SUPPORTING STATEMENT

Part A

Phase II of a Longitudinal Program Evaluation of Health and Human Services (HHS) Healthcare Associated Infections (HAI) National Action Plan (NAP)

Version: March 14, 2014

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

This request is for approval of data collections for the *Phase II of a Longitudinal Program Evaluation of Heath Human Services' (HHS) Healthcare Associated Infections National Action Plan (HAI NAP)*.[1] The evaluation contains two components:

- A process evaluation that explores the activities of Federally-supported quality improvement efforts within the Department of Health and Human Services (HHS) that are directed at reducing the incidence of healthcare acquired infections (HAIs).

- A product evaluation that focuses on the effects of the various HHS programs and projects, jointly and in tandem, on stakeholders in terms of HAI prevention capacity and HAI incidence/rates.

The purpose of this information collection is to describe, as part of the process evaluation, the progress of programs that have been outlined in the HHS National Action Plan, and to identify the unique and aggregate contributions of each program to the mitigation and prevention of HAIs.

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.

[1] U.S. Department of Health and Human Services. HHS Action Plan to Prevent Health Care-Associated Infections. Retrieved from http://www.hhs.gov/ash/initiatives/hai/actionplan/hhs_hai_action_plan_final_06222009.pdf.

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.

This evaluation of HHS' Healthcare Associated Infections National Action Plan will assess the efficacy, efficiency and coordination of federal efforts to mitigate and prevent Healthcare Associated Infections (HAIs). As such, it represents a critical component of AHRQ's mission to promote health care quality improvement.

Background

Healthcare Associated Infections (HAIs) are infections that patients acquire while receiving treatment for other conditions while in a healthcare setting. They affect care in hospitals-hereafter referred to as "acute care", ambulatory care settings, and long-term care facilities, and represent a significant cause of illness and death in the United States. Over one million HAIs occur across health care settings every year.

In 2008, amidst growing demands on the healthcare system, rising healthcare costs, and increasing concerns about antimicrobial-resistant pathogens, HHS established a senior-level Steering Committee for the Prevention of HAIs. Charged with improving coordination and maximizing the efficiency of prevention efforts across HHS, the Steering Committee released the first "National Action Plan to Prevent Health Care-Associated Infections" (HAI NAP) in 2009.[2] This plan outlined a systematic and phased approach to reducing HAIs and associated morbidity, mortality, and costs.[3] Phase One of HAI NAP, which concluded in 2012, focused on HAI prevention in acute care hospitals, where data on prevention and the capacity to measure improvement were most complete. Additionally, the plan set specific targets for reducing rates of six high priority HAIs or specific causative organisms: surgical site infection (SSI), central-line associated bloodstream infection (CLABSI), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infection (CAUTI), *Clostridium difficile* infection, and methicillin-resistant *Staphylococcus aureus* infection (MRSA).

Phase II of the Action Plan, entitled *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination* was released in April 2012. Phase II expanded the Action Plan to include prevention of HAIs in ambulatory surgical centers

[2] U.S. Department of Health and Human Services. HHS Action Plan to Prevent Health Care-Associated Infections. Retrieved from .http://www.hhs.gov/ash/initiatives/hai/actionplan/hhs_hai_action_plan_final_06222009.pdf

[3] U.S. Department of Health and Human Services. (2009). Action Plan to Prevent Healthcare-Associated Infections. 3Washington, DC: Author.

(ASCs) and end-stage renal disease (ESRD) facilities, and increasing influenza vaccination coverage of healthcare personnel. Phase III of the HAI NAP, released for public comment in April 2013, further expanded the Action Plan to include prevention of HAIs in long-term care facilities.

Evaluation of HAI NAP. In 2009, AHRQ funded an independent, outside evaluation of HHS' HAI prevention efforts, as guided by the Action Plan. The goals of this evaluation were to: (1) record the content and scope of the Action Plan, its current design, its progress, and impact on the future; (2) establish baseline data and provide additional information on the HAI landscape prior to and following the initiation of the Action Plan effort; and (3) provide strategic insights from ongoing processes for reducing HAIs and outcomes of these processes.

This research in the current evaluation will expand upon this initial effort, encompassing the additional health care settings outlined in Phases II and III of the HAI NAP.

The goals of this Phase II evaluation are to:

1. identify commonalities, gaps, themes, and opportunities for collaboration across six Federal quality improvement and patient safety efforts to eliminate HAIs; and

2. highlight actionable opportunities across HHS to collaborate and efficiently utilize resources in these quality improvement and patient safety efforts; and

3. assess the unique and aggregate contributions of each quality improvement and patient safety effort to the mitigation and prevention of HAIs.

To achieve the goals of the HAI NAP evaluation, the following data collections will be implemented:

Semi-structured interviews. Key informant interviews with stakeholders of the HAI National Action Plan or the Quality Improvement (QI) initiatives that the Action Plan seeks to coordinate and align. These stakeholders will have knowledge of the QI initiatives as implemented in acute care, ambulatory care, long term care or ESRD facilities. AHRQ plans to conduct 33 interviews each year, over the course of two years. The semi-structured interviews will inform the process evaluation. See Attachment A for the interview protocol for stakeholders with expertise in acute care settings. See Attachment B for the interview protocol for stakeholders with expertise in ambulatory care settings. See Attachment C for the interview protocol for stakeholders with expertise in long term care settings. See Attachment D for the interview protocol for stakeholders with expertise in ESRD facilities. See Attachments E through H for associated respondent materials.

