SUPPORTING STATEMENT

Part A

Spreading Techniques to Radically Reduce Antibiotic Resistant Bacteria (Methicillin Resistant Staphylococcus aureus, or MRSA)

Version September 10 2010

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.

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, with Methicillin Resistant Staphylococcus aureus (MRSA) being the most rapidly growing, and among the most virulent, pathogens. Resistance is increasing rapidly in all types of hospitals (Huang 2007). Despite evidence that routinely applied, simple interventions do work, most hospitals have failed to make notable progress in reducing MRSA infections. Hospitals in some European countries and select US hospitals, however, have succeeded with impressive results.

Sites that have already achieved dramatic decreases in their MRSA infection rates have done so by implementing precautions to prevent transmission, using system redesign approaches. Further, many hospitals have successfully instituted isolation procedures for patients suspected to be MRSA carriers. In doing so, these hospitals have followed the broadly disseminated guidelines for hand hygiene and contact isolation precautions. This study is a follow up to a recent study implemented in 6 hospital systems in the Indianapolis metropolitan area that used a “MRSA intervention bundle” composed of active surveillance screening, contact isolation precautions, and increased hand hygiene.

Preliminary data from that initial study suggest a 60% decrease in MRSA rates in participating intensive care units (ICUs) (Doebbeling, B. *Redesigning Hospital Care for Quality and Efficiency : Applications of Positive Deviance and Lean in Reducing MRSA*. Presentation at AHRQ Annual Meeting, Rockville, MD. Sept 2009).

This project, a case study, will utilize the same guidelines and precautions that were applied in the original study, and will add an innovative feature that will use electronic medical record systems to improve identifying, communicating and tracking MRSA infections among healthcare systems. More specifically, this study has five aims:

1) Further test the "MRSA intervention bundle" from the original Indianapolis MRSA study, in additional units in the 4 original Indianapolis hospital systems and in an additional 3 hospital systems beyond Indianapolis;
2) Identify and monitor healthcare associated community onset (HACO) MRSA cases and controls who receive care in participating hospitals and affiliated settings, identify strategies to reduce HACO MRSA and demonstrate reduction of HACO MRSA;
3) Assess the relative effectiveness of various antibiotics in abatement or eradication of MRSA carriage in hospital patients;
4) Evaluate the effectiveness of the tested implementation strategies and innovations by applying information technology to enable consistent collection, sharing, analysis and reporting of data;
5) Disseminate findings and promote outreach to target audiences and other stakeholders.

While many secondary data are available for this study, Aims 1 and 2 involve primary data collection. Use of the intervention bundle requires that opinion leaders and front line workers be equipped with techniques used in the reorganization of healthcare delivery to improve health outcomes (Singhal and Greiner, 2007; IHI, 2005). These techniques will assist in identifying goals, implementing the interventions to meet local needs and measuring and feeding back progress on key processes and outcomes to staff and others.

The study also incorporates an additional informatics surveillance system to allow participating hospitals to more efficiently communicate, share and track MRSA infections. This system will save infection control and clinicians' time – for example, by electronically identifying patients with a known history of drug-resistant infections when they first contact a new institution.

This study is being conducted by AHRQ through its contractor, Indiana University and the Regenstrief Institute, 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 study is designed to further test the MRSA intervention bundle in non-ICU settings in hospital systems currently using the intervention bundle in their ICUs, as well as in additional ICUs in newly recruited hospital systems. The lessons learned will be useful to hospitals in further reducing their MRSA rates.

To achieve the aims of this project the following data collections will be implemented:

- Electronic medical record data (see Attachment B) on MRSA infections and screening rates will be collected from an existing and unique healthcare information exchange (Indiana Network for Patient Care or INPC) in the Indianapolis area, and the CDC's National Healthcare Safety Network (Aims 1-5). These data will be used to calculate the rate of MRSA Nosocomial Bloodstream Infections among individuals admitted to the project units at all seven participating hospital systems. These seven hospital systems include a total of 11 participating hospitals. Screening rates for MRSA at time of admission and at discharge or transfer will also be collected on project units. These data will be used to evaluate the impact of the intervention on infection rates within the participating hospital units.

