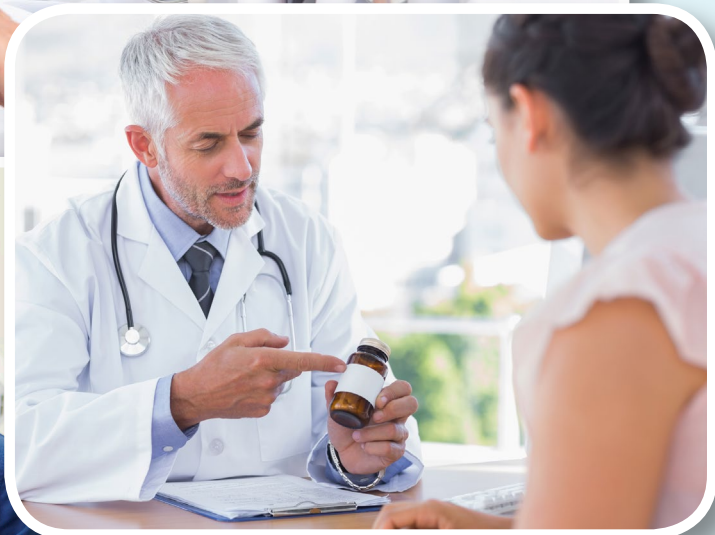


# Advances in Patient Safety and Medical Liability



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AHRQ Publication No. 17-0017-EF  
August 2017

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### **Suggested citation:**

Advances in Patient Safety and Medical Liability. Battles J, Azam I, Grady M, and Reback K, Eds. AHRQ Publication No. 17-0017-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2017.

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## Preface

Since the Institute of Medicine report “To Err is Human” was issued in 2000, the Agency for Healthcare Research and Quality (AHRQ) has served as the lead Federal agency to fund research and the development of tools and resources to improve patient safety. Through these activities, AHRQ seeks to prevent, mitigate, and decrease medical errors, patient safety risks and hazards, and quality gaps associated with health care and their harmful impact on patients. While we have made great strides in reaching this goal, and health care providers continue their efforts to deliver high-quality, evidence-based care, patients continue to be harmed by the health care system.

To address the need to improve patient safety and the medical liability system, the AHRQ Patient Safety and Medical Liability (PSML) Initiative was established in October 2009. Funding was intended to address four goals: (1) putting patient safety first by reducing preventable injuries, (2) fostering better communication between doctors and patients, (3) ensuring fair and timely compensation for medical injuries while reducing malpractice litigation, and (4) reducing liability premiums.

Under the PSML initiative, AHRQ funded 13 planning grants and 7 demonstration grants. This initiative aimed to help States and health systems seek comprehensive solutions that improve patient safety and address the underlying causes of the malpractice problem.

Advances in Patient Safety and Medical Liability presents contributions and findings from several of these projects to illustrate that, despite the complexity of this work, this initiative has contributed important insights to guide future research. In addition to a prologue, the volume includes two commentaries and nine papers, organized into two primary themes: improving communication and improving patient safety. Topics include the role of the patient and family in supporting improved care and patient safety; shared decision-making initiatives; the use of reporting systems; the harmful impact of institutional silence when patient harm occurs; implementation of disclosure, apology, and offer programs; safety culture and disclosure culture surveys; medication safety initiatives; and more.

Many of the activities and findings from the PSML initiative will serve as the groundwork for future patient safety and medical liability projects, as these grants sustained successful implementation and maintenance of their interventions. The papers presented in this volume offer new insights, raise new questions, and identify new areas for further exploration. We hope that this contribution to the field will more firmly establish the importance of emerging research in patient safety and medical liability.

Sharon B. Arnold, PhD  
Deputy Director  
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## **Acknowledgments**

Advances in Patient Safety and Medical Liability has been produced in a collaborative effort among Federal staff, grantees, and contractors from the Department of Health and Human Services (HHS), other Federal departments, and the private sector. Many individuals guided and contributed to this publication. Without their magnanimous support, this volume of Advances would not have been possible.

Specifically, we thank Karen Migdail for her helpful guidance throughout the publication process, as well as Michelle Pillen, Susan Ridgely, Michael Greenberg, and Robin Campbell for their advice and constructive suggestions regarding the development of this work. We thank Sharon Arnold, Jeff Brady, Erin Grace, and Margie Shofer for their review of the manuscripts and participation in the publication process.

Thank you to our colleagues in AHRQ's Office of Communications, including Joel Boches for preparing cover designs, and Sandra Cummings, Karen Fleming-Michael, and Farah Englert for their work in the development and clearance of this publication.

We are indebted to our peer reviewers for their time and diligent feedback. Most of all, we thank the participating authors and their research teams who patiently and willingly shared their stories and their work with the aim of advancing the research base in this field. We hope that this collection of manuscripts will inform and benefit future investigators and researchers who seek to improve the safety of health care and patient outcomes.

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# Prologue

**Kenneth Sands, Alan Woodward, and Melinda Van Niel**

Research in patient safety and medical liability in recent years has widened our definition of these terms. Patient Safety improvement is no longer a preventive strategy to protect medical facilities from lawsuits – it is a serious and wide-reaching effort to measurably improve the safety culture among staff in medical institutions, to find lasting and systemic prevention strategies for adverse events, and to work with patients—and with their families and caregivers—as equals to both address their care needs and to earnestly reconcile when their care does not go as planned. Working with patients as partners has become increasingly important in our rapidly changing medical landscape. Patients are experts in their own care and their own needs. Too often, we medical professionals ignore their expertise and opinion. In addition, caregivers and family members have knowledge and perspectives about the patient and his or her condition that can contribute to better care and improved patient safety. Transparency between and among medical colleagues and a supportive just culture<sup>1</sup> are also central aspects to improving safety and creating a climate less prone to medical liability in health care facilities.

The articles included in this publication demonstrate a wide variety of studies that investigate the importance of openness and collaboration with medical colleagues and patients before, during, and after patient care. Many of the papers reveal the merits of involving patients as team members from the planning stages for their care, with programs like shared decision-making and team building. Several authors also demonstrate the need for internal transparency with regard to near-miss reporting and medication discrepancies during transfers to improve safety. And finally, there are several illuminating studies on working with patients when things go wrong, including communication and resolution programs (CRPs) and other disclosure strategies.

Patient safety, as a field, has come a long way in a short time, but there is still significant progress to be made. The National Patient Safety Foundation was formed fewer than 20 years ago, and in many places in the country, patient safety is not a central component of health care operations, but instead it is a patch to reflexively plug problematic holes in a system. Likewise, initiatives to address medical liability have only taken the progressive turn noted by our fellow authors in this publication in the last 20 years, and programs that embrace transparency and prevention of adverse event recurrence like CRPs are still few and far between. In order to create true progress in patient safety and medical liability and spread adoption of these successful programs, committed stakeholders must join together to press these programs forward. Our experience in Massachusetts has demonstrated that understanding the barriers and concerns of the stakeholders involved and working with those stakeholders to remove those barriers and collaboratively move toward safer, more transparent care together represent the best way to achieve lasting success.<sup>2</sup> Engaging traditionally opposing sides and finding common ground and a higher purpose are strong drivers toward change, and the absence of this buy-in from all constituents – patients, physicians, insurers, attorneys, and others – stops rapid progress and adoption of programs that are demonstrated to show significant benefit for all stakeholders.

Likewise, additional research in patient safety and medical liability is crucial to overcome barriers and demonstrate value. The studies described herein are at the forefront of their field;



this research is important pioneering work that must be continued to remove roadblocks such that prevent widespread adoption of these progressive patient safety and medical liability improvement measures.

Studying patient safety and medical liability takes diligence and patience, as the challenges of researching lawsuits, claims, and other patient harm include long resolution time (for example, the average medical malpractice lawsuit that goes to trial in the United States takes about 3.5 years to resolve),<sup>3</sup> different insurance models (i.e., captive vs. commercial) that have the loci of control outside or inside the medical facility itself, and the common fear that engaging patients in dialogue around harm, safety, or even fallibility will create increased legal activity from patients. We must continue our research efforts to address these concerns and demonstrate that for each of the variables listed above, time and again, engaging with patients for safety in their care only improves their care and increases the quality of service that we, as health care professionals provide.

Additional research in patient safety and medical liability will also continue to emphasize the value in creating a culture of safety and in engaging with patients to improve quality of care. Using measures of patient experience such as the Consumer Assessment of Healthcare Providers and Systems Hospital Survey (HCAHPS),<sup>4</sup> and patient-reported outcomes will assist health care facilities in composing a complete picture of patient safety by better understanding how patients feel physically and emotionally after the care they receive. In addition, using tools to measure staff and clinician experience through culture of safety surveys,<sup>5</sup> and human resources (HR) metrics such as staff turnover and retention, will give health care facilities a 360-degree view of where their patient safety culture stands and areas in which they can improve.

Fortunately, over the past several years, many valuable tools have been built to help support positive changes in patient safety and medical liability through low- or no-cost measures. Organizations on both a national and local scale have created toolkits to help facilities implement programs like CRPs (see the AHRQ CANDOR Toolkit<sup>6</sup> and the Massachusetts Alliance for Communication and Resolution following Medical Injury Implementation Guide<sup>7</sup>) and shared decision-making (see the AHRQ SHARE Program toolkit<sup>8</sup>) and have also built communities of stakeholders already doing the work who can provide support and encouragement to those who are at the beginning of their journey. These toolkits and communities were built with the express purpose of helping these concepts spread quickly, without reinventing the wheel and with low barriers to entry. We encourage you to take advantage of these valuable resources.

Patient safety and medical liability is a dynamic field, and we hope that in the next several years the concepts presented in these articles will be rapidly adopted to help ensure that we take the best care of our patients that we can. This, in turn, will enable staff and clinicians to feel secure and supported and our systems to be as close to error-free as possible. We must continue to build on those concepts tested here and help make the case for more honest, transparent partnership with patients before, during, and after their care and more open engagement with our staff around problems and solutions. This way forward will lead to delivering care and handling unexpected outcomes in a way that supports iterative improvement, so that all of the care delivered in the future is care of which we can be proud.

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# Silence

## A Commentary

Carole Hemmelgarn

Three years, seven months and twenty-eight days, or 1,745,280 minutes, it does not matter the measurement of time used, your world stands still and silent. You watch the hands of the clock move and hear the tick tock, tick tock, but you are frozen in time. The sands in the hourglass no longer drop, and yet the world continues moving forward around you, while you are paralyzed. This is what it feels like when you lose a loved one to a medical error. This is what it felt like after I lost my 9-year-old daughter, Alyssa. However, what compounds the pain is when you are not told the truth about what has happened to your loved one and what kind of care they received.

Patients and families realize no provider comes to work with the intent to cause harm. Yet, when harm does occur, and honest and transparent conversations are not conducted, you harm us again, and this is the second tragedy. We can only maneuver through the world in survival mode when we do not know the truth, and we lose the ability to actually live. Having these difficult conversations is not easy, but they are paramount to the healing process for patients, families, providers, and organizations.

There are four things patients and families want after medical harm has occurred: tell us what happened, tell us how you are going to fix the problem, take responsibility, and apologize.<sup>1</sup> First, when we say “Tell us what happened,” it means what we need and want to hear, not what you feel comfortable telling us, what you think we should hear, or what you want to share with us.<sup>2</sup> It is simply about the truth, no more, no less. Second, we need to know that what happened to our loved one is not going to happen to anyone else. If it does, we feel their injury or the loss of their life was in vain.

Doing a thorough event investigation and analysis, or root cause analysis, is an important step in the learning process for the organization, and it assists the organization in providing answers to the patient and/or family.<sup>3</sup> The process should include a narrative from the patient and/or family, since they are typically the only constant in the 24-hour-care provided while the patient is in the medical setting.<sup>4</sup> Third, taking responsibility for the event is part of the communication process, whether the harm resulted from a human error, a systems error, or both. In some cases, it may be a provider or team that takes responsibility for the error; in other cases, it may be the leadership of the organization. Regardless of who comes forward, it is about displaying empathy and remorse to the patient and family so they feel you genuinely care. Finally, the two little words “I’m Sorry” can be some of the most powerful words spoken after medical harm.<sup>5</sup>

I believe there is a fifth desire for some patients and families after harm has occurred, and it is being part of the solution to fix the problems that led to the error. Some people need to do this to make sure the problem or system is fixed, others do it to honor their loved one, and for many, it is a way to heal and give back. Yes, many patients and families will walk back through the very doors of the organizations where they were harmed, and they want to be a partner in improving

the care that organization provides and in making sure patient safety is a priority. This is a gift health care providers, leaders, and organizations should embrace.

In recent years, there has been a growing movement among hospital systems toward implementing Communication and Resolution Programs (CRPs). These programs continue to evolve since their inception in the 1990s. Some of the key elements of CRPs are reporting and responding to adverse events, continuous communication with patients and families throughout the disclosure process, event analysis, system improvements, emotional support for caregivers, and compensation.<sup>6</sup> The Agency for Healthcare Research and Quality (AHRQ) has created a toolkit called CANDOR (Communication AND Optimal Resolution) that provides important resources and educational materials regarding these topics for organizations that want to undertake the CRP process.<sup>3</sup>

Communication and Resolution Programs help provide for the many different needs of individuals after harm. In the past, patients experienced only silence and abandonment after a medical error. CRPs and their participants now realize the importance of talking with the patient and family immediately after harm and continuing those conversations until all of their questions have been addressed and answered. Disclosure is not an event, it is a process, and it does not end until the patient or family says it ends, which can take days, weeks, months, and even years. This occurs when they are able to find a space and place in their heart to store the pain, try to forgive, and learn how to live in a different world.

While some patients and families may need monetary compensation, this is not always the case. For patients who require ongoing health care, compensation is necessary and appropriate. Others may need immediate assistance to cover daily living expenses while they cannot work or to pay for funeral costs. When there is loss of life due to a medical error, some families do not want any money because they feel you cannot put a 'price' tag on their loved one's life; others, may need compensation in order to survive financially and to take care of their children. However, some patients and families want compensation that benefits the organization and honors their loved one. This can be a yearly Grand Rounds lecture in the name of their loved one, staff training around the error, protocols implemented, or a bench, piece of artwork, or room dedicated in their loved one's name. There is a great fear among families that their loved one will be forgotten, so knowing their name lives on can be a powerful form of compensation.

It is important to have a designated plan after medical harm occurs, but equally, if not more important is recognizing there is not a one-size-fits-all program for patients and families. Their needs can vary greatly based on race, ethnicity, age, language, culture, religion, family structure, socioeconomic status, and the degree of harm or loss of life. The significance of having a well-developed, leadership-led, and staff-supported CRP cannot be stressed enough. Even though the primary focus of the program is to help patients and families who have experienced harm, the larger programmatic scope is to identify those latent issues in the system so that they never reach the patient, while keeping those providing patient care supported and safe as well.

Three years, seven months, twenty eight days, and millions of minutes of endless pain that could have been alleviated. No one should ever have to wait that long to find out answers about what happened to their loved one, have the organization accept responsibility, and say the two most

powerful words “I’m Sorry” and mean them. The barrier to not being honest and transparent with patients and families can no longer be fear. It is unacceptable. It is time to turn the hourglass over and shift the paradigm. Instead of letting fear drive the actions and behaviors after harm, it is the mindset of courage and ethical obligation that will lead us to the next frontier.

## Acknowledgments

I would like to thank Brian Parker, MD for his thoughtful guidance in composing this commentary.

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# Reforming the Medical Liability System in Massachusetts: Communication, Apology, and Resolution (CARE)

Kenneth E.F. Sands, Alan C. Woodward, and Melinda B. Van Niel

## Abstract

**Introduction:** The Agency for Healthcare Research and Quality awarded a planning grant to Beth Israel Deaconess Medical Center, partnering with the Massachusetts Medical Society, to explore the feasibility of broadly implementing a Disclosure, Apology, and Offer (DA&O) program in Massachusetts.

**Methods and Results:** The study comprised 27 key stakeholder interviews that explored the perceptions of the DA&O model, the perceived barriers to implementation, and strategies for overcoming the barriers. The majority of stakeholders found the DA&O model to be the most promising strategy to improve medical liability and patient safety environments in the State, and most interviewees believed it was “the right thing to do.” For each of the 12 barriers, multiple strategies were identified—based on feasibility, importance, and impact—and prioritized into a Roadmap for transforming the medical liability system in Massachusetts.

**Discussion:** Using the Roadmap as a guide, a statewide alliance was created to implement the Roadmap and promote the use of the DA&O model. The Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI) was formed, and members titled their approach, Communication, Apology, and Resolution (CARE). It includes hospitals, provider organizations, patient advocacy and safety organizations, insurers, and the State bar association. A demonstration of the CARE model is underway, including a formal study to track outcomes, at six hospitals. Enabling legislation was passed, and educational materials and a resource Web site were created. MACRMI also developed algorithms, best practices, policies, and procedures and launched educational initiatives, including an annual CARE Forum, that have reached numerous stakeholder groups representing a broad variety of constituencies.

**Conclusion:** Data on the feasibility of the CARE model, its barriers, and strategies for overcoming those barriers were essential in understanding the challenges in implementing this model, not only in Massachusetts but nationally as well. While some of the identified barriers and strategies are unique to Massachusetts, most of the Roadmap’s components are applicable in other States.

## Introduction

Massachusetts has long been a pioneer in health care reform, and this innovative spirit extends to medical liability reform. Massachusetts was the first State to adopt protections for statements of regret in December 1986,<sup>1</sup> and it has been an early adopter of the Disclosure, Apology, and Offer (DA&O) approach to adverse events in some health care settings.<sup>2</sup> DA&O emphasizes honesty and transparency with patients regarding adverse events and errors. Its goals are to



(1) proactively identify adverse events, (2) differentiate between injuries caused by negligence and those arising from complications of disease or intrinsically high-risk medical care, (3) offer patients full disclosure and honest explanations about what went wrong and why, and (4) offer an apology and rapid, fair compensation, with patient representation, when unreasonable care caused injury. Proponents believe that DA&O is “the right thing to do,” not only because it compensates patients who deserve it in a more timely manner, but also because it allows safety improvements to be made to prevent similar errors from recurring, thus protecting future patients. The primary goal of the approach is to improve safety for patients, while an added benefit is a reduction in costs and claims.

The DA&O approach to adverse events initially did not gain momentum as a risk management practice and was used sparingly in the United States in the early 2000s. Early reports from the University of Michigan Health System (UMHS)—which had implemented the approach in 2001 by fully disclosing adverse events and compensating those patients who were harmed by unreasonable care outside of the court system—were promising, but it was not until 9 years later, when UMHS published data on processes, outcomes, costs, and volume that the medical liability community began to seriously consider the approach viable. One UMHS study, published in 2010, included a before-and-after review of claims frequency, transactional costs, incidence of litigation, and time to resolution and found that all of these indicators improved with the DA&O approach.<sup>3</sup> Other early pioneers, like Stanford University Hospital and Clinics, experienced a 38 percent reduction in overall costs over 5 years, as well as a reduction in the number of claims.<sup>4</sup>

In July 2010, the Agency for Healthcare Research and Quality (AHRQ) awarded Beth Israel Deaconess Medical Center (BIDMC) and their partner organization, Massachusetts Medical Society, a planning grant to determine the feasibility of widespread implementation of a DA&O program in Massachusetts and to isolate both the barriers to utilizing the approach and strategies that could overcome those barriers and allow DA&O to succeed. There had been previous suggestions of reasons for the slow adoption of this approach,<sup>5,6,7,8</sup> but the Massachusetts study aimed to empirically investigate these issues and, if feasible, build a model that would best address impediments to DA&O. Once these challenges and strategies to overcome them were identified, the team used the suggested strategies to build a thriving, broad-based DA&O pilot program and supportive infrastructure.

## Methods

The methods and results of this study have been published previously in the *Milbank Quarterly*.<sup>9</sup> The institutional review boards of BIDMC and the Harvard School of Public Health (HSPH) reviewed and approved the project. Structured interviews were conducted with 27 respondents representing a broad range of stakeholder groups in Massachusetts who were key to implementation of the DA&O approach: the Massachusetts legislature and administration, hospital systems (including academic health centers and community hospitals), practicing physicians, liability insurers, health insurers, medical professional associations, patient advocacy organizations, malpractice attorneys, patient safety experts, major physician practice groups, and a major business association. Overall, nine of the 27 respondents were physicians.<sup>10</sup>

Using an interview guide developed by the HSPH, four main areas were covered: (1) the respondent's institutional setting and relevant experience, (2) perceived potential for the DA&O model to improve medical liability and patient safety, (3) perceived barriers to implementing DA&O programs, and (4) suggested strategies for overcoming identified barriers.<sup>11</sup> Investigators led the interviews, which lasted 45-60 minutes.

## Results

A summary of the Roadmap and the central messages of the study are provided below.<sup>10</sup> As a result of the study, three central messages emerged:

1. There is strong support for the DA&O approach—above any other model—among respondents. The consistent view that such a model is the “right thing to do” ethically, with cost savings as an additional benefit.
2. Many proposed strategies can be pursued relatively quickly and easily.
3. The DA&O approach benefits patient safety by encouraging open discussion of error, leading to improved reporting and deeper understanding of safety risks.

The barriers and strategies collectively identified during the interviews were then shared with the project's interviewees for individual feedback. The project team integrated stakeholder feedback into the Roadmap prior to presentation at a symposium entitled “Roadmap for Transforming Medical Liability and Improving Patient Safety in Massachusetts” (Roadmap) in March 2011. The overall Roadmap, including the barriers and strategies, was then further refined based on additional feedback from the approximately 150 symposium participants, made up primarily of physicians but also representatives of each of the other stakeholder groups.

## Barriers and Strategies

The interviews revealed several barriers and potential solutions to implementation of a DA&O model. Below are the 12 most commonly cited barriers (table 1), followed by a high-level summary of the proposed strategies for overcoming them.

In the summary of the strategies below, “Fairness to patients” and “Accountability for the process” have been combined into a single barrier “Fairness and Accountability” because the specific concerns and strategies voiced were complementary. In addition, “Opposition by insurers” was added as an additional barrier because several stakeholders observed that the current system is familiar and relatively predictable for liability insurers, whereas the impact of a change to a more proactive DA&O model cannot be predicted and thus might be opposed by this constituency.<sup>11</sup>

**Table 1. Barriers to DA&O Model Implementation<sup>9</sup>**

<b>Barrier</b>	<b>% (n)</b>
Charitable immunity <sup>1</sup>	81 (22/27)
Physician discomfort with disclosure	78 (21/27)
Attorneys' interest in maintaining the status quo	74 (20/27)
Coordination across insurers	74 (20/27)
Physicians' name-based reporting	70 (19/27)
Concern about increased liability	59 (16/27)
Forces of inertia	48 (13/27)
Fairness to patients	44 (12/27)
Concern it may not work in other settings	41 (11/27)
Insufficient evidence	30 (8/27)
Supporting legislation needed	30 (8/27)
Accountability for the process	19 (5/27)

<sup>1</sup> At the time of this study, Massachusetts' charitable immunity law limited to \$20,000 the tort liability of any charitable corporation, trust, or association (which includes nonprofit hospitals and health care institutions). Mass. Gen. Laws Ann. ch. 231, § 85K [2012]. This law covers nearly all hospitals in Massachusetts. In August 2012, a provision increasing the charitable immunity cap to \$100,000 for medical liability was signed into law (ch. 224 of the Acts of 2012), which was noted by the authors still to be very low.<sup>9</sup>

- **Fairness and accountability:** education of the public and media; legal representation for patients/families; standardized root cause analysis processes; transparent compensation formulas; and mechanisms for sharing “lessons learned” to improve patient safety.
- **Physician discomfort with disclosure:** physician education and training, including peer mentors; establishment of a “just culture”; support from hospital/health enterprise leadership.
- **Concern about increased liability:** data dissemination from sites having implemented the model.
- **Physician name-based reporting:** education; process change allowing institution-based reporting for adverse outcomes deemed to be system failures; and clear reporting requirements.
- **Charitable immunity law:** system liability through a voluntary waiver-by-settlement approach.
- **Difficulty coordinating insurers:** Convening a forum for insurers to cooperatively resolve codefendant issues.
- **Opposition by liability insurers:** data collection to better quantify the financial bottom line; education; and early involvement of liability insurers in cases where error is suspected.
- **Concern that the model may not be replicable in certain settings:** creation of a centralized resource center; standardized policies; education and training; and statewide risk-pooling.

- **Attorneys' interest in maintaining the status quo:** education of attorneys regarding cost-effectiveness and the role of legal representation in the model; sharing of experiences by attorneys who have participated in DA&O models.
- **Difficulty of getting supporting legislation passed:** education of legislators; identification of key supporters among the legislators, as well as other key stakeholders such as State court judges.
- **Forces of inertia:** creation of resources to support leaders; identification of champions in each constituency; capitalizing on opinion leaders and patient representatives; dissemination of data on the shortcomings of the current system; collaborative influence of key stakeholders.
- **Insufficient evidence that the DA&O approach works:** collection and dissemination of data from institutions that have implemented the model, including pilot programs in varied settings.

## Discussion

In this study, we confirmed some of the potential barriers identified in previous commentary,<sup>4-7</sup> uncovered new barriers, and measured the frequency with which diverse stakeholders perceive them as problems. The study also highlighted potential solutions that stakeholders saw as feasible and important to pursue. We were able to discern that the DA&O program is the best alternative to the current dysfunctional medical liability system, and that it provides the strategies necessary to meet the challenges implementation could bring.

Following dissemination of findings from the study through a variety of media channels, stakeholders were interested in moving towards broader implementation of a DA&O approach in Massachusetts. Building on this momentum, a Roadmap to DA&O implementation was developed from this study's recommendations as an outline for starting a DA&O program.

As recommended in the Roadmap, an alliance was formed to sustain this momentum around building DA&O models in the State: the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI). MACRMI currently comprises members from a variety of stakeholder groups, including six pilot hospitals, liability insurers, the Board of Registration in Medicine, the Massachusetts Bar Association, the Massachusetts Coalition for the Prevention of Medical Errors, the Massachusetts Hospital Association, the Massachusetts Medical Society, and Medically Induced Trauma Support Services. To begin, MACRMI renamed the DA&O approach to better embody its spirit and mission, calling it Communication, Apology, and Resolution (CARE).

Over a 6-month period, parallel with the launch of MACRMI, the Massachusetts Medical Society negotiated consensus legislation with the Massachusetts Bar Association and the Massachusetts Academy of Trial Attorneys for the purpose of facilitating the implementation of CARE. Passed in August 2012, this legislation established a 6-month pre-litigation notice period

with shared access to all pertinent medical records, expanded the protections for apology which now include protection of statements of fault (e.g., “I am sorry that I caused your injury”), and provided guidelines for disclosure of adverse events.

In order to build on the empirical experiences of stakeholders who were interviewed through the planning grant and to understand how CARE could work in a variety of settings, MACRMI pursued implementing CARE programs through a pilot program at six institutions in Massachusetts. MACRMI developed clear policies, procedures, and algorithms for CARE programs and also created guides for facilities to implement each of these elements. Using its own tools, MACRMI facilitated the launch of pilot CARE programs in six hospitals across Massachusetts, including two academic medical centers and their four affiliated community hospitals. The sites have a variety of insurance models, including a captive model (e.g., hospitals insure themselves), a shared-captive model, and a combination of captive and commercial models. The pilot began in December 2012, when the HSPH began collecting data for a 3-year study of the effort, measuring costs, volume, and perceptions of key health care leaders. The 3-year study period ended in December 2015, and analysis continues with publication of the data expected in Fall 2017.

MACRMI has also developed strategies to help physicians with disclosure practices and training. Several of the pilot sites implemented “just in time” communication coaching. A rapid response pager number is available 24 hours a day for clinicians to call for assistance with properly communicating an adverse event to a patient and guidance on what to expect from the patient in that conversation. Pilot sites also educated their staff about the merits of CARE programs and the steps clinicians need to take after an adverse event to make the program successful (e.g., where resources are located, how to document the disclosure in the chart).

MACRMI is also working with the National Practitioner Data Bank (NPDB) and Massachusetts Board of Registration in Medicine (BORM) to clarify reporting requirements for CARE cases so that they can better inform physicians of the implications of resolving a case through CARE. The original pilot sites continue their CARE programs. Two additional entities joined MACRMI and implemented CARE, and several more are in the implementation planning process. By the end of 2017, there will be three academic medical centers, seven community hospitals, and an outpatient multispecialty group running CARE programs in Massachusetts.

Finally, MACRMI has launched a comprehensive resource Web site ([www.macrmi.info](http://www.macrmi.info)), which includes a variety of relevant articles, algorithms, policies, and tools that are freely accessible for facilities interested in starting their own CARE programs. The Web site has sections specifically geared toward patients and providers with frequently asked questions, a blog, and all of MACRMI’s resources, including a CARE brochure aimed at guiding patients through the CARE process. Resources are developed and approved by all members of MACRMI, and requests are solicited from MACRMI members and the local risk/patient safety community so that resource development directly responds to need. Resources include Best Practices for facilities and attorneys, conversation guides, algorithms, and a program implementation guide.

MACRMI also hosts an annual CARE forum. The first forum was held in April 2013. Each year, the forum brings together experts from around the country to a wide audience of risk managers,

hospital administrators, physicians, and patients who are interested in making this model a reality in their institutions. Topics and panels are selected based on feedback from attendees and challenges or questions voiced from MACRMI constituents. Some topics have included physician perspectives on CARE, insurer and attorney collaboration in CARE, and a panel discussion involving all parties from a resolved CARE case. Attendees find the forums helpful in increasing their understanding of how the CARE model is different from the status quo and what elements need to be in place at their own institutions to make a successful transition to CARE. These forums will continue to be held annually to encourage the use of CARE in health care facilities throughout the region.

## **Conclusion**

The Massachusetts study clarified the benefits of a DA&O model, the roadblocks that may be encountered in implementing such a model, and the strategies for overcoming those impediments. DA&O offers an avenue for bringing diverse stakeholders together because it presents a plausible value proposition to patients. Most stakeholders believe it is “the right thing to do,” despite its challenges. 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 that they believe will create a better health care system for all.

## **Acknowledgments**

The initial work in planning for this project was supported by the Agency for Healthcare Research and Quality (AHRQ grant HS19537). We acknowledge and thank our sponsors who, through their generosity, have enabled us to implement the Roadmap and make the CARE program and MACRMI a reality in Massachusetts: Baystate Health Insurance Company, Blue Cross Blue Shield of Massachusetts, Coverys, CRICO RMF, Harvard Pilgrim Health Care, the Massachusetts Medical Society, Reliant, and Tufts Associated Health Plan. The statements and opinions in this paper are those of the authors and do not represent the position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

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# Planning and Implementing the Patient Advocacy Reporting System<sup>®</sup> in the Sanford Health System

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## Abstract

**Background.** Patient complaints can help health care organizations identify physicians whose behaviors undermine a culture of safety and increase lawsuit risk. In 2010, the Sanford Health System (SHS) sought to plan and implement the Vanderbilt Center for Patient and Professional Advocacy's (CPPA) Patient Advocacy Reporting System<sup>®</sup> (PARS<sup>®</sup>), which effectively addresses "high-risk" physicians identified via analysis of unsolicited patient complaints. More than 1,400 SHS-affiliated physicians provide care for a large patient volume outside major metropolitan areas, and SHS sought ways to enhance its culture of safety using the PARS tool and process for promoting professional self-regulation. This study describes planning for SHS's PARS program launch and results of ongoing implementation through August 2016.

**Methods.** This retrospective, descriptive, planning and implementation project began with application of CPPA's Project Bundle assessment tool, which directed development of key people, processes, and systems until PARS launch-readiness was achieved. SHS patient complaint databases were coded and analyzed to calculate a "Risk Score" for all affiliated physicians. SHS peer physicians were trained as "messengers" to share local and national PARS data comparisons with physicians whose Risk Scores exceeded intervention thresholds. Six rounds of annual interventions have been completed.

