Designing Consumer Reporting Systems for Patient Safety Events

![AHRQ logo] **AHRQ**
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Contract Final Report

Designing Consumer Reporting Systems for Patient Safety Events

Prepared by:
RTI International, Washington, DC and Research Triangle Park, NC[*]
    and
Consumers Advancing Patient Safety, Chicago, IL[†]

Investigators:
[*] Michael T. Halpern, M.D., Ph.D.
  Senior Fellow, RTI International

[*] Amy Elizabeth Roussel, Ph.D.
  Vice President, RTI International

[*] Katherine Treiman, Ph.D., M.P.H.
  Senior Research Scientist, RTI International

[*] Patrick A. Nerz, B.A.
  Health Services Analyst, RTI International

[†] Martin J. Hatlie, J.D.
  CEO, Project Patient Care and
  Co-founder and Program Director, Consumers Advancing Patient Safety

[†] Susan Sheridan M.I.M., M.B.A.
  Co-Founder, Consumers Advancing Patient Safety and
  Expert Lead, Patients for Patient Safety, World Health Organization

This document is in the public domain and may be used and reprinted without permission, except those copyrighted materials that are clearly noted in the document. Further reproduction of those copyrighted materials is prohibited without the specific permission of the copyright holders.

Suggested Citation:

Halpern, M.T., Roussel, A.E., Treiman, K., Nerz, P.A., Hatlie, M.J., and Sheridan, S. Designing Consumer Reporting Systems for Patient Safety Events. Final Report (Prepared by RTI International and Consumers Advancing Patient Safety under Contract No. 290-06-00001-5). AHRQ Publication No. 11-0060-EF. Rockville, MD: Agency for Healthcare Research and Quality. April 2011.

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

Peer reviewer's comments on a preliminary draft of this report were considered in preparation of this final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

Acknowledgments

Contents

Executive Summary

The Agency for Healthcare Research and Quality (AHRQ) funded the *Designing Consumer Reporting Systems for Patient Safety Events* project to develop recommendations for ideal reporting systems that consumers would use to report experiences with patient safety events. The iterative process for developing these recommendations involves extensive support from a Technical Expert Panel (TEP), input from consumer focus groups and stakeholder interviews, and an environmental scan and literature review. The ultimate outcome of this project is to outline the key design specifications for the development of consumer reporting systems for patient safety events. This report presents recommendations developed by the TEP following the fourth expert panel meetings. These recommendations incorporate input from the focus groups, stakeholder interviews, and environmental scan report as well as from external peer reviewers.

RTI International, a nonprofit research organization, is carrying out this research contract for AHRQ in collaboration with Consumers Advancing Patient Safety (CAPS), a nonprofit, consumer-led organization dedicated to creating new pathways for consumers and providers to work collaboratively to achieve health care that is safe, compassionate, and just.

Methods

The recommendations contained in this report were created using the IDEALS framework, in which a recommended system evolves through three stages:

1. A theoretical system capturing a vision of what an ideal system would be (even if, realistically, that cannot be attained).
2. An ultimate ideal system that is built on the theoretical ideal system, but contains achievable operational and practical goals.
3. A technologically workable ideal system (TWIS).

As a result of this process, recommended systems were specified in terms of currently available technologies and components while meeting the specifications of the prior steps of the process (theoretical ideal, ultimate ideal, and technologically workable systems).

The implementation of the IDEALS concept has been extensively supported by the TEP at every stage. The TEP includes experts in patient safety, patient safety event reporting systems, health care delivery and quality improvement, patient-centered care, and patient advocacy. TEP members were chosen not only for their knowledge and reputation in their respective fields, but also for their ability to think creatively and work collaboratively with colleagues. Appendix A lists the names, affiliations, and components of the project in which they participated for each of the TEP members.

Members of the TEP initially participated in three rounds of questionnaires using the Delphi Method. These iterative questionnaires were designed to elicit information related to key design

features for consumer reporting systems in response to a set of six research questions developed by AHRQ:

1. What type 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?
2. What are the scope and range of options for consumer reporting mechanisms? How would these options differ at the national, regional, State, or local level?
3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?
4. What is the most effective operational approach for consumers to report patient safety event information?
5. How would consumer reporting of patient safety events be linked to quality and/or patient safety improvement efforts?
6. How can a reporting system maximize the willingness and ability of consumers to report on patient safety events?

Following completion of the three rounds of Delphi questionnaires, the TEP met for the first time in June 2009. Using the Delphi results as a basis, potential recommendations for consumer reporting system design features were elicited from the TEP members using the nominal group technique (NGT). Using this technique, design features related to a particular area of consumer reporting systems were elicited from the panel members. The list of design features was then discussed and features were added, removed, or combined. TEP members then voted on the features they felt were most important, and the panel moved on to the next topic.

A second meeting was held in December 2009. At this meeting, the TEP reviewed the results of the first TEP meeting, consumer focus groups, key stakeholder interviews, and the environmental scan and literature review. A half day of this meeting was used to discuss the results of the aforementioned activities, and a subsequent full day was used to further develop TEP recommendations for design features of TWIS for consumer reporting of patient safety events.

The TEP convened for a third time in February 2010 to resolve unanswered questions and address additional issues remaining from the previous two meetings. The goal of the meeting was to develop draft recommendations regarding consumer reporting systems for patient safety events, to transition from initial discussions of TWIS to the complete specification of TWIS. This included finalizing consensus points, discussing unresolved issues from the second TEP meeting to develop recommendations on key design features, and discussing new (that is, previously undiscussed) design features, if necessary.

Following the third TEP meeting, a draft final report was prepared presenting a summary of the activities to date in this project, the draft design feature recommendations, a series of graphics illustrating how these design features may be organized within a consumer reporting system, and a discussion of limitations and additional issues. The draft report was reviewed by a group of external peer-reviewers, whose names and afiliations are presented in Appendix B. A

summary of the draft recommendations was also presented at a second set of consumer focus groups to obtain a consumer perspective on the emerging system design.

Comments from the consumer focus group participants, the external reviewers, and members of the TEP were presented at a fourth TEP meeting held in October 2010. The goals of this final TEP meeting were to discuss the feedback received on the draft final report and reach consensus regarding materials for the final report. The results of this fourth meeting are the recommendations found in this final report.

Findings

During the first TEP meeting, the TEP established assumptions that underlie the resulting recommendations. Specifically, the TEP agreed that consumers have valuable information about the health care system and their experiences within it, and that health care systems and providers may not have access to this information. Based on this, the TEP confirmed that there is great value in obtaining information from consumers.

The TEP reached consensus on many recommendations for design features of consumer reporting systems. Table ES-1 summarizes these recommendations made by the TEP. TEP members stressed that, while reporting of patient safety events may often be associated with hospital-based incidents, these recommendations are applicable to patient safety events in all health care settings. There were also some disagreements among TEP members regarding specific design features, which led to development of recommendations for alternative models of reporting systems. For example, TEP members' opinions diverged on whether consumer reporting systems should perform their own Root Cause Analysis (RCA) for selected patient safety events. Further, for certain other recommendations, the TEP noted the importance of specific design features but chose not to specify details of these features because of their dynamic nature. For example, the TEP commented on the importance of public reporting, but elected not to specify details for public reporting as this area was rapidly changing. In these cases, the TEP generally agreed that detailed recommendations would need to be made at system implementation.

Table ES-1.   Recommendations for Key Features of Ideal Consumer Reporting Systems from the Technical Expert Panel

1. What type 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 systems should collect information on all types of events, ranging from near-miss and no-harm events to adverse events. The systems 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 an event was reported; what happened when an event was reported; and the impacts or consequences of the event.

Recommendation 1.2: Sources of Reports. The systems should allow for reporting by any individual, but the emphasis is 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, or 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 is 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. Reporting systems will need to be flexible regarding analysis and other activities occurring at local levels, based on needs, capabilities, and funding/resources for these local activities.

3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?

Recommendation 3.1: Linkages. Systems 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 for the purpose of encouraging consumer reporting, improving analysis, sharing results, and changing delivery for quality improvement. Linkages will also ensure timely information sharing. Because linkages are dynamic and rapidly changing, their exact nature and specifications will be more fully specified at implementation.

Recommendation 3.2: Analytic Functionality. Systems will need decision rules for what kinds of events receive different levels or types of analysis. Systems should collect information and conduct aggregate causal analyses. Systems should also gather responses of organizations to reports 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 are the following: independent entity with a steady stream of sustainable funding, where "independent" is defined as an entity that is 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' fiduciary responsibility is to represent the public; neutral oversight body with consumer representation; transparency of goals, process, and results; consumer involvement in organizational governance and operations; and dedication 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. Systems should allow reporting at any point in time.

Recommendation 4.3: Reporting Modalities. To maximize reporting, systems should allow multiple routes or modalities for reporting.

Recommendation 4.4: Reporting Format. Systems should allow a mix of structured and unstructured reporting.

Recommendation 4.5: Anonymity. The system will allow anonymous reporting, but the system should be designed to discourage anonymous reporting by ensuring and encouraging well-designed

confidential reporting. The system could 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. Systems should be linked to efforts to improve quality and patient safety. If the reporter allows, his or her reports to the consumer reporting system will be automatically forwarded to appropriate existing reporting systems at the local or facility level.
Recommendation 5.2: Public Reporting. Public reporting should be used to hold systems accountable to their own goals. Systems should: • Publish information such as how much a system was used. • Publish information on what was learned. • Publish information about what recommendations and changes were made as a result of the system. • To the extent determinable, publish information about the responsiveness of institutions to patient safety issues. Because this is an evolving and dynamic issue, the exact specifications will be developed at implementation and will be determined over time as the issue develops.

6. How can a reporting system maximize the willingness and ability of consumers to report on patient safety events?
Recommendation 6.1: Maximizing Reporting. System design should facilitate reporting to ensure maximum use; that is, maximize the ease/ability of consumers to submit reports. 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. Systems should be designed to facilitate access for diverse populations (e.g., age, race/ethnicity, education, language, disability).
Recommendation 6.3: Feedback. Systems should provide meaningful and timely feedback to reporters. Feedback will include public reporting, awareness campaigns, and meaningful acknowledgement of the receipt of a report. Systems will not be able to assure reporters that they will receive meaningful and timely feedback from the health care facility/system where a patient safety event took place.

Discussions by the TEP provided clarification and elaboration on these draft recommendations and recommendations for alternative models for consumer reporting systems. Specific discussion points include the following:

1. What type 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?

The TEP recommendations focused on collecting broad and diverse input from consumers for patient safety event reporting systems. This includes collection of all types of information, including both objective findings and those from the consumer's unique 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, or local levels?

The TEP described dual purposes of a consumer reporting system: to learn and to be accountable to consumers providing reports. In this context, accountability is defined as consumer reporting systems being accountable to those who submit reports, where systems have a responsibility to actively use reported information in the pursuit of meaningful improvements to patient safety.

The TEP described two system models with respect to level of operations. The first model (Recommendation 2.2) separated data collection/reporting capabilities at the local level from data aggregation, analysis, and distribution activities at a centralized (potentially national) level. A second model for consumer reporting systems included additional capabilities at the local level. These additional local capabilities could include data analysis and direct interactions with health care providers or facilities. The TEP did not make recommendations about international systems.

3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?

The TEP recognized that system linkages represent a dynamic, rapidly changing area. As such, the TEP chose not to specify how such linkages would work operationally. The exact nature and specifications of linkages can be specified more fully based on pilot testing and at system implementation. For Recommendation 3.1, TEP members did not indicate specific entities that comprise the "broad range of organizations" to which consumer reporting systems should link. However, discussion by the TEP indicated that these organizations should include State and Federal regulatory and financing organizations (e.g., the Food and Drug Administration [FDA]); health care facilities and systems; accrediting bodies; insurers; employer health care groups; user groups or communities of interests; and organizations that can provide assistance to consumers submitting reports beyond that available directly from consumer reporting systems.

In discussions related to Recommendation 3.2, the TEP identified three system models regarding analytic functionality. In one model, systems do not expend resources to conduct RCAs, but request RCAs when performed by other organizations and analyze the collected RCA information. In an alternative model, systems are able to perform RCAs on selected events. In this model, public decision rules are used to determine which events warrant an RCA and the performance of RCAs are subject to financial constraint. A third alternative model discussed by the TEP was collection of data using a standardized form for focused initiatives. This would involve development of a data collection instrument to gather information on a particular type of patient safety event. The instrument would be submitted to relevant health care facilities (presumably facilities where events of the specified type occurred based on reports to the system) and used to collect information related to the event. Related to this discussion, external reviewers and TEP members recognized that there are only limited numbers of individuals trained to perform RCAs at hospitals— and even fewer such individuals in other health care settings. This could affect the quality of RCAs produced.

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

The TEP explicitly chose not to specify the types of organizations to operate consumer reporting systems, electing instead to recommend characteristics of such organizations. However, the TEP agreed that these could be either public or private organizations. Four potential business models were discussed: commission model, Patient Safety Organization (PSO) model, quality improvement organization (QIO) model, or a subscription/co-op/consumer-driven model (similar to Consumers Union, where members pay dues to support the organization). The TEP did not reach consensus on the type or types of business models appropriate for operating consumer reporting systems. Some TEP members indicated that consumer reporting systems should not be owned or operated by accreditation or regulatory agencies such as the Joint Commission, the Centers for Medicare & Medicaid Services (CMS), or State Departments of Health; however, there was not universal agreement on this point. The TEP did not develop specific recommendations regarding financing of consumer reporting systems. However, this was described as a crucial issue because it could influence consumer perceptions regarding the reporting system. TEP members agreed that there is a need to align the scope and activities of a consumer reporting system with the available funding. Members also discussed that because multiple stakeholders may benefit from consumer reporting systems, it would be desirable to have a funding model that included all entities that benefit. Funding of the Pennsylvania State reporting system was described positively in that it is based on a fixed State government budget item (funded by hospitals) and not subject to annual legislative appropriations

Regarding other design features, TEP members indicated that both structured and unstructured (narrative) responses in reports are useful for conveying a consumer's unique perspective, and each type of information has different uses in analysis. The TEP therefore recommended that systems collect both types of responses.

The TEP endorsed confidential (as opposed to anonymous) reporting, to allow systems to provide feedback to consumers as well as the opportunity to collect additional information from individuals who submitted reports. However, the TEP recognized that some reporters will prefer to report anonymously, and therefore recommended that anonymous reporting be allowed, although confidential reporting was to be encouraged. There was also concern regarding the ability of consumer reporting systems to keep information confidential when involved in legal proceedings (e.g., if served with a subpoena). An alternative model suggest by several TEP members was for a system to pursue legislative protection from releasing any confidential information, thereby assuring people that their information will not be used against them.

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

The TEP emphasized that new consumer reporting systems should not replace existing systems and efforts to improve quality or patient safety, but should link to existing QI, RCA, or reporting systems. Systems could give reporters the option of having their report automatically forwarded to the appropriate local facility, system, or organization related to the reported events and to appropriate State or national systems. Further specification of this design feature may

have to wait until implementation because the technology required for such interoperability is likely to change rapidly.

TEP members broadly agreed that public reporting (that is, allowing public access to nonconfidential information from patient safety events reports) was a key approach to linking consumer reporting of patient safety events to patient safety improvements. However, the TEP also recognized that public reporting is a dynamic area that will become more important and more accepted over time. As such, although the TEP endorsed public reporting as an important system component and stated that systems should have the capability to engage in public reporting, the TEP did not include specific types of public reporting in the consensus recommendation (5.2). Rather, the TEP explicitly recommended that specifics regarding public reporting be developed based on pilot testing and at system implementation.

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

TEP recommendations in this area focused on systems being highly inclusive and responsive. TEP members recognized that beyond development of consumer reporting systems, additional activities will be required to inform the public about such systems and encourage patient safety event reporting. TEP members emphasized that a main feature (perhaps the main feature) with respect to maximizing consumer reporting is timely feedback. Systems will also need to interact with consumers to assess their own performance. The TEP acknowledged that meaningful consumer feedback is an area that will need to be explored as a system develops; that is, it will not be known what feedback is meaningful to consumers until the system starts.

