect of a "disclosure-and-offer" program on inpatient mortality, length of stay, and charges. Presented at AHRQ; 2011 Oct 17; Rockville, MD.

Helmchen LA. A cure for defensive medicine? The effect of a "disclosure-and-offer" program on inpatient mortality, length of stay, and charges. Presented at Center for Health Policy Research and Ethics, George Mason University; 2011 Nov 10; Fairfax, VA.

Helmchen LA, Richards MR, McDonald TB. Successful remediation of patient safety incidents: A tale of two medication errors. Health Care Manage Rev. 2011 Apr-Jun;36(2):114-123. PMID: 21317663.

McDonald TB. Alternative approaches in responding to medical errors. Trial. 2013 May;49(5) 34-41.

McDonald T, Centomani N, Mayer D, et al. The Seven Pillars Approach to Adverse Events: Effect on Patient Safety and Medical Liability. Poster presented at the 2011 AHRQ Annual Meeting; 2011 Sep 19; Bethesda, MD.

Selected Other Products Developed by Grantee

- Pilot-tested and refined Seven Pillars gap analysis toolkit
- List of the Seven Pillars components required for successful implementation
- Pilot-tested communication assessment survey and scoring mechanism to identify hospital employees who are the most effective communicators to participate in the patient communication consult service
- Educational modules and tools, including a 7-hour training program for the global trigger tool, a 40-hour CME-accredited program for education around the Seven Pillars process, several cases, standardized patient encounters, and training video vignettes
- Resident reporting handbook for all resident physicians and program directors
- Data dictionaries and templates for collecting safety and liability outcome measure data

Source Documents for This Grantee Profile

Helmchen, LA, McDonald TB, Lambert BL. Changes in physician practice patterns after implementation of a communication-and-resolution program. Manuscript in preparation. 2014.

Lambert B, Centomani N, Smith K, et al. The “Seven Pillars” response to patient safety incidents: Effects on medical liability processes and outcomes. Manuscript in preparation. 2014.

McDonald T. The Seven Pillars: Crossing the Patient Safety–Medical Liability Chasm. Final Progress Report. Prepared by University of Illinois at Chicago under grant number R18 HS019565. Prepared for the Agency for Healthcare Research and Quality. Chicago, IL; Jun 2013.

University of Texas (UT) Health Science Center

Title: The Texas Disclosure & Compensation Study: Best Practices for Improving Safety
Award Number: R18 HS19561-01
Principal Investigator: Eric Thomas, M.D., M.P.H. **Award:** $1,796,575
Period of Performance: 7/01/10–6/30/14

Goals

The project aimed to implement and evaluate a disclosure and compensation model and identify best practices for using disclosure to improve patient safety, with a focus on incorporating patient and family input into efforts to understand why errors occur.

Methods and Analysis

Implementation of a Disclosure and Apology Training. During the first year of the grant (2010), the grantee provided disclosure training to staff at six participating health institutions (four medical schools, one cancer center, and one health science center) across the UT System. The purpose of the training was to provide an overview of key underlying principles and key communication skills necessary for disclosure of unanticipated outcomes and to set the stage for hospital-based teams to build and implement a disclosure consultation team model adapted to their own institutions. According to the grantee, "Physicians chosen to attend training were respected leaders in their institutions who could serve as disclosure coaches to other physicians and could help educate students and residents about disclosure" (Etchegaray, Gallagher, Bell, et al., 2015, p. 5). Each of the six hospitals implemented its own intervention based on the disclosure training. Some of the UT System hospitals developed more established disclosure processes; in other UT System hospitals, the program was more "organic."

Development of a "Culture of Disclosure" Survey. The grantee developed and tested a new "culture of disclosure" survey, which fills an existing gap for the patient safety field and provides a tool for institutions to assess their disclosure culture. Health care organizations and researchers can use this survey as a stand-alone measure or as an add-on to any existing safety culture survey. The survey measures disclosure culture over time and identifies barriers to disclosure. It contains four scales: error disclosure general culture, error disclosure trust culture, safety, and teamwork, and also includes items on "intent to disclose" a hypothetical error. The items in the tool include those from a previous study conducted by the researchers as well as another instrument, the Safety Attitudes Questionnaire.

Before and after the disclosure training (2010 and 2013), the grantee administered the new culture of disclosure survey to all clinical faculty in the six participating institutions. The survey was completed by 496 and 1,217 clinical faculty before and after the training, respectively. Each participant was randomly given one of two hypothetical scenarios depicting a medical error of comparable severity and was asked questions about the assigned scenario. The grantee analyzed one of the scenario response questions: "How likely would you be to disclose this error to the patient?" A factor analysis was also completed to determine how many scales within the survey were needed to measure error disclosure.

Incorporating Patient Experiences and Perspectives. Another significant component of the grant was the exploration of ways to involve patients/families who have experienced an adverse event or a near miss in the patient safety improvement processes (e.g., event analyses) in health care organizations. Several methods were used to explore these issues. The first step was to conduct structured interviews with stakeholders about the disclosure process at the six participating UT System hospitals. Stakeholders included 6 clinicians, 13 hospital administrators, and 5 patients and 4 family members involved in an adverse event at the hospital. The researchers developed two sets of interview questions: one for clinicians and administrators and one for patients and family members.

Researchers shared the findings from the structured interviews with experts in disclosure and patient and family engagement at a national conference held by project leaders in 2011. These participants consisted of 5 risk managers or hospital administrators, 3 nurse clinicians, 3 patient safety experts, 3 patients, one frontline clinician, and 10 members of the multidisciplinary research team. Participants discussed aspects of "involving patients as partners" after an adverse event, including establishing the needs of patients and clinicians in the post-event period, contextual factors, and barriers (e.g., fear of legal action). The experts voiced some concern about the level and type of information that patients and families could provide, perhaps due to a lack of understanding of hospital workflow processes and of the event itself. Rather than establishing best practices for involving patients and family members as was originally planned, the grantee decided to examine the following questions: What can patients (and their family members) report about adverse events, and what value could be added by including them in the analysis of their own adverse event?

From August 2012 to July 2014, the grantee conducted structured interviews with 72 participants who had experienced medical harm after an adverse event and disclosure of that event. These participants were recruited by risk managers from 20 hospitals or heard about the study from one of three patient advocacy groups. The interviews, which ranged from 30 minutes to 2 hours, aimed to determine whether patients and family members were aware of contributing factors to the event, how their description of the event differed from the findings of the root cause analysis, and how they would want to be involved after the event. Transcriptions of the audiotaped interviews were used to conduct content analysis. Although hospital leaders were generally supportive, it was difficult for risk managers and other UT staff to find the time to identify and contact UT patients for interviews as originally planned. The project had to expand its search for additional patients beyond the participating UT System, and most of the interviews were conducted with patients treated outside the system.

Using the structured interview guide as a starting point and information gleaned from the parents and family members through the structured interviews, the grantee aimed to develop a new tool, the Improving Post-event Analysis and Communication Together (IMPACT) tool. The intent was for this tool to be used to gather information from patients and family members closely after the occurrence of adverse events.

Malpractice claims. Lastly, the grant aimed to assess malpractice claims against the six institutions within the UT System. The UT System self-ensures claims against all the health providers who practice and train at these sites. The grantee reviewed records on a total of 715

malpractice claims closed over 5 years: 2001–2002 (244 claims, 59 settlements), 2006–2007 (142 claims, 24 settlements), 2009–2010 (100 claims, 17 settlements), 2010–2011 (114 claims, 24 settlements), and 2011–2012 (115 claims, 24 settlements). According to the grantee, the analysis aimed to establish a baseline level of legal claims and outcomes and to develop an approach that could be used to assess the effects of disclosure on legal claims and outcomes over time. Importantly, several changes to the landscape occurred within the years in which claims were evaluated. In 2003, the state passed tort reform that established a cap for non-economic damages ("pain and suffering") and a statute of limitations for claims. Further, the UT System made a system-wide commitment to the disclosure of medical errors in 2008 and operationalized that commitment in 2010 with the work of the grant. The analysis examined several claim-related outcomes. For example, the number of claims, lawsuits, and paid claims differed by year. All of these measures dropped after Texas enacted malpractice reform.

