

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

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Request for Approval of a Nonsubstantive 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 for the 2014 and 2015 data collections 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% 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 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.

For the 2014 Antimicrobial Prescribing Quality Assessment, EIP sites will recruit a convenience sample of up to 10 acute care general and children's hospitals in which to conduct the assessment. Participation in the assessment is voluntary. Because of limited resources and time constraints, hospitals will likely be selected in part based on location within driving distance of EIP site headquarters. EIP sites will attempt to engage approximately equal numbers of small, medium and large hospitals, where possible. In some EIP sites, there may be too few hospitals of a certain size to ensure equal numbers. Within each hospital, a random sample of acute care inpatients will be selected from lists of patients who received selected antimicrobial agents (intravenous vancomycin or fluoroquinolones) during 2013 or who have an admitting or discharge diagnosis of community-acquired pneumonia or urinary tract infection during 2013. Lists of eligible patients will be generated through use of hospital pharmacy and billing/administrative (ICD-9 code) data.

EIP personnel will recruit facilities to participate in the 2014 data collection through email, telephone and in-person communications. Based on the long-standing relationships that EIP sites have with their facilities, we anticipate that we will meet our 2014 recruitment goals.

Because a goal of the next phase of the prevalence survey (2015) is to assess changes in HAI and antimicrobial use prevalence and distribution over time, in 2015 EIP sites will 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 2015 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.

In the 2015 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 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 will use 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 for the 2014 data collection will be selected based on convenience, although EIP sites will be asked to engage equal numbers of small, medium and large hospitals, for a total of up to 10 hospitals per site. For the 2015 survey, 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 2014 data collection and the 2015 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 2014 data collection, we based this calculation on a desired precision in the estimate of incorrect antimicrobial use of +/- 2% to +/- 5%, and an estimated proportion of incorrect use of 35% for each of 7 separate prescribing events (e.g., adult and pediatric community-acquired pneumonia, adult and pediatric urinary tract infection, adult and pediatric intravenous vancomycin prescribing, and adult fluoroquinolone prescribing). We are aiming to generate estimates of incorrect use in adult patients separately from pediatric patients. Fluoroquinolone prescribing will not be assessed in children because these drugs have few indications and are not commonly used in pediatric patients.

The total number of patients across all EIP sites needed to achieve +/- 4 to 5% precision for each of the 4 prescribing events in adults and in each of the 3 prescribing events in children is approximately 500 patients per event. Therefore, EIP site personnel are anticipated to review approximately 3500 medical records across the 7 prescribing events. For each event, each site will review 50 records so that the burden of data collection is evenly distributed as much as possible. Therefore, each site will review approximately 350 medical records in total. In the event that one or more sites are unable to review pediatric patient records due to ethical regulations, the total number of pediatric patients per event will be evenly distributed among the remaining sites.

EIP staff members will collect data in 2014 using the antimicrobial prescribing quality assessment forms. Hospital staff with assistance from EIP staff will complete the healthcare facility assessment. 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. Hospital staff will not collect patient-level data. EIP data collectors will receive training via webinar in 2014 data collection procedures. This training will be developed and conducted by CDC personnel and/or by EIP personnel.

In the Phase 3 survey, 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 sample size for the next survey in 2015 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 2015 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 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 2015 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 2015 survey.

As noted above, EIP personnel will provide information about the 2015 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 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 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 the antimicrobial prescribing quality assessment and the 2015 survey 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. 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 pilot assessment of antimicrobial prescribing was performed in 2013. This has informed plans for the 2014 data collection. A hospital assessment has been added. The OMB number for Phases 2 and 3 was 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

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.