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

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Supporting Statement A

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- **Goal of the study:** The goal of the *Shigella* Hypothesis Generating Questionnaire (SHGQ) is to define a core set of data elements to be used for hypothesis generation as part of investigations of clusters or outbreaks of shigellosis.
- **Intended use of the resulting data:** The SHGQ will be used by federal, state, and local public health officials responsible for conducting interviews with reported cases of shigellosis in their jurisdiction in order to systematically assess core exposure elements and risk factors among cases of shigellosis. Collected data will be used by CDC staff to inform shigellosis outbreak and cluster prevention and control strategies.
- **Methods to be used to collect:** The SHGQ data elements and form were designed for administration via telephone interviews and self-administered web-based survey.
- **Respondent population:** Individuals ill with shigellosis, or their designated proxy, who are part of a shigellosis cluster or outbreak.
- **How data will be analyzed:** Primarily univariate analyses of exposures, risk factors, and demographic characteristics among case patients interviewed as part of outbreak and cluster investigations of shigellosis. Statistical software like SAS and R will be used for analyses.

1. Circumstances Making the Collection of Information Necessary

This is an existing Information Collection Request. We are requesting an extension approval for a period of 3 years.

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 (SPC) 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 SPC Program's current scope of work includes leading cluster and outbreak investigations, partnership development, training and capacity building, research and evaluation, health promotion and communication, and policy consultation and development. The SPC Program also collaborates with other groups in DFWED and in other centers 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.

Shigella are a family of bacteria that cause the diarrheal disease shigellosis [1]. It is estimated that *Shigella* causes about 450,000 cases of diarrhea in the United States annually, with increasing evidence of antimicrobial resistance [2]. *Shigella* bacteria are spread through the fecal-oral route [1]. This can occur when hands can become contaminated with the feces of someone sick with shigellosis, contaminated food or water are ingested, or if contaminated objects come into contact with one's mouth. *Shigella* have a low infectious dose [3] and a short incubation period [4], and as a result person-to-person transmission of *Shigella* bacteria is common. Sexual person-to-person contact has also been

identified as a mode of transmission for shigellosis [5]. *Shigella* bacteria have also been reported to survive on a range of surfaces, therefore there is potential for transmission through contaminated fomites [6-8]. Strategies to prevent becoming sick with shigellosis include washing hands, following safe food and water behaviors when travelling, avoiding swallowing water when swimming, and following safe sex behaviors to avoid contact with feces during sex [9]. To prevent secondary transmission of shigellosis among individuals who are sick, prevention behaviors include washing hands, avoiding cooking for others when sick, avoiding swimming until fully recovered, and avoiding sex until fully recovered [9].

From 2009 through 2021, there have been 1,252 outbreaks of shigellosis in the United States, with most of these outbreaks attributed to person to person spread [10]. Outbreaks of shigellosis have been reported in a range of settings such as community-wide [11-14], daycares [12, 15, 25], schools [12, 26, 27], cruise ships [28], airplanes [29, 30], mass gatherings [31, 32], and retirement homes [33]. Outbreaks of shigellosis have impacted a range of populations such as children [12, 15-24], men who have sex with men [34-49], people experiencing homelessness [50], tight knit religious communities [14, 23, 51, 52], older adults [33], and refugees/displaced persons [53-55]. Finally, outbreaks of shigellosis have been attributed to a range of transmission modes including person-to-person/no common source [13, 15, 17, 18, 24-26, 32], sexual person-to-person contact [34-49], contaminated food [56-64], and contaminated water [65-70].

As part of *Shigella* outbreak investigations, it is common for state and local health departments to conduct interviews with cases and contacts to identify how individuals became sick with shigellosis, to identify individuals who could have come into contact with an individual sick with shigellosis, and to identify strategies to control the cluster or outbreak. As person-to-person contact is the most common mode of transmission for shigellosis, and shigellosis is highly contagious, it can be challenging to identify how individuals could have become ill. As a result, comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities.

The SPC Program, in collaboration with other branches in DFWED, is responsible for leading investigations of multistate clusters and outbreaks of shigellosis, and for providing technical assistance for single state clusters and outbreaks upon request by local jurisdictions. To improve the SPC Program's ability to investigate, respond to, and control clusters and outbreaks of shigellosis, there is a need for the SPC Program to be able to collect case demographic and exposure data in a systematic way when clusters or outbreaks are identified. State and local health department staff have also requested that the SPC Program have a systematic data collection tool for shigellosis case interviews and self-administered web-based surveys that local jurisdictions could use as part of their investigations [71].