**Results.** Planning efforts resulted in a successful SHS PARS launch and ongoing implementation. The peer physician messengers have delivered PARS data with high fidelity to intervention elements over the past 6 years to 124 high risk physicians; 60 percent have improved, 7 percent have departed, and 33 percent are so far unimproved. Overall, recipients' Risk Scores have declined 24 percent ( $p < .001$ ). SHS's return on investment in PARS exceeds \$4 for every \$1 spent.

**Discussion.** SHS and CPPA participated in a collaborative, comprehensive planning effort that has resulted in successful and sustained PARS implementation throughout SHS's multi-State regional facilities. Lessons learned and limitations are discussed.

**Conclusion.** First, the Project Bundle offers health care leaders a useful pre-launch heuristic for identifying needs and addressing readiness of quality/safety and/or risk-prevention projects. Second, PARS works to reduce patient dissatisfaction and overall claims-related expenditures via interventions involving high-risk physicians in a large, geographically complex health care system.



## Introduction

Patients and families are well positioned to help identify physicians whose behaviors undermine a culture of safety and increase lawsuit risk.<sup>1</sup> If patient complaints—a proxy for malpractice claims—are reported, addressed via service recovery efforts, recorded, analyzed, aggregated, and used to provide feedback to the health care professionals involved, risk can be reduced.<sup>2,3,4,5,6</sup> Specifically, research demonstrates a small proportion of physicians in any medical group are associated with disproportionate numbers of patient/family complaints.<sup>2,6,7, 8,9,10,11,12,13,14</sup> Research also demonstrates strong relationships between physicians' unsolicited patient complaints, malpractice claims, and other risk management actions.<sup>7,8,15,16,17,18</sup>

Taking advantage of patients' perspectives, the Vanderbilt Center for Patient and Professional Advocacy (CPPA) developed the evidence-based Patient Advocacy Reporting System<sup>®</sup> (PARS<sup>®</sup>) to: (1) promote professional accountability and self/group regulation; (2) optimize service recovery to address patient dissatisfaction; (3) identify physicians at increased risk for malpractice claims and effectively reduce their risk; (4) implement system-wide surveillance for behaviors that undermine a culture of safety, and (5) promote behavioral and practice/system changes that enhance a culture of safety.

CPPA currently partners with more than 140 hospitals nationally to implement PARS, resulting in a national comparative database of unsolicited patient complaints and shared operational best practices. CPPA continuously works with patient relations directors and representatives to achieve and maintain best practices in centralizing and increasing the recording of patient and family complaints for both immediate service recovery and pattern identification.<sup>6,19</sup> CPPA codes, aggregates, and analyzes unsolicited patient complaint narratives recorded by patient relations staff. The data are used to calculate a Risk Score for all affiliated physicians. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in more recent years have greater impact than those from previous years. As a result of these efforts, CPPA creates evidence-based, actionable reports that include local and national peer comparisons from the PARS national database (described below), and extracts the text of relevant patient complaints.<sup>5,6,7,11,12,13,14,20</sup>

The PARS process of tiered interventions is depicted in Figure 1.<sup>2,3,21</sup> PARS interventions are physician driven and have been implemented by trained peer physician “messengers” with excellent fidelity.<sup>3</sup> High risk physicians—those whose PARS Risk Scores are associated with malpractice claims risk, generally those in the top 3-8 percent of a medical group's members<sup>4</sup>—are recommended to be recipients of an Awareness Intervention. In these, a messenger physician colleague meets with a high-risk physician recipient to share PARS data (i.e., local and national comparisons, aggregated coded complaints, and full narratives). Most physicians take self-corrective actions that address behavioral and systems issues that dissatisfy patients and are associated with risk.<sup>3</sup>



**Figure 1. PARS Model of Tiered Interventions**

Source: Adapted from Hickson, Pichert, Webb, et al., 2007. Used with permission.

As a large, growing, geographically complex, multi-hospital, multi-outpatient-facility system, Sanford Health System (SHS) leadership sought tools and processes for continuing its tradition of promoting safety, quality, and risk reduction and doing so reliably. SHS expressed interest in PARS beginning in 2009 after learning CPPA had by that time supported several thousand initial and follow-up interventions nationally on physicians with high Risk Scores (“high risk” professionals) and that reductions in overall patient concerns and malpractice claims rates had resulted.<sup>3,4,5,6</sup> SHS then applied for and was awarded an AHRQ planning grant in collaboration with CPPA.

Successful PARS planning and implementation deserve and require considerable thought and collaborative effort. Leadership of both SHS and CPPA were substantially involved in both the planning study and the move to implement PARS throughout SHS. Collaborative decisionmaking was guided by CPPA’s “Project Bundle” (Table 1), a heuristic for assessing an organization’s readiness to launch and implement PARS.<sup>2,22</sup> The bundle includes three major categories—people, processes, and systems—and 10 subcategories. The tool simply but effectively reminds leaders and project initiators of essential elements that influence PARS success. Leaders, stakeholders, and other decisionmakers use professional judgment to reflect on each essential element’s capacity and ability to support PARS (or other safety, quality, or risk prevention projects). The bundle first helps identify project-critical elements deemed not sufficiently present or robust enough for program implementation. Those elements undergo development until launch readiness is mutually deemed sufficient to proceed. Perfection is not required, but willingness and commitment to improve current practices and sustain best practices are essential. The bundle also guides program planners’ and organizational leaders’ ongoing post-launch decisionmaking and development efforts when project goals are not being achieved.

**Table 1. PARS-Specific Project Bundle: Characteristics of Organizations With Successful PARS Programs<sup>2</sup>**

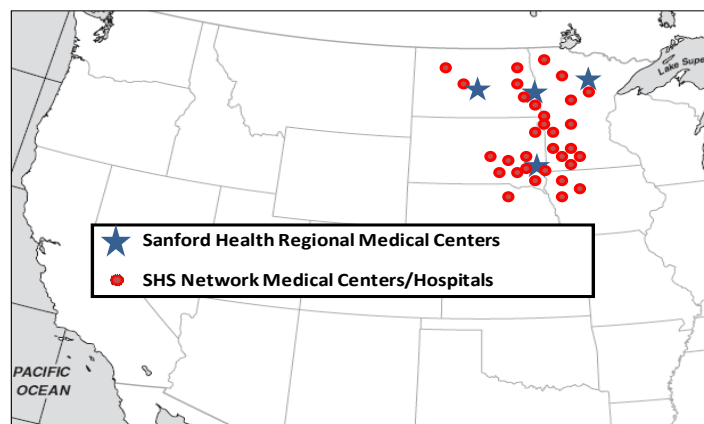
<b>People</b>	1. <b>Leadership commitment</b> to PARS. Leaders are prepared to address <i>any</i> and <i>all</i> professionals or other colleagues (regardless of seniority, rank, or financial considerations) whose behaviors appear to undermine a culture of safety.
	2. <b>Project champion(s)</b> . These persons are trusted with key data and a commitment to confidentiality and have a history of persevering and inspiring others to overcome barriers to achieving aims.
	3. <b>An implementation team—a “messenger committee” of medical group members, patient relations representatives, legal and human resources experts, risk managers, physician and nursing leaders, and key administrators</b> . Important team member characteristics include a reputation for trustworthiness and commitment to confidentiality; clinicians who are in practice or not far from it, willing to undergo training, able to communicate distressing information non-judgmentally, and are willing to hold accountable those unwilling or unable to make changes.
<b>Processes</b>	4. <b>Clearly articulated organizational values and goals</b> that align with PARS.
	5. <b>Policies and procedures</b> that address expectations for professional conduct and professional accountability.
	6. <b>A tiered model for interventions</b> (Figure 1) when unsolicited patient and family complaints are aggregated over time.
	7. <b>Resources</b> appropriate and sufficient to create (or improve) and sustain best practices in service recovery (e.g., patient relations staff, training, software for documenting and aggregating patient/family complaints). Also resources for professional assessment and wellness services, coaching/shadowing, practice redesign assistance, and other forms of support for high risk professionals.
<b>Systems</b>	8. <b>Measurement tools, data and metrics</b> for capturing, monitoring, reporting, and securely transferring data files to CPPA containing patient/family complaints, staff complaints, selected clinical metrics, affiliated physicians, and locations to assess risk.
	9. <b>Processes for reviewing the data</b> prepared by the CPPA PARS team, including individual points, trend lines, aggregated local comparisons, national comparisons.
	10. <b>Multi-level professional training for leaders and peer messengers about PARS science and politics</b> for long-term implementation, management, and sustainability.

The project had two major goals. The first was to assess SHS’s PARS readiness during a pre-launch planning and development phase. The second was to assess results of the PARS post-launch implementation phase, now in its sixth year. This paper will describe the pre-launch planning steps taken to increase the chances of PARS program success, changes in Risk Scores for recipients of PARS interventions, and evidence of return on investment for PARS program implementation. The methods employed during the pre-launch planning phase are presented and then followed by the methods used during the implementation phase. The results section is

similarly organized. Key project bundle elements addressed during each phase are highlighted in each section.

## Methods

**Setting.** SHS is a relatively young system, formed in November 2009 via merger of mature regional systems with 100+ year histories centered in Sioux Falls, SD (hereafter “SHS South”) and Fargo, ND (hereafter “SHS North”) (Figure 2). SHS is one of the largest health systems in the Nation with 43 hospitals and nearly 250 clinics in nine States and three countries. SHS’s 27,000 employees include more than 1,400 physicians practicing in 80 specialty areas of medicine. SHS is committed to continuously raise its high standards for delivering compassionate, comforting care for patients, promising both patients and staff “a flawless experience that inspires.”



**Figure 2. Sanford Health Medical Center Sites in the North (Fargo, Bismarck) and South (Sioux Falls, Bemidji) Regions**

**Planning Phase.** Evaluating “readiness” began with identifying and then addressing gaps in the project bundle elements. CPPA and SHS leaders continuously reviewed and, based on mutual experience and professional judgment, addressed the robustness of each bundle element via structured site visits, face-to-face meetings, frequent conference calls and email communications, training sessions, and discussions with all levels of SHS leadership and participants. The iterative nature of actions undertaken and length of time required to assure sufficient presence of each element prior to launching the PARS program are summarized in the Appendix Table, which indicates the people-specific, process-specific, and systems-specific methods and timeline. The methods used to address the various bundle elements are presented in the Appendix Table in order to illustrate how common program development and implementation challenges may be addressed, they reflect experiences similar to those employed by other organizations adopting PARS, they signal need for organizational commitment, and they are consistent with CPPA’s experience implementing a system for addressing co-worker concerns.<sup>22</sup> These processes and activities resulted in the initial SHS PARS launch in late 2011.

**Implementation Phase.** As background, the Vanderbilt Center for Patient and Professional Advocacy (CPPA) currently works with more than 140 hospitals and medical groups

(“participating health care organizations”) across 17 States to identify affiliated physicians who are associated with disproportionate levels of patient and family complaints relative to peers. CPPA maintains an electronic database containing securely transferred patient complaint and medical/surgical specialty data for more than 28,000 physicians with active practices who are credentialed at participating organizations.<sup>2,3,5</sup> CPPA data analysis identifies physicians whose patient/family-reported complaints show them to be outliers from both their local peer groups and physicians from the other medical centers represented in the database.<sup>11,12,13,14</sup> The Vanderbilt University Medical Center (VUMC) institutional review board approved a retrospective review of the patient complaint data from SHS and other participating health care organizations.

**Complaint Data.** Patient complaint data were obtained from the SHS North and South regions’ Offices of Patient Relations (“OPR”). The OPRs collected and recorded each patient or family complaint, identified the physician(s), if any, associated with alleged concerns, and created a narrative electronic report (“report”) describing the issue(s). Reports were securely submitted to CPPA for entry into the PARS database for analysis. This study focused on complaints recorded between August 16, 2007 and August 15, 2016.

**Coding System, Database, and Risk Scores.** Trained research coders reviewed each SHS patient complaint report, identified distinct concerns embedded within them, and assigned each complaint a code. One report might contain several complaints (e.g., “doctor was very late for my appointment,” “did not do a thorough exam,” “did not let me know my test results”). All complaints were coded using a standardized system that sorted complaints into six categories: accessibility, billing, care and treatment, communication, concern for patient and family, and environmental. The system’s inter-rater and test-retest reliabilities have been previously established through related research.<sup>20</sup> Coded data are used to calculate a Risk Score for all affiliated physicians. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in more recent years have greater impact than those from previous years.

**Intervention Process.** The principle underlying the PARS process is that identifying unnecessary variations in professionals’ behavior/performance and support system reliability is necessary, but not sufficient to increase patient safety, reduce malpractice claims, improve reliability, and increase professional accountability. In addition, the organization must support a systematic approach to promoting change in behavior or performance through peer-driven (at least initially), evidence-based, tiered conversations (Figure 1).<sup>2,6,21,23</sup>

Figure 1 reflects that the majority of health care professionals exhibit exemplary behavior, perform consistently well, and need only be given appropriate recognition and feedback about progress toward goals. The Pyramid’s first intervention level suggests that when what appears to be a single slip or lapse occurs, all that may be needed is an informal, non-authority conversation between peers, what we call a “Cup of Coffee” conversation.<sup>24,25</sup> Note, however, that single incidents involving alleged violations of law, regulation, or policy (e.g., sexual boundary violations, practicing impaired, harassment) are mandated to be immediately referred to appropriate leadership and/or offices, agencies, and/or law enforcement for evaluation and consideration of corrective/disciplinary action. Other serious breaches of normative behavior

that impact the work environment may be considered sufficiently egregious that they should be urgently addressed by the individual's authority figure/supervisor or institutional authority.

If a documented pattern of concerning behavior/performance appears to have emerged, the PARS process calls for a Level 1 "Awareness" intervention. Awareness interventions are designed to be confidential, nondirective, non-punitive, evidence-based conversations in which a peer professional (most often) delivers observations/data that the recipient's behavior/performance appears to vary from group expectations. If the pattern persists despite two or three rounds of Awareness interventions, the next step in the process is a Level 2 "Guided Intervention by Authority." These involve an individual up the recipient's chain of command (e.g., Department Chair, Chief Medical Officer [CMO], Chief of Staff, or other) and development of a specific action plan. Consistent with bylaws or other governing documents, the organization's disciplinary process and higher levels of administration are involved in rare Level 3 "Disciplinary" interventions.<sup>6,21,24,25</sup>

For peer-based comparisons involving patient complaints, CPPA used SHS patient complaint data to calculate a Risk Score for each SHS-affiliated physician. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in the most recent year have greater impact than those reported during the 3 previous years. The Risk Score is presented in PARS feedback materials created for each SHS physician whose score exceeds CPPA's threshold for assessment and further analysis.<sup>3,4,6,17</sup> Details about the PARS intervention process and supporting feedback materials have been published and discussed elsewhere.<sup>3,6</sup>

## Results

First, results of the planning phase are described in terms of the three major Project Bundle elements (Table 1) used to direct development efforts during the planning phase. Then we present outcomes achieved to date during PARS implementation.

**People.** The first important result of the planning phase occurred when highest level SHS leadership, Physician Board of Governors, and Board of Trustees signaled their commitment to the project by providing endorsements and support for PARS as a proactive risk reduction strategy. Then, at the end of the planning period, SHS made a financial commitment as well, signing a multi-year PARS implementation contract. The four SHS-affiliated co-authors (WH, DD, CB and RK) served throughout the planning process and initial PARS implementation as project champions, providing essential institutional memory and access to other leaders. SHS's North- and South-centered geography required regional PARS peer messenger committees, Co-Chairs, and administrative point persons so each could take regional ownership. A single individual (DD) with system-wide responsibilities was appointed as a co-chair on both committees to coordinate training; facilitate safe, secure document distribution; review data; promote system-wide consistency; and serve as a focal point for questions or issues that arose throughout the process. SHS's Medical Director for Clinical Services (CU) now serves those roles as the Medical Director for Sanford PARS.

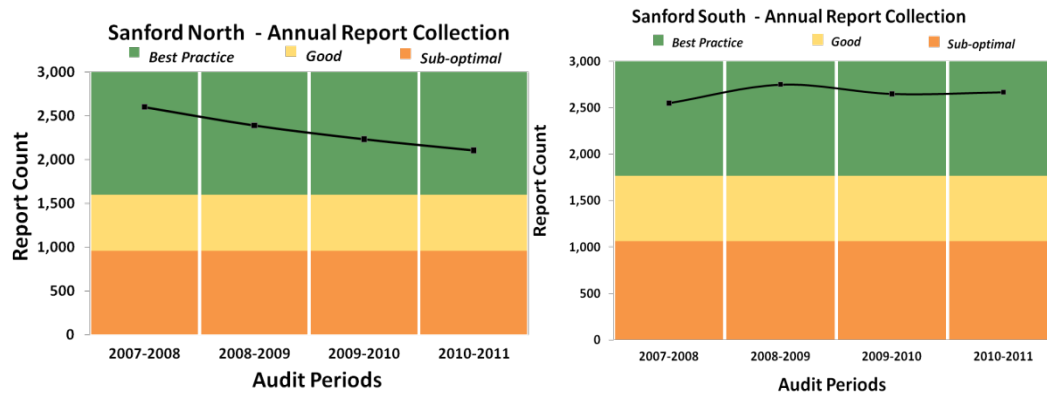
**Process.** SHS's published values, goals, and codes of professional conduct aligned with PARS principles (<http://www.sanfordhealth.org/about>). In addition, results of the planning phase

included SHS's leadership adoption of the CPPA intervention model (Figure 1) and receipt of training in its implementation. Legal issues were far less straightforward. Significant planning was devoted to addressing legal issues, including messenger committee structure, State-to-State variations in Peer Review laws and protections, language to be included on PARS work products, safety-related professional legal language, and procedures to be taken when Level 1 "Awareness" interventions did not reduce patient complaints. A novel aspect of this project was development of a secure system by which peer messengers could share awareness intervention data electronically with a high-risk colleague who worked at a significant distance from the messenger, not uncommon within SHS.

**Systems.** Another key planning phase result was achieved when SHS's OPRs and Information Technology (IT) teams expressed willingness to support PARS. While the SHS North and South flagship hospitals had reliable systems and dedicated staff for patient advocacy, SHS's small-town locations were just beginning in 2010 the work of adopting a unified process for systematically receiving and addressing patient concerns about their health care experiences. Therefore, CPPA provided training, "Getting the Most from Your Patient Relations Department and Service Recovery Program"<sup>19</sup> to all SHS North and South OPR staff, focusing on best practices in complaint reporting and service recovery. Meetings supplemented with email and phone communications with SHS database managers and IT support personnel resulted in smooth, secure data transfer. As a result of the PARS planning process, SHS patient advocates now enter all patient comments in electronic complaint capture software.

CPPA and SHS North and South OPR leaders collaborated on qualitative and quantitative assessments of complaint reports (e.g., includes clearly identifiable physicians, number of codable complaint(s), and needed attachments). One goal was an overall 80 percent rate of uniquely identified physicians associated with physician-related concerns (some patients simply do not recall which physician(s) they saw, and the physicians' identities cannot be determined from a review of records). During the pre-launch planning period, SHS North had an 84 percent physician identification rate, and SHS South had a 77 percent rate, both of which were deemed sufficient for launching PARS. Each OPR has since achieved and exceeded the 80 percent goal. The second goal, to demonstrate sufficient complaint capture relative to organization size well in advance of PARS' launch, was also achieved by 2011 during the planning phase project period (Figure 3). SHS complaint capture has continuously stayed well above each region's Best Practice baseline through the 2016 intervention cycle.

Prior to being shared with high-risk physicians, PARS intervention data underwent multi-level reviews, including six quality checks by CPPA staff, faculty, and physicians, plus local reviews by SHS co-chairs and the assigned messenger physician.<sup>3,6</sup> In order to move forward with an intervention, the co-chairs and messenger physicians must agree the data are sufficiently compelling that the high-risk colleague stands out from his or her peers. CPPA recommends and trains committee chairs not to pair messenger and recipient physicians with known conflicts of interest (e.g., direct competition for patients or resources), poor prior relationships, or a social relationship that makes the messenger role just too uncomfortable. Finally, 12 physicians from SHS South and 7 from SHS North completed CPPA's PARS Messenger training, described elsewhere.<sup>3,6</sup>



**Figure 3. Annual SHS Complaint Report Capture, June 2007–July 2011, plotted as a function of CPPA pre-PARS launch indicators of readiness**

**Patient Complaints and Risk Scores During the Implementation Phase.** The first round of PARS Interventions occurred in both the North and South regions in October-November 2011. As of 2016 a total of 124 SHS physicians have received awareness interventions, including five currently receiving interventions guided by authority (Level 2 on the Promoting Professionalism Pyramid, Figure 1). Messengers’ fidelity to intervention elements exceeds 95 percent compliance. Overall, Risk Scores of physicians receiving interventions have declined 24 percent ( $p < 0.001$ ). Sixty percent of the physicians have succeeded in substantially reducing their Risk Scores, 33 percent remain unimproved, and the rest (7 percent) have departed SHS (similar to physician turnover elsewhere). These results are similar to those achieved in other studies.<sup>3,5</sup>

**SHS Return on Investment (ROI) in PARS.** ROI evaluation compared SHS’s pre- and post-PARS intervention paid claims and claims-related expenses. The analysis used dollars spent per insured physician pre- and post-PARS within the statute of limitations period, adjusting for time (CPI) and published statewide market experience.<sup>26,27</sup> Based on CPPA research, 25 percent of any savings were attributed to PARS.<sup>4,6</sup> The remainder was attributed to SHS’s other safety, quality, and risk prevention initiatives. PARS contract charges for the intervention period were then applied to calculate SHS’s system-wide ROI of 4 to 1. ROI remained positive when sensitivity analyses (e.g., 10 percent impact attributed to PARS) were conducted.

## Discussion

This article presents a study of the planning process leading to successful initiation and ongoing implementation of the Vanderbilt CPPA PARS program in the Sanford Health System. Steps taken to increase the probability of PARS program success revolved around attention to key elements of a Project Bundle. These steps proved effective: Risk Scores declined for the majority of PARS intervention recipients, and the program’s positive ROI supports PARS’ sustainability.

The planners learned important lessons worth consideration before health care leaders launch PARS or other safety, quality, or risk prevention initiatives. The most important lessons are organized around the Project Bundle’s three major elements.



**People-Related Lessons.** Project planning and implementation required commitment of both titled leadership (e.g., CMOs, Department Chairs) and influential physicians whose opinions shape what really happens “on the ground.” These leaders must be willing to have the PARS process address every physician who appears to have a pattern of concerning behavior/performance, regardless of status or stature. Messenger committee members must be willing to deliver PARS data in a timely fashion, and all involved must be willing to give high risk professionals opportunities to self-correct in the earliest stages of intervention.

**Process-Related Lessons.** Organizational values must deem patients to be valuable health care team members. Partnership with Legal Affairs and Human Resources is essential to help craft and implement committees, policies, and procedures that provide peer review protections and fully align PARS within (and make PARS integral to) the organization. The organization must be willing to consistently and reliably implement the model of tiered interventions. Finally, the organization must be committed to employ the right number of Patient Relations Representatives and to invest in training in best practices for service recovery and documentation of patient/family complaints.

**Systems-Related Lessons.** Partnership with the Patient Relations teams and their database managers is essential, first for promoting institutional efforts to have a common, system-wide database. Patient Relations leaders need to receive regular feedback regarding best practices in complaint capture and narrative records so that high standards are sustained. Training for peer messengers must include practice delivering peer-comparative data and responding to recipients’ comments, questions, concerns, and emotions. In addition, there must be multi-level, regularly scheduled sharing of PARS progress and aggregated data to keep all levels of leadership aware of and up to date on the program to promote long-term implementation and sustainability.

**Limitations.** This study has limitations. First, SHS has unique characteristics as a large, multi-State, multi-facility, predominantly rural health care provider, so generalizability is unknown. Nevertheless, one reason this study was conducted was to assess and demonstrate PARS’ viability in just such a system. SHS, like all PARS partner sites, was self-selected and thus is motivated to provide high quality patient experiences and mitigate risk exposure and thus is motivated to capture complaints and record service recovery activities.<sup>19</sup> Second, we did not measure potential confounding physician characteristics (e.g., years in practice, clinical volume), aspects of the practice environment (e.g., local physician group characteristics) or patient characteristics (demographics, payer, and case mix) that may be associated with patient complaints and lawsuit risk.

The literature rightly directs much attention to systems issues but less to individual professional accountability. This study focused on use of the PARS tool for analysis of individual physicians’ relative risk. We acknowledge that promoting safety also requires attention to systems failures and team functioning. We would argue that all three—self- and group-regulation, support systems, and teamwork—are must-haves for a strong patient safety culture. While this study highlighted individual accountability, if PARS data reveal multiple high-risk members of a division, department, or location in a large system, that group’s risk may not be a function of the individual; it may instead signal systems and/or team issues. For example, patient complaints about surgeons’ communication and respectfulness have been shown to be related to surgical

complications, which may indicate that similar behaviors toward colleagues may negatively impact high-complaint surgeons' team functioning.<sup>28,29</sup>

## Conclusion

This project resulted in the successful launch, implementation, and sustainability of the CPPA PARS program at SHS after the conclusion of the planning grant. The project demonstrated how in 1 year, a large multi-State 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. By sustaining the PARS program, SHS has:

- A process for supporting fair, constructive, peer-delivered, evidence-based, peer-comparative self- and group regulation
- Ongoing training for cohorts of “messengers”
- A tiered approach to addressing unnecessary variation in other domains
- Consistent data monitoring that is applied to both rural and metropolitan sites
- Reduced patient complaints about most physicians identified as high risk
- A positive return on investment

The results of this work have at least six implications. Our first conclusion is that the plan to assess, develop, and implement SHS's PARS-related infrastructure could serve as a model for other large, multi-site institutions. Second, the Project Bundle tool provides leaders a useful heuristic for identifying and addressing pre-launch needs of other potential quality, safety, and/or risk prevention projects. Third, by attending to the Project Bundle's elements, the SHS champions succeeded in demonstrating that potential pre-launch issues due to SHS's size and complexity could be addressed and overcome, thus making the case for ongoing PARS program funding. SHS PARS implementation is now in its 6th year past the AHRQ-funded planning period and continues. Fourth, results on individual physicians receiving PARS interventions are positive and consistent with results achieved elsewhere, and fifth, the experience shows that a positive return on investment in PARS can be achieved in a geographically widespread health care system.

Finally, these findings have potential national significance. As U.S. medical centers continue to combine into major systems, the need for plans for promoting system-wide consistency in professionalism and professional self-regulation will expand. SHS and CPPA learned a great deal from this project, and we conclude that the experience can generalize to other dynamic health care systems, so long as the necessary people, processes, and systems are in place.

## Acknowledgments

The planning phase of this project was supported by grant number HS19571 from the Agency for Healthcare Research and Quality. The authors gratefully acknowledge the SHS messengers, patient relations representatives, information technology team, risk managers, legal affairs department, grants officers, and administrators, and the many CPPA team members who participated throughout.

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## Appendix

# PARS Program Planning Methods and Procedures Timeline

Timeline and Events	Corresponding Project Bundle Element(s)
<b>November 2009.</b> MeritCare (Fargo, ND) and Sanford Health (Sioux Falls, SD) systems combine to form SHS.	Background
<b>March 2010.</b> Gerald Hickson, MD, presents PARS to first combined SHS Board of Governors (physician leadership) retreat.	1 - Leadership commitment
<b>June 2010.</b> Business Associates Agreement signed by Vanderbilt CPPA with SHS to permit the exchange of data.	1 - Leadership commitment
<b>July 2010.</b> Vanderbilt CPPA leadership introduce PARS to SHS Leaders and discuss its relationship to SHS goals and values.	1 - Leadership commitment 4 - Goals, values
<b>August 2010.</b> Vanderbilt CPPA receives four back-years of patient complaint data from Fargo, ND hospital (North) and Sioux Falls, SD hospital (South) to be coded in the PARS program; South complaints were largely scanned handwritten reports, North's were electronic.	7 - Pt Relations and IT resources 8 - Measurement tools
<b>September 2010.</b> Vanderbilt CPPA begins receiving monthly deliveries of patient complaint data for PARS coding—South complaints are largely handwritten, North's are electronic. Plans are implemented for system-wide electronic reporting. Based on CPPA PARS team feedback, complaint reporting nomenclature is standardized across SHS.	7 - Pt Relations and IT resources 8 - Measurement tools
<b>October 2010.</b> Local institutional IRB forms approved. Focused discussion of conduct policies and intervention model with SHS Champions and Legal Affairs.	4 - Goals, values 5 - Conduct policies 6 - Intervention model
SHS physician messenger candidates representing North and South are nominated and selected.	2 - Champions 3 - Messengers
SHS demographic data needed to develop complaint benchmarking estimates are assembled (facility locations, number of beds, number of physicians).	8 - Measurement tools
<b>November 2010.</b> Vanderbilt CPPA leadership conduct initial Physician Messenger Training in SHS North (9 physicians) and South (12 physicians). All participants agree to continue as messengers.	2 - Champions 3 - Messengers 6 - Intervention model 10 - Leader training
CPPA team initiates relationship-building, learning about and discussions with North and South Patient Relations offices and IT support team.	7 - Pt Relations and IT resources 8 - Measurement tools

**Appendix. Timeline and Events (continued)**

<b>Timeline and Events</b>	<b>Corresponding Project Bundle Element(s)</b>
<b>December 2010.</b> Post-site visit Assessment Report provided to SHS leadership.	10 - Ongoing Leader follow-up, training
Discussion of SHS organizational structure and patient complaints committee formation.	1 - Leadership commitment 6 - Intervention model
Sample documentation and guidance shared for developing patient complaints committees and content of letters to physicians.	2 - Champions 3 - Messengers 6 - Intervention model
At Enterprise Risk Management day-long retreat, SHS champions lead discussion about PARS.	1 - Leadership commitment 4 - Goals, values
<b>January 2011.</b> Coding, analysis, and feedback related to patient complaints continues.	7 - Pt Relations and IT resources 8 - Measurement tools
<b>March 2011.</b> SHS PARS champions present PARS® program to leadership and receive 2012 budget approval by AHRQ.	1 - Leadership commitment 10 - Ongoing Leader follow-up, training
<b>April 2011.</b> Unnamed Physician List distributed to SHS North and South Patient Relations (PR).	8 - Measurement tools
South begins 100% complaint reporting via a software system.	7 - Pt Relations resources
SHS complaint reports are reviewed and feedback provided to PR teams.	7 - Pt Relations and IT resources 8 - Measurement tools
<b>May 2011.</b> SHS PR teams supply additional complaint report text and attachments. Following additional coding, complaint data are ready for analysis to identify physicians with high risk scores.	7 - Pt Relations and IT resources 8 - Measurement tools
<b>June 2011.</b> South and North Patient Relations and risk management representatives visit CPPA to learn about best practices in complaint collection, CPPA complaint coding, and CPPA data processing.	7 - Pt Relations and IT resources 8 - Measurement tools
AHRQ grant extension requested and approved for ongoing data analysis and PARS launch readiness.	1 - Leadership commitment
Complaint data coding continues for all SHS complaints	7 - Pt Relations resources 8 - Measurement tools
<b>August 2011.</b> SHS commits to using the PARS program over the next 4 years by signing a contract with Vanderbilt CPPA.	1 - Leadership commitment 10 - Ongoing Leader follow-up, training
SHS identifies Senior VP of Clinical Risk Management, who has a system-wide “presence” and reasonable “need to know,” to serve/collaborate with physician messenger co-chairs. Process for Provider Quality Analysis & Research Committee (PQARC), chairs/co-chairs is documented.	2 - Champions 6 - Intervention model 9 - Process for reviewing PARS data
Champions update SHS Leadership and Messengers regarding process of providing PARS intervention folders to PQARC chair/co-chairs, committee chairs’ reviews of PARS data, and ongoing Messenger training.	1 - Leadership commitment 2 - Champions 3 - Messengers 6 - Intervention model 9 - Process for reviewing PARS data

<b>SHS PARS Program Launch</b>
<b>September 2011.</b> IRB continuing review forms were approved. CPPA prepares initial PARS intervention folders.
<b>November 2011–Present.</b> CPPA conducts site visits to SHS North and South to update SHS Messengers and Leadership about PARS progress, provide intervention folders to messenger committee co-chairs, and offer additional messenger training. Interventions on 124 SHS physicians with high risk scores have been conducted to date; follow-up results are positive.





