Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Hospitals

(OMB Control No. 0920-0852, Expiration 10/31/2022)

Extension ICR

Supporting Statement A

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Table of Contents

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- **Goals of project**: Estimate the prevalence of healthcare-associated infections (HAIs) in a large sample of inpatients in U.S. acute care hospitals; determine types of HAIs and causative pathogens; and identify changes in HAI prevalence. Estimate the prevalence and describe indications for antimicrobial use (AU); describe the quality of antimicrobial prescribing and identify changes for selected clinical circumstances; and estimate the prevalence of antimicrobial resistance among pathogens causing HAIs.
- **Intended use of the resulting data**: Provide current, national estimates of the HAI and AU burden in U.S. acute care hospitals, and assess progress made in preventing HAIs, controlling antimicrobial resistance, and improving the quality of hospital antimicrobial prescribing.
- **Method to be used to collect**: Cross-sectional approach via point-prevalence surveys in participating U.S. short-term, acute care hospitals.
- **Subpopulation to be studied**: Patients of all ages in U.S. short-term, acute care hospitals.
- **How data will be analyzed**: The proportions of patients with HAIs and on antimicrobial drugs will be calculated. Factors associated with HAIs and AU will be analyzed using log binomial regression modeling and/or other appropriate methods. Prevalence will be converted to incidence using established methods to estimate the burden of HAIs and AU in the U.S. [1].

1. Circumstances Making the Collection of Information Necessary

This is a request for OMB approval of an extension to an approved data collection for the Centers for Disease Control and Prevention (CDC) Healthcare-Associated Infections (HAI) and Antimicrobial Use (AU) Prevalence Survey (OMB Control Number 0920-0852). A request for extension was most recently approved in December 2019, with an expiration date of 10/31/2022. On March 2020, the World Health Organization (WHO) declared the novel SARS-CoV-2 outbreak a global pandemic. Due to the COVID-19 pandemic, the HAI and AU Prevalence Survey was postponed to 2023. CDC is requesting a new three-year extension of the approval to conduct a full-scale survey in acute care hospitals in 2023 with non-substantive changes in data collection instruments.

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 A.2). Conducted through CDC's Emerging Infections Program (EIP) (www.cdc.gov/ncezid/dpei/eip/), this project is a collaboration between CDC and 10 state health departments and their academic partners.

Conducting the survey at regular intervals provides important information about changes in HAIs and AU over time. This information is necessary to evaluate the success of infection control and antimicrobial stewardship interventions and to understand HAIs and types of AU that should be targeted for more intensive surveillance and prevention efforts.

The elimination of HAIs is a priority of the U.S. Department of Health and Human Services (HHS) (see www.hhs.gov/ash/initiatives/hai/) and CDC (see https://www.cdc.gov/hai/prevent/prevention.html). Improving antimicrobial prescribing is also a critical component of strategies to reduce antimicrobial resistance in healthcare facilities (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6309a4.htm?s_cid=mm6309a4_w), such as the National Strategy for Combating Antibiotic Resistant Bacteria (CARB),(https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf). Data from the prevalence survey are essential to understanding the scope and magnitude of all types of HAIs and AU in patient populations across the spectrum of U.S. healthcare facilities and to the development of effective prevention strategies and policies.

CDC currently conducts surveillance through the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666) for priority HAIs such as device-associated HAIs and HAIs related to select types of surgeries; however, CDC cannot currently estimate the scope and magnitude of all HAIs affecting inpatient populations in acute care hospitals using NHSN data alone. Furthermore, CDC does not currently collect detailed, patient-level data within NHSN or other surveillance systems on inpatient AU in a national sample of hospitals. Such data are essential in the effort to develop and implement strategies to reduce inappropriate AU and prevent the emergence of resistant pathogens.

Currently, the EIP HAI and AU Prevalence Survey is the only large-scale CDC project in the U.S. designed to measure the scope and magnitude of all HAIs affecting acute care inpatient populations and to assess the quality of antimicrobial prescribing for selected clinical conditions. Prevalence surveys, in which data are collected during a defined time period, provide a snapshot of the frequency and nature of HAIs and AU and represent an efficient, cost-effective alternative to on-going surveillance initiatives for all HAIs hospital-wide.

Results on HAI prevalence, types of HAIs, and estimated national HAI burden from the 2015 survey have been published and shared with internal and external public health partners [2]. Since the most recent approval for this data collection in December 2019, results on the appropriateness of antimicrobial use in U.S. hospitals have been published [3].

2. Purpose and Use of Information Collection

Essential steps in reducing the occurrence of HAIs and prevalence of antimicrobial resistant pathogens are to estimate the burden of HAIs in U.S. hospitals, describe the types of infections and causative organisms, and assess the nature and extent of AU. Updated estimates are needed for public health priority setting, for policy-making purposes, and for communications with the public and other stakeholders. These estimates are also necessary for collaborations with partners in other parts of the world and internally within state health departments and the CDC for setting surveillance and prevention priorities. The EIP HAI and AU Prevalence Survey has been conducted 4 times previously: in 2009, 2010, 2011, and 2015.

