

**Methicillin-Resistant *Staphylococcus aureus* (MRSA)
Infection Control Practices Survey**

Request for OMB Review and Approval

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A. Justification

1. Circumstances making the collection of information necessary

The National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC), in collaboration with state public health authorities, is requesting OMB approval to conduct a cross-sectional web-based survey of infection control professionals to evaluate the status of infection control practices related to the control of methicillin-resistant *Staphylococcus aureus* (MRSA) at healthcare facilities participating in the Emerging Infections Program / Active Bacterial Core surveillance (EIP/ABCs) invasive MRSA surveillance project.

Infections with MRSA are difficult to treat, are associated with increased length of hospital stay and morbidity, and occur during at least 125,000 hospitalizations annually in the U.S. with an estimated cost of \$3.2 to \$4.2 billion. The epidemiology of MRSA disease has rapidly changed over the past few years; thus, prevention strategies must also adapt to the changing patterns of transmission. At the same time, several governmental and non-governmental healthcare organizations are initiating either national or regional initiatives to reduce MRSA transmission and infection using multiple strategies of prevention (i.e., a prevention “bundle”) as outlined in the October 2006 publication of CDC’s HICPAC guideline on prevention of transmission of multi-drug resistant organisms (MDRO) in healthcare settings (Attachment C). Several of the strategies have proven to be successful in reducing MRSA in several centers. The critical question to CDC is to know when to implement these bundles, and more importantly, how to assess the efficacy of these strategies before the strategies become incorporated into state or federal law.

CDC is requesting an expedited review of this information collection request by OMB. Several events have occurred recently that necessitate this request. On October 17, 2007, an article in the Journal of the American Medical Association reported that over 90,000 Americans become infected each year with MRSA. Just 2 days earlier, a high school football player in Virginia died of an MRSA infection. The resulting media interest from these two events also fueled interest by Congress in MRSA infections and reporting mechanisms for these infections. To date, CDC has provided briefings to staffers from three Congressional Committees and participated in two Congressional Town Hall meetings. In addition to increased Congressional interest, CDC has been given the lead responsibility at HHS to develop a strong HHS plan for fast action on eliminating MRSA infections in healthcare. CDC is working with CMS and AHRQ to standard case definitions, measurement tools, and reporting systems. The revisions to the NHSN will allow CDC to provide leadership in this assignment.

Section 301 of the Public Health Service Act (42 U.S.C. 241) authorizes the collection of these data (Attachment A).

2. Purpose and use of the information collection

The purpose of this survey is to: 1) to learn the degree of MRSA prevention practice implementation as outlined in the CDC prevention guidelines in the context of various levels of MRSA disease measured by the EIP/ABCs Invasive MRSA surveillance project and 2) evaluate the success of health care facilities' MRSA control activities in reducing the incidence of invasive MRSA, as measured by the EIP/ABCs Invasive MRSA surveillance project.

This survey will be administered, using a web based survey tool, to infection control professionals who are located at the EIP/ABCs healthcare facilities. This survey will be administered to them yearly for three years. The first administration will address our first goal, and the subsequent administrations will address our second goal as stated in the previous paragraph.

3. Use of improved information technology and burden reduction

The survey will be developed in M.R. Interview. This program provides the ability to develop a web based survey. A URL link will be emailed out to each of the participating ABCs infection control professionals (ICP). The ICP will enter all information into this web site. There will be no need for paper distribution of this survey. In accordance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, all means to maintain records electronically have been taken.

Preliminary Screen Shots of this survey are provided in Attachment B.

4. Efforts to identify duplication and use of similar information

One of the purposes of this survey is to evaluate the implementation of the National Management of Multidrug-Resistant Organisms in Healthcare Setting guidance written by CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) (Attachment C). In the fall of 2006, CDC's Healthcare Infection Control Practices Advisory Committee revised guidelines for the prevention of MRSA in healthcare facilities. The guidelines call for a tiered approach to prevention based on various levels of MRSA disease.