Findings

Culture of Disclosure Survey. In a manuscript for publication, the evaluators report significant improvements from pre- to posttest on the survey for minor error disclosure, serious error disclosure, safety culture, and teamwork culture (all $p<.05$) (Etchegaray, Gallagher, Bell, et al., 2015)—but not for error disclosure trust culture (potential for loss of patient and peer trust in physician disclosing errors). In addition, at posttest, the 472 individuals who had participated in error disclosure training had significantly better perceptions of their work culture across all five domains ($p<.001$ for all analyses) than the 599 who had not. The grantee also examined whether the culture domains correlated with an individual's intent to disclose a hypothetical error. For those having received training, minor error disclosure culture, serious error disclosure culture, and error disclosure trust culture were significantly associated with intent to disclose ($p<.05$ for all analyses), whereas all five culture domains were significantly correlated with intent to disclose among those not receiving training ($p<.05$ for all analyses). However, it is difficult to assess the strength and meaning of these findings with regard to the impact of the disclosure training at UT System hospitals, in part because it is not clear from the manuscript exactly how some of the statistical comparisons were constructed. The grantee also noted that low response rate to the survey limits the generalizability of the findings.

Structured Interviews With UT System Stakeholders. The stakeholder discussions through the structured interviews yielded several important findings: (1) Clinicians and administrators endorsed the current best practices for analyzing events and the goal of improving transparency and the safety culture, (2) all stakeholders agreed that patients and family members had not previously been involved in the analysis of events, and (3) patients and family members and many clinicians and administrators believed patients and family members should be involved in the event analysis process. Clinicians and administrators were unsure how to involve patients and family members, however, due to their lack of familiarity with hospital processes and medical/technical terms.

Interviews with Patients and Family Members Who Had Experienced Medical Harm After Adverse Event. Of the 72 participants, 37 were patients and 35 were family members. The relevant events primarily involved infection (25%), medication errors 18(%), or diagnostic errors 15(%) and resulted in permanent harm (39%) or death (36%). The discussions with patients and

family members yielded a wealth of knowledge about their view of the disclosure and event analysis processes. Notably, most patients would like to participate in the event analysis process and be asked for their perspectives, but the ideal timing of that involvement might vary by individual and the nature and severity of the event. Further, patients may have different needs regarding the ideal person to conduct debriefing and the number of opportunities for debriefing. In addition, most respondents had no intention of pursuing legal action but felt in some cases it was the only way to access information about what happened to them. About half of participants indicated they would prefer to engage in event analysis through a structured interview format. Reasons for wanting to contribute to the event analysis included "1) to help those involved gain a deeper understanding of what happened and identify the causes of the event; 2) to present recommendations which might prevent future patients from harm and provide the hospital with insight about quality issues; and 3) provide emotional healing and post-event support for patients and families" (Ottosen, Etchegaray, Sedlock, et al., 2015, p. 7).

The grantee developed the IMPACT tool after removing irrelevant, redundant, and confusing items from the structured interview guide. Feedback was provided via teleconference by four of seven expert risk managers who were given the tool to review. They agreed it was a "useful way to engage patients and families in a conversation about their events" (Ottosen, Etchegaray, Sedlock, et al., 2015, p. 10) but expressed concern about discussing specific details about the factors that contributed to adverse events with patients and family members. The IMPACT tool could be useful for engaging patients and families after an adverse event, possibly revealing new information about the event and allowing those involved a chance to heal by expressing their feelings (Ottosen, Etchegaray, Sedlock, et al., 2015).

Malpractice Claims. Of the 715 claims reviewed, 148 cases (21%) resulted in a payment, with the remaining being closed without payment. All 148 payments were reached through settlement, none through trial judgment. Across all claims, cases most commonly involved treatment (35%) and surgery (30%), with the most common allegations being improper performance of procedure (13%) and failure to adequately treat (11%). An analysis comparing data from before (2001–2002) with after (2009–2012) tort reform revealed the following:

- The proportion of claims resulting in settlements did not change significantly, but the proportion of claims in which lawsuits were filed decreased (54% vs. 31%; $p<.001$).
- The proportion of claims that were dismissed decreased (34% vs. 22%; $p=.001$), but the proportion of claims that were closed due to an expired statute of limitations increased (32% vs. 51%; $p<.001$).
- Mean payments decreased from $290,992 to $90,429 ($p<.001$).
- Settlements reached after tort reform were significantly more likely than those before tort reform to prohibit disclosure. Across all years, in a subset of relevant settlement agreements (124), the great majority (89%) included nondisclosure agreements.
- The time from the event to a claim decreased, but there was no significant change in the time from a claim to closure.

Selected Publications and Presentations Developed by Grantee

Etchegaray JM, Gallagher TH, Bell SK, et al. Error disclosure: A new domain for assessing safety culture. Presented at the 2011 Agency for Healthcare Research and Quality Annual Conference; 2011 Sep 19; Bethesda, MD.

Etchegaray JM, Gallagher TH, Bell SK, et al. Error disclosure: A new domain for safety culture assessment. BMJ Qual Saf. 2012 Jul;21(7):594-599. PMID: 22562878.

Etchegaray JM, Ottosen MJ, Aigbe A, et al. Patients' knowledge about the factors that contributed to their own unexpected events. Poster presented at the 2014 Annual Research Meeting of Academy Health; 2014 June 8; San Diego, CA.

Etchegaray JM, Ottosen MJ, Aigbe A, et al. Understanding reasons that clinicians do not speak up. Poster presented at the 2014 Annual Research Meeting of Academy Health; 2014 June 8; San Diego, CA.

Etchegaray JM, Ottosen MJ, Burress L, et al. Structuring patient and family involvement in medical error event disclosure and analysis. Health Aff. 2014 Jan;33(1):46-52. PMID: 24395934.

Ottosen M, Etchegaray J, Burress L, et al. Learning from errors through patients and families. Poster presented at the 2012 Summer Institutes on Evidence-Based Quality Improvement; 2012 Jul 19-21; San Antonio, TX.

Sage WM, Gallagher T, Armstrong S, et al. How policymakers can smooth the way for communication-and-resolution programs. Health Aff. 2014 Jan;33(1):11-19. PMID: 24395930.

Selected Other Products Developed by Grantee

- Patient-centered interview tool, IMproving Post-event Analysis and Communication Together, (IMPACT) for eliciting patient and family perspectives on their harmful events
- Survey to measure both safety culture and error disclosure culture
- Institutional Reference Guide, with recommendations for patient and family partnership in postevent analysis

Source Documents for This Grantee Profile

Etchegaray JM, Gallagher TH, Bell SK, et al. The Error Disclosure Culture Survey and its implications for organizational culture. Manuscript submitted for publication. 2015.

Ottosen MJ, Etchegaray JM, Sedlock EW, et al. Developing the Improving Post-event Analysis and Communication Together (IMPACT) tool to involve patients and families in post-event analysis. Manuscript submitted for publication. 2015.

Sage WM, Dougherty JR, Colvard MJ, et al. The far side of tort reform: Experience and opportunities for improving resolution of malpractice claims against physicians in a public academic health system. Manuscript submitted for publication. 2015.

Thomas E, Gallagher T, Etchegaray J, et al. The Texas Disclosure and Compensation Study: Best Practices for Improving Safety. Final Progress Report. Prepared by University of Texas

Health Science at Houston under grant number R18 HS019561. Prepared for the Agency for Healthcare Research and Quality. Houston, TX; Jun 2014.

University of Washington

Title: Communication to Prevent and Respond to Medical Injuries: WA State Collaborative
Award Number: R18 HS19531-01
Principal Investigator: Thomas H. Gallagher, M.D. **Award:** $2,972,209
Period of Performance: 7/01/10–6/30/14

Goals

This grantee conducted a statewide initiative involving many stakeholders, including hospitals, multi-specialty physician groups, integrated healthcare delivery systems, professional associations representing the fields of medicine, nursing, and pharmacy, patient advocates, regulators, and an external insurer. The grantee aimed to implement a set of interventions to prevent and respond to medical injuries with adverse event analysis, disclosure, and compensation. It tested whether these "open" hospital systems and an insurer for physicians and clinics could collaborate on communication and resolution and whether these interventions would affect patient safety and liability costs.

Methods

The University of Washington implemented and evaluated three interventions to improve patient safety and reduce medical liability costs. **The first intervention was the development of a diverse statewide collaborative, HealthPact,** which included attorneys; State legislators; patient advocates; and representation from health care systems, insurance companies, medical and related associations, and the State board of medicine. The HealthPact collaborative hosted several statewide meetings that addressed communication and accountability in health care and established an information-sharing and skill-building community.