- Observational data on hand washing (see Attachment C) will be collected for at least three hours each week per hospital (Aims 1, 2, and 4). Observations will be conducted in 10 minute blocks per patient selected. In total, 18 observations per hospital will be conducted each week. Hand hygiene rates will be based on observing the number of opportunities for hand hygiene and the number of actual times completing hand hygiene. Hand hygiene opportunities include when a provider enters a patient room, moves from a contaminated site to a clean site, helps with an invasive procedure, or leaves a patient room.

- A Social Network Analysis (SNA) Questionnaire (see Attachment D), will be administered twice, pretest and posttest, to about 75 healthcare workers with direct patient care on project units (Aims 1, 4, and 5). The purpose of this questionnaire is to reveal the communicative patterns of complex groups and teams in order to identify; 1) the strength and frequency of the connections between members, 2) the level of knowledge members have concerning the structure of the network, and 3) the evaluation by members concerning the overall success of the network.

- A Culture Questionnaire (see Attachment E) will also be administered twice, pretest and posttest, to about 75 healthcare workers with direct patient care (Aims 1, 4, and 5). The purpose of this questionnaire is to understand the cultural beliefs, attitudes, and knowledge of the hospital staff.

- Implementation Assessment Interviews (see Attachment F) will be conducted quarterly with key informants - about 4 individuals on the implementation team at each hospital (Aims 1, 4, and 5). This will allow the project team to understand and monitor how the intervention is proceeding on project units. By monitoring progress the barriers and facilitators that could affect the project implementation can be identified.
- A Patient Healthcare Use Questionnaire (see Attachment G) will be mailed to a sample of patients from the seven participating hospitals (Aims 2 and 4). The purpose of this survey is to identify risk factors for developing healthcare associated community onset (HACO) MRSA infections during a 12-month period after discharge from a healthcare facility.

3. Use of Improved Information Technology

Data from hospitals around the Indianapolis metro area are currently being collected and stored in the Indianapolis Network for Patient Care (INPC) system, an extensive network of real-time electronic interfaces to hospital information systems. Careweb, the specific application used for this data collection, is secure and web-based.

We will coordinate with participating hospitals to develop a common data infrastructure, including common process and outcome measures. This infrastructure development will begin with refining current data collection tools (Careweb) and standardizing application of these tools. Additionally, we will develop a new web-based data entry tool within Careweb to standardize definitions and policies and minimize data entry for MRSA reporting across all participating sites. Where possible, we will integrate electronic data (Health Level 7 or HL7 feeds) from existing hospital data sources (e.g. Admit Discharge Transfer or ADT, microbiology) to minimize administrative burden.

For the three hospital systems outside Indianapolis, Dr. John Stelling will offer WHO-NET software. WHONET is a flexible, user-friendly tool for the management and analysis of microbiology test results, to participating hospitals, in order to share data with Center for Disease Control's (CDC) National Health Safety Network initiative (NHSN). Interested Indianapolis hospitals will be able to implement electronic downloads of laboratory electronic data into CDC's national surveillance network to allow benchmarking with other hospitals across the U.S. This will allow the hospital to analyze its own data and provide external comparison of the impact of interventions on MRSA infection prevalence pre- and post-intervention. Each of the participating hospitals outside Indiana has been offered implementation of this system.

4. Efforts to Identify Duplication

There is no similar information on infection rates, SNA growth, cultural change, and HACO spread for a project of this magnitude. We have performed literature searches and used the information gathered from smaller and less complex projects to inform our efforts.

5. Involvement of Small Entities

The hospitals participating in this research are from hospital systems with multiple locations that serve a large population and are not considered small entities.