# Patient, Family Member, and Clinician Perceptions of Disclosure of Adverse Events in Labor and Delivery

David P. Baker, Anthony D. Slonim, and Patrice Weiss

## Abstract

**Background.** A prevailing strategy for reducing patient liability claims is full disclosure. Research has shown that when health care professionals disclose their mistakes, payouts for claims against providers and the hospital are reduced. Therefore, it is important to understand how to include patients and families in the care team and how to communicate with patients about the risks and mistakes that can occur throughout the care process.

**Methods.** To explore these important issues, this project addressed two aims. First, we sought to identify adverse clinical events that are highly dependent on provider teamwork, require patients and families to be effective members of the team, and vary in terms of risk and liability (high risk, high liability; high risk, low liability; low risk, high liability; low risk, low liability). The resulting events created four distinct clinical situations in Labor and Delivery for studying the second aim. Specifically, we wanted to determine if patients, family members, and providers agreed about what kinds of information should be disclosed regarding each event and explore how communication should occur to mitigate risk and reduce liability. As this study was exploratory in nature, we used surveys, interviews, and focus groups to address these two aims.

**Results.** Our preliminary findings demonstrated that across the four obstetrical events (that varied in terms of risk and liability), there was far more agreement among patients and family members regarding what should be disclosed when an adverse event occurs as compared to clinicians. Type of event seemed to affect what failures clinicians indicated should be disclosed, while type of event had little effect on what failures patients and family members indicated should be disclosed.

**Conclusion.** Despite several limitations—including small sample size, the use of qualitative information, and application in just one clinical area—our work provides a starting point for further studies around disclosure and communication among clinicians, patients, and families about errors in medical care.

## Introduction

Since the release of the Institute of Medicine (IOM) report *To Err is Human*, the argument that teamwork is essential for the effective delivery of health care has been undisputed.<sup>1</sup> In 1999, Risser and colleagues demonstrated that teamwork breakdowns in the emergency department (ED) were a critical root cause of sentinel events at eight hospitals, costing approximately \$3.50 per ED visit.<sup>2</sup> Mann, Marcus, and Sachs<sup>3</sup> found that team training improved team performance in Labor and Delivery (L&D) and reduced the number of claims made against the L&D service at Beth Israel Deaconess Medical Center by 50 percent over a 3-year period. Arguably, team training has tremendous potential as a risk mitigation and liability reduction strategy because

of its ability to improve care quality. To address this vital need, the Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense (DoD) released TeamSTEPPS<sup>®</sup> (Team Strategies and Tools to Enhance Performance and Patient Safety) as a public domain resource to improve team performance and coordination of care within the national health system.<sup>4</sup>

In addition to improving teamwork, another prevailing strategy for improving care quality and reducing liability claims is full disclosure. Research has shown that when providers disclose their mistakes, payouts for claims against the doctor and the hospital are reduced. Many States now have medical disclosure laws that require physicians and health systems to disclose information related to the event to the patient and the patient's family. In their MEDiC legislation, then Senators Clinton and Obama proposed that hospitals should receive grant money for being up front with patients and families after a medical error. They would then immediately negotiate compensation with the patient or patient's family. The patient's family would still be able to bring their case to court; however, research found that this was less likely to happen.<sup>5</sup>

A central tenet of improving teamwork in health care is that the patient and the patient's family members are critical members of the team. The concept of patient-centered care and the growing implementation of patient-centered medical homes reinforce the important role patients and their family members play in the delivery of effective and efficient health care. Studies have shown increases in patient satisfaction and self-efficacy when patients and families are included in the care team.<sup>6,7</sup> Therefore, from a quality, risk, and liability standpoint, it is important to understand how to include patients and families in the care team, how to equip patients and families to be effective team members, and how to communicate with patients and families about the risks and mistakes that can occur throughout the care process. Combined, inclusion of patients and family members in the care team and preparation through team training should yield better communication between providers and patients and therefore better care with reduced risk.

Research, however, has yet to specify how to include patients and their family members as part of the care team, how to train patients and their family members to be effective team members, what this training should consist of, when this training should occur, and what would be the result. Such work is critical in understanding how to foster better communication and ultimately teamwork between providers and their patients.

To begin to investigate these important issues, we sought to explore two aims. First, we wanted to identify clinical events that are highly dependent on provider teamwork, require patient and families to be effective members of the team, and vary in terms of risk and liability. Aim 1 was important because it yielded a set of events that could be used to explore issues related to provider disclosure and how patients and families can be active participants of the care team. Second, we wanted to ascertain how patient and family and provider communication should occur to mitigate risk and reduce liability. Aim 2 focused specifically on provider disclosure and patient, family, and clinician perceptions of what should be disclosed related to Aim 1 events.

Below, we describe the two sequential exploratory studies that were conducted to address each aim. Results from Aim 1 were used specifically to investigate Aim 2. For each study, we present the methodology employed and the results and findings.

## Research Study 1

The goal of Study 1 was to identify four clinical events that are highly dependent on provider teamwork, require patients and families to be effective members of the team, and vary in terms of risk and liability. Once the events were identified, we used a series of interviews to identify the critical breakdowns that can occur to yield each event. The resulting events served as a set of stimuli that could be used to explore Aim 2.

### Methods

To identify events, two activities were performed. First, we reviewed a report by the RAND Corporation<sup>6</sup> that identified adverse events in which team performance was critical.<sup>8</sup> RAND was contracted by AHRQ to investigate where indicators of teamwork were most evident in the clinical environment. Using a modified Delphi technique, RAND identified 11 events in different clinical settings that required high degrees of teamwork. More details about this study are presented in the next section.

We used the resulting RAND events to develop a survey. The survey was used to collect ratings from several clinicians regarding their perceptions of risk, liability, and requirements for teamwork associated with each event. These ratings were used to select a subset of events that could be used to explore teamwork, communication, and liability issues under Aim 2. Each of these steps is described in more detail below.

### RAND Report

The purpose of the RAND investigation was to identify adverse outcomes for which teamwork is a critical factor. RAND relied on a modified Delphi method in which a multidisciplinary group of clinical experts rated the relationship between teamwork and a pre-selected list of clinical outcomes in L&D, acute myocardial infarction (AMI), and surgery. RAND identified the following events in L&D: birth trauma, injury to neonate–C-sections; birth trauma, injury to neonate–vaginal birth; uterine rupture; maternal death; and intra-partum fetal death of full-term infant. In the surgical area, RAND identified the following adverse patient outcomes: failure to rescue; foreign body left in during procedure; and mortality despite low-mortality Diagnosis Related Groups (DRG) code. However, for the AMI domain, RAND was unable to recommend any outcome measures related to teamwork.

### Survey Development and Administration

Based on the RAND report and discussions among our research team, we decided to focus our research on identifying obstetrical events that required teamwork and varied in terms of risk and liability. L&D events can be high risk and often yield the highest liability payouts.

To explore the characteristics of the seven L&D events identified in the RAND report, we developed a short survey that listed these adverse obstetrical events and asked clinical experts to rate each regarding the degree of risk, likelihood of liability, and the requirement for teamwork using 5-point Likert scales. Because the RAND report yielded only seven adverse outcomes (i.e., a small number), two physicians knowledgeable about obstetrical care identified 11 additional events to include on the survey. The goal of this activity was to ensure that the survey had a variety of events that varied along the risk, liability, and teamwork dimensions.

One expert was an obstetrician, and the other was a pediatric critical care physician (the final survey instruments are available upon request from the authors).

## **Participants**

The survey was completed by a convenience sample of 10 clinicians from the Mother-Baby Unit of a large southeastern health system. Respondents had an average of 5.7 years of experience as an obstetrician. Of the 10 participants, four were residents and six were attending physicians. Three of the participants had previously participated in team training; the other seven had no prior team training experience.

## **Results**

To identify a set of adverse obstetrical events that could be used to study Aim 2, we used the survey responses of the 10 clinicians to create average risk, liability, and teamwork scores for each event (Table 1). Each event was then categorized as “high” or “low” on each particular attribute (i.e., risk, liability, and teamwork), using the respective mean rating across events. For example, the mean rating for risk across adverse events was 2.47. Events scoring above 2.47 were considered to be “high” risk, and those scoring below 2.47 were considered “low” risk. We also examined the degree of inter-rater agreement across respondents to see if our clinical experts agreed regarding the relative risk, liability, and teamwork associated with each event. Except in the case of Respondent C regarding the risk ratings, reliabilities were observed to be moderate to high (see Appendix A).

Next, because a primary objective of this research was to focus on events (regardless of their degree of risk or liability) that required teamwork, we identified those events that received high scores in terms of teamwork (i.e., above the mean teamwork rating). Events that scored high in teamwork were then allocated to four different categories of risk and liability: high risk, high liability; high risk, low liability; low risk, high liability; and low risk, low liability (Table 2). The study team then reviewed these events and selected one event to represent each category (Table 2). The final, selected events were: Shoulder Dystocia, Post-Partum Hemorrhage, Intra-Partum Fetal Death due to Group B Strep, and Unplanned Return to L&D or Operating Room (OR).

Last, we interviewed 12 clinicians about the common failures that can occur leading to each event. Specifically, we interviewed a sample of three clinicians about the failures that can lead to each of the four events: Shoulder Dystocia, Post-Partum Hemorrhage, Intra-Partum Fetal Death due to Group B Strep, and Unplanned Return to L&D or OR. For each event type, one of the three interviewees was a physician, and the other two were nurses. We then examined the failures across events to create a common set of failures by the phases of the L&D care process (e.g., pre-hospital, triage/assessment, monitoring/laboring; Table 3).

The four final events and common failures provided a context (or stimuli) for the exploratory activities that were conducted under Aim 2. Specifically, Aim 2 sought to (1) identify if patients and family members and providers agreed about what kinds of information should be disclosed regarding each event and (2) explore how communication should occur to mitigate risk and reduce liability. The results of Study 1 were essential for conducting Study 2.

**Table 1. Adverse L&D Events, Average Risk, Liability, and Teamwork Ratings (N=10)**

Survey Items	Average Risk	Average Liability	Average Teamwork
1. Birth Trauma, Injury to Neonate—C-Section	2.10	4.20	3.30
2. Birth Trauma, Injury to Neonate—Vaginal Birth	2.60	4.20	3.60
3. Uterine Rupture	1.60	3.30	4.80
4. Maternal Death	1.40	4.90	4.60
5. Intrapartum Fetal Death due to Group B Strep	1.50	4.20	3.90
6. Unplanned Admission to Intensive Care (Mother or Baby)	2.20	2.40	3.70
7. Unplanned Return to Labor and Delivery Unit or Operating Room	2.00	2.40	3.90
8. 5-Minute Apgar Score < 7 (term baby)	2.65	2.00	2.80
9. Shoulder Dystocia	3.00	4.00	4.90
10. Post-Partum Hemorrhage	3.90	2.10	4.80
11. Surgical Site Infection for C-Section	3.20	1.80	1.80
12. Development of Chorioamnionitis in Labor	3.70	1.40	2.00
13. Unexpected Removal of Ovary/Hysterectomy	2.00	2.70	3.00
14. Obstetric Trauma (3rd and 4th Degree Lacerations)—Vaginal Delivery With Instrument	2.60	2.20	2.70
15. Obstetric Trauma (3rd and 4th Degree Lacerations)—Vaginal Delivery Without Instrument	2.20	1.90	2.60
16. Obstetric Trauma—Cesarean Delivery	2.30	2.70	3.20
17. Pre-Term Delivery	3.60	1.80	3.10
18. Unnecessary Elective C-Section	1.90	1.70	1.60
<b>Average Rating</b>	<b>2.47</b>	<b>2.77</b>	<b>3.35</b>

Note: N= 10 for all average risk, liability, and teamwork scores. Risk, Liability, and Teamwork were rated on a 5-point scale where a rating of 5 was the high end of the scale, and a rating of 1 was the low end of the scale.

**Table 2. Candidate and Final L&D Adverse Events (Final events appear in bold)**

		Liability	
	Ratings	High	Low
<b>Risk</b>	<b>High</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
		Birth Trauma—Injury to Neonate—Vaginal Birth	
	<b>Low</b>	Maternal Death	Unplanned Admission to ICU (Mother or Baby)
		<b>Intra-Partum Fetal Death due to Group B Strep</b>	<b>Unplanned Return to L&amp;D or OR</b>
		Uterine Rupture	

**Table 3. Individual, Team, and System Failures Common Across the Four L&D Adverse Outcomes, by L&D Phase**

	<b>Common Failures</b>
<b>Pre-Hospital</b>	Clinician does not sufficiently educate patient/family about risks.
	Clinicians do not collect adequate information on patient's history.
	Patient/family does not provide adequate/honest information on patient's history.
	Clinician does not properly record patient's history.
	Clinicians do not understand patient or patient's family due to a language barrier.
	Clinician does not conduct an interview with patient privately to identify any important factors patient does not wish to be shared with other family members/father.
	Clinicians do not assess if patient is compliant with expectations for prenatal care.
	Clinician does not collect information on patient's history with the correct people present.
	Individual physicians' documentation differs within clinic.
	Clinician does not sufficiently educate patient/family about risks.
<b>Triage/ Assessment</b>	Clinicians do not collect adequate information on patient's history.
	Patient/family does not provide adequate/honest information on patient's history.
	Clinician does not properly record patient's history.
	Clinicians do not understand patient or patient's family due to a language barrier.
	Clinician does not conduct an interview with patient privately to identify any important factors patient does not wish to be shared with other family members/father.
	Clinicians do not assess if patient is compliant with expectations for prenatal care.
	Clinician does not collect information on patient's history with the correct people present.
	Patient information is documented in different places (i.e., paper and electronic).
	Physician and nursing documentation procedures differ.
	Clinician does not verbally communicate plan of care to nursing (not just electronically).
<b>Monitoring/ Laboring</b>	Prenatal records are not available.
	Clinician does not properly assess patient's condition.
	Patient's records are inaccurate or missing.
	Nursing does not monitor vital signs appropriately.
<b>Delivery</b>	Clinicians do not properly monitor labor.
	Clinician fails to communicate patient risk factors/situation to new clinical team members.
	Clinicians fail to anticipate/plan for possible complications.

## Research Study 2

The goal of Study 2 was to assess how patient, family, and provider communication should occur related to the four adverse events and their common causes identified in Study 1. Specifically,

we sought to identify what information should be disclosed, when it should be disclosed, and how it should be communicated in order to mitigate risk and reduce liability.

## Methods

### Participants

We recruited two types of participants to address Aim 2. One group comprised patients and family members, and the second group comprised clinicians.

Regarding patients and family members, individuals were recruited to participate in one of four focus groups. The purpose of each focus group was to review and discuss one of the adverse L&D events identified during Study 1. Participants were recruited from mother-baby educational classes from an 850-bed academic medical center. Because these focus groups were 2 hours long and dealt with delicate issues that might make recruitment difficult, participants were paid \$200 each to participate.

Table 4 presents the demographic information on the patient and family participants in each focus group. Forty-seven participants were recruited, of whom 18 were pregnant, 28 either had experienced or had a family member that had experienced a medical mistake, and nine worked in a health care setting.

**Table 4. Patient and Family Focus Group Participants**

Event	Participants	Pregnant	Experienced a Medical Mistake	Works in Health Care
Unplanned Return to OR or L&D for Bleeding	10	5	7	1
Shoulder Dystocia	18	7	10	5
Post-Partum Hemorrhage	9	4	5	1
Intra-Partum Fetal Death due to Group B Strep	10	2	6	2
<b>TOTAL</b>	<b>47</b>	<b>18</b>	<b>28</b>	<b>9</b>

Regarding the clinician group, providers were recruited to complete a survey about what to disclose related to the common failures that can result in each of the four adverse L&D events. Thirteen clinicians—including physicians, residents, and nurses—participated in the survey. Each clinician was assigned one of the four adverse events about which to respond to the survey questions. Table 5 presents the information about the provider participants.

### Patient and Family Focus Groups

Recruited patients and family members participated in focus groups that lasted 2 hours. Each focus group addressed one of the adverse event types, with all focus groups conducted using the same process. First, participants were asked to review the patient and family responsibilities identified for the specific adverse event assigned to that focus group. Following this review, the focus group leader led a discussion about disclosure and what patients and families preferred clinicians to disclose when a mistake occurred. Possible scenarios were proposed to the group to facilitate the conversation around disclosing mistakes and failures.



**Table 5. Providers Surveyed About Disclosure of L&D Events**

<b>Event</b>	<b>Participants</b>	<b>Experienced a Medical Mistake</b>	<b>Completed TeamSTEPPS Training</b>
Unplanned Return to OR or L&D for Bleeding	Physicians (1) Residents (1) Nurses (1)	3	1
Shoulder Dystocia	Physicians (1) Nurses (2)	1	0
Post-Partum Hemorrhage	Physicians (2) Residents (1) Nurses (1)	0	1
Intra-Partum Fetal Death due to Group B Strep	Physicians (1) Nurses (2)	1	0
<b>TOTAL</b>	<b>13</b>	<b>5</b>	<b>2</b>

Next, a survey was distributed and completed by all participants (the survey instrument is available from the authors). For each focus group, the survey presented the same series of individual, team, and system failures organized by the phases of L&D that were identified as being common to all four events. Each participant was asked to rank the failures from most important to disclose to least important to disclose by phase of L&D care for the adverse event the respective group was assigned. For example, participants in the group discussing Intra-Partum Fetal Death due to Group B Strep ranked the failures in the context of this event, participants in the group assigned Shoulder Dystocia ranked the failures in terms of this event, and so on. We employed a ranking rather than rating process to ensure variability among events.

### **Clinician Survey**

Using the same survey that was administered to patients and family members as part of the focus group process, we surveyed clinicians regarding their perceptions around disclosing to patients and families individual, team, and system failures that occur. As described, the survey presented the same series of individual, team, and system failures organized by the phases of L&D that were identified as being common to all four events. Each clinician was asked to rank the failures from most important to disclose to least important to disclose by L&D phase of care regarding the adverse event he or she was assigned. For example, three clinicians were surveyed regarding Intra-Partum Fetal Death due to Group B Strep, three clinicians were surveyed about Shoulder Dystocia, and so on (Table 5).

## **Results**

### **Patient and Family Focus Groups**

Table 6 reports the mean rating for each individual, team, and system failure ranked by the patient and family focus group participants. As described, failures were ranked from 1 (Most Important to Disclose) to 5 (Least Important to Disclose) for each phase of the L&D process. Furthermore, recall that while the failures were common across the four focus groups, the adverse obstetrical outcome that was the focus of each group was different. This approach

added insight into whether type of event (high risk, high liability; high risk, low liability, and so on) moderated the type of information patients and family members wanted disclosed.

**Table 6. Mean Ratings by Patient and Family Focus Group Participants for Failures by L&D Phase**

Phase	Failure	Unplanned Return	Shoulder Dystocia	Post-Partum Hem.	Intra-Partum Fetal Death
<b>Pre-Hospital</b>	Clinician does not educate mother/family about risks	3.60	3.06	4.33	4.00
	Clinicians do not collect adequate information on mother's history	4.00	3.56	3.56	3.50
	Clinician does not properly record mother's history	3.90	3.89	3.67	3.40
	Clinician does not conduct appropriate prenatal tests	3.20	2.22	2.44	1.80
	Clinician fails to diagnose problems with mother or baby	1.80	1.72	1.00	1.30
<b>Triage/ Assessment</b>	Clinicians do not assess if mother is compliant with expectations for prenatal care	3.20	3.41	3.22	3.30
	Mother's information is documented in different places (i.e., paper and electronic)	3.90	4.18	4.33	3.70
	Physician and nursing documentation procedures differ	3.20	3.53	3.78	2.70
	Clinician does not verbally communicate plan of care to nursing (not just electronically)	3.10	2.24	2.11	2.40
	Prenatal records are not available or missing	2.60	1.35	1.56	2.20

**Table 6. Mean ratings by patient and family focus group participants for failures by L&D phase (continued)**

<b>Phase</b>	<b>Failure</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hem.</b>	<b>Intra-Partum Fetal Death</b>
<b>Monitoring/ Laboring</b>	Clinician does not properly assess mother's condition	2.90	1.82	2.44	3.20
	Mother's records are inaccurate or missing	4.20	4.47	4.44	3.10
	Clinicians do not follow appropriate procedures	3.60	2.65	3.56	3.00
	Clinicians do not properly monitor labor	2.40	2.76	2.22	2.20
	Clinicians do not order/administer appropriate medications	3.30	2.76	2.33	2.50
<b>Delivery</b>	Clinician fails to communicate mother's risk factors/situation to new clinical team members	3.00	2.82	2.44	2.00
	Clinicians fail to anticipate/plan for possible complications	3.10	2.29	2.89	2.50
	Clinician does not properly assess tears	3.10	3.06	2.11	3.90
	Nurse fails to assess mother every 15 minutes during first hour	3.20	3.06	3.67	2.70
	Clinician fails to instruct team members of their roles and responsibilities	4.10	3.41	3.89	3.10

**Table 6. Mean ratings by patient and family focus group participants for failures by L&D phase (continued)**

Phase	Failure	Unplanned Return	Shoulder Dystocia	Post-Partum Hem.	Intra-Partum Fetal Death
<b>Post-Partum—L&amp;D</b>	Clinician team fails to inform the new born care team about problems with delivery	2.10	2.53	2.11	2.40
	Clinician does not inform the patient's family about any concerns	3.60	3.24	4.22	3.9
	Clinical team does not educate the patient and family about "normal" behavior for the baby so they can assist in observing and reporting any abnormalities	3.90	3.47	3.22	2.90
	Nursing does not monitor mother's vital signs appropriately	3.40	2.18	2.78	2.40
	Clinician fails to communicate mother's or baby's risk factors/situations to new clinical team members	2.90	3.18	2.67	2.40

Note: N=the number of participants ranking each failure. Unplanned Return (N=10); Shoulder Dystocia (N=18); Post-Partum Hemorrhage (N=9); Intra-Partum Fetal Death due to GBS (N=10).

Table 7 presents the correlation among the mean rankings for each event presented in Table 6. To calculate these correlations, we computed a correlation between the participant mean rankings by phase of L&D. For example, we calculated a correlation between the rankings of failures that can occur during the Pre-Hospital phase for Shoulder Dystocia and Post-Partum Hemorrhage. These correlations provide insight as to whether the adverse event type affected how patients and family members prioritized the failures that they would want disclosed. If adverse event affected the ranking of these common failures, then the correlations would be low. If adverse event type had no effect on ranking failure, these correlations would be high. Referring to Table 7, type of event had little effect on the rank ordering of the individual, team, and system failures for patients and family members.

### **Clinician Survey**

As reported above for the patients and family members, Table 8 reports the mean rating for each individual, team, and system failure ranked by the clinicians that were surveyed.

Similar to the analyses reported in Table 7 for patients and family members, Table 9 presents the correlation among the mean rankings for each event. To calculate these correlations, we computed a correlation between the clinician mean rankings by phase of L&D. Table 9 provides

insight as to whether the adverse event type affected how clinicians prioritized the failures that they would want to disclose.

**Table 7. Correlations Among the Mean Rankings for Each Event by L&D Phase**

<b>Pre-Hospital</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.91		
Post-Partum Hemorrhage	0.91	0.84	
Intra-Partum Fetal Death due to GBS	0.85	0.87	0.97
<b>Triage/Assessment</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.90		
Post-Partum Hemorrhage	0.88	0.98	
Intra-Partum Fetal Death due to GBS	0.89	0.89	0.85
<b>Monitoring/Laboring</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.72		
Post-Partum Hemorrhage	0.90	0.78	
Intra-Partum Fetal Death due to GBS	0.60	0.07	0.59
<b>Delivery</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.67		
Post-Partum Hemorrhage	0.73	0.42	
Intra-Partum Fetal Death due to GBS	0.26	0.47	-0.14
<b>Post-Partum L&amp;D</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.47		
Post-Partum Hemorrhage	0.75	0.55	
Intra-Partum Fetal Death due to GBS	0.54	0.53	0.94

Note: The N for each correlation was the number of common failures for each phase of L&D. Therefore, N=5 for all correlations.

Referring to Table 9, unlike the results from patients and family members found in Table 7, type of event had an impact on the rank ordering of the individual, team, and system failures. Event type (e.g., Shoulder Dystocia, Post-Partum Hemorrhage) mattered least during the Delivery phase, with correlations ranging from .62 to .84. Examining the other L&D phases shows quite

a bit of variability in results, with the Triage/Assessment phase showing the largest range (-.58 to .72).

**Table 8. Mean Ratings for Failures by L&D Phase**

Phase	Description	Unplanned Return	Shoulder Dystocia	Post-Partum Hem.	Intra-Partum Fetal Death
<b>Pre-Hospital</b>	Clinician does not educate mother/family about risks	4.00	5.00	3.50	4.67
	Clinicians do not collect adequate information on mother's history	3.70	2.33	4.00	3.00
	Clinician does not properly record mother's history	3.70	2.00	3.67	2.67
	Clinician does not conduct appropriate prenatal tests	2.70	3.67	1.67	1.67
	Clinician fails to diagnose problems with mother or baby	1.00	2.00	1.33	3.00
<b>Triage/Assessment</b>	Clinicians do not assess if mother is compliant with expectations for prenatal care	2.70	4.00	5.00	5.00
	Mother's information is documented in different places (i.e., paper and electronic)	2.70	1.67	3.67	2.33
	Physician and nursing documentation procedures differ	3.00	4.33	1.67	3.00
	Clinician does not verbally communicate plan of care to nursing (not just electronically)	3.70	3.67	2.33	2.33
	Prenatal records are not available or missing	3.00	1.33	2.33	2.33
<b>Monitoring/Laboring</b>	Clinician does not properly assess mother's condition	2.30	2.67	1.67	2.00
	Mother's records are inaccurate or missing	3.70	2.67	4.33	4.33
	Clinicians do not follow appropriate procedures	3.00	3.00	2.67	4.00
	Clinicians do not properly monitor labor	2.30	2.33	3.67	3.00
	Clinicians do not order/administer appropriate medications	3.70	4.33	2.67	1.67

**Table 8. Mean ratings for failures by L&D phase (continued)**

Phase	Description	Unplanned Return	Shoulder Dystocia	Post-Partum Hem.	Intra-Partum Fetal Death
Delivery	Clinician fails to communicate mother's risk factors/situation to new clinical team members	2.00	2.67	3.00	2.00
	Clinicians fail to anticipate/plan for possible complications	1.70	1.67	1.67	2.00
	Clinician does not properly assess tears	3.70	3.33	3.33	4.67
	Nurse fails to assess mother every 15 minutes during first hour	3.30	2.33	3.33	2.67
	Clinician fails to instruct team members of their roles and responsibilities	4.30	5.00	3.67	3.67
Post-Partum—L&D	Clinician team fails to inform the new born care team about problems with delivery	2.00	2.33	3.00	2.00
	Clinician does not inform the patient's family about any concerns	2.30	2.00	4.00	2.67
	Clinical team does not educate the patient and family about "normal" behavior for the baby so they can assist in observing and reporting any abnormalities	5.00	4.67	3.33	4.67
	Nursing does not monitor mother's vital signs appropriately	2.70	3.00	2.33	3.33
	Clinician fails to communicate mother's or baby's risk factors/situations to new clinical team members	3.00	3.00	2.33	2.33

Note: N=the number of participants ranking each failure. Unplanned Return (N=3); Shoulder Dystocia (N=3); Post-Partum Hemorrhage (N=4); Intra-Partum Fetal Death due to GBS (N=3).

### Comparing Clinician and Patient and Family Rankings

Finally, we compared the patient and family rankings of the individual, team, and system failures to the clinician rankings of the same failures. This analysis was conducted to determine if patients and family members agree regarding what should be disclosed and if this agreement is consistent or varies by event type. Table 10 presents the results of this analysis.

**Table 9. Correlations Among the Mean Rankings for Each Event**

<b>Pre-Hospital</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.41		
Post-Partum Hemorrhage	0.89	0.07	
Intra-Partum Fetal Death due to GBS	0.35	0.49	0.45
<b>Triage/Assessment</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.25		
Post-Partum Hemorrhage	-0.58	0.00	
Intra-Partum Fetal Death due to GBS	-0.46	0.55	0.72
<b>Monitoring/Laboring</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.64		
Post-Partum Hemorrhage	0.40	-0.28	
Intra-Partum Fetal Death due to GBS	0.21	-0.51	0.66
<b>Delivery</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.83		
Post-Partum Hemorrhage	0.84	0.76	
Intra-Partum Fetal Death due to GBS	0.82	0.64	0.62
<b>Post-Partum L&amp;D</b>	<b>Unplanned Return</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>
Shoulder Dystocia	0.97		
Post-Partum Hemorrhage	0.05	-0.15	
Intra-Partum Fetal Death due to GBS	0.90	0.87	0.15

**Table 10. Relation Between Patient and Family and Clinician Disclosure Rankings**

<b>Phase</b>	<b>Unplanned Return to L&amp;D</b>	<b>Shoulder Dystocia</b>	<b>Post-Partum Hemorrhage</b>	<b>Intra-Partum Fetal Death</b>
Pre-Hospital	0.21	-0.08	0.89*	0.62
Triage/Assessment	-0.37	0.28	0.30	0.37
Monitoring/ Laboring	0.80*	-0.08	0.55	0.30
Delivery	0.71	0.86*	0.28	0.96*
Post-Partum L&D	0.65	0.39	0.74	0.12
<b>Across All Phases</b>	<b>0.70*</b>	<b>0.19</b>	<b>0.57*</b>	<b>0.48*</b>

Note: \* indicates significance at  $p < .05$ .



Referring to Table 10, agreement between patients and family members and clinicians regarding what failures were most important to disclose varied tremendously. The highest level of agreement was for those failures that could occur during the Delivery phase for the event Intra-Partum Death due to Group B Strep ( $r=.96$ ), while the lowest agreement was for those failures that made up the Triage/Assessment Phase for the adverse event Unplanned Return to L&D or OR ( $r=-.37$ ). Across all failures, however, there was generally positive agreement among what patients and families wanted clinicians to disclose and what clinicians felt was important to disclose, with Unplanned Return to L&D or OR demonstrating the highest level of agreement ( $r=.70$ ), and Shoulder Dystocia demonstrating the lowest ( $r=.19$ ).

## Discussion

In summary, two exploratory studies were performed to begin to understand the relation among risk and liability and the types of information patients would like clinicians to disclose. Four adverse events from L&D, that all require teamwork but vary in terms of risk and liability, were the focus of these studies. Across the two studies described here, several interesting findings emerged.

First, clinicians generally showed high agreement when assessing the degree of risk, liability, and teamwork associated with specific clinical events in L&D (see Appendix A). This finding is important because procedures like Failure Mode Event Analysis (FMEA) often rely on the judgment of clinical experts regarding the characteristics of clinical events. These data seem to support that experts are in fact capable of making such judgments with fairly high levels of agreement with little or no training. Future research should test whether such judgments are also valid by comparing such judgments to independent, objective measures of these variables.

Second, patients and family members were found to agree about which failures were important to disclose, and the type of adverse event did not affect these results. Clinicians, on the other hand, showed far more variability among themselves regarding what should be disclosed; these results did appear to be affected by adverse event, although this finding may have been a result of a small sample of clinicians completing the survey. Interestingly, however, there did appear to be some agreement between clinicians and patients and family members about what failures to disclose. This finding provides some preliminary insight about the importance of disclosure, which can reduce or offset liability claims.

## Limitations

Given the exploratory nature of this work, there obviously are a number of limitations. First, all the information was qualitative in nature. We used interviews, surveys, and focus groups as the core methods of our investigation. Second, our sample sizes were extremely small. Finally, our investigation was limited to one clinical domain, L&D. Collectively, these limitations make our findings potentially unreliable and difficult to replicate.

## Conclusion

Despite these limitations, we do believe our work provides an important first look into the issue of disclosure and how patients and family members and clinicians perceive how best to deal with individual, team, and system failures in L&D that can lead to poor outcomes. Future empirical research needs to test the propositions we discovered here to ensure our conclusions are valid. As health care reform continues to expand and the emphasis moves from fee-for-service to quality, the role of patients and family members in the care team will also expand. Understanding disclosure and how to communicate with patients and families about sensitive care issues will be critical for enhancing patient and family engagement.

