Developing and Testing the Health Care Safety Hotline

A Prototype Consumer Reporting System for Patient Safety Events

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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 chose) on a secure website 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 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 also be of interest to policymakers in Congress, 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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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 (Weissman, Schneider, Weingart, et al., 2008), minimum dimensions for reporting patient safety events laid out by the Institute of Medicine (Institute of Medicine, 2004), and the AHRQ Common Formats,[1] 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 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.

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[1] 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 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.

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 "patient safety work product" under the Patient Safety and Quality Improvement Act of 2005.

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, 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 experience 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 differ, depending on patient 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 website 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 all 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 below:

- **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? There appear to have been three principal problems. First, although a variety of means of marketing (brochures, hospital websites, pamphlets included in discharge materials) were employed, 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 website 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 website 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 website, there were probably also 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 website 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.

Acknowledgments

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CAPS	Consumers Advancing Patient Safety
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
DUA	Data Use Agreement
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
HCSH	Health Care Safety Hotline
HHS	Department of Health and Human Services
HTTPS	Hypertext Transfer Protocol Secure
IOM	Institute of Medicine
IP	Internet Protocol
ISMP	Institute for Safe Medication Practices
IT	Information Technology
MERP	Medical Error Reporting Program
MOU	Memorandum of Understanding
NRLS	National Reporting and Learning System
OMB	White House Office of Management and Budget
PDF	Portable Document Format
PFAC	Patient and Family Advisory Council
PSES	Patient Safety Evaluation System
PSO	Patient Safety Organization
PSWP	Patient Safety Work Product
RCA	Root Cause Analysis
RTI	Research Triangle Institute
SSL	Secure Sockets Layer

TEP   Technical Expert Panel

UK   United Kingdom

URL   Uniform Resource Locator

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 (Louis Harris and Associates, 1997). A more recent public opinion poll in Massachusetts found that nearly one in four adults had personally experienced a medical error in the past five years (or someone close to them had), and half of them reported that the medical error resulted in serious health consequences (Harvard School of Public Health, 2014). 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 (Agency for Healthcare Research and Quality, 2015).

Researchers have confirmed that 5 to 10 percent of hospitalized patients suffer injuries,[2] 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 to improve medication safety.[3] 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 (Institute of Medicine, 2000). A subsequent IOM report called for standardization of reporting and the development of a common taxonomy (Institute of Medicine, 2004). 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.

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[2] See Aranaz-Andrés, Aibar-Remó, Vitaller-Burillo, et al., 2009; Baker, Norton, Flintoft, et al., 2004; Brennan, Leape, Laird, Herbert, Localio, et al,, 1991; Michel, Quenon, Djihoud, Tricaud-Vialle, de Sarasqueta, 2007; Thomas, Studdert, Burstin, et al., 2000; Vincent, Neale, and Woloshynowych, 2001; Wilson, Runciman, Gibberd, Harrison, and Hamilton, 1996.

[3] See The Health Foundation, undated; World Health Organization, undated; Institute for Healthcare Improvement, 2001.

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 (Hibbard et al., 2005). 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 (Lyons, 2007). 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.[4]

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 (Levtzion-Korach, Frankel, Alcalai, et al., 2010), and are willing and able to report this information reliably.[5] As demonstrated in the United Kingdom, these reports can strengthen the ability of health care organizations to detect systemic problems in care.

In an early study, Weingart found that 8 percent of inpatients reported adverse events and 4 percent experienced "near misses" (Weingart, Pagovich, Sands, et al.). 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.[6] In the largest study of its kind, Weissman and colleagues 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 colleagues 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 (Weingart, Gandhi, Seger, et al., 2005). Similarly, Weingart and colleagues, studying adverse event reports from ambulatory oncology patients, reported that 20 percent of patients identified a concern about safety (Weingart, Price, Duncombe, et al., 2007; Wolosin, Vercler, and Matthews, 2006).

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[4] See Hibbard, Peters, Slovic, and Tusler M., 2005; Blendon, DesRoches, Brodie, et al., 2002; Marella, Finley, Thomas, and Clarke, 2007; Schwappach, 2010; Schwappach and Wernli, 2010; The Kaiser Family Foundation/Agency for Healthcare Research and Quality, 2008; Waterman, Gallagher, Garbutt, Waterman, Fraser, and Burroughs, 2006.

[5] See Basch, Artz, Dulko, et al., 2005; Kuzel, Woolf, Gilchrist, et al., 2004; Weingart, Gandhi, Seger, et al., 2005; Weingart, Pagovich, Sand, et al., 2005; Weingart, Pagovich, Sands, et al., 2006; Weingart, Price, Duncombe, et al., 2007; Zhu, Stuver, Epstein, Schneider, Weissman, and Weingart, 2011.

[6] See Agoritsas, Bovier, and Perneger, 2005; Blenkinsopp, Wilkie, Wang, and Routledge, 2007; Friedman, Provan, Moore, and Hanneman, 2008.

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 (RTI International, 2010), multiple patient safety reporting systems exist, but only a minority 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 three-year operation (UK National Reporting and Learning System, 2015). 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 (Danish Cancer Society, undated). 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 (Dana-Farber Cancer Institute, 2015). The Danish Cancer Society's consumer reporting system invites both adverse event reports and positive anecdotes (Danish Cancer Society, undated). (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 ten days after receiving a new or changed prescription, inquiring about problems with the medication (Weingart, Hamrick, Tutkus, et al., 2008). 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 patient safety organization (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]").[7] Information obtained from clinician reports can help to better understand 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, and their patient safety concerns will remain unaddressed.

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 are acceptable to patients, that elicit structured and narrative reports using strategies designed to maximize the volume of reports, that address care

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[7] 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 a variety of practice settings, that take advantage of electronic technologies, and that 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)

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; and
- 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, 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 one or more 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; and
- 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, it 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. It 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 information technology (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[8] for public comment, in accordance with requirements of the Paperwork Reduction Act of 1980,[9] 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

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[8] "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 Federal Register.gov, accessed August 30, 2015.

[9] 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.

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 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 website, 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,[10] 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 website 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.

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[10] See UK National Reporting and Learning System, 2015; Dana-Farber Cancer Institute, 2015; Institute for Safe Medication Practices, 2015; Lipczak, Knudsen, and Nissen, 2011.

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

An effective 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 follow-up 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.[11] 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.[12] 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.[13]

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 (Weissman, Schneider, Weingart, et al., 2008; Weingart, Gandhi, Seger, et al., 2005; Weingart, Pagovich, Sands, et al., 2005). In contrast, passive solicitation strategies, which involve simply making a

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[11] Institute of Medicine, 2000, Chap. 6, "Protecting Voluntary Reporting Systems from Legal Discovery."

[12] The patient's rights provisions of CMS Conditions of Participation are found at 42 C.F.R. 482.13.

[13] 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.

website 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 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 websites such as Yelp or in *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 (Weissman, Schneider, Weingart, et al., 2008). 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 below.

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.

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 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, and our intent was to update the form in future iterations, based on the number and type of responses received.

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, to offer Spanish and English versions, to offer multiple modes of reporting (i.e., web and phone), to follow up with those who report an event, and to 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[14] by OMB when standardized data collection from ten 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, 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, 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 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 five 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 (Pear, 2012).

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 nonretaliation 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

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[14] "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).

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 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 website and toll-free phone number through marketing efforts (e.g., posters, postcards, publication of the URL on their websites); 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 website 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 (Lewis, 1995), 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 follow-up.
- 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,[15] 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

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

> **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.
> What happened? [text box]
> Where do you believe it happened? [text box]
> When did it happen? [text box]
> Why do you think this happened? [text box]

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[15] 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.

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.

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 and 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 their 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 website and entering a new event. The patient or caregiver's responses are entered in the first person.

Web

The hotline website was tested in a "staging" environment prior to deployment. All testing steps were intended to ensure that the website would be usable and efficient for all users. Functionality testing was conducted to ensure proper functioning of the website, 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 website 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 website 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 identifying 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.

Figure 2.2
Overview of the Steps to Process a Hotline Report
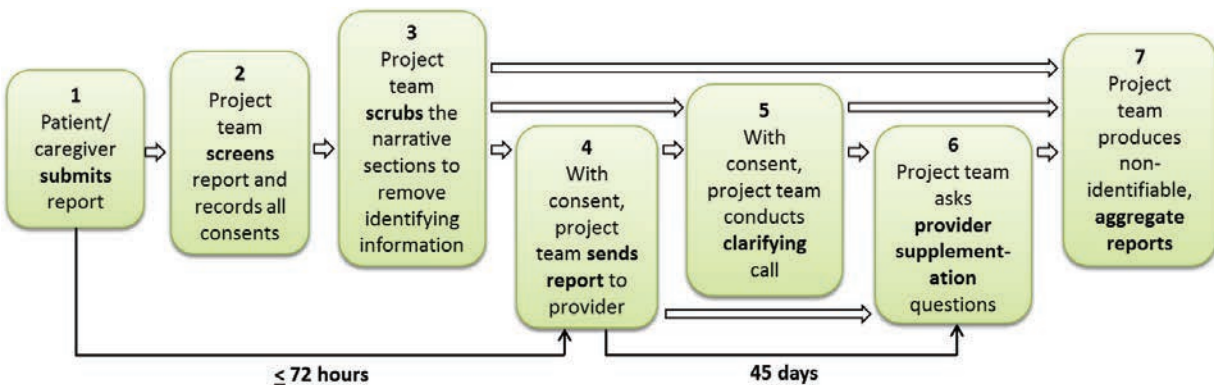
Step 1: Patient or Caregiver Submits Report

In Step 1, the hotline receives information about safety concerns through the reporting form (from the secure website or the toll-free phone number).

Before a patient or caregiver can answer questions about a safety concern, he or she is screened for age (a respondent must be at least 18 years old). Next, the respondent reads (or is read over the phone) text describing the types of safety concerns that should be reported to the hotline, the types of concerns that should not be reported to the hotline, and the types of information patients or caregivers may need access to in order to describe their safety concerns (e.g., month and year of the event, where the event occurred). Respondents must indicate that they understand this information (those using the web-based form must click "Accept"), and they are then asked to answer the questions in the reporting form, as described earlier. The Operations Manual in Appendix C contains the full content of the web-enabled form.

Back-end administrators (referred to as SuperUser – Administrators) process the reports after intake and collect additional information (where possible) from the health care delivery organization.

Step 2: Research Team Screens Report and Records All Content

Once a report is submitted, a member of the research team screens the report to confirm that it meets the inclusion criteria. During the screening process, the team member also notes whether the patient or caregiver consented to receive a follow-up call, whether permission was granted to share the report with the named provider, and whether the consumer's name and contact information can be shared with the provider when a summary is sent. All activities are documented in an Excel tracking spreadsheet for administrative purposes (see the Operations Manual).

Step 3: Research Team Scrubs the Narrative Sections to Remove Identifying Information

To safeguard confidentiality, a research team member scrubs the narrative sections provided by the consumer, removing identifying information, such as names of people and institutions. 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. 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 website 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 e-mail, with a link to the report on the secure website.

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 follow-up call is made to the person who made the report. The additional information elicited through the clarifying call is uploaded to the secure website if the patient or caregiver gives permission. The revised, clarified report is uploaded to the secure website, and the relevant health care organization or provider is notified via an e-mail with a link to the clarified report. The Operations Manual 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 on 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 follow-up 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 .)

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[16] requires that information obtained in the course of AHRQ-supported activities and that identifies individuals or establishments be used only for the purpose for which it was supplied. Information that is obtained in the course of AHRQ-supported activities and that

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

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.[17]

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.

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[17] 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
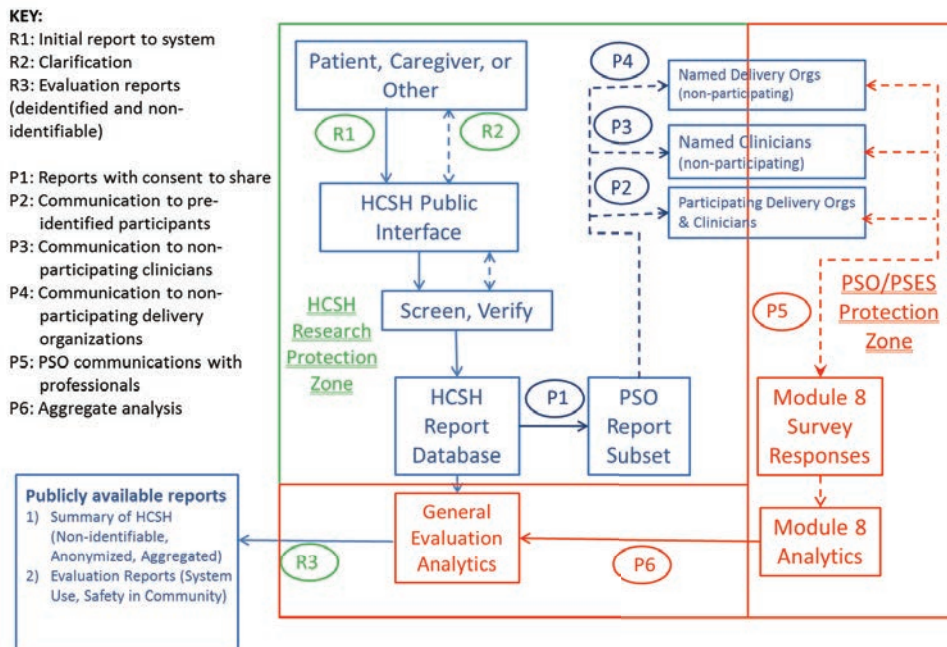
Summary

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 collocation 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 ten 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, to improve service quality, and to 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 website, 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 website 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 website platform and content and to better engage consumers.

During the first year of implementation phase (2013–2104), 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 website 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 website included

- Be clearer on the website 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 website, 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 follow-up 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 follow-up 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 website, 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 e-mail 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 website 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 website but not completing the patient event reporting form or not completing the entire form. Statistics reported included date, time, 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 follow-up 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.)

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 six 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 fifteenth 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), 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 which 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 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 website 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 clicking "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 website 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 first page of the website 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 hotline reports were submitted. 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 website 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 gender of the patient. 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,[18] as shown in Table 4.2.

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[18] 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.

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[a]	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.

[a] 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, one or more medical mistakes[19] were 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).

Fifteen of the 20 safety concerns involved both mistakes and negative effects.[20] 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.

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[19] "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.

[20] 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.

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 follow-up.

Processing of the Patient and Caregiver Reports

In 34 of the 37 reports, the respondent agreed to be contacted for a follow-up 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 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 follow up 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.[21] Of the 37 reported events, 23 were classified as "incidents," that is, patient safety events that reached a patient.[22] Some incidents result in patient harm, and some do not.[23]

As shown in Table 4.4, about half of the reported incidents (n=12) resulted in mild harm,[24] about a quarter (n=6) resulted in no harm, and the other quarter (n=5) resulted in moderate harm,[25] as classified by the physician reviewers.[26] None of the incidents resulted in severe harm[27] 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.[28] 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

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[21] 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 (Institute of Medicine, 2000).

[22] The AHRQ Common Formats characterize "reaching a patient" as "any action by a healthcare practitioner or worker or healthcare circumstance that exposes a patient to harm."

[23] 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."

[24] 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."

[25] 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."

[26] When a reported event described multiple harms, the physician classified the event according to the most serious harm.

[27] 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."

[28] 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	

of the report to ask a series of questions about what the organization did with the information provided on the report. As of June 30, 2015, 32 reports had completed this step.

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 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 website—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.

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 are asked to check all that apply, so the numbers do not equal the total.

Aim #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.

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 missions, 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 website 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 website, 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 following:

- The staff effort required to prepare for launching the hotline was unexpectedly large.
- The [prototype's] follow-up 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 #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 website may have failed 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 is the primary action we want users to perform when they go to the hotline website, 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 website 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 website 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 website, they should be presented with key content and a call to action as quickly as possible.

Unfortunately, the home page of the hotline website 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 website can convince people to perform, even if incentives are nonexistent. When a website 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 website 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 inform users that their use of the hotline website 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 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 website 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.

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 efforts.

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. There may be several possible explanations. 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 (Weissman, Schneider, Weingart, et al., 2008). 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 eighth-grade (or lower) reading level in all materials aimed at potential respondents: the patient event reporting form, the website pages, and the outreach materials. Ultimately, we achieved a seventh-grade, ninth-month reading level in the reporting form (without the consent language, it would have been a seventh-grade reading level). However, the home page had a ninth-grade reading level, and the outreach materials had a twelfth-grade reading level. One of the health care delivery organizations in the pilot community indicated that it attempts to achieve a sixth-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 communitywide 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 website (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 aim 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 utilized, 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, nor were risk management operations 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 websites, pamphlets included in the 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 website 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 website, there were probably 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 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 is 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 the Operations Manual (which includes all the forms, surveys, and website 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 (Institute for Safe Medication Practices, 2015; Lipczak, Knudsen, and Nissen, 2011). 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.[29] 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 this 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.

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[29] See Wilson, Runciman, Gibberd, Harrison, and Hamilton*,* 1996; Institute for Healthcare Improvement, 2001; Institute of Medicine, 2000; Hibbard, Peters, Slovic, and Tusler, 2005; Pear, 2012; Lewis, 1995; Hall, Peat, Birks, et al., 2010; Longtin, Sax, Leape, Sheridan, Donaldson, and Pittet, 2010; Davis, Koutantji, and Vincent, 2008.

Table 5.1

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	• 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.	• 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	• Soliciting reports by phone may be too resource-intensive for public monitoring.
Legal and regulatory protections: • Research protections • PSO/PSES protections	• Research protections necessary for research projects.	• Under PSO authority, health care organizations have the option of analyzing patient- or caregiver-reported information within a PSES. Patient safety work product 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.	• Not necessary for public monitoring.
Patient identification options: anonymous, confidential, or identified	• 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.	• 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.	• Public monitoring uses would not require identification of patients.

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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	• The current version of the reporting form provides the data elements necessary for research use.	• The current form provides the information necessary to allow matching of reports to specific institutions.	• 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: • Provider websites • Posters and notecards in provider facilities • Notification in admission and discharge packets • Calls to targeted patient groups	• Passive outreach strategies proved insufficient to recruit enough patients.	• 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	• Identifiable information provided in fields that do not request this information need to be removed for research projects.		
Collecting clarifying information from the patient, family member, or caregiver.	• Follow-up 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.	• 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.	• May have little added value.
Hotline initially serving as intermediary between patients and provider organization.	• Critical for research.	• Not necessary for patient safety improvement.	• 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.	• Critical for understanding whether reported information is unique to the hotline as well and how the partner organizations use that information.	• Critical to patient safety improvement.	• Not necessary for public monitoring.
Classification of events by type, severity, and contributing factors.	• Necessary for research.	• Not necessary for patient safety improvement.	• Useful for showing trends.
Usability survey (post-submission by web).	• Provides feedback that could be used to improve the web-based user interface.		

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Appendix A. Recommendations for Ideal Consumer Reporting Systems

A 2010 report by RTI and Consumers Advancing Patient Safety, *Designing Consumer Reporting Systems for Patient Safety Events,* outlined recommendations for an ideal reporting system that consumers could use to report experiences with patient safety events. Table A.1 summarizes these recommendations.

Table A.1
Recommendations for Key Features of an Ideal Consumer Reporting System

1. What types of information can consumers provide concerning their health care experience with patient safety events that may be useful and/or actionable in a patient safety event reporting system?
Recommendation 1.1: Types of Information. The system should collect information on all types of events, ranging from near-miss and no-harm events to adverse events. The system should capture both objective information about what occurred and more-subjective information based on the consumer's unique perspective. Information collected from consumers should include where a patient safety event occurred; what contributed to the event; whether or to whom the event was reported; what happened when the event was reported; and the impacts or consequences of the event.
Recommendation 1.2: Sources of Reports. The system should allow for reporting by any individual, but the emphasis should be on obtaining the consumer perspective.
2. What are the scope and range of options for consumer reporting mechanisms? How would these options differ at the international, national, regional, state, and local levels?
Recommendation 2.1: Purpose and Goals. The dual purposes of a consumer reporting system are to learn and to be accountable to consumers providing reports. *To learn* means obtaining the consumer perspective and experience to identify, mitigate, and prevent risks, hazards, and harms; improve outcomes; and advance patient safety. *To be accountable to consumers providing reports* means that reported information will be actively used to design meaningful improvements in patient safety.
Recommendation 2.2: Level of Operation. Reports should be collected locally and communicated to a centralized (national) level that can aggregate and analyze data and triage or distribute information to state and local levels for action. The reporting system will need to be flexible regarding analysis and other activities occurring at local levels, based on needs, capabilities, and funding/resources for them.
3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?
Recommendation 3.1: Linkages. The system should have linkages to a broad range of organizations that can change health care practices and demonstrate that reported information was used. Linkages should be formed to encourage consumer reporting, improve analysis, share results, and change delivery for quality improvement. Linkages will also ensure timely information sharing. Because linkages are dynamic and rapidly changing, their exact nature and specifications should be more fully specified at implementation.
Recommendation 3.2: Analytic Functionality. The system will need decision rules for the levels or types of analysis performed for different kinds of events. The system should collect information and conduct aggregate causal analyses. It should also gather responses of organizations and evaluate their feedback.

4. What is the most effective operational approach for consumers to report patient safety event information?

Recommendation 4.1: Type of Organization. Guiding principles and characteristics that should be sought for organizations that own or operate consumer reporting systems include being an independent entity with a steady stream of sustainable funding, where "independent" is defined as being completely separate in ownership, governance, and affiliation from entities that provide health care and whose members, employees, or affiliate entities may be the subjects of reports about adverse events; governing body members having a fiduciary responsibility to represent the public; being a neutral oversight body with consumer representation; transparency of goals, process, and results; having consumer involvement in organizational governance and operations; and being dedicated to analyzing incoming information to identify threats to patient safety and feeding it back to systems that may be able to act on it.

Recommendation 4.2: Access at Different Points in Time. The system should allow reporting at any point in time.

Recommendation 4.3: Reporting Modalities. To maximize reporting, the system should include multiple routes or modalities for reporting.

Recommendation 4.4: Reporting Format. The system should enable a mix of structured and unstructured reporting.

Recommendation 4.5: Anonymity. The system should allow anonymous reporting, but it should be designed to discourage such reporting by ensuring and providing well-designed confidentiality safeguards. The system should allow reporters to opt out of confidentiality to increase the report's efficacy in certain situations.

5. How would consumer reporting of patient safety events be linked to quality and/or patient safety improvement efforts?

Recommendation 5.1: Linking to Quality and Patient Safety Improvement Efforts. The system should be linked to efforts to improve quality and patient safety. If the reporter allows his or her reports to be shared, the consumer reporting system will automatically forward them to appropriate reporting systems at the local or facility level.

Recommendation 5.2: Public Reporting. Public reporting should be used to hold the system accountable to its own goals. The system should

- Publish information such as how much the system is used.
- Publish information on what has been learned.
- Publish information about recommendations and changes that were made as a result of patient and caregiver reports.
- To the extent determinable, information about the responsiveness of institutions to patient safety issues should be published.
- Because this is an evolving and dynamic issue, the exact specifications will be developed at implementation and will be determined over time.

6. How can a reporting system maximize the willingness and ability of consumers to report on patient safety events?

Recommendation 6.1: Maximizing Reporting. The system design should facilitate reporting to ensure maximum use; that is, it should maximize the ease of submitting reports and the ability of consumers to do so. This will include public awareness campaigns or other outreach/marketing activities and getting buy-in from appropriate individuals and organizations as part of implementation.

Recommendation 6.2: Accessibility. The system should be designed to facilitate access for diverse populations (e.g., persons of different age, race/ethnicity, education, language, disability).

Recommendation 6.3: Feedback. The system should provide meaningful and timely feedback to reporters. Feedback includes a report to the public, awareness campaigns, and meaningful acknowledgment of receipt of a report. However, the system will not be able to assure reporters that they will receive meaningful and timely feedback from the health care facility where a patient safety event took place.

Appendix B. Technical Expert Panel Members

The TEP for the hotline project provided multi-stakeholder expertise on relevant dimensions of the project, including patient safety, reporting systems, patient and consumer perspectives, and survey methodology.

TEP Panel Members	
Troy Brennan, MD, MPH	Executive Vice President and Chief Medical Officer, CVS Caremark Corporation and CVS Pharmacy, Inc.
John Clarke, MD	Professor of Surgery, Drexel University; Clinical Director, Patient Safety and Quality Initiatives at ECRI Institute
James Conway, MS	Principal, Governance and Executive Leadership at Pascal Metrics; Adjunct Faculty, Harvard School of Public Health
Jack Fowler, PhD	Senior Research Fellow, Center for Survey Research at University of Massachusetts, Boston
Helen Haskell	Founder and President, Mothers Against Medical Error
Lisa McGiffert	Campaign Director, Consumers Union's Safe Patient Project
Tejal Gandhi, MD, MPH	President, National Patient Safety Foundation (NPSF); President, Lucian Leape Institute at NPSF; Associate Professor of Medicine, Harvard Medical School
Richard Roberts, MD, JD	President, World Organization of Family Doctors; Professor of Family Medicine, University of Wisconsin School of Medicine & Public Health

The Health Care Safety Hotline: Operations Manual

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Operations Manual Table of Contents

Figures

Tables

1. Contents of the Manual

This operations manual describes the main components and functions of the hotline, including instructions for processing, sharing, classifying, and using the event data; detailed scripts; tracking methods; web tool text; required hardware and software; and information on maintenance and data storage. Section 2 summarizes the required hardware and software. Section 3 presents the functional and non-functional requirements for operation. Section 4 describes the report form and the handling of the toll-free telephone report form, including suggested scripts. Section 5 describes the instructions for processing and sharing reports. Section 6 provides the details on maintenance of the system and data storage.

2. Hardware and Software Requirements

This section describes the required hardware and software that are needed to operate the Health Care Safety Hotline, as well as the design assumptions.

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.

The hotline employs 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. Table C.1 shows the minimum requirements on a single server.

Table C.1
System Processing Requirements

Operating system	Microsoft Windows 64-bit 2008 R2 Servers
Database	SQL Server 2012 64-bit
Web server	IIS 7
Security	SSL Certificate

The prototype utilizes Hypertext Transfer Protocol Secure (HTTPS), which is a combination of the Hypertext Transfer Protocol and the SSL protocol that provides 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.

Supported Browser

The prototype supports the current and previous version of Internet Explorer.

Prototype Design Assumptions

- The hotline team is able to review data based on role level.
- There are six user types: SuperUser – Administrative; SuperUser – Research; Intake Administrative User; Consumer – Guest; Consumer – Registered; and Post Audit Review.
- The Consumer – Registered is required to provide an e-mail address for registration. An e-mail is sent to the Consumer – Registered containing a link to

the site where he or she is able to enter and verify a password and then is allowed to access the prototype.

- A user password must contain a minimum of eight characters and at least one upper-case letter and one number.
- Context-sensitive help will be implemented as pop-ups in module development.
- The application does not require an install package.
- The prototype is hosted at ECRI Institute.
- If another organization wants to subsequently host the application, the minimum hardware and software requirements must be met as defined in Minimum System Requirements.
- The administrative section is a web-based interface.
- The software is maintained by mid- to senior-level developers fluent in C# and the newer Microsoft technologies.
- SQL Server 2012 is used for the system.
- This application is built as a standalone prototype and is not intended to interoperate with other applications.
- The prototype is not intended to be a distributed system that will synchronize data among multiple instances of the application. A data synchronization strategy and distributed data security model were outside the scope of this project.
- There is workflow around the initial entering of the data by the patient, family member, or caregivers to make sure that the skip logic integrity is kept. No specific workflow is kept beyond that point. The users will maintain any business flow operationally.
- Exporting of the information from our SQL Server database into an Excel file occurred during the prototype phase.
- Analytics of the data is handled at the database level. Only simple tabulations of the patient/family/caregiver-reported RSO data based on the taxonomy categories were developed. (See details under Reporting Function.)

In addition, the prototype was designed to meet the following standards of 508 compliance:

- A text equivalent for non-text elements shall be provided (e.g., via "alt," "longdesc," or element content).
- Web pages are designed so that all information conveyed with color is also available without color, for example, from context to markup.
- Redundant text links are provided for active regions of a server-side image map.
- Row and column headers are identified for data tables.

- When a timed response is required, the user is alerted and given sufficient time to indicate more time is required.

For organizations that decide to adopt or create a similar website, we recommend a series of usability considerations to make the submission process more streamlined. See Appendix C.1.

3. Functional and Non-Functional Requirements for Operation

This section describes the functional and non-functional requirements for the Health Care Safety Hotline, including the reporting.

Functional Requirements

General Requirements

The prototype is web-enabled. Access is controlled based on the role of the user (e.g., public reporter, back-end hotline administrator) and also according to specific data types. The prototype web interface captures the details of patient-reported safety events from reporters (e.g., patients, families, and caregivers). The main data entity is called a reported safety occurrence (RSO). Data are entered via a report form.

The report form was developed in a modular format and allows for the capture of the information from reporters within the following modules:

- Module 1: Introduction – who is reporting a safety concern
- Module 2: Description of your safety concern – description of the safety concern
- Module 3: Mistake – details of the mistake
- Module 4: Negative effect – details of the negative effect
- Module 5: Contributing factors, changes in care, discovery, and reporting – details of the contributing factors, changes in care, discovery, and reporting of the patient safety concern
- Module 6: Patient and clinician/facility information – details of the patient and clinician/facility information.

See Appendix C.2 for the web version of the report form and Appendix C.3 for the phone version.

The prototype is also utilized by back-end administrators (referred to as SuperUser – Administrators), who process the report form after intake and then collect additional information (where possible) from the health care delivery organization. The back-end processing information is also captured in a modular format and allows for the inclusion of the following information from the hotline team within the modules:

- Module 7: Comments/clarifications – additional details/clarifications from the reporter of the RSO
- Module 8: Administrative script – details of provider supplementation follow-up information with the identified health care organization (Step 6 in Figure C.29).

See Appendix C.4 for provider supplementation process follow-up questions and administrative script (Module 8).

Embedded Patient Safety Event Taxonomy

The prototype allows the display of an embedded patient safety event taxonomy using drill-down (multilevel) menus. The prototype contains two top-level categories; each category has a drill-down list from which reporters select items to describe the mistake and/or negative effect (subcategories) experienced.

The taxonomy is
- 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.

Administrative Requirements

The prototype allows a web-based administrative interface with the following administrative requirements:

- Only users with the SuperUser – Administrative role are allowed to access the administrative interface.
- The prototype allows SuperUser – Administrative to manage users and their effective role-based permissions.
- Users include: SuperUser – Research, Intake Administrative User, and Post Audit Review.
- The SuperUser – Administrative is not able to manage Consumers – Registered accounts.
- The prototype allows SuperUser – Administrative to manage roles.

- Managing roles include setting and changing roles for those accounts created (excluding Consumer – Guest, Consumer – Registered).

- The prototype allows the SuperUser – Administrative to set the e-mail notification preference of new RSOs to the following users: SuperUser – Administrative, SuperUser – Research, Intake Administrative User, Post Audit Review.
  - The e-mail preference is set at prototype level for each user and sends a change of status of the RSO.

- The prototype enables a SuperUser – Administrative (for the prototype, the role was assigned by ECRI Institute) to view all the information for the purposes of assisting health care delivery organizations in working through any issues related to the patient- or caregiver-reported safety occurrence.

The prototype distinguishes between reports submitted by patients/families/ caregivers and those submitted by intake staff over the phone. The prototype records the User ID of the intake staff in relation to the report he or she submits.

Business Process/Rules

The prototype was designed using the following business processes and rules:

- The Patient Safety Act prohibits the impermissible disclosure of patient safety work product, and thus, publicly available data must be rendered non-identifiable in accordance with the Patient Safety Rule.

- The prototype requires all users to read and accept the hotline consent and attestations prior to any significant interaction with the prototype (refer to Section 4 of this Operations Manual).

- The prototype stores each user's acceptance of the agreement by event ID (e.g., patient submitting an event anonymously); the acceptance is stored by a unique identifier. To the extent possible, the prototype makes individuals accept the general terms and conditions only once.

- The RSO moves to an activity status of "Submitted" when it is initially saved.

- The RSO automatically saves when the user clicks the button to move to the next module.

- "Submit" status is applied when the "Submit" button is clicked after completing modules 1–6. "[Submitted]" is auto-selected after the consumer has submitted the report.

- A prototype-generated RSO # ID is established when submitted.

- The prototype has a time-out feature established at 20 minutes of inactivity and displays a warning at 15 minutes of inactivity, at which point the user will either respond or be logged out of the prototype, thus losing any unsaved information.

- Once a resolution is submitted by the user, the hotline team may alter the status to one of the following five options:
  - Screened
    - Is selected by the Intake Administrative User/SuperUser – Research after the inclusion/exclusion criteria have been applied.
  - Audited – needs patient/caregiver/other reporter follow-up.
    - Is selected by the SuperUser – Administrative when clarification of the RSO by the reporter is needed.
  - Audited – needs team decision (free text reviewed and sanitized).
  - Clarified (questions answered by reporter team; ready for matching to provider).
    - Is selected by the SuperUser – Administrative after auditing and clarification of the RSO is completed and all free text fields have been reviewed and de-identified.
  - Finalized
    - Is selected by the SuperUser - Administrative once the supplementation process is completed.

The details of these processes and the handling of the RSO are detailed in Section 5 of this Operations Manual.

Operational Requirements

All systems are kept up-to-date within three to five days of every security and system update released by the vendor. The prototype retains a full audit trail, with each version of the RSO accessible for review. The audit trail maintains the entire version of the record at each update of the RSO each time it is committed to the database. The prototype shows by whom (user) and when (date and time) an RSO was accessed. Only the SuperUser – Administrative has access to this information.

Reporting Function

The following reports are made available for viewing the RSO details only as appropriate after assessment for the potential to de-identify the RSO when the user has requested anonymity. There are functional reports and administrative reports. See Appendix C.5 for the detailed content of both the functional and administrative reports.
- Functional reports
  - Summary and report by mistake type
  - Summary and report by negative effect (mistake type, type, location)
  - Summary and report of contributing factors (mistake type, type, location)
  - Summary and report by type of reporter
  - Summary of patient demographics (gender, age, race, language, insurance)
  - Print RSO to PDF

- Administrative reports
  - Summary by "How did you learn about the hotline?"
  - Summary by modality used to submit the report (phone/computer)
  - Export data set – Modules 1–7
  - Export data set – Module 8: Provider supplementation process information
  - Web traffic report

The reports available in the system allow for the data to be filtered based upon certain criteria for additional analysis. The additional filtering criteria include

- Criteria for community and aggregate reports
  - Date submitted criteria
  - Mistake type (3.1) criteria
  - Negative effect (4.2) criteria
  - Where? (3.2) criteria
- Criteria for aggregate reports

The following criteria are applicable for both detail and aggregate reporting:

- Date submitted
- Event ID #
- RSO status
- Community

Non-Functional Requirements

Overview of User Community

The main user community for the website consists of patients, families, and/or caregivers and the administrative phone-intake personnel. The prototype's intention is to assist policymakers in understanding the variety, extent, and seriousness of the consumer-reported safety occurrences.

To access the hotline, consumers (patients, families, and other caregivers) are assigned a user role (Consumer – Registered or Consumer – Guest). Users can log in as a guest to provide anonymity, or they may establish a username and password to edit and review established RSOs. The Consumer – Registered user is required to submit an e-mail address, and after e-mail confirmation and password creation, is permitted to access the RSO via a link in an e-mail.

Intake personnel and the hotline analysis team (SuperUser – Administrative, SuperUser – Research, Intake Administrative User, and Post Audit Review) must use their unique passwords and user IDs, which are set up through the same e-mail method as those of the consumers.

There is also an administrative web-based interface to the prototype that is secured by role for internal, non-public use. This interface is restricted to users by role.

User Profile(s)

    There are several levels of access to the prototype that are controlled by the roles assigned to each user by the website administrator. These levels of access are

- Consumer – Registered
- Consumer – Guest
- Admin SuperUser – Administrative
- Admin SuperUser – Research
- Intake Admin User
- Post Audit Review

See Appendix C.6 for an overview of user profiles.

4. Report Form

Patients and their caregivers, families, and friends are able to voluntarily report safety observations through a safety report form that can be completed on the web or by calling a toll-free telephone line.

Report Form (Web Tool) Plus Post-Submission Survey

The report form contains ten domains of items, described in Table C.2.

Table C.2
Hotline Report Form Content by Domain

Count	Domain
14 items	Type of safety problem (negative health effect or medical mistake) and whether it involved medications, tests, procedures or surgery, pregnancy, diagnosis, cleanliness, or other health care processes
5 items	Impact on the patient and caregivers (financial, physical, emotional)
2 items	Subsequent care (need for additional medical treatment or new providers)
8 items	Contributing factors
3 items	How the safety issue was discovered
2 items	Prior reporting about the safety issue
2 items	Mitigation efforts
8 items	Descriptive characteristics (e.g., when, where)
12 items	Information about providers
14 items	Information about the patient (and caregiver, if applicable)

The survey contains 77 items formatted with skip patterns to allow for reporting concerns that are considered medical mistakes, negative effects, or both, followed by demographic questions about the reporter. The reading level of the report form, including the required consent language is seventh grade, ninth month—7.9 on the Flesch-Kincaid reading scale, with 4 percent passive sentences. Without the consent language, the reading level of the report form is seventh grade (7.7 on the Flesch-Kincaid reading

scale). Appendix C.2 contains the final web version of the report form. Appendix C.3 contains the final phone version.

The report form includes a structured set of questions that enable patients, families, and caregivers to report about two types of safety events: negative effects related to health care (e.g., harm, injury, adverse event) and/or suspected medical errors or mistakes, whether or not they are associated with harm or injury. Figure C.1 presents the report form modules and key questions.

Figure C.1
Flow Chart of Report Form Questions
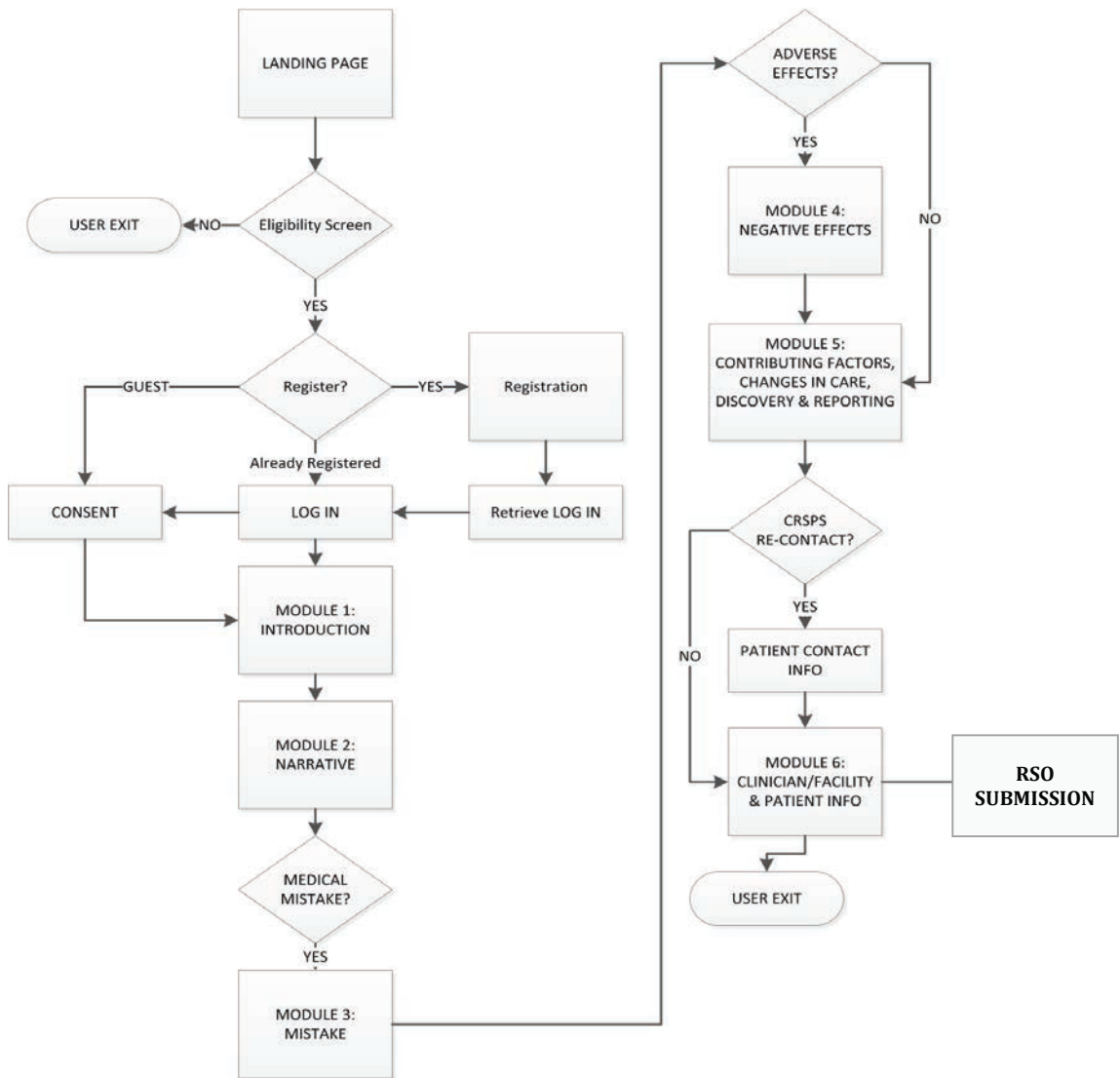
The landing page, also referred to as the introduction page, contains an introductory script, along with an overview of the hotline, general instructions, and links to additional reporting resources and FAQs. The OMB Paperwork Reduction Act Statement is also included on the landing page.

The welcome message appears at the very top of the landing page. This message gives a very brief description of the hotline, including definition and purpose.

Figure C.2
Welcome to the Health Care Safety Hotline

Welcome to the Health Care Safety Hotline - Share your concerns

The Health Care Safety Hotline is a website and toll-free number that patients and caregivers can use to report on safety concerns and negative effects of health care. The purpose of collecting this information is to make health care better by making it safe.

After the welcoming messaging, how it works, how to report, and what to report, script guides walk reporting patients or caregivers briefly through the process of using the hotline (Figures C.3, C.4, and C.5).

Figure C.3
How It Works

How It Works

You, your family, friends and caregivers can confidentially and securely tell us about concerns you have about health care safety. Only with your permission will your report be sent to a health care provider.

- You decide what will be sent
- You can choose to send the report anonymously or with your name and contact information
- You choose whether to have your hospital or clinic call you to discuss your report

Researchers will then review and sum up all of the safety concerns to help doctors, nurses, pharmacists, and other health care providers make health care safer.

Figure C.4
How to Report

How to Report

Online: [Click here] to report a safety concern online.

By Phone: Please call 1-888-580-7732
Para reporter en español, llame al 1-888-580-7732

Figure C.5
What to Report

> ## What to Report
>
> We want to hear about anything that worries you because you think something wasn't safe that happened with your doctor, hospital, pharmacy, or other health care provider or facility. Maybe there was a mistake or you were harmed. Or maybe you were almost harmed. You might be concerned if you or a family member:
>
> - Notice a health care provider not washing their hands
> - Receive the wrong medicine or the wrong dose of medicine
> - Get an infection after having an operation or other procedure
> - Get the wrong diagnosis
> - Have the wrong surgery performed
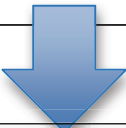
Reporting patients or caregivers are also given a brief description of what *not* to report, or what is not appropriate to report to the hotline. The link on the landing page leads to the portion of the FAQs that discusses a reportable health care safety concern compared with a complaint (Figure C.6).

A FAQs list is included as a reference for patients, family members, and caregivers. The FAQs answer a series of questions that the reporter may have and also provide directions to links or 800 numbers where they can get answers to their questions or concerns. Appendix C.7 contains the FAQs.

Figure C.6
What *Not* to Report

> ## What <u>NOT</u> to Report
>
> **Complaints about bills, insurance, parking, hospital food, or long wait times.**

> **What is a health care safety concern?** A safety concern is anything that happens with your doctor, hospital, pharmacy, or other health care provider or facility that worries you because you think it isn't safe. It does not have to be something that resulted in harm. It does not even have to be a mistake; perhaps it was *almost* a mistake - we call this a "near miss." You may have a safety concern if you or a family member:
>
> - Notice a health care provider not washing their hands
> - Receive the wrong medicine or the wrong dose of medicine
> - Get an infection after having an operation or other procedure
> - Get the wrong diagnosis
> - Have the wrong surgery performed
>
> **What is a complaint?** Complaints about parking, food, long wait times in the doctor's office, etc. usually do not affect the safety of the health care you receive, and so should not be reported to the Health Care Safety Hotline. However, if the complaint does relate to safety, it can be reported to the Health Care Safety Hotline. The Health Care Safety Hotline has a list of other places in your community where you can share your concern as well as places where you can report complaints.

A resources link appears after the series of scripts (Figure C.7). This link opens to a new pop-up site that contains information for reporting complaints, including how to report a complaint and contact information for various reporting agencies. One link identifies local patient advocates from the pilot community, including those from the participating facilities. The site also identifies other systems that are designed for reporting concerns.

Figure C.7
Resources

Resources: Other Places to Report

Click here to find out about other places where you can report safety concerns and complaints.
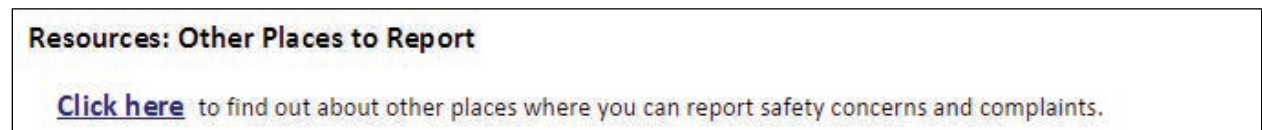
Finally, for the purpose of research and human-subjects protection, the landing page includes the OMB Paperwork Reduction Act Statement (Figure C.8).

Figure C.8
OMB Paperwork Reduction Act Statement

The OMB Paperwork Reduction Act Statement

(The United States government Office of Management and Budget (OMB) requires this statement is on the web site. It explains how long the data collection procedures will maximally take and how we minimize paperwork.)

Public reporting burden for this collection of information is estimated to average 25 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

AHRQ Reports Clearance Officer, Attention: PRA
Paperwork Reduction Project (0935-0214)
AHRQ
540 Gaither Road, Room # 5036
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

To begin a report, patients, or caregivers can either call the hotline's toll-free number or use the website URL. Once on the landing page of the website, the reporter can start the process by clicking either "Enter a New Event" or "Click Here" (Figure C.9).

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Figure C.9
Entering Events
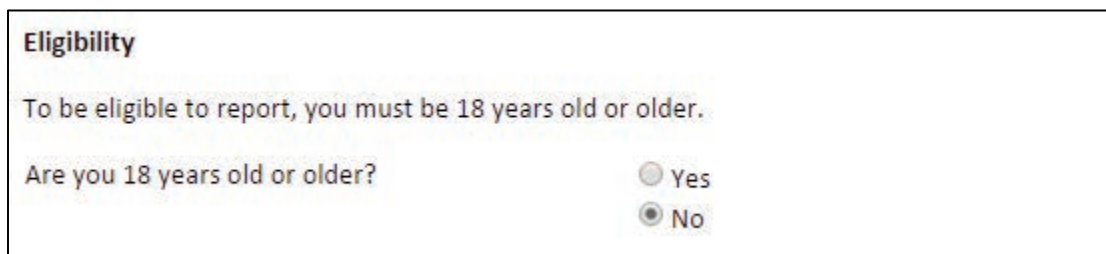
Enter a new event
Report by Telephone: 1-(888) 580-7732

Online: Click here to report a safety concern online.

After the landing page, the patient or caregiver is taken through a series of screening and introductory steps.

In the first step, before providing answers questions about the safety concern, the patient or caregiver is screened for age—reporters must be at least 18 years old (Figure C.10).

Figure C.10
Eligibility

Eligibility

To be eligible to report, you must be 18 years old or older.
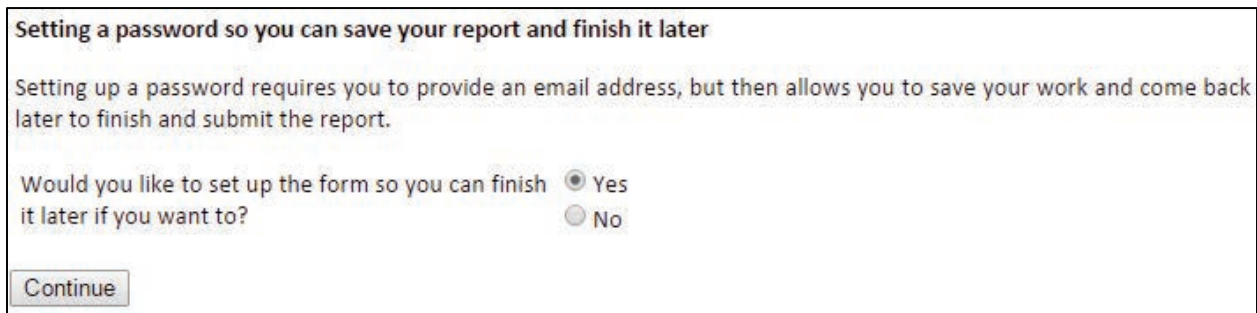
Are you 18 years old or older?   ○ Yes
                                   ● No

Next, the reporter is offered the option of registering with a username connected to his or her e-mail address so he or she they can save and return to the report. The reporter can register by using an e-mail address (Figure C.11).

Figure C.11
Setting a Password

Setting a password so you can save your report and finish it later

Setting up a password requires you to provide an email address, but then allows you to save your work and come back later to finish and submit the report.

Would you like to set up the form so you can finish   ● Yes
it later if you want to?   ○ No

Continue

Next, the reporter is directed to an overview of the hotline that describes the types of safety concerns that should be reported and advises that complaints about services like food or parking should not be reported (Figure C.12). The text briefs the reporter on the length of time it should take to complete the report and discusses options for sharing the report and the steps that will take place if consent is given to do so.

The next section of the website reviews the types of information patients or caregivers may need to answer the questions about their safety concerns (e.g., month and year of the concern, where the concern occurred) (Figure C.13).

The reporter then must click "Accept" to indicate that he or she understands the information provided (Figure C.14).

For the patient or caregiver who chooses to enter a report, the report form provides a series of open-ended questions about what happened, when and where it occurred, whether there were negative effects, and the types of negative effects (Figure C.15). The section also requests the name of the patient, provision of which is optional (Figure C.16).

Figure C.12
Health Care Safety Hotline Overview

The *The Health Care Safety Hotline* allows patients and their families or caregivers to voluntarily report on the safety of their health care. "Safety concerns" include medical mistakes and negative effects. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications. Safety concerns might come up during a visit to a doctor's office, at a pharmacy, or in the hospital.

Complaints about services like food or parking should not be reported here. Please refer to the resources link on the home page for where to report those in your area.

It should take about 20-25 minutes to complete a report. You may skip any question by leaving it blank. The more information you provide, the more we can learn from your experience.

You will have the option to give permission for the *Health Care Safety Hotline* staff to share your report with any doctor, nurse, or other health care provider (or facility) that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety. The facility might also need to use or disclose information in your report if it is required or permitted to do so by law.

Figure C.13
What Is Needed to Complete a Report

To complete this form, you will need:

- Month and Year of the concern [NOTE: Concerns that occurred more than ten years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures or surgery that were involved (if any)
- Your email address if you would like to leave the web-site and return to it to finish reporting the concern
- Your own contact information if you wish to be contacted to discuss the details of the concern

Figure C.14
Consent

> **Please read, then accept or decline:**
>
> I have read and understood the information that describes *the Safety Hotline* staff and this web site. I promise that I am 18 years old and that I will give information that is true and complete. I give my permission to *the Safety Hotline* staff team to use my information as long as they do not share my name and other identifying information. I will not share my access to my report (e.g., passwords) with anyone. I understand that I will not be paid for my participation.
>
> I understand my individual answers to the survey questions are strictly confidential and will not be seen by anyone outside *the Safety Hotline* staff team, unless during the reporting process I agree to allow *the Safety Hotline* staff team to share this information. This confidentiality is established by provisions in the AHRQ authorization legislation.
>
> ⦿ Accept
> ○ Decline
>
> [Continue]

Figure C.15
Describe Safety Concern

> 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.
>
> NOTE: If a patient died as the result of a mistake, please tell us about the mistake that led to the death and consider the negative effect "death"
>
> **What happened?**
>
> [   ]
>
> **Where do you believe it happened?**
>
> [   ]
>
> **When did it happen?**
>
> [   ]
>
> **Why do you think this happened?**
>
> [   ]

Figure C.16
Name of Patient

What is the name of the patient?

ENTER FIRST NAME:

ENTER LAST NAME:

After this open-ended narrative information is collected, the patient or caregiver is asked if either a medical mistake or negative event occurred (Figure C.17). Depending on the nature of the patient safety concern, one or both of these options may apply. Reporting patients or caregivers may also indicate that they do not know.

Figure C.17
Medical Mistake

In your opinion, did a doctor, nurse, or other health care provider make a medical mistake or error in the patient's care? ⓘ

◯ Yes

◯ No

◯ Don't know

Depending on the selection made by the reporter, additional screens with questions will be prompted. For example, if the patient or caregiver notes that a medical mistake occurred, he or she will then be directed to the section of the report that asks specifically about the medical mistake. Similarly, patients who report the occurrence of a negative effect will be directed to the section of the report that asks specifically about the negative effect (Figure C.18). Patients and caregivers who report the occurrence of a medical mistake will be prompted to answer whether they believe a negative effect also occurred. Those who report that a medical mistake did *not* occur but that a negative effect did will be prompted to answer questions *only* about the negative effect.

Figure C.18
Negative Effect

> Do you think a negative effect took place as a result of the patient's care?
> ○ Yes
> ○ No
> ○ Other
> ○ Don't know

The person making the report is given the option to describe in his or her own words the factors that might have contributed to the safety event and is asked whether each of a limited list of potential factors might have contributed to the event. This limited list includes only those factors that are plausibly directly observable by a patient or caregiver and considered valid and reliable based on prior testing (e.g., communication with providers using constructs that have been tested on prior surveys such as the Consumer Assessment of Healthcare Providers and Systems [CAHPS] survey series) or have been used in other safety reporting instruments.

In both sections of the form (medical mistake or negative effect), patients or caregivers are asked to answer questions related to the nature of the mistake or negative effect and to provide specific details, such as when and where the mistake or negative effect occurred and the results of the occurrence.

Reporters are then offered the opportunity to submit the report to the health care facility, doctor, nurse, or other health care provider involved (Figure C.19). A Yes response results in an additional question series to obtain contact information about the facility or provider. The remaining three responses do not prompt these additional questions but skip to asking about consent to share the report.

Figure C.19
Identify the Facility

> Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?
> ○ Yes
> ○ Yes, but I do not know the name of the facility or provider
> ○ No, I do not know the name of the facility or provider
> ○ No, I do not want to tell you

Patients or caregivers are asked if they consent to sharing the report with the relevant health care facility or providers and to sharing the patient's name (Figure C.20).

Figure C.20
Consent to Share

> May we share your report with the health care facility or provider?
>
> ○ Yes
>
> ○ No

> May we share the name of the patient with a safety concern with the health care provider (or facility)?
>
> ○ Yes
>
> ○ No

Reporters are also asked to provide consent to link the report with name and contact information.

In addition, the intake portion of the medical mistake or negative event sections on the report form asks whether the patient reported the event to a health professional, manager, or other person (Figure C.21), and it asks whether the event was disclosed to the patient by a health professional.

Figure C.21
Notification of Mistake or Negative Effect

> Did the patient tell anyone about the mistake or negative effect?
>
> ● Yes
>
> ○ No
>
> ○ Don't know
>
> Who did the patient tell about the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.
>
> ☐ A family member or friend
>
> ☐ A doctor, nurse, or other health care provider
>
> ☐ A health care administrator or manager
>
> ☐ Someone at the pharmacy
>
> ☐ A minister or other religious leader
>
> ☐ A lawyer
>
> ☐ Someone else, such as a licensing agency, etc.

The form then asks patients or caregivers to answer questions regarding contributing factors, changes in care, and discovery and reporting. In this section, reporters are asked to identify potential contributing factors to the mistake or negative effect and to comment on the outcome, aftermath, or result.

Contributing factors are broken down by section: communication, responsiveness, coordination, access, verification, and other. Each of these sections offers several options that reporting patients or caregivers can choose to describe the factors contributing to the mistake or negative effect. The example in Figure C.22 outlines the communication section for reference.

Figure C.22
Contributing Factor Example

Communication - Was it because the doctors, nurses, or other health care providers...
- ☐ did not listen to the patient?
- ☐ did not explain things to the patient in the patient's language?
- ☐ used terminology the patient could not understand?
- ☐ spoke with an accent that was hard to understand?
- ☐ did not spend enough time with the patient?
- ☐ ignored what the patient told them?
- ☐ did not explain medications or their side effects?
- ☐ did not provide a clear explanation of the diagnosis or care plan?
- ☐ did not explain follow up care instructions?

The reporter may opt to allow a hotline intake staff person to follow up in order to clarify details about the report (Figures C.23 and C.24). Those who opt in will be contacted by telephone by the hotline staff, who will clarify information in the initial report and annotate the report accordingly. This service is available in both English and Spanish.

Figure C.23
Consent to Follow Up

A member of the Health Care Safety Hotline staff can follow up by telephone. Please give us your name and how to reach you. We will make sure that your name and other contact information is kept secure. It will be shared only with your permission. If you decide NOT to give us your contact information, we will not contact you in the future.

May we contact you if we need more information?
   ⦿ Yes
   ◯ No

Figure C.24
Contact Information

Please tell us your name and your address, telephone number, or email.

NAME:

STREET ADDRESS:

CITY:

STATE:
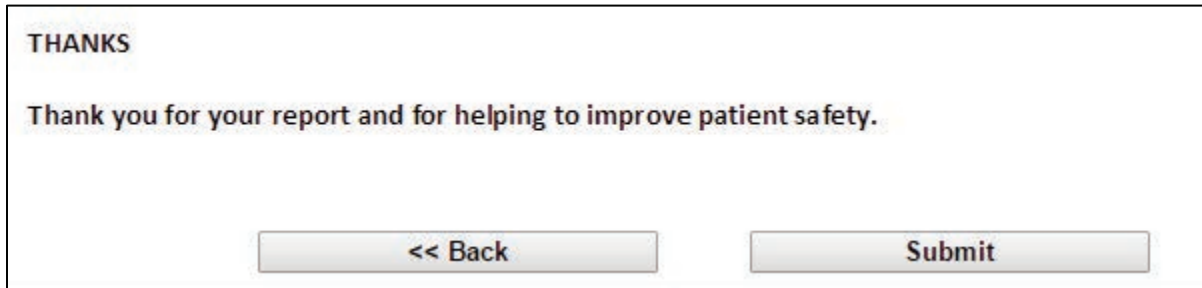
ZIP:

PHONE:

Finally, at the end of the form, a series of questions asks about the demographics of the patient or caregiver: sex, age, race and ethnicity, and type of insurance. Patients or caregivers are also asked how they learned about the hotline.

The report is complete only when the reporting patient or caregiver clicks the "Submit" button (Figure C.25).

Figure C.25
Submission of Report

THANKS

Thank you for your report and for helping to improve patient safety.

| << Back | Submit |

Reporters are then directed to an RSO submission review page, which allows them to download a copy of the PDF version of the report and, finally, to officially submit the report by clicking the "Finished" button (Figure C.26).

Figure C.26
Finishing the Report

| Generate PDF | Finished |

The hotline form also provides a place for reporters to voluntarily rate their experience via a brief, confidential survey (Figure C.27). The survey is reproduced in Appendix C.8 below.

Figure C.27
Patient Satisfaction Survey

Please rate your experience with the hotline. Participation is voluntary and confidential. This will take less than 5 minutes.

Click **here** to access the survey

Upon leaving the safety report form page, patients and caregivers are directed back to the landing page.

Handling Toll-Free-Number Phone Intake (Including Suggested Scripts)

Individuals may also access the Health Care Safety Hotline by telephone via the designated toll-free number. A phone-intake administrator will guide consumers through the intake process in either English or Spanish. The phone-intake administrator will start by introducing himself or herself and the hotline. The administrator will then guide the

reporter through the hotline prompts by accessing the web page and entering a new event (Figure C.28). The administrator has been trained to input the reporter's responses in the first person, as though the reporter were entering the report. A phone script is available to guide the phone-intake administrator through the hotline questions (Appendix C.3).

Figure C.28
Entering an Event by Phone

When the phone intake administrator has finished entering the information in the report, and if the patient or caretaker has consented to being contacted to clarify the information, the administrator should advise the reporter that a person may call to ask any clarifying questions that are necessary to better understand the nature and specifics of the report. If the patient or caregiver has consented to sharing the report with the health care organization, the phone-intake administrator will also advise him or her that an individual from the health care organization may call.

Messages that are left on the hotline voicemail are returned and processed as soon as possible. A total of five attempts are made to reach a caller; the attempts are made at different times of the day to maximize the chance of making contact. Because of the confidential nature of the hotline, messages are not left on the caller's voicemail or with individuals other than the caller. If after five attempts the caller cannot be reached, this information is documented on the tracking sheet, and the caller is considered lost to contact.

5. Processing and Sharing Reports

The project team collaborated with the health care delivery organization to develop detailed protocols for each step of processing patient and caregiver reports of safety concerns. Figure C.29 shows a high-level overview of the processing steps.

Figure C.29
Processing and Sharing Reports
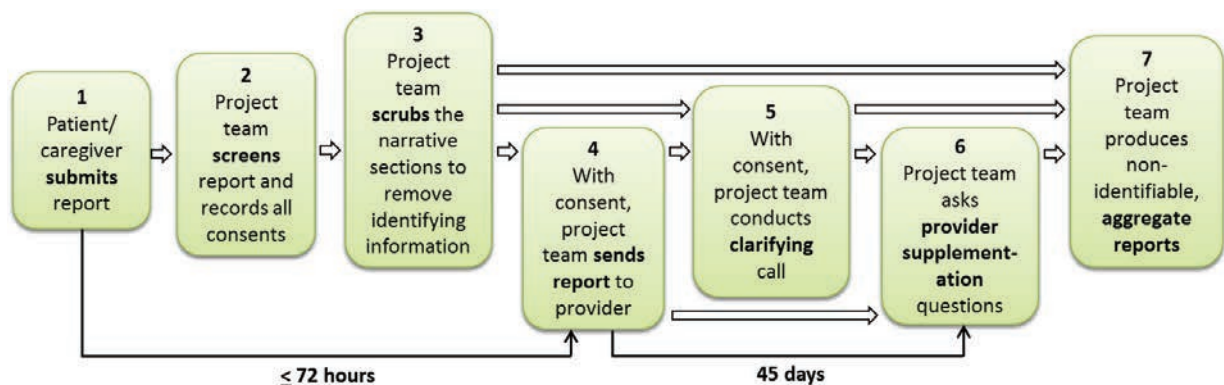
In Step 1 (described in Section 4 of this Operations Manual), the hotline receives information about the safety concern through a series of questions that patients and caregivers can answer on a secure website or by a toll-free phone number. The patient or caregiver goes through the series of screens described above in order to make a report. Once a report is submitted, a project team member screens the report to confirm that it meets the inclusion criteria.

In Step 2, a project team member reviews the report, noting whether the patient or caregiver consented to receive a follow-up call and whether permission was granted to share the report with the named provider; if permission is given, the patient or caregiver is asked whether his or her name and contact information can be shared with the provider when a summary is sent. All activities should be included on an Excel tracking spreadsheet (an example is shown in Figure C.30). Appendix C.9 provides details on the Excel tracking sheet.

In Step 3, the team member scrubs the narrative sections provided by the patient or caregiver to safeguard confidentiality, removing identifying information such as names of people and institutions. 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, can be found in Appendix C.10. The screening and auditing process is to be completed within 72 hours of receipt of the report.

