Prevalence Survey of Healthcare-Associated Infections (HAIs)
and Antimicrobial Use in U.S. Acute Care Hospitals
Request for Approval of New Data Collection
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This is a request for OMB approval of a new data collection, Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey. This data collection is funded with the American Recovery and Reinvestment Act of 2009 (ARRA) dollars. CDC is requesting a three-year approval to collect the data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for OMB approval of a new data collection for Phases 2 and 3 of a three-phase project. The Centers for Disease Control and Prevention (CDC) proposes to conduct two surveys to evaluate the prevalence of healthcare-associated infections (HAIs) and antimicrobial use in acute care hospitals in multiple states. This is a three-phase project. The first phase, a small, single-city pilot survey with less than 9 respondents, is complete. Phases 2 and 3 will be conducted in collaboration with state public health authorities and with CDC's Emerging Infections Program (EIP). Phase 2 will be a limited roll-out survey (Attachment C) involving up to 30 healthcare facilities in the 10 states with EIP sites. Phase 3, built upon experience gained in the limited roll-out, will involve up to 500 facilities in the 10 states with EIP sites using the same survey. CDC does not anticipate making changes to the data collection instrument in Phase 3.

Healthcare-associated infections (HAIs) and antimicrobial resistance in U.S. acute care hospitals are major public health problems, causing significant morbidity and mortality. Estimating the scope and magnitude of all types of HAIs across all patient populations in U.S. hospitals is essential to the development of effective prevention and control strategies and policies. CDC currently conducts limited HAI surveillance through the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666, expiration date 09/30/2012), which focuses on incident device- and procedure-associated HAIs in high-risk patient locations; therefore CDC currently cannot estimate the scope and magnitude of all HAIs affecting the wide spectrum of patient populations in acute care hospitals (i.e., all patient-care locations). Furthermore, CDC does not currently collect detailed data within NHSN or other surveillance systems on antimicrobial use in a national sample of acute care hospitals. Such data are essential in the effort to develop and implement strategies to reduce inappropriate use and prevent the emergence of resistant pathogens. HAI prevalence estimates as well as estimates of antimicrobial use can be obtained through point prevalence surveys, in which data are collected in acute care facilities during a short, specified time period. Although providing only a snapshot of the frequency and nature of HAI and antimicrobial use, point prevalence studies represent a cost-effective alternative to prospective, hospital-wide incidence studies in which the magnitude of HAIs across the wide variety of patient populations can be assessed.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A) and the American Recovery and Reinvestment Act of 2009 (ARRA) (Attachment D).

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 and entered into a web-based data management system for transmission to CDC. Data collection and data entry partners will include local healthcare facility staff, EIP staff, academic collaborators, and local and state public health professionals. EIP sites will have access to data submitted from facilities within their catchment areas. The information in the CDC database will be maintained indefinitely, since this data collection will be repeated at regular intervals for comparison purposes. Personal identifying information will be maintained by EIP sites until completion of all survey activities, but will not be transmitted to CDC.

Items of Information to be Collected

Information transmitted to CDC may include: age, gender, survey date, hospital admission date, state, patient location within the healthcare facility (e.g., medical unit, surgical intensive care unit, etc.), presence of medical devices (urinary catheter, central line, ventilator), previous hospital admissions, previous operative or non-operative procedures, white blood cell counts and other laboratory data, antimicrobial treatment (including drug names, route of administration, indication or rationale for use, and therapeutic site), body temperature, and data on the presence of different types of healthcare-associated infections (including location of onset, causative pathogens, and antimicrobial susceptibility of these pathogens). Hospital admission date will be transmitted to CDC; other patient identifiers, such as name, medical record number and address, will not be transmitted to CDC. Each patient will be assigned a unique identification code that will not contain identifying information. Healthcare facilities who participate in the information collection will be identified by facility identification codes. These facility identification codes are assigned codes that EIP sites use currently in the course of their surveillance activities, and although EIP personnel are able to link facility codes with facility names, CDC will not have these linkages. Local data collectors at participating healthcare facilities and EIP personnel will need to collect information in identifiable form (IIF) for patients within their own facility or catchment area, such as patient name, date of birth, medical record number, healthcare facility unit name and patient's room number. This information will not be transmitted to CDC.