## Acknowledgments

This work was supported by a grant from the Agency for Healthcare Research and Quality (HS19512).

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# Appendix

## Inter-rater Reliability for Risk

Rater	A	B	C	D	E	F	G	H	I	J
A	1									
B	0.61	1								
C	<b>-0.20</b>	<b>-0.28</b>	1							
D	0.52	0.31	<b>-0.39</b>	1						
E	0.46	0.52	<b>-0.28</b>	0.40	1					
F	0.59	0.55	<b>-0.22</b>	0.52	0.68	1				
G	0.75	0.62	<b>-0.25</b>	0.69	0.61	0.60	1			
H	0.60	0.40	<b>-0.56</b>	0.45	0.59	0.53	0.68	1		
I	0.61	0.81	<b>-0.29</b>	0.50	0.61	0.58	0.74	0.48	1	
J	0.59	0.82	<b>-0.25</b>	0.36	0.76	0.66	0.69	0.66	0.75	1

**Inter-rater Reliability for Liability**

<b>Rater</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>	<b>H</b>	<b>I</b>	<b>J</b>
<b>A</b>	1									
<b>B</b>	0.74	1								
<b>C</b>	0.54	0.70	1							
<b>D</b>	0.54	0.54	0.64	1						
<b>E</b>	0.82	0.56	0.48	0.61	1					
<b>F</b>	0.41	0.33	0.23	0.66	0.61	1				
<b>G</b>	0.77	0.68	0.74	0.55	0.82	0.42	1			
<b>H</b>	0.77	0.74	0.63	0.39	0.66	0.44	0.83	1		
<b>I</b>	0.50	0.24	0.31	0.52	0.68	0.49	0.45	0.25	1	
<b>J</b>	0.69	0.59	0.76	0.62	0.77	0.52	0.85	0.75	0.51	1

Inter-rater Reliability for Teamwork

Rater	A	B	C	D	E	F	G	H	I	J
A	1									
B	0.57	1								
C	0.34	0.56	1							
D	0.19	0.63	0.34	1						
E	0.22	0.59	0.51	0.64	1					
F	0.39	0.69	0.51	0.39	0.73	1				
G	0.36	0.60	0.65	0.54	0.70	0.77	1			
H	0.39	0.62	0.54	0.40	0.73	0.63	0.67	1		
I	0.82	0.56	0.53	0.06	0.44	0.56	0.50	0.55	1	
J	0.30	0.62	0.68	0.58	0.71	0.66	0.58	0.60	0.40	1



# **Patient Safety Culture and Medical Liability— Recommendations for Measurement, Analysis, and Interpretation: A Commentary**

**Sallie J. Weaver, Jill A. Marsteller, Albert W. Wu, Mohd Nasir Mohd Ismail,  
and Peter J. Pronovost**

Efforts by health care organizations to promote a culture of safety and regularly evaluate progress toward that goal are two cornerstones of the movement to improve care safety and quality.<sup>1,2,3</sup> A culture of patient safety reflects the values, assumptions, and norms related to communication, error management, transparency, a learning orientation, and teamwork that are shared among clinicians and staff.<sup>4,5</sup> The culture of safety in a given team, unit, department, or organization is a contextual variable that shapes clinician and staff perceptions about the importance of patient safety relative to other practice goals, as well as norms related to speaking up and disclosing unanticipated issues.<sup>4,6</sup> However, limited empirical work examines linkages between organizational cultures of safety and the approaches clinicians and provider organizations take to medical liability. This commentary offers some food for thought regarding how patient safety culture may be more effectively measured and analyzed in order to better understand relationships with disclosure and proactive organizational approaches to liability. We offer recommendations to enhance measures of safety culture as useful tools for (1) identifying improvement needs and (2) evaluating interventions targeting liability-related issues, such as disclosure, transparency, and event reporting.

## **The Intersection of Liability and Patient Safety Culture**

Patient safety culture and liability intersect in the presence of events that harm patients and are perceived as unsafe. Studies of claims have shown that the perceived cause, context, outcome, and response to a given adverse event influence the probability that a claim is pursued, whether it is deemed meritorious, and the type and amount of remuneration.<sup>7,8,9</sup> In theory, an effective organizational approach to managing liability ideally should synergistically support a culture of safety by: (1) encouraging learning and continuous improvement; (2) motivating departments, units, and care teams to role model, prompt, and reward behaviors that support safety and transparency; and (3) inspiring individual clinicians to engage in mindful practice, to report errors and near misses, and to actively learn from both their own experiences and those of others.<sup>10,11</sup>

Given this, communication-and-resolution programs (CRP) that emphasize early, transparent disclosure of unanticipated events, systematic learning, system improvement, and proactive resolution by providers and insurers represent a promising strategy for improving medical liability while simultaneously improving patient safety.<sup>12</sup> These interventions promote transparency, apology, and proactive approaches to remuneration. Theoretically, implementation of CRP programs should be facilitated by an organizational culture in which speaking up and working to improve care systems are valued. Recent evaluations of CRP programs support this hypothesis and suggest that such programs may also, in turn, help to strengthen and support an organizational culture of safety.<sup>13,14</sup> Future evaluation studies should also strive to explicitly



examine the impact of baseline organizational safety culture on the implementation and sustainment of these types of interventions. While existing measures of patient safety culture offer many opportunities,<sup>14,15</sup> we suggest several ideas that may help future research and evaluation efforts to examine how cultural safety norms and attitudes may influence the implementation, effectiveness, and sustainment of CRP interventions, as well as other strategies to repair trust with patients and their loved ones when unanticipated events occur.

## **Recommendations for Exploring the Intersection of Patient Safety Culture with Organizational Approaches to Patient Safety and Liability**

We suggest using measures of patient safety culture to enhance our understanding of the role cultural norms and attitudes play in safety and liability mitigation interventions and related outcomes. These recommendations are organized in three categories: (1) measure content, (2) measurement strategies, and (3) analytics. They are grounded in reviews of the safety culture measurement landscape<sup>16</sup> and related interventions,<sup>3</sup> as well as evidence examining relationships between culture, clinician behavior, and patient outcomes.<sup>5,17,18,19,20,21,22</sup>

### **Content Recommendations**

In addition to studies that empirically examine the association of existing safety culture measures with claims activity, liability outcomes, and associated interventions, we also recommend:

***Recommendation 1: Consider evaluating clinician perceptions of organizational support for second victims.*** Clinicians experience errors and near misses as deeply personal and painful events.<sup>23,24</sup> Even if no claim results from a given incident, clinicians can experience severe self-doubt, anxiety, depression, and isolation, which, in turn, can affect future episodes of patient care, absenteeism, and turnover.<sup>23,25,26</sup> The term “second victim” refers to caregivers and staff that experience psychological harm as a result of their involvement in an adverse event.<sup>23,26</sup> Thus, while the patient safety improvement literature underscores the importance of a non-punitive response to events, we argue that salient mechanisms to support clinicians in coping with the psychological and personal impacts of such events are also critical for achieving true transparency. Support programs for clinicians are prominent artifacts of an organizational orientation toward learning that may facilitate desirable norms regarding reporting and timely disclosure.<sup>27,28</sup> Other important aspects of culture not fully reflected in existing culture measurement tools include aspects of “just culture,” such as the degree to which (1) expected behaviors are salient, (2) enacted policies reinforce expected behaviors, and (3) sanction-worthy behaviors are defined and differentiated from other behaviors.<sup>29,30,31,32</sup> Capturing clinician perceptions of the degree to which these elements are characteristic of their work environment may help strengthen our understanding of the complex relationships between safety culture, patient safety, and the effectiveness of organizational approaches to addressing liability.

***Recommendation 2: Consider evaluating clinician attitudes and organizational norms surrounding consent, disclosure, and patient/caregiver input.*** The majority of existing patient safety culture assessment tools do not capture attitudes or norms concerning patient-clinician interactions or openness to questions or concerns voiced by patients and families. Evaluating clinician perceptions of organizational norms surrounding consent, disclosure, and openness to

patient and family input could make culture assessments more patient-centered. This is a necessary path for understanding the full range of cultural norms that may enhance (or impede) efforts to implement interventions aiming to enhance safety and mitigate liability.

***Recommendation 3: Consider integrating indices of systems thinking and mindful organizing.***

Recognizing system influences on care delivery and learning from mistakes are key elements of a culture of safety. This arguably requires creating shared assumptions and mindsets,<sup>33,34</sup> in addition to creating behavioral norms and routines. Scales that provide insight into concepts like systems thinking<sup>35</sup> and mindful organizing (i.e., the cognitive and social processes that form the foundation of high reliability organizations)<sup>36</sup> may offer important insight when attempting to examine the interplay between organizational culture and efforts to proactively address unintended outcomes and other liability risks.

## **Measurement Recommendations**

These recommendations focus on strategies to ensure that metrics designed to capture clinician and staff perceptions of safety culture elicit valid measurements.

***Recommendation 4: Examine sub-cultures and clearly define the perspective your metric is asking respondents to adopt, particularly for those working across multiple care areas.*** Many established patient safety culture metrics ask respondents to identify with a single “work area” or department (e.g., surgery, anesthesia), in addition to a discipline or role. Theoretically, individuals from each of these groups have attitudes, experiences, and training related to patient safety that vary in meaningful ways. For example, studies using the AHRQ Hospital Survey on Patient Safety (HSOPS) culture survey and other metrics report significant differences among physicians, nurses, and administrators on several dimensions.<sup>15,37,38</sup> Despite documentation of sub-cultures in the peer-reviewed literature, responses to culture assessment tools in practice are often collated across very large, diverse groups to create organization-level scores. This may introduce unnecessary noise in efforts to examine changes in culture related to safety and liability interventions, particularly those implemented in phases across different departments or clinician groups.

Additionally, clinicians and staff working across multiple care areas may be unsure about which area they should consider when responding to survey-based measures of safety culture. Clinicians likely observe distinct differences in cultural assumptions and norms across different departments, units, or care teams. These issues present conceptual and practical questions worthy of further consideration.

***Recommendation 5: Consider multiple levels of analysis when examining patient safety culture data.*** Safety culture is primarily operationalized as a group-level concept (i.e., a property of a unit, department, or organization); however, the organizational science literature highlights the role that individual-level attitudes and perceptions of organizational culture (i.e., psychological climate) play in shaping safe behavior on the job.<sup>39,40</sup> Bearing respondent confidentiality in mind, health care organizations might consider using anonymous linking methods to link clinician responses to safety culture surveys over time in order to examine changes over time at the individual-level of analysis. This would enable assessments of changes in individual-level attitudes over time, as compared to assessments of changes in unit,

department, or organization-level scores that are biased by changes in the population of respondents.

## **Analytic Recommendations**

Analytic recommendations suggest strategies for analysis and interpretation using existing scales:<sup>16</sup>

***Recommendation 6: Collect, analyze, and report data on relationships between patient safety culture, liability related processes (e.g., error reporting, proactive risk analysis, disclosure), and outcomes (e.g., insurance costs, claims frequency, indemnity costs).*** Specifically, studies examining how the multiple-aspects of patient safety culture are differentially related to indicators of safety, disclosure of errors, patient perceptions of care, and claims are needed.

***Recommendation 7: Account for both professional affiliation and role when examining the relationships between patient safety culture and liability outcomes.*** Perceptions of patient safety culture tend to vary by profession (e.g., physicians, nurses, technicians), as well as by role (e.g., primarily administrative vs. primarily patient care).<sup>41,42</sup> Therefore, we recommend examining potential variation by profession and role in the analyses suggested in recommendation 6.

***Recommendation 8: Consider how the multiple dimensions of safety culture interact to impact disclosure, apology processes, and outcomes.*** Patient safety culture is a multidimensional concept comprising several different dimensions (e.g., communication openness, degree to which there is an orientation toward learning from errors versus a punitive orientation). Theoretically, these different dimensions interact and, as a whole, reflect the larger concept of patient safety culture. Culture is rarely operationalized in this way in practice or in evaluations of safety improvement or liability mitigation interventions, however. There is a need to understand how the multiple aspects of safety culture interact to impact reporting and disclosure processes, as well as outcomes.<sup>43,44</sup> The concept of patient safety culture profiles<sup>21,45</sup> may offer one method for more robustly examining the culture-liability relationship. Culture profiles, or configurations of cultural dimensions, offer a more comprehensive way to operationalize culture that may help robustly examine relationships among safety culture, reporting and disclosure processes in practice, claims, and outcomes.

## **Conclusion**

There is a need to better understand the role patient safety culture plays in organizational approaches to safety and liability management. In seeking this enhanced understanding, we suggest that the many strengths of existing patient safety climate measures<sup>16</sup> could be complemented by enhanced analysis, improved measurement, and potentially, expanding the range of concepts captured by these measures.

## **Acknowledgments**

This article was prepared while Sallie J. Weaver was employed at the Johns Hopkins University School of Medicine. The opinions expressed in this article are the author's own and do not reflect

the view of the National Institutes of Health, the Department of Health and Human Services, or the United States Government.

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# Error Disclosure Training and Organizational Culture

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and Eric J. Thomas

## Abstract

**Objective.** Our primary objective was to determine whether, after training was offered to participants, those who indicated they had received error disclosure training previously were more likely to disclose a hypothetical error and have more positive perceptions of their organizational culture pertaining to error disclosure, safety, and teamwork.

**Methods.** Across a 3-year span, all clinical faculty from six health institutions (four medical schools, one cancer center, and one health science center) in The University of Texas System were offered the opportunity to anonymously complete an electronic survey focused on measuring error disclosure culture, safety culture, teamwork culture, and intention to disclose a hypothetical error at two time points - both before (baseline) and after (follow-up) disclosure training was conducted for a subset of faculty.

**Results.** There were significant improvements (all p-values < .05) in the follow-up surveys compared with the baseline surveys for the following domains (percent refers to percent positives before and after, respectively): minor error disclosure culture (33 percent vs. 52 percent), serious error disclosure (53 percent vs. 70 percent), safety culture (50 percent vs. 63 percent), and teamwork culture (62 percent vs. 73 percent). Follow-up survey data revealed significant differences (all p-values < .001) between faculty who had previously received any error disclosure training (n = 472) and those who had not (n = 599). Specifically, we found significant differences in culture (all p-values < .001) between those who received any error disclosure training and those who did not for all culture domains: minor error disclosure (61 percent vs. 41 percent), serious error disclosure (79 percent vs. 58 percent), trust-based error disclosure (61 percent vs. 51 percent), safety (73 percent vs. 51 percent), and teamwork (78 percent vs. 66 percent). Significant differences also existed for intent to disclose an error (t = 4.1, p < .05). We also found that error disclosure culture was significantly associated with intent to disclose for those who received previous error disclosure training, whereas all types of culture we measured were significantly associated with intent to disclose for those who did not receive error disclosure training.

**Conclusions.** Error disclosure, teamwork, and safety culture all improved over a 3-year period during which disclosure training was provided to key faculty in these six institutions. Self-reported likelihood to disclose errors also improved. The precise impact of the training on these improvements cannot be determined from this study; nevertheless, we present an approach to measuring error disclosure culture and providing training that may be useful to other institutions.



## Introduction

Informing patients about medical errors will continue to be necessary, given that no foreseeable improvement in health care delivery will eliminate all errors that seriously harm patients. Patients want to know about medical errors, with virtually all patients wanting to know about errors that directly harm them.<sup>1,2</sup> Although disclosing an error and its consequences to a patient can be challenging, the benefits of disclosing errors to patients and institutions are multiple.<sup>3</sup> First, some errors have important consequences for patients' health, and knowing about such errors can help patients make more informed health care choices. Second, disclosing errors preserves the trust fundamental to the doctor-patient relationship. Third, disclosing errors allows patients to communicate what information, compensation, or services they need to cope with the consequences of the error. Good disclosures can also involve soliciting patients' perceptions of what caused the adverse event, thereby helping organizations to learn and improve.<sup>4</sup> When organizations have a two-way dialogue with patients/family members about errors and subsequently learn from patients/family members about additional causes of errors, the organization is in a better position to develop patient safety-focused interventions to address the root causes of errors.

On the other hand, a minority of patients report that they have been told about errors in their care,<sup>5</sup> and physicians report disclosing events in around 25 percent of the cases.<sup>6,7</sup> One reason that physicians do not disclose errors is because they lack the training that would help them to provide effective disclosures.<sup>8</sup> The conflict between patients' needs and actual disclosure practices of physicians creates a tension that needs to be addressed. One possible way to address this tension is by training physicians to disclose errors to patients and family members.<sup>3</sup>

A factor that has been linked with the effectiveness of training in general is organizational culture. Organizational culture refers to the shared beliefs from those working together about how work gets accomplished.<sup>9,10,11</sup> Health services researchers have focused on understanding several types of cultures in health care settings, notably safety culture and teamwork culture.<sup>9,10,11</sup> Organizational culture has been identified as an important factor in the extent to which training is effectively transferred from the training setting to the workplace setting.<sup>12,13</sup> Specifically, units in an organization that have a positive safety culture may be more likely to foster opportunities for physicians to use knowledge and skills learned in training programs in the workplace, while units with neutral or negative safety cultures may be less likely to provide the same opportunities to transfer such training to the workplace. We have previously examined organizational culture as it pertains to error disclosure (herein error disclosure culture) and in so doing focused on three main types of culture: trust-based error disclosure culture, minor error (i.e., error that causes harm that is neither permanent nor life-threatening) disclosure culture, and serious error (i.e., error that causes permanent injury or transient but potentially life-threatening harm) disclosure culture.

According to the research to date, error disclosure training has been shown to improve medical students' self-efficacy in disclosing errors,<sup>14</sup> with similar findings for residents<sup>15,16,17</sup> and more experienced physicians.<sup>18</sup> Despite increased attention to error disclosure nationally, less is known about the relationship among training, perceptions of organizational culture, and intent to disclose future errors. We sought to address this gap in two ways. First, we extended our previous work<sup>19</sup> on the creation and validation of a survey to measure error disclosure culture

by investigating whether those who reported receiving error disclosure training were more likely to disclose a hypothetical error and perceive important aspects of their organizational culture—namely error disclosure, safety, and teamwork culture—in a more positive way. Second, we compared culture scores before and after error disclosure training was offered to faculty.

## Methods

### Participants

We sent surveys to all clinical faculty from six health institutions (four medical schools, one cancer center, and one health science center) in The University of Texas (UT) System two times – in 2010 before offering error disclosure training<sup>19</sup> and in 2013 after error disclosure training was provided (herein referred to as baseline and follow-up, respectively). A consulting firm experienced in disclosure training was hired to provide training to key leaders in the six UT System health campuses. At each site, they provided an institution-wide grand rounds followed by a training session for a small group of key faculty. Clinical faculty included nurses and physicians. Managers or administrators who were not clinical faculty attended training, but they were not surveyed unless they were also clinical faculty. Leadership of the hospitals and medical schools selected participants, and participation was voluntary. Participants were chosen based on their clinical experience, type of clinical experience, and expected ability to serve as resources for their colleagues.

The training included lectures that presented relevant information, video clips of disclosure conversations, and opportunities for role-playing, followed by feedback. This was a “train-the-trainer” approach in which the attendees learned about disclosure coaching and were expected to provide additional training and support to other faculty. Grand rounds attendance ranged from 70-150 at each site and disclosure training attendance ranged from 15–43 participants per session, which was 6 hours in duration. The curriculum included a review of the institution’s own culture survey results before the training, practice of coaching strategies based on reviews and discussion of video-recorded cases and live simulations, care for the caregiver after an event, review of recent cases from the institution, and creation of a sustainable disclosure culture. Institutional review board (IRB) approval was obtained prior to initiating data collection.

We sent all clinical faculty (approximately 5,000 individuals) from these institutions an email with a link to an anonymous, electronic survey once a week for 4 weeks. For the baseline sample, 496 faculty members completed the survey, resulting in a response rate of 9.9 percent. In order to increase the response rate, we offered all participants in the follow-up survey administration an incentive (either \$20 or \$40 depending on the site) for completing our survey. In all, 1,217 participants completed the follow-up survey, resulting in a response rate of 22 percent. We asked participants if they received error disclosure training, but we did not specify that they needed to have received the training we offered, so we cannot be certain that everyone received training from us. Participation was anonymous, and we did not collect identifying information from participants during either the baseline or follow-up surveys.

## Measures

We measured error disclosure culture, safety culture, teamwork culture, intent to disclose a hypothetical error, and demographics in our survey. The error disclosure culture survey items were from a previous study we conducted<sup>19</sup> where we found that clinical faculty were significantly more likely to indicate agreement with disclosure of serious errors as opposed to minor errors. Yet, patients expect truthful information about minor harmful errors, and organizations may benefit from committing to quality improvements (part of a full disclosure process) following the relatively greater number of minor events compared to serious errors. Therefore, in this study we examined these constructs separately, with four items focused on minor error disclosure as one construct and four items focused on serious error disclosure as a separate construct. We also examined error disclosure trust culture with two items focused on losing patient and peer trust in one's competence as a result of disclosing medical errors.

The safety and teamwork culture items (seven items for each scale) come from the Safety Attitudes Questionnaire,<sup>10</sup> although the first teamwork item was created for this study. All culture survey items were measured on a 5-point Likert-type scale, where 1 = disagree strongly and 5 = agree strongly. Each participant was asked to read a hypothetical scenario depicting a ten-fold medication overdose of insulin where the patient was unresponsive but expected to make a full recovery; the participant was then asked "How likely would you be to disclose this error to the patient?" with response options ranging from 1 = I would definitely not disclose this error to 4 = I would definitely disclose this error. Table 1 presents all of the items we measured in this study.

## Statistical Analysis

In addition to examining demographics, we conducted several analyses. We examined the percent positive scores for error disclosure, safety, and teamwork culture for each of the six institutions and overall across the system. Percent positive scores represent the percent of participants who averaged at least a 4 (i.e., agree slightly) on their Likert-type responses to all of the items that measure a specific type of culture. These scores are routinely used in culture measurement when providing feedback to organizations because they allow organizations to see variability between units so they know where to focus their improvement efforts. A general guideline is that percent positive scores of 60 or less indicate areas in need of immediate attention, those between 61 and 79 as needing improvement, and those at 80 or above reflecting strengths of the organization. We used t-tests to determine whether significant differences existed between those in the baseline dataset and follow-up dataset to address our secondary objective. We compared culture perceptions between baseline and follow-up surveys by examining percent positive scores for each type of culture. Further, we examined associations between culture perceptions and intent to disclose a hypothetical error for those who reported on the follow-up survey that they received prior error disclosure training and those who did not.

**Table 1. Descriptive Statistics for Constructs and Items**

<b>Construct</b>	<b>Item</b>	<b>Mean (sd) – No training</b>	<b>Mean (sd) – Training</b>	<b>t-test value</b>
Minor Error Disclosure Culture ( $\alpha = .81$ )		3.57 (.90)	3.99 (.91)	7.5*
	1. We routinely disclose MINOR ERRORS to patients/families in my clinical area.	3.89 (1.19)	4.14 (1.11)	3.6*
	2. The culture in my clinical area makes it easy to disclose MINOR ERRORS.	3.68 (1.21)	4.07 (1.12)	5.4*
	3. I am encouraged by my colleagues to disclose MINOR ERRORS to patients/families.	3.37 (1.13)	3.82 (1.17)	6.3*
	4. I am encouraged by hospital leadership to disclose MINOR ERRORS to patients/families.	3.35 (1.12)	3.93 (1.10)	8.5*
Serious Error Disclosure Culture ( $\alpha = .79$ )		3.91 (.89)	4.36 (.78)	8.8*
	1. We routinely disclose SERIOUS ERRORS to patients/families in my clinical area.	4.46 (.99)	4.69 (.75)	4.5*
	2. The culture in my clinical area makes it easy to disclose SERIOUS ERRORS.	3.69 (1.27)	4.14 (1.14)	6.1*
	3. I am encouraged by my colleagues to disclose SERIOUS ERRORS to patients/families.	3.86 (1.14)	4.30 (1.03)	6.6*
	4. I am encouraged by hospital leadership to disclose SERIOUS ERRORS to patients/families.	3.65 (1.22)	4.33 (1.01)	9.9*
Error Disclosure Culture Trust ( $\alpha = .80$ )		3.59 (1.14)	3.77 (1.17)	2.6*
	1. Disclosing a MEDICAL ERROR in my clinical area damages patient's trust in my competence. <sup>f</sup>	3.55 (1.26)	3.75 (1.29)	2.5*
	2. Disclosing a MEDICAL ERROR in my clinical area damages peer's trust in my competence. <sup>f</sup>	3.62 (1.24)	3.78 (1.25)	2.1*

**Table 1. Descriptive statistics for constructs and items (continued)**

<b>Construct</b>	<b>Item</b>	<b>Mean (sd) – No training</b>	<b>Mean (sd) – Training</b>	<b>t-test value</b>
Safety Culture ( $\alpha = .83$ )		3.89 (.76)	4.24 (.73)	6.4*
	1. I would feel safe being treated in this clinical area as a patient.	4.39 (.97)	4.45 (.97)	0.86 <sup>ϕ</sup>
	2. Medical errors are handled appropriately in this clinical area.	4.11 (.95)	4.42 (.88)	4.8*
	3. I know the proper channels to direct questions regarding patient safety in this clinical area.	4.02 (1.11)	4.50 (.83)	6.7*
	4. I receive appropriate feedback about my performance.	3.61 (1.20)	3.96 (1.18)	4.0*
	5. In this clinical area, it is difficult to discuss medical errors.	3.73 (1.18)	3.95 (1.25)	2.5*
	6. I am encouraged by my colleagues to report any patient safety concerns I may have.	3.77 (1.14)	4.32 (.97)	7.4*
	7. The culture in this clinical area makes it easy to learn from the errors of others.	3.62 (1.24)	4.08 (1.14)	5.4*
Teamwork Culture ( $\alpha = .83$ )		4.14 (.73)	4.34 (.68)	3.9*
	1. Patient and family input is well received in this clinical area.	4.37 (.91)	4.57 (.69)	3.5*
	2. Non-physician staff input is well received in this clinical area.	4.33 (.92)	4.50 (.76)	2.7*
	3. In this clinical area, it is difficult to speak up if I perceive a problem with patient care.	3.87 (1.29)	4.02 (1.33)	1.6 <sup>ϕ</sup>
	4. Disagreements in this clinical area are resolved appropriately (not who is right, but what is best for patient).	3.90 (1.16)	4.19 (1.08)	3.6*
	5. I have the support I need from other personnel to care for patients.	4.00 (1.19)	4.25 (1.05)	3.1*
	6. It is easy for personnel here to ask questions when there is something that they do not understand.	4.27 (.95)	4.47 (.83)	3.1*
	7. The physicians and nurses in this clinical area work together as a well-coordinated team.	4.26 (1.01)	4.41 (.91)	2.2*
Intent To Disclose a Hypothetical Error		3.70 (.56)	3.84 (.49)	4.1*

Note: † refers to items that were reverse coded. \* refers to t-tests significant at  $p < .05$ . <sup>ϕ</sup> refers to a non-significant t-test value.

## Results

We previously published demographics for the baseline survey,<sup>19</sup> and those demographics are similar to demographics for the follow-up survey participants (Table 2). As seen in Table 2, of all respondents in the follow-up survey administration, 472 participants (44 percent) indicated they had not previously received error disclosure training, and 599 participants (56 percent) reported having received such training; 10 participants did not provide information on prior training and were excluded from our analyses. Also, both groups (those who did not receive training and those who did) were mostly physicians (70 percent for “no training” group; 72 percent for “training” group), male (57 percent in both groups), practicing in either Internal Medicine (25 percent for both groups) or Surgery (16 percent and 14 percent, respectively), had 5 years or more experience (78 percent and 74 percent, respectively, for “no training” and “training” groups), and spent 51 percent or more of their time in clinic (80 percent and 71 percent, respectively).

Table 3 includes percent positive scores for each type of culture by institution and overall across all institutions. To address our first objective, we compared whether culture scores were significantly higher in the follow-up than baseline surveys. Minor error disclosure culture was significantly higher in the follow-up surveys than in the baseline surveys for all institutions and overall, with percent positive scores overall being 33 percent and 52 percent for baseline and follow-up, respectively ( $p < .05$ ). Four of the six institutions had significantly higher percent positive scores for serious error disclosure culture, with overall scores improving from 53 percent to 70 percent. Although error disclosure culture trust did not show significant increases for any of the institutions or overall (58 percent and 56 percent, respectively), safety culture improved overall from 50 percent to 63 percent ( $p < .05$ ), and teamwork culture improved from 62 percent to 73 percent ( $p < .05$ ).

In examining the follow-up survey data only, we computed Cronbach’s alpha for each of the key constructs, descriptive statistics for the constructs and survey items, and t-test and corresponding p-values comparing those who received training and those who did not (Table 4). The constructs and all but two items were significantly higher for those who received training. Table 5 contains correlational results between the different types of culture we measured and intent to disclose a hypothetical error. For those who did not receive training, all types of culture and intent to disclose were significantly correlated with each other. In contrast, for those who received training, minor, serious, and trust error disclosure were associated with intent to disclose, but safety and teamwork cultures were not (Table 5).

**Table 2. Demographics**

	No Training (n = 472)	Training (n = 599)
<b>Profession</b>		
MD	331 (70%)	432 (72%)
RN	5 (1%)	4 (1%)
Other	26 (6%)	26 (4%)
Missing	110 (23%)	137 (23%)
<b>Gender</b>		
Female	189 (40%)	235 (39%)
Male	269 (57%)	343 (57%)
Missing	14 (3%)	21 (4%)
<b>Specialty</b>		
Internal Medicine	120 (25%)	151 (25%)
Surgery	76 (16%)	83 (14%)
<b>Years in Specialty</b>		
5 years or more	366 (78%)	445 (74%)
<b>Time Spent in Clinic</b>		
51% or more	376 (80%)	423 (71%)

## Discussion

The results from our study highlight the potential importance of error disclosure training, given the association between different types of culture and intent to disclose errors. The improvements in minor error disclosure culture and serious error disclosure culture observed between baseline and follow-up point to an interesting association between culture and training. While we cannot infer from these results that training caused the improved perceptions of culture, it is possible that merely offering training to faculty signifies to them the importance of the topic that is the focus of training (i.e., error disclosure), and this in turn influences more positive perceptions of culture. Further, disclosure training might have benefits for the individuals attending training because it allows them to improve their disclosure skills. Organizations might also benefit from such training via effects from “train the trainer” programs that also enhance other’s perceptions of culture.

For those who received training, error disclosure culture played a more important role in explaining whether they intended to disclose an error as compared to safety and teamwork culture. In contrast, all types of culture played a role for those who had not received training. This suggests that perceptions of error disclosure and intent to disclose an error are more closely aligned in those who received specific training on error disclosure. The percent positive scores for the two types of participants revealed higher percentages for those who received training, with the percent positives dramatically higher for the error disclosure items focused on minor errors and serious errors.

**Table 3. Percent Positive Culture Scores Pre- and Post-training Across Sites**

	Institution A		Institution B		Institution C		Institution D		Institution E		Institution F		Overall	
	Pre train (n = 125)	Post train (n = 194)	Pre train (n = 63)	Post train (n = 226)	Pre train (n = 102)	Post train (n = 292)	Pre train (n = 99)	Post train (n = 159)	Pre train (n = 66)	Post train (n = 178)	Pre train (n = 41)	Post train (n = 32)	Pre train (n = 496)	Post train (n = 1081)
Jason														
Minor Error Disclosure Culture	35	48*	46	59*	25	50*	27	51*	35	50*	44	74*	33	52*
Serious Error Disclosure Culture	51	64*	67	73	50	72*	49	69*	48	69*	61	77	53	70*
Error Disclosure Trust Culture	57	48	60	59	60	57	65	60	50	58	54	59	58	56
Safety Culture	46	57	65	68	44	NA	47	64*	49	61	56	76	50	63*
Teamwork Culture	58	69*	73	73	57	NA	57	76*	61	72	85	81	62	73*

Note: NA = Institution C opted to not survey providers about safety culture and teamwork culture; \* denotes significant difference between pre- and post-training at  $p < .05$



**Table 4. Percent Positive Scores for Culture Constructs**

<b>Construct</b>	<b>No Training (n = 472)</b>	<b>Training (n = 599)</b>	<b>p-value</b>
Error Disclosure Minor	41%	61%	< .001
Error Disclosure Serious	58%	79%	< .001
Error Disclosure Trust	51%	61%	< .001
Safety Culture	51%	73%	< .001
Teamwork Culture	66%	78%	< .001

Note: While 1,217 participants completed part/all of the survey in the follow-up administration, not specifying whether training was received (n=10) and providing incomplete survey responses (n=136) resulted in a usable sample size lower than 1,217.

