Risk Factors for Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) among Patients Recently Discharged from Acute Care Hospitals through the Active Bacterial Core Surveillance for Invasive MRSA infections (ABCs MRSA)

Request for OMB Approval of a New Data Collection

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The Centers for Disease Control and Prevention (CDC) is requesting OMB approval of a new data collection, Risk Factors for Invasive MRSA Among Patients Recently Discharged from Acute Care Hospitals.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion (DHQP), in collaboration with state public health authorities, plans to assess risk factors for invasive methicillin-resistant *Staphylococcus aureus* (MRSA) among patients recently discharged from acute care hospitals in the United States through the CDC's Emerging Infections Program (EIP)/Active Bacterial Core Surveillance for Invasive MRSA (ABCs MRSA).

Methicillin-resistant *Staphylococcus aureus* (MRSA) infections are associated with increased medical costs, morbidity and mortality relative to methicillin-susceptible *S. aureus* (MSSA).[1,2] MRSA is resistant to first-line antimicrobial therapies, including penicillin and cephalosporins. The CDC's Division of Healthcare Quality Promotion (DHQP) supports active, population-based laboratory surveillance for invasive MRSA in nine sites in the United States, including specific counties in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon and Tennessee. This is ongoing public health surveillance through the ABCs MRSA under the Emerging Infections Program (EIP). At each of these sites laboratory reports of cultures growing MRSA from normally sterile body-sites among residents in the catchment areas (combined population 18.8 million) have been collected since July 2004. Through this surveillance system, an estimated 94,360 invasive MRSA infections occurred in the United States in 2005; resulting in 18,650 deaths. The majority of these infections (58%) had onset in the community and occurred among individuals with recent healthcare exposures (healthcare-associated community onset [HACO]).[3]

More recent data from the CDC's Emerging Infection Program (EIP)/Active Bacterial Core Surveillance (ABCs) for Invasive MRSA, an active population-based surveillance for invasive MRSA infections in 9 U.S metropolitan areas, have shown that two thirds of invasive HACO MRSA infections occur among persons who are discharged from an acute care hospital in the prior 12 weeks. Although several risk factors for MRSA infection during hospitalization have been well described in the literature and include antimicrobial exposure, intensive care unit stay, intravenous catheterization, presence of soft tissue wounds and prior MRSA colonization, little is known about MRSA risk factors post-discharge.[4-6]

Reduction of invasive healthcare-associated MRSA infections is a national priority and a 5-year prevention target for 50% reduction in incidence of these infections has been set by the U.S. Department of Health and Human Services (HHS) in the recently finalized Action Plan to Prevent Healthcare-Associated Infections (http://www.hhs.gov/ophs/initiatives/hai/draft-hai-plan-01062009.pdf). Identification of risk factors for MRSA invasive infections post-acute care discharge will help develop targeted prevention measures to reduce the overall burden of invasive MRSA healthcare-associated infections.

We propose to conduct a matched case-control study at selected facilities in six EIP ABCs MRSA sites (California, Connecticut, Georgia, Minnesota, New York and Tennessee) among patients who develop invasive MRSA infections as outpatients within 12 weeks of most recent hospital discharge. A pilot retrospective evaluation at one EIP ABCs MRSA site (Rochester, NY), that did not include interview of participants, was performed in September 2009 to assess study feasibility. A total of 77 case- and control-patients were included in this evaluation and the data collection was performed by a CDC epidemic intelligence service officer through review of medical records. Preliminary findings suggest that patients discharged with chronic wounds or central venous catheters (CVC),as well as those with history of MRSA infection or colonization or hemodialysis are at increased risk of developing post-discharge MRSA infections.[7] It was determined that a prospective study including phone interviews of both case- and control- patients would be necessary to facilitate identification of behavioral factors or subsets of patients that may benefit from MRSA decolonization or improved

line/wound management. The findings of the pilot retrospective evaluation were used to guide the development of the proposed risk factor study. Section 301 of the Public Health Service Act (42 USC 241) (Attachment A) authorizes the collection of these data.

