

**Prevention and control of shigellosis:
A needs assessment of state and local health
departments**

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

Submitted: May 16th, 2018

Program Official/Project Officer

Amanda Garcia-Williams, MPH PhD

Behavioral Scientist

Division of Foodborne, Waterborne, and Environmental Diseases

1600 Clifton Rd NE

Atlanta, GA 30329

Office: 770-488-3936

Fax: 404-718-4842

GVL8@cdc.gov

Table of Contents

Table of Contents..... 2

Section A – Justification..... 3

1. Circumstances Making the Collection of Information Necessary..... 3

2. Purpose and Use of the Information Collection..... 6

3. Use of Improved Information Technology and Burden Reduction..... 7

4. Efforts to Identify Duplication and Use of Similar Information..... 7

5. Impact on Small Businesses or Other Small Entities..... 7

6. Consequences of Collecting the Information Less Frequently 7

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5..... 8

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

9. Explanation of Any Payment or Gift to Respondents..... 8

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents..... 8

11. Institutional Review Board (IRB) and Justification for Sensitive Questions..... 8

12. Estimates of Annualized Burden Hours and Costs..... 9

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers..... 9

14. Annualized Cost to the Government..... 9

15. Explanation for Program Changes or Adjustments..... 10

16. Plans for Tabulation and Publication and Project Time Schedule..... 10

17. Reason(s) Display of OMB Expiration Date is Inappropriate..... 11

18. Exceptions to Certification for Paperwork Reduction Act Submissions..... 11

LIST OF ATTACHMENTS – Section A..... 11

REFERENCE LIST 11

- **Purpose of the data collection:** The purpose of this needs assessment is to describe the scope of local shigellosis prevention and control activities, challenges associated with prevention and control of shigellosis, and to identify how CDC and the *Shigella* Program can best provide technical assistance and support to address those needs.
- **Intended use of the resulting data:** The results of this assessment will be used to inform future activities and shape priorities of the *Shigella* Program, and the results will help local and state health department partners have a broader understanding of the scope of *Shigella* related work being conducted nationally.
- **Methods to be used to collect data:** Data will be collected via in-depth telephone-based interviews using a semi-structured interview guide.
- **Respondent Universe:** The respondent universe includes 80 (40 state and 40 local) health department stakeholders including epidemiologists/communicable disease investigators and medical officers, who engage in *Shigella* related work.
- **How data will be analyzed:** Field notes taken during the interviews will be qualitatively analyzed using thematic analysis.

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. Data will be collected from a total of 80 (40 state and 40 local) health department stakeholders including epidemiologists/communicable disease investigators and medical officers, who engage in *Shigella* related work.

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

X 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 ¹

The Waterborne Disease Prevention Branch (WDPB) in the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) works to prevent domestic and global water, sanitation, and hygiene (WASH) related disease. WDPB is comprised of four teams, including the Domestic WASH Epidemiology Team, which focuses on the prevention and control of waterborne and WASH-related disease and outbreaks in the United States. One of the diseases included in the team's work is shigellosis, an acute diarrheal disease caused by infection with *Shigella* bacteria.

The *Shigella* Prevention and Control Program is a sub-unit within the Domestic WASH Epidemiology Team which focuses on the prevention and control of shigellosis in the United States. The *Shigella* Prevention and Control Program's current scope of work includes support of surveillance activities (in collaboration with others across the division), consultation in ongoing outbreak investigations, partnership development, training and capacity building, research and evaluation, health promotion and communication, and policy consultation and development. The *Shigella* Prevention and Control Program also collaborates with other key groups in DFWED that engage in *Shigella* related activities. This includes, but is not limited to, the Enteric Disease Epidemiology Branch, Enteric Diseases Laboratory Branch, and the Outbreak Response and Prevention Branch.