6. Consequences if Information Collected Less Frequently

In order to measure change over time, both in infection rates, and the secondary measurements of SNA and cultural changes, we plan to measure twice; once at baseline and once one year later. This will allow us to understand the impact of the intervention on participating units and infection rates. Without the second collection it would be difficult to assess changes in culture or network growth. We expect these measures to have a correlation with MRSA infection rates on participating units.

Electronic medical data will be collected weekly to assess MRSA infection rates. Less than weekly rates would not be as robust as our planned sampling rate. We will compare MRSA incidence rates of hospital units actively implementing the intervention bundle and control units. This will be done with the nosocomial surveillance data and automated clinical incidence measure where possible. Correlations between these two measures will be conducted to validate the clinical incidence measure. Further comparisons will be made across hospital units.

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 November 25th, 2009 for 60 days (see Attachment H). No comments were received.

8.b. Outside Consultations

The project team has had extensive consultation with representatives from the CDC (Dr. John Jernigan and Dr. Alex Kallen) in order to assure both compatibility and synergy with evolving data collection efforts such as the CDC's National Health Safety Network. Dr. Jernigan is the task order technical advisor and has had input at multiple points of this project, including the study design, collection procedures, and analysis. Drafts of all project documents relating to data collection and infection rates have been shared with the above representatives of the CDC during the drafting phase to insure that they have significant input into design and methods for the project.

9. Payments/Gifts to Respondents

As this is a quality improvement project aimed at reducing infection rates, we will not provide 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.

All physical data will be protected by storing in a locked filing cabinet in a locked office. Our office areas require ID badge to enter, protecting our offices from random or unwanted entry. All electronic data will be stored on a password-protected secure server and only study personnel, who each have completed local privacy and protection training, will have access to this server.

Identifiable health information will not be re-used or disclosed to any other person or entity except as required by law. Our questionnaires will have randomly generated unique identifier numbers on the front page. A unit chief or designated member of the project will compile a list of every staff member who works on their unit and assign a uniquely identified questionnaire to each staff member. The unit chief will keep a list with contact information that matches staff members to their unique identifier. The contact information list will be kept separately from the questionnaires, ensuring respondent confidentiality.

11. Questions of a Sensitive Nature

We do not ask questions of a sensitive nature for this project.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours associated with the hospital's time to participate in this research. Electronic medical record data will be collected weekly from seven participating hospital systems, however only two of the participating hospitals will use their staff to perform this data collection. Over the course of the project electronic medical record data will be extracted 52 times and each data extraction will take about 10 hours. Observational data will be collected 18 times each week from all participating hospitals, however only three hospitals will use their staff to perform the observations. The project will require 52 weeks of observations per hospital and will last 10 minutes per observation.

Both the social network analysis questionnaire and the culture questionnaire will be administered twice, pretest and posttest, to about 75 personnel at each of the seven hospitals. The social network analysis questionnaire will take about 15 minutes to complete while the culture questionnaire will take 30 minutes. The implementation assessment questionnaire will be administered quarterly to three key informants at each hospital and will take about one hour.

The patient healthcare use questionnaire will be completed by 200 patients sampled from the seven participating hospital systems. Each patient will respond once which will require about 15 minutes. The total annualized burden hours for all the associated data collections are estimated to be 2,458.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be $77,387.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of hospitals	Number of responses per hospital	Hours per response	Total burden hours
Electronic Medical Record Data Collection	2	52	10	1,040
Observational Data Collection	3	936	10/60	468
Social Network Analysis Questionnaire	7	150	15/60	263
Culture Questionnaire	7	150	30/60	525
Implementation Assessment Interviews	7	16	1	112
Patient Healthcare Use Questionnaire	200	1	15/60	50
Total	226	na	na	2,458

