

SUPPORTING STATEMENT

Part A

**A PROTOTYPE CONSUMER REPORTING SYSTEM FOR PATIENT SAFETY
EVENTS**

Version: May 17, 2013

Agency of Healthcare Research and Quality (AHRQ)

Table of contents

A. Justification.....3

- 1. Circumstances that make the collection of information necessary.....3
- 2. Purpose and use of information.....7
- 3. Use of Improved Information Technology.....7
- 4. Efforts to Identify Duplication.....8
- 5. Involvement of Small Entities.....8
- 6. Consequences if Information Collected Less Frequently.....8
- 7. Special Circumstances.....8
- 8. Consultation outside the Agency.....8
- 9. Payments/Gifts to Respondents.....9
- 10. Assurance of Confidentiality.....9
- 11. Questions of a Sensitive Nature.....10
- 12. Estimates of Annualized Burden Hours and Costs.....10
- 13. Estimates of Annualized Respondent Capital and Maintenance Costs.....11
- 14. Estimates of Annualized Cost to the Government.....11
- 15. Changes in Hour Burden.....11
- 16. Time Schedule, Publication and Analysis Plans.....11
- 17. Exemption for Display of Expiration Date.....12

Attachments.....12

References.....13

A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99.pdf>), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and
2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for a Prototype Consumer Reporting System for Patient Safety Events. This project aims to design and evaluate a prototype system that can collect voluntary reports from patients about health care safety using standard definitions and formats that would enable systematic analysis and identification of opportunities for safety improvement.

Background on the Consumer Reporting System for Patient Safety (CRSPS). The reauthorization of the Agency for Healthcare Research and Quality (AHRQ) in 1999 established the Agency as a leader in support of research designed to improve the quality of health care, reduce its costs, promote patient safety and reduce medical errors, and broaden access to effective services. As provider of operational support to the chair of the Quality Interagency Task Force (QuIC), AHRQ coordinated the Federal response to the Institute of Medicine's (IOM) 1999 report on medical errors. As part of its patient safety research initiative, AHRQ is interested in assessing the feasibility of collecting information about the patient safety events from consumers (including patients, caregivers, family members, and others with an interest in patient welfare).

Over the past decade, health care delivery systems have increasingly adopted the approaches used in other industries to detect and mitigate safety problems. (Pronovost, Thompson et al. 2006) These include routine data collection to identify adverse events, non-punitive

mechanisms that encourage staff to report medical errors and near misses, and root cause analysis of safety incidents. Legislative and regulatory actions have enabled the creation of Patient Safety Organizations, encouraging the collection and analysis of safety-related incidents across health care organizations and nationally. Increasing the detection of adverse events, errors, and near misses is particularly important to inform the design of error prevention strategies.(Van Der Schaaf, 2002).

Despite these important efforts, a significant body of research suggests that persistent under-reporting of adverse events and medical errors may hamper efforts to redesign care delivery systems and improve the safety of care for patients (Weissman et al., 2008). In particular, observations about patient safety made by patients, their families, and other caregivers are not routinely collected or recorded. With some exceptions, even sophisticated safety monitoring systems do not presently accept or elicit reports from patients and their families (RTI, 2010). This is an important gap because the unique perspective of health care consumers could reveal important information about safety that may not be immediately available to health care providers. For example, adverse events related to health care provided during hospitalization may not be apparent until days or weeks after discharge. Miscommunications during transitions may not be readily apparent to clinicians, and systems for routine reporting of adverse events and medical errors are relatively less well developed in ambulatory settings outside of hospital and integrated delivery system settings. To increase the information available to provider organizations seeking to reduce the risk for errors and improve safety, patient and caregiver reports could complement and augment reports from providers and produce a more complete and accurate understanding of the prevalence and characteristics of health-care related adverse events (RTI, 2010).

While prior published research suggests the potential value of collecting reports from patients and caregivers about adverse events, many questions about this approach remain to be answered. The optimal designs for a system enabling consumers to report about potential safety events are not yet known. A pilot project is necessary to identify the optimal approaches to making the public aware of such a reporting system, the organizational home for the system, the elicitation and intake strategy, and the protocols for analyzing patient and caregiver reports. The best protocols for sharing such information with providers (with patient consent) and sharing aggregated reports to regulators and the public given current federal and state regulation of health care are not yet fully defined. The relationship between a consumer reporting system of this type and other existing reporting systems operated by institutional, state, and federal regulators of health care has yet to be fully defined.