The *Shigella* Prevention and Control Program regularly interfaces with state and local health department partners to provide technical assistance for outbreak detection and investigation. Through these interactions the *Shigella* Prevention and Control Program has learned more about local needs related to the control and prevention of shigellosis. This includes interest in receiving assistance to better understand exposure risk assessment in clusters and outbreaks affecting gay, bisexual, and other men who have sex with men (MSM), application of exclusion policies when outbreaks occur in childcare populations,

and health promotion materials that can be used at the state and local level for specific populations. Questions and consults from state and local health departments have included questions about what other states are doing to prevent and control shigellosis, requests for support with questionnaire or data collection tool development, subject matter consultation, and assistance with health promotion, health communication and messaging strategies or materials.

Anecdotal feedback from state and local health department epidemiologists has also identified ongoing challenges to the prevention and control of shigellosis. These include challenges with controlling childcare associated outbreaks, limited evidence base for effective approaches for childcare outbreaks/clusters, questions about testing (e.g., PCR vs. culture), balancing patient confidentiality when collecting comorbidity and exposure data (particularly for MSM related outbreaks/clusters), strategies to communicate susceptibility findings to clinicians, understanding of the literature related to sexually transmitted infections and their relationship with shigellosis, and interviewer comfort and capacity to complete sexual histories. The types of support that state and local partners have discussed needing from CDC include guidance related to childcare exclusion policies, comprehensive materials for low-literacy and multi-lingual populations, support with clinician and provider communication and education, and general health education about managing diarrheal disease.

The feedback and lessons learned from supporting state and local health departments with multi-state *Shigella* clusters or outbreaks, and other *Shigella* related requests or consultations, has provided insight into the challenges associated with prevention and control of shigellosis. This feedback is limited, however, to interactions with states that have been involved in multi-state clusters of shigellosis, or that have asked for technical assistance or requested consults from CDC. To date, no systematic assessment has been conducted to broadly understand the scope and challenges of shigellosis prevention and control work at a local level, and no assessment has been done to identify how CDC could better support prevention and control efforts at the local level.

The purpose of this needs assessment is to describe the scope of local shigellosis prevention and control activities, challenges associated with prevention and control of shigellosis, and to identify how CDC and the *Shigella* Prevention and Control Program can best provide technical assistance and support to address those needs. CDC will be coordinating the overall project and leading data collection related to telephone interviews, which includes developing the interview guides, scheduling interviews, conducting interviews, and analyzing and reporting findings.

The results of this assessment will be used to inform future activities and shape priorities of the *Shigella* Prevention and Control Program, and the results will help local and state health department partners have a broader understanding of the scope of *Shigella* related work being conducted nationally.

Overview of the Information Collection System

Data will be collected from 80 (40 state and 40 local) health department stakeholders via in-depth telephone-based interviews using a semi-structure interview guide (**see Attachment A – Telephone Interview Guide**). The instrument will be used to gather information from state and local health department stakeholders (i.e., epidemiologists/communicable disease investigators and medical officers) who engage in *Shigella* related work regarding the scope of local shigellosis prevention and control activities, challenges associated with prevention and control of shigellosis, and technical assistance and support needs.

The information collection instrument was pilot tested by 4 public health professionals. Feedback from this group was used to refine in-depth interview questions and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The data collection instrument consists of 33 main questions that are all open-ended. The instrument will collect data on the following:

- [Role]: Current role in shigellosis prevention and control
- [General]: Overall shigellosis control activities
- [Childcare]: Shigellosis control activities related to children and childcare settings
- [MSM]: Shigellosis control activities related to gay, bisexual, and other men who have sex with men
- Proactive prevention strategies for shigellosis
- [CDC]: Experience working with CDC on prevention and control activities and needs from CDC for prevention and control support
- [Closing]: Closing questions related to shigellosis prevention and control

2. Purpose and Use of the Information Collection

The purpose of this needs assessment is to describe the scope of local shigellosis prevention and control activities, challenges associated with prevention and control of shigellosis, and to identify how CDC and the *Shigella* Prevention and Control Program can best provide technical assistance and support to address those needs.

