SUPPORTING STATEMENT

Part A

"Reduction of *Clostridium difficile* Infections in a Regional Collaborative of Inpatient Healthcare Settings through Implementation of Antimicrobial Stewardship"

Version: June 15th, 2010

Agency for Healthcare Research and Quality (AHRQ)

Section A: Justification

1. Circumstances of Information Collection

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, safety, efficiency, and effectiveness of health services for all Americans, 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;
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. Alarmingly, 70% of HAIs are due to bacteria that are resistant to commonly used antibiotics (Huang 2007). This project is designed to evaluate the implementation of a program to reduce *Clostridium difficile* Infection (CDI) in acute care facilities via Antimicrobial Stewardship Programs (ASPs). Working with an already existing collaborative network of acute care facilities in New York that currently collect and report mandatory data on CDI rates and practice strict environmental controls, this project will go beyond environmental strategies in order to attempt to reduce rates of CDI. ASPs seek to promote the appropriate use of antimicrobials via several methods including selecting the appropriate dose, duration and route of administration of antibiotics. Using antibiotics appropriately can potentially improve efficacy, reduce costs, and keep drug-related adverse events to a minimum. The project is a partnership with Boston University School of Public Health (BUSPH), Montefiore Medical Center (MMC), and Greater New York Hospital Association (GNYHA).

The overall aims of the research are to evaluate the implementation of ASPs specific to CDI at 11 participating hospitals (6 intervention sites and 5 control sites) and to create a draft ASP Toolkit. More specifically, the pilot study has been designed to provide information to meet the following objectives:

1. Identify the antimicrobial stewardship activities, both currently in place and those yet to be identified, specific to each site's individual needs, to optimize antimicrobial prescribing practices to reduce CDI
2. Assess prescriber perceptions related to ASP
3. Assess barriers and facilitators to ASP implementation
4. Develop a draft ASP Toolkit to help hospitals optimize their antimicrobial prescribing practices to reduce CDI.

New York (NY) State currently requires ongoing reporting of C-*difficile* data for both clinical and surveillance purposes. As part of an arrangement with NY State, the Greater New York Hospital Association (GNYHA) also collects and analyzes these data through their CDI collaborative. These data include tracking baseline rates of CDI, including pharmacy data, data related to rates of CDI, patient outcomes, and data about infection control practices (such as hand-washing and other environmental controls to prevent spread of infection). The data are collected on standardized forms that are required by both the state and the Centers for Disease Control and Prevention (CDC). The data collected at these participating hospitals are also collected at multiple hospitals nationwide as part of routine patient care and quality. In addition to new data collections initiated specifically for this project, this routine and ongoing mandatory data collection will serve as the project's knowledge base to allow the assessment of ASP programs.

From the GNYHA data, a three-month sample from the participating hospitals will be analyzed by Montefiore Medical Center (MMC) and GNYHA to obtain baseline information. This data will enable a comparison of the rates of CDI before and after the implementation of an ASP. The ASP will be implemented at 6 hospitals (intervention sites), while 5 other hospitals will serve as control sites and continue with their current practices, including conducting general infection and environmental controls. The specific elements of the ASPs will vary by hospital based on priorities and what is possible at each facility as well as by the antibiotic(s) targeted and will likely include some of the following:

- Formulary review/changes, restrictions and preauthorization of implicated antimicrobials
- Feedback to providers of implicated antimicrobials
- Processes and algorithms for empiric and streamlined regimens for specific diagnoses/pathogens
- Antibiotic order form with automatic stop orders
- Novel combinations of approaches to the use of stewardship staff or technology for stewardship (e.g., software, text paging, *pyxis* pharmacy machines for tracking and promoting proper antibiotic prescribing), and
- Educational efforts for clinicians and patients upon diagnosis

While the ongoing mandatory reporting will allow the measurement of change over time in CDI rates, it does not provide the necessary information that hospitals need about the challenges of implementing an ASP.

