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

Planning Grants Final Evaluation Report

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Contents

Executive Summary

On September 9, 2009, President Obama directed the Secretary of the U.S. Department of Health and Human Services (HHS) to establish an initiative to help States and health care systems test new models of care delivery, adverse event disclosure, and dispute resolution, with the joint aims of (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.

In response, the Secretary launched the HHS Patient Safety and Medical Liability Initiative in October 2009. Under this initiative, the Agency for Healthcare Research and Quality (AHRQ) funded 13 planning grants totaling $3.5 million. These funds aimed to help States, health systems, and risk management organizations plan for new programs, expand or modify existing resources, and conduct feasibility studies to explore the early phases of implementation and testing. The planning grants were originally scheduled to run for 1 year beginning in late summer 2010. Many of the grantees requested and received no-cost extensions of varying lengths. All the planning grants were completed by December 2012.

The planning grants were designed to provide initial funding to States and health systems so they could explore new initiatives that address patient safety and medical liability. Given their limited budget and time period, it was anticipated that the planning grants would result solely in preliminary findings, primarily lessons learned from laying the groundwork for future patient safety and medical liability reform projects.

Findings and Observations

In general, the funded projects covered three main areas, although there was some overlap in activities: (1) improving communication by assessing attitudes toward error and harm disclosure and implementing clinical communication interventions; (2) improving patient safety by measuring safety problems, characterizing adverse events, and conducting clinical safety interventions; and (3) exploring resolution methods as a means to divert potential claims out of the malpractice system.

Below, Table 1 lists each of the 13 projects, highlighting the project's main focus and summarizing selected findings. More detail about the individual projects (e.g., principal investigator, grant award amounts, goals, methods, activities) can be found in the grantee profiles in Appendix A.

Several general observations can be made about the experiences of the planning grants. Grantees who sought to improve communication learned that the beliefs, preferences, and behaviors of physicians play a key role in facilitating or impeding the adoption of new practices and processes. Taking the time to identify areas of shared agreement and concern regarding communication between patients and providers can help hone communication improvement efforts. Activities undertaken by the grantees that sought to improve patient safety appear to effectively identify the causes of and contributors to medical errors, and there appear to be some promising interventions and strategies available to prevent or minimize them. And finally,

promising alternative models exist for reducing liability costs and, at the same time, improving patient safety.

Table 1. Selected Findings by Focus Area and Planning Grant Organization

Areas of Focus	Organization	Summary of Selected Findings
Improving Communication	Carilion Medical Center	This project identified four obstetric events that varied in terms of risk and liability, but all required provider teamwork and the involvement of the patient and family members. About half of the identified individual, team, and system failures associated with these events were common to all four, suggesting that systemic changes could mitigate multiple events. Patients and family members who participated in an adapted TeamSTEPPS® training program demonstrated knowledge improvement in medical communication and teamwork, suggesting that the intervention may improve patient knowledge.
	University of Washington	Researchers planned for and implemented a shared decisionmaking (SDM) model in spine surgery clinics. The project culminated in the development of a train-the-trainer toolkit that integrates the processes developed and lessons learned. The toolkit is available online and can be implemented in other settings. A separate analysis of patient complaints indicated that 78% involved an element of informed consent or SDM and suggested that complaints involving informed consent or SDM represent significant potential cost savings.
	University of Utah	This project developed a 10-step protocol for disclosing unanticipated medical outcomes and implemented it across a large regional health system with a long history of collaboration and an established culture of patient safety. The protocol appears to be easily taught and well received by patients, family members, and physicians. A center was established at the University's School of Medicine to promote the inclusiveness of medical communication.
	Sanford Research	This project successfully planned for and implemented a Patient Advocacy Reporting System—which uses patient complaints to identify and intervene with physicians with high complaint levels—in a large multistate health care system. Analysis of previously collected patient complaint data suggests that patient complaints may be a predictor of adverse events.
Improving Patient Safety	Washington State University	The project found that medication discrepancies in the transition from hospital to home care occurred across all types of medications and in 41% of cases sampled in this study may have caused adverse drug events. Risk can be minimized with solutions that integrate medication risk management efforts into transitional care models.
	Johns Hopkins University	Analysis of hospital claims showed that suboptimal care at hospital discharge accounted for a considerable proportion of malpractice claims and involved failures in multiple domains of the hospital work system. To fill a gap in existing tools, two surveys were developed and tested to assess care transition quality and identify patients at risk of safety problems at hospital discharge. The

Areas of Focus	Organization	Summary of Selected Findings
		instruments can be further tested and revised for broader use.
	North Carolina Department of Health and Human Services	Pilot testing of a near-miss and remediation reporting system in primary care practices indicated that nearly half of near-miss events involved office administration, electronic medical records were associated with 14% of errors, and some of the near misses would likely have compromised patient safety. No significant implementation barriers were identified, and some sites continued to use the system. The project showed that near-miss reporting systems can be implemented for a fairly minimal cost and be used effectively to identify and remediate potential contributors to medical errors.
	The Ohio State University	Researchers successfully developed and refined a Pregnancy Associated Mortality Review (PAMR) for the State of Ohio. This work resulted in PAMR data and contributed to preliminary quality improvement initiatives to improve death certificate data, educate providers, evaluate readiness for patient safety initiatives, conduct reviews of maternal morbidity, and enhance stakeholder networking.
	Jackson Memorial Hospital	Researchers developed and pilot tested the Initiative to Reduce Inpatient Suicide model to intervene with hospitalized medical/surgical patients at risk for suicide. Pilot test results indicate a high rate of suicide risk among patients receiving inpatient care. More work is needed to improve the screening instrument, increase adherence to the model, and further train nurses in detecting and managing at-risk patients.
Exploring Resolution Methods	Beth Israel Deaconess Medical Center	The project resulted in a roadmap for starting a disclosure, apology & offer (DA&O) program in Massachusetts, historic partnerships between stakeholders coming to consensus on DA&O legislation, and State legislation allowing health care organizations to develop DA&O programs to settle malpractice claims. Stakeholders strongly supported the model because it is "the right thing to do" and can potentially improve patient safety, promote fairness and trust, and reduce costs.
	Multicare Health System	This grant resulted in the development of criteria for Avoidable Classes of Events that would also be Automatically Compensable Events (ACEx2), a list of 18 events meeting these criteria, components of the ACEx2 model, a standardized approach to compensation, and recommendations for implementing ACEx2 in lieu of the current tort system in the Seattle, Washington, area.
	Wishard Health Services (now subsumed under Eskenazi Health)	The project evaluated a new claims model, which features peer review, apology, and offer. Staff rated the new system favorably. Claims processed through the new system fared better than or the same as those processed through the old system.
	Office for Oregon Health Policy and Research	This project concluded that the safe harbor approach appears to be valuable for improving patient safety but less so for reducing medical liability costs. A significant challenge to this approach may be the difficulty in achieving consensus on evidence-based clinical guidelines.

Introduction

On September 9, 2009, President Obama directed the Secretary of the U.S. Department of Health and Human Services (HHS) to establish an initiative to help States and health care systems test new models of care delivery, adverse event disclosure, and dispute resolution, with the joint aims of (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.

In response, the Secretary launched the HHS Patient Safety and Medical Liability Initiative in October 2009. Under this initiative, the Agency for Healthcare Research and Quality (AHRQ) funded 13 planning grants totaling $3.5 million. These funds aimed to help States, health systems, and risk management organizations plan for new programs, expand or modify existing resources, and conduct feasibility studies to explore the early phases of implementation and testing. The planning grants were originally scheduled to run for 1 year beginning in late summer 2010. Many of the grantees requested and received no-cost extensions of varying lengths. All the planning grants were completed by December 2012.

The planning grants were designed to provide initial funding to States and health systems so they could explore new initiatives that address patient safety and medical liability. Given their limited budget and time period, it was anticipated that the planning grants would result solely in preliminary findings, primarily lessons learned from laying the groundwork for future patient safety and medical liability reform projects. Details about the grantees (e.g., project titles, principal investigators, grant award amounts, goals, methods, and findings) can be found in the profiles in Appendix A.

Methodology

AHRQ commissioned James Bell Associates, in partnership with RAND Corporation, to conduct an independent evaluation of the planning grants. Reviews were conducted of the planning grant applications, grantees' quarterly progress reports and final reports, and manuscripts the grantees drafted for an upcoming publication in AHRQ's *Advances in Patient Safety* series. Telephone interviews were completed with a few of the grants' principal investigators to gather additional data. Information from these reviews and interviews were synthesized and selectively included in this final evaluation report. The sources used in developing this report appear in Appendix B.

Findings

Improving Communication

Four planning grants (Carilion Medical Center, University of Washington, University of Utah, and Sanford Research) addressed improved communication by assessing attitudes toward error and harm disclosure and by implementing communication interventions in clinical environments.

