

Developing and Testing the Health Care Safety Hotline: A Prototype Consumer Reporting System for Patient Safety Events



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DEVELOPING AND TESTING THE HEALTH CARE SAFETY HOTLINE: A PROTOTYPE CONSUMER REPORTING SYSTEM FOR PATIENT SAFETY EVENTS

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Prepared by:

RAND Corporation
RANDHealth
Santa Monica, CA

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None of the investigators have any affiliations or financial involvements that conflict with the material presented in this report.

The opinions presented in this report are those of the authors, who are responsible for its content, and do not necessarily reflect the position of the U.S. Department of Health and Human Services or the Agency for Healthcare Research and Quality.

Preface

Two decades of research have demonstrated the feasibility and promise of collecting information from health care professionals about adverse events, errors, and unsafe conditions in health care settings (such as hospitals and physician practices). This information can be used to understand the extent and nature of real and potential harms and to develop interventions that improve patient safety. Recently, investigators have begun to develop and evaluate systematic approaches to gathering information from patients and their caregivers about safety issues in a form that health care organizations can use as they seek to improve patient safety. This research on consumer reporting of patient safety information has highlighted a number of challenges.

Under contract to the Agency for Healthcare Research and Quality (AHRQ) and with its input, a research team led by RAND Corporation investigators undertook a project to design, pilot, and evaluate a prototype for collecting narrative and structured data about concerns that patients have about the safety of their health care, including errors and adverse events. The Health Care Safety Hotline was designed to allow consumers (patients, family members, friends, and other caregivers) to report patient safety problems (anonymously, if they choose) on a secure Web site or by calling a toll-free phone number. The prototype was also designed to enable the hotline to provide data (with the consumer's permission) back to the health care organization.

This report describes the development and testing of the hotline prototype, its implementation and use in two health care delivery organizations within one pilot community, and its evaluation. The evaluation is based on the totality of the design and implementation experience, the feedback of a technical expert panel, and descriptive data on patient and caregiver reports collected and analyzed over a field period of 17 months (February 2014 through June 2015).

The report should be of interest to policymakers, leaders of health care systems and their related organizations, patient safety leaders, health services researchers, and others who are interested in the development and deployment of patient safety reporting systems.

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We also extend our gratitude to our two pilot community partners—health care delivery organizations that participated with us in implementing and testing the consumer hotline prototype. We are indebted to these organizations, their patient safety leadership, and their Patient and Family Advisory Councils for the generosity of their time commitment and the valuable input they provided. We also thank Shaela Moen, Monica Hertzman, Lee Floyd, and Deanna Lee of RAND and Gregory Lee of ECRI Institute for their contributions to the project and this report.

The RAND quality assurance process employs peer reviewers, including at least one who is external to RAND. This report benefited from two rigorous technical reviews that improved the quality and clarity of the material presented.

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Summary

With funding from the Agency for Healthcare Research and Quality (AHRQ), researchers at the RAND Corporation, its ACTION II Teaming Partner ECRI Institute, Tufts Medical Center, and Brigham and Women's Hospital designed, developed, implemented, and evaluated a prototype consumer reporting system for patient safety, called the Health Care Safety Hotline. The prototype was intended to enable collection of reports from consumers (i.e., patients and their proxies, including families, friends, and other caregivers) about patient safety problems with their health care. During the first phase of the project, the research team designed and assembled the key building blocks of the hotline prototype, including a patient-oriented event reporting form, a Web-based data collection platform and content, and protocols for data collection, data processing, and data sharing. In the second phase of the project, the hotline prototype was implemented and evaluated in a carefully selected pilot community, with the participation of two local health care delivery organizations.

Development of the Hotline

The patient reporting form in the prototype was based on existing resources, including a previously published survey developed by the project team members,¹ minimum dimensions for reporting patient safety events laid out by the Institute of Medicine,² (Institute of Medicine, 2004), and the AHRQ Common Formats,^a which includes definitions of adverse events and forms for adverse event reporting. The team conducted an environmental scan of all existing consumer-enabled reporting systems and identified 27 relevant systems. These systems were then analyzed by event type, reporting mode, key terms used, and other criteria. Analysis of these instruments highlighted several gaps and also a lack of consensus on key issues, such as the optimal terminology to be used for consumer reporting and consumer expectations about what might occur as a result of a submitted report.

To fill gaps in existing knowledge and to address unresolved issues, the research team conducted two focus groups, one in English and one in Spanish. The focus groups helped us to determine whether patients and caregivers could recognize and were willing to report adverse events, to identify the preferred terminology to be used in reporting, and to understand consumer concerns and expectation about reporting.

The patient reporting form was revised in response to the focus group findings, and the revised form was tested in cognitive interviews with patients and family members. Using insights obtained in the cognitive interviews, the research team refined question content and wording, shortened the reporting form dramatically, replaced some of the terminology, and added open text boxes to encourage narrative reporting.

^a The AHRQ Common Formats provides precise definitions of patient safety events, examples of patient safety reports, forms to guide development of data collection instruments, and a metadata registry. Information on the Common Formats is available at the Patient Safety Organization Privacy Protection Center (PSOPPC) at www.psoppc.org/web/patientsafety.

The team next developed protocols for handling consumer-reported patient safety observations. An intake protocol was designed for assessing the confidentiality and anonymity preferences of the patient or caregiver and for screening the reports on the basis of inclusion and exclusion criteria (such as completeness, coherence, and type of report).

A process was developed for following up with the consumers to clarify details (as appropriate and with permission from the consumers) and to enter the report into a database. If a patient gave permission for the information to be shared with the relevant health care organization, a copy of the report was provided to that organization. This enabled health care organizations to match and supplement the consumer report with any relevant information collected from other sources within their organizations (such as an existing adverse event reporting system for health care professionals). The information provided by the health care organization was entered into a second database, a patient safety organization (PSO) database, within which the report was protected as a “patient safety work product” under the Patient Safety and Quality Improvement Act of 2005.³

After the reporting form and protocols for handling reports were developed, the research team initiated the prototype review process. They first presented the prototype to a technical expert panel (TEP). The TEP members provided multi-stakeholder expertise on relevant dimensions of the project, including patient safety, reporting systems, patient and consumer perspectives, and survey methodology. In response to feedback from the TEP, the researchers revised the patient event reporting form and other aspects of the prototype before submitting it to the Office of Management and Budget (OMB) for public comment (required under the Paperwork Reduction Action of 1980). Additional revisions were made in response to the public comments, and the final versions were submitted to OMB for review. The team then demonstrated the prototype to project officers at AHRQ, the TEP, and organizational leaders in the candidate pilot community. RAND received OMB approval to deploy the prototype on August 31, 2013.

Implementation and Evaluation of the Hotline

In the next phase of the project, the research team implemented, refined, and evaluated the hotline prototype to assess its feasibility, yield, and potential scalability and to recommend any necessary modifications. Two highly integrated health care organizations in a single community—each of which already had a relationship with a PSO—were recruited. Together with these health care organizations, the research team developed and implemented an outreach and marketing plan to alert consumers to the availability of the hotline.

The Health Care Safety Hotline was launched in January 2014, and staffed by members of the research team, who kept in close contact with the two health care organizations over the 17 months of hotline operations. Health care leadership, patient safety and risk management staff, and Patient and Family Advisory Councils provided guidance and feedback. Because of OMB requirements, only minor adjustments to the patient event reporting form and Web content were made during the operation period.

The evaluation of the prototype was designed to analyze how resources related to the marketing and promotion of the hotline and the modes used to provide access to it affected the flow of its operations and the numbers and types of reports received. The research team also examined the

experiences of health care organizations and health care professionals who received and used consumer reports to improve patient safety in their institutions and identified remaining technical and content challenges that would need to be addressed prior to scaling up from the prototype. Finally, recognizing that perhaps a single hotline could not meet all of the identified goals (patient safety improvement, public monitoring and accountability, research on adverse events), the researchers identified a range of opportunities for the hotline (and its components) to be deployed in other settings and for other uses.

Challenges and Lessons Learned

This project highlighted several challenges inherent in involving consumers in reporting about safety concerns. Safety-related events do not surface in a predictable way, and their causation is complex. This makes standardized data collection approaches for health safety events difficult to design and implement. Further, the reporting process must be acceptable to the person making a report. Current systems for classification and coding of events may be useful to clinicians and patient safety managers, but they may not be easily adaptable to the unique perspective that consumers bring to health care safety improvement. In addition, the optimal timing for soliciting reports may vary, depending on a patient's health status, experience, and expectations. A patient safety reporting system must also respect current legal and regulatory requirements regarding confidentiality and data protection that come into play when soliciting, storing, and transmitting safety-related information.

The project demonstrated that “we can build it,” that is, it is possible to put into place a high-quality patient reporting system with the help of willing partner health care organizations, but that does not mean that “they will come.” In addition, the outreach strategy used to bring consumers to the Web site did not produce the hoped-for volume of reports. Although the outreach strategy was refined and expanded, with help from the health care partners and guidance from our TEP throughout the 17 months of hotline operation, the volume of reporting remained suboptimal for testing the prototype.

A related issue was whether the prototype was perhaps trying to “serve too many masters.” The AHRQ-sponsored design report that gave rise to the development of the prototype recommended that patient reports be gathered locally but also communicated to a centralized (national) level to be aggregated, analyzed, and triaged or distributed to State and local levels for action. Based on our experience with the hotline, we now question whether improving patient safety at the local level, aggregating data for public monitoring and accountability, and conducting research on patient-reported errors are compatible objectives that can be addressed by a single consumer reporting system without undue burden on either the consumers or the health systems involved. Attempting to address all of these goals within one prototype resulted in an instrument and a process that were much more cumbersome than they needed to be to achieve any one objective (for example, patient safety improvement within a single health system), and this may have contributed to the lower-than-hoped-for response rates.

Given the many challenges revealed by the pilot study, the takeaway conclusions are summarized here:

- **Patient safety reporting is both desirable and feasible.** The hotline created a mechanism, accessed via a Web-based platform or a toll-free phone number, that patients and families used to report meaningful clinical information about perceived errors and physical and emotional injuries.
- **The hotline yielded information that was previously unavailable.** The hotline provided information that the sophisticated health care organizations would not have had despite the existence of mechanisms such as patient experience surveys and complaint departments and information about patient safety concerns from staff (e.g., adverse event reporting systems).
- **The hotline was readily incorporated into existing patient safety systems and was not disruptive to health system operations.** Although health system leadership initially worried that there would not be sufficient bandwidth to respond appropriately to all reported patient concerns, they ultimately tried to elicit more reports from patients. Further, the hotline was not disruptive; instead, its implementation reinforced organizational commitment to safety, quality, patient engagement, and transparency.
- **Legal and regulatory obstacles to soliciting, storing, analyzing, and sharing event reports were manageable through the use of PSOs.** These obstacles are likely to be even less problematic if hotlines are adopted by individual health care systems for their own use.
- **The option of proxy reporting was an important component of the hotline.** Proxies (such as family members and friends of patients) submitted about half of the total number of reports.
- **The prototype has a number of components that can be utilized separately, depending on the specific goals of the end user.** Which components are employed and how they are adapted would depend on the individual project's purposes.

Given the many positive findings associated with the hotline, how should the discrepancy between its potential high value and the low response rate among patients and caregivers in the pilot project be addressed? It appears there were three principal problems. First, although a variety of marketing vehicles were employed (brochures, hospital Web sites, pamphlets included in discharge materials), it was assumed that, when given the opportunity and invitation, patients would reach out to institutions to report problems. However, this passive outreach strategy (simply making a Web site or a toll-free phone number available) did not generate a large volume of reports. Second, Web traffic data showed that more individuals accessed the Web site than actually made reports—many potential users dropped off after reading the introductory materials or completing only the narrative portion of the report. This suggests that, despite the time and care taken in developing the Web site, there also most likely were problems with the platform itself. Third, the presence of alternative mechanisms for reporting at the hospital level (e.g., discharge surveys) or the community level (e.g., State regulatory agencies) could have depressed the number of reports.

Conclusion

The design and development of the Health Care Safety Hotline represents a significant effort on the part of the research team and AHRQ to move promising research findings “from bench to bedside.” The effort yielded important information about the feasibility of consumer reporting of safety events and also some critical constraints. Overall, the number of consumer reports was disappointing, given the potential reservoir of adverse events and the yield of research-oriented methods. Nevertheless, the data the reports provided were rich compared with the data available from standard data collection methods.

The reports revealed events that were largely unknown to the well-informed health care organizations and prompted them to reach out to those patients and to directly address their concerns through patient safety improvement mechanisms. The hotline demonstrated that telephone and online reporting are feasible methods for collecting patient safety information and that consumers are largely willing to share this information with the organizations that delivered the care they found problematic. While the logistics of managing patient-reported safety information poses certain challenges to confidentiality, timeliness, and peer review, these potential barriers can be addressed in a way that advances patient engagement in patient safety. The hotline prototype developed in this project, with some modifications, is scalable to diverse settings and can be a valuable piece of the patient safety improvement puzzle for years to come.

On the basis of our experience in designing, developing, operating, and evaluating the Health Care Safety Hotline prototype, we make the following recommendations to AHRQ:

- **Sponsor further development work on the prototype.** While we are not at this time recommending a full scale-up of the prototype, we urge AHRQ to consider follow-on work to answer the primary question raised in this report: whether a “prompted” outreach strategy will succeed in generating a reasonable volume of reports. As a corollary, we also recommend a full usability study of the Web platform and content.
- **Put all of the hotline materials, including the Operations Manual (which has all the forms, surveys, and Web site specifications) into the public domain and encourage their use.** AHRQ has considerable influence on organizations involved in patient safety reporting, monitoring, and improvement. Encouraging health care organizations, regulatory agencies, and others to use the prototype (or components of it) would increase the likelihood that the tools developed here will be employed for a variety of research, patient safety improvement, and public reporting purposes.

This report offers further specifics about the project, including a detailed description of the design, development, and implementation of the prototype; a review of the patient reporting form, the data collection platform and content, and the protocols for data collection, data processing, and data sharing; the findings, challenges, and lessons learned during all stages of the project; and conclusions and recommendations for AHRQ’s next steps. The report also includes detailed appendixes, including the full Operations Manual, with copies of the event reporting forms, surveys, Web content, Web specifications, and instructions.

I. Introduction

Patient safety is a public health problem in the United States and abroad. In the late 1990s, up to 42 percent of the respondents in a Louis Harris Poll reported that they or a close friend or relative had experienced a medical mistake.⁴ A more recent public opinion poll in Massachusetts found that nearly one in four adults had personally experienced a medical error in the past 5 years (or someone close to them had), and half of them reported that the medical error resulted in serious health consequences.⁵ Most of the reported errors (75 percent) occurred in hospitals. The 2014 National Quality and Disparities Report showed that more Americans are getting safer care now than in the past, but it also indicated that the problem persists: there were 121 adverse events per 1,000 hospitalizations in 2013.⁶

Researchers have confirmed that 5 to 10 percent of hospitalized patients suffer injuries,^{7,8,9,10,11,12,13} many of which could be prevented by implementing patient safety-related activities such as those focused on reducing infections, implementing surgical checklists, and introducing health information technology (IT) to improve medication safety.^{14,15,16} To guide such improvement initiatives and to provide for accountability, the Institute of Medicine (IOM) report *To Err is Human: Building a Safer Healthcare System* recommended establishment of a nationwide reporting system for collecting standardized information about serious adverse events, which would be used to identify issues that require additional analyses or a broad-based response and would allow for public investigation and remediation of serious events.¹⁷ A subsequent IOM report called for standardization of reporting and the development of a common taxonomy.² This report listed the critical “domains” that should be included in patient safety event reports, including discovery (by whom and how); attributes (what, when, where, who, why, and an assessment of risk); a narrative account including contributing factors; and, if appropriate, a causal analysis with lessons learned. However, the primary focus of the IOM recommendations was on the reporting of patient safety events by health care professionals. Most adverse event reporting systems (with a few exceptions) are designed to be used by health care providers rather than consumers.

Value of Patient Reporting

In recognition of the fact that some patients have the capacity to serve as “vigilant partners,” patient participation in their own safety has been identified as a potentially important safety improvement strategy.¹⁸ At least three attributes account for the potential power of patients’ participation: intimate knowledge of their symptoms and treatments, motivation to ensure favorable outcomes, and proximity to care.¹⁹ In a series of studies, patients endorsed their willingness to perform error-prevention activities such as asking questions about medications and medical care, helping to mark a surgical site, and reporting an error to the medical staff.^{18,20,21,22,23,24,25}

Building on the concept of the vigilant partner, researchers have shown that patients are able to recognize medical errors, some of which are not otherwise identified by existing health care monitoring systems,²⁶ and are willing and able to report this information reliably.^{27,28,29,30,31,32,33} As demonstrated in the United Kingdom (UK), these reports can strengthen the ability of health care organizations to detect systemic problems in care.