Three other surveys looking at MRSA disease and infection control (IC) practices have recently been developed and administered by other non governmental organizations. The first survey was developed and administered by Association of Professionals in Infection Control (APIC) in the fall of 2006. The purpose of this survey was to look at MRSA colonization and infection at US Healthcare Facilities. They took a "snapshot" of MRSA prevalence in the US on a single day in October or November, 2006 (http://www.apic.org/Content/NavigationMenu/ResearchFoundation/NationalMRSAPrevalenceStudy/APIC_MRSA_STUDY_EXEC.pdf). This survey was inadequate to fulfill the purpose of the proposed data collection for two reasons; first, the sample was not representative of the US population. Of all acute care facilities surveyed, only 21% responded. Secondly, the data was not linked to a valid measure of MRSA disease such as the ABCs Invasive MRSA surveillance project.

The second survey was developed and administered by researchers working with Hospital Corporation of America (HCA) facilities. The HCA owns and operates approximately 283 hospitals and surgical centers in 21 US states, England and

Switzerland. The purpose of this survey was to assess general IC practices at each HCA facility, specifically assessing information about staff, tools and resources available for infection control activities. This survey did not focus on MRSA specifically. Again, this survey does not provide the information we are trying to assess with this proposed data collection. The HCA survey did not evaluate the degree of implementation of the national HICPAC MRSA guidelines. Nor did they look at the impact these guidelines had on a MRSA disease, as is necessary to successfully complete the purpose of the proposed study. The HCA survey results have not been published.

The third survey was developed and administered by a joint effort between the Society of Healthcare Epidemiology in America (SHEA) and the Association of Professionals in Infection Control (APIC) in March of 2007. The purpose of this survey was to gain insight into which Multi-Drug Resistant Organisms (MDROs) members of SHEA and APIC find most problematic and to gauge the range of current practices for a few areas of controversy regarding MDROs. The results of this survey have not been published at this time. However, based on review of the survey, limitations are as follows: 1) this survey addressed current MDRO IC practices that SHEA/APIC considered “controversial”, 2) they only generally assess the national guidelines, and 3) they did not evaluate the status of successful implementation of the national guidelines. Again, the main purpose of our survey is to evaluate the level of implementation and the impact of implementation of the national guideline. In summary, the prior three surveys have not accomplished our objectives nor will there be significant overlap with our data collection.

Literature searches conducted by CDC staff did not identify any other published reports assessing the implementation of the national MRSA control guidelines at healthcare facilities. Nor was literature found looking at the evaluation of the success of healthcare facilities’ MRSA control activities in reducing the incidence of invasive MRSA disease.

5. Impact on small businesses or other small entities

Since this survey will be sent to hospitals participating in the ABCs Invasive MRSA Disease surveillance project, some small hospitals will be invited to participate. Regardless of size, all hospitals interact with the federal government. We estimate that completing this survey will take the same amount of time regardless of size of the hospital. In addition, in the development of this survey questions have been held to the absolute minimum required for the intended use of the data and are estimated to require no more than 30 minutes to complete. Small hospitals that participate in this survey are not being over-burdened as only the minimum amount of information is being asked of respondents.

6. Consequences of collection of the information less frequently

Respondents will be asked to fill out this survey once annually over a three year time period. This is necessary to assess the impact and adoption of the national MRSA control guidelines. In addition we will not be able to measure the reduction of incidence without multiple assessments over time. 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. As required by 5 CFR 1320.8(d), a notice of this proposed data collection appeared in the Federal Register (Vol. 72, No. 65, page 16791) on Thursday, April 5, 2007 (Attachment D). No comments were received from the public.
- B. The following representatives were consulted during the development of this study methods and data collection instruments. Both of the following contacts were consulted several times between January and July 2007.

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9. Explanation of any payment or gift to respondents

There will be no payments or gifts to the respondent.

10. Assurance of confidentiality provided to respondents

This Information Collection Request has been reviewed for Privacy Act applicability and it has been determined that the Privacy Act is not applicable. Respondents will be speaking from their roles as infection control professionals employed by healthcare facilities. Although respondents' names will be collected when the survey is administered, a unique hospital identifier will be created and transmitted to CDC. CDC will not hold the link between the facility name and the unique identifier. Respondents' names will not be transmitted to CDC. While the local EIP/ABC site contacts will know who completed the survey, survey responses will not be linked to the respondent.

