SUPPORTING STATEMENT

Part A

Reductions of Infection Caused by Carbapenem Resistant Enterobacteriaceae (KPC) Producing Organisms through the Application of Recently Developed CDC/HICPAC Recommendations

Version *2/26/2010*

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 (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.

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. On March 20, 2009, the Centers for Disease Control (CDC) and the Healthcare Infections Control Practices Advisory Committee (HICPAC) developed infection control (IC) guidance for Klebsiella pneumonia carbapenemase-producing (KPC) isolates, as they have been rapidly emerging as a significant challenge in healthcare settings (see Attachment B). The danger of these bacteria is that they are resistant to carbapenem (a class of beta-lactam antibiotics with a broad spectrum of antibacterial activity) and cannot be treated by the most commonly prescribed antibiotics. Limited treatment options mean that infections caused by carbapenem resistant bacteria result in substantial mortality and morbidity.

The CDC and HICPAC recommendations draw on infection control strategies which have been applied to these pathogens in other settings, and other evidence based strategies in infection control. There has been little research, however, on the implementation of control strategies to prevent the spread of these KPC infections. The goal of this project is to understand how these recommendations can best be implemented

and how effective these recommendations will be in practice. This research will advance private and public efforts to improve health care quality by improving measures to control the spread of a dangerous organism. This research will also provide data for the development of an implementation toolkit that hospitals can use to prevent the spread of carbapenem resistant bacteria. The toolkit may include the following types of resources: general information about the implementation of evidenced-based clinical practices, resource materials, and tools and methods that users can adopt to conduct point prevalence surveys, protocols and tools that users can adopt to specify when active KPC surveillance is needed, and resources for approaching the problem as a team-based quality-improvement effort. OMB clearance will be sought for this toolkit once it is developed.

This study is being conducted by AHRQ through its contractor, Boston University, pursuant to AHRQ's statutory authority to conduct and support research 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

This project will include the following data collections from the intensive care unit (ICU) staff within each of three participating hospitals:

1) Pre-intervention focus groups will be conducted separately with managers and staff (see Attachments C and D). The purpose of these focus groups is to identify potential problems in the implementation that can be addressed through various means (e.g., additional education, other changes in process). Another purpose is to understand the existing approach to quality improvement, the connection(s) between overall approach to quality improvement and to KPC infection control practices, current practices at the hospital of quality reporting and accountability, and constraints and obstacles to quality improvement as seen in their roles. Staff members identified for the focus groups will be those with the most first-hand knowledge of existing quality improvement efforts, and KPC infection control practices.

2) Clinical staff survey (see Attachments E and F). Factors identified in the pre-intervention focus groups will be used to inform the development of a self-administered survey of staff knowledge of and attitudes toward KPC surveillance and infection control procedures. Respondents will be health care workers on the units where these new guidelines have been implemented. Findings from the survey will be used to assess barriers perceived by the staff, potential differences across units, and potential differences by employee/occupational group.

3) Post-intervention focus groups (6 months after implementation of new KPC IC guidelines) will be conducted separately with managers and staff (see Attachments G and H). The purpose of these focus groups is to identify actual problems experienced in the initial implementation and possible measures to address, and to identify

successful practices to include in a toolkit that hospitals can use to implement the CDC and HICPAC recommendations.

In addition to developing a toolkit, AHRQ plans to disseminate the lessons learned from this project about how hospitals can best implement the CDC guidance for KPC screening and infection control, in order to inform efforts to change practice in this area.

3. Use of Improved Information Technology

The collection of information does not use information technology; the small numbers of staff interviewed and surveyed do not merit such methods.

4. Efforts to Identify Duplication

A literature review produced limited data regarding the impact of control strategies on preventing horizontal transmission of KPC resistant bacteria in hospital settings. Findings that exist suggest that active surveillance coupled with aggressive adherence to hand hygiene, isolation and barrier precautions, patient and staff cohorting and perhaps increased attention to environmental cleaning may result in a reduction in KPC bacterial infections, including in hospitals with an endemic KPC presence. Moreover, none of these studies explicitly addressed the process of implementing new protocols in this area.

The involvement of the CDC, in the person of Dr. Arjun Srinivasan, is an additional way to ensure that we identify any duplication with other studies. The CDC has been integrally involved in this issue from its identification through the development of the guidelines, and in its contacts with other stakeholders who have interest in this topic will learn of any other research efforts in this area.

5. Involvement of Small Entities

The collection of information does not impact small businesses or other small entities.

6. Consequences if Information Collected Less Frequently

This is a one-time 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), a notice has been prepared for publication in the Federal Register on March 31st, 2010. No comments were received.

8.b. Outside Consultations

Throughout this project, the study team has been and will continue to be in touch with our contact at CDC in order to assure that we are collecting the necessary data and not

collecting more data than are necessary in order to answer the study questions. To our knowledge, there are no unresolved issues.

9. Payments/Gifts to Respondents

There will be no 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.

Information that can directly identify the respondent, such as position at the hospital, will be collected during the interviews.

The focus groups will take place in conference rooms on-site, and informed consent will be obtained. Detailed notes will be taken and will also be audio-recorded as a back-up to the notes. All focus group data will be taken off-site immediately following each site visit, and will be coded and securely stored at the principal investigator's institution. The clinical staff survey will be distributed to employees by the primary contact at the site, and will include a mailing envelope so that each respondent can mail it directly back to the research team. However, the survey forms themselves will not contain respondent names, nor will the research team be able to link specific survey responses with any specific employees.