In an early study, Weingart and colleagues³¹ found that 8 percent of inpatients reported adverse events, and 4 percent experienced “near misses.” Importantly, none of these events were documented in the hospital’s adverse event reporting systems. Other groups have used similar methods to elicit patient reports in the emergency department and in a children’s hospital.^{34,35,36} In the largest study of its kind, Weissman and colleagues¹ compared patient reports with medical records and found that 23 percent of the study patients had at least one adverse event detected by interview, and 11 percent had at least one adverse event identified by medical record review. Two-thirds of the adverse events were detected by patient interview alone, demonstrating that patients could identify adverse events of which the hospital was unaware.

This principle applies in ambulatory settings as well. Weingart and colleagues²⁹ found that 73 percent of adverse events occurring in primary care practices were identified by patient report only, 9 percent by chart review only, and 19 percent by both. Similarly, Weingart and colleagues, studying adverse event reports from ambulatory oncology patients, reported that 20 percent of patients identified a concern about safety.^{32,37}

These researchers succeeded in eliciting patient safety reports through patient interviews; however, patient reports frequently require recoding or classification to enable the extraction of the key content, resolve discrepancies or inconsistencies, and assess the attribution of symptoms or complications to care rather than to the natural history of disease. To achieve scale would require the development and deployment of consumer reporting systems that can routinely collect such information, analyze these reports efficiently, and generate results that can motivate patient safety improvement actions within and across health care organizations. In the absence of such simplified data collection approaches, widespread implementation of a consumer-oriented reporting system would be difficult.

Consumer Reporting Systems: Realizing the Potential

Patient reporting remains a promising but unrealized approach for identifying patient safety hazards in health care operations. As reported by Research Triangle Institute (RTI) and Consumers Advancing Patient Safety (CAPS) for AHRQ,³⁸ multiple patient safety reporting systems exist, but only a minority of them permit consumer reporting. These include the Joint Commission; the Institute for Safe Medication Practices’ Medication Event Reporting Program (MERP); the Food and Drug Administration Safety Information and Adverse Event Reporting Program (MedWatch); and the United Kingdom’s National Reporting and Learning System (NRLS). Three systems focus exclusively on patient reports (a Kaiser Permanente system and medication reporting systems in the Netherlands and Australia). These systems, typically focused on communities or patients, have had mixed success in improving the quality, volume, representativeness, and utility of patient safety reports. For example, the UK National Patient Safety Agency recorded only 12 reports in its 3-year operation.³⁹ In contrast, the Danish Cancer Society’s patient reporting system provided enough information and value to encourage the creation of a national patient safety reporting system.⁴⁰ However, no well-established model exists for eliciting consumer-identified patient safety events on the scope envisioned by AHRQ.

Although consumer reporting has the potential to increase knowledge about system failures amenable to analysis and remediation, patient input about care received is currently solicited

mainly through patient experience surveys (such as the Consumer Assessment of Healthcare Providers and Systems [CAHPS] and Press Ganey), which tend to focus on interpersonal aspects of care, communication, and access. These surveys do not explicitly include questions on adverse events, and they typically feature closed-ended questions that do not allow patients to provide narrative information.

In addition to the need for technical infrastructure, logistic considerations, and analytic capabilities for consumer-specific event reporting systems, measures must be taken to ensure that event reporting is acceptable to patients. At Dana-Farber Cancer Institute, for example, a proposal to collect patient event reports was initially met with concern about putting patients in the position of criticizing caregivers.⁴¹ The Danish Cancer Society's consumer reporting system⁴⁰ invites both adverse event reports and positive anecdotes. (This is not to suggest that one effort got it wrong and another got it right—both projects went through various iterations before settling on an approach.)

These past efforts illustrate the importance of design decisions to the success of consumer reporting systems. One important design decision is whether to use “prompted” methods or “passive” strategies to generate reports. For example, an application called PatientSite sent patients an electronic message 10 days after they received a new or changed prescription, inquiring about problems with the medication.⁴² In an evaluation, 50 percent of 267 respondents reported problems filling their prescriptions, 12 percent noted problems with drug effectiveness, and 10 percent described a medication-related symptom. Prompted reporting may lower the threshold for reporting without reducing the severity of reported incidents.

A second design decision is whether to link patient reports with provider reports. Doing so may have some advantages. Patients may be able to provide unique information that is not already collected by health care organizations and reported to a PSO for the conduct of patient safety activities. A PSO, authorized under the Patient Safety and Quality Improvement Act of 2005, can collect, aggregate, and analyze confidential information reported by health care providers. The law provides Federal privilege and confidentiality protections for information that is assembled and reported by providers to a PSO (“patient safety work product [PSWP]”).^b Information obtained from clinician reports can further understanding of patient reports and vice versa. Consumer-reported information may spark safety improvement actions that might not be identified otherwise. Connecting risk management to the patient complaint and grievance process required by the Centers for Medicare & Medicaid Services (CMS) is a well-established practice, and it is therefore not difficult to envision that providers will glean useful information from consumer safety reports.

A third design decision is whether to allow patients and family members to report anonymously—and whether the advantage of having identifiable reports outweighs the possibility that some patients, fearing retribution against themselves or their health care providers, will not report at all, meaning their patient safety concerns will remain unaddressed.

^b The law has specific requirements for PSOs, including the participation of multiple entities and the use of standard reporting formats. For a brief description, see archive.ahrq.gov/news/newsroom/press-releases/2008/psoact.html, accessed August 21, 2015.

In summary, existing research has identified the opportunity to engage consumers in reporting about health-related safety events, but it also points to many difficult challenges, including the need to design systems that: (1) are acceptable to patients, (2) elicit structured and narrative reports using strategies designed to maximize the volume of reports, (3) address care in a variety of practice settings, (4) take advantage of electronic technologies, and (5) allow for coding and classification of preliminary patient reports in a way that ensures quality control and utility to providers and other stakeholders seeking to improve the quality and safety of care.

The Charge from AHRQ

In an effort to explore the untapped potential of having health care consumers provide important information about patient safety events, AHRQ initially awarded a contract to RTI and CAPS to identify key design elements of a consumer reporting system. The researchers collected and summarized information about a variety of patient safety reporting systems around the world and highlighted a unique and critical role for consumer reporting systems. Their report states, in part:

Several reasons can be provided to substantiate the importance of consumer reporting systems. First, not all patient safety events are known (or knowable) in the absence of consumer reporting; many events may not be noticed or detected if ... not reported by a consumer. This may particularly apply to ... events that occur in outpatient settings, where there is less likely to be surveillance than in hospitals. Also, even if an event is identified without consumer reporting, consumers are likely to be able to provide additional important information.... the consumer perspective is a unique source of information for understanding the contributing factors associated with patient safety events, the response of health care providers and systems to these events, and the subsequent impact of events on patients and their families. In many cases, information from health care professionals may not be sufficient to understand a patient safety event ... Further ... providing consumers with the opportunity to report events allows them to be active participants in the pursuit of improvements in patient safety. Beyond positive impacts of this role for consumers, involvement of consumers ... may increase the level of vigilance among providers and organizations, and may increase motivation to produce system change and thereby improvements in patient safety (RTI International, 2010, pp. 6-1 and 6-2).³⁸

Using an iterative, consensus-building process, RTI and CAPS identified six recommendations (and sub-recommendations) for developing an “ideal” consumer reporting system (see Appendix A). These recommendations provided general guidance on the type of information to be collected, the source of the reporting, the types of mechanisms that could be used, the level of operations (local, regional, national, international), the type of infrastructure and analytic functionality needed, modalities and formatting of reports, and whether such data should be linked to provider reports. No implementation recommendations were made other than strongly encouraging pilot development and testing.

AHRQ subsequently sought to determine the feasibility of creating a robust and scalable patient safety reporting system. On June 14, 2011, AHRQ requested proposals through its Accelerating Change and Transformation Through Organization and Networks (ACTION) II contracting mechanism to develop and test a prototype reporting system for patient safety events. As stated in the Request for Task Order, the purpose of the project was to:

- Design and develop a consumer reporting system for patient safety events, using previously determined recommendations for such a system.
- Test the prototype consumer reporting system in a variety of settings and utilizing a variety of methods for patient reporting.
- Collect and analyze consumer reports to determine patterns in events and root causes of such events.
- Compare and contrast those events reported by consumers with those reported by health care professionals, noting the differences and similarities.
- Develop plans for any needed modification and recommendations for expansion of such a system (or systems) nationwide, based on the results of the prototype testing.

The contract was awarded to the RAND Corporation and its ACTION II teaming partner, ECRI Institute, along with collaborators at Tufts Medical Center and Brigham and Women's Hospital in Boston.

Focus of This Research

The research team undertook a project to design, pilot test, and evaluate a prototype for collecting narrative and structured data about concerns that patients have about the safety of their health care, including errors and adverse events. In developing the prototype, called the Health Care Safety Hotline, the research team sought to address several requirements:

- Patients (and other potential reporters, such as family members and other caregivers) had to be able to report online or over a toll-free phone number with a human interface.
- The prototype had to include a formal relationship with a PSO or PSOs.
- The collection of data was to focus on adverse events, near-miss events, and unsafe conditions as perceived by patients to describe the risks and hazards in the delivery of care across the continuum of care.
- The AHRQ Common Formats were to be used to describe patient safety events.

The contract also specified the need for an outreach and information campaign for recruiting health care delivery organizations and for marketing the hotline to consumers. The prototype was to be designed to enable feedback of the narrative and structured data to health care organizations and PSOs.

Project Phases

In the first phase of the project (September 2011 to September 2013), the research team designed and developed the prototype. In the second phase (September 2013 to September 2015), the team implemented the hotline in the pilot communities, tested and refined the prototype, evaluated the types of reports entered by patients and caregivers, and documented the experience of the health care organizations and professionals using the patient event report data to improve care. A multi-stakeholder technical expert panel (TEP) reviewed and provided feedback on each step of the design, implementation, and evaluation process.

Overview of Methods

The research team employed a variety of methods to design, develop, and evaluate the hotline prototype. First, we conducted a comprehensive environmental scan and literature review to identify promising models of consumer patient safety reporting systems, instruments used to collect data, and lessons learned to date. We then used focus groups to identify important domains and language to be included in the event reporting form and used cognitive interviews to create and test the wording of individual items. Using the results of the scan and literature review and employing the new event reporting form, the research team designed the architecture and infrastructure required to operationalize a Web- and phone-based process for data collection, refinement, classification, and reporting. The proposed model was reviewed by the TEP, which included consumer representatives, patient advocates, patient safety experts, health IT experts, physicians, patient and consumer reporting experts, and survey research and reporting experts. Modifications were made in response to the TEP review. In addition, the prototype model was published in the Federal Register^c for public comment, in accordance with requirements of the Paperwork Reduction Act of 1980,^d under direction of the Office of Management and Budget (OMB). Two opportunities for public comment were provided as part of the OMB process, resulting in several hundred comments that led to additional modifications of the prototype. The team conducted several live “webinars” to demonstrate the final Web-based prototype to the TEP, AHRQ officials, and candidate health care organizations.

After the design and development phase was completed, the team recruited two health care delivery organizations within a single community to pilot-test the prototype. The team worked with the two organizations to clarify the legal and regulatory framework for operation of the prototype, developed and implemented an outreach and marketing plan, refined protocols and tested the prototype, and began hotline operations in January 2014.

During the operations period, the research team collected and analyzed Web traffic statistics, analyzed patient-reported events, standardized event descriptions, and revised the reporting instrument. As a part of the evaluation of implementation, the team also conducted a site visit to each of the health care delivery organizations and also met with their Patient and Family Advisory Councils (PFACs) to solicit advice and feedback.

Purpose and Outline of This Report

This report provides findings from all phases of the research project. Chapter II provides additional detail on hotline design and development, including the design of the patient report form. Chapter III describes hotline implementation and refinement. Chapter IV describes the

^c “Agency for Healthcare Research and Quality, Agency Information Collection Activities (Proposed Collection; Comment Request),” Federal Register 77:175 (September 10, 2010) p. 55475. Available from FederalRegister.gov, accessed August 30, 2015.

^d The Paperwork Reduction Act of 1980 (Pub. L. No. 96-511) is a federal law designed to reduce the total paperwork burden the federal government imposes on businesses and individual citizens. The Act imposes procedural requirements on federal agencies (such as AHRQ) that wish to collect information from the public. The statute authorized the White House Office of Management and Budget (OMB) to establish policies on the collection of information and to oversee the implementation of the requirements.

aims, methods, and results of the evaluation. The goal of the evaluation was to test whether the prototype could be used to collect meaningful information about patient safety concerns across a range of settings and to understand challenges in triaging and sharing that information with health care organizations and the public. Chapter V summarizes some of the challenges and lessons learned. Chapter VI presents conclusions and recommendations to AHRQ. The report also contains four appendixes. Appendix A includes the RTI recommendations for an ideal consumer reporting system. Appendix B lists the members of our TEP and their professional affiliations. Appendix C is the Operations Manual, which contains the consumer event reporting forms, surveys, Web content, telephone scripts, specifications for operating the Web site, and other materials. Finally, Appendix D includes the interview discussion guide for the site visits to our community partner organizations.

II. Hotline Design and Development

Although a number of entities and organizations—including governments, professional societies, hospitals, and consumer advocacy organizations—have developed consumer reporting tools to elicit information that might inform patient awareness and improvement initiatives,^{39,41,43,44} no well-established model exists for eliciting consumer-identified patient safety events on a national scale, as envisioned by AHRQ. Therefore, with support from AHRQ and knowledge gleaned from prior efforts, the project team undertook the design and development of a new prototype for a consumer hotline for reporting patient safety events. The first phase of the effort, design and development, was completed between September 2011 and September 2013.

From the beginning of the design phase, the research team intended for the hotline to enable patients and caregivers to voluntarily report their safety concerns through an event reporting form that could be completed online or by phone. The hotline was designed to focus on care across a continuum of settings (hospitals, physician practices, etc.) and to include care provided to both adults and children. The hotline had four key building blocks:

1. A patient event reporting form.
2. A Web-based data collection platform.
3. Protocols for data collection, processing, and sharing.
4. Legal and regulatory protections for the data.

During the development process, the research team had to devise strategies to address many challenges that arose. These included the complexities of the legal context for collecting patient and provider information on safety concerns (including issues of consent and confidentiality), the need to develop language and format acceptable to consumers, and the need to test various report solicitation approaches. We developed procedures for classifying events and for identifying reports about the same events within the health care delivery organizations and devised ways for this information to be protected within a PSO structure. We also developed a marketing campaign and community-specific outreach materials and previewed the Web site interface with patients, families, and caregivers.

This chapter begins with a discussion of design considerations that influenced our work. We then discuss the methods used to develop each of the four key building blocks.

Design Considerations

Translating the observations of patients and caregivers into usable data for safety improvement required maximizing the utility of the voluntarily reported observations while also protecting sensitive information that must be kept confidential under Federal and State laws. A few of the most important design considerations are noted here.

Acceptability of a Hotline to Patients and Caregivers

To be effective, a patient safety hotline must be acceptable to patients and caregivers. In particular, the process used to elicit a report must be easy to understand, and it must be complete. It must protect privacy by ensuring that the person who makes the report (patient, family member, or other caregiver) controls the information that is shared. It should allow for anonymous reporting or offer confidentiality, and it should also offer an option for the patient or caregiver to provide identifying information to enable followup with both the patient and providers who may have been involved in the reported events.

Awareness of Obligations Created by Patient Reporting

The architecture of a patient reporting system must take into account the fact that patient-reported information about patient safety-related health care experiences is not subject to the same peer-review protections as information that health professionals submit to hospital-based adverse event reporting systems.¹⁷ To the extent that patient reports represent grievances under CMS Conditions of Participation (Medicare), health care delivery organizations are obliged to respond in a timely and formal manner.^e While health care organization analyses of patient safety reports are protected under many State peer-review protection laws and by the Federal PSO umbrella, the initial reports themselves may represent a potential liability risk that health delivery organizations will need to take into account.^f

Prompted Versus Passive Outreach Strategies

The method used to solicit reports may affect the number and type of reports received. The research literature shows that a prompted reporting method (i.e., actively soliciting reports from subjects in person or by phone outreach) can result in higher patient participation.^{1,29,31} In contrast, passive solicitation strategies, which involve simply making a Web site or phone number available, typically achieve substantially lower reporting rates. Because the reports are likely to come from highly motivated patients and caregivers, the sample may not be representative of the range of patient safety issues occurring in practice. Low response rates also suggest underreporting of events, and when the number is very small, it is difficult to track trends reliably over time. Approaches that incorporate aggressive public education and outreach may achieve higher reporting rates, although this strategy has not been fully evaluated. To date, no study has specifically compared prompted and passive solicitation modalities. In addition, national and locally based reporting systems may perform differently, as patients and families may be more motivated to report to local systems, where they have greater affiliation and perceive greater potential to benefit personally from improvements.

