

**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 A**

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- **Goal of the study:** The goal of this investigation is to identify additional cases and better characterize cases of acute gastroenteritis (AGE) and shigellosis associated with Cruise X.
- **Intended use of the resulting data:** The results of data collected as part of this investigation is to inform strategies to prevent introduction and transmission of XDR *Shigella* within the United States, and to identify future prevention strategies.
- **Methods to be used to collect:** Two web-based surveys will be administered to passengers of Cruise X and confirmed cases with shigellosis that is epidemiologically or molecularly linked to Cruise X.
- **Respondent population:** Passengers of Cruise X and confirmed cases with shigellosis that is epidemiologically or molecularly linked to Cruise X.
- **How data will be analyzed:** Univariate and multivariate analyses of exposures, risk factors, and demographic characteristics among individuals interviewed as part of this investigations. Statistical software like SAS and R will be used for analyses.

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

This is a new Information Collection Request. We are requesting approval for a period of 90-days. This study is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

*Shigella* is a group of bacteria that cause the diarrheal disease shigellosis [1]. It is estimated that *Shigella* causes about 500,000 cases of diarrhea in the United States annually [2]. *Shigella* bacteria are spread through the fecal-oral route [1]. This can occur when hands 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]; 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 [4]. As *shigella* bacteria can survive on a range of surfaces, there is potential for transmission through contaminated fomites [5-7]. 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 [8]. To prevent secondary transmission of shigellosis among individuals who are ill, prevention behaviors include washing hands, avoiding cooking for others, avoiding swimming, and avoiding sex until fully recovered [8]. Since 2013, drug-resistant *Shigella* has been listed as a "serious threat" by the Centers for Disease Control and Prevention, because of increases in drug-resistance strains identified in the United States.

On February 13, 2020 CDC was notified by Australian public health authorities of three cases of infection with extensively drug-resistant (XDR) *Shigella* associated with Cruise X. The Miami, Florida-based Cruise X, left port on January 19, 2020 and returned on January 26, 2020. The cruise made stops in St. Maarten, Puerto Rico, and Haiti. The strain of *Shigella* that was reported by Australian health officials is of concern because of its resistance to all major treatment agents, including ampicillin, cotrimoxazole, ceftriaxone, ciprofloxacin, and azithromycin. On February 20, 2020, CDC notified state and local enteric disease epidemiologists of these cases, and asked states to notify CDC of any patients with *Shigella* infection who reported taking a cruise matching the characteristics of Cruise X. As a result of preliminary case finding, a total of 9 U.S. cases were identified as associated with Cruise X. This

included cases of both *Shigella sonnei* and *Shigella flexneri*, and at least one case with a resistance profile matching that of the Australian cases. As a result of preliminary case finding, which indicated multiple Cruise X associated cases of shigellosis, including a case of infection with the XDR strain, an investigation was initiated.

The goal of this investigation is to identify additional cases and better characterize cases of acute gastroenteritis (AGE) and shigellosis associated with Cruise X. This will inform strategies to prevent introduction and transmission of XDR *Shigella* within the United States, and to identify future prevention strategies.

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**

The objects of this investigation are to:

1. Identify additional cases of shigellosis and AGE associated with Cruise X
2. Characterize the epidemiology of shigellosis and AGE cases associated with Cruise X
3. Identify risk and protective factors of shigellosis and AGE cases associated with Cruise X
4. Characterize the epidemiology of community shigellosis cases not associated with Cruise X but molecularly related to cases associated with Cruise X
5. Assess clinical outcomes of patients with XDR shigellosis to correlate resistance with response to antibiotics *in vivo*.

## **3. Use of Improved Information Technology and Burden Reduction**

The two survey instruments developed for this investigation were designed for administration via a secure web-based survey. This method was chosen to reduce the overall burden on respondents because it allows for the participant to complete the survey when it is most convenient. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project.

## **4. Efforts to Identify Duplication and Use of Similar Information**

For this investigation, there is currently no existing data collection instrument that could be used. This is because questions included in the developed data collection tools were designed specifically to understand how passengers for Cruise X could have become ill. The information that will be gathered through the study questionnaires are not available from other data sources or through other means. Prior to developing the two surveys included as part of this data collection activity, WDPB staff consulted with both internal and external 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 data collection.

## **6. Consequences of Collecting the Information Less Frequently**

Not collecting data as part of this investigation will limit the ability of identifying additional cases of shigellosis, and will reduce the ability to develop strategies to prevent and control further transmission of XDR *Shigella* associated with Cruise X in the United States.

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

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

## **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 MONTH DAY, YEAR, vol. XX, No. X, pp. XXXX (Attachment 2). CDC did/did not receive public comments related to this notice. [The language above can remain as is until the 60-day notice publishes. Before the 30-day notice publishes, though, the date, vol., number, page numbers, and information about comments needs to be updated.]
- B. No consultations outside of CDC occurred.