One group formed as part of HealthPact—the Patient and Family Advisory Council (PFAC)—developed, tested, and modified a simulation to heighten stakeholder awareness about the experience of patients and family members following adverse events. The simulation, which involves a patient whose cancer diagnosis is delayed as a result of miscommunication among her providers, takes the audience from the disclosure to the patient through the patient's experience with the hospital, attorneys, and the medical board. The grantee implemented the interactive 2-hour exercise at two 100-person meetings, each time seating diverse stakeholders (e.g., patient advisors, clinicians, administrators, risk managers, insurers, patient safety experts, attorneys, regulators) together at each table to discuss the scenario as groups at various times throughout the activity. A narrator led the exercise, which also included an actor as the patient and two trained professionals. In demonstrating breakdowns in the response to medical injury, the exercise helped participants understand the perspectives and needs of injured patients and family members in new ways and revealed challenges they face. The grantee suggested some solutions, such as new ways of providing support to and representation of patients and family members, as well as possible adaptations and guidance for other groups interested in using this tool.

The grantee noted, "Participants considered the session to be extremely valuable and unlike anything they had encountered, largely due to the pervasive influence of the patient and family

advisors. Not only did the PFAC design the entire exercise, their presence at each table helped surface barriers to responding to medical injury that stakeholders were unaware of. More importantly, their presence forced stakeholders to come face-to-face with the suffering patients and families experience from gaps in the response to medical injury, problems that stakeholders understood intellectually but perhaps discounted their significance. For many stakeholders, these interactions with the patient and family advisors heightened their motivation to seek novel solutions" (Gallagher, Etchegaray, Bergstedt, et al., 2015, p. 12).

The second intervention aimed to prevent and respond to medical injuries through enhanced, sustained communication practices at 5 hospitals and 3 large multi-specialty provider groups. This intervention included two components:

- **Team communication training** (including the additional train-the-trainer sessions), which aimed to create and support a small group of local trainers at each site to implement team communication training largely based on TeamSTEPPS (3-13 trainers from each site were trained). Prospective trainers attended a 2.5-day master TeamSTEPPS training, participated in a 4-hour training of trainers, and conducted their first onsite communication training with observation by the grantee's trainers. Trainers were selected to participate primarily from two or three units identified as "early adopters." They included opinion leaders across professions who were comfortable with teaching the team communication concepts and were involved with patient safety initiatives.
- **Error disclosure training,** which aimed to create a group of disclosure coaches at each site who could provide frontline clinicians with guidance and just-in-time coaching on error disclosure in partnership with risk managers (20–40 coaches from each site were trained). Prospective trainers participated in a tailored 4-hour, onsite training and monthly follow-up calls. Selected coaches were individuals with strong communication skills, a visible position, knowledge of local policies, and respect of peers, and they included a mix of representation (e.g., clinicians, risk managers, medical directors).

Training was developed using best practices from education theory: adult learning theory, Bloom's taxonomy, interprofessional education for collaborative practice, and Kotter's stages of change model. Training involved interactive sessions and skill building. Notably, the initial intent for the communication training component was to conduct a 4-hour training at each site. Subsequently, a train-the-trainer model was adopted; this approach proved beneficial to building confidence and enhancing the teaching skills of the onsite trainers but, as a significant expansion of the scope of the project, put enormous stress on the grantee and the sites. Among the lessons learned, the grantee noted that its conceptual model ("transparent communication, before and after preventable adverse events, as a unified whole with patient-centered care at the core") was common to both trainings and could be linked to the sites' mission, increasing buy-in from leaders and participants.

For the team communication training, 71 participants have fulfilled the Master TeamSTEPPS training, 69 participants have completed the train-the-trainer module, and over 1,300 providers have completed the front-line clinician training. Almost 400 disclosure and apology coaches have been trained.

The third intervention was the development, implementation, and evaluation of a communication and resolution program (CRP), formerly called a disclosure and resolution program (DRP), with 5 hospitals and Physicians Insurance (a provider of medical professional liability *insurance* for *physicians* and clinics). CRP entails early investigation and enhanced communication between the health care team and patient after an adverse event. The program was based on the model used by the University of Michigan Health System (UMHS). According to the grantee, "The crux of the program is that health care providers who injure a patient should report the incident promptly, disclose it to the patient or family, initiate and carry out a timely investigation of why the injury occurred, feedback investigation findings to the patient/family, and proactively seek an appropriate resolution, which may include financial compensation" (Gallagher, Shannon, Brock, et al., 2014, p. 14). The grant's work was unique in that it attempted to apply the UMHS model, used primarily in closed systems (self-insured hospitals), in an open system (in which "facility and physicians carry separate insurance and most physicians are not employed by the hospital." (Gallagher, Shannon, Brock, et al., 2014, p. 14).

The CRP model differed from the UMHS model in some ways. Notably, all incidents of unanticipated harm were eligible for the CRP, not only cases of serious harm, and CRP partner organizations were expected to collaborate on the analysis of events, disclosure, and compensation. Participating sites received an implementation toolkit, training, readiness assessment with feedback, and ongoing coaching.

CRP Certification pilot. In an effort to encourage disclosures, HealthPact has planned to pilot a novel approach called CRP Certification in partnership with Washington State's Medical Quality Assurance Commission (MQAC). This approach responds to a commonly reported barrier to participation in CRPs: Clinicians fear that reporting adverse events may result in punitive consequences by regulators such as state medical boards. The grantee has been planning the pilot program for 24 months and aims to begin the 18-month implementation beginning in July 2015. Under the program, physicians and institutions that participate in CRP following an error can document the CRP process in a CRP Certification application and submit it to the Foundation for Health Care Quality. A review panel consisting of at least two physicians, a risk or claims manager, a quality improvement expert, and two patient advocates reviews the application. If members unanimously agree that the case meets all the established CRP requirements, the case is deemed "CRP certified." The applicant can submit the review panel's report to MQAC, which intends to close CRP-certified cases as satisfactorily resolved without further investigation. The grantee noted a few challenges it has encountered in the planning process, particularly those related to concerns about accountability to and protection of the public. The grantee will evaluate the pilot program using a set of key metrics.

Analysis

HealthPact Leadership Group. One-on-one interviews were conducted with members of the HealthPact Leadership Group, first in 2012 and then again in 2014.

Team communication training and disclosure and apology coach training. The grantee conducted a multifaceted evaluation of the trainings that included the following:

- Qualitative interviews, 3 with organizational leaders and 10 with participants in the disclosure and apology coach training.
- Training evaluations completed by 159 of 251 participants in disclosure and apology coach training. The instrument measured content, training, instruction, and efficacy.
- Attitude surveys (including the Organizational Change Scale and Disclosure Culture Scale), completed by 85 of 251 participants in disclosure and apology coach training.
- Training satisfaction for team communication training and disclosure and apology coach training using a paper-and-pencil instrument.

Communication and resolution program. Plans to evaluate the CRP included the following components:

- Semistructured telephone interviews with organization leaders and risk and claims managers before and after the interventions—coupled with information gathered through meetings with partner sites and data on incidents—to measure the extent to which policies, structures, and processes were changed.
- Analysis of claims data to measure costs and related liability outcomes. Data on each CRP case were to be entered by risk and claims managers on an ongoing basis into a customized REDCap data entry form.
- Satisfaction surveys for patients/family members and physicians who had cases undergo the CRP process.

Assessment of rates of communication-sensitive adverse events. In addition to these evaluations, the grantee initiated a novel assessment of the rates of communication-sensitive adverse events (CSAEs) and quality metric adherence at participating intervention hospitals and control hospitals. A CSAE was defined as "an adverse clinical event for which a lack of adequate communication may have been a contributing factor" (Slade, Kramer, Beck, et al., 2015, p. 5). HealthPact experts reviewed a list of national clinical quality metrics drawn from several sources and identified CSAEs, the metrics for which communication failure could have been a factor. Two sets of state data were obtained to conduct retrospective analyses—administrative data from the Comprehensive Hospital Abstract Reporting System (CHARS) and clinical registry data from the Surgical Care and Outcomes Assessment Program (SCOAP)—for the baseline period of 2009–2011 and the post-intervention period (2013).

Findings

HealthPact Leadership Group. As reported in interviews with members of the group, members found their initial goals for HealthPact to be lofty (e.g., "transform communication in health care"). However, most agreed that "the forums successfully increased the visibility of the issues around communication by bringing together diverse populations of concerned stakeholders, including adversaries (the plaintiff's bar and the defense bar, and to some extent competing

hospitals and physicians) to discuss disclosure and resolution" (Gallagher, Shannon, Brock, et al., 2014, p. 4).

Team communication training and disclosure and apology coach training.