Carilion Medical Center. This project examined patient, family, and clinician attitudes about the disclosure of individual, team, and system failures associated with four adverse obstetric

outcomes. Analysis of focus group and survey data revealed that patients and their family members tended to agree on which system failures were important to disclose, regardless of the type of adverse obstetric outcome. Clinician responses were more varied and were affected by type of adverse event, but they did agree with patients in some instances. The highest correlation in patient/family member and clinician responses was found in regard to failures that occur during delivery and result in intrapartum (the period from the onset of labor to the end of the third stage of labor) fetal death due to group B strep.

In another component of the grant, a customized TeamSTEPPS® training was tested with focus groups and implemented with participants recruited from mother–baby education classes at the Carilion Medical Center. Class participants reported that the training was useful, and they had very positive reactions to the curriculum. The training did not change participant attitudes about communication and teamwork skills, but it did significantly increase participant knowledge about medical communication and teamwork and their effect on quality and safety in patient care.

University of Washington. This planning grant intended to improve communication between patients/family members and providers through the testing and use of shared decisionmaking (SDM) processes and tools, in effort to more actively engage the patient in his or her clinical decisions. Numerous barriers to adoption and implementation were identified and addressed as the result of implementing the SDM model in orthopedic spine surgery clinics. Results based on the observation and assessment of physician–patient encounters indicate that physicians "were most effective in discussing the nature of the clinical condition and less effective in engaging patients as partners in decisionmaking."[1] The elements of SDM most often lacking in clinical encounters were seeking input from others (65%), establishing the patient role in decisionmaking (53%), using teach-back to assess patient understanding (42%), eliciting patient preference for treatment choices (24%), communicating uncertainty (24%), and discussing treatment alternatives (18%).

The project culminated in the development of an SDM train-the-trainer toolkit that integrates the processes developed and lessons learned. Available through the Association of American Medical Colleges MedEdPORTAL (http://www.mededportal.org/publication/9413), the toolkit can be implemented more broadly in other settings. In addition, decision aids have been developed for use with anesthesia patients but have not yet been implemented.

University of Utah. This project aimed to facilitate the disclosure of unanticipated medical outcomes through use of a "systemwide, evidence-based, ethical, and legally sound standardized recommended process."[2] A review of medical records, focus groups with families and risk managers, and other activities resulted in the development of a 10-step disclosure protocol that researchers implemented within a large, regional health care system. The research team found that implementation of a disclosure protocol across a large regional health system is not only possible, but it can also produce successful results. Disclosure protocols support improved communication among patients and providers and suggest a linkage with reduced liability claims. As of the final report, the grantee was establishing the Center for Medical Communication and Conflict Resolution at the University of Utah School of Medicine to promote the inclusiveness of medical communication.

Sanford Research. This project prepared for and implemented Vanderbilt's Patient Advocacy Reporting System (PARS) in the Sanford Health System, a large, multistate, not-for-profit health care provider. PARS is a tool for identifying and reducing unnecessary variation in a targeted safety/quality indicator—in this case, using patient complaints to identify and intervene with physicians who stand out from peers because of high complaint levels. As part of PARS implementation, a "Project Bundle"[a] readiness assessment was conducted to assess the presence of 10 elements deemed critical to success and to address any gaps. 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. In this case, the "Project Bundle" refers to a set of 10 intervention elements associated with PARS. Using a variety of methods, the health system was able to ensure it met requirements in these 10 areas. The researchers concluded that through key stakeholder engagement and leadership commitment, a large multistate health care system was able to successfully implement PARS and doing so was dependent on key stakeholder engagement and leadership commitment.

Observations

As a group, these grantees learned that the beliefs, preferences, and behaviors of physicians play a key role in facilitating or impeding the adoption of new practices and processes. Taking the time to identify areas of shared agreement and concern regarding communication between patients and providers can help hone communication improvement efforts.

Improving Patient Safety

The five projects in this category (Washington State University, Johns Hopkins University, North Carolina Department of Health and Human Services, The Ohio State University, and Jackson Memorial Hospital) sought to improve patient safety by measuring safety problems, characterizing adverse events, and conducting clinical safety interventions.

Washington State University. Pharmacists examined data on medication discrepancies collected for patients ages 50 and older transitioning from hospital to home care to determine the potential for discrepancies to result in an adverse drug event (ADE), the severity of the ADE (i.e., serious, significant, minor), the potential health consequences (e.g., death, permanent or temporary disability, abnormal lab results), and any anticipated additional health care services needed. Of the medication discrepancies examined, pharmacists found that 41 percent may contribute to an ADE, of which 69 percent could be considered serious or significant. Discrepancies were found to occur across all classes of medications. None of the discrepancies involved permanent disability or death, but almost half of the discrepancies involved symptoms or temporary disability, of which 16 percent were judged to require an office visit, emergency department visit, or hospitalization.

This grantee also explored hospital-to-home medication discrepancies in 10 focus groups of diverse stakeholders, including patients and family members, care providers, pharmacists, and lawyers. Barriers included patient factors (lack of understanding about medications and how to manage them, retaining and using old prescriptions, and problems with access to medications) and health system factors (poor communication and coordination of care, lengthy and complex

discharge processes, and staffing and time constraints). This planning grant demonstrated that risk might be minimized with solutions that integrate medication risk management efforts into transitional care models.

Johns Hopkins University. This project assessed closed malpractice claim files over a 10-year period to explore the frequency of and factors related to suboptimal care during hospital discharge. Cases involved discharge from one of four hospital sites affiliated with the academic medical center. Of the 230 claims examined, 13 (5.7%) were determined to involve a potential transition of care event, defined by a multidisciplinary team as occurring after discharge and clearly involving the suboptimal transfer of equipment, information, or components of the management plan. For each of these 13 cases, the researchers collected and reviewed the hospital's clinical and administrative documents to identify potential failures occurring during the transition.

Themes and subthemes emerging from the analysis suggest failures may occur in multiple domains of the hospital work system (tasks, organization, patient/caregiver, provider, technology and tools, and environment) and care transition processes. This project also found that of the 13 claims judged to have potentially involved a suboptimal care transition, only 3 (23%) had associated event reports noted in hospital reporting systems, suggesting that most of the cases would not have been identified without the claim being filed by a patient.

Following the claims analysis and a literature review, two predischarge surveys were developed to identify patients who are at risk for safety problems after hospital discharge: one for patients and their families and caregivers, and one primarily for inpatient providers. In a feasibility test of the two surveys, hospital case managers reported that the provider surveys were easy to use and not disruptive during multidisciplinary rounds. Patients reported that the patient survey's length and response burden were acceptable. The survey and processes were revised based on the findings from the pilot. These instruments respond to a need in clinical safety and can be further tested and revised in preparation for broader use.

North Carolina Department of Health and Human Services. This project designed an electronic system allowing clinical and administrative staff to anonymously report near-miss events (errors that do not result in patient harm) and implement remediation efforts. This approach was pilot tested in seven diverse primary care practices across North Carolina. Over the 12-month period, the sites reported a total of 770 near-miss events (with a range from 43 to 177 each) and 34 practice improvement projects to remediate near misses (with a range from 1 to 15 each). An assessment of the 632 near-miss events reported over a 12-month period and included in the analysis revealed the frequency of various types of near-miss events.

Notably, almost half (299 of 632) of reported near misses involved office processes. "Common human error" and "not taking time to do the task correctly" were the two most commonly identified causes of medical errors by reporters of the near-miss events. The researchers were surprised to find that electronic medical records, designed in part to prevent errors, were a contributing factor in 14 percent of errors in the sample.

The primary care practices continued to report near-miss events after the 12-month pilot when they were no longer receiving any compensation for participation, and some of the practices reported plans to continue using the system.

The Ohio State University. This project successfully developed a statewide pregnancy-associated mortality review (PAMR) system in Ohio in an effort to understand the factors associated with maternal death cases and identify opportunities to improve patient safety and health care quality. A retrospective analysis of maternal death cases covering a 2-year period prior to the receipt of grant funding provided data on the frequency and causes of pregnancy-associated and pregnancy-related deaths, as well as the factors involved in these deaths. In 2008, 39 percent of cases were categorized as pregnancy related or possibly pregnancy related, resulting in a pregnancy-related mortality ratio of 9.4 per 100,000 live births. In 2009, 58 percent of cases were categorized as pregnancy related or possibly pregnancy related, resulting in a pregnancy-related mortality ratio of 20.8 per 100,000 live births.

In the assessment of the factors involved in pregnancy-associated and pregnancy-related deaths, the top three individual factors identified were chronic medical conditions, substance abuse, and delay and/or failure to seek care; the top three system factors were lack of case coordination and management, poor patient–provider communication, and lack of continuity of care; and the top three clinical factors were delay or lack of diagnosis or treatment, risk screening, and consultation with another provider. After the end of grant funding, project leaders continued to refine the system and began collecting data for a third year. In 2012, Ohio's maternity licensure authority began requiring mandatory maternal death reporting.

Jackson Memorial Hospital. This planning grant was used to develop and pilot test the Initiative to Reduce Inpatient Suicide (IRIS), an enhanced suicide screening, assessment, and psychosocial intervention for hospitalized medical/surgical patients who have been identified as vulnerable for attempting or completing suicide. Although researchers were not able to compare the hospital's medical/surgical patients in the IRIS condition with those receiving the hospital's usual care as they intended, they did find that the hospital's medical/surgical patients have a high rate of suicide risk.