Discussion

A variety of policy considerations arise from the TEP recommendations. This report highlights considerations that can broadly be classified in three groups: issues of rapidly changing technology use and practices, collaboration and coordination among groups and agencies involved in patient safety, and ownership/operation of consumer reporting systems. It is likely that new legislation, regulations, and policies will be needed to address these issues.

Throughout the course of this project, there has been an expected tension between the goal to develop design features for ideal consumer reporting systems and the knowledge of real-world barriers and limitations in the design and operation of such systems. To some extent, this has reflected an interest by TEP members in issues related to implementation of the consumer reporting systems that they were designing. Implementation of consumer reporting systems and related activities that go beyond specifying recommendations for system design features are outside of the scope of this project. However, for future work, it will be critical to consider these issues. TEP members stressed the need for pilot testing in multiple local and regional settings prior to broad-scale implementation of a consumer reporting system. The TEP also recognized that while all of the recommended design features are important for the final consumer reporting system, only a subset of the recommendations need to be specified at initial system implementation; other recommendations can be specified at a later time.

Although reporting of patient safety events is often associated with hospital-based incidents, these recommendations are applicable to patient safety events in all health care settings. TEP members indicated that the consumer perspective may be particularly important for patient safety events that occur during health care transitions (i.e., when care for a patient transfers from one provider or health care organization to another).

External reviewers also discussed a broader question regarding expectations for what can be accomplished by consumer reporting systems. Multiple reporting systems have been developed and implemented over the past decade; as such, consumer reporting systems may not be able to contribute substantially to information on the incidence or types of events. However, the dual purpose recommendations for consumer reporting systems (to learn with the intention of improving patient safety and to be accountable to those who submit reports) highlights a unique and critical role for consumer reporting systems.

The idea of consumer reporting systems for patient safety events holds great promise. Turning that idea into a reality will require significant political will, policy coordination, and resource investment. The design features presented in this report provide an actionable foundation for the necessary next steps of implementation and operation.

Limitations

Resource constraints—as well as attempts to minimize the already considerable time that members of the TEP graciously devoted to this project—limited our ability to explore all possible areas for recommended consumer-reporting-system design features. In addition, although the TEP consisted of a diverse group of individuals with experience in a range of relevant areas, it is not possible to include individuals with all types of appropriate backgrounds and expertise on a single panel. This limitation was addressed by providing TEP members additional information from consumer focus groups, stakeholder interviews, and an environmental scan and literature review. Information from the consumer focus groups in particular provided additional perspectives and viewpoints for TEP members to take into account in developing recommendations for key design features.

There are several areas in which the TEP chose not to develop explicit recommendations. For example, although TEP members discussed the types of organizations that would be most appropriate to operate consumer reporting systems, members elected not to recommend specific organizations or organization types, and instead specified characteristics of such organizations. Similarly, although TEP members discussed several potential financial models for consumer reporting systems, the TEP chose not to present a recommended approach to finance such systems.

Other recommendations recognize the importance of certain key design features, but do not specify the operational aspects of those features. For example, Recommendation 3.1 emphasizes the importance of linkages for consumer reporting systems and states that systems should have linkages with a broad range of organizations. However, recognizing that linkages are a dynamic and rapidly changing area, the TEP chose to specify neither how such linkages should operate

nor the exact types of organizations with which to establish linkages. The operational details of such recommendations will need to be specified based on pilot testing and at implementation of consumer reporting systems.

There were numerous discussions and comments by TEP members regarding implementation issues for consumer reporting systems. However, this project focused on recommendations for system key design features and did not develop recommendations specific to implementation issues. Implementation challenges described by TEP members are presented in the Discussion section of this report.

Chapter 1. Background

Evidence documenting health care-associated injury/harm and mortality rates has appeared regularly in the health care literature since the 1950s, but the Institute of Medicine report, *To Err is Human: Building a Safer Health System* (IOM, 1999), raised national awareness of the prevalence and severity of medical error to a new level. Since that report, individual States and health care systems have established reporting systems to detect preventable medical harm. However, recent research indicates that progress in improving patient safety has been limited. A recent report found little evidence of improvements in patient safety in the decade since publication of the landmark IOM report (Landrigan et al., 2010).

Many current reporting systems do not accommodate the desire of patients and their families to provide input on their experiences with care. Incorporating consumers' experiences and perspectives into patient safety reporting may represent a new opportunity to address this persistent challenge to health care. The Agency for Healthcare Research and Quality (AHRQ) recognizes that the unique perspective of health care consumers could reveal important information not reported by providers. Information from consumers may complement input from other reporting mechanisms, and diversify and augment our understanding of the nature and causes of preventable harm.

In an effort to realize the latent and often untapped potential of health care consumers to provide important information about patient safety events, AHRQ awarded RTI International and Consumers Advancing Patient Safety (CAPS) a contract to identify recommendations for key design elements of consumer reporting systems for patient safety events through an iterative, consensus-building process. The research questions specified by AHRQ that guide this project are:

1. What type 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?

   - What happened?
   - Was the problem reported? To whom?
   - What happened when the problem was reported?
   - What caused the patient safety event to happen?
   - Where did the patient safety event happen?
   - What impact did the patient safety event have?
   - What were the consequences of the patient safety event?

2. What are the scope and range of options for consumer reporting mechanisms? How would these options differ at the national, regional, State, or local level?

3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?

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

- In what kind of organization (e.g., public–private partnership, public, private) should a consumer reporting system be housed?
- How should a consumer reporting system for patient safety events be financed?

5. How would consumer reporting of patient safety events be linked to quality and/or patient safety improvement efforts?
6. How can a reporting system maximize the willingness and ability of consumers to report on patient safety events?

The draft consensus recommendations presented in this report were developed in response to these questions, using the resources described in the Description of Methods (Chapter 3, below).

Chapter 2. Conceptual Framework and Design

Frequently, new systems are created based solely on existing systems and the problems and advantages that are associated with them. This approach prematurely narrows the focus of options so that system solutions that could be substantially more effective and efficient are never considered. In an attempt to bypass the self-imposed restrictions of basing a design on existing systems, the project design is based on Nadler's "Ideal Design of Effective and Logical Systems" (IDEALS) design concept (Nadler, 1967).

The IDEALS concept is intended to result in recommendations for achieving, as closely as possible, an optimal system. According to the IDEALS concept, a recommended system evolves through three stages:

1. A theoretical system capturing a vision of what an ideal system would be (even if it is realistically unobtainable).

2. An ultimate ideal system that is built on the theoretical ideal system, but contains achievable operational and practical goals.

3. A technologically workable ideal system (TWIS).

The result of this process is a recommended system that is specified in terms of currently available technologies and components, while meeting the specifications of the prior steps of the process (theoretical ideal, ultimate ideal, and technologically workable systems).

Chapter 3. Description of Methods

Technical Expert Panel (TEP), Delphi Surveys, and First TEP Meeting

The creation of recommendations for design features of consumer reporting systems was driven by extensive input and review from a Technical Expert Panel (TEP). The TEP included experts in patient safety, patient safety event reporting systems, health care delivery and quality improvement, patient-centered care, and patient advocacy. The project team chose the TEP members for their knowledge and reputation in their respective fields, and for their proven ability to think creatively and work collaboratively. The TEP was tasked with considering design features of potential consumer reporting systems and making recommendations on preferable system attributes.

Draft TEP recommendations for consumer reporting system design features were generated using the Delphi Method and three rounds of consensus-building meetings. The Delphi Method is an anonymous process for developing consensus on topics that require input from individuals with a wide range of expertise and background. Through an iterative series of three questionnaires (i.e., a three-round Delphi process), the TEP described the ideal attributes of a consumer reporting system without full specification. After the completion of the Delphi Method, the TEP met to discuss and clarify their recommendations and provide greater specificity.

Additional Project Activities

The work of the TEP was enhanced and supplemented by four sets of activities:

- Initial round of consumer focus groups to discuss ideal system design features
- Stakeholder interviews
- Environmental scan and literature review
- Second round of consumer focus groups to provide feedback on draft recommendations

I. Initial Round of Consumer Focus Groups

Methods and recruitment process. We conducted six consumer focus groups in three geographic areas: two in Denver, two in Houston, and two in Boston during June through September 2009. Focus groups were conducted with individuals (or their family members) who had experienced patient safety events, to discuss design features for consumer reporting systems. We recruited participants by working closely with consumer advocacy organizations in each

location as well as with CAPS community contacts. All participants had experienced a patient safety event (either personally, through a family member, or through someone for whom they care) in the last 10 years. Recruitment efforts focused on obtaining participants who experienced patient safety events in three different settings of care:

- Hospital or home immediately following discharge from a hospital
- Ambulatory or outpatient care settings (such as health centers and clinics, doctor's offices, hospital outpatient centers for diagnostic tests, same-day surgery, cancer treatment, and rehabilitation care)
- Long-term care facilities (nursing homes, assisted living, or other residential care facilities such as group homes)

The focus groups explored the research questions developed by AHRQ that were presented above.

Characteristics of participants. Three groups included 9 participants, one group included 8 participants, one group included 7 participants, and one group included 6 people, for a total of 48 consumers across all six groups. The participants were predominantly female (79 percent), while 65 percent were aged 50 and older, 77 percent were white, and 77 percent had a college degree or higher. One third of the participants had experienced a patient safety event themselves; over three quarters of the participants (77 percent) had a family member who had experienced a patient safety event. Some participants also worked in the patient safety field, many were members of consumer networks, and some were active in advocacy activities. About 88 percent of the patient safety events occurred in a hospital setting. One quarter of patient safety events occurred in an ambulatory setting and 10 percent in a long-term care facility. (Respondents could report more than one person who experienced a patient safety event and more than one setting, so these numbers do not add up to 100 percent)

Findings. Focus group participants were able to generate many key design features of ideal consumer reporting systems. Many of these features emerged in multiple focus groups. Participants reported universal agreement on several key design features relating to accessibility, levels of operations, reporting modalities, and maximization of reporting. Participants strongly supported the value of consumer reporting systems to contribute to improvements in health care quality and safety, strengthen accountability, support patient empowerment, and aid learning. They said that consumers can report extensive information about patient safety events, including details about the sequence and timing of events, the individuals involved and their roles in the event, and communication or coordination issues that contributed to the event. Participants stressed that the consumer's perspective provides critical insight into what happened and why. Frequently, consumers can provide information that clinicians miss or may not consider salient. Other frequently mentioned types of information that consumers can provide were the consequences (emotional and physical) of the event; information about near misses; and information about hygiene and sanitation, staff attitudes and behaviors, and other issues.

Table 1. Key features of ideal consumer reporting systems from focus groups

Scope and range—Accessibility
System should allow reporting in both real time and after the event, and allow reporters repeated access to update the report.
System should facilitate access for diverse populations (e.g., age, race/ethnicity, education, non-English speakers) and should also be available to health care workers.

Scope and range—Anonymity and confidentiality
System should offer reporters the opportunity to be identified, with the option for anonymity.
System should allow reporters to decide how and where information is shared.

Scope and range—Voluntary vs. mandatory
System should be voluntary.

Levels of operation
System should be multilevel and integrated from local (health care organization-based) to State, regional, national, and even international.
Local-level reporting is important for consumer convenience and to provide immediate feedback to health care facility. Higher-level reporting is important for accountability, learning, and quality improvement.

Organizations suitable to operate a consumer reporting system
Independent, private, nonprofit organizations were preferred because participants viewed them as independent and less likely to have conflicts of interest.
Participants' views on government's role were conflicting or ambivalent (pro: has authority; con: too bureaucratic).
Organization should have consumer involvement, ability to make changes or linkages to organizations that can affect change.

Operational approach—Staffing
System should have staff to help consumers report, act as advocates, and provide a "human touch."

System Infrastructure and design
System should have multiple reporting modalities (in-person, telephone, paper-based forms, electronic submission) and allow both structured and unstructured reports.
System should provide meaningful and timely feedback to reporters.

Table 1. Key features of ideal consumer reporting systems from focus groups (continued)

System should have linkages with providers, provider organization, accrediting organizations, government agencies, educators, and others.
Purpose and Goals
Primary goals should be to improve health care quality, patient safety, accountability for providers and provider organizations, and learning (including educating providers and consumers).
System should empower consumers by providing information to use in selecting sources of care.
Linkages to quality improvement
Consumer-reported data should be publicly available.
System should provide feedback to providers and provider organizations.
Maximizing reporting
Need to implement public awareness campaigns about consumer reporting systems and patient safety, generally.
Need to disseminate information about consumer reporting within health care facilities (e.g., at intake in hospitals).
Essential to demonstrate that consumer reports of patient safety events are actionable and make a difference in improving patient safety.

Table 1 summarizes key findings related to participants' views about the scope and range of possible consumer reporting systems, operational approach, infrastructure and design features, purpose and goals of a system, linkages to quality improvement, and ways to maximize utilization of the system.

Accessibility of consumer reporting system(s). Participants thought it was important for patients, family members, and others to be able to report a patient safety event from the time the event occurred ("real time") to well after the event, once they have had time to heal, grieve, care for people harmed, and gather information for reporting. In addition, participants said it was important that consumers be able to review and update their report as new information becomes available. They recommended designing the system to facilitate access for consumers who may face language, literacy, or cultural barriers to reporting and making it available for health care workers and witnesses, not just patients and families.

Anonymity and confidentiality. The ability to self-identify was another important concern for participants. However, they also thought it was critical that reporters have options to choose anonymity or different levels of privacy. Patients, family members, and others who submit reports need to feel confident that they are not jeopardizing their care. Several thought whistle-blower protection for health care professionals was an important feature.

Levels of reporting. Most of the participants envisioned an integrated multilevel reporting system, or "one big system," rather than the current fragmented situation. As one participant said, "*Our biggest problem now is fragmentation of places to report. Ideally, this system should fix that.*" Participants perceived advantages to reporting at the local level (generally referring to reporting at the point of care) in terms of convenience for the consumer and rapid feedback to the health care institution.

However, some participants also questioned whether they could trust a local reporting system. Participants generally thought of local-level reporting as linked to a State, regional, national, or even an international system.

Organizations suitable to operate a consumer reporting system(s). Independence was a top consideration for participants in determining what type of organization(s) would be best suited to operate a consumer reporting system. In their view, organizations should not have any conflicts of interest raised by association with health care institutions, providers, or insurance companies. Although many participants favored private, independent, nonprofit organizations because of their independence, participants also recognized the value of a government agency's authority. Even among participants who opposed government operation of a consumer reporting system (e.g., because it would be too bureaucratic), participants often recognized that the government would need to be involved in some way for the system to be effective. It was critical in participants' views that the organization(s) have the authority to hold providers and health care institutions accountable for responding to reports or remedying the risks that led to patient safety events.

Operational approach. Participants thought that a consumer reporting system should have staff who could help individuals file a report, act as their advocates, and provide a "human touch." Assigning a staff member to follow through on a report would offer continuity to the reporter.

Infrastructure and design preferences. Participants offered opinions about various infrastructure and design elements. They thought the system should offer multiple reporting modalities, including face-to-face, Internet, phone, and mail, to accommodate the preferences of different consumers. Many participants also thought the system should allow for both structured and unstructured (e.g., narrative) reports or use some combination. One participant advised that the system be "evolvable" to keep pace with developing platforms for electronic communication.

Feedback to reporters was voiced as an essential element of an ideal consumer reporting system, beginning with acknowledgement of the report. Participants said that consumers should be informed about the results of any investigation, why the event happened, and what actions have been taken to prevent recurrence (e.g., policy and procedure changes). Without this feedback, consumers have no way of knowing that their report made a difference. Participants contrasted this ideal feedback loop to their experience with the Joint Commission, which provides no feedback beyond an acknowledgement. Participants' interest in identifying themselves was tied to their interest in feedback. As one stated, "*If I'm going to report, I am going to put my name on it. How else will I know if something was done?*"

Participants thought the consumer-reported data should be linked to other organizations and systems. They see the value of such linkages as facilitating change and improvement of patient safety; regulating and enforcing accountability, including tracing provider and organizational performance over time; and improving coordination of care across providers and facilities.

