

GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development
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Supporting Statement A

Core Elements of Antimicrobial Stewardship in Nursing Homes

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Contact Information:
Sarah Kabbani, MD, MSc
Medical Officer
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-31
Atlanta, GA 30329
Telephone: (404) 718-5524
E-mail: nfq8@cdc.gov

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Attachments

- **Goals of the study:** The goal of the formative research is to assess the knowledge, attitudes, practices, and perceived provider-level barriers to appropriate antibiotic prescribing in a sample of health care providers in nursing homes.
- **Intended use of the resulting data:** To better inform interventions aimed at improving the antibiotic stewardship behaviors of prescribers in long-term care settings.
- **Methods to be used to collect data:** Computer-assisted online survey.
- **The subpopulation to be studied:** 992 healthcare providers in 47 nursing homes
- **How data will be analyzed:** Descriptive analyses of assessment tool data and closed-ended feedback data, and thematic analysis of qualitative, open-response data.

1. Circumstances Making the Collection of Information Necessary

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. The low clinical threshold for prescribing antibiotics leads to 70% of nursing home residents to receive one or more courses of antibiotics each year. Some studies estimate that 75% of these prescriptions are inappropriate or unnecessary. Antibiotic stewardship is a high national priority: in 2016, Medicare included stewardship and antimicrobial reporting in its proposed nursing home rule and the Centers for Disease Control & Prevention (CDC) released the Core Elements of Antibiotic Stewardship for Nursing Homes to guide efforts in this setting. This contract aims to assess the implementation of the Core Element of Antibiotic Stewardship for Nursing Homes.

2. Purpose and Use of Information Collection

The purpose of this survey is to conduct formative research to assess the knowledge, attitudes, practices and perceived provider-level barriers to appropriate antibiotic prescribing in a sample of health care providers in nursing homes.

Information will be used to provide descriptive analysis reports of the prescribing climate within long-term care settings. We will use these data to characterize the current antimicrobial stewardship environment with an effort to identify key elements based on staff interactions, perceived challenges, and any identifiable gaps in knowledge. The specific elements within the survey will be used to identify common needs shared across prescribers as areas for further training or intervention development e.g., identified barriers to education or training resources will result in a more robust education component to be included in future work. Only prescribers receiving the intervention will receive the same assessment twice: first as part of the full prescriber pool used to develop a baseline, and a second time, following the completion of the 12-month intervention implementation to assess for changes in knowledge, attitudes, practices and perceived provider-level barriers to appropriate antibiotic prescribing. The follow-up assessment will be submitted to OMB as a separate information collection request.

3. Use of Improved Information Technology and Burden Reduction

This study will consist of data collection through completion of a survey (attachment A) and sent by email (attachment B) to the prescribers by the respective corporations. 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

The survey will be developed via a software package that allows for individualized survey administration: each respondent will be sent a survey and completion is linked to the email address. Duplication can be determined by screening or multiple submissions filtered by unique email address. To our knowledge, no similar work is being done to collect data on provider attitudes and perception of antibiotic stewardship in the long-term care setting at CDC or elsewhere in the federal government.

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 a one-time information collection.

After a period of twelve months, a second OMB package will be prepared and submitted to cover a follow-up assessment.

Data gathered as part of this gen-IC 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 intervention program across the United States would not be gathered. The information collected in this survey provides a much-needed understanding of the current state of antimicrobial stewardship in a long-term care setting: beliefs, knowledge levels, perceptions of barriers, and attitudes regarding appropriate prescribing practices. Responses will provide a narrative background highlighting possible differences across settings such as: demographics, credential type, rurality, staffing and facility size, elements that warrant consideration when designing a large-scale program. Responses will also provide a baseline to assess changes to the above-mentioned elements: beliefs, knowledge levels, perceptions of barriers, and attitudes regarding appropriate prescribing practices.

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

- A. A Federal Register notice was published for this generic information collection request on July 18, 2016, Vol. 81, No. 137, pp. 46680. No public comments were received.
- B. Information about this project was shared with CMS and other federal partners during the PACCARB (Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria) meeting.

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.

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) determined that the Privacy Act is not applicable.

No personally identifiable information will be collected as part of this formative research. All assessment questions focus on antibiotic prescribing practices do not request any personally identifiable information. Demographic questions used to characterize the respondent pool will be categorical whenever possible. Data will be reported to the study investigators via email.

The assessment will be delivered digitally via Qualtrics, a secure survey deployment software program utilized by Brown University, accessible only via a link to the survey provided in the invitation email. Consent will be obtained during the first question: respondents will be informed that their participation is voluntary, and that data will not be analyzed or presented in such a way that their individual nursing home will be identifiable, and given two options: consent and continue or exit the assessment (attachment C).

All data will be analyzed at the aggregate level with unique identifiers being given to the individual facilities to prevent identification.

Data will be housed within a secure, FISMA compliant environment within Brown University, with access only granted to the research team at Brown University. Baseline characteristics will be identified and reported at the corporate level with each facility masked to prevent identification.

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

IRB Approval

The survey was reviewed and was determined not to meet the definition of human subjects research as defined in Title 45 CFR 46.102 (attachment D).

Justification for Sensitive Questions

There is one question about respondents' race and one about respondents' gender. There is literature that suggests prescribing differences from different demographic groups. These questions are meant to help illuminate any differences in prescribing practices that may exist.

Though we will not ask for respondents' ages, we will ask how many years it had been since graduation from medical school. This is meant to help assess prescriber differences in practice.

12. Estimates of Annualized Burden Hours and Costs

The tables below provide details about the estimates of annualized burden hours and costs. The prescriber assessment will be completed by 992 respondents. Each response will take an average of 30 minutes. The total estimated burden is 496 hours and \$92,752.

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 for the purposes of this generic request.

Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Medical Prescriber- <i>Baseline</i>	Prescriber assessment	992	1	30/60	496
Total					496

Annualized Cost Burden

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medical Prescriber- <i>Baseline</i>	Prescriber Assessment	496	\$187	\$92,752
Total				\$92,752

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

There are no other costs to respondents or record keepers.

14. Annualized Costs to the Government

The estimated annual cost to the Federal government is \$100,000 (contract no 200-2016-91773-0001).

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the questionnaire will be collected via Qualtrics and be entered into a statistical software program (SAS or Stata). Data will be analyzed by the project analyst from Brown University, Tingting Zhang, PhD. and/or Project Coordinator, David Manning, ScM. 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.

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.

Project Activities and Time Schedule

Activity	Time Schedule
Begin recruitment	May, 2018
Complete formative research	Baseline: June, 2018- At the start of the intervention
Report of findings and recommendations completed	Aug. 2019
Final tool completed	Sept. 2019

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

- A. Prescriber assessment
- B. Email invitation
- C. Consent
- D. Non-research determination