In addition, "patients who participated in the study received a psychiatric evaluation, on average, 3 days after admission and have an average length of stay of 8 to 9 days,"[3] indicating that screening and intervention need to be conducted earlier in the hospital stay. Data collected from participating nurses suggest the need for more training for nurses in detecting and managing patients at risk for suicide and more research on obtaining reliable and valid data from nurses. Including nurses and other clinical staff in the formal root cause analysis (a common error analysis tool in health care) of the underlying problems after an attempted suicide event at the hospital led to the development of a Suicide Risk Advisory Committee (an inter-disciplinary safety committee) at Jackson Memorial Hospital.

Observations

In general across these projects, efforts appear to be effectively identifying the causes of and contributors to medical errors, and there appear to be some promising interventions and strategies available to prevent or minimize them.

Exploring Resolution Methods

The third category, Exploring Resolution Methods, includes four projects (Beth Israel Deaconess Medical Center, Multicare Health System, Wishard Health Services, and the Office for Oregon Health Policy and Research) that focused on medical liability interventions—variations of a disclosure, apology & offer (DA&O) model, as well as a safe harbor model.

Beth Israel Deaconess Medical Center. Findings from the stakeholder interviews conducted through this planning grant laid the foundation for developing a guide on how to start a DA&O program in Massachusetts, which is now being used by other States interested in DA&O. The findings also led to the establishment of the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI), which comprises a variety of stakeholder groups. Since forming, MACRMI renamed the approach Communication, Apology, and Resolution (CARe); developed clear policies, procedures, algorithms, and guides for facilities implementing CARe; helped develop projects to implement CARe in six hospitals in the State; and created a resource Web site (http://www.macrmi.info).

Importantly, this planning effort resulted in a historic and unprecedented partnership among physicians and attorneys from the Massachusetts Medical Society, Bar Association, and Academy of Trial Lawyers. These three groups have held traditional and, in some cases, opposing viewpoints on tort reform policies. The grant's work culminated in the passage of a law in Massachusetts that allows all health care delivery organizations to develop DA&O programs to settle medical malpractice claims.

Multicare Health System. This project conceptualized an ACEx2 system, which is used to identify Avoidable Classes of Events that would also be Automatically Compensable Events through disclosure, apology, and early offer of compensation following a standardized compensation schedule. Experts in health care quality assurance and peer review developed criteria for such events that warrant an offer of compensation (e.g., they are preventable and reliably identifiable, and the harm is measurable), and they identified 18 safety events meeting the criteria as well as others worthy of further investigation.

An implementation plan was recommended that outlines the process for identifying and disclosing events to the patient or patient's family, apologizing, and having early discussions with patients or families about compensation. A standardized approach to compensation for Avoidable Classes of Events was also developed. The grantee offered recommendations for implementing a voluntary ACEx2 program in lieu of the current tort system in the Seattle metropolitan area.

Wishard Health Services (now subsumed under Eskenazi Health). This study aimed to evaluate the Wishard Health Services Reformulated Medical Claims Model (RMCM), which was instituted in 2008 based on the successful University of Michigan Claims Management Model. In the first part of the study, researchers surveyed patients and medical staff involved in 41 claims closed since the RMCM was instituted. Overall, staff members rated the RMCM favorably, with 100 percent of respondents reporting being "very satisfied" or "satisfied" with the risk management/peer review process, the RMCM process, and the claims committee process, and 75 percent stating that the RMCM was "very efficient" or "efficient." Although one-third of staff

respondents indicated the RMCM improved on the claims system used prior to 2008, two-thirds of respondents were unsure due to limited knowledge about the previous process.

In the second part of the study, researchers compared the same 41 claims closed under the new system to 125 cases processed through the old system and found that the RMCM approach fared better or the same in the length of time for processing cases, the size of settlement awards made, and the amount of legal fees encumbered by Wishard. Also, a significantly larger percentage of cases under the RMCM reached a settlement than under the old claims model (48.8% vs. 12.7%).

Office for Oregon Health Policy and Research. This grantee concluded that diverse stakeholders in Oregon view the safe harbor approach as valuable for improving patient safety based on a preliminary analysis of medical claims closed over an 11-year period; a retrospective analysis of selected closed claim files to determine if (1) better adherence to medical guidelines could have prevented some patient harms that led to medical liability claims and (2) a safe harbor rule could have altered the course or outcome of medical liability claims; and discussion with stakeholders. There is less clear support, however, for the legal safe harbor approach as a means for reducing liability costs; in Oregon, it would likely yield savings of only 5 percent of total annual medical liability costs. The grantee found that a significant challenge to the safe harbor approach would be the development, adoption, and use of evidence-based medical guidelines addressing clinical situations that result in significant numbers of patient injuries and medical liability claims. Without such guidelines, a safe harbor rule would be ineffective.

Observations

These grantees learned that engaging diverse stakeholders to assess the strengths and weaknesses of the current system and creating vehicles for ongoing stakeholder involvement (e.g., subcommittees that meet regularly) help to identify key issues, obtain buy-in, and effectively design solutions. The findings from these planning grants represent promising strategies and models for reducing liability costs and, at the same time, improving patient safety.

Appendix A. Grantee Profiles

Carilion Medical Center

Title: Modeling Risk and Reducing Liability Through Better Communication and Teamwork

Award Number: R21 HS19512-01

Principal Investigator: David Baker, Ph.D.

Award: $280,924

Goals

The goal of this project was to understand how to engage patients and their family members as part of the obstetric care team. Obstetric and perinatal cases represent the costliest and most frequent types of liability claims, some of which result from inadequate communication among patients, families, and the health care team.

Methods and Findings

To this end, the project sought to identify obstetric clinical events that vary in terms of risk and liability (high vs. low) but that all depend on provider teamwork and the involvement of the patient and family members. Using a 2008 report by the RAND Corporation and subsequent clinician input, the grantee identified four obstetric clinical events—shoulder dystocia, postpartum hemorrhage, intrapartum fetal death, and unplanned return to labor and delivery or the operating room—meeting these criteria. Further, clinical experts identified the individual, team, and system failures associated with each event. The project team noted that approximately half the failures associated with these four adverse obstetric outcomes were common to all four events, suggesting that that "multiple events may be mitigated by the introduction of more systemic interventions" (Baker et al., 2012).

The research team then examined patient/family and clinician attitudes about the disclosure of individual, team, and system failures associated with these four adverse obstetric outcomes to mitigate patient risk and reduce liability. The researchers conducted focus groups with patients and family members and administered surveys to these focus group participants as well as clinicians. Patients and their family members tended to agree on which failures were important to disclose, regardless of the type of adverse event. Clinician responses were more varied and were affected by type of adverse event, but clinicians did agree with patients in some instances. The highest correlation in patient/family member and clinician responses ($r = 0.96$) was found in regard to failures that occur during delivery and result in intrapartum fetal death due to group B strep.

As the final step, researchers pilot tested a customized TeamSTEPPS® training designed to teach patients and family members how to be members of the care team and to enhance communication between patients and families and their care providers, thus reducing the risks of adverse obstetric outcomes. (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.) In focus groups to solicit feedback about various TeamSTEPPS tools and strategies such as situation-background-assessment-recommendation (SBAR) and debriefs, patients and their family members thought the tools were clear and would be easy to use, they would be comfortable using the tools, and it would be beneficial to teach patients and their family members about using the tools during prenatal education classes. Subsequently, participants recruited from mother–baby education classes at an 850-bed academic medical center attended a TeamSTEPPS training. Trainees reported that TeamSTEPPS training was useful, and they had very positive reactions to the curriculum. The training did not change participants' attitudes about communication and teamwork skills but did significantly increase their knowledge ($p < 0.05$). Since many patients lack familiarity with the clinical processes associated with obstetric care, their positive feedback demonstrated that these TeamSTEPPS tools and strategies offer significant use for patients as well as providers.

Source Documents

Baker DP, Weiss P, Slonim AD. Modeling Risk and Reducing Liability Through Better Communication and Teamwork. Final Progress Report. Prepared by Carilion Medical Center under grant number R21 HS19512-01. Prepared for the Agency for Healthcare Research and Quality. Roanoke, VA; April 2012:39.

University of Washington

Title: Shared Decision Making in Surgery To Improve Patient Safety and Reduce Liability

Award Number: R21 HS19532-01

Principal Investigator: Karen Domino, M.D., M.P.H.

Award: $295,837

Goals

The goal of this project was to develop and implement user-friendly shared decisionmaking (SDM) tools and processes for patients undergoing elective orthopedic surgery in the University of Washington Health Care System. Many patients have an incomplete understanding of the clinical procedures for which they must provide consent, and in some cases, patients may unknowingly make a poorly informed decision that conflicts with their preferences or may worsen their health. The project team noted that physician–patient miscommunication and inadequate risk communication during the informed consent process contribute to patient dissatisfaction, complaints, and medical liability associated with surgical procedures. Shared decisionmaking improves patient safety by enhancing patient understanding and empowering patients to actively participate in their care, and this emphasis on communication improvement is linked with reduced liability risk. Researchers recognized that an existing Washington State statute provides specific protections from malpractice lawsuits if SDM is practiced, and they sought to test the efficacy of this standardized process.

