

SUPPORTING STATEMENT

Part A

Reducing Healthcare Associated Infections (HAI): Barriers and Challenges to
Improving Patient Safety and Infection Prevention at the Point of Care

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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 Attachment A), 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.

Since 1999, AHRQ has funded research focused on preventing and mitigating Healthcare Associated Infections (HAI) and disseminating this information to clinicians, healthcare organizations, and the public. The goal of the HAI project is to identify the barriers and challenges to reducing infections associated with the process of care. As indicated by the World Health Organization (WHO) World Alliance for Patient Safety, HAIs are a major risk to patient safety worldwide. In the U.S., infectious diseases are the third most common cause of death with an increasing majority of these deaths due to HAIs. One critical area of research for HAIs is the challenges and barriers to improving patient safety at the point of care in hospitals.¹²³⁴ The objective of the HAI project is to facilitate the sharing of information by clinicians and hospital staff on their opinions and experiences with improving patient safety and preventing and mitigating HAIs. In addition, the HAI project will gather exploratory information at the point of care on current hospital patient safety and infection prevention activities, tools, and training.

For the HAI project, AHRQ has used the Accelerating Change and Transformation in Organizations and Networks (ACTION) which is a program of task order contracts to support field-based

Pittet D, Donaldson L. 2006. Challenging the world: patient safety and health care-associated infection. *International Journal for Quality in Health Care*, 18(1), 4-8¹

².Burke J. 2003. Infection control – a problem for patient safety. *The New England Journal of Medicine*, 348, 651-656²

Leape L, Berwick D. 2005. Five years after to err is human – what have we learned? *The Journal of the American Medical Association*, 293, 2384-2390³

Auerbach A, Landefeld C, Shojania K. 2007. The tension between needing to improve care and knowing how to do it. *The New England Journal of Medicine*, 357, 608-613⁴

partnerships for conducting applied research. In order to understand the challenges of infection prevention and patient safety at the point of care, AHRQ has funded five ACTION partnerships, each of which has experience with implementing interventions and tools to improve the processes of care and the safety of health care delivery. The goal of the HAI project is to obtain information on the barriers and challenges of infection prevention in order to assist other hospitals with improving patient safety. These ACTION partnerships will be working collaboratively with 34 hospitals, ranging from large academic teaching hospitals to community hospitals, in 11 states. At each of these hospitals, the ACTION partnerships are focused on understanding and assessing the barriers and challenges to improving patient safety and reducing HAIs at the point of care. This information will be used by the ACTION partnerships to develop case studies focusing on the hospitals' activities and efforts to improve patient safety and reduce infections. The case studies will be made publicly available in order to assist other hospitals with safety improvements and infection prevention.

In order to facilitate collaboration and information sharing among the HAI Project partners, AHRQ has funded an assessment program. The objective of the HAI assessment contract is to facilitate the collection of infection information across the HAI project hospitals, including providing technical assistance and support for the administration of the common data collection instruments. In addition through reports and manuscripts, the assessment contractor will assist AHRQ in sharing the lessons learned about the barriers and challenges to improving infection safety at the point of care.

In order to assist the ACTION partnerships, common data collection instruments were developed which focus on three areas: (1) summarizing HAI information collection and reporting by the hospitals; (2) gathering the perspectives and opinions of hospital staff about patient safety and infection prevention, particularly the barriers and challenges; and (3) cataloguing hospital patient safety and infection training, activities and tools. Through these instruments, information will be solicited on opinions of the usefulness of current HAI information collection activities and the identification of barriers, challenges, and successes in infection prevention. The data collection instruments will be administered at each hospital. Respondents include both direct patient care providers such as nurses, doctors and therapists; and administrative personnel such as hospital administrators, patient safety officers, and risk managers. The proposed paper-based data collection instruments (See Attachments B, C, D) are:

HAI Information Collection and Reporting Summary

Patient Safety and Infection Prevention Catalogue

Patient Safety and Infection Prevention Assessment

The three proposed common data collection instruments will provide critical information that will help AHRQ, other federal partners, and hospitals better understand the challenges and barriers to improving infection safety (See Attachment E). Each ACTION partnership will be responsible for collecting and tabulating the responses for their own partnership. The information collected through the proposed instruments will be used by each ACTION partnership to help inform their efforts in patient safety and infection prevention and mitigation. While each partnership can analyze the individual results, the information will not be reported out individually. Each ACTION partnership will aggregate information on the challenges and barriers to reducing HAIs for their case study which will be published and disseminated at the end of the project. Further, the assessment program will gather the aggregate information from the five ACTION partnerships for synthesis and analysis and assemble and report on an overall assessment of lessons learned assemble and report on an overall assessment of

lessons learned from the HAI Project case studies for healthcare organizations interested in learning about the barriers and challenges to improving infection safety.

2. Purpose and Use of Information

As highlighted in the April 16, 2008, testimony by HHS to the House Oversight and Reform Committee, HHS and AHRQ recognize that more work and leadership is necessary to enhance infection safety. The purpose of this proposed information collection is to advance patient safety by facilitating clinician and hospital staff insights and perceptions on the challenges of and barriers to improving infection safety at the point of care. Through investment in this project, AHRQ is furthering its' mission to support research on improving healthcare quality and safety. AHRQ will synthesize and disseminate the case studies to hospitals and other health care organizations in order to share information on the challenges and barriers in infection safety and provide some insights on potential opportunities for infection safety improvements.

3. Use of Improved Information Technology

Because this is a one time limited project, investments in improved technology are not planned, nor would they be cost effective.

4. Efforts to Identify Duplication

There is no similar information currently available on the hospital staff perspectives on patient safety and infection mitigation activities at the point of care. While there were no formal efforts to identify duplication, program staff has discussed the HAI project goals and the proposed common data collection instruments with colleagues at the Centers for Disease Control and Prevention and infection control professionals within the ACTION partnerships. This study is not duplicative of another information collection.

5. Involvement of Small Entities

The instruments are designed to minimize burden on all respondents and will not have a significant effect on small businesses. However, the collection of information under consideration in this supporting statement does not include small businesses as part of the respondent universe.

6. Consequences if Information Collected Less Frequently

This request is for a one-time study.

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 3rd, 2008 for 60 days (See attachment F). No comments were received.

8.b. Outside Consultations

During the development HAI project common data instruments, AHRQ was in contact with infection prevention colleagues at CDC. After the funding of the five ACTION partnerships, AHRQ has been holding monthly teleconferences. The partnerships have been involved in all of the stages of the instrument development including input on the objectives of the information collection, the proposed respondents, suggestion and revision of proposed questions, and format and length of the instruments. There are no unresolved issues with CDC or the ACTION partnerships.

9. Payments/Gifts to Respondents

There are no payments or gifts to 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. 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). Each of the 34 participating hospitals will be responsible for securing clearance from their own Institutional Review Boards for their activities as part of the HAI project, including administration of the proposed data collection instruments. The data collection will be conducted in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164, and with the Protection of Human Subjects regulations, 45 CFR Part 46. Identifiable data for provider organizations and individuals will only be used for the above-stated purposes and will be kept confidential.

11. Questions of a Sensitive Nature

No questions of a sensitive nature are anticipated under this clearance.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated burden hours to the respondents for providing all of the data needed to meet the study's objectives. For both the HAI Information Collection and Reporting Summary and the Patient Safety and Infection Prevention Catalogue instruments, the number of respondents is based on an estimate of one respondent at each of the 34 hospitals. For the Patient Safety and Infection Prevention Assessment, the number of respondents is based on an estimate of 250 respondents from the five ACTION Partnerships' participating hospitals.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to participate in this project. The total annualized cost burden is estimated to be \$32,715.93.

Exhibit 1. Estimated annualized burden hours

Data Collection Instrument	Number of Respondents	Number of responses per respondent	Hours per response	Total burden hours
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HAI Information Collection and Reporting Summary	34	1	45/60	25.50
Patient Safety and Infection Prevention Catalogue	34	1	1.00	34.00
Patient Safety and Infection Prevention Assessment	5	250	30/60	625.00
Total	34	na	na	684.50

Exhibit 2. Estimated annualized cost burden

Data Collection Instrument	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
HAI Information Collection and Reporting Summary	34	25.50	\$28.99	\$739.25
Patient Safety and Infection Prevention Catalogue	34	34.00	\$39.02	\$1,326.68
Patient Safety and Infection Prevention Assessment	5	625.00	\$49.04	\$30,650
Total	34	684.50	na	\$32,715.93

* Based on the planned respondents, the average hourly rates are the average of the mean hourly wage estimates for the following occupational groups: epidemiologists, health care support aides, medical and health services managers, pharmacists, physicians, physician assistants, registered nurses, and respiratory therapists. The wage estimates are derived from the National Occupational Employment and Wage Estimates, Bureau of Labor Statistics, May 2006

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. There will be no additional costs for capital equipment, software, computer services, etc.

14. Estimates of Annualized Cost to the Government

This data collection effort is one aspect of a larger effort focused on reducing healthcare associated infections. The cost of developing the data collection instruments by a one-time statistical support task order is \$25,000. The costs of implementing the data collection instruments and analyzing and publishing the results are \$108,650 annually. Finally, the estimated costs for federal staff time for supporting the common data collection efforts are \$24,000 annually. Thus, the estimated annual cost to the federal government is \$145,150.

15. Changes in Hour Burden

This is a new data collection.

16. Time Schedule, Publication and Analysis Plans

As discussed above, the collection of the information will not be individually tabulated or reported. The aggregate information will be included in the case studies from the five ACTION partnerships and the assessment program contact which will be published at the end of the HAI project.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: AHRQ's Authorizing Legislation

Attachment B: HAI Information Collection and Reporting Summary

Attachment C: Patient Safety and Infection Prevention Catalogue

Attachment D: Patient Safety and Infection Prevention Assessment

Attachment E: HAI Project – Summary of Common Data Collection Instruments

Attachment F: 60 Day Federal Register Notice