The most recent prevalence survey was conducted in 199 participating hospitals in 2015. Approximately 74% of these hospitals had previously participated in the 2011 survey [2], allowing CDC to assess changes in HAI prevalence. In 2018, these findings were published in the *New England Journal of Medicine* [2]. Notably, the percentage of inpatients with HAIs in 2015 was lower than in 2011. Patients' risk of having a HAI was 16% lower after adjusting for certain factors. Pneumonia, gastrointestinal infections (most of which were due to *Clostridium difficile* [now *Clostridioides difficile])*, and surgical-site infections were the most common HAIs. Ultimately, 23.6% of HAIs were device-associated [i.e., ventilator-associated pneumonia, central line-associated bloodstream infections (CLABSIs), and catheter-associated urinary tract infections (CAUTIs)], highlighting a need for continued surveillance and adjustments to prevention strategies. Using National Inpatient Sample (NIS) data stratified according to the categories of age and length of stay, we estimated that there were 633,300 inpatients with a HAI and 687,200 total HAIs in U.S. hospitals in 2015 [2].

In 2011, AU was prevalent, with approximately half of all surveyed inpatients receiving at least one antimicrobial agent at the time of the survey. Intravenous vancomycin, a drug used to treat infections with resistant Gram-positive pathogens such as methicillin-resistant *S. aureus* (MRSA), was the most common antimicrobial used in 2011 [5]. Data from the 2015 survey showed that the overall prevalence of AU was not significantly different than it was in 2011, although there were changes in the percentages of inpatients receiving certain types of antimicrobial drugs; for example, fewer inpatients were receiving fluoroquinolones in 2015, likely reflecting antimicrobial stewardship efforts. The same data also showed that antimicrobial use deviated from recommended practices for 55.9% of patients who received antimicrobials for community-acquired pneumonia or urinary tract infection present at admission or who received fluoroquinolone or intravenous vancomycin treatment [3].

Results from previous surveys have been used in a variety of settings, including the following:

1) State health departments of participating EIP sites have shared survey data with their HAI Committees to inform priority setting for public health initiatives to reduce HAIs and to improve AU.
2) The CDC has collaborated with the European Centre for Disease Prevention and Control (ECDC) to harmonize HAI and AU prevalence survey methods to allow for selected comparisons of prevalence and burden, and to facilitate international situational awareness of HAI and AU. Collaborations on prevalence survey methods between the CDC and the ECDC and other countries are included in the work plan for the Transatlantic Task Force on Antimicrobial Resistance (TATFAR; https://www.cdc.gov/drugresistance/tatfar/index.html.
3) Burden estimates for selected HAIs generated using survey data have been used to validate estimates obtained through other surveillance systems, such as NHSN [e.g. CLABSIs, surgical site infections (SSIs), etc.].

As there is no on-going surveillance for all HAI types occurring across inpatient populations and no large-scale patient-level assessment of inpatient antimicrobial prescribing quality in U.S. acute care hospitals, repeating this survey at regular intervals is critical to measure the impact of prevention strategies. Without on-going surveys, knowledge of the entire spectrum of HAIs and

AU in U.S. acute care hospitals will be lost. The 2023 EIP HAI and AU Prevalence Survey will allow CDC and its partners to continue to monitor HAI and AU trends, to measure progress in meeting national targets, and to further refine prevention strategies. Antimicrobial prescribing quality data collected in the 2015 survey will serve as a baseline to measure progress in 2023.

3. Use of Improved Information Technology and Burden Reduction

Data collection and data entry partners outside of CDC will include local hospital staff (e.g., Infection Preventionists or other staff), EIP site personnel (i.e., employees and contractors), academic collaborators, and local and state public health professionals. The survey primarily utilizes paper data collection forms as EIP site personnel will often travel to multiple inpatient units within hospitals to collect data and will not necessarily have reliable, timely access to computers or the internet. Electronic health record systems, access, and information technology resources vary widely among hospitals and EIP sites. If resources and capabilities allow, CDC will explore options for electronic data collection. After collection, data will be entered by EIP site personnel into a web-based, CDC-developed database. No personal identifiers such as name or medical record number will be submitted to CDC.

As part of the proposed data collection and public burden estimate, hospital staff will complete the Healthcare Facility Assessment (HFA, Attachment C) on a one-time basis and in some cases may assist EIP site personnel in the completion of Patient Information Forms (PIF, Attachment D) as needed (e.g., assistance locating records, answering questions, etc.). HFAs will be used to gain information on hospital infection control and antimicrobial stewardship policies, practices, and resources. This information is critical for identifying facility-level risk factors and for enhancing understanding of challenges and key opportunities for intervention. PIFs will be used to assess patient-level risk factors and potential indicators of infection, such as the presence of a medical device or AU. Patients will not be interviewed. Additional forms, such as the HAI, AU, and the Antimicrobial Quality Use Assessment (AQUA) forms (Attachments E-I), will be completed by EIP site personnel and are not considered public burden (See Section 14).

EIP site personnel will provide HFA instructions to hospital staff either in person or via electronic communication (Attachment J). Due to the wide array of electronic communication capabilities across hospitals and to the potential need for hospital staff to consult with other colleagues in the facility to answer some of the questions, the HFA is anticipated to be completed in paper form in most hospitals. Some hospitals may elect to complete the form electronically (e.g., fillable PDF). EIP site personnel will also provide training to hospital staff for completing the PIF as needed, although it is expected that most or all PIF data collection will be completed by EIP site personnel with minimal assistance from hospital staff.