The following data collection activities will be implemented to achieve the objectives of this project:

1. Focus Groups with no more than 6 staff members at the intervention and control hospitals. The focus groups will be conducted one time only, by telephone and approximately 12 months after the implementation begins. The focus group guides will differ for the intervention and control sites, although there will be a common core of questions (see Attachments B and C). The common core of the focus group protocol will address the following: issues related to experience with the GNYHA environmental and infection control practices they have already been utilizing, strategies they have already used to reduce CDI and perceptions of those strategies, barriers to the environmental practices, particular areas of challenge, facilitators, and factors they think have contributed most to their institution's CDI rates. For the intervention sites, the goal of the focus group will be to understand in a more in-depth and qualitative manner, the experience of actually implementing the ASP. For the control sites, the goal will be to understand what they have learned in being a control

site and their plans moving forward. In addition to the core questions, questions will be asked about their interest in starting an ASP program, goals and priorities, expectations of facilitators and barriers and if and when they plan to implement an ASP.

2. ASP Questionnaire will be administered twice, pre and post implementation, to a sample of about 70 hospital staff at both the intervention and control hospitals. Intervention and control facilities will receive the same questionnaire (see Attachments D and E). The purpose of this survey is to measure the staff's perception of the scope of CDI at their facility, current antibiotic prescribing practices, the perceived need for ASPs and how these change over time. The questionnaire also collects some background information such as the staff members' primary work area, time worked in their profession and time worked in this hospital.

While the reporting/surveillance data required by the State of NY and the CDC can measure rates of CDI and compare how hospitals are doing, these data do not capture many important issues. A major reason that most hospitals do not have active, robust ASPs is because they can be incredibly challenging to develop, administer and manage. They require changes in prescribing practices and the active agreement and participation of physicians, pharmacists and administrators. Physicians and pharmacists may challenge restrictions in formularies and determine that a patient may not be given a specific antibiotic. But the severity of CDI makes it very important for hospitals to determine optimal methods for implementing successful ASPs. This pilot study will collect data to allow the comparison of perceptions and experiences between hospitals that do and do not attempt to implement an ASP. Reflections and feedback directly from prescribers and the ASP team using qualitative data collection procedures are needed to fully understand what it means or would mean to implement an ASP. The lessons learned from this project will be useful to health care facilities considering implementing an ASP, and will inform the development of a draft ASP Toolkit; this Toolkit will be evaluated in a separate project before being disseminated.

This study is being conducted by AHRQ through its contractor, BUSPH and their partners Montefiore Medical Center (MMC), and Greater New York Hospital Association (GNYHA), 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:
The purpose of this data collection is to achieve the objectives outlined in the previous section.

The data collected will assist the facilities and AHRQ in understanding the multiple occurrences, general medical practices, environmental issues and antimicrobial prescribing practices that result in CDI, as well as the perceptions of the problem and the challenges to implementing ASPs. The data collected will also assess and identify enabling factors and barriers to future implementation of ASPs. The collected data will enable AHRQ and CDC to determine whether it is feasible to use ASPs to reduce CDI and the challenges to anticipate in implementing these programs. Given the scale and scope of the healthcare issues related to CDI, it is critically important to have effective data from this pilot study to inform AHRQ, CDC and the draft ASP Toolkit.

3. Use of Improved Information Technology
For the focus groups, the interviews will be audio-recorded to allow for later transcription.

For the surveys, after discussion with GNYHA which has been working extensively with these hospitals their experience is that prescribers have a strong preference to respond to brief data collection activities in a short written survey. The survey will take about 7 minutes to complete and it is best handed out and administered at a provider/prescriber meeting, to achieve a reasonable response rate. The survey will be one page, two-sided.

4. Efforts to Identify Duplication:
The information being collected is unique to this study. There are many indications of increases in the severity of CDI, including increased complications and mortality, and several agencies have recently published guidelines around antimicrobial stewardship as a way to reduce CDI rates. In 2007, the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) published Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship[1]. The Association for Professionals in Infection Control and Epidemiology (APIC) also published a guide to eliminating CDI within healthcare settings[2].

