Agency for Healthcare Research and Quality

Medical Liability Reform and Patient Safety Initiative Progress Report

Introduction

One of our major goals is to prevent patients from being injured in the course of their care and ensure that they receive high-quality, evidence-based services. When patients are injured, they are not always well-served by a medical liability system with high overhead costs that often fails to compensate those who are harmed through negligence. In addition, the medical community reports serious problems with the medical liability system, such as it does little to promote patient safety and higher quality care and leads to the provision of unnecessary medical procedures.

On September 9, 2009, President Obama directed the Secretary of Health and Human Services to establish an initiative that would help States and health care systems test models that meet the following goals:

- Put patient safety first and work to reduce preventable injuries.
- Foster better communication between doctors and their patients.
- Ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits.
- Reduce liability premiums.

In June 2010, the Agency for Healthcare Research and Quality (AHRQ) announced $23.2 million in funding for seven 3-year demonstration grants, thirteen 1-year planning grants, and a contract to evaluate the initiative and its projects. The Medical Liability Reform and Patient Safety Initiative is now well underway. The demonstration grants have been in place for approximately 18 months and will operate through June 2013. Further, a number of the planning grants have been completed, and others will be finalized in the coming months.

This progress report provides a description and early observations of the planning and demonstration projects funded under the initiative. JBA/Rand received a contract to conduct a comprehensive evaluation of the initiative after the project concludes to provide an assessment of findings from multiple grants across the entire initiative. This evaluation will help to answer questions about the effects of various interventions on issues such as patient safety, liability premiums, communication between doctors and their patients, the timeliness and fairness of compensation for medical injuries, and the number of medical liability lawsuits.

Development of the Initiative

In the fall of 2009, AHRQ consulted with a broad range of experts and stakeholders regarding medical liability reform, reviewed the landscape of existing evidence, and released Funding Opportunity Announcements (FOAs) for the Medical Liability Reform and Patient Safety Initiative in October 2009. The FOAs invited partners in the medical and research communities to submit proposals for innovative projects that would improve the quality of care and patient safety, compensate fairly and expeditiously patients who are harmed, reduce liability premiums and the costs associated with defensive medicine, and reduce the number of frivolous lawsuits.

Stakeholder Input

In October 2009, the ad hoc Patient Safety and Medical Liability Reform Subcommittee of the AHRQ National Advisory Council held a day-long, public meeting on the pending initiative. The 27 members of the Subcommittee represented a broad range of stakeholders from consumer organizations, legal groups, medical societies, the insurance industry, institutional health care, and Federal and State governments. Members heard public testimony and discussed the initiative and what it should achieve.

Several themes emerged throughout the meeting:

- Many innovative and promising models for medical liability reform already exist — that is, idea generation does not need to start from scratch — but these models have not been rigorously tested or evaluated.
- For new evidence to translate into meaningful change, projects should include broad sets of stakeholders, not just researchers.
- Successes achieved in individual projects should be scalable to other States.

All meeting materials and conclusions are posted on the AHRQ Web site (http://www.ahrq.gov/qual/liability/).

Review of Existing Evidence

Additionally, AHRQ researchers thoroughly examined the literature regarding the impact of medical liability reforms on the frequency and size of malpractice claims, malpractice costs, and patient safety. They found some research on the impact that various medical liability system reforms had on the frequency and severity of malpractice claims, but scant evidence exists on how reforms affect patient safety. The results of their literature review were posted on the AHRQ Web site on December 31, 2009, and public comments were accepted for a 3-month period (http://www.ahrq.gov/qual/liability/reforms.htm).

Funding Opportunity Announcements

In October 2009, AHRQ announced two funding opportunities for the clinical and research communities to participate in the Medical Liability Reform and Patient Safety Initiative:

- *Demonstration grants*. Grants for up to 3 years for up to $3 million each were to be given on a competitive basis to States and health systems for implementation and evaluation of evidence-based medical liability reform and patient safety demonstrations.
- *Planning grants*. Grants for up to 1 year for up to $300,000 each were to be given on a competitive basis to States and health systems that want to plan evidence-based medical liability reform and patient safety demonstrations. Planning grant recipients were also eligible for technical assistance.

AHRQ received 40 applications in response to the FOA for demonstration grants and 24 applications for planning grants. All applications underwent rigorous peer review by independent, scientific experts, followed by internal reviews of those applications that met the peer-review standard. Award decisions were based on peer review, program balance, technical merit, and feasibility.

In June 2010, AHRQ announced $23.2 million in funding for seven 3-year demonstration grants ($19.7 million total) and thirteen 1-year planning grants ($3.5 million total), and a contract to evaluate the initiative and its projects. The seven demonstration grants are now halfway through the 3-year demonstration period and have made significant progress during their first 18 months. Eight planning grants are in their last stages and will be completed shortly, and five planning grants were given extensions into 2012.

Selected Projects: Focusing on Areas of Promise

Although all of the projects are unique, they generally incorporate the following categories of patient safety and medical liability reform innovations; some projects include elements from more than one category.

- *Preventing Harm Through Best Practices*. These projects seek to improve care in clinical areas that frequently are the subject of a large number of medical malpractice claims. In doing so, they will test whether implementing new ways to prevent medical errors and poor health outcomes can improve patient safety and reduce the number of malpractice lawsuits.
- *Improving Communication With Patients.* These projects seek to understand how health care providers can best communicate medical errors and incidents of medical negligence to patients and their families so that all involved understand the situation and their options for prompt and fair resolution. In doing so, they will test whether better communication can lead to fewer lawsuits, fairer and faster compensation, and improved patient safety.
- *Alternative Methods of Dispute Resolution.* These projects seek to improve dispute resolution after a malpractice claim has been filed. Investigating new methods for negotiating settlements may prevent protracted legal battles that delay resolutions for patients and their families.

Descriptions of Demonstration Grants

Following are descriptions of the seven demonstration grants, including the status of each project and early observations based on the projects' first 18 months, when available. None of these projects has been completed or formally evaluated, so observations here may differ from the final conclusions drawn from the comprehensive evaluation that JBA/Rand will conduct when the initiative concludes in 2013.

Preventing Harm Through Best Practices

Fairview Health Services, Minneapolis, MN *Award: $2,982,690*
Primary Investigator: Stanley Davis, M.D.
7/1/10 - 6/30/13

The objective of this project is to improve perinatal (the period prior to and just after birth) patient safety and demonstrate the relationship between improved patient safety and a reduction in the number of malpractice claims. Funding through AHRQ extended a national collaborative that aims to reduce preventable birth-related injuries. Specifically, Fairview Health Services has implemented and will evaluate the use of perinatal best practices in 16 hospitals, representing 12 States. These best practices are designed to significantly lower the incidence of certain infrequent, though serious, injuries that could result in a wide range of harmful outcomes, including birth asphyxia or permanent neurologic disability.

The research team completed a baseline analysis of data on birth injuries and previous medical liability claims and litigation. All hospitals participating in the project have received teamwork training using simulation and TeamSTEPPS®, a system designed for health care professionals to improve communication and teamwork skills to improve patient safety within a health care organization.

Early Observations

- All participating hospitals have demonstrated high compliance with the improvement interventions, resulting in a significant reduction in the number of adverse events. These preliminary results will be monitored as the project continues, and a detailed evaluation will be conducted upon completion.

Ascension Health System, St. Louis, MO *Award: $2,990,612*
Primary Investigator: Ann Hendrich, M.S., R.N., F.A.A.N.
7/01/10 - 6/30/13

The goal of this project, entitled "Excellence in Obstetrics," is to identify the best methods to reduce or eliminate birth complications. The project focuses on shoulder dystocia, a common birth injury that occurs when a baby's shoulder becomes lodged behind a mother's pubic bone and prevents normal delivery of the shoulders and body. Serious long-term effects may occur if the shoulder is not dislodged and the baby is not delivered in a timely manner. Ascension has established a uniform, evidence-based obstetrics practice model based on the idea that eliminating variation in obstetrics practice will translate to improved patient safety. Baseline data has been collected in five Ascension hospitals in Alabama, Florida, Maryland, Michigan, and Wisconsin.

Early Observations

- There have been no liability cases or notices of intent to file lawsuits for shoulder dystocia since the project started. Historical rates from the five participating hospitals suggest that at least three cases would have been filed in this time period, absent this project's interventions.

- Occurrences of shoulder dystocia have been significantly under reported in the past. Since the project began, there has been a threefold increase in the reporting of shoulder dystocia but also a dramatic reduction in the severity of cases reported.[1]

- Since the project began, the number of birth traumas has decreased significantly in the 5 project hospitals compared with the 32 control hospitals in the system. This preliminary result will be monitored as the project continues, and a detailed evaluation will be conducted upon completion.

<u>Improving Communication With Patients</u>

University of Illinois at Chicago, IL *Award: $2,998,083*
Primary Investigator: Timothy McDonald, M.D., J.D.
7/1/10 - 6/30/13

[1] Efforts to enhance transparency and safety culture often result in increased reporting of events but a decrease in severity.

The objective of this project, which is being spearheaded by the University of Illinois at Chicago's (UIC's) Institute for Patient Safety Excellence, is to obtain evidence regarding the impact on patient safety and litigation rates of programs that feature improved communication with patients, disclosure of adverse events, early offers of compensation to patients that have been harmed, and learning from mistakes. The project will expand to additional hospitals a process for responding to patient safety events that has been in place at UIC's medical center and its affiliated health clinics since 2006.