There are two notable implications from this study. First, those who were trained perceived their work environment in a more positive way. This finding suggests the content of the training was important (as evidenced by the higher error disclosure culture scores), the focus on openly discussing errors (which is vital to having positive safety and teamwork cultures), and intent to disclose an error. Second, this study shows that developing a culture that embraces disclosing minor errors might be more difficult to accomplish than one focused on serious errors. While our findings were higher than previous research indicating agreement (around 50 percent) about whether minor errors and serious errors should be disclosed,<sup>3</sup> the percentage of faculty perceiving a culture conducive to disclosing minor errors is still lower than serious errors, suggesting that clinicians are even less likely to meet patients' expectations after minor harm. Clinicians may worry that damage to their relationship with the patient may outweigh the benefit to the patient of knowing about minor harm. Greater educational emphasis may be needed to help physicians and institutions fully support disclosing minor errors. Leadership will play a central role in helping make this initiative an important part of an organization's culture.

It would be beneficial in the future to link culture survey responses with additional outcomes, such as assessments of disclosure quality. In other words, do higher scores on disclosure quality correlate with higher scores on safety, teamwork, or disclosure culture scales? Further, longitudinal studies linking more positive error disclosure cultures with better outcomes from increased quality improvement initiatives would help build knowledge in this area.

**Table 5. Correlations Between Key Constructs for Those Not Receiving Previous Error Disclosure Training**

<b>Construct</b>	<b>Minor Error Disclosure</b>	<b>Serious Error Disclosure</b>	<b>Error Disclosure Trust</b>	<b>Safety Culture</b>	<b>Teamwork Culture</b>	<b>Intent To Disclose</b>
Minor Error Disclosure	-	.62	.16	.61	.49	.10
Serious Error Disclosure	.65	-	.12	.65	.54	.20
Error Disclosure Trust	.22	.23	-	.13	.13	.16
Safety Culture	.48	.54	.23	-	.77	.08 (ns)
Teamwork Culture	.48	.43	.17	.70	-	.07 (ns)
Intent to Disclose	.19	.26	.17	.21	.19	-

Note: Correlations above diagonal are for participants who received training while below diagonal correlations are for patients who did not receive training. All correlations significant at  $p < .05$  unless noted by ns (where ns means non-significant).

## Limitations

There are several limitations to this study. First, while we expect that clinical faculty should know whether they received training in how to disclose errors, we do not have independent confirmation that they actually received training. Despite the fact that participation in training was a self-reported measure, it was likely a memorable event and one that participants should therefore remember. Second, for those clinical faculty members who indicated that they received training, we do not know if they attended the training offered as part of this study or received it in some other way. While the results reported here were collected after error disclosure training was offered to clinical faculty, it would be scientifically and methodologically stronger to offer training via a randomized design to better understand the role that training plays in changing physician perceptions. Relatedly, our methodology would have been stronger if we linked participants with their baseline and follow-up surveys. Third, those who reported receiving previous training might be different from those who did not receive previous training. For example, those previously attending training might have more positive perceptions of culture and a higher propensity to disclose an error. Fourth, our response rate was lower than we expected, especially given that we had incentives for participants. Fifth, our results represent perceptions of clinical faculty from one university system and might not be generalizable to other settings.

## Conclusion

In summary, several different culture measures are sensitive to differences between those participants who received training in disclosing errors and those who did not. Incorporating error disclosure training into medical schools and/or as part of physician continuing education might be an important step towards addressing the tension between patients' need for error disclosure and physicians' reluctance to disclose errors. Such training also might have a positive association with different types of organizational culture, including safety, teamwork, and disclosure cultures, which could also have a positive impact on patient safety.

## Acknowledgments

This project was funded by an R18 grant award from the Agency for Healthcare Research and Quality (HS19561).

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# Applying a Novel Organization Change Scale in a Multisite Patient Safety Initiative

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## Abstract

**Purpose.** The AHRQ-funded, 3-year demonstration project “Communication to Prevent and Respond to Medical Injury: A Washington State Collaborative,” sought to improve patient safety culture in eight health care organizations, with a focus on enhanced error disclosure practices. Establishing a robust culture of patient safety requires broad support from providers and staff. Yet, many organizations struggle to align attitudes and behaviors, in part because leaders often overestimate readiness for change. This study describes the development of the Organizational Change Scale (OCS), an instrument designed to assess organizational change in response to organization-wide interventions.

**Methods.** The 14-item OCS is grounded in the Kotter eight-stage model of organizational change and takes only a few minutes to complete. The instrument underwent expert review, pilot testing, and was ultimately administered to select providers, staff and leadership who were trained to support error disclosure at their health care organizations (disclosure coaches).

**Results.** A total of 251 participants across eight health care organizations attended disclosure coach training sessions; 79 (31.5 percent) completed the OCS. The OCS exhibited good internal consistency ( $\alpha = 0.90$ ) and was able to discriminate between programs. The highest organizational scale scores were seen for the first Kotter stage “Sense of Urgency,” and the lowest readiness was reflected by how organizations “Communicated the Vision” of patient safety to employees. Findings generally reflected ongoing organizational change but also evidence of improvement.

**Conclusions.** The OCS allows health care organizations to capture “snapshots” of readiness, from an organization’s first recognition that change is required to the establishment of policy reflecting successful adoption of new processes. It also holds promise for examining change across time. Rooted in theory, brief, and applicable to all health care employees, the OCS has a wide range of potential applicability.

## Introduction

Health care organizations often struggle to implement and sustain programs targeting broad organizational culture and behavior change. Despite some high-level guidance,<sup>1</sup> large-scale interventions focused on patient safety generally have not proven effective.<sup>2,3,4</sup> When success does occur, the results are typically modest, difficult to sustain, and based on low quality study designs with little generalizability.<sup>5</sup> Furthermore, health care leaders often find it challenging to predict their organizations’ chance of success.

Organizations go through a myriad of incremental shifts when seeking to transform the beliefs, actions, and policies that form their culture of patient safety. Inaccurate assessment of an organization's readiness for change or progress through change may be one reason why culture change efforts fail. The literature thus far has principally focused on tools for measuring the success of specific interventions within a given context. These instruments are valuable for empirically guiding resource allocation and determining effectiveness in improving patient safety. For example, the widely used Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPS) <sup>6</sup> assesses perceptions of an organization's state of patient safety and helps to identify areas for improvement. However, the HSOPS instrument does not assess the specific organizational factors that determine how, or if, change is occurring. Such tools that can examine readiness and organizational change are lacking. An ideal instrument would be based on current theory, <sup>7</sup> brief, applicable across stakeholders, and settings, and easily interpreted.

John Kotter established a widely respected theoretical approach for understanding complex organizational change based on patterns found across industry and business settings. <sup>8,9,10,11</sup> He described successful organizational change as a functional completion of a series of ordered phases. Progression through Kotter's phases (Figure 1) occurs gradually and success can unfold across years or even decades. An organization's successful completion of each phase is essential for overall success. AHRQ and the Department of Defense's (DoD) have used Kotter's model <sup>10,11</sup> as a means to describe as a means to describe health care organizations' efforts to establish a culture dedicated to the improvement of patient safety.



**Figure 1. Kotter's Phases of Organizational Change**

Adapted from: Kotter JP. Leading change: Why transformation efforts fail. Harv Bus Rev 1995; 73:59-67.

Kotter's model for organizational change provides a theoretical framework for capturing an organization's state of readiness for change, its adoption of new methods, and the impact of these methods on organizational culture. Using Kotter's model, we developed the Organizational Change Scale (OCS). The OCS was designed to take only a few minutes to complete, to have broad application in health care settings, and to have longitudinal utility. In this paper, we first describe the development of the OCS. We then report on the preliminary use of this instrument in a multi-site, complex demonstration project designed to improve patient safety. Specifically, we administered the instrument to assess each participating organization's readiness to change their culture of disclosure to patients and families following harmful medical errors. Interventions to improve skills around error disclosure constitute a good test of the OCS; successful interventions must navigate complex barriers, require routine monitoring and reporting, and will unfold across years.

## **Methods**

### **The Intervention**

The "Communication to Prevent and Respond to Medical Injury: A Washington State Collaborative" was a 3-year demonstration project funded by the AHRQ. Eight Washington State health care organizations (five hospitals and three multi-specialty provider groups) agreed to participate in a two-component intervention to enhance patient safety. The first component aimed to reduce medical errors by improving team communication through adoption of TeamSTEPPS<sup>®</sup> (<https://www.ahrq.gov/teamstepps/officebasedcare/index.html>). TeamSTEPPS is a validated training program to reduce errors and improve health outcomes through improved communication within teams.

The second component of the intervention focused on a culture of transparency around error disclosure.<sup>12</sup> Select providers, staff, and leadership were trained to be "disclosure coaches," individuals who could respond to and support the needs of clinicians and patients following a medical error. Medical error was defined as the failure of a planned action to be completed or the use of a wrong plan to achieve an aim. Disclosure coaches strengthen clinician confidence and allow disclosure to occur in a timely fashion.<sup>13,14,15,16</sup> In-person disclosure coach training sessions were conducted between March 19, 2012 and February 8, 2013, at all participating organizations. Training involved a mix of didactic and error disclosure simulation. A full description of the curriculum has been previously published.<sup>17</sup>

### **Participants**

At each participating organization, disclosure coaches were selected by organizational leadership as well-respected individuals with excellent communication skills from varying professions and disciplines. At most organizations, this resulted in a mix of physicians, medical directors, nurse managers, risk managers, patient safety officers, and pharmacist managers. Total attendance at these eight sessions was 251 disclosure coach trainees (range 11-49 per institution). The activation of disclosure coaches varied between sites, depending on local protocols.

### **Instrument Development**

The Organizational Change Scale (OCS) was developed to measure organizational change readiness at baseline and across time. Fourteen items were formed from existing descriptions



of the key elements of each phase of the Kotter model (Table 1). Each of the items provides a Likert-style question with response options ranging from 1=strongly disagree to 5=strongly agree (Figure 2). An arithmetic average is calculated for the items composing each subscale. After development, items were then reviewed by demonstration project team investigators, each with significant expertise in program evaluation or psychometric design of scales. The first administration of the scale served as a pilot and did not raise any concerns for continuing to administer the scale. The instrument was designed to be used at multiple times during the demonstration project, supplementing other project instruments employed to explore the success of specific interventions. The University of Washington Internal Review Board (IRB) approved this study.

**Table 1. Descriptive Statistics Aggregated Across Eight Hospitals**

<b>Change Scale Category</b>	<b>n</b>	<b>Min</b>	<b>Max</b>	<b>mean</b>	<b>se</b>	<b>sd</b>
Increase urgency	78	1.0	5.0	4.09	0.12	1.05
Build guiding teams	79	1.0	5.0	3.87	0.09	0.77
Get the vision right	79	1.3	5.0	3.66	0.09	0.84
Communicate for buy-in	79	1.0	5.0	3.25	0.10	0.88
Enable action	79	1.0	5.0	3.58	0.09	0.84
Create short-term wins	77	2.0	5.0	3.78	0.09	0.77
Don't let up	79	1.5	5.0	3.58	0.09	0.79
Make it stick	78	1.0	5.0	3.68	0.10	0.85

### **Instrument Implementation**

The OCS was administered as part of the second component of the demonstration project. We recruited all 251 trained disclosure coaches to complete the OSC via Web-based questionnaire. The survey was administered to participants an average of 40 weeks after the training session (range 3 to 75 weeks). The variation in administration time was due to the variation in training dates combined with a 5-month delay introduced by a revision to the IRB application.

Figure 3 shows two organizations (Hospitals 1 and 2) and illustrates observed differences in cultural readiness and achievement of change. These two hospitals were selected to demonstrate patterns observed across hospitals. They are not meant to suggest the relative success of these institutions. For Hospital 1, “Sense of Urgency” is relatively high; but later change stages, such as “Enabling action” and “Making it stick” through policy shifts are not strongly present. Both of these factors are predicted later in an organization’s culture evolution. Hospital 2 illustrates an organizational pattern that has achieved relative success for the majority of the Kotter phases. This is also true for “Policy,” defined as one of the last phases to emerge.

### **Discussion**

We have described the OCS as an instrument to measure the “state” of readiness for changing culture within health care organizations. We have used data collected as part of a large-scale demonstration project, providing preliminary support for use of the instrument.

**Organizational Change Scale items, grouped by their corresponding phase of organizational phase of change**

**Increase Urgency\***

1. Our organizations' leaders and stakeholders hold a shared vision that organizational change needs to occur in the immediate future.

**Build Guiding Teams**

2. A guiding coalition of leaders and stakeholders exists to guide positive organizational change.
3. This coalition is able to commit the time necessary to complete trainings and lead implementation of new initiatives.

**Get the Vision Right**

4. Our organization's leaders and stakeholders hold a shared vision that organizational change needs to occur.
5. Our organization's leaders and stakeholders hold a shared vision of what organizational change needs to occur.
6. Our organization's leaders and stakeholders hold a shared vision of how organizational change needs to occur.

**Communication for Buy-In**

7. Clinicians understand the organizational vision.
8. Support staff understand the organizational vision.

**Enable Action**

9. Clinicians have the support of their leadership to enact necessary changes.
10. Support staff have the support of their leadership to enact necessary changes.

**Create Short-Term Wins**

11. Incremental changes made by individuals and teams are acknowledged and rewarded.

**Don't Let Up**

12. Organizational change is effectively measured and reported.
13. Organization changed are used to develop new pathways for success.

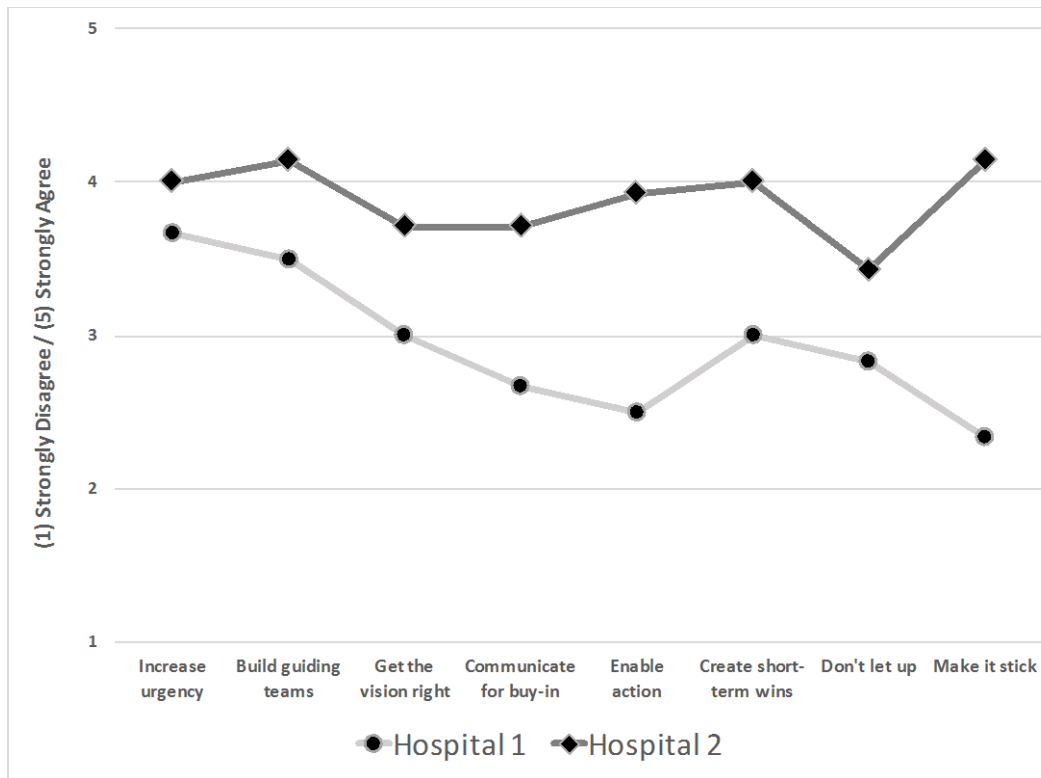
**Make It Stick**

14. Change is reflected in organization policy.

**Instructions to participant:** This instrument asks you to indicate how you feel about statements that describe your health care organization's readiness and support for organizational change. For each of the following questions please respond on the provided scale from 1= "Strongly Disagree" to 5= "Strongly Agree". A "Not Applicable" response has also been provided.

**\*Note:** During implementation, the "Phase of change" headings as noted above were not part of the administered tool.

**Figure 2. Organizational Change Scale Instrument and Instructions**



**Figure 3. Two Hospitals in Different Stages of Cultural Readiness and Achievement of Change**

Three key themes emerged from our analyses of the OCS. First, organizations generally reported an urgent need for change, expressed significant concern that they could do better in meeting patient and organizational needs, and held interest in integrating efficient, effective, and sustainable programs to improve the culture of error disclosure. The OCS provides a theory-based profile of each organization's dynamic state of change. Second, change is difficult. However, knowing which specific stages are showing success and which require additional support may guide individual organizations in focusing their attention and tailoring their change activities. Third, inspection of the profiles demonstrated that the OCS is sensitive across the range of Kotter's stages of change.<sup>8,9,10,11</sup> Some organizations exhibited patterns such as early recognition of urgency but having had little time or success in shifting the cultural of error disclosure. Some organizations exhibited patterns of more mature developmental shifts, with both early and later phases of Kotter's model demonstrating success. The majority of organizations showed complex patterns suggesting it may not be optimal to think of each of Kotter's phases as strictly building on previous phases. For example, positive policy changes might be demonstrated as a response to high-level shifts, while progress at lower phases is yet to be fully achieved.

## Limitations

This study has limitations that must be taken into consideration when interpreting the reported results and in considering the OCS for future studies. First, each of the organizations described in this study agreed to participate in the demonstration project. Voluntary participation in a

demonstration project may be correlated with an increased likelihood for promoting organizational change. Therefore, the results may not be generalizable to other organizations. Secondly, training implementation and data collection were challenging. Difficulties included obtaining support from leadership and securing time from participating clinicians to complete the OCS and other project activities. While the OCS took little time to complete, other aspects of the study data collection effort, including additional self-report questionnaires, may have been perceived as burdensome to the participants. These challenges may have contributed to a low response rate. For these reasons, further implementations of the OSC would contribute valuable validation evidence. Finally, the engagement of different organizations varied, and it proved difficult to obtain the necessary IRB approvals to administer surveys in a timely fashion. In the end, our instruments were administered at only a single point in time. Consequently, different amounts of time had elapsed between intervention and data collection at each organization.

## **Conclusion**

The Organizational Change Scale (OCS) holds promise for health care organization stakeholders (e.g., leadership, insurers) as a means to provide a “snapshot” of the state of an organization. The instrument may also be of value to assess cultural change across time. The instrument’s ease of use and limited time requirements support its use in surveying employees broadly across organizations or narrowly within organizational units or to specific populations such as key leaders or organizational “change agents.”

## **Acknowledgments**

Support for this work came from the Agency for Healthcare Research and Quality (Grant HS19531). The funder had no role in the design, conduct, or reporting of the study. We acknowledge and thank Benjamin Dunlap and Emily Brulotte for their contributions to coordination of data collection.

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# Implementing Near-Miss Reporting and Improvement Tracking in Primary Care Practices: Lessons Learned

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## Abstract

**Introduction.** Near-miss events, where no actual harm comes to the patient, represent a lower-risk opportunity to improve patient safety and address patient expectations regarding disclosure of medical errors, both factors associated with medical malpractice claims. The Institute of Medicine and others have called for the creation of voluntary reporting systems to detect near-miss events to allow for analysis of patterns of errors; widespread adoption of near-miss reporting systems in primary care could improve safety in that setting where more than 70 percent of medical encounters occur. Barriers to reporting near-miss errors include the additional workload burden imposed by a reporting system, concern over punitive action arising from a report, lack of confidence that positive change will result from such reporting, and psychological barriers to admitting an error. Furthermore, unless practices find this information useful to correct errors, near-miss reporting will be unlikely to become a routine procedure in ambulatory practice.

**Objective.** A primary goal for this project was to better understand barriers and facilitators of implementing a near-miss reporting and remediation system in primary care.

**Methods.** We designed and implemented an anonymous, near-miss reporting and improvement tracking system in seven diverse primary care medical practices to demonstrate that such a system could be successfully adopted in a variety of settings.

**Results.** In this paper we describe the reporting program, how it was implemented in the practices, the measured impact on practice and safety culture, and how practice leaders used the near-miss reports to improve care processes.

**Conclusion.** Near-miss reporting within primary care practices can help guide performance improvement activities and lead to meaningful changes in policy and practice. Successful implementation requires leadership commitment, incentives for staff, periodic reminders, and a system that allows reporting to be easy and anonymous.

## Introduction

Near-miss events are errors that occur in the process of providing medical care that are detected and corrected before a patient is harmed. The Institute of Medicine (IOM) and others have identified near-miss reporting and analysis as vital to understanding and correcting weaknesses in the health care delivery system and to preventing actual adverse events (AEs) that harm patients.<sup>1,2</sup> Although the majority of health care encounters take place in ambulatory settings, most attempts to record and address near-miss events to date have been carried out in hospitals.

Few examples of such efforts can be found in the United States to date, even though reporting systems have been successfully implemented in other countries.<sup>3,4,5</sup> At least one voluntary, anonymous reporting system has been established in U.S. primary care settings;<sup>6</sup> others have demonstrated that near-miss reporting systems can increase awareness of patient safety.<sup>7</sup>

There are many potential barriers to reporting near-miss events in other care settings, such as hospitals, including the additional workload burden imposed by a reporting system, varying perceptions of staff responsibility for reporting, concern over punitive action arising from error reporting, lack of confidence that positive change will result from such reporting, and psychological barriers to admitting involvement in an error in patient care.<sup>8,9,10,11,12</sup> Factors cited to facilitate reporting include improved confidentiality, evidence that the reports would be used to improve patient care and not for punitive action, reporting forms that can be completed in 2 minutes or less, coupling reporting with an explicit process of quality improvement, and reminders to stimulate recall of near-miss events.<sup>13,14</sup>

The primary goal of this Agency for Healthcare Research and Quality (AHRQ) planning grant (Medical Liability Reform and Patient Safety Planning Grant RFA-HS-10-022 Regional Ambulatory Near-Miss Reporting and Tracking to Improve Patient Safety) was to better understand the barriers and facilitators of implementing a near-miss reporting system in primary care practices. The North Carolina Office of Rural Health and Community Care (ORHCC), which was the grantee for this AHRQ pilot project, proposed to test a voluntary near-miss reporting and improvement tracking system across a variety of primary care practices and settings, including safety net providers, family medicine residency training programs, rural clinics, and small private practices. The goal was to narrow gaps in knowledge regarding near-miss events—including patterns of near misses in different types of primary care practices—and factors that contribute to successful implementation of near-miss reporting; another goal was to observe how practice leaders use near-miss reports to address identified safety issues.

The specific aims were to measure differences in reporting rates between practices after a standardized orientation and common small incentive program, to measure changes in the practice and safety culture after near-miss reporting had been implemented, and to assess how practice leaders engaged in the near-miss reporting and subsequent practice improvement activities and their perceived value of this type of activity. By selecting a range of practices in terms of ownership, size, and urban and rural settings, the pilot was designed to be generalizable to a wide range of outpatient practices. A better understanding of these factors should inform efforts to adopt near-miss reporting and quality improvement more widely in the ambulatory care setting.

## Methods

We recruited seven diverse practices to participate in the 1-year pilot project. The intervention itself had four components: (1) develop and conduct a standardized orientation for each practice with regards to reporting near-miss events; (2) collect and analyze near-miss reports from each of the practices for 6 to 9 months; (3) facilitate a practice improvement collaborative with the participating groups that included regular reminders and feedback to practice leaders about

their reporting performance; and (4) provide a platform for the practices to establish and track efforts to remediate near-miss events.

The seven practices selected all belonged to the Community Care of Western North Carolina (CCWNC—formerly Access II Care) network and included two residency practices (which included three small rural satellite clinics), two safety net providers (one rural), and three private practices (two rural and one urban pediatric group). Together, these practices and sites employed more than 70 medical providers and 200 clinical support staff, provided over 2,000 office visits per month, and represented the full scope of primary care, including pediatric, geriatric, adult, and obstetrical care. Details of these practices are reported elsewhere.<sup>15</sup>

Prior to implementation, we attempted to collect anonymous surveys from all staff involved in clinical operations using the AHRQ Medical Office Survey on Patient Safety Culture<sup>16</sup> to establish baselines. Staff were asked to complete the same surveys 6 to 9 months later, at the end of the official reporting period.

Each practice was enrolled in a rolling 3-month process that brought on one to three practices each month. The standardized orientation for each practice included a detailed overview of the project that was presented to leadership personnel at each of the participating practices, the goal of which was to develop an individualized implementation plan for their practice. A second presentation included all clinical and administrative staff and was intended to instruct staff how to recognize a near-miss event (as opposed to an adverse event or an error that had no potential for patient harm) and how to use the system to report these events as close to when they occurred as was possible. These included video instruction vignettes that were posted on the Internet and available for review from within the reporting system.<sup>17</sup>

After the initial orientation and each practice began reporting near-miss events, we sent electronic monthly diaries to practice leaders to gather ongoing snapshot views of how implementation was proceeding. We also provided monthly feedback through the electronic database and during the monthly conference calls to each practice about how many near-miss reports had been filed.

The near-miss reporting system was anonymous but allowed staff to include their name if they chose to do so. A previous trial of the system had determined that the 14-question form could be filled out accurately in most cases with minimal instruction in 2 minutes or less. Access to the online reporting system was through a desk-top icon that was installed on all work computers in each of the practices. The reporting system was structured so that the initial report was forwarded first to designated leaders in each practice who would review the report to make sure that the report was a near-miss (i.e., no harm came to the patient) and not an adverse event (AE, where the patient had suffered some harm). Only when determined to be a near-miss would the report be released into the general database. Each practice leader had access to all their own reports, but only those that originated in their practice; the evaluation team had access to the entire database, but the coders were blinded to the practice where the error had occurred.

Once practices had been reporting for at least 2 months, practice leaders were introduced to the near-miss remediation tracking program. The orientation to process improvement was based on



the Plan-Do-Study-Act (PDSA) or Deming cycle; the practice was provided with a tracking tool integrated with the reporting system to allow practice leaders to assign each near-miss event (or a bundle of similar events) to an individual or group. The assignment included a “charter” outlining the problem to be addressed, expected outcomes, and a timeframe for reporting back to leadership. The program contained embedded references and links to help staff implement the PDSA model. The platform allowed the individual and/or group to keep a record of their steps and progress and provided automated email reminders to both those assigned the task and the manager(s) tracking the progress. Practices could choose to make this database open and viewable by other practice leaders in the collaborative.

We also conducted several conference calls with the practice leaders during this phase of the project to allow practices to share ideas about how to encourage staff to make near-miss reports, and how each was implementing the remediation process. Finally, at the end of the reporting period, we conducted structured focus groups with practice leaders at each of the practices.

Each of the practices was reimbursed the following amounts if they met the following monthly benchmarks:

1. Initiation of the project: Practices received \$5,000 if they identified a core implementation team, participated in two planning meetings, made time for the all-staff orientation, and returned all of the baseline survey information.
2. Monthly near-miss reporting and participation goals: Practices then received \$1,500 a month for 6 months if their practice reported at least 10 near-miss events a month and identified at least one near-miss event to remediate and track.

The total official reporting period for near-miss reports and initiating remediation projects was 9 months; depending on when the practice was enrolled, each practice had 6-9 months participation.

The near-miss reports themselves were reviewed by a team of six coders, all of whom went through a standardized training course. Using a previously developed taxonomy of ambulatory care errors developed in 2002 from a database of 344 near-miss reports from family practice,<sup>18</sup> we classified each near-miss event and validated the coding with a second coder for 10 percent of the reports. The primary error was defined as “the breakdown in process, or knowledge/skill deficit that led to the problem.” Each reported error was coded with just one primary error but with up to four additional associated or cascade errors that could be included in the coding. In addition to classifying the type of errors, contributing factors, and possible preventive measures, the coders were also asked to provide a second rating of the potential seriousness of the event, the potential cost to the patient, and the estimated cost to the practice to remedy the problem. The potential cost to patients was defined as direct costs or lost wages; these were placed into one of three ranked categories: “None/minimal,” “some,” or “a lot,” with “a lot” defined as “a major financial loss for the patient.” Similarly, the estimated costs to the practice to remedy the problem were ranked, with “a lot” in this case defined as “a major investment in time or money.” After the events were coded, the coding and evaluation teams then developed a more succinct taxonomy of the errors contained in this contemporary database, eliminating codes of errors that

did not appear and consolidating others that the coders agreed were equivalent events into a single code. This process was done by consensus of the primary coders, the primary investigator, the evaluation team, and the national consultant.

The pilot was reviewed by an institutional review board (IRB) and approved as a waived performance improvement project.

## Results

### Near-Miss Event Reporting by Practices

The practices were all largely successful in reporting near-miss events. The original target was for the combined enrolled practices to produce at least 300 near-miss reports over a 6-month period or seven reports per practice per month. The practices reported a total of 632 near-miss events during the official reporting period; most of the practices reached the minimum per month threshold. The mean number of reports per 1,000 patient visits was 9.1, with a range of 5.1 to 21.2 (see Table 1).

Somewhat surprisingly, the practices continued to report near-misses even after the official reporting period and small financial incentives had ended; collectively, they reported an additional 138 near-miss events; by the end of the 12-month project period, 770 events had been logged into the database. Practices were allowed to continue to log-in and use the reporting and tracking software; reports continued to trickle in but at a declining rate for another year. Because the overall target of 300 near-miss events were reported by the group, all the practices were awarded their participation incentive as outlined in the methods section.

**Table 1. Near-Miss Events Reports by Practice, per month and per 1,000 patient visits**

Practices	All	A	B	C	D	E	F	G
Month enrolled	52	6	9	7	9	7	6	8
Visits during enrolled months	69392	6832	17085	3767	16688	13563	2292	9167
Near-miss reports	632	43	177	80	139	69	43	81
Reports per month	12.2	7.2	19.7	11.4	15.4	9.9	7.2	10.1
Reports per 1000 visits	9.1	6.3	10.4	21.2	8.3	5.1	18.8	8.8

The 632 reports that were logged in during the study period were coded and analyzed for type of event and seriousness. This analysis has been reported elsewhere.<sup>15</sup>

### Impact of Near-Miss Reporting on Practice and Safety Culture

The participating practices baseline levels of office safety culture and those at 9 months into the project, compared with previously published cohort, are shown in Table 2. We did observe a five percentage point improvement in five of the twelve measures in the survey which corresponds to a “better than comparison” according to the scoring guide of this measurement tool. The percentage of staff completing the follow-up surveys was significantly below the baseline survey participation rate.

**Table 2. Practice Safety Culture**

Staff Opinions About Office Safety Culture	Percent With Positive Response <sup>b</sup>		Comparison Data <sup>a</sup>
	Baseline (n=141)	Follow-up (n=49)	
Teamwork	73 percent	<b>78 percent</b>	82 percent
Patient care tracking and followup	68 percent	67 percent	77 percent
Organizational learning	66 percent	66 percent	74 percent
Overall perceptions of patient safety and quality	61 percent	<b>56 percent</b>	74 percent
Staff training	59 percent	57 percent	72 percent
Leadership support for patient safety	60 percent	<b>68 percent</b>	67 percent
Communication about error	58 percent	<b>65 percent</b>	67 percent
Communication openness	55 percent	59 percent	65 percent
Patient safety and quality issues	49 percent	<b>42 percent</b>	50 percent
Office processes and standardization	44 percent	42 percent	59 percent
Information exchange with other settings	49 percent	53 percent	54 percent
Work pressure and pace	38 percent	<b>54 percent</b>	46 percent

<sup>a</sup> Source: 2010 Preliminary Comparative Results: Medical Office Survey on Patient Safety Culture. (Prepared by Westat, Rockville, MD, under Contract No. HHSA 290200710037). Rockville, MD: Agency for Healthcare Research and Quality; November 2010. AHRQ Publication No. 11-0015-EF.