Figure C.30
Excel Tracking Sheet for Screening and Auditing

Rpt_ID	Full_Rpt_ID	Owner	Rpt_date	Rpt_timeET	Notify_ECRI_date	Notify_ECRI_timeET	Notify_MD_date	Notify_MD_timeET	Assigned_MD
40	40_ERROR		9/19/2014	12:33	9/19/2014				
41	41_PI	AB	10/9/2014	8:31	N/A	N/A			
42	42_PSI	AB	10/9/2014	8:58	10/12/2014	2:58	10/12/2014	4:58	EF
46	46_PSI	CD	11/13/2014	17:16	11/14/2014	9:00	11/14/2014	13:30	GH
47	47_PS	CD	11/13/2014	18:21	11/14/2014	9:00	11/14/2014	14:15	EF
48	48_PSI	AB	12/29/2014	9:24	12/29/2015	10:05	1/3/2015	12:30	IJ
51	51_P	CD	1/5/2015	9:42	N/A	N/A	1/5/2015	15:30	EF

In Step 4, if the patient or caregiver consented to have the report shared with the relevant health care facility or provider, a PDF file of the scrubbed report is uploaded to a secure website accessible to the named provider. This is done within 72 hours to minimize delays and 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 e-mail with a link to the report on the secure website.

In Step 5, hotline staff review the report for incomplete or inconsistent information that requires clarification from the patient or caregiver. Detailed instructions for making the clarification call are given in Appendix C.11. As part of this process, the hotline staff works with one of the clinicians on the team, who reviews the report to identify any issues or areas that require clarification. If clarification is required by either the doctor, the staff person, or both, a project team member conducts a follow-up call with the person who made the report. The additional information elicited through the clarifying call is uploaded to the secure website if the patient or caregiver has given permission. Appendix C.12 provides more information on the clarification call and gives examples of the types of questions that should be included.

If the report has been clarified (Step 5), a revised version is uploaded to the secure website, and the relevant health care organization or provider is notified via an e-mail with a link to the clarified report.

In Step 6, within 45 days of sharing the report with the named provider in Step 4 (to accommodate the 30-day CMS grievance follow-up period), the project team reaches out to the health care delivery organization or health care facility with a series of questions about what the organization did with the reported information. These questions are on an administrative intake page linked to each report, referred to as Module 8.

The sharing process is documented by the PSO project team on an Excel spreadsheet (Figure C.31), which contains the report ID 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, when the follow-up supplementation call from the PSO staff with the provider about the specific report is due (e.g., 45 days after receipt of the initial report),

and when the supplementation process with the relevant health care facility or provider was completed.

Figure C.31
Excel Tracking Sheet for Sharing Reports

	RSO#	Pilot Site	Submitted	Date Sent	Clarification Sent	Follow-up Due	Follow-up Completed
1	13	1	3/21/2014	3/24/2014	n/a	5/8/2014	5/5/2014
2	15	1	4/25/2014	4/28/2014	5/6/2014	6/12/2014	5/12/2014
3	16	2	4/29/2014	5/1/2014	5/8/2014	6/15/2014	8/7/2014
4	20	1	6/9/2014	6/10/2014	7/18/2014	7/25/2014	8/1/2014
5	21	2	6/23/2014	6/23/2014		8/7/2014	8/20/2014
6	22	2	6/23/2014	6/24/2014	6/24/2014	8/8/2014	8/20/2014
7	24	1	6/25/2014	6/28/2014	7/18/2014	8/12/2014	8/26/2014

With each report, progress through the seven processing steps (shown in Figure C.29) is tracked on an administrative page linked to the report. The administrative page is viewable by the project team but not by the patient or caregiver who made the report. To access the hotline website, administrative users click on the link in the e-mail that refers them to the URL. To access the administrative page that lists the reports, the administrator enters his or her e-mail address and password in the appropriate text fields on the left side of the website landing page. Then the administrator clicks on "View Entered Patient Safety Events." An example of the Entered Patient Safety Events spreadsheet is shown in Figure C.32.

Figure C.32
Entered Patient Safety Events

In Step 7, for research and summary purposes, the hotline generates non-identifiable aggregated reports on the types of events reported.

After the hotline receives a report and any additional information elicited through the patient or caregiver clarification process is added to it, a clinician reviews the report and classifies the event(s) described according to the AHRQ Common Formats event type,

harm scale, and duration of harm. The clinician also comments on the preventability of the event and contributing factors.

Instructions for Classifying Events

After a report is submitted, a clinician on the hotline team classifies the reported event(s). The classification form is shown in Appendix C.13. The clinician first classifies the type of event, using the AHRQ Common Formats, Version 1.2, as either an incident, a near miss, or unsafe conditions. An incident is an event that reaches a patient; that is, an event that exposes a patient to harm, regardless of whether the patient is ultimately harmed. A near miss is an event that does not reach a patient. An unsafe condition is "any circumstance that increases the probability of a patient safety event."

After classifying the report according to the type of event, the clinician identifies the level of harm associated with the event, again using the AHRQ Common Formats. (This step occurs only if the event is classified as an incident; near misses and unsafe conditions, by definition, do not expose patients to harm.) There are six levels of harm in the Common Formats: unknown, no harm, mild harm, moderate harm, severe harm, and death. The Common Formats provide definitions for each level; for example, mild harm is defined as "minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay." For events classified as resulting in any level of harm, the clinician indicates the duration of harm: unknown, temporary (less than one year), or permanent (one year or more).

The clinician then provides a short narrative (typically two to three sentences) describing the preventability of the event, drawing on his or her clinical expertise in addition to the patient perspective contained in the report. A patient may believe that a certain aspect of the event was preventable, but when the clinician reviews the report and reflects on relevant clinical knowledge, he or she may disagree. After describing the event's preventability, the clinician provides a short narrative describing the contributing factors—that is, the factors that contributed to the event. Again, the clinician draws on his or her clinical expertise and selects relevant contributing factors from a structured list— the same list that patients and caregivers use when reporting to the hotline. The list of contributing factors is organized into categories: communication with health care providers, staff responsiveness, care coordination, access, verification, and other.

In many instances, a project team member successfully completes a clarification call with the patient or caregiver who submitted the initial report. After a clarification call occurs, the clinician reviews the completed classification form and evaluates whether it needs to be revised to reflect the new information elicited through the call. If the form does need to be revised, the clinician revises it.

Instructions for Generating Aggregated Reports of Events
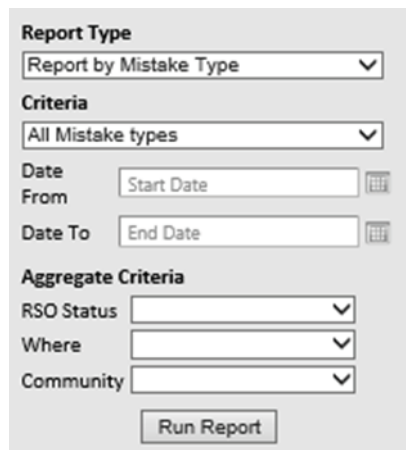
Aggregated reports for all RSOs can be generated in real time via the web-based system. Aggregated reports include

- Report by mistake
- Report by negative effect
- Report by contributing factors
- Person reported for
- Summary patient demographics (gender, age, race, and insurance)
- How the reporter learned about the hotline
- Modality reported by (phone/computer).

Descriptions of the individual reports are shown in Table C.3.

To conduct the initial analysis of the RSOs, reports can be filtered based upon criteria within the report, such as date range, and aggregate criteria, such as RSO status, where care was provided (i.e., the type of health care facility/provider), and community (Figure C.33).

Figure C.33
Filtering Options for Reporting
Function

Administrative reports can also be generated for additional analysis. These reports include

- Export data set – Modules 1–7
- Export data set – Module 8
- Evaluation report (web traffic).

Descriptions of the administrative reports are shown in Table C.4.

Table C.3
Descriptions of Individual Hotline Reports

Type of Report	Description
Report by mistake type	This report provides a tabular and pie chart representation of mistake type and mistake subtypes. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each mistake type or mistake subtype.
Report by negative effect	This report provides a tabular and pie chart representation of negative effect and physical negative effects. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each negative effect and physical negative effects.
Report by contributing factor	This report provides a tabular and pie chart representation of mistake type and contributing factors. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each mistake type and contributing factors.
Person reported for	This report provides a tabular and pie chart representation of the person reported for. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of events submitted on behalf of a child, spouse/domestic partner/other family member, friend, patient or client, or someone else.
Summary patient demographics	This report provides a tabular and pie chart representation of patients' gender, age, race, and insurance. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of gender, age, race, and insurance.
How reporter learned about the hotline?	This report provides a tabular and pie chart representation of the provider website, flyer/poster, kiosk, conversation, mail, and other. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of provider website, flyer/poster, kiosk, conversation, mail, and other.
Modality reported by (phone/computer)	This report provides a tabular and pie chart representation of events submitted by phone or computer (online). Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of events submitted by phone or computer (online).

Table C.4
Descriptions of Administrative Reports

Type of Report	Description
Export data set – Module 1-7	This report exports all the questions and answers of modules 1–7 to a CSV file based on the criteria and date range (up to 6 months of data) selected. This report is accessible only by Super User – Administrators.
Export data set – Module 8	This report exports all the provider supplementation information follow-up questions and answers in Module 8 to a CSV file based on the criteria and date range (up to 6 months of data) selected. This report is accessible only by Super User – Administrators.
Evaluation report (web traffic)	This report exports all the web traffic data to a CSV file based on the date range (up to 1 month of data) selected. This report is accessible only by Super User – Administrators.

6. Maintenance of the System and Data Storage

Change Management

During the pilot project, we used a formal change management process for any application changes, feature additions, and bug fixes. Documentation was very important, so we used a Microsoft Team Foundation Server to track all changes, including requirements and code check-ins. User stories, test cases, tasks, bugs, conversations, and code were all associated together to keep track of them for documentation purposes.

Backups

ECRI's backups were performed on a daily basis and written to disk. We then put these data on weekly tapes and sent them to Iron Mountain. The tapes were cycled back to ECRI on a monthly basis and stored in an internal locked vault. The disaster recovery (DR) site was built and tested to handle all of the applications in case of a failure at the main facility. All ECRI data is replicated instantaneously to the DR site within the storage area network (SAN), which allows a very quick turnaround time. The recovery point objective (RPO) is 30 minutes, and the recovery time objective (RTO) can occur in less than 12 hours.

Disaster Recovery

ECRI's data center has two HVAC and two UPS backup systems. The facility has two generators as backup sources for power and a redundant internet connection. In addition to this, it has a DR site, which is a Tier II equivalent facility with N+1 capability with redundancies built in. There is one SAN in the data center and another at the DR site. Data are replicated between the two SANs every 30 to 60 minutes, which is less than 4 hours RPO.

ECRI's DR site is housed at a separate geographical location about 56 miles away from the primary site and is on a separate power and Internet grid. The RTO is less than 12 hours, and the RPO is less than 4 hours. In the event of a disaster that cannot be handled by the redundancies in the main facility, ECRI is able to switch to the DR site.

Encryption

Data transfer is encrypted through Secure Socket Layer (SSL), using at least 128-bit encryption. The prototype uses FIPS Compliant Servers and Transparent Data Encryption (TDE) on all Protected Health Information SQL Servers.

Security

Access to the application is managed by ASP.NET Forms Authentication, using ASP.NET Application Services, which are built-in web services that provide access to features such as forms authentication, roles, and profile properties:

   I.   Authentication service. This service allows users to log on to an application. It accepts user credentials and returns an authentication ticket.
   II.   Roles service. This service determines the application-related roles for an authenticated user, based on information that is made available by an ASP.NET roles provider, which determines the user's permissions to edit and view RSOs information.

Profile Service

This service provides per-user information as a user profile that is stored on the server.

Knowledge Transfer

All programming source code and prototype documentation is to be transferred to AHRQ at the end of the contract period.

Appendix C.1. Web Strategy and Communications Team Technical Review of the Health Care Safety Hotline Website

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The technical comments provided in this appendix focus on what the user sees or experiences when submitting a patient safety concern via the July 2015 version of the hotline website. We approached this review with an eye toward usability and accessibility best practices, among other issues. In testing the site, we used Chrome and ChromeVox (a screen reader). Testing in other browsers (Safari, Firefox, IE) may result in additional areas that could benefit from review.

If another organization (health care organization, state regulatory agency, university, etc.) decides to adopt or create a similar website, we recommend the usability considerations described below to streamline the report submission process. Several usability suggestions pertain to the process of creating an account or using it after having logged in and are relevant to nearly all online forms, not only the one on the hotline website (see the discussion in Chapter IV in the main report). As noted in Chapter IV of the report, we recommend against using accounts unless it is absolutely necessary (e.g., if the organization anticipates that many users will return to the form). If a login/account creation process is included on a site, the link to enter a new event should be more prominent than the login form for accessing an existing event. Similarly, the option for setting up a password should be presented only after the estimated completion time and/or the list of required information is provided. If a user does choose to create an account, password restrictions (length, required characters) should be shown as visible text, and error messages should be written in plain language (e.g., "Please use at least one special character" rather than "Non-alphanumeric characters in 'newPassword' needs to be greater than or equal to '1'."). Then, after submitting the form to create an account, the user should remain on a page that presents a "success" message rather than being sent back to the home page. Ideally, the message should include the e-mail address entered, making it easy to log in at that point. If a user has logged in and is entering a new event, the form should omit certain questions that were answered when the user created an account, e.g., the user's e-mail and the fact that the user is over 18 years of age (a requirement for creating the account).

The following suggestions are also relevant for all web forms and are worth considering regardless of account/login status. First, unless required for compliance, timing out a session should be avoided. If the timeout must be retained, the user should see a warning message a few minutes prior to the timeout. Second, it is important to use

the right size/type of input field for each question and to carefully consider what restrictions are used. For example, the phone number field should just be a plain input; the JavaScript that is in place on the hotline website form restricts use to entering only numbers, which prevents the user from using the delete key to fix mistakes. Also, the name field in the contact information section might be better as an input, and "What could have been done?" might be better as a text area. Third, when coding pop-up messages, consider how the user will react. Exclamation points and all caps in error messages could be perceived as scolding and could increase user frustration (e.g., "The password MUST contain at least one capital letter, one number and one special character!"). Use of a polite tone, punctuation, and sentence case is preferred. Fourth, as the user goes from one page to another, it is useful to make that transition obvious. When a significant portion of the page stays the same, it may not be clear what has changed. Rather than repeat introductory text from one page to another, offer a link or toggle (defaulting to closed) to the repeated content. Also, use unique headlines and titles on each page. Fifth, it is best to minimize the risk that the user will click off the form before completing it. Unless all transitions automatically save changes, nonlinear navigation through the form (e.g., back buttons and left column links) should be avoided.

Although there are myriad interpretations of Section 508 compliance, we recommend using a tool such as Chrome Vox to test sites; we often find that improving a site for the visually impaired will also improve it for sighted users. For example, forms should allow keyboard submission using the return/enter key; this helps people using screen readers and also helps regular users who prefer to tab through forms. Forms should be coded such that making a selection (via radio buttons or checkboxes) lets the user proceed to the next field. We noticed that in some cases, the hotline website's forms would return users to the top of the page rather than to the next field. This means that users who have visual impairments must re-read the entire page to return to the question, and that sighted users must scroll back down to the next form field. Finally, information icons that provide additional context for questions should be coded so as to be accessible to screen readers as well as sighted users; while less common today, some people do browse websites with image displays turned off for security reasons.

Several other considerations are also helpful for both usability and accessibility. For example, using "Click here" as the link text is fine, but offering descriptive text is more useful for regular visitors as well as screen readers. Similarly, links ("href" code) should contain paths to actual pages, rather than to on-click attributes. If pop-up or other functionality is desired, JavaScript events can be attached. This allows default browser behavior to work as expected and ensures that the site will be usable by a larger number of users. Finally, modern websites can be coded to respond to the available space in the browser window. This technique, called responsive web design, makes it easier for users

on mobile devices to use the site and is also frequently useful for people who have visual impairments, as elements of the page can be skipped easily when using screen readers.

Additional suggestions are presented below. They are listed in order of website access and use (i.e., what the user sees or experiences when submitting a concern), rather than in order of importance.

- Input buttons <input type="submit"> should be used only for submitting forms. For links, use anchor tags <a>, which can be styled to look like buttons.
- In the quick links, the "Complaints about bills and insurance" link does not link to a particular FAQ.
- Since the user will need to receive the e-mail to continue, a single e-mail address field is sufficient.
- Form elements (input, select, text area) should have associated labels. Some questions use other tags (e.g., Enter the city, Enter the state).
- Save/submit/continue buttons should be aligned under the other form elements on each screen.
- In the post-submission survey, the text area is too large.
- The filter options on the entered-events list seem too robust for an individual user; perhaps they could be added only if the number of records is greater than n (e.g., 10).
- Display pagination only if items span more than one page
- The generated PDFs appear blank in Preview on OSX.
- Nearly all web users are comfortable with the concept of scrolling; there is no need to add messaging about it on the form pages.

Appendix C.2. Survey Report Form – Web Version

SECTION 1: INTRODUCTION

The *Health Care Safety Hotline* allows patients and their families or caregivers to
voluntarily report on the safety of their health care. "Safety concerns" include
medical mistakes and negative effects. Negative effects can be physical or emotional
and they may include infections, drug reactions, or other complications. Safety
concerns might come up during a visit to a doctor's office, at a pharmacy, or in the
hospital.

Complaints about services like food or parking should not be reported here. Please
refer to the resources link on the home page for where to report those in your area.

It should take about 20–25 minutes to complete a report. You may skip any question
by leaving it blank. The more information you provide, the more we can learn from
your experience.

You will have the option to give permission for the Health Care Safety staff to share
your report with any doctor, nurse, or other health care provider (or facility) that
was involved in the negative effect. This would alert the facility's staff so they can
learn about what went wrong and improve safety.

To complete this form, you will need:
- Month and year of the concern [NOTE: Concerns that occurred more than 10
  years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street
  address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures, or survey that were involved (if any)
- Your e-mail address if you would like to leave the website and return to it to
  finish reporting the concern
- Your own contact information if you wish to be contacted to discuss the details of
  the concern

1.1 Who is the patient with a safety concern?
□_A Me
□_B A child
□_C A spouse, domestic partner or other family member (for example, a grandparent, aunt, etc.)
□_D A friend
□_E A patient or client
□_F Someone else → [DISPLAY AS TEXT BOX: Who is the patient?]

1.1.1   In what city and state did the safety concern occur?

Enter the city:
Enter the state:

SECTION 2: DESCRIPTION OF YOUR SAFETY CONCERN

2.1   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.

2.1a. What happened?

NOTE: If you believe a patient died as the result of a mistake, please tell us about the mistake and record the negative effect as "death."

2.1b. Where do you believe it happened?

2.1c. When did it happen?

2.1d. Why do you think this happened?

2.2   What is the name of the patient?
ENTER FIRST NAME:
ENTER LAST NAME:

Now we will ask some questions to make sure we understand what happened.

2.3   In your opinion, did a doctor, nurse, or other health care provider make a medical mistake or error in the patient's care?

POP-UP: A medical mistake or error is something that was done (or not done) by a health care provider that would be considered incorrect at the time it happened. Sometimes medical mistakes can result in harm or injury to the patient, but not every time.

□_A Yes → GO TO 3.1

□_B No → GO TO 2.3.1
□_C Don't know → GO TO 2.3.1

**When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.

2.3.1   Do you think a negative effect took place as a result of the patient's care?
□_A Yes → GO TO 4.1
□_B No → GO TO 2.3.1.1
□_C Other → [DISPLAY AS TEXT BOX: Please describe]
        → GO TO 2.3.1.1
□_D Don't know → GO TO 2.3.1.1

2.3.1.1 You told us that a mistake did not take place (or that you don't know) and that a negative effect did not take place (or that you don't know). Is this correct?
□_A Yes → GO TO 6.0
□_B No → GO TO 6.0
□_C Don't know → GO TO 6.0

SECTION 3: MISTAKE

3.1   Did the medical mistake or error involve any of the following? Please <u>choose the one answer</u> that fits best.
□_A A mistake related to a medicine
[POP-UP: Medicines can include prescription or non-prescription medication, herbs, dietary supplements, vaccines, contrast dye or other injected medicines] → GO TO 3.1.1.1

□_B A mistake related to a test, procedure, or surgery
[POP-UP: This includes tests that involve taking samples of skin or tissue, inserting tubes to examine internal parts of your body, or other tests involving blood, urine, or X-rays.] → GO TO 3.1.2.1

□_C A mistake related to pregnancy or childbirth
[POP-UP: This includes errors in diagnostic testing during pregnancy and errors during labor and delivery] → GO TO 3.2

□_D A mistake related to a diagnosis or advice from a doctor, nurse, or other health care provider → GO TO 3.1.3.1

□_E A mistake related to poor cleanliness or poor hygiene → GO TO 3.2

□_F Something else, or more than one mistake [GO TO 3.1f1]

3.1.f1 In your opinion, what was the mistake? [FREE TEXT BOX]

3.1.1.1 As best as you can, please name or describe the medicine. [FREE TEXT BOX]

3.1.1.2 Was it a prescription medicine?
[POP-UP: Don't include over-the-counter medicines that you can buy without a prescription from a doctor or nurse.]
□$_A$ Yes
□$_B$ No
□$_C$ Don't know

3.1.1.3 Did the mistake with medicine involve any of the following? Please <u>choose the one answer</u> that fits best.
□$_A$ Wrong medicine→ GO TO 3.2
□$_B$ Wrong dose→ GO TO 3.2
□$_C$ Something else→ [GO TO 3.1.1.3-OTHER: What did the mistake involve? FREE TEXT BOX, ALLOW 50. GO TO 3.2]

3.1.2.1 As best as you can, please name or describe the test, procedure, or surgery. [FREE TEXT BOX]

3.1.2.2 Did the mistake with a test, procedure, or surgery involve any of the following? PLEASE CHECK ALL THAT APPLY.

□$_A$ Wrong patient [POP-UP: The patient was not correctly identified.]
□$_B$ Wrong test, procedure, or surgery [POP-UP: The wrong type of test, procedure, or surgery was done.]
□$_C$ Wrong part of the body [POP-UP: The test, procedure, or surgery was on the wrong part of the body.]
□$_D$ A mistake was made <u>during</u> the test, procedure, or surgery
□$_E$ The test, procedure, or surgery was delayed
□$_F$ The test results were lost and the patient did not receive them
□$_G$ The patient developed an infection
□$_H$ A problem with anesthesia
□$_I$ Something else→ What did the mistake involve?