Exhibit 2. Estimated annualized cost burden

Form Name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Electronic Medical Record Data Collection	2	1040	$30.03	$31,231
Observational Data Collection	3	468	$20.98	$9,819
Social Network Analysis Questionnaire	7	263	$38.28	$10,068
Culture Questionnaire	7	525	$38.28	$20,097
Implementation Assessment Interviews	7	112	$45.33	$5,077
Patient Healthcare Use Questionnaire	200	50	$21.90	$1,095
Total	226	2,458	na	$77,387

*Based upon the mean of the average wages for Nursing Care Providers ($30.03), Primary Care Physicians ($84.97), Allied Health Providers ($20.98), Administrators,

Chief Executives ($76.23) and All Workers ($21.90); National Compensation Survey: Occupational wages in the United States May 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

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 Cost to the Government

Exhibit 3 shows the total and annualized cost of this project to the Federal Government over a two-year period. The total cost of this project is $1.8 million dollars which includes $785,000 for project development, $70,000 for data collection activities, $235,000 for data analysis, $125,000 for publication of the results, $170,000 for project management and $415,000 for overhead costs.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$785,000	$262,000
Data Collection Activities	$70,000	$35,000
Data Processing and Analysis	$235,000	$78,000
Publication of Results	$125,000	$125,000
Project Management	$170,000	$57,000
Overhead	$415,000	$138,000
Total	$1,800,000	$900,000

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Multiple analytic methods will be utilized to evaluate the effectiveness of the MRSA bundle interventions. MRSA infection rates of hospital units actively implementing the intervention bundle and control units will be compared. This will be done with both validated nosocomial infection surveillance data collected prospectively, as well as the automated clinical incidence measure. Correlations between these two measures will be conducted to validate the clinical incidence measure. Further comparisons will be made across hospital units. By uniquely identifying patients across institutions, a longitudinal history of a patient's record of infection will be created to prevent redundant entry of cases. Dr. Stelling (Harvard and WHO-NET) is working to adapt the automated download of MRSA clinical incidence data and reporting from the CDC MRSA Prevention Initiative to use the WHO-Net software to build a clinical incidence measure of new MRSA at the participating hospitals.

Descriptive statistics will be used to characterize institutional context and cultural factors affecting implementation. Multivariate models will be developed to assess the impact of MRSA bundle interventions on process uptake between units implementing MRSA bundle interventions and control units (Subtask 6.1).

Regarding the data obtained from the Patient Health Care Use Questionnaire, we plan a series of analyses to examine the impact of limiting the measure to only sterile sites, which would increase the likelihood of calling a true infection, but might increase the misattribution of MRSA acquisition. Regarding screening/surveillance isolates, the CDC excludes these from the primary analyses focusing just on clinical, diagnostic isolates. A primary reason for excluding screening isolates is that practices for screening vary widely between institutions and over time within an institution. These data will be validated in a variety of ways, by comparing with validated nosocomial infections, trends in adherence with prevention measures (such as hand washing, isolation and active surveillance cultures, etc.).

We will use an interrupted time series design to evaluate the longitudinal effects of the interventions on house-wide and unit-based rates of MRSA colonization and infection. Since the intervention's effects may vary across hospitals and units, stratified regression analyses will also be performed. If the incidence of MRSA infection is low on the given study units, as was the case in our recent AHRQ-funded work, we will utilize methods for Poisson counts, including the generalized autoregressive moving-average (GARMA) model. For larger samples, the count data will be transformed into monthly rates and conventional time series methods will be employed.

We have budgeted time in the third year of the project for the researchers to analyze our data and complete manuscripts from our work. Lessons learned through the research and implementation activities of the overall initiative project will be published and shared through a variety of forums, including peer reviewed journals, key conferences and symposia, and via the web.

We will also produce a field guide to provide guidance to healthcare organizations interested in MRSA prevention, help them deal with common barriers, and understand the leadership support needed. Articles and presentations will be prepared that describe the interventions and research results. The articles, after AHRQ review, will be submitted to carefully selected peer reviewed journals. Abstracts for presentations and symposia will be submitted to AHRQ for review as well.