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 Information Collection

Preventing healthcare-associated infections (HAIs) and encouraging appropriate use of antimicrobials are CDC priorities. Essential steps in reducing the occurrence of HAIs and prevalence of resistant pathogens are to estimate accurately the burden of HAIs in U.S. hospitals, describe the types of infections and causative organisms, and assess the nature and extent of antimicrobial use. These goals will be accomplished in the proposed HAI and antimicrobial use prevalence survey.

In 2008-2009, CDC developed and conducted a pilot HAI point prevalence survey (Phase 1). The first phase, a small, single-city pilot survey with less than 9 respondents, is complete. The proposed surveys covered in this application would expand the scope of the pilot to include up to

30 acute healthcare facilities in 10 states in the Phase 2 limited roll-out survey, followed by the full-scale, Phase 3 survey including up to 500 acute healthcare facilities in the same 10 states.

Facilities participating in Phase 2 will be 1-3 volunteer facilities within the catchment areas of each of the 10 EIP sites. In Phase 3, eligible facilities will be those located within the 10 states participating in the EIP (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). Although the goal will be to include all facilities within usual EIP catchment areas for participation in Phase 3 (a total of approximately 467 facilities), we may also explore the feasibility of expanding the geographic scope of the survey outside of usual EIP catchment areas. Participation in the Phase 3 survey is voluntary. EIP personnel have established working relationships with infection prevention personnel in healthcare facilities within their catchment areas; we anticipate that these relationships will be strengthened in the coming years as states build their HAI surveillance and prevention activities. For both Phases 2 and 3, EIP personnel will recruit facilities to participate through email and telephone communications. Based on the long-standing relationships that EIP sites have with their facilities, and based on the response from facilities that we experienced in Phase 1, we do not anticipate that recruitment will present a problem.

Data collected during Phase 3 will be used to estimate national HAI prevalence and antimicrobial use. Data collected through the EIP have been used previously to generate national estimates of disease rates: recent examples include invasive pneumococcal disease [29] and methicillin-resistant *Staphylococcus aureus* infections [30]. In addition, based on a comparison performed internally in CDC's Division of Healthcare Quality Promotion (DHQP), the bed size and regional distribution of the 467 hospitals within the EIP catchment areas were similar to the distribution of the 6346 hospitals participating in the 2006 American Hospital Association (AHA) survey. Similarly, the National Hospital Discharge Survey (NHDS), conducted yearly by the National Center for Health Statistics at CDC, utilizes a sample of approximately 500 acute care hospitals for its national estimates (for example, see 2006 NHDS results, available at: http://www.cdc.gov/nchs/data/nhsr/nhsr005.pdf). For these reasons we believe that data collected from facilities within the EIP catchment areas will be sufficient to describe national HAI and antimicrobial use prevalence.

In both Phases 2 and 3, EIP personnel and local facility staff members will participate in data collection. Data will be collected on CDC-defined HAIs (using existing NHSN definitions, available at: http://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf) for a sample of eligible acute care inpatients. Patients will be randomly selected from the acute care patient population in each facility on the facility's survey date. Sample size targets will be established for each facility based on factors such as the overall number of participating facilities and the numbers of active acute care beds in each facility. Facilities will supply lists of active bed numbers in advance of the survey date; these lists will be randomly sorted using a random number generator tool. The randomly sorted bed number list will be matched to the facility's patient census list on the morning of the survey. Medical records will be reviewed for each patient on the census list occupying a bed included in the randomly sorted bed number list, up to the target sample size. Patients in outpatient areas of healthcare facilities, including the Emergency Department, will be excluded. Data collected in the Phase 3 survey will be used to estimate the national scope and burden of HAIs and antimicrobial use and to inform efforts to achieve CDC's Health Protection Goals and the prevention of HAIs. This proposed project supports CDC's Strategic Goal of "Healthy Healthcare Settings," specifically the objectives to "Promote compliance with evidence-based guidelines for preventing, identifying, and managing

disease in healthcare settings" and "Prevent adverse events in patients and healthcare workers in healthcare settings" (http://www.cdc.gov/osi/goals/places/healthcare.html).