→ GO TO 3.2 ONCE ITEMS CHECKED

3.1.3.1 In your opinion, what was the mistake with the diagnosis or medical advice? [FREE TEXT BOX]

3.2   Where did the mistake happen? Please <u>choose the one answer</u> that fits best.
□$_A$ In a doctor's office or a clinic
□$_B$ In a pharmacy
□$_C$ In the emergency department

□_D In a hospital
□_E At home
□_F Don't know
□_G Somewhere else

3.3   Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?

□_A Yes
□_B Yes, but I do not know the name the facility or provider → GO TO 3.4
□_C No, I do not know the name of the facility or provider → GO TO 3.4
□_D No, I do not want to tell you → GO TO 3.4

3.3.1   Please write the name and address of the health care facility or provider involved.

    NAME OF HEALTH CARE FACILITY/PROVIDER:
    STREET ADDRESS:
    CITY:
    STATE:

3.3.2   Was a second health care facility or provider involved?
□_A Yes
□_B No→ GO TO 3.3.5

3.3.3   Would you like to tell us the name of the second health care facility or provider involved?
□_A Yes
□_B Yes, but I do not know the name and address of the facility or provider → GO TO 3.3.5
□_C No, I do not know the name of the facility or provider → GO TO 3.3.5
□_D No, I do not want to tell you → GO TO 3.3.5

3.3.4   Please write the name and address of the second health care facility or provider involved.

    NAME OF HEALTH CARE FACILITY/PROVIDER:
    STREET ADDRESS:
    CITY:
    STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any doctor, nurse, or other health care provider (or facility) that was involved in the mistake. This would alert the facility's staff so they can learn about what went wrong and improve safety.

3.3.5   May we share your report with the health care provider or facility?
□_A Yes
□_B No

3.4   In what month and year did the mistake happen? (Your best estimate is fine.)

ENTER MONTH:
ENTER YEAR:

3.5   Did a doctor, nurse, or other health care provider tell you the mistake happened?
□_A Yes→GO TO 3.6
□_B No [FREE TEXT BOX: How did you find out that the mistake happened

Sometimes medical mistakes affect patients financially. For example, patients may have to miss work, pay for extra tests or procedures, or take additional trips to a health care facility.

3.6   Did the mistake affect the patient financially?
□_A Yes
□_B No
□_C Don't know

When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.

3.7   Did the patient experience any negative effects as a result of the mistake or error?
□_A Yes
□_B No → GO TO 5.1
□_C Don't know → GO TO 5.1

Table 3-4
SECTION 4: NEGATIVE EFFECT

4.1   Did the negative effect involve any of the following? Please <u>choose the one answer</u> that fits best.
□_A A negative effect related to a medicine
□_B A negative effect related to a test, procedure, or surgery
□_C A negative effect related to pregnancy or childbirth
□_D A negative effect related to a diagnosis
□_E A negative effect related to medical advice
□_F Unclean or unsanitary care

□_G Something else or more than one negative effect

4.2   What kind of negative effect did the patient experience?

□_A Physical
□_B Emotional → GO TO 4.4
□_C Both

4.3   What kind of <u>physical</u> negative effect did the patient experience? PLEASE CHECK ALL THAT APPLY.

□_A Dizziness
□_B Sick to the stomach (nausea)
□_C Infection
□_D Pain
□_E A fall that caused an injury
□_F Open sores on skin
□_G A sexual problem
□_H Blood clot
□_I Uncontrolled bleeding
□_J Breathing difficulty
□_K Numbness or weakness
□_L Injury to teeth
□_M Injury to an eye
□_N Burn
□_O Heart attack or stroke
□_p Continuing symptoms
□_q Worsening of a health problem
□_r Patient died
□_s Other physical effect→ [Please describe]
□_T The negative effect was not physical

4.4   Where did the negative effect first happen? Please <u>choose the one answer</u> that fits best.

□_A In a doctor's office or a clinic
□_B In a pharmacy
□_C In the emergency department
□_D In a hospital
□_E At home
□_F Somewhere else→ [Where did this first happen?]
□_G Don't know

4.5   Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?

□_A Yes
□_B Yes, but I do not know the name of the facility or provider → GO TO 4.6
□_C No, I do not know the name of the facility or provider → GO TO 4.6
□_D No, I do not want to tell you → GO TO 4.6

4.5.1   Please write the name and address of the health care facility or provider involved.

       NAME OF HEALTH CARE FACILITY/PROVIDER:
       STREET ADDRESS:
       CITY:
       STATE:

4.5.2   Was a second health care facility or provider involved?
□_A Yes
□_B No→ GO TO 4.5.5

4.5.3   Would you like to tell us the name of the second health care facility or provider involved?
□_A Yes
□_B Yes, but I do not know the name of the facility or provider → GO TO 4.5.5
□_C No, I do not know the name of the facility or provider → GO TO 4.5.5
□_D No, I do not want to tell you → GO TO 4.5.5

4.5.4   Please write the name and address of the second health care facility or provider involved.

       NAME OF HEALTH CARE FACILITY/PROVIDER:
       STREET ADDRESS:
       CITY:
       STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety.

4.5.5   May we share your report with the health care facility or provider?
□_A Yes
□_B No

4.6   In what month and year did the negative effect happen? (Your best estimate is fine.)

ENTER MONTH:
YEAR:

4.7   Did the patient get additional medical testing or treatment because of the negative effect?
□_A Yes
□_B No
□_C Don't know

4.8 How did the patient find out that the negative effect happened?   Please <u>choose the one answer</u> that fits best.

□_A The patient noticed it.

□_B A doctor, nurse, or other health professional noticed it.

□_C A friend or family member noticed it and told the patient.

□_D A doctor, nurse, or other health care provider told the patient about it.

□_E An administrator or manager told the patient about it

□_F The patient found out in some other way. → [How did patient find out?]

□_G The patient never knew about it.

4.9   Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the negative effect?

□_A Yes

□_B No → GO TO 4.9

□_C Don't know → GO TO 4.9

4.9.1   How helpful were they?

□_A Extremely helpful

□_B Very helpful

□_C Somewhat helpful

□_D Slightly helpful

□_E Not at all helpful

4.10   Did the negative effect cause the patient to miss work, school, or other regular activities?

□_A Yes

□_B No

□_C Don't know

Sometimes patients experience negative <u>financial</u> effects. For example, patients may have to miss work, pay for extra testing or treatment, or take additional trips to a health care facility.

4.11   Did the negative effect cause <u>financial</u> problems for the patient?

□_A Yes

□_B No

□_C Don't know

<u>Table 3-5</u>
<u>SECTION 5: CONTRIBUTING FACTORS, CHANGES IN CARE, DISCOVERY, & REPORTING</u>

Now we will ask some questions about why the mistake or negative effect happened, and what the patient did afterward.

5.1 In your opinion, could anything have been done differently to prevent this mistake or negative effect from happening?
□_A Yes→ [What could have been done?]
□_B No
□_C Don't know

5.2 Why do you think this mistake or negative effect happened?

5.3 In your opinion, did any of the following lead to the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.

Communication with doctors, nurses or other health care providers

5.3.1 Was it because the doctors, nurses, or other health care providers…
□_A did not listen to the patient?
□_B did not explain things to the patient in the patient's language?
□_C used terminology the patient could not understand?
□_D did not spend enough time with the patient?
□_E spoke with an accent that was hard to understand?
□_F ignored what the patient told them?
□_G did not explain medications or their side effects?
□_H did not explain follow-up care instructions?

Responsiveness

5.3.2 Was it because of not getting…
□_A help as soon as the patient needed it?
□_B a referral as soon as the patient needed it?
□_C an appointment as soon as the patient needed it?
□_D care as soon as the patient needed it?
Coordination

5.3.3 Was it because…
□_A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?
□_B of the lack of follow-up by the doctors, nurses, or other health care providers?
□_C doctors, nurses, or other health care providers did not seem to work well together as a team?

Access

5.3.4 Was it because the patient…
□_A was not able to get in to see a specialist for care?
□_B was not able to get the tests or treatments that the patient believed necessary?
□_C was not able to get the tests or treatments that a provider believed necessary?
□_D did not get help or advice they needed?

Verification

5.3.5 Was it because someone did not…
□_A correctly identify the patient?
□_B have the most recent and up-to-date information about the patient?

Other

5.3.6 Was it because the patient…
□_A couldn't afford the care the patient believed necessary?
□_B couldn't afford the care a provider believed necessary?
□_C had no insurance to pay for the care the patient believed necessary?
□_C had no insurance to pay for the care a provider believed necessary?
□_D Something else? → [What do you believe led to the mistake or negative effect?]

5.4 Did this mistake or negative effect cause the patient to switch to a different doctor, nurse, or other health care provider or transfer to a different medical facility? PLEASE CHECK ALL THAT APPLY.

□_A Yes – Switched to a different health care provider
□_B Yes – Transferred to a different hospital
□_C Yes – Transferred to a different pharmacy
□_D Yes – Other→ [What was the switch?]
□_E No – There was no change

5.5 Did the patient tell anyone about the mistake or negative effect?
□_A Yes
□_B No → GO TO 6.1
□_C Don't know → GO TO 6.1

5.5.1 Who did the patient tell about the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.
PROGRAMMER NOTE: ALL CHECKED ITEMS GET CODE OF "1"; ALL THAT ARE NOT CHECKED GET CODE OF "0"
□_A A family member or friend
□_B A doctor, nurse, or other health care provider
□_C A health care administrator or manager
□_D Someone at the pharmacy
□_E A minister or other religious leader
□_F A lawyer
□_G Someone else, such as a licensing agency, etc. → GO TO 5.5.1other

5.5.1Other   Who did the patient tell?

Table 3-6
SECTION 6: CLINICIAN/FACILITY & PATIENT INFORMATION

6.0   Would you like to tell us the name and address of the health care doctor, nurse, or other health care provider (or the health care facility) involved?
□_A Yes
□_B Yes, but I do not know the name and address of the provider → GO TO 6.0.5
□_C No, I do not know the name and address of the provider → GO TO 6.0.5
□_D No, I do not want to tell you → GO TO 6.0.5

6.0.1   Please write the name and address of the health care facility or provider involved.

    NAME OF HEALTH CARE FACILITY/PROVIDER:
    STREET ADDRESS:
    CITY:
    STATE:

6.0.2   Was a second health care facility or provider involved?
□_A Yes
□_B No→ GO TO 6.0.5

6.0.3   Would you like to tell us the name of the second health care facility or provider involved?
□_A Yes
□_B Yes, but I do not know the name of the facility or provider → GO TO 6.0.5
□_C No, I do not know the name of the facility or provider → GO TO 6.0.5
□_D No, I do not want to tell you → GO TO 6.0.5

6.0.4   Please write the name and address of the second health care facility or provider involved.

    NAME OF HEALTH CARE FACILITY/PROVIDER:
    STREET ADDRESS:
    CITY:
    STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved. This would alert the facility's staff so they can learn about what went wrong and improve safety.

6.0.5   May we share your report with the health care facility or provider?
□_A Yes
□_B No

6.1 May we contact you if we need more information
□_A Yes
□_B No → GO TO 6.2

6.1.1 Please tell us your name and your address, telephone number or e-mail.

Name:
Street Address:
City:
State:
Zip:
Phone:

      This is my
      □_A Home number
      □_B Work number
      □_C Cell number
E-mail:

6.1.2 Is it better to reach you on weekdays or weekends? PLEASE CHECK ALL THAT APPLY
      □_A Weekday
      □_B Weekend

6.1.3 What is the best time of day to reach you? PLEASE CHECK ALL THAT APPLY
      □_A Morning
      □_B Afternoon
      □_C Evening

6.1.4 When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information? This will help the provider or facility match your report with their records.
□_A Yes
□_B No

Our last questions will help us to understand whether some people are more likely than others to experience medical mistakes and negative effects.

6.2 What is the patient's sex?
□_A Male
□_B Female

6.3   At the time of the mistake or negative effect, approximately how old was the patient?

Age of patient at time of mistake or negative effect: Years

Note: If the patient was a child and less than 1 year, enter 1 year.

6.4   Is the patient Hispanic, Latino/a, or Spanish origin? (One or more categories may be selected)
□_A No
□_B Yes, Mexican, Mexican American, Chicano/a
□_C Yes, Puerto Rican
□_D Yes, Cuban
□_E Yes, another Hispanic, Latino, or Spanish origin

6.5   What is the patient's race? (One or more categories may be selected)
□_A White
□_B Black or African American
□_C American Indian or Alaska Native
□_D Asian Indian
□_E Chinese
□_F Filipino
□_G Japanese
□_H Korean
□_I Vietnamese
□_J Other Asian
□_K Native Hawaiian
□_L Guamanian or Chamorro
□_M Samoan
□_N Other Pacific Islander

6.6   What type of health insurance did the patient have at the time of the mistake or negative effect? Please <u>choose the one answer</u> that fits best.
□_A Private insurance through an employer
□_B Private insurance that the patient bought
□_C Medicare
□_D Medicaid (including Medicaid managed care plans)
□_E Tricare (for active military personnel and their families)
□_F Veterans care
□_G Other → 6.7eTYPE
□_H Not insured (please select this only if you have not picked any other answer)
□_I Don't know
□_J I do not wish to disclose this information

6.6eTYPE   What other type of health insurance did patient have?

6.8   How did you learn about the Health Care Safety Hotline? Please <u>choose the one answer</u> that fits best.
□_A Website
□_B Flyer or poster at a hospital
□_C Admission or discharge paperwork
□_D Doctor, nurse, or other health care provider
□_E Other [How did you learn about the Safety Hotline? [FREE TEXT BOX. ALLOW 100]

>THANKS<
Thank you for your report and for helping to improve patient safety.

Appendix C.3. Survey Report Form Document – Phone Version

>INTRO<
Hello, you have reached the Health Care Safety Hotline.

*My name is [**XXX**]. I will be talking with you about your health care safety concern. First I will go over a few instructions with you.*

>AGE<
*To provide a report, you must be older than 18. **Are you 18 years or older?***

____ YES→ PROCEED
____ NO → THANK and EXIT

>INTRO2<
Thank you for providing that information.

This interview will take about 20–25 minutes. We will ask you questions about the experiences you or your family members have had with health care. We will ask if you have ever had an experience where you think a mistake was made or where you had concerns about your safety. There are no right or wrong answers. If there are any questions you don't want to answer, tell me and we will just go on to the next one. You do not have to participate. You may change your mind and stop at any time, even after we start.

*The Health Care Safety Hotline allows patients and their families **or caregivers** to voluntarily report on the safety of their health care. Hotline staff will use the information that you and others give us to understand patients' concerns. Hotline staff are researchers from the RAND Corporation and the ECRI Institute. We will only tell doctors, hospitals, and pharmacists a compilation of what we learn; no individual reports are shared. We hope they will make changes and that health care will be safer.*

The information you give us is completely private. We will not use your name or your address or your phone number. Nobody will see your answers except people on the Health Care Safety Hotline team unless you say it is OK to share it. In some cases, my supervisor might listen to this call to make sure that I am doing a good job.

We will write a report about what we learn from the data collected in the Health Care Safety Hotline. We will give the report to doctors, hospitals, and pharmacists so they can do a better job and make health care safer. But we will combine all the answers we get from lots of people. Nobody will know the names of the people who helped us, and nobody will be able to tell who said what.

The Health Care Safety Hotline was paid for by an agency that is part of the United States government. The agency is called the Agency for Health Care Research and Quality. It has strict laws about protecting patients' privacy.

You will not receive any payment or any other direct benefits for your help. But by sharing your story, you can help make health care safer for the people in your town and in towns all across the United States.

>PHONE<
Would you mind giving me your phone number? If our phone call gets disconnected, I will call you right back.

ENTER TELEPHONE NUMBER: (_____) _____ - _____

❖ *Ask:*
- o *Do you have any questions?* [***If so, refer to FAQs list***]
- o *Do you understand everything I said or is there anything I should go over again?*
- o *May I use a tape recorder as we talk so I will remember what you tell me exactly right?*

____ *YES→ START RECORDING Thanks. I'll start recording now.*
____ *NO→ Thanks. I will take notes only but not record our conversation.*

I am ready to ask you questions about your health care safety concern. Are you ready to begin?

To complete the questions, you will need

- Month and year of the concern [NOTE: Concerns that occurred more than ten years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures, or survey that were involved (if any)
- Your own contact information if you wish to be contacted by the Safety Hotline staff to discuss the details of the concern

Do you know this information? Or would you like a minute to grab any documents.
[WAIT IF NECESSARY}
{When they are back on the line} Ask again*: Thank you. Are you ready to begin?*

1.1 Who is the patient with a safety concern?
□_A Me
□_B A child
□_C A spouse, domestic partner or other family member (for example, a grandparent, aunt, etc.)
□_D A friend
□_E A patient or client
□_F Someone else → [DISPLAY AS TEXT BOX: Who is the patient?]

1.1.2 In what city and state did the safety concern occur?

Enter the city:
Enter the state:

SECTION 2: DESCRIPTION OF YOUR SAFETY CONCERN

2.1 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.

2.1a. What happened?

NOTE: If you believe a patient died as the result of a mistake, please tell us about the mistake and record the negative effect as "death."

2.1b. Where do you believe it happened?

2.1c. When did it happen?

2.1d. Why do you think this happened?

2.2   What is the name of the patient?
ENTER FIRST NAME:
ENTER LAST NAME:

Now we will ask some questions to make sure we understand what happened.

2.3   In your opinion, did a doctor, nurse, or other health care provider make a <u>medical mistake or error</u> in the patient's care?

POP-UP: A medical mistake or error is something that was done (or not done) by a health care provider that would be considered incorrect at the time it happened. Sometimes medical mistakes can result in harm or injury to the patient, but not every time.

□_A Yes → GO TO 3.1
□_B No → GO TO 2.3.1
□_C Don't know → GO TO 2.3.1

When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.

2.3.1   Do you think a negative effect took place as a result of the patient's care?
□_A Yes → GO TO 4.1
□_B No → GO TO 2.3.1.1
□_C Other → [DISPLAY AS TEXT BOX: Please describe]
      → GO TO 2.3.1.1
□_D Don't know → GO TO 2.3.1.1

2.3.1.1 You told us that a mistake did not take place (or that you don't know) and that a negative effect did not take place (or that you don't know). Is this correct?
□_A Yes → GO TO 6.0
□_B No → GO TO 6.0
□_C Don't know → GO TO 6.0

SECTION 3: MISTAKE

3.1   Did the medical mistake or error involve any of the following? Please <u>choose the one answer</u> that fits best.
□_A A mistake related to a medicine

[POP-UP: Medicines can include prescription or non-prescription medication, herbs, dietary supplements, vaccines, contrast dye or other injected medicines] → GO TO 3.1.1.1

□_B A mistake related to a test, procedure, or surgery
[POP-UP: This includes tests that involve taking samples of skin or tissue, inserting tubes to examine internal parts of your body, or other tests involving blood, urine, or X-rays.] → GO TO 3.1.2.1

□_C A mistake related to pregnancy or childbirth
[POP-UP: This includes errors in diagnostic testing during pregnancy and errors during labor and delivery] → GO TO 3.2

□_D A mistake related to a diagnosis or advice from a doctor, nurse, or other health care provider → GO TO 3.1.3.1

□_E A mistake related to poor cleanliness or poor hygiene → GO TO 3.2

□_F Something else, or more than one mistake [GO TO 3.1f1]

3.1.f1   In your opinion, what was the mistake? [FREE TEXT BOX]

3.1.1.1 As best as you can, please name or describe the medicine. [FREE TEXT BOX]

3.1.1.2 Was it a prescription medicine?
[POP-UP: Don't include over-the-counter medicines that you can buy without a prescription from a doctor or nurse.]
□_A Yes
□_B No
□_C Don't know

3.1.1.3 Did the mistake with medicine involve any of the following? Please <u>choose the one answer</u> that fits best.
□_A Wrong medicine→ GO TO 3.2
□_B Wrong dose→ GO TO 3.2
□_C Something else→ [GO TO 3.1.1.3-OTHER: What did the mistake involve? FREE TEXT BOX, ALLOW 50. GO TO 3.2]

3.1.2.1 As best as you can, please name or describe the test, procedure, or surgery. [FREE TEXT BOX]

3.1.2.2 Did the mistake with a test, procedure, or surgery involve any of the following? PLEASE CHECK ALL THAT APPLY.

□A Wrong patient [POP-UP: The patient was not correctly identified.]
□B Wrong test, procedure, or surgery [POP-UP: The wrong type of test, procedure, or surgery was done.]
□C Wrong part of the body [POP-UP: The test, procedure, or surgery was on the wrong part of the body.]
□D A mistake was made <u>during</u> the test, procedure, or surgery
□E The test, procedure, or surgery was delayed
□F The test results were lost and the patient did not receive them
□G The patient developed an infection
□H A problem with anesthesia
□I Something else→ What did the mistake involve?