Purpose and goals for consumer reporting system. Participants offered that the primary purpose of a consumer-focused reporting system was to improve the quality of health care, particularly patient safety; patients and family members are highly motivated to share their experiences "*to make sure it never happens again.*" In participants' view, another primary goal is accountability for providers and health care institutions. Specifically, participants mentioned linking consumer reporting to accrediting and licensure. Also important to participants is that the systems provide information about providers and health care organizations (e.g., patient safety track records, "report cards") that the public can use to make informed choices about sources of care. Education of health care professionals and consumers was mentioned several times as a goal of consumer reporting systems.

Linking consumer reporting system to quality improvement. To link the consumer reporting system to quality improvement, participants advised that consumer-reported information should be publicly available to raise awareness of providers' performance and highlight improvements. In addition, they said the system should provide timely feedback to providers and provider organizations to facilitate corrective actions.

Maximizing reporting. The success of a consumer reporting system depends on consumers' awareness of and their willingness and motivation to use the system. Participants suggested launching a public information campaign for the community at large to raise awareness of the system and of patient safety more generally. They also favored disseminating information within health care settings (e.g., on hospital TV channels, through print materials, at intake). The message needs to be clear and convincing that consumer-reported information is used and makes a difference.

Limitations. Although we attempted to identify participants who had experienced patient safety events in three different settings of care (hospitals, ambulatory care settings, and long-term care facilities), the majority of the focus group participants (88 percent) had experiences in the hospital setting. A different mix of participants (e.g., higher proportion of those who had experienced patient safety events in ambulatory care settings or long-term care facilities) may have generated different ideas about ideal reporting systems.

The focus groups included participants who had experienced a range of patient safety events, from near misses to those that caused serious harm or death of a family member. This may have created a different dynamic than if the group composition had been more uniform with regard to the severity of the patient safety event.

II. Stakeholder Interviews

Methods and recruitment process. The project team conducted 25 telephone interviews with stakeholders during August through October 2009. We conducted the interviews using a

semistructured interview guide that focused on AHRQ's key research questions. These questions provided a consistent framework for gathering information from stakeholders and other groups across different aspects of the project. Stakeholders were chosen to represent a variety of groups, including consumer advocacy, public and private health care systems, risk management, and patient safety reporting, and others.

Findings Most of the stakeholders strongly supported the value of consumer reporting systems to aid in learning, contribute to improvements in health care quality and patient safety, and support consumer empowerment. They recognized that patients and family members offer a unique perspective and can provide valuable insights into patient safety events over the continuum of care, such as problems that occur during transitions of care or after discharge. The consumer perspective also offers insight into the consequences of the event for the individual harmed and family members, whether and how the event was disclosed, cultural and environmental issues in the health care setting that may set the stage for patient safety events, and many other factors that contribute to patient safety events.

Stakeholders discussed a wide range of issues related to the scope, design, infrastructure, operation, and purpose of ideal consumer reporting systems. Table 2 summarizes the primary themes and ideas that emerged across the interviews.

Accessibility of consumer reporting systems. Stakeholders stressed the importance of designing a reporting system that is accessible and easy to use for a wide range of consumers, including those with limited health literacy and for whom English is not their first language. Other access considerations included offering multiple modalities for reporting, ensuring availability in multiple settings of care, building on existing systems/platforms that are familiar to consumers, not limiting what can be reported, and providing a safe environment for reporting.

Table 2. Key features of ideal consumer reporting systems from stakeholder interviews

Scope and range—Accessibility
Allow reporting in real time and after the event, including after an extended period of time. Allow access to system at multiple points so that reporters can update their account of the event.
Facilitate access for diverse reporters (e.g., lower literacy, non-English speakers) and allow patient, family members, caregivers, and others who witness an event to report.
Scope and range—Anonymity and confidentiality
Mixed opinions about allowing anonymous reporting. Anonymity allows reporter to feel safer but precludes follow-up and investigation.
Acceptability of anonymous reporting is linked to goals of system; anonymous reporting acceptable if goal is to accumulate data for future action but not workable if goal is to take action.
System should protect the identity of users and assure them of confidentiality.
Scope and range—Voluntary vs. mandatory reporting
System should be voluntary

Table 2. Key features of ideal consumer reporting systems from stakeholder interviews (continued)

Levels of Operation
Most stakeholders favor a multilevel system in which reports "roll up" from the local level to State, regional, or national levels.
Opinions about levels of operation linked to goals of system. Local-level reporting important to provide immediate feedback to health care facility and institute rapid change. Higher-level reporting important for accountability and system-wide learning.
Consumer advocates favored a reporting system outside the health care institutions, where consumers feel safe.
Some stakeholders suggested the reporting system be implemented in stages or tested in pilot programs.

Organizations suitable to operate consumer reporting systems
Many stakeholders favored Federal government agencies and private/independent/nonprofit organizations. Advantages of government are neutrality and authority; disadvantages are potential to become politicized and government inefficiency.
Mixed views about hospitals and health care institutions; have experience collecting patient safety data and will be more readily accepted by providers; consumer advocates opposed because not a safe place for consumers to report, and institutions can skew data.
Little support for consumer advocacy organizations because would be challenging to get buy-in from health care professionals.
Primary factors to consider: independence/neutrality/transparency, consumer involvement, authority, and ability to investigate.

Operational approach
Staff needed to serve as patient advocates, aid in reporting, triage reports, and conduct investigations; skilled analytic staff also needed.
Divided opinions about whether system should be federally funded or funded by health care organizations.
Some stakeholders suggested implementing the reporting system in stages or testing it in pilot programs.

System Infrastructure and design
Offer multiple reporting modalities and allow both structured and unstructured reports.
Provide meaningful and timely feedback to reporters.

Purpose and goals
Primary goals are organizational-level and system-wide learning and improving quality of care/patient safety (closely linked); also support for consumer empowerment.
Less support for accountability as goal, which would duplicate existing organizations and mechanisms; also focus on punishment could undermine trust and partnership needed for effective system.

Table 2. Key features of ideal consumer reporting systems from stakeholder interviews (continued)

Linkages to quality improvement
Stakeholders generally supported linking to existing efforts to improve quality and patient safety. They did not suggest linking to programs that offer financial incentives for quality (pay-for-performance models) or providing feedback to health care facilities or providers.
Maximizing reporting
Communication efforts needed in health care institutions (e.g., at intake) and public information campaigns; also work through trusted community organizations and employers.
Communication about system should convey importance of consumer reporting to improve patient safety.

Timing of reporting. Stakeholders supported real-time reporting, with some discussing it in conjunction with rapid response teams, positing that real-time reporting would allow for real-time response, remediation, or investigation. They also supported reporting after the fact, including after extended periods of time. This approach would allow consumers time to come to terms with their experience emotionally, in addition to allowing time for the full consequences of an event to be experienced.

Anonymity and confidentiality. Most stakeholders favored allowing consumers to choose whether to reveal their identity or remain anonymous. The consumer advocates advised that most patients want to provide their name or identity, but some fear that their care may be compromised if providers learn that they have reported. However, a sizable minority of stakeholders (none of whom was a consumer advocate) thought anonymous reporting should not be permitted. Their concern was that anonymous reporting would not allow follow-up with the reporter to conduct a thorough investigation, make improvements, or reconcile the patient's perception with the provider's perception.

Who can report. Stakeholders generally offered the view that consumer reporting systems should receive reports from patients, family members, caregivers, and others who witness a patient safety event. However, a minority opinion was that only patients or their family members/caregivers should be allowed to report because others might not have sufficient information about the event.

Voluntary vs. mandatory reporting. There was consensus that consumer reporting systems should be voluntary.

Levels of operation. Stakeholders' views about the appropriate level or levels of operation were closely linked to views about the purpose and goals of a reporting system. Most stakeholders envisioned a multilevel system in which reports "roll up" from the local level (i.e., generally referring to the health care institution) to State, regional, and national levels. Many thought that local-level reporting would be appropriate if the goal was to feed back information to the health care institution and implement rapid changes. Stakeholders from provider organizations particularly favored this approach. Several of the consumer advocates expressed

the opposite viewpoint and felt strongly that consumer reporting systems should be outside the health care institution and implemented at higher levels (i.e., State, regional, national). Stakeholders thought that a State-level system would be appropriate if the goal was accountability. A national-level system was essential if the goal is system-wide learning. There was little discussion about the possibility of international-level consumer reporting systems.

Organizations suitable to operate consumer reporting systems. Federal government agencies and private, independent, nonprofit organizations were mentioned most frequently, followed by hospitals and other health care institutions. However, for each of these organization types, opinions were divided with some stakeholders also opposed.

The primary arguments for a Federal government agency were neutrality and authority. Stakeholders who opposed a Federal government role expressed concern that the system would become politicized. In addition, some viewed government agencies as inefficient and thought the consumer reporting agency should be operated by a "lean" organization.

Private, independent, nonprofit organizations were preferred by many of the stakeholders because of their neutrality. Specifically, stakeholders said the organization should be independent of government, health care systems, providers, malpractice insurers, and other interest groups.

A number of stakeholders thought hospitals and other health care institutions should be responsible for consumer reporting systems. This view was particularly marked among stakeholders from health care organizations. They thought that health care institutions were well positioned because they already have experience collecting patient safety data and are trusted by health care providers; in addition, the system would not be perceived as outside interference. Other stakeholders, particularly consumer advocates, opposed this approach because it does not provide a safe and neutral place for consumers to report.

There was limited support for consumer advocacy organizations, although a number of stakeholders said that consumers need to be at the table to design consumer reporting systems. Some stakeholders were concerned that a reporting system operated by a consumer advocacy organization would not be accepted or trusted by health care professionals.

A number of stakeholders named organizations they thought would *not* be suitable to operate consumer reporting systems, including the Joint Commission and patient safety organizations (PSOs). The primary objections to the Joint Commission were perceptions that it does not provide meaningful feedback to consumers and it does not "*do anything with this data.*" Objections to the PSOs related to the confidentiality provisions and lack of accessibility of the data. Some stakeholders also thought that the enforcement and licensing agencies would not be suitable because they receive a high volume of complaints and only follow-up on a small percentage.

Several stakeholders suggested building the reporting system on an established organization with a relevant mission and experience. Stakeholders named the following factors as important to consider in identifying organizations suitable to operate consumer reporting systems (in descending order of frequency of mention): independence, neutrality, transparency; consumer

involvement; authority, ability to investigate; efficiency; and health care professional involvement in designing the system.

Operational approach. Stakeholders said that system support staff would be needed to respond to consumer reports, assist individuals with reporting, serve as patient advocates and provide support, triage reports based on agreed-upon criteria, and conduct investigations. In addition, analytic staff would be needed for coding and data analysis.

Stakeholders' views about financing consumer reporting systems were divided; several stakeholders thought the system should be federally funded because patient safety is a national concern and responsibility; also, Federal funding would increase the perception of neutrality. Others thought health care organizations are obligated to fund the system.

Infrastructure and design. Most of the stakeholders thought that consumer reporting systems should offer multiple modalities for consumer reporting; they mentioned telephone most frequently, followed by Web-based (e.g., e-mail, Web portals), in person, and regular mail. Most stakeholders also thought it would be important to incorporate both structured and unstructured reporting formats. Narrative reports would provide rich information and would likely be preferred by consumers. However, analysis is time intensive, expensive, and challenging. For structured reporting formats, stakeholders suggested surveys (e.g., outreach surveys, Hospital Consumer Assessment of Healthcare Providers and Systems [HCAHPS]®), algorithm-based questionnaires, and other standardized data collection instruments. Structured formats were identified as a low-cost approach that could build on existing organizational mechanisms.

Almost all of the stakeholders thought that feedback to consumers was critical. Their suggestions about the nature and content of feedback included acknowledging the report and thanking consumers for reporting, providing information about what action has been/will be taken, informing the consumer about the impact of the report on identifying a problem and making improvements, providing a time frame for when the reporter will receive additional information, and sharing information about the number of similar reports received.

Goals and purpose. Stakeholders voiced strong support for learning about and improving health care quality and patient safety as closely linked goals. They viewed learning as a goal at both the organizational and system-wide levels. Several stakeholders also considered patient empowerment as a goal. However, there was little discussion of exactly how the system would empower consumers beyond giving them "a voice."

Fewer stakeholders expressed support for accountability as a goal. They argued that there was no reason to duplicate existing accountability organizations and mechanisms (e.g., Joint Commission, medical boards, legal system). In addition, stakeholders pointed out that the punishment of individuals would not result in systemic improvement. Several stakeholders believed that focusing on accountability would threaten the collaboration and trust needed for the reporting system to be effective. Ultimately, a focus on punishment would undermine the system because providers and health care institutions would discourage reporting.

The stakeholders who believed accountability was an important goal discussed it in terms of measurement, follow-up, and changed behavior rather than punishment. For example, one

stakeholder described consumer reporting as a "measurement tool" that could hold people accountable. Some stakeholders said that an ideal reporting system would not have regulatory authority itself but would have linkages to regulators (e.g., to licensing boards).

Linkages to quality improvement. Stakeholders generally supported the idea of linking consumer reporting systems to existing efforts to improve quality of care and patient safety, although they offered few specific suggestions about how such linkages could be accomplished. Stakeholders did not suggest linking to programs that offer financial incentives for quality (pay-for-performance models) or providing feedback to health care facilities or providers. Ideas about linking consumer reporting to other quality and patient safety improvements appeared to be shaped by the stakeholder's views about system goals and levels of reporting. According to one stakeholder, if consumer reporting systems operated locally (i.e., at the level of the health care facility) with a goal to improve quality of care, then linkages are not needed, and concerns about interoperability would be misplaced; this suggests that consumer reporting systems could function as an independent effort to improve quality and patient safety. However, if consumer reporting systems operate at a State or national level, some see linkage to the local level as essential.

The issue of public reporting drew both support and skepticism. Supporters invoked the goal of transparency and described public reporting as a tool for quality improvement. Skeptics were concerned about the quality of data and the lack of a robust denominator, making comparisons difficult.

Maximizing reporting. Almost all of the stakeholders agreed that communications and marketing efforts were needed to create awareness of consumer reporting systems and encourage reporting. They suggested communication strategies within health care institutions and public campaigns in the community at large. Specific suggestions for communications campaigns included orientation and literature given to patients when they first enter the hospital/health care facility and also at discharge, signage and materials (e.g., newsletter, brochures, waiting room videos) in health care facilities, information on hospital advertisements and Web sites, TV and radio advertising, use of social media (e.g., YouTube, Facebook, viral marketing), and working through trusted community organizations. Stakeholders advised that communication strategies need to focus on consumer empowerment and stress the critical importance of consumer reporting to improve patient safety. Several stakeholders suggested that consumer testimonials could be powerful.

Some stakeholders thought that to maximize reporting the system needed to be proactive and actively reach out to patients. A few stakeholders suggested post-discharge surveys or exit interviews to solicit information about patient safety events.

Limitations. Because constraints on the numbers of stakeholders we could interview, we were unable to include individuals from all sectors or perspectives relevant to consumer reporting of patient safety events (e.g., did not include individuals from pharmaceutical and medical device companies or from the malpractice field). The small numbers of stakeholders from different categories precluded analysis of findings by category. Furthermore, many of the stakeholders brought multiple perspectives to bear on the issues discussed and thus cannot be

placed in a single category. In some cases, where there appeared to be marked differences, we note these apparent trends, but they should be interpreted with caution.

III. Environmental Scan and Literature Review

Methods. To inform the development of recommendations of key design features of ideal consumer reporting systems for patient safety events, we identified a broad group of existing reporting systems and collected information on their characteristics. Three methods were used to collect information for this report:

1. An environmental scan that reviewed information available on the Internet describing patient safety event reporting systems.
2. A literature review that abstracted information mainly from articles published in peer-reviewed journals on reporting systems. To a lesser extent, reports and other literature that were not published in peer-reviewed journals were also included.
3. Nine key informant interviews with representatives from important patient safety event reporting systems.

The environmental scan and literature review largely focused on the characteristics and features of systems, providing information on the design and operations of these systems. The key informant interviews also provided some of this information, but generally went beyond this to include more qualitative and explanatory information. That is, although the environmental scan and literature review provided information on the "what" associated with systems, the interviews helped address the "how" and "why" for the systems.

