

SUPPORTING STATEMENT

Part A

Synthesis of AHRQ-Funded HAI Projects

February 10, 2012

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 (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.

For approximately a decade, AHRQ has conducted research on preventing healthcare-associated infections (HAIs), both internally and through contracts and grants. AHRQ's grant- and contract-supported projects have been directed at the major types of HAIs: central-line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), surgical site infections (SSI), ventilator-associated pneumonia (VAP), methicillin-resistant *Staphylococcus aureus* (MRSA), and *Clostridium difficile* (*C. diff.*). Projects have addressed the problem of HAIs in diverse healthcare settings, including hospitals, ambulatory settings (ambulatory surgery centers, end-stage renal disease facilities, and outpatient clinics and offices), and long-term care facilities. AHRQ's portfolio of HAI projects has emphasized a combination of research and implementation initiatives. In the latter category, a major focus of AHRQ's efforts has been to deploy tools that can improve provider performance and reduce HAIs. Based on the earlier success of the Michigan Keystone project, AHRQ has funded projects to implement the Comprehensive Unit-based Safety Program (CUSP) to address CLABSI and

CAUTI nationwide. Data are now emerging that demonstrate the success of CUSP in reducing CLABSI in hospitals across the nation.

Between 2007 and 2010, AHRQ funded 40 contracts and 18 grants focusing on expanding the HAI knowledge base and implementing HAI prevention strategies. Today it is necessary to look across these projects in order to (1) identify, document, and synthesize their findings and results to ensure that AHRQ, healthcare professionals, and the public can make best use of these findings and (2) identify remaining gaps in the HAI science base to enable AHRQ to fund future studies that will address these needs. The synthesis will draw on several data sources, including review of project documents (solicitation materials, technical proposals, progress reports, project reports, other project deliverables) and peer-reviewed literature emerging from the projects. In addition, we will conduct interviews with project leaders. The interviews will complement the information gathered from the documents by providing details that are not typically available in publications and other documents, such as the project leader's motivation for responding to the request for proposal, challenges faced in implementing the project, changes in the project's delivery schedule or work plan, experts' views on how HAI prevention evidence generated by a specific project fits into the HAI research agenda more broadly, and remaining gaps in the HAI knowledge base.

AHRQ has contracted with IMPAQ International LLC to develop this synthesis, identify gaps, and promote the widespread application of successful HAI prevention approaches.

This research has the following goals:

1. Identify and document findings and synthesize results of AHRQ-funded HAI projects
2. Disseminate key findings from the HAI projects
3. Identify remaining gaps in the HAI knowledge base

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

- 1) Interviews with contractors – Interviews will be conducted with the project leaders (project directors or project managers) from 40 HAI contractors (see Attachment A). The purpose of these interviews is to identify a) key findings, b) gaps in knowledge base, c) lessons learned, d) effective approaches for preventing and reducing HAIs, and e) opportunities for additional projects focused on generating and implementing knowledge on preventing HAIs.
- 2) Interviews with grantees – Interviews will be conducted with the project leaders (principal investigators) from 18 HAI grantees (see Attachment B). Similar to the interviews with contractors, the purpose of these interviews is to identify a) key findings, b) gaps in knowledge base, c) lessons learned, d) effective approaches for preventing and reducing HAIs, and e) opportunities for additional projects focused

on generating and implementing knowledge on preventing HAIs. While the goals of the interviews with contractors and grantees are similar, the two audiences require separate interview protocols because their funding mechanisms and project structures differ. For example, contracts have more structured deliverable schedules than do grants and grants are more likely than contracts to be on investigator-initiated topics.

This study is being conducted by AHRQ through its contractor, IMPAQ International, LLC and its subcontractor, the RAND Corporation, pursuant to AHRQ's statutory authority to conduct and support research and disseminate information on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

AHRQ will interview key project leaders to learn about the processes and methods used, results achieved, and lessons learned under the AHRQ-funded HAI contracts and grants. This information will enable AHRQ to identify effective approaches for preventing and reducing HAIs and for promoting the widespread application of these approaches. Finally, collecting data from these audiences will allow AHRQ to detect gaps in the HAI science base and identify opportunities for additional projects focused on generating and implementing knowledge on preventing HAIs.

3. Use of Improved Information Technology

For this project, telephone interviews will be conducted to minimize respondent burden and maximize cost effectiveness. Interviews will be conducted with the universe of AHRQ-funded HAI projects (40 HAI contracts and 18 HAI grants). Conducting interviews by telephone eliminates travel burden, reduces costs, and allows participants to participate at a convenient time.

4. Efforts to Identify Duplication

In addition to conducting interviews with project leaders, a substantial amount of effort will be directed at gathering, reviewing, coding and synthesizing documents related to the AHRQ-funded projects included in the Synthesis, and each project's documents will be reviewed prior to the interview. Documents of interest include solicitation materials, progress reports, project reports, project deliverables such as HAI prevention toolkits, and peer-reviewed literature associated with the projects. The interviews will complement the information from these documents, which are unlikely to include investigators' motivations for applying for funding, barriers to and facilitators of project success, researchers' perspectives on the gaps filled by their funded projects, remaining gaps in the HAI knowledge base, applicability of results to other HAIs or healthcare

settings, dissemination strategies, and lessons learned. Also, some projects will not have had time to publish results or will not yet have written up results for project deliverables. In these cases, the interviews will serve as the primary source of information. No other data collection effort has been conducted or has been planned to collect similar information.