<sup>b</sup> Percentages in bold font differ by at least 5 percentage points from baseline. A change of 5 percentage points corresponds to 'better' or 'lower' than comparison, per scoring guide.

## Practice Leader Engagement

We observed very good practice leader buy-in to the project, based on focus group data and monthly online diaries. We did not identify any significant barriers to the implementation of this near-miss reporting system in this group of practices. Two of the seven practices with the highest near-miss reports per 1,000 patient visits appear to be those that provided direct incentives to staff for reporting, but one of the lowest also provided direct reporting incentives. The consensus from the group leader focus group was that the financial incentives did not greatly impact either the decision to participate in the pilot or to encourage staff to submit reports.

All seven practices initiated practice improvement projects based on the near-miss reports, ranging from 1 to 15, for a total of 34 near-miss-related formal projects reported in the tracking database. Of these projects, seven were followed through to completion, seven were placed on hold, four were inactivated, and the remainder were in progress at the close of the pilot (see Table 4).

The practice leader focus group revealed considerable variation in how practices approached remediation. Several of the practices had robust continuous quality improvement (CQI) processes in place prior to their participation in this project; near-miss reports were incorporated in some of these existing committees or efforts. Other practices had almost no formal practice improvement process in place at the beginning of the project; these practices appeared to use the near-miss reporting to begin address quality and safety in a more formal way. A common theme in the focus group was that practice leaders used near-miss reports to address and fix faulty

processes immediately, based on perceived potential seriousness of the reported error. We observed that practice leaders were willing to share information with regards to remediating near-miss errors with others in the collaborative. We heard frequently from practice leaders that the mechanics of getting practices together at a particular time for a real-time conference call proved to be difficult and cumbersome.

## Discussion

As previously noted, others have reported a number of potential barriers and facilitators to implementing near-miss event reporting generally. Our pilot built on a number of those facilitators, including anonymous reporting and using an online near-miss reporting form that had been previously tested and shown that it could be reliably completed by most users in 2 minutes or less with minimal training. The reporting process was coupled with explicit quality improvement activities in the practice. It was introduced practice-wide with a standardized staff training module that focused on the importance of near-miss reporting to create a safer care environment for patients and staff that should be undertaken in a non-blame management culture. Our results indicate that these facilitators appeared to overcome the other barriers of the small additional workload burden imposed by the reporting system, varying perceptions of staff responsibility for reporting, concern over punitive action arising from error reporting, and the psychological barriers to admitting involvement in an error in patient care. In fact, many of the near-miss event reports contained statements from those submitting the report that they felt personal relief bringing to light an error they had made in hopes that changes could be made in the care process to make such an error less likely to occur in the future.

The standardized training we developed for staff was focused and modular; although we presented the training in all-staff meetings (usually over lunch) aided with visual presentation slides, the training could easily be adapted to short online video training that could facilitate broader implementation.

We chose to make the reporting anonymous by default (although staff could indicate their name if they chose to do so) because we were unsure at the outset of the pilot how such reporting would be viewed and handled by practice leaders. This turned out to be a right choice because the participating practices appeared to have a marginally lower baseline culture of safety score than benchmark practices. In practices that have a well-established no-blame culture for error reporting, anonymous reporting is probably unnecessary and could restrict following up on a report with more specific inquiry. But, beginning with anonymous reporting until a culture is well established could facilitate reporting and the development of trust in the process of reporting.

We now also know that practices use the information from near-miss reports to improve care processes, even if they do so by using more informal methods. While some practices incorporated near-miss reports into existing formal quality improvement activities or created new teams to address certain flawed processes, managers reported that they also used information from near-miss reports to remedy problems identified by the reports in real time. Understanding how practices on a wider scale use near-miss reports to improve practice processes is a vital next

step in the development of best practice strategies to implement safety improvements in ambulatory practice.

Reporting of near-miss events without establishing clear and transparent process improvement is not only a missed opportunity to utilize important information to improve care, but it sends a clear message that the information isn't really desired. We observed that the practices that not only actively encouraged reporting in regular staff meetings but also included reports on what had been done in the interval to address the most serious potential errors had the highest rates of reports per 1,000 patient visits. Several practice leaders in practices that already had robust performance improvement processes reported that the energy generated around near-miss reporting appeared to invigorate their efforts to improve other aspects of care.

Practice improvement collaboratives have been demonstrated in other settings to stimulate practice transformation.<sup>19</sup> Although practice leaders reported that the monthly conference calls were cumbersome and somewhat burdensome, we believe that the participating practices did respond somewhat to group norms established around success of the project. As the pace and scope of practice improvement work accelerates, better methods to exchange ideas quickly and efficiently should be explored.

Although this was a short pilot, and the gains in practice and safety culture were not large, implementing near-miss reporting and process improvement appeared to lead to positive changes in culture. A longer study with larger numbers of staff would be important to document if this observation holds, is durable, and to what extent it would reduce AEs, lower cost, and improve the patient experience.

Although we included a small financial incentive for practices to participate in the pilot, the incentives did not appear to be instrumental in determining if a practice participated or have a demonstrable impact on reporting. Although our sample practices were diverse in type, size, and location, the practices were more representative of early-adopter practices. Wider adoption of near-miss reporting and process improvement around safety may require more tangible financial incentives, such as those adopted by the Centers for Medicare & Medicaid Services (CMS) to incentivize outcome reporting through the Physician Quality Reporting System (PQRS).

Finally, a probable (and positive outcome) of widespread reporting of near-miss events would be to begin a conversation with patients about if and how to share this information with them. Ultimately, disclosure of errors in the care process, particularly those events where no harm came to the patient, represents an opportunity not only for care providers to become more comfortable with the process of disclosure when the stakes may be lower, but also an opportunity for patients to become partners in helping make the care system safer for them and others. Both developments would likely result in reduced AEs through improved safety but perhaps also fewer liability claims.

## **Limitations**

The practices that participated in this pilot project were selected and not randomized. We purposely chose practices to represent a diversity of size, ownership, specialty, and range of

clinical services, but these practices are not necessarily representative of “average” practices in the region. Also, because this was a pilot project, we wanted to keep the number of practices confined to our region where we could deal in person if issues arose during implementation. Finally, we allowed practices to use the modest financial incentives in any way they saw fit. While we tracked what each practice did to motivate staff, including some that used the financial incentive to reward reporting, we did not design the intervention to test which incentive plan was the most effective.

The pilot project was designed as a natural experiment to observe how practice leaders would use near-miss reports to address safety and quality issues revealed by this information. We did provide a tool and structure for tracking remediation efforts, limited training and resources for designing quality improvement activities around the near-miss reports, and provided opportunities for participants to share their experiences and ideas with other practices engaged in similar efforts. We did not provide detailed training or attempt to impose a rigid structure on the practices. Until there is further study, there does not appear to be sufficient evidence to support best practices for near-miss remediation in ambulatory practice.

Our pre- and post-surveys of practice and safety culture showed a drop in participation in the post-surveys, which may have skewed our results. Also, because there was only about 9 months between surveys, it is unclear if that is a sufficient time to measure culture change reliably. Finally, nearly all the practices experienced some turnover in staff over the course of the year. Observed changes in the culture measures could simply reflect staff turnover rather than a change in attitude among the same staff. A subsequent study should track individual staff assessments of culture over time.

Finally, we made great efforts to exclude AE reports from this database because of feedback we received in developing the pilot that practices were very reluctant or were excluded by legal counsel from voluntarily sharing information about AEs. As a result, we have no way of correlating the total of 770 near-miss reports we collected during the study with the number of AEs that occurred in the practices over the same period of time. This correlation deserves additional study.

## **Conclusions**

This pilot demonstrated that a near-miss reporting and remediation system can be successfully implemented in primary care practices representing a range of size, ownership, and clinical mission, and that practice leaders find the information useful and appear willing to act on this information to improve care processes. Practices demonstrated consistent reporting numbers during the observation period with relatively small inducements to do so (\$1,500 per month), through simple automated monthly email reminders to clinical staff, encouragement from practice leaders, and coupling reporting with a transparent process improvement process.

We believe these findings suggest that a larger, longer demonstration of near-miss event reporting should be undertaken to demonstrate the marginal, tangible benefit in lowering overall cost, reducing AEs, reducing liability claims, and improving the patient care experience. A larger, standardized database of near-miss reports could be valuable in identifying systemic

problems that lead to errors and formulating solutions to reduce their incidence. A larger database of near-miss events could also be used in conjunction with root cause analysis from actual AEs to estimate systemic risk and to focus remedial efforts on the most pressing safety issues.

Finally, a large demonstration project could be designed to measure the marginal impact of practice transformation collaboratives in sharing data and information and whether this hastens innovation in practice improvement and to test if this model could increase the rate of adoption of best practices.

## Acknowledgments

This project was funded by Grant No. HS19558 from the Agency for Healthcare Research and Quality. Key administrative support was provided by the North Carolina Office of Rural Health and Demonstrations, Community Care of Western North Carolina. Consultation on research methods and analytic support was provided by Generativity LLC. The Near-miss Reporting and Tracking system was designed and maintained by WindSwept Solutions (WSS).

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# Implementing Shared Decision-Making: Barriers and Solutions

## An Orthopedic Case Study

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### Abstract

**Background.** Effective communication is a key ingredient of safe, high-quality health care. Shared decision-making (SDM) is a collaborative decision-making (DM) process between the patient and provider for preference-sensitive treatment decisions. The goal of SDM is to empower patients to participate as active partners in their health care decisions. The Shared Decision-Making in Surgery to Improve Patient Safety and Reduce Liability investigators implemented SDM in two orthopedic spine surgery clinics. The purpose of this paper is to identify barriers and solutions for shared decision-making that resulted from this study.

**Methods.** Patient activation brochures and decision aids (DAs) were developed and disseminated. Pre-implementation patient surveys assessed baseline SDM elements in routine practice. SDM education and training materials were developed, and surgeons were trained. Observation assessments were used with surgeons during training. Clinical DM interactions were audiotaped before and after training and assessed for the presence or absence of SDM elements.

**Results.** Barriers to SDM implementation included adoption and dissemination of patient activation materials and DAs, concern for increased time commitments, surgeons' beliefs they were already doing SDM, and entrenched clinic procedures. An SDM "Train-the-Trainer" Toolkit was developed to overcome training barriers and disseminate the methodology. Trainer observation and surgeon self-assessments of clinical encounters suggested that the SDM elements most overlooked were a patient seeking input from trusted others (65 percent), establishing a patient's role in DM (53 percent), teach-back (42 percent), eliciting patient preference (24 percent), and communicating uncertainty (24 percent). Pre- and post-training audiotaping of clinical DM showed surgeons made minimal improvement in the element establishing the patient role in DM. No surgeons used teach-back to check for understanding prior to SDM training, and only one surgeon incorporated teach-back into his clinical interactions after training.

**Conclusions.** In conclusion, physicians in this study did not include all elements of SDM during clinical DM with patients. Successful implementation of SDM requires a process to engage stakeholders, identify barriers, and develop interventions to overcome barriers, including novel teaching strategies and data-driven individual feedback.

## Introduction

Effective communication is a key ingredient of safe high-quality health care. Shared decision-making (SDM) is a collaborative decision-making (DM) process between the patient and provider for preference-sensitive treatment decisions that takes into account patient preferences and values.<sup>1,2</sup> The goal of SDM is to empower patients to participate as active partners in their health care decisions.<sup>3</sup> The Shared Decision-Making in Surgery to Improve Patient Safety and Reduce Liability investigators implemented SDM in two orthopedic spine surgery clinics to better explore barriers and opportunities for shared decision-making as a means to improving patient safety.

Poor communication between health care providers and patients represents a risk to patient safety. Informed consent with patient “teach-back” of key information about the proposed treatments or procedures is part of the 2009 National Quality Forum’s (NQF) Safe Practices for Better Healthcare.<sup>4</sup> The NQF’s Consensus Panel had great concern with the frequency with which patients do not receive adequate informed consent. As communication failures between patients and health care providers are at the root of systems’ failures and human errors that lead to harm,<sup>5</sup> the NQF Consensus Panel agreed that communication is key to preventing patient harm related to lack of informed consent. Better-informed patients serve as an additional layer of protection against medical errors.<sup>6</sup>

A Washington State statute provides specific protections from lawsuits if SDM occurs.<sup>7,8</sup> As part of such SDM, decision aids (DA) that are peer-reviewed and use patient-friendly language must be used. Also the SDM process must include “teach-back” from patient to provider. The intent is to produce an improved informed consent process that is both standardized by procedure and more informative for patients. It contains elements to ascertain that the patient understands and appreciates the treatment options and their risks and benefits.

SDM recognizes that patients and health care providers each bring their own unique perspectives, preferences, and values to the DM process.<sup>3</sup> SDM attempts to integrate these sometimes different perspectives into a cohesive process of DM. This process recognizes that health can be defined as “a dynamic state of well-being characterized by a physical and mental potential, which satisfies the demands of life commensurate with age, culture, and personal responsibility.”<sup>9</sup> Our study used an SDM model composed of nine core elements,<sup>10</sup> plus the addition of the “Teach-Back” component required by Washington State statute<sup>8</sup> (Table 1).

Patient activation is a key early component of the SDM process. Since SDM is not the current norm in health care, the concept and expectation for SDM needs to be introduced to patients prior to the clinical encounter so they will be prepared to engage in SDM with their physicians. Patient activation leads to better health outcomes and care experiences.<sup>11,12</sup>

We implemented SDM for patient preference-sensitive orthopedic spine treatment in orthopedic spine surgery clinics in two hospitals within the university health care system. Our primary aim was to introduce SDM to the hospitals through these two clinical settings, identify barriers in achieving this aim, and develop strategies to mitigate the barriers. In order to accomplish this aim, we developed and disseminated patient activation and DAs to patients, developed a provider

training module on conducting SDM during the clinical encounter, and assessed providers' success in following SDM elements in their treatment discussions with patients.

**Table 1. SDM Elements and the Patient Teach-Back Component**

<b>SDM Element</b>	<b>Definition</b>
Role	Establish the patient's preferred role in the DM process: the patient may choose to make the decision independent of the physician, defer to the physician, or decide collaboratively.
Context	Discuss how the condition, treatment choices, and decision might impact the patient's daily life. Explore with patient how activities of daily living are, and will be, affected by both their condition and treatment choices.
Nature	Discuss the essential clinical issues including the patient's presenting condition and relevant medical issues.
Alternatives	Discuss the medically appropriate alternatives and treatment options. Alternatives and options are the basis for a patient preference sensitive decision.
Pros and Cons	Discuss the relevant risks and benefits of the options based on objective research evidence.
Uncertainty	Discuss the likelihood that treatment options would succeed or fail based on objective research evidence.
Understanding	Establish that the patient understands the topics discussed and the decision being made. Does the patient have any additional questions?
Input From others	Encourage the patient to gather additional input from trusted others. Would the patient like to obtain a second medical opinion, talk to trusted others, or do additional research?
Preference	Elicit the patient's preferred course of action. Based on the patient's expressed values and preferences, how would they like to move forward, including the option of "doing nothing."
Teach Back	The patient explains back to provider the decision that was made and how they got to that decision. Can the patient explain their condition, the treatment options, risks, benefits, and uncertainties?

## Methods

After approval by our institutional review board (IRB), an implementation process occurred in two university hospital orthopedic spine clinics. Implementation of SDM required a multi-stage process engaging all levels of the organization, including institutional approval, stakeholder engagement, development/identification of patient activation and DA materials, provider training, dissemination of patient activation and DA materials to patients, and ongoing assessment and provider feedback.

We conducted a series of meetings with senior hospital administration to obtain approval for adoption of SDM into the current informed consent regimen and to facilitate implementation. The decision was made to conduct a limited pilot of SDM before deploying this new process more broadly within the health care system.

Project leaders met with all stakeholders throughout the implementation process. There were two core stakeholder groups in each of the two orthopedic spine clinic locations: physicians (including residents, if applicable) and physician assistants (hereafter referred to as “surgeons”), and medical staff and clinic administration (hereafter referred to as “staff”). Surgeons were the primary personnel implementing SDM with patients during the clinical encounter. Ongoing engagement and support from surgeons were a crucial component of SDM implementation.

### **Patient Activation Brochure**

A patient activation brochure was created by the project team and edited by the Patient Education Services in the health care system to assure patient-friendly language and consistency with health system document style. The brochure introduced the concept of SDM and provided tools that patients could use to be more engaged in the DA process with their provider. The activation brochure was intended to function as a catalyst to foster patient engagement in the SDM process. Activation brochures were designed to be disseminated to a broad range of patients, regardless of presenting condition or reason of visit, prior to the visit. Patient activation brochures were given to staff for inclusion in patient hand-outs and mailings.

### **Decision Aid Selection and Dissemination**

Meetings were held with the orthopedic spine surgeon group to develop procedure-specific DAs for dissemination to patients. We gathered together all the health care system’s orthopedic patient education materials and developed DAs that were consistent with them but were written in patient-friendly language, presented evidence-based risks/benefits, and included required elements of SDM. Due to surgeon disagreement with the specific content and quality of the evidence base of the DAs, the surgeons agreed to use two commercially available DAs that were purchased from Health Dialog, Inc. (Boston, MA) for two conditions: herniated disc and spinal stenosis.<sup>13,14</sup> DAs were given to surgeons, physician assistants, and patient care coordinators for dissemination. Desk copies were disseminated to all clinic staff.

### **Clinic Implementation**

Following administration and surgical group approval, meetings were conducted with clinic managers and other staff to obtain their support for the implementation process. Clinic managers played key roles in the implementation process. They identified members of the clinic team that were best suited to carry out implementation tasks, assisting in coordinating ongoing project support tasks as needed. These managers were in control of the actual facility and identified where materials could be posted or placed in the clinic space, such as copies of training materials and DAs. Patient care coordinators were a key component as they had ongoing communication with a patient prior to, during, and after a visit. Strategies and tools for SDM implementation were developed with active participation by staff.

### **Pre-implementation Survey**

Prior to implementation, an anonymous patient exit survey was conducted in the two orthopedic spine clinics to assess surgeon performance of specific elements of informed consent and SDM.

Patients who were visiting for a new problem or a pre-operative visit were eligible to participate in the survey. Performance elements were: nature of the condition or procedure, alternatives or choices for treatment, risks and benefits, and preferences. For each item, we included a follow-up question: Did he/she use words you could understand? We also elicited general satisfaction with the clinic visit and provided an opportunity for open-ended responses. All surveys included demographic information such as age, sex, education, and overall health status that have been found to be correlated with patient satisfaction. The survey also elicited information about how patients prepared for their visit (eliciting input from trusted others, searching the internet, consulting written resources, and writing down questions to ask).

## **SDM Training**

Surgeon training involved a short, 20-30 minute, individual or small group training on SDM. Participants were provided with pocket reminder cards, and posters were placed in the workplace that had reminders and prompts on how to conduct SDM. They were exposed to the patient activation brochures and DAs. This was followed with “on-the-fly coaching” during clinical encounters. Providers were observed, and an SDM “scorecard” was kept by the observer. Providers completed matching self-assessments. These were compared, and “on-the-fly” coaching was provided on missing elements. These trainings occurred over a 3-week training period and were done in the clinic to decrease additional time burdens on already busy physicians.

## **Surgeon/Patient Clinical Decision-Making Audio-Recording Protocol**

Clinical DM encounters between surgeons and patients were recorded before and after implementation of SDM. All patients and surgeons subject to these procedures provided written informed consent. New patients and patients making pre-operative visits were eligible to participate. Visits in which treatment options were not discussed (e.g., referral to a different specialist, diagnostic discussion with orders for further testing to determine the nature of the condition) were excluded.

All recordings were transcribed for scoring. Two investigators/staff members scored a sample of transcriptions to ascertain inter-rater reliability. Once inter-rater reliability was determined, the remaining transcripts were scored by the two same raters, and consensus was used to establish a reliable final score for the surgeon. Scoring was conducted using the IDM-18 scoring system of Braddock,<sup>10</sup> giving 0-2 points for each of the nine elements of SDM evident. In addition, a 10th element of “teach-back” was scored to address the specific requirements in Washington State for SDM.<sup>8</sup> Scores from the pre-implementation phase were compared to post-implementation to assess whether providers improved their performance of SDM after the training. We compared scores before and after training by linear mixed model on 61 total transcripts to assess training effect. We compared the presence of individual SDM elements before and after training with Fisher’s exact test with  $p < 0.05$  considered statistically significant.

## **Results**

The results from this study describe a patient survey conducted before implementation of SDM. Results were also obtained through trainer observations and surgeon self-assessments of their clinical encounters during training and also by scoring transcripts of surgeon-patient clinical interactions before and after the intervention. We also summarize several implementation

barriers and solutions for both staff and surgeons. These barriers and their solutions are described in Table 2, and we will elaborate on findings for each group, separately.

**Table 2. SDM Implementation Barriers and Solutions by Surgeons, Medical Staff, and Research Team**

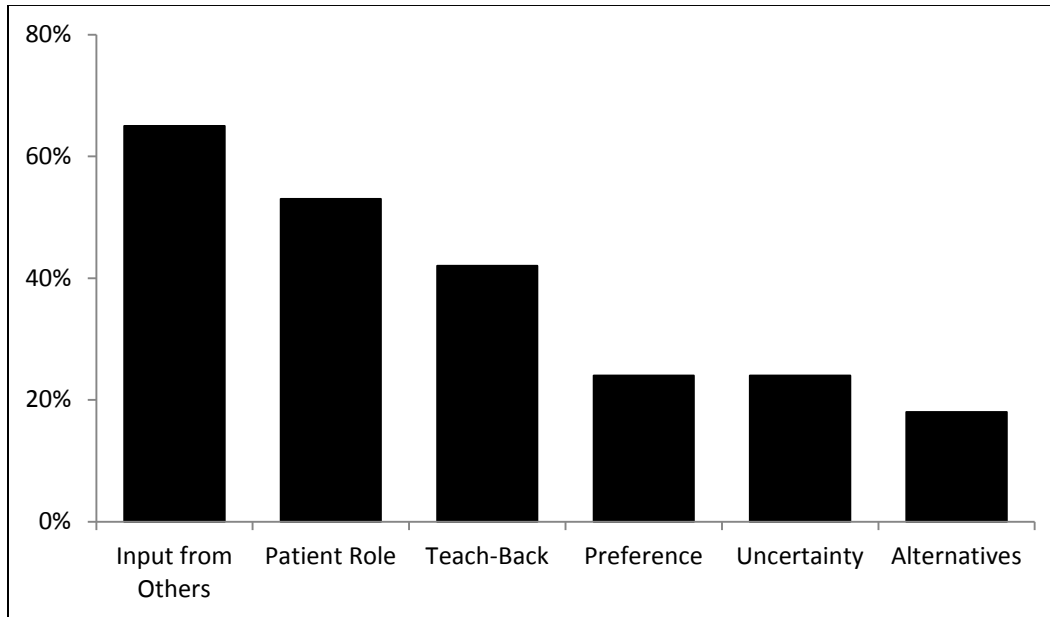
<b>Barrier</b>	<b>Solution</b>
Patient activation brochure selection	Revise and update existing material in a low-cost format.
Decision aid selection	Obtain physician buy-in for decision aids, including the scientific evidence base. Purchase a peer-reviewed decision aid from an external vendor.
Provider resistance	Motivate change by demonstrating institutional need. Engage physician champions. Engage other physician opinion-leaders. Hold ongoing stakeholder meetings to address concerns and garner feedback to develop trainings. Provide feedback with individual performance data.
Time constraints	Provide “on-the-fly” training and individual coaching.
Activation brochure dissemination	Adapt patient intake processes to what worked best within each clinic site.
Decision aid dissemination	Engage providers to disseminate decision aids.
Provider training	Provide short, focused training, “on-the-fly” coaching, and ongoing “scorecard” and self-assessment. Provide “pocket reminder cards” with SDM elements and conceptual prompts. Provide workplace “reminder posters” with SDM elements and conceptual prompts.
Dissemination, placement, and use of SDM ancillary training materials	Provide feedback to surgeons to carry and use the reminder cards and posters in daily practice. Place reminder posters in clinic exam rooms and workspaces.

## **Patient Surveys and Surgeon Self-Assessments**

In pre-implementation planning meetings, surgeons expressed the belief that they were already conducting SDM with patients. Our pre-implementation survey of 137 patients demonstrated that this was not the case. Although patients reported that surgeons explained their condition(s) in 93 percent of the cases, the surgeons failed to discuss many elements of SDM. They failed to tell patients that there was more than one treatment choice 23 percent of the time, failed to discuss the pros and cons 25 percent of the time, and failed to elicit patient preference 26 percent of the time during clinical encounters. The survey results showed that surgeons were effective in discussing the clinical nature of the visit, but they were less effective in engaging the patient as a partner in the DM process.

Similar to the pre-implementation survey, results from training assessments showed that providers were most effective in discussing the nature of the clinical condition and less effective in engaging patients as partners in DM. Trainer observation and surgeon self-assessments of

clinical DM during implementation suggested that the SDM elements most overlooked were seeking input from others (65 percent), establishing the patient role in DM (53 percent), teach-back (42 percent), eliciting patient preference and communicating uncertainty (24 percent each), and alternatives (18 percent) (Figure 1).



**Figure 1. Elements of Shared Decision-Making Included in Surgeon-Patient Decision-making Assessed by Trained Observers**

## Using Audiotapes to Assess Surgeon Performance on SDM Elements Before and After Training

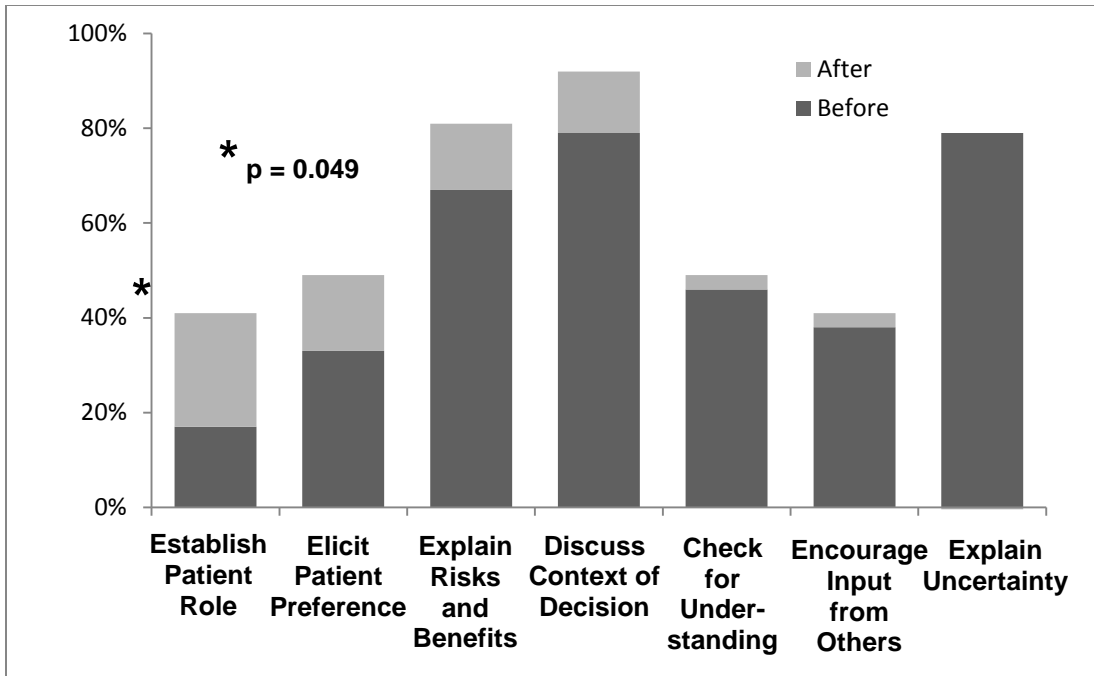
There was improvement in the element establishing the patient role in DM (17 percent before vs. 41 percent after training,  $p=0.049$ , Figure 2). No surgeons used teach-back to check for understanding prior to SDM training; one surgeon incorporated teach-back into his clinical interactions after training (0 percent vs. 31 percent,  $p=0.131$ ). A mild, but non-significant, improvement in overall scores of approximately 1 point was observed (effect [regression coefficient] 0.9,  $p=0.2$ ). The surgeon with the lowest pre-training score was the only subject to exhibit a meaningful increase in average score from 6 to 8.6 points (18 possible); the remaining surgeons had similar average scores before and after training (Figure 3).

## Staff and Surgeons: Barriers and Solutions

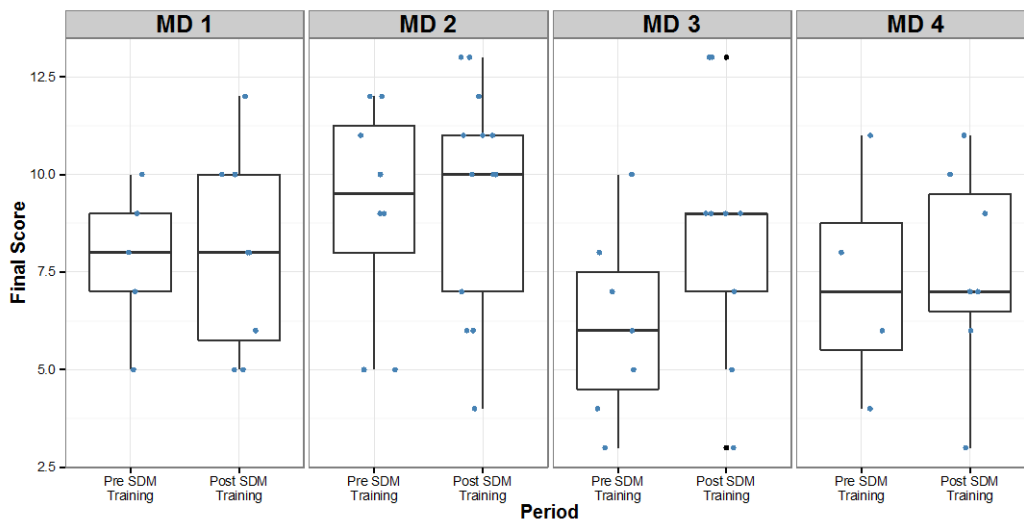
### Staff Barriers and Solutions

**Patient Activation Brochure.** A primary barrier to the activation brochure was a staff belief that these materials were redundant and in competition with existing patient materials. Concern was also voiced over possible additional costs associated with the production and distribution of the materials and with overloading patients with paperwork/educational material. The solution was to revise and update existing materials in a low-cost format.





**Figure 2. Presence of SDM Elements in Surgeon-Patient Decision-making Before and After Training**



**Figure 3. Shared Decision-Making Element Scores of Individual Surgeons Assessed by Audiotapes Before and After Training**

Consistent dissemination of the patient activation brochure prior to the patient visit was also a barrier. Two solutions were identified. At one clinic location, the brochure was made available to patients on the counter for all orthopedic patients and targeted to spine patients. At the second clinic location, a staff person was identified who would include the brochure in the pre-

visit mailing. Ideally, the activation pamphlet should be delivered prior to the visit so the patient arrives activated.

**Decision Aid Dissemination.** Disseminating DAs proved to be a significant barrier. Initial attempts at disseminating DAs through the new-patient mailing packet process were ineffective and subject to a number of barriers. Patient mailings to new patients included more generic materials, and the staff preparing them did not have an effective method of identifying which patients were scheduling visits due to conditions that would be appropriate for a DA. Patients sometimes did not have a condition-specific diagnosis prior to a visit, so they could not be identified for a specific DA. Concerns about additional mailing costs due to the size and weight of the DA were also raised.

