

# **Assessment of Health Department Antibiotic Stewardship Roles and Activities**

OSTLTS Generic Information Collection Request  
OMB No. 0920-0879

## **Supporting Statement – Section A**

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- Goal of the study: To collect tools, success stories, and strategies from state and local health departments implementing antibiotic stewardship. The information we gather will help us identify services, strategies, and tools used to implement antibiotic stewardship in health departments. It will also help define the important role of the public health department with regards to antibiotic stewardship and give concrete examples of implementation for the purpose of incorporating them into technical guidance for health departments across the entire country.
- Intended use of the resulting data: The resulting data will be used to develop a technical package for state and local health departments with real world examples of antibiotic stewardship implementation and provide a practical “how to guide” for public health departments.
- Methods to be used to collect data: A standardized interview guide will be used to conduct telephone interviews with healthcare-associated infections coordinators (HAI coordinators).
- The subpopulation to be studied: HAI coordinators for state and local health jurisdictions and relevant public health practitioner team members who work with the HAI coordinators to implement stewardship.
- How will data be analyzed: Tools will be cataloged and grouped according to the Core Components of Antibiotic Stewardship Programs Implemented by Health Departments; answers to interview questions will be analyzed through qualitative methods using Excel to identify key themes and emerging trends.

## Section A – Justification

### 1. Circumstances Making the Collection of Information Necessary

#### Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. (**See Attachment A, States/Local Listing**) Data will be collected via group interviews from Healthcare Associated Infection Coordinators (HAI) of 19 state and 1 local health departments (n=20 total interviews; see Attachment A, States/Local Jurisdiction Listing). Up to three staff persons per state or local health department will be included in the group interview (n=60). All interviews conducted will include the healthcare associated infection coordinator (HAI) from each state or local health department. Often, the HAI coordinators work with others in their health department to implement stewardship activities. HAI coordinators will have the option of including up to two additional staff persons in the group interview, such as the Antibiotic Stewardship Coordinators and State Epidemiologists. As a result,

the total number of interviews will be 20, with the total number of potential respondents as 60 (3 staff persons per site).

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems <sup>1</sup>

Inappropriate antibiotic use has led to an increase in antibiotic resistance and a loss of effective antibiotic treatments. In 2013, CDC issued the report “Antibiotic Resistance Threats in the United States” which sounded the alarm on the urgent and growing threat of antibiotic resistant organisms and reported that two million people are sickened every year with antibiotic resistant infections and at least 23,000 dying as a result. Furthermore, almost 250,000 persons require hospital care for *Clostridium difficile* infections each year, which is often associated with antimicrobial use. In 2015, the US government released the *National Action Plan for Combating Antimicrobial-Resistant Bacteria*<sup>2</sup> The goals of this national plan include (1) prevent the development and spread of resistant infections, (2) increase surveillance efforts, (3) develop new drugs and diagnostic tests, and promote international collaboration to prevent and control antimicrobial resistance.

Antibiotic stewardship (AS) refers to formally implemented programs and interventions to promote optimal antibiotic prescribing to limit antibiotic resistance and prevent infections associated with inappropriate use, such as *Clostridium difficile*. CDC has developed materials for the implementation of antibiotic stewardship programs in acute care hospitals and long term care facilities (Core Elements of Hospital Antibiotic Stewardship Programs and Core Elements of Antibiotic Stewardship for Nursing Homes)<sup>3</sup> which give these facilities practical implementation advice.

As public health and the healthcare system transition to a more integrated and coordinated approach for solving complex problems such as antibiotic resistance, health departments are encouraged to take on a larger role. Antibiotics are a shared resource and if they are not used wisely, many will suffer the consequences. Health departments play a role in preventing antibiotic resistance because they are responsible for protecting patients across the healthcare continuum

and serve as a bridge between healthcare organizations and the community. State and local health departments are uniquely positioned to act as convener, coordinator and promoter of antibiotic stewardship activities in their local hospitals, long term care facilities and outpatient clinics.

However, antibiotic stewardship activities are relatively new to health departments and many may not understand their role in antibiotic resistance prevention. Departments with minimal clinical and laboratory expertise may not feel confident to tackle this problem. Furthermore, there is a lack of knowledge on services, strategies, and tools used to implement antibiotic stewardship in health departments, leaving public health practitioners without guidance on how to proceed with these new responsibilities. There are some health departments, however, that are leading the way in terms of antibiotic stewardship and have innovative solutions and strategies. Dissemination of these ideas would benefit those health departments who have not yet started implementation and would help prevent the need to “re-invent the wheel.”

To better define this important antibiotic resistance prevention role of the public health department, learn about the activities promoting antibiotic stewardship in health jurisdictions, and give concrete examples of implementation, CDC seeks to reach out to HAI coordinators and collect information on how health departments are currently addressing this urgent problem. Therefore, the purpose of this collection is to collect tools, success stories, and strategies from state and local health departments implementing antibiotic stewardship.

CDC is partnering with the Public Health Foundation (PHF) on this proposed data collection. PHF is a private, non-profit, 501(c)3 organization based in Washington, DC, which improves the public’s health by strengthening the quality and performance of public health practice. CDC and PHF are partnering through a cooperative agreement (Grant number# U38OT000211-03) to understand strategies, tools, and lessons learned about antibiotic stewardship activities at health departments so that this information may help others interested in pursuing or improving antibiotic stewardship activities. The role of PHF will be to schedule and conduct the interviews and collect and catalog identified tools. CDC will take the lead on developing the structured interview guide, providing technical expertise on antibiotic stewardship. The information collected will help identify services, strategies, and tools used to implement antibiotic stewardship in health departments. It will also help define the important role of the public health department with regards to antibiotic stewardship and give concrete examples of implementation for the purpose of incorporating them into technical guidance for health departments across the entire country.