To avoid duplication of data collection efforts internally and externally, the study's data collection instruments are designed to gather only the data needed using the most efficient methods available. AHRQ and CDC have reviewed the instruments and have confirmed that the data are not available from another source. The involvement of the CDC, in the person of Dr. Carolyn Gould who is an expert in this arena, also helps 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; in its contacts with other stakeholders who have an interest in this topic would learn of any other research efforts in this area. Further, a preliminary literature review was conducted and we are presently unaware of other duplicative research being conducted.

5. Involvement of Small Entities:
The proposed data collection does not involve small business entities.

6. Consequences if Information is Collected Less Frequently:
This is a one-time data collection activity.

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 July 23rd, 2010 for 60 days (see Attachment F). No comments were received.

8.b. Consultation Outside the Agency
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

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[1] Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. 2007, http://www.guideline.gov/summary/summary.aspx?doc_id=10482&nbr=5505&ss=6&xl=999

[2] Guide to the Elimination of *Clostridium difficile* in Healthcare Settings. An APIC (Association for Professionals in Infection Control & Epidemiology, Inc) 2008 guide. http://www.apic.org/AM/Template.cfm?Section=Search&Template=/Search/SearchDisplay.cfm

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

9. Payments to Respondents:
No payments will be made 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.

Surveys will be anonymous and focus group notes will not contain names of participates. All results will only be reported in the aggregate.

No protected health information will be collected. We will inform participants that we will keep their responses private to the extent permitted by law. The data files will be secured consistent with Boston University IRB regulations. All project staff have completed research and human subjects' certification from National Institutes of Health (NIH), Boston University Medical Center, or Montefiore Medical Center.

Both the focus group and survey data will be kept in secure files and computer databases. Access will be strictly limited to project staff. 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:
Questions of a sensitive nature are not being asked in the proposed data collection.

12. Estimates of Annualized Burden Hours and Costs
Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this pilot study. Focus Groups will be conducted post-intervention with approximately 6 staff members at each of the 11 study sites (5 control sites and 6 intervention sites) for a total of 66 individuals, approximately 36 at the intervention sites and approximately 30 at the control sites. The control site focus groups will last approximately 45 minutes. The intervention site focus groups will last approximately 60 minutes.

The ASP questionnaire will be administered twice, pre and post-intervention, to about 70 staff members at each of the 11 participating sites and takes about 7 minutes to complete. The total annualized burden is estimated to be 239 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this study. The total cost burden is estimated to be $15,037.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of hospitals	Number of responses per hospital	Hours per response	Total burden hours
Focus groups at intervention sites	6	6	1	36

Focus groups at control sites	5	6	45/60	23
ASP Questionnaire	11	140	7/60	180
Total	22	n/a	n/a	239

Exhibit 2. Estimated annualized cost burden

Form Name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Focus groups at intervention sites	6	36	$57.38	$2,066
Focus groups at control sites	5	23	$57.38	$1,320
ASP Questionnaire	11	180	$64.73	$11,651
Total	22	237	n/a	$15,037

*The hourly wage for the focus groups is based upon the mean of the average wages for physicians ($79.33), pharmacists ($50.13), and medical and health services managers ($42.67). The hourly wage for the surveys is based upon the average wages for physicians ($79.33) and pharmacists ($50.13). These data come from the May 2008 National Occupational Employment and Wage Estimates, United States,- U.S. Bureau of Labor Statistics Division of Occupational Employment Statistics, May 2008, National Occupational Employment and Wage Estimates, http://www.bls.gov/oes/2008/may/oes_nat.htm#b11-0000.

13. Estimates of Annual 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 Costs

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 BUSPH staff, contracted staff at MMC and GNYHA, 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 $999,995.

