**SUPPORTING STATEMENT**

**Part B**

**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)

**Table of contents [regenerate to include all page numbers]**

B. Collections of Information Employing Statistical Method3

 1. Respondent Universe and Sampling Methods

 2. Information Collection Procedures

 3. Methods to Maximize Response Rates

 4. Tests of Procedures

 5. Statistical Consultants

# Background

In a recent AHRQ-funded contract titled **Testing Techniques to Radically Reduce Antibiotic Resistant Bacteria [Methicillin Resistant *Staphylococcus aureus*, or MRSA]**, implemented evidence-based practices to reduce MRSA as an intervention bundle. The implementation was supported by principles from Positive Deviance (Complexity Science), Lean Engineering, and Implementation Science to enable identification and elimination of operational barriers limiting compliance with the intervention bundle and identification and amplification of existing good infection prevention practices. This approach encourages individual and social behavior change, organizational culture change, engagement of all personnel needed to prevent transmissions, and supports the spread of solutions. This prior project also supported development of a citywide electronic infection control network in Indianapolis, which delivers patient microbiologic information to Indianapolis hospitals where patients present for care. The results were profound: MRSA was reduced by 60% or more in study units (across the initial three participating systems). There has been a rapid uptake of these approaches by participating hospitals in and outside Indianapolis.

# The primary goal for this project is to identify effective strategies and approaches to redesign care to spread adoption of evidence-based practices to reduce MRSA infection to other units and hospitals. Additionally, AHRQ has a strong commitment to measure the impact of these interventions on infection rates. Factors related to healthcare associated community onset (HACO) of MRSA infection after receiving medical care or discharge from a hospital or nursing home will be identified. These efforts will build upon further development of informatics tools, databases and strategies to streamline data collection strategies.

# B. Collections of Information Employing Statistical Methods

***1. Respondent Universe and Sampling Methods***

This project consists of seven case studies, which will document the experiences of non-ICU settings in seven hospital systems (that include 11 participating hospitals) as they implement a MRSA intervention bundle. The seven case study sites are a **purposive sample of four hospital systems that have continued to** use the MRSA intervention bundle in their ICUs since beginning a previous AHRQ-funded study on this intervention in 2006, as well as in additional ICUs in three newly recruited hospital systems. The 11 participating hospitals in this project have either successfully completed a previous MRSA reduction effort with the research team or have been selected by an invited application process. To ensure sufficient interest and commitment from the staff level to the hospital leadership, a structured application was used to select the participating hospitals. Interested hospitals identified a leadership champion and representatives from front line staff and infection control, described current efforts to limit MRSA and explained why they were interested in participating. The hospital Chief Medical Officer (CMO) or CEO signature was also required on the application.

Since the seven hospital systems were not randomly selected, the results are not generalizable in the statistical sense. Rather, the project seeks to expand and enhance understanding of factors that facilitate or impede planning, decision-making, and adoption of a MRSA intervention bundle and will increase the likelihood of broader and more successful implementation of these tools in the future by enhancing hospitals’ understanding of the contextual factors that may underpin success.

Table 1 lists the seven hospital systems selected for participation: four in Indianapolis (Community Health Hospital, Clarian Health, St. Vincent Indianapolis Hospital, and St. Frances Hospital and Health Center), and one each in Billings, MT (St. Patrick’s Health), Portland, ME (Maine Medical Center), and Toronto, Canada (University Health Network).

**Table 1. Participating Hospital Systems**

|  |  |  |
| --- | --- | --- |
| **Health System** | **Participating Hospitals** | **Hospital Type** |
| Clarian Health | University HospitalMethodist HospitalClarian North |

|  |
| --- |
| Tertiary ReferralTertiary ReferralCommunity |

 |
| Community Health Network | Community Hospital North |

|  |
| --- |
| Large Community (Secondary Referral) |

 |
| St. Francis Hospital and Health Centers | St. Francis Hospital – Beech Grove |

|  |
| --- |
| Large Community (Secondary Referral) |

 |
| St. Vincent Hospitals | St. Vincent Indianapolis |

|  |
| --- |
| Large Community (Secondary Referral) |

 |
| University Health Network | Princess MargaretToronto GeneralToronto Western |

|  |
| --- |
| Tertiary ReferralTertiary ReferralLarge Community (Secondary Referral) |

 |
| St. Patrick | St. Patrick Hospital |

|  |
| --- |
| Large Community (Secondary Referral) |

 |
| Maine Medical System | Maine Medical Center |

|  |
| --- |
| Tertiary Referral |

 |

Scope of Work: To 1) conduct a systematic, comparative analysis of infection rates, process compliance rates, implementation acceptance and spread within and among participating hospitals and within the region; 2) assess the organizational context and social networks impacting intervention acceptance and spread.

