

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

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Revision ICR

Supporting Statement B

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents for the prevalence survey are healthcare facilities in states with EIP sites. There were approximately 420 facilities in the 10 EIP site survey catchment areas in 2015 (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). 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. Healthcare facilities are selected for participation using a stratified random sampling scheme. General acute care facilities (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). Facilities are randomly selected for participation within each stratum, with a goal in each EIP site of recruiting (where possible) a total of 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.

In some cases, EIP sites did not meet the 25-facility target in previous surveys; this may have been due to few facilities within a particular bed size stratum, or due to competing priorities and resource limitations of facilities 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 the number of eligible facilities. The decision as to whether an individual EIP site expands its catchment area is left up to that EIP site. In the Phase 3 2011 survey, the recruitment goal was 232 hospitals. One-hundred eighty-three hospitals (79% of the goal) agreed to participate. Of the 183 participating hospitals, 93 (51%) were small, 68 (37%) were medium, and 22 (12%) were large. In the 2015 survey, preliminary participation information indicates that 152 of 200 participating hospitals (76%) had previously participated in the 2011 survey; 2011 survey participants were prioritized for 2015 participation, and approximately 83% of 2011 survey hospitals agreed to participate again in 2015. Of the 200 hospitals participating in the 2015 survey, approximately 48% are small, 39% are medium, and 14% are large hospitals.

Because a goal of the prevalence survey is to assess changes in HAI and antimicrobial use prevalence and distribution over time, in 2019 EIP sites will seek participation from the same group of facilities that participated in the 2011 and 2015 surveys. In addition, each EIP site may have the option of recruiting additional facilities, for a total of up to 30 facilities per EIP site. EIP sites that did not expand state-wide in previous surveys have the option to do so, where possible, for the next surveys. Where state-wide expansion is not feasible, EIP sites also have the option to increase the number of counties included in the catchment area.

Hospital participation in the survey is voluntary. EIP personnel will recruit facilities to participate through email, telephone and in-person communications. Based on the long-standing relationships that EIP sites have with their facilities, and based on the response from facilities that we experienced in previous survey phases, we anticipate that we will meet our recruitment goals.

In the survey, data will be collected on a sample of eligible acute care inpatients in each participating facility. Patients will be randomly selected from the acute care patient population in each facility on the facility's survey date. As was done in previous phases of the survey, and to allow for comparisons of data collected in the proposed surveys with data collected during those previous phases, patient sample size targets will be established for each facility based on the number of staffed acute care beds in each facility. For example, in Phase 3, small and medium hospitals were 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 were asked to review medical records of 100 randomly-selected acute care inpatients. This "fixed n" sampling scheme was chosen for practical reasons. In earlier phases of the survey, we asked facilities to review one-third of the patients on the morning census on the survey date. This was a difficult goal to achieve for larger facilities. Because of this, in 2011 we changed to the "fixed n" sampling scheme described above. This scheme worked well; having a fixed number of patients per hospital based on bed size category makes resource planning and allocation easier for hospitals and EIP sites. We used this same approach in the 2015 survey, and plan to use it for the 2019 survey.

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

2. Procedures for the Collection of Information

Facilities will be selected through a stratified random sampling process, based on facility staff bed size. Patients within participating facilities will be randomly selected from the morning inpatient census on the survey date.

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

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

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

In the previous survey phases, 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 patients necessary to achieve this precision was 2500. To increase the utility of data for an individual state health department, 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 Phase 3 survey was lower (4%), but because our total sample size in Phase 3 was 11,282 patients, we had acceptable precision of the overall HAI and antimicrobial use prevalence estimates.

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

As stated in Part A, Section A.6, surveys are anticipated to be conducted intermittently (e.g., once every three years or four years). This will reduce the burden of the data collection.

The survey data will be collected by local healthcare facility staff and by EIP personnel. Data will be obtained from medical records and/or other hospital information systems. To obtain information about the presence of medical devices, such as central lines and urinary catheters and ventilators, data collectors may review medical records and/or consult with healthcare facility staff on inpatient units. Patients are not interviewed. To obtain information needed to complete the healthcare facility assessment, the hospital staff member completing the assessment or EIP team member providing assistance to hospital staff may need to consult with others within the facility.

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

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

As noted above, EIP personnel will provide information about the survey to facilities in their catchment areas through electronic, in-person and telephone communications. An example of an informational document provided to facilities for the Phase 3 survey is shown in Attachment I. We may also work with key stakeholder professional organizations (e.g., the Society for Healthcare Epidemiology of America and the Association of Professionals in Infection Control and Epidemiology) to disseminate information about the survey to members and encourage participation.

If resources are available, a validation component will be incorporated into the proposed surveys. A validation was conducted in the Phase 2 limited roll-out survey in 2010. If resources are available to support validation activities by an external party, it will be performed by a

Contractor. The Contractor will assemble a team of experienced, expert infection preventionists, who will review a 10-20% sample of surveyed patient records in each EIP site. EIP sites may also perform internal data quality checks.

Other quality control measures used in Phase 3 will continue to be used in the 2015 survey. The web-based data management system includes multiple business rules that prevent erroneous data entry in a number of circumstances (e.g., entry of a hospital admission date that is after the survey date). In addition, CDC personnel will query the submitted data to identify unusual data to be verified by sites; for example, adult patients located in pediatric patient units, patients who have very long hospital stays, patients 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 prevalence and antimicrobial use in U.S. hospitals. It is not a survey in the traditional sense of the word. Facilities will be identified for participation based on location within EIP catchment areas or more broadly within states that have EIP sites. Facilities in EIP catchment areas already have working relationships with EIP personnel. EIP site personnel will send emails and/or make phone calls or visits to infection control practitioners at facilities in their catchment areas asking them to participate. We believe that facilities will have significant interest in participating as part of national efforts to prevent HAIs and improve antimicrobial use and reduce the emergence and spread of antimicrobial resistant pathogens. Our Phase 1 pilot experience confirmed a high level of enthusiasm for this project among local infection control practitioners. In Phase 2, EIP personnel in each of the 10 sites were able to successfully engage 1-3 facilities, as planned. In Phase 3, despite a number of competing priorities occurring at the same time as the Phase 3 prevalence survey (e.g., new state legislative HAI reporting mandates enacted), EIP sites overall were able to recruit 79% of the total recruitment goal. In the 2015 survey, most hospitals that had participated in 2011 agreed to participate again, despite competing priorities. We expect a similar or better response for the 2019 survey.

We may also work with key stakeholder professional organizations (e.g., the Society for Healthcare Epidemiology of America and the Association of Professionals in Infection Control and Epidemiology) to disseminate information about the survey to members and encourage participation.

4. Tests of Procedures or Methods to be Undertaken

As mentioned previously, the survey was developed in three phases. Phase 1 (2009) was a pilot survey involving fewer than 10 respondents. Phase 2 was a limited roll-out effort in 22 facilities conducted following OMB approval in the summer of 2010. Phase 2 has informed the design of Phase 3, and Phase 3 has informed the design of the proposed surveys. Minor modifications to the data collection instruments were made, based on experience in previous phases. Assessments of antimicrobial prescribing were performed in 2013 and 2014. A hospital assessment was added to the survey. The OMB number for the survey is 0920-0852. The expiration date was May 31, 2013, and the reinstatement was approved through 12/31/2016.

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

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