

**Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ)
During Investigations of Foodborne Disease Clusters and Outbreaks
Supporting Statement A**

**Request for OMB Revision
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List of Attachments

- A. Section 301 of the PHS Act (42 U.S.C. 241)
- B. 60-Day Federal Register Notice
- C. Cyclosporiasis National Hypothesis Generating Questionnaire - Data Elements
- D. Cyclosporiasis National Hypothesis Generating Questionnaire - Epi Info Survey
- E. Cyclosporiasis National Hypothesis Generating Questionnaire - PDF fillable
- F. Determination of Non-Applicability of Human Subjects Regulations

- The goal of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) is to improve consistency of data collection (of pertinent exposure variables for *Cyclospora*), and thereby increase the likelihood that future outbreaks of cyclosporiasis will be recognized and that vehicles/sources will be identified (implicated).
- The data gathered through the CNHGQ will be used for hypothesis generation during periods of increased numbers of reported cases of cyclosporiasis (typically, during spring and summer months).
- The CNHGQ has been developed with the intent that it will be administered over the telephone by state and local public health officials to patients (with confirmed or probable cases of cyclosporiasis) or their proxies and then submitted to CDC.
- The population covered in this data request includes persons with confirmed or probable cases of cyclosporiasis.
- The analysis plan for data collected using the CNHGQ is to conduct descriptive analyses, primarily univariate analyses, of food exposures among patients interviewed as part of multistate outbreak investigations.

Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ)

This is a request for revision of an OMB-approved Questionnaire to facilitate the collection of standard data during investigations of multistate outbreaks of cyclosporiasis.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Cyclosporiasis is an intestinal illness caused by the microscopic parasite *Cyclospora cayetanensis*. People can become infected with *Cyclospora* by consuming food or water contaminated with the parasite. Symptoms of cyclosporiasis begin an average of 7 days (range, 2 days to ≥ 2 weeks) after ingestion of the infective form of the parasite, and may include watery diarrhea, loss of appetite, weight loss, cramping, bloating, increased gas, nausea or fatigue. Although cyclosporiasis is usually not life threatening, if not treated, symptoms can persist for several weeks or longer.

The Centers for Disease Control and Prevention (CDC) works with local, state, and federal public health partners to ensure rapid and coordinated surveillance for, detection of, and response to multistate outbreaks of cyclosporiasis, to limit the number of illnesses and to learn how to prevent similar outbreaks from occurring in the future.

Foodborne outbreaks of cyclosporiasis have been reported in the United States since the mid-1990s and have been linked to various types of imported fresh produce, including raspberries, basil, snow peas, mesclun lettuce, and cilantro. During the 15-year period of 2000–2014, 31 U.S. foodborne outbreaks of cyclosporiasis were reported; the total case count was 1,562. Outbreaks were reported during 12 of the 15 years. Overall, a median of two outbreaks were reported per year, with a median of 20 reported cases per outbreak (range, 3 to 582 cases). However, it is likely that more cases (and outbreaks) occurred than were reported; in addition, because of insufficient data, many of the reported cases could not be directly linked to an outbreak or to a particular food vehicle. During the intervening years (i.e. 2015-2019), the numbers of reported cases have steadily increased and larger multistate outbreaks have been reported. For example, there were an estimated 2,299 laboratory-confirmed, domestically acquired cases among persons who became ill during May to August (the typical timeframe of the cyclosporiasis “season” in the United States) reported in 2018. This was markedly higher than the numbers of cases reported for the same time period in 2016 (174) and 2017 (623). In 2019, as of November 13, there were an estimated 2,408 laboratory-confirmed cases reported for the same time period.

For many bacterial foodborne pathogens, molecular methods exist to compare DNA fingerprints from patient specimens and to identify clusters of infections (outbreaks) caused by genetically similar strains. However, molecular typing methods are not yet available for the parasite *C. cayetanensis*. Therefore, all temporally associated patients in whom cyclosporiasis is diagnosed must be interviewed to help determine if their case of infection could be part of an outbreak.