Privacy Impact Assessment

The data collected will be used to determine the prevalence of HAIs, the types of HAIs and causative pathogens, the nature and extent of antimicrobial use in acute care healthcare facilities, the prevalence of antimicrobial resistance among pathogens causing HAIs, and the prevalence of certain risk factors for infection, such as medical devices. HAIs are recognized as a major cause of morbidity and mortality in the United States, as well as a major contributor to excess healthcare costs (see http://www.hhs.gov/ophs/initiatives/hai/). Eliminating HAIs is a priority of the CDC and other federal agencies. This survey will provide estimates of the magnitude and burden of HAIs in the United States, forming the foundation for development and implementation of effective prevention measures. During this data collection, CDC will neither receive nor share IIF, with the exception of medical information as described above. No sensitive information is being collected on individual patients. Data will be entered into the electronic data management system and retrieved by CDC using identification codes that do not contain patient identifiers. CDC will analyze and report aggregated data obtained during the survey. The results of the survey will be used by local, state and federal public health authorities to inform the development of HAI prevention strategies and policies. Individual healthcare facilities may also use the data to inform institution-level practice and policy.

3. Use of Improved Information Technology and Burden Reduction

The survey will use paper data collection forms because survey personnel will need to travel to multiple patient units within healthcare facilities to collect data and will not necessarily have reliable, timely access to computers or the internet. All data will be entered by survey personnel into a web-based, electronic data management system. No paper forms will be submitted to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's first HAI prevalence survey was conducted in the 1970s (Study on the Efficacy of Nosocomial Infection Control, SENIC), using a team of trained abstractors to collect comprehensive HAI data from a probability sample of 338 hospitals [2]. The SENIC project found that approximately 5% of hospitalized patients acquired an infection not present or incubating at the time of admission [3]. At a cost of $27 million, the SENIC project has not been repeated. In the 1980s and 1990s CDC conducted voluntary, hospital-wide infection surveillance through the National Nosocomial Infections Surveillance (NNIS) system (OMB Control Number 0920-0012); in NNIS, data were reported from local hospital personnel rather than a common team of CDC-trained data collectors (http://www.cdc.gov/ncidod/dhqp/nnis.html). As demands on infection control grew, voluntary NNIS hospitals began to perform targeted surveillance in high-risk hospital areas (such as intensive care units) that were most useful in calculating risk-adjusted HAI incidence rates. The NNIS system's hospital-wide HAI surveillance component was eliminated in 1996. CDC's successor to the NNIS system, the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666), is not designed to estimate the scope and magnitude of HAIs hospital-wide; rather, it focuses on device-associated and procedure-associated infections (central-line associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, ventilator-associated pneumonia and post-procedure

pneumonia) (http://www.cdc.gov/nhsn/about.html). In its current form, the NHSN cannot provide estimates of HAI for all types of HAIs or antimicrobial use throughout an entire hospital. Measurements of the magnitude and types of HAIs and nature and extent of antimicrobial use occurring across all acute care patient populations are needed to inform decisions by local and national policy makers and by hospital infection control personnel regarding appropriate targets and strategies for HAI prevention, measures to encourage appropriate antimicrobial use, and/or justification to focus efforts at specific antimicrobial resistant infections. Such measurements, while not possible within the current NHSN infrastructure, can be obtained in prevalence surveys. Such surveys have been conducted in several countries around the world in recent years [4-28]; no such recent, national-scale effort has occurred in the United States. There are no duplicate efforts underway within the United States.

While the information collected in the prevalence survey is broader in scope than the data collected in the NHSN, there may be some minimal overlap. It is important to note that while we estimate that approximately 3% of the HAIs identified in the prevalence survey in a given hospital will have to be entered in to the NHSN system, each facility will conduct the prevalence survey over a very short period of time (one day) and will only be collecting data on a sample of patients in the facility during that short time period. For example, a hospital with 500 acute care beds may be asked to review 165 patients' medical records for the purposes of the prevalence survey. If 7% of these patients have HAIs (12 patients) and we estimate that 3% of HAIs detected will also need to be entered into NHSN, that represents a burden of less than one patient record for that facility.

