

Request for genIC Approval

CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: National Center for Emerging and Zoonotic Infectious Diseases

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

PURPOSE AND USE OF COLLECTION:

The mission of CDC's Division of Healthcare Quality Promotion (DHQP) is to protect patients; protect healthcare personnel; and promote safety, quality, and value in healthcare delivery systems. Part of DHQP's portfolio is a large investment in combatting healthcare associated infections and antibiotic resistance. While antibiotics are critical to treating many infections and have made medical advances such as cancer chemotherapy and organ transplants possible, it is estimated that between 20-50% of all antibiotics prescribed in acute care hospitals are either unnecessary or inappropriate, resulting in potentially serious side effects for patients and a growing problem of antibiotic resistance (Centers for Disease Control and Prevention [CDC], 2014). Modifying antibiotic use is one of the most important means to address the growing issue of antibiotic resistance (File et al., 2014).

To improve antibiotic use and prescribing practices, CDC is working with partners to implement antibiotic stewardship programs, practices and policies in all healthcare settings in all 50 states. To spearhead this effort, CDC published the Core Elements of Hospital Antibiotic Stewardship Programs (available at <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>) in 2014, which outlines seven core elements of successful hospital antibiotic stewardship programs: leadership commitment, accountability, drug expertise, action, tracking, reporting, and education. However, the complexity of medical decision making surrounding antibiotic use and the variability in the size and types of care among U.S. hospitals require flexibility in implementation of antibiotic stewardship programs (McGregor & Furuno, 2014). Despite variability in hospital implementation, CDC must be able to provide guidance, recommendations, and assistance on establishment and improvement of antibiotic stewardship programs, and must be able to assess implementation of the programs within facilities, across states, and nationally. CDC's current assessment methodology (available at https://www.cdc.gov/nhsn/forms/57.103_pshospSurv_blank.pdf) has provided initial insight into hospitals' implementation of stewardship programs, but does not provide sufficient detail for CDC to objectively assess their quality. To this end, CDC is developing a revised approach to assessing implementation of hospital antibiotic stewardship programs.

The purpose of this study is to conduct formative research to inform the development of a new methodology to assess the implementation of CDC's Core Elements of Antibiotic Stewardship for Hospitals. The research results will be used to finalize the assessment tool by identifying necessary changes to the content to ensure relevance and importance in a variety of hospital settings; identifying necessary changes to wording to ensure clarity and consistent interpretation of items; and providing information, in combination with input from subject matter experts, for CDC to develop of a scoring mechanism for the tool.

CDC staff will oversee and conduct all data collection related to the proposed study. Data

collection will consist of completion of the draft assessment tool and provision of additional written feedback on the perceived relevance, importance, and clarity of the assessment tool items via a feedback questionnaire. Data will be collected from 40 healthcare providers (physicians and/or clinical pharmacists) representing 30 hospitals, serving in the official capacity of antibiotic stewardship program (co)leader(s) for their hospital. The study is designed to ensure collection of data from a combination of academic acute care hospitals, non-academic acute care hospitals, and small critical access hospitals to ensure findings reflect the differing levels of human, financial, and technical resources available in each of these settings for implementation of antibiotic stewardship programs.

Completed assessment tools will be analyzed to identify any patterns in responses either within or across hospital types, as well as to identify any inconsistencies or unanticipated answers. Data collected via the feedback questionnaire will provide information on the perceived clarity, relevance, and importance of items in the draft assessment tool from the perspective of antibiotic stewardship program leaders in the three hospital settings. All information obtained through the study will be used to inform improvements to the assessment tool and provide input into decisions about an associated scoring mechanism for the tool.

DESCRIPTION OF RESPONDENTS:

Healthcare providers (physicians and clinical pharmacists) responsible for leading antibiotic stewardship programs in academic acute care hospitals, non-academic acute care hospitals, and critical access hospitals.

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: *Anita W McLees*

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [] Yes [] No
3. If Applicable, has a System or Records Notice been published? [] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [] Yes [X] No

BURDEN HOURS

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Physicians	Assessment Tool	20	1	45/60	15
	Feedback Questionnaire	20	1	1	20
Clinical Pharmacists	Assessment Tool	20	1	45/60	15
	Feedback Questionnaire	20	1	1	20
	Totals	80			70

FEDERAL COST: The estimated annual cost to the Federal government is \$58,346. The federal government personnel estimate is based on cost of three CDC staff and one CDC fellow. Federal staff responsibilities include overall management and oversight of the project and provision of content matter expertise in the development of the research strategy and data collection instruments, as well as consultation on interpretation and use of research findings. One CDC staff is working with the fellow on development of instruments, data collection, analysis, and reporting.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? Yes No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

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).

Recruitment will begin within one month of receiving OMB approval and should be completed 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 hospital 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.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

Web-based or other forms of Social Media

Telephone

In-person

Mail

Other, Explain – via email / Word documents

2. Will interviewers or facilitators be used? Yes No

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 3 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. This study was determined to be non-research from an IRB/human subjects perspective since findings will not be generalized (Attachment D).

Please make sure all instruments, instructions, and scripts are submitted with the request.

- **Attachment A:** Hospital Antibiotic Stewardship Core Element Assessment
- **Attachment B:** Feedback Questionnaire
- **Attachment C:** Letter to Study Participants
- **Attachment D:** IRB Determination Letter

References:

Centers for Disease Control and Prevention. (2014). Core Elements of Hospital Antibiotic Stewardship Programs. Atlanta, GA: US Department of Health and Human Services, CDC. Retrieved May 31, 2017 from <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.

File, T.M., Srinivasan, A., & Bartlett J.G. (2014). Antimicrobial Stewardship: Importance for Patient and Public Health. *Clinical Infectious Diseases*, 59(Suppl. 3), S93-S96.

McGregor, J. C., Furuno, J. P. Optimizing Research Methods Used for the Evaluation of Antimicrobial Stewardship Programs. *Clinical Infectious Diseases*, 59(Suppl. 3), S185-S192.

Please make sure all instruments, instructions, and scripts are submitted with the request.

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

TITLE OF INFORMATION COLLECTION: Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use and Related Harms

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

The data collection does involve collection of sensitive or identifiable personal information (PII). All PII will be kept secure in a locked file cabinet or secure online servers.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.