### **Overview of the Information Collection System**

Information will be collected from a maximum total of 60 respondents via telephone interviews. Interviews will be conducted by PHF staff; CDC staff will join each interview to listen to the conversations as observers. A standard interview guide will be used (**see Attachment B: Interview Guide**) The interview guide was pilot tested by 3 public health professionals. Feedback from this group was used to refine questions as needed, and establish the estimated time required to complete the information collection instrument.

## **Items of Information to be Collected**

The telephone interview guide consists of 22 main questions. The majority of questions are open-ended, however there are a few dichotomous and multiple response questions. Questions will inquire about the health department's overall antibiotic stewardship strategy and specifically will collect information on the following:

- Stewardship activities: What types of antibiotic stewardship activities are occurring in the jurisdiction across the healthcare continuum?
- Stewardship collaboration: Level of coordination and communication about antibiotic stewardship activities in health department – specifically, who are the partners the health department are collaborating with and how?
- Stewardship communication: How are messages about antibiotic stewardship communicated to the general public and partners?
- Education and stewardship tools: How do health departments provide education about stewardship to partners and the general public?
- Stewardship leadership: Does the health department have expertise in infectious disease and laboratory diagnostics supporting stewardship activities?
- Stewardship surveillance: How are departments using surveillance to understand and track antibiotic resistance in their jurisdiction? Stewardship policy: What antibiotic stewardship policy measures are prompted?

An effort was made to limit the time burden on the participants by keeping the question number low and allowing for group interviews to minimize the burden on one person.

## **2. Purpose and Use of the Information Collection**

The purpose of this collection is to collect tools, success stories, and strategies from state and local health departments implementing antibiotic stewardship.

The information gathered will help identify services, strategies, and tools used to implement antibiotic stewardship in health departments. It will also help define the important role of the public health department with regards to antibiotic stewardship and give concrete examples of implementation for the purpose of incorporating them into CDC technical guidance for health departments across the entire country. The tools and success stories gathered from this project will be distributed as real world examples via a technical package for state and local health departments that includes a practical “how to guide” for public health departments.

## **3. Use of Improved Information Technology and Burden Reduction**

Data will be collected via group telephone interviews. This group interview format was chosen to limit the need for follow-up calls. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 22 questions).

**4. Efforts to Identify Duplication and Use of Similar Information**

A literature review was conducted. Few resources related to the role of public health departments in antibiotic resistance prevention or technical advice for health departments on antibiotic stewardship implementation were identified. As a result, this data collection will not be duplicative of past efforts.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this information collection.

**6. Consequences of Collecting the Information Less Frequently**

This request is for a one time information collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Develop technical guidance about antibiotic stewardship for health departments that is relevant and practical
- Provide real world implementation examples of antibiotic stewardship in a health department
- Identify the strategies for health departments to be successful at this crucial public health activity (safeguarding antibiotics)

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center

for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

**9. Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this information collection. STLT governmental staff and / or delegates will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This information collection is not research involving human subjects.

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

No information will be collected that are of personal or sensitive nature.

**12. Estimates of Annualized Burden Hours and Costs**

The estimate for burden hours is based on a pilot test of the information collection instrument by 3 of public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 35 minutes (range 30-40 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 40 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations- administrative service managers (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$33.74 is estimated for all 60 respondents. Table A-12 shows estimated burden and cost information.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents

<b>Information collection Instrument: Form Name</b>	<b>Type of Respondent</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Interview	State & Local	60	1	40/60	40	\$33.74	\$1,349



Guide	HAI Coordinators & additional public health practitioner team members						
	<b>TOTALS</b>	<b>60</b>	<b>1</b>		<b>40</b>		<b>\$1,349</b>

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

**14. Annualized Cost to the Government**

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff. The total estimated cost to the federal government is \$66,020. Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Medical Officer (O4 Commissioned, Corps)	250	\$50	\$12,500
PHF staff from cooperative agreement (3 staff members)	1338	\$40	\$53,520
<b>Estimated Total Cost of Information Collection</b>			<b>\$66,020</b>

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

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

CDC will publish technical guidance for states implementing antibiotic stewardship activities using the real world examples identified by this information collection. Our data analysis plan includes reviewing the tools shared by the HAI coordinators and cataloging them into an excel spreadsheet according to the Core Components of Antibiotic Stewardship Programs implemented by Health Departments (DRAFT) (**Attachment C: Core Components of ASP**). Information collected will also be reviewed and developed into a narrative about how the specific tool was used to provide context.

Project Time Schedule

- ✓ Design questionnaire ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test questionnaire ..... Pending, 2 weeks
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- OMB approval ..... (TBD)
- Conduct assessment ..... 2 months
- Code, quality control, and analyze data..... 2 months
- Prepare reports ..... 1 month
- Disseminate results/reports ..... (1 month)

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

We are requesting no exemption.

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

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

**LIST OF ATTACHMENTS – Section A**

- A. Att.t A—States Local Listing
- B. Att.t B—Interview Guide
- C. Att.t C—Core Components of ASP

**REFERENCE LIST**

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.
2. Centers for Disease Control and Prevention (CDC). "Antibiotic Resistance Threats in the United States, 2013." Available at <http://www.cdc.gov/drugresistance/threat-report-2013/index.html> Accessed on 11/17/2015
3. Centers for Disease Control and Prevention (CDC). "Core Elements of Hospital Antibiotic Stewardship Programs" Available at <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html> Accessed on 12/18/15