5. Impact on Small Businesses or Other Small Entities

CDC does not anticipate that small businesses will participate in the surveys. Small hospitals may participate in Phases 2 or 3 of the prevalence survey. Participation is voluntary, but we anticipate that most if not all facilities selected for participation will agree to participate. Elimination of HAIs is a major goal of all U.S. healthcare institutions, large and small, and we expect that facilities will be highly motivated to participate. This has been our experience in developing the single-city pilot effort. The data collection and management burden for participating healthcare facilities will be minimized as much as possible. This will be accomplished by having EIP personnel perform most of the data collection.

6. Consequences of Collecting the Information Less Frequently

Following completion of the Phase 2 limited roll-out, facilities will be asked to participate in the Phase 3 prevalence survey, with the possibility that the survey will be repeated at regular but infrequent intervals in the future (once every 3-5 years). Repeating the survey will provide information on changes in HAI prevalence over time as well as changes in the burden and distribution of infection types and causative organisms. 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. 75, No. 17, pp. 4396-4397 on Wednesday, January 27, 2010 (Attachment B). No comments were received from the public.

B. The following individuals were consulted during the development of the study methods and data collection instruments.

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9. Explanation of Any Payment or Gift to Respondents

Not applicable.

10. Assurance of Confidentiality Provided to Respondents

A unique identifier will be assigned to each patient to allow the reporting facility to link reported data back to the individual patient, however this link will not be shared with CDC. Hospital admission date 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 EIPs and will not be shared with CDC. Individual facility data will not be reported by CDC (although individual facilities may have access to their own data), but rather will be aggregated to provide HAI and antimicrobial use prevalence estimates. All patient-level data will be kept in a secure manner and will not be disclosed unless otherwise compelled by law. The data management system will undergo certification and accreditation, including a determination of the sensitivity of the data. We anticipate that the data management system will be certified and accredited as a level 2 system.

Privacy Impact Assessment

A) This information collection request has been reviewed by CDC/ICRO who has determined that the Privacy Act does not apply. Patients included in the survey will be assigned unique

identification codes; these codes will not contain identifying information. With the exception of hospital admission dates, personal identifiers will not be transmitted to CDC.
B) Information received by CDC will be stored in a secure, password-protected database (anticipate certification and accreditation at level 2). Information received by CDC will be provided only to those individuals at CDC with a need to know.
C) Respondent consent: Not applicable. Individual persons are not the survey respondents in this case. Data collectors, including EIP personnel, will perform review of existing medical record data in participating facilities and submit these data to CDC. There is no interaction with individual patients.
D) Participation by facilities in this project is voluntary. Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law.

11. Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and race and ethnicity will not be collected. The reporting of adverse events occurring in hospitalized patients, including infections, could be considered sensitive unless healthcare facilities are assured that the data-aggregating organization will provide security for the data and maintain the institution's confidentiality. Data security will be assured as described above.

12. Estimates of Annualized Burden Hours and Costs

A. While target sample sizes will be individualized for each participating facility based on factors previously mentioned (Section A2), we anticipate that each facility may review records for one-third of its acute care bed size. Infection Control Practitioners will be asked to collect a minimal amount of data, limited to basic demographic and risk factor/antimicrobial use information. We anticipate that this data collection will take 5 minutes per patient. We estimate that in facilities with paper records, an additional 5 minutes per patient could be needed for travel between patient units. Therefore, we are estimating a total time for response of 10 minutes per patient.

CDC has assumed an average daily patient census of 250 patients for each of the 30 participating facilities in Survey #1. An Infection Control Practitioner (ICP) in his/her own facility will be asked to review 1/3 or 33% of this number (250); thus, the ICP would review 82.5 records (rounded up to 83). This number is estimated to be the same in each phase of the prevalence survey effort. We also estimate that ICPs may spend approximately 2 hours in administrative activities, such as gathering information related to the daily patient census and bed numbers, and completing activities such as training. These are one-time activities.