From the environmental scan, literature review, and key informant interviews, we collected information on the relevant system characteristics and design features consistent with those identified by the TEP during the three rounds of Delphi questionnaires and the first TEP meeting:

- Scope and range of patient safety event reporting systems
  – Level of operations (local, regional, national, or international)
  – System ownership (public, private, or mixed)
  – Degree of focus on consumer reporting
- System goals, purpose, or mission
- System reporting characteristics
  – Voluntary versus mandatory reporting
  – Confidentiality/anonymous reporting and user feedback
  – Availability of staff to assist with reporting
- System Infrastructure
  – System staff
  – System funding
  – Links to other systems
- System Design
  – Methods of reporting permitted

- – Format of reports
- – Types of events that can be reported
- – Investigations of reported events
- – Analysis of reports
- Information Dissemination and Responses to Reports
  - – Dissemination of reported information
  - – Responses to reported information
- Strategies for Maximizing Reporting
  - – Publicity/outreach/marketing
  - – Direct involvement of those who report

We also collected general comments from the environmental scan, literature review, and key informant interviews related to desired or ideal characteristics and features of patient safety event reporting systems.

Findings. A total of 74 patient safety event reporting systems were identified. For an illustrative subset of 13 systems, we were able to gather detailed information from the environmental scan, literature review, or key informant interviews; these 13 systems are discussed in more detail in the report.

The identified systems range from local operations (i.e., at a single hospital) to national systems (in the United States and other countries) and one international system. Most systems currently operate at local/regional, State, or national levels. Few systems appear to operate at multiple levels, which suggest that targeting new consumer reporting systems to a single level may be advantageous.

There is a mix of government-run and private-sector reporting systems. However, even privately-run systems rely on government funding, at least for development and initial periods of operation. Based on the collected information, only a minority of systems (20.3 percent) permitted consumer/patient reporting. Most systems involved reporting by health care providers or systems.

The most common goal among the identified reporting systems is learning about patterns and causes of patient safety events. Other common goals include monitoring the types and occurrences of patient safety events (surveillance), improving patient health and safety, and improving the quality of medical care.

Most systems, particularly those attempting to elicit consumer input, generally allow for a mix of anonymous and confidential reporting. Most identified systems involve voluntary reporting. However, mandatory reporting is seen among a majority of State systems, where the system owners have regulatory authority over the potential reporters. Mandatory systems do not (in general) permit anonymous or confidential reporting, although voluntary systems almost always allow these reporting options. Few reporting systems have links to other systems or databases.

Little information was collected on system funding or on systems staff, including whether staff are available to assist with reporting. Key informant interviews indicated that staff based in

call centers will likely require health care backgrounds and/or special training in eliciting needed information to collect complete reports. In addition, systems will require staff skilled in designing and maintaining reporting systems (i.e., information technologies); entering and coding data; analyzing and investigating reports; disseminating information; and preparing recommendations and strategies to address patient safety events.

The identified systems include a range of reporting methods, with online submission being the most common. Although computer-based submission requires specific activities to ensure anonymity or confidentiality of the reporter, this method permits rapid evaluation and analysis of reports from multiple locations. A majority of systems accept reports using a combination of narrative and standardized forms. A small number of systems use more advanced methods for prompting users for needed information (such as the hierarchical classification system of AIMS) to obtain more complete reports.

Reporting systems generally permit (or encourage) reports on a diverse range of events. The type of event that can be reported is often unspecified or described only in general terms such as incidents or complaints. Only a minority of systems indicate that they investigate reported events. Details on the types of analyses of reported events are often unspecified, although a number of systems do perform root cause analysis.

Many systems do not specify how (or whether) reported information is disseminated. Full public dissemination of reported information appears to be uncommon. Beyond dissemination, a variety of activities are undertaken using information from reports, including establishment of priorities, development of guidelines or recommendations, and development of educational interventions. Few systems undertake activities to encourage or maximize event reporting, and almost no information was collected on subsequent direct involvement of individuals providing reports.

Overall, there is not a single set of characteristics or design features representative of the majority of patient safety event reporting systems. Rather, there is a broad range of characteristics and features that reflect the diversity of system goals. These goals likely determine many system features, such as levels of operation, reporting specifications, and dissemination activities. This suggests that it is important to define the goals, purpose, and mission for a consumer reporting system before attempting to specify detailed system characteristics.

Limitations. The environmental scan and literature review is not meant to be a complete listing of all characteristics and features of all existing patient safety event reporting systems. The summary report is also not meant to be a complete listing of all characteristics and features of the identified systems; that would not be possible without more detailed research and interviews with individuals at every system.

IV. Second Round of Consumer Focus Groups

Methods. We conducted four consumer focus groups in May 2010: two groups in Chicago and two in San Francisco. We recruited participants by working closely with consumer advocacy organizations in each location, as well as with CAPS community contacts. All participants had experienced a patient safety event (either personally or regarding a family member or someone for whom they care) in the past 10 years.

A total of 33 patients and family members participated in the focus groups. Most of the participants were female (79 percent), aged 50 or older (58 percent), White (57 percent), and had a college degree or higher (79 percent). Over half of the participants (55 percent) had experienced a patient safety event themselves and 70 percent had a family member who had experienced a patient safety event. Among the participants, about 91 percent reported that the event occurred in a hospital setting, 21 percent in an ambulatory care setting, and 18 percent in a long-term care setting.[1]

Recruitment focused on individuals who reported or tried to report the patient safety event. Across all four focus groups, 67 percent of participants reported the event and 12 percent tried to report the event.

Findings. The participants agreed with many of the draft recommendations proposed by the TEP. However, they had mixed reactions to some recommendations and in some cases agreed with elements of a recommendation but thought that clarifications, modifications, or additions were needed. Table 3 provides an overview of participants' responses to all of the draft recommendations.

Table 3. Overview of participant responses to draft recommendations for key design features of consumer reporting systems

Recommendation	Summary of Participants' Responses
Types of information/Sources of reports (Recommendations 1.1, 1.2)	• Support for recommendation
Purpose and goals of reporting system (Recommendation 2.1)	• Support for main recommendation • Strong support for accountability as a primary purpose of system; interpretation of "accountability" varied • Add patient empowerment as a purpose
Level of operation (Recommendation 2.2)	• Support for recommendation • Interpretation of "local level" varies

---

[1] Participants could report more than one person who experienced a patient safety event (i.e., self and family) and more than one setting. Consequently, percentages sum to more than 100 percent.

Table 3. Overview of participant responses to draft recommendations for key design features of consumer reporting systems (continued)

Recommendation	Summary of Participants' Responses
Access, reporting modalities, format, and accessibility (Recommendations 4.2, 4.3, 4.4, 6.2)	• Support for recommendations • Mixed opinions about reporting through a live system representative • Specify that system should be accessible to people with disabilities
Anonymity and confidentiality (Recommendation 4.5)	• Support for consumers having the option of confidential reporting • Concerns about anonymous reporting, although most support as an option for health care providers and other health care system employees • Support for legal protection for confidential information
Type of organization (Recommendation 4.1)	• Support for consumer involvement • System should not be exclusively consumer led; health care providers and other experts are necessary for governance and operation of the system • Should be linked with government in some way, but also expressed concerns about governmental ties
Feedback to consumers (Recommendation 6.3)	• Support for recommendation • Need to define "timely" and "meaningful" • Mixed opinions about system not being able to guarantee that the hospital or health care setting will give feedback to patient/family member • Need to make clear to consumers what system can and cannot do
Linkages (Recommendations 3.1, 5.1)	• Support for recommendations • Should be consumer's decision whether reported information is forwarded to health care facility
Analytic functionality (Recommendation 3.2)	• Mixed reactions to recommendation that system will analyze causes of patient safety events on a broad scale (versus individual cases) • Some concern that consumer's may be less motivated to report if they know their case might not be prioritized for analysis
Public reporting (Recommendation 5.2)	• Most support recommendation • Questions about whether public reporting will lead to improvements in health care and patient safety
Maximizing reporting (Recommendation 6.1)	• Support for recommendation • Dissemination efforts necessary in health care settings and community at large

Types of information and sources of reports. The participants agreed that all types of patient safety events, including no-harm and near-miss events, should be reportable. They also supported a system design that captures the subjective experience of the consumer (i.e., their story) as well as objective information about the event. They agreed that the system should be available to all potential reporters, including health care providers and bystanders.

Purpose and goals for consumer reporting system. Across all four focus groups, the participants supported the notion that the consumer reporting system should be a learning system, oriented to identifying and addressing problems in patient safety. The participants also voiced strong support for accountability as a system goal, although their interpretations of accountability varied. Some thought accountability meant making changes based on what was learned from consumer reports, through training, and by modifying policies or procedures. Others viewed accountability as a matter of "consequences" or "punishment," such as warning, reprimanding, or firing providers.

Level of operation. The participants generally agreed with the recommendation for a multilevel system and with the alternative model that includes analysis at the local level, although there was less extensive discussion about this alternative. They felt that personalized and timely feedback would be more readily achieved locally. However, they indicated that national-level reporting is essential to identify trends in patient safety events and to raise awareness of patient safety issues and the importance of reporting.

Access, reporting modalities, format, and accessibility. The participants agreed with the recommendations that the consumer reporting system allow for multiple reporting modalities as well as a mix of structured and unstructured reporting, and that it be designed to facilitate access for diverse populations. They felt that system success depends to a large extent on designing the system to be easy to use by a wide range of consumers.

Anonymity and confidentiality. The participants agreed that consumers should be able to submit confidential reports. There was some difference of opinion about allowing anonymous reporting because of concerns about the inability to follow-up about reports and about "*bogging down the system*" because consumers could potentially be less thoughtful and selective about reporting. Also, anonymity could open the system up to false reports (e.g., for vindictive purposes). Some participants supported anonymous reporting for health care providers.

Type of organization. The participants were supportive of the guiding principles and characteristics of an operating organization, as proposed by the TEP. They supported strong consumer involvement with respect to oversight, but also believed that health care professionals and other experts need to be involved to lend credibility to the system and provide the necessary expertise. Many participants thought the system should be connected with the government in some way; however, they were concerned with how ties to government could affect system independence, neutrality, and efficiency. Some participants also were concerned with potential tension between financing and independence.

Feedback to consumers. The participants agreed that the system should respond to consumers in a timely manner and provide meaningful feedback. They stressed that

acknowledgement of receipt of a report does not constitute meaningful feedback. The system should make it clear to consumers when they can expect different types of feedback. Some participants were disappointed that the recommendations did not guarantee a response from the health care setting where the patient safety event occurred; others thought this limitation was reasonable and to be expected.

Linkages. The participants agreed that the consumer reporting system should have linkages with a wide range of organizations that could help the system to improve health care and use the reported information. They were clear that a consumer must be able to choose whether his or her report is shared outside of the consumer reporting system, specifically back to the facility where the patient safety event took place.

Analytic functionality. There were mixed reactions to the analytic functionality recommendations set out by the TEP. Some participants cautioned that if consumers understand that causal analysis would be conducted at the aggregate level rather than at an individual level, they may perceive the system as less useful and be less willing to report. Others thought it was appropriate that the system be focused on improvements in the larger health care system, not individual cases.

Public reporting. Most participants strongly supported public reporting, believing that it would make the system more visible and foster legitimacy. They suggested that public reports could demonstrate how consumer reports lead to change and improvement in the health care system. However, one group of participants questioned whether the public reporting would truly be effective in improving health care outcomes.

Maximizing reporting. The participants agreed with the TEP recommendation to maximize reporting and suggested various methods for raising awareness and encouraging use of the system. Discussion about maximizing reporting focused on specific ways to disseminate information about the system within health care settings and in the community at large. Some participants suggested actively soliciting patient safety experiences, for example through hospital exit interviews or patient surveys.

Limitations. We recruited individuals who had experienced a patient safety event, either reported or attempted to report the event, and considered the topic of reporting patient safety events to be important. Because of these recruiting requirements, which we considered essential to receiving thoughtful feedback, the opinions of and feedback from the focus groups participants may not be representative of all patients and family members.

Although we sought to recruit a mix of participants in terms of race, ethnicity, and other sociodemographic characteristics, the participants were generally well educated (79 percent had earned a college degree or higher) and White (57 percent). Recruiters were able to increase the percentage of African American participants in the Round 2 focus groups compared with the Round 1 focus groups (34 percent and 21 percent, respectively), likely the result of working with an African American community contact. However, we were less successful in recruiting Hispanic participants, as several Hispanic participants initially agreed to participate, but changed their minds prior to the focus group. Consequently, it would be useful to obtain additional

feedback from groups that were underrepresented in these focus groups, particularly Hispanics and individuals with low education levels.

Given the time constraints for conducting the focus groups, it was challenging to fully explain and explore the details of each recommendation—some of which are quite complex— and to ensure a common understanding. It was particularly challenging for participants to fully grasp the elements of the recommendations related to accountability, public reporting, and levels of operations. Consequently, interpretations of these recommendations differed somewhat among participants.

Second, Third, and Fourth TEP Meetings

After receiving reports on the first TEP meeting, consumer focus groups, key stakeholder interviews, and the environmental scan and literature review (all of which are included in Appendices to this report), the TEP convened for a second meeting. At this meeting, the TEP further crystallized their recommendations with an eye toward feasibility and considering barriers to an ideal system.

A third TEP meeting was held to resolve unanswered questions from the previous two meetings. The third TEP meeting was held by Webinar on February 23, 2010. The goal of the meeting was to develop draft recommendations for consumer reporting systems for patient safety events, transitioning from initial discussions of TWIS to the complete specification of TWIS. This included finalizing consensus points, discussing unresolved issues from the second TEP meeting to develop consensus on key design features, and discussing new design features (not previously discussed) if necessary.

Following the third TEP meeting, a draft final report was prepared presenting a summary of the activities to-date in this project, the draft design feature recommendations, a series of graphics illustrating how these design features may be organized within a consumer reporting system, and a discussion of limitations and additional issues. The draft report was reviewed by a group of external peer-reviewers, whose names and affiliations are presented in Appendix B. A summary of the draft recommendations was also presented at a second set of consumer focus groups.

Comments from the consumer focus group participants, the external reviewers, and members of the TEP were presented at a fourth TEP meeting held in October 2010. The goals of this final TEP meeting were to discuss the feedback received on the draft final report and reach consensus regarding materials for the final report. The results of this fourth meeting are the recommendations found in this final report.

Chapter 4. Results and Key Findings

The objective of this study is to provide recommendations from the iterative, consensus development process on key design features for consumer reporting systems for patient safety events. The six research questions listed in the Background section of this report provided the framework for developing these recommendations.

Through the Delphi questionnaires and TEP meetings, with input from the focus groups, stakeholder interviews, and environmental scan/literature review, the TEP has developed recommendations for the key design features. The TEP and external reviewers emphasized that these recommendations are applicable to consumer reporting systems based not only in hospitals but also in a variety of other health care environments. Below, we present the consensus recommendations related to each of the six research questions from the third TEP meeting. Following this, the Analysis section then combines these recommendations to present potential holistic frameworks for the design of consumer reporting systems. Finally, the Discussion and Policy Implications section concludes this report by highlighting possible next steps in the development of consumer reporting systems, focusing on implementation issues that go beyond the scope of the current project.

1. What type 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?

- What happened?
- Was the problem reported? To whom?
- What happened when the problem was reported?
- What caused the patient safety event to happen?
- Where did the patient safety event happen?
- What impact did the patient safety event have?
- What were the consequences of the patient safety event?

Recommendation 1.1: Types of information. The systems should collect information on all types of events, ranging from near-miss and no-harm events to adverse events. The systems 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 an event was reported; what happened when an event was reported; and the impacts or consequences of the event.

Recommendation 1.2: Sources of reports. The systems should allow for reporting by any individual, but the emphasis is on obtaining the consumer perspective.

The TEP recommendations focused on collecting broad and diverse input from consumers for patient safety event reporting systems. However, the TEP expressed concerns about asking consumers what "caused" an event, and felt it was more appropriate to request information on what "contributed" to an event from the consumer's unique perspective. TEP members and an

external reviewer also cautioned that consumers are likely to identify and report incidents that don't represent patient safety events or errors. The TEP emphasized that consumer reporting systems will not provide an immediate or urgent intervention/response. Systems will, if possible, provide general guidance on the types of individual or resource to contact when an urgent intervention is desired.

2. What are the scope and range of options for consumer reporting mechanisms? How would these options differ at the international, national, regional, State, or 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 is actively used to design meaningful improvements in patient safety.