In an effort to re-examine public burden and to improve data collection to capture SARS-CoV-2 infection status, CDC and EIP site personnel have conducted reviews of the PIF, AU form, and AQUA General Patient Assessment (GPA) form. As a result, non-substantive changes to these instruments have been made. In regard to the addition of new data collection elements, all changes were thoroughly evaluated and deemed necessary to enhance future analysis and utility of survey data for CDC, EIP, and other public health partners. These changes are not expected to

increase the public reporting burden. Detailed descriptions of changes to the PIF, AU form, and AQUA GPA form are provided in Section 15.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's first large-scale 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 [6]. 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 team of CDC-trained data collectors (https://wwwnc.cdc.gov/eid/article/7/2/70-0295_article). 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 (e.g., central line-associated bloodstream infections [CLABSIs], catheter-associated urinary tract infections [CAUTIs], surgical site infections [SSIs], etc. http://www.cdc.gov/nhsn/about.html) and selected infections due to resistant organisms. An AU reporting module also allows hospitals to submit location-specific antimicrobial consumption data to NHSN; data submission must be done electronically (i.e., no manual data entry), and facility-wide data submission is not required. Patient-level data are not submitted to this AU reporting option. Hospital participation in NHSN is in many cases driven by state HAI reporting mandates and by requirements of the Centers for Medicare and Medicaid Services' (CMS) Hospital Inpatient Quality Reporting (IQR) Program (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html), which includes selected HAIs.

While the information collected in the EIP HAI and AU Prevalence Survey is broader in scope than the data collected in NHSN, there may be some minimal overlap. Based on CMS hospital IQR program requirements (https://www.cdc.gov/nhsn/pdfs/cms/cms-reporting-requirements.pdf), most hospitals in the United States report the following HAI surveillance data to NHSN: CLABSIs and CAUTIs in intensive care units and selected ward locations; deep incisional and organ/space SSI following colon surgeries and abdominal hysterectomies; and hospital-wide MRSA bacteremia and *C. difficile* infections. We estimate that these infections account for approximately 31% of all HAIs, based on 2011 and 2015 prevalence survey results [2,4]. It is important to note that each hospital will conduct the prevalence survey over a very short period of time (one day) and will only be collecting data on a sample of inpatients in the hospital during that short time period. For example, a hospital with 500 acute care beds may be asked to review 100 inpatient medical records for the purposes of the prevalence survey. If 3% of these inpatients have HAIs (3 inpatients) and we estimate that 31% of HAIs detected will also need to be entered into NHSN, that represents a burden of less than one inpatient record for that hospital.

Other CDC systems that have the capability of collecting information on HAIs in acute care hospitals include the National Hospital Care Survey (NHCS), run by the National Center for Health Statistics (NCHS) (https://www.cdc.gov/nchs/nhcs/index.htm). The NHCS collects data on hospital inpatients and visits to emergency departments and outpatient departments, including ambulatory surgery. We have previously had communications with NCHS colleagues to explore the possibility of using the NHCS infrastructure in future years to conduct or enhance the prevalence survey, and we will continue to explore these possibilities as implementation of the NHCS progresses. Currently, it is necessary to use the prevalence survey with the same data collection methods to assess changes in HAIs and AU over time and to evaluate changes in antimicrobial prescribing quality in a similar group of hospitals.

Although other prevalence surveys have been conducted in several countries around the world [7-31], there are currently no duplicate efforts underway within the United States. A global prevalence survey supported by BioMérieux is currently on-going (https://www.global-pps.com/project/); the survey's focus is AU and antimicrobial resistance, although there is an optional data collection module pertaining to HAIs and device use. The extent to which U.S. hospitals have been included in this effort is uncertain. A report presented at the European Conference on Clinical Microbiology and Infectious Diseases in 2016 indicated that 15 U.S. hospitals (all part of the Healthcare Corporation of America) had participated in this survey (https://www.global-pps.com/wp-content/uploads/2016/04/ECCMID-2016_USA.pdf). In 2018, a paper published in *Lancet Global Health* reported that 24 hospitals in North America participated (http://www.global-pps.com/wp-content/uploads/2018/05/1-1-LANGH-2015_Global-PPS_results-on-adults_main-article_Versporten_April2018.pdf). Information on the project website indicates that since the introduction in 2019, there have been two versions of prevalence survey: the original basic survey that allows participating healthcare facilities to report antimicrobial use, HAIs, and antimicrobial resistance; and the full version of survey that includes an extra HAI module allowing for reporting of data pertaining to invasive device use.

5. Impact on Small Businesses or Other Small Entities

Small hospitals may participate in the data collection for the survey. Participation is voluntary, but we anticipate that most hospitals selected for participation will agree to participate. Elimination of HAIs and improving antimicrobial prescribing are major goals of all U.S. healthcare institutions, large and small, and we expect that hospitals will be highly motivated to participate. The data collection and management burden for participating hospitals was reviewed following the 2015 survey and reassessed for the 2023 survey. In general, burden is minimized by having CDC-trained EIP site personnel perform the majority of data collection. In participating hospitals that have insufficient resources to assist EIP site personnel in PIF data collection, EIP site personnel may perform all of the PIF data collection.

6. Consequences of Collecting the Information Less Frequently

The survey was developed with the goal of repeating it at regular but infrequent intervals (e.g., once every 3-5 years). We granted approval from OMB to conduct the fifth survey in 2020, but due to the COVID-19 pandemic the survey was postponed to 2023. Repeating the survey will provide information on changes in HAI and AU prevalence over time as well as changes in the

estimated burden and distribution of infection types and causative organisms. These data are critical to inform CDC decisions and national policy makers, to assess progress in meeting national reduction targets, and to validate data from other sources such as NHSN. In addition, these data will allow CDC to assess changes in antimicrobial prescribing quality. A baseline assessment was included in the 2015 survey; this is a key area of importance to public health researchers and the medical community, particularly regarding efforts to combat antimicrobial resistance.