Data will be treated in a secure manner by the EIP contacts. All data collected is completely voluntary as stated in the introductory forward of the survey (Attachment E). We will be collecting information at the hospital level only; no patient specific information will be collected (Attachment E). The only information that will be collected is the state where the facility is located. Respondent's name and hospital name will be kept in a secure manner by the local EIP/ABCs site and not transmitted to CDC. Only the unique hospital identifier will be transmitted to CDC and CDC will not know the link between this id and the actual facility name.

All information provided through our web based system will be kept confidential and housed on a secure CDC server. State specific data will be provided to each EIP/ABCs site. Local state authorities may use data to improve their understanding of infection control practices in their hospitals.

The information provided through this survey will neither be used to influence funding nor to scrutinize the hospital in any way. CDC does not hold a regulatory role and will not share data with any regulatory agencies. CDC provides guidance in public health practice. The information is provided specifically to assess the degree of implementation of the national guidelines.

11. Justification for sensitive questions

No questions of a sensitive nature are included in this survey. The unique identifier will be created by the EIP/ABCs site. CDC will not have access to hospital names. No infection rates are being reported as part of this survey.

12. Estimates of annualized burden house and costs

- A. It is estimated that respondents will require no more than 20 to 30 minutes to complete a facility survey on line; this time includes logging on to the website. Respondents are being asked to complete a total of 40 questions about their facility, we suspect that much of this information is something that the respondent will know, and will not require them to research. Table 1 shows the time requirements associated with the survey. We used the upper limit of 30 minutes for our estimates.

Table A: Estimated total response burden, in hours

| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent/year | Average Burden per Response (in hours) | Total Burden Hours/year |
|--------------------|----------------------|--------------------|-----------------------------------|--|-------------------------|
| Hospital ICP | Facility Survey Form | 210 | 1 | 30/60 | 105 |
| Total per year | | | | | 105 |

- B. With a maximum annual burden of 105 hours for respondents, the over all cost of respondent's time for the proposed survey will be a maximum of \$2276.40 (105 hrs x \$27.54). We used the average hourly wage for a Healthcare Practitioner. The hourly wage of \$21.68 is the average hourly wage for this profession and was obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2006 data (access July 19, 2007 at <http://www.bls.gov/oes/current/oes299099.htm>). These will be no direct costs to respondents other than their time to participate in the study. Our goal is to perform this survey annually for a total of three years.

Table B: Annualized cost to respondents

| Total Respondent Hours | Hourly Pay Rate Healthcare Practitioner | Total Respondent Burden |
|------------------------|---|-------------------------|
| 105 | \$21.68 | \$2276.40 |

13. Estimates of other total annual cost burden to respondents or record keepers

None.

14. Annualized costs to the federal government

Upon OMB approval, this project will take approximately 3 years to complete. The total cost to the government will be \$25,811. All costs have been described in the tables below. There will be no physical administrative costs (i.e. photocopying, postage etc) for this study because it is web based. In addition the current infrastructure is already established through the EIP so this will also not incur additional cost.

Annualized Cost to the Federal Government – Year One

| Government Employee Title | Total Number of Hours Dedicated to Survey per Year | Description of Duties | Hourly Rate | Total Burden per Year |
|---------------------------|--|-----------------------|-------------|-----------------------|
| | | | | |

| | | | | |
|---------------------------|-----|---|----------|--------------------|
| Research Fellow 1 | 250 | Design Survey, Develop OMB packet | \$30.20 | \$7550.00 |
| M.R. Interview Developer | 15 | Develop online survey and database | \$100.00 | \$1500.00 |
| Surveillance Officers (9) | 15 | Dissemination of survey, follow up on non-responses | \$30.20 | \$4,077.00 |
| Total | | | | \$13,127.00 |