After extensive discussions, the TEP recommended that consumer reporting systems have two purposes. The first is focused on learning by obtaining the consumer perspective, improving outcomes, and advancing patient safety. The second purpose focuses on accountability, which is specifically defined as consumer reporting systems being accountable to those who submit reports. In this context, systems have a responsibility to actively use reported information in the pursuit of meaningful improvements to patient safety. These two purposes are linked, as use of reported information to design meaningful changes in patient safety is predicated by learning from these reports. In general, it will be an aggregate of reports (rather than a single, individual report) that leads to learning and resultant activities to pursue improvements in safety; as such, systems need to consider accountability to all those who have submitted reports.

The TEP acknowledged that others, particularly in consumer groups, advocate a definition of accountability for consumer reporting systems that involves "consequences" for providers and medical entities responsible for a patient safety event. However, a majority agreed that accountability related to this recommendation most appropriately refers to the system being accountable to consumers, <u>not</u> systems holding others (e.g., health care providers or medical care entities) accountable. TEP members cautioned that a more punitive definition of accountability could triggers concern and hesitation with many potential stakeholders and could widen gaps between providers and patients, resulting in systems being less effective. An external reviewer provided similar comments, emphasizing that without buy-in from health professionals and hospitals, a consumer reporting system could increase division between providers and consumers. The report by the Institute of Medicine, *Patient Safety: Achieving a New Standard for Care*, discussed a continuum of applications, ranging from accountability (which is generally the focus of public-sector legal and regulatory bodies) to learning (both for professionals and for organizations). The two related purposes recommend by the TEP may reflect this continuum of potential purposes and goals for consumer reporting systems.

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. Reporting systems will need to be

flexible regarding analysis and other activities occurring at local levels, based on needs, capabilities, and funding/resources for these local activities.

The TEP separated data collection/reporting capabilities at the local level from data aggregation, analysis, and distribution activities at a centralized (potentially national) level. TEP members indicated that certain reporting system functions need to occur at a national (or central) level, such as aggregation of data from multiple sources. However, the TEP was reluctant to specify reporting system functions and activities that should or should not occur at local levels; they emphasized that there needs to be flexibility regarding local level activities based on the need, capabilities, and funding available for these activities. Members discussed the substantial resources needed for system development and stressed the importance of system pilot testing at different levels and in multiple localities. Decisions regarding potential system activities at local levels can be informed by pilot testing during system implementation. Similarly, the TEP indicated that potential differences in their recommendations at the international, national, regional, State, or local levels would need to be assessed during implementation. The TEP did discuss potential advantages of State-based reporting systems, which include the ability to assess care at multiple sites (that is, not only hospitals). The Pennsylvania system was used an example of a State-based system. While issues and examples from State-based reporting systems were provided by certain TEP members during meeting discussions, the TEP did not provide any design feature recommendations specific to State-based systems.

The TEP did not address issues related to interoperability among consumer reporting systems that operate at different levels. However, in an issue related to interoperability, the TEP chose not to specify how linkages between organizations would function in Recommendation 3.1 (below).

3. What type of infrastructure is needed to enable effective, actionable consumer reporting of patient safety events?

Recommendation 3.1: Linkages. Systems 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 for the purpose of encouraging consumer reporting, improving analysis, sharing results, and changing delivery for quality improvement. Linkages will also ensure timely information sharing. Because linkages are dynamic and rapidly changing, their exact nature and specifications will be more fully specified at implementation.

Although the TEP recommendations focused on the importance of linkages for consumer reporting systems, the TEP also recognized that system linkages represent a dynamic, rapidly changing area. As such, the TEP chose not to specify how such linkages would work operationally. The exact nature and specifications of linkages can be specified more fully at system implementation. Regardless of the exact nature of linkages, the TEP also emphasized the importance of considering the purpose of linkages, and evaluating whether current linkages achieve these purposes in a timely manner. The "broad range of organizations" specified in Recommendation 3.1 should include all stakeholders who are part of the current construct of how health care services are delivered or financed. Many types of organizations are involved (directly or indirectly) in health care and can play important roles in improving patient safety,

either by changing provider practices and/or by changing their own practices. Such organizations should include State and Federal regulatory and financing organizations (e.g., the Food and Drug Administration [FDA], the Centers for Medicare & Medicaid Services [CMS]); health care facilities and systems; accrediting bodies; PSOs; insurers; employer health care groups; user groups or communities of interests, where individuals who experienced patient safety events can share their stories; and organizations that can provide assistance to consumers submitting reports beyond that available directly from consumer reporting systems. TEP members also indicated that consumer reporting systems should share information with other patient safety event reporting systems, such as FDA's MedWatch system, but did not provide details as to how interactions with other reporting systems would occur. Sharing of information with other organizations would be subject to confidentiality constraints specified by the reporter and stated by the consumer reporting system.

Recommendation 3.2: Analytic functionality. Systems will need decision rules for what kinds of events receive different levels or types of analysis. Systems should collect information and conduct aggregate causal analyses. Systems should also gather responses of organizations to reports and evaluate their feedback.

In discussions related to recommendation 3.2, the TEP identified three system models regarding analytic functionality. In one model, systems do not expend resources to conduct RCAs, but request RCAs when performed by other organizations and analyze collected RCA information. A barrier to this approach may be confidentiality rules prohibiting sharing of RCAs, particularly those conducted by PSOs. In an alternative model, systems are able to perform RCAs on selected events. In this model, public decision rules are used to determine which events warrant an RCA and the performance of RCAs are subject to financial constraint. When RCAs are conducted, patients will be consulted during the RCA process. For this alternative model, TEP members commented that there could be barriers to accessing needed information (from health care organizations in particular) to perform RCAs, in addition to associated costs and the need for trained personnel. The TEP did discuss that many hospitals do not have personnel trained to perform RCAs correctly. This is even a greater difficulty in nonhospital environments, and thus may limit the availability of high-quality RCA from multiple health care settings. A third alternative model discussed by the TEP was collection of data using a standardized form for focused initiatives. This would involve development of a data collection instrument to gather information on a particular type of patient safety event. The instrument would be submitted to relevant health care facilities (presumably facilities where events of the specified type occurred based on reports to the system) and used to collect information related to the event. Information from the standardized form would be aggregated and analyzed by consumer reporting systems and disseminated as part of feedback and reports. This model was described as a means for consumer reporting systems to actively gather information related to patient safety events but involving less cost than performing RCAs.

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

- *In what kind of organization (e.g., public–private partnership, public, private) should a consumer reporting system be housed?*
- *How should a consumer reporting system for patient safety events be financed?*

Recommendation 4.1: Type of organization. The following are guiding principles and characteristics that should be sought for organizations that own or operative consumer reporting systems:

- Independent entity with a steady stream of sustainable funding, where "independent" is defined as an entity that is 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' fiduciary responsibility is to represent the public.
- Neutral oversight body with consumer representation.
- Transparency of goals, process, and results.
- Consumer involvement in organizational governance and operations.
- Dedication to analyzing incoming information to identify threats to patient safety and feeding it back to systems that may be able to act on it.

The TEP explicitly chose not to specify the types of organizations to operate consumer reporting systems, electing instead to recommend characteristics of such organizations. However, the TEP indicated that multiple stakeholders should be involved in the operation of consumer reporting systems. Consumer focus group participants also supported the involvement of multiple stakeholders, indicating that systems should not be operated exclusively by consumers. In discussing the potential types of organizations or business models that could operate consumer reporting systems, the TEP agreed that these could be either public or private organizations. Four potential business models were discussed: commission model, PSO model, quality improvement organization (QIO) model, or a subscription/co-op/consumer-driven model (similar to Consumers Union, where members pay dues to support the organization). The TEP did not reach consensus on the type or types of business models appropriate for operating consumer reporting systems, nor did the TEP indicate that these four were the only possible business models for operating such systems. The TEP also indicated that ownership of consumer reporting systems should be credible to multiple stakeholders. Some TEP members indicated that consumer reporting systems should not be owned or operated by accreditation or regulatory agency such as the Joint Commission, CMS, or State Departments of Health; however, there was not universal agreement on this comment. TEP members also discussed whether independent coalitions or partnerships between organizations operating at different levels (e.g., between regional and national organizations) could operate consumer reporting systems. The TEP did not reach consensus on this point.

TEP members discussed in detail whether Patient Safety Organizations (PSOs) may be relevant models for consumer reporting systems. Members identified characteristics of PSOs that are consistent with the recommended design features for consumer reporting systems, including having a goal of learning; being devoted to analyzing reported information to identify threats to patient safety and feed information back to systems that may be able to act on it; and having statutory confidentiality protections. However, the confidentiality rules for PSOs vary among

States, which was viewed as a negative characteristic by the TEP; that is, for consumer reporting systems, confidentiality protections should be consistent across all regions in which a system operates. Other features of PSOs were also felt not to be a good "fit" for consumer reporting systems. The TEP concluded that PSOs are not the right model for consumer reporting systems, but that there are many areas in which consumer reporting systems can learn from PSOs.

Financing of consumer reporting systems

The TEP chose not to develop specific recommendations regarding financing of consumer reporting systems. However, this issue was discussed by TEP members. Key points in this discussion included:

- There is a need to align the scope and activities of a consumer reporting system with the available funding. Systems should not "overpromise" on what they can deliver, and should make their expectations consistent with their available funding.
- Consumer reporting systems may be viewed as a "public good". Thus, there may be a role for granting and nonprofit organizations in funding such systems.
- Multiple stakeholders may benefit from consumer reporting systems; it would be desirable to have a funding model that included all entities that benefit.
- The source of financing could influence consumer perceptions regarding the reporting system. The Joint Commission was cited as an example of possible difficulties with consumer perception because it is funded by facilities that it accredits and surveys. However, funding of the Pennsylvania State-reporting system was described positively in that it is based on a fixed State government budget item (funded by hospitals) and not subject to annual appropriations. TEP members also discussed the funding model used by ECRI, which is funded through subscription services; findings from research conducted by ECRI are distributed to paying subscribers.

Other design features of consumer reporting systems

Recommendation 4.2: Access at different points in time. Systems should allow reporting at any point in time.

Recommendation 4.3: Reporting modalities. To maximize reporting, systems should allow multiple routes or modalities for reporting.

Recommendation 4.4: Reporting format. Systems should allow a mix of structured and unstructured reporting.

The TEP recommended that consumer reporting systems be broad with respect to access to the system at different points in time and reporting modalities. TEP members indicated that both structured and unstructured (narrative) responses in reports are useful for conveying a consumer's unique perspective, and each type of information has different uses in analysis. The TEP therefore recommended that systems collect both types of responses.

Recommendation 4.5: Anonymity. The system will allow anonymous reporting, but the system should be designed to discourage anonymous reporting by ensuring and encouraging

well-designed confidential reporting. The system could allow reporters to opt out of confidentiality to increase the report's efficacy in certain situations.

The TEP endorsed confidential (as opposed to anonymous) reporting, to allow systems to provide feedback to consumers and the opportunity to collect additional information from individuals who submitted reports. However, the TEP recognized that some reporters will prefer to report anonymously, and therefore recommended that anonymous reporting be allowed, although confidential reporting was to be encouraged. The characteristics of system confidentiality (called "well-designed confidentiality" by one TEP member) specified in the TEP recommendation were not fully specified; some members described it as being similar to confidentiality used for the aviation industry reporting system, where links to a reporter's identity are discarded after a period of time. TEP members did express concerns that, in some cases, providing information about a patient safety event could lead to the identification of a reporter. There was also concern regarding the ability of consumer reporting systems to keep information confidential when involved in legal proceedings (e.g., if served with a subpoena). An alternative model suggested by several TEP members was for consumer reporting systems to pursue legislative protection from releasing any confidential information, thereby assuring people that their information will not be used against them.

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. Systems should be linked to efforts to improve quality and patient safety. If the reporter allows, his or her reports to the consumer reporting system will be automatically forwarded to appropriate existing reporting systems at the local or facility level.

The TEP emphasized that new consumer reporting systems should not replace other system, but should link to existing QI, RCA, or reporting systems. System should encourage patients to register their report directly to existing systems at the facility where an event took place; one TEP member commented that a well-intentioned facility will be able to do more to correct errors than a national system, although there was not universal agreement on this statement. Systems could give reporters the option of having their report automatically forwarded (presumably by the hub or central operations facility of a consumer reporting system, although this was not explicitly stated) to the appropriate local facility, system, or organization related to the reported events and to appropriate State or national systems. To this end, one TEP member commented that consumer reporting systems should understand the type and format of reports or other information that can best be understood and acted on at health care facilities. This would allow information shared by consumer reporting systems to "interdigitate" with materials from health care facilities (that is, provide information that is understandable by personnel in health care facilities and supplements their own information, leading to greater opportunities to address patient safety issues). Consumer reporting systems will need to ensure that their reports can be used by "downstream" users (e.g., health care facilities and systems) so they can address problems. Further specification of this design feature may have to wait until implementation because the technology required for such interoperability is likely to change rapidly.

Recommendation 5.2: Public reporting. Public reporting should be used to hold systems accountable to their own goals. Specifically, systems should:

- Publish information, such as how much a system was used
- Publish information on what was learned
- Publish information about what recommendations and changes were made as a result of the system
- To the extent determinable, publish information about the responsiveness of institutions to patient safety issues.

However, because this is an evolving and dynamic issue, the exact specifications will be developed at implementation and will be determined over time as the issue develops.

TEP members broadly agreed that public reporting (that is, allowing public access to nonconfidential information from patient safety events reports) was a key approach to linking consumer reporting of patient safety events to patient safety improvements. TEP members discussed that public reporting will inform consumers about rates of patient safety events, although this is subject to multiple caveats including incomplete or unknown denominators, small sample sizes, and rare events. Furthermore, public reporting will allow consumers to assess the responsiveness of consumer reporting systems. However, the TEP also recognized that public reporting is a dynamic area that will become more important and more accepted over time. One TEP member emphasized the lack of data linking public reporting to actual improvements. As such, although the TEP endorsed public reporting as an important system activity for the purposes listed above and stated that systems should have the capability to engage in public reporting, the TEP did not include specific types of public reporting in the consensus recommendation (5.2). Rather, the TEP explicitly recommended that specifics regarding public reporting be developed as part of pilot testing and at system implementation. TEP members discussed several types of public reporting, but did not include these as part of the recommendation. However, the TEP did agree that more often an aggregate of reports (rather than a single, individual report) leads to learning and resultant improvements in safety (as discussed under Recommendation 2.1). Therefore, information coming from reporting systems about what it has accomplished would be targeted to all those who have submitted reports, rather than to each individual who submitted a specific report. The TEP also indicated that they did not specify all circumstances, caveats, and limitations for when public reporting should or should not occur.

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

Recommendation 6.1: Maximizing reporting. System design should facilitate reporting to ensure maximum use, that is, maximize the ease/ability of consumers to submit reports. 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. Systems should be designed to facilitate access for diverse populations (e.g., age, race/ethnicity, education, non-English speakers).

TEP recommendations in response to this AHRQ research question focused on systems being highly inclusive and responsive. TEP members recognized that, beyond development of consumer reporting systems, additional activities will be required to inform the public about such system and encourage patient safety event reporting. TEP members also recommended that systems be aware of the diversity of consumers who experience patient safety events and include features to facilitate access for diverse and underserved populations. However, the TEP did not recommend specific design features to facilitate access; these are likely to evolve over time as technology evolves.

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

TEP members emphasized that a main feature (perhaps the main feature) with respect to maximizing consumer reporting is meaningful and timely feedback. This will include acknowledgements when reports are initially submitted and additional updates as more information is obtained or actions are taken. Systems will also need to interact with consumers to assess their own performance. The TEP acknowledged that meaningful consumer feedback is an area that will need to be explored as part of pilot testing and as a system develops; that is, we will not know what feedback is meaningful to consumers until the system starts. The type and extent of feedback provided will also need to be tailored to the available funding. Further, TEP members recognized that although systems should provide feedback on their own activities, they may not be able to provide feedback on what other entities (e.g., health care facilities) do with shared information. As part of this recommendation, the TEP also specified that public reporting should be included as part of feedback, although public reporting is addressed separately in Recommendation 5.2.