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 this request fully complies with regulations.

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

A. A Federal Register Notice was published on 08/03/2021, volume 86, No. 154, page 44723-44725. One non-substantive public comment was received and responded to (Attachment N).

B. As required in the Notice of Action for the 2010 survey, on June 14, 2010 we consulted with colleagues in the National Center for Health Statistics (Dr. Jane Sisk, former Director of the Division of Health Care Statistics, Attachment K). In the process of developing and conducting previous surveys, we also consulted with experts in the ECDC, where our primary point of contact is Dr. Carl Suetens, Senior Expert. We have continued our communications with ECDC experts, participating in conference calls and TATFAR meetings. A TATFAR meeting was held at CDC in March 2018. ECDC also hosted an experts meeting to discuss methods for estimating national and regional burden of HAIs in hospitals and nursing homes in Stockholm in May 2019. The implementers for the TATFAR action items on prevalence survey collaborations have met via conference calls regularly.

9. Explanation of Any Payment or Gift to Respondents

Participating hospitals may receive a certificate or letter of appreciation and a summary of project results. EIP sites or state health departments may choose to provide education and/or training resources to participating hospitals.

10. Protection of Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by NCEZID's Information Systems Security Officer who has determined that the Privacy Act does not apply. Hospitals selected to participate in the data collection are informed that participation is voluntary. Individual patients are not the respondents for this data collection, and are not informed of their inclusion in the data collection. There is no interaction between EIP site or CDC personnel and individual patients.

Most data collection and data collection forms will be completed by EIP site personnel. Hospital staff (e.g., Infection Preventionists or other facility staff members) will complete the HFA and

may assist EIP site personnel in completion of PIFs, depending on resources. Data collection performed by EIP site personnel is not considered public burden (See Section 14). Descriptions of information to be collected and measures to protect the privacy and confidentiality of information are provided below. These data (HFA and PIF) are included in the public burden estimate.

- Healthcare-Facility Assessment (HFA) Form [Attachment C]: Data will be collected primarily by hospital staff with assistance from EIP site personnel. Information to be collected includes facility demographics and information about infection control and antimicrobial stewardship resources, policies, and practices.
    - EIP site personnel will assign a unique code to each hospital participating in the survey for completion of data collection forms. These codes will not include facility identifiers and will only be linked to the individual facility name at the EIP site and facility levels. Links to hospital names will not be shared with CDC, although CDC will know the complete list of hospitals participating in the survey.

- Patient Information Form (PIF) [Attachment D]: Data will be collected via review of medical records primarily by EIP site personnel. In some cases, hospital staff may provide assistance. Patients will not be interviewed. Information to be collected includes state, data collection date, age, sex at birth, race, ethnicity, primary payer, survey date, patient location within the hospital, hospital admission and discharge dates, weight and height (or birth weight in neonatal locations), body mass index, outcome, presence and numbers of medical devices (urinary catheter, central line, ventilator), presence of pressure injuries or ulcers, COVID-19 status, and whether the patient was on antimicrobial therapy.
    - EIP site personnel will assign a unique code to each patient included in the survey for completion of data collection forms. These codes will not include patient identifiers and will only be linked to the individual, direct patient identifiers at the EIP site and facility levels. Links and patient identifiers, other than certain dates, will not be shared with CDC.

Descriptions of information to be collected by EIP site personnel (only) are included below as supplemental information. Data collection by EIP site personnel is not part of the public burden estimate (See Section 14). As with the HFA and PIF, data will be collected using unique codes to protect the identities of patients and hospitals.

- Draft Healthcare-Associated Infection (HAI) Form [Attachment E]: Includes presence of HAIs, types of HAIs, and specific details for each HAI (the specific type, whether device or procedure-associated, location and dates of onset and treatment, dates on which all definition criteria were met, causative pathogens, and antimicrobial susceptibility of those pathogens). Note: Additional changes to this form may be made prior to data collection.

- Draft Antimicrobial Use (AU) Form [Attachment F]: Includes drug names, route of administration, start dates, indication or rationale for use, documentation of sepsis and COVID-19, location of onset for the infection in which antimicrobials were prescribed, and therapeutic sites. Note: Additional changes to this form may be made prior to data collection.

- Draft Antimicrobial Quality Use Assessment (AQUA) Form(s) [Attachments G-I]: Include detailed information on antimicrobial treatment, patient allergies or other adverse events, underlying conditions and diagnoses, clinical signs and symptoms of infection, and results of laboratory and microbiological testing. Prescribing quality will be assessed for the following prescribing events: adult and pediatric pneumonia, adult and pediatric urinary tract infection, adult and pediatric intravenous vancomycin prescribing, and adult fluoroquinolone prescribing. Note: Additional changes to this form may be made prior to data collection.

As described above, local data collectors in participating hospitals and EIP site personnel will need to collect personally identifiable information (PII) for patients within their own facility or catchment area. Medical information and hospital admission and discharge dates, survey dates and data collection dates, infection and therapy dates, and other dates pertaining to clinical information (such as date of specimen collection for testing) will be transmitted to CDC. Identifiable information, such as patient name, date of birth, medical record number, hospital unit name, and patient room number will not be transmitted to CDC.