Annualized Cost to the Government – Year Two

| Government Employee Title | Total Number of Hours Dedicated to Survey per Year | Description of Duties | Hourly Rate | Total Burden per Year |
|---------------------------|--|---|-------------|-----------------------|
| Surveillance Officers (9) | 15 | Dissemination of survey, follow up on non-responses | \$30.20 | \$4,077.00 |
| Total | | | | \$4,077.00 |

Annualized Cost to the Government – Year Three

| Government Employee Title | Total Number of Hours Dedicated to Survey per Year | Description of Duties | Hourly Rate | Total Burden per Year |
|---------------------------|--|---|-------------|-----------------------|
| Surveillance Officers(9) | 15 | Dissemination of survey, follow up on non-responses | \$30.20 | \$4,077.00 |
| Research Fellow 2 | 150 | Data analysis, manuscript preparation | \$30.20 | \$4530.00 |
| Total | | | | \$8,607.00 |

The total cost to the Federal government for this data collection over three years is \$25,811.00. The annualized cost to the Federal government is \$8,603.67.

15. Explanation for program changes or adjustments

This is a new data collection.

16. Plans for tabulation and publication and project time schedule

Tabulation

A surveillance dataset of aggregate data (e.g., sum of number of cases of invasive MRSA infection) per hospital will be created at CDC (organized by hospital identification number (ID)). Survey data will be linked to the hospital-level aggregate dataset by hospital ID, the link will be maintained at the state EIP/ABCs sites. Summary descriptions of programs in each surveillance area, and rates of hospital-specific invasive MRSA rates will be correlated with MRSA control efforts in order to assess suitability of these programs in the context of current national guidelines. All analysis will occur in SAS version 9.1 (SAS Institute, Cary, NC).

Publication

Results from this survey will be published in a manuscript format in a peer-reviewed medical science journal. Conference abstracts and manuscripts will be developed as appropriate to disseminate the findings of this survey.

Project time schedule

Data collection will commence immediately following OMB approval. Once all three surveys are collected, an additional 6 months will be needed to perform analysis and develop the manuscript.

Table D: Project time line

| Activity | Time Schedule |
|--|---------------------------------|
| Development of web based version of survey | Immediately after OMB approval |
| Data Collection Form Email Out to Respondents | 1 months after OMB approval |
| Respondents complete data collection form | 2 months after OMB approval |
| Second Survey Form Emailed Out to Respondents | 13 months after OMB approval |
| Second Survey, respondents complete data collection form | 14 months after OMB approval |
| Third Survey Form Emailed Out to Respondents | 25 months after OMB approval |
| Third Survey, respondents complete data collection form | 26 months after OMB approval |
| Analysis | 27-32 months after OMB approval |

| | |
|--|---------------------------------|
| Publication | 32-36 months after OMB approval |
| Thank you emails from sites to each respondent | 27 months after OMB approval |

17. Reason(s) display of OMB expiration data in inappropriate

The proposed survey instrument will display the expiration date.

18. Exemptions 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.

A. Collection of information employing statistical methods

1. Respondent universe and sampling methods

The sample population for this survey will be one infection control professional (ICP) per healthcare facility that is currently participating in ABCs Invasive MRSA surveillance project. No sampling methods will be used to identify additional hospitals nor will we eliminate hospitals from the sample population.

The ABCs Invasive MRSA surveillance project is active population based surveillance that incorporates 14,755,694 persons living in 9 different states across the US. The 9 locations are California, Connecticut, Georgia, Maryland, Minnesota, Oregon, and Tennessee. This is approximately 5% of the entire US population (<https://www.cia.gov/library/publications/the-world-factbook/print/us.html>, July 19, 2007). Because this is active population based surveillance, valid national estimates of disease burden have been made and published regularly (<http://www.cdc.gov/abc>)

In order to assess our objective of evaluating the success of health care facilities MRSA control activities in reducing the incidence of invasive MRSA disease in our ABCs Invasive MRSA surveillance area, all hospital ICPs must be surveyed. If we were to expand this survey area, we would not be able to assess our proposed objective using EIP/ABCs population rates.