A primary focus for the evaluation of this project is to develop and implement plans for data collection that can be used across different health care settings (each with different electronic health record platforms) to enable analysis of the impact of redesign interventions and culture change interventions to assess performance data directly associated with the MRSA intervention. The five aims for the overall project are:

1. Further test the “MRSA intervention bundle” from the original Indianapolis MRSA study, in additional units in the 4 original Indianapolis hospital systems and 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.

Data collection would ideally include standard measures for MRSA colonization and infection rates, compliance rates, implementation acceptance and spread among participating hospitals. Additionally, qualitative tools and methodologies should be developed and informatics infrastructure created to enable synthesis of open-ended structured interview data of healthcare implementation teams regarding identifying the barriers, facilitators and identified solutions (Lessons Learned) to continually improving the system obtained using these tools (see Table 2).

**Table 2.  Respondent Universe and Sampling Methods**

|  |  |  |  |
| --- | --- | --- | --- |
| Form Name | Respondent universe | Sampling method | Planned sample size |
| Electronic Medical Record Data Collection Process Measures:--Screening for MRSA on Admit (to unit or hospital)--Screening for MRSA on Discharge or Transfer (from unit or hospital)-Done  | Individuals admitted to the project unit(s) at participating hospitals | Complete sample of all individuals at risk for MRSA infection | All individuals admitted to observation units during the project (It is estimated that there will be at least 30 and up to ~300 individuals who will be observed through routine infection control surveillance and electronic microbiologic data regarding whether infection occurs) |
| Observational Data Collection  | Opportunities for hand hygiene on entering the room, moving from contaminated to clean site, invasive procedure or after leaving patient. | Ideally capture at least 3 hours per week of observation, spread across different patient beds and locations. For example, this might be operationalized as observing opportunities for hand hygiene during patient interactions in 10 minute blocks per patient selected (3 hours per week) | 18 observations (10 minutes each) per week \* 52 weeks =936 observed blocks per hospital |
| Social Network Analysis Questionnaire | All healthcare workers on unit with direct patient contact (~100 healthcare providers per unit, 7 hospitals) | Purposive | ~100 workers \* 7 hospitals = 525, 75% participation) |
| Culture Questionnaire | All healthcare workers on unit with direct patient contact (~100 healthcare providers per unit) | Purposive | ~100 workers \* 7 hospitals = 525, 75% participation) |
| Implementation Assessment Interviews | Implementation team at each hospitals is 5-8 individualsSample 3-5 key informant interviews quarterly | Purposive | 4 interviews per quarter per hospital (100% participation) 16 per hospital per year  |
| Patient Healthcare Use Questionnaire | Patients cared for in Indianapolis hospitals or healthcare settings in prior year | Stratified random sample  | Cases of MRSA meeting HACO infection definition and controls without HACO infection (~100 each group) |

## 2. Information Collection Procedures

Data from 14 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.

With coordination from participating hospitals, a common data infrastructure will be developed, including common process and outcome measures. This infrastructure development will begin with refining current data collection tools (Careweb) and standardizing application of these tools.

Implementation process measures will be collected through regular interviews of team members and/or coaches after each in-person visit. It is anticipated that these will include assessments of resources to the team, number of front line staff involved in co-creating solutions within and among nursing units, data feedback mechanisms to support process adherence measurement, informatics support for process measurement, data sharing and support services before and after the intervention and over time.

Adherence to bundle components will also be collected on a monthly basis in order to support the implementation process at each site. These measures will include an observation estimating percent appropriate hand hygiene practice by health care workers, proportion of time contact precautions are used for patients with known or suspected MRSA infection at admission, screening at admission and discharge for MRSA colonization.

To reveal communicative patterns of our participating hospital units, a Social network analysis (SNA) will be performed. SNA has been used 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.

The purpose of this effort is to describe the current social network for work in general and the MRSA Bundle implementation in particular. Multi-method data gathered will reveal the overall connectivity of the initial social network (during early implementation) and the post-implementation network. Administration of the SNA instrument will be done by local project staff that will be trained by our research staff in proposed administration of the SNA questionnaire.

An epidemiologic study is also proposed to evaluate risks for healthcare-associated community onset (HACO) MRSA in the time between discharge and onset of the infection. In collaboration with CDC partners and colleagues investigating risks for hospitalization of community onset MRSA, the Patient Healthcare Use Questionnaire will be used to supplement data available through the electronic health record (INPC) data. Here the likely questions of interest include: 1) number of healthcare exposures in between time periods (dialysis, long term care, home health care); 2) presence of CVC, and other healthcare risk factors; 3) presence of family MRSA infections or colonization; 4) antimicrobial use; 5) circumstances surrounding infection and 6) environmental or contextual factors of interest.

