GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement A

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

OMB number 0920-1154

Contact Information:

Anita McLees, MA, MPH
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS A-07
Atlanta, GA 30329

Telephone: (404) 498-0316
E-mail: zdu5@cdc.gov

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- **Goals of the study:** To inform the development of a new methodology to assess the implementation of CDC's Core Elements of Antibiotic Stewardship for Hospitals by pilot testing a draft assessment tool. The pilot test will assess the relevance and perceived importance of proposed components of the tool in various hospital settings and identify necessary clarifications to terminology and format used within the draft tool.

- **Intended use of the resulting data:** To 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 final tool will be incorporated into the Division of Healthcare Quality Promotion's National Healthcare Surveillance Network Annual Hospital Survey.

- **Methods to be used to collect data:** Completion of draft assessment tool and written response to a series of feedback questions related to clarity, relevance, and importance.

- **The subpopulation to be studied:** 40 healthcare providers representing 30 unique hospital antibiotic stewardship programs.

- **How data will be analyzed:** Descriptive analyses of assessment tool data and closed-ended feedback data, and thematic analysis of qualitative, open-response data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval for a new genIC entitled "Antibiotic Stewardship in Hospitals: Assessing Comprehensive Implementation of the Seven Core Elements." The goal of this formative research is to inform the development of a new methodology to assess the implementation of CDC's Core Elements of Antibiotic Stewardship for Hospitals by pilot testing a draft tool. The pilot test will assess the relevance and perceived importance of proposed components of the draft tool in various hospital settings and identify necessary clarifications to terminology and format used within the draft tool.

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. In 2015, CDC incorporated an initial set of questions about antibiotic stewardship programs into the Patient Safety Component of the National Healthcare Safety Network's Annual Hospital Survey (available at https://www.cdc.gov/nhsn/forms/57.103_pshospsurv_blank.pdf) (OMB Control No. 0920-0666). These questions have provided CDC with initial insight into hospitals' implementation of stewardship programs, but do not provide sufficient detail for CDC to objectively assess their quality. A priority for DHQP is to better understand the extent to which these programs are being implemented nationally, with a focus on assessing the quality of their implementation in various hospital settings. To this end, CDC is developing a revised approach to assessing implementation of hospital antibiotic stewardship programs.

2. Purpose and Use of Information Collection

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 (Attachment A) and provision of additional written feedback on the perceived relevance, importance, and clarity of the assessment tool items via a feedback questionnaire (Attachment B). An introduction to the study will be provided via an introductory letter (Attachment C) that will accompany the draft assessment and 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.

3. Use of Improved Information Technology and Burden Reduction

This study will consist of data collection through completion of a draft assessment tool and response to a set of written feedback questions about the tool. All data will be collected via Microsoft Word and will be returned to CDC via email. The assessment tool was designed to include the minimum number of items required to assess the quality of stewardship program implementation. The feedback questions were designed to collect the minimum information necessary for the purposes of this formative research.

4. Efforts to Identify Duplication and Use of Similar Information

No nationally recognized, standardized metrics for stewardship programs exist (Nagel et. Al., 2014). CDC is the sole collector of national level data on implementation of antibiotic stewardship programs in hospitals. These data are currently collected through the National Healthcare Safety Network's Annual Hospital Survey. Data currently collected are insufficient for CDC to understand the extent to which the core elements of antibiotic stewardship programs are being implemented. Once this formative research is completed and findings are used to modify the draft assessment tool, this final, revised tool will replace existing questions in the National Healthcare Safety Network's Annual Hospital Survey.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This is an ad hoc data collection (i.e., a one-time study to inform tool improvements that does not require periodic collection of data). There are no legal obstacles to reduce burden. The present study will provide the primary data needed to address the goals of this formative research. If this study was not conducted, information needed to inform the development of a final tool for use with hospitals across the United States would not be gathered.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. No public comments were received.

CDC project staff are responsible for the study design and data collection instruments, and are listed below in Exhibit A.8.1. No major problems were identified that could not be resolved.

Exhibit A.8.1. CDC Project Staff

Anita McLees, MA, MPH Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention 1600 Clifton Road, NE, MS A-07 Atlanta, GA 30329 Phone: (404) 498-0316 Fax: (404) 315-2374 E-mail: zdu5@cdc.gov	Arjun Srinivasan, MD Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention 1600 Clifton Road, NE, MS A-07 Atlanta, GA 30329 Phone: (404) 639-2303 Fax: (404) 639-2647 E-mail: beu8@cdc.gov
Lauri Hicks, DO Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention	Margaret Paek, MPH Division of Scientific Education and Professional Development Center for Surveillance, Epidemiology, and Laboratory Services

1600 Clifton Road, NE, MS A-31 Atlanta, GA 30329 Phone: (404) 639-2204 Fax: (404) 315-2010 E-mail: auq3@cdc.gov	Centers for Disease Control and Prevention 1600 Clifton Road, NE, MS E-92 Atlanta, GA 30333 Phone: (404) 498-6563 E-mail: kvz3@cdc.gov

9. Explanation of Any Payment or Gift to Respondents

No incentives will be provided for participation in this study.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

This information collection was reviewed by the National Center for Emerging and Zoonotic Diseases (NCEZID)'s human subjects advisor who determined that the privacy act does not apply.