Methods and Findings

Implementing the SDM model in orthopedic spine surgery clinics involved obtaining institutional approval; engaging stakeholders; developing patient activation materials and securing decision aids to introduce the concept of SDM to patients and encourage them to engage in this activity with their providers; training providers; disseminating patient activation and decision aid materials to patients; and conducting ongoing provider assessment, training, and coaching. The grantee identified numerous barriers to adoption (e.g., the belief that new patient materials would be redundant and costly to produce and distribute, concerns about the evidence and other content presented in decision aids, time constraints, physician resistance, lack of understanding about the use of SDM in only "preference-sensitive" treatment decisions) and implementation (e.g., ineffective and inconsistent dissemination of materials to patients, time constraints, use of "deeply ingrained scripts" with patients, minimal use of physician pocket reminder card and posters, bureaucracy, physician turnover). Numerous approaches were used to address these barriers with varying success, such as using a leadership team to initiate collaboration, working with all stakeholders to develop procedures, and purchasing peer-reviewed decision aids. Results based on the observation and assessment of physician–patient encounters indicate that physicians "were most effective in discussing the nature of the clinical condition and less effective in engaging patients as partners in decisionmaking" (Mincer et al., 2013). The elements of SDM most often lacking in clinical encounters were seeking input from others (65%), establishing the patient role in decisionmaking (53%), using teach-back to assess patient understanding (42%), eliciting patient preference for treatment choices (24%), communicating uncertainty (24% each), and discussing treatment alternatives (18%). The project culminated in an SDM train-the-trainer toolkit that integrates the processes developed and

lessons learned. Available through the Association of American Medical Colleges MedEdPORTAL (http://www.mededportal.org/publication/9413), the toolkit can be implemented more broadly in other settings. In addition, decision aids have been developed for use with anesthesia patients but have not yet been implemented.

In a second component of the project, researchers examined University of Washington Medical Center complaint files from 2010 (including claims and lawsuits) in which patients reported clinical error or medical harm. For each claim, researchers determined whether the claim was related to an aspect of the informed consent or SDM process, whether the patient or institution found the informed consent insufficient, and how many hours staff and physicians likely would have spent to resolve the claim. Of the 82 complaint files examined, 78 percent involved an element of informed consent or SDM, primarily in the areas of treatment risks (52%) and treatment alternatives (20%). Complaints involving informed consent or SDM were more commonly associated with clinical procedures (e.g., surgery) and anesthesia, whereas complaints not involving informed consent or SDM were more commonly associated with nonprocedural care ($p = 0.002$). In 11 of the 15 cases in which patients found the informed consent to be insufficient, the institution did not agree, suggesting that patients did not fully understand all the information presented to them during the informed consent process. No significant difference was found in the estimated staff and physician time required to resolve complaints involving informed consent or SDM compared with other complaints, but the resource consumption across all 82 complaints was substantial (a total of 866 hours for staff and 443 hours for physicians). Lastly, the grantee reports, "All complaints involved some additional patient care and most complaints (70%) resulted in some new injury to the patient. New injuries were more common in informed consent (IC)/SDM complaints, with 80 percent resulting in some new unanticipated injury compared to non-IC/SDM complaints (35%; $p = 0.001$)" (Posner et al., 2013). Thus, patient complaints involving the elements of shared decisionmaking represent significant potential cost savings.

Source Documents

Mincer SL, Lee MJ, Bransford RJ, et al. Adopting and implementing shared decisionmaking: Barriers and solutions. Manuscript in preparation. 2013.

Posner KL, Severson JR, Domino KB. The potential for shared decisionmaking to reduce hidden liability costs for healthcare organizations. Manuscript in preparation. 2013.

University of Utah

Title: Regional Implementation of a Protocol To Disclose   **Award Number:** R21 HS19498-01
Unanticipated Events
Principal Investigator: Elisabeth Guenther, M.D., M.P.H.   **Award:** $299,999

Goals

The goal of this project was to implement and evaluate a "systemwide, evidence-based, ethical and legally sound standardized recommended process" for disclosing unanticipated medical outcomes (Guenther et al., 2012). The researchers wanted to test if health care team members could improve their delivery of the disclosure process and whether this disclosure affected the likelihood of a resulting liability claim.

Methods and Findings

A review of medical records, focus groups with families and risk managers, a literature review, survey analysis, and expert consensus resulted in a 10-step disclosure protocol that includes explaining the facts, sincerely apologizing, speaking accountably, and inviting questions. Researchers implemented the protocol within a large, regional health care system that combines two governing entities (University of Utah Health Care and Intermountain Healthcare) with a long history of collaboration and an established culture of patient safety.

Implementation began by training risk management staff through an intensive and multifaceted educational intervention that included regional conference presentations; Webcast disclosure symposia; self-paced Web-learning modules and refresher courses; and "just-in-time" peer-coaching. According to the authors, "This protocol is uniquely nuanced and informed by constituents from across a large health care region. It has allowed a more precise strategy to communicate with patients and appears to improve satisfaction for patients, family members, and physicians alike. We have found that this protocol can be easily taught and applied across many different clinical settings and institutional environments" (Guenther et al., 2012).

Data collection on implementation was ongoing at the time of the grant final report's writing; therefore, results on patient, family, and health care provider satisfaction with the disclosure process were not available. The grantee reported that timely data collection was hampered by (1) delays in seeking and obtaining institutional review board approval from two separate boards and (2) already under-resourced and overburdened risk management staff. However, preliminary analysis indicates a high level of reported satisfaction from patients and family members. The research team found that implementation of a disclosure protocol across a large regional health system is not only possible, but it can also produce successful results. Disclosure protocols support improved communication among patients and providers and suggest a linkage with reduced liability claims. As of the final report, the Center for Medical Communication and Conflict Resolution was being established at the University of Utah School of Medicine to promote the inclusiveness of medical communication.

Source Documents

Guenther E, Junkins EP, McDonnell WM, et al. Regional Implementation of a Protocol To Disclose Unanticipated Events. Final Progress Report. Prepared by the University of Utah School of Medicine under grant number R21 HS19498. Prepared for the Agency for Healthcare Research and Quality. Salt Lake City, UT; March 2012:11.

Sanford Research

Title: A Plan To Use Sanford Health Patient Complaints To Promote Safety/Reduce Claims

Award Number: R21 HS19571-01

Principal Investigator: Wendell Hoffman, M.D.

Award: $294,137

Goals

The goals for this project included the establishment and assessment of a patient complaint reporting system to determine its effect on reducing harm and improving care and patient safety culture. By implementing a patient reporting system throughout Sanford Health System—a large, not-for-profit, multistate health care provider—the project team aimed to improve capture of patient and family complaints, enhance service recovery, and identify physicians at highest risk for unsafe practices and unnecessary lawsuits.

Methods and Findings

The grantee planned for and implemented the Patient Advocacy Reporting System (PARS) developed by the research team at Vanderbilt University's Center for Patient and Professional Advocacy to meet this end. PARS is a tool for identifying and addressing "unnecessary variation in a targeted safety/quality indicator"—in this case, using patient complaints to identify and intervene with physicians who stand out from peers because of high complaint levels. Prior to implementation, Vanderbilt's Center for Patient and Professional Advocacy staff performed a "Project Bundle" readiness assessment to assess the presence of the following 10 elements deemed critical to success and to address any gaps: leadership commitment, project champions, an implementation team, alignment of organizational goals with PARS, policies, a model for interventions, resources, measurement and surveillance tools, process to review data, and professional training. Using site visits, meetings, calls, and trainings, the health system was able to ensure it met requirements in these 10 areas. According to the grantee, "We conclude: (1) the Project Bundle offers health care leaders a useful prelaunch tool for identifying needs and addressing readiness of projects that aim to improve quality/safety and/or prevent risk, and (2) with effective planning and institutional commitment, PARS can work well in a large, geographically complex health care system" (Pichert et al. 2013). The researchers concluded, "The project demonstrated how in 1 year, a large multistate health care system became prepared to implement an intervention process that promotes professional self-governance, fosters a fair and just culture of safety and kindness, and reduces avoidable lawsuit risk" (Pichert et al., 2013).

Other large health care systems interested in implementing projects similar to PARS can learn from Sanford Health System's experience conducting the pre-intervention assessment, developing needed infrastructure (e.g., locally administering the PARS process through the formation of an active PARS committee but coordinating at the system level to ensure the integrity of the process), taking advantage of local resources (e.g., strong organizational leadership, organizational goals and policies that are in alignment with PARS), and overcoming barriers and challenges (e.g., obtaining and retaining a physician champion, reconciling safety culture practice across participating institutions).