Information received by CDC will be stored in a secure database. This database will comply with applicable information technology and information security standards at CDC and will undergo the applicable evaluation and approval processes prior to deployment. Access to the CDC database will be provided only to those individuals at CDC (e.g., employees, trainees/fellows, and contractors) who are members of the CDC project team. Data will be stored and analyzed in a secure manner, and will not be disclosed, unless otherwise compelled by law. The information in the CDC database will be maintained indefinitely, since this data collection will be repeated at regular intervals for comparison purposes.

Designated EIP site personnel will have access to data submitted from hospitals within their site only and will not be able to access data from other sites. PII (e.g., name, address, birthdate, medical record numbers, and other medical information) will be maintained by local hospitals and/or EIP sites until completion of all survey activities, and according to local and/or state requirements and regulations. However, PII (other than demographic characteristics, clinical information, and certain dates) will not be transmitted to CDC. EIP site personnel may provide a participating hospital with its own data to facilitate prevention, improvement, and stewardship initiatives. Results of analyses of data aggregated at the EIP site level or across EIP sites may also be provided to participating hospitals.

Following the conclusion of the 2023 survey, data may be analyzed to determine whether certain hospital characteristics (e.g., bed size, etc.) or patient characteristics are associated with aspects of HAI prevalence or antimicrobial prescribing. Individual EIP sites and/or CDC may choose to

present or publish aggregated, site-specific survey data. Individual EIP sites, in consultation with participating hospitals in that site, may elect to present or publish facility-specific information. Survey results may be shared in local, state, national and international presentations and publications, and will be used by local, state, and federal public health authorities to inform the development of HAI prevention and antimicrobial stewardship strategies and policies.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

The 2011 survey and the 2015 survey were determined not to be human subjects research (Attachment L). A formal determination has not yet been sought for the 2023 survey, but we do not anticipate it to differ from previous survey determinations, since the objectives, methods and the nature of the data collection have not changed substantially.

Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, and religious beliefs, will not be collected, with the exception of collection of drug use (which impacts the need for vancomycin treatment in patients with skin and soft tissue infections). We will collect information on inpatient location within hospitals (one type of location is a jail unit), and we will collect information on locations of patients prior to admission and upon discharge from the hospital (such as a correctional facility).

Race and ethnicity will be collected by local hospital staff and EIP site personnel. We believe it is important to collect data on race and ethnicity because studies have indicated that there is a higher burden of some types of HAIs in patients of certain races or ethnicities. For example, a study published in 2010 showed that post-operative infections were significantly more common among black patients than white patients [32]. Similarly, data from the EIP's invasive MRSA surveillance have shown that the incidence of healthcare-associated invasive MRSA infections was significantly higher in black persons than in white persons [33]. Data on race and ethnicity will be collected in accordance with federal standards, except that a classification of "other race" will be provided. This category is present in the National Inpatient Sample database (NIS) (see https://www.hcup-us.ahrq.gov/db/vars/race/nisnote.jsp), and where possible we have sought to align prevalence survey patient demographic variables with those in the NIS. Also, some medical records allow race to be reported as "other," and this is a data collection based on medical records. Additionally, "not documented" will be provided as an option for race and ethnicity questions on the PIF data collection instrument because information on race and ethnicity may not be available on the medical records.

We will collect information on the presence of underlying conditions, including alcoholism, drug use and HIV/AIDS, because these conditions are risk factors for certain types of infections and may warrant modifications to antimicrobial treatment in certain circumstances. The reporting of adverse events occurring in hospitalized patients, including infections, could be considered sensitive unless hospitals are assured that the data-aggregating organization will provide security

for the data and maintain the institution's confidentiality. Data security will be protected as described in Section A.10.

12. Estimates of Annualized Burden Hours and Costs

A. Infection preventionists (or other designated staff) in participating hospitals will be asked to do the following: 1) participate in survey training; 2) complete the HFA (Attachment C); and 3) assist EIP site personnel with PIF data collection if resources are available (Attachment D).

Note: Any reference to the number of patients surveyed or included in the survey should be interpreted as the number of patients' *medical records* reviewed/included in the survey; patients are *not* interviewed or interacted with directly.

For the HFA, we anticipate a total of no more than 300 respondents, one HFA for each participating hospital. The HFA will be completed in close proximity to the survey date (ideally during the month before the survey date). The time required to complete the HFA is estimated to be 45 minutes (Table A).

For training and the PIF, we incorporated knowledge gained from the 2011 and 2015 surveys to estimate burden. In these prior surveys, EIP site personnel asked each participating hospital to survey a fixed number of patient medical records, 75−100 randomly-selected acute care inpatients, depending upon hospital size. Small and medium hospitals were asked to survey 75 inpatients each (or, if the hospital has <75 beds, the hospital surveyed all inpatients), while large hospitals were asked to survey 100 inpatients each. Small hospitals accounted for approximately 51% of hospitals in the survey (and not all of these hospitals had 75 inpatients to survey), medium hospitals accounted for approximately 37% of hospitals in the survey, and large hospitals accounted for 12% of hospitals in the survey [4].

Using the maximum estimate of 300 participating hospitals, 153 of these would be small hospitals, 111 would be medium hospitals, and 36 would be large hospitals. Of the 153 small hospitals, we estimate that 20% of these (31 hospitals) would be able to review 75 inpatients. In the other 80% of small hospitals (122 hospitals), we estimate that 37 inpatients would be available for review.