In some cases, the contract or grant performance period will have expired at the time of the interview. In such cases, recall bias is unlikely to be a serious shortcoming of the study. The reasons are that interviewees will have spent a substantial amount of time and effort leading the projects and that the project team will have documents that can be used to triangulate and verify some of the information provided by interviewees.

5. Involvement of Small Entities

The interviews will only involve individuals; therefore they will not pose a burden to small businesses or other small entities.

6. Consequences if Information Collected Less Frequently

This is a one-time data collection.

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 Friday, April 6, 2012, page 20820 for 60 days (see Attachment H). No comments were received.

8.b. Outside Consultations

AHRQ consulted with many individuals in developing the evaluation design, data collection plan, and data collection instruments. This includes AHRQ program staff and staff from the contractor (IMPAQ International LLC and its subcontractor, RAND Corporation). No unresolved problems were identified by any of these individuals.

9. Payments/Gifts to Respondents

AHRQ does not plan to provide any payments or gifts to the respondents.

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.

Respondents' identifying information, including name, will be obtained for the study. All data items that identify respondents will be kept by AHRQ, the contractor, IMPAQ International, and its subcontractor, RAND Corporation. Identifiable information will be used for 1) contacting individuals for conducting telephone interviews and 2) analysis of interview results based on differences within the projects. Identifiable information will not be disclosed to anyone outside of AHRQ, IMPAQ International, and RAND Corporation. Measures to safeguard data will be emphasized in written and verbal training procedures for project personnel, and all project personnel will sign an Assurance of Confidentiality statement. IMPAQ International and RAND Corporation will use a secure website to exchange personal identifying information, and all electronic files will be encrypted prior to sharing.

11. Questions of a Sensitive Nature

The data collection instruments being submitted for clearance do not include questions of a sensitive or personal nature, nor do they request Social Security Numbers, Medicare Numbers, or Medicaid Numbers.

Each respondent will receive an informed consent statement (see Attachment F). This will include information on the purpose of the project and interview, how their privacy will be maintained, and how the information they share will be used.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in this evaluation. Interviews will be conducted with 40 contractors and 18 grantees and each will last about 90 minutes. The total burden hours are estimated to be 87.

Exhibit 1. Estimated annualized burden hours

Data Collection Activity	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Interviews with contractors	40	1	1.5	60
Interviews with grantees	18	1	1.5	27
Total	58	n/a	n/a	87

The respondents are the project leaders, that is project directors for the contracts and principal investigators for the grants. Based on the type of grant and the project leaders' qualifications, the project leaders were categorized into three labor categories: Social Scientists and Related Workers; Epidemiologists; and Medical Scientists. For example, one project director conducting a randomized controlled trial is a physician and was categorized into the Medical Scientist labor category. Other project leaders have advanced degrees in the social sciences (e.g., gerontology) or epidemiology and were included in the Social Scientist or Epidemiologist labor categories, as appropriate.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in the evaluation. The total cost burden is estimated to be \$3,450.

Exhibit 2. Estimated annualized cost burden

Data Collection Activity	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Interviews with contractors	40	60	\$39.66	\$2,380
Interviews with grantees	18	27	\$39.66	\$1,070
Total	58	87	n/a	\$3,450

*Based upon the weighted average of the mean wages for 19-3099 Social Scientists and Related Workers, All Other (\$37.45 per hour; n=17), 19-1041 Epidemiologists (\$32.83; n=5) and 19-1042 Medical Scientists ((\$41.69; n=36), National Compensation Survey: Occupational Wages in the United States May 2010, 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 government for conducting the evaluation. The total cost is estimated to be \$87,502.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	\$6,135	\$2,045
Data Collection Activities	\$17,400	\$5,800
Data Processing and Analysis	\$29,000	\$9,667
Publication of Results	\$0	\$0
Project Management	\$5,800	\$1,933
Overhead	\$29,167	\$9,722
Total	\$87,502	\$29,167

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

16a. Time Schedule

The tentative time schedule for data collection activities is below. These dates may change depending on when OMB grants clearance.

Activity	Due Date
Submit Draft Interview Protocols	12/16/11
Submit Preliminary List of Proposed Respondents for Process Component	12/16/11
Submit Final Interview Protocols	1/31/12
Submit OMB Clearance Package	1/31/12
Conduct interviews	12/1/12-8/31/13
Analyze interview data	9/1/13-12/31/13
Interim results: Synthesis of Project Activities	5/16/14
Final Report	9/12/14

16b. Publication Plans

There are currently no specific plans to publish results based on these data.

16c. Analysis Plan

The analyses of the interview data will be conducted in an iterative manner and include analyses of the major topics covered in the interviews; then an overall analysis across topics will be conducted. For the first step of analysis, a debriefing will be conducted after an initial set of interviews has been completed. The debriefing will include a discussion of key findings and overall observations. The notes from the debriefings will facilitate rapid reporting of the initial findings and will facilitate the in-depth analyses of the data.

A lead reviewer will review each set of notes for content on a particular set of topics to identify themes. In addition, a designated backup reviewer will serve as a second independent reviewer to check the themes identified by the lead reviewer and minimize any idiosyncratic readings of the data. Throughout the interview analysis process, audio recordings of the interviews will be referenced to clarify items in the interview notes.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: Interview Guide for Contractors

Attachment B: Interview Guide for Grantees

Attachment C: Recruitment Email

Attachment D: AHRQ Letter

Attachment E: Confirmation Email

Attachment F: Informed Consent Form

Attachment G: Thank You Letter

Attachment H: Federal Register Notice