→ GO TO 3.2 ONCE ITEMS CHECKED

3.1.3.1 In your opinion, what was the mistake with the diagnosis or medical advice? [FREE TEXT BOX]

3.2   Where did the mistake happen? Please <u>choose the one answer</u> that fits best.
□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Don't know
□G Somewhere else

3.3   Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?
□A Yes
□B Yes, but I do not know the name the facility or provider → GO TO 3.4
□C No, I do not know the name of the facility or provider → GO TO 3.4
□D No, I do not want to tell you → GO TO 3.4

3.3.1   Please write the name and address of the health care facility or provider involved.

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

3.3.2   Was a second health care facility or provider involved?
□_A Yes
□_B No→ GO TO 3.3.5

3.3.3   Would you like to tell us the name of the second health care facility or provider involved?
□_A Yes
□_B Yes, but I do not know the name and address of the facility or provider → GO TO 3.3.5
□_C No, I do not know the name of the facility or provider → GO TO 3.3.5
□_D No, I do not want to tell you → GO TO 3.3.5

3.3.4   Please write the name and address of the second health care facility or provider involved.

        NAME OF HEALTH CARE FACILITY/PROVIDER:
        STREET ADDRESS:
        CITY:
        STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the mistake. This would alert the facility's staff so they can learn about what went wrong and improve safety.

3.3.5   May we share your report with the health care facility or provider?
□_A Yes
□_B No

3.4   In what month and year did the mistake happen? (Your best estimate is fine.)

ENTER MONTH:
ENTER YEAR:

3.5   Did a doctor, nurse, or other health care provider tell you the mistake happened?
□_A Yes→GO TO 3.6
□_B No [FREE TEXT BOX: How did you find out that the mistake happened

Sometimes medical mistakes affect patients financially. For example, patients may have to miss work, pay for extra tests or procedures, or take additional trips to a health care facility.

3.3.2   Was a second health care facility or provider involved?
□A Yes
□B No→ GO TO 3.3.5

3.3.3   Would you like to tell us the name of the second health care facility or provider involved?
□A Yes
□B Yes, but I do not know the name and address of the facility or provider → GO TO 3.3.5
□C No, I do not know the name of the facility or provider → GO TO 3.3.5
□D No, I do not want to tell you → GO TO 3.3.5

3.3.4   Please write the name and address of the second health care facility or provider involved.

        NAME OF HEALTH CARE FACILITY/PROVIDER:
        STREET ADDRESS:
        CITY:
        STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the mistake. This would alert the facility's staff so they can learn about what went wrong and improve safety.

3.3.5   May we share your report with the health care facility or provider?
□A Yes
□B No

3.4   In what month and year did the mistake happen? (Your best estimate is fine.)

ENTER MONTH:
ENTER YEAR:

3.5   Did a doctor, nurse, or other health care provider tell you the mistake happened?
□A Yes→GO TO 3.6
□B No [FREE TEXT BOX: How did you find out that the mistake happened

Sometimes medical mistakes affect patients financially. For example, patients may have to miss work, pay for extra tests or procedures, or take additional trips to a health care facility.

3.6   Did the mistake affect the patient financially?
□_A Yes
□_B No
□_C Don't know

When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.

3.7   Did the patient experience any negative effects as a result of the mistake or error?
□_A Yes
□_B No → GO TO 5.1
□_C Don't know → GO TO 5.1

SECTION 4: NEGATIVE EFFECT

4.1   Did the negative effect involve any of the following? Please <u>choose the one answer</u> that fits best.
□_A A negative effect related to a medicine
□_B A negative effect related to a test, procedure, or surgery
□_C A negative effect related to pregnancy or childbirth
□_D A negative effect related to a diagnosis
□_E A negative effect related to medical advice
□_F Unclean or unsanitary care
□_G Something else or more than one negative effect

4.2   What kind of negative effect did the patient experience?
□_A Physical
□_B Emotional → GO TO 4.4
□_C Both

4.3   What kind of <u>physical</u> negative effect did the patient experience? PLEASE CHECK ALL THAT APPLY.
□_A Dizziness
□_B Sick to the stomach (nausea)
□_C Infection
□_D Pain
□_E A fall that caused an injury
□_F Open sores on skin
□_G A sexual problem
□_H Blood clot
□_I Uncontrolled bleeding
□_J Breathing difficulty
□_K Numbness or weakness
□_L Injury to teeth
□_M Injury to an eye
□_N Burn

□O Heart attack or stroke
□p Continuing symptoms
□q Worsening of a health problem
□r Patient died
□s Other physical effect→ [Please describe]
□T The negative effect was not physical.

4.4   Where did the negative effect first happen? Please <u>choose the one answer</u> that fits best.
□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Somewhere else→ [Where did this first happen?]
□G Don't know

4.5   Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?
□A Yes
□B Yes, but I do not know the name of the facility or provider → GO TO 4.6
□C No, I do not know the name of the facility or provider → GO TO 4.6
□D No, I do not want to tell you → GO TO 4.6

4.5.1   Please write the name and address of the health care facility or provider involved.

        NAME OF HEALTH CARE FACILITY/PROVIDER:
        STREET ADDRESS:
        CITY:
        STATE:

4.5.2   Was a second health care facility or provider involved? PROGRAMMER NOTE: SELECT "1"
□A Yes
□B No→ GO TO 4.5.5

4.5.3   Would you like to tell us the name of the second health care facility or provider involved?
□A Yes
□B Yes, but I do not know the name of the facility or provider → GO TO 4.5.5
□C No, I do not know the name of the facility or provider → GO TO 4.5.5
□D No, I do not want to tell you → GO TO 4.5.5

4.5.4   Please write the name and address of the second health care facility or provider involved. [FREE TEXT BOX]

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety.

4.5.5   May we share your report with the health care facility or provider?
□_A Yes
□_B No

4.6   In what month and year did the negative effect happen? (Your best estimate is fine.)

ENTER MONTH:
YEAR:

4.7   Did the patient get additional medical testing or treatment because of the negative effect?
□_A Yes
□_B No
□_C Don't know

4.8   How did the patient find out that the negative effect happened?   Please <u>choose the one answer</u> that fits best.
□_A The patient noticed it.
□_B A doctor, nurse, or other health professional noticed it.
□_C A friend or family member noticed it and told the patient.
□_D A doctor, nurse, or other health care provider told the patient about it.
□_E An administrator or manager told the patient about it
□_F The patient found out in some other way. → [How did patient find out?]
□_G The patient never knew about it.

4.9   Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the negative effect?
□_A Yes
□_B No → GO TO 4.9
□_C Don't know → GO TO 4.9

4.9.1   How helpful were they?
□_A Extremely helpful
□_B Very helpful
□_C Somewhat helpful
□_D Slightly helpful
□_E Not at all helpful

4.10   Did the negative effect cause the patient to miss work, school, or other regular activities?
□_A Yes
□_B No
□_C Don't know

Sometimes patients experience negative <u>financial</u> effects. For example, patients may have to miss work, pay for extra testing or treatment, or take additional trips to a health care facility.

4.11   Did the negative effect cause <u>financial</u> problems for the patient?
□_A Yes
□_B No
□_C Don't know

<u>Table 3-5</u>
<u>SECTION 5: CONTRIBUTING FACTORS, CHANGES IN CARE,</u>
<u>DISCOVERY, & REPORTING</u>

Now we will ask some questions about why the mistake or negative effect happened, and what the patient did afterward.

5.1   In your opinion, could anything have been done differently to prevent this mistake or negative effect from happening?
□_A Yes→ [What could have been done?]
□_B No
□_C Don't know

5.2   Why do you think this mistake or negative effect happened?

5.3   In your opinion, did any of the following lead to the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.

Communication with doctors, nurses or other health care providers

5.3.1 Was it because the doctors, nurses, or other health care providers…
□_A did not listen to the patient?
□_B did not explain things to the patient in the patient's language?

□$_C$ used terminology the patient could not understand?
□$_D$ did not spend enough time with the patient?
□$_E$ spoke with an accent that was hard to understand?
□$_F$ ignored what the patient told them?
□$_G$ did not explain medications or their side effects?
□$_H$ did not explain follow up care instructions?

Responsiveness

5.3.2 Was it because of not getting…
□$_A$ help as soon as the patient needed it?
□$_B$ a referral as soon as the patient needed it?
□$_C$ an appointment as soon as the patient needed it?
□$_D$ care as soon as the patient needed it?

Coordination

5.3.3 Was it because…
□$_A$ the doctors, nurses, or other health care providers were not aware of care that took place someplace else?
□$_B$ of the lack of follow-up by the doctors, nurses, or other health care providers?
□$_C$ doctors, nurses, or other health care providers did not seem to work well together as a team?

Access

5.3.4 Was it because the patient…
□$_A$ was not able to get in to see a specialist for care?
□$_B$ was not able to get the tests or treatments that the patient believed necessary?
□$_C$ was not able to get the tests or treatments that a provider believed necessary?
□$_D$ did not get help or advice they needed?

Verification

5.3.5 Was it because someone did not…
□$_A$ correctly identify the patient?
□$_B$ have the most recent and up-to-date information about the patient?

Other

5.3.6 Was it because the patient…
□$_A$ couldn't afford the care the patient believed necessary?
□$_B$ couldn't afford the care a provider believed necessary?
□$_C$ had no insurance to pay for the care the patient believed necessary?
□$_C$ had no insurance to pay for the care a provider believed necessary?
□$_D$ Something else? → [What do you believe led to the mistake or negative effect?]

5.4   Did this mistake or negative effect cause the patient to switch to a different doctor, nurse, or other health care provider or transfer to a different medical facility? PLEASE CHECK ALL THAT APPLY.

□_A Yes – Switched to a different health care provider
□_B Yes – Transferred to a different hospital
□_C Yes – Transferred to a different pharmacy
□_D Yes – Other→ [What was the switch?]
□_E No – There was no change

5.5   Did the patient tell anyone about the mistake or negative effect?
□_A Yes
□_B No → GO TO 6.1
□_C Don't know → GO TO 6.1

5.5.1   Who did the patient tell about the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.
PROGRAMMER NOTE: ALL CHECKED ITEMS GET CODE OF "1"; ALL THAT ARE NOT CHECKED GET CODE OF "0"
□_A A family member or friend
□_B A doctor, nurse, or other health care provider
□_C A health care administrator or manager
□_D Someone at the pharmacy
□_E A minister or other religious leader
□_F A lawyer
□_G Someone else, such as a licensing agency, etc. → GO TO 5.5.1other

5.5.1other   Who did the patient tell?

SECTION 6: CLINICIAN/FACILITY & PATIENT INFORMATION

6.0   Would you like to tell us the name and address of the doctor, nurse, or other health care provider (or the health care facility) involved?

□_A Yes
□_B Yes, but I do not know the name and address of the provider → GO TO 6.0.5
□_C No, I do not know the name and address of the provider → GO TO 6.0.5
□_D No, I do not want to tell you → GO TO 6.0.5

6.0.1   Please write the name and address of the health care facility or provider involved.

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

6.0.2   Was a second health care facility or provider involved?
□_A Yes
□_B No→ GO TO 6.0.5

6.0.3   Would you like to tell us the name of the second health care facility or provider involved?
□_A Yes
□_B Yes, but I do not know the name of the facility or provider → GO TO 6.0.5
□_C No, I do not know the name of the facility or provider → GO TO 6.0.5
□_D No, I do not want to tell you → GO TO 6.0.5

6.0.4   Please write the name and address of the second health care facility or provider involved.

       NAME OF HEALTH CARE FACILITY/PROVIDER:
       STREET ADDRESS:
       CITY:
       STATE:

You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved. This would alert the facility's staff so they can learn about what went wrong and improve safety.

6.0.5   May we share your report with the health care facility or provider?
□_A Yes
□_B No

6.1   May we contact you if we need more information
□_A Yes
□_B No → GO TO 6.2

6.1.1 Please tell us your name and your address, telephone number or e-mail.

Name:
Street Address:
City:
State:
Zip:
Phone:

       This is my
       □_A Home number
       □_B Work number
       □_C Cell number
E-mail:

6.1.2 Is it better to reach you on weekdays or weekends? PLEASE CHECK ALL THAT APPLY

□_A Weekday
□_B Weekend

6.1.3 What is the best time of day to reach you? PLEASE CHECK ALL THAT APPLY

□_A Morning
□_B Afternoon
□_C Evening

6.1.4   When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information? This will help the provider or facility match your report with their records.

□_A Yes
□_B No

Our last questions will help us to understand whether some people are more likely than others to experience medical mistakes and negative effects.

6.2   What is the patient's sex?

□_A Male
□_B Female

6.3   At the time of the mistake or negative effect, approximately how old was the patient?

Age of patient at time of mistake or negative effect: Years

Note: If the patient was a child and less than 1 year, enter 1 year.

6.4   Is the patient Hispanic, Latino/a, or Spanish origin? (One or more categories may be selected)

□_A No
□_B Yes, Mexican, Mexican American, Chicano/a
□_C Yes, Puerto Rican
□_D Yes, Cuban
□_E Yes, another Hispanic, Latino, or Spanish origin

6.5   What is the patient's race? (One or more categories may be selected)

□_A White
□_B Black or African American
□_C American Indian or Alaska Native
□_D Asian Indian
□_E Chinese

☐F Filipino
☐G Japanese
☐H Korean
☐I Vietnamese
☐J Other Asian
☐K Native Hawaiian
☐L Guamanian or Chamorro
☐M Samoan
☐N Other Pacific Islander

6.6   What type of health insurance did the patient have at the time of the mistake or negative effect? Please <u>choose the one answer</u> that fits best.
☐A Private insurance through an employer
☐B Private insurance that the patient bought
☐C Medicare
☐D Medicaid (including Medicaid managed care plans)
☐E Tricare (for active military personnel and their families)
☐F Veterans care
☐G Other → 6.7eTYPE
☐H Not insured (Please select this only if you have not picked any other answer)
☐I Don't know
☐J I do not wish to disclose this information.

6.6eTYPE   What other type of health insurance did patient have?

6.8   How did you learn about the Health Care Safety Hotline? Please <u>choose the one answer</u> that fits best.
☐A Website
☐B Flyer or poster at a hospital
☐C Admission or discharge paperwork
☐D Doctor, nurse, or other health care provider
E Other ☐ [How did you learn about the Safety Hotline?
SECTION 7: BARRIERS TO REPORTING/ USABILITY

7.0   You could have reported by phone or the web. Why did you choose to call in?

7.1 Did you attempt to report this concern using the web?

☐A Yes, but I did not answer any of the questions; instead I called the toll-free number. →
END
☐B Yes, but I only answered some of the questions and then quit to call this toll-free number. → **GO TO 7.1**
☐C No. I only called the toll-free number → END

7.2   When filling out the questions on the web, what problems did you encounter: CHECK ALL THAT APPLY

□$_A$ The web form took too long

□$_B$ The web form hotline information was not clear

□$_C$ On the web, it was hard to find the information I needed

□$_D$ The organization of the information on the hotline screens was not clear

□$_E$ The hotline did not have all the functions and capabilities that I needed it to have

□$_F$ On the web, I was not able to explain "in my own words" what happened

□$_G$ On the web, I was often frustrated when answering the hotline questions

□$_H$ Many of the questions asked for unnecessary information

7.3   What changes could be made to the Health Care Safety Hotline to better allow you to report a safety concern? [OPEN ENDED]

END:
>THANKS<
Thank you for your report and for helping to improve patient safety.

Appendix C.4. Provider Supplementation Process: Provider Follow-up Questions and Administrative Script

The following is the administrative intake page that is linked to each report, referred to as Module 8. It is a checklist of Steps 2 through 6 in the processing of a report, as outlined in Figure C.30. Second, it contains questions (8.1 through 8.8) that gather information during a follow-up phone call with the health care delivery organization/provider. The information captured in these questions documents the actions taken by the health care delivery organization. Specifically, Question 8.4 identifies and documents whether the health care delivery organization found a matching incident report in their incident reporting system that is from the same patient, family member, or caregiver about the same incident that was submitted to the hotline.

Module 8 – Processing Checklist

8.0 RSO Status

☐ Screened   **GO TO → 8.0.1   ---- Clickable by SuperUser – Research AND SuperUser – Administrative**

☐ Audited – Needs reporter/patient follow-up (free text reviewed and sanitized)
GO TO → 8.1.0   ----- Clickable by Intake Admin User AND SuperUser – Administrative

☐ Audited – Needs team decision (free text reviewed and sanitized)
GO TO → 8.1.0   ----- Clickable by Intake Admin User AND SuperUser – Administrative

☐ Clarified (questions answered by reporter team; ready for matching to provider)
GO TO → 8.1.0   ----- Clickable by Intake Admin User AND SuperUser – Administrative

☐ Finalized (ready for patient safety concern classification by team)

8.0.1 Exclusion reason:
☐ Age
☐ Grievance
☐ Service complaint
☐ Other

8.1.0 Community
   a. Not applicable
   b. Community 1
   c. Community 2

Module 8: Questions 8.1 – 8.8
Administrative Script When Matching Consumer Submission with Incident
Reporting System

8.1.1   Was patient's report edited based on follow-up with patient/consumer?
a. Yes
b. No, we spoke to the reporter and there were no changes
c. No, we were <u>not able to contact</u> the reporter
d. No, we did not have permission to contact the reporter

8.1.2   Patient, family, or caregivers/consumer gave permission to speak to the
facility
a. Yes
b. No (if no, do not proceed)

8.2   Was the health care facility (HCF) aware of the patient safety concern?
a. Yes
b. No
c. Uncertain

8.3   Was the patient safety concern reported internally within the health care
facility as a patient safety event?
a. Yes
b. No
c. Uncertain (e.g., no match found)

8.4   Was the patient safety concern reported within the PSO as a patient safety
event?
a. Yes
b. No
c. Uncertain (e.g., no match found)

8.5   Who reported the event or unsafe condition?
a. Health care professional (if selected, go to 7.4.1)

8.4.1. What is the type of health care professional?
a. Doctor, dentist (including student)
b. Nurse, nurse practitioner, physician assistant (including student or trainee)
c. Pharmacist, pharmacy technician (including student)
d. Allied health personnel, paramedic
e. Health care worker, including liaison officer, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, domestic/hotel service personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, or biomedical engineer
f. Emergency service personnel, including police officer, firefighter, or other emergency service officer

g. Patient/relative/volunteer/caregiver/home assistant
h. Anonymous or unknown

8.6 Was a root cause analysis (RCA) completed?
a. Yes
b. No
c. Unknown

8.7 Are any contributing factors to the event known?
a. Yes (if yes, go to 8.6.1)
b. No
c. Unknown

8.7.1 What factor(s) contributed to the event? CHECK ALL THAT APPLY:
☐ **Team coordination factors**
   a. Communication: supervisor to staff
   b. Communication: staff to patient
   c. Communication: among staff or team members
   d. Clinical supervision
   e. Managerial supervision
   f. Scheduling conflicts
   g. Heavy workload
   h. Shift change
☐ **Staff/individual factors**
   a. Adherence to policy, protocols, or orders
   b. Cognitive factors
   c. Competence (qualifications, experience)
   d. Familiarity with environment
   e. Familiarity with policy and procedure
   f. Fatigue
   g. Health issues
   h. Inattention
   i. Long work hours
   j. Stress
   k. Training
☐ **Operating environment factors**
   a. Biohazards and sharps management
   b. Equipment/device availability
   c. Equipment/device design
   d. Equipment/device function
   e. Equipment/device maintenance
   f. Housekeeping
   g. Physical surroundings (e.g., lighting, noise)
   h. Unlocked/unsecured area
   i. Interruptions (human)

Workflow/task factors

    a. Bed capacity
    b. Delay in response to code
    c. Delay in discharges
    d. Staffing ratios
    e. Transport delays
    f. Consent error/not completed
    g. Completion of patient/resident assessment
    h. Data legibility
    i. Data availability
    j. Data accuracy
    k. Management of test results
    l. Order/requisition difficulties

☐ **Patient/resident factors**

    a. Agitated/aggressive
    b. Confused/disoriented
    c. Impaired hearing or speech
    d. Language barrier
    e. Refusal of care or non-compliance
    f. Unresponsive

☐ **Management/organization factors**

    a. Clarity of policy/procedure
    b. Culture of safety management
    c. Empowerment (e.g., any health care provider can call a code)
    d. Presence of policy/procedure
    e. Resource constraints (financial or human)

☐ Other

  a. Please Specify

8.8 Lessons Learned? [OPEN TEXT BOX]

Appendix C.5. Content of Functional and Administrative Reports

Table C5.1 lists the functional and administrative reports generated by the hotline.

Table C5.1
List of Reports Generated by the Hotline

Module	Report	Aggregate and/or Community
Mistake	Summary & report by mistake type	Aggregate and community
Negative effect	Summary & report by negative effect (mistake type, type, location)	Aggregate and community
Contributing factors, changes in care, discovery and reporting	Summary & report of contributing factors (mistake type, type, location)	Aggregate and community
Patient & clinician/facility information	Summary & report by type of reporter	Aggregate and community
Patient & clinician/facility information	Summary patient demographics (gender, age, race, language, insurance)	Aggregate and community
Administrative	Summary by how reporter learned about the hotline	Aggregate and community
Administrative	Summary by modality used (phone/computer)	Aggregate and community
Administrative	Export data set – Module 1–7	All fields (Modules 1–7)
Administrative	Export data set – Module 8	All fields (Module 8)
Administrative	Web traffic report	All metrics
Administrative	Print RSO to PDF	All completed questions and answers

The detailed content of each of these reports is shown in Tables C5.2–C5.12.

