

Special Bacteriology Reference Laboratory Assessment

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Contact person:

Shannon Cooney, MPH candidate, Emory Rollins School of Public Health
Graduate Researcher, Special Bacteriology Reference Laboratory
Bacterial Special Pathogens Branch
Office of Infectious Disease
Centers for Disease Control & Prevention
1600 Clifton Road NE,
Atlanta, Georgia 30333
Phone Number: 404-639-0270
Fax Number: 404-639-3172
E-mail: yqj1@cdc.gov

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- The goal of the study is to determine the annual number of *Nocardia* isolates submitted to the U.S. public health jurisdiction laboratories, and to identify barriers to laboratory use of SBRL services.
- Data will be used to estimate the annual number of *Nocardia* submissions to public health laboratories, and to determine the validity of SBRL's *Nocardia* database, which collects information on isolate submissions and laboratory testing results. Data will also be used to determine why public health laboratories collective use of SBRL's services has decreased in recent years, and feedback will be requested so that we can determine how SBRL can better meet the needs of the laboratories.
- Methods to be used include a one-time online data collection instrument created in Epi Info that will be emailed to public health laboratory officials.
- The subpopulation to be studied includes laboratory officials from 55 of the 57 U.S. public health jurisdictions (there are currently no laboratory managers in America Samoa or the U.S. Virgin Islands).
- Data will be analyzed quantitatively using Epi Info and Excel, generating a report for SBRL employees showing summary statistics and results for each question (i.e. frequency and counts for categorical responses).

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 (Expiration date: 03/31/2018). The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from 55 of the 57 U.S. public health jurisdictions (which include the 50 states, plus U.S. territories, NYC and District of Columbia) from public health laboratory officials acting in their official capacities (there are currently no laboratory managers in America Samoa or the U.S. Virgin Islands) (**Attachment A: Public Health Laboratory Name and Type List**). These public health laboratory officials assume the roles of either director, administrator, chief, supervisor, commissioner, or supervisory microbiologist. Regardless of title, the individuals asked to participate in the assessment were chosen because of their managerial role in a state public health laboratory.

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 and (9) Evaluating effectiveness, accessibility, and quality of personal and population-based health services.

- 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 problems¹

Nocardia species (a grouping of organisms) are found commonly in the environment. There are more than 90 *Nocardia* species, and at least 30 of these can cause infections in humans². The resulting disease, nocardiosis, is most often found in immunocompromised individuals. Invasive nocardiosis can have up to a 60% mortality rate in certain populations, and can lead to serious health outcomes such as brain abscesses and pneumonia³. Since nocardiosis is not a nationally notifiable disease, the true number of infections caused by this bacteria is difficult to determine. Monitoring incidence of bacterial infection and resistance is important so that we can better understand where efforts and resources should be spent to improve population-based health.

CDC's Special Bacteriology Reference Laboratory (SBRL) in the Division of High Consequence Pathogens and Pathology, conducts species identification and antibiotic susceptibility testing on unusual, rare, or novel bacteria, including *Nocardia*. The U.S. jurisdictional public health laboratories have the option to send *Nocardia* isolates to SBRL for this testing. Over the past several years, SBRL has noticed a decrease in the number of *Nocardia* isolates received from laboratories for testing⁴. In the most recent four year span between 2011 and 2014, submissions of *Nocardia* isolates to SBRL from the United States and its territories decreased nearly two fold from 122 to 67⁴. The reason for this decrease is unknown, though we hypothesize it may be due to improved testing technologies at public health laboratories, and not because incidence has truly declined.

Our assessment will help us determine if there are any gaps in our services that we provide to public health laboratories. Improving SBRL processes to become more accessible to laboratories is important and should increase utilization of our unique laboratory services, which will improve the monitoring for *Nocardia* and other difficult to characterize bacterial pathogens.

The purpose of this assessment is to determine the annual number of *Nocardia* isolates public health laboratories identified in 2015, and also to identify barriers to use of SBRL services. The respondent universe consists of public health laboratory officials from the 55 of the 57 U.S. public health jurisdictions (there are currently no laboratory managers in America Samoa or the U.S.

Virgin Islands). Through assessing the effectiveness and accessibility of SBRL services to these laboratories, SBRL will be able to better monitor community health problems. *Nocardia* isolates received by SBRL will be compared to the isolates reported by the public health jurisdictions to determine what species are most common, and what technologies the laboratories have available for species and susceptibility testing. Additionally, the information that health departments report about barriers to submitting to SBRL will be used to improve SBRL processes. In turn, this will help improve sample submission processes for all bacterial isolates sent to SBRL, not solely for *Nocardia*.

Overview of the Information Collection System

Data will be collected via a web-based assessment allowing respondents to complete and submit their responses electronically (**see Attachment B: SBRL Instrument – Word Version & Attachment C: SBRL Instrument - Web Version - Screenshots**). The online information collection instrument will be used to gather information from public health laboratory officials regarding the approximate number of *Nocardia* isolates their laboratories process each year, and what the most common *Nocardia* species were that they isolated in 2015 (if applicable). Additionally, the instrument will ask about their awareness and usage of SBRL services. These public health laboratory officials assume the roles of either director, administrator, chief or supervisor. This method of data collection was chosen to reduce the overall burden on respondents, as they can complete the assessment at a time convenient to them. The information collection instrument was pilot tested by 5 public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns, and to establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The online assessment consists of 17 questions designed to determine the annual number of *Nocardia* species isolated by the U.S. public health jurisdictions, and to identify barriers to laboratory use of SBRL services. The questions are of various types, including dichotomous (yes/no), multiple response, and open-ended. Skip patterns were utilized in the assessment so that if a question was no longer relevant because of a previous response, the question is disabled.

