

Dated: April 17, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-12II]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Ron Otten, at CDC 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

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)—NEW—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated invasive MRSA infections is one of CDC's priorities. The goal of this project is to assess risk factors for invasive healthcare-associated MRSA infections, which will inform the development of targeted prevention measures. This activity supports the HHS Action Plan for elimination of healthcare-associated infections.

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. CDC's current 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 three 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 three months. Risk factors for invasive MRSA infections post-discharge have not been well evaluated, and effective prevention measures in this population remain uncertain.

For this project, an estimated total of 450 patients (150 patients with HACO MRSA infection post-acute care discharge and 300 patients without HACO MRSA infection) will be contacted for the MRSA interview annually. This estimate is based on the numbers of MRSA cases reported by the ABCs MRSA sites annually (<http://www.cdc.gov/abcs/reports-findings/survreports/mrsa08.html>) who are 18 years of age or older, had onset of the MRSA infection in the community or within three days of hospital admission, and history of hospitalization in the prior three months. ABCs MRSA surveillance case report forms will be used to identify HACO MRSA cases to be contacted for a telephone interview. For each HACO MRSA case identified; two patients without HACO MRSA infection (control-patients) matched on age with MRSA case will be contacted for a health interview. All 450 patients (both cases and controls) will be screened for eligibility and those considered to be eligible will complete the telephone interview. We anticipate that 350 of the 450 patients screened will complete the telephone interview across all six participating ABCs MRSA sites per year. We anticipate the screening questions to take about 5 minutes and the telephone interview 20 minutes per respondent.

There are no costs to respondents. The total response burden for the study is estimated as follows:

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hospital Patients	Screening Form	450	1	5/60	38
	Telephone interview	350	1	20/60	117
Total	155

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Proposed Project

Quarantine Station Illness and Death Investigation Forms—Airline, Maritime, Land/Border Crossing Illness and Death Investigation Forms—Revision—National Center for Zoonotic and Emerging Infectious Diseases (NCEZID) (0920-0821, expires 9/30/2012), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision to an existing data collection of patient-level clinical, epidemiologic, and demographic data from ill travelers and their possible contacts in order to fulfill its regulatory responsibility to prevent the importation of communicable diseases from foreign countries (42 CFR part 71) and interstate control of communicable diseases in humans (42 CFR part 70).

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. The regulations that implement this law, 42 CFR parts 70 and 71, authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances (e.g., airplanes, cruise ships, trucks, etc.), persons, and shipments of animals and etiologic agents in order to protect the public's health. The regulations also require conveyances to immediately report an "ill person" or any death on board to the Quarantine Station prior to arrival in the United States. An "ill person" is defined in statute by:

- Fever (≥ 100 °F or 38 °C) persisting ≥ 48 hours
- Fever (≥ 100 °F or 38 °C) AND rash, glandular swelling, or jaundice
- Diarrhea (≥ 3 stools in 24 hours or greater than normal amount)

The 2003 Severe Acute Respiratory Syndrome (SARS) situation and concern about pandemic influenza and other communicable diseases have prompted CDC Quarantine Stations to recommend that all illnesses be reported prior to arrival.

CDC Quarantine Stations are currently located at 20 international U.S. Ports of Entry. When a suspected illness is reported to the Quarantine Station, officers promptly respond to this report by meeting the incoming conveyance in person (when possible), collecting information and evaluating the patient(s), and determining whether an ill person can safely be admitted into the U.S. If Quarantine Station staff is unable to meet the conveyance, the crew or medical staff of the conveyance is trained to complete the required documentation and forward it (using a secure system) to the Quarantine Station for review and follow-up.

To perform these tasks in a streamlined manner and ensure that all relevant information is collected in the

most efficient and timely manner possible, Quarantine Stations use a number of forms—the Air Travel Illness or Death Investigation Form, Maritime Conveyance Illness or Death Investigation Form, and the Land Travel Illness or Death Investigation Form—to collect data on passengers with suspected illness and other travelers/crew who may have been exposed to an illness. These forms are also used to respond to a report of a death aboard a conveyance.

The purpose of all three forms is the same: to collect information that helps quarantine officials detect and respond to potential public health communicable disease threats. All three forms collect the following categories of information: Demographics and mode of transportation, clinical and medical history, and any other relevant facts (e.g., travel history, traveling companions, etc.). As part of this documentation, quarantine public health officers look for specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; SARS; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as most communicable diseases in general. These signs and symptoms include fever, difficulty breathing, shortness of breath, cough, diarrhea, jaundice, or signs of a neurological infection. The forms also collect data specific to the traveler's conveyance.

These data are used by Quarantine Stations to make decisions about a passenger's suspected illness as well as its communicability. This in turn enables Quarantine Station staff to assist conveyances in the public health management of passengers and crew.

The estimated total burden on the public, included in the chart below, can vary a great deal depending on the severity of the illness being reported, the number of contacts, the number of follow-up inquiries required, and who is recording the information (e.g., Quarantine Station staff versus the conveyance medical authority). In all cases, Quarantine Stations have implemented practices and procedures that balance the health and safety of the American public against the public's desire for minimal interference with their travel and trade. Whenever possible, Quarantine Station staff obtain information from other documentation (e.g., manifest order, other airline documents) to reduce the amount of the public burden.

There are no costs to respondents other than their time.