SUPPORTING STATEMENT

Part A

National Hospital Adverse Event Reporting System: Questionnaire Redesign and Testing

Version: March 23rd, 2010

Agency for Healthcare Research and Quality (AHRQ)

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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, 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.

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 and outlined specific initiatives the QuIC agencies will take. The Errors Workgroup within the QuIC identified the need for measures to evaluate the use of adverse medical event reporting for managing and improving patient safety within healthcare institutions. In response, AHRQ created the Hospital Adverse Event

Reporting Survey to provide national estimates. This survey has been fielded twice, first in 2005 and again in 2008.

Revisions to the questionnaire and sample selection are now necessary in response to the Patient Safety and Quality Improvement Rule (Patient Safety Rule), 42 CFR Part 3, issued by the United States Department of Health and Human Services, which implements the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 through 299b-26. The Patient Safety Rule and Patient Safety Act authorize the creation of Patient Safety Organizations (PSO) to enhance quality and safety by collecting patient safety reports of adverse events. AHRQ started listing PSOs in late 2008 pursuant to the Patient Safety Act. These organizations have begun working with hospitals and other providers to monitor patient safety events according to common reporting formats, and to improve patient safety. This revised survey will be used for the third round of data collection in 2011, under a separate OMB clearance, to assess the impact of the PSOs and the Patient Safety Act on the use of adverse event reporting systems and will incorporate questions about reporting using the AHRQ Common Formats, and reporting information to a Patient Safety Organization.

Adverse event reporting systems record incidents that have, or could have caused harm to a patient. Anecdotal evidence indicates that while many hospitals report events, there appears to be little consistency in the manner of reporting and in the information reported. This information was verified by findings of the baseline survey. Follow-up survey data are still being analyzed, so results are not yet available. First, since no overarching federal legislation mandates the collection of such information, many hospitals report information under a variety of mandatory and voluntary reporting structures. Several states require reporting of adverse events and others encourage voluntary reporting. Accreditation agencies, specifically, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), encourages voluntary reporting of specific “sentinel events,” however, many hospitals don’t report to this system. In some instances, the reporting is specific only to certain types of events or hospital departments. For example, several hundred hospitals have elected to participate in the Centers for Disease Control and Prevention’s National Health and Safety Network. Inconsistencies in

reporting also stem from the fact that some facilities have highly sophisticated hospital-wide reporting from easily accessible computer work stations, while others are in the beginning stages of establishing paper-based systems. Another contribution to inconsistent reporting is that some hospitals allow for confidential and anonymous reporting in a blame-free environment, while others use reports for personnel action.
In the Fiscal Year 2002 Senate Appropriations Report for the Departments of Labor, HHS, and Education (Rpt.- 107-84) AHRQ was given the following specific requirements:

> "The Committee further directs AHRQ to provide a report detailing the results of its efforts to reduce medical errors. The report should include how hospitals and other healthcare facilities are reducing medical errors; how these strategies are being shared among healthcare professionals; how many hospitals and other healthcare facilities record and track medical errors; how medical error information is used to improve patient safety; what types of incentives and/or disincentives have helped healthcare professionals reduce medical errors and; a list of the most common root causes of medical errors. The report should provide data showing the effectiveness of State requirements in reducing medical errors. The report should also describe how AHRQ is responding to some of the findings in the IOM's report, "To Err is Human: Building a Safer Health System."

This survey revision and cognitive testing activity will redesign an instrument that will further develop the understanding of adverse event reporting systems used in US hospitals, in continued response to the specific requirements stated in the above congressional mandate and resulting from the changes from the enactment of the Patient Safety Act and the Patient Safety Rule by examining how hospital use of adverse event reporting systems is changing over time.

This project is being conducted by AHRQ's contractor, Westat, pursuant to AHRQ's statutory mandates to (1) promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality (42 U.S.C. 299(b)(1)(F)) and (2) conduct and support research on health care and on

systems for the delivery of such care, including activities with respect to quality measurement and improvement (42 U.S.C. 299a(a)(2).

2. Purpose and Use of Information

This project will include the following data collections:

1) Semi-structured interviews (see Attachment B) will be conducted with one risk manager or other representative responsible for adverse event reporting from 7 participating hospitals and with one person from the two participating PSOs. These interviews will be conducted to learn more about the current hospital adverse event reporting environment and to understand how adverse event reporting may have changed in response to the Patient Safety Act. Survey developers will use the information from these interviews to develop questions for the revised questionnaire.
2) Cognitive interviews (see Attachment C) will be conducted with one risk manager or other representative responsible for adverse event reporting in 30 participating hospitals. The purpose of these cognitive interviews is to test and refine the revised questionnaire. The questionnaire will be tested among respondents in hospitals with no reporting affiliation with a PSO, with reporting affiliations with one PSO, and with reporting affiliations with more than one PSO.

Results from these interviews will help inform actions by AHRQ to encourage effective adverse event reporting by hospitals, as part of its patient safety initiative, including standardization of reporting so that consistent concepts, information, and terminology are used in the patient safety arena. The survey can also serve as a baseline for changes about hospital-based adverse event reporting to Patient Safety Organizations and how the Patient Safety Act might have affected reporting structures and processes.

3. Use of Improved Information Technology

This survey revision and testing process will not involve the use of automated or electronic collection techniques, other than completing a cognitive interview by telephone.

4. Efforts to Identify Duplication

The Adverse Event Reporting Survey is the only survey that collects information from a national sample of Risk Managers about hospitals' adverse event reporting systems, the dissemination of this information within hospitals, and its possible use for quality or performance improvement. There are no surveys that have examined how hospital use of adverse event reporting systems is changing over time. In addition, there are no surveys capturing the experience of reporting using the AHRQ Common Formats and reporting to a Patient Safety Organization.

5. Involvement of Small Entities

None of the respondents represent institutions that would be considered a small business.

6. Consequences if Information Collected Less Frequently

This is a one time data collection to revise an existing questionnaire and its associated survey methodology.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

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 May 3rd, 2010 (see Attachment D). No comments were received.

8.b. Outside Consultations

The survey was originally developed by AHRQ and Westat, who consulted with the American Hospital Association (AHA) in the development of the pilot adverse events survey instrument. They met with and had several staff review the instrument and made changes to the instrument based on their recommendations. Based on the success of the pilot and the high response rate obtained in fielding of the baseline survey, RAND, the contractor that administered the first two rounds of the survey, did not ask for further consultation. Westat will not require further outside consultation for the development of third round of the survey.

9. Payments/Gifts to Respondents

No payments or gifts will be provided to the respondents participating in the project.

10. Assurance of Confidentiality

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.

11. Questions of a Sensitive Nature

This survey does not ask about specific adverse events. Rather, it asks about the system that tracks such events and how the events are discussed among hospital staff. Nonetheless, given the sensitive topic of inquiry, some respondents might refuse to participate in the cognitive interviewing. As stated above, we will inform respondents that all information will be kept strictly confidential and no respondent or organization will ever be named. Respondents will be made aware of this in advance in writing and again prior to cognitive testing, and will be told that they may refuse to answer any question.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this project. Semi-structured interviews will be conducted with 9 persons representing 7 hospitals and 2 PSOs and will last for about an hour. Cognitive interviews will be conducted with one person in each of 30 participating hospitals and are expected to take one hour to complete. The total annual burden hours are estimated to be 39 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in the research. The total annual cost burden is estimated to be $1,664.

Exhibit 1. Estimated annualized burden hours

Form Name	**Number of organizations**	**Number of responses per responding organization**	**Hours per response**	**Total burden hours**
Semi-structured interviews	9	1	1	9
Cognitive interviews	30	1	1	30
Total	39	NA	NA	39

Exhibit 2. Estimated annualized cost burden

Form Name	**Number of respondents**	**Total burden hours**	**Average hourly wage rate***	**Total cost burden**
Semi-structured interviews	9	9	$42.67	$384
Cognitive interviews	30	30	$42.67	$1,280
Total	39	39	NA	$1,664

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

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 facilities 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 the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated total and annualized cost to the federal government to conduct this redesign of the Adverse Event Reporting Questionnaire and associated sample design. Since this project will last for one year the total and annualized costs are the same. The total cost is estimated to be $120,000.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$24,000	$24,000
Data Collection Activities	$46,000	$46,000
Data Processing and Analysis	$26,000	$26,000
Project Management	$24,000	$24,000
Total	$120,000	$120,000

15. Changes in Hour Burden

This is a new information collection.

16. Time Schedule, Publication and Analysis Plans

Both semi-structured and cognitive interview data will assist in the revision of the Adverse Event Reporting Questionnaire. The information will allow the survey developers to revise and then diagnose potential areas of difficulty in the revised instrument and will allow survey developers to find the best way of asking questions. There are no plans for publication of the information collected as part of the survey revision process.

The table below presents an estimate of the time required to complete the proposed work:

Task/Activity	TIMELINE AND PROPOSED Date of Completion
Conduct semi-structured interviews and develop 3rd version of the survey	August 2010

Conduct cognitive testing	October 2010
Revise survey	December 2010

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A – Healthcare Research and Quality Act of 1999

Attachment B – Semi-structured interview guide

Attachment C – Cognitive interview guide

Attachment D – Federal Register Notice