In an effort to begin to answer these and other research and policy questions about the collection of safety reports from consumers, patients, and caregivers, AHRQ has funded the development and study of a prototype Consumer Reporting System for Patient Safety (CRSPS). This prototype is being designed to collect information from patients and caregivers about adverse events that patients experienced (and that *may* have been caused by health care) as well potential errors that patients and caregivers may have observed whether or not they caused harm. The project will develop and test approaches for classifying patient- and caregiver-reported patient safety events as incidents or near misses under the definitions used by the AHRQ Common Formats (AHRQ, 2010, details at:

www.pso.ahrq.gov/formats/commonfmt.htm). As a research study, the first stage of the project develops and evaluates the capability of the intake form to elicit and properly record data from consumers (patients and their caregivers). Later stages of the project will pilot the prototype in a carefully selected community, engaging the voluntary participation of local health care delivery organizations such as hospitals, ambulatory physician groups, pharmacies, as well other local interested parties such as consumer and patient advocacy groups. This pilot implementation will be used to assess the feasibility of implementing a community-based system and collect qualitative and quantitative information about the opportunities and challenges to deploying and operating such a system, including the risks and benefits for each of the involved stakeholders. This research is necessary to establish whether such a system should be deployed more widely and the conditions necessary to support successful deployment.

This demonstration project is being conducted by AHRQ through its contractor, RAND Corporation with Brigham and Women's Hospital, Dana Farber Cancer Institute, and ECRI Institute, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Rationale for the information collection. Currently there are a limited number of mechanisms for consumers, patients, or caregivers to report information about patient safety events (defined as an incident or near miss by the AHRQ Common Formats). Systems that exist, such as the FDA Medwatch, specify narrowly defined types of safety issues. While some patient reporting systems are emerging in organizations such as hospitals, many hospitals and settings such as ambulatory care are not systematically collecting patients' reports about safety. Few systems enable reporting about the safety of transitions in care, a known area of safety risk that may fall between settings. Information from consumers, patients, and caregivers could be used by delivery organizations as they seek to promote patient safety and reduce medical errors. In addition, current evidence suggests that patients and caregivers may report information that can augment or complement information collected by the existing safety improvement systems operated by provider organizations.

This research has the following goals:

1. To develop and design a prototype system to collect information about patient safety events
2. To develop and test web and telephone modes of a prototype questionnaire
3. To develop and test protocols for a follow-up survey of health care providers

To achieve the goals of this project the following data collections will be implemented:

1. *Safety event intake form and follow up.* Consumers, patients, or caregivers (hereafter referred to as "consumers") will be able to voluntarily report safety events through a *safety event intake form* on a web site (see Attachment B) or by telephone (Attachment D). The safety event intake form includes a structured set of questions that enables consumers to

report about two types of safety events: “negative effects” related to health care (e.g., harm, injury, adverse event) and/or a suspected medical error or mistake whether or not that medical error was associated with harm or injury. The introductory page will include a definition of the types of safety events to be reported to this system. The introductory page will advise consumers that other types of issues such as complaints about amenities (like food and parking) or grievances that are not related to the safety of care should be reported to other systems. A list of these other reporting resources will be made available to the consumer.

If the patient or caregiver chooses to enter a report, the safety event intake form walks that person through a series of questions about what happened, details of the event, when and where it occurred, whether there were negative effects, the type of negative effect. The consumer is given the option to describe in his or her own words what factors might have contributed to the safety event. The consumer is also asked about a selected list of potential factors that in the opinion of the consumer might have contributed to the event. The selected list of factors has been derived from the contributing factors that have been identified through prior research as issues that are directly observable by a patient or caregiver and considered valid and reliable based on prior testing (e.g. communication with providers using constructs that have been tested on prior surveys such as the CAHPS survey series) or have been used in other safety reporting instruments.