- **Qualitative interviews.** Themes emerging from the interviews "can be summarized as increased need for organizational support, questions regarding what constitutes adequate training, resources available to support sustainability of efforts, continuing uncertainty regarding best-practice management of error, accounting for the… [different perspectives] of coaches from different disciplines, and innovation in application and support of ongoing error disclosure training" (Gallagher, Shannon, Brock, et al., 2014, p. 9).
- **Evaluations of disclosure and apology coach training.** The training was well received, with ratings in each item and subscale being high.
- **Attitude surveys** (including the Organizational Change Scale and Disclosure Culture Scale). In combination with the interviews, the Organizational Change Scale showed that respondents were enthusiastic about the training but lacked confidence that stakeholders would effect real change in the near future. The Disclosure Culture Scale revealed respondents' general agreement that there was support for disclosure of error to patients, but their responses were less in agreement about whether adequate training on disclosure was provided or whether retaliation, loss of trust, or damaged reputations were concerns.

The grantee noted that some components of the planned evaluation could not be implemented for a variety of reasons (e.g., length of time to meet IRB requirements, time required of participants to complete tools, lack of validated instruments) and argued that developmental evaluation may be a more appropriate approach in future studies like this one.

CSAEs. Although the analysis will assess differences between CSAEs over time (before vs. after implementation of the communication training), only baseline data are currently available. CHARS data from 2009 to 2011 included 4 implementation sites and 93 comparison sites, and SCOAP data from this period included the same 4 implementation sites as well as 48 comparison sites. The CHARS dataset contained 1,684,916 unique patients, including 211,593 who experienced a CSAE. The SCOAP dataset contained 51,537 unique patients, including 5,004 who experienced a CSAE. The baseline rates for individual CSAEs were generally very low, <0.001% for CHARS and <1% for SCOAP, with most rate ratios favoring HealthPact hospitals over comparison sites. The grantee speculated that CSAEs are underreported.

Communication and Resolution Program.

- **Semistructured telephone interviews** with organization leaders and risk and claims managers before and after the interventions—coupled with information gathered through meetings with partner sites and data on incidents. Overall, the participating sites were not able to implement the CRP as intended. The grantee's final report presented a number of challenges identified in interviews and observations: "reluctance to be in the vanguard," "practical constraints arising from the liability insurer's distance from the point of care," "delays in incident reporting," "lack of a clear implementation plan with assigned roles

and responsibilities," "overcoming distrust and missteps," "risk managers' and claim managers' heavy workloads," "persistent focus on serious-harm events," "major disruptions and distractions," and "uneven support for the CRP among key personnel in the organization" (Gallagher, Shannon, Brock, et al., 2014, pp. 17-19).

- **Analysis of claims data to measure costs and related liability outcomes.** Due to the selective use of the CRP process and risk and claims managers not using REDCap to track cases for a number of reasons (e.g., time needed to gather the information), the grantee collected data on only 30 CRP cases, an insufficient number to draw any conclusions about the effect of the CRP on liability.

The grantee concluded that "operating CRPs in which two or more insurers must collaborate to resolve cases is highly challenging and likely requires several preconditions not present for our sites, including a commitment from physicians to collaborate with facilities to resolve incidents, mechanisms for quickly transmitting information to remote insurers, tolerance for missteps in early attempts at collaboration, and clear protocols for joint investigations and resolutions" (Gallagher, Shannon, Brock, et al., 2014, pp. 17-18).

Selected Publications and Presentations Developed by Grantee

Bell SK, Delbanco T, Anderson-Shaw L, et al. Accountability for medical error: Moving beyond blame to advocacy. Chest. 2011 Aug;140:519-526. PMID: 21813531.

Brown SD, Lehman CD, Truog RD, et al. Stepping out further from the shadows: Disclosure of harmful radiologic errors to patients. Radiology. 2012 Feb:262(2);381-386. PMID: 22282177.

Etchegaray JM, Gallagher TH, Bell SK, et al. Error disclosure: A new domain for safety culture assessment. BMJ Qual Saf. 2012 Jul;21(7);594-599. PMID: 22562878.

Gallagher TH, Levinson W. Physicians with multiple patient complaints: Ending our silence. BMJ Qual Saf. 2013 Jul;22(7)521-524. PMID: 23576772.

Lu D, Guenther E, Wesley AK, et al. Disclosure of harmful medical errors in pre-hospital care. Ann Emerg Med. 2013 Feb;61(2):215-221. PMID: 22883681.

Sage WM, Gallagher TH, Armstrong S, et al. How policy makers can smooth the way for communication-and-resolution programs. Health Affairs. 2014 Jan:33(1);11-19. PMID: 24395930.

Selected Other Products Developed by Grantee

- HealthPact Web site, http://www.healthpact.org/, that includes HealthPact materials used for team communication training, disclosure coach training, and Communication and Resolution Program (e.g., implementation, training, and evaluation material)

Source Documents for This Grantee Profile

Gallagher TH, Etchegaray J, Bergstedt B, et al. Improving stakeholder understanding of accountability following medical injury using a patient-created simulation exercise. Manuscript submitted for publication. 2015.

Gallagher TH, Farrell M, Karson H, et al. Collaboration with regulators to support quality and accountability following medical errors: The CRP certification pilot. Manuscript submitted for publication. 2015.

Gallagher TH, Shannon S, Brock D, et al. Communication To Prevent and Respond to Medical Injuries: WA State Collaborative. Final Progress Report. Prepared by University of Washington under grant number R18 HS019531. Prepared for the Agency for Healthcare Research and Quality. Seattle, WA; Jun 2014.

Slade IR, Kramer CB, Beck SJ, et al. Communication-sensitive adverse events and quality metrics: A retrospective database analysis in Washington State hospitals. Manuscript submitted for publication. 2015.

Ascension Health

Title: Healing without Harm: A Multi-Site Demonstration Project to Develop New Models for Medical Liability and Improve Patient Safety
Award Number: R18 HS19608-01
Principal Investigator: Ann Hendrich, Ph.D., R.N., F.A.A.N. **Award:** $2,990,612
Period of Performance: 7/01/10–6/30/13

Goal

This project focused on ways of improving both the quality of perinatal patient care delivery and the management of adverse perinatal events in five geographically dispersed hospitals to decrease occurrences of birth trauma and reduce resulting medical claims. The project established a uniform, evidence-based obstetrics practice model for dealing with shoulder dystocia based on the idea that eliminating variation in obstetrics practice would translate to improved patient safety. The project also aimed to identify risk factors for shoulder dystocia.

Methods

The grantee recruited five Ascension Health hospitals to implement both clinical and coordinated communication protocols based in part on elements of a previously tested perinatal safety initiative, Handling All Neonatal Deliveries Safely (HANDS). The geographically dispersed hospitals were diverse in patient demographics, birth volume, and other factors.

Training. The clinical interventions targeted the "most injurious deliveries" by training physicians and nurses in labor and delivery units about electronic fetal monitoring (EFM) and the management of shoulder dystocia with the goal of improving the response to obstetric emergency.

- Training on fetal monitoring included best practices in EFM use, communication of readings, and interpretation and response to readings.
- Clinicians received didactic education in shoulder dystocia management (some of which was done through an Elearning module), TeamSTEPPS® teamwork and communication training, and interdisciplinary simulation training using a high-fidelity simulator, the Noelle mannequin.

All 76 clinicians serving on an Obstetrics Event Response Team (OBERT) received training on implementation of the high reliability cause analysis and quick response model, 93% of 302 clinicians completed the training on disclosure and documentation of unintended events, and 90% of clinicians completed the shoulder dystocia simulation training and Elearning module as well as an Elearning module on fetal assessment and monitoring (Santos, Ritter, Hefele, et al., 2015).

Shoulder dystocia policy and bundle implementation. The shoulder dystocia management plan included the adoption of the American Congress of Obstetricians and Gynecologists (ACOG) definition of shoulder dystocia; development of new guidelines; simulation training in

handling shoulder dystocia events using a new bundle[h] that focused on improving situational awareness and communication, particularly the initial call-out of the event; and improving documentation of these events. The project team used the principles and practices of a High Reliability Organization (HRO) to facilitate adoption and spread of these standardized practices. The guidelines were developed by the Ascension Health perinatal steering committee, representing obstetricians, labor and delivery nurses, and a national expert. The steering committee followed the Institute of Medicine's clinical guideline development standards. The process included an environmental scan (collection of information through peer-reviewed literature, unpublished documents, and interviews) and the sharing of meeting minutes to ensure a transparent process.

The shoulder dystocia guidelines call for the following steps during delivery (obstetric teams use digital timers and a shoulder dystocia delivery note for tracking):

- Record the delivery time of the head
- Call out shoulder dystocia if present, with documentation of the time of the call-out
- Attempt maneuvers to deliver the shoulders, with documentation of the sequence of maneuvers
- Announce elapsed time using 30 second intervals following call-out of shoulder dystocia to maintain situational awareness
- Document the delivery time of the shoulders
- If the shoulders are not delivered within 3 minutes of the head, prepare for emergent abdominal rescue

The shoulder dystocia bundle was implemented from July 2010 through June 2011, and data were collected for this year and the 2 following years.

