Progress at the Intersection of Patient Safety and Medical Liability: Insights from the AHRQ Patient Safety and Medical Liability Demonstration Program

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Objective. To identify lessons learned from the experience of the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Medical Liability (PSML) Demonstration Program.

Data Sources/Study Setting. On September 9, 2009, President Obama directed the Secretary of Health and Human Services to authorize demonstration projects that put “patient safety first” with the intent of reducing preventable adverse outcomes and stemming liability costs. Seven demonstration projects received 3 years of funding from AHRQ in the summer of 2010, and the program formally came to a close in June 2015.

Study Design. The seven grantees implemented complex, broad-ranging innovations addressing both patient safety and medical liability in “real-world” contexts. Some projects featured novel approaches, while others implemented adaptations of existing models. Each project was funded by AHRQ to collect data on the impact of its interventions. In addition, AHRQ funded a cross-cutting qualitative evaluation focused on lessons learned in implementing PSML interventions.

Data Collection/Extraction Methods. Site visits and follow-up interviews supplemented with material abstracted from formal project reports to AHRQ.

Principal Findings. The PSML demonstration projects focused on three broad approaches: (1) improving communication around adverse events through disclosure and resolution programs; (2) preventing harm through implementation of clinical “best practices”; and (3) exploring alternative methods of settling claims. Although the demonstration contributed to accumulating evidence that these kinds of interventions can positively affect outcomes, there is also evidence to suggest that these interventions can be difficult to scale.

Conclusions. In addition to producing at least preliminary positive outcomes, the demonstration also lends credence to the idea that targeted interventions that improve some aspect of patient safety or malpractice performance may also contribute more broadly to institutional culture and the alignment of all parties around reducing risk

and preventing harm. However, more empirical work needs to be carried out to quantify the effect of such interventions.

Key Words. Patient safety, adverse events, medical error, medical malpractice, claims, disclosure, offer

Under the Patient Safety and Medical Liability Demonstration Program, AHRQ funded a diverse set of health care and legal system interventions, aimed at improving some aspect of patient safety and malpractice outcomes, and (more fundamentally) the medical–legal environment in which those outcomes occur (Battles, Reback, and Azam 2016). Each of the seven demonstration grantees implemented complex, broad-ranging innovations in “real-world” contexts. Some projects featured novel approaches, while others put into practice continuations, replications, or adaptations of existing models. The PSML 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 was completed by June 2014; the New York project received an extension through June 2015.

Each PSML demonstration project was funded by AHRQ to collect data on the impact of its own interventions. In addition to providing funds to each project for a local evaluation, AHRQ also contracted with James Bell Associates (JBA), an evaluation research firm, and the RAND Corporation, a nonprofit research organization, to conduct an independent evaluation of the PSML Initiative. Although the cross-cutting evaluation plan initially included both quantitative and qualitative elements, it soon became apparent that the PSML demonstration grants were highly varied in the specific interventions that they fielded; in the relevant outcomes that they attempted to impact; and in the degree to which they were successful in collecting data to measure those outcomes. Because of this heterogeneity, together with the lack of a common data infrastructure for capturing adverse event and malpractice claims, qualitative assessment of the PSML demonstration program became the focus for the cross-cutting evaluation. Case-study methods were used to glean significant insight into each of the PSML demonstration projects and to understand

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how a common set of barriers and facilitators impacted implementation and outcomes across the sites.

METHODS

The evaluation of the PSML demonstration aimed to describe the antecedent conditions and context into which the PSML projects were introduced; assess grantee progress in accomplishing the intent and objectives of the program; and determine the overall impact of the program, including diffusion of program-related interventions beyond the projects funded by AHRQ. It was designed to provide ongoing feedback to AHRQ and to the demonstration projects. In accordance with AHRQ specifications, the evaluation was based on the CIPP (context, input, process, product) evaluation model, an approach to evaluating system improvement that includes a broad spectrum of factors that can affect program performance (Stufflebeam 2003).

A final evaluation report on the PSML demonstration was provided to AHRQ in 2016 (Pillen et al. 2016). This paper reports on findings from the process evaluation—which focused on lessons learned in implementing PSML interventions. Data for the process evaluation were derived from site visits conducted at two points in time (early and late in the demonstration) by multidisciplinary teams led by senior qualitative researchers using a semi-structured interview guide and consisting of interviews with the project leadership and a broad range of stakeholders in each of the seven demonstration sites. Site visit interview data were supplemented with annual follow-up telephone interviews with the project leaders and material abstracted from annual project reports to AHRQ. In the next two sections, we describe our findings and observations, supported by these interview and documentary data.