The primary audiences for this project are (1) state and local public health partners (foodborne epidemiologists, public health nurses, and other interviewers) and (2) the CDC. The maintenance of the data collection instrument and the associated data will be coordinated by the *Shigella* Prevention and Control Program in the Waterborne Disease Prevention Branch in the Division of Foodborne, Waterborne, and Environmental Diseases at CDC.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

2. Purpose and Use of Information Collection

To meet the needs of the SPC Program, and the needs of state and local public health officials, the *Shigella* Hypothesis Generating Questionnaire (SHGQ) was developed (Attachments C1-C4). This questionnaire includes a set of data elements that can be used as part of *Shigella* cluster and outbreak investigations to generate hypotheses about the source(s) of infection, to characterize the cluster or outbreak, and to identify strategies to control the cluster or outbreak. The SHGQ is also used as part of single state cluster or outbreak investigations when these investigations are requested by state and local health department partners. There are no research questions addressed.

The data collected from the SHGQ is used to identify exposure trends inform cluster or outbreak control strategies and recommendations. Aggregated summaries of SHGQ findings to describe outbreak and cluster investigations are shared as part of cluster and outbreak investigation communications, including state calls and internal CDC meetings. Additionally, aggregated summaries of SHGQ findings may be shared externally through conference presentations and peer-reviewed journal articles to describe cluster and cluster investigation activities and control strategies. Staff in the SPC Program in WDPB oversee data analyses and dissemination of information collected with the SHGQ during cluster or outbreak investigations.

State and local public health officials and the SPC Program in WDPB have been able to identify case clusters, outbreaks, and sources of exposure through the information learned from the SHGQ. One of the initial steps in investigating a suspected or confirmed *Shigella* case, cluster, or outbreak, is deploying the SHGQ. It allows state health departments to conduct interviews and collect crucial information such as case demographics, clinical and treatment information, medical history, and exposure information, which has helped move investigations along. The SHGQ has been instrumental in identifying the mode of transmission for *Shigella* outbreaks and case clusters in the United States, thereby public health officials to focus prevention efforts where they will do the most good.

3. Use of Improved Information Technology and Burden Reduction

The SHGQ data elements and form were designed for administration via telephone interview (Attachment C1 and C2) or self-administered web-based survey (Attachment C3 and C4) with cases of shigellosis or their proxies. Telephone interviews can 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. Self-administered web-based surveys allow for CDC to provide capacity support to state and local health departments by reducing 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. SHGQ links can be sent individually to cases involved in shigellosis clusters for self-paced questionnaire completion, which provides cases with an additional option to complete the SHGQ. The data collection instruments (interview guide and web-based survey) include all of the same questions and were designed to collect the minimum information necessary for the purposes of this project.

4. Efforts to Identify Duplication and Use of Similar Information

The SHGQ is the only national, standardized hypothesis generating interview data collection instrument for use during single or multistate shigellosis cluster or outbreak investigations. The information gathered through the SHGQ is not available from other data sources or through other means. Prior to developing the SHGQ in 2020 and this data collection activity, WDPB staff in SPC Program consulted with both internal and external stakeholders to confirm that this effort is not duplicative.

5. Impact on Small Businesses or Other Small Entities

“This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Lack of comprehensive data about cases of shigellosis will slow down the outbreak and cluster investigation process.

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

This request fully complies with the regulation 5 CFR 1320.5..

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on July 14, 2023, vol. 88, no. 134, 45217 (Attachment B). CDC received two non-substantive public comments related to this notice (Attachments B1 & B2).

B. No consultations outside of CDC occurred including with local health department partners

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration to respondents.

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

NCEZID’s Information Systems Security Officer reviewed this submission and determined that the Privacy Act applies (Attachment E).

Individuals and organizations will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent, unless required by law upon the demand of a court or other governmental authority.

SHGQ data will be securely shared with CDC by local officials, and data shared with CDC will be stored in a limited access folder and in a password protected database. Following data entry, the original SHGQ form will be destroyed. Before data entry, the original SHGQ will be kept in a locked file cabinet or in a folder on the limited access CDC drive.

The SHGQ data elements and SHGQ data collection tool will ascertain information from respondents about exposures (e.g., food, water, person to person contact, travel) preceding onset of shigellosis, known risk factors for shigellosis (e.g., race/ethnicity, poverty, homelessness, crowding), and clinical characteristics of case patient illness (e.g., symptoms, duration of illness, medications). It will not collect any information that could be used to identify individual case patients. Local or State public health officials with jurisdictional responsibility will maintain the respondent’s name, telephone number, and other personally identifiable information. This information will be not be included in the data collection tool and no identifying information will be transmitted to CDC.