Therefore, the total number of records reviewed was estimated as follows: [(31 small hospitals)*(75 records)] + [(122 small hospitals)*(37 records)] + [(111 medium hospitals)*(75 records)] + [36 large hospitals)*(100 records)] = 18,764 patient records, which translates to an average of 63 PIF responses per hospital. The time required to participate in training and data collection to complete the PIF is estimated to be 17 minutes.

In summary, one full-scale survey is planned for the three-year approval period. In total, 300 facility respondents will complete the HFA 1x and the PIF, on average, 63x. To annualize the burden over a three-year period in Table A below, the number of respondents has been set at 100 per year. The total estimated annualized public burden is 1,860 hours, which represents no change from the 2019 OMB approval.

Table A: Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
Hospital Staff (i.e., Infection Preventionist)	Healthcare Facility Assessment (HFA)	100	1	45/60	75
	Patient Information Form (PIF)	100	63	17/60	1,785
Total (Hours)					**1,860**

B. To calculate the total cost burden for hospital respondents (i.e., Infection Preventionists), we utilized the mean hourly wage of $38.47 for a Registered Nurse (RN) (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2020 data, accessed June 29, 2020 at http://www.bls.gov/news.release/ocwage.t01.htm). We utilized this wage because: 1) Infection Preventionists are in many cases RNs; and 2) there is no wage information available for Infection Preventionists in the Bureau of Labor Statistics database cited above. There will be no direct costs to hospitals and local data collectors other than their time to participate in the project.

With an estimated annualized burden of 1,860 hours (Table A), the estimated annualized cost of time to respond to the survey is $71,554.20 (Table B). This represents a minor increase from the estimate approved in 2019 (+ $5,784.60) due to an increase in the estimated mean hourly wage for RNs.

Table B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospital Staff (i.e., Infection Preventionist)	HFA	100	1	45/60	75	$38.47	$2,885.25
	PIF	100	63	17/60	1,785	$38.47	$68,668.95
Total							**$71,554.20**

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 CDC and EIP site personnel to develop and coordinate data collection activities, EIP site personnel to perform local coordination and data collection and entry activities, and costs for photocopying survey materials.

CDC personnel working on the data collection are estimated to include 1 full-time-equivalent (FTE) public health analyst or epidemiologist (Table C), 0.5 FTE business analyst, 0.25 FTE data analyst, 0.05 FTE statistician, 1 FTE database developer, and a 0.5 FTE database administrator (see Table C). The mean hourly wage for an epidemiologist is $40.20 ($83,616 annually); for a business analyst is $46.91 ($48,786 annually); for a data analyst is $44.37 ($23,072 annually); for a statistician is $46.72 ($4,859 annually); for a database developer is $54.94 ($114,275 annually); and for a database administrator is $48.60 ($50,544 annually) [obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2020 data, accessed June 29, 2020 at (http://www.bls.gov/news.release/ocwage.t01.htm].

EIP sites (Table C) are supported through a Cooperative Agreement with CDC. During a May 7, 2010 teleconference with Dr. Margo Schwab and Ms. Julie Wise from OMB, Dr. Schwab informed CDC prevalence survey personnel that because the EIP is a CDC-run program under a Cooperative Agreement, EIP site personnel are not be included in the annualized public burden estimate, but rather in the estimate of annualized cost to the government. We estimate that on an annualized basis, 2.0 FTE employees are needed in each EIP site to conduct survey activities. These employees are epidemiologists, with an estimated mean hourly wage of $40.20 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2020 data). The estimated annual cost across the 10 EIP sites is $1,672,320 (Table C), which represents a minor increase from the 2019 estimate (+ $147,680) due to an increase in the estimated mean hourly wage for epidemiologists.

There will also be costs related to photocopying of forms and instructions. The cost is estimated to be $16,765 ($0.10 to copy each page, estimated 167,648 copies made to support survey activities in 300 hospitals in 10 EIP sites), or $5,588 per year.

The total annualized cost to the federal government for personnel and photocopying is therefore estimated to be $2,003,060.00 (Table C), which represents a net increase of $175,365 from the 2019 estimate.

Table C: Annualized Cost to the Federal Government

Government Employee Title	Total Number of Hours Dedicated per Year	Hourly Rate	Total Annualized Cost
CDC Epidemiologist	2080	$40.20	$83,616

CDC Business Analyst	1040	$46.91	$48,786
CDC Data Analyst	520	$44.37	$23,072
CDC Statistician	104	$46.72	$4,859
CDC Database Developer	2080	$54.94	$114,275
CDC Database Administrator	1040	$48.60	$50,544
EIP Epidemiologists (2.0 FTE in each of 10 sites)	41,600	$40.20	$1,672,320
Photocopying	--	--	$5,588
Total			**02,003,060.00**

15. Explanation for Program Changes or Adjustments

The annualized public burden for this request (1,860 hours) is equal to the burden approved in the most recent OMB request in October 18, 2019 as proposed changes to the three data collection instruments (PIF, AU form, and AQUA GPA form) are non-substantive and not determined to impact the average burden per response.

Since the 2019 approval, the estimated annualized cost of time to respond to the survey has increased (+ $5,784.60) due to an increase in estimated mean hourly wage for hospital infection preventionists (RNs). The total annualized cost to the federal government has also increased (+ $175,365) due to increases in salary estimates and photocopying costs.

