CDC/National Center for Immunization and Respiratory Diseases

Information Collection Request for:

Active Bacterial Core Surveillance (ABCs) Project (ABCs)

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Active Bacterial Core Surveillance Project
(ABCs)

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Active Bacterial Core Surveillance (ABCs)

A. Justification

1. Circumstances making the collection of information necessary

Background

Classification of Information Collection Request (ICR): New

The National Center for Immunization and Respiratory Diseases (NCIRD) of the Centers for Disease Control and Prevention (CDC) is requesting OMB approval for four data collection forms that will be used to conduct surveillance to determine the incidence and epidemiologic characteristics of invasive disease due to *Haemophilus influenzae*, *Neisseria meningitidis*, group A *Streptococcus*, group B *Streptococcus*, *Streptococcus pneumoniae*, and methicillin-resistant *Staphylococcus aureus*. This new information Collection Request includes a revision of previously approved forms, as well as existing data collection forms that are in use without an OMB control number.

The forms in this package include:

1. ABCs Case Report Form—OMB no. 0920-0009 (Attachment 3)
2. Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form—OMB no. 0920-0009 (Attachment 4)
3. ABCs Invasive Pneumococcal Disease in Children Case Report Form (Attachment 5)
4. Neonatal Group B Streptococcal Disease Prevention Tracking Form (Attachment 6)

The ABCs Case Report Form and the Invasive Methicillin-resistant *Staphylococcus arueus* ABCs Case Report Form are based on forms that have been previously approved under the National Disease Surveillance Program I. Case Reports Package. Since the last approval in 2007, CDC has determined that these data collection instruments should be included in a separate package that includes all data collection forms that are included in the Active Bacterial Core surveillance (ABCs) project. The ABCs surveillance projects are different from the surveillance projects included in the National Disease Surveillance Program package and maintaining separate OMB numbers for these two types of data collections will greatly assist CDC in managing surveillance activities.

Surveillance of the incidence and distribution of disease has been an important function of the US Public Health Service (PHS) since an 1878 Act of Congress authorized PHS to collect morbidity reports. CDC is conceived of as a well-equipped,

broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases.

Active Bacterial Core surveillance (ABCs) is a core component of CDC's Emerging Infections Program Network (EIP), a collaboration between CDC, state health departments, and universities. ABCs is an active laboratory- and population-based surveillance system for invasive bacterial pathogens of public health importance. ABCs was initially established in four states in 1995. It currently operates among 10 EIP sites across the United States, representing a population of approximately 40 million persons. At this time, ABCs conducts surveillance for six pathogens: group A and group B streptococcus, *Haemophilus influenzae*, *Neisseria meningitidis*, *Streptococcus pneumoniae*, and methicillin-resistant *Staphylococcus aureus*. ABCs also provides infrastructure for additional special studies including those aimed at identifying risk factors for disease, post-licensure evaluation of vaccine efficacy and monitoring effectiveness of prevention policies.

ABCs data is critical for documenting disease burden and describing the epidemiology of these 6 bacterial pathogens, tracking trends in antimicrobial resistance, contributing to the development and evaluation of new vaccines, developing and assessing public health prevention measures, and improving overall public health practice. Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1) authorizes the collection of these data.

Privacy Impact Assessment

A.1.A. Overview of the Data Collection System

Case finding is active and laboratory-based. Since isolation of one of the ABCs organisms from a normally sterile site is essential to the case definition, the microbiology laboratories in acute care hospitals and reference laboratories processing sterile site specimens for residents of the surveillance area are the most efficient sites for case identification. In addition, some of the data of interest on cases of invasive bacterial disease is readily accessible in the microbiology laboratory. However, most data that are essential for describing the population-based epidemiology of these diseases (e.g., age, residence within the surveillance area, outcome) may not be available in many microbiology laboratories. Therefore, a standard case report is completed on all identified cases through medical record review. The standard case report form contains questions on basic demographics, underlying conditions, vaccinations and risk factors for infection. Data collection is done differently in each surveillance area; for example, through the cooperation of on-site hospital personnel (e.g., Infection Control Practitioners or Medical Records personnel), through medical record review or clinician interview by county health department personnel, or through medical record review by surveillance personnel.

Haemophilus influenzae vaccination history for cases <5 years of age with *Haemophilus influenzae* serotype B or unknown serotype must be verified. Likewise,

pneumococcal vaccination history for cases 3- 59 months of age with Invasive Pneumococcal Disease must be verified. If available/accessible, state vaccination registries may be used to verify information on vaccination history. If state registries are not available/accessible OR vaccination history is missing from the state registry, vaccination history should be verified by the child's healthcare provider.