No personally identifiable information will be collected as part of this formative research. Respondents will provide data on their hospital setting and position title. All assessment questions focus on organizational capacity, processes, or activities, and feedback questions do not request any personally identifiable information. Data will be reported to the CDC study lead via email. CDC will maintain all data files on a multi-user shared drive that will be under the control of the project lead, with access limited to project staff for the duration of the project. Data will be analyzed by hospital setting, by respondent type, and in aggregate. Findings will be used internally at CDC, and any reporting on the findings will be done in summary form.

Respondents will be informed in writing that their participation is voluntary, and that data will not be analyzed or presented in such a way that their individual hospital will be identifiable.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This project has been deemed non-research due to the CDC IRB definition of research per 45 CFR 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." While the pilot test is

indeed formative research per the definition of this generic clearance mechanism, the results of this study will not contribute to generalizable knowledge and no personally identifiable information will be collected; therefore a determination of non-research from an IRB perspective was made. The determination letter is included as Attachment D.

Justification for Sensitive Questions

No sensitive questions will be asked as part of this information collection.

A.12. Estimates of Annualized Burden Hours and Costs

Exhibits A.12.1 and A.12.2 provide details about the estimates of annualized burden hours and costs, and how these estimates were calculated. CDC anticipates collecting data from 40 healthcare providers in 30 hospitals, including a combination of physicians and clinical pharmacists. 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 are estimating burden based on 40 respondents across 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 (30 burden hours) and the feedback questionnaire (40 burden hours). Total burden hours are 70.

Department of Health and Human Services, Centers for Medicare and Medicaid Services data (https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-13925.pdf) were used to estimate the hourly wage rate for physicians and clinical pharmacists for the purposes of this generic request. Total annualized cost to respondents is $10,500.

Exhibit A.12.1 Annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Physicians	Assessment	20	1	45/60	15

	Tool				
	Feedback Questionnaire	20	1	1	20
Clinical Pharmacists	Assessment Tool	20	1	45/60	15
	Feedback Questionnaire	20	1	1	20
Total		80			70

Exhibit A.12.2 Annualized Cost to Respondents

Respondents	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Physicians	Assessment Tool	15	$187.00	$2,805.00
	Feedback Questionnaire	20	$187.00	$3,740.00
Clinical Pharmacists	Assessment Tool	15	$113.00	$1,695.00
	Feedback Questionnaire	20	$113.00	$2,260.00
Total				$10,500.00

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents or record keepers.

A.14. Annualized Costs to the Government

The average annualized cost to the Federal Government to collect this information is $58,346. The federal government personnel estimate is based on cost of the 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 (Exhibit A.14.1).

Exhibit A.14.1. Government Costs

		Percent Time	Total ($)
Federal Government Personnel Costs	CDC Health Scientist (GS-14)	25%	$31,028
	CDC Medical Officer (O-6)	5%	$9,000
	CDC Medical Officer (O-6)	2%	$2,600
	CDC Fellow	30%	$15,718
Total Annualized Cost to Government			**$58,346**

A.15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data from the assessments and the feedback questionnaire will be entered into Microsoft Excel databases by the fellow as they are received and stored in a secure CDC shared drive, accessible only to project staff. Data will be analyzed by a CDC Health Scientist and the fellow. Analysis of assessment data and closed-ended feedback questions will consist of simple descriptive statistics. Narrative comments in the feedback questionnaire will be analyzed qualitatively and aggregated by common themes. Comparisons will be made across hospital settings and type of respondent (physician vs. pharmacist). Analysis will not require advanced, complex statistical techniques. Analyses will be presented in a written report describing the major findings and recommended edits to the assessment based on those findings. The key events and reports to be prepared are listed in Exhibit A.16.1.

Exhibit A.16.1. Project Activities and Time Schedule

Activity	Time Schedule
Begin recruitment	1 month after OMB approval
Complete formative research	4 months after OMB approval
Report of findings and recommendations completed	6 months after OMB approval
Final tool completed	8 months after OMB approval

It is anticipated that respondents will be identified within 1 month of receiving OMB approval and data collection will commence within 2 months of receiving OMB approval.

Research findings will be used internally at CDC to make improvements to the draft assessment tool. Findings related to clarity, relevance, and importance of assessment tool items will be used to make improvements to wording of items in the assessment tool, as well as to potentially add and/or delete items. Additionally, findings will be used, in conjunction with input from CDC subject matter experts, to develop a scoring system and assign appropriate weights to different items. This scoring system will eventually allow CDC to produce both element-specific scores and a composite score for assessing the quality of hospital antibiotic stewardship programs.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date in not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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.

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Nagel, J. L., Stevenson J. G., Eiland III, E. H., & Kaye, K.S. (2014). Demonstrating the Value of Antimicrobial Stewardship Programs to Hospital Administrators. *Clinical Infectious Diseases, 59(Suppl. 3),* S146-S153.