In response to these barriers, a process was established where surgeons and patient care coordinators (PCCs) would be responsible for disseminating the DAs. This process was only moderately effective. These providers sometimes forgot to take aids with them to the patient visit. After the visit, surgeons operating under strong time pressures, moved on to another patient and did not go back with a DA or develop a system where other providers following up with the patient could give the patient the DA. Another problem was that patients were sometimes diagnosed and made a preference-sensitive treatment decision during the same visit, without the ability to access the DA in a timely fashion. To adequately fulfill the requirements of SDM, a patient must have the DA in a manner that allows them the time to access the materials before making a decision. Dissemination of DAs in a timely manner to assist in the DM process was a consistent problem throughout the implementation process and was not adequately solved.

**Multiple Clinics.** The project was piloted at two clinic locations in two different hospitals within the health care system. Varying clinic policies and procedures meant that all proposals had to go through two different processes to be approved and/or implemented. This led to delays and extra time spent seeking approval for the same intervention at two sites.

### **Surgeon Barriers and Solutions**

**Subspecialty Buy-In.** The project proposed piloting SDM in all orthopedic surgery subspecialties with preference-sensitive elective treatment options (e.g., total knee, total hip, total shoulder, spine surgery). The department chair (a spine surgeon) served as the champion for implementation of SDM throughout his department. Meetings were held to engage orthopedic surgeon subspecialty groups. Resistance from opinion-leaders in the total joint group led to a focus on orthopedic spine surgery. The process of obtaining support from the spine group was facilitated by the leadership of the department chair and participation of spine surgeons on the project team. Teams proposing wider system change should strive to have key opinion leaders of all stakeholders represented on the team. They should also demonstrate the necessity of making any system change, especially with presentation of performance data.

**Decision Aids.** DAs were initially developed from existing patient education materials being used by surgeons; however, the surgeons did not recognize them as a repackaging of their own patient education information. The spine group subsequently chose two commercially available DAs. Surgeons had multiple concerns with these DAs. They were concerned that a single DA describing a condition with treatment alternatives would not be appropriate for all patients, as “one size doesn’t fit all.” Surgeons also believed that treatment options are not always

appropriate, and that they have the best insights into a proposed course of treatment for a patient. The surgeons disagreed with the clinical content and the scientific quality of the evidence in the DA. They believed that their outcomes were statistically different than the outcomes presented in the DA. They also were concerned that the explicit numerical estimation of risks and surgery success would unnecessarily scare patients.

**Surgeon Training.** Surgeon training presented a series of implementation barriers. The time constraints and scheduling demands of busy practice settings impacted training on multiple levels, including initial trainings, on-going assessments, and on-the-fly coaching. Assessment and on-the-fly coaching, which were designed to occur between visits, were often rushed or deferred in order to stay on the clinic schedule. The solutions developed were to keep the trainings short and focused and to observe and assess patient and provider interactions and provide on-the-fly coaching as time and workflow permitted. The project was successful at meeting this goal in most situations.

Support training materials were developed to address the time constraints to training and to support ongoing learning. A pocket reminder card was laminated, double-sided, and small enough to be carried in a jacket pocket, on a clipboard, or positioned at a work station to assist as both a learning aid and prompt. One side had the 10 elements in a checklist format, while the second side had the elements clustered by conceptual dimension. These conceptual dimensions were developed as another way to assist providers in learning and implementing all the elements of SDM, and they have been incorporated into an SDM “Train-the-Trainer” Toolkit.<sup>15</sup>

Posters with the elements laid out in the conceptual dimension format, as shown on the pocket reminder card, were posted in locations where surgeon and patient interactions occurred. At one clinic location, there were alcoves near the entrance to the exam rooms where patient records were placed for the visit. The posters were placed there each day so providers could pull one out with the records and review it if needed. Posters were also placed in common areas but not in exam rooms. The impact of these passive approaches was not assessed.

To also address the time limitations in training, “on-the-fly coaching” was instituted. This included trainer observation (“scorecard”) plus surgeon self-assessment. These coaching sessions were short, focused sessions that occurred in the clinic immediately following the observation of a surgeon-patient interaction. The surgeon and trainer compared their assessments, identified missing SDM elements, and discussed ways to more effectively engage in SDM in future encounters.

## Discussion

Our study implemented SDM in orthopedic spine clinics in two hospitals within a university health care system to improve the treatment decision process and informed consent discussions between physicians and patients. Inadequate informed consent is an underlying and significant contributor to patient dissatisfaction, complaints, and medical liability. Poor communication is correlated with patient complaints against physicians, as well as high physician liability.<sup>16</sup> Patient complaints often arise from differences in understanding regarding risks and benefits,

with a relatively large proportion of complaints (25 percent) focused on issues surrounding treatment options and alternatives.<sup>17</sup>

Shared decision-making with DAs has been shown to improve patient understanding of procedures, risks, and alternatives.<sup>18</sup> Theoretically, a patient who is better informed of the risks, who is more satisfied with the physician-patient communication process, and who takes greater ownership of the shared decision, would be less likely to file a lawsuit in the event of a poor outcome. Washington State statute provides specific protections from lawsuits if SDM occurs.<sup>7,8</sup> The use of patient DAs has been shown to change mock juror conclusions regarding medical negligence, with use of a DA leading jurors to nearly unanimously conclude that care met standards.<sup>19</sup>

Successful organizational change, including implementation of SDM, involves motivating the change, creating a vision adapted to local needs, garnering political support with clinical champions and stakeholders, managing the transition through coaching and data collection, and sustaining the momentum with continued resources and coaching.<sup>20,21</sup> Studies of implementation of a surgical checklist, another formalized communication process, identified training techniques, feedback, senior clinician buy-in, and local adaptation as important facilitators of successful implementation.<sup>20</sup> Barriers for checklist implementation included an imposed approach, resistance to change, repetition with current practice, key opinion-leader resistance, and tool content and evidence base. To maximize success, an institutional commitment of ongoing resources must be made to provide continuing support for implementation. Both structural and individual change of deeply entrenched procedures takes substantial time to accomplish.

Most studies of SDM have studied implementation within primary care.<sup>1,2,22,23,24</sup> Effective implementation of SDM with DAs for joint replacement surgery reduced hip replacement by 26 percent and knee replacement by 38 percent, and it lowered costs by 26 percent in a managed care environment.<sup>22</sup> Many of the barriers and facilitators for implementation of SDM in primary care were similar to ones that we found in surgical specialty care, including time constraints, high physician workload, physician training/culture, and DA distribution problems.<sup>1,2,23,24</sup> Advocacy by leadership at all levels, cultural embracement of the financial/safety need to reduce practice variation coupled with the Washington State statute, physician training programs with feedback, and constant evaluation and iterative improvement were key facilitators of implementation of SDM.<sup>22,24</sup> Automatic triggers for DA distribution (e.g., referral to an orthopedic surgeon for a total knee replacement) and engagement of teams other than physicians have also been suggested as solutions.<sup>1</sup> These facilitators may not be effective when SDM is employed to improve physician-patient treatment and informed consent discussions, which require the physician to take primary responsibility for SDM. In addition, referral for total joint surgery is more straightforward than referral to see an orthopedic surgeon specializing in spine surgery. Many patients with spine disorders are not surgical candidates and lack the option to make a treatment choice involving surgery.

An important observation of our study is that physicians have deeply ingrained scripts for patient interactions that are significant barriers to learning new communication methods and incorporating new SDM techniques. Experienced physicians developed schema that guide their

patient interactions to work efficiently. A barrier to disrupting schema is that surgeons often believe they are already doing SDM prior to implementation.

Our training had a limited impact on the communication schema of these physicians. Our analysis of the audiotape transcripts of surgeons' clinical DM with patients showed minimal increase in their use of SDM elements, especially relating to the patient's role in treatment DM. A bias currently exists in medical education about the patient's role in making decisions that ultimately affect their care. Many physicians believe that the patient has a minor role in decisions regarding their health care treatments. This bias must be addressed throughout the system in order to effect structural change and make SDM a viable long-term success in physician/patient discussions of treatment options.

Lessons learned and processes developed during this project were incorporated into an SDM "Train-the Trainer" Toolkit. The SDM "Train-the-Trainer" Toolkit was developed to overcome training barriers and disseminate the training methodology.<sup>15</sup> The Toolkit includes an instructor guide plus a number of "tools" to be used as part of the training process. The "tools" consist of a teaching guide, provider pocket reminder card, SDM elements cue poster, patient activation pamphlet, assessment checklist, SDM implementation recommendation and troubleshooting guide, external resource list, and an evaluation survey. The SDM Toolkit is available for download through the Association of American Medical Colleges MedEdPORTAL at [www.mededportal.org/publication/9413](http://www.mededportal.org/publication/9413).

Interjecting new communication protocols into existing schema requires ongoing training and a commitment to make changes. Our findings suggest a need for more extensive SDM training interventions and extended follow-up to interrupt these communication schema. Disrupting deeply entrenched scripts and schema used in practice must be a priority in an ongoing SDM implementation training process if the training is aimed at a large number of providers, rather than utilizing specially trained nurses who review SDM alternatives with patients. Training requires a multi-stage training process, with supportive training materials, to train physicians and experienced providers to change the scripts they use and to add the missing SDM components into their patient interactions. Future studies should incorporate improved training methods, including a longer period of training, and focus on both SDM elements and patient engagement techniques.

## **Limitations**

This was a cross-sectional study on the implementation of SDM. We did not implement permanent institutional structural changes to support and expand the project. No budget or resources were available for additional purchase of DAs, additional staffing, training resources, or other materials needed to maintain the ongoing practice of SDM at these locations or to expand it to other locations beyond the conclusion of the study. However, the project has been successful in describing institutional barriers and providing practical solutions to inform ongoing implementation of SDM within the hospital system.

## Conclusions

Physicians and other health care providers do not routinely include all elements of SDM during clinical DM. Successful implementation of SDM requires a complete process to engage stakeholders, identify barriers to adoption and implementation, and develop interventions to overcome barriers that are unique to each implementation setting.

## Acknowledgments

This work was supported by a grant (HS19532) from the Agency for Healthcare Research and Quality. We would like to acknowledge the Foundation for Informed Medical Decision Making and Health Dialog for their gift-in-kind of providing the decision aids used in this project at a reduced research rate.

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# Transitional Care Medication Safety: Stakeholders' Perspectives

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## Abstract

**Purpose:** To identify barriers to and solutions for improving medication safety and reducing medical liability during patients' transition from hospital to home.

**Methods:** A qualitative descriptive study, guided by the Sensemaking Conceptual Framework, was completed with 10 focus groups of stakeholders that were segregated according to whether they represented patients and family members or a professional group. During each focus group, two case studies about patients experiencing medication discrepancies following a hospital to home transition were presented. Participants were asked to identify factors contributing to medication discrepancies, health system solutions to prevent medication discrepancies, and how assignment of responsibility should be accomplished if patients were permanently harmed because of a medication discrepancy.

**Results:** Stakeholder groups identified common barriers and solutions to hospital-home transitional care medication safety. Barriers to medication safety included themes related to patient- and family-level factors (competency, retaining old prescriptions, and access to medication), as well as health system-level factors (communication and care coordination, complex discharge processes, and staffing and time constraints). Solution themes were improving information management, increasing access to medicines, and enhancing human resources. Participants across focus groups also reported that attributing responsibility for medication discrepancies was contextual and complex, but they agreed that full disclosure was desired when an error that caused harm occurred.

**Conclusions:** A wide range of stakeholders identified similar themes regarding barriers contributing to medication discrepancies during care transitions and solutions for reducing or overcoming barriers. Approaches to address many of the identified barriers are available. Full disclosure when harm occurs from a medication error is a best practice. Study findings support more widespread adoption of evidence-based strategies and legislative provisions to improve transitional care medication safety and to reduce medical liability.

## Introduction

Health systems expend considerable resources to reduce medication errors in hospital settings. Increasingly, inpatient medication risk management efforts focus on preventing errors by improving systems and creating safety cultures rather than assigning blame for unsafe practice.<sup>1,2,3</sup> Unfortunately, the potential for patient harm and increased medical liability due to medication discrepancies and errors does not end at hospital discharge. The transition from hospital to community settings is an exceptionally risky time for patients.<sup>4,5,6,7,8</sup> Data suggest



that up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home, and discrepancies occur for all classes of medicines.<sup>9,10,11</sup> Medication discrepancies that occur during the transition from hospital to home are defined as differences in the medicines that patients are actually taking compared to medicines listed on the hospital discharge list.<sup>12</sup> Patients with hospital-to-home medication discrepancies are almost twice as likely to be readmitted to the hospital within 30 days as patients with no transitional care medication discrepancies.<sup>13</sup>

The transitional care period begins the day the patient is discharged from the hospital and continues for the next 29 days.<sup>14</sup> During this period, the hospital provider transfers care to the outpatient primary care provider (PCP), but there is usually minimal follow-up to this hand over. The transitional care period is a time of concern because it is when patients are particularly vulnerable to experiencing adverse events. An adverse event is defined as an injury resulting from health care management, rather than the underlying disease, within 3 weeks of discharge.<sup>15</sup> Poor care coordination that occurs during the transitional period may lead to adverse events that could result in hospital readmissions and/or greatly increase the patient's chances of morbidity and mortality. A recent study suggests that up to 23 percent of patients experienced an adverse event within 5 weeks of discharge, 72 percent were drug related, and up to one-third were preventable.<sup>16</sup>

Patients at high risk to experience medication discrepancies and errors include older adults, those with polypharmacy (both prescribed and non-prescribed medicines), drug interactions, multiple comorbidities, altered drug pharmacokinetic profiles and/or pharmacodynamic responses as a result of aging, and altered medication adherence caused by depression or cognitive impairment.<sup>17,18</sup> Preventable medication errors are estimated to impact more than 7 million patients, contribute to 7,000 deaths, and cost \$21 billion in direct health care costs annually in the United States.<sup>19</sup> Adverse drug events (ADEs) are multifactorial and are attributed to both human and system errors. Some of these factors include a breakdown in health professionals' communication, medication discrepancies, poor patient follow-up, and inadequate patient education. To emphasize the importance of eliminating the occurrence of adverse events and ADEs, several health care agencies have acknowledged them as a patient safety priority. For example, the National Priorities Partnership declared patient safety from potentially preventable adverse events, including medication discrepancies, a national priority.<sup>20</sup> The hospital-to-home transitional care period provides an important opportunity to reduce medication discrepancies and ADEs and improve patient safety. Furthermore, Joint Commission National Patient Safety Goals state, "when a patient leaves an organization's care directly to his or her home, the complete and reconciled list of medications is provided to the patient's known primary care provider, or the original referring provider, or a known next provider of service."<sup>21</sup> The Joint Commission's safety goals confirm the importance of medication reconciliation as a way to prevent ADEs, yet despite the medication reconciliation mandate, transitional care medication discrepancies remain high, and safety concerns persist.<sup>10,11,16</sup>

The focus of this paper is on identifying stakeholders' perceptions of barriers to and solutions for improving medication safety and reducing medical liability during patients' transition from hospital to home. The medication management components of transitional care that are perceived by stakeholders as most important for improving patient outcomes, reducing health care costs,

and minimizing medical liability have not been systematically explored. As part of a larger study to understand how to maximize medication safety while improving patient outcomes and minimizing medical liability during transitional care, our team gathered data from diverse stakeholders during segregated focus groups (N=10).

The study aims were to identify barriers to and solutions for accurate and complete medication information transfer during patients' transition from hospital to home. Thus, the primary purpose of this study was to make sense of the phenomenon of medication discrepancies during the hospital-to-home transition and, using sensemaking processes, identify stakeholders' strategies for reducing medication discrepancies to improve patient safety, which may offer potential solutions for medication information transfers. A secondary aim was to explore medical liability issues associated with medication discrepancies that result in permanent patient harm.

## Methods

The study was guided by the "Sensemaking Conceptual Framework" described by Weick.<sup>22</sup> Sensemaking involves conversations about ambiguous issues with the goal of, literally, trying to make sense of them.<sup>23</sup> Conversations allow for a shared representation of a phenomenon.<sup>23</sup> Following Institutional Review Board (IRB) approval, the study was implemented using a descriptive qualitative design.<sup>24</sup> Divergent groups of stakeholders were recruited to participate in one of ten focus groups. Participants were identified based on their membership in a stakeholder population. A total of 69 participants made up the 10 stakeholder focus groups, which were segregated according to stakeholder status (e.g., comprising either solely patients and family members or solely professionals from a specific discipline). The 10 stakeholder focus groups included: patients and family members from urban hospitals (n=11); patients and family members from rural hospitals (n=6); primary care ambulatory physicians and hospitalist physicians (n=7); home care nurses (n=4); urban hospital nurses (n=5); rural hospital nurses (n=7); retail and acute care pharmacists (n=8); acute care, home care, and long-term care social workers (n=12); health plan contract administrators (n=3); and health care lawyers (n=6).

In all cases, potential participants were invited to participate via written letter and asked to contact the research assistant (Balogh) for more information about the study. Focus groups lasted 1½ - 2 hours and were held at public locations convenient to the participants, such as conference rooms at area hospitals and universities. Notes were taken during the focus group conversations by the principal investigator and by a research assistant who also recorded the focus group discussions using a smart pen.

At each focus group, researchers presented two case studies about medication discrepancies experienced during a hospital-to-home transition. The case studies were based on actual medication discrepancies that occurred during a hospital-to-home care transition. They were selected to capture critical safety and medical liability risk characteristics based on the following criteria: (1) adult patient with multiple chronic conditions; (2) patient prescribed five or more medicines when discharged from the hospital; and/or (3) medication discrepancy identified that involved a medicine on the Institute for Safe Medication Practices' list of high-alert medications in community/ambulatory health care.<sup>25</sup> Pseudonyms were used for the patient names, and some of the details were changed in each case study to ensure patient anonymity. After presentation of

the case studies, we sought the stakeholders' perspectives and interpretation of barriers to and solutions for transition-related medication discrepancies.

### **Case Study One: Mrs. Brown**

Mrs. Brown was a 61-year-old woman who had been admitted to the hospital with sepsis. Her past medical history included diabetes mellitus, cellulitis, and pyelonephritis. She reported taking 16 medicines at home. During the hospital-to-home transition period, several discrepancies were noted when her discharge medication list was compared to the medicines she reported taking at home. Focus group participants were asked to specifically consider two medication discrepancies that involved Lantus<sup>®</sup> and NovoLog<sup>®</sup> insulin. The Lantus<sup>®</sup> dose noted on the discharge instructions was half the dose Mrs. Brown reported as her usual home medication dose. Mrs. Brown had also been using NovoLog<sup>®</sup> prior to her hospitalization, and there was not a discharge prescription for NovoLog<sup>®</sup>; thus she was unsure if she should continue using Novolog<sup>™</sup> and if so, what the correct dose would be.

### **Case Study Two: Mr. Adams**

Mr. Adams was a 69-year-old man admitted for difficulty walking. His past medical history included obesity, arthritis, hypertension, and hypercholesterolemia. The patient reported taking nine home medicines, including warfarin. The warfarin was not written on the discharge medication orders, and other discrepancies were also found when comparing his home medicines to his discharge list.

At each focus group, Mrs. Brown's case study was presented to the focus group members, followed by Mr. Adams's case study. Four questions/issues were addressed separately through group discussion:

1. Based on your professional expertise and/or personal experience, what factors may have contributed to the medication discrepancies described in the case studies?
2. Now, let's consider the reason each of those contributing factors have occurred.
3. Considering these potential contributing factors or causes, what systems could be implemented to prevent this from occurring in the future?
4. If you or, for example, Mrs. Brown or Mr. Adams, had been permanently harmed because of a medication discrepancy, at what point should someone be responsible for that harm?

### **Data Analysis**

Notes and recordings from all focus groups were independently analyzed by two members of the research team (Corbett and Smith) with the goal of transforming (making sense of) the data by identifying concepts and themes.<sup>26</sup> Concepts identified as important were written in the margins of the transcripts. The two investigators then compared and discussed their findings to establish shared meaning of terms and phrases. There was overall accordance between the two investigators' findings; on the rare occasions when interpretations differed, discussion ensued until consensus was reached. Discussion primarily centered on refining and labeling the concepts and then identifying themes that reflected the best transformation of the data. For example,

one investigator identified a barrier related to “financing medications,” whereas the other investigator labeled this barrier as “access to medications.” The investigators then jointly reviewed the data and observed that multiple barriers to medication access (e.g., transportation to obtain medications, pharmacy closures on evenings and weekends) were discussed in several focus groups. Therefore, the concept “access to medications” was chosen as a better reflection of the data. Concepts to support the main themes were identified in each focus group.

Using the same sensemaking approach and qualitative descriptive techniques,<sup>26</sup> other members of the research team independently analyzed a subset of randomly selected focus groups. Their notes and identified concepts, written in the margins of the transcripts, were reviewed and found to be congruent with those identified by Corbett and Smith, which provided additional reliability to the study findings. Transforming or making sense of the data allowed the researchers to identify strategies that best addressed the transitional care medication safety themes generated by the diverse groups of stakeholders.

## Results

Throughout the 10 focus groups, although there were some unique perspectives, participants’ answers from the disparate stakeholders shared many commonalities. Based on participants’ responses to the case study questions, we identified three major themes related to barriers to medication safety, potential solutions to medication discrepancies, and liability for medication discrepancies.

**Theme 1: Barriers to medication safety during transition from hospital to home.** We asked participants to identify factors that may have contributed to the medication discrepancies identified in the case studies. Two sub-themes emerged: patient specific barriers and health system barriers (see Table 1).

*Sub-themes related to patient level barriers.* Three patient-level factors were reported as obstacles to medication safety and included: (a) competency; (b) retaining old prescriptions; and (c) access to medications. Competency refers to a patient’s limited understanding of the medications or how to successfully manage medications. This concern was raised in all of the focus groups. A social worker commented, “Patients are overwhelmed and may not have prior education on medications.” Health literacy, was also identified as a component of patient competency that many patients face.

**Table 1. Theme 1: Barriers to Medication Safety**

<b>Sub-theme 1: Patient Level Barriers</b>	<b>Sub-theme 2: Health System Level Barriers</b>
Competency	Poor communication and coordination of care between physicians
Retaining old prescriptions	Lengthy and confusing discharge process/paperwork
Access to medications	Staffing and time constraints

Nearly all groups of stakeholders mentioned the issue of patients’ abilities to provide accurate and complete medication histories at hospital admission. When patients are unable to provide

accurate medication histories, it reflects less than optimal competence in medication management. An inaccurate medication history often initiates a trail of medication discrepancies that sets up an erroneous medication reconciliation process, culminating in an inaccurate discharge medication list. A lawyer stated, “The intake case history (self-reported) is incomplete,” and a nurse from a rural hospital commented, “It’s not uncommon to have an inaccurate list from the patient or family at intake.” Finally, in regard to competency, focus groups with patients and family members confirmed that the information communicated to them was often too complex, and that they sometimes were unable to understand the discharge instructions, either due to their educational level or their comprehension of terminology when reading through the medication instructions. The situation may be further compounded by patients’ reluctance to ask questions. One patient commented that he did not ask questions because he “doesn’t want to look uneducated.”

Another common patient-specific barrier was patients’ use of medicines already in the home. A lawyer stated, “Patients stockpile medicines at home—sometimes for cost reasons or because ‘they might need it later.’” A home care nurse reported that “Patients want to take the same (medicines) because they are at home and have already purchased the meds.” Pharmacists noted that patients often retain old medicines and do not fill new prescriptions if they happen to be for the same medicine, but the new post-discharge prescription order may contain changes in the dosage or frequency of administration. A home care nurse confirmed this as an issue, stating that when patients continue to use the same medicines after discharge “they take what it says on the bottle label, not what it says on the discharge list.”

Finally, a frequently mentioned patient barrier was that medication discrepancies sometimes stem from patients’ challenges in accessing medicines. Medication access had multiple contributing factors including financial constraints experienced by patients, an inability to pick up prescriptions related to mobility confinement, and limited pharmacy access due to living in a rural location.

***Sub-themes related to health system issues.*** The three specific health system-level barriers identified were: (a) poor communication and coordination of care between physicians; (b) lengthy and confusing discharge process/paperwork; and (c) staffing/time constraints. Poor communication and coordination of care between providers stemmed from either specialists not communicating adequately with hospitalists or hospitalists not communicating adequately with PCPs. One social worker commented, “(Specialists) all come in at different times and add discharge orders. One might add COUMADIN® when the patient is already on aspirin.” A health plan administrator stated “Hospitalists aren’t getting information back to the PCPs,” and a physician concurred with that perception, indicating that “Only 1 in 20 of the discharge summaries are being sent to the PCP in a timely manner.”

Lengthy and confusing discharge forms further complicate communication issues and contribute to the likelihood of discrepancies. One patient stated, “It was a blizzard barrage of paperwork.” A rural-dwelling patient stated “Too much red tape.....most people don’t read all that!” While the discharge paperwork in general is confusing, several stakeholder groups identified that in regard to medication discrepancies, electronic health record (EHR) systems that print prescriptions on regular paper make it difficult for patients and family members to distinguish

between prescriptions and other discharge forms. A nurse from an urban setting asked “Why do the home discharge sheets look like the prescription sheets?” A pharmacist further noted that “Prescription paper is another layer of confusion for the patient. The patient brings in a reconciliation sheet, and it looks just like the discharge (prescription) sheet.”

Finally, time limitations were discussed as another system barrier. Hospital staff often have limited time to thoroughly discuss discharge paperwork with patients, and consequently, important patient education may not happen. The lack of information transfer and education may lead to further patient and family confusion. An urban patient stated, “Moving too fast without enough time spent with explanations.” An urban nurse shared, “The family is there and ready to go, but there are many other patients that need help and then you may also have an admit or two thrown in.” A rural patient commented on staffing patterns saying “There are too many duties, too few nurses, short-staffed--unrealistic staffing patterns because administration is disassociated with what’s happening on the floor.”

**Theme 2: Potential solutions to hospital to home medication discrepancies.** We asked stakeholders to identify systems to prevent future medication discrepancies. Three sub-themes emerged from the data: (a) improving information management; (b) increasing access to medicines; and (c) enhancing human resources. Solutions to these sub-themes include those that may be fairly easily addressed by health systems within a short timeframe and solutions that require longer-term planning and/or significant resource allocation.

*Sub-theme related to improving information management.* Several common solutions for system improvements centered on information management, such as having unified EHRs, using e-scripts, and simplifying discharge forms. While focus group participants reported understanding the barriers (e.g., the Health Insurance Portability and Accountability Act [HIPAA]) to establishing unified or universal EHRs, many mentioned how this strategy could reduce medication discrepancies. A nurse from a rural hospital commented that a solution would be “One registry that all pharmacies use,” while a lawyer advocated for “a central database,” and a physician suggested a “universal med list that is stored in the clouds.” A centralized health record has significant privacy implications and will require policy changes and a significant investment in resources and, thus is a potential solution with a long-term timeline.

Additional common solutions proposed in most focus groups could have a shorter timeframe for change, including having prescriptions sent electronically to pharmacies and simplifying discharge forms. A pharmacist stated, “The discharge form given to the patient needs to be very simple,” and a physician commented, “The community should have the same forms, but they must be better than what’s out there now!” A patient from a rural hospital recommended “Organize the paperwork with separate categories to clearly define ‘wound care,’ ‘medicines,’ etc.”

*Sub-theme related to increasing access to medicines.* Each of the potential solutions suggested by stakeholders could be implemented by health systems within a fairly short timeframe by integrating the activities into the health care team’s workflow. Several stakeholder groups noted that receiving prescriptions at the hospital would be a primary solution to increasing access. However, both physician and pharmacist stakeholder focus groups cautioned that if this were

done, the patient's usual pharmacy would have to be alerted to the new prescriptions so as to prevent future confusion that could lead to medication discrepancies. Other suggestions were pre-planning and coordinating with community pharmacies to ensure they had the required medicines and to ensure that the pharmacy would be open at the time the patient was discharged, particularly if a weekend discharge was expected. Another issue with regard to medication access was cost. One patient remarked "Options for costs need to be given so we can plan ahead." Others concurred that being apprised of the cost of the prescriptions they would receive at discharge and knowledge as to whether their insurance would cover that medicine would be helpful. If they were aware of potential financial barriers prior to discharge, they felt they could discuss options with the hospital staff.

***Sub-theme related to enhancing human resources.*** More hospital staff to allow for better communication and care coordination during hospitalization was cited by nearly all stakeholder groups as a solution to reduce medication discrepancies during the hospital-to-home transitional period. For example, providing special interventions, such as post-discharge follow-up, for patients receiving prescriptions for medicines considered "high risk," was thought to be particularly important. A physician stated, "Anticoagulants, insulins, steroids, oral hypoglycemic and BP meds need extra attention at intake and discharge." A nurse from a home health agency asserted that the "main (high risk) meds such as warfarin and other anticoagulants and insulin need to be in line before the patient goes home." Care management services were suggested as a potential solution to both preventing and resolving medication discrepancies because the care manager would move through the care settings with the patient and could facilitate communication about a variety of issues, including an accurate medication list. In our study, stakeholder consensus was that hospital personnel had the knowledge and skills to improve communication and care coordination, but they were overburdened with responsibilities and often did not have time to thoroughly communicate nor coordinate care with one another or with patients and families. Thus, it was felt that care quality could be improved by reducing the workload of current staff or hiring additional staff to specifically focus on communication and care coordination with patients and families, including a focus on medication management. Such solutions could be done in a short timeframe if health systems had the financial resources for more personnel or could alter workflow to improve communication and care coordination activities without additional human resources.

**Theme 3: Liability for medication discrepancies is contextual and complex.** In each focus group, we also explored medical liability issues associated with medication discrepancies that resulted in permanent patient harm. Each group consistently responded that more information about the context and the details of the case would be required to assign responsibility about the medication discrepancy. However, a sub-theme emerged that when someone is harmed as a result of a discrepancy that leads to harm from a medication error, there are generally multiple layers of responsibility. Several groups mentioned that patients also have some degree of accountability, particularly for medication discrepancies during hospital-to-home transitions, and that solutions for improvement included enhanced patient education that could be done prior to hospital discharge and/or with a follow-up phone call or home visit after discharge. A patient from an urban hospital stated "Follow-up phone calls after discharge would be helpful because now we are 'tuned in.'"

When harm resulted from a medication error, the second sub-theme of full disclosure emerged.<sup>27,28</sup> There was consensus from each group of stakeholders 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, stakeholder groups were in uniform agreement that health systems had a responsibility to implement system improvements to prevent similar errors in the future.

## Discussion

Relying on the Sensemaking Conceptual Framework to evaluate information from the voices of crucial stakeholders, we identified both patient-level and health system-level barriers that stakeholders noted as important contributors to medication discrepancies. Acutely ill patients are often discharged with instructions to follow complex inpatient-initiated therapeutic regimens at home. Stakeholders noted that patients and family members frequently lack the knowledge, education, or competency to understand these complex regimens. The competency level of patients is compounded by the fact that they are extremely vulnerable during this transition due to illness severity and/or functional impairment.<sup>29</sup> During this fragile transition, patients and their family members require simplified, yet thorough, medication instructions. Kripalani and colleagues<sup>30</sup> provide specific guidance for communicating medication instructions for patients at discharge: (1) patients should receive a complete list of medicines to be taken at home, with indications and instructions for administration written in everyday language; (2) overarching orders such as “continue home medications” and “resume all medications” need to be avoided to prevent confusion between the current medication regimen and the pre-hospitalization medication regimen; and (3) specific instructions should be provided regarding changes in medicines that the patient had been taking at home prior to hospital admission. In addition, stakeholders from our study noted the importance of assuring patient access to new prescriptions, both in terms of affordability and ability to obtain them from the pharmacy.

In regard to health system-level barriers, stakeholders reported that poor communication, limited staff, time, and complex discharge processes were also problematic. In line with these findings, Bayley and colleagues<sup>31</sup> described similar failures associated with medication information communication during transfers: wrong or incomplete admitting order input by staff, inadequate or incomplete discharge orders, insufficient explanation of discharge medications, and poor communication with the PCP regarding discharge medications. To improve information transfer from hospitalist to PCP, attention must be paid to the content, format, and timely delivery of discharge information. According to Kripalani and colleagues,<sup>30</sup> the following information should be included in discharge summaries: diagnoses, abnormal physical findings, important test results, discharge medications, follow-up arrangements made and appointments that still need to be made, counseling provided to the patient and family, and tests still pending at discharge.

