

**OMB Change Request:
Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ)
OMB Control Number 0920-1198
Expiration Date: 09/30/2020**

**Date of Request: 3/27/2018
OMB approval is requested by: 4/6/2018**

Program Contact

Shannon Cooney
Parasitic Diseases Branch
Division of Parasitic Diseases and Malaria
Center for Global Health
Centers for Disease Control and Prevention
1600 Clifton Road N.E.
Atlanta, Georgia 30329
Phone: 404-718-1057
Fax: 404-471-8812
Email: yqj1@cdc.gov

Summary

Foodborne outbreaks of cyclosporiasis have been reported in the United States since the mid-1990s and have been linked to various types of fresh produce. 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. The Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) was developed to capture information from case-patients that is pertinent to *Cyclospora* and fresh produce vehicles of infection to aid in the investigation and detection of outbreaks. The CNHGQ is the only nationally representative survey for collecting extended exposure information from cyclosporiasis case-patients. The CNHGQ was initially approved by OMB for use in 2017; modifications to the collection instrument have been made in response to feedback provided by public health partners and to help improve data quality.

Change request

We request OMB approval for the revised CNHGQ data collection instrument, **Attachment 1. CNHGQ 2018 Revisions**. Revisions from the previously approved 2017 version of the questionnaire are summarized in **Attachment 2. Crosswalk of Non-substantive changes to 2018 CNHGQ**.

The annualized burden hours and cost to reporting jurisdictions to submit these data to CDC do not change substantially from the original estimates; updated burden tables are provided below to account for the ~1 minute increase in interview time using the revised CNHGQ. There are no changes to the respondent universe, sampling methods or procedures for the collection of information.

Background and justification

This is a nonmaterial/non-substantive change request for OMB No. 0920-1198, expiration date 09/30/2020, for the reporting of Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) data for use during periods in which increased numbers of cyclosporiasis cases are reported (typically, during spring and summer months). The CNHGQ is a tool used during investigations of clusters/outbreaks of cyclosporiasis cases; the data collected using this questionnaire allow CDC to obtain information from state and local public health partners in a consistent manner for analysis. Cyclosporiasis is a nationally notifiable disease and is currently reportable in 45 U.S. public health jurisdictions (43 states, the District of Columbia, and New York City). However, the data received via the National Notifiable Diseases Surveillance System are not sufficient for investigating outbreaks of cyclosporiasis. Rather, information about exposures among case-patients is needed in order to determine whether cases may be part of a cluster or outbreak. Once analyzed, data are shared with pertinent public health partners (e.g., FDA and state/local partners) to aid in ongoing investigations and prevention efforts.

If approved, the revised CNHGQ will be used beginning in May 2018. This request is for the addition of 6 new disease-specific data elements and 1 new optional data element, modifications of 23 data elements, and deletions of 7 data elements (see **Attachment 2. Crosswalk of Non-substantive changes to 2018 CNHGQ**). The proposed changes were made following discussions with public health partners (from four jurisdictions) who have used the OMB-approved version of the CNHGQ and thought that the modifications would increase the utility of the questionnaire. The instrument was revised by editing it for flow, continuity, and clarity (e.g., changed the order of questions, revised response options, and repartitioned/split questions so the data are more analyzable). The proposed changes to the questionnaire were made to improve the quality of the data collected using this instrument.

Additional perspective: Some state public health partners asked us to include questions in the CNHGQ to capture intrastate travel (even though data in such regards are not analyzed at the national level) so states that

would like to be able to collect this type of information can do so without having to create a separate (additional) form for local use. In response to this request, we have now added questions about intrastate travel. However, we have indicated on the revised CNHGQ that these questions are optional.

The length of the CNHGQ has not changed substantially. The revised CNHGQ was pilot tested internally among 5 program staff, and we found that the average time to administer the questionnaire is 21 minutes (range: 4.5 – 29 minutes; note, there is a wide range in time to complete the interview, in part because persons with a history of international travel only complete through Section 3 of the questionnaire). Therefore, we expect a slight change (~1 minute increase) to the original burden estimate of 20 minutes for actual interview time