This study is being conducted by AHRQ through its contractor, Insight Policy Research, Inc., and subcontractors, the RAND Corporation, and IMPAQ International, pursuant to AHRQ's statutory authority to conduct and support research and evaluation 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 use the interview data from key project leaders to assess the processes and methods used, results achieved, and lessons learned from patient quality and safety programs that are directed at reducing the incidence of HAIs. This information will enable AHRQ to identify redundancies in program efforts and provide effective approaches for coordinating and aligning Federal efforts to prevent the incidence of HAIs. Finally, collecting data from these audiences will allow AHRQ to detect gaps in the HAI science base and opportunities for funding additional projects focused on generating and implementing knowledge on preventing HAIs.

The information gathered through the key informant interviews will be presented to members of a Federal Action Working Group (FAWG), comprising representatives from the various federal agencies and operating divisions of HHS who are actively involved in the HAI NAP. Presentations to the FAWG will provide continual and rapid-cycle feedback on evaluation findings. This feedback will accomplish several goals—namely, it will apprise the FAWG members of the study's formative findings, provide a medium to obtain feedback from the FAWG regarding the unique and aggregate impact of the national programs, and engage the FAWG in a discussion about gaps and future requirements.

Ultimately, the information gathered through this data collection effort will appear in annual reports, along with results of secondary data analyses. These reports will provide AHRQ and HHS with comprehensive, evaluative findings across and within individual patient safety programs as well as findings specific to the HAI NAP, and the extent to which the goals outlined in the plan have been achieved.

3. Use of Improved Information Technology

All semi-structured interviews will be conducted by telephone.

4. Efforts to Identify Duplication

The semi-structured interviews will collect information from HAI NAP stakeholders to identify key findings and lessons learned from the implementation of HAI NAP and related QI initiatives.

No other data collection effort has been conducted for this purpose. AHRQ is aware of one other HHS evaluation that is collecting data regarding gaps in the HAI knowledge base; IMPAQ International and its partner the RAND Corporation support AHRQ in its "Synthesis of AHRQ-Funded HAI Projects: Fiscal Year (FY) 2007 – 2010." Although the subject of study is HAI prevention, this project differs from the HAI NAP evaluation in several ways. First, the Synthesis study looks only at projects funded by one agency (AHRQ). The HAI NAP evaluation looks across HHS agencies and encompasses activities with non-government partners (e.g., HRET). Secondly, the large majority of projects included in the Synthesis are smaller-scale interventions and research projects, not the large, national QI initiatives that are the focus of this evaluation.

Additionally, the Synthesis study examines the set of projects funded in FY 2007 through FY 2010. By contrast, this longitudinal evaluation of HAI NAP focuses on more recent and current events and developments in HAI prevention. Finally, the aim of the two projects differs: the goal of the Synthesis study is to identify and disseminate findings from the AHRQ-funded projects, as well as identify opportunities for AHRQ to fund future HAI prevention research. The goals of the HAI NAP evaluation are to continue and expand on an iterative, longitudinal, comprehensive program evaluation of HAI NAP, including activities and evaluations conducted by individual operational divisions consisting of AHRQ, Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and the Office of the Secretary (OS). While the two projects may share a common goal (preventing and eliminating HAIs), their scope and objectives differ such that these two inquiries remain complementary but distinct.

5. Involvement of Small Entities

This information collection does not impact small entities.

6. Consequences if Information Collected Less Frequently

Because this evaluation includes both formative and summative research, it is necessary to collect information annually for two years. If the information were collected less frequently, HHS would not be able to obtain timely input and recommendations that can be used to re-shape the HAI NAP initiative as it is being implemented.

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 April 23rd, 2014 on Page 22683 for 60 days (see Attachment E). No comments were received.

8.b. Outside Consultations

The interview protocols AHRQ plans to use are based on earlier versions that were pretested with AHRQ officials and selected other stakeholders during the previous phase of this evaluation. The pretests indicated that the interview could be completed in approximately 60 minutes, and pretest respondents reported no difficulty interpreting or responding to the questions. The revised protocols have been updated to cover additional healthcare setting (Ambulatory Surgical Centers (ASCs), End Stage Renal Disease (ESRDs) and Long Term Care (LTC) facilities and an additional patient safety initiative), but the language and the nature of the questions are sufficiently similar to the previous versions to conclude that the original pretest results still hold true.

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, Insight Policy Research, Inc. and its subcontractors, IMPAQ International and 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 QI programs. Identifiable information will not be shared with anyone outside of AHRQ, Insight Policy Research, 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.

Insight, IMPAQ, and RAND Corporation will use a secure SharePoint site to exchange personal identifying information, and all electronic files will 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 personal information.

