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

(OMB Control No. 0920-0852, Expiration 5/31/2013)

Request for Reinstatement with Change

Part B

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Contact:
Amy McMillen
Public Health Analyst
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Phone: (404) 639-1045
Fax: (404) 639-7090
Email: auh1@cdc.gov

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents are healthcare facilities in states with EIP sites. There were approximately 406 facilities in the 10 EIP site Phase 3 survey catchment areas (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). In some EIP sites, catchment areas consisted of a few counties within a particular region of the state. In other EIP sites, catchment areas were expanded to include the entire state. Healthcare facilities were selected for participation in Phase 3 using a stratified random sampling scheme. General acute care facilities (including children's hospitals) in each of the 10 EIP site catchment areas were divided into three bed size strata: small (<150 staffed beds), medium (150-399 staffed beds) and large (400+ staffed beds). Facilities were 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% or 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 for Phase 3; 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 established the catchment areas they used 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 would expand its catchment area was left up to that EIP site. In Phase 3, 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.

Because a goal of the next phases of the prevalence survey is to assess changes in HAI and antimicrobial use prevalence and distribution over time, EIP sites will be asked to seek participation from the same group of facilities that participated in Phase 3. In addition, each EIP site may have the option of recruiting additional facilities, for a total of up to 50 facilities per EIP site. EIP sites that did not expand state-wide in Phase 3 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.

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 Phase 3, we anticipate that we will meet our recruitment goals.

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 Phase 3, and to allow for comparisons of data collected in the proposed surveys with data collected during Phase 3, 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 Phase 3 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 anticipate using a similar scheme in the next surveys.

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

As described above, 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:

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

where $Z\alpha/2 = 1.96$, P = expected proportion of patients with HAIs (or on antimicrobials), and *m* = precision of the estimate (half the width of the desired confidence interval). In the Phase 3 survey, we based this 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 sample size in the next surveys 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 Phase 3, with the possibility of including more patients depending on resource

availability (up to a maximum of approximately 31,000 patients, as outlined in the Part A Section 12).

As stated in Part A, Section A.6, surveys are anticipated to be conducted once every three years. This will reduce the burden of the data collection

The 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 hospital 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 Phase 3, 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 Phase 3, surveys were conducted between May and September 2011. We expect a similar date range to be used in the proposed surveys.

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 J. We expect similar communications to be developed and used for the proposed surveys. 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. Resources were not available to support validation of the Phase 3 survey data. If validation is conducted, 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.

Other quality control measures used in Phase 3 will continue to be used in the proposed surveys. 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 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 this survey as part of national efforts to prevent HAIs. 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. We expect a similar or better response in future surveys.

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 have been made, based on experience in previous phases. A hospital assessment has been added. The OMB number for Phases 2 and 3 was 0920-0852. The expiration date was May 31, 2013.

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

CDC statistician consulted for project design and data analysis:

Jonathan R. Edwards, MStat
Leader, Statistics Team
Surveillance Branch, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Rd, NE
Atlanta, GA 30333
(404) 639-4177
Email: JREdwards@cdc.gov

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.