Chapter 5. Analysis—Potential Consumer Reporting System Design

In broad overview, consumer reporting systems for patient safety events involve several design components (Exhibit 1). First, an interface is available to facilitate submission of reports when consumers experience or notice actual or potential patient safety events. The system will provide multiple options for report submissions, including submitting directly to a national "hub" (that is, a single physical or virtual location where activities of a consumer reporting system are centralized) and potentially reporting locally through face-to-face interactions with system representatives.

Exhibit 1. Consumer reporting system summary design features

.
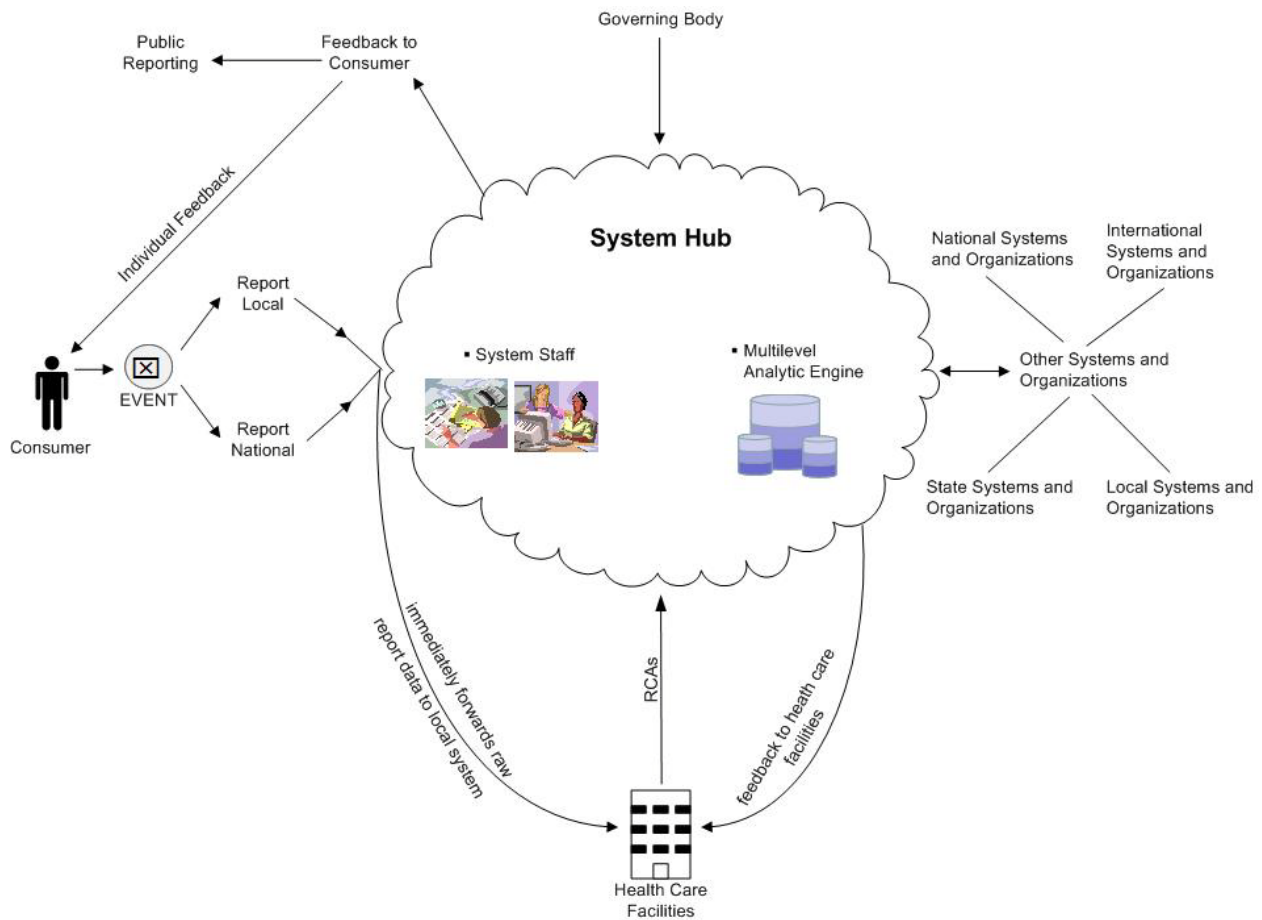
After submission, reported information is transmitted to the system's central hub. The central hub has two purposes. First, system staff determines how to categorize, triage, and respond to an individual report. Second, the hub acts as a multilevel analytic engine—it collects report information, performs aggregate causal analysis, and identifies problems at involved health care

facilities/systems. In one model, the system hub will collect information from the health care facility where an event took place, including RCA data, but will not perform its own RCAs. RCA data from health care facilities will be combined with other report information (both information submitted in a report and that subsequently collected following a report submission) for use in subsequent analyses. As discussed by one TEP member, additional legislation/regulations may be required to facilitate sharing of information by health care facilities. The RCA data may also be part of public reporting (providing broad public access to nonconfidential information from reports and other data sources) by systems. A caveat discussed by the TEP is the limited number of individuals trained to correctly perform RCAs, which may affect the usefulness of available RCAs. In an alternative model, systems will have the capability to perform RCAs on selected events. In this model, public decision rules are used to determine which events warrant an RCA and the performance of RCAs are subject to financial constraint. When RCAs are conducted, patients will be consulted during the analysis process. In this alternative model, there could be barriers to accessing needed information (from health care organizations in particular) to perform RCAs, in addition to associated costs and the need for trained personnel (see Exhibit 5. for more detail).

The TEP recommended that reporting systems for patient safety events have a governing body to ensure that actions and results align with goals. In this context, a governing body is a group of individuals who oversee operations of a consumer reporting system and are responsible for strategic decision making. The governing body must be neutral and independent of the health care delivery system.

The system central hub will have direct links to three types of external entities. First, after receiving and processing consumer report information, the system will provide timely and meaningful feedback to consumers. This will include notices of receipt of reports (i.e., personalized acknowledgements when reports are first transmitted to the system) as well as later communications from the system when analyses are performed, additional information is received, or actions are taken related to reports. Systems will also engage in public reporting (as defined above) to demonstrate the system's functions and operations, increase transparency, and improve the quality and safety of health care delivery. The exact nature of public reporting and extent of such activities is not specified in the system design features, and will be determined during pilot testing and at system implementation. Reporting systems may also operate campaigns to increase awareness of the systems and their goals among the general public.

Second, the system hub will interact with the health care facility where an event took place. If the consumer is willing, the hub will immediately forward all information about a specific event to the facility in question. This will provide the facility with the opportunity to respond to its consumers and engage in meaningful quality improvement. The system will also provide feedback to the facility regarding system findings. This feedback will be screened to protect the identity of the reporting consumer.

Third, reporting systems will link to other external systems and organizations when those linkages could encourage reporting, improve analysis, positively change care delivery, and improve care quality. Links can include State, national, or international organizations. Links can

also include local organizations as part of the local effector arm, a reporting system capability that permits direct interactions with health care providers or facilities. Reporting systems would need to demonstrate that these linkages add value to the systems and increase the effectiveness of actions to improve patient safety.

Exhibit 2. Components of consumer reporting systems

Components of Consumer Reporting Systems
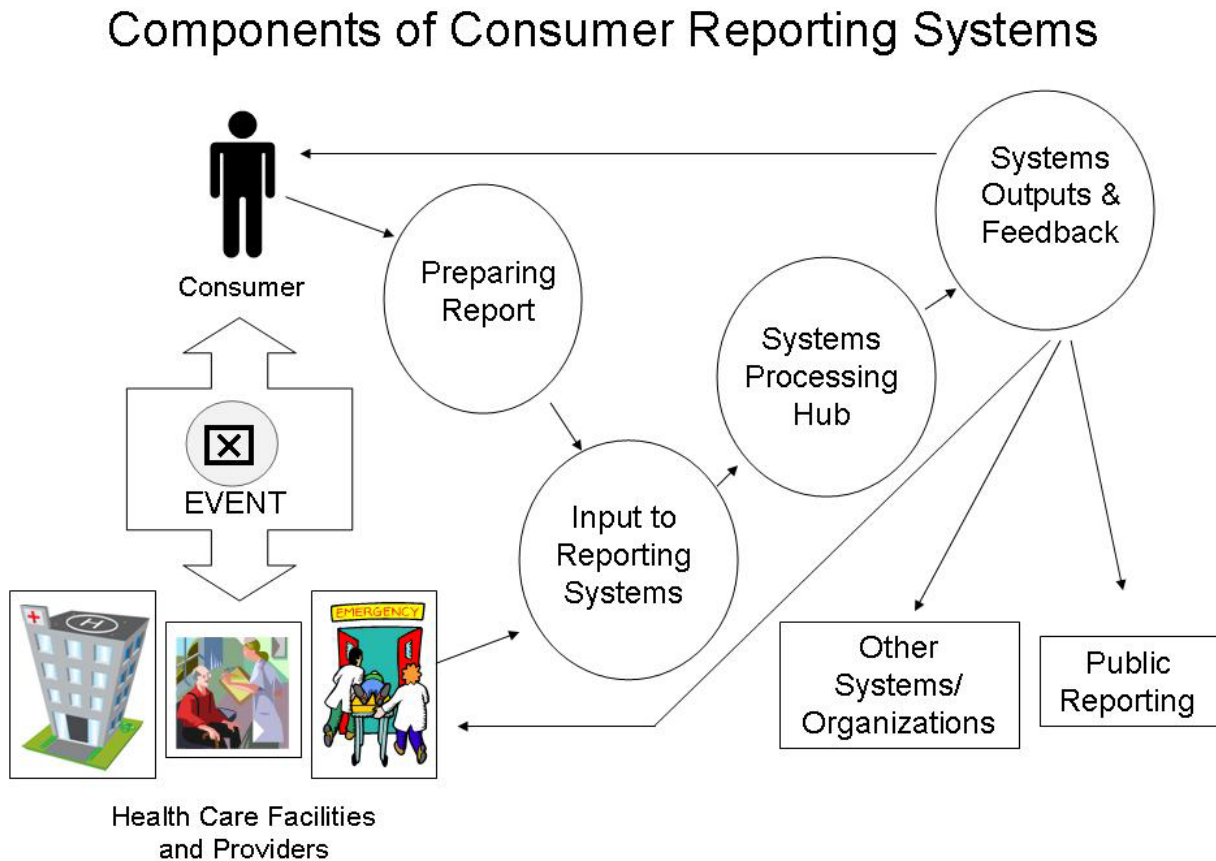
The consumer reporting system recommended by the TEP can be broken into four main components (Exhibit 2). To establish an effective system with high user satisfaction, each of these stages must function properly.

The first stage is initiated when a health care consumer who has experienced a patient safety event (which occurs as a result of an interaction between the consumer and a health care facility or provider) seeks a place to report. Once a consumer has committed to making a report, the system will assist him or her in providing all necessary information. Report preparation will also involve multiple design features that improve accessibility and consumer trust (e.g., allowing consumers to decide between confidential or anonymous reports and with whom a report can be shared).

Inputting the report to the system is the second component. After consumers select from an array of transmission modes for inputting the report, information from the report is standardized

and categorized for subsequent analyses. Information related to the event may also be provided by health care providers or facilities after the report is processed (e.g., RCAs performed at a health care facility).

In the third component, the system's central hub will aggregate and analyze reported information. Reports will be reviewed by well-qualified staff who understand patient safety issues and are trained to extract and triage information effectively. The system will analyze trends and conduct aggregate causal analysis, but may also evaluate selected individual incidents.

After data have been processed, the system must communicate results to a variety of stakeholders, at the local level (including reporters and health care facilities) and possibly at the State level (e.g., licensing and accreditation bodies) and national level (e.g., regulatory and financing agencies). Communications may also take place at the international level (e.g., with other reporting systems), to further a system's goal of learning. These communications are the final, and most visible, components in a consumer reporting system. First and foremost, the system will provide the consumer with timely acknowledgement of receipt of the report and meaningful subsequent updates regarding actions taken. The system will also provide feedback to health care facilities and providers with the goals of fostering health care system delivery change and quality and safety improvement. To this end, information provided by consumer reporting systems should "interdigitate" with systems at health care facilities; that is, consumer reporting systems should understand the type and format of reports or other information that can best be understood and acted on at health care facilities, and provide feedback in this manner. All information released to the care facility will be de-identified (unless the consumer explicitly indicates otherwise), and every precaution will be taken to protect the identity of the reporter.

The system may also share information with entities (including organizations, government agencies, for-profit and nonprofit enterprises, or individuals) not involved in the event. Depending on the nature of the report and whether the reporter permits, systems and organizations outside of the consumer reporting system (for example, other existing reporting systems, State regulatory agencies, or the FDA) may be consulted and provided with report data. This may require decisions regarding de-identification of providers or facilities in reports, beyond de-identification of the reporter.

Finally, aggregate system information will be released publicly. Public reporting (providing broad public access to nonconfidential information from reports and other data sources) will serve two main types of functions. First, it will hold the system accountable to its own goals. This will include providing information on how often the system was used, what the system learned from reports, and what recommendations or changes were made as a result of the system. Second, to the extent determinable, it will provide information on the responses of health care institutions to patient safety issues highlighted in reports. As public reporting is an evolving and dynamic issue, the exact specifications for this reporting will be developed during pilot testing and at implementation, and will be reassessed over time. Important considerations in the development of any public reporting program will include decisions regarding reporting of individuals incidents versus aggregate information; identification of health care facilities and/or providers; ensuring confidentiality for individuals who submitted reports; and legal protections

for system information that could be subject to subpoenas or discovery during legal proceedings. Considerable attention is needed regarding the circumstances, caveats, and limitations for when public reporting should or should not occur.

Exhibit 3. Reporting of patient safety events

Reporting of Patient Safety Events
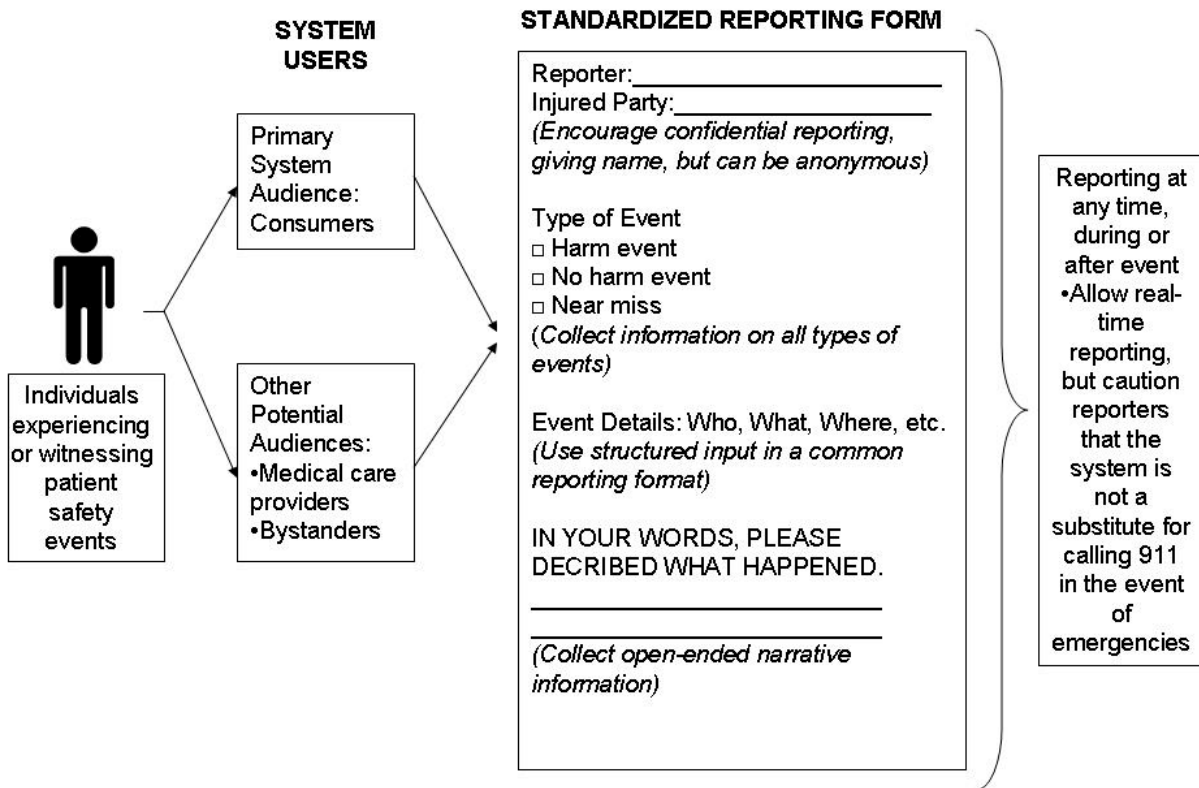
The reporting system will collect reports from several categories of individuals who experienced or witnessed patient safety events (Exhibit 3). The primary users of the system will be consumers—the patients receiving care and their friends and family. The system will also accept reports from medical care providers (although there was not universal agreement among TEP members on this) and from bystanders (individuals who witnessed an event, but were not directly involved with the individual receiving care).