Table C5.2
Report 1, Report by Mistake Type

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date, mistake type (3.1), mistake subtype(s) (3.1.1.3, 3.1.2.2, 3.1.3.1)
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID#, community (8.1)
Data series - pie chart	Mistake type (3.1) Mistake types: a.) medicine, b.) test / procedure / surgery, c.) pregnancy or childbirth, d.) diagnosis or advice, e.) other/more than 1 mistake
Data label - pie chart	Series name and percentage
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.3
Report 2, Report by Negative Effect

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date, negative effects (4.2), physical negative effect (4.2.1).
Aggregate criteria	RSO status (8.1), where (3.2), RSO id#, community (8.1)
Data series - bar chart	Negative effect (4.2) Negative effect: a.) physical, b.) emotional, c.) both Physical negative effect: a.) dizziness, b.) sick to the stomach (nausea), c.) infection, d.) pain, e.) a fall that caused an injury, f.) open sores on skin, g.) a sexual problem, h.) blood clot, i.) uncontrolled bleeding, j.) breathing difficulty, k.) numbness or weakness, l.) injury to teeth, m.) injury to an eye, n.) burn, o.) heart attack or stroke, p.) other, q.) the negative effect was not physical.
Data label - bar chart	Series name and percentage
Row data - tabular	Same as data series – bar chart
Column data - tabular	Number, percentage

Table C5.4
Report 3, Report by Contributing Factor

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date, mistake type, contributing factors (5.1), CF processes
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID#, community (8.1)
Data series - pie chart	Contributing factors (5.1) Contributing factors: communication (a-d), staffing and overwork (e-f), coordination of care (g-i), access (j-k), other (l)
Data label - pie chart	Series name and percentage
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.5
Report 4, Report on Person Reported For

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID #, community (8.1)
Data series - pie chart	Reported by
Data label - pie chart	Reported by (1.1) Reported by (a-l) a.) me, b.) child, c.) spouse/domestic partner/other family member, d.) friend, e.) patient or client, f.) someone else
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.6
Report 5, Summary of Patient Demographics

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID#, community (8.1)
Data series - pie chart	Patient information
Data label - pie chart	Demographics: gender (6.2), age (6.3), race (6.4, 6.5), insurance (6.7)
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.7
Report 6, How Reporter Learned About Hotline

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID#, community (8.1)
Data series - pie chart	How
Data label - pie chart	How (6.9) How: (a-f) a.) website, b.) flyer/poster c.) admission or discharge paperwork d.) doctor, nurse or other health care provider, e.) other
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.8
Report 7, Report of Modality Used (Phone/Computer)

Report Properties	Comments
Style	Pie chart, tabular
Data source	Aggregate and community
Criteria	Submission date
Aggregate criteria	RSO status (8.1), where (3.2), RSO ID#, community (8.1)
Data series - pie chart	Phone/computer (fields??)
Data label - pie chart	Modality: a.) phone, b.) computer
Row data - tabular	Same as data series – pie chart
Column data - tabular	Number, percentage

Table C5.9
Report 8, Report of Export Data Set – Modules 1–7

Report Properties	Comments
Style	Export to .csv using ID codes
Data source	Aggregate and community
Criteria	Status: all (saved, submitted, screened, audited, finalized) RSO ID# Latest RSO version Will export question names – answer names as columns Will export answer names if user selected
Aggregate criteria	All
Data series -	All fields (Modules 1–7)

Table C5.10
Report 9, Report of Export Data Set – Module 8

Report Properties	Comments
Style	Export to .csv using ID codes
Data source	Aggregate and community
Criteria	Status: all (saved, submitted, screened, audited, finalized) RSO ID # Latest RSO version Will export question names – answer names as columns Will export answer names if user selected
Aggregate criteria	All
Data series	All fields (Module 8)

Table C5.11
Report 10, Report That Prints Out the RSO to a PDF File

Report Properties	Comments
Style	PDF
Data source	Only questions and answers completed
Criteria	Status: submitted
Consumers	Modules 1–6 only
SuperUsers - administrative	All modules (1–8)
SuperUsers - research	Modules 1–7 only
Intake administrative user	Modules 1–6 only

Table C5.12
Report 11, Evaluation Report (Web Traffic)

Report Properties	Comments
Style	Export to .csv using ID codes
Data source	Aggregate
Criteria	e-mail address, user role, page clicked, date, time, IP address
Aggregate criteria	All
Data series	All fields

Appendix C.6. Overview of User Profiles

Access to the web-based system is based upon user profiles. The user profile determines what modules/reports a user has access to. There are six user profiles:

- SuperUser – Administrative
- SuperUser – Research
- Intake Administrative User
- Consumer – Guest
- Consumer – Registered
- Post Audit Review

Table C6.1 provides the user profiles by privilege.

Table C6
User Profiles by Privilege

Privilege	Consumer - (Registered / Guest)	Admin SuperUser - Adminis-trative	Admin Super-User - Research	Intake Admin User	Post Audit Review
Submit a new event (Modules 1–6)	Allow	Deny	Deny	Allow	Deny
Complete (Modules 7–8)	Deny	Allow	Allow (except status: finalize)	Allow (except status: finalize)	Deny
Edit existing event (saved RSOs only)	Allow (registered only)	Allow	Deny	Allow	Deny
Edit existing event (submitted RSOs only)	Deny	Allow	Deny	Allow	Deny
View and run reports (Modules 1–7 & 10)	Deny	Allow	Allow	Deny	Allow
View and run reports (Modules 8–9)	Deny	Allow	Deny	Deny	Deny
View aggregate/community type data	Deny	Allow	Allow	Deny	Deny
View RSO	Allow	Allow	Allow	Allow	Deny
Print RSO	Allow	Allow	Allow	Allow	Deny
Screen RSO (inclusion/exclusion criteria)	Deny	Allow	Allow	Allow	Deny
Audit RSO (edit/de-identify)	Deny	Allow	Deny	Deny	Deny
Finalize RSO	Deny	Allow	Deny	Deny	Deny
Flag test event	Deny	Allow	Deny	Deny	Deny

Appendix C.7. Frequently Asked Questions (FAQs)

The FAQs section of the Health Care Safety Hotline provides information to patients and caregivers about the hotline, including background and procedural information, as well as information on privacy and security.

Frequently Asked Questions (FAQs) about the Health Care Safety Hotline

Here are some questions that other people have asked about the Health Care Safety Hotline. The answers might help you understand the hotline.

- What is the Health Care Safety Hotline for?
- What is a health care safety concern?
- What is a complaint?
- Who is developing the Health Care Safety Hotline?
- How are people recruited or how do they find out about the Health Care Safety Hotline?
- Why should I participate?
- What will I get if I report to the Health Care Safety Hotline?
- What are the risks of reporting a concern through the Health Care Safety Hotline?
- Do I have to participate?
- What happens to my doctor, nurse, hospital, or pharmacy if I submit a Health Care Safety Hotline report about my safety concern involving them?
- How will you protect my privacy?
- Why are you recording the reports made by phone?
- Will my report be secure when submitted over the Internet?
- How do I share a safety concern through the Health Care Safety Hotline?
- Who can I call if I have problems submitting the form online?
- Will I be able to print my form or save it on my computer?
- Can I submit other documents using this online reporting form?
- How will I know that my report has been received?
- What if I want more information?
- What if I want to tell a different organization about my health care safety concerns?

What is the Health Care Safety Hotline for? The purpose of Health Care Safety Hotline is to make health care better by making it safer. Researchers are testing a tool for patients and their caregivers to make reports about the safety of their care. Here is how it works: You and other patients and caregivers will tell us about any health care safety concerns you have. Researchers will then look at the safety concerns you report to see how doctors, nurses, pharmacists, and other health care providers need to make changes

that will make health care safer. Also, we give you the opportunity to share your report directly with your provider if you would like to do so.

What is a health care safety concern? A health safety concern is anything that happens with your doctor, hospital, pharmacy, or other health care provider or facility that worries you because you think it isn't safe. It does not have to be something that resulted in harm. It does not even have to be a mistake; perhaps it was almost a mistake—we call this a "near miss." You may have a safety concern if you or a family member

- Notice a health care provider not washing his or her hands
- Receive the wrong medicine or the wrong dose of medicine
- Get an infection after having an operation or other procedure
- Get the wrong diagnosis
- Have the wrong surgery performed.

What is a complaint? Complaints about parking, food, long wait times in the doctor's office, etc., usually do not affect the safety of the health care you receive, so they should not be reported to the Health Care Safety Hotline. However, if the complaint does relate to safety, it can be reported to the Health Care Safety Hotline. The Health Care Safety Hotline has a list of other places in your community where you can share your concern, as well as places where you can report complaints.

Who is developing the Health Care Safety Hotline? Several organizations that want to make health care better are working together to create and test the Health Care Safety Hotline. They are the RAND Corporation, ECRI Institute, Tufts Medical Center, and Brigham and Women's Hospital. The U.S. federal government through the Agency for Healthcare Research and Quality (AHRQ) is paying to develop the Health Care Safety Hotline.

How are people recruited or how do they find out about the Health Care Safety Hotline? The doctors, nurses, hospitals, and pharmacies in your community want to make health care safer. They are helping us advertise the Health Care Safety Hotline by providing brochures, talking with patients, and communicating information about the Health Care Safety Hotline in other ways. The Health Care Safety Hotline has a secure website and a toll-free telephone number available. Information you submit to the Health Care Safety Hotline is kept private unless you give permission for it to be shared. You may enter your name, but you do not need to. Doctors, nurses, hospitals, and pharmacies will never know if you participate unless you want to tell them.

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.

What will I get if I report to the Health Care Safety Hotline? You will not be paid if you choose to report information. Your report will not be sent to a health care provider unless you give us permission. You decide what will be sent and when it will be sent. If

you want to send a report, you can request that it be sent anonymously or sent with your name and contact information. If you include your name and contact information, someone from the hospital or clinic may call you to discuss your report. Providers can use the reports to learn about many different types of safety concerns and will have a chance to do better. All issues are written about together; no one individual story, mistake, or name is listed. Your story may help to make health care safer.

What are the risks of reporting a concern through the Health Care Safety Hotline? Your health and your family's health will not be at risk if you participate. The participating health care providers and facilities have rules that protect people who report concerns. Participation will not affect your health care or your health insurance. The Health Care Safety Hotline team will keep everything private unless you give permission for your information to be shared with a provider. If you choose to have your information shared with a health care provider or facility, you should review it and make sure you're comfortable having it shared. We also suggest that you fill out the report or talk to us on the phone in a place where you have privacy.

Do I have to participate? No. You do not have to participate. If you do choose to participate, you can stop providing information at any time. Some of the questions might make you feel upset. You do not have to answer all the questions.

What happens to my doctor, nurse, hospital or pharmacy if I submit a Health Care Safety Hotline report about my safety concern involving them? Providers that participate have a policy that they will use this information to improve safety and will not embarrass or punish your care providers. All of the health care concerns will be part of the written report that will go to doctors, nurses, hospitals, and pharmacies. They will learn about all of the types of mistakes and have a chance to do better. In the written report, all issues are written about together; no one individual story, mistake, or name is listed. Your story may help to make health care safer. If you agreed to share your report with a provider, then we will send it to that provider; if you did not agree to share your report, then your doctor, nurse, hospital, or pharmacy will receive only an overall report.

How will you protect my privacy? All of the reports are kept in locked file cabinets or on computers that are protected with passwords. Only a few people on the research team have access to the files and computers. If you agreed to share your report with a provider, then we will contact that provider. The federal agency that supports the research has strict laws about patient privacy. We cannot use the information for another project unless we obtain your permission first. If you have questions about privacy, please call this telephone number: 1-800-XXX-XXXX.

Why are you recording the reports made by phone? If you talk to us by telephone, we will record the call to make sure that we capture everything you say correctly. The research team will listen to the recording and type the information into a computer. Then they will destroy the recording.

Will my report be secure when submitted over the Internet? If you fill out the form on your computer and send it to us, the report will go through a special Internet connection to make sure the report stays private. The information will be encrypted through Secure Socket Layer (SSL) using at least 128-bit encryption. We can tell you more about this and answer other questions at the toll-free number 1-888-XXX-XXXX.

How do I share a safety concern through the Health Care Safety Hotline? You can complete the Health Care Safety Hotline form on your computer and then send it through the Internet. Once you're on the home page for the Health Care Safety Hotline website, you click "Click here." There are instructions at the beginning of the form. Other instructions will pop up on your computer screen as you go through the form. Or you can call the toll-free telephone number 1-888-XXX-XXXX to leave a message saying you would like to provide your information by phone. A staff person will then call you back and can guide you through the form in either English or Spanish.

Who can I call if I have problems submitting the form online? If you have questions or have problems submitting the form, please call help-line telephone number 1-866-247-3004 to leave a message. A staff person will then call you back and can help you in English or Spanish.

Will I be able to print my form or save it on my computer? Yes. When you send the form to us through the Internet, you can choose to look at your report, print it, and save it as a PDF document on your computer. If you have Adobe Reader, you can view and print the report. If you have Adobe Acrobat, you can also save it.

Can I submit other documents using this online reporting form? No. When you send the report to us through the Internet, you cannot attach and submit other documents. If you have text in another document that you want to include, you might be able to copy the text and paste it into the form.

How will I know that my report has been received? You will see a message on your computer screen telling you that we have received your report. If you do not see this message, call us at the toll-free telephone number 1-888-XXX-XXXX and we can check to see if your report has been received.

What if I want more information? If you want to know more, call _____ at _____. Her phone number is 1-800-XXX-XXXX.

What if I want to tell a different organization about my health care safety concerns? Other groups also are working to make health care safer for patients. The Health Care Safety Hotline has a list of other places in your community where you can share your concern. If you have trouble locating the list, please call _____ at the _____. Her phone number is 1-800-XXX-XXXX. She can provide you with the list.

Appendix C.8. Post-Submission Survey

This appendix presents an example of the post submission survey for individuals who use the web to report to the Health Care Safety Hotline.

Final Post-Submission Survey

Thank you for using the Health Care Safety Hotline.

Please rate your experience with the hotline. Participation is voluntary and confidential. This will take less than 5 minutes.

Q1. It was easy to use the hotline

Strongly Agree   Strongly Disagree   Not Applicable
     1……...2………3………4………5………6………7   NA

Q2. I was able to report the important details of my safety concern.

Q3. Reporting a safety concern did not take too long.

For questions Q4, Q5, and Q6, we ask your opinion about the information within the Health Care Safety Hotline, such as instructions, frequently asked questions, and definitions of terms.

Q4. The hotline information is clear.

Q5. It was easy to find the information I needed.

Q6. The organization of the information on the hotline screens is clear.

Q7. The hotline has all the functions and capabilities that I need it to have.

Q8. The hotline helped me to explain "in my own words" what happened.

Q9. I was often frustrated when answering the hotline questions.

Q10. Many of the questions asked for unnecessary information.

Q11. Overall, I am satisfied with the hotline.

Q12. I would recommend that others use the hotline if they have a safety concern.

Q13: What changes could be made to the Health Care Safety Hotline to better allow you to report a safety concern?

Appendix C.9. Script and Instructions for Step 2 – Tracking Date, Time, and Consents via Excel Tracking Sheet

This appendix describes how to utilize the Excel spreadsheet, shown in the Instructions for Back-End Screening and Auditing of Reports (Including Excel Spreadsheets) section of the report, to track the date, time, and consents of submitted reports.

Step 2 (Outlined in Figure C.30): Track Date, Time, and Consents

1. Record the report ID in column A of the tracking spreadsheet. This number is in the e-mail alert (RSO) and the table of entered events on the website (Event ID).
2. Access the report by clicking "Edit" (to enter into the report itself) or the Adobe image (to view a PDF of the report). Record the full report ID in column B of the tracking spreadsheet using one of the following extensions:
   a. IF consent to receive **P**hone call[1] = yes

AND consent to **S**hare report with provider[2] = yes

AND consent to include name and contact **I**nformation[3] = yes

THEN add extension: "_PSI"

   b. IF consent to receive **P**hone call = yes

AND consent to **S**hare report with provider = yes

AND consent to include name and contact **I**nformation = no

THEN add extension: "_PS"

   c. IF consent to receive **P**hone call = yes

AND consent to **S**hare report with provider = no

THEN add extension: "_P"

   d. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = yes

AND consent to include name and contact **I**nformation = yes

THEN add extension: "_SI"

   e. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = yes

---

[1] Q6.1: "May we contact you if we need more information?"

[2] Q3.3.5 or Q4.5.5: "May we share your report with the health care provider (or facility) you identified?"

[3] Q6.1.4: "When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information?"

AND consent to include name and contact **I**nformation = no

THEN add extension: "_S"

        f. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = no

THEN add extension: "_N"

3. Record your initials in column C.
4. Record the date and time the report was received by the e-mail listserv in columns D and E. The time should be in military time and the Eastern time zone.
5. **If the patient/caregiver consented to share the report with the provider**, then add 66 hours to the date and time in which the report was received. Record this date and time in columns F and G.
   a. **If the patient/caregiver did <u>not</u> consent to share the report with the provider**, then enter "NA" in columns F and G.
6. **If the patient/caregiver consented to receive a clarification phone call**, then add 68 hours to the date and time in which the report was received. Record this date and time in columns H and I.
   a. **If the patient/caregiver did <u>not</u> consent to receive a clarification phone call**, then enter "NA" in columns H and I.
7. Access the report by clicking on "Edit," go to the Administrative Script module, and click "Screened." Click "Submit" at the bottom of the page.

Appendix C.10. Script and Instructions for Step 3 – Auditing and Scrubbing the Report

This appendix describes exactly how to audit or scrub a report.

Step 3 (Outlined in Figure C.30): Audit (Scrub) the Report

1. Beginning with the Introduction module of the report, review all open text fields for references to names, including names of delivery organizations, facilities, clinicians, staff, patients, and caregivers. "Scrub" all names; that is, replace the names with "XXXX."
   a. **If the patient/caregiver consented to share the report with the provider**, then do not scrub the names in questions Q2.1b,[4] Q3.3.1,[5] or Q4.5.1[6] and Q3.3.4[7] or Q4.5.4.[8]
   b. **If the report was made by a patient, and the patient consented to include his or her name and contact information with the report**, then do not scrub Q2.2[9] and Q6.1.1.[10]
   c. **If the report was made by a caregiver, and the caregiver consented to include his or her name and contact information with the report**, then do not scrub Q6.1.1. **DO, HOWEVER, SCRUB Q2.2**. Consent to share the patient name (Q2.2) can be requested during the clarification call, if the caregiver consented to such a call.
   d. If Q2.2 is being scrubbed, then record this information in the relevant columns of the tracking spreadsheet.
   e. If Q6.1.1 is being scrubbed, then record this information in the relevant columns of the tracking spreadsheet.
   f. In the tracking spreadsheet, record "scrubbed" in the column corresponding to each question that has been scrubbed.
   g. Go to the "Administrative Script" module and click "Submit" at the bottom of the page to save the scrubbing.

---

[4] Q2.1b: "Where do you believe it happened?"

[5] Q3.3.1: "Please write the name and address of the health care provider (or facility) involved in the mistake."

[6] Q4.5.1: "Please write the name and address of the health care provider (or facility) involved in the negative effect."

[7] Q3.3.4: "Please write the name and address of the second health care provider (or facility) involved in the mistake."

[8] Q4.5.4: "Please write the name and address of the second health care provider (or facility) involved in the negative effect."

[9] Q2.2: "What is the name of the patient?"

[10] Q6.1.1: "Please tell us your name and your address, telephone number, or e-mail."

2. Go to the Administrative Script module of the report and click "Audited – Needs reporter/patient follow-up." Click "Submit" at the bottom of the page.
3. **If the patient/caregiver consented to share the report with the provider**, then send the following e-mail to _____ by the date and time in columns F and G:

"Hi [_____ team member name],

The Health Care Safety Hotline received RSO [number] on [month day] at [time] Eastern. I reviewed the report and scrubbed [number of text fields] text fields that contained names.

The report is ready to be shared with the relevant health care organization.

Please let me know if you have any questions.

Thanks,
[Your name]"

4. In the tracking spreadsheet, record "999" in the column that corresponds to each question that the patient/caregiver did not answer but should have answered, given the skip patterns.
5. If the patient/caregiver appears to have "broken off" the survey (i.e., did not answer several questions at the end of the survey), then record "yes" in the relevant column of the tracking spreadsheet.
6. **If the patient/caregiver did not consent to receive a clarification call**, then go to the Administrative Script module of the report and click "Audited – Needs Team Decision (Free Text Reviewed and Sanitized)." Click "Submit" at the bottom of the page. Go to Stage 4 below.

Appendix C.11. Script and Instructions for Stage 3 – Clarification Call

This appendix describes exactly how to clarify a report.

1. **If the patient/caregiver consented to receive a clarification call**, then save HCSH_Clarification_Script_RSOXX.doc with the relevant RSO number in the file name.
2. Read the full report and identify any inconsistencies or issues needing clarification.
   a. In the clarification script, highlight questions needing clarification. Add probes below the questions and highlight the probes.
   b. Highlight any questions that the patient/caregiver did not answer but should have answered, given the skip patterns.
   c. If the patient/caregiver appears to have "broken off" the survey (i.e., did not answer several questions at the end of the survey), then highlight the Section 7 questions.
   d. If the report was made by a caregiver, then highlight Q2.2 and add the following probe: "We have that you would like us to share your report with the health care provider or facility that you identified, and that you would like us to include your name and contact. If we also include the patient's name, it will be easier for the provider or facility to identify the problem. May we share the patient's name?"
3. Complete section 1 of the classification form (HCSH_Classification_Form_v5.docx) and record a team clinician's name (Michael Smith or Eric Newman) in question 1 of section 2. Select the clinician who is next in the cycle. In the tracking spreadsheet, record the clinician's name in column J.