Time Schedule for Project

Subtask #	**Deliverable**	**Month/ Year**
Subtask 1.1	Initial meeting with TOO and other AHRQ staff	10/08
Subtask 1.2	Draft report on the overall study design and proposed analysis plan	7/09
Subtask 1.3	Bi-Monthly Progress Report	Bi-monthly
Subtask 1.4	Conduct regular phone calls with the TOO and technical advisor	At least monthly
Subtask 1.5	Additional meetings and conference calls as needed with other collaborators	As needed
Subtask 2.1	Report on composition of TEP	11/08
Subtask 2.2	Recruit all participating hospital systems	2/09
Subtask 2.3	Confirm the units in which specific intervention(s) shall be implemented and develop proposed Implementation Plans	5/09
Subtask 2.4	Adapt existing ICU interventions to make them suitable for	3/09

	testing and spread in non-ICU units	
Subtask 2.5	Submit to the TEP, TOO and the technical advisor a Draft Implementation Plan for each participating hospital	12/09
Subtask 2.6	The contractor shall submit a Final Implementation Plan within 2 weeks of receiving AHRQ's comments	1/10
Subtask 2.7	Each hospital shall implement the intervention according to its Final Implementation Plan	9/09 to 09/11
Subtask 3.1	Initiate work with the TEP to develop and prioritize strategies to mitigate and eliminate HACO MRSA infections	2/10
Subtask 3.2	Conduct controlled study to identify risk factors for HACO MRSA infection (including obtaining OMB clearance)	6/10
Subtask 3.3	Study design developed, reviewed and approved by the TEP, the TOO and the technical advisor.	8/09
Subtask 3.4	Implementation plan developed to test strategies to measurably reduce HACO MRSA infection rates	6/10
Subtask 3.5	Implement the intervention(s) for Task 3 according to its Final Implementation Plan, and measure the impact of the intervention on HACO infection rates	12/10
Subtask 4.1	Collaborate with the TEP to develop a practical, standardized implementation protocol for the use of topical antimicrobials for inpatients colonized with MRSA	2/10
Subtask 4.2	Develop method for systematically recording aspects of the implementation of the decolonization protocol	3/10
Subtask 4.3	Develop method for comparing the impact of the MRSA prevention program between units using decolonization protocols and those not	3/10
Subtask 5.1	Coordinate with participating hospitals to further develop a common data infrastructure	2/09 and ongoing
Subtask 5.2	The contractor shall finalize a single, integrated platform for tracking and reporting information on MRSA cases and interventions in hospitals and care facilities	3/10
Subtask 5.3	Collect and aggregate process and outcome data to provide a mechanism for data display and feedback of site-specific and aggregated data through secure web interfaces	3/10 and on
Subtask 6.1	Evaluate the impact of MRSA bundle interventions on process uptake, and adherence on house wide and unit based MRSA rates of colonization and infection (baseline and follow-up measures, including obtaining OMB clearance)	6/10 to 6/11
Subtask 6.2	Assess the role of active surveillance in identification of colonized patients (i.e., stratification of high risk groups and units)	3/10 to 3/11
Subtask 6.3	Submit the assessment and evaluation plans to the TEP	1/10
Subtask 6.4	Conduct assessment and evaluation	6/10
Subtask 6.5	Summarize lessons learned from assessment and in interim and final reports	10/11
Subtask 7.1	Submit a draft Dissemination and Outreach Plan to the TEP, TOO and technical advisor for review	2/10
Subtask 7.2	Submit a final Dissemination and Outreach Plan within two weeks of receiving comments	3/10

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: AHRQ's Authorizing Legislation

Attachment B -- Electronic Medical Record Data Collection

Attachment C -- Observational Data Collection

Attachment D -- Social Network Analysis Questionnaire

Attachment E -- Culture Questionnaire

Attachment F -- Implementation Assessment Interview

Attachment G -- Patient Healthcare Use Questionnaire

Attachment H: 60 Day Federal Register Notice