In another component of the grant project, researchers analyzed Sanford Health System's patient complaint data from a 3-month period (prior to PARS implementation) and data from AHRQ's Hospital Survey on Patient Safety (HSOPS) to determine if a correlation exists between patient complaints and safety culture. (The AHRQ survey is intended to assess various aspects of patient safety culture, identifying strengths and areas for improvement.) The analysis identified some areas in which patient complaints and staff safety concerns were correlated. The grantee stated:

> "This is the first time, to our knowledge, that unsolicited patient complaints have been significantly linked to culture of safety assessments. Even though only 2 of the 12 composites of patient safety culture measured by the HSPSC [HSOPS] were found to be significantly related to patient complaints, this establishes new ground for future studies within the patient safety movement, given that the 2 constructs measured teamwork and communication, which consistently [have] been shown to be related to harm and its potential…This holds out the possibility that patient complaints may be a predictor for actual adverse events. Future studies will be necessary to study this possible relationship" (Hoffman, 2011).

Source Documents

Hoffman WW. A Plan To Use Sanford Health Patient Complaints To Promote Safety/Reduce Claims. Final Progress Report. Prepared by Sanford Health under grant number 1 R21 HS019571-01. Prepared for the Agency for Healthcare Research and Quality. Sioux Falls, SD; December 2011:16.

Pichert JW, Hoffman WW, Danielson D, et al. Application of a Project Bundle to planning implementation of the Patient Advocacy Reporting System throughout the Sanford Health System. Manuscript in preparation. 2013.

Washington State University

Title: Transitional Care Medication Safety and Medical Liability: Closing the Chasm

Award Number: R21 HS19552-01

Principal Investigator: Cynthia Corbett, Ph.D., R.N.

Award: $298,810

Goals

The goal of this project was to characterize the impact of medication discrepancies on patient safety and medical liability and to identify strategies to improve the safe use of medication and the quality of care during the hospital-to-community transition in Washington State. A 2010 study by the project's principal investigator assessed hospitalized adults ages 50 and older with a chronic illness who were referred to home health care services following hospital discharge. Findings suggested that up to 90 percent of patients experience at least one medication discrepancy in the transition from a hospital to their home. (Within this research, medication discrepancies are defined as any difference between what was prescribed at discharge from the hospital and what the patient reported taking at home.)

Methods and Findings

Through the grant, pharmacists examined data on medication discrepancies collected in this previous study to determine the potential for discrepancies to result in an adverse drug event (ADE), the severity of the ADE (i.e., serious, significant, minor), the potential health consequences (e.g., death, permanent or temporary disability, abnormal lab results), and any anticipated health care utilization needed. Of the 1,389 medication discrepancies they examined, pharmacists found 566 that may contribute to an ADE, 69 percent of which could be serious or significant. Discrepancies were found to occur across all classes of medications. The five most common classes of drugs involved in potential ADEs were antihypertensive agents, opioids, anticoagulants, antidiabetic agents, and inhaled chronic obstructive pulmonary disease/asthma medications, and the drugs deemed most likely to result in a serious ADE were exemestane, enoxaparin, warfarin, and sublingual nitroglycerin. Of the 566 potential ADEs, none involved permanent disability or death, but almost half (278) involved symptoms or temporary disability, and 86 were judged to require an office visit, emergency department visit, or hospitalization. A data review of State, regulatory, and appellate law identified factors that contributed to the medication discrepancies, ADEs, and the medical liability risk associated with ADEs.

Also during the grant period, the project team explored hospital-to-home medication discrepancies in 10 focus groups of diverse stakeholders, including patients and family members, care providers, pharmacists, and lawyers. In spite of their various perspectives, the groups identified common barriers to medication safety and solutions for improving medication discrepancies in the hospital-to-home transition. Barriers included patient factors (lack of understanding about medications and how to manage them, the retaining of old prescriptions, and problems with access to medications) and health system factors (poor communication and coordination of care, lengthy and complex discharge processes, and staffing and time constraints).

The stakeholders also suggested system solutions for improving these discrepancies. Potential solutions included improving information management (e.g., using universal electronic health records, refining hospital discharge forms), improving access to medication, and allocating more resources when coordinating transitions. The grantee noted that provisions in recent legislation such as the Patient Protection and Affordable Care Act and Health Information Technology for Economic and Clinical Health Act correspond to some of the solutions suggested by the focus groups. In addition, some evidence-based practices are available to improve hospital-to-home medication discrepancies. The work of the grantee underscores that liability risk associated with medications is a tangible concern with viable solutions.

Stakeholder participants were also asked to discuss medical liability when a medication discrepancy leads to patient harm. Although researchers could not elicit specific responses assigning responsibility, perhaps because responsibility is often shared across multiple parties, stakeholders agreed on several aspects of disclosure: "Stakeholders universally agreed that when errors are discovered they should be reported, an apology given, and, when appropriate due to patient harm or inconvenience, compensation should be offered. Further, stakeholders agreed that health systems had a responsibility to ensure that errors invoke system improvements to prevent similar errors in the future" (Corbett et al., 2013).

Source Documents

Corbett CF, Dupler AE, Smith S, et al. Transitional care medication safety: Stakeholders' perspectives. Manuscript in preparation. 2013.

Johns Hopkins University

Title: Effective Enterprise-Wide Care Transitions at Discharge

Award Number: R21 HS19519-01

Principal Investigator: Richard Davis, Ph.D.

Award: $293,225

Goals

The goal of this project was to use malpractice claims from the institution's specialty insurance company, complaints to the institution's patient relations, medical records, and other patient safety data to develop a set of key measures as a means to identify suboptimal care transition processes at discharge, in real time.

Methods and Findings

Researchers from Johns Hopkins University assessed closed malpractice claim files over a 10-year period from the university's specialty insurance company to explore the frequency of and factors related to suboptimal care during hospital discharge. Cases involved discharge from one of four hospital sites affiliated with the academic medical center. Of the 230 claims examined, 13 (5.7%) were determined to involve a potential transition of care event, defined by a multidisciplinary team as occurring after discharge and clearly involving the suboptimal transfer of equipment, information, or components of the management plan. For each of these 13 cases, the researchers collected and reviewed the hospital's clinical and administrative documents (medical records, patient complaint documents, risk mitigation files, and incident reports from the target hospital) to identify potential failures occurring during the transition. Themes and subthemes emerging from the analysis suggest failures may occur in multiple domains of the hospital work system (tasks, organization, patient/caregiver, provider, technology and tools, and environment) and care transition processes. The project team also found that of the 13 claims judged to have potentially involved a suboptimal care transition, only 3 (23%) had associated event reports noted in hospital reporting systems, suggesting that most of the cases would not have been identified without the claim being filed by a patient.

To examine existing tools for assessing care transition quality, the project team reviewed articles on care coordination and/or care transitions from the AHRQ Patient Safety Network Web site. The review did not uncover any measures suitable for administration at time of discharge. Combining the results of the literature review and claims analysis, a group of physicians, patient safety officers, and leaders in safety and quality developed two predischarge surveys to identify patients who are at risk for safety problems after hospital discharge: one for patients and their families and caregivers, and one primarily for inpatient providers. The grantee subsequently conducted a feasibility test of the two surveys in a single inpatient medical unit in one hospital. Hospital case managers reported that the provider surveys were easy to use and not disruptive during multidisciplinary rounds. Patients reported that the patient survey's length and response burden were acceptable. A primary concern of this survey was that patients and caregivers were often waiting for additional information (e.g., about test results or future appointments) at the time they received the survey, making it difficult to complete. The survey and processes were

revised based on the findings from the pilot. These instruments respond to a need in clinical safety and can be further tested and revised in preparation for broader use.

North Carolina Department of Health and Human Services

Title: Regional Ambulatory Near-Miss Reporting and Tracking To Improve Patient Safety

Award Number: R21 HS19558-01

Principal Investigator: Steven Crane, M.D.

Award: $297,710

Goals

The main goal of this project was to better understand the barriers, facilitators, and implications of implementing a near-miss reporting and tracking system in primary care practices.

Methods and Findings

The project team designed an electronic system allowing clinical and administrative staff to anonymously report near-miss events (errors that are corrected before a patient is harmed) and remediation efforts and pilot tested it in seven diverse primary care practices across western North Carolina. This group included safety net and private practices from both rural and urban environments. Evaluating and monitoring system use and resulting clinical care improvements were a significant focus in this study, and researchers wanted to understand how improvement could be optimized.

Over a 12-month period, sites reported a total of 770 near-miss events (with a range from 43 to 177 each) and 34 practice improvement projects to remediate near misses (with a range from 1 to 15 each). An assessment of 632 near-miss events reported over the 12-month period and included in the analysis revealed the frequency of various types of near-miss events. Notably, almost half (299 of 632) of reported near misses involved office processes, including filing; across all seven sites, office processes contributed to a greater number of near-miss events than any other category (i.e., equipment or building problem, investigations, medications or other treatments, communication, and clinical knowledge or performance). In spite of the "relatively mundane" nature of these events, the researchers report, "a disturbing proportion of these near-miss errors were … likely to have potentially serious negative impacts on patient safety if they had not been caught in time" (Crane et al., 2013). "Common human error" and "not taking time to do the task correctly" were the two most commonly identified causes of medical errors by reporters of the near-miss events. The researchers were surprised to find that electronic medical records, designed in part to prevent errors, were a contributing factor in 14 percent of errors in the sample. The researchers also learned through the project that the taxonomy used to classify errors could be streamlined without sacrificing important data.