Each of the five sites implemented the shoulder dystocia program using a practice engagement team that included an obstetrical practitioner principal investigator, obstetrics nurse lead, risk manager, project manager, and medical coder. This group managed implementation, provided training to the obstetrics staff, shared project materials, and communicated with other sites to share experiences and improve the program over time.

Shoulder dystocia risk factors. As a separate grant activity, the grantee enrolled pregnant women in a substudy to identify demographic and clinical risk factors for a delivery involving shoulder dystocia. The substudy required extensive data collection on hundreds of demographic and clinical variables from participating mothers.

Communication intervention aimed at reducing harm. The Rapid Report Investigate and Disclosure Intervention, included processes for addressing all harm events, including "immediate identification and reporting of events that result in patient harm; uniform and expedited investigation and analysis of root and common causes of obstetrical events; prompt, transparent, and ongoing disclosure; and quick resolution of events involving probable liability" (Hendrich,

[h] A bundle is a structured way of improving the processes of care and patient outcomes, a small, straightforward set of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes (Resar et al., 2005).

McKoy, Gale, et al., 2013, p. 8). An Obstetrics Event Response Team (OBERT) was established at each site and was trained in emergency response, communication with patients and families, and conduct of apparent and root cause analysis. This team determined when an error needed to be elevated to the resolution stage.

Analysis

The grant aimed to assess the effects of the interventions on the application of clinical protocols, injury rates and infant harm, reporting of serious safety events, and severity of claims and settlement amounts. A case study methodology was used to assess outcomes before and after implementation of the model, which was fully implemented by April 2011. Outcomes were compared for the 15 months before implementation (January 1, 2010–March 31, 2011) with the 27 months afterward (April 1, 2011–June 30, 2013). The project team solicited extensive feedback around the education and training program. Data were collected through interviews with team members and document review. Practice data were collected for 3 years from the five participating demonstration sites implementing the shoulder dystocia bundle. A regression model was used to control for the large number of demographic and clinical variables in the quantitative analysis of the shoulder dystocia risk factor data.

Findings

Training. A key finding is that most participants value and are willing to participate in training, but the training has to be relevant and accessible. Clinicians reported that the training increased their confidence in communicating with families about unintended events. They also believed that the simulation training improved their performance by preparing them for shoulder dystocia and other perinatal emergencies (Santos, Ritter, Hefele, et al., 2015).

Shoulder dystocia management and bundle implementation. Findings related to the implementation of the new shoulder dystocia management plan and application of the shoulder dystocia bundle included the following:

- After adoption of the bundle, 99% of deliveries involving shoulder dystocia had a head-to-body delivery time of within the required 3-minute window, a finding sustained for 2 years after implementation (Cusick, Cox, Welch & Firneno, 2015).
- Reporting of shoulder dystocia increased threefold in the year following implementation, reaching 99% compliance. In the second and third year following implementation, documentation of head-to-shoulder delivery time reached 99% compliance (Burstein, Zalenski, Edward, et al., 2015).
- The grantee noted facilitators that optimized adoption of the bundle, including: practices based on evidence and guidelines, clinicians participated in protocol development and opinion leaders at each site supported it, guidelines were simple and did not require a lot of time, and clinicians could gain experience using the guidelines in a simulation before implementing it in a real situation (Burstein, Zalenski, Edward, et al., 2015).

Shoulder dystocia risk factors. The grantee enrolled about 20,000 women across the five demonstration hospitals. Generally, the findings indicate a higher risk of shoulder dystocia for non-Hispanic Black and Hispanic women, confirm well-documented risk factors (e.g., maternal age, body mass index), and suggest some newly identified risk factors (Hendrich, McKoy, Gale, et al, 2013). The specific findings of this substudy are pending publication.

Shoulder dystocia-related claims. Three years after establishing the new guidelines, none of the five demonstration sites had any malpractice claims based on shoulder dystocia (Cusick, Cox, Welch & Firneno, 2015). As a result of these safety improvements, money that had been saved for malpractice claims were diverted to support implementation of the model at 42 additional Ascension Health sites (Santos, Ritter, Hefele, et al., 2015).

Event reporting. Following 27 months of implementation, the sites demonstrated improvement in event reporting, nearly doubling their rate of event reporting per 1,000 births (43 vs. 84 per 1,000 births; $p<.01$) (Santos, Ritter, Hefele, et al., 2015).

Harm. Following 27 months of implementation, the grantee also demonstrated improvement in high-risk malpractice events, decreasing the rate of high-risk malpractice events per 1,000 births by half (14 vs. 7 per 1,000 births; $p<.01$). Further, incidents of shoulder dystocia and fetal distress decreased 50% (Santos, Ritter, Hefele, et al., 2015).

Selected Publications and Presentations Developed by Grantee

Hendrich A, McCoy CK, Gale J, et al. Ascension Health's demonstration of full disclosure protocol for unexpected events during labor and delivery shows promise. Health Aff. 2014 Jan;33(1):39-45. PMID: 24395933.

Santos P, Ritter GA, Hefele JL, et al. Decreasing intrapartum malpractice: Targeting the most injurious neonatal adverse events. J Healthc Risk Manag. 2015 Apr;34(4):20-27. PMID: 25891287.

Selected Other Products Developed by Grantee

- Perinatal Safety Implementation Kit containing: shoulder dystocia bundle and a sample minutes/seconds timer, Simulation and Team Training Trainer Guide, a pamphlet listing the Elearning education programs for Advanced Fetal Assessment and Monitoring, Introduction to EFM, Managing Shoulder Dystocia and Simulation and Team Training, Essentials to TeamSTEPPS® and associated material and Early Elective Delivery, Induction and Augmentation of Labor bundles.
- A video on high reliability and the effects of disclosure, with highlights from parents of an infant injured from birth trauma.
- Curriculum for the disclosure process.
- Caregiver survey tool to document perceptions and changes over time following disclosure and related educational offerings.

Source Documents for This Grantee Profile

Burstein PD, Zalenski DM, Edward JL, et al. Changing labor and delivery practice to achieve sustainable decreases in neonate injury. Manuscript submitted for publication. 2015.

Cusick W, Cox RL, Welch RA & Firneno C. Devising obstetric best practice guidelines to address variation, improve patient outcomes, and decrease malpractice risk. Manuscript submitted for publication. 2015.

Hendrich A, McKoy C, Gale J, et al. Healing Without Harm: A Multi-Site Demonstration Project. Final Progress Report. Prepared by Ascension Health under grant number R18 HS19608. Prepared for the Agency for Healthcare Research and Quality. St. Louis, MO; Jun 2013.

Resar R, Pronovost P, Haraden C, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. Jt Comm J Qual Patient Saf. 2005;31(5):243-248. PMID: 15960014.

Santos P, Ritter GA, Hefele JL, et al. Decreasing intrapartum malpractice: Targeting the most injurious neonatal adverse events. J Healthc Risk Manag. 2015 Apr;34(4):20-27. PMID: 25891287.

Fairview Health Services

Title: Eliminating Preventable Perinatal Injuries and Reducing Malpractice Claim
Award Number: R18 HS19587-01
Principal Investigator: Kristi K. Miller, RN, MS **Award:** $2,982,690
Period of Performance: 7/01/10–12/31/13

Goals

The project, a continuation of the Premier Patient Safety Initiative (PPSI), primarily aimed to create high-reliability teams and care processes in the perinatal units of 14 acute care hospitals and, by improving safety practices, reduce harms and associated malpractice claims and costs.

Methods

This grant supported Phase II of the PPSI study (2011–2012), which built on the successes of PPSI Phase I (2008–2010). The 16 hospitals in Phase I were diverse in birth volume, academic status (teaching vs. nonteaching), size, and geography. Fourteen of the 16 Phase I hospitals continued participation into Phase II. The grantee described the project as a quality improvement collaborative, whereby interdisciplinary teams from multiple organizations learned best practices, shared experiences, and used quality improvement methods and techniques.