Questions will focus on:

- Questions about the respondent (Question 1 & 2)
- Questions about species identification testing (Question 3-7)
- Questions about antibiotic susceptibility testing (Questions 8-10)
- Questions about use of CDC SBRL and awareness of SBRL services (Questions 11-15)
- Prompt for feedback and question about their willingness to collaborate on an annual *Nocardia* summary of incidence of disease and antibiotic susceptibility of cases in their state (Questions 16-17)

2. Purpose and Use of the Information Collection

The purpose of this information collection instrument is to determine the number of *Nocardia* isolates identified by laboratories and thus give a rough estimate of the annual burden of *Nocardia* infection in the United States, and to assess use of SBRL services.

Data will be used to estimate the annual burden of *Nocardia* infection in the United States and determine the validity of SBRL's current dataset. Specifically, Data will be used to determine why health department laboratories collective use of SBRL's services has decreased in recent years, by asking why (if applicable) their laboratory is not submitting isolates to SBRL (i.e. Inefficient turnaround time, shipping costs, ability to test samples locally, etc.), so that we can better understand their needs. Data will be analyzed and disseminated in a report to SBRL employees showing summary statistics and results for each question. We will also include suggestions from the laboratories in a section for steps moving forward, and attempt to categorize these responses to determine the most important changes.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based instrument allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden to respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e. limited to 17 questions).

The instrument was created in Epi Info, and data will be stored on internal CDC servers that are fully CDC compliant. Data will only be shared with the Bacterial Special Pathogen Branch (BSPB) and will be stored on a secure CDC network drive. Only those BSPB staff who work directly on the project will have access to the folder. A report will be created using Epi Info and Excel data analysis tools, and shared with SBRL staff.

4. Efforts to Identify Duplication and Use of Similar Information

SBRL experts in the field of *Nocardia* were questioned about their knowledge of any previous information collection instruments that have attempted to gather similar information. Additionally, the Georgia Public Health Laboratory (GPHL) was contacted to see if there was ever a request to provide information similar to this information collection assessment⁵. Both SBRL experts and GPHL were unaware of this information having ever been systematically collected from state public health laboratories. Also, no formal documentation or publications were found through literature searches on PubMed using keywords like "*Nocardia* United States" and "*Nocardia* laboratory testing."

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:

- Improve testing services provided by SBRL and make them easier for public health laboratories to utilize
- Increase awareness of SBRL in U.S. public health jurisdiction laboratories
- Strengthen relationships with U.S. public health jurisdiction laboratories
- Assess *Nocardia* species distribution and ability for public health laboratories to perform species identification and susceptibility testing for *Nocardia* isolates

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 5 public health professionals. In the pilot test, the average time to complete the assessment including time for reviewing instructions, gathering needed information and completing the assessment, was approximately 5 minutes (range 5-10 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for diagnostic related technologists and technicians http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of \$29.84 is estimated for all 55 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents—SBRL Information Collection

| Type of Respondent | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|-----------------------------------|--------------------|---------------------------------|--|--------------------|------------------|------------------------|
| Public Health Laboratory Official | 55 | 1 | 10 /60 | 9 | 29.84 | 269 |
| TOTALS | 55 | 1 | | 9 | | \$269 |

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. One contractors (a graduate researcher), is being used to support development of the assessment tool, data collection, and data analysis. The only cost to the federal government would be the salary of CDC staff and contractors. The total estimated cost to the federal government is \$600. 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 |
|--|------------------------------|---------------------|--------------|
| Graduate Researcher, Bacterial Special Pathogens Branch (Emory Contractor) | 75 | \$6.00 | \$450 |
| Microbiologist, Bacterial Special Pathogens Branch (GS-14) | 3 | \$50.00 | \$150 |
| Estimated Total Cost of Information Collection | | | \$600 |

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The data will be collated and analyzed by the graduate researcher. The results will be compiled and put into a briefing for staff in the Special Bacteriology Reference Laboratory (SBRL).

Project Time Schedule

- ✓ Design questionnaire (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan (COMPLETE)
- ✓ Pilot test questionnaire (COMPLETE)
- ✓ Prepare OMB package (COMPLETE)
- ✓ Submit OMB package (COMPLETE)
- OMB approval (TBD)
- Conduct assessment (Assessment open 4 weeks)
- Code, quality control, and analyze data..... (2 weeks)
- Prepare reports (2 weeks)
- Disseminate results/reports (1 weeks)

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

Attachment A: Public Health Laboratory Name and Type List

Attachment B: SBRL Instrument - Word Version

Attachment C: SBRL Instrument - Web Version - Screen Shots

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.
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3. Lebeaux, D et al. Nocardiosis in transplant recipients. *European Journal of Clinical Microbiological Infectious Diseases* 2014; 33(5):689-702. doi: 10.1007/s10096-013-2015-5
4. Special Bacteriology Reference Laboratory, Actinomycetes Data Set, 2006-2015. Unpublished Raw Data.
5. "CDC Special Bacteriology Reference Laboratory: Info Request." Message to the author. 10 Dec. 2015. E-mail.