Prevalence Survey of Healthcare-Associated Infections (HAIs)
and Antimicrobial Use in U.S. Acute Care Hospitals 0920-0852

Supporting Statement B

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents are acute care facilities in states with EIP sites. There are approximately 467 facilities in the 10 states with EIP sites (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). Each EIP site recruited 1-3 facilities for Phase 2. The facility selection plan in Phase 3 involved drawing a random sample of acute care facilities within three bed size strata (small, medium and large facilities) in each EIP site. No other states were included in Phase 3. Each EIP site aimed to engage 25 facilities across these three bed size strata, where possible. In some cases, EIP sites did not meet the 25-facility target; 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 will expand its catchment area was left up to that EIP site. Overall, EIP sites were able to achieve approximately 80% of the goal for facility recruiting. The same approach is anticipated for future surveys, including the 2014 survey; statewide facility selection will be encouraged in as many sites as possible.

Participation in the survey is voluntary. As stated in Section A2, 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 Phases 1-3, we anticipate that we will meet our recruitment goals.

Data collected during Phase 3 will be used to estimate HAI prevalence and antimicrobial use in a large sample of U.S. acute care inpatients. As stated in Section A2, we consulted with colleagues in the National Center for Health Statistics (NCHS, see attached correspondence from Dr. Jane Sisk, Director, Division of Health Care Statistics). Although data collected by the EIP have been used previously to generate national estimates of disease rates (recent examples include invasive pneumococcal disease [29] and methicillin-resistant *Staphylococcus aureus* infections [30]), we will not be able to generate national estimates of HAI prevalence and antimicrobial use from the Phase 3 survey effort. As per Dr. Sisk's consultation letter (see Attachment E), it is not possible at present to utilize administrative data to obtain valid HAI prevalence estimates, nor is it possible to conduct an HAI and antimicrobial use prevalence survey using the existing National Hospital Discharge Survey. Given funding under ARRA and time and resource constraints, we believe that utilizing the EIP infrastructure and facilities in EIP catchment areas to obtain HAI and antimicrobial use prevalence estimates is a reasonable

approach and will permit us to gain experience necessary for refining the methodology for future survey efforts that will seek to generate national estimates.

Data will be collected on CDC-defined HAIs for 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. Sample size targets will be established for each facility based on factors such as the overall number of participating facilities and the numbers of active acute care beds in each facility. Facilities will supply lists of active 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 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, including the Emergency Department, will be excluded.

2. Procedures for the Collection of Information

Data will be collected on paper data collection forms and entered into an electronic web-based data collection system. Basic demographic data and information on presence of medical devices and receipt of antimicrobial therapy will be collected by infection control practitioners within each facility and/or by EIP personnel. Information related to HAIs (HAI present or not, dates of symptom and therapy onset, type of HAI, specific site of HAI, pathogens, presence of secondary bloodstream infection, location of attribution for the HAI, and selected antimicrobial resistance data) and antimicrobial use (type, rationale, location of infection onset, site being treated, etc.) will be collected by EIP personnel. Infection Control Practitioners will perform data collection on the day of the survey, and when necessary will complete data collection within 14 days after the survey date (collecting only data present on or prior to the survey date). EIP personnel may also participate in collection of basic demographic and device and antimicrobial use data on the survey date, and EIP personnel will retrospectively review medical records to collect HAI and antimicrobial use data (again, collecting only data present on or prior to the survey date—including results of cultures collected on the survey date). CDC staff will train EIP personnel in survey methods, terminology and HAI definitions. EIP personnel, in some cases with assistance from CDC staff, will in turn provide training to the infection control practitioners in survey methods and terminology.

Data collection will be validated by a team of external experts contracted by DHQP, known as the Evaluation Team (pending funding availability). Evaluation Team members will have no interaction with patients, and will perform their activities retrospectively. If data validation is able to be performed in future surveys, Local or regional expert infection preventionists in or close to each of the EIP site catchment areas will be identified to serve as the Evaluation Team. The Evaluation Team will perform retrospective medical record review for a sample of surveyed patients in each EIP site. We anticipate that the patient sample in each EIP site will consist of an approximately 10-20% random sample of patients surveyed by local hospital staff and/or EIP personnel. The Evaluation Team will collect similar data as the local hospital staff and EIP personnel. The EVALT will also be asked to record on a worksheet the criteria utilized in making HAI determinations for those patients found to have HAIs.

The sample size formula for random samples can be used to determine the total minimum number of patients targeted for inclusion in the survey across all EIP sites. This formula is as follows:

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

where $Z\alpha/2 = 1.96$, P = expected proportion of patients with HAI (assumed to be 7% in this example), and *m* = precision of the estimate (half the width of the acceptable confidence interval, 1% in this case). The sample size in this example is therefore 2,500 patients. However, because facilities and individual EIP sites may want to increase the utility of their own data collections for their individual institutions and sites, aiming for an increased sample size would be highly desirable. In a recent HAI prevalence survey performed in the United Kingdom, for example, some facilities sought to review records for all eligible patients present on the survey date [5]. The number of records reviewed in any given facility may depend upon factors such as whether the medical record is fully electronic and how many local data collectors are available. Based upon our pilot experience, a reasonable target sample size in each Phase 2 facility was felt to be 33% of the facility's active acute care beds. In practice, this was an achievable goal for many facilities, but was at times a challenge for larger facilities participating in Phase 2. With this in mind, for Phase 3 EIP sites asked each participating facility to survey a fixed number of patient records, 75-100 randomly-selected acute care inpatients, depending upon hospital size. Small facilities were asked to survey 75 patients each (or, if the hospital has <75 beds, the facility will survey all patients), while medium and large hospitals were asked to survey 100 patients each. This sampling scheme has operational and practical advantages over the Phase 2 proportional scheme. Having a fixed number of patients per hospital based on bed size category makes resource planning and allocation easier for hospitals and EIP sites. It also relieves some of the burden faced by larger hospitals (for example, those with >500 beds) participating in the survey; such hospitals may have difficulty reviewing one-third of their acute care daily census. We expect the Phase 3 approach to be used in future surveys.

3. Methods to Maximize Response Rates and Deal with Nonresponse

This project is an assessment of HAI prevalence and antimicrobial use in U.S. acute care 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 addition, facilities in EIP catchment areas already have established relationships with EIP personnel. For these reasons, in planning for Phase 3 we anticipated a high degree of participation (at least 80% response rate). 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 approximately 80% of the total recruitment goal. We expect a similar response in future surveys.

4. Tests of Procedures or Methods to be Undertaken

As mentioned previously, Phase 2 was a limited roll-out effort conducted following OMB approval in the summer of 2010. Phase 2 has informed the design of Phase 3, and Phase 3 has informed future surveys. Minor modifications to the data collection are anticipated to be requested, once data analysis is completed. Approval of these modifications will be requested in a revision, to be submitted in several months' time. OMB will be informed of changes to the survey procedures or data collection instruments.

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 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.

References