Input from practice leaders at each of the sites indicated that they had "very good" buy-in to the project, and the researchers did not identify any significant barriers to implementation, demonstrating that "a near-miss reporting and remediation system designed to minimize barriers and take advantage of facilitators can be successfully implemented in regional practices representing a range of size, ownership, and clinical mission" (Crane et al. 2013). Further, the project revealed that the sites used the information gathered about near misses to advise practice improvement efforts. The grantee also noted that the primary care practices continued to report near-miss events after the 12-month project, when they were no longer receiving any

compensation for participation, and some of the practices reported plans to continue using the system. The researchers recommended the use of Web-based technologies to connect practices so they can share their experiences with remediation. The project demonstrated that near-miss reporting systems can be implemented within a practice for a fairly minimal cost and that nominal to modest awards for clinical practices were useful incentives.

The project also explored expectations, attitudes, and feelings about the disclosure of near-miss events. Researchers developed two similar online surveys, one for patients and one for clinicians. Patients in one primary care practice involved in the project and medical providers from all seven participating practices completed the survey. More than 90 percent of patients reported they would want disclosure and details of near misses, compared with about 75 percent of physicians who would provide disclosure, but not necessarily at the level of detail desired by the patients. Although their responses varied, the great majority of both patients and clinicians supported disclosure with details about what happened, how it happened, how it will be corrected, and an apology. One barrier identified by the survey is the belief, on the part of patients (38%) and clinicians (51%), that patients would lose confidence in a physician who disclosed a mistake. While patients and providers had differing opinions about the driving circumstances for disclosure, this research team found that education-based interventions may help align both groups.

Source Documents

Crane S, Sloane PD, Elder NC, et al. Implementing near-miss reporting and improvement tracking in primary care practices: Lessons learned. Manuscript in preparation. 2013.

The Ohio State University

Title: Developing a Plan To Address Maternal Mortality and Disparities in Ohio

Award Number: R21 HS19576-01

Principal Investigator: Cynthia Shellhaas, M.D., M.P.H.

Award: $187,437

Goals

This project aimed to implement an effective peer review of pregnancy-associated deaths across Ohio by creating a Pregnancy Associated Mortality Review (PAMR) system. PAMR systems can be effective research measurement tools to assess pregnancy-related deaths; they are designed to identify public health, medical, and social systems changes that could be implemented to improve patient safety by preventing and reducing adverse events associated with the complications of pregnancy, labor, or delivery. The State's Department of Health recognized an increase in pregnancy-associated mortality in Ohio and found that patient clinical records may not always provide comprehensive information regarding a pregnancy-associated cause of death. These adverse events are relevant because obstetric and perinatal-related claims are among the most frequent and costly medical liability expenditures in the United States.

Methods and Findings

The grant project successfully developed a statewide PAMR by first consulting with the Centers for Disease Control and Prevention's Division of Reproductive Health and other States that had well-functioning PAMR systems about the composition and processes required for development, and then recruiting interdisciplinary volunteers to serve on a review board. The team represented a diverse group of medical specialties, along with legal, risk management, research, and social services experts. During the grant, the board reviewed maternal death cases covering a 2-year period; cases were identified through a review of death certificates, relevant records were obtained (e.g., primary and prenatal care records, hospital records, medical examiner files), nurse abstracters created a case summary for every fatality, and summaries were examined by Ohio PAMR board members. Implementation challenges included locating records (which was improved by working with Medicaid for some patients) and preparing case summaries using a large volume of paper and electronic records that were not standardized.

The PAMR provided data on the frequency and causes of pregnancy-associated and pregnancy-related deaths, as well as the factors involved in these deaths. The PAMR categorized maternal deaths as pregnancy related or non-pregnancy related. In 2008, 39 percent of cases were categorized as pregnancy related or possibly pregnancy related, resulting in a pregnancy-related mortality ratio of 9.4 per 100,000 live births. In 2009, 58 percent of cases were categorized as pregnancy related or possibly pregnancy related, resulting in a pregnancy-related mortality ratio of 20.8 per 100,000 live births. The researchers noted several ways in which the Ohio data were inconsistent with data collected from other PAMRs. Unlike in other States, the majority of cases involved vaginal delivery rather than cesarean section, White women rather than Black women, and drug overdose played a greater role in deaths than hemorrhage or thromboembolic disorders. In the assessment of the factors involved in pregnancy-associated and pregnancy-related deaths, the top three individual factors identified were chronic medical conditions, substance abuse, and

delay and/or failure to seek care; the top three system factors were lack of case coordination and management, poor patient–provider communication, and lack of continuity of care; and the top three clinical factors were delay or lack of diagnosis or treatment, risk screening, and consultation with another provider.

Following implementation, the PAMR board continued to refine the system and began collecting data for a third year. In addition, preliminary quality improvement initiatives are underway to improve the quality of death certificate data, educate providers, evaluate readiness for patient safety initiatives, conduct reviews of maternal morbidity, and enhance networking among stakeholders. The grantee noted that Ohio's maternity licensure authority began requiring mandatory maternal death reporting in 2012, and members of the Ohio PAMR board contributed to the report format. It also suggested that obstetric patient outcomes could be improved through use of a system of maternal levels of care (like those used for neonatal levels of care, stroke care, and emergency care). The grantee is also considering the expansion of clinical training opportunities using toolkits, establishing a clinical workgroup, and potentially furthering programs for opiate-addiction prevention and treatment.

Jackson Memorial Hospital

Title: Improve Patient Safety and Reform Medical
Liability by Planning the Implementation of the Initiative
to Reduce Inpatient Suicide

Award Number: R21 HS19506-01

Principal Investigator: Nicoletta Tessler, Psy.D.

Award: $299,576

Goals

The goal of this study was to develop and test an intervention to reduce the risk of medical inpatient suicide in a diverse Florida public hospital. In 2007, the Joint Commission published National Patient Safety Goals that acknowledged four components as major contributors for inpatient suicide attempts and completed suicides: staff training, patient care, environmental safety, and incident reporting. Recognizing the lack of systematic studies in this area, the project team developed and piloted the Initiative to Reduce Inpatient Suicide (IRIS) intervention.

Methods and Findings

IRIS is an enhanced suicide screening, assessment, and psychosocial intervention for hospitalized medical/surgical patients who have been identified as vulnerable for attempting suicide. Prior to the 5-month implementation of IRIS in a diverse public teaching hospital, study team members developed a screening questionnaire based on risk factors relevant for medical/surgical patients. Data collection included pretest and post-test assessment of nurses' suicide knowledge and preparedness, opinions on suicide, and stress and coping when treating patients at risk of suicide, as well as pretest and post-test measures of safety culture and post-test assessment of satisfaction with the intervention. Focus groups with nurses were also conducted before, during, and after the intervention.

Nursing staff received training on the use of electronic systems for record keeping and clinical protocols for treating high-risk patients. The intervention included the use of new procedural and structural environmental safeguards. In addition to nurse training, procedural changes included using safety stickers in the charts of patients deemed to be at risk for suicide, sign inserts on the patients' doors, and patient attendant guidelines, as well as creation of a psychiatric nurse consultation team. Structural safeguards included making windows shatterproof.

Data were collected from IRIS and usual care group nurses and patients to assess the effectiveness of the IRIS intervention and examine the feasibility for broader implementation across other hospital units. Although researchers were not able to complete post-treatment measures to compare the hospital's medical/surgical patients in the IRIS condition to those receiving the hospital's usual care as they intended, they did find that the hospital's medical/surgical patients have a high rate of suicide risk. In terms of implementation, overall there was "moderate adherence to the IRIS model and inadequate quality of documentation and assessment for at-risk patients" (Tessler 2011, p. 3). In addition, "patients who participated in the study received a psychiatric evaluation on average, 3 days after admission and have an average length of stay of 8 to 9 days" (Tessler 2011, p. 13), indicating that screening and intervention need to be conducted earlier in the hospital stay. The grantee team suggested that use of an

automated process and other technologies could improve adherence to and sustainability of the process. The screening measure could be modified to decrease sensitivity—particularly in the areas of alcohol and drug use, depression, and agitation—but it appeared to effectively identify at-risk patients.

To provide continued education and support, the participating nurses and other clinical staff were included in the formal root cause analysis (a common error analysis tool in health care) to identify the underlying problems after an attempted suicide at the hospital. Clinicians and researchers noted that the analysis provided reinforcement for this effort and was deemed an instrumental approach for implementing hospitalwide changes and policies for broader incident tracking and reporting. This effort also led to the development of a Suicide Risk Advisory (SRA) committee at the participating hospital. The researchers and the SRA committee provided a number of recommendations, including the identification of patients at risk for suicide early in the process to enable provision of the full range of available mental health services; consistent assessment of clinical staff needs, attitudes, and resources to ensure staff are equipped to care for at-risk patients; and ongoing review of policies to enhance access to care, such as empowering frontline staff to request a psychiatric consult. The Initiative to Reduce Inpatient Suicide—Medical Liability Reform was also developed to explore issues of liability related to inpatient suicide.

