

***Shigella* Hypothesis Generating Questionnaire**

Request for OMB approval of an extension to an existing Information
Collection Instrument
(OMB Control No. 0920-1307)

October 7, 2023

Supporting Statement B

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1. Respondent Universe and Sampling Methods

There will be no statistical methods used to select respondents for this data collection. Interviews will be conducted with or web-based surveys distributed to cases of shigellosis, or their proxy, who are part of a shigellosis cluster or outbreak that meets the following definitions: (1) Multi-state cluster or outbreak: Multi-state clusters are defined as at least two cases of shigellosis from different states that are either molecularly related or epidemiologically related. Multi-state clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, states reaching out to CDC for technical assistance, and through media scans; (2) Single-state cluster or outbreak: Single-state cluster or outbreaks are defined as at least two cases of shigellosis from the same state that are either molecularly related or epidemiologically related. Single state clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, states reaching out to CDC for technical assistance, and through media scans.

Based on the estimated number of cases of shigellosis in the U.S. and the proportion of those cases that are outbreak associated, the Standardized *Shigella* Hypothesis Generating Questionnaire (SHGQ) is administered to approximately 1,500 individual respondents across all jurisdictions each year. This estimate is based on the previous three years of data collection under the current OMB approval.

2. Procedures for the Collection of Information

Cluster and Outbreaks: The SHGQ will be administered by state and local public health officials via telephone interviews or self-administered web-based surveys with cases of shigellosis or their proxy who are part of a shigellosis cluster or outbreak that meets the following definitions: (1) *Multi-state cluster or outbreak*: Multi-state clusters are defined as at least two cases of shigellosis from different states that are either molecularly related or epidemiologically related. Multi-state clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, states reaching out to CDC for technical assistance, and through media scans. (2) *Single-state cluster or outbreak*: Single-state cluster or outbreaks are defined as at least two cases of shigellosis from the same state that are either molecularly related or epidemiologically related. Single state clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, states reaching out to CDC for technical assistance, and through media scans.

Participants: Respondents will be cases that are part of a cluster or outbreak that meets the aforementioned definition, or their proxy, identified as part of a cluster or outbreak investigation. Participation in the interview or completion of the survey is voluntary.

Recruitment: Officials in state and local public health departments will contact cases that are part of a cluster or outbreak that meets the aforementioned definition, or their proxy, to conduct the interviews. Alternatively, state and local public health officials may choose to collect information from this questionnaire through a secure Epi Info survey platform, which are sent individually to cases involved in shigellosis clusters for self-administration.

SHGQ Content: The SHGQ contains questions on the following content area that would allow for the following: (1) characterizing the cluster or outbreak, (2) characterizing the clinical presentation of cases involved in a cluster or outbreak, (3) describe treatment failure of cases in a cluster or outbreak, (4) identifying mode of transmission, (5) identifying connections between cases, (6) identifying setting of outbreak or cluster, (7) identifying strategies to control and end the cluster or outbreak. The SHGQ includes the following modules (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) Contact with international travelers or other ill individuals, (7) Event and activity attendance, (8) Limited food and water exposure, (9) Work, visit, and volunteer locations, (10) Childcare and school attendance, (11) Recent sexual partner(s) and activity. Module 11 includes sensitive questions including those related to sexual orientation, gender identity, number of sexual partners, where sexual partners are met, sexualized drug use, and recent diagnosis with an STD. The questions included in this module are essential to the complete investigation of clusters or outbreaks of shigellosis in which sexual contact is suspected as a mode of transmission. The more specific the information on cases, the more specific and tailored the strategies that can be used to control the cluster or outbreak. The questions included in this module have been used before by state and local health departments during past investigations of clusters and outbreaks of shigellosis.

Sampling: No sampling will be involved in the administration of the SHGQ. Officials in state and local public health departments will contact cases of shigellosis, or their proxies, identified as part of a cluster or outbreak that meets the aforementioned definition to ask if they would be willing to complete the SHGQ to support the cluster or outbreak investigation.

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

Data collection: The SHGQ will be administered by state and local public health officials via telephone interviews or self-administered web-based survey with cases of shigellosis, or their proxy, who are part of a cluster or outbreak that meets the aforementioned definition. Collection of the SHGQ data elements will employ quantitative and qualitative methods. Qualitative methods will be used to elicit additional information about potential exposures from respondents. Interviewers will be able to probe further about specific exposures reported by ill persons using the open-ended elements included in the SHGQ. For example, when an ill person reports traveling outside their home state, the interviewer would ask about the specific travel destination(s) and dates of the travel as well as any specific events the ill person participated in while traveling. There are no research questions addressed through this data collection activity. Standardized data will be compiled on recent exposures related to shigellosis in the context of a cluster or outbreak. Data will be used to inform cluster and outbreak control activities. The data collected from the SHGQ will be used to inform cluster or outbreak control strategies and recommendations. Staff in the SPC Program in WDPB will oversee data collection, data management, analyses and dissemination of information collected with the SHGQ during cluster or outbreak investigations.

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

In general, state and local public health officials will make every effort to contact cases identified as part of a multistate outbreak, as resources allow. Policies vary, but many jurisdictions attempt to contact a case at least three times before deeming them 'lost to follow-up'. The SHGQ is designed to be administered in approximately 45 minutes via telephone interview, so the burden on cases to complete the interview should be sufficiently low to maximize response rates. Alternatively, state and local health officials may choose to collect information from the questionnaire through a self-administered web-based survey, which may reduce the burden of administering the questionnaire by phone for

states/territories that do not have the capacity to conduct interviews for every ill case in a shigellosis cluster. Web-based surveys also provides cases with an additional option to complete the SHGQ.

4. Tests of Procedures or Methods to be undertaken

The estimate for burden hours is based on the previous three years of data collection using the SHGQ. Based on previous experience, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 45 minutes (range: 30 to 60 minutes). For the purposes of estimating burden hours, the average time to complete the instrument was used.

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

Individual consulted:

Individuals consulted on statistical aspects of the design: not applicable.

The SHGQ was developed based on subject matter expertise of SPC Program staff (listed below) and was reviewed by staff in the National Antimicrobial Monitoring System, and at the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Data will be analyzed by SPC Program staff in CDC's Waterborne Disease Prevention Branch.

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