Reporters will be asked to complete a standardized reporting form. As described in the report *To Err is Human, Building a Safer Health System* (IOM, 1999), a standardized reporting form can permit data to be combined and tracked over time; lessen the burden on health care organizations that operate in multiple states or are subject to regulation by multiple organizations; and facilitate communications about patient safety. As discussed in the report *Patient Safety: Achieving a New Standard for Care* (IOM, 2004), domain areas for a common patient safety reporting format include information on:

- The discovery: who discovered/reported the event (roles, not names) and how it was discovered
- The event itself: the type of event; where (in the process of care) and when it occurred; who was involved (functions, not names); why it occurred (most dominant cause); and risk assessment (including event severity, preventability, and likelihood of recurrence)
- Narrative of event, including contributory factors
- Ancillary information, including medical product information and patient demographic and clinical information
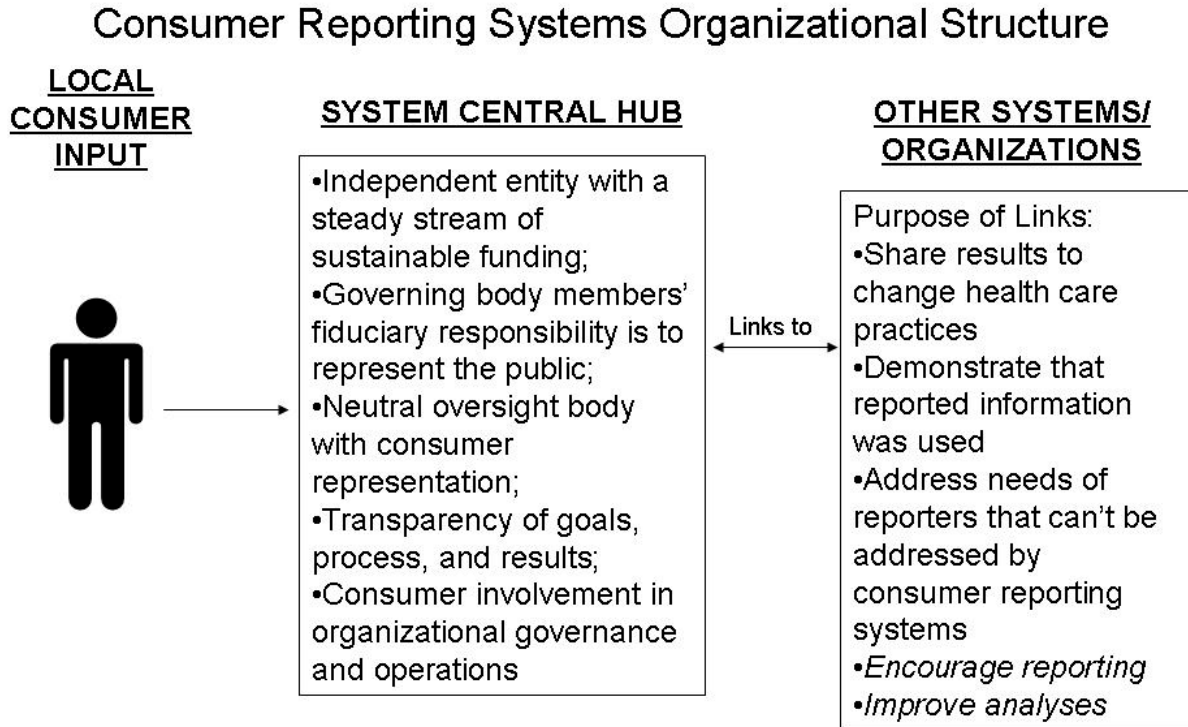
The form will guarantee user confidentiality but will also offer users the option of reporting anonymously. The form will discourage users from reporting anonymously by noting the limitations of this type of reporting (e.g., being able to contact the individual making the report subsequently to gather additional information or provide feedback). The form will assure users that confidential information protection is a top priority for the system.

The standardized reporting form will allow both structured and unstructured reporting. Structured reporting—possibly in the form of multiple choice questions—ensures that the system will capture standardized information necessary to analyze and classify reports. These prompts will be designed to capture the type of event (e.g., harm event, no harm event, close call/near miss), the location of the event, the people involved, and basic information regarding what happened. This information will allow the system to route the report appropriately and make quick initial judgments as to how the report will be used. Standardized questions will also be helpful in collecting system-level aggregate information. The reporting form may use an existing taxonomy such as the WHO-ICPS structure to facilitate standardization and aggregation.

Reporters will also be given the opportunity to provide a narrative account of the patient safety event that they experienced or witnessed. This unstructured report allows the reporter to identify the most salient issues from his or her perspective and ensures that valuable information is not lost when it does not fit into a standardized format. By eliciting specific information with standardized questions and allowing unstructured narratives, the standardized reporting form is balanced and calibrated to provide the system with rich and usable information. Pilot testing will likely be important for finalizing the reporting form.

Individuals will be able to submit reports at any time during or after the event. The systems could flag reports that occur significantly after the event, which may be used differently from more concurrent information. Systems will also caution reporters that this is not a substitute for calling 911, and other approaches should be used for emergencies requiring rapid responses. Systems may provide general guidance regarding the types of individuals or resources to be contacted if an immediate or urgent response is desired. Users will also be able to update their reports over time, providing additional information as they learn more or have continued experiences related to their patient safety event.

Exhibit 4. Consumer reporting systems—Organizational structure and characteristics

Consumer Reporting Systems Organizational Structure

LOCAL CONSUMER INPUT	SYSTEM CENTRAL HUB	OTHER SYSTEMS/ ORGANIZATIONS
	•Independent entity with a steady stream of sustainable funding; •Governing body members' fiduciary responsibility is to represent the public; •Neutral oversight body with consumer representation; •Transparency of goals, process, and results; •Consumer involvement in organizational governance and operations	Purpose of Links: •Share results to change health care practices •Demonstrate that reported information was used •Address needs of reporters that can't be addressed by consumer reporting systems •*Encourage reporting* •*Improve analyses*

Links to

After consumer reports are submitted, they are transmitted to the reporting system's central hub (Exhibit 4). To ensure effective use of reported information at the central hub, the TEP identified several structural and organizational characteristics of consumer reporting systems as important. These characteristics emphasize the central role of consumers as the focus of the system.

TEP members discussed two main themes regarding the system's organizational characteristics. First, the structure and governance of the system's central hub will ensure that the system is answerable to consumers. In support of this consumer focus, the system will be independent with a steady stream of sustainable funding. Second, the system will be structured and organized to inspire consumer trust and demonstrate credibility. To this end, the system will be governed by a neutral oversight body that strives for transparency of goals, processes and results, and obtains consumer involvement in organizational governance and operations. In keeping with the purposes of the system (Recommendation 2.1), the oversight body will assist the system to be accountable to those who submit reports.

The reporting system will also link to other systems or organizations that have capabilities outside of the scope of a patient safety event reporting system and that add value to the system. Attempts should be made to link to organizations that can use system results to change health care practices, demonstrate that reported information was used, encourage reporting, improve

analyses, and address those needs of reporters that cannot be addressed internally. These other organizations may function at local, regional, State, national, or international levels.

Exhibit 5. Consumer reporting systems inputs and analytic capabilities1

Consumer Reporting Systems Analytic Capabilities
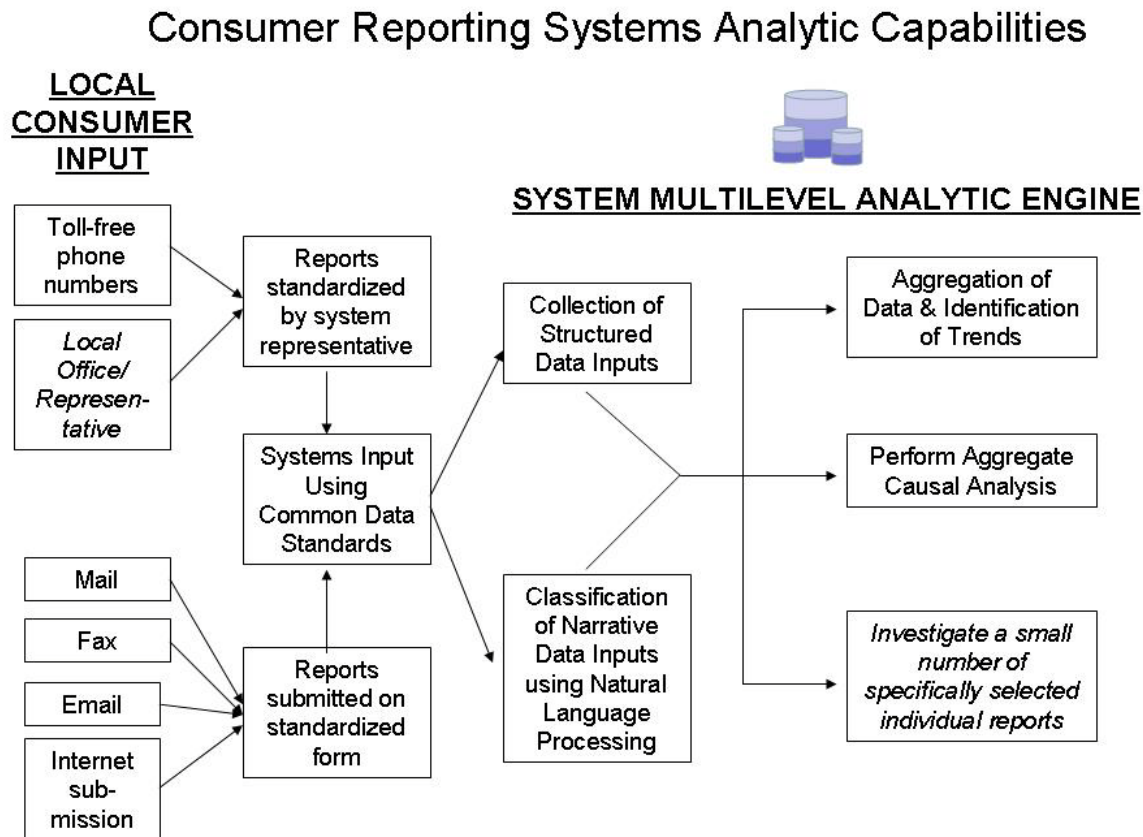
[1]: Text in *italic* indicates design features that do not represent complete consensus of the TEP.

A reporting system for patient safety events will have multiple entry points (i.e., methods for submitting reports) to increase consumer ease and accessibility and maximize reporting (Exhibit 5). Reporters will have the option to input their information directly to the system or through a system representative. If they choose the former option, the reporter can make his or her submission by mail, fax, e-mail, or Internet. A "smart form" would be used for each of these options, allowing submitted information to be entered into the reporting system with standardized data fields. If the reporter prefers a human interaction for report submission, a toll-free telephone line will be available and staffed with trained representatives who will gather relevant information and submit standardized reports.

TEP members disagreed on the need (or desirability) of having local offices collect reports. As an alternative system model, local offices with in-person representatives (indicated in italic to reflect lack of consensus) may make systems more user friendly and increase reporting. However, TEP members indicated that it is not clear that systems would have the resources to accommodate the infrastructure necessary to operate local offices.

Regardless of the input channel, all information received from consumers will be entered into systems using common data standards and processed by multilevel analytic engines. Structured inputs (e.g., drop-down menus, multiple choice questions) are immediately useable; narrative descriptions can be classified using natural language processing. After this processing, structured and unstructured information collected during the reporting phase will be functional data that can be used to aggregate information, identify trends, and perform aggregate causal analysis. A standard taxonomy may be used to guide data aggregation. A number of such taxonomies exist; AHRQ has developed common data formats for the PSO program, and one TEP member advocated use of the WHO-ICPS taxonomy structure.

Although TEP members agreed that the system should collect RCA when it has been conducted, they also agreed with concerns expressed by external reviewers about the dearth of individuals trained to perform RCAs. There are limited numbers of trained individuals present at most hospitals, and even fewer individuals based in other health care settings. This may have substantial impacts on the quality and usefulness of available RCAs. TEP members disagreed about the depth at which consumer reporting systems should investigate individual reports. As an alternative model, some experts thought that the system should develop public decision rules that indicated when the system should perform RCA on select events, subject to financial restraints (presented in italics to indicate an area of lack of consensus among the TEP). This relates to work by Tjerk van der Schaaf regarding the PRISM system, as described in the report *Patient Safety: Achieving a New Standard for Care* (IOM, 2004). Others felt that the system should not expend resources to conduct costly RCAs. The split in expert opinion suggests the development of two separate system models.

Chapter 6. Discussion and Policy Implications

Reasonable expectations for consumer reporting

This report presents the draft consensus recommendations from the TEP and illustrates potential reporting systems described by these recommendations. As discussed above, while reporting of patient safety events is often associated with hospitals-based incidents, these recommendations are applicable to patient safety events in all health care settings. TEP members indicated that the consumer perspective may be particularly important for patient safety events that occur during health care transitions (i.e., when care for a patient transfers from one provider or health care organization to another). Transitions are thought to be high-risk intervals for patient safety events, and often no single health care provider or organizations has complete information on or "ownership" of the transition. As such, consumers may be able to provide much more information on events occurring during transitions.

A broader question discussed by certain TEP members and external reviewers focused on what are reasonable expectations for accomplishments from consumer reporting, and whether development of consumer reporting systems would be worth the required investment. Some level of doubt was expressed regarding the potential impacts of consumer reporting systems on improving patient safety. Multiple reporting systems have been developed and implemented over the past decade, and their value is still uncertain. Reviewers commented that consumer reporting systems may not be able to contribute substantially to information on the incidence, types, or causes of events. For example, errors resulting in patient harms may involve multiple health care providers, systems, and interactions among humans and technologies. Descriptions of events provided by consumers may not provide useful information to understand the activities and system features (often substantially removed from the consumer) that enabled a patient safety event to occur. As such, it may be difficult for consumer reporting systems to design meaningful improvements in patient safety (part of the system purpose included in Recommendation 2.1) if the factors precipitating patients safety events are distant from or even invisible to the experience of consumers. Reviewers also commented that vigilant health care professionals and systems will attempt to both prevent patient safety events from occurring and understand the causes of events that do occur, regardless of whether consumer reporting is involved.

However, 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 they are not reported by a consumer. This may particularly apply to patient safety events that occur in outpatient settings, where there is likely to be less 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. TEP members agreed that 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 impacts 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. As illustrated in the discussion of health care transitions above, there are instances in which consumers are likely to have more complete information regarding a patient safety event than will any individual health care provider or entity. Further, even if consumers do not provide additional useful information regarding events, 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 in patient safety event reporting may increase the level of vigilance among health care providers and organizations, and may increase motivation to produce system change and, thereby, improvements in patient safety.

Issues related to the TEP recommendations

There are a number of limitations, implementation issues, and policy considerations related to the TEP recommendations. These are discussed below.

Limitations

Because of resource constraints and attempts to minimize the already considerable time members of the TEP graciously devoted to this project, we were unable to explore all possible areas for recommended consumer reporting system design features. In addition, although the TEP consisted of a diverse group of individuals with experience in a range of relevant areas, it is not possible to include individuals with all types of appropriate backgrounds and expertise on a single panel. This limitation was addressed by providing TEP members additional information from consumer focus groups, stakeholder interviews, and an environmental scan and literature review. Information from the consumer focus groups in particular provided additional perspectives and viewpoints for TEP members in developing recommendations for key design features.