The consumer is asked whether the patient reported the event to a health professional, manager, or other person. The consumer is also asked whether the event was disclosed to the patient by a health professional. The consumer will have the option to identify the involved professionals and providing contact information. Consumers will also have the option to grant consent for the report to be shared with a contact person at the facility, which may be an administrator or patient safety officer, or with individuals doctors, nurses, or other health care professionals identified by the consumer as having some involvement. The consumer can choose to share the report anonymously or include his or her name in the shared report.

The consumer may also opt to allow a CRSPS intake staff person to follow up in order to clarify details about the report. Those who opt in will be contacted by telephone by CRSPS staff that will clarify information in the initial report and annotate the report accordingly (see Attachment E).

Upon leaving the safety intake form page, a reference page will contain several links to other resources and information about patient safety. One link will identify to local patient advocates from the pilot community including those from the participating facilities. The site will identify other systems, such as MedWatch, which is designed for reporting medication problems (MedWatch).

A Frequently Asked Questions is included for consumers (see Attachment C, CRSPS FAQs information sheet). The FAQs answer a series of questions that the reporter may have as well as provides directions to links or 800-numbers to answer their questions or concerns. After the consumer submits a report its content will be reviewed by an experienced health care professional (physician and/or nurse) for verification and classification based on a

review protocol. This protocol will mirror prior research approaches to classification and clarification. Reviewers will flag information that needs clarification. If the reporter has consented for follow-up, then we would contact the consumer for clarification information (See Attachment E).

2. Health care provider follow up. If a consumer consents to sharing the report with a health care professional or organization, CRSPS staff will send a formatted version of the consumer's report to a designated contact at the health care organization (such as a patient safety officer, medical practice leader, or other previously identified liaison). Participating organizations and professionals in the pilot community (i.e. all participating facilities and staff) will be PSO members, thus allowing them to analyze patient safety data as patient safety work product within the PSO framework. If the organization has an internal incident reporting system, the liaison will look for a matching report, and if appropriate, may wish to append the consumer's information to the incident recorded in the organization's incident reporting system (see Attachment G). Consumers will not have the option to receive information back from the incident reporting system because incident reports maintained by facilities must remain patient safety work product within the Patient Safety Organization (PSO) framework.

The CRSPS database of collected information will be protected as confidential research data and will be protected under AHRQ's federal authority to protect research data from public disclosure (see <http://www.ahrq.gov/hrqa99.pdf>). Results of the analyses conducted as part of this project will be included in a report to AHRQ and these results will be reported in aggregate and summary form to prevent the identification of any individual patient, consumer, or individual clinical provider.

Organizations that agree to participate in the pilot project will be identifiable as they would be in any research project even though the reports of consumers will not be made public. To minimize the risk of inadvertently disclosing information otherwise protected by HIPAA or PSQIA, we anticipate allowing relevant organizations to pre-review summary or aggregate results and report any information that might enable identification of a patient or specific health care professional.

2. Purpose and Use of Information

This demonstration project will allow AHRQ to develop, evaluate, and improve methods for engaging consumers in reporting health-related safety events across the spectrum of practice settings. Eliciting structured and narrative reports and leveraging electronic technologies are necessary to allow for the coding and classification of preliminary patient reports in a manner that ensures quality control and utility to providers and other stakeholders seeking to improve the quality and safety of care. The results of the pilot will inform AHRQ about the types of information that might be feasible to collect from patients and health care providers about patient safety events. Data from the safety intake form will help inform AHRQ of the patterns (type and distribution) of adverse event reporting across various settings within a community. Aggregated data about the consumer-reported patient safety events will be useful to the health care providers in the pilot community in quality or performance

improvement. The evaluation will also inform stakeholders about the potential feasibility and challenges of replicating such consumer reporting systems in other local areas.

3. Use of Improved Information Technology

The intake form will collect data via a web-based interface and a toll-free telephone number.

4. Efforts to Identify Duplication

This type of study has not been done before. Weissman et al. (2008) examined consumer-reported patient safety events in the hospital setting. Lipczak, et al. (2011) investigated cancer patient's reporting of safety events. The current research builds on prior studies by including all types of patients and health care settings.