The process involves event reporting, investigation and root-cause analysis, communication and disclosure, apology and remediation, patient safety and systems improvements, data tracking and performance evaluation, and education and training. This demonstration project will expand UIC's program to nine diverse hospitals outside of UIC's system. The hospitals have been randomly assigned to use the "Seven Pillars" program, which consists of improved event reporting, event investigation, communication with patients, an apology and correction of the problem, investigation of findings, data collection, and education and training of staff. This will allow researchers to analyze the feasibility and effectiveness of the program to improve patient safety and reduce medical liability.

The research team has collected baseline data from these greater Chicago area hospitals in an effort to evaluate the impact of expanding UIC's model. The project emphasizes the involvement of resident physicians in reporting patient safety events, learning from these events, and using near-miss reports to improve safety.

University of Texas Health Science Center, Houston, TX *Award: $1,796,575*
Primary Investigator: Eric Thomas, M.D., M.P.H.
7/1/10 - 6/30/13

The project aims to evaluate how a model within the University of Texas (UT) system that informs injured patients and families promptly and makes efforts to provide prompt compensation affects patient safety and medical malpractice litigation. The project builds upon and further evaluates an error-disclosure program that has already been implemented in the UT system. The program incorporates patient and family input into efforts to understand why errors occur, and it places a special emphasis on training all resident physicians in these methods. The project has already identified best practices for using disclosure to improve patient safety and has disseminated them to serve patients' needs and improve safety for subsequent patients. One such best practice involves providing information to the patient at each step in the communication process as facts are revealed during an investigation. Ultimately, this may involve an apology, admission of unreasonable care, an acknowledgement of responsibility, and a correction of the problem.

University of Washington, Seattle, WA *Award: $2,972,209*
Primary Investigator: Thomas Gallagher, M.D.
7/1/10 - 6/30/13

This project includes development, implementation, and evaluation of a disclosure and resolution program (DRP) that entails early investigation and enhanced communication between the health care team and patient after an adverse event. Physicians Insurance and five partner sites are collaborating on

joint adverse event investigations, analyses, disclosure, and, when appropriate, compensation for patients. Hospitals and clinics, providers, and their insurers are using the process to respond promptly in a coordinated fashion when an adverse patient outcome occurs. Stakeholders who agree to participate in the DRP will tailor their system policies to align with the DRP process.

Massachusetts State Department of Public Health, Boston, MA *Award: $2,912,566*
Primary Investigator: Madeleine Biondolillo, M.D.
7/1/10 - 6/30/13

This project has engaged clinicians, patients, malpractice insurers, and the State public health agency to ensure more timely resolution of medical errors that occur in outpatient practices and improve communication in all aspects of care. It has identified key areas contributing to medical errors in outpatient settings and malpractice suits in an effort to redesign systems and care processes that will prevent, minimize, and mitigate such errors in a group of Massachusetts primary care practices. The project also is focused on transforming communication culture, processes, and outcomes in these practices so that they are more patient and family centered, particularly with respect to proactively seeking out, handling, and learning from patients' safety experiences, concerns, and complaints.

More than 30 primary care practices are enrolled in the project throughout Massachusetts. They reflect a representative sample of practices in the State, with an emphasis on small, one- or two-physician offices. Baseline data is now being collected at each of these practices. Half of the practices will receive a comprehensive patient safety intervention focusing on diagnostic errors, and the remaining practices will receive the intervention after the reporting period. Process improvement coaches — consultants who work with the practices — will help physicians identify deficiencies in areas, such as management of patient phone calls and communication of test results, and help them develop tailored solutions for problems they identify. The coaches will return after several months to determine the extent to which the practices made improvements to address the problems.

Alternative Methods of Dispute Resolution

New York State Unified Court System, New York, NY *Award: $2,999,787*
Primary Investigator: Judy Kluger, J.D.
7/1/10 - 6/30/13

This project aims to protect surgery patients from injuries caused by providers' mistakes and reduce the cost of medical malpractice through the use of an expanded and enhanced "judge-directed negotiation" program currently used in New York's courts, coupled with a new hospital early disclosure and settlement model. Under this model, a judge with expertise in medical matters becomes the point person when a plaintiff files a medical malpractice lawsuit. The judge supervises the entire process and convenes the parties to discuss the case and help broker a settlement. The judge facilitates the negotiations but does not impose a settlement amount. The plaintiff may move ahead with a lawsuit if the parties do not agree on a settlement. One significant advantage of this program is that it does not require any changes in law.

To date, more than 200 cases have gone through the judge-directed negotiation program, and the project has already been expanded the Erie County, New York, jurisdiction, which includes the Buffalo area. Key stakeholders are also involved in the program through a consortium of five major teaching hospitals in New York City, the New York State Department of Health, and New York City medical liability insurers.

