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

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Extension ICR

Supporting Statement B

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B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents for the prevalence survey are hospitals in states with Emerging Infections Program (EIP) sites. There were approximately 420 hospitals in the survey catchment areas of the 10 EIP sites (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN) in 2015. In some EIP sites, catchment areas consist of a few counties within a particular region of the state. In other EIP sites, catchment areas are the entire state. Hospitals are selected for participation using a stratified random sampling scheme. General acute care hospitals (including children's hospitals) in each of the 10 EIP site catchment areas are divided into three bed size strata: small (<150 staffed beds), medium (150–399 staffed beds) and large (400+ staffed beds). Hospitals are randomly selected for participation within each stratum, with a goal in each EIP site of recruiting 25 hospitals: 13 small hospitals (52% of total), 9 medium hospitals (36% of total), and 3 large hospitals (12% of total). This distribution of hospitals approximates the distribution across the 10 EIP site catchment areas. EIP sites may recruit additional hospitals, for a total of 30.

In some cases, EIP sites did not meet the 25-hospital target in previous surveys; this may have been due to a limited number of hospitals within a particular bed size stratum, or due to competing priorities and resource limitations of hospitals selected for participation. EIP sites establish the catchment areas they use for the prevalence survey based on catchment areas used for other EIP surveillance projects. In some cases, EIP sites expanded to additional counties or to the entire state to increase their number of eligible hospitals. The decision as to whether an individual EIP site expands its catchment area is made by the EIP site. In the 2015 survey, 148 of 199 participating hospitals (74%) had previously participated in the 2011 survey; 2011 survey participants were prioritized for 2015 participation [1].

Because a goal of the prevalence survey is to assess changes in Healthcare-Associated Infections (HAIs) and Antimicrobial Use (AU) prevalence and distribution over time, in 2023 EIP sites will seek participation from the same group of hospitals that participated in the 2011 and 2015 surveys. In addition, each EIP site will have the option to recruit additional hospitals, for a total of up to 30 hospitals per EIP site. EIP sites that did not expand their catchment areas state-wide in previous surveys will again have the option to do so, where possible, in the next survey. Where state-wide expansion is not feasible, EIP sites will also have the option to increase the number of counties included in their catchment areas.

Hospital participation in the survey is voluntary. EIP site personnel will recruit hospitals to participate via email, mail, telephone, fax, and in-person communications. An example of an informational document provided to facilities participating in the 2015 survey is included in Part A, Attachment M. This informational document will be updated for the 2023 hospital survey. Based on the long-standing relationships that EIP sites have with hospitals in their catchment areas, and based on the response from hospitals that previously participated, we anticipate that we will meet our recruitment goals in 2023.

In the survey, data will be collected on a sample of eligible acute care inpatients in each participating hospital. Patients will be randomly selected from the acute care inpatient population in each hospital on the survey date. To allow for comparisons of data collected in the previous phases, inpatient sample size targets will be established for each hospital based on the number of staffed acute care beds in the hospital. Based on experience in prior surveys, having a fixed number of inpatients' medical records to review per hospital makes resource planning and allocation easier for hospitals and EIP site personnel. In 2023, small and medium hospitals will be asked to review medical records of 75 randomly-selected acute care inpatients (or the total number of acute care inpatients, where the number is <75). Large hospitals will be asked to review medical records of 100 randomly-selected acute care inpatients. This is the same approach applied in 2015. If it becomes necessary to reduce the survey sample due to resource limitations, hospitals may be asked to review a slightly smaller number of patients than noted above.

To assist in generation of the random sample, hospitals will supply lists of staffed bed numbers (those beds that could potentially hold eligible inpatients) to EIP site personnel in advance of the survey date; these lists will be randomly sorted using a random number generator tool. The randomly sorted bed number list will be matched to the hospital's inpatient census list on the morning of the survey. Medical records will be reviewed for each inpatient on the census list occupying a bed included in the randomly sorted bed number list, up to the target sample size for the hospital. Patients in outpatient areas of hospitals will be excluded.

2. Procedures for the Collection of Information

Hospitals will be selected through a stratified random sampling process, based on hospital staffed bed size. Patients within participating hospitals will be randomly selected from the morning inpatient census on the survey date as described in Section B.1.

The sample size formula for random samples can be used to estimate the number of inpatients targeted for inclusion in the survey across all EIP sites:

$$N \geq \frac{Z\alpha/2^{2}}{m} \times P \times (1-P)$$

where $Z\alpha/2 = 1.96$, P = expected proportion of inpatients with HAIs (or for whom antimicrobials were incorrectly prescribed), and *m* = precision of the estimate (half the width of the desired confidence interval).

In previous surveys, we based the sample size calculation on a desired precision in the overall HAI prevalence estimate of +/- 1% and an estimated HAI prevalence of 7%. The number of inpatients necessary to achieve this precision was 2500. To increase the utility of data for an individual state health department or EIP site, and to have the ability to describe the distribution of different HAI types, we needed to survey a larger number of patients. The actual overall HAI prevalence in the 2015 survey was lower (3.2%), but because our total sample size in 2015 was 12,299 patients, we had acceptable precision of the overall HAI and AU prevalence estimates [1].

Advantages to increasing the overall survey sample size include increased precision of prevalence estimates for individual HAI types as well as for HAI and AU prevalence within individual EIP sites. However, due to resource constraints, expansion may not be feasible. For the 2023 survey, we will aim to achieve approximately the same sample size as we did in the 2011 and 2015 surveys (~12,000 inpatients), with the possibility of including more inpatients depending on resource availability (up to a maximum of 18,764 inpatients as described in Part A, Section 12).

As stated in Part A, surveys are anticipated to be conducted intermittently (i.e., once every 3-5 years) to reduce the burden of data collection. 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. The survey data will be collected by hospital staff and by EIP site personnel (Note: Data collection by EIP site personnel is not considered public burden, See Part A, Section 14). Data will be obtained from medical records and/or other hospital information systems. To obtain information about the presence of medical devices (i.e., central lines, urinary catheters, and ventilators) and pressure injuries and ulcers, data collectors may review medical records and/or consult with hospital staff on inpatient units. Patients will not be interviewed. To obtain information needed to complete the Healthcare Facility Assessment (HFA) form, the hospital staff member completing the assessment or EIP team member providing assistance may need to consult with others within the hospital.

Data collectors will receive training in data collection procedures. This training will be developed and conducted by CDC personnel and/or by EIP site personnel. In previous surveys, webinar training was provided to data collectors in hospitals. EIP site personnel received in-person training at CDC and webinar-based training.

Each hospital and/or EIP site will decide in advance the date on which the survey will be conducted. The survey is performed on one day in each hospital. A range of acceptable survey dates from which to choose will be provided. In previous surveys, dates were scheduled between May and September. This period was selected to avoid influenza season in the United States.

If resources are available, a validation component will be incorporated into the 2023 survey and will be performed by EIP site personnel. In prior surveys, this was proposed to be conducted by external contractors. We have modified this proposal to utilize EIP site personnel, if possible, as use of EIP site personnel is more cost-effective.

Other quality control measures used in 2015 will continue to be used in the 2023 survey. The CDC-developed, web-based data management system includes multiple business rules that prevent erroneous data entry (e.g., entry of a hospital admission date that is after the survey date). CDC personnel will conduct a full-scale review of these business rules and perform system testing using sample data to identify other opportunities for quality improvement. In addition as survey data becomes available, CDC personnel will query submitted data to identify outliers or unusual values to be verified by EIP site personnel (e.g., adult inpatients located in pediatric inpatient units, inpatients who have very long hospital stays, inpatients receiving antimicrobial agents for unusual indications, etc.).

3. Methods to Maximize Response Rates and Deal with Nonresponse

This project is an assessment of antimicrobial prescribing quality and HAI and AU prevalence and epidemiology in U.S. acute care hospitals. Hospitals will be identified for participation based on location within EIP catchment areas or more broadly within states that have EIP sites. Hospitals that participated in the 2015 or 2011 surveys will be prioritized; however, new hospitals are also eligible.

Many hospitals in EIP catchment areas already have working relationships with EIP site personnel. EIP site personnel will send emails and/or make phone calls and in-person visits to infection control practitioners at hospitals in their catchment areas to provide information on the survey. Based on prior experience and current national HAI and AU efforts, we believe that hospitals will be motivated to participate. In 2011, despite a number of competing priorities occurring at the same time as the survey (e.g., new state legislative HAI reporting mandates enacted), EIP sites were able to recruit 79% of the total recruitment goal [2]. In 2015, the majority of hospitals that had participated in 2011 agreed to participate again, despite competing priorities [1]. Despite the significant impact from COVID-19 pandemic in 2020 and 2021, we expect most hospitals will recover by the survey date and a similar or better response will be achieved for the 2023 survey.

EIP site personnel will provide information about the survey to hospitals in their catchment areas through electronic, in-person, and telephone communications. An example of an informational document provided to facilities participating in the 2015 survey is included in Part A, Attachment M. This informational document will be updated for the 2023 hospital survey. CDC and/or EIP sites may also work with key stakeholder professional organizations [e.g., the Society for Healthcare Epidemiology of America (SHEA) and the Association of Professionals in Infection Control and Epidemiology (APIC), etc.] to disseminate information about the survey to members and to encourage hospital participation.

4. Tests of Procedures or Methods to be Undertaken

As mentioned previously, the survey was developed in four phases. Phase 1 (2009) was a pilot survey involving fewer than 10 hospitals. Phase 2 (2010) was a limited roll-out effort in 22 hospitals. Phase 3 (2011) was a full-scale survey conducted in 183 hospitals. Phase 4 (2015) was a second full-scale survey conducted in 199 hospitals. Modifications to the Patient Information Form, , Antimicrobial Use form, and Antimicrobial Quality Assessment: General Patient Assessment form have been made to include relevant questions about COVID-19 (e.g., COVID-19 status and SARS-CoV-2 test date) and simplify data collection for hospital staff and to enhance the utility of data for future prevention initiatives. Please refer to Part A, Section 15, for a detailed description of these changes.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC statistician consulted for project design and data analysis:

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Data will be collected by EIP site personnel and by hospital staff, as described previously. Identification of the specific EIP site personnel and local hospital staff members who will participate in training and data collection activities is at the discretion of the EIP site or the hospital, respectively.

6. References

1) 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.

2) 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.