4. Send the following e-mail to the assigned clinician by the date and time in columns H and I:

> Hi [clinician name],
>
> The Health Care Safety Hotline received a report on [month day] at [time] Eastern. We would like you to review the report, add probes to the clarification call script, and return the clarification call script and classification form to me by no later than [48 hours after e-mail is sent] so that we can complete the clarification call on time. Please let me know if this deadline is not doable with your schedule.
>
> Please do the following by [48 hours after e-mail is sent]:
> 1. Review the report (1st attachment)
> 2. Highlight questions and add probes to the clarification call script, starting on page 5 (2nd attachment). Please be especially thoughtful about any probes that may be needed to classify the type, harm/severity, duration of harm, preventability, and contributing factors. You'll see that I have taken a first pass at highlighting questions and adding probes.
> 3. E-mail the revised clarification call script to me.
>
> Please let me know if you have questions.
>
> Thanks,
> [Your name]

5. In column K of the tracking spreadsheet, record the date that you sent the e-mail to the assigned clinician.
6. When the clinician returns the revised clarification call script and the classification form, record the date in column L of the tracking spreadsheet.
7. In column M of the tracking spreadsheet, record the initials of the person who will be completing the clarification call. Most of the time, you will complete the clarification calls for the reports that you process.

8. Make five attempts to complete the clarification call. Use column N for notes about each attempt. The last attempt should take place no later than 10 days after the report was received by the e-mail listserv (see columns D and E).
    a. If the patient/caregiver is reached and agrees to complete the clarification call:
        i. Walk the patient/caregiver through the clarification call script. Enter the patient/caregiver's responses into the script. Audio record the call and password-protect the audio recording.
        ii. Record the questions and answers in the Comments/Clarifications module of the report. Go to the Administrative Script module and click "Audited – Needs Team Decision (Free Text Reviewed and Sanitized)" and "Clarified (Questions answered by reporter team; Ready for matching to provider)." Click "Submit" at the bottom of the page.
        iii. Enter the date of the clarification call in column O of the tracking spreadsheet.
        iv. Record "clarified" in the relevant columns of the tracking spreadsheet.
        v. Send the following e-mail to _____:

Hi [_____ team member name], I completed the clarification call for RSO [number] and have recorded notes from the clarification call in the Comments/Clarification module of the report. The updated report is ready to be shared with the relevant health care organization. Please let me know if you have any questions. Thanks, [Your name]

    b. If the clarification call does not take place, then go to the Administrative Script module of the report and click "Audited – Needs Team Decision (Free Text Reviewed and Sanitized)." Click "Submit" at the bottom of the page.
9. Record the disposition of the attempts to complete the clarification call in column P.

Appendix C.12. Clarification Call Instructions and Script Samples

A clarification call with the reporting patient or caregiver may be necessary to provide the most accurate and complete information in the report. The purpose of this call is to ensure that all the facts within the report are clear and easy to understand when the report is passed on to the health care organization for review. The clarification call may also gather any other necessary information or consent to process the report.

When the report is initially received and processed, it should be reviewed for clarity and consistency. Questions related to the specifics of the report should be noted and added to a clarification call script. Any questions added to the clarification script are highlighted in yellow.

Clarification questions can be broad, especially when more information about the event itself is necessary (see Figure C12.1). In Figure C12.1 the example clarification questions are highlighted in yellow.

Figure C.12.1
Examples of Broad Clarification Questions

> 2.1 **We have the following information about the safety concern. [READ WHAT WAS IN THE TEXT BOX]**
> 12.1 *Could you please clarify in your own words:*
> *What happened?*
> *Where do you believe it happened?*
> *When did it happen?*
> *Why do you think this happened?*
>
> *Q: Can you tell me a little more about the event itself?*
>
> *Q: Can you describe your symptoms at the clinic? When did they start? When did they improve?*
>
> *Q: What actions would have been sufficient in maintaining a safe environment for you?*

Clarification questions may also be very specific, especially when the focus of the report is much more narrow (see Figure C.12.2).

Figure C.12.2
Example of a Narrower Clarification Question

> **2.1** **We have the following information about the safety concern.** [READ WHAT WAS IN THE TEXT BOX]
>
> *12.1* *Could you please clarify in your own words:*
> *What happened?*
> *Where do you believe it happened?*
> *When did it happen?*
> *Why do you think this happened?*
>
> *Q: Do you know the name of the specific medication?*
>
> *Q: Approximately what time was the medication given?*

An individual with a medical background should review all clarification questions. This helps to ensure that the questions being asked of the reporting patient or caregiver will clarify confusing or unclear aspects of the report as it pertains to patient safety and appropriate care. In Figure C12.2 the example clarification questions are highlighted in yellow.

When the administrator has reviewed all clarification questions with the reporter, answers to the questions, as well as the questions themselves, should be added back into the RSO in the Comments/Clarification section.

Appendix C.13. Classification Form

The Health Care Safety Hotline classification form provides insight into the incident after the report has been completed. The classification form attempts to categorize the type of reported incident, assigning a level of harm, preventability, contributing factors, and incident type. This form should be filled out by the reviewing physician.

Health Care Safety Hotline
Classification of Reported Safety Occurrence (RSO)

----

1. BASIC INFORMATION ABOUT RSO
(TO BE COMPLETED BY THE PERSON WHO "SCREENED AND SCRUBBED" THE RSO)

Reported safety occurrence (RSO) #: _____
Date/time RSO submitted to HCSH website: _____
Name of person who "screened and scrubbed" RSO: _____
Date person who "screened and scrubbed" RSO e-mailed classification request to person who conducted the initial classification: _____

----

2. INITIAL CLASSIFICATION (BEFORE CLARIFICATION CALL)
(TO BE COMPLETED BY THE PERSON WHO IS CONDUCTING THE INITIAL CLASSIFICATION)
Directions: Please use the information provided in the RSO, as well as your own clinical knowledge, in completing the <u>initial</u> classification.

Name of person who is conducting initial classification: _____

AHRQ Common Formats Event Type (Version 1.2):
    ___ **Incident**: A patient safety event that reached a patient and resulted in either no harm (no-harm incident) or harm (harm incident). The concept "reached a patient" encompasses any action by a health care practitioner or worker or health care circumstance that exposes a patient to harm.
    Example: If a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.

___ **Near miss:** An event that did not reach a patient. **[SKIP TO QUESTION #6]**

Examples: Discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident).

___ **Unsafe condition**: 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. An unsafe condition does not involve an identifiable patient. **[SKIP TO QUESTION #6]**

For example, an out-of-date medicine on a shelf represents an unsafe condition. The medicine might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).

AHRQ Common Formats Harm Scale (Version 1.2)

___ **Death**: Dead at time of assessment.

___ **Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.

___ **Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

___ **Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

___ **No harm**: Event reached patient, but no harm was evident. **[SKIP TO QUESTION #6]**

___ **Unknown**

AHRQ Common Formats Duration of Harm (Version 1.2)

___ **Permanent** (one year or greater)

___ **Temporary** (less than one year)

___ **Unknown**

Preventability: _____

_____

_____

_____

_____

Contributing factors:

_____

_____

_____

_____

_____.

In addition to the narrative above, please also select any contributing factors below.

Communication with doctors, nurses or other health care providers

Was it because the doctors, nurses, or other health care providers…

___A did not listen to the patient?

___B did not explain things to the patient in the patient's language?

___C used terminology the patient could not understand?

___D spoke with an accent that was hard to understand?

___E did not spend enough time with the patient?

___F ignored what the patient told them?

___G did not explain medications or their side effects?

___H did not provide a clear explanation of the diagnosis or care plan?

___I did not explain follow-up care instructions?

Responsiveness of staff

Was it because of not getting…

___A help as soon as the patient needed it?

___B a referral as soon as the patient needed it?

___C an appointment as soon as the patient needed it?

___D care as soon as the patient needed it?

Coordination of care

Was it because…

___A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?

___B of the lack of follow-up by the doctors, nurses, or other health care providers?

___C doctors, nurses, or other health care providers did not seem to work well together as a team?

Access
Was it because the patient…
___A was not able to get in to see a specialist for care?
___B was not able to get the tests or treatments that the patient believed necessary?
___C was not able to get the tests or treatments that a provider believed necessary?
___D did not get help or advice he or she needed?

Verification
Was it because someone did not…
___A correctly identify the patient?
___B have the most recent and up-to-date information about the patient?

Other
Was it because the patient…
___A couldn't afford the care the patient believed necessary?
___B couldn't afford the care a provider believed necessary?
___C had no insurance to pay for the care the patient believed necessary?

----

3. FINAL CLASSIFICATION (AFTER CLARIFICATION CALL)
(TO BE COMPLETED BY THE PERSON WHO CONDUCTED THE INITIAL CLASSIFICATION)

Directions: Please use the information provided in the RSO (including the information gained from the <u>clarification call</u>), as well as your own clinical knowledge, in completing the <u>final</u> classification.

IF YOU DO NOT RECOMMEND ANY CHANGES TO THE INITIAL CLASSIFICATION, PLEASE MARK AN 'X' HERE: __

AHRQ Common Formats Event Type (Version 1.2):
___ **Incident**: A patient safety event that reached a patient and resulted in either no harm (no-harm incident) or harm (harm incident). The concept "reached a patient" encompasses any action by a health care practitioner or worker or health care circumstance that exposes a patient to harm.

Example: If a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.

___ **Near miss:** An event that did not reach a patient. **[SKIP TO QUESTION #6]**

Examples: Discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident).

___ **Unsafe condition**: 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. An unsafe condition does not involve an identifiable patient. **[SKIP TO QUESTION #6]**

For example, an out-of-date medicine on a shelf represents an unsafe condition. The medicine might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).For example, an out-of-date medicine on a shelf represents an unsafe condition. It might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).

AHRQ Common Formats Harm Scale (Version 1.2)

___ **Death**: Dead at time of assessment.

___ **Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.

___ **Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

___ **Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

___ **No harm**: Event reached patient, but no harm was evident. **[SKIP TO QUESTION #6]**

___ **Unknown**

AHRQ Common Formats Duration of Harm (Version 1.2)

___ **Permanent** (one year or greater)

___ **Temporary** (less than one year)

___ **Unknown**

Preventability:

_____

_____

_____

_____

_____

Contributing factors:

_____

_____

_____

_____

_____

In addition to the narrative above, please also select any contributing factors below.

Communication with doctors, nurses or other health care providers

Was it because the doctors, nurses, or other health care providers…

___A did not listen to the patient?

___B did not explain things to the patient in the patient's language?

___C used terminology the patient could not understand?

___D spoke with an accent that was hard to understand?

___E did not spend enough time with the patient?

___F ignored what the patient told them?

___G did not explain medications or their side effects?

___H did not provide a clear explanation of the diagnosis or care plan?

___I did not explain follow-up care instructions?

Responsiveness of staff

Was it because of not getting…

___A help as soon as the patient needed it?

___B a referral as soon as the patient needed it?

___C an appointment as soon as the patient needed it?

___D care as soon as the patient needed it?

Coordination of care

Was it because…

____A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?

____B of the lack of follow-up by the doctors, nurses, or other health care providers?

____C doctors, nurses, or other health care providers did not seem to work well together as a team?

Access

Was it because the patient…

____A was not able to get in to see a specialist for care?

____B was not able to get the tests or treatments that the patient believed necessary?

____C was not able to get the tests or treatments that a provider believed necessary?

____D did not get help or advice he or she needed?

Verification

Was it because someone did not…

____A correctly identify the patient?

____B have the most recent and up-to-date information about the patient?

Other

Was it because the patient…

____A couldn't afford the care the patient believed necessary?

____B couldn't afford the care a provider believed necessary?

____C had no insurance to pay for the care the patient believed necessary?

Appendix D. Hotline Site-Visit Interview Protocol

Interviewee(s):

Interviewee(s) title and location:

Number to call if person is late or does not show:

Interviewee(s)' department (circle):
1. Implementation/operation of Health Care Safety Hotline (HCSH)
    a. Director of Patient Safety/VP of Quality & Safety
    b. Patient Safety Program Manager/point person to HCSH
2. Leadership/Governance
    a. C Suite, CEO of hospital or health system, or board member
3. Quality and Safety for Medical Staff and/or Ambulatory Services
4. Marketing/Communications
5. Patient Relations and or Patient/Family Advisory Council members/VP Patient Experience
6. Legal/Risk Management
7. Human Subjects Protection

Clinic site location (circle):
     XXX
     XXX

Date:
Time:

A. Introduction

Thank you for your time today. I am (introductions).

Facilitate introductions of the interviewee(s).

Ask if the interviewee(s) received the fact sheet and if they have any questions.

Review the purpose of the study (review fact sheet).

Explain the general purpose and format of the interview and the interviewee's role in this effort.

1. We are researchers from RAND, a nonprofit research institution, and from Tufts University and Brigham and Women's Hospital.
2. We are doing a research project funded by the Agency for Health Care Research and Policy (AHRQ), which is part of the federal government's Department of Health and Human Services.
3. The project is intended to learn about your organization's experiences with the Health Care Safety Hotline and how that may influence patients' experiences with health care.
4. We want to learn from you and your experiences in order to improve the current hotline and recommend lessons for other organizations that may want to implement a similar hotline in the future.
5. The discussion should take about 45 minutes. If you need to take a break at any time, please let us know.
6. Data will be reported so that neither you nor your organization can be identified. We will be aggregating the interviews across the pilot communities and reporting the information in aggregate form.
7. Your participation is voluntary, and you can decline to discuss any topic that we raise. Your names were provided to us today by your health care organization; however, we will not be reporting your participation to anyone outside of the research team.
8. We would like to record this discussion for note-taking purpose only. We will destroy the tape as soon as the notes have been completed. You do not have to agree to be taped; you can still participate in this conversation if you do not want to be taped.

May we record this discussion? (Circle: YES   NO)
→ *Turn on recorder.*

B. Background

1. For the record, can you please state your name and that you have consented to the interview?

2. What is your job within *[name of org]* and what role, if any, do you play in monitoring and/or improving patient safety?

3. What has been your involvement in the Health Care Safety Hotline so far, if any?

C. Decision to participate in the pilot

1. We want to learn a bit about how your organization decided to participate in the hotline pilot project. First, can you tell how you were involved in the decision to participate, if at all? **[*If not involved, SKIP to Question 3.*]**

Probe: What was your level of involvement in the decision to participate? Peripheral? Central?

2. OK, so now can you describe the process that *[name of org]* went through in deciding whether or not to participate? Please tell us about the people involved and the factors that were considered.

Probe: Who else was involved in making the decision to participate? When did they get involved? Who had to "sign off" on the decision?

Probe: Was there a champion?

Probe: What factors were considered in the decision process?

Probe: What pluses and minuses (or advantages and disadvantages) were perceived in the decision process?

Probe: **[ASK EVERYONE BUT ESPECIALLY RISK MANAGEMENT]** What about involving legal or risk management? Can you tell us anything about what risks were identified? Any concerns that emerged?

3. Were there any major "sticking points" or concerns that had to be overcome, before *[name of org]* decided to move forward with participating in the pilot?

4. So clearly, those sticking points were overcome. In the end, what would you say were the one or two primary motivators for deciding to participate in this pilot?

[Probe for both internal (e.g., reputation in the community) and external (pressures) factors. Come up with better terms.]

5. Thinking of your role as *[xxx]*, we are specifically interested in your view about the pluses and minuses in the decision to participate in the hotline. Can you tell us about your thoughts?
6. Was there anything unusual about how your organization decided to participate in the project, compared to how the organization usually decides to participate in other quality improvement or safety projects?

7. Here at *[name of org]*, you decided to limit the hotline to *[abc]* [see table below] and not include *[xyz]*. What factors were considered in that decision process?

ASK HUMAN-SUBJECTS PROTECTION OFFICE RESPONDENTS ONLY:
8. Can you tell us anything about how your IRB or human-subjects committee was involved? What was the process like for determining whether this project was quality improvement or research?

PROBE: Would the Human-Subjects Protection Office consider the project to be quality improvement if there was no evaluation component?

D. "Pre-launch" period (from the decision to participate until February 2014)

1. Let's talk for a bit about the time that we call "pre-launch," that is, between when *[name of org]* agreed to participate in the pilot and the actual launch in February 2014. How were you involved in this pre-launch period, if at all? **[Skip if not involved.]**

2. In what department or group within your organization did responsibility for the pre-launch sit?

3. What was the plan for the rollout?

4. Within your unit, what kind of resources, support, or direction did you need to prepare to launch the pilot? What did you receive? What didn't you receive?

5. Now let's talk about what you and your staff had to do to get ready for the launch. What were the biggest tasks or challenges that you and your staff faced?

Probe: Were these expected or unexpected?
Probe: What resources and support were needed vs. supplied?
Probe: Can you tell me about how participating in the hotline affected your unit's fiscal year budget? Did you have to reallocate funds from other projects?

6. Thinking about the organization as a whole, what about the things that *[name of org]* had to do to get ready for the launch. What were the biggest tasks or challenges the organization faced?
7. Now please tell us, from the perspective of your own unit, what challenges did you face that were different from the tasks or challenges that you just mentioned?

Probe for hospital, ambulatory, pharmacy.

Probe: Were these expected or unexpected?

E. Post-launch

OK, thank you for telling us about the pre-launch period. Now let's talk about how the pilot has gone since its launch, that is, the "post-launch" period.

1. For starters, how has it gone so far?

Probe: What are the biggest strengths or successes of the program so far? We also want to know about the weaknesses. It might help to think about this like a SWOT (strengths, weaknesses, opportunities, threats) analysis.

[Probes: Have you experienced any problems or issues that you had to work through?
- *Any glitches on launch day*
- *Barriers to patients using the system*
- *Barriers to implementation or operation*
- *Barriers to marketing the HCSH*

2. What problems do you foresee going forward?

3. Think back to the pluses and minuses that were considered during the decision to participate. Have your perceptions of the pluses and minuses changed since the decision to participate? If yes, how?

F. Reaction to the hotline within the organization

We now want to understand how the hotline has been received in *[name of org]*. Let's start by asking you about whether you think people in *[name of org]* are aware of the program?

1. How were employees and staff notified? Do you believe that most clinicians are adequately aware of the program?

2. What has been the main reaction to participation in the hotline by hospital staff? Here is a list. Can you indicate whether they are generally positive or negative about the hotline?
[Probe for reasons why for each group below. Mark "Not applicable" as needed.]
- Physicians
- Other clinical staff, including nurses
- Pharmacy
- Leadership such as the board or C-suite
- Patients
- Anyone else I missed?

3. To your knowledge, has *[name of site]* received any safety reports through the hotline? If yes, what happened? If no, what will happen?

Probe: have there been any glitches that we should know about?

G. [OPERATIONS ONLY]: Responding to hotline reports/ linking with other systems

1. How well does the hotline complement other existing safety reporting systems? Is it augmenting your ability to collect important information or is it redundant? (Or do you not know? Or is it too early to tell?)
2. How are you organizing the process of receiving reports from the hotline and responding to the reports?

Probe: How are the reports triaged?

3. How are the patient-relations department at the hospital and the physicians at ambulatory sites or pharmacies involved in reviewing the reports?

4. How do you handle patient-provided reports differently from reports that come from the Joint Commission or the state health department?

H. Lessons and advice

1. Are there aspects of the hotline that you would have preferred to be different in order to facilitate the integration of the pilot into your health system? Think about things like the culture, preferences, and current work styles and practices.

2. What advice would you give to another health system like yours about implementing the HCSH? What lessons have you learned so far that could be useful for others?

3. From what you know as of today, including what you could have done differently, how encouraging or discouraging would you be to other organizations thinking about starting a hotline?

[USE HANDOUT TO GAIN ANSWERS FROM EACH PARTICIPANT]

NAME: _____
[*CIRCLE RESPONSE*]
>   *Very encouraging*
>   *Somewhat encouraging*
>   *Neutral*
>   *Somewhat discouraging*
>   *Very discouraging*

NAME: _____
[*CIRCLE RESPONSE*]
>   *Very encouraging*
>   *Somewhat encouraging*
>   *Neutral*
>   *Somewhat discouraging*
>   *Very discouraging*

NAME: _____
[*CIRCLE RESPONSE*]
>   *Very encouraging*
>   *Somewhat encouraging*
>   *Neutral*
>   *Somewhat discouraging*
>   *Very discouraging*

ASK RISK MANAGEMENT, LEGAL, AND HUMAN-SUBJECTS RESPONDENTS ONLY:

4. Knowing what you know now about the risks, legal environment, and privacy issues, and once the research study is over, how would you recommend the hotline be structured in the future?

    FOR EXAMPLE: Run out of a Patient Safety Organization?
    A different type of organization?
    A government agency or organization?
    A not-for-profit or for-profit organization?

    [Probes:
    What benefits and drawbacks might each of these have?]

I. Conclusion/follow-up

1. Thinking back about all the things you've told us, are there any areas that we failed to cover or important questions that we should have asked?

2. Are there any other ways that you believe the HCSH pilot will affect the organization, its patients, and providers either positively or negatively?

3. If you were going to summarize the most important points of our discussion today that relate to implementation of a safety hotline, what would they be?

Thank you for your time.