There are several areas in which the TEP chose not to develop explicit recommendations. For example, although TEP members discussed the types of organizations that would be most appropriate to operate consumer reporting systems, members elected not to recommend specific organization types, and instead specified characteristics of such organizations. Similarly, although TEP members discussed several potential financial models for consumer reporting systems, the TEP chose not to present a recommended approach to financing systems.

Implementation issues

Throughout the course of this project, there has been an expected tension between the goal to develop design features for ideal consumer reporting systems and the knowledge of real-world barriers and limitations in the design and operation of such systems. To some extent, this has reflected an interest by TEP members in issues related to implementation of the consumer reporting systems that they were designing. Implementation of consumer reporting systems and related activities that go beyond specifying recommendations for system design features are

outside of the scope of this project. However, for future work, it will be critical to consider these issues.

One implementation issue strongly emphasized by the TEP is the need for pilot testing. Determination of many design features of consumer reporting systems will depend on the scope, key activities, available resources/personnel, and other factors specific to each system; pilot testing will be needed to assess how best to implement system design features given these factors. Other system design features, such as ways to maximize consumer reporting and provide timely and meaningful feedback, are not well understood; pilot testing will be needed to collect empirical data and explore potential options to develop best practices. Pilot testing will need to assess not just whether these system design features are feasible, but whether they are useful. Pilot testing will also yield insights with regard to the number and volume of consumer reports, which will have implications for cost and feasibility of full system implementation. TEP members also emphasized the need for pilot testing in multiple local/regional settings, potentially including settings that cross geographic or political borders; a system cannot credibly or efficiently start with national implementation. It will be important for systems to have sufficient resources to allow appropriate pilot testing.

Other topics related to system implementation that were raised by TEP members include the following:

- Before a system is initiated, it will be important to develop a monitoring and evaluation program to be able to assess the system's costs and benefits and thus provide long-term justification for the system. How will the efficiency, costs, and benefits of a system be demonstrated? What sorts of outcomes are needed from a system (or a pilot test of a system) to demonstrate that it is worth the expenditures? What evidence will be needed to garner support at local, State, and national levels for the system?

- More attention will be needed regarding specifics for consumer awareness campaigns. In particular, it will be important to convey to consumers the need to report near misses/close calls and successful error recovery events. That is, why did some initial problems/errors *not* result in patient harm? What actions/insights by staff or consumers made this possible?

- Training will be needed for system personnel, particularly regarding making submitted data uniform. How will staff be selected? How will training be designed and accomplished?

- Decisions regarding system functions/activities that occur at the "system hub" versus those that occur locally will need to be specified.

- Consumer reporting systems will need to monitor changes in relevant laws and regulations, and to dynamically alter their functions with respect to such changes. An example of this could be passage of "no fault" laws related to patient safety events.

The TEP also recognized that certain design features are critical for consumer reporting systems to have specified at initial implementation; other features, while equally important, can be implemented at a later time. The TEP agreed that the following recommendations were critical features for consumer reporting systems to have specified at the first stage of implementation:

- Purpose and Goals (Recommendation 2.1)
- Level of Operation (Recommendation 2.2)
- Type of Organization (Recommendation 4.1)
- Anonymity (Recommendation 4.5)
- Feedback (Recommendation 6.3)

While all of the recommended design features are important for the final system, many of the other design features do not need to be present or fully specified at initial system implementation. For example, consumer reporting systems may chose to initially collect reports only for specific types of patient safety events (Recommendation 1.1) from a select group of individuals (Recommendation 1.2) using a limited number reporting modalities (Recommendation 4.3). Systems may have limited analytic capabilities (Recommendation 3.2) and few or no linkages (Recommendation 3.1) at initial implementation. Following system implementation, these design features could then develop towards the recommendations specified by the TEP.

Policy Considerations

A variety of salient policy considerations arise from the TEP recommendations. We have described a number of considerations below, categorized in three groups:

I. Areas of rapidly-changing technologies and practices. For several of the recommendations presented in this report, the TEP indicated that design features were important or even critical, but elected not to specify the exact nature of these design features. In many instances, this reflected the realization that technologies or accepted practices are changing rapidly; if specified too fully (or perhaps at all), design features in these areas would be obsolete by the time a system is operational. As such, the TEP recommended that full specification of such features would need to wait until system implementation. Policy considerations related to these rapidly changing areas include the following:

A. Data sharing and interoperability. The TEP emphasized the importance of linkages. That is, consumer reporting systems should share information with other organizations to address patient safety events indicated in reports; provide assistance to reporting individuals that goes beyond the scope of services offered by consumer reporting systems; and enhance efforts to broadly enhance patient safety. The TEP also emphasized data sharing in comments on linking to quality and patient safety improvement efforts, stating that consumer reporting systems should not replace existing patient safety event reporting systems but should work with such systems. However, implementation of these recommendations would need to address multiple technical considerations. Organizations choosing to share data may not have compatible systems, and thus would be unable to integrate information from other sources. Interoperability is a substantial

issue in health information technology today, posing a barrier to the sharing of medical information between sites of care such as hospitals, outpatient physician practices, urgent care centers, pharmacies, and skilled nursing facilities. A number of organization, including government agencies (such as the Office of the National Coordinator for Health Information Technology) and private sector groups (such as the American Medical Informatics Association), are attempting to develop standard protocols and specifications to provide greater interoperability of health care data. It will be important for members of the patient safety event reporting systems community to participate in such discussions, so that plans and decisions regarding interoperability take into account the needs and goals of reporting systems.

B. Confidentiality. While allowing for anonymous reporting, the TEP expressed strong support for confidential reporting, which would allow collection of additional information from and permit feedback to be provided to reporting individuals. Confidentiality of patient safety event reports, which may include protected health information (PHI), is crucial for building trust in systems and maximizing reporting. A number of statues and regulations already exist, such as the Health Insurance Portability and Accountability Act (HIPAA), which address the security and privacy of individual health-related information. However, ensuring "well-designed confidentiality" (a term used by a TEP member) involves numerous challenges. Three areas in particular in which policies are needed to maintain confidentiality are data transmission/storage; access to confidential information; and legal considerations.

- Data transmission/storage: Confidential information transmitted to a system's central operating facility or shared with other systems or organizations may be at risk of being intercepted and divulged. Similarly, information stored within a consumer reporting system may be vulnerable if adequate security procedures and safeguards are not employed. Current standards regarding data safeguards for medical data (i.e., data collected by and provided to licensed clinicians and health care facilities) may not apply to information submitted to consumer reporting systems. To ensure appropriate confidentiality of patient safety event reports and thereby encourage consumers to provide confidential rather than anonymous reports, it may be necessary to develop regulations governing the minimum permissible level of computer security for reporting systems.

- Access to confidential information: Beyond issues in transmitting and storing confidential information, a separate consideration is limiting access to this information at consumer reporting systems. Not all personnel working for or otherwise affiliated with a consumer reporting system will need access to confidential-level data. To better protect confidentiality, policies will need to be established to determine which personnel are allowed to access these data and how access is prevented for unauthorized personnel. This may involve passwords, data encryption, and secure severs (e.g., computers that can be accessed only at the physical location of a consumer reporting system, not remotely via the Internet). Tracking capabilities may also be needed, to assess which reporting system personnel accessed confidential information and when it was accessed; regular audits to identify any inappropriate access of confidential

information could then be performed. In addition, policies may be needed to specify training for reporting system personnel related to data confidentiality and security issues.

- Legal considerations: Beyond the issues discussed above related to maintaining confidentiality, there are also concerns regarding possible legal actions. Private individuals or government agencies could obtain legal orders (e.g., subpoenas) requiring the release of information from consumer reporting systems despite assurances of such information's confidentiality. In addition to discouraging future confidential consumer reports of patient safety events, release of confidential information could jeopardize the future medical care for involved individuals and potentially even result in legal challenges (e.g., defamation suits) with associated economic damages. For whistleblowers (individuals who submit reports on patient safety events at health care facilities where they work), the release of confidential information could result in loss of employment and substantial damage to future career options. PSOs have been granted protections related to such legal actions. Similar policies, government regulations, or laws may be needed to clarify the nature of information submitted to patient safety event reporting systems, and to protect the confidentiality of such information.

C. Public reporting. The TEP strongly supported the concept of public reporting, and specified several purposes for public reporting, but electing not to specify the format or design of such reporting due to ongoing rapid changes in this area. However, a related issue is the response of regulatory agencies to such information. Although there are numerous caveats regarding the use of publicly reported patient safety event information (due in large part to incomplete information on both the numerators and denominators related to such events), there is an inherent desire to compare rates of patient safety events across different facilities or clinicians. There would likely be concerns (justified or not) that facilities or clinicians associated with higher rates of patient safety events are potentially negligent in some manner. Should local, State, or Federal government regulatory agencies or private sector accreditation organizations respond to such information? Should these agencies/organizations be required to respond? As the debate on the use of publicly reported patient safety information evolves, policies regarding the rights of facilities and clinicians identified in such information versus the obligations of regulatory agencies and accreditation bodies will need to be developed.

II. Coordination and collaboration among organizations/agencies involved in patient safety. Other policy considering resulting from the TEP recommendations are related to coordination and collaboration among different organizations involved in collecting information on and attempting to prevent or address patient safety events. Policy considerations in this area include the following:

A. Coordination among government agencies and consumer reporting systems. A particularly salient policy consideration relates to integrating or coordinating the work of consumer reporting systems with existing systems and activities of AHRQ and other Federal agencies. There may be

issues with other Federal agencies that currently have consumer reporting systems or may consider such a system to be within their mission—for example, FDA and the Centers for Disease Control and Prevention. In addition, many States have their own reporting systems. There is a need to be aware of whether such a system would be considered to impinge on the "turf" of other government agencies. Further, the continued development of consumer reporting systems may suggest potential policy changes for government agencies. For example, a TEP member suggested that the Medicare Conditions of Participation (for health care facilities) require institutions to have a formal process for the receipt of information from consumer reporting systems and incorporation of such reports into their quality and patient safety improvement efforts. AHRQ may find it useful to convene a policy summit bringing together representatives from State and Federal agencies with overlapping interests to clarify the boundaries of consumer reporting systems and address the issues raised above. An external reviewer also commented that the framework of recommended design features described in this report will be useful only if AHRQ and other agencies link these recommendations to specific, funded activities where they are implemented and tested.

B. Information sharing with health care facility-based reporting systems. The TEP emphasized that consumer reporting systems should not replace other reporting systems, but should work with these other systems. In particular, the importance of sharing information with reporting systems based at health care facilities (as permitted by confidentiality restrictions specified by individuals submitting reports) was highlighted, to encourage learning by health care professionals and increase opportunities to improve patient safety. However, this type of collaboration cannot occur unless facility-based reporting systems are in operation and are specifically tasked with accepting reports from consumer systems. Although many (perhaps most) health care facilities have existing procedures for submitting information on patient safety events, requirements for such reporting systems vary widely by State and by type of facility (e.g., hospitals, urgent care centers, skilled nursing facilities, outpatient physician practices). Furthermore, there are no uniform requirements regarding whether facility-based systems accept reports from outside systems or respond to such reports. To encourage collaborations among reporting systems for addressing patient safety issues, policies are needed to facilitate development of facility-based systems that can review and act on information from consumer reporting systems.

The TEP also recommended that consumer reporting systems request information from health care facilities on RCAs when such analyses have been performed for submitted events. However, there are no uniform requirements for health care facilities to share RCAs or other analyses when performed; in some jurisdictions, there may be barriers to sharing such information even when requested by the involved patients. Policies are needed to remove these barriers and encourage or require sharing of analyses and other relevant information from health care facilities with consumer reporting systems. Furthermore, as few individuals in hospitals or other health care environments have been trained to perform RCAs, these analyses may have limited usefulness.

III. Ownership/operation of consumer reporting systems. The TEP chose not to specify the specific type or types of organizations to own and operate consumer reporting systems.

Rather, the TEP provided recommendations as to the characteristics of such organizations. These characteristics include independence; fiduciary responsibility to the public; neutrality; and transparency. Parallel to the process created for the development and operation of PSOs, State or national legislation may be needed to specify the requirements, operations, and protections for consumer reporting systems. Legislation could specify who (individuals or organizations) are allowed to operate consumer reporting systems (to maintain independence); the required level of oversight by neutral bodies with consumer representation; mandatory reports by such systems to provide transparency regarding organizational priorities, actions, and finances; and protections for information submitted to consumer reporting systems (potentially addressing legal consideration and whistleblower issues mentioned by the TEP). Legislation could also address funding of consumer reporting systems, potentially using the models highlighted by the TEP (e.g., the Pennsylvania State reporting system). It will also be important to distinguish the roles of PSOs and consumer reporting systems, although this may or may not be a component of legislation.

The idea of consumer reporting systems for patient safety events holds great promise. Turning that idea into a reality will require significant political will, policy coordination, and resource investment. The design features presented in this report provide an actionable foundation for the necessary next steps of implementation and operation.

Chapter 7. References

Institute of Medicine (IOM). To err is human: Building a safer health system. Kohn LT, Corrigan JM, Donaldson MS, eds. Washington, DC: National Academy Press; 1999.

Institute of Medicine (IOM). Patient safety: Achieving a new standard for care. Aspden P, Corrigan JM, Wolcott J, et al., eds. Washington, DC: National Academy Press; 2004.

Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010 Nov 25;363(22):2124-34.

Nadler G. Work systems design: The IDEALS concept. Homewood, IL: Richard D. Irwin; 1967.

Appendix A. Members of the Technical Expert Panel

Name	Title (at project initiation)	Organization (at project initiation)	TEP Activities in which Member Participated D= Delphi Surveys 1= First TEP Meeting 2= Second TEP Meeting 3= Third TEP Meeting 4= Fourth TEP Meeting
Steve Jencks (MD, MPH)	Independent Consultant in health care safety and quality		D, 1, 2, 3
Linda Kenney	President, Executive Director	Medically Induced Trauma Support Services	D, 1, 2, 3, 4
Marilyn Kramer (MBA)	Executive Director	The Partnership for Healthcare Excellence	D, 1, 2
Timothy McDonald (MD, JD)	Professor of Anesthesiology and Pediatrics	University of Illinois College of Medicine	D, 1, 2, 3
Peter Pronovost (MD, PhD, FFCM)	Professor of Anesthesiology and Critical Care physician	Johns Hopkins University Schools of Medicine	D
Bill Runciman (PhD)	President	Australian Patient Safety Foundation	D
Paul Schyve (MD)	Senior Vice President	The Joint Commission	D, 1, 2, 3, 4
Susan Sheridan	President, Co-founder	Consumers Advancing Patient Safety (CAPS)	D, 1, 2, 3, 4
Tjerk van der Schaaf (PhD)	Professor of Patient Safety Research	Hasselt University, Dept of Business Economics, Patient Safety Group	D, 1, 2, 3, 4
Rafael Gutierrez Vega (MD)	Medical Director	CONAMED	D, 1, 2, 3
Emma Forbes	Patient Engagement Lead	National Patient Safety Agency (NPSA), U.K.	D, 1, 2, 3
Nancy Foster	Vice President for Quality and Patient Safety	American Hospital Association (AHA)	D, 1, 3, 4
Rosemary Gibson (MSc)	Senior Program Officer	Robert Wood Johnson Foundation	D, 1, 2, 3, 4
Suzanne Graham (RN, PhD)	Director of Patient Safety	Kaiser Permanente	D, 1, 2, 3
Sue Gullo (MS, RN)	Managing Director	Institute for Healthcare Safety	3
Martin Hatlie (JD)	CEO	Coalition for Quality and Patient Safety of Chicagoland	D, 1, 2, 3, 4

Appendix B. Peer-Reviewers

Name and affiliation

- John Banja, PhD
  Center for Ethics and Department of Rehabilitation Medicine
   Emory University
  Atlanta, GA
- Edward Kelley, PhD
  Patient Safety Secretariat
  World Health Organization (WHO)
  Geneva, Switzerland
- Lucian Leape, MD
  Department of Health Policy and Management
  Harvard School of Public Health
  Boston, MA