Therefore, the estimated total time burden is 475 hours for ICPs in the phase 2 survey.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Responses (in hours)	Total Burden Hours
Infection Control Practitioners	Administrative and other preparatory activities	30	1	2	60
Infection Control Practitioners	Survey #1	30	83	10/60	415
Total		30			475

B. The total cost burden for respondents is estimated as follows: With a total annual burden of 475 hours, the total cost of the time to respond to the proposed survey is estimated to be $12,993.65 (475 hrs x $31.31, Table B). The average hourly wage for a Registered Nurse, $31.31, was obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2008 data (access May 19, 2009 at http://www.bls.gov/oes/2008/may/oes_nat.htm#b29-0000). The Infection Control Practitioners are typically registered nurses. There will be no direct costs to facilities and local data collectors other than their time to participate in the study.

Estimated Annualized Burden Costs

Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Register Nurse	415	$31.31	$12,993.65

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

None.

14. Annualized Cost to the Government

Costs to the government include costs for surveillance officers (epidemiologists) to develop and coordinate survey activities at CDC, EIP personnel to perform local survey coordination and data collection and entry activities, costs for a database manager, costs for photocopying survey materials, and costs for an external contractor to perform data validation activities (Phase 2 only).

CDC will contract with external experts to perform data validation in Phase 2 only. See Table C below for costs related to personnel.

There will also be costs related to photocopying of survey forms and instructions. In Phase 2, this is estimated to be $354 ($0.05 to copy each page, estimated 7078 copies made to support survey activities in 30 facilities in 10 EIP sites). In Phase 3, the cost is estimated to be $8000 ($0.05 to copy each page, estimated 160,000 copies made to support survey activities in 500 facilities in 10 EIP sites).

The total annualized cost for personnel and photocopying is therefore estimated to be $103,030 + $8,354 = $111,384.

Annualized cost to the federal government is $111,384.

Government Employee Title	*Total Number of Hours Dedicated to Survey per Year*	*Hourly Rate*	*Total Burden per Year*
CDC surveillance officer/epidemiologist	500	$31.01	$15,505
Database manager	500	$35.05	$17,525
Contractors/infection control (approx. 4)	200	--	$70,000
Total personnel cost			$103,030

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A patient-level surveillance dataset will be maintained at CDC. This dataset will be used to determine HAI prevalence (e.g., number of HAIs or number of patients with HAIs / total number of patients surveyed), antimicrobial use prevalence (e.g., number of patients on antimicrobials / total number of patients surveyed), the distribution of HAI types and causative organisms, and the distribution of types of antimicrobials and rationale for their use. Analysis will occur in SAS version 9.2 (SAS Institute, Carey, NC).

Publication

Results from this survey will be presented at national meetings and published in a manuscript format in a peer-reviewed scientific journal. Publications will include a discussion of potential biases and other limitations of the project.

Project time schedule

Phase 2 will be conducted as soon as possible following OMB approval. Because of funding concerns and the need to complete the Phase 3 survey during the period covered by the American Recovery and Reinvestment Act of 2009, it is extremely important that the Phase 2 survey be conducted by the end of August 2010. Our goal is to conduct Phase 3 in 2011 (see Table below).

Project time schedule

Activity	*Time Schedule*
Conduct of Phase 2 survey	Within 1 month after OMB approval
Transmission of data to CDC (local data collectors and EIP personnel)	Within 3 months after OMB approval

Analysis and presentation of Phase 2 results	Within 5 months after OMB approval
CDC and collaborators finalize protocol and data collection forms for Phase 3	Within 6 months after OMB approval
CDC and collaborators submit Phase 3 protocol for IRB review	Within 7 months after OMB approval
Training for data collectors (Phase 3)	Within 9 months after OMB approval
Conduct of survey (Phase 3)	Within 12 months after OMB approval
Transmission of data to CDC (Phase 3)	Within 14 months after OMB approval
Analysis and presentation of results (Phase 3)	Within 16 months after OMB approval
Repeat of Survey	Approximately 30 months after OMB approval
Transmission of data to CDC	Approximately 32 months after OMB approval
Analysis of results	Approximately 34 months after OMB approval

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.

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List of Attachments

A: United States Code, Title 42, Chapter 6A Part 241

B: 60-day Federal Register Notice

C: Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey Form

D: American Recovery and Reinvestment Act of 2009