Phase I included the following components:

- Onsite High Reliability Perinatal Safety Assessments, which measured the safety and reliability of each hospital's perinatal care processes
- Implementation of three standardized care processes called clinical care bundles[i]: elective induction, augmentation, and vacuum extraction (described below)
- Electronic fetal monitoring interpretation training for doctors and nurses using National Institute of Child Health and Human Development terminology
- Performance feedback via monthly educational webinars as well as conference calls and emails, with topics including processes, outcomes, barriers, and best practices
- Two all-team meetings to share best practices
- Periodic individual team coaching

Researchers concluded that the period of Phase I was insufficient to achieve the goal of 90 percent bundle compliance and to measure the effect of improved reliability of perinatal care on patient harm. Phase II continued Phase I components but enhanced the intervention with onsite in situ simulation and TeamSTEPPS® training. (TeamSTEPPS®—Team Strategies and Tools to Enhance Performance and Patient Safety—is an evidence-based teamwork system developed by AHRQ and the Department of Defense's Patient Safety Program to improve communication

[i] A bundle is a structured way of improving the processes of care and patient outcomes, a small, straightforward set of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes (Resar et al., 2005).

among health care providers.) Further, Phase II included an evaluation of perinatal liability claim outcomes and a second round of onsite High Reliability Perinatal Safety Assessments.

Each of the intervention hospitals initiated use of the three evidence-based bundles during Phase I. Although the three bundles contain different elements, they "share a common objective of standardizing processes and reducing practice variation" (Riley, Begun, Meredith, et al., 2015, p. 8). The bundles included the following:

- Elective induction (elements include gestational age greater than 39 weeks, normal fetal status prior to start of oxytocin, pelvic exam prior to start of oxytocin, and recognition and management of tachysystole)
- Augmentation (elements include documentation of estimated fetal weight, normal fetal status, pelvic exam prior to the start of oxytocin, and recognition and management of tachysystole)
- Vacuum extraction (elements include alternative labor strategies considered, prepared patient, maximum application time and number of pop-offs predetermined and documented, cesarean and resuscitation teams available at delivery, and high probability of success)

The primary intervention introduced in Phase II was interdisciplinary team training using in situ simulation and a condensed TeamSTEPPS® curriculum. At each site, expert clinicians conducted a 3-day training to train participants to become expert team leaders. A train-the-trainer experiential learning method was used with the goal that 100 percent of members within a multidisciplinary team (staff from labor and delivery, neonatal, operating room, anesthesia, lab, and other staff) would be trained using the in situ simulation within 1 year of the onsite training. The 3-day training included 4 hours of education on "Improving Individual and Team Communication" and "Debriefing" as well as the simulation scenarios that involved postpartum hemorrhage, uterine rupture, abruption, shoulder dystocia, and/or resuscitation of the hypovolemic newborn. Each simulation involved a setting of the stage, the simulation experience, and a facilitated debriefing that included a review of a videotape of the simulation. Performing simulation in the hospital units where clinicians work was beneficial because it revealed latent conditions related to care and allowed teams to simultaneously address processes and equipment issues. The goal of the simulations was to normalize a "culture of safety," standardize communication, and achieve high reliability of patient care.

Across the 14 hospitals, 1,883 (45.7%) perinatal staff participated in the in situ simulation training. Sending trainers to the 14 hospitals to conduct simulations at no cost to the sites increased the sites' commitment to the project and gave them an opportunity for experiential learning. The sites reported some challenges to participation in simulation training, including competing tasks (e.g., scheduling conflicts) and problems with physician buy-in.

Analysis

A prospective cohort study design was used consisting of a 5-year intervention period (January 1, 2008–December 31, 2012) across Phases I and II and a 2-year baseline period (January 1, 2006–December 31, 2007). For some outcomes, the study used eight geographically diverse

comparison hospitals that included those with small, medium, and large birth volumes and teaching and nonteaching hospitals. The study examined the following outcomes:

- **Bundle compliance.** Data were collected from chart audits to assess bundle compliance.

- **Safety and reliability of perinatal care processes.** A 2-day High Reliability Perinatal Safety Assessment on labor and delivery care was conducted at baseline and 2012, and the AHRQ Hospital Survey on Patient Safety Culture was administered in 2008, 2010, and 2012.

- **Harm and clinical measures.** Hospitals submitted data on perinatal discharges to the National Perinatal Information Center (NPIC) to assess changes in the following harm measures: Adverse Outcomes Index (AOI), which divides the number of mothers or infants with an adverse event by the number of deliveries; Weighted Adverse Outcomes Scale (WAOS), which sums the weights for each of the adverse events that occurred and divides by the number of total deliveries; Severity Index (SI), which sums the weights for each adverse event that occurred and divides by the number of patients that had an adverse event; AHRQ Patient Safety Indicators (PSI) 17–birth trauma, 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; and other clinical outcomes (e.g., cesarean section rates). For the eight comparison hospitals used in the study, data on harm and clinical outcomes were gathered.

- **Claims.** The grantee accessed litigation records and malpractice claims data for the baseline period prior to implementation (January 1, 2006–December 31, 2007) and the implementation period (January 1, 2008–December 31, 2012). (Litigation records were obtained through American Excess Insurance Exchange through a special arrangement for this study. Malpractice claims data were available through confidentiality contracts with Premier Insurance Management Services, Inc.) For the purpose of the analysis, only records from 2008 and 2009 were used for the intervention period to account for a possible lag time in the filing and adjudication of claims. Although 14 hospitals participated, the analysis used data from only 13 in the liability assessment because of unreliable data. Researchers compared claims data two ways: (1) obstetric claims during the baseline period compared with the intervention period (2006–2007 vs. 2008–2009) and (2) the baseline-to-intervention change in obstetric claims compared with the baseline-to-intervention change in non-obstetric claims in the same hospitals.

Findings

Training. Team communication training was considered to be an important aspect of implementation, however, participation in training varied greatly by hospital, ranging from an estimated 10 percent to 93 percent of clinicians, with a median attendance of 50 percent of clinicians per participating hospital (Miller, Riley, Meredith, et al., 2013).

Bundle compliance. The study revealed increases in bundle compliance from rates established during Phase I. In Phase II, between Quarter 3 of 2010 and Quarter 4 of 2012, average

compliance increased from 54 percent to 70 percent for the vacuum extraction bundle, 74 percent to 86 percent for the augmentation bundle, and 87 percent to 88 percent for the elective induction bundle. Participating hospitals improved overall bundle compliance from 72 percent to 81 percent during this time. The grantee had aimed to reach 100 percent compliance, which was achieved by several teams with specific bundles for one or more quarters; however, none of the hospitals achieved 100 percent compliance across all three bundles for any quarter. Some challenges noted to implementing the bundles included competing tasks (e.g., implementing electronic medical records), staff turnover, and a lack of active physician champions who were able to change peer behavior, and the difficulty of successfully implementing all the components of a bundle (since compliance for the bundle is scored on an all-or-nothing basis). The grantee noted that the development and use of checklists appeared to improve bundle compliance.

Safety and reliability of perinatal care processes. Overall, all 14 hospitals improved their High Reliability Perinatal Safety Assessment scores significantly from 2008 (baseline) to 2012. At baseline, 66 percent of the demonstration hospitals were partially compliant with industry standards. By the end of the project, 89 percent of the demonstration hospitals were meeting industry standards. For the AHRQ Hospital Survey on Patient Safety Culture, researchers detected significant improvement from 2008 to 2010 on only one of the 12 dimensions (staffing), and no significant improvement from 2010 to 2012.

Harm and clinical measures. During Phase II, AOI improved for implementation hospitals and worsened for comparison hospitals ($p=.025$), with participating hospitals outperforming comparison hospitals on rates of total adverse events and maternal adverse events. Differences between the intervention and comparison hospitals were not detected with the other measures of harm or clinical outcomes. For the intervention hospitals, from baseline through Phase II (Quarter 1 of 2006 through Quarter 4 of 2012), AOI decreased 14.4 percent ($p=.032$), while no significant change was detected for WAOS, SI, or PSI 17. The overall process behavior for the AOI over the 7 years includes two occurrences of special cause: (1) from Quarter 1 of 2006 to Quarter 1 of 2008 ($p<.001$), which corresponds to the baseline period, and (2) from Quarter 1 of 2010 to Quarter 4 of 2012, the end of the project ($p<.003$). Common cause variation is observed between the two process shifts.

Claims. From 2006 to 2009, the 13 hospitals had 185,373 deliveries, with 125 resulting in a lawsuit claim and 25 resulting in claims paid. Although the 25 claims represented only 9 percent of the hospitals' share of total claims, they represented 24 percent of the amount of losses paid and 27 percent of legal defense costs. In comparing the baseline to intervention period, the grantee found a significant reduction in total amount of losses paid per 1,000 deliveries and total indemnity per 1,000 deliveries ($p<.05$ for both analyses). Further, in the analysis comparing claims activity during this period in obstetrics vs. non-obstetrics in the same hospitals, claims paid, total losses paid, and total indemnity paid were reduced significantly for obstetrics (43.9%, 77.6%, and 84.6%, respectively) compared with non-obstetrics ($p<.05$ for all analyses).