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

Institutional Review Board (IRB)

It has been determined that IRB review is not required for this data collection (Attachment D).

Justification for Sensitive Questions

Shigella bacteria can be spread in multiple ways. This includes through contaminated food and water, and via sexual and non-sexual person-to-person contact. To determine if cases became ill via sexual person-to-person contact, case patients will be asked questions about sexual activity and behavior, sexual partners, drug and alcohol use during sexual activity, and previous diagnosis with a sexually transmitted infection. To inform prevention and control efforts, questions about sexual orientation and gender identity will also be asked to characterize the demographics of case patients. As part of this module, case patients are given an explanation for why the sensitive questions are asked and are provided the option to opt out of answering these questions.

In addition to sexual health related questions, other potentially sensitive questions are asked of case patients. This includes questions related to insecure housing, homelessness, and family income. These questions are asked because people experiencing homelessness have been identified as a risk population, and poverty has been identified as a risk factor for *Shigella* infection.

All questions in the SHGQ are optional, and case patients can choose to answer the questions they feel comfortable responding to.

12. Estimates of Annualized Burden Hours and Costs

A. Interviews will be conducted with case patients who are part of a cluster or outbreak of shigellosis. Based on the estimated number of cases of shigellosis in the U.S. and the proportion of those cases that are cluster or outbreak associated, the SHGQ is administered to approximately 1500 individual respondents across all jurisdictions each year. The estimate for burden hours is based the previous three years of data collection using the SHGQ under its initial OMB approval. The average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, is approximately 45 minutes (range: 30 to 60 minutes). For the purposes of estimating burden hours, the average time to complete the instrument was used. This data collection uses qualitative methods, including telephone interviews guided by semi-structured protocols designed to elicit core elements exposures from respondents. On September 6, 2022, a non-substantive change was approved to add a web-based survey as an optional method of administering the SHGQ. There are no specific research questions addressed.

Exhibit 1: Estimated Annual Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Shigellosis case patients identified as part of outbreak or cluster investigations	Shigella Hypothesis Generating Questionnaire	1500	1	45/60	1,125 hours
Total					**1,125 hours**

Exhibit 2 shows the estimated annual cost burden associated with individual's time to participate. We used the 2022 mean average hourly wage for all occupations in the United States. This wage of $29.76 was obtained from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm). Burden

in hours is taken from Exhibit 1. The total annual cost burden is calculated by multiplying the mean hourly wage by the burden in hours. The total cost burden is estimated to be $33,480.

Exhibit 2. Estimated Annual Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
All occupations in the United States	Shigella Hypothesis Generating Questionnaire	1,125 hours	$29.76	$33,480
Total				**$33,480**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
There are no direct costs to respondents other than their time to participate in this study.

14. Annualized Cost to the Government
The estimated total cost to the Federal Government for this project is $14,176 annually. Exhibit 3 provides a breakdown of the estimated total costs.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Behavioral Scientist – (GS-13, equivalent); Project development and project management, data analysis, publication and dissemination of results	100	$58.27	$5,827
Epidemiologist – (GS-11, equivalent); Project development and project management, data analysis, publication and dissemination of results	300	$35.89	$10,767
Estimated Total Cost of Information Collection			**$14,176**

15. Explanation for Program Changes or Adjustments
This is a 3-year extension request for existing information collection activities (OMB Control No. 0920-1307).

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Utilize the SHGQ to conduct interviews during cluster and outbreak investigations	Months 1-36
Ongoing data analysis	Months 1-36

The analysis plan for data collected using the SHGQ is to conduct primarily univariate analyses of exposures, risk factors, and demographic characteristics among case patients interviewed as part of outbreak and cluster investigations of shigellosis. Statistical software like SAS and R will be used for

analyses. All data collected and databases will be housed on a secure drive on the CDC network that is only accessible to the project members.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The display of the OMB expiration date is not inappropriate.
18. Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.

Attachments

A. Authorizing Legislation
B. 60-day Federal Register Notice
    1. Public Comment & Response #1
    2. Public Comment & Response #2
C. *Shigella* Hypothesis Generating Questionnaire (SHGQ)-English; *Shigella* Hypothesis Generating Questionnaire (SHGQ)—Spanish
    1. SHGQ_English_Health Department Phone
    2. SHGQ_Spanish_Health Department Phone
    3. SHGQ_Spanish_Web
    4. SHGQ_English_Web
D. Human Subjects Determination
E. Privacy Impact Assessment
F. Supplemental Documents
    1. English SHGQ by Mode of collection
    2. Spanish SHGQ by Mode of collection

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