Privacy Impact Assessment

Overview of the Data Collection System

Data will be collected on paper forms from existing sources of information, including electronic and paper medical records (Attachment C and D). Data will be transferred to CDC via mailing hard copies or scanning and uploading electronic copies in a CDC secure file transfer protocol (FTP) site. FTP users authenticate themselves using a clear-text sign-in protocol in the form of a username and password, with secure transmission that hides (encrypts) the username and password, as well as encrypts the content using the file transfer protocol. Data collection and data entry partners will include ABCs MRSA staff. A second data collection step will require a telephone interview (Attachment F and G). ABCs MRSA staff will contact case- and control-patients eligible for the interview based on medical record review for a telephone interview. Both case- and control-patients will be initially screened for eligibility using a short screening form (Attachment F) after verbal is provided (Attachment E) and, if eligible for inclusion in the study, a full interview (Attachment G) will be performed. It is expected that 15-20% of the patients eligible for interview will be in nursing homes by the time of phone interview. For these patients, a nursing home medical record review form was developed (Attachment H) containing screening questions to ensure nursing home resident is eligible to be included in the study, in addition to questions related to resident functional status, device use and maintenance, wound care, and antimicrobial exposures. Data collected through telephone interview or nursing home medical review will also be transferred to CDC via mailing hard copies or scanning and uploading electronic copies in a CDC secure ftp site by the ABCs MRSA personnel. ABCs MRSA sites will have access to data submitted from facilities within their catchment areas. The information transferred to CDC will be entered in a password protected

database on a secure limited access server, and will be destroyed 3 years after the study completion. No patient identifiers such as name, address, phone number, medical record number, and facility name will be sent to CDC.

Items of Information to be Collected

Information transmitted to CDC may include: state, county of residence, age, date of birth, gender, race/ethnicity, and details on the hospitalization (e.g. admit and discharge diagnoses, invasive procedures, placement of devices, discharge with an invasive device (such as a central vascular catheter [CVC]), antimicrobial exposures, MRSA infection or colonization status, chronic wounds, patient disposition at discharge, and outcome). CDC will not receive patient names, patient addresses, medical record numbers or hospital names. Microbiology records and infection control records will also be reviewed. Phone interview will be used to ascertain outpatient exposures that occurred from the time of hospital discharge to the onset of the invasive MRSA infection of interest. The phone interview and nursing home medical review form will include details on device maintenance and duration after discharge (e.g. CVC type, insertion site, duration, indication, number of lumens, use patterns, catheter care and bathing practices), outpatient surgical procedures, outpatient antimicrobial exposures, emergency room visits, type of wound care after discharge, training of caregivers, and patient functional status.

Information in Identifiable Form (IIF) in the form of name, mailing address, phone number, and medical record number will be collected by collaborators as part of their state health department routine activities but removed prior to data transmission to CDC. Names or other personal identifying information are not collected by CDC on data abstraction forms. There are no personal identifiers submitted to CDC for any of the forms included in this package.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection will not involve a website with content directed at children less than 13 years of age.

2. Purpose and Use of the Information Collection

For this project, an eligible case for the study is defined as a patient aged 18 years or older with a positive MRSA culture from a normally sterile site (e.g. blood, pleural fluid, joint, bone) within 3 days after hospital admission (community-onset) and who was discharged from an acute care hospital in the 12 weeks prior to this invasive MRSA episode. Eligible cases for the study will be identified through routine EIP/ABCs MRSA surveillance. After an eligible case is identified, pertinent clinical information will then be abstracted from the most recent hospitalization (i.e. the last hospitalization prior to initial MRSA invasive culture; also known as hospitalization of interest). Based on this information, ABCs MRSA personnel will apply inclusion and exclusion criteria. Each person can be enrolled as a case only once during the study period; from the date of most recent hospitalization forward in the study period, a person enrolled as a case cannot serve as a control. For each case included in the study, two controls without MRSA infection will be identified. Eligible controls will be randomly selected from a list of patients matched to each case on the following criteria: hospital where case's most recent hospitalization occurred, date of hospital discharge on the same day or in the 29 days previous to the case's most recent hospital discharge date, and age group.

The information collected will be used by CDC to identify modifiable risk factors that put patients at increased risk for developing invasive MRSA after a hospitalization. The risk factors identified through this study will inform the development of targeted prevention measures to be applied by healthcare providers in order to improve patient care and safety. This activity supports the HHS Action Plan for elimination of healthcare-associated infections, specifically CDC's Strategic Goal of "Healthy Healthcare Settings" (http://www.cdc.gov/HAI/prevent/prevention.html#hhs).

Privacy Impact Assessment Information

The information is being collected to understand better the clinical and epidemiologic characteristics of patients who developed invasive MRSA infection within 12 weeks post-discharge, and to identify modifiable risk factors for invasive MRSA infection post-discharge, including those present during most recent hospitalization as well as those present after acute care hospitalization. The data will benefit public health by identifying prevention targets for a disease with high morbidity and mortality and that poses treatment challenges and has its presentation after acute care hospitalization. The data will be analyzed after the study is complete and the results will be shared in scientific presentations to the stakeholders and publications.