In the U.S., there are no comparable community-based reporting systems for consumers, patients, family and caregivers to report the full range of safety issues that might occur during health care including adverse events, mistakes, near misses, or unsafe conditions. The U.S. Food and Drug Administration (FDA) MedWatch Online Voluntary Reporting Form focuses on reporting "serious adverse events for human medical products, including potential and actual product use errors and product quality problems associated with the use of: FDA-regulated drugs, biologics (including human cells, tissues, and cellular and tissue-based products), medical devices (including in vitro diagnostics), and special nutritional products and cosmetics". The proposed system will enable consumers to report on adverse events, mistakes, near misses, unsafe conditions, or other safety issues that are not related specifically to drugs, biologics, and devices or that consumers do not recognize as related. Consumers who report events that might be related to drugs, biologics, medical devices, and special nutritional products and cosmetics could be encouraged by the proposed system to make a report to MedWatch.

5. Involvement of Small Entities

Information being requested from provider organizations has been held to the absolute minimum required for the intended use.

6. Consequences if Information Collected Less Frequently

This is a one-time rolling data collection effort that will occur over a two-year period.

7. Special Circumstances

This request has special circumstances that are not consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). Namely, the project is not a statistical survey, but rather a convenience sample of adults who voluntarily report information. The information collected does not provide generalizable results because it depends on voluntary responses from a non-systematic sample. Such a system is being piloted to understand the type and quantity of data that could be collected from consumers on the occurrence of patient safety events. These consumer reports will be new information (i.e. not collected through provider based reporting system) and therefore highly valuable, even if not fully generalizable.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on September 11th, 2012 for 60 days and again on June 6th, 2013 for 30 days (see Attachment L). AHRQ received substantive comments from 45 members of the public, some of which included supporting documentation (See Attachment I). The comments also included 64 personal stories. These comments and personal stories raised 37 issues in the wording of the intake form, two issues with wording in other supporting documentation to the intake form, and 69 individual design issues that we categorized into 18 types of design concerns. For the detailed listing of our revisions and responses to these public comments, please refer to Attachment H.

8.b. Outside Consultations

Five sources informed the development of the intake form: (1) a previous survey instrument previously developed and tested by Drs. Schneider, Weissman, and Weingart (Weissman et al., 2008); (2) reporting forms summarized in the RTI (2010) report and others identified at the start of the project; (3) the domains and forms previously described by the IOM and ARHQ (Institute of Medicine, 2003; AHRQ, 2010); (4) two focus groups (one in English and one in Spanish) held in December 2011 and cognitive interviews conducted in March 2012; and (5) advice and insight from a Technical Expert Panel (Schneider and Jones, 2012). The focus group and cognitive interviews were critical because consumers did not necessarily recognize the AHRQ common formats. For example, consumers may initially consider safety occurrences the same as “complications,” “negative effects,” or “unexpected after effects.”

9. Payments/Gifts to Respondents

No payments or gifts will be provided to the pilot community partners or to anyone reporting information.

10. Assurance of Confidentiality

Respondents will be informed that all information will be kept strictly confidential and no respondent or organization will ever be named (see Attachment C, CRSPS FAQs information sheet). Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

Any information collected via telephone will ensure that both parties are in a private setting so that the call cannot be overheard. Any data collected with personal identifiers will have the personal identifiers removed during the auditing process including the scrubbing of all text fields for any references to provider names or patient names. The identifiable information will be kept in a separate database that links to the analysis files via a unique

report number. The identifiable information and linking files will be stored with password protection. The responses will be aggregated with those of other respondents before any information is reported to any other party outside of the research team.

11. Questions of a Sensitive Nature

Respondents will be asked if they consent to answer several questions of a sensitive nature. First, if the respondent consents, the system will record the names and addresses of the doctor, nurse, or other health care provider or facility involved in the patient safety event. Second, the system asks whether the respondent gives permission for the CRSPS staff to share their report with the doctor, nurse, or other health care provider that was involved in the event. The respondent has the option of sharing their report with or without their name. This sensitive information is necessary for matching the consumer-reported event to the provider's records of the incident. Third, the respondent is asked whether they are willing to share additional details about their safety concern via telephone. This follow-up is necessary in the case of inconsistencies across the patient's responses that require clarification.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for respondents' time to participate in this information collection based on the expected number of respondents, 840 to the intake form and 84 to the provider follow up. The number of respondents is based on the size of the selected community, estimates of health care utilization, rates of adverse events, and response rates in similar investigations. The intake form is expected to maximally require 25 minutes via the web or telephone plus an optional 10 minutes of follow-up questions, resulting in a total burden of 490 hours. The health care provider follow up is expected to take 20 minutes and only occurs for the estimated 10% of patients consenting; this form carries a total burden of 28 hours. The total burden is 518 hours annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Safety event intake form and follow up	840	1	35/60	490
Health care provider follow up	84	1	20/60	28
Total	924	NA	NA	518