Early Observations

- Judge-led conferences have not encountered any major obstacles, and, notably, far more judges signed up for training than initially expected. Attorneys have been receptive to a more hands-on approach to discovery and are very open to early settlement negotiations. Defense attorneys have demonstrated improved communication with hospitals and carriers regarding early case conferences.

Descriptions of Planning Grants

The 13 planning grants for the Medical Liability Reform and Patient Safety Initiative give States and health systems the opportunity to create detailed plans for patient safety and medical liability reform.

Preventing Harm Through Best Practices		
Johns Hopkins University	**Baltimore, MD**	**$293,224**
This project developed a measurement and analysis system to monitor the quality of care at hospital discharge to identify safety concerns and improve patient safety, alert Johns Hopkins leaders in real time of events that place the health care organization at risk for malpractice claims, and identify patient safety problems.		
Washington State University	**Pullman, WA**	**$298,810**
This project used stakeholder focus groups to design best practices for medication risk management systems to be used as patients transition between care settings. Researchers expect to demonstrate that integrating medication risk management efforts into transitional care models maximizes safety, quality, and cost-effectiveness while reducing medical liability.		
Ohio State University	**Columbus, OH**	**$187, 437**
This project planned an effective Statewide pregnancy-associated mortality review system in Ohio and developed comprehensive, coordinated Statewide recommendations with short- and long-term, evidence-based interventions focusing on patient safety to address maternal mortality and disparities. The project received an extension through February 2012.		
Jackson Memorial Hospital	**Miami, FL**	**$299,576**
This project developed and piloted a model to reduce patient suicides and suicide attempts at its health system by focusing on staff training, patient care, environmental safety, and incident reporting.		
North Carolina Department of Health and Human Services	**Raleigh, NC**	**$297,710**
This project implemented and examined a "near-miss" reporting and improvement tracking system in primary care. Analysis of near-miss safety events will be used to improve care practices.		
Carilion Medical Center	**Roanoke, VA**	**$280,924**
The project examined how improved teamwork — through better communication among providers, patients, and patients' families — can improve the quality of obstetrical care and patient safety and reduce risk and liability claims. The project received an extension through January 2012.		
Wishard Health Services	**Indianapolis, IN**	**$154,124**
The project collected, analyzed, and evaluated data regarding Wishard Health Services' Claims Management Model to promote open communication and identify risk-prone areas, ultimately increasing patient safety by removing risks early. This project received an extension through June 2012.		

Improving Communication With Patients		
University of Utah	**Salt Lake City, UT**	**$299,994**
This project implemented and evaluated a system-wide, evidence-based, ethical and legally sound policy on disclosing safety issues and other unanticipated outcomes of care. The goal was to develop a standardized protocol that will be used to disclose these events to patients and their families.		
University of Washington	**Seattle, WA**	**$295,837**

This project developed and implemented patient-friendly shared decisionmaking tools and processes for patients undergoing orthopedic surgery in the University of Washington Health Care System. Shared decisionmaking improves patient safety by enhancing patient understanding and empowering patients to actively participate in their care. This project received an extension through August 2012.		
Sanford Research	**Sioux Falls, SD**	**$294,137**
This project developed the infrastructure for implementing a patient advocacy reporting system throughout a multi-State, multi-facility system. This included improving the collection of information on patients' and families' concerns about their care and identifying the parts of the system and individual physicians with disproportionate risk for unsafe care and possible lawsuits.		
Multicare Health System	**Tacoma, WA**	**$291,810**
This project developed a plan for providing an acknowledgement, apology, and standardized compensation to patients who are harmed by avoidable patient safety problems.		
Beth Israel Deaconess Medical Center	**Boston, MA**	**$273,782**
This project developed a roadmap for implementation of a "disclosure-and-offer" patient safety initiative in Massachusetts. Based on this roadmap, Governor Deval Patrick introduced legislation in the State legislature that has strong support from a wide array of stakeholders.		

Alternative Methods of Dispute Resolution		
Office for Oregon Health Policy and Research	**Portland, OR**	**$299,458**
This project crafted a broadly supported "safe harbor" legislative proposal that defines a legal standard of care and offers an alternative method for medical liability compensation for care provided outside this legal standard of care. The project received an extension until March 2012.		

Next Steps for the Medical Liability Reform and Patient Safety Initiative

As the work of the Medical Liability Reform and Patient Safety Initiative continues, AHRQ will release a report each year on the progress and early observations of the demonstration projects. JBA/Rand will conduct a comprehensive evaluation of the initiative after the demonstration projects conclude in 2013. The evaluation will help to answer questions about the effects of various interventions on issues such as patient safety, liability premiums, communication between doctors and their patients, the timeliness and fairness of compensation for medical injuries, and the number of medical liability lawsuits.