## **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**

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act applies.

Data collected during patient notification and survey will come from sources with identifiable information. For notifications and interviews conducted by CDC, paper call logs and telephone scripts will necessarily contain personal identifiers, including name and telephone numbers. All individuals contacted by CDC will be assigned a unique identification number. Interview data will be entered into in a RedCap database without personal identifiers. Electronic files (e.g., interview database) will be stored on the secure CDC Share Network. Worksheets, call logs, and paper surveys will be stored in locked files in a laboratory and/or office.

Descriptive data presented in final reports, presentations, and scientific publications will not include patient identifiers. There are no planned uses for the data beyond the public health investigation described above.

Interview data will be entered into in a RedCap database without personal identifiers. However, CDC will maintain the contact information of individuals referred to Facility 1 by Travel Agency A. Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994.

CDC will treat information in a secure manner and will not disclose, unless otherwise compelled by law. Electronic files (e.g., interview database) will be stored on the secure CDC Share Network. Worksheets, call logs, and paper surveys will be stored in locked files in a laboratory and/or office. Any electronic database that maintains such information will be kept in secure computers accessible to only CDC staff."

## **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, and sexual partners. 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.

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

All questions in the two survey instruments 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. Surveys will be distributed via a web-link to passengers on Cruise X, and will be distributed to confirmed cases of shigellosis matching the case definition for the outbreak cluster. The total number of passengers on the cruise 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.
- B. We used the 2018 mean average hourly wage for all occupations in the United States. This wage of \$24.98 was obtained from the Bureau of Labor Statistics ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm))

Exhibit 1 shows the estimated annual burden hours for each organization's time to participate in this research. The total annual burden is estimated to be 704 hours.

*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.)
Cruise ship passengers (Group 1)	Survey 1	4017	1	10/60	670
Confirmed shigellosis cases (Group 3)	Survey 2	100	1	10/60	17
Confirmed shigellosis cases (Group 2)	Survey 1	100	1	10/60	17
<b>Total</b>					<b>704</b>

Exhibit 2 shows the estimated annual cost burden associated with individual's time to participate. We used the 2018 mean average hourly wage for all occupations in the United States. This wage of \$24.98 was obtained from the Bureau of Labor Statistics ([http://www.bls.gov/oes/current/oes\\_nat.htm](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 \$17,585.92.

*Exhibit 2. Estimated Annual Burden Costs*

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cruise ship passengers (Group 1)	Survey 1	670	\$24.98	\$16,736.60
Confirmed shigellosis cases (Group 3)	Survey 2	17	\$24.98	\$424.66
Confirmed shigellosis cases (Group 2)	Survey 1	17	\$24.98	\$424.66
<b>Total</b>				<b>\$17,585.92</b>

**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 \$12,741.60 over the period of data collection, analysis, and dissemination. Exhibit 3 provides a breakdown of the estimated total costs.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
<b>Behavioral Scientist – (GS-13, equivalent);</b> Project development and project management, data analysis, publication and dissemination of results	100	\$47.68	\$4768
<b>Epidemiologist – (GS-13, equivalent);</b> Project development and project management, data analysis, publication and dissemination of results	20	\$47.68	\$953.60
<b>Epidemiologist – (GS-12, equivalent);</b> Project development and project management, data analysis, publication and dissemination of results	100	\$38.84	\$3,884
<b>Epidemiologist – (GS-11, equivalent);</b> Project development and project management, data analysis, publication and dissemination of results	100	\$31.36	\$3136
<b>Estimated Total Cost of Information Collection</b>			<b>\$12,741.60</b>

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

This is a new information collection.

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

This new data collection will use quantitative methods, including the administration of a web-based that participants will complete on their own.

Project Time Schedule	
Activity	Time Schedule
Collect quantitative survey data from participants	Months 1-3
Ongoing data analysis	Months 1-12

The analysis plan for data collected as part of this investigation is to conduct univariate and multivariate analyses of exposures, risk factors, and demographic characteristics among individuals completing the online investigation survey. Statistical software like SAS and R will be used for analyses. All data collected and databases will be housed on a secure web-server and secure drive on the CDC network that is only accessible to the project members.

Data collected from the surveys will be analyzed and aggregate summaries will be developed. These aggregate summaries may be shared externally through conference presentations and peer-reviewed journal articles.

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

None.

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

There are no exceptions to the certification.

**Attachments**

- A. Section 301 of the PHS Act (42 U.S.C. 241)
- B. 60-Day Federal Register Notice
- C. Email invitation
- D. Survey 1
- E. Survey 2
- F. Determination of Non-Applicability of Human Subjects Regulations
- G. Response to Public Comment