Data collected from nurses suggest the need for more work in this area. While nurses indicated at pretest they were moderately prepared to deal with potentially suicidal patients, they answered less than half of the suicide knowledge questions correctly, on average, and the nurses indicated in focus groups the need for more training and a higher comfort level when dealing with patients at risk of suicide. Further, about one-third of the nurses were unsure of their hospital's policies and procedures for treating at-risk patients. Likewise, in spite of the high incidence of suicide risk identified in the study, 70 percent of nurses indicated at pretest that they had not treated a patient with suicidal behavior in the past 3 months, and 30 percent indicated that they never asked patients about suicidal ideation when patients were dealing with a difficult situation or appeared to be anxious or depressed. Assessments at followup, after training and implementation of the intervention, found no significant changes in suicide knowledge or preparedness, opinions on suicide, stress and coping, or safety culture. At the same time, most nurses agreed in the satisfaction survey that the IRIS program's safety procedures were effective. Together, these findings indicate the need for more training for nurses in detecting and managing patients at risk for suicide and more research on obtaining reliable and valid data from nurses. Further exploration may also explain the factors that influenced the lack of significant nurse outcomes.

Source Documents

Tessler NB. Improve Patient Safety and Reform Medical Liability by Planning the Implementation of the Initiative to Reduce Inpatient Suicide. Final Progress Report. Prepared by Jackson Health System under grant number 1R21 HS19506-01. Prepared for the Agency for Healthcare Research and Quality. Miami, FL; August 2011.

Beth Israel Deaconess Medical Center

Title: Removing Barriers to Disclosure-and-Offer Models   **Award Number:** R21 HS19537-01
Principal Investigator: Kenneth Sands, M.D., M.P.H.   **Award:** $278,212

Goals

In a joint initiative with the leadership of the Massachusetts Medical Society, researchers from the Beth Israel Deaconess Medical Center used this planning grant to initiate the transformation of the medical liability system in the State of Massachusetts. The goals of this planning grant were fourfold: identify barriers to implementation of disclosure, apology & offer (DA&O) programs in Massachusetts; develop strategies for overcoming these barriers; and create a roadmap or implementation guide for use by other organizations. The team also wanted to assess the applicability of its work in Massachusetts to other States.

Methods and Findings

The grant project began with semistructured interviews of 27 stakeholders representing physicians, insurance companies, legislators, attorneys, and patient advocates to solicit information about attitudes, barriers to implementing a DA&O model, and strategies for overcoming those barriers. Stakeholder attitudes about disclosure strongly supported a DA&O process for ethical and professional reasons (e.g., "it is the right thing to do") and because of its benefits for both the liability system and patient safety. Barriers to implementation reported by at least half the participants were Massachusetts charitable immunity law (which limited the liability of a charitable corporation, trust, or association to $20,000), physician discomfort with the process, attorneys' resistance, disparate coordination across insurers, State requirements to report physicians involved in liability payment, and fear of increased liability risk. Participants offered suggestions for overcoming each barrier. For example, training, peer mentoring, and clear disclosure protocols could be used to prepare physicians, and educating attorneys about the benefits of DA&O (e.g., more efficient resolution) could allay their concerns. Respondents indicated that DA&O was the most promising liability reform model, and they identified no insurmountable barriers to its broad implementation in Massachusetts. Additional feedback was obtained from 180 clinicians and other attendees during a subsequent public symposium about this research effort.

The data gathered in the stakeholder interviews laid the foundation for a guide on how to start a DA&O program in Massachusetts (*A Roadmap for Transforming Medical Liability and Improving Patient Safety in Massachusetts*), which is now being used by other States interested in DA&O, and establishment of the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI), which comprises representation of a variety of stakeholder groups. Since forming, MACRMI renamed the approach Communication, Apology, and Resolution (CARe); developed clear policies, procedures, algorithms, and guides for facilities implementing CARe; helped in developing projects piloting CARe in six hospitals in the State; and created a resource Web site (http://www.macrmi.info).

Importantly, this planning effort resulted in a historic and unprecedented partnership among physicians and attorneys from the Massachusetts Medical Society, Bar Association, and Academy of Trial Lawyers. These three groups have held traditional and, in some cases, opposing viewpoints on tort reform policies. The grant's work culminated in the passage of enabling legislation in Massachusetts that allows all health care delivery organizations to develop DA&O programs to settle medical malpractice claims. The legislation, which took effect in November 2012, includes three provisions that were central to the consensus roadmap:

- Implementing a 6-month prelitigation notice period, otherwise known as a cooling-off period, that provides for full disclosure by both parties, with sharing of all pertinent medical records.

- Making statements of apology (e.g., sympathy, commiseration, regret) inadmissible as evidence in any judicial or administrative proceeding unless the maker of the statement or defense expert witness makes a contradictory or inconsistent statement as to material facts or opinion under oath.

- Requiring health care providers to fully inform the patient when a patient suffers an unanticipated outcome with significant medical complications resulting from a provider's mistake.

The project team concluded:

> "Forming a statewide alliance, such as MACRMI, has been successful in rapidly disseminating the Roadmap's strategies and supporting pilots of DA&O in Massachusetts. We believe this model can be highly successful in other States, not only because we believe the barriers are applicable to most other settings, but because we have seen the power of a variety of organizations, some formerly at odds, working together toward a common goal because they believe it will create a better health care system for all" (Sands et al. 2013).

Although 35 other States and the District of Columbia have "doctor apology laws," few State-based DA&O programs exist. Massachusetts became the first State in the Nation to have comprehensive legislation that resulted in the development of DA&O programs across a diverse array of health insurance programs and health care settings.

Source Documents

Sands KEF, Woodward A, Van Niel M. Reforming the medical liability system in Massachusetts: Communication, apology, and resolution (CARe). Manuscript in preparation. 2013.

Multicare Health System

Title: Improving Patient Safety and Restructuring Medical Liability Using Avoidable Classes of Events

Award Number: R21 HS19496-01

Principal Investigator: Dianne Garcia, J.D.

Award: $291,810

Goals

The goal of this project was to prepare a comprehensive plan for implementing an integrated disclosure, apology & offer (DA&O) program to replace the current tort system throughout major health care delivery organizations in the Seattle metropolitan area. The project focused on identifying the occurrence of clinically Avoidable Classes of Events (ACEs), which providers recognize as preventable patient injuries incurred during the course of receiving health care. Researchers wanted to understand how a health care team could quickly (1) identify the occurrence of such an event using a predefined set of ACEs and (2) offer resolution. As a result, the researchers titled this effort ACEx2 to refer to Avoidable Classes of Events that would be Automatically Compensable. An ACEx2 program differs from other disclosure and offer models "because it focuses on adverse events identified with a relatively high degree of expert consensus to have likely been caused by errors of omission or commission, system flaws, or ineffective interactions within and among loosely linked care teams" (Garcia et al., 2013).

Methods and Findings

Experts in health care quality assurance and peer review developed criteria for ACEs warranting an offer of compensation (e.g., they are preventable and reliably identifiable, and the harm is measurable), and they identified 18 safety events meeting the criteria as well as others worthy of further investigation. These 18 events included those occurring during surgeries and other procedures (e.g., failure of sterility, surgery on the wrong body part); pregnancy, labor and delivery, and newborn care (e.g., nondetection of Rh factor, failure to treat newborn hypoglycemia); and general care and infectious disease (e.g., administration of the wrong intravenous fluid or medication). An implementation plan was recommended that outlines the process for identifying and disclosing events to the patient or patient's family, apologizing, and having early discussions with patients or families about compensation. A standardized approach to compensation was also developed. The grantee offered recommendations for implementing a voluntary ACEx2 program, including using nonadversarial methods (e.g., mediation) to resolve disagreements about compensation, uniform standards for data collection to advise decisions about compensation and legislative changes, and available data to advise compensation offers and schedules of compensation amounts.

Two other components of the project demonstrated the potential benefits of an ACEx2 approach. First, an actuarial review of claims concluded that the use of an ACEx2 system might stabilize claims inflation and reduce costs through an accelerated claims process. Second, a review of medication errors (1 of the 18 ACEs identified) in 2 health care facilities led to the following conclusions: "Frequency and severity of Avoidable Clinical Events are likely to be reduced if a patient safety program successfully partners with all segments of the health care continuum

during a timely and effective root cause analysis; an ACEsx2 program can remove fear of litigation as a barrier to patient safety analysis if the discussion includes issues of legal responsibility and allocation of compensation amounts. This discussion has not been a standard part of our current review" (Gregg and Garcia 2013).