Balancing Multiple Objectives

A patient safety reporting system created to support health system-based improvements has a different aim than one intended primarily to make information freely available to the public. A

^e The patient's rights provisions of CMS Conditions of Participation are found at 42 C.F.R. 482.13.

^f Materials that are not gathered to be reported to a PSO and are not actually transmitted to a PSO by a health care organization do not qualify for the privilege and confidentiality protections of the Patient Safety and Quality Improvement Act of 2005. A significant amount of data remains outside the "patient safety work product" definition.

system designed to provide information to the public might have little screening or editing and would seek to make reports quickly and efficiently available to those potentially seeking care. Patient and caregiver ratings could be aggregated and displayed on Web sites such as Yelp or in publications such as Consumer Reports. In contrast, a system designed to support patient safety improvements within a health delivery operation would seek to combine patient reports with other sources of information and would prioritize peer review, regulatory compliance, and quality improvement over public reporting and public accountability.

Creating the Event Reporting Form

We used multiple methods to develop the new event reporting form for collecting patient safety observations from patients and caregivers. We modeled the form, in part, on a survey previously developed by three of the research team members (Weissman, Schneider, and Weingart) for a study of patient-reported adverse events in Massachusetts.¹ We first conducted an environmental scan (i.e., a review of existing instruments) and reviewed development guidelines for patient surveys. Then, after we developed the initial form, we elicited feedback from two focus groups. We used a series of cognitive interviews to refine the questions and revised the draft form in response to the interviews and feedback from technical experts, patient advocates, and the public. We provide more information on each of these methods in the following sections.

Environmental Scan

The research team conducted an environmental scan of existing patient safety reporting instruments to identify the state of the art in patient safety reporting. We also reviewed the minimum dimensions for adverse event reporting recommended by IOM and the AHRQ Common Formats.^g

We examined instruments for collecting adverse events, errors, near misses, and unsafe conditions in the United States and other countries and identified 27 consumer-enabled reporting systems and 14 survey tools with questions about health care safety. We focused on event type (e.g., medication or device concerns, clinician or facility concerns), reporting mode (e.g., online, phone), key terms used (e.g., mistake, problem, near miss), and specific health care patient safety survey items.

We found none of the existing data collection tools to be completely satisfactory for the purpose at hand. Our prior work suggested the importance of distinguishing injury (negative effects) from errors, which we corroborated in subsequent focus groups. We used the literature review and the environmental scan to develop a catalog of potential questions, from which we created a limited set. Our primary concerns were the clarity of the questions, their face validity, and the frequency of reported response categories. We selected response items that we believed to be most commonly encountered and reported. Because of space constraints, we could list only a limited number of response elements. Each category included an open-ended response; our intent was to update the form in future iterations, based on the number and type of responses received.

^g For more information on AHRQ's PSO program and the Common Formats, visit <https://psa.ahrq.gov/common>.

Patient and Caregiver Focus Groups

In December 2011, we conducted two focus groups with patients and patients' family members. The first focus group took place in Boston and was attended by 12 English-speaking adults who had either experienced a safety event personally (n=7) or had a family member who had experienced a safety event (n=5) in the previous 12 months. The second focus group took place in Los Angeles and was attended by nine Spanish-speaking adults who had either experienced a patient safety event personally (n=5) or had a family member who had experienced a safety event (n=4) in the previous 12 months. Participants in both groups were diverse with regard to gender, race/ethnicity, and education.

In advance of the focus groups, we gave the participants a short reporting form (which could be completed in 5 to 10 minutes) that asked about patient safety concerns they had experienced. The responses provided us with an idea of the breadth of the participants' experience and their specific concerns. The form also focused the participants' attention on the matter at hand and essentially primed them for the discussion to follow. During the focus groups, a moderator used exploratory and confirmatory approaches to investigate terminology, concepts related to patient safety and relationships between the concepts, discovery of patient safety events, reporting preferences, awareness of existing reporting systems, and the draft reporting form.

Cognitive Interviews

To inform the choice of specific terminology to be used in the patient event reporting form, the order of topics, and the wording of individual items, we conducted seven cognitive interviews. Cognitive interviews are a form of pre-testing in which the investigator asks a sample of likely respondents how they understood the questions that were asked and then compares their responses to the intent of the questions, in order to identify any problems with formatting, comprehension, or acceptability. The cognitive interviews took place in February and March 2012. All interviews were conducted in English; four of the interviewees had experienced a patient safety event, and three were family members. Participants were diverse with regard to gender and education, as well as type of patient safety event. We tested interviewee understanding of specific terminology, the flow and redundancy of questions, and the interpretation of items on the event reporting form.

Design Changes in Response to Patient and Family Member Feedback

The research team made a number of changes in the design of the event reporting form in response to the input received. For example, focus group participants did not mention events with adverse or negative effects when they were asked about patient safety issues. They understood the concepts of "medical mistake" and "harm/injury" more clearly than they understood "patient safety." We found that the term "patient safety concern" elicited comments on service complaints and communication issues. Both focus groups found the term "complication" ambiguous. Participants agreed that three categories of patient safety concerns were understandable and sufficient: medical mistakes, harm or injury, and unsafe conditions.

We therefore revised the initial reporting form to use the terms "mistake" and "harm" throughout, added specific questions about setting, and added a question about whether a patient

was told about possible negative effects. The revised form was designed to ensure that a patient or caregiver would report only one concern or event at a time.

The focus group findings also confirmed the need to target the reporting form to the seventh-grade reading level, offer Spanish and English versions, offer multiple modes of reporting (i.e., Web and phone), follow up with those who report an event, and prioritize patient confidentiality within the system.

We also refined question content in response to the cognitive interviews. We focused the content and shortened the number of structured questions from 69 to 25. We also reordered the topics, rephrased and simplified wording, and limited response set lists to no more than five items. Open-ended questions with free-text narrative boxes were included at the beginning of the reporting form to allow patients and caregivers to tell what happened in their own language, and we limited the list of “contributing factors” to those that patients and families can observe directly and report on reliably.

External Review

In March 2012, the research team convened the first in-person meeting of the TEP. (The TEP members and their affiliations are listed in Appendix B.) The TEP members provided multi-stakeholder expertise on relevant dimensions of the project, including patient safety, reporting systems, patient perspectives, and survey methodology. The following topics were discussed during the initial in-person meeting: background and policy context, project goals and timeline, opportunities for stakeholders, instrument development, sections of the draft event reporting form, outstanding design issues, and criteria for partner health care delivery organization selection.

OMB and Public Comment

The Paperwork Reduction Act of 1980 requires clearance^h by OMB when standardized data collection from 10 or more respondents is to be performed on behalf of the Federal Government.

In June 2012, RAND submitted the Web and phone reporting forms, the phone interview protocol for the patient clarification process, and the protocol and questions to be used for the provider supplementation process. As required by the clearance process, notice was published in the Federal Register on Monday, September 10, 2012, and ran for 60 days. After revisions were made to the patient event reporting form, a second notice was published in the Federal Register on Thursday, June 6, 2013, and ran for 30 days. More than 100 sets of comments (45 with supporting documentation) were submitted by the public and reviewed by the research team.

Design Changes in Response to Public Comment

Some of the people who made public comments misconstrued the intent of the project to be the creation of a national government-run consumer reporting system. The team clarified that the intent was to create and evaluate a local prototype system—a potentially replicable model that

^h “Clearance” is the term used for the process of obtaining approval from OMB for federally sponsored data collections (see www.hhs.gov/ocio/policy/collection/infocollectfaq.html, accessed July 27, 2015).

health care organizations and other entities could use to elicit patient safety information directly from patients and caregivers with first-hand knowledge of their experience. Lessons derived from the testing of the prototype were intended to inform the design of future systems, with an emphasis on local adoption and replication rather than national deployment (which was seen to have had limited effectiveness based on 5 years of experience in the United Kingdom). Media and advocacy organizations took a generally supportive editorial view of the proposed reporting system, acknowledging the opportunity to enlist consumers in improving care safety.⁴⁵

In response to the public comments and on the basis of the associated extensive review of the instrument, the research team revised the design of the hotline to include additional specific strategies to protect patient privacy, as well as protections for non-retaliation and for providers. No patient reports were to be shared with professionals or facilities unless the patient consented explicitly to such sharing and designated the facility or provider that should receive the information. All members of the research team would become members of the ECRI Institute PSO workforce. In compliance with the PSO statute, any material shared with the PSO regarding a report would include a header specifying that the included material is a patient safety work product (PSWP). Finally, in response to specific comments, the team made 19 revisions to the reporting form—changes in wording, the deletion of two items, and revisions of two items to be open-ended questions. There was no change in the survey burden or intent.

RAND submitted the final Section 508-compliant documents to AHRQ for submission to OMB on July 29, 2013, and received OMB approval on August 23, 2013.

Final Design Choices

Under the contract, AHRQ envisioned a passive solicitation strategy that relied on the participating health care delivery organizations to advertise the existence of the Web site and toll-free phone number through marketing efforts (e.g., posters, postcards, publication of the URL on their Web sites); the contract (and budget) did not envision the use of prompted solicitation methods such as post-discharge surveys or training a cohort of patients to record their observations about safety. Phone access was offered to accommodate non-English-speaking patients and families (the project budget did not allow for replicating the Web site in multiple languages).

The approach we adopted was to explore the challenges and opportunities of using consumer reports to drive health system-based patient safety improvements (rather than focusing on public accountability or patient safety research).

We used a variety of methods to ensure that the prototype reporting form was acceptable to patients and other caregivers, (e.g., we incorporated user perspectives on focus and terminology). We tested the wording of our data collection instruments to ensure that it was patient-friendly, but also that it tracked with the AHRQ Common Formats, enabling it to serve as a standard for reporting.

We also paid careful attention to creating a prototype structure that would make use of PSOs to allow health care organizations to analyze (and learn from) information contained in consumer reports without fear of liability risk.

We made these design choices prior to implementation, but we also realized that ongoing feedback from hotline users would be useful. We therefore created a voluntary and confidential post-report “usability” survey to collect such feedback.

Usability Survey

The 13-item post-submission usability survey was to be offered to consumers immediately after they completed a report online. It was intended to evaluate whether patients and caregivers found the hotline easy to use, effective, and efficient and whether they were satisfied with their hotline experience.

The survey was a modified Lewis Post-Study System Usability Questionnaire,⁴⁶ with minor edits to make it relevant to the hotline (e.g., we replaced “this system” with “hotline” and added several questions). Completing the survey was estimated to take 5 minutes or less. The reading level of the survey was fourth grade, seventh month. The Operations Manual presented in Appendix C contains additional information about the survey, as well as the survey itself.

The Final Reporting Form

The final prototype patient reporting form has several innovative qualities that give patients options about the use of the information they provide and that allow for the collection of information specific to the concern being reported:

- The reporting form gathers information about the patient safety concern in both an open-ended narrative format and through a structured set of questions.
- The reporting form has a modular construction, and screener questions allow patients and caregivers to answer only those questions that pertain to their concern. The use of screener questions within a modular format allows the form to “drill down” to gain specific information based on the type of concern reported, as well as standard information collected for all concerns.
- Reports can be made by patient or by proxy (i.e., family member or other caregiver).
- The person making the report has the options of anonymity and confidentiality.
- The person making the report has the option of whether or not to allow followup.
- The patient or caregiver can control the sharing or accessing of the information within the health care delivery organization.
- The patient or caregiver has the option of identifying a particular clinician or health care facility.

Overview of the Patient Event Reporting Form Content

The final reporting form can be used with either the Web or the phone. It was constructed in modular form to capture key information about the event and the circumstances surrounding it in the following modules:

- Module 1: Introduction
- Module 2: Description of your safety concern
- Module 3: Mistake

- Module 4: Negative effect
- Module 5: Contributing factors, changes in care, discovery, and reporting
- Module 6: Patient and clinician/facility information

The modular format facilitates the input of information by providing some guidance, while also allowing patients/caregivers to skip around and answer only those questions they are able to answer. The reporting form is formatted with skip patterns to allow for reporting concerns that are considered medical mistakes, negative effects, or both.

With the required consent language, the event reporting form is at the eighth-grade reading level and scored an 8.0 on the Flesch-Kincaid reading scale,¹ with 4 percent passive sentences. Without the consent language, the reading level of the reporting form is seventh grade (7.7 on the Flesch-Kincaid reading scale).

We describe the contents of each module briefly below. The Operations Manual (Appendix C) contains the Web and phone versions of the event reporting form and includes a more detailed description of the form.

Module 1: Introduction

The introduction module provides information about the purpose of the reporting form, the time required to complete it, and other requirements and asks some questions pertaining to informed consent and the age of the patient or other person making the report. It includes a definition of the types of safety events that are appropriate for reporting to the hotline. It also advises patients and caregivers that other types of concerns, such as complaints about amenities (e.g., food or parking) or grievances that are not related to the safety of care, should be reported through other systems.

Module 2: Description of Your Safety Concern

This module contains a set of open-ended questions designed to obtain a narrative description of the patient safety concern. Examples of the questions are shown in Figure 2.1. The open-ended questions are followed by a series of questions with structured response elements about what happened, when and where it occurred, whether there were negative effects, and the type of such negative effects. A pop-up box provides definitions of the terms used.

Figure 2.1. Sample Open-Ended Questions in the Patient Event Reporting Form

<p>Please tell us in your own words about the safety concern. Then we will ask some specific questions to make sure we understand what happened.</p> <p>What happened? [text box]</p> <p>Where do you believe it happened? [text box]</p> <p>When did it happen? [text box]</p> <p>Why do you think this happened? [text box]</p>
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ⁱ The Flesch-Kincaid reading scale is a tool designed to test how difficult a reading passage is to understand. It has become a standard readability formula used by U.S. government agencies.

Modules 3 and 4: Mistake and Negative Effect

A structured set of questions enable patients and caregivers to report about two types of safety events: (1) a suspected medical error or mistake—whether or not that medical error was associated with harm or injury; and (2) negative effects related to health care (e.g., harm, injury, adverse event). The patient or caregiver is asked whether he or she believes a doctor, nurse, or other health care provider made a medical mistake or error in the patient’s care; whether there was a negative effect; or whether he or she does not know if there was a mistake or a negative effect. If the respondent does not know whether the patient experienced a medical error or mistake or a negative effect, the form allows him or her to skip ahead to answer other questions (e.g., consent to share the response, contributing factors).

A patient safety event taxonomy using drill-down (multilevel) menus is embedded in the form. The prototype contains two top-level categories, each of which has a drill-down list of subcategories from which patients or caregivers select items to describe the mistake and/or negative effect experienced:

- Mistake
 - Related to medicine
 - Related to test, procedure, or surgery
 - Related to pregnancy or childbirth
 - Related to a diagnosis or advice from a doctor, nurse, or other health care provider
 - Related to poor cleanliness or poor hygiene
 - Related to something else, or more than one mistake

- Negative effect
 - Related to medicine
 - Related to test, procedure, or surgery
 - Related to pregnancy or childbirth
 - Related to a diagnosis
 - Related to advice
 - Related to unclean or unsanitary care
 - Related to something else, or more than one negative effect

- Type of negative effect
 - Physical
 - Emotional
 - Both

Module 5: Contributing Factors, Changes in Care, Discovery, and Reporting

Module 5 asks about the patient or caregiver’s perception of contributing factors. The respondent is given the option of describing in his or her own words the factors that might have contributed to the safety event; he or she is also asked whether each of a limited list of potential factors might have contributed. Included in this list are those factors that are plausibly directly observable by a patient or caregiver and are considered valid and reliable based on prior testing (e.g., prior surveys such as the CAHPS) or have been used in other patient safety reporting instruments. The list was not designed to be comprehensive; rather, it offers the most common

responses. The form also offers opportunities for open-ended responses on many questions so that future versions can be refined. This section of the reporting form also asks whether the patient reported the event to a health professional, manager, or other person.