No Information in Identifiable Form (IIF) will be sent to CDC. CDC partners (i.e. ABCs MRSA staff) will collect IIF about cases consistent with their usual local and state public health mandates for surveillance, and therefore there will be a likely effect on the patients' privacy if there were a breach of confidentiality. In an effort to prevent a breach of confidentiality, project paperwork maintained by each participating site will never be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted. Each participating EIP site will destroy identifiers within 3 years after the completion of the study. IIF of any type will not be shared outside of ABCs MRSA personnel.

3. Use of Improved Information Technology and Burden Reduction

This study will use paper data collection forms. Personnel collecting data may need to travel to multiple healthcare facilities and will not necessarily have reliable, timely access to computers or the internet. Data collected through telephone interview will be transferred to CDC via mailing hard copies or scanning and uploading electronic copies in a CDC secure ftp site by the ABCs MRSA personnel. The information transferred to CDC will be entered in a password

protected database on a secure limited access server, and will be destroyed 3 years after the study completion. In accordance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, all means to maintain records electronically have been taken.

4. Efforts to Identify Duplication and Use of Similar Information

Essential steps in reducing the occurrence of healthcare-associated invasive MRSA infections are to quantify the burden and to identify modifiable risk factors associated with invasive MRSA disease. The current CDC's ABCs MRSA surveillance has been essential to quantify the burden of invasive MRSA in the United States. Through this surveillance CDC was able to estimate that 94,360 invasive MRSA infections associated with 18,650 deaths occurred in the United States in 2005. The majority of these invasive infections (58%) had onset in the community or within 3 days of hospital admission and occurred among individuals with recent healthcare exposures (healthcare-associated community-onset [HACO]). More recent data from the CDC's ABCs MRSA system have shown that two thirds of invasive HACO MRSA infections occur among persons who are discharged from an acute care hospital in the prior 3 months. Risk factors for invasive MRSA infections post-discharge have not been well evaluated, and effective prevention measures in this population remain uncertain. Because ABCs MRSA is a longitudinal surveillance system and includes multiple partners in different states, it represents an unique system to capture MRSA infections after acute care hospitalization across a variety of geographic locations. These MRSA infections occurring after acute care hospitalization are not captured by current hospital surveillance systems where patients are followed until discharge only.

ABCs MRSA staff routinely attends local, national, and international conferences relevant to the pathogens of interest and communicates frequently with non-federal colleagues at universities and health departments, as well as colleagues within the government in order to prevent duplication of effort.

5. Impact on Small Businesses or Other Small Entities

This study will unlikely impact small business or entities as only large acute care hospitals will be participating in the study and the burden of data collection will be on the surveillance officers appointed by the states, and not on the hospital staff where the cases and controls are identified.

6. Consequences of Collecting the Information Less Frequently

ABCs MRSA personnel will complete data collection on cases and controls as they are identified from laboratory reports and medical records on an ongoing basis. Performing data collection on cases and controls as they are identified (versus a quarterly or annual basis) will allow for rapid identification of epidemiologic changes, including rates and severity of disease in geographically diverse patient population segments over time and timely interview of cases and controls to avoid recall bias. Identification of risk factors after acute care hospitalization when most of the patients will be at home and clinical data will unlikely be documented requires timely interview of patients and consistent data collection. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require the information to be collected in any of the formats identified, and the request fully complies with regulations.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on April 23, 2012 vol. 77, No. 78, pp 24209-24210.

B. The following representatives were consulted during the development of the study methods and data collection instruments. Both of the following contacts were contacted several times between January 2010 and July 2011.

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9. Explanation of Any Payment or Gift to Respondents

Upon completion of the interview, respondents will be sent a $10 Target gift card to show our appreciation for their time and effort in participating in the study. CDC will purchase these gift cards and send them to the sites to distribute to the cases and controls who were interviewed. Many of study patients are hard-to-reach and multiple attempts may be required. The amount proposed is not of such a magnitude to interfere with voluntary participation. A Thank You letter with the gift card will be sent to respondents.

10. Assurance of Confidentiality Provided to Respondents

Data will be treated in a secure manner, unless otherwise compelled by law. A unique identifier will be assigned to each patient to allow the reporting ABCs MRSA facility to link

reported data back to the individual patient, however this link will not be shared with CDC. Hospital admission date, birth date and race/ethnicity data will be transmitted to CDC; no other patient identifiers will be transmitted to CDC. Each facility will also have an assigned code. Links between facility codes and names will be maintained by ABCs MRSA personnel and will not be shared with CDC. Individual facility data will not be reported by CDC, but rather will be aggregated to assess risk factors of invasive MRSA across several healthcare facilities. The data management system is kept in a CDC a secure limited access server. All paper forms transmitted to CDC are destroyed after completion of data entry.