A.1.B. Items of Information to be collected

Information in Identifiable Form (IIF) will be collected by collaborators, and de-identified prior to its transmission to CDC. Please refer to section A.10 for further description of the process for de-identifying data.

A.1.C. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Information transmission occurs via a secure CDC website, but the information collection forms do not involve web-based data collection methods and do not refer respondents to websites.

2. Purpose and use of the information collection

The data collection has important practical utility to the government as well as EIP populations and the American population as a whole. The original purpose for reporting communicable diseases was to determine the prevalence of diseases dangerous to public health. However, collecting data also provided the basis for planning and evaluating effective programs for prevention and control of infectious diseases. Current information on disease incidence is needed to study present and emerging disease problems. The ABCs surveillance system provides data for those engaged in research or medical practice, health education officials, and manufacturers of pharmaceutical products which may lead to effective prevention strategies and enhanced interventions. CDC coordination of standardized reporting in EIP sites maintains uniformity so that comparisons can be made from state to state and year to year.

Two of the forms in this package are based on forms that have previously approved by OMB. ABCs data has been used to track disease trends, including the decline in pneumococcal disease following introduction of the pediatric pneumococcal conjugate vaccine and the emergence of serogroup Y meningococcal disease. ABCs has also impacted public health policy by providing information which formed the basis of revised CDC guidelines recommending the use of universal screening of pregnant women to prevent early onset GBS infections and the prevention of GAS infections among household contacts of persons with invasive disease and among postpartum and post-surgical patients. ABCs data is also being used to characterize the changing epidemiology of methicillin-resistant *Staphylococcus aureus*.

ABCs data and methodology have also been shared with both domestic and international programs. Domestically, a program based primarily on lessons learned from ABCs has been developed to assist state and local health departments with surveillance for MRSA and drug-resistant *Streptococcus pneumoniae*. Internationally, ABCs data has been shared with colleagues in an effort to assist with the development, introduction and evaluation of new vaccines in countries outside the U.S.

A.2.A. Privacy Impact Assessment Information

The information is being collected to determine the incidence and epidemiologic characteristics of invasive disease due *Haemophilus influenzae, Neisseria meningitidis,* group A *Streptococcus*, group B *Streptococcus*, *Streptococcus pneumoniae* and methicillin-resistant *Staphylococcus aureus* in large diverse U.S. populations. The data will benefit public health by aiding in the estimation of disease burden, identification of high risk populations, development of vaccines, and modification of prevention and control recommendations.

No IIF will be collected by CDC. CDC partners will collect IIF about cases, 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 at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or are required to by law.

3. Use of improved information technology and burden reduction

Case report forms will be entered and maintained at each surveillance area. CDC will provide to each EIP site a Microsoft Access database that mirrors the data collection forms. Surveillance staff at each participating EIP site will enter data from the data collection form into the database. The computerized databases, with personal identifiers removed, will be transmitted to CDC by the fifth of every month. 100% of the forms included in this package will be submitted to CDC electronically. Password-protected databases are posted to site-specific folders on a secure CDC ftp site.

4. Efforts to identify duplication and use of similar information

ABCs is the gold standard for the collection of population- and laboratory-based invasive bacterial disease data in the U.S. No other nationwide surveillance systems which monitor these diseases exist. While similar information may be collected on a sample basis or from a particular area of the country, for most diseases, sampling would

not be sufficient for the states' need of conducting prevention or control programs. ABCs collect data from EIP sites in a uniform manner.

ABCs 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

In most cases, the data collection itself will not impact small businesses because the burden of completing the case report form rests with the surveillance officers appointed by the states, not the hospitals where the cases are identified. However, in some sites, data collection is performed in cooperation with on-site medical personnel (e.g., Infection Control Practitioners or Medical Records Personnel). The impact on these facilities should be minimal, since the hospital has entered into an agreement with the State health department.

6. Consequences of collection of the information less frequently

Partnering state health departments submit data collection forms to CDC on a monthly basis. Prompt notification to CDC allows for timely data analysis, tracking of the effects of prevention measures, and policy development. There are no legal obstacles to reduce the burden.

7. Special circumstances relating to the guidelines of 5 CFR 1320.5

For the reasons described in A.6 above, respondents are required to report information more often than quarterly (monthly). Surveillance reports are requested on a periodic basis to permit timely data analysis and prompt initiation of prevention and control measures.

