**Investigation of a cluster of extensively drug resistant shigellosis associated with a cruise ship.**

Request for OMB approval of a New Information Collection Instrument

**Today's Date**
January 14, 2021

**Supporting Statement B**

**Contact:**
Amanda Garcia-Williams, PhD, MPH
Behavioral Scientist
Waterborne Disease Prevention Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Office: 770-488-3936
Fax: 404-718-4842
Email: GVL8@cdc.gov

## Table of Contents



### 1. Respondent Universe and Sampling Methods

There will be no statistical methods used to select respondents for this data collection. Online surveys will be conducted with three groups of individuals: **Group 1:** Passengers with and without acute gastroenteritis on Cruise X. Eligibility criteria for Group 1 participants are: (1) passenger on Cruise X; (2) age 18 years or older; **Group 2:** Confirmed cases of shigellosis associated with Cruise X identified through state and local health departments. Eligibility criteria for Group 2 participants are: (1) passenger on Cruise X; (2) age 18 years or older; (3) confirmed diagnosis of shigellosis; **Group 3:** Confirmed cases of shigellosis who were not passengers on Cruise X but whose *Shigella* matches the XDR *Shigella* strain by molecular analysis. Eligibility criteria for Group 3 participants are: (1) age 18 years or older; (3) confirmed diagnosis of shigellosis with strain of *Shigella* that matches the XDR *Shigella* strain identified in Australia, by molecular analysis.

The total number of passengers on the Cruise X was 4017, and based on previous clusters, we estimate the total number of confirmed cases of shigellosis matching the case definition for the outbreak cluster to be 200.

### 2. Procedures for the Collection of Information

Participants: Participants in this investigation will fall into the following three groups: (1) **Group 1:** Passengers with and without acute gastroenteritis on Cruise X. Eligibility criteria for Group 1 participants are: (1) passenger on Cruise X; (2) age 18 years or older. (2) **Group 2:** Confirmed cases of shigellosis associated with Cruise X identified through state and local health departments. Eligibility criteria for Group 2 participants are: (1) passenger on Cruise X; (2) age 18 years or older; (3) confirmed diagnosis of shigellosis. (3) **Group 3:** Confirmed cases of shigellosis who were not passengers on Cruise X but whose *Shigella* matches the XDR *Shigella* strain by molecular analysis. Eligibility criteria for Group 3 participants are: (1) age 18 years or older; (3) confirmed diagnosis of shigellosis with strain of *Shigella* that matches the XDR *Shigella* strain identified in Australia, by molecular analysis.

Recruitment: The three groups of participants in the investigation will be recruited in the following ways: (1) **Group 1:** An email will be sent by the charter of Cruise X to all passengers with a link to the investigation survey (Appendix A). Passengers will be encouraged by the charter to complete the survey, however participation will be voluntary. No incentives for participation will be provided. (2) **Group 2:** State and local health department epidemiologists who identify confirmed cases of shigellosis associated with Cruise X will be provided with a link to the investigation survey. They will provide the survey link to the confirmed case to complete on their own, and participation will be voluntary. No incentives for participation will be provided. (3) **Group 3:** State and local health department epidemiologists who identify confirmed cases of shigellosis that molecularly match the XDR *Shigella* strain associated with Cruise X will be provided with a link to the investigation survey. They will provide the survey link to the confirmed case to complete on their own, and participation will be voluntary. No incentives for participation will be provided.

Survey Content: Two survey instruments will be used as part of this investigation. Survey Instrument 1 (Appendix B) will be used for Group 1 and 2; Survey Instrument 2 (Appendix C) will be used for Groups 3. Participants can complete the surveys anonymously or can provide contact information if they would like to be followed up with by their health department. All survey items are voluntary. The survey content will include the following: (1) **Survey Instrument 1:** (1) demographic characteristics, (2) clinical signs and symptoms, (3) medical care and treatment information, (4) events and activities participated in during the cruise, (5) risk and protective behaviors engaged in during cruise, (6) sexual partner(s) and activity on cruise, (7) activities engaged in since becoming sick. (Appendix B); (2) **Survey Instrument 2:** (1) demographics characteristics, (2) household information and family member event and activity attendance, (3) clinical signs and symptoms, (4) medical care and treatment information, (5) travel history, (6) event and activity attendance, (7) limited food and water exposure, (8) work, visit, and volunteer locations, (9) childcare and school attendance, (10) recent sexual partner(s) and activity, (11) events and activities participated in during the cruise, (12) risk and protective behaviors engaged in during cruise, (13) activities engaged in since becoming sick. (Appendix C)

Sampling: No sampling will be involved in the administration of the investigation surveys.

Incentives: No incentives will be provided to individuals completing the investigation questionnaires.

Data collection: Both survey instruments will be administered online using an Epi-Info secure web survey. The surveys will be programmed through Epi-Info, which will include appropriate pattern logic to accommodate screening questions and skip patterns. The Epi-Info web survey allows for secure collection of data that is stored in a centralized database at CDC. Data entered into the Epi-Info survey is automatically sent to CDC and stored in a secure web server housed behind the CDC firewall. Sufficient security measures have been implemented for data storage to ensure data confidentiality is protected. Finally, the Epi-Info web survey is an enterprise-grade data collection software approved for the collection of PII by CDC information security officials.

### 3. Methods to maximize Response Rates and Deal with No Response

The survey instruments designed for this investigation were designed to be short, taking about 10 minutes to complete, and accessible online (both on computer and mobile based platforms). The survey also includes skip patterns to limit participant burden so they are only answering questions relevant to their experience. This was done so that the burden on cases to complete the surveys was sufficiently low to maximize response rates.

### 4. Tests of Procedures or Methods to be undertaken

The estimate for burden hours is based on a pilot test of the data collection instrument by 4 public health professionals. In the pilot test, the average time to complete Survey 1 and Survey 2 including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 10 minutes.

### 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

**Individual consulted**:

Individuals consulted on statistical aspects of the design: Sarah Collier.

Data collection instruments were developed based on subject matter expertise of staff in DFWED, including the following individuals:

**Individuals collecting and/or analyzing data:**

Amanda Garcia-Williams, PhD, MPH
Behavioral Scientist
Waterborne Disease Prevention Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Email: GVL8@cdc.gov

Zachary Marsh, MPH
Epidemiologist
Waterborne Disease Prevention Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Email: zmarsh@cdc.gov

Kevin O'Laughlin, MD
Epidemic Intelligence Service Officer
Waterborne Disease Prevention Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Email: pgv6@cdc.gov

Sarah Collier, MPH
Epidemiologist
Waterborne Disease Prevention Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Email: sau9@cdc.gov

Ian Plumb, MD
Medical Epidemiologist
Enteric Disease Epidemiology Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9
Atlanta, GA 30329
Email: ydk9@cdc.gov

Louise Francois-Watkins, MD
Medical Officer
Enteric Disease Epidemiology Branch
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Rd NE, MS H24-9

Atlanta, GA 30329
Phone: 404-718-3125
Email: hvu9@cdc.gov