The results of this assessment will be used to inform future activities and shape priorities of the *Shigella* Prevention and Control Program, and the results will help local and state health department partners have a broader understanding of the scope of *Shigella* related work being conducted nationally.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via in-depth telephone-based interviews. This method was chosen to reduce the overall burden on respondents because it allows for the assessment team to ask for clarification from participants during the interview, and this limits the need for additional follow-up. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 33 questions).

4. Efforts to Identify Duplication and Use of Similar Information

To date, no other information has been conducted to assess the scope of local shigellosis prevention and control activities, challenges associated with prevention and control of shigellosis, and identification of technical assistance and support needs. The information that will be gathered through this information collection is not available from other data sources or through other means. Prior to developing this information collection, staff in CDC's *Shigella* Prevention and Control Program consulted with internal stakeholders to confirm that this effort is not duplicative.

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 data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Identify shigellosis prevention and control activities being implemented in state and local health departments.
- Share the above information with public health partners to help them have a broader understanding of the scope of *Shigella* related prevention and control work being done nationally.
- Gain an understanding of how CDC could better support local shigellosis prevention and control activities

- Utilize the results of this assessment to inform future activities and priorities of the *Shigella* Prevention and Control Program.

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

There are no special circumstances with this data 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 data 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 April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

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 data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

All information will be kept on secure, password protected servers maintained by CDC, accessible only to project team members. Data collected during the assessment will be shared only in aggregate form.

This data 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 data collection instrument by 4 of public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, and responding to the open ended questions was approximately 40 minutes (range: 20-60 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 60 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 Epidemiologists and Medical Scientists. http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of \$36.65 is estimated for Epidemiologists/Communicable Disease Investigators and \$45.64 for Medical Officers. Table A-12 shows estimated burden and cost information.

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

Data collection Instrument: Form Name	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
In-depth Interview Guide	Epidemiologist/ Communicable Disease Investigators	40	1	60 / 60	40	\$36.65	\$1,466
	Medical Officers	40	1	60 / 60	40	\$45.64	\$1,825.60
	TOTALS	80	1		80		\$3,291.60

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 data 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 to develop the data collection instrument, collect data, and perform data analysis. The total estimated cost to the federal government is \$15,063.00. 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	Total Average Cost
Behavioral Scientist – (GS-12/2); Develop OMB package, plan and implement data collection, perform data analysis, develop any summary reports/presentations.	300	\$37.48 /hour	\$11,244.00
ORISE Fellow – (GS-9, equivalent); Assist with data collection, perform data analysis, support summary reports/presentation writing.	150	\$25.46 /hour	\$3,819.00
Estimated Total Cost of Information Collection			\$15,063.00

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Activity	Time Schedule
Design instrument	Complete
Develop protocol, instructions, and analysis plan	Complete
Pilot test instrument	Complete
Prepare OMB package	Complete
Submit OMB package	Complete
OMB approval	In progress
Begin recruitment	1 month after OMB approval
Complete in-depth interviews	9 months after OMB approval
Report of findings completed	12 months after OMB approval

Analysis

During the in-depth interviews field notes will be taken by a non-participatory observer on the phone call. Field notes will be imported into MAXQDA software and will be analyzed using thematic analysis. All field notes and databases will be housed on a secure drive on the CDC network that is only accessible to the project members.

Dissemination of results

Resulting data will be used to develop aggregated summary reports to be used for decision making and strategic planning purposes of the *Shigella* Prevention and Control Program and other internal *Shigella* associated groups within DFWED. Aggregated results will also be shared with local and state health department stakeholders, in addition to other stakeholders through internal and external presentations, reports, and/or publications. Qualitative findings may be published in a peer-reviewed journal article.

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

Note: Attachments are included as separate files as instructed.

A. Attachment A – Telephone Interview Guide

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.