FINDINGS FROM PSML DEMONSTRATION SITES

The PSML demonstration projects focused on three broad approaches to improving patient safety and reducing medical liability: (1) improving provider–patient communication around adverse events through disclosure and resolution programs, (2) preventing harm through the implementation of clinical “best practices,” and (3) exploring alternative methods of settling claims.

Improving Provider–Patient Communication through Disclosure and Resolution Programs

Four of the PSML 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), which were loosely based on a model developed at the University of Michigan Health System (Boothman et al. 2009; Boothman, Imhoff, and Campbell 2012). Under a DRP, 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 to the injured party (or their family). A DRP seeks to reduce litigation pressure by enhancing open communication between provider and patient in the wake of an adverse event and facilitating an offer of compensation, when appropriate, without the need for the patient or family to resort to litigation. A DRP can also improve patient safety outcomes if it is set up to identify patient safety problems that are then prioritized and addressed by a well-functioning patient safety improvement infrastructure in the hospital. As argued by Boothman, the intent of the DRP is to improve transparency and accountability to patients and families—not just to improve the efficiency of malpractice claims management (Boothman 2016).

The PSML experience showed that building robust DRPs involves serious challenges for both implementation and evaluation. For example, convincing hospitals to establish and abide by a DRP, when that program did not originate from within the hospital itself, requires nontrivial effort, significant culture change, and serious financial and infrastructure commitments. Although DRP interventions have the potential to reduce malpractice risk, they also have the potential to shift risk in complex ways among a hospital, its physicians, outside liability insurer(s), and patients. Various difficulties in aligning the interests of these stakeholder groups, and in building institutional support for DRP adoption, were a challenge described by several of the PSML demonstration projects. The challenge was not fully overcome by any of them.

Thus, although there is accumulating empirical evidence (including some from the PSML portfolio) that DRPs can positively affect both patient safety and malpractice outcomes (Kraman and Hamm 1999; Hersch, O'Connell, and Viscusi 2006; Boothman et al. 2009; Kachalia et al. 2010;

McDonald et al. 2010; Helmchen, Lambert, and McDonald 2016; Lambert et al. 2016; Mello et al. 2016b), there is also ample evidence from the PSML portfolio to suggest that DRPs are difficult to scale, to disseminate, and to implement across multiple institutions and in nonacademic settings (Mello et al. 2014). For example, in the New York project, hospitals implemented the “disclosure” part of the model but struggled to implement “resolution” when it involved making an unsolicited offer of compensation. Fear lingered that introducing a discussion of compensation would encourage litigation (Mello et al. 2016b). The Illinois project demonstrated the impact of “Seven Pillars” in its academic medical setting (Lambert et al. 2016) but failed to produce impact data for the replication of the model across the 10 participating community hospitals. In the Washington project, very few claims were referred to the nascent DRPs—starving the project of any demonstrable quantitative impact (Mello et al. 2016a). The Texas project implemented in a state with a “low-tort” environment—where the malpractice litigation risk for a public university was already diminished substantially (Sage, Harding, and Thomas 2016). The fact that challenges were encountered across the PSML portfolio of demonstration projects in no way diminishes the accomplishments of individual projects, but the failure to fully implement in nonacademic settings leaves an unanswered policy question. At present, there is no empirical evidence for speculating on the outcomes that reasonably could be expected from DRP implementation across a broad range of hospital types (such as academic medical center versus community hospital, fully insured versus self-insured, and urban versus rural) because the PSML demonstration program was unable to implement DRPs at scale in nonacademic settings and because no other studies that have included a broad range of hospital types have been published to date.

Preventing Harm through Best Practices

Three PSML 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 clinical “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 (for example, making sure laboratory test results are

communicated to the ordering clinician and to the patient) in a group of ambulatory primary care practices (Schiff et al. 2016).

Several broad observations about these projects are salient. First is that two of the three demonstration projects achieved some positive impacts on patient safety outcomes (Burststein et al. 2016; Riley et al. 2016a,b). Second, although these demonstration projects also intended to assess the impact of best practice adoption on malpractice claiming, only one of the projects was successful in testing this possibility because of varied resource, data, and empirical design limitations. One project documented a significant reduction in perinatal claims in participating hospitals—while there was no significant decrease in nonperinatal claims in the same hospitals (Riley et al. 2016b). Finally, as with the DRPs described above, these grantees also faced some serious implementation challenges in scaling up on a multi-institution basis.