Gleason and colleagues<sup>32</sup> also noted that medication discrepancies often begin with the initial input of the medicines and continue throughout the hospital stay, due to communication deficits between staff and patients. The researchers suggested incorporating improved medication history taking and reconciliation skill attainment in health professions’ curricula and pointed out that because physicians, nurses, and pharmacists all play key roles in medication management



throughout hospitalization and into the transitional care period, a multidisciplinary team approach is required for optimal outcomes.<sup>32</sup> The importance of implementing an up-to-date medication reconciliation program is also noted in a study completed by McMillan and colleagues.<sup>33</sup> Overall, when taken together, both patient- and family-level barriers, along with health system-level barriers, often lead to chaotic, inefficient, and ineffective hospital-to-home transitions and give rise to the potential for medication discrepancies and errors. Feasible solutions to these barriers are critically needed to improve medication safety.

Importantly, stakeholders also offered insight as to practical system solutions that could be implemented to improve medication safety during the transitional period. Preventing or promptly resolving medication discrepancies during the hospital to home transition are crucial for improving patient safety. The stakeholder focus groups were conducted during 2010, shortly after the Patient Protection and Affordable Care Act (ACA) was passed into law. In the ensuing years, we are heartened to report that there are available, evidence-based strategies that coincide with our stakeholder-suggested solutions to improve medication safety during transitional care and/or legislative provisions that provide resources to improve medication safety during care transitions. Evidence-based strategies that can be used to improve medication safety throughout hospitalization and during the transitional care period include the Medications At Transitions and Clinical Handoffs (MATCH) program<sup>34</sup> and Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS).<sup>35</sup> The Health Information Technology for Economic and Clinical Health Act, which created incentives for health systems and ambulatory care providers to initiate EHRs, commonly known as meaningful use, has several benefits that contribute to better utilizing information management.<sup>36</sup> In addition, the ACA, research, quality improvement efforts, and other trends in health care delivery have prompted many health systems, including our partner health system, to implement strategies to improve the quality of care transitions, including the safety of medication use. For example, since the completion of this study, our health system partner now:

1. Employs hospital-based transitional care registered nurse coordinators who work closely with hospitalists and with patients and their families to plan and execute safe transitions.
2. Uses aggregated data to predict which patients are at high risk for readmission and assures that resources, such as care coordinators and social services, are provided to facilitate safe transitions.
3. Provides ambulatory care RN coordinators who assist with navigation across the care continuum and utilizes ACA care coordination and transition codes as payment mechanisms.
4. Provides comprehensive medication consultation to patients and families following hospital discharge at an outpatient pharmacotherapy clinic.

Strategies that enhance care coordination across the continuum are critical for reducing medical liability, since it is anticipated that the advent of health care reform may lead to the creation of coordinated care systems, such as Accountable Care Organizations (ACOs), that could increase the likelihood of medical liability if medication errors are experienced during the transitional period. Despite the 2009 Transitions of Care Consensus Policy Statement asserting that the

sending provider, institution, or team maintains responsibility for patient care until the receiving clinician or institution confirms the transfer and assumption of responsibility,<sup>15</sup> assigning liability for errors that occur during transitions in a fragmented system remains confusing and complex. Stakeholders in our focus groups recognized that medication errors resulting in harm are generally multi-focal in origin, and they resisted assigning responsibility. However, ACOs are designed to provide more comprehensive care across the continuum and share financial risk associated with that care. Thus, as less fragmented systems, ACOs may create entities that are seen as accountable for errors across the continuum, and liability may be pursued more frequently than is currently realized.

The unanimous sub-theme of our focus group findings regarding patient harm and liability was that full disclosure should occur when an error that causes harm is identified. This conclusion is consistent with other research. Further, such a policy has been endorsed as a best practice by The Joint Commission and the National Quality Forum.<sup>37</sup> Earlier research suggests a relationship between full disclosure and decreased liability claims and overall costs.<sup>38</sup> Despite widespread support for full disclosure, it is not uniformly implemented, and there is little attention to the topic in health professional education programs.<sup>39</sup> Stroud and colleagues<sup>40</sup> found the training in the skill of full disclosure had not been well studied among medical professionals, and attention to the skill is rare for other health professionals. The Sorry Works! Coalition is attempting to change the culture of full disclosure and offers resources for health care professionals and health systems.<sup>41</sup> In summary, our findings in support of full disclosure for medication errors that result in harm are consistent with other research, but there are opportunities to improve educational strategies so that health care professionals have the skills to implement full disclosure and to establish full disclosure as a standard practice across disciplines.

## **Limitations and Strengths**

Our stakeholder focus group members were all recruited from a limited demographic area of the Northwest, which means our findings may not be generalizable to other regions or groups. Participants also volunteered for the study, possibly introducing self-selection bias. Additionally, as with any focus group study, a limitation of the study included the possibility of a social desirability bias or participants feeling pressured to give similar answers as other members to the facilitator's questions.

The use of focus groups was a unique strength of this study because it allowed participants to generate new ideas from each other. Furthermore, a qualitative approach using the Sensemaking methodology allowed us to obtain detailed information directly from a diverse group of stakeholders. To our knowledge, this is the most detailed and inclusive analysis of transitional care medication discrepancies carried out to date, in that it reflects the voices of patients, family members, and multiple groups of professionals from both rural and urban settings.

## **Conclusion**

Preventing medication discrepancies and ADEs remains a national priority. Our findings indicate that stakeholders are aware of both barriers and solutions to medication safety, and they are motivated to implement change to improve outcomes. Recent policy shifts have promoted

changes that were suggested by stakeholders to improve medication safety during care transitions. Improved hospital systems (staffing and EHRs), patient education, and provider communication and preparation can minimize the occurrence of medication discrepancies and ADEs, thereby improving patient satisfaction and safety. When errors that result in harm occur, full disclosure is the best practice. Public policy may reinforce progress; however, more widespread implementation and adoption of these provisions and strategies is now needed at the health care system-level to improve transitional care medication safety.

## Acknowledgments

This project was funded by grant from the Agency of Healthcare Research and Quality (HS19552). In memoriam, we acknowledge the leadership and vast contributions to this work from Dr. Stephen M. Setter. Finally, we appreciate revision suggestions and assistance from the AHRQ staff and from Amy Barrett Thomas.

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# Medication Discrepancies and Potential Adverse Drug Events During Transfer of Care from Hospital to Home

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## Abstract

**Purpose.** Evaluate the potential for medication discrepancies to contribute to adverse drug events (ADEs) by rating the seriousness of potential ADEs and further characterizing their potential impact on health consequences and subsequent health care utilization during transitions from hospital to home care.

**Methods.** A secondary analysis of medication discrepancy data involving patients aged 50 years and older transitioning from hospital to home care was performed. Two pharmacists independently determined if a potential ADE could result from each medication discrepancy and subsequently rated the potential consequences for patient health and health care utilization.

**Results.** A total of 1,389 discrepancies were evaluated among 212 patients with 566 (40.7 percent) determined to potentially contribute to an ADE. Of these 566 potential ADEs, 1 percent, 68 percent, and 31 percent were rated as serious, significant, or minor, respectively. Drugs resulting in serious potential ADEs included exemestane, enoxaparin, warfarin, and sublingual nitroglycerin. Potential ADEs ascribed significant ratings included opioids, anti-hypertensives, anti-coagulants, diuretics, anti-diabetic agents, anti-arrhythmics, anti-infectives, systemic corticosteroids, anti-psychotics, immune suppressants, and anti-epileptic medications. No potential ADEs were considered to have potentially resulted in death or permanent disability. It was judged, however, that potential ADEs could lead to temporary disability in 0.2 percent of the cases, symptoms lasting 30 or more days in 1.3 percent of the cases, symptoms lasting less than 30 days in 47.5 percent of the cases, abnormal laboratory data or vital signs in 47 percent of the cases, and no subsequent health care consequences in 4 percent of the cases. The potential ADEs were anticipated to require hospitalization in 0.6 percent of cases, emergency department visits in 2.1 percent of cases, office visits in 12.5 percent of cases, telephone calls in 73.3 percent of cases, or no additional health care utilization in 11.5 percent of cases.

**Conclusion.** Medication discrepancies are common during hospital-to-home transitions and may result in ADEs that potentially impact patient outcomes and subsequent health care utilization.

## Introduction

The goal of patient safety is to reduce the risk of injury or harm to patients by improving both the structure and process of care delivery. Therefore, when unintended risks and hazards associated with the delivery and management of care are eliminated or reduced, patient safety is maximized. To reduce safety risks to patients, health systems expend considerable resources to prevent medication errors in the hospital setting.<sup>1,2,3</sup> Increasingly, inpatient medication risk management

efforts focus on preventing errors by improving systems for medication administration and creating a culture of safety.<sup>1,3</sup>

Unfortunately, the potential for patient harm and increased medical liability due to medication discrepancies, defined as unexplained differences among documented regimens across different sites of care, continues after hospital discharge. Preventable adverse drug events (ADEs) have been shown to frequently occur in a variety of settings, including the hospital,<sup>4,5</sup> nursing homes,<sup>6</sup> and the ambulatory/outpatient setting.<sup>7</sup> In addition to poor clinical outcomes associated with preventable ADEs, several studies have highlighted the significant liability claim costs associated with preventable ADEs occurring in both inpatient and outpatient settings.<sup>8,9</sup> The transition from hospital to community settings, including transfers for those receiving home care services, is an exceptionally risky time, particularly for older adults with multiple chronic morbidities that place them at particular risk for medication discrepancies and associated ADEs.<sup>10,11,12,13</sup>

In general, home health care is inclusive of a range of health care services that can be provided within the home environment to manage illness and/or injury. As part of the study described in this paper, participants were receiving skilled services from a certified home care agency. Our previous work indicates that up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.<sup>14,15</sup> Patients with hospital-to-home-care medication discrepancies are almost twice as likely to be readmitted to the hospital within 30 days as patients with no medication discrepancies.<sup>16</sup> Recent research aimed at improving transitional care and medication safety also demonstrates enhanced patient outcomes and reduced costs.<sup>17,18,19</sup>

ADEs occur frequently in both inpatient and outpatient settings and are a major patient safety concern.<sup>20,21,22,23,24,25,26</sup> ADEs result in increased resource utilization, including additional diagnostic tests, physician visits, medication use, emergency department (ED) visits, and hospitalizations,<sup>27</sup> and in 2000, ADE-associated costs were estimated to exceed \$117 billion.<sup>28</sup> ADEs that are primarily the result of human errors occur when health care team members fail to communicate effectively, do not document information adequately, and/or neglect to “handoff” relevant information to subsequent providers.<sup>29</sup> Furthermore, confusion in lines of authority and failure to appropriately consult experts when prescribing and administering medications to selected populations of patients may result in ADEs.<sup>29</sup> Such human factors resulting in ADEs are particularly common during transition within or between health systems.<sup>29</sup>

A critical need exists to develop and implement medication risk management strategies in conjunction with emerging transitional care practices. The purpose of this secondary analysis was to evaluate the potential for medication discrepancies to contribute to ADEs during care transition from the hospital to home care setting. Medication discrepancies were analyzed for their potential to result in an ADE and then classified based on potential health consequences and anticipated health care utilization associated with the potential ADEs. The results of this study are intended to aid in the development of effective risk management strategies to improve medication information transfer and enhance patient safety during care transition from hospital to home care.

## Methods

Following institutional review board approval, an analysis was performed of secondary data from a previous study that evaluated and categorized hospital-to-home medication discrepancies via review of medical records and participant interviews. Recruited participants were those discharged from one of two hospitals who received home health care services from a Medicare-certified home health agency. Both recruitment hospitals and the home care agency are part of the same health system. One of the hospitals is the region's largest tertiary referral center, with nearly 30,000 inpatient admissions annually, while the other is a community medical center with approximately 9,000 annual inpatient admissions. In the larger parent study, medication records on 212 patients discharged from the hospital to home care were examined. Most (89 percent) patients had at least one medication discrepancy, and a total of 1,389 medication discrepancies were identified. Each discrepancy was classified using the Medication Discrepancy Tool (MDT<sup>®</sup>).<sup>30</sup> The MDT<sup>®</sup> is a tool by which a medication discrepancy can be described and subsequently categorized by causes and/or contributing factors. The "types" of discrepancies that can be categorized utilizing the MDT<sup>®</sup> are as follows: adverse drug reaction or intolerance; prescription not filled; medication not needed; financial barriers exist; intentional or non-intentional non-adherence; performance deficit in taking medication; conflicting information from care providers; brand/generic confusion; discharge instructions incomplete or inaccurate; incorrect dosage, quantity or label; unrecognized cognitive impairment; or unmet need for caregiver assistance.<sup>30</sup>

For the current secondary analysis, each discrepancy was further independently evaluated by two pharmacists with experience identifying and resolving medication discrepancies. For each discrepancy, the reviewing pharmacists were provided with the following information:

1. Patient age and sex.
2. Medication name.
3. A brief narrative description of the discrepancy (e.g., medication not listed on patient's discharge list, prescription states 5 mg but the patient takes 10 mg, patient did not want to take any more pills, etc.).
4. A categorization for the type of discrepancy (as categorized by use of the MDT<sup>®</sup>).

ADE review and classifications reported in the current study utilized the conceptual model and scheme developed by Weingart and colleagues to assess drug-drug interaction safety alerts.<sup>31</sup> Weingart's model (see Figure 1) was tailored to better assess the potential of a medication discrepancy to cause or contribute to an ADE that would then require additional health care utilization. Based on the medications within each patient's regimen and the type of discrepancy identified, the pharmacists projected whether a medication would provoke a potential ADE and, if so, the potential severity of the ADE (serious, significant, or minor). Minor potential ADEs were defined as those that could result in minimal injury or discomfort such as flushing or mild stomach upset, for example. Significant potential ADEs were defined as those that could cause or contribute to symptoms, such as fever or pruritus; laboratory changes, such as hypoglycemia or hyperkalemia; or result in changes in vital signs, such as tachycardia. Lastly, serious ADEs were defined as those that could potentially result in significant organ failure or injury, such as major gastrointestinal bleeding or onset of angina.<sup>31</sup>



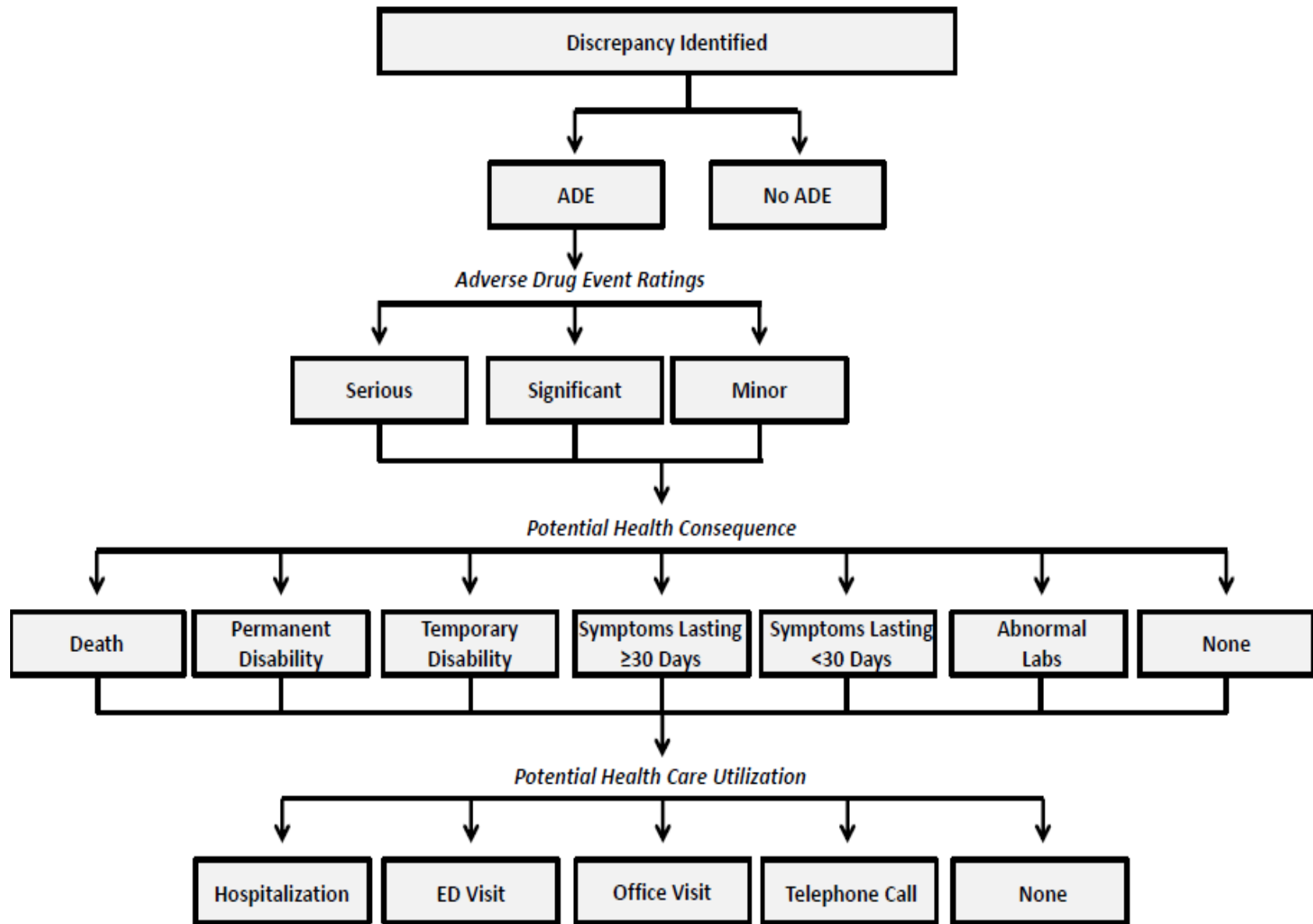
Furthermore, the predicted health consequences of the potential ADEs were categorized as follows: death, permanent disability, temporary disability, symptoms present 30 days or greater, symptoms present less than 30 days, abnormal lab results, or ADE but with no practical consequence. Finally, the pharmacists also independently rated the impact of a potential ADE for health care utilization (hospitalization, ED visit, office visit, provider phone call, or ADE but with no practical impact on health care use).

Cross tabulations among the independent pharmacists' judgments for whether medications would potentially provoke an ADE revealed 84 percent agreement for medications judged to provoke an ADE and 62 percent agreement for medications not considered to provoke an ADE. The overall agreement in judgments across all 1,389 medications was 68 percent, leading to a Cronbach's alpha for inter-rater reliability of 0.59. We deemed this as an insufficient level of agreement among raters, and therefore, we used an adjudication method for disagreements. For each medication in which there was disagreement on the potential for an ADE or its impact, the pharmacists discussed the medication in the context of the entire regimen until consensus was reached with regard to potential ADE risk. If a disagreement still existed, the physician co-investigator evaluated the case to make the final assignment of risk category. In the event of physician co-investigator review, the physician independently reviewed disputed cases using our predetermined conceptual model (Figure 1). In all cases of disagreement, the physician co-investigator's assessment agreed with that of one of the pharmacist investigators. Accordingly, the assessment of the physician co-investigator was utilized in such cases.

## Results

A total of 1,389 medication discrepancies were identified in 212 patients. This equated to an average of 6.6 discrepancies per patient. Of the total 1,389 discrepancies identified, 566 (40.7%) discrepancies involving 182 individual patients were determined to result in a potential ADE (a mean of 3.1 ADEs per patient). Of these, 6 (1.1%), 386 (68.2%), and 174 (30.7%) of the potential ADEs were rated as serious, significant, or minor, respectively. The 6 discrepancies determined to potentially result in a severe ADE occurred in 6 individuals, while 386 ADEs were rated as significant and 174 rated as minor occurred in 152 and 174 individual patients, respectively.

Medication classes most commonly involved in potential ADEs are displayed in Table 1. Medication discrepancies determined to contribute to serious potential ADEs involved the antineoplastic agent exemestane (1 patient), enoxaparin (1 patient), warfarin (1 patient) and sublingual nitroglycerin (5 patients). Potential ADEs ascribed a significant rating often involved opioids, antihypertensives, anticoagulants, diuretics, antidiabetic agents, antiarrhythmics, antiinfectives, systemic corticosteroids, antipsychotics, immune suppressants, and antiepileptic medications. Minor potential ADEs most often involved OTC agents, antacids, cholesterol lowering drugs, allergic rhinitis agents, nonsteroidal anti-inflammatory drugs (NSAIDs), and thyroid supplements. While 566 of the 1,389 (40.7%) medication discrepancies were judged to contribute to a potential ADE, 833 discrepancies (59.3%) were assessed as unlikely to cause or contribute to a potential ADE. Medications commonly involved in discrepancies assessed to have insignificant consequences involved acetaminophen, laxatives, aspirin, allergic rhinitis agents, and antihistamines.



**Figure 1. Conceptual Model for Assessing the Potential of Medication Discrepancies To Contribute to an ADE and Increased Health Care Needs.**

Note: ADE, adverse drug event; ED, emergency department. Adapted from Weingart, Simchowicz, Padolsky, et al. Arch Intern Med 2009; 169(16):1465-73.

**Table 1. Top Ten Therapeutic Drug Classes Resulting in Potential Adverse Drug Events (ADEs)**

<b>Therapeutic Class</b>	<b>Frequency of Discrepancies *</b>	<b>Percent (%) †</b>
Antihypertensive Agents	94	16.6
Opioids	65	11.5
Anticoagulants	57	10.1
Antidiabetic Agents	46	8.1
Inhaled COPD/Asthma Medications	36	6.4
Diuretics	35	6.2
Laxatives	27	4.8
Oral Electrolytes	24	4.2
Antiinfective Agents	23	4.1
Antacids	18	3.2

\* Of the 566 total medication discrepancies potentially resulting in an ADE, 425 (75 percent) involved these top 10 therapeutic drug classes.

† Percent (%) of total 566 medication discrepancies potentially resulting in an ADE.

The most common potential health consequence assessed was “symptoms lasting less than 30 days,” which equated to 269 (47.5 percent) of the 566 total potential ADEs evaluated (Table 2). The potential health consequence of “abnormal laboratory values or altered vital signs” was also a common consequence accounting for 266 potential ADEs (47 percent). The pharmacist reviewers determined that none of the potential ADEs were likely to have resulted in “death or permanent disability.” “Temporary disability” was assessed as the likely outcome for one (0.2 percent) of the identified potential ADEs, while the health consequence of “symptoms lasting 30 or more days” accounted for seven (1.3 percent) potential ADEs. No likely subsequent health consequences were evaluated for 23 (4 percent) potential ADEs.

**Table 2. Study Identified Potential Health Consequences of Potential Adverse Drug Events by Rated Severity**

<b>Potential Health Consequence Category</b>	<b>Number (%) * of Potential Health Consequences Identified by Rated Severity of ADE</b>		
	<b>Minor</b>	<b>Significant</b>	<b>Serious</b>
None	20 (3.5)	3 (0.5)	0 (0)
Abnormal Labs or Vital Signs	49 (8.7)	217 (38.3)	0 (0)
Symptoms Lasting <30 Days	105 (18.5)	159 (28.1)	5 (0.9)
Symptoms Lasting ≥30 Days	0 (0)	6 (1.1)	1 (0.2)
Temporary Disability	0 (0)	1 (0.2)	0 (0)
Permanent Disability	0 (0)	0 (0)	0 (0)
Death	0 (0)	0 (0)	0 (0)
<b>Total</b>	<b>174 (30.7)</b>	<b>386 (68.2)</b>	<b>6 (1.1)</b>

\* Number (%) of identified potential health consequences for the 566 total medication discrepancies potentially resulting in an ADE.

If an ADE was determined to have the potential to result in a subsequent health consequence, it was then assessed for the type of health care entity or modality most likely utilized to address and manage the health consequence. It was deemed that inpatient hospitalization would likely be required to manage three potential ADEs (0.6 percent), with an ED visit likely required to manage 12 (2.1 percent) of the potential ADEs (Table 3). Discrepancies and resulting potential ADEs involving exemestane, warfarin, and enoxaparin were deemed to potentially require hospitalization in each of three separate patients. ADEs anticipated to potentially require an ED visit involved enoxaparin, warfarin, aspirin, dipyridamole + aspirin, albuterol and/or ipratropium, and levofloxacin in 12 separate patients. While 65 (11.5 percent) of the potential ADEs were deemed unlikely to require any additional contact with health care providers, 71 (12.5 percent) were assessed to potentially necessitate an office visit. The great majority of discrepancies (n=415 or 73.3 percent) were judged to be most appropriately communicated and managed with a phone call to the health care provider's office.

**Table 3. Study Identified Potential Health Care Utilization of Medication Discrepancies Leading to Potential Adverse Drug Events**

Potential Health Care Utilization Categories	Number (%) * of Potential Adverse Drug Events Requiring Subsequent Health Care Utilization
None Required	65 (11.5)
Telephone Call	415 (73.3)
Office Visit	71 (12.5)
Emergency Department Visit	12 (2.1)
Hospitalization	3 (0.6)

\* Number (%) of identified potential ADEs identified as potentially requiring health care utilization for the 566 total medication discrepancies evaluated to result in an ADE.

## Discussion

Our findings in a home care population further support the frequency and potential severity of medication discrepancies during care transitions from hospital to home. These findings further support the need for the development of effective risk management strategies to improve medication information transfer to enhance patient safety during care transitions from hospital to home care. In this study of 1,389 medication discrepancies, 40.7 percent were evaluated to likely result in an ADE; 69.3 percent were assessed to be potentially serious or significant. Six serious potential ADEs were identified in six individual patients, with 386 significant potential ADEs identified in 153 patients. Gandhi and colleagues estimated that ADEs occurred at a rate of 27.4 per 100 ambulatory patients, with 13 percent (3.6 per 100 patients) classified as serious.<sup>32</sup> In a hospital study involving 563 patients, 225 (40 percent) of the patients were found to have a discrepancy at admission or discharge.<sup>33</sup> Discrepancies were rated on a 1-3 harm scale (1 being minor, 2 being moderate, and 3 being severe), with 162 patients having a discrepancy rated as 2 or 3, roughly correlating with our scale of significant or serious, respectively. Specifically at discharge, 51 percent of the 167 discrepancies identified were rated as a 2, with 23 percent being rated as a 3.<sup>33</sup> In an ambulatory care population, there were 5.24 discrepancies identified per patient, and medication errors were identified in 88.9 percent of the study visits, with 75 percent, 24 percent, 0.3 percent of the medication errors being rated as minor, significant, and serious, respectively.<sup>34</sup>

In our study, the top five medication classes involved in a potential ADE were antihypertensives, opioids, anticoagulants, injectable and oral antidiabetic agents, and inhaled medications for chronic obstructive pulmonary disease (COPD) or asthma. Classes of medications most frequently contributing to an ADE in a study involving outpatients from four different primary care offices were selective serotonin reuptake inhibitors (SSRIs), beta-blockers, angiotensin converting enzyme inhibitors (ACEIs), calcium channel blockers (CCBs), and nonsteroidal anti-inflammatory agents (NSAIDs).<sup>32</sup> Similar to this study, we identified antihypertensives (which include beta-blockers, ACEIs, and CCBs) as likely to result in an ADE commonly in community-dwelling patients. However, the remaining top medication classes differ; a possible explanation being that the participants involved in Gandhi's study were able to report actual ADEs, and the associated symptoms directly related to the offending drug (e.g., sexual dysfunction and SSRI use, loop diuretic use associated urinary incontinence). Furthermore, our study involved patients discharged from hospital to home care, while the Gandhi study involved patients receiving primary care services, apart from a recent hospitalization, further distinguishing among differences in ADEs that may be experienced by two different community dwelling populations with potential variability in health acuity.

Findings from our secondary analysis additionally identified discrepancies involving medications considered to be high risk medications for contributing to ADEs and ED visits, per previous studies and reports. In regard to ADEs leading to acute care utilization, we identified approximately 2 percent of the potential ADEs involving 10 patients that were likely to result in an ED visit. The involved medicines were anticoagulants or antiplatelets (e.g., enoxaparin, warfarin, dipyridamole + aspirin), and sublingual nitroglycerin. Hospitalization was deemed likely necessary in 0.5 percent of potential ADEs, involving three patients, and associated with the antineoplastic drug exemestane and the anticoagulants enoxaparin and warfarin. In a different study examining community-dwelling older adults, insulin, digoxin, and warfarin were identified as medications commonly leading to an ADE requiring an ED visit.<sup>34</sup> In another investigation, the top five categories of medicines implicated in ADEs requiring an ED visit included the following broad classes: (1) central nervous system agents (including opioids); (2) systemic antimicrobial agents; (3) hormone modifying agents, including insulin and oral antidiabetic medications; (4) hematologic agents, including anticoagulants and platelet inhibitors; and (5) cardiovascular agents (e.g., ACEIs, digitalis).<sup>23</sup> Thus, insulin and antidiabetic medicines, as well as anticoagulants and platelet inhibitors, were identified in all three studies as contributing to an ADE or potential ADE that may require subsequent acute care utilization. Overall, medications and medication classes identified in our study as high risk for potential ADEs and subsequent health care utilization largely align with other studies reported in the literature.

In addition to patient safety and quality of care implications associated with the potential ADEs identified, our findings have additional implications in terms of medical liability. As discussed previously, preventable ADEs have been shown to occur frequently in a variety of settings, including the hospital,<sup>4,5</sup> nursing homes,<sup>6</sup> and the outpatient setting.<sup>7</sup> A retrospective analysis of a New England malpractice insurance company claims records from January 1, 1990 to December 31, 1999, concluded that ADEs represented 6.3 percent of malpractice claims filed.<sup>9</sup> Of the ADE claims analyzed, 73 percent of them were deemed preventable and were nearly evenly divided between ADEs occurring in the inpatient and outpatient settings. Similar to our findings, the

most common medication classes involved were antibiotics, antidepressants, antipsychotics, cardiovascular drugs, and anticoagulants.<sup>9</sup> Because the occurrence of medication discrepancies during transition from hospital to home are frequent, interventions designed to identify and resolve medication discrepancies during transitions of care is one potential strategy in preventing ADEs to improve patient care and mitigate medical liability risk.

Our findings concerning medications and medication classes frequently associated with medication discrepancies and potential ADEs are supported by the findings of other studies in other settings and health care environments. The study described herein additionally provides important insight into the frequency and potential severity of medication discrepancies that can help identify patients who may be at risk for experiencing medication-related ADEs during transition from hospital to home. The results of our study should, however, be considered within its limitations. The impacts of actual ADEs were not contained in the data and therefore were unknown. Furthermore, study participants in the present study included patients receiving care from one health system in the Northwestern United States, and our findings may not be generalizable to other health systems or health care that patients receive in other parts of the country.

## **Conclusion**

Medication discrepancies frequently occur during the transition from hospital to home care. In the current study, more than 40 percent of all medication discrepancies were classified as having the potential to result in an ADE. Of these, a majority were classified as potentially serious or significant, with the most common likely resultant health consequences being transient symptoms lasting fewer than 30 days or alterations in laboratory values or vital signs. Many of the potential ADEs were assessed as likely to be resolved by a telephone call to a provider, with a lesser percent requiring a visit to the physician's office, ED, or hospital.

This project highlights the need to proactively implement strategies to minimize potential ADEs occurring as a result of medication discrepancies surfacing between hospital discharge and home care. Additionally, specific medications and drug classes that were associated with the greatest potential of conveying a negative impact on the patient's health or resources should be given priority for improvements. Ultimately, this information creates a foundation for developing an effective risk management strategy for improving patient safety. Our findings can be utilized by health care professionals and health systems to develop interventions to improve the safe use of high risk medicines frequently associated with discrepancies that are likely to result in ADEs requiring further health care utilization.

## **Acknowledgments**

This project was funded by the Agency of Healthcare Research and Quality (AHRQ grant HS19552). In memoriam, we acknowledge the leadership and vast contributions to this work from Dr. Stephen M. Setter.

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