SUPPORTING STATEMENT

Part A

NATIIONAL HOSPITAL ADVERSE EVENT REPORTING FOLLOW-UP SURVEY

Version: July 8, 2008

Agency of 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.

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 healthcare, 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 and outlined specific initiatives the QuIC agencies will take. As part of its patient safety research initiative,

AHRQ is interested in the development of measures to document existing conditions at the start of the patient safety improvement initiatives. The Errors Workgroup within the QuIC has identified the need for two such measures. One of these measures should evaluate the use of adverse medical event reporting for managing and improving patient safety within healthcare institutions.

This proposed information collection is to conduct a national follow-up survey on adverse event reporting within hospitals to understand how hospital reporting systems have changed over time. This survey will provide data for a second point in time on the status of hospital reporting systems, following upon baseline data established by a baseline survey completed in 2005. Adverse event reporting systems record incidents that have, or could have caused harm to a patient. Anecdotal evidence indicated 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. 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 Nosocomial Infections Surveillance System. 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."

The purpose of this follow-up national survey is to 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, by examining how hospital use of adverse event reporting systems is changing over time. The survey asks about whether hospitals collect information on such occurrences, store it centrally, and the mechanisms used for such. In addition, the survey asks what types of data are collected by the reporting system for reported events, and asks for estimates of completeness of reporting by degree of severity of events. The survey inquires about who might report information and whether they can report to a system which is confidential and/or anonymous. The survey also asks about the uses of the data that are collected, for example, whether information is used for purposes such as analytic uses, personnel action, and intervention design. Finally the survey asks about the other sources of information that are useful for patient safety-related interventions.

2. Purpose and Use of Information

This study will allow AHRQ to understand changes that are occurring over time in the status of hospital adverse event reporting systems, the type of information collected, and

uses for the information. Survey results 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 followup survey will include many questions that were in the baseline survey, allowing analyses of changes in practices over time.

3. Use of Improved Information Technology

This collection of information will not involve the use of automated or electronic collection techniques. However, participants who do not respond to the mail survey will complete a telephone interview.

4. Efforts to Identify Duplication

The baseline survey is the only survey that has collected 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.

5. Involvement of Small Entities

We do not believe that any of the participating hospitals would be considered a small business.

6. Consequences if Information Collected Less Frequently

Activities in support of AHRQ's Congressionally mandated activities to collect information on adverse event reporting systems will be severely hindered by the absence of this information on changes in hospital adverse event reporting processes. Survey results will be crucial to understanding the extent to which hospitals have made changes since 2005 in what information they are collecting, how they are collecting it, and how they are using the collected information. These results also will be needed to assess the feasibility of instituting national standards for adverse event data collection. In addition, without data on the progress over time in hospitals' collection and use of adverse event

data, it will be more difficult to understand and monitor national progress towards attaining the goal of a 50 percent reduction in medical errors.

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 July 24th, 2008 for 60 days. No comments were received.

8.b. Outside Consultations

AHRQ and contract organization who conducted the pilot survey 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 will not ask for further consultation.

9. Payments/Gifts to Respondents

No payments or gifts will be provided to the hospitals 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.

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.

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

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 study. 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 letters and prior to an interview 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 information collection. The questionnaire is expected to require 25 minutes to complete, resulting in a total burden of 425 hours.

Exhibit 1. Estimated annualized burden hours

Form Name	**Number of respondents**	**Number of responses per respondent**	**Hours per response**	**Total burden hours**
Risk manager questionnaire	1,020	1	25/60	425
Total	1,020	NA	NA	425

Exhibit 2 shows the estimated annualized cost burden for the respondent, which is estimated to be $11,518. The respondent 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 hours**	**Average hourly wage rate***	**Total cost burden**
Risk manager questionnaire	1,020	425	$27.10	$11,518
Total	1,020	425	NA	$11,518

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2006, "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

The Agency is supporting the conduct of this survey and analysis of survey data as part of the contract with RAND as the Patient Safety Evaluation Center. The estimated cost for this work is $190,000 over six months of data collection. The estimated costs of data collection include $154,319 labor costs and fringe expenses, $9,136 administrative expenses, and $26,545 in costs associated with reproduction, postage and telephone expenses.

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, basic descriptive statistics, examine the variability of responses to questions, and conduct correlations, cross tabulations of responses, or other statistical analysis. The results of the survey will be submitted for publication in health-related peer-review and/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
Complete baseline survey	December 2005
Clean and analyze baseline survey data	Ongoing
Submit 60 and 30 day notice for follow-up survey	April 2008
Submit OMB package for follow-up survey	July 2008
Conduct follow-up survey	March 2009
Write & Submit Final Report	December 2010
Write and submit papers for professional journals	September 2011

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments

A. Risk Manager Questionnaire – Mail Version

B. Risk Manager Questionnaire – Phone Version

C. Questionnaire Cover Letter

D. Reminder Post Card

E. Remail Cover Letter

F. Phone Interview Introductory Script

G. RAND HSPC Approval Notice

References

Brick JM, Kalton G. Handling missing data in survey research. *Statistical Methods in Medical Research* 1996;5:215-238.