Exploring Alternative Methods of Settling Claims

One of the PSML demonstration projects sought to improve the dispute resolution process after the filing of a malpractice claim. The New York State Unified Court System worked with the New York State Department of Health and five academic medical centers on a multifaceted approach to improving patient safety and reducing malpractice litigation. It was originally designed with the idea that patient safety interventions in hospitals would reduce adverse events and thus claims. The thinking was that DRPs would be utilized by each of the hospitals to disclose adverse events, and the investigations would lead to litigation-reducing decisions by the hospitals, including providing apologies and offers of compensation. But if claims were nevertheless filed through the court system, a “judge-directed negotiation” program, expanded from an existing program (McKeon 2011–2012), would expedite settlement of those claims. Judge-directed negotiation focuses on early court intervention with the presiding judge facilitating negotiation among attorneys about claims and potential settlements. This type of early intervention accelerates the movement of cases through the claims process; increases the number of settlements; and, over time, lowers malpractice costs and premiums for the participating hospitals.

Hospital leadership and staff were enthusiastic about implementing judge-directed negotiation. Participation was viewed as both helpful and cost reducing. Anecdotal accounts have credited the program with decreasing the number of malpractice claims and annual costs to participating hospitals by a

material amount (Gamboa 2013); however, as of this date no results from the formal evaluation have been published.

OBSERVATIONS AND SUGGESTIONS TO IMPROVE FUTURE EFFORTS

A natural question to ask is, what have we learned across the PSML demonstration projects? Each demonstration grantee was funded by AHRQ to collect data on the impact of its intervention(s). Some grantees focused on assessing the impact of interventions on malpractice outcomes, but others focused their assessment on patient safety outcomes such as changes in patient safety culture in institutions. All seven 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 lessons about what it takes to develop and sustain an operational patient safety and medical liability program. However, in spite of these achievements and development of useful products, a number of the grantees struggled to produce outcomes data that were timely in collection, inclusive of patient safety and medical liability outcomes pertinent to the interventions being piloted, and sufficiently robust (i.e., with comparison populations) to support causal inference. A few observations below help to explain the grantee experiences.

Efforts to Intervene in Patient Safety and Malpractice Liability Are Complex and Varied

In its RFP, AHRQ deliberately set out a broad agenda for this body of work, inviting applicants to proffer diverse ideas. Applicants for the PSML demonstration grants were required to address *both* patient safety and malpractice liability outcomes. However, AHRQ did not specify how patient safety and medical liability were supposed to fit together in the demonstration projects, and the grantees varied considerably in how they sought to bridge those issues. Because there is more than one way to intervene with patient safety and malpractice risk, PSML demonstration projects are not directly comparable to one another, nor are they all aimed at affecting the same outcome variables.

Conceptually, patient safety performance in a hospital is both a *precursor* to malpractice litigation (i.e., through the occurrence of adverse events that give rise to litigation) and also a *consequence* of malpractice litigation (which can either serve to harden adversarial positions or promote change). Interventions to address PSML are similarly varied. Efforts to improve patient safety outcomes can, in principle, lead to corresponding reductions in malpractice claiming. And likewise, efforts to reduce malpractice litigation can, in principle, help to strengthen provider efforts to address the system failures that give rise to adverse events. Meanwhile, each of these conceptual vectors is itself a complex pathway. The PSML demonstration program was noteworthy for the ambition to intervene on both pathways, but also for the lack of clarity in distinguishing between them.

Loosely speaking, the clinical patient safety interventions that were implemented by several of the PSML projects (e.g., best practices in obstetrics) can be understood as addressing the first causal pathway, while the DRPs can be understood as addressing the second. Notably, efforts to document the impact of any of these interventions require adequate time and robust data. Both time and data limitations proved to be very challenging for the PSML demonstrations, given the way that these were structured. Future PSML demonstration and evaluation efforts will be strengthened by building in a considerably longer time period for implementation and data-gathering efforts and striving to improve PSML data infrastructure and common measures on a regional and national basis, as a fundamental building block for future intervention efforts along these lines.