Both focus group and survey data will be kept in secure files and computer databases. Access will be strictly limited to project staff. Appropriate encryption methods will be used for the transmission of the data. Study records will be kept the required length of time, and then destroyed. When they are destroyed, paper documents will be shredded and electronic records will be expunged.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature being asked of participants.

12. Estimates of Annualized Burden Hours and Costs

The estimated annualized burden hours for respondents to participate in this two year research project are presented in Exhibit 1. Pre-intervention focus groups with clinical staff will be conducted with 18 staff members (an average of 9 per year for 2 years) from each of the 3 participating hospitals and will take about 1 hour. Pre-intervention focus groups with also be conducted with 2 managers (an average of 1 per year for 2 years) from each hospital and will take about an hour to complete.

The clinical staff survey will be administered to 20 clinical staff (an average of 10 per year for 2 years) from each hospital and will take 15 minutes to complete.

Finally, respondents from the pre-intervention focus groups will participate in post-intervention focus groups approximately four months after the initiation of the intervention. They will not last more than an hour each. The total annualized burden hours are estimated to be 68 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annualized cost burden is estimated to be $3,108.

Exhibit 1. Estimated annualized burden hours

Data Collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Pre-intervention focus groups with clinical staff*	3	9	1	27
Pre-intervention focus groups with managers*	3	1	1	3
Clinical staff survey	3	10	15/60	8
Post-intervention focus groups with clinical staff*	3	9	1	27
Post-intervention focus groups with managers*	3	1	1	3
Total	15	n/a	n/a	68

* Individuals that cannot attend the focus groups will be interviewed one-on-one. Clinical staff includes IC leaders, QI team members and unit staff. Managers include the chief nursing officer and chief medical officer.

Exhibit 2. Estimated annualized cost burden

Data Collection	Number of Respondents	Total burden hours	Average hourly wage rate	Total cost burden
Pre-intervention focus groups with clinical staff	3	27	$36.73*	$992
Pre-intervention focus groups with managers	3	3	$138.38**	$415
Clinical staff survey	3	8	$36.73*	$294
Post-intervention focus groups with clinical staff	3	27	$36.73*	$992
Post-intervention focus groups with managers	3	3	$138.38**	$415
Total	15	68	na	$3,108

*Based upon the mean hourly wage for Registered Nurses in Nassau and Suffolk County, NY as reported by the Bureau of Labor Statistics in May 2008.

** Based on report of a private survey of HR departments conducted in November 2009 in New York, NY published by http://www.salary.com; 3 chief nursing officers at $101.14/hr and 3 chief medical officers at $175.61/hour.

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 annualized and total cost to the federal government for this two year research project. Project Management includes activities related to coordination between Boston University staff, contracted staff at Montefiore and monthly phone calls with the task order officer. Project development covers steps taken to revise the research plan and begin implementation. The total cost is estimated to be $500,001.

Exhibit 3. Annualized and Total Cost to the Federal Government

Cost Component	Annualized Cost	Total Cost
Project Management	$3,096	$6,192
Project Development	$1,355	$2,710
Data Collection Activities	$11,907	$23,814
Travel	$2,500	$5,000
Sub-Contract with Montefiore	$200,740	$401,480
Overhead	$23,754	$47,507
Total	$250,001	$500,001

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

It is the intention of the study team to submit results of this project for presentation at national meetings potentially including SHEA, IDSA, APIC, ASM and Society of Critical Care national meetings, as well as, to submit the results in manuscript form for publication. Candidate journals include JAMA, ICHE, American Journal of Infection Control, Journal of Critical Care, Clinical Infectious Diseases and the Journal of Microbiology. In addition, data will be presented at national meetings of professional societies in which the co-PI, the Director of Infection Control and the Director of the Microbiology Laboratory are involved.

Furthermore, the co-PI intends to offer a presentation of the results in lecture form and via workshops at the Greater New York Hospital Association Infection Control Committee.

A timeline of this project can be seen in Exhibit 4.

Exhibit 4: Project Timeline

Pre-intervention interviews	Month 9
Field staff surveys to assess barriers	Month 12
Post Intervention interviews	Month 13
Conduct Preliminary Data Analysis	Month 12, 15 and 18
Submit a draft implementation tool kit to TOO and TA	Month 15
Submit final implementation tool kit to TOO and TA	Month 15
Submit at least one peer-reviewed manuscript reporting on the research activities to TOO and TA	Month 20
Submit at manuscript to at least one revised manuscript within two weeks of receiving AHRQ's and CDC's comments	Month 15, Month 24
Submit to TOO and TA a draft final report of all activities undertaken and products produced	Month 22
Submit to TOO and TA a final report within 2 weeks of receiving AHRQ's comments	Month 23

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: Infection prevention and control guidance for carbapenem-resistant *Enterobacteriaceae* (or carbapenemase-producing *Enterobacteriaceae*) in acute care facilities – CDC and the Healthcare Infection Control Practices Advisory Committee

Attachment C: Pre-intervention focus group guide with clinical staff

Attachment D: Pre-intervention focus group guide with managers

Attachment E: Cover letter for employee survey

Attachment F: Placeholder for clinical staff questionnaire

Attachment G: Placeholder for post-intervention focus group guide with clinical staff

Attachment H: Placeholder for post-intervention focus group guide with managers

Attachment I: Federal Register Notice