Exhibit 2 shows the estimated annualized cost burden for patients, \$10,652, and for the health care organization, \$885, for a total annualized cost burden of \$11,537. Respondents will not incur any other costs beyond those associated with their time to participate.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden	Average hourly wage	Total cost burden
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		hours	rate	
Safety event intake form and follow up	840	490	\$21.74*	\$10,652
Health care provider follow up	84	28	\$31.61**	\$885
Total	924	518	NA	\$11,537

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, May 2011, U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#00-0000

** Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, May 2011: Occupational Health and Safety Specialists (General Medical and Surgical Hospitals). U.S. Department of Labor, Bureau of Labor Statistics. <http://www.bls.gov/oes/current/oes299011.htm>

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers, or computer software or services, or storage for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in this project.

14. Estimates of Annualized Cost to the Government

AHRQ is supporting the conduct of this project as part of a contract with the RAND Corporation and the ECRI Institute. The estimated cost for this work is \$899,827.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Intake Form Development	\$364,375	\$242,917
System Development	\$413,860	\$275,907
Project Management	\$35,325	\$23,550
Overhead	\$86,267	\$57,511
Total	\$899,827	\$599,885

15. Changes in Hour Burden

This is a new information collection.

16. Time Schedule, Publication and Analysis Plans

Data collected will be analyzed to produce estimates and basic descriptive statistics. We will conduct correlations, cross tabulations of responses and other statistical analyses. We will examine the quantity and type of consumer-reported patient safety events and examine the variability of responses to questions. The main two event types are: medical mistake or error and negative effects. We will also examine the distribution of negative effects that were reported related to medicine, a test, procedure or surgery, pregnancy or childbirth, a diagnosis or medical advice or unsanitary care. These analyses will provide a descriptive overview of the quantity and type of events reported/submitted.

We will examine the mode of data collection by event types, negative effect type, and setting of event (including institutionalized vs. inpatient vs. outpatient), who reported event,

if healthcare was changed as a result of the event. For example, we will evaluate whether the quantity or nature of the web-based reports are significantly different than the phone-reported events. In addition, we will examine if the quantity or nature of the reports varies based on how they learned about the system (e.g., from an HCAHPS survey, a kiosk, or the other specific marketing methods (Question 6.8)). The specific marketing methods that will be evaluated are contingent upon the interest and resources available in the pilot community selected. We will also evaluate which demographic characteristics are associated with a reporter’s willingness to be re-contacted for clarification. Finally, if sample size allows, we will also evaluate whether or not health care providers making special efforts to help the patient remediate the negative effects is associated with reduced likelihood of changing their healthcare provider. (Question 5.4).

The results will be submitted for publication in health-related peer-review or social science research journals and other types of reports.

The table below presents the project’s current schedule:

TASK/ACTIVITY	TIMELINE AND PROPOSED DATE OF COMPLETION
<u>Base Period:</u>	
Complete intake forms	May 2012
Submit 60 and 30 day notice	June 2012
Submit OMB package	May 2013
Write /submit Base Year Report	September 2013
<u>Option Years:</u>	
Collect reports	Oct 2013 –May 2015
Write /submit Final Report	August 2015
Write /submit papers for professional journals	April 30 th 2016

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: Introductory pages of website

Attachment B: Intake reporting form – web version

Attachment C: FAQs list

Attachment D: Intake reporting form – phone version

Attachment E: Intake reporting form follow up

Attachment F: Marketing flyer

Attachment G: Health care provider follow-up form

Attachment H: Revisions and Responses to FRN Public Comments

Attachment I: Public Comments

Attachment J: Illustrative example of Non retaliation policy

Attachment K: Illustrative example of No blame policy for providers

Attachment L: Federal Register Notice

References

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