

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

(OMB Control No. 0920-0852, Expiration 12/31/2019)

Extension ICR

Supporting Statement A

January 15, 2021

Contact:

Nancy Khalil, J.D.

MS H16-5

Centers for Disease Control and Prevention

1600 Clifton Road NE

Atlanta, Georgia 30329-4027

Phone: (770) 488-2070

Email: kuj2@cdc.gov

Table of Contents

| | |
|---|----|
| 1. Circumstances Making the Collection of Information Necessary..... | 3 |
| 2. Purpose and Use of Information Collection..... | 4 |
| 3. Use of Improved Information Technology and Burden Reduction..... | 6 |
| 4. Efforts to Identify Duplication and Use of Similar Information..... | 7 |
| 5. Impact on Small Businesses or Other Small Entities..... | 8 |
| 6. Consequences of Collecting the Information Less Frequently..... | 9 |
| 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5..... | 9 |
| 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency..... | 9 |
| 9. Explanation of Any Payment or Gift to Respondents..... | 9 |
| 10. Protection of Privacy and Confidentiality of Information Provided by Respondents..... | 9 |
| 11. Institutional Review Board (IRB) and Justification for Sensitive Questions..... | 12 |
| 12. Estimates of Annualized Burden Hours and Costs..... | 13 |
| 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers..... | 14 |
| 14. Annualized Cost to the Government..... | 15 |
| 15. Explanation for Program Changes or Adjustments..... | 16 |
| 16. Plans for Tabulation and Publication and Project Time Schedule..... | 18 |
| 17. Reason(s) Display of OMB Expiration Date is Inappropriate..... | 19 |
| 18. Exceptions to Certification for Paperwork Reduction Act Submissions..... | 19 |
| List of Attachments..... | 22 |

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

- **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 the formula of Rhame and Sudderth 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 2016, with an expiration date of 12/31/2019. CDC is requesting a new three-year extension of the approval to: 1) conduct a full-scale survey in acute care hospitals in 2020; and 2) describe 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 and control of antimicrobial resistance are priorities of the U.S. Department of Health and Human Services (HHS) (see www.hhs.gov/ash/initiatives/hai/) and CDC (see www.cdc.gov/winnablebattles/healthcareassociatedinfections/index.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.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibiotic-resistant_bacteria.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. Although approximately 3883 acute care hospitals across the country participate in NHSN surveillance for selected types of HAIs in specific inpatient locations, CDC cannot currently estimate the scope and magnitude of all HAIs affecting inpatient populations in acute care hospitals using NHSN data alone. In addition, although inpatient location-specific antimicrobial use data can be submitted by healthcare facilities to NHSN (see <https://www.cdc.gov/nhsn/acute-care-hospital/aur/index.html>), detailed, patient-level information on the reasons for prescribing or the quality of prescribing are not collected. 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 [2-6] is the only large-scale CDC project in the United States designed to measure the scope and magnitude of all HAIs (not limited to device-associated HAIs and HAIs related to surgical procedures) across 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.

Following the original approval for this data collection, a limited roll-out survey (2010) and the first full-scale survey (2011) were conducted. Since the most recent approval in December 2016, data cleaning for the second-full scale hospital survey (2015 EIP HAI and AU Prevalence Survey) has been completed and results on HAI prevalence, types of HAIs, and estimated national HAI burden have been published and shared with internal and external public health partners [2]. Initial analyses of AU data and prescribing quality data have been presented to infectious disease and epidemiology professionals, and additional analyses are projected for release in 2019–2020 [3, 6].

The prevalence of HAIs determined through these surveys can be used to estimate incidence and HAI burden by applying the formula of Rhame and Sudderth and using data from the National Inpatient Sample (Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality) [7]. The following excerpt from Magill, et al. [4] explains the formula and the approach we have taken to estimating national HAI burden from prevalence survey data:

“To generate estimates of the national burden of health care–associated infections, we converted infection prevalence to incidence using the formula of Rhame and Sudderth³³: $I = P \times [LA \div (LN - INT)]$, where I denotes incidence, P prevalence, LA the mean length of hospitalization for all patients, LN the mean length of hospitalization for patients who acquired one or more health care–associated infections, and INT the mean interval between admission and the onset of the first such infection. Numbers of patients with health care–associated infections were obtained by multiplying infection incidence by numbers of U.S. hospital discharges, obtained from the 2010 Nationwide Inpatient Sample (NIS).³⁴ This database of hospitalizations from a sample of U.S. community hospitals was developed as part of the Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality; discharge weighting allows national estimates to be generated from the sample.

We sought to improve the precision of the burden-estimation process by performing log-binomial regression modeling to identify factors significantly associated with the prevalence of health care–associated infections. Through a process described in the [Supplementary Appendix](#), the results of regression modeling were used to create multiple strata based on patient age and a proxy measure of the length of the hospital stay. Within each stratum, the predicted prevalence of health care–associated infections was converted to incidence with the use of the median length of the hospital stay for surveyed patients for whom such information was available (LA in the formula of Rhame and Sudderth), the median length of hospital stay for patients with health care–associated infections (LN), and the median interval from admission to the onset of the first health care–associated infection (INT). Median rather than mean values were used owing to a skewed distribution. The incidence in each stratum of age and length of stay was multiplied by the total number of U.S. discharges in that stratum (with the use of weighted discharge data from the NIS), under the assumption that each discharge represented a unique patient, to get stratum-specific numbers of patients with health care–associated infections. These stratum-specific numbers were summed to obtain an estimate of the total number of inpatients with health care–associated infections in U.S. acute care hospitals in 2011. Because our estimates of the median length of the hospital stay for all patients were based on data from patients receiving antimicrobial therapy, who may have had a longer median length of stay than patients not receiving such therapy, we also performed the burden-estimation process using data from the NIS for the median length of the hospital stay for all patients in the formula of Rhame and Sudderth.

Burden estimates for major types of health care–associated infection were generated by multiplying the proportion of surveyed patients with each infection type by the estimated total number of patients with health care–associated infections. The numbers of each major type of infection were summed to obtain an estimate of the total number of inpatient health care–associated infections in U.S. acute care hospitals in 2011.”

This approach was used in the two full-scale EIP HAI and AU Prevalence Surveys performed in 2011 and 2015. Limitations of the approach have been described [2, 4]. Because the survey includes a limited number of hospitals and patients in 10 states, the results may not be generalizable. The population of the EIP surveillance catchment area has been shown to be similar to the U.S. population with respect to certain demographic characteristics and health indicators [8, 9, unpublished data], although the catchment area may differ by EIP project. The

prevalence survey is not population-based, and therefore it is more important to consider the similarity of the survey sample of hospitals and patients to all hospitals and patients in the nation. The hospital stratified random sampling scheme based on acute care staffed bed size that was developed for the prevalence survey was designed to approximate the hospital bed size distribution in the EIP sites as a whole, rather than the nation. However, when we compare selected characteristics of hospitals included in the EIP survey, they are similar to characteristics of all acute care hospitals in the United States. For example, staffed bed size, intensive care unit bed numbers, and the mean number of hospital epidemiologists in 2015 prevalence survey hospitals was similar to that of the 3883 acute care hospitals participating in NHSN in 2018. Hospital prevalence survey patients are also similar with respect to age distribution when compared to the NIS (2015 prevalence survey: mean age 51 years, median age 58 years, interquartile range 32-73 years, vs. 2014 NIS: mean age 49, median age 52, interquartile range 31-71 years). Age has been shown to be an important risk factor for HAIs [2, 4]. Hospital length of stay, which has also been shown to be a risk factor for HAIs [2, 4], was longer among 2015 prevalence survey patients than in the NIS. This is an expected consequence of the prevalence survey method, which is biased toward inclusion of longer stay patients. Among 2015 prevalence survey patients, the median length of stay was 5 days (interquartile range 3-11 days), whereas in the 2014 NIS the median length of stay was 2.43 days (interquartile range 1.35-4.57 days).

The Rhame and Sudderth formula has several recognized limitations [2], although it remains a commonly used method for generating national or regional HAI burden estimates. Because it was developed approximately 40 years ago, changes in healthcare delivery may not be accounted for by the formula. As an example, the formula incorporates the time from hospital admission to HAI onset, whereas in the current healthcare environment, many HAIs have their onset outside of the hospital [1, 2]. The formula was also intended to include active and cured HAIs, but due to the methods employed in our survey and other prevalence surveys, only active HAIs are included [1, 2]. More details can be found in Magill, et al. [2].

In addition to burden estimation, a main objective of the EIP HAI and AU Prevalence Survey is to describe changes over time in HAI prevalence and antimicrobial use in hospitals. Overall, 183 hospitals participated in the 2011 survey and 199 hospitals in the 2015 survey; of these, 148 participated in both surveys. The large number of hospitals participating in both surveys facilitated comparisons of HAI prevalence and distribution in 2011 and 2015 [2]. We observed that the percentage of patients with HAIs in the 2015 survey was significantly lower than in the 2011 survey (2015: 3.2%, 95% confidence interval 2.9 to 3.5%, vs. 2011: 4.0%, 95% confidence interval 3.7 to 4.4%), suggesting progress in prevention of HAIs. Recognizing that even among the same group of hospitals, the characteristics of the hospitals and their inpatients may change over time and affect HAI prevalence, we performed multivariable log-binomial regression modeling to adjust for key differences between 2011 and 2015 hospitals and patients [2]. The final model adjusted for patient age, the presence of medical devices, hospital size, and days from hospital admission to the survey date. After adjusting for these factors, patients in the 2015 survey were 16% less likely to have an HAI than patients in the 2011 survey [2].

Although the population of hospitals and patients included in the EIP HAI and AU Prevalence Surveys may not be nationally representative, a number of factors build confidence in the robustness and usefulness of the survey results. These include: 1) the similarity of the survey

sample of hospitals and patients to the populations of hospitals and inpatients in the United States based on selected key characteristics; 2) participation of a large group of the same hospitals in the 2011 and the 2015 surveys; 3) adjustment for differences in survey hospitals and patients between 2011 and 2015; and 4) the multiple sensitivity analyses we performed [2].

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 HAI and AU Prevalence Survey has been conducted four times previously: in 2009, and three times with the EIP, in 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. The percentages of HAIs that were device-associated [i.e., ventilator-associated pneumonia, central line-associated bloodstream infections (CLABSIs), and catheter-associated urinary tract infections (CAUTIs)] remained low (23.6%), highlighting a need for continued surveillance and adjustments to prevention strategies. Using National Inpatient Sample (NIS) data [7] 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 [3]. Additional analyses from the 2015 survey, such as AU estimates and antimicrobial prescribing quality findings, are expected in 2019–2020.

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 (<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 2020 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 also now be used as a baseline to measure progress in 2020.

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, CDC and EIP site personnel have conducted reviews of the two primary data collection instruments, HFA and PIF. As a result, non-substantive changes to these instruments have been made. In regards 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 HFA and PIF 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 [10]. 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. CLABSIs, CAUTIs, SSIs, etc.] (<http://www.cdc.gov/nhsn/about.html>), and select 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. In its current form, NHSN cannot provide estimates of all types of HAIs or of AU throughout an entire hospital. However, these estimates can be obtained using prevalence surveys.

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. Most hospitals in the United States are participating in CLABSI surveillance and CAUTI surveillance in intensive care units through NHSN as part of required reporting for the CMS IQR program. Most hospitals are also reporting deep incisional and organ/space SSI data from colon surgeries and abdominal hysterectomies to NHSN due to CMS requirements. Other, more recent additions to the CMS IQR program requirements include reporting of hospital-wide MRSA bacteremia and *C. difficile* infection through NHSN. We estimate that these infections account for approximately 24% of all HAIs, based on 2011 and 2015 prevalence survey results [2,4]. It is important to note that while we estimate that approximately 24% of the HAIs identified in the prevalence survey in a given hospital will also be entered into NHSN, 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 24% 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 in the Division of Healthcare Quality Promotion (DHQP) previously worked with NCHS staff to incorporate a CLABSI event detection component into a precursor to NHCS, in 2007-2008. After the conclusion of a 9-facility pilot of the CLABSI component, it was determined that the burden of medical record abstraction rendered the component impractical. In addition, hospitals participating in NHCS submit inpatient and ambulatory UB-04 administrative claims data, and studies have shown that administrative claims data are not acceptable for identifying HAIs [11-14]. We have previously had communications with NCHS colleagues (Clarice Brown, Paul Beatty and Carol DeFrances) 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 [11-35], there are currently no duplicate efforts underway within the U.S. A global prevalence survey supported by bioMérieux and focusing on AU and not HAIs is currently on-going (<https://www.antimicrobial-resistance.biomerieux.com/popup/global-point-prevalence-survey/>), but 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 (http://www.global-pps.com/wp-content/uploads/ECCMID-2016_USA.pdf). In 2018, a paper published in *Lancet Global Health* reported that 24 hospitals in North America recently participated ([10](http://www.global-pps.com/wp-content/uploads/2018/05/1-</p></div><div data-bbox=)

[1-LANGH-2015 Global-PPS_results-on-adults_main-article_Versporten_April2018.pdf](#)).

Information on the project website indicates that an optional HAI data collection component is being introduced in 2019 (<http://www.global-pps.com/ourproject/>). Although HAI definitions are not yet available, it is very unlikely that this global survey will use the HAI definitions of the CDC's NHSN.

CDC has conducted analyses of purchased datasets from electronic health records to provide information about changes in inpatient antimicrobial use over time [15, 16]. Although these datasets contain electronic health record data, including prescribing data, from a large number of hospitals and patients, hospital participation may change from year to year, and the ability to determine the indications for antimicrobial use in individual patients is limited.

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 2020 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). 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 60-Day Federal Register Notice was published in the Federal Register on June 10, 2019, Vol 84, No. 111, page 26876-26877 (Attachment N). No public comments were received.

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 Transatlantic Task Force on Antimicrobial Resistance (TATFAR) meetings. The most recent TATFAR meeting was held at CDC in March 2018. The implementers for the TATFAR action items on prevalence survey collaborations have met via conference call as recently as January 2019. ECDC will host an experts meeting to discuss methods for estimating national and regional burden of HAIs in hospitals and nursing homes in Stockholm in May 2019.

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, 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, 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 2020 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 been sought for the 2020 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 [36]. 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 [37]. 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 <http://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.

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 2016 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 \$35.36 for a Registered Nurse (RN) (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2017 data, accessed January 03, 2019 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 \$65,769.60 (Table B). This represents a minor increase from the estimate approved in 2016 (+ \$2,269.20) 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 | \$35.36 | \$2,652.00 |
| | PIF | 100 | 63 | 17/60 | 1,785 | \$35.36 | \$63,117.60 |
| Total | | | | | | | \$65,769.60 |

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 \$36.65 (\$76,230 annually); for a business analyst is \$44.92 (\$46,720 annually); for a data analyst is \$41.59 (\$21,627 annually); for a statistician is \$42.78 (\$4,449 annually); for a database developer is \$51.30 (\$106,710 annually); and for a database administrator is \$42.81 (\$44,525 annually) [obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2017 data, accessed January 03, 2019 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 \$36.65 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2017 data). The estimated annual cost across the 10 EIP sites is \$1,524,640 (Table C), which represents an increase from the 2016 estimate (+ \$371,176) due to an increase in the estimated number of FTE EIP epidemiologists needed (1.5 to 2.0 FTEs) to conduct survey activities. However, this increase is offset by removing funds (-\$127,166) proposed in 2016 for external contractors to perform data validation. Upon review, this proposal was modified to include data validation by EIP site personnel only, if resources are available, as use of EIP site personnel is more cost-effective with the addition of the extra 0.5 FTE per site.

There will also be costs related to photocopying of forms and instructions. The cost is estimated to be \$8,382 (\$0.05 to copy each page, estimated 167,648 copies made to support survey activities in 300 hospitals in 10 EIP sites), or \$2,794 per year.

The total annualized cost to the federal government for personnel and photocopying is therefore estimated to be \$1,827,695.00 (Table C), which represents a net increase of \$277,779 from the 2016 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 | \$36.65 | \$76,230 |
| CDC Business Analyst | 1040 | \$44.92 | \$46,720 |
| CDC Data Analyst | 520 | \$41.59 | \$21,627 |
| CDC Statistician | 104 | \$42.78 | \$4,449 |
| CDC Database Developer | 2080 | \$51.30 | \$106,710 |
| CDC Database Administrator | 1040 | \$42.81 | \$44,525 |
| EIP Epidemiologists (2.0 FTE in each of 10 sites) | 41,600 | \$36.65 | \$1,524,640 |
| Photocopying | -- | -- | \$2,794 |
| Total | | | 0 |

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 December 2016 as proposed changes to the two data collection instruments (HFA and PIF) are non-substantive and not determined to impact the average burden per response.

Since the 2016 approval, the estimated annualized cost of time to respond to the survey has increased (+ \$2,269.20) 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 (+ \$277,779) due to the addition of a 0.5 FTE Epidemiologist per EIP site for survey activities such as data validation, the addition of a 0.25 FTE CDC Data Analyst and a 0.05 FTE CDC Statistician for internal operations and guidance, and other changes in salary estimates for CDC staff.

Non-substantive changes to the Healthcare Facility Assessment (HFA, Attachment C) form include the following:

- 1) Formatting/general appearance of the form was updated;
- 2) General instructions were removed from pg. 1 of the form and added to a separate instructions document (Attachment J);
- 3) Section titles were reworded for simplification and to improve clarity;
- 4) Sub-questions on the total number of annual discharges, patient rooms, single patient rooms, intensive care unit beds, and the average daily acute care census were removed from *Question #3* as data collection is no longer needed for analyses;
- 5) *Question #3* responses and format for “Number” were adjusted to provide additional options;
- 6) *Question #3* response options for “What year are data from?” were adjusted to reflect data collection in 2020;
- 7) *Question #3* instructions for how to calculate the number of full-time equivalent infection preventionists, hospital epidemiologists, and interns/residents were adjusted to provide more specific calculation examples;
- 8) Individual questions on the “Number of Interns/Residents” and “Official Intern/Resident to Bed Ratio (IRB)” were removed and added as sub-questions to *Question #3* to better organize questions of similar response type; response options for these questions were also simplified to improve collection;
- 9) A new question on the “Average Registered Nurse (RN) to Patient Ratio” was added (*Question #4*) to better capture and identify areas where staffing could impact quality of patient care;
- 10) *Question #6* was renumbered as *Question #5* and reworded to improve question clarity;
- 11) Response options for *Questions #7* and *#26* were changed from text descriptions to numeric;
- 12) *Unknown* was added as a response option to *Questions #12, #13, #14, #16 and #29*;
- 13) *Clostridium difficile* was changed to *Clostridioides difficile* in relevant questions to reflect the official change in genus;
- 14) A new question (*Question #17*) on “Primary Testing Method for *Clostridioides difficile* (*C. difficile*)” was added to complement data collected on *C. difficile* infection control practices and to better understand the changes in *C. difficile* prevalence;
- 15) *Other (specify)* was added as a response option to *Questions #18* and *#32* to improve consistency of data collection;
- 16) Sub-questions in *Question #29* were adjusted to better capture the implementation of CDC’s recommendations on Core Elements of Hospital Antibiotic Stewardship;
- 17) *Unknown* was removed as a response option from *Questions #32* and *#33* to improve consistency of data collection;

- 18) The NHSN’s Standardized Antimicrobial Administration Ratio (SAAR) was added as a response option in *Question #33* to capture data on facilities using the SAAR to monitor antimicrobial consumption.

These changes were based on experience conducting prior surveys, findings highlighted in recent research [2-5], and a need to improve clarity and enhance guidance for hospital staff. All changes were discussed with and approved by EIP site partners. There is no change in the total number of questions proposed. As a result, these changes are not expected to increase public reporting burden for hospital staff.

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*, an example of the requested format for “Admission Date” was added to provide more specific instruction;
- 3) In *Section II*, a question on “Gender” was reworded to ask for “Sex at birth”;
- 4) In *Section III*, “BMI” was adjusted to be completed only if “Weight” or “Height” are unavailable; *NA* was also added as a response since this question is now optional;
- 5) In *Section IV*, the section title was adjusted to “Devices and pressure injuries/ulcers present on the survey date”;
- 6) In *Section IV*, a new question, “Pressure Injury or Ulcer Present?” with two sub-questions “Pressure Injury or Ulcer Present on Admission?” and “Stage of Pressure Injury or Ulcer” was added to better understand the prevalence and onset locations of pressure ulcers/injuries among inpatients in acute care hospitals. Moreover, the addition of this question was added following a request by the Organization for Economic Co-operation and Development (OECD) who has recently sought collaboration with CDC and ECDC to expand research efforts on pressure injuries/ulcers and to establish global metrics for prevention initiatives (http://ewma.org/fileadmin/user_upload/EWMA.org/EWMA_and_EPUAP_added_values_to_OECD_efforts.pdf).

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 (with two sub-questions) 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 ongoing 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 hospital staff for survey activities | 4-5 months after OMB approval (March 2020 - April 2020) |
| Survey Implementation by EIP site personnel and hospital staff | 6-10 months after OMB approval (May 2020 - September 2020) |
| Data collection by EIP site personnel and transmission of data to CDC | 6-18 months after OMB approval (May 2020 – June 2021) |
| Data cleaning activities by EIP site personnel and CDC personnel | 18-24 months after OMB approval (June 2021- December 2021) |
| Analysis and presentation of 2020 survey results by CDC personnel | 24-36 months after OMB approval (December 2021 – December 2022; anticipate new extension request in 2022) |

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. Prevalence of Antimicrobial Use in U.S. Hospital Patients, 2011 vs. 2015. IDWeek 2018. Oct 3-7 San Francisco, CA. Abstract no 1859.
- 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) Magill SS, O’Leary E, Nadle J, et al. Measuring the quality of fluoroquinolone prescribing in hospitals: results from the Emerging Infections Program Hospital Prevalence Survey Antimicrobial Quality Assessment. IDWeek 2019. Oct 2-6 Washington, D.C. Abstract no 1009.
- 7) Healthcare Cost and Utilization Project (HCUP). Overview of the National (Nationwide) Inpatient Sample (NIS). Rockville, MD: Agency for Healthcare Research and Quality (<http://www.hcup-us.ahrq.gov/nisoverview.jsp>.)
- 8) Pinner RW, Rebmann CA, Schuchat A, Hughes JM. Disease surveillance and the academic, clinical, and public health communities. *Emerg Infect Dis* 2003;9:781–7.
- 9) Hardnett FP, Hoekstra RM, Kennedy MH, Angulo FJ; EIP Foodnet Working Group. Comparability of FoodNet and United States populations. March 24–27, 2002. International Conference on Emerging Infectious Diseases. Atlanta, GA.
- 10) 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.
- 11) Sherman ER, Heydon KH, St John KH, et al. Administrative data fail to accurately identify cases of healthcare-associated infection. *Infect Control Hosp Epidemiol* 2006;27:332-7.
- 12) Jung MA, Banerjee SN. Administrative coding data and health care-associated infections. *Clin Infect Dis* 2009;49:949-55.
- 13) Cass AL, Kelly JW, Probst JC, et al. Identification of device-associated infections utilizing administrative data. *Am J Infect Control* 2013 Jun 12 (Epub ahead of print).
- 14) Moehring R, Staheli R, Miller BA, et al. Central line-associated infections as defined by the Centers for Medicare and Medicaid Services’ Hospital-acquired Condition versus standard infection control surveillance: why Hospital Compare seems conflicted. *Infect Control Hosp Epidemiol* 2013;34:238-44.
- 15) Baggs J, Fridkin SK, Pollack LA, Srinivasan A, Jernigan JA. Estimating national trends in inpatient antibiotic use among US hospitals from 2006 to 2012. *JAMA Intern Med* 2016;176:1639-1648.
- 16) Baggs J, Kazakova S, Hatfield K, et al. Trends in inpatient antibiotic use in U.S. hospitals, 2012-2017. IDWeek 2019. Oct 2-6 Washington, D.C. Abstract no. 2891.
- 17) Lanini S, Jarvis WR, Nicastrì E, et al. Healthcare-associated infection in Italy: annual point-prevalence surveys, 2002-2004. *Infect Control Hosp Epidemiol* 2009;30:659-65.
- 18) 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.

- 19) Reilly J, Stewart S, Allardice GA, et al. Results from the Scottish National HAI Prevalence Survey. *J Hosp Infect* 2008;69:62-68.
- 20) 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.
- 21) Gastmeier P, Kampf G, Wischnewsky N, et al. Prevalence of nosocomial infections in representative German hospitals. *J Hosp Infect* 1998;38:37-49.
- 22) Scheel O, Stormark M. National prevalence survey on hospital infections in Norway. *J Hosp Infect* 1999;41:331-5.
- 23) Vaque J, Rossello J, Arribas JL, et al. Prevalence of nosocomial infections in Spain. *J Hosp Infect* 1999;43:105-11.
- 24) 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.
- 25) Azzam R, Dramaix M. A one day prevalence survey of hospital-acquired infections in Lebanon. *J Hosp Infect* 2001;49:74-8.
- 26) 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.
- 27) 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.
- 28) 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.
- 29) 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.
- 30) 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.
- 31) 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.
- 32) 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.
- 33) 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.
- 34) Duerink DO, Roeshadi D, Wahjono H, et al. Surveillance of healthcare-associated infections in Indonesian hospitals. *J Hosp Infect* 2006;62:219-29.
- 35) 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.
- 36) Kallel H, Bahoul M, Ksibi H, et al. Prevalence of hospital-acquired infection in a Tunisian hospital. *J Hosp Infect* 2005;59:343-7.
- 37) 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.
- 38) 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.

- 39) 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.
- 40) 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.
- 41) 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.
- 42) 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.
- 43) 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.** 30-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.** Published 60-Day FRN