There Is No Single, Most Relevant Set of Measures for Capturing PSML Outcomes across Diverse Studies

Expanding on the last point about data infrastructure, it is important to recognize that future PSML interventions are unlikely to be reducible to a single set of common outcome measures across diverse clinical settings, widely varying types of interventions, and competing causal perspectives that either try to influence malpractice outcomes through patient safety interventions or patient safety outcomes through malpractice interventions. In light of the complexity of this landscape, there is no single data pipeline for capturing relevant measures in a consistent way. Patient safety interventions may be focused on narrow clinical contexts (e.g., reducing preventable injuries in labor and delivery) that put boundaries on the relevant outcome metrics, in ways that are both challenging to capture and may legitimately involve the use of

noncomparable patient safety outcome measures across studies. Meanwhile, our search for a national source for meaningful and consistent data on malpractice claims failed to uncover one—other than the National Practitioner Data Bank, which has some significant limitations (Mello 2016).

Given these sorts of conceptual and architectural challenges, it is important that those who decide to field PSML interventions in the future adopt reasonable starting assumptions about data and measurement. Future studies could be facilitated by starting from a clear understanding of the data that are readily available to assess key outcomes of interest, and how those data correspond to any existing regional or national resource for warehousing similar data. Here again, improving the national data infrastructure on patient safety and malpractice performance could offer a focal point for future efforts, and particularly so with regard to data on malpractice claims.

“Time” as a Basic Design Challenge for PSML Intervention Projects

One of our earliest observations from the struggles of the PSML grantees involved the problem of the malpractice “claims tail” (i.e., that malpractice claims frequently take years from discovery to claim to resolution—whether through settlement or litigation). Outcomes research on malpractice claims, consequently, requires years of observation and data collection to carry out, quite apart from any time that is involved in actually fielding a PSML intervention. When taken together with the time that is required to start up a DRP or best practice intervention in multiple sites and to gather baseline performance data, the implication is that a PSML demonstration project is more likely to require 6–10 years, rather than 3–4 years (which was the PSML demonstration grant period).

CONTRIBUTIONS OF THE PATIENT SAFETY AND MEDICAL LIABILITY INITIATIVE

What can the health care and policy communities learn from the PSML initiative? Importantly, PSML grantees generated a plethora of tools, training modules and curricula, program models, evaluation instruments, videos, written products, and other materials that have the potential to spur or assist in the replication of these PSML interventions elsewhere—and in the development of new PSML innovations.

Additionally, preliminary findings from several of the PSML demonstration projects suggest positive (or at least promising) outcomes associated with some facet of the interventions, either in terms of patient safety performance, malpractice claiming, or both. These findings suggest that under the right conditions, PSML interventions can have a positive impact on various facets of malpractice and patient safety performance within the health care and civil justice systems. An equally important aspect of the learning generated by the PSML demonstration involves the implementation barriers and challenges they encountered and their efforts to overcome them. 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 PSML portfolio itself.

It is important to point out that the initial plans for the PSML portfolio (dating back to AHRQ's original Request for Proposals) implicitly assumed that (1) all the PSML projects would tie patient safety and malpractice liability together; (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 to implement the demonstration projects and collect and analyze data on all relevant outcomes. None of these initial assumptions proved to be true. Partly in consequence, results across the PSML portfolio cannot easily be reduced to a simple quantitative "box score" or effect size estimate.

Notwithstanding the fact that some initial expectations for the PSML demonstrations were unrealized and formal outcomes data and analysis from the PSML projects are limited (as reflected by the papers in this special issue), the projects have nevertheless contributed many useful and important lessons to the field's knowledge base. For example, several of the PSML projects did useful piloting, replication, and dissemination work on DRPs. The projects helped to identify the conditions under which such programs can readily be adopted and conditions under which their adoption becomes more difficult. The projects showed that under optimal conditions, DRPs can produce measurable, positive impacts on a series of patient safety and medical liability outcome measures (Lambert et al. 2016). The projects also showed 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 (Mello et al. 2016a,b); and the early offer (or "resolution") component of DRPs tends to be more difficult to carry out than the disclosure (or "communication") component (Mello et al. 2016a,b).

Meanwhile, several of the projects generated positive preliminary findings of improved safety practices based on adoption of clinical “best practices.” With this being acknowledged, future efforts to prevent harm through adoption and diffusion of best practices will likely confront two fundamental problems. One involves documenting that such interventions go beyond improving patient safety outcomes to show that clinical best practice interventions are also associated with improvements in malpractice outcomes for providers. A second problem is that best practice interventions tend to be specific to a particular clinical context. Thus, future studies of best practice adoption will likely be needed in *many* different clinical domains to gradually build an empirical base for broadly concluding that such interventions “work” to protect physicians from malpractice litigation and their patients from adverse events.