In some previous outbreak investigations, insufficient data were available to link domestically acquired cases of cyclosporiasis to each other or to particular food vehicles/sources. Consistent use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) has improved data collection and quality. For example, in 2018 there were two large multistate outbreaks identified by state partners utilizing information collected via the CNHGQ. Continued use of the CNHGQ will increase the likelihood that future outbreaks will be recognized and that vehicles/sources will be identified (implicated). Epidemiologic data collected via the CNHGQ is also being used to validate molecular typing methods currently under development.

During outbreak investigations, if cases from multiple jurisdictions are identified, CDC may coordinate the investigations to help ensure data are collected consistently and to analyze aggregate data. Once sufficient epidemiologic data have been collected to identify a suspect vehicle for the pertinent outbreak, the appropriate regulatory agencies become involved to determine whether ill persons can be linked via product traceback to a common (i.e., the same) source. If a common source is identified, CDC, state and local health departments, and the appropriate regulatory agencies work collaboratively to control ongoing outbreaks. Of note, more than one outbreak may occur during the same time frame.

With the development of the CNHGQ, the Parasitic Diseases Branch (PDB) has established data elements that are used for hypothesis generation during periods of increased numbers of reported cases of cyclosporiasis (typically, during spring and summer months). The CNHGQ was based on CDC's Standardized National Hypothesis Generating Questionnaire (SNHGQ; OMB No. 0920-0997) but was modified—e.g., to address the exposure period of interest for *Cyclospora*, to delete questions about food items that are not considered biologically plausible for transmission of this parasite (e.g., meat and dairy products), and to expand the data elements regarding fresh produce exposures (e.g., include more detailed information about grocery stores and restaurants).

CDC requests OMB approval for 3 years. The CNHGQ has been and will continue to be administered over the telephone by state and local public health officials to patients or their proxies and then submitted to CDC. In the event of a large outbreak, CDC staff may help in administering the survey if requested by state partners. Public health officials could use the CNHGQ or a locally developed form that includes CNHGQ data elements to collect information. The CNHGQ data elements and form will continue to improve the timeliness of hypothesis-generating analyses during multistate investigations. This will be accomplished through the use of the CNHGQ to collect and submit data elements that will be maintained centrally for rapid pooling and analysis (described in Supporting Statement B). The only change that has been made is an increase in the number of respondents since the previous approval, commensurate with an increasing number of reported cases of cyclosporiasis. This increase in the number of reported cases may be due to, for example, changes in the use and availability of diagnostic tests or greater awareness by healthcare providers.

The primary audiences for the CNHGQ include (1) state and local public health partners (foodborne epidemiologists, public health nurses, and other interviewers) and (2) CDC. The maintenance of the CNHGQ will be coordinated by CDC; data collected using this tool will be maintained by the pertinent public health jurisdictions and CDC.

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

2. Purpose and Use of Information Collection

The CNHGQ will continue to be used by federal, state, and local public health officials responsible for interviewing persons in their jurisdiction with cyclosporiasis. The CNHGQ is needed to provide a standard method of ascertaining core cyclosporiasis exposure elements during times when there are increased reports of temporally associated cases (typically during spring and summer months). Without the CNHGQ, hypothesis-generating questionnaires would need to be designed repeatedly (e.g., by each jurisdiction for each investigation). This could delay data collection and analysis, which, in turn, could delay outbreak investigations and limit the ability of public health officials to identify a likely vehicle and to take necessary public health actions. Use of the CNHGQ is expected to improve timeliness during the hypothesis-generating phase of

investigations and potentially shorten the time to determine how and where contamination events occurred.

3. Use of Improved Information Technology and Burden Reduction

The CNHGQ data elements and form have been designed for administration via telephone interviews with persons who have cyclosporiasis or their proxies. The CNHGQ will be available as a fillable electronic survey (Epi Info™ v7.2.3.1), to allow the interviewer to submit completed interview data directly to a secure database server at CDC (Attachment D. Cyclosporiasis National Hypothesis Generating Questionnaire - Epi Info Survey). The use of the electronic questionnaire limits the burden that otherwise would be associated with needing to enter data from a paper-based form submitted via facsimile into an electronic format. However, the CNHGQ will be available in a PDF format for those who choose not to submit data electronically (Attachment E. Cyclosporiasis National Hypothesis Generating Questionnaire - PDF fillable). In this scenario, data will be submitted via facsimile to CDC, where CDC epidemiologists will transcribe the data into an electronic format. The time required to complete the electronic version of the CNHGQ form is expected to be comparable to the time to complete the non-fillable form. Use of the electronic form will be encouraged to limit data entry burden. Although it is expected that the majority of interview data will be submitted electronically, the means by which state and local health departments transmit data to CDC (e.g., via facsimile or electronically) will be left to the discretion of the health department.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has conferred with internal and external staff to avoid duplication of data collection and surveillance efforts. The CNHGQ typically should not lead to collection of duplicate information. (See next paragraph.)