IRB Approval

The routine ABCs MRSA surveillance is not considered research. Therefore the ABCs MRSA system and associated case report form (Attachment C) included in this package was exempt from IRB review (Attachment I).

The risk factor study protocol utilizing the screening and full interview questions to assess risk factors for invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) infections among recently discharged patients has been approved by CDC's IRB C (Attachment J). The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 5 and 7. The IRB approved the inclusion of pregnant women under 45 CFR 46.204, Subpart B. The IRB determined that the study poses no greater than minimal risk to subjects.

Privacy Impact Assessment

A) This information collection request has been reviewed by CDC/ICRO who has determined that the Privacy Act does not apply. Information submitted to CDC will not include names or individually identifying numbers (such as Social Security Numbers). Patients included in the study will be assigned unique identification codes;

these codes will not contain identifying information. With the exception of hospital admission dates and date of birth, personal identifiers will not be transmitted to CDC.

B) Project paperwork maintained by each participating site will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the surveillance project, or for other research for which the use or disclosure of protected health information would be permitted. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or as required to by law. Information received by CDC will also be stored in a secure, password-protected database. Information received by CDC will be provided only to those individuals at CDC with a need to know.

C) Respondent consent: a waiver of informed consent was made for information collected primarily through chart review. Only individual persons eligible for the study based on medical record review and contacted for interview will be asked to provide a verbal consent. Patients eligible for the telephone interview will be initially screened using attachment F to confirm eligibility to participate in the study; only those confirmed to be eligible to be included in the study based interview screening question will proceed to full telephone interview (attachment G).

D) Participation in this project is voluntary and study participants can stop the interview at any point during the interview process. Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law.

11. Justification for Sensitive Questions

Epidemiological and clinical characteristics such as age, race, sex, geographic location, date of admission and discharge from the hospital and comorbidities are associated with invasive MRSA infection. The collection of these data is critical to public health in order to identify groups at risk for disease that should be targeted for prevention efforts. Clinical, epidemiologic and laboratory

data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health. Social Security Numbers will not be collected in this study. As discussed in item A.10 above, participating individual's and institution's privacy will be treated in a secure manner, unless otherwise compelled by law.

12. Estimates of Annualized Burden Hours and Costs

A. ABCs MRSA under the Emerging Infections Program is a cooperative agreement between CDC and state health departments. As part of this program, ABCs MRSA epidemiologists under the cooperative agreement are paid to abstract data from medical records using attachments C, D, and H. Therefore, only the interview forms (attachment F and G) represent a burden to the public and were included in the annualized burden and costs estimates on table A.12-A All other forms related to medical record reviews (attachments C, D and H) have been included in the costs to the Federal government.

We estimate to contact each year a total of 150 invasive MRSA cases who are 18 years of age or older, had onset of the MRSA infection in the community or within 3 days of hospital admission, and history of hospitalization in the 3 months prior to infection. These cases will be identified across 15 acute care hospitals in the six ABCs MRSA participating sites (California, Connecticut, Georgia, Minnesota, New York and Tennessee). Of these 150 contacted for an interview, we estimate that approximately 95 will complete full telephone interview; the other 55 patients will be either ineligible or will refuse participation. For each case-patient with complete telephone interview, 2 control-patients without MRSA infection will be identified. We estimate that 300 patients without MRSA infection (i.e. control-patients) will have to be contacted each year to reach our target of 190 control-patients enrolled in the study annually. We anticipate that of the 300 control-patients contacted annually, 90 (30%) will refuse participation and 20 (7%) will not be eligible to participate yielding a total of 190 control-patients with complete telephone interview enrolled. The data collection will take place in two years. Table 12-A provides details about the annualized burden and how the estimated annual burden of 133 hours was calculated.

Table 12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Post-discharge Hospital Patients with MRSA infection (**Case-Patients**)	Screening and Consent Process	150	1	5/60	13
	Telephone interview	95	1	20/60	32
Post-discharge Hospital Patients without MRSA infection (**Control-Patients**)	Screening and Consent Process	300	1	5/60	25
	Telephone interview	190	1	20/60	63
Total					133

B. The total cost burden for respondents is estimated as follows: With a total annual burden of 133 hours, the total cost of the time to respond to the proposed study is estimated to be $2,891.41 (Table B). We used the 2011 mean average hourly wage for all occupations in the United States. This wage of $21.74 was obtained from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm).