Module 6: Patient and Clinician/Facility Information

This module offers the patient or caregiver the option of identifying the health care personnel involved and providing contact information. It asks whether the patient or caregiver would like to grant consent for the report to be shared with a contact person at the facility, (e.g., an administrator or patient safety officer, or with individual doctors, nurses, or other health care professionals identified by the person making the report). The patient or caregiver has the option of recording the report anonymously or including his or her name and, if the respondent is a caregiver, his or her relationship to the patient. This module also asks whether the research team may contact the patient or caregiver for more information about the report. Finally, the form asks for demographic information about the patient and contact information about any clinician/facility involved.

Designing a Web-Based Data Collection Platform

The hotline prototype is Web-enabled. Access is controlled based on the role of the user (e.g., hotline administrator) and also on the specific types of data being collected. The Web interface captures the details of patient-reported safety events.

System Processing Requirements

The hotline employs a Microsoft Technology platform, including the latest operating system and software. It utilizes Microsoft Windows 64-bit 2008 R2 servers, Microsoft SQL Server 2012 64-bit, and ASP.NET Architecture. It uses a well-known Web server architecture, in which a front-end tier (a Web browser) communicates with a back-end tier (a database) through a Web server tier. The minimum requirements on a single server are shown in Table 2.1.

Table 2.1. System Processing Requirements

Operating system:	Microsoft Windows 64-bit 2008 R2 servers
Database:	SQL Server 2012 64-bit
Web server:	IIS 7
Security:	Secure sockets layer (SSL) certificate

The prototype utilizes Hypertext Transfer Protocol Secure (HTTPS), which is a combination of the Hypertext Transfer Protocol with the SSL protocol to provide encrypted communication and secure identification of a network Web server. An SSL certificate was procured by ECRI Institute to establish this secure transfer of data. The prototype supports the current and previous versions of Internet Explorer.

Telephone

Individuals may also access the hotline via the designated toll-free phone number. A phone-intake administrator (in the case of the prototype, a member of the research team) guides the

person making the report (in either English or Spanish) by accessing the Web site and entering a new event. The patient or caregiver's responses are entered in the first person.

Web

The hotline Web site was tested in a “staging” environment prior to deployment. All testing steps were intended to ensure that the Web site would be usable and efficient for all users. Functionality testing was conducted to ensure proper functioning of the Web site, survey skip logic, and decision support. Integration/usability testing was conducted to ensure that users of the system would be able to interface in a proper and efficient manner pertaining to workflow. Editorial content testing was conducted to confirm correct spelling and punctuation. Performance testing was completed to ensure that the database is properly architected and that the Web site code is efficiently written. Regression testing was performed along with functional testing to ensure that any changes made or “bugs” fixed did not introduce new problems. A Section 508 compliance review was conducted to ensure that the Web site is accessible to people with disabilities.

A more detailed description of the functional and nonfunctional requirements for operating the hotline is given in the Operations Manual in Appendix C.

Protocols for Data Collection, Processing, and Sharing

The protocol for processing hotline reports was designed to address several related priorities. First, the reports were to be screened for ongoing risks of harm that require immediate action or escalation, assuming the patient or caregiver has provided sufficient identifying information and has given permission to be contacted. This issue requires timely review by physician members of the research team. Second, we sought to ensure the confidentiality of respondents and personally identifiable information about care providers. Third, to clarify areas of a report that were confusing or ambiguous (e.g., degree or nature of harm, patients' or caregivers' attribution of causes, persistence of symptoms), the research team needed a process to elicit clarifying questions with an initial screen by a member of the research team as well as physician review. Fourth, a process for sharing information with key contacts at the partner health care organizations was needed to ensure that the information was received in time for the organization to conduct its own analysis and respond within the CMS regulatory timeline for addressing potential grievances. Figure 2.2 provides an overview of the steps for processing hotline reports. The steps are described below.

Answers to questions that explicitly request identifying information, however, are not scrubbed. Complete instructions on how to audit or scrub a report, which prepares it for being shared, are given in the Operations Manual (Appendix C). The screening and auditing process is to be completed within 72 hours of receipt of the report.

Step 4: With Consent, Research Team Sends the Report to Provider

If the patient or caregiver consents to having the report shared with the relevant health care facility or provider, a PDF file of the scrubbed report is uploaded to a secure Web site that is accessible to the named provider. This is done within 72 hours to minimize delays and to enable the health care delivery organization to follow up with the patient or caregiver. Notification to the relevant health care facility or provider is sent via email, with a link to the report on the secure Web site.

Step 5: With Consent, Research Team Conducts a Clarifying Call

As part of Step 5, a physician on the research team reviews the report to determine whether there are any concerns or areas that require clarification. If clarification is required, a followup call is made to the person who made the report. The additional information elicited through the clarifying call is uploaded to the secure Web site if the patient or caregiver gives permission. The revised, clarified report is uploaded to the secure Web site, and the relevant health care organization or provider is notified via an email with a link to the clarified report. The Operations Manual (Appendix C) provides more information on the clarification call and gives examples of the types of questions asked.

Step 6: Research Team Asks Provider Supplementation Questions

Within 45 days of sharing the report with the named provider (Step 4), the research team reaches out to the health care delivery organization or facility with a series of questions about what the organization did with the patient-reported information. For example, the health care organizations participating in the pilot project were asked whether they were able to match the patient event report with any internal source of information (e.g., adverse event report, patient complaint) and what actions they took (e.g., conducting a root cause analysis [RCA], reaching out to the patient) after having received the information to improve patient safety within the organization. These questions are included in an administrative intake page linked to each report and are referred to as Module 8 questions (see the Operations Manual).

The sharing process is documented in an Excel spreadsheet. The research team documents the report identification number; the relevant health care organization; the date submitted; the date sent to the facility/provider; the date the clarified report was sent, if applicable; the date when the followup supplementation call is due (e.g., 45 days after receipt of the initial report); and the date on which the supplementation process with the relevant health care facility or provider was completed.

Step 7: Research Team Produces Non-Identifiable Aggregate Reports

Both before and after completing the clarification process, a physician member of the research team reviews and classifies each event according to the AHRQ Common Formats event type, harm scale, and duration of harm. The clinician also comments on the event's preventability and contributing factors. The same reviewer classifies the initial and (if completed) clarified report.

For research and summary purposes, the hotline can generate non-identifiable aggregated reports on the types of events reported.

With each report, progress through the seven processing steps is tracked in an administrative page linked to the report. The administrative page can be viewed by the research team but not by the patient or caregiver who made the report (details are outlined in the Operations Manual, Appendix C).

Clarifying Legal and Regulatory Protections for the Data

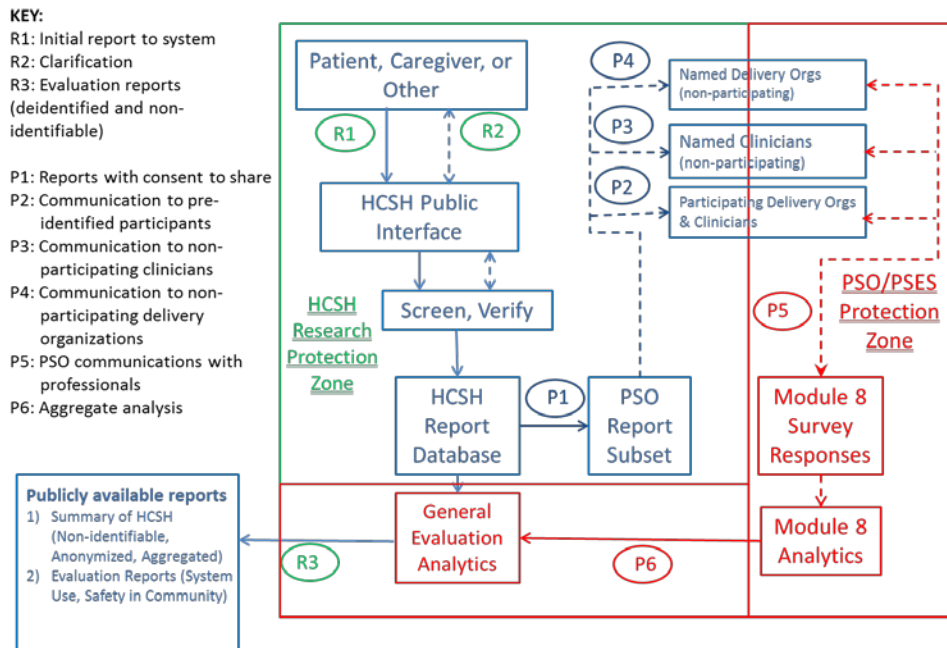
The research team consulted with legal counsel for AHRQ and the Department of Health and Human Services (HHS) to develop a clear and detailed understanding of the legal protections applicable to information provided to the hotline by patients and caregivers (see Figure 2.3). At least two forms of legal protection are applicable: First, the confidentiality provisions of the statute that created AHRQ^j requires that information obtained in the course of AHRQ-supported activities that identifies individuals or establishments can be used only for the purpose for which it was supplied. Information that is obtained in the course of AHRQ-supported activities and that identifies an individual may be published or released only with the consent of the individual who supplied the information or is described in it. There are civil monetary penalties for violation of the statute. The research team and AHRQ also determined that there is currently no requirement for destruction of the research data. However, reuse of the data would be allowed only for analyses consistent with the original purpose for which the data were collected. Second, the Patient Safety and Quality Improvement Act of 2005 establishes a framework with which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events.^k

The information in the hotline database is considered confidential research data. Under AHRQ's authority to protect such data, this information cannot be publicly disclosed. If the consumer provides permission, the reported information can be sent to any named health care delivery organization or clinician. These organizations and clinicians can choose to analyze this information within a patient safety evaluation system (PSES) and can match the information to, for example, adverse event reports made by their health care staff. The information is treated as PSWP and cannot be publicly disclosed. The patient- and caregiver-reported information held by the hotline is kept in a database separate from the data provided by health care organizations to the PSO, in order to prevent disclosure of PSWP. The research team may produce aggregate, non-identifiable summaries and advisories. Once this research project is completed, the hotline database will be retained within the PSO.

^j The Healthcare Research and Quality Act of 1999, Pub. L. 106-129, codified at 42 U.S.C. 299c-3(c).

^k The Patient Safety and Quality Improvement Act of 2005, Pub. L. 109-41, codified at 42 U.S.C. 299b-21-b-26.

Figure 2.3. Hotline Data Flows and Legal Protections



Summary

Through the design and development process, the research team identified the following key findings and attempted to address them in the development of the prototype. First, a number of design choices must be taken into consideration in developing a patient safety reporting system for consumers, including acceptability to patients and caregivers, awareness of the obligations created by patient reporting, and the choice of an outreach and marketing strategy. In addition, because health care organizations have existing requirements for responding to complaints and grievances—including those in State and Federal law—the consumer event reporting system must be in line with these requirements. Second, language is important in developing a reporting form for consumers. The patients and caregivers with whom we spoke struggled to understand the language and structured responses in the AHRQ Common Formats, which were developed to standardize reporting by health care professionals. However, there are some patient safety terms that are well understood by patients and caregivers, and these should be used in event reporting forms for patients. Third, encouraging narrative through the use of open text boxes at the beginning of a reporting form allows patients and caregivers to tell their entire story in their own words before answering structured questions. Both narratives and responses to questions are meaningful, and encouraging narrative responses may encourage consumers to finish their reports, even if the following structured items do not appear to be responsive to their specific experiences. Fourth, because patients and caregivers fear that reporting may have a negative impact on their future care, sufficient patient protections need to be in place and must be communicated early and well to patients and caregivers. Focus group participants told us that patients and caregivers are also skeptical about the impact that their reports will have on the health care system, so marketing materials should explain how the information will be used to

improve patient safety at health care organizations and should provide assurances about the importance of respondents' contributions.

III. Hotline Implementation and Refinement

The second phase of the project, from September 2013 to September 2015, included both implementation and refinement of the prototype and involved the following activities:

- Selecting the pilot community and health care organizations.
- Developing and implementing an outreach and marketing plan.
- Launching the hotline.
- Refining the prototype.
- Extending the outreach.

We used multiple methods for selecting the pilot community and participating health care delivery organizations; clarifying the legal framework for prototype operation; developing and carrying out an outreach and marketing plan for notifying organizational leadership, physicians, nurses, professional associations, and other community stakeholders about the prototype; developing and implementing a marketing plan for consumers; refining the prototype and protocols through testing; operating the hotline; and processing the reports that were submitted.

The evaluation was also conducted during this phase. The activities related to the evaluation are described in Chapter IV, but we discuss here the implementation of the hotline in the pilot community and ongoing efforts to refine it, as well as efforts to reach out and inform patients and caregivers about the opportunity to report patient safety problems they observe in their own care.

Selecting the Pilot Community and Health Care Organizations

To select an appropriate pilot community to test the hotline, the team sought health care organizations that had a demonstrated commitment to patient safety improvement and a representative patient population and that resided in a community of moderate size, so that an outreach effort could effectively reach the target audience. Participation in a PSO was also an important consideration because PSO protection would offer a mechanism for sharing and analyzing reports.

We identified 18 health care delivery organizations that had a history of patient safety work in a PSO context and that might have an interest in collaborating on deployment and testing of the prototype. The primary criteria for selection were (1) affiliation with ECRI Institute PSO, which simplified PSO issues; (2) geographic colocation as major health care providers in one community; (3) representativeness of the population served (adult, pediatric, mixed socioeconomic status, and race/ethnicity); and (4) enthusiasm for participation. Based on these criteria and the initial information we gathered, we reached out to 10 organizations and then convened teleconferences with the four that best fit our criteria to discuss their interest in the project. Two health care delivery organizations in one metropolitan area were selected and agreed to participate. The organizations were in the northeastern United States, which facilitated site visits, but this was not a determining factor. Other sites we considered and explored (including a large health system in a major metropolitan area) did not fit all of the criteria. Together, the two selected organizations had several favorable features. Both were integrated health care delivery organizations and members of a PSO. Both also had leaders committed to improving quality and patient safety, interest in transparency about care and in reaching out to

patients and caregivers, representation of a broad population, and a history of community collaboration.

Legal and Organizational Requirements

To participate in the pilot project, the leadership of the two health care delivery organizations each signed a memorandum of understanding (MOU) and a data use agreement (DUA) with RAND, as well as a PSO agreement with ECRI Institute PSO. The purpose of the PSO agreement was to ensure privilege protection for internal analyses of patient-reported events. Each health care delivery organization designated one person from its implementation team to serve as the primary liaison with the hotline research team on all aspects of implementation, including the development of protocols for processing patient and caregiver reports and for identifying any matching adverse event reports made by staff within the organization.

The research team confirmed that the participating organizations had policies in place that would prevent retaliation against any patient or caregiver who reported safety concerns. The team also collected the organizations' policies and training materials related to patient safety to confirm that they upheld "just culture" principles, emphasized opportunities for learning rather than blaming individuals, and recognized the role of systems in introducing or failing to mitigate patient safety risks.

Organizational Characteristics of Participating Organizations

One organization serves a specialty population and engaged one large hospital and more than 15 ambulatory practices in the pilot project. The other organization serves adult and pediatric populations and engaged two hospitals, in-hospital pharmacies, more than 20 ambulatory practices, several specialty centers, and libraries associated with it. Both organizations have a history of hospital-based adverse event and complaint reporting systems that share reported events with quality and patient-relations departments. Both encourage adverse event reporting by staff and have internal mechanisms for staff to report incidents in order to promote learning, improve service quality, and enhance risk management.

Developing and Implementing an Outreach and Marketing Plan

To communicate the availability of the hotline to patients and caregivers, the research team, AHRQ, and the pilot organizations developed clear descriptions of the hotline that could be featured in materials selected by the organizations, including 4-by-9-inch cards/brochures, folded business cards, and posters. The descriptions were developed in both English and Spanish. The materials contained the ECRI Institute and RAND logos, referenced the two participating health care delivery organizations, indicated that the project was funded by AHRQ, and referred to the hotline as a "research project."

The research team and the health care organizations discussed additional options for communicating hotline information to patients and caregivers, such as "piggybacking" on patient experience survey mailings and adding links to Web portals. In collaboration with the partner health care delivery organizations, the research team determined that these options would require additional time to implement because of existing vendor contracts and work flows and thus were not realistic for the remaining time period of the project.

Clinicians and staff of the participating health care organizations who had not participated in the initial planning and roll-out of the hotline received a letter from the leadership of their own organization that discussed the purpose of the hotline, the plan for communicating information about it to patients and caregivers, how the patient and caregiver reports would be used, and how clinicians and staff could help.

As part of the announcement of the launch of the pilot project and to gain buy-in from provider organizations, we also drafted and sent letters from RAND and the two health care organizations to other relevant entities, such as State-level professional associations and State regulatory agencies.