Cyclosporiasis national surveillance—via the Nationally Notifiable Disease Surveillance System (NNDSS)—occurs year-round; health departments may supplement the NNDSS surveillance data by submitting a 2-page cyclosporiasis national case report form (OMB No. 0920-0007) to CDC. Data collected through NNDSS include generic core data elements, such as state and county of residence, age, sex, race, ethnicity, etc. The supplemental CRF collects some additional data elements (e.g., regarding symptoms, travel history, and fresh produce exposures). However, the CRF does not collect detailed information about fresh produce exposures or include any questions about restaurant or grocery store exposures, which limits the utility of the CRF for identifying clusters of cases and for generating hypotheses in outbreak investigations. The CNHGQ will be used in lieu of the CRF during periods of increased numbers of reported cases. If a case is reported through NNDSS (during a period of increased numbers of reported cases), CDC

will initiate follow-up with the public health department to obtain CNHGQ data. Health departments could prepopulate a case-patient's CNHGQ with the relatively few generic data elements (e.g., basic demographic information) that also are collected via NNDSS.

The CNHGQ will allow CDC to make hypotheses about vehicles of infection and clusters or outbreak of cases; data obtained through NNDSS and CRF are not sufficient to make these hypotheses.

The function provided by CDC's Standardized National Hypothesis Generating Questionnaire (SNHGQ; OMB No. 0920-0997) for bacterial foodborne outbreaks is similar to the intended function of the CNHGQ for cyclosporiasis. However, as noted in Section A-1, the SNHGQ has been modified to be relevant to cyclosporiasis; the SNHGQ has not been used during (and is not appropriate for) investigations of outbreaks of cyclosporiasis.

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

Lack of a standard data collection instrument would slow down epidemiologic investigations and limit the ability of public health officials to identify the likely vehicle of infection (e.g., a particular produce item) and to take public health action (e.g., issue an import alert).

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. Federal Register 60-day Notice was published on February 25th, 2020 (Attachment B. 60-Day Federal Register Notice). No public comments were received (Federal Register /Vol. 85, No. 37, Pg. 10698).

B. The CNHGQ, when originally developed, was based on the SNHGQ, which was developed in collaboration with public health partners through OutbreakNet, a national voluntary network of epidemiologists and other public health officials who investigate outbreaks of foodborne illnesses in the United States. OutbreakNet

members include local, state, federal, and regulatory partners. The CNHGQ was developed from the SNHGQ, with input from external public health and internal CDC partners. In 2018, the CNHGQ was revised and updated based on feedback received from state partners; this renewal request utilizes the most recent version of the CNHGQ.

9. Explanations 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

Respondents 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 why and for what purposes the information is being 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.

The CNHGQ data elements and collection tool will ascertain information from respondents, including data regarding exposures (food and other) that preceded the onset of symptoms from cyclosporiasis (Attachment C. Cyclosporiasis National Hypothesis Generating Questionnaire - Data Elements). The CNHGQ will not collect any information that could be used to identify individual 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 not be included in the data collection tool, and no identifying information will be transmitted to CDC.

This activity has been classified as non-research, and it has been determined that IRB review is not required for this data collection (Attachment F. Determination of Non-Applicability of Human Subjects Regulations).

Privacy Impact Assessment Information

Overview of the Data Collection System

Collection of the CNHGQ data elements will employ quantitative and qualitative methods, including telephone interviews, designed to elicit core element exposures from respondents. No research questions will be addressed; data will be compiled regarding

recent food exposures and risk factors relevant to cyclosporiasis, in the context of responding to potential and documented outbreaks.