Table B: Annualized cost to respondents

Respondents	*Total Respondent Hours*	Hourly Wage Rate	Total Cost
Post-discharge hospital patients	133	$21.74	$2,891.41

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

None.

14. Annualized Cost to the Federal Government

Costs to the government include costs for surveillance officers (epidemiologists) to develop and coordinate study activities at CDC, costs for the EIP ABCs MRSA personnel to perform local study coordination and data collection, costs for a database manager, costs for photocopying data collection forms, costs for mailing data abstraction forms, and costs for local principal investigators to participate on regular conference calls, update IRB approvals, and ensure study progress. The costs for the government related to this study are depicted on the table below.

ABCs MRSA personnel will perform comprehensive medical record review to abstract information on hospitalized patients and those that were transferred to nursing homes for continuation of medical care. The data collection forms that will be completed by EIP ABCs MRSA personnel are included in Attachment C, D and H. Collection of data on attachment C and D will occur in 150 patients annually, and is estimated to take approximately 30 minutes per patient. Therefore, a total of 75 hours of work to abstract data on attachment C and D will be

required. For attachment H, we estimate the collection to occur in 60 patients transferred to nursing homes. The data collection for nursing home residents is estimated to take 45 minutes, which will require a total of 45 hours per year of work.

There will also be costs related to photocopying of study forms and instructions at each participating site and to mailing complete forms to CDC.

Table 14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
CDC surveillance epidemiologist	Develop the protocol, data collection forms, training. Assist with data entry and analysis	51,258
Database manager (0.25 FTE)	Create and manage data management system	11,775
	Subtotal, Direct Costs to the Government	63,033
Cooperative Agreement	Abstraction of data using attachments C, D and H, photocopies and mail costs, participation on conference calls, and submission of study protocol to local IRBs.	
	California Site Cost and Fees	27,000
	Connecticut Site Cost and Fees	35,000
	Georgia Site Cost and Fees	46,000
	Minnesota Site Cost and Fees	20,000
	New York Site Cost and Fees	40,000

	Tennessee Site Cost and Fees	39,000
	Subtotal, Contracted Services	207,000
	TOTAL COST TO THE GOVERNMENT	270,033

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC will provide each surveillance area with several forms of feedback including data integrity checks, patient enrollment, and summary tables. Specifically, data from multiple sites will be concatenated approximately 3 weeks after receipt at CDC.

Statistical analysis will be performed at CDC, with input of co-investigators, using SAS software, version 9.2 (SAS Institute Inc., Cary, NC). Matched odds ratios (mOR) and *P* values will be calculated for univariate and multivariate analysis using conditional logistic regression. Variables from univariate analysis with a *P* value <0.20 will be included as candidates for the risk model. Multivariate analysis using stepwise conditional logistic regression will be performed to identify independent risk factors. A two-sided *P* value of < 0.05 will be considered statistically significant.

Publication

Results from this study will be presented at national meetings and published in a manuscript format in a peer-reviewed medical science journal. Conference abstract and manuscript will be developed as appropriate to disseminate the findings of this project.

Project time schedule

The study will begin as soon as possible following OMB approval. This is a prospective study and based on a sample size calculation a total of 570 patients (190 cases and 370 controls) should be enrolled. Therefore, the study should be completed in approximately 24 months based on the estimated annual numbers of cases. Analysis and presentation of the results will be completed annually.

Table D: Project Time Schedule

Activity	Time Schedule
Conduct Data Collection	Within 1 month after OMB approval
Conduct Health Interview on subset of cases	3 months after OMB approval
Transmission of data to CDC	3 months after OMB approval
Analysis and presentation of results	Upon study completion

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The proposed survey instrument will display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-I. No exceptions to certification are requested.

References:

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7) Duffy J, Kit B, Dumyati G et al. Risk Factors for Healthcare-Associated Community-Onset Methicillin-resistant *Staphylococcus aureus* Infections. *Society of Healthcare Epidemiology of America*, March 18-22, 2010, Atlanta, GA. Abstract #526

List of Attachments

A:	United States Code, Title 42, Chapter 6A Part 241
B:	60-day Federal Register Notice
C:	ABCs MRSA Surveillance Case Report Form
D:	Eligibility Criteria for Cases and Controls to be contacted for Interview
E:	Verbal Consent
F:	Screening questions
G:	Telephone interview
H:	Nursing Home Medical Record Review Form
I.	Non-Research Determination letter for ABCs MRSA Surveillance
J:	IRB approval letter for the HACO Study