This program was intended to enable rapid handling of ACE claims through an objective process unlike adversarial litigation. The project team concluded that a voluntary DA&O program for clinically avoidable classes of events is easiest to accomplish in an integrated system where physicians are employed by the facility. While significantly harder to implement in settings of care that do not provide direct employment to the majority of physicians, the research team demonstrated that patient compensation programs can complement patient safety efforts and potentially decrease defense costs, defensive medicine costs, and the cost of care while increasing certainty about claim values.

Source Documents

Garcia D, Markus CA, Vassall J. Improving patient safety and restructuring medical liability using ACE. Manuscript in preparation. 2013.

Gregg M, Garcia D. Improving patient safety and restructuring medical liability using ACEs: Medication errors. Manuscript in preparation. 2013.

Wishard Health Services (Now Under Eskenazi Health)

Title: Open Disclosure and Medical Claims Study   **Award Number:** R21 HS19585-01
Principal Investigator: John Buckley, M.D., M.P.H.   **Award:** $161,808

Goals

The goal of this project was to evaluate the effectiveness and claim filing experience of using the Wishard Health Services (now subsumed under Eskenazi Health) Reformulated Medical Claims Model (RMCM). This model was developed to promote open communication among providers and patients and to identify risk-prone areas, which could ultimately improve patient safety in one of the largest safety net providers in the United States. The RMCM was modeled after the University of Michigan Claims Management Model. Wishard had been using its new model since 2008 but had not yet documented and evaluated the new data or assessed whether provider and patient experiences had improved since changing the claims process.

Methods and Findings

Prior to implementation of RMCM in 2008, medical claims at Wishard were handled individually and were not integrated into a quality improvement system. With the RMCM, potential medical errors from multiple sources are entered in a customized database and tracked along with associated data, such as disclosures and findings from peer review. In addition, the new process ensures that each claim is investigated and undergoes peer review, which results in a disclosure, apology, and discussion of a settlement if it is determined that a medical error occurred.

In the first part of the study, researchers surveyed patients and medical staff involved in claims closed between 2008 and May 2012. During this time period, 41 claims had sufficient data for analysis. Of the 41 patients involved, 9 were located and 5 participated in a survey, too small a sample to draw conclusions. Of the 27 medical personnel identified in the claims, 13 completed surveys, 2 chose not to participate, and 12 could not be reached. Overall, staff members rated the new system favorably, with 100 percent of respondents reporting being "very satisfied" or "satisfied" with the risk management/peer review process, the RMCM process, and the claims committee process, and 75% stating that the RMCM was "very efficient" or "efficient." Although one-third of respondents indicated the new system improved on the previous system, two-thirds of respondents were unsure or indicated the question was not applicable due to limited knowledge about the previous process.

In the second part of the study, researchers compared the 41 claims closed under the new system to 125 cases processed through the old system. Claims were categorized by six unique claim types that ranged from grievances to formal claims against Wishard alleging malpractice or other actions leading to patient injury or damage. Compared with the old claims model, the RMCM approach fared better or the same in the length of time for processing cases, the size of settlement awards made, and the amount of legal fees encumbered by Wishard. A significantly larger percentage of cases under the RMCM reached a settlement than under the old claims model (48.8% vs. 12.7%; $p < .001$).

The researchers faced challenges in locating patients due to the length of time between the closure of cases and the study (which was up to 4 years) as well as the transience of the disadvantaged population served, which suggests the need for a system to solicit feedback from patients closer in time to their experience. Likewise, the delay between cases and the study limited medical staff's memory of case-specific information. This study concluded that the RMCM approach favors over the previous claims management approach and also highlighted the persistent need for addressing patient harm expeditiously and fostering better provider–patient communication. The project team recommended implementing a regularly administered, anonymous satisfaction reporting process for integration into the claims management system to enhance understanding of the benefits or drawbacks of the model.

Office for Oregon Health Policy and Research

Title: Medical Liability and Patient Safety Guidelines Project **Award Number:** R21 HS19535-01
Principal Investigator: Jeanene Smith, M.D., M.P.H.   **Award:** $299,458

Goals

The goal of this project was to explore how to improve patient safety and reduce medical liability claims by testing the application of legal safe harbor policies in Oregon. The safe harbor framework grants liability protection to clinicians if they can demonstrate adherence to State-endorsed, evidence-based medical guidelines. When applied in any health care setting, a legal safe harbor allows clinical practice guidelines a special status in the medical liability system and is intended to provide greater clarity about the standard of care expected of medical professionals.

Methods and Findings

Researchers conducted a preliminary analysis of 2,632 medical claims closed over an 11-year period to identify and prioritize clinical issues and key clinical and legal cost drivers. The analysis identified the most common procedures (surgeries, medication administration, diagnostic tests, use of equipment, and labor and delivery-related procedures) and diagnoses (cancer, fractures, infection, and disease) related to claims. The data were intended to advise the adoption of evidence-based medical guidelines for clinical situations associated with high rates of patient injuries and liability claims.

In a feasibility assessment, researchers analyzed selected closed medical liability claim files from 2002 through 2009 to determine if (1) better adherence to medical guidelines could have prevented some of the patient harms that led to medical liability claims and (2) a safe harbor rule could have altered the course or outcome of the medical liability claims. Of the 907 claims examined, reviewers identified 133 in which an existing medical guideline applied to the claim. Of the 907 claims, about 5 percent would have been avoided if clinicians had followed guidelines. Further, 9.5 percent of the claims would have been resolved more quickly using the safe harbor model. Although some payments could have been avoided altogether, the savings would have been small, and some claims would likely have been paid that were not, depending on the type of safe harbor rule adopted. Researchers estimated that the cost savings of a safe harbor rule in Oregon in 2008 would have been $4 million, but they did not estimate the additional costs associated with using this approach.

After the findings from this assessment were shared with each of six stakeholder groups involved in the fields of medical liability and patient safety (e.g., Oregon Medical Association, Oregon Trial Lawyers Association, Oregon Patient Safety Commission, consumer advocates), a facilitated discussion with each group revealed perspectives about the potential benefits of a safe harbor rule. Participants expressed "mixed feelings" about the potential for safe harbor. While safe harbor may improve patient safety by increasing the use of clinical guidelines, the cost savings would be minimal. One serious concern was the challenge associated with developing and obtaining consensus on evidence-based clinical guidelines, which would need to be

developed and used by physicians and be easily accessed through provider education for a safe harbor rule to be effective. These participants also expressed that the "medical liability system should be reformed and frequently pointed to the successes of disclosure and offer programs in other States" (Smith 2012).

As a followup, researchers then conducted a survey of more than 2,000 providers to seek input about the feasibility of implementing a legal safe harbor. Respondents agreed that a safe harbor rule would likely reduce the impact of medical liability on their clinical decisionmaking (72%), would be an effective approach to medical liability reform (71%), would increase their adherence to guidelines (82%), and would therefore result in improved patient safety (69%).

In addition, in 14 one-on-one interviews, stakeholders (e.g., physicians, attorneys, risk managers, patient safety experts, medical liability insurance providers) shared their perspectives on key safety issues and the selection of safe harbor guidelines. Some common themes included "use medical guidelines specific to providers that are simple, clear, and noncontroversial"; "involve stakeholders extensively, particularly physicians, throughout the process of designing and adopting a safe harbor legislative proposal"; and "set high standards for the strength of evidence supporting medical guidelines" (Smith 2012).

The team later assessed methods that could best evaluate and measure the outcomes of any future legislative safe harbor proposal and conducted a legal scan to develop and gauge the feasibility of a safe harbor framework.

Based on the results of this work, the safe harbor approach appears to be most valuable for improving patient safety but would have a less significant impact on medical liability costs. This research study has better informed the Oregon State government about its existing liability claims reporting system and the relationship among patient harm reduction with respect to practice guidelines. It also brought forward issues regarding medical liability claims data availability, adequacy, and accuracy. There will be efforts to use what was learned to improve the claims reporting system, further the development and use of practice guidelines, and continue to explore the concept of a legal safe harbor, particularly for its benefits to patient safety.

Source Documents

Smith J. AHRQ Medical Liability & Patient Safety Planning Grant. Final Progress Report. Prepared by Oregon Health Policy and Research under grant number 1 R21 HS019535-01. Prepared for the Agency for Healthcare Research and Quality. Portland, OR; March 2012:12.

Appendix B. References

1. Mincer SL, Lee MJ, Bransford RJ, et al. Adopting and implementing shared decisionmaking: Barriers and solutions. Manuscript in preparation. 2013.

2. Guenther E, Junkins EP, McDonnell WM, et al. Regional Implementation of a Protocol To Disclose Unanticipated Events. Final Progress Report. Prepared by the University of Utah, School of Medicine under grant number R21 HS19498. Prepared for the Agency for Healthcare Research and Quality. Salt Lake City, UT; March 2012:11.

3. Tessler NB. Improve Patient Safety and Reform Medical Liability by Planning the Implementation of the Initiative to Reduce Inpatient Suicide. Final Progress Report. Prepared by Jackson Health System under grant number 1R21 HS19506-01. Prepared for the Agency for Healthcare Research and Quality. Miami, FL; August 2011:13.