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 the PSML projects, the nature of the “culture” focus varied. Regardless, hospital “culture” is interesting as a mediating variable in that it does not directly translate into either patient safety or malpractice outcomes, but nevertheless has the theoretical potential to influence both. The work of the PSML demonstration projects in carrying out innovations such as measuring “disclosure” culture (Etchegaray et al. 2012); collaborating with regulators to respond to adverse events (Gallagher et al. 2016a); and involving patients and family members in disclosure and resolution efforts (Etchegaray et al. 2016; Gallagher et al. 2016b) could offer a lode-star to future efforts in this area, and consequently to the design of new interventions in the patient safety and malpractice policy space.

CONCLUSION

In the wake of the PSML initiative, continuing efforts to reduce preventable adverse events will remain a high priority for the U.S. health care system. Meanwhile, concerns about malpractice liability and cost will likewise continue to generate debate and controversy among policy makers. In our view, what was most innovative about the PSML portfolio was the simple idea that these two problems can be understood as fundamentally related and (therefore) addressed simultaneously. This basic idea comports well with the last decade of the U.S. patient safety movement and the underlying belief that adverse events in health care are better understood as the result of complex

“systems” failure, rather than of individual negligence. In part, the response of the health care system has been to try to analyze adverse events, prevent their recurrence, and to become more transparent and responsive while carrying out related self-improvement processes. None of this logic aligns well with traditional malpractice liability, which instead assumes fault on the part of individual providers, and which creates an adversarial incentive to defend and protect against potential claims, rather than to collaborate in investigating and reducing risk. Whatever viewpoint one has regarding the merits of statutory tort reform, one thing most people can agree on is that if other factors are held constant, it would be a good idea to reduce preventable injury rates in health care settings.

The PSML portfolio has demonstrated that related, large-scale interventions can be fielded and such interventions can produce at least preliminary positive outcomes in some important ways. The PSML demonstration also lends credence to the idea that targeted interventions that improve some aspect of patient safety or malpractice performance may also contribute more broadly to institutional culture and to the alignment of all parties in the system around reducing risk and preventing harm. Analytically, more work needs to be carried out to quantify the effects of PSML interventions in the future. And practically, new PSML interventions will need to demonstrate that they can overcome substantial implementation barriers in order to scale and to achieve meaningful systems change in new locations and settings.

President Obama’s purpose in authorizing the PSML initiative was not to focus on traditional malpractice reform as a “silver bullet” but instead to stimulate the development of a range of innovative ideas that put “patient safety first and let doctors focus on practicing medicine” (Obama 2009). The legacy of the PSML initiative is that it accomplished the goal of addressing the challenges of the current medical liability system using a nontraditional approach. The PSML initiative empowered states and health care organizations to think “outside the box” about innovative 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. Whereas the quantitative results on the impact of the innovations are equivocal, in part because of time and resource limitations, the products available from the grantees and the lessons learned from the PSML demonstration program provide direction for policy makers, health care institutions, and practitioners to continue on the path initiated by the President. Much work has been carried out; much more work remains. Some of this work can be

funded by AHRQ as an extension of its current activities—but other funders need to be involved.

The current portfolio of PSML demonstration grants can reasonably be viewed as the first step in a longer term effort to build replicable models as well as a national capacity for tracking and evaluating new policies and programs on medical liability and patient safety. A reasonable next step is to incorporate what was learned through the PSML demonstration—and subsequent efforts—to identify the *most promising* models for a much more rigorous “road test” in multiple host organizations around the country. In any future demonstrations, a particular focus should be placed on (1) planning for, monitoring, and troubleshooting implementation of the chosen 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 (4) choosing investigators and host organizations that have a demonstrated capacity for longitudinal data collection.

Future funders of this work (including AHRQ) also need to proactively address the data challenges. 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 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; however, 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.

In addition, future work on “best practices” would be a natural extension of AHRQ’s existing efforts to disseminate and encourage the uptake of models (such as patient safety “bundles”) aimed at reducing variation in care and improving patient safety. 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.

Finally, two of the PSML demonstration projects together 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 already gather in root cause analysis and other investigatory processes? What is unique (if anything) about the contribution the patient voice can make? These intriguing questions have been raised, but not fully answered, by the work of these grantees. More emphasis on—and exploratory work examining—the role of patients and families in the investigation and remediation of patient safety problems is long overdue.

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SUPPORTING INFORMATION

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

Appendix SA1: Author Matrix.