GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement B

Antibiotic Stewardship in Hospitals: Assessing Comprehensive Implementation of the Seven Core Elements

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The purpose of this formative research is to obtain feedback on a new assessment methodology from physician and pharmacist leaders of antibiotic stewardship programs in three different hospital settings (academic acute care hospitals, non-academic acute care hospitals, and critical access hospitals). Specifically, this study will assess the relevance and perceived importance of proposed components of a draft assessment tool in various hospital settings and identify necessary clarifications to terminology and format used within the draft tool. The research results will inform modifications to the assessment tool, including changes to the content of items to ensure relevance and importance in various hospital settings and changes to wording or phrasing to ensure clarity of items. Findings on relative importance and relevance will also inform the development by CDC of a scoring mechanism for the tool.

The study sample will be a nonprobability-based purposeful sample as opposed to probability-based. Therefore, the results are not generalizable to the general population. CDC anticipates collecting data from a sample of 40 (co)leaders of antibiotic stewardship programs within 30 hospitals.

The 30 hospitals will be purposively selected to ensure that they meet two criteria that will provide CDC with a combination of perspectives to ensure applicability of the final assessment tool to all hospitals:

1. The sample will include a combination of three hospital settings: academic acute care hospitals (n=10), non-academic acute care hospitals (n=10), and small critical access hospitals (n=10). These three types of hospitals have access to differing levels of human, financial, and technical resources for implementation of antibiotic stewardship programs and therefore will be able to provide differing perspectives on the relevance of various items within the tool given those contexts.

2. Established antibiotic stewardship leadership in the hospital. Purposive selection of participating hospitals will also ensure that respondents are familiar enough with the antibiotic stewardship core elements for hospitals to be able to provide accurate and

informed feedback on how realistic the assessment tool items are for their respective hospital category.

The 40 respondents will represent a combination of physician and pharmacist leaders, or co-leaders, of antibiotic stewardship programs within the selected hospitals. According to analyses of calendar year 2015 hospital antibiotic stewardship data from CDC's National Healthcare Safety Network Annual Hospital Survey, hospitals reporting that they had a leader responsible for stewardship programs (n=3,499) displayed an approximately equal distribution of physician-only, pharmacist-only, and co-leads (29%, 37%, and 30%, respectively). The remaining 4% had other positions fill the role of lead. To ensure the pilot represents a similar distribution of hospitals, we anticipate that within the 30 participating hospitals: 10 hospitals will have a physician lead only, 10 will have a pharmacy lead only, and 10 will have physician and pharmacist co-leads (2 respondents per hospital within this last group). All 40 respondents will complete the assessment tool (Attachment A) and the feedback questionnaire (Attachment B).

Study Population

The audience for this research will be physician and clinical pharmacist leaders of hospital antibiotic stewardship programs.

B2. Procedures for the Collection of Information

CDC will be responsible for the collection of all study information. As participants are recruited for the study, recruitment grids will be prepared by CDC study staff to keep track of recruitment and ensure that the sample meets the aforementioned criteria. The grids will not contain any personally identifying information and will not be shared with respondents. The recruitment grids will be stored in a multi-user shared drive at CDC that will be accessible only to study staff.

Recruitment will begin within one month of receiving OMB approval and should be complete within about one month. Respondents within the 30 participating hospitals will be recruited in two ways:

1. Respondents from academic acute-care hospitals and non-academic acute care hospitals will be recruited through leadership of the health system within which

each hospital resides. CDC currently has working relationships with several large health systems that have a diversity of hospitals types (e.g. Intermountain Healthcare, Hospital Corporation of America, Ascension Healthcare, Carolinas Healthcare System). CDC will contact leadership within these health systems and, in consultation with these individuals, identify hospitals that meet the above-mentioned criteria (established antibiotic stewardship leadership and a combination of hospital settings). The health system leadership will facilitate contact with participating hospitals, so that CDC can request participation in this formative research project.

2. Given few large health systems include critical access hospitals, respondents from critical access hospitals will be identified and contacted directly by CDC staff. CDC has a working relationship with many critical access hospitals across the country due to other activities within the Division of Healthcare Quality Promotion, such as convening critical access hospitals to discuss antibiotic stewardship issues. The CDC project team will directly contact administrators from 10 critical access hospitals to recruit them for participation in the study. If any of the original 10 hospitals decline participation, CDC will reach out to additional hospitals to reach the study goal of 10 participating critical access hospitals.

All potential respondents will be informed that participation is voluntary and no personally identifying information will be collected.

Within each hospital, data will be collected on a one-time basis from the antibiotic stewardship program leader. This leader will be either a physician or a clinical pharmacist depending upon the hospital, and is the individual accountable for overseeing implementation of the hospital's antibiotic stewardship program. If a participating hospital has co-leaders for their program (both a physician and a pharmacist), they will be asked to work together to complete one draft assessment tool for their hospital and one feedback questionnaire. In total, 40 individuals will participate in the study. Each data collection will last a total of 105 minutes.

Data collection will occur on a rolling basis over a 3-month period. As participants are enrolled in the study, the CDC project lead will send, via email, an introductory letter (Attachment C), the draft assessment tool (Attachment A), and feedback questionnaire (Attachment B) to the hospital antibiotic stewardship program leader (or co-leaders), who will complete the assessment for their facility. These same individuals will provide feedback on the relevance, clarity, and importance of the assessment tool items via the feedback questionnaire. No monetary or other incentives will be provided. Respondents will be provided approximately three weeks to complete data collection and submit responses to CDC. No personally identifiable information will be collected during this pilot study. Only data about organizational capacity and processes will be collected.

Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearances.

B3. Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used to maximize cooperation and achieve the desired participation rates:

- Reminder e-mails will be sent to participants after one week of enrollment in the study, and again after two weeks post-enrollment if responses are not submitted within that timeframe.

B4. Test of Procedures or Methods to Be Undertaken

To estimate the burden of data collection, two different project team members conducted mock assessments of antibiotic stewardship programs to complete the draft assessment tool (Attachment A). The mock assessments involved scenarios where the respondent needed to follow-up with other staff to obtain answers to select questions in the assessment, rather than already knowing all answers. In this way, the burden estimate most closely resembles a maximum average burden. All project team members also extensively reviewed the feedback questionnaire (Attachment B) to ensure questions will provide the necessary data to inform improvements to the assessment tool.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals consulted on technical and statistical issues related to data collection are listed below. The data will be collected and analyzed by the CDC fellow and CDC Health Scientist.

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