Non-substantive changes to the Patient Information Form (PIF, Attachment D) include the following:

1) Formatting/general appearance of the form was updated;
2) In *Section II*, Race "Unknown" was reworded as "Not documented" and Ethnicity "Not documented" was added as a response option;
3) In *Section IV*, if a pressure injury or ulcer was present on the survey date the subsequent question was reworded to "did any pressure injuries or ulcers develop after admission?";
4) *Section V* was added to include COVID-19 status by asking if a "SARS-CoV-2 viral test was performed during the 14 days before hospital admission through the survey date". Test collection dates closest to the survey date are required for positive and negative test results.
5) In *Section VI*, the statement "must be at least 6 months after the survey date if hospital discharge date is unknown or patient is still in hospital" was added for "Enter date of follow-up data collection".

Non-substantive changes to the Antimicrobial Use Form (AU, Attachment F) include the following:

1) Formatting/general appearance of the form was updated;
   In *Section IV*, COVID-19 was added to the Treatment Table as one of the infections options on each of the therapeutic sites. Instructions on when to check "Y" for COVID-19 were also added.

Non-substantive changes to the Antimicrobial Quality Assessment (AQUA) General Patient Assessment Form (AQUA GPA, Attachment H) include the following:

1) Formatting/general appearance of the form was updated;
2) In *Section VI*, COVID-19 was added to the table as an infection option present during hospitalization.

These changes were made to simplify data collection for hospital staff and to enhance the utility of data for future prevention initiatives. All changes were discussed with and approved by EIP site partners. There is a net increase of one question proposed. As a result, these changes are not expected to increase public reporting burden for hospital staff.

16. Plans for Tabulation and Publication and Project Time Schedule

Patient-level and hospital-level survey datasets, containing the data elements described in previous sections and in the Attachments, will continue to be maintained at CDC. These datasets will be used to determine HAI and AU prevalence, the distribution of HAI types and pathogens, and the distribution of types of antimicrobials and rationale for use. They will also be used to describe hospitals participating in the survey, to assess factors associated with HAIs and AU, and to describe antimicrobial prescribing quality.

Categorical and continuous variables will be compared in patients with and without HAIs (and receiving and not receiving antimicrobials) using chi-square tests and Wilcoxon rank-sum or median tests, respectively. Associations between patient and facility-level characteristics and HAIs and AU will be explored using univariate and multivariable log binomial regression modeling or other appropriate methods. HAI and AU prevalence will be converted to incidence using the formula of Rhame and Sudderth [1]. Other methods may be employed based on on-going collaboration with external partners such as TATFAR. HAI and AU burden estimates will be generated using prevalence survey data and data from the National Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), and Agency for Healthcare Research and Quality (AHRQ). Analysis will occur in SAS version 9.4 or a newer version as it becomes available (SAS Institute, Carey, NC).

Results from this data collection will be presented at local/state/national meetings and in peer-reviewed scientific journals. Publications will include a discussion of potential biases and other limitations of the project.

Table D: Project Timeline

Activity	Time Schedule

Training of EIP sites staff for survey activities	1–2 months before survey date (March – April 2023)
Survey Implementation by EIP site personnel and hospital staff	May – September 2023
Data collection by EIP site personnel and transmission of data to CDC	12 months after survey start date (May 2023 – June 2024)
Data cleaning activities by EIP site personnel and CDC personnel	Simultaneously during data collection and 2 months after end of data collection (May 2023 – July 2024)
Analysis and presentation of 2023 survey results by CDC personnel	August – December 2024

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

None.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

None.

References

1) Rhame FS, Sudderth WD. Incidence and prevalence as used in the analysis of the occurrence of nosocomial infections Am J Epidemiol 1981;113:1-11.

2) Magill SS, O'Leary E, Janelle S, et al. Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. *N Engl J Med* 2018;379:1732-44.
3) Magill SS, O'Leary E, Ray S, et al. Assessment of the Appropriateness of Antimicrobial Use in US Hospitals. JAMA Netw Open. 2021;4(3):e212007. doi:10.1001/jamanetworkopen.2021.2007
4) Magill SS, Edwards J, Bamberg W, et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med* 2014;370:1198-208.
5) Magill SS, Edwards J, Beldavs Z, et al. Prevalence of Antimicrobial Use in U.S. Acute Care Hospitals, May-September 2011. *JAMA* 2014;312:1438-46.
6) Haley RW, Culver DH, White JW, et al. Study on the Efficacy of Nosocomial Infection Control (SENIC project): summary of study design. Am J Epidemiol 1980;111:472-85.
7) Lanini S, Jarvis WR, Nicastri E, et al. Healthcare-associated infection in Italy: annual point-prevalence surveys, 2002-2004. *Infect Control Hosp Epidemiol* 2009;30:659-65.
8) Smyth ETM, McIlvenny G, Enstone JE, et al. Four Country Healthcare Associated Infection Prevalence Survey 2006: overview of the results. *J Hosp Infect* 2008;69:230-48.
9) Reilly J, Stewart S, Allardice GA, et al. Results from the Scottish National HAI Prevalence Survey. *J Hosp Infect* 2008;69:62-68.
10) Kanerva M, Ollgren J, Virtanen MJ, Lyytikäinen O, for the Prevalence Survey Study Group. Estimating the annual burden of healthcare-associated infections in Finnish adult acute care hospitals. *Am J Infect Control* 2009;37:227-30.
11) Gastmeier P, Kampf G, Wischnewsky N, et al. Prevalence of nosocomial infections in representative German hospitals. J Hosp Infect 1998;38:37-49.
12) Scheel O, Stormark M. National prevalence survey on hospital infections in Norway. J Hosp Infect 1999;41:331-5.
13) Vaque J, Rossello J, Arribas JL, et al. Prevalence of nosocomial infections in Spain. J Hosp Infect 1999;43:105-11.
14) The French Prevalence Survey Study Group. Prevalence of nosocomial infections in France: results of the nationwide survey in 1996. J Hosp Infect 2000;46:186-193.
15) Azzam R, Dramaix M. A one day prevalence survey of hospital-acquired infections in Lebanon. J Hosp Infect 2001;49:74-8.
16) Zotti CM, Messori G, Charrier L, et al. Hospital-acquired infections in Italy: a region wide prevalence study. J Hosp Infect 2003;56:142-9.
17) Gikas A, Pediaditis J, Papadakis JA, et al. Prevalence study of hospital-acquired infections in 14 Greek hospitals. J Hosp Infect 2002;50:269-75.
18) Plowman R, Graves N, Griffin MA, et al. The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialities of a district general hospital in England and the national burden imposed. J Hosp Infect 2001;47:198-209.
19) Emmerson AM, Enstone JE, Griffin MA, et al. The Second National Prevalence Survey of infection in hospitals—overview of the results. J Hosp Infect 1996;32:175-90.
20) Pittet D, Harbarth S, Ruef C, et al. Prevalence and risk factors for nosocomial infection in four university hospitals in Switzerland. Infect Control Hosp Epidemiol 1997;20:37-42.

21) Faria S, Sodano L, Gjata A, et al. The first prevalence survey of nosocomial infections in the University Hospital Centre Mother Teresa of Tirana, Albania. J Hosp Infect 2007;65:244-50.
22) Hajdu A, Samodova OV, Carlsson TR, et al. A point prevalence survey of hospital-acquired infections and antimicrobial use in a pediatric hospital in north-western Russia. J Hosp Infect 2007;66:378-84.
23) Lee MK, Chiu CS, Chow VC, et al. Prevalence of hospital infection and antibiotic use at a university medical Center in Hong Kong. J Hosp Infect 2007;65:341-74.
24) Duerink DO, Roeshadi D, Wahjono H, et al. Surveillance of healthcare-associated infections in Indonesian hospitals. J Hosp Infect 2006;62:219-29.
25) Klavs I, Luznik TB, Skerl M, et al. Prevalence of and risk factors for hospital-acquired infections in Slovenia—results of the first national survey, 2001. J Hosp Infect 2003;54:149-57.
26) Kallel H, Bahoul M, Ksibi H, et al. Prevalence of hospital-acquired infection in a Tunisian hospital. J Hosp Infect 2005;59:343-7.
27) Metintas S, Akgun Y, Durmaz G, et al. Prevalence and characteristics of nosocomial infections in a Turkish university hospital. Am J Infect Control 2004;32:409-13.
28) Danchaivijitr S, Judaeng T, Sripalakij S, Naksawas K, Plipat T. Prevalence of nosocomial infection in Thailand 2006. J Med Assoc Thai 2007;90:1524-9.
29) Gravel D, Matlow A, Ofner-Agostini M, et al. A point prevalence survey of healthcare-associated infections in pediatric populations in major Canadian acute care hospitals. Am J Infect Control 2007;35:157-62.
30) Gravel D, Taylor G, Ofner M, et al. Point prevalence survey for healthcare-associated infections within Canadian adult acute-care hospitals. J Hosp Infect 2007;66:243-8.
31) Ansari F, Erntell M, Goossens H, et al. The European Surveillance of Antimicrobial Consumption (ESAC) point-prevalence survey of antibacterial use in 20 European hospitals in 2006. Clin Infect Dis 2009;49:1496-1504.
32) Mayr FB, Yende S, Linde-Zwirble WT, et al. Infection rate and acute organ dysfunction risk as explanations for racial differences in severe sepsis. JAMA 2010;303:2495-2503.
33) Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States. JAMA 2007;298:1763-71.

List of Attachments

A. United States Code, Title 42, Chapter 6A Part 241 (referenced in Part A)

A.2 American Recovery and Reinvestment Act of 2009 (referenced in Part A)

B. 60-Day FRN

C. Healthcare Facility Assessment (HFA) (referenced in Part A)

D. Patient Information Form (PIF) (referenced in Part A)

E. Draft Healthcare-Associated Infection (HAI) Form (referenced in Part A, supplemental information only)

F. Draft Antimicrobial Use (AU) Form (referenced in Part A, supplemental information only)

G. Draft Antimicrobial Quality Use Assessment (AQUA) Form 1: Case Eligibility (referenced in Part A, supplemental information only)

H. Draft Antimicrobial Quality Use Assessment (AQUA) Form 2: General Patient Assessment (referenced in Part A, supplemental information only)

I. Draft Antimicrobial Quality Use Assessment (AQUA) Forms 3 (a-d) (referenced in Part A, supplemental information only)

J. Draft HFA and PIF instructions for data collection (referenced in Part A)

K. Email correspondence from Dr. Jane Sisk, Director, Division of Healthcare Statistics, National Center for Health Statistics (referenced in Part A)

L. Non-research determination (referenced in Part A)

M. Draft Example of informational document distributed to healthcare facilities in EIP catchment areas (referenced in Part B)

N. Public comment on the 60-Day FRN (referenced in 30-Day FRN Extension form)