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 June 2, 2008, vol. 73, No. 106 , pp. 31489-31490 (See Attachment 2). There were no public comments.

B. ABCs is the gold standard for the collection of population- and laboratory-based invasive bacterial disease data in the U.S. CDC conducts a conference call with site surveillance officers to discuss ABCs-related issues monthly. CDC also organizes two annual meetings: the ABCs Steering Committee meeting with attendance by the ABCs Principle Investigators and one surveillance officer from each site, and the ABCs Surveillance Officers meeting with attendance by at least two surveillance officers from each site.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Names or other personal identifying information are not routinely collected by CDC on case report forms. There are no personal identifiers in the database submitted to CDC for any of the forms included in this package. Thus, the subjects whose charts are reviewed will not be able to be identified through data submitted to CDC; only the EIP site collecting the case information will be able to link personal identifiers with case information.

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 are required to by law. 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.

IRB Approval

The data collection forms included in this package constitute public health surveillance and are not considered research. Therefore the protocols associated with the forms included in this package are exempt from IRB review.

Privacy Impact Assessment

A. This submission has been reviewed by the Information Collection Review Office (ICRO), who determined that the Privacy Act does not apply.

B. 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 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 are required to by law.

C. Since information is collected primarily through chart review a request to waive written documentation of informed consent is being made for all data collections in this package.

11. Justification for Sensitive Questions

Epidemiological characteristics such as age, race, sex, geographic location, etc., are collected only when these factors may produce health problems. Clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health.

12. Estimates of Annualized Burden Hours and Costs

A. CDC is requesting approval of four data collection forms. Earlier versions of the case report forms have been used previously by investigators and the time required to complete these forms has been used to calculate the burden in this package. "Respondents" for each of the forms are health departments who submit surveillance case report forms. "Responses" for the case report forms indicate the number of cases that are identified. Number of "responses" for all case report forms must be estimated as we do not know before hand how many cases will occur.

Table A.12-A. Estimated Annualized Burden Hours

Form Name	Type of Respondent	No. of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
ABCs Case Report Form	State Health Department	10	809	20/60	2697
Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form	State Health Department	10	609	20/60	2030
ABCs Invasive Pneumococcal Disease in Children Case Report Form	State Health Department	10	41	10/60	68
Neonatal Group B Streptococcal Disease Prevention Tracking Form	State Health Department	10	37	20/60	123
	Total				4918

B. Because these data collections are supported through a cooperative agreement, there is minimal additional cost to respondents (see table 14-1).

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

There are not costs to respondents other than their time.

14. Annualized Cost to the Federal Government

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	Subtotal, Direct Costs to the Government	
Cooperative Agreement Expenses	California Site Cost and Fees	585,745
	Colorado Site Cost and Fees	379,078
	Connecticut Site Cost and Fees	715,610
	Georgia Site Cost and Fees	798,195
	Maryland Site Cost and Fees	1,072,991
	Minnesota Site Cost and Fees	1,009,726
	New Mexico Site Cost and Fees	333,460
	New York Site Cost and Fees	564,156
	Oregon Site Cost and Fees	432,057
	Tennessee Site Cost and Fees	724,648
	Subtotal, Contracted Services	6,615,666
	TOTAL COST TO THE GOVERNMENT	

15. Explanation for Program changes or Adjustments

The ABCs Case Report Form and the Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report From have historically been included in the National Disease Surveillance Program package (OMB No. 0920-0009). Minor revisions (Attachments 12 and 13) have been made to the forms since the last approval in 2007, however the changes did not result in a change to estimated burden hours. NCIRD is requesting OMB approval for the ABCs Invasive Pneumococcal Disease in Children Form and the Neonatal Group B Streptococcal Disease Prevention Tracking Form for the first time. The ABCs surveillance projects are different from the surveillance projects included in the National Disease Surveillance Program package (OMB No. 0920-0009) and

maintaining separate OMB numbers for these two types of data collections will assist CDC in managing surveillance activities.

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 and summary tables. Specifically, data from multiple sites will be concatenated approximately 3 weeks after receipt at CDC. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site.

CDC generates pathogen-specific ABCs surveillance reports two times a year. Preliminary surveillance reports are produced in March for the previous calendar year; final surveillance reports are produced in October (http://www.cdc.gov/ncidod/dbmd/abcs/survreports.htm). CDC also summarizes data for presentation in written manuscripts for peer-reviewed journals, and at national and local scientific meetings. These analyses are on-going throughout the calendar year.

17. Reasons Display of OMB Expiration Date is Inappropriate

OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification.