Prevalence Survey of Healthcare Associated Infections (HAIs) and Antimicrobial Use in U.S. Acute Care Hospitals
Request for Approval of New Data Collection

This is a request for OMB approval of a new data collection, Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey. This data collection is funded with the American Recovery and Reinvestment Act of 2009 (ARRA) dollars. CDC is requesting a three-year approval to collect the data.

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 will recruit 1-3 facilities for Phase 2 and all facilities within its own catchment area for Phase 3. Participation in the survey is voluntary. As stated in Section A2, EIP personnel will recruit facilities to participate through email and telephone 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 1, we do not anticipate that recruitment will present a problem.

Data collected during Phase 3 will be used to estimate national HAI prevalence and antimicrobial use. Data collected through the EIP have been used previously to generate national estimates of disease rates: for example, invasive pneumococcal disease [29] and methicillin-resistant *Staphylococcus aureus* infections [30]. In addition, based on a comparison performed internally in DHQP, the bed size and regional distribution of the 467 hospitals within the EIP catchment areas were similar to the distribution of the 6346 hospitals participating in the 2006 American Hospital Association (AHA) survey. Similarly, the NHDS, conducted yearly by the National Center for Health Statistics at CDC, utilizes a sample of approximately 500 acute care hospitals for its national estimates. For these reasons we believe that data collected from facilities within the EIP catchment areas will be sufficient to describe national HAI prevalence.

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. Information related to HAIs (HAI present or not, 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 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 practitionerss in survey methods and terminology. Data collection will be validated by a team of external experts contracted by DHQP, known as the Evaluation Team. The Evaluation Team will review a subset (estimated to be approximately 30%) of medical records reviewed by the local data collectors and EIP personnel. Evaluation Team members will have no interaction with patients, and will perform their activities retrospectively.

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

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

where $Z\alpha/2 = 1.96$, P = expected proportion of patients with HAI (assumed to be 10% in this example), and *m* = precision of the estimate (half the width of the acceptable confidence interval, 0.02 in this case). The sample size in this example is therefore 865; if we account for an estimated 20% of beds being empty, holding ineligible patients, or holding patients for whom medical records are unavailable on the survey date, the total sample size becomes 1038 (to be distributed proportionately among participating facilities, based on numbers of facilities and active acute care beds in each facility). However, because facilities may want to increase the utility of their own data collections for their individual institutions, 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 facility is 33% of the facility's active acute care beds.

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 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 addition, facilities in EIP catchment areas already have established relationships with EIP personnel. For these reasons we anticipate a high degree of participation (at least 80% response rate).

4. Tests of Procedures or Methods to be Undertaken

As mentioned previously, Phase 2 is a limited roll-out effort that is submitted for approval in combination with the main collection of information, Phase 3. Phase 2 will inform the design and conduct of Phase 3, although we anticipate only minor changes to the data collection. 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.