Administration of the questionnaire will be via mail, with an option to complete the questionnaire through a secure, on-line web site. Questionnaires will be mailed to at least 100 individuals meeting the definition for HACO MRSA infection and an approximately equal number of individuals without HACO MRSA infections who had an inpatient stay or significant contact with the healthcare system (dialysis, outpatient surgery, etc) in the prior 6 months. Administration is planned early in the second year of the project. Cases will be sampled within four weeks of hospital discharge, in order to minimize recall bias.

## 3. Methods to Maximize Response Rates

Similar methods will be used to maximize response rates that have been used on past projects with successful response rates. Methods to maximize response are as follows:

The individuals selected to participate in the hospital Culture Questionnaire and Social Network Analysis Questionnaire will be sent an introductory letter and information summary about the study. A modified Dillman process will be used, with an initial mailing of a cover letter outlining the request, approval and support letters from the IRB and the Technical Expert Panel , AHRQ and CDC, and a self-addressed stamped envelope. Subjects will also be provided a toll free number to ask questions about the project and complete the questionnaire over the phone if they prefer at a convenient time. The purpose of the study, measures taken to protect confidentiality, and potential contributions of the study’s results will be included in the cover letter and information summary. A statement disclaiming endorsement of any particular practices or procedures will be included at the beginning and end of the questionnaire. This letter will also assure the potential participant of confidentiality, and inform the potential participant that he/she can refuse to participate without concern for reprisals.

This letter will be followed with a phone call to obtain permission to conduct the questionnaires. Written questionnaires will be administered using a modified Dillman method. Respondents will receive the paper-based questionnaires during staff meetings and will return them anonymously. A study ID will serve to determine which staff has responded and allow linkage of baseline and follow-up questionnaires. Persons who do not wish to participate will be asked to return their blank questionnaire, identified by its study ID code. For all individuals, a reminder note will be sent to persons who have not returned the first questionnaire approximately 3 weeks after its initial distribution. Approximately 3 weeks after the second distribution, another reminder and a new questionnaire will be sent to persons who have not returned a questionnaire. All materials will be identified only by a confidential study identification number, and all procedures and materials approved by the institutional review board (IRB).

To complete the Implementation Assessment Interview, project team leaders will identify three to five key informants at each hospital to be interviewed. In many cases, it is expected that key informants are staff members who are participating actively in the implementation team, such as nurse clinicians, physicians, respiratory therapists, transportation aids, housekeeping staff. The candidates will be sent an introductory letter and information summary about the study. The purpose of the study, measures taken to protect confidentiality, and potential contributions of the study’s results will be included in the cover letter and information summary. This letter will be followed with a phone call to obtain permission to conduct the interviews. Key informants will be contacted by project personnel to set a time for the interview.

The Patient Health Care Use Questionnaire will be obtained in order to supplement the information obtained electronically from Indianapolis citizens in our RI EMR databases to assess risk factors for HACO MRSA. This questionnaire will be administered to at least 200 patients. Administration of this questionnaire will also follow a modified Dillman method as outlined above. Patients identified as a case or control will receive a written questionnaire in the mail. Nonrespondents will receive a postcard several weeks later encouraging their participation, then a remailing of the questionnaire and packet. This pattern will be repeated again about 3 weeks later.

## 4. Tests of Procedures

Although proposed measurements were not pretested, they were adapted from earlier projects with similar types of data collection and methods by internal subject experts, colleagues from the Center for Disease Control, and a Technical Expert Panel assembled to serve and advise this project. Retaining scientific rigor was a specific aim, while remaining aware of respondent burden. For example, for primary outcome of interest, MRSA nosocomial bloodstream infections, as well as other measures of infection and colonization, the CDC NHSN definitions and data definitions adapted from the Robert Wood Johnson (RWJ) beta site hospitals are used. (see[**http://www.cdc.gov/ncidod/dhqp/pdf/nnis/nosinfdefinitions.pdf**](http://www.cdc.gov/ncidod/dhqp/pdf/nnis/nosinfdefinitions.pdf)**)**

##  5. Statistical Consultants

Senior biostatistician Dr. Siu Hui, from Indiana University Division of Biostatistics, served as lead statistical consultant. Her phone number is (317) 423-5589. In addition to Dr. Hui, Drs. Joanne Daggy and Xiaochun Li have discussed this project and the issues above. Drs. Alex Kallen and John Jernigan from the CDC provided guidance on key components of the proposed design, especially of the epidemiologic study. Our seven member Technical Expert Panel, with methodologists and clinical and research experts from academia, CDC and AHRA also provided guidance in project design.