Selected Publications and Presentations Developed by Grantee

Damon AL, Parrotta CD, Wallace LA, et al. The effectiveness of providing evidence-based perinatal practice to low-income populations providing perinatal care: Does patient income influence the delivery of quality care? J Hosp Adm. 2013;2(4):82-90.

Davis SE, Miller KK, Riley W. Improving individual and team performance: The power of in situ simulation and TeamSTEPPS®. International Meeting on Simulation in Healthcare; 2012 Jan 27-Feb 1; San Diego, CA.

Davis SE, Miller KK, Riley W. Improving individual and team performance: The power of in situ simulation and TeamSTEPPS®. TeamSTEPPS® National Conference; 2011 Jun 21-23; Denver, CO.

Doyle JL, Kenny TH, von Gruenigen VE, et al. Implementing an induction scheduling procedure and consent form to improve quality of care. J Obstet Gynecol Neonatal Nurs. 2012;41:462-473. PMID: 22697170.

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Premier Healthcare Alliance. Reducing preventable birth injuries and liability claims through evidence-based care, enhanced teamwork. Premier Perinatal Safety Initiative, Phase I Summary, 2008-2010. 2012, December. Accessed at http://gshrm.org/images/meeting/091313/premier_white_paper_nov2012_final.pdf

Premier Healthcare Alliance. Reducing Preventable Birth Injuries and Liability Claims Through Evidence-Based Care, Enhanced Teamwork. Premier Perinatal Safety Initiative Results Summary 2008-2013. Released May, 2013. Accessed at http://aeixrrg.com/files/PPSI%20White%20Paper5-13-14Final.pdf

Riley W. Creating high reliability to reduce patient harm. Florida State University College of Medicine, Grand Rounds; 2012 March 1; Tallahassee, FL.

Riley W, Davis S, Miller K, et al. An analysis of latent conditions and their association with active failures through in-situ simulation [abstract]. In: Proceedings of the 11th International Meeting on Simulation in Healthcare; 2011 Jan 21-16; Phoenix, AZ. Minneapolis, MN: Society for Simulation in Healthcare; 2011:81.

Riley WJ, Meredith L. Implementing standardized clinical best practice and measuring success. Oral poster presentation. Annual Global Healthcare Conference; 2012 August 27-28; Singapore.

Riley WJ, Meredith L. Utilizing a standardized clinical best practice and assessing reliability of perinatal care. GSTF Digital Library. 2012 Dec.

Riley WJ, Meredith L, Parrotta C. The determinants of implementing best practices for perinatal units. Poster presentation. Annual Research Meeting, AcademyHealth; 2012 June 24-26; Orlando, FL.

Riley WJ, Meredith L, Parrotta C. Measuring high reliability in hospital perinatal units. GSTF Digital Library, Journal of BioSciences. 2013 Feb.

Selected Other Products Developed by Grantee

- High Reliability Perinatal Safety Assessment
- Sets of guidelines and protocols for simulation and bundle compliance
- Simulation training tools, including a 15-minute didactic video, Improving Individual & Team Performance: The Power of TeamSTEPPS® and In Situ Simulation
- Webinars on various topics, including bundle compliance, safety culture and accountability, physician engagement and leadership, obstetric staffing, and project updates

Source Documents for This Grantee Profile

Miller K, Riley W, Meredith L, et al. Eliminating Preventable Perinatal Injuries and Reducing Malpractice Claims. Final Progress Report. Prepared by Fairview Health Services under grant number R18 HS019587. Prepared for the Agency for Healthcare Research and Quality. Minneapolis, MN; Dec 2013.

Resar R, Pronovost P, Haraden C, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. Jt Comm J Qual Patient Saf. 2005;31(5):243-248.

Riley W, Begun JW, Meredith L, et al. Integrated approach to reduce perinatal adverse events: Standardized processes, teamwork training, and performance feedback. Manuscript submitted for publication. 2015.

Massachusetts State Department of Public Health

Title: Medical Malpractice & Patient Safety Proposal
Award Number: R18 HS19508-01
Principal Investigator: Madeleine Biondolillo, M.D. **Award:** $2,912,566
Period of Performance: 7/01/10–3/31/14

Goals

The Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and Satisfaction (PROMISES) project aimed to determine whether implementation of one or more quality improvement (QI) activities in a group of Massachusetts outpatient primary care practices would improve safety and reduce medical malpractice risk in targeted "3+1" risk areas that contribute to a large proportion of medical errors in these settings (laboratory test results management, referral management, and medication management, as well as communication among care providers and with patients). The project extended the work of the Harvard Malpractice Study by broadening the focus from hospitals to the ambulatory realm where most health care is delivered.

Methods

This grantee recruited 25 small- to medium-sized adult primary care practices in Massachusetts to participate in this randomized control trial. Sixteen of the practices were randomly assigned to participate in a 15-month intervention (from January 2012–April 2013). The grant, led by the Massachusetts Department of Public Health, involved collaborators in the State's public and private sector, many of which had a track record of successful collaborations: Massachusetts Coalition for the Prevention of Medical Errors, a public–private partnership comprising health care stakeholders including consumer organizations; the Institute for Healthcare Improvement, offering QI expertise; Brigham and Women's Hospital, Center for Patient Safety Research and Practice, offering clinical and research expertise; two insurance companies, CRICO/RMF and Coverys, who together covered a large majority of the State's physicians; Harvard Schools of Medicine and Public Health, providing expertise in organizational behavior and statistics; and Health Care for All, a consumer group knowledgeable about patient engagement.

The pre-existing relationships and "the degree of trust" among the various PROMISES collaborators were mentioned as a facilitator to getting buy-in to the project from both insurance companies. The partnership of collaborators was described as "strengthening" over time, with greater "collegiality." For this group and its subgroups, a profound commitment to the cause was the driving force.

The interventions implemented for 15 months in the 16 intervention practices targeted the 3+1 key risk areas, with each of the 16 practices choosing 1 or more of the 4 areas to improve: laboratory test results management (11), referral management (11), and medication management (3), as well as communication among care providers and with patients (13). Some targeted areas of improvement specific to communication included communication with the

patient before, during, and after an office visit and methods for engaging patients who have concerns or insights about their care.

The grantee established a quality improvement learning collaborative with the 16 practices, which participated to varying degrees in monthly didactic and interactive webinars taught by workflow and efficiency experts and quarterly face-to-face learning sessions; they also received ongoing coaching by an Improvement Advisor with expertise in quality, efficiency, and safety. The practices implemented the Model for Improvement, including the Plan, Do, Study, Act method. They "were coached to perform rapid, small-scale tests of change and to iteratively improve performance of high-risk clinical systems, as well as to embed simple measurements into routine work streams to guide improvement efforts" (Schiff, Reyes Nieva, Griswold, 2015, p. 4). The adjustments were intended to improve inefficient and ineffective processes that could affect patient safety liability. The Improvement Advisors had weekly communication with the intervention practices by email and phone and visited the sites once or twice monthly for onsite coaching. The Improvement Advisors determined where each site was on the "innovation curve" and responded to their specific needs. Based on the variation in the sites' innovation readiness, support needed to be targeted to each practice.

Each site selected three or more people to serve on its QI team; members were usually a practice manager, a physician, and one or more members of the nursing or administrative staff. The grantee encouraged the sites to select team members to ensure representation of a senior leader, a clinical champion, and a day-to-day champion.

Through the intervention, the practices aimed to show improvement in one or more of the following four key system improvement drivers: (1) culture of quality and safety, (2) effective communication and collaboration, (3) reliable tracking and management processes, and (4) enhanced operational efficiency.

Challenges to implementation included short timeframes for start-up, delays in obtaining institutional review board (IRB) approval, resistance to change among physicians and office staff, multiple and competing priorities (e.g., meaningful use, other QI projects), staffing issues (e.g., chronic understaffing, turnover in leadership positions), and local IT workflow issues.

Analysis

This cluster randomized control trial collected data through chart reviews and surveys. In addition, a retrospective claims analysis was conducted before implementation.

Claims. Prior to implementation, the grantee's partners CRICO/RMF and Coverys analyzed closed claims data for a 5-year period (January 1, 2005–December 31, 2009) to assess key failures contributing to medical errors and medical claims in primary care. Claims data were provided by CRICO/RMF and Coverys. All claims involving primary care practices insured by CRICO/RMF and Coverys were screened.