Interviewers will ask each respondent to provide verbal consent for participating in the interview and to have it recorded for transcription purposes. The language for verbal consent can be found on pages 1and 2 of the interview protocols (Attachments A, B, C and D).
Each interview protocol also explains the purpose of the overall project and the role of the interview, how respondents' privacy will be maintained, and how the information shared during interviews will be used. This information will be read aloud to each respondent prior to the interview.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation. The total burden hours are estimated to be 138.2, which covers two years of interviews. The exhibits below indicate annualized burden hours in one year.

In-Depth Interviews with Stakeholders: AHRQ plans to conduct 33 semi-structured interviews each year for two years, totaling 66 semi-structured interviews during the course of the evaluation. These interviews will be conducted with key HAI NAP stakeholders with expertise in one or more of the four targeted healthcare settings. These healthcare settings include: acute care hospital settings, ambulatory surgical centers, ESRD facilities, and long term care settings. Respondents will be interviewed by telephone. Participant recruitment should take no longer than five minutes. Scheduling will take place through email (Attachments F and G) and will include an attached letter of support from AHRQ (Attachment H). Interviews will last up to one hour.

Exhibit 1. Estimated annualized burden hours

Data Collection Activity	Number of respondents per year	Number of responses per respondent	Hours per response	Total burden hours
In-depth Interviews with HAI NAP Stakeholders with expertise pertaining to:				
• Acute Care Hospital Settings	9	1	1	9
• Ambulatory Surgical Centers	8	1	1	8
• ESRD facilities	8	1	1	8
• Long Term Care Settings	8	1	1	8
Total	**33**	**1**	**1**	**33**

Exhibit 2. Estimated annualized cost burden

Data Collection Activity	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
In-depth Interviews with external stakeholders:				
• Acute Care Hospital Settings	9	9	$34.33*	$309.00
• Ambulatory Surgical Centers	8	8	$34.33*	$275.00
• ESRD facilities	8	8	$34.33*	$275.00
• Long Term Care Settings	8	8	$34.33*	$275.00
Total	33	na	na	$1,134.00

* Based upon May 2012 National Occupational Employment and Wage Estimates for Epidemiologists, retrieved from http://www.bls.gov/oes/current/oes_nat.htm#19-0000 on February 20, 2014.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Costs to the Government

Exhibit 3 shows the total and annualized cost of this information collection. The cost associated with the design and data collection of the semi-structured interviews is estimated to be $697,400 over the course of two years covered by this information collection request. Exhibit 4 shows the estimated annualized cost to AHRQ for project oversight.

Exhibit 3. Estimated Annualized Cost

Cost Component	Total Cost*	Annualized Cost
Develop Interview Protocols and Interview Participant List	$12,000	$8,000
Data Collection Activities	$520,800	$260,400
Report Development	$164,600	$82,300
Total	$697,400	$350,700

*Includes two years. Assumes reduced cost for development of interview protocols in Year 2.

Exhibit 4: Estimated annualized cost to AHRQ for project oversight

Project Officer GS 15 Step 10 $ 157,100	5%	$ 7,855
Measurement Analyst GS 13 Step 3 $ 95,919	5%	$ 4,796
Total		$ 12,651

Annual salaries based on 2014 OPM Pay Schedule for Washington/DC area: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf

15. Changes in Hour Burden

This is a new data collection effort and does not build on a previous submission.

16. Time Schedule, Publication and Analysis Plans

16a. Time Schedule

The tentative time schedule for data collection activities is provided in Exhibit 5. These dates may change depending on the length of time needed for OMB review.

Exhibit 5. Data Collection Schedule

Activity	Time Schedule
Develop interview protocols	December 2013 – January 2014
Receive OMB approval	September 2014
Interviews scheduled and conducted – Year 2	September – November 2014
Interview Data Analysis – Year 2	December 2014 – February 2015
Interview Findings Report and FAWG Presentation – Year 2	May – June 2015
Annual Report to AHRQ – Year 2	August 2015
Interviews scheduled and conducted – Year 3	September – November 2015
Interview Data Analysis – Year 3	December 2015 – February 2016
Interview Findings Report and FAWG Presentation – Year 3	May – June 2016
Annual Report to AHRQ – Year 3	August 2016

16b. Publication Plans

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

16c. Analysis Plan

Using NVivo qualitative data analysis software, the research team will code interview notes for key themes. Insight will develop a preliminary coding tree based on project research questions which will be revised to include additional nodes as necessary through iterative rounds of coding. All coders will be trained and inter-rater reliability will be maintained through an ongoing review process. Insight, IMPAQ, and RAND will also conduct content analyses to identify trends, common themes, and differences among the programs, as well as potential synergies and opportunities for future collaboration. Based on the results from the NVivo-enabled analysis, the team will present a report of the findings and themes to AHRQ.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: Interview Protocol for Acute Care Settings
Attachment B: Interview Protocol for Ambulatory Surgical Centers
Attachment C: Interview Protocol for End Stage Renal Disease Facilities
Attachment D: Interview Protocol for Long Term Care Settings
Attachment E: Federal Register Notice
Attachment F: Recruitment Email
Attachment G: Confirmation Email
Attachment H: AHRQ Letter