Exhibit 3. Estimated Total and Annualized Cost to the Government

Cost Component	**Annualized Cost**	**Total Cost**
Project Management	$ 28,315	$ 56,629
Project Development	$ 84,944	$169,400
Data Collection and Analysis	$169,888	$339,776
Technical Assistance and Consultation	$60,750	$121,500
Confirmatory lab testing	$20,000	$ 40,000
Travel	$7,500	$ 15,000
Project Supplies and materials	$2,450	$ 4,900
Overhead	$126,395	$252,790
Total	**$499,998**	**$999,995**

15. Changes in Hour Burden:

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plan

Tabulations and statistical analyses
For the survey data, standard empirical methods will be used. All data will be entered into a database at BUSPH using the PASW 18.0 statistical software package. After data are collected, they will be double entered to ensure accuracy. Once the database is completed, we will perform standard statistical analyses to compare the intervention and control group sites and to examine change at each hospital individually from pre-implementation to post-implementation. Given the small number of sites, we will conduct simple analyses. Descriptive analyses to describe each site will include frequencies, means and mode. The comparative analyses will include Pearson's chi-square test for independence for categorical variables and t-tests to assess whether the means of the continuous variables are statistically different from each other.

The focus group data will be analyzed using standard qualitative analytic methods. The data will be transcribed into text files for data analysis and entered into the HyperRESEARCH qualitative data management program for analysis. The analysis will take a thematic approach, using the Constant Comparative Method[1,2]. According to this method, conceptual categories are developed from early responses. These initial conceptual categories are then applied to new data, and the categories are revised to reflect the new data. Issues of validity and reliability will be handled as follows. Two members of the project team will independently code the initial data and meet to identify similarities and differences. Discrepancies will be resolved and coding rules modified through discussions, which will validate the emerging coding scheme through a process of discussion and consensus-building. This process will be repeated until all transcripts are coded. Reports associated with the major themes will then be constructed and we will compare and contrast instances within and across themes, and more specifically examine the data to identify the strongest themes.

An important part of the focus group analysis will be to help identify additional education or other issues that will be important to identify issues that may arise in the implementation of these practices and to build the dissemination plan.

The limitations of these data are the same as that from any statistical analysis in which one is taking only a sample of data over a circumscribed time period. Because there will be some discussion at the sites about the use of the new system prior to implementation, it is possible that there may be a Hawthorne affect during the pre-implementation period. In addition, we recognize that this sample cannot be generalized to all facilities.

Time Schedule and Publication Plan
The outcome of this pilot study will be a draft toolkit and a dissemination plan for the research findings of the evaluation component of the pilot study. Research findings may include the following: general information about the implementation of ASPs; detailed written accounts of each individual intervention and control site; a published journal article about the pilot study, including both the process itself and whether or not CDI rates declined at the intervention sites, in a health services research or quality improvement-focused journal. It is also the intention of the study team to submit results of this project for presentation at national meetings, such as SHEA and IDSA. We also expect to present at AHRQ's annual ACTION meeting. Finally, the materials from this project will be used in ongoing quality improvement activities and workshops at the GNYHA. An estimated timeline for project activities can be seen in Exhibit 4.

Exhibit 4: Timetable for Data Collection, Analysis, and Publication
(Months are calculated from time of OMB approval)

Activity	Expected Month (s)
Initial focus groups and survey administration	0-1

Post-implementation focus groups and survey administration	12
Data analysis	1-16
Draft toolkit to TOO and TA	16
Draft dissemination plan to TOO and TA	16
Revised draft toolkit to TOO and TA	18
Final dissemination plan to TOO and TA	18
Publications and presentations	14-18
Final report to TOO and TA	18

17. Expiration Date Display Exemption
AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Healthcare Research and Quality Act of 1999

Attachment B: Focus Group Guide-Control Sites

Attachment C: Focus Group Guide- Intervention Sites

Attachment D: ASP Questionnaire – intervention sites

Attachment E: ASP Questionnaire – control sites

Attachment F: Federal Register Notice