Chart reviews. Chart reviews were conducted by the grantee at each of the intervention sites before and after the intervention to capture objective information about how abnormal lab

results, referrals, and medications were handled; up to 100 charts were reviewed at each of the 16 sites. Chart reviews were triggered by a set of defined abnormal test results. Specifically, "reviewers examined charts to determine if a) abnormal test results were present in the chart, b) the abnormality was noted by a responsible provider, c) there was documentation of an action or referral plan, d) the patient was notified of the abnormality, and e) there was evidence that the treatment or plan was completed for these trigger results as well as other predefined high-risk results or findings" (Schiff, Reyes Nieva, Griswold, 2015, p. 5). In total, the grantee reviewed 815 charts before the intervention and 762 charts afterward, representing 1,629 and 1,530 abnormal lab tests, respectively.

Surveys. Improvement Advisors were asked to state which intervention sites were "more likely" or "less likely" to show an impact based on their experience working with the sites (i.e., the site's level of engagement).

Staff (e.g., providers, practice managers, administrators) at intervention and control sites were administered a 63-item, online survey both before and after the intervention. The survey assessed 11 domains related to the targeted areas and other areas (e.g., malpractice concerns, patient-focused care, teamwork). Across all 25 sites, 292 and 287 staff completed the pre- and posttest surveys, with a response rate of 61 percent and 60 percent, respectively. In addition, administrators in the 25 practices were given an online survey before and after the intervention that assessed the existence of standardized safety processes in the four targeted areas and the practice's technology capabilities. The response rates for administrators were 61 percent and 100 percent at baseline and post-intervention, respectively. Staff from the 16 intervention practices additionally completed a practice characteristics questionnaire and participated in site visits, interviews, and observations of their workflow and processes.

Patients at intervention and control sites were surveyed both before and after the intervention using a 34-item paper-and-pencil survey based primarily on the CAHPS Patient-Centered Medical Home Survey as well as other instruments. The survey covered seven domains related to patient experience (e.g., level of trust, communication, patient-centered care). A group of 150 patients from each site were randomly selected to receive the survey, which was sent by mail. Across all 25 sites, 1,767 and 1,521 patients completed the pre- and posttest surveys, with a response rate of 48 percent and 42 percent, respectively. In terms of the process of administering the patient survey, collecting patient names for the survey was a major undertaking for some practices.

Exit interviews. Exit interviews were conducted with leaders at all intervention sites.

Findings

Claims. In the retrospective analysis of closed claims data, 551 closed claims from the primary care setting represented 7.7% of all closed claims (7,224). These 551 claims named 595 physicians, with some physicians being named in two cases (53) or more cases (17). Most (72%) of the 551 cases were related to failures in the diagnostic process, most frequently for some form of cancer. In terms of the outcomes of claims, the grantee found that claims in primary care, especially those involving diagnostic error, were significantly more likely than claims in other

medical settings to be settled (14% vs. 10%) or result in a verdict for the plaintiff (35% vs. 20%) ($p<.001$).

Safety practices. From pre- to post intervention, chart reviews revealed significant improvements in four of the five measures of abnormal test follow-up: result not in chart (2.2% vs. 0.8%; $p<.001$), action plan not documented (20.4% vs. 14.4%; $p<.001$), patient not notified (20.8% vs. 15.0%; $p<.001$), and action plan not completed (19.3% vs. 10.8%; $p<.001$). Chart reviews from pre- to post intervention showed improvement in the rates of potential risks: per 1,000 patients with an abnormal lab result, rates of potential safety risks decreased from 155 to 54 and rates of serious potential safety risk decreased from 28 to 13 ($p<.05$).

Patient and staff perceptions and attitudes. Survey responses from patients before and after the intervention were positive or very positive across most domains. At pretest, patients provided more than 500 comments in response to an item requesting suggestions for the doctor's office to improve the care and services it provides. The Improvement Advisors shared the results with providers at their respective sites, who appreciated the suggestions and took them into consideration when planning improvement activities. No significant pre- to post intervention improvement in the intervention sites compared with the control sites was found. However, among intervention sites, those identified by Improvement Advisors as more engaged had significant patient-rated improvement in some domains than those identified as less engaged.

Survey responses from clinic providers and staff before the intervention revealed a lack of fully implemented safety systems and processes in at least one-third of practices, which—in combination with communication and safety culture problems—"frequently left staff feeling vulnerable to malpractice suits." Respondents felt the least positive in the areas of referral management safety, talking openly about safety problems, willingness to report mistakes, and feeling rushed while caring for patients.

From pre- to post intervention, intervention sites had greater improvement on mean staff ratings than control sites overall and in the three high-risk domains targeted by the intervention; however, these differences were not significant. Based on mean scores, intervention sites improved relative to control sites on 9 of the 11 domains, with no significant differences. In an analysis of the percent of negative responses, intervention sites improved relative to control sites on 7 of 11 domains, with significant differences in test results management ($p<.001$) and teamwork ($p<.05$). Few significant differences were detected across the domains between intervention sites identified by Improvement Advisors as more engaged versus less engaged.

In exit interviews, primary care practices provided positive feedback on PROMISES, particularly the individualized support from coaches, participation in the learning collaborative, and use of the Model for Improvement and PDSA cycles.

Selected Publications and Presentations Developed by Grantee

Kerrissey M, Satterstrom P, Leydon N, et al. Integrating vs. isolating: The integrative role of clinic managers in improving primary care. Manuscript in preparation. 2015.

Reyes Nieva H, Foskett C, O'Malley M, et al. Baseline malpractice and safety risks in 3 key areas: Failures in high-risk outpatient test, referral, and medication management and documentation. Manuscript in preparation. 2015.

Schiff G, Griswold P, Ellis BR, et al. Doing right by our patients when things go wrong in the ambulatory setting. Jt Comm J Qual Patient Saf. 2014;40(2):91-96. PMID: 24716332.

Schiff G, Puopolo AL, Huben-Kearney A, et al. Primary care closed claims experience of Massachusetts malpractice insurers. JAMA Internal Medicine. 2013;173(22):2063-2068. PMID:24081145.

Singer SJ, Reyes Nieva H, Brede N, et al. Evaluating ambulatory practice safety: the perspectives of administrators and practice staff. Med Care. 2015; 53(2):141-152. PMID: 25464161.

Selected Other Products Developed by Grantee

- When Things Go Wrong in the Ambulatory Setting, a 4-page tool published in 2013 that is a companion to When Things Go Wrong: Responding to Adverse Events (2006)
- When Things Go Wrong in the Ambulatory Setting video, available at https://vimeo.com/76550944
- PROMISES Patient Safety Curriculum, 14 Web-based modules and materials (e.g., videos, handouts, tools) to improve patient safety in the ambulatory setting
- Continuing medical education (CME) materials for sessions that involve practice coaches and an interpractice collaborative learning network (CME credit was available through the Massachusetts Medical Society Web site, http://www.massmed.org/Continuing-Education-and-Events/Online-CME/Online-CME-Courses/#.U6olH_ldVvU)
- Evaluation tools, including patient survey, staff and provider survey, administrator survey, chart review instrument, qualitative exit interviews instrument, and analysis of practice change management
- Malpractice closed claims database
- Automated, abnormal lab query reports in collaboration with Quest Diagnostics, Inc., for assistance with PROMISES postintervention chart review.
- PROMISES project Web site, www.brighamandwomens.org/pbrn/promises, that includes many of the project's products

Source Documents for This Grantee Profile

Biondolillo M, Schiff GD. PROMISES Project. Final Progress Report. Prepared by Massachusetts State Department of Public Health under grant number R18 HS019508. Prepared for the Agency for Healthcare Research and Quality. Boston, MA; Mar 2014.

Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324(6):370-376.

Schiff G, Reyes Nieva H, Griswold P, et al. Reducing ambulatory safety risk: Results of Massachusetts PROMISES project. Manuscript in preparation. 2015.

Appendix B: References

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2. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Ann Intern Med. 2010;153(4):213-221. PMID: 20713789.

3. Mello MM, Greenberg Y, Senecal SK, Cohn JS. Case outcomes in a communication-and-resolution program in New York hospitals. Manuscript submitted for publication. 2015.

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11. Santos P, Ritter GA, Hefele JL, et al. Decreasing intrapartum malpractice: Targeting the most injurious neonatal adverse events. J Healthc Risk Manag. 2015 Apr;34(4):20-27. PMID: 25891287.

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16. Schiff G, Reyes Nieva H, Griswold P, et al. Reducing ambulatory safety risk: Results of Massachusetts PROMISES project. Manuscript submitted for publication. 2015.

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