Description of Information to be Collected

- Responses to interview questions (i.e., CNHGQ data elements)
- No individually identifiable information will be collected on the CNHGQ

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

This activity has been classified as Non-Research, per the Division of Parasitic Diseases and CGH Human Research Protection Coordinator, and it has been determined that IRB review is not required for this data collection (Attachment F. Determination of Non-Applicability of Human Subjects Regulations).

No questions of a sensitive nature will be asked. During the introduction to the interview, respondents will be informed that their participation is voluntary and that they can refuse to answer any question and stop the interview at any time.

12. Estimates of Annualized Burden Hours and Costs

A. Interviews will be conducted with case-patients identified as potentially part of a multistate outbreak. On the basis of previous years’ case counts, it is estimated that the CNHGQ would be administered to approximately 2,500 individual respondents across all jurisdictions each year, although the number may fluctuate from year to year. This is an increase from estimates in the previous ICR, commensurate with the increasing numbers of cases reported in recent years.

Exhibit 1 shows the estimated annual burden hours associated with administering the CNHGQ. The estimated total annual burden for all organizations combined is 1875 hours.

Exhibit 1: Estimated Annual Burden Hours

| Type of respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs) | Total Burden (in hrs) |
|---------------------|-----------|--------------------|---------------------------------|-----------------------------------|-----------------------|
|---------------------|-----------|--------------------|---------------------------------|-----------------------------------|-----------------------|

| | | | | | |
|---|---|-------|---|-------|------|
| Ill individuals identified as part of an outbreak investigation | Cyclosporiasis National Hypothesis Generating Questionnaire | 2,500 | 1 | 45/60 | 1875 |
| Total | | | | | 1875 |

B. We used the 2018 mean hourly wage for all occupations in the United States. This wage (i.e., \$24.98) was obtained from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm).

Exhibit 2 shows the estimated aggregate annual cost burden associated with the interviewees' time to participate. The estimated burden in hours is provided in Exhibit 1. The total annual cost burden was calculated by multiplying the mean hourly wage by the burden in hours. The estimated total annual cost burden is \$46,837.50.

Exhibit 2. Estimated Annual Cost Burden to Respondents

| Respondent Category | Average Hourly Wage | Burden (in hours) | Cost Burden |
|--------------------------------------|----------------------------|--------------------------|--------------------|
| All occupations in the United States | \$24.98 | 1875 | \$46,837.50 |
| Total | | | \$46,837.50 |

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

There will be no direct costs to respondents other than their time to participate in the outbreak investigation (i.e., to be interviewed).

14. Annualized Cost to the Government

The estimated total cost to the Federal Government per year of data collection is \$7,137.15. Exhibit 3 lists the components of the estimated total annual cost.

Exhibit 3. Estimated Costs to Federal Government

| Cost Component* | Total Cost (in dollars) |
|---------------------------------|--------------------------------|
| Project Development and Project | \$2,560.40 |

| | |
|--|-------------------|
| Management (including CDC staff time) | |
| Data Collection Activities | \$1,920.30 |
| Data Analysis | \$2,016.35 |
| Publication and Dissemination of Results | \$640.10 |
| Total | \$7,137.15 |

*Costs based on 2018 General Schedule Pay Tables for Atlanta, hourly rate, GS 9-1.

15. Explanation for Program Changes or Adjustments

This is a request for a revision of a previously approved data collection instrument. The data collection instrument has not been changed since the most recent revision that was approved by OMB in 2018. The number of respondents has increased since the previous approval, commensurate with an increasing number of reported cases of cyclosporiasis. This increase in the number of reported cases may be due to, for example, changes in the use and availability of diagnostic tests or greater awareness by healthcare providers.

16. Plans for Tabulation and Publication and Project Time Schedule

| Activity | Estimated time schedule following OMB clearance |
|--|---|
| Conduct interviews using the CNHGQ during multistate outbreak investigations | Months 1–36 |
| Ongoing data analysis | Months 1–36 |

The analysis plan for data collected using the CNHGQ is to conduct descriptive analyses, primarily univariate analyses of food exposures among patients interviewed as part of multistate outbreak investigations (further description of analyses is provided in Supporting Statement B). Data analysis software (e.g., SAS) will be used to determine the proportions of case-patients who reported consumption of particular food items and thereby to generate hypotheses about potential food vehicles.

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

None.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.