We anticipate a response rate of at least 80% of these facilities; however, based on previous interactions with these facilities, the response rate will likely be close to 100%.

2. Procedures for the collection of information

Statistical methodology

Not applicable.

Data Collection

Data collection will occur over three years. The first year, a single survey will be administered to each participating hospital Infection Control Professional (ICP). This initial survey will be conducted to assess several aspects of MRSA control programs at the ABCs Invasive MRSA Disease surveillance hospitals. During the second and third years, the same survey will be administered again to the same population (Table D). The purpose of the subsequent surveys is to re-evaluate adherence.

The data collected by the survey will include; facility demographics; policies related to recommended MRSA infection control measures outlined in the HICPAC guidance; use of MRSA screening methods; and behavioral, knowledge, and attitude markers that will be used to approximate the cultural acceptance of the MRSA control program (Attachment E). Please note that all skip patters, as they appear in Attachment E, will be incorporated into the web based survey.

A single ICP at each facility will be asked to complete the 40 question survey. An electronic link to the survey will be emailed to each ICP by a Surveillance Officer (SO) at each site. As part of ABCs Invasive MRSA Disease surveillance project, Surveillance Officers routinely work with ICPs at each of their surveillance hospitals. The Surveillance Officer at each EIP/ABCs site will email the survey URL to the hospital ICP because of this preexisting relationship. The contents of the email containing the URL for the survey will be informal and scripted personally by each Surveillance Officer. This process will be repeated each year for three years.

Participation in this survey will be completely voluntary. An introductory forward will appear before the survey that stresses that the participation is completely voluntary and that respondent's information will be kept secure (Attachment E). Further more, any report of these data will not link survey responses specifically to hospital name.

We anticipate a response rate of at least 80% of these facilities; however, based on previous interactions with these facilities, the response rate will likely be 100% participation overall. This is based on past surveys performed within the EIP system that were also distributed by site Surveillance Officers. To ensure this participation rate, we will ask Surveillance Officers to mention the upcoming survey during routine hospital visits or at any other venue they feel is appropriate.

3. Methods to maximize response rates and deal with nonresponse

In order to maximize response rates, we will be partnering with our EIP/ABCs partners at each of the surveillance sites, who have existing relationships with their surveillance hospitals. We will be asking each EIP/ABCs Surveillance Officer to identify the best ICP contact at their surveillance hospital who would know the most about MRSA infection control practices at their healthcare facility. In addition, because of the existing relationship between the EIP/ABCs site's Surveillance Officer and the ICP, the Surveillance Officer will be emailing out the link to the online survey. Therefore the survey will be coming from someone that the ICP knows which will increase participation. We are expecting at least an 80% response rate using this method;

however, based on previous interactions with these facilities, the response rate will be closer to 100%.

We will also ask the Surveillance Officer to identify other venues that this survey could be discussed. We have suggested to each EIP/ABCs site to have someone speak about the survey at upcoming Association of Professionals in Infection Control meetings and at their site specific EIP/ABCs conferences.

The Surveillance Officer will follow up with all non-respondents either during their routine hospital visit or via email.

Test of procedures or methods to be undertaken

This survey protocol and corresponding data collection instrument has been reviewed within the Division of Healthcare Quality Promotion by researchers with over thirty years of experience conducting epidemiologic studies. In addition, we worked closely with Vanderbilt University in Nashville, TN, in the development of this survey. Vanderbilt was chosen as a study partner for two reasons, 1) because they are part of the EIP/ABCs Invasive MRSA surveillance project, and 2) they expressed interest in performing this survey. Changes in length and content were made based on their review.

4. Individuals consulted on statistical aspects and individuals collecting and/or analyzing data

Statistician consulted for data analysis:

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List of Attachments

- A:** United States Code, Title 42, Chapter 6A Part 241
- B:** Screen Shots of MRSA Infection Control Survey.
- C:** Guidance Document: National Management of Multidrug-Resistant Organisms in Healthcare Setting
- D:** Federal Register Notice
- E:** MRSA Infection Control Practices Survey
- F:** IRB Non-Research Letter