Although media outreach was not in the initial marketing plan (the team had decided not to consider active outreach to the media until the hotline had been operating for several months), the team and the health care organizations developed a plan for responding to media inquiries, including designated points of contact and sample frequently asked questions (FAQs). We did not receive any media inquiries.

Launch

In February 2014, after the research team and organizations had adequately tested the Web site, the notification letters and other communication materials (e.g., posters, business cards) were circulated publicly and throughout the two health care delivery organizations. Outreach materials were distributed to hospitals (posters and brochures for hallways and lobbies/registration desks, and business cards placed in admission packets), outpatient practices (posters, brochures, and business cards), pharmacies (brochures and business cards), and other facilities affiliated with the organizations (posters, brochures, and business cards). At this time, the Web site went live and started accepting reports.

Refining the Prototype

During this period, the research team, the TEP, AHRQ, and the participating health care organizations (including their PFACs) continued to identify opportunities to improve the “look and feel” of the Web site platform and content and to better engage consumers.

During the first year of the implementation phase (2013–2014), changes in the patient event reporting form included revisions to formatting, clarification, and more consistent use of the terms “grievance” and “complaint” throughout the introductory Web site pages and FAQ pages. We also added a request for permission to share the name of the patient in the case of reports submitted by caregivers who agree to have it shared with the relevant clinician or delivery organization. We also increased the character limit of free text boxes to allow for longer narratives. These and other changes were incorporated as the need arose and were batched for quarterly implementation.

Convening Stakeholders

In June 2014, the research team convened the second in-person meeting of the TEP, which was attended by the AHRQ Project Officer, TEP members, and implementation leaders at the two health care delivery organizations.

Technical Expert Panel Feedback

The research team used feedback from the TEP as formative evaluation data, drawing from the TEP's recommendations and those of the PFACs (described below) to make midcourse corrections. The TEP members focused their comments on how to improve outreach and marketing, not on changing the data collection strategy. Key recommendations from the TEP for the reporting form and Web site included:

- Be clearer on the Web site and in outreach materials about the type of safety concerns that are of interest and what the benefits to patients might be.
- Terms like “safety” and “error” may suggest that the hotline is interested only in serious adverse events, whereas terms like “concern” may suggest that it is interested in a broader set of issues.

Key recommendations for outreach included:

- Add information about the hotline to discharge packets, since patients are reflecting on their care at that time.
- Reach out to patients who are known to have experienced safety concerns.
- Share information about the hotline with the broader community.
- Raise the project's profile in the media.
- Include a reference to the hotline in CAHPS, Press Ganey, or other patient experience surveys.
- Engage patient advisors in discussions about how to improve and promote the hotline.

Patient and Family Council Feedback

In September 2014, the research team met with the PFACs to obtain input on the prototype. The meeting started with a presentation that included a short demonstration of the prototype. After the demonstration, members of each PFAC were asked to address two main questions:

- Given what you heard here about our current dissemination and outreach strategies, how would you suggest that we focus or improve our approach to providing patients and families with an opportunity to report? How would you suggest that we go about raising awareness among patients and families?
- Do you have any suggestions for different or preferred dissemination and outreach strategies involving the community?

Those discussions brought forward another set of recommendations for the reporting form and Web site, including:

- Focus less on research and more on the opportunity for learning.
- Remove the term “investigator,” which might suggest a “government investigator” to some people.

- Emphasize that the hotline aims to use the reported data to try to prevent future patient safety events.
- Emphasize the options of reporting anonymously and confidentially.
- Make clearer that family members and other caregivers can submit reports.
- Reference the names of the participating health care delivery organizations on the home page.
- Emphasize that patients will not be retaliated against and that making a report will not result in providers getting into trouble.

Key recommendations for further outreach efforts included:

- Move information about the hotline from admissions packets (which patients and caregivers rarely have the time or energy to review) to discharge packets (which patients and caregivers sometimes review when they get home).
- Include information about the hotline in followup calls completed a few days after a hospitalization.
- Post information about the hotline in hallways, family resource rooms, elevators, emergency departments, and surgery areas.
- Spend more time educating health system staff—including social workers and case managers—about the hotline.
- Publicize the hotline to the larger community.
- Add a reference to the hotline to Press Ganey or other patient experience surveys.

While we considered all of the recommendations carefully, some were clearly outside the scope of both the contract and the agreements we had made with the partner organizations testing the prototype. Some recommendations would have required changes to procedures or additional staffing by the health care systems themselves (e.g., actively recruiting patients known to have been injured, conducting discharge followup calls using the event reporting form), and others would have required the cooperation of vendors (e.g., Press Ganey or CAHPS surveys).

During 2015, additional changes were made to improve the functionality of the Web site, including text revisions to the introductory pages of the reporting form and the addition of the participating organizations' logos. We updated the FAQs and the resources page hyperlinks to provide additional resources for assistance and reporting to other organizations/agencies. Further refinements to the consent process for sharing reports with the health care delivery organizations were also made. The team completed a total of five iterations of refinements.

Extending the Outreach

The research team, in collaboration with one of the health care delivery organizations, decided to extend the “human touch” outreach to consumers, with the following efforts:

- Case managers, nurses, and social workers began to hand out a brochure describing the hotline on day 2 of the hospital stay rather than at admission (when it might get overlooked among the admission paperwork).
- Nurses began to include the hotline information in discharge discussions.
- Case managers began to remind patients of the hotline during post-discharge and post-emergency-department outreach calls.

- Outreach materials were provided to Spanish-language interpreters to share with patients during translation encounters.

The same health care delivery organization also discussed other options for outreach, including prompting patients by portal-generated email notifications; identifying additional locations for distribution of outreach brochures (e.g., emergency departments, chemotherapy infusion, obstetrics departments, ambulatory surgery centers); inviting PFAC volunteers to learn about the hotline and share its availability with friends and colleagues; and inviting community organizations (senior centers, barbershops, faith-based organizations) to distribute the outreach materials.

Summary

Building a consumer-oriented patient safety reporting system using a Web portal and a toll-free phone number is feasible and relatively easy to implement. However, building one does not mean that consumers will use it. A passive strategy for bringing consumers to the Web site did not produce a high volume of reports. It is unclear whether consumers were having trouble finding the hotline, suggesting that our outreach and marketing strategy did not work, or that they were having trouble with the Web page or event reporting form once they found it.

We do not have evidence that more outreach is necessarily better, although it is plausible that different consumers might attend to and respond to different types of outreach modalities. There is also a fundamental problem of presenting individuals with the opportunity to report at a time when they have something to say.

Many ideas were generated about possible ways to increase the visibility of the hotline, but data to inform a choice among the myriad of recommendations are scarce. We appreciated the ideas generated by the PFACs, the TEP, and others, but not all were necessarily practical, and the failure to implement some of them was both logistical and resource-related.

IV. Evaluation Aims, Methods, and Results

The goal of the evaluation was to test the capability of the hotline prototype to collect meaningful information about patient safety concerns across a wide range of settings and to understand challenges in triaging and sharing that information with professionals who can improve the safety of health care and (as appropriate) with the public. Therefore, the evaluation effort had three principal aims:

1. To characterize the hotline reports entered by patients and caregivers. This part of the evaluation effort was designed to analyze how resources related to the marketing and promotion of the hotline and the modes used to provide access to it affected the flow of its operations and the numbers and types of reports received. Once we realized that the volume of reports was going to be low, we also looked at web traffic metrics to try to identify problems in the event reporting form or the web design.
2. To document and report on the experience of health care organizations and health care professionals who received and used the patient and caregiver reports to improve patient safety in their institutions. Lessons learned from the implementation of the prototype will help to identify needs for further refinement and circumstances under which implementation can be successful.
3. To identify remaining technical and content challenges that would need to be addressed prior to scaling up the prototype.

Methods

Web Traffic Reports

During the implementation phase, the research team developed a monthly Web traffic report to inform the research team about the number of people who were visiting the Web site but not completing the patient event reporting form or not completing the entire form. Statistics reported included date, time, Internet protocol (IP) address, referring URL, and pages clicked.

Analysis of Patient-Reported Events

The research team abstracted and tabulated the following kinds of information from the hotline reports: the mode of reporting (Web or phone), whether the information was complete or incomplete, whether it was provided by the patient or a proxy, patient demographic information, the type(s) of safety concerns reported, whether the event involved a mistake and/or a negative effect, and contributing factors. The team also tabulated how frequently patients and caregivers agreed to receive a followup clarification call from the hotline team and how frequently the clarification call was completed.

The way the physicians on the team classified the patient safety events using the AHRQ Common Formats was also reviewed. As described in Chapter II, before and after additional information is elicited through the patient or caregiver clarification process, a physician reviews the event report and classifies the event(s) described within it by event type, harm scale, and duration of harm. (See the classification form in the Operations Manual, Appendix C.)

Finally, we reviewed data on what the health care delivery organizations reported they did with the consumer reports they received (e.g., whether an RCA was conducted, what contributing factors were identified, whether a matching report was found in the staff adverse event reporting system), and what the organizations learned as a result. This information was collected as part of the provider supplementation process that occurred 45 days after a report was made. The analysis was performed to determine whether hotline-reported events provided information that was otherwise unavailable to the organizations and whether the information was a factor in subsequent actions or improvements.

Interviews with the Participating Health Care Delivery Organizations

To understand organizational context and readiness, the research team conducted site visits at the two health care delivery organizations that were implementing the prototype in June 2013—approximately 6 months before the hotline went live. We specifically sought to understand the features of the organizations that made the prototype project attractive to them, sources of potential concern or resistance, and how the organizations had prepared for hotline deployment.

During each site visit, members of the research team conducted 45- to 60-minute interviews with the organization’s hotline implementation team, communications leaders, quality and safety leaders, patient-relations leaders, legal staff, risk management staff (at one organization only), and Institutional Review Board leaders.

A semi-structured interview guide was developed (see Appendix D) to elicit information on the organization’s reason for deciding to participate in the pilot, challenges encountered throughout the first year of participation, anticipated challenges moving forward, the value added by the hotline, and opportunities to increase the volume of reports submitted. A note-taker took notes during the interviews, except for two interviews that were digitally recorded and transcribed. We then used a variation of content analysis to summarize stakeholder comments on each interview topic, noting differences by type of stakeholder and by health care delivery organization.

In May 2015 (after the 15th month of hotline operation), the research team convened a webinar with both participating health care delivery organizations. The discussion included updates from the two organizations, a summary of reported events, a summary of provider supplementation data (Module 8 in the Operations Manual, Appendix C), a review of Web traffic data, and a discussion of lessons learned and possible next steps.

Feedback from Web Designers

We asked a Web design team at RAND that had not been involved in the design of the Web platform or content to review the prototype and provide expert opinions on access and technical and content challenges that may have affected the volume of reports received.

Feedback from the TEP

In June 2015, the hotline team convened the third—and final—in-person meeting of the TEP. The discussion at the meeting included a recap of modifications made to the hotline since the last TEP meeting, results of the Web traffic and patient event reporting analysis to date, a summary of input from the health care organizations, and a discussion of lessons learned and next steps.

Evaluation Results

Aim No. 1: Characterize Hotline Reports from Patients and Caregivers

Web Traffic

Between October 1, 2014 (when the research team began tracking Web metrics) and June 30, 2015, the hotline home page received a monthly average of 170 visitors with a unique IP address (see Table 4.1). The majority of the visitors (70 percent) accessed the hotline home page through Google or another search engine. The remaining 30 percent accessed the hotline home page from the Web site of one of the two health care delivery organizations.

The most frequently visited hotline Web page (after the home page) was the FAQ page, which had an average of 72 visitors per month during this period.

Table 4.1. Average Number of Visitors Per Month to the Hotline via the Web

Page	Average Number of Visitors per Month
Home	170
FAQs	72
First page of reporting form	45
Second page of reporting form	44
Third page of reporting form	12

The first page of the patient event reporting form (which consumers accessed by selecting “Click here” on the home page) received an average of 45 visitors per month (25 percent of the visitors to the home page). If each of these 45 visitors had completed the event reporting form, the hotline would have received 516 reports via the Web per year. However, only 20 individuals over a 17-month period ultimately used the hotline Web site to complete an event report; an additional 17 individuals used the toll-free phone number to complete a report.

The first page of the event reporting form requires potential reporters to indicate whether they are 18 years of age or older. Seven visitors indicated that they were under 18 years of age and so were not allowed to complete a report. The initial Web page also offers the option of creating a password so that the reporter may finish the report at a later date. A total of seven visitors created passwords.

The second page of the reporting form provides information about the hotline, including assurance that the reported information will not be shared with anyone outside of the research team unless the patient or caregiver gives permission. The page requires potential reporters to indicate that they accept a series of statements, (e.g., that they have read the background information on the Web page, and that they will provide accurate information). Only one visitor declined the request and was not allowed to complete a report.

The third page of the reporting form asks the first set of questions about the patient or caregiver’s safety concern. An average of 12 visitors per month visited this page. If each of these visitors

had completed the reporting form, the hotline would have received 144 reports via the Web each year.

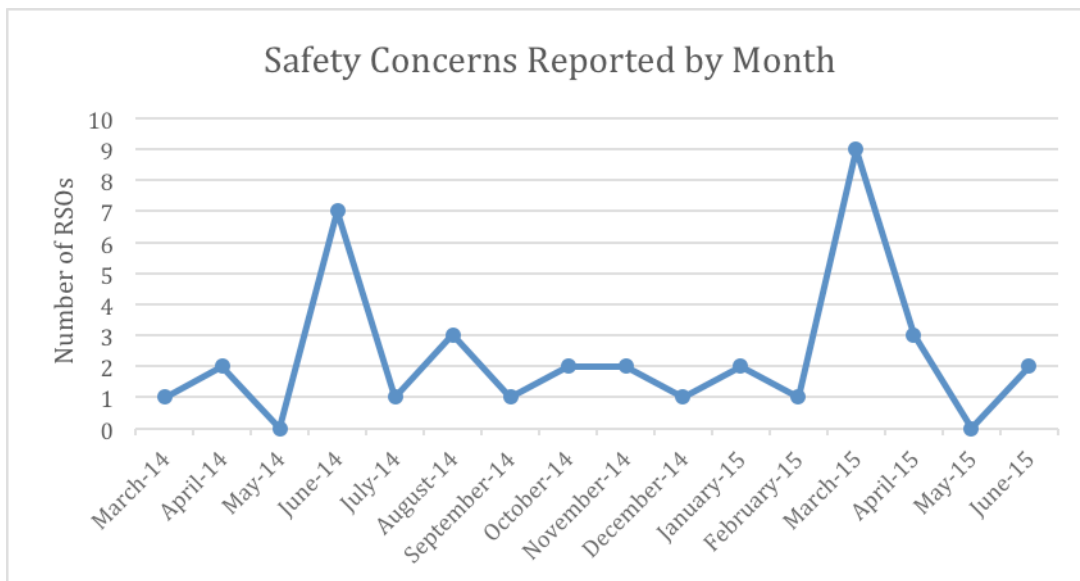
As noted above, the largest drop-off was from the home page to the first page of the reporting form. On average, only 25 percent of the 170 monthly visitors to the home page continued to the first page of the reporting form.

Patient Event Reports

During the 17 months of operation from February 2014 through June 2015, only 37 reports of safety occurrences (RSOs) were submitted to the hotline. This is an average of 2.3 completed reports per month (See Figure 4.1). Of the 37 completed reports, 20 were submitted via the Web, and 17 were submitted by phone. All reports were made in English.

For comparison, spontaneous reporting from hospital-based adverse event reporting systems for health care professionals yields about one report per 10,000 admissions per year. Research studies using patient surveys or chart reviews produce roughly five to ten reports per 100 admissions; sometimes as many as 25 reports per 100 admissions. We had hoped for at least one report per 10,000 admissions.

Figure 4.1. Safety Concerns Reported by Month



Seventeen additional reports were started on the hotline Web site but were not completed. Of the 17 incomplete reports, 13 contained no information after Module 1 (Introduction), and 3 contained no information after Module 2 (Description of your safety concern).

Of the 37 completed reports, 14 were from patients, and 23 were from caregivers (11 by a parent and 12 by a spouse, domestic partner, or other family member). Four people entered multiple reports, accounting for a total of 12 reports.

Demographics

Of the 37 completed reports, 25 pertained to female patients, 11 pertained to male patients, and one did not indicate the patient's sex. The majority of reports (n=19) involved adult patients 18 to 64 years of age. The majority of patients (n=22) identified as white, four identified as black or African American, and one identified as Hispanic, Latino, or Spanish origin. Fifteen reports involved patients with private insurance through an employer, three involved patients with Medicare, and three involved patients with Medicaid.

Reported Patient Safety Concerns

The reports addressed a wide range of safety concerns,¹ as shown in Table 4.2.

Table 4.2. Safety Concerns Reported via the Hotline

Type of Safety Concern	Number of Reports
Communication	9
Environmental	6
Care coordination	6
Process-related*	6
Documentation	4
Treatment-related	4
Discharge-related	3
Medication errors	1
Failure to diagnose	1
Infection	1
Physical assault	1

Note: The number of concerns (42) does not equal the number of reports (37) because some reporters indicated more than one concern.

* Process-related events include, for example, staff not washing their hands before examining a patient or failing to remove an IV during discharge.

In 20 of the 37 completed reports, at least one medical mistake^m was reported. The mistakes involved prescription drugs (n=1); tests, procedures, or surgery (n=1); pregnancy or childbirth (n=1); diagnosis or advice from a doctor, nurse, or other health care provider (n=5); poor cleanliness or poor hygiene (n=2); and something else or more than one mistake (n=10).

¹ The term “safety concern” is used throughout the reporting form because it tested well in focus groups and cognitive interviews during the development phase of the project. Safety concerns include both medical mistakes and negative effects. Safety concerns might arise during a visit to a doctor's office, at a pharmacy, or in the hospital.

^m “Medical mistake” is defined as something that was done (or not done) by a health care provider that would be considered incorrect at the time that it happened. Medical mistakes can result in harm or injury to the patient, but not necessarily in every case.

Fifteen of the 20 safety concerns involved both mistakes and negative effects.ⁿ Seven reports involved negative effects only (for a total of 22 reports of negative effects.) Three categories of negative effects were reported: only physical (n=3), only emotional (n=5), and both physical and emotional (n=14). In addition to these negative effects associated with a mistake, patients and caregivers categorized six safety concerns as having a negative effect that did not involve a mistake. Seven of the safety concerns involved negative effects only.

When patients or caregivers were asked to identify where the mistake or negative effect occurred, 18 were reported to have occurred in the hospital, seven in the emergency department, and three in a doctor's office or clinic.

Patients and caregivers were also asked to identify the individual they told about the mistake or negative effect. Most shared it with a doctor, nurse, or other health care provider (n=23), a family member or friend (n=17), a health care administrator or manager (n=15), a lawyer (n=5), or someone else (n=4), such as a licensing agency.

Three respondents said that as a result of the event, the patient switched to a different health care provider; three said the patient transferred to a different hospital; four said they did something else; and 17 said there was no change in the care provider.

The list of contributing factors was organized into six categories for the patient event reporting form: communication with doctors, nurses, or other health care providers; responsiveness of staff; coordination of care; access; verification; and other. The most commonly identified contributing factors were communication (n=21) and care coordination issues (n=19), followed by access (n=14) and responsiveness of staff (n=13).

Patients/caregivers had the opportunity to select more than one cause within a contributing factor. Table 4.3 shows the most commonly identified causes within a contributing-factor category. Seventeen patients and caregivers reported that staff did not listen to the patient, 17 reported that staff ignored what the patient told them, and 12 reported that staff did not spend enough time with the patient. Twelve patients and caregivers reported that doctors, nurses, or other health care providers did not seem to work well together as a team, and 11 reported that they lacked followup.

Processing of the Patient and Caregiver Reports

In 34 of the 37 reports, the respondent agreed to be contacted for a followup call if the research team wished to ask any clarifying questions. Twenty-two individuals completed a clarification call; the other reports did not require clarification.

Thirty-four of the patient or caregiver respondents consented to have the report shared with a named health care organization or clinician. Fourteen of the 34 shared reports were completed by

ⁿ The term "negative effect" tested well in focus groups and cognitive testing, in contrast to "adverse event," which many patients and caregivers did not understand. Negative effects can be physical or emotional, and they may include infections, drug reactions, or other complications.

the patient who experienced the concern (rather than a caregiver); 13 of these patients agreed to include their names and contact information with the shared report. Twenty-three of the 37 shared reports were completed by a caregiver; 18 of these caregivers agreed to share their names and contact information with the shared report.

Table 4.3. Contributing Factors Identified by Patients and Caregivers, Overall and by Type

Area of Concern	Contributing Factor	Number of Reports
Communication	Total reports	21
	Doctors, nurses, or other health care providers did not listen to the patient.	17
	Doctors, nurses, or other health care providers ignored what the patient told them.	17
	Doctors, nurses, or other health care providers did not spend enough time with the patient.	12
	Doctors, nurses, or other health care providers did not provide a clear explanation of the diagnosis or care plan.	6
	Doctors, nurses, or other health care providers did not explain follow-up care instructions.	3
	Doctors, nurses, or other health care providers did not explain things to the patient in the patient's language.	2
	Doctors, nurses, or other health care providers used terminology the patient could not understand.	2
	Doctors, nurses, or other health care providers spoke with an accent that was hard to understand.	2
Coordination	Total reports	19
	Doctors, nurses, or other health care providers did not seem to work well together as a team.	12
	There was a lack of followup by the doctors, nurses, or other health care providers.	11
	Doctors, nurses, or other health care providers were not aware of care that took place someplace else.	2
Access	Total reports	14
	The patient did not get help or advice he or she needed.	10
	The patient was not able to get the tests or treatments that he or she believed necessary	6
	The patient was not able to get the tests or treatments that a provider believed necessary.	2
Responsiveness	Total reports	13
	Was it because of not getting help as soon as the patient needed it?	11
	Was it because of not getting care as soon as the patient needed it?	9
Verification	Total reports	7
	Was it because someone did not have the most recent and up-to-date information about the patient?	4
	Was it because someone did not correctly identify the patient?	3

Classification of the Reports

A physician on the research team reviewed each completed report and classified the event(s) according to the AHRQ Common Formats classification scheme for event type, harm, and duration of harm.^o Of the 37 reported events, 23 were classified as “incidents,” that is, patient safety events that reached a patient.^p Some incidents result in patient harm, and some do not.^q

As shown in Table 4.4, about half of the reported incidents (n=12) resulted in mild harm,^r about a quarter (n=6) resulted in no harm, and the other quarter (n=5) resulted in moderate harm,^s as classified by the physician reviewers.^t None of the incidents resulted in severe harm^u or death. Table 4.4 also shows the duration of the harm associated with these reported events.

Only one of the 37 reported events was classified as a near miss—that is, an event that did not reach a patient. Eight of the events were classified as an unsafe condition.^v The remaining four reported events were service complaints (e.g., concerns about non-clinical aspects of care such as food, parking, or long wait times in the doctor’s office).

For 28 of the reported events, a clarification call with the patient or caregiver was successfully completed; however, no changes were made to the classification of the type of event, harm, or duration of harm. While the clarification calls provided useful information about the context of the patient safety concern and the sequence of events, they offered no additional value for classifying reported events.

Provider Actions in Response to the Hotline Reports (Module 8)

As described earlier, if an individual consented to having the report shared with a named health care organization, the research team contacted the health care organization within 45 days of the report to ask a series of questions about what the organization did with the information provided in the report. As of June 30, 2015, this step had been completed for 32 reports.

^o The IOM has also created a classification system for safety events. The system distinguishes between adverse events that are preventable, adverse events that are not preventable, and near misses.¹⁷

^p The AHRQ Common Formats characterize “reaching a patient” as “any action by a health care practitioner or worker or health care circumstance that exposes a patient to harm.”

^q An “adverse event” in the IOM classification system is equivalent to an “incident” in the AHRQ Common Formats. A “near miss” that reaches a patient but does not cause harm is equivalent to an incident with no harm, and a “near miss” that does not reach a patient is equivalent to a “near miss.”

^r The AHRQ Common Formats define “mild harm” as “minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.”

^s The AHRQ Common Formats define “moderate harm” as “bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.”

^t When a reported event described multiple harms, the physician classified the event according to the most serious harm.

^u The AHRQ Common Formats define “severe harm” as “bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.”

^v The AHRQ Common Formats define an “unsafe” condition as “any circumstance that increases the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event.”

Table 4.4. Physician Classification of Reported Patient Safety Events

Event Type and Harm	Number of Reports	Duration of Harm
No harm	6	N/A (no harm)
Mild harm	12	<1 year: 8 ≥1 year: 0 Unknown: 4
Moderate harm	5	<1 year: 3 ≥1 year: 1 Unknown: 1
Severe harm	0	No reported events
Death	0	No reported events
Near miss	1	N/A (no harm)
Unsafe condition	8	N/A (no harm)
Service complaint	4	N/A (no harm)
Unclassified	1	
Total	37	

No match was found for 26 of the 32 patient event reports. The health care organizations were able to identify only six patient-reported events in their internal databases (referred to here as “able to match”). When they did find a match, however, they were able to identify the patient and the incident with a high degree of confidence (see Table 4.5).

Table 4.5. Ability to Match Hotline Report with Internal Information

Was the health care provider or facility able to match the patient safety concern?	Number of Reports
Matched with the provider.	1
Matched with the patient.	6
The mistake or negative effect was matched with a high degree of confidence.	5

In addition to trying to identify whether a patient safety event was already known, the organizations undertook a variety of actions in response to hotline reports (see Table 4.6). In half of the cases, the health care organization followed up with the patient involved.

Table 4.6. Actions Taken as a Result of a Hotline Report

Action Taken	Number of Reports
Department quality review, such as peer review, morbidity and mortality conference, or “tumor board.”	21
Contact made with the patient involved.	16
Contact made with the provider involved.	5
Institutional level review.	5

Note: Other possible actions were RCA, reporting to PSOs, and reporting to national or State regulatory agencies.

The primary contacts at the health care organizations were also asked to identify what they felt were contributing factors to the events reported through the hotline. The most commonly

identified contributing factors were a lack of team coordination and environmental factors (see Table 4.7). Organizations also had the opportunity to select more than one issue within a contributing factor. The most common contributing factor identified by the health care organizations was a lack of staff-to-patient communication (n=12) and a lack of communication among staff or team members (n=9). Other contributing factors included the behavior of individual staff (e.g., adherence to policy, protocols, and orders) and deficits in the environment (e.g., lack of equipment).

In six of the reports, staff identified specific quality improvement opportunities for health care organizations, including the need for better communication between staff and patients and their family members, the need for a discharge checklist, the need for a handoff communication tool, and the need to monitor low-volume, high-risk complications associated with certain medical conditions. One event associated with a low-volume/high-risk complication resulted in an increase in staff education concerning the medical condition, and it may result in a performance improvement project including simulation training and creation of a rapid-response protocol for this type of condition.

Usability Surveys

Four of the 37 hotline reports were accompanied by a completed post-submission survey about the usability of the Web site—a sample that is too small for the data to be meaningful. Three individuals accessed the first page of the post-submission survey but did not complete it.

Aim No. 2: The Experience of the Participating Health Care Delivery Organizations

We sought to understand the features of health care organizations that made the hotline an attractive proposition—and by contrast, the sources of potential concern or resistance—and how our partners prepared for and responded to hotline deployment.

The Decision to Participate

At one of the two participating organizations, several departments, interdepartmental committees, and leaders (including the board and management council) provided input to the decision to participate. A leader in the safety department learned about the project, vetted the idea of participation with the vice president of safety, and then discussed it with multiple stakeholders within the health care system. Input was also solicited from communications/outreach, risk management, clinical chairs, and patient relations. The chief executive officer made the final decision. The safety department leader described her role in the organization's decision to participate as “key influencer.”

At the other organization, the vice president of quality and safety was primarily responsible for the decision to participate. This executive shared information about the project with stakeholders but was ultimately the decisionmaker. In both organizations, the individual who learned about the opportunity and brought it to the attention of the rest of the organization went on to lead the implementation team.

Table 4.7. Contributing Factors Identified by Health Care Organization, Overall and by Type

Category	Contributing Factor	Number of Reports
Team coordination	Overall	16
	Communication: staff to patient	12
	Communication: among staff or team members	9
	Communication: supervisor to staff	3
	Clinical supervision	1
	Heavy workload	1
Operating environment	Overall	6
	Equipment/device availability	2
	Housekeeping	2
	Physical surroundings (e.g., lighting, noise)	1
Workflow/task	Overall	4
	Bed capacity	1
	Data availability	1
	Data accuracy	1
	Management of test results	1
Staff/individual	Overall	3
	Adherence to policy, protocols, or orders	3
Patient/resident	Overall	2
	Agitated/aggressive	1
	Impaired hearing or speech	1
Management/organization	Overall	1
	Culture of safety management	1
Other	Other	2

Note: For subcategories, respondents were asked to check all that apply, so the numbers do not equal the total.

When describing their organization’s decision to participate, stakeholders from both health systems emphasized the importance of the alignment of the goals of the hotline with the organization’s mission, priorities, and current practices. One stakeholder explained, “This particular decision was easy because we’re doing this type of thing already.” Another interviewee noted, “[There were] a lot of linkages to what we’re currently doing in our safety program.” Stakeholders also identified the following reasons for participating in the pilot project:

- Linking to patient-centered care and preventable-harm reduction strategies.
- Promoting patient and family engagement as a method of building safe health care.
- Improving patient and family experience.
- Validating that the organization provides high-quality, safe care.

- Identifying any blind spots.
- Communicating the organization’s commitment to transparency.
- Advancing the use of Web-based technology as an alternative method of communicating with patients and families.
- Providing an additional avenue for educating the community about patient safety.

When asked if there was anything unique about the organization that influenced the implementation and integration of the hotline into the workflow, one stakeholder noted that the organization was created recently, stating, “We’re unusual in that we’re relatively young so there aren’t a lot of bureaucratic pitfalls. If it’s rational and reasonable, it’s easy to do.”

Although both organizations ultimately decided to participate in the pilot project, they identified several risks associated with participation. The two main risks raised by quality and safety leaders were that the project might “open the floodgates,” and that the organizations might not have sufficient staff to manage events effectively and respond quickly. A member of the legal team asked, “How do we know that we’re going to get the patient’s name? How do we know we could get back to the patient? What would our process look like in terms of timeliness of referrals?” Leaders of the communications and external affairs teams, in comparison, were most concerned about reputational risk and protection of the brand. These teams noted that individuals who submit a report through the hotline might experience survey fatigue and be less likely to respond to the organization’s patient experience survey. A member of the implementation team also noted the risk that the Web site might not work properly when launched.

Deciding How to Process Patient Event Reports from the Hotline

Both organizations had an existing mechanism for addressing safety concerns determined by the organizations to be grievances. Reports of grievances are processed by the patient- and family-relations department, which follows up promptly with individuals who provide their names and contact information. Both organizations decided to treat reports received through the hotline in the same way they treat grievances.

Challenges Encountered Prior to Launch

Stakeholders at both organizations indicated that one challenge prior to the launch was the amount of staff effort required for participating in meetings with the research team and the other delivery organization, reviewing and revising outreach materials, and ensuring that the organization was ready to process any reports received from the hotline. The implementation team at one organization felt that this was a significant challenge: “[There were] a lot of meetings, a lot of calls with all of you, integrated calls with [organization name], marketing calls, a lot of communication that had to take place, a lot of coordination and facilitation. It took our administrative assistant and me a lot of time.” In comparison, the implementation team at the other organization took steps to limit the draw on staff time, “I was ... worried about people getting over-involved. Let’s blend it into our normal processes.”

Challenges Encountered After Launch

The primary challenge identified by the stakeholders at both organizations was the much-lower-than-expected volume of reports. Stakeholders wondered if this signified limited awareness of the hotline, a low incidence of safety events, or reluctance of patients and caregivers to report, perhaps due to features of the prototype (the Web interface design, introductory materials on the

Web site, difficulty getting through to the toll-free number). Several stakeholders, especially those on the outreach and marketing teams, suspected that limited awareness might be the primary contributor and wondered what more could be done to engage patients and families. By contrast, staff at ambulatory offices at one of the health care organizations pushed back against circulating outreach materials, asserting that “there is too much stuff that doctors are trying to hand out: discharge papers, public health information, and the business cards about the hotline.” Others were concerned about a lack of direct feedback to either the patient or the facility when hotline reports did not include the patient’s name.

Anticipated Challenges to Scale-Up

Stakeholders at both organizations identified two sets of challenges that will need to be addressed in any effort to scale up the hotline: the need to encourage more patients and families to report their patient safety concerns (to make the amount of effort involved in implementing the hotline worthwhile), and the difficulty health care organizations may have in allocating an appropriate level of resources to manage the hotline on an ongoing basis. Specific comments made with regard to engaging more consumers include the following:

- The hotline is reaching people at the time of inpatient admission to a hospital or at the time of service in an ambulatory clinic. This may not be the time when a mistake has happened (or a patient realizes that a mistake has happened). The current outreach method may not be reaching the patient or caregiver at the right moment.
- There is information overload and competition for patient reporting. The hotline is competing against the statewide hotline for safety concerns, Health Grades, the Joint Commission, and other efforts.
- There is currently no “buy-in” from clinical staff—in fact, few were aware of the hotline. One stakeholder added, “In general, the hotline is a huge positive, but the natural reaction among clinical staff is not to take reports from patients seriously.”

Comments made with regard to allocating sufficient resources to manage the hotline include:

- The staff effort required to prepare for launching the hotline was unexpectedly large.
- The [prototype’s] followup processes and procedures are currently required for all hotline reports, regardless of an event’s severity. A tiered approach might be more appropriate; that is, resources invested should be aligned with the severity of the event. For example, a sentinel event might be followed by a concerted effort, whereas fewer resources would be allocated to identifying contributing factors in a report about the lack of a urinal at the bedside.
- Initially, leaders at one organization were worried that they would not be able to keep up with the volume of reports; later, they worried about whether the low volume of reports made the investment worthwhile.

Value of the Hotline

Participants had mixed views about a business case for the hotline, given the low volume of reports received in the pilot project. However, one member of the implementation team endorsed the hotline reports as more valuable than reports made to the State or another entity. The same person noted that the comprehensive nature of hotline reports might speed up the process of learning in some hospitals because the reports provide a better understanding of what a patient

has experienced and what additional information might be needed from a patient before reaching out to him or her. Finally, this person stated that the organization is currently engaged in a “deep analysis” of an issue identified in one of the reports it received from the hotline. A member of the implementation team from the other health system stated that the hotline reports provide “appropriate, detailed enough information so that [the organization] knows where to send the report and process it through patient relations.” This individual also characterized the reports as “extremely complete.”

Lessons Learned

The research team and the two participating health care delivery organizations held an evaluation webinar in May 2015 for a final discussion of lessons learned. Representatives of one of the organizations identified aspects of the hotline that were “useful” and “less useful.” The most useful aspect from the point of view of one implementation team leader was the elicitation of patient concerns of which the organization was not previously aware; the staff had prior knowledge of only one or two of the events that were reported through the hotline.

A less useful aspect was that the involvement of an intermediary (RAND) led to a delay of 72 hours in receiving and being able to address patient concerns, when the organization standard was to reach out to a patient/family within 24 hours of a reported grievance. While the intermediary enabled several different options for reporting (e.g., anonymous, de-identified), the back-end review and processing that led up to sharing a report delayed the organization’s receipt of the concern. Another participant noted that the low volume of reports raised the question of whether the hotline added value but said that the reports did contain such “granular information” that they were useful.

Aim No. 3: Identify Technical and Content Challenges to Address Prior to Scale-Up

We asked RAND Web designers to look at the prototype and make suggestions about changes that should be made prior to scale-up. They identified two problems: (1) the content of the Web site may have been insufficient to make patients and caregivers see the benefit of using the hotline rather than other available options; and (2) technical problems caused the Web-based version of the hotline to be somewhat difficult to use. We begin with the suggestions concerning content.

Report a Safety Concern

The Web team pointed out that because filling out and submitting the form are the primary actions we want users to perform when they go to the hotline Web site, the link/button to submit the form should be very prominent on the page. Therefore, all unnecessary barriers to completing this action should be removed.

Hotline users will have been exposed to outreach materials before they come to the Web site and will therefore have a basic understanding of its purpose, so most other content, although important, should be considered secondary to getting users to report a legitimate patient safety concern.

What's in it for me?

A key challenge for Web site producers and content developers is keeping the visitor in mind and remembering that his or her attention span is often quite short. When visitors access the home page of the hotline Web site, they should be presented with key content and a call to action as quickly as possible.

Unfortunately, the home page of the hotline Web site is heavy on text but light on explaining the benefits of submitting a report. The one FAQ that discusses the benefit of the hotline is buried and does not offer a particularly strong call to action:

Why should I participate? You can share your experiences and help make health care safer for people in your community. We need to hear from many people. We need to hear about many health care experiences and concerns.

To encourage use, this information should be front and center on the home page, with a stronger call to action. If the call is strong enough, a Web site can convince people to perform, even if incentives are nonexistent. When a Web site requires more time to use than an alternative option, it is especially important for the call to action to be strong.

There are established sites that already collect patient safety complaints, notably www.jointcommission.org, but these sites allow users to input large blocks of text that must then be read and coded, whereas the hotline uses structured form fields that can be processed more easily and accurately. Therefore, a key element of the call to action for the hotline Web site should include the benefits of collecting structured data. The site could also emphasize the benefits of using a form that asks specific questions, rather than only requesting open-ended feedback. A patient or caregiver using an open-ended form may forget to mention or not realize the importance of some aspects of the complaint; the hotline form ensures that all key issues are addressed, even if the user chooses not to answer specific questions.

How long will this take?

Rather than warning users that the form will take 20 to 25 minutes to complete, mention that the time required to write up a detailed narrative can far exceed 20 minutes. In other words, the site can save users time when submitting a concern.

What happens after I use the form?

If the prototype is to be scaled up, the Web designers strongly recommend that it be rebranded as something other than a hotline. Many people think of hotlines as a way of getting a quick response to a problem or as a forum for asking questions about a product or service; by contrast, the FAQs point to submissions as being suggestions for the health system to consider.

The home page call to action should more strongly address the question of what will be done with the user's submission. This may require working with the participating health systems to offer a guarantee that they will respond to submissions that are not anonymous (not just that they "may call you"). If possible, users who submit a concern anonymously should be provided with a submission ID number so they can check on what has happened since the complaint was reported. Finally, if it is feasible to share concerns with other groups outside of the health care

institution, this could be stated to inform users that their use of the hotline Web site and the concerns they submit are not simply being logged as part of a research effort.

Why do I need to create an account?

The need to create an account may be considered burdensome by users of this site because they may not need to visit it frequently, and the account creation process is often clunky from a user's perspective. However, if enabling users to save their work and return to the site later is seen as valuable, it may be better to work this functionality into the submission process, rather than placing it on the first page. One option is to add a "Save for later" (or "Save and exit") button. Different from the "Save and continue" option, this button would prompt the account creation process and would be selected only when a user realizes he or she will not be able to complete the form in one sitting. This might remove one of the initial barriers to completing the form.

The designers also tested the Web site using Chrome and Chrome Vox (a screen reader) and made technical suggestions concerning general bugs, usability and accessibility issues, and the need to make sure that the Web page responds to the available space in the browser window (so-called responsive Web design) to make it easier for users to access on mobile devices. The technical suggestions are included in the Operations Manual (Appendix C).

Summary of TEP Input

After reviewing the findings from the pilot project, several of the TEP members noted the value the hotline had offered to the health care delivery organizations that participated, particularly the provision of detailed, actionable information on safety concerns about which the organizations had not previously been aware.

Despite the fact that the hotline had provided useful information to the participating organizations, and as good as the prototype was, several TEP members noted that the hotline was probably capturing only a small percentage of the safety concerns occurring at these organizations. Continuing barriers to reporting include fear of retaliation, concern that reporting will not result in change, the desire to avoid "getting anyone in trouble," and patients not wanting to revisit a difficult or traumatic experience.

Some members noted the difficulty of obtaining high response rates and advocated more active recruitment methods. Others thought a better approach would be for AHRQ to advocate that questions about safety concerns be added to the CAHPS survey (an option that the research team and partner organizations had explored but found infeasible, given time limitations and a lack of enthusiasm among the vendors).

Given the research team's finding that most of the "story" of the safety concern was described in response to the form's first few open-ended questions, one TEP member suggested that a future project could implement a dramatically shortened form—perhaps one using only three questions. Since completing such a form would be less time-consuming than completing the current form, the questions could potentially be asked of each patient before discharge. Benefits of this approach include employing a more prompted recruitment strategy and capturing safety concerns in nearly real time.

One TEP member suggested that the current hotline effort had too many objectives, which muddled the messaging to patients and caregivers. Different opinions were offered about whether a consumer-oriented reporting system should ideally provide publicly available hospital-level data, publicly available aggregated data, or no public data (instead providing data only to health care delivery organizations to use for internal quality improvement). The group discussed successful examples of each type of effort.

Finally, several TEP members emphasized the value of early and ongoing patient input, such as the information we received through PFACs.

Summary

Building a consumer-oriented patient safety reporting system using a Web portal and a toll-free phone number is a feasible approach. However, a passive strategy for bringing consumers to the hotline did not produce a high volume of reports. Several explanations for this are possible. For example, the outreach and marketing strategy may have been insufficient to draw consumers to the hotline, or they may have had difficulty navigating the system once they found it. More research is needed to understand how best to facilitate consumer reporting.



V. Challenges Identified and Lessons Learned

Challenges

This research project highlighted several challenges to obtaining consumer-generated reports about safety concerns.¹ Safety-related events do not surface in a predictable way, and their causation is complex. This makes standardized surveys and other data collection approaches difficult to design and implement. Moreover, the reporting process must be acceptable to the person making a report. Serious problems may arise during transitions among a wide variety of delivery organizations, creating uncertainty about how best to notify relevant professionals and organizations about patient and caregiver reports. New information technologies are evolving rapidly, so patients and caregivers may not know which channels to use for reporting. The optimal timing for soliciting reports may differ, depending on patients' health status, their experience, and their expectations. Current systems for classification and coding of events may be useful to clinicians and patient safety managers, but they may not be easily adaptable to the unique perspective that patients and caregivers bring to health care safety improvement. A system for obtaining patient and caregiver reports of health safety concerns must respect current legal and regulatory requirements regarding confidentiality and data protection that come into play when soliciting, storing, and transmitting safety-related information.

Communicating in Patient-Friendly Language

Collecting reports in a language that is both patient-friendly and possible to analyze and categorize in a way that is useful to health care providers to improve patient safety is inherently challenging. The reporting system must communicate to patients in a language they understand. We had hoped to use the AHRQ Common Formats language in the hotline, but we learned in focus groups with patients and family members that the language health care professionals have come to accept as the standard—including such terms as “adverse events,” “medical error,” and “harm”—is potentially confusing or ambiguous to patients. Drawing fine distinctions between errors and harm, making attributions of causality, and assessing impact are all somewhat subtle and nuanced. Furthermore, if the reporting system is to be used to inform health delivery organizations, it must also enable complaints to be categorized and communicated in terms that are useful to risk managers and patient safety officers in retrospective case analyses and for fashioning interventions.

The research team sought patient-friendly language to communicate complex and nuanced information about the purpose of the hotline, how it works, and how patient information would be protected. This challenge was compounded by the requirement to use specific informed-consent language and to include the OMB Paperwork Reduction Act Statement—which raised the overall reading level of the Web content we produced. The informed-consent issue may be an unavoidable challenge for any patient reporting system, but hotlines that are not sponsored by a Federal agency will avoid the additional burden of OMB requirements.

We attempted to use an 8th grade (or lower) reading level in all materials aimed at potential respondents: the patient event reporting form, the Web site pages, and the outreach materials. Ultimately, we achieved a 7th grade, 9th month reading level in the reporting form (without the

consent language, it would have been a 7th grade reading level). However, the home page had a 9th grade reading level, and the outreach materials had a 12th grade reading level. One of the health care delivery organizations in the pilot community indicated that it attempts to achieve a 6th grade reading level in all patient-use materials. Doing so with the hotline materials could improve access. A reporting system that is not intended for use in the context of research—such as a quality improvement effort or a public monitoring effort—would be able to achieve a lower-grade reading level.

A related challenge was that of communicating to patients and caregivers the options for sharing information without confusing them or losing their attention. Patients and proxies filling out the form may report anonymously (neither the research team nor the partner organization has their names or contact information) or confidentially (the research team does not share the report with the partner organization); they may report de-identified data (the research team has identifying information but shares a de-identified version of the report with the partner organization); or they may report identified data (the research team and the partner organization both have the report with identified information). The PFACs worked with the research team to develop language that was simple, straightforward, and accurate, such as “You can choose to send the report anonymously or with your name and contact information.” However, having too many options may have led some patients or caregivers to give up before making a report.

Creating Awareness Among Patients and Caregivers (Outreach)

A reporting system is effective only if patients and caregivers know that it exists at the time they have something important to report. Making patients and caregivers aware of the hotline in the pilot project was difficult. The research team, the pilot organizations, and the TEP agreed that a community-wide outreach strategy might not be an optimal model for eliciting patient safety reports, since its impact is diluted across a broad audience. When the hotline prototype launched, partner organizations distributed posters, 4-by-9-inch cards, and business cards throughout their hospitals, outpatient practices, pharmacies, and other facilities. Information about the hotline was also provided in admission packets. Nevertheless, most members of the PFACs indicated that they had not been aware of the hotline. Since PFAC members tend to spend more time than the average patient in health care delivery organizations and are more familiar with activities occurring within the system, the research team concluded that overall awareness of the hotline was low. Information about it may have low salience to most patients, and the promotional information may not have been as clear or understandable as the team intended.

In retrospect, we realize we should have gone to the PFACs earlier in the process to engage them in order to reach out to their communities through local churches or schools or community activities. We could have better utilized the PFACs.

When we did reach out, the PFACs emphasized the difficulty of getting the attention of patients and caregivers during a hospital stay. TEP members emphasized the importance of timing in presenting information to patients. Information may be presented upon admission, during a hospital stay, at discharge, a few days after discharge, and weeks or months after discharge. Each option has benefits and drawbacks. Upon admission, patients and their family members are focused on a number of pressing issues, such as the medical problem that brought them to the hospital, insurance and payment issues, and the retrieval of relevant medical information. An

introduction to the hotline at that stage is unlikely to have much effect. Real-time capture of safety concerns during the hospital stay presents an opportunity to fix such concerns before they have a negative effect on the patient. However, a system that allows patients to report in real time would need to focus on the information needed to resolve the issue and would minimize or omit questions that could inform later analyses, such as RCAs. At discharge and a few days after discharge, patients and caregivers are typically no longer concerned about a pressing medical issue and may be more inclined to read information sent home with them. However, they may also be more interested in moving on and reluctant to revisit negative experiences. In sum, there may not be a single optimal time to approach patients with information about patient safety reporting, which is why our outreach strategy emphasized multiple modes and methods.

During the second phase of the project, in response to feedback from the PFACs and TEP members, the research team expanded the avenues through which information about the hotline was disseminated. At one partner organization, information was added to discharge packets and even to post-discharge phone-call scripts for three patient cohorts: congestive heart failure, stroke, and outpatient surgery. However, even after the outreach methods were enhanced, the volume of reports did not increase meaningfully.

Given the relatively high volume of visitors to the Web site (as evidenced by the analysis of Web traffic), there are several potential explanations for the low volume of reports. Visitors to the home page may—correctly or incorrectly—determine that the hotline does not meet their needs. Visitors may have the false impression that the hotline does not offer a way to share a de-identified report with the relevant health organization(s). The home page of the hotline may not be providing sufficiently clear, user-friendly information on the purpose of the hotline and how to complete a report. Finally, the number of visitors to the home page may not provide an accurate count of the number of consumers who were considering making a report because the count also includes visitors who are simply curious about the hotline, including researchers, clinicians, advocates, and lawyers.

Lessons Learned

Given the many challenges associated with the hotline, we learned a number of useful lessons:

- **Patient safety reporting is both desirable and feasible.** Prior research and the present study demonstrate that patient safety reporting is desirable because it elicits information that may lead to action and improvement within health care organizations. It is potentially empowering for patients and families in that it acknowledges their experiences and perspectives and uses the information they provide to improve care and ensure accountability. Methodologically robust and rigorous tools for eliciting, reviewing, processing, and presenting patient safety reports would benefit health care organizations, public reporting, and patient safety research. The hotline created a mechanism that patients and families used to report meaningful clinical information about perceived errors and physical and emotional injuries. We assessed the feasibility of creating an approach and a platform that could manage a limited volume of reports; additional research may be needed to determine whether this same approach could support a high volume of reports.

- **The hotline yielded information that was previously unavailable.** The hotline provided information that sophisticated health care organizations would otherwise not have had, despite the existence of other mechanisms for eliciting patient safety reports (e.g., patient experience surveys and complaint departments) and information about patient safety concerns from staff (e.g., adverse event reporting systems). The hotline reports were more detailed and richer than information collected through other reporting mechanisms and included previously unreported events. The reports were credible and led to actions—they were just few in number.
- **The hotline was readily incorporated into existing patient safety systems and was not disruptive to health system operations.** Two feared scenarios never materialized. First, hospital administrators had worried that they would not have sufficient bandwidth to respond appropriately to all reported patient concerns. Instead, they ultimately tried to elicit more reports from patients. The hotline was not only manageable for participating health systems but was readily incorporated into their patient-relations and patient safety systems. However, having a third party (RAND and ECRI) process the reports before sharing them with the organizations—as was done in the hotline pilot—may not be an ideal arrangement, since the organizations goal is to be in contact with the patients as quickly as possible after an event occurs. Second, some leaders were concerned at the outset that the hotline would be disruptive; this was not the case, and its implementation actually reinforced organizational commitment to safety, quality, patient engagement, and transparency.
- **Legal and regulatory obstacles to soliciting, storing, analyzing, and sharing event reports are manageable through the use of PSOs.** Together with AHRQ, we investigated the nature of various protections for patient-reported information early in the project, concluding that such information was covered by AHRQ research protections. Data from individual health care organization hotlines can be protected in a PSO/PSES environment. These obstacles are likely to be even less problematic if hotlines are adopted by individual health care systems for their own use.
- **Responses to open-ended questions were considerably more useful than the responses to structured questions that followed.** The physicians who classified the patient event reports according to event type, harm, duration of harm, preventability, and contributing factors found that most of the value of patient reports lies in the narrative. This finding is consistent with findings of previous studies and with safety reporting by professionals in health care and aviation.
- **Although the narratives were most helpful, collecting structured report elements from patients offers potential benefits.** To the extent that we can standardize questions and validate that reporters interpret the questions and response elements in a consistent way, the use of structured questions would facilitate data aggregation, preparation of summaries, and use of statistical analytic tools. However, this is an area that requires additional research.
- **The option of proxy reporting, in which family members or other caregivers report on safety concerns, was an important component of the hotline project.** Proxies submitted about half of the hotline reports we received.

- **The platform we developed has a number of components that could be used, depending on the specific goals of the end user.** Which components are employed and how they are adapted would depend on the user's purposes.

Although the hotline had many positive features and benefits, the potential for broader adoption or deployment of consumer reporting systems remains uncertain. While technical, regulatory, and organizational issues appear to be tractable, the challenge of creating the opportunity to report at a time and in a way that motivates patients or caregivers to do so has not yet been satisfactorily resolved. The research team, our partners, and the TEP considered several future scenarios involving patient safety reporting, including:

- Incorporating patient safety screening and/or survey questions into routine patient experience surveys (CAHPS, Press Ganey, and others) that are already used in inpatient and ambulatory settings.
- Incorporating safety screening into patient portal-based surveys that are keyed to emergency department visits, hospital discharge, or office encounters.
- Enrolling and training patients with chronic conditions (e.g., chronic obstructive pulmonary disorder, cancer, congestive heart failure, diabetes, cystic fibrosis) as professional reporters, a kind of “Nielsen rating” program for health care.
- Identifying family members of patients with high-risk conditions (e.g., neonatal intensive care patients, patients with pediatric cancers) who may be motivated to make real-time reports.
- Placing tablets or kiosks in ambulatory care areas to facilitate reporting, or creating a mobile app that can be used in real time in any setting.

VI. Summary and Conclusions

It is important to emphasize not only how much was known, but also how much was not known at the outset of this project. What was known after two decades of prior research is that adverse events, errors, and even near-miss events can be identified, a nomenclature can be created to structure and catalog reports of such events, and systems can be built to enable health care professionals to reliably report these events in real time. What was less well known was whether patients could contribute unique information that health care organizations did not already have—that is, whether a parallel system of reporting could allow patients to help identify the health safety problems they experienced in health care institutions. Also unanswered was the question, “Is it worth getting patient reports about safety events?” That is, is obtaining patient reports an important thing to do?

Even stakeholders who (provisionally) supported an attempt to gather patient-reported data on safety problems had concern that patients might overwhelm health care organizations with reports, or that patients who complained about quality and safety issues might face retribution from health care providers. Neither of these fears was realized in the deployment of the Health Care Safety Hotline prototype; likewise, risk management operations were not overrun or compromised in any way.

The experience of developing and deploying the hotline answered some of the outstanding questions. There clearly is an appetite among health care organizations for collecting information from consumers about things that go wrong. The prototype successfully elicited information that was considered useful by our partner health care organizations and that had little overlap with the information received from other sources (such as internal adverse event reporting systems). The partner organizations were not overwhelmed by patient reports and valued the detail and complexity captured by both the narrative and structured portions of the hotline instruments. However—and this is a big however—the hotline prototype elicited far fewer reports than the project team, the health care organizations, the TEP members, and AHRQ had hoped for.

How, then, do we begin to address the discrepancy between the potential high value of the hotline tool we developed and the low response rate among patients and caregivers in this test of the prototype? The project team, partner organizations, and TEP members identified a range of possibilities that could account for the low number of reports. We think there were three principal problems.

First, although we employed a variety of means of marketing and outreach (brochures, hospital Web sites, pamphlets included in packets of discharge materials), we assumed that when given the opportunity and invitation, patients would reach out to institutions to report problems. We employed a passive outreach strategy (in which patients and caregivers must choose to opt in and make a report). We did so believing that we had avoided the problems documented in other such efforts. We learned, however, that affording patients an opportunity to report their patient safety concerns in real time did not generate a large volume of reports.

Second, based on Web traffic data, we know that more individuals accessed the Web site than actually made reports; many potential users dropped off after reading the introductory materials or completing only the narrative portion of the report. This suggests that despite the time and care that were taken in developing the Web site, there most likely were problems with the platform itself.

Third, the presence of alternative mechanisms for reporting at the hospital level (discharge surveys) or community level (State regulatory agencies) could have depressed the number of reports. A next natural step in the evolution of the prototype would be to determine whether a modified patient event reporting form, together with a prompted deployment effort (such as contacting patients at discharge) would substantially increase the volume of useful reports.

While we are not at this time recommending a full scale-up of the prototype, we urge AHRQ to consider a follow-on effort to this project designed to answer the specific questions raised here. For example, a full usability study of the Web tool would address the content and platform issues we have identified. After modifications are made to the hotline tools, additional partners could easily be identified and recruited to help test a prompted deployment strategy. Another alternative AHRQ might explore would be to expand the patient experience survey to incorporate patient safety screeners or questions.

A second, related issue we struggled to resolve was whether the prototype was, perhaps, trying to serve too many purposes. The Research Triangle Institute (RTI) report commissioned by AHRQ (which gave rise to this project) recommended that patient reports be collected locally but also communicated to a centralized (national) level, where they would be aggregated, analyzed, and triaged or distributed to State and local levels for action. On the basis of our experience with the hotline prototype, we now question whether all of these objectives (e.g., improving patient safety at the organizational level, aggregating data for public monitoring and accountability, conducting research on patient-reported errors) are compatible and whether it is realistic to think that they can all be addressed with a single reporting system. Our attempt to address all of these goals in one prototype resulted in an instrument and a process that were probably much more cumbersome than would be necessary to serve a single objective (in this case, patient safety reporting within a single health care system). The need to serve too many “masters” also may have contributed to the lower-than-hoped-for response rates.

We believe that one of the most important lessons learned from this experience is that it is possible to build a single technology platform that can meet diverse objectives, but the technology has to be rolled out differently to meet different objectives. The platform we developed has a number of components that can be used separately, depending on the specific goals of the end user. Which components are employed and how they are adapted are highly dependent on a project’s purpose. For example, if the hotline is used as an internal patient-reporting mechanism, it would not be necessary to work through an external partner (a research organization such as RAND), nor would events (necessarily) need to be classified by type, severity, and contributing factors for the reports to be useful for patient safety improvements.

The current version of the event reporting form may request information that is not necessary for public monitoring, so the number of elements could be reduced, making the reporting burden on

consumers lighter. In addition, research or public monitoring uses would not require patients to identify themselves, removing the need for that portion of the Web page and perhaps encouraging patients who may fear retribution for themselves or their providers to make a report for research or public accountability purposes.

Table 6.1 shows the components of the hotline prototype and discusses how they might be employed in future research, patient safety improvement, and public monitoring efforts.

We urge AHRQ to put all of these materials, including Appendix C, the Operations Manual (which includes all the forms, surveys, and Web site specifications), into the public domain and to encourage health care organizations, regulatory agencies, patient safety organizations, and others to use these tools (or pieces of them) for a variety of research, safety improvement, and public reporting purposes.

AHRQ is tasked by Congress to produce evidence to make patient care safer and to ensure that such evidence is understood and used. Over the past two decades, AHRQ has sponsored a plethora of activities to improve the quality and safety of health care systems through research and implementation of evidence. Those projects have included sponsoring user-driven research to improve measurement and event reporting and to reduce and remediate patient safety risks. Much of this research has resulted in the development of practical and widely used tools for improving patient safety in hospitals and other health care settings, including surveys to assess patient safety culture, training to improve communication and reduce errors by health care teams (TeamSTEPPS), and CAHPS to assess patient experience with health care. AHRQ is also responsible for the development of the Common Formats (a voluntary effort to help standardize reporting of adverse events) and PSOs to confer privilege and confidentiality protections on providers in order to promote shared learning to enhance patient safety nationally. In the present project, many of these threads related to reporting and patient safety improvement came together.

As AHRQ considers scaling up the prototype and generalizing from the pilot project findings, it will be important to assess both the relative value of this particular method for gathering consumer input and how continued efforts to promote the patient voice in improving patient safety could be integrated with other ongoing AHRQ efforts—in particular, the support of CAHPS and the PSOs.

Finally, we would note that AHRQ's support for a culture change around patient safety in health care institutions (i.e., moving away from blaming individuals toward identifying and addressing systemic risks) was critical to the agency's efforts to promote adverse event reporting by health care professionals. When adverse event reporting systems were first built, they did not receive many reports. It was not until the culture in hospitals changed around adverse event reporting that reports started flowing in from health care professionals. It may be that a complementary effort to change the culture around consumer reporting is necessary, in addition to building a prototype model to effectuate reporting.

A decade of research on consumer engagement in patient safety has demonstrated the capacity of patients and their caregivers to identify errors and injuries experienced in the course of medical

care.^{43,44} While patients and their proxies may sometimes be reluctant to report, especially if they believe that reporting may be futile or could alienate providers, patients have knowledge that professionals do not possess, and this information can reveal vulnerabilities in health care delivery organizations, inform and motivate improvements, and convey a degree of respect for patients and professional humility that are sometimes lacking in patient-provider interactions.^{2,13,15,18,45,46,47,48,49}

The design and development of the Health Care Safety Hotline represents a significant effort on the part of the research team and AHRQ to move promising research findings “from bench to bedside.” The effort yielded important information about the feasibility of and constraints upon consumer reporting of patient safety events. Overall, the number of reports received was disappointing, given the potential reservoir of adverse events and the yield of research-oriented methods. Nevertheless, the data provided were rich compared to the information available from standard data collection methods. The events reported had previously been largely unknown to the well-informed participating health systems, and the reports prompted them to reach out to those patients and directly address their concerns through patient safety improvement mechanisms.

The hotline demonstrated that phone and online reporting are feasible methods for collecting patient safety information, that patients and caregivers welcome the opportunity to clarify the information in their reports, and that they are largely willing to share this information with the organizations that delivered the care they found problematic. While the logistics of managing patient-reported safety information pose certain challenges related to confidentiality, timeliness, and peer review, these potential barriers can be addressed in a way that advances consumer engagement in patient safety. We are confident that the hotline platform developed in this project, with some modifications, is scalable to diverse settings and will be a valuable piece of the patient safety improvement puzzle in years to come.

Table 6.1
Application of Prototype Components to Future Research, Patient Safety Improvements, and Public Monitoring

Prototype Components	Use of Patient Event Reporting for Patient Safety Research	Use of Patient Event Reporting for Operational Quality and Patient Safety Improvements Within Health Systems	Use of Patient Event Reporting for Public Information and Accountability
Reporting methods: Web and phone	<ul style="list-style-type: none"> Patients and caregivers in the pilot utilized both Web and phone. Incorporating both options maximizes accessibility for users with different needs and preferences. Pilot suggests that limiting to the Web option would require fewer resources, but its impact on volume and potential reporter bias is undetermined. 	<ul style="list-style-type: none"> Incorporating both reporting methods would maximize the accessibility to users with different needs and preferences, but using a single method would reduce costs of data collection 	<ul style="list-style-type: none"> Soliciting reports by phone may be too resource-intensive for public monitoring.
Legal and regulatory protections: <ul style="list-style-type: none"> Research protections PSO/PSES protections 	<ul style="list-style-type: none"> Research protections necessary for research projects. 	<ul style="list-style-type: none"> Under PSO authority, health care organizations have the option of analyzing patient- or caregiver-reported information within a PSES. Patient safety work products created within a PSES cannot be publicly disclosed. A patient safety improvement effort may wish to employ a PSO to protect the data and analyses from discovery. 	<ul style="list-style-type: none"> Not necessary for public monitoring.
Patient identification options: anonymous, confidential, or identified	<ul style="list-style-type: none"> Patients and caregivers in focus groups indicated a strong preference for an anonymous reporting option. Information about the quality and safety of care may still be gained from anonymous reports. While most reports submitted during the pilot contained patient identification, a few patients and caregivers preferred to report anonymously. 	<ul style="list-style-type: none"> Some patients and caregivers prefer to report anonymously—and since information about the quality and safety of a provider’s care can be gained from anonymous reports, institutional programs may wish to offer both options, even though anonymous reports may be difficult to link to adverse event reports. 	<ul style="list-style-type: none"> Public monitoring uses would not require identification of patients.

Prototype Components	Use of Patient Event Reporting for Patient Safety Research	Use of Patient Event Reporting for Operational Quality and Patient Safety Improvements Within Health Systems	Use of Patient Event Reporting for Public Information and Accountability
Structured, modular reporting form	<ul style="list-style-type: none"> The current version of the reporting form provides the data elements necessary for research use. 	<ul style="list-style-type: none"> The current form provides the information necessary to allow matching of reports to specific institutions. 	<ul style="list-style-type: none"> The current version of the reporting form may contain information that is unnecessary for public monitoring, so the number of elements in the structured reporting form could be reduced.
Outreach efforts to patients: <ul style="list-style-type: none"> Provider Web sites Posters and notecards in provider facilities Notification in admission and discharge packets Calls to targeted patient groups 	<ul style="list-style-type: none"> Passive outreach strategies proved insufficient to recruit enough patients. 	<ul style="list-style-type: none"> Institutions may need to consider tying error reporting to existing patient satisfaction data collection (such as CAHPS or Press Ganey surveys). 	
Administrative process for cleaning and auditing information	<ul style="list-style-type: none"> Identifiable information provided in fields that do not request this information must be removed for research projects. 		
Collecting clarifying information from the patient, family member, or caregiver.	<ul style="list-style-type: none"> Followup calls were useful to clarify facts and add nuance to the report, but the research team did not find that they were needed to correct errors in the initial reports. 	<ul style="list-style-type: none"> Depending on whether the information is used to supplement an existing adverse event report or is a new report, clarifying calls may provide additional information that would be useful in addressing an individual case or performing an RCA for quality improvement purposes. 	<ul style="list-style-type: none"> May have little added value.
Hotline initially serving as intermediary between patients and provider organization.	<ul style="list-style-type: none"> Critical for research. 	<ul style="list-style-type: none"> Not necessary for patient safety improvement. 	<ul style="list-style-type: none"> Not necessary for public monitoring.

Prototype Components	Use of Patient Event Reporting for Patient Safety Research	Use of Patient Event Reporting for Operational Quality and Patient Safety Improvements Within Health Systems	Use of Patient Event Reporting for Public Information and Accountability
Provider analysis of reports and provision of updates on how patient information was used.	<ul style="list-style-type: none"> • Critical for understanding whether reported information is unique to the hotline and how the partner organizations use that information. 	<ul style="list-style-type: none"> • Critical to patient safety improvement. 	<ul style="list-style-type: none"> • Not necessary for public monitoring.
Classification of events by type, severity, and contributing factors.	<ul style="list-style-type: none"> • Necessary for research. 	<ul style="list-style-type: none"> • Not necessary for patient safety improvement. 	<ul style="list-style-type: none"> • Useful for showing trends.
Usability survey (post-submission by Web).	<ul style="list-style-type: none"> • Provides feedback that could be used to improve the Web-based user interface. 		

Note: CAHPS = Consumer Assessment of Healthcare Providers and Systems; PSES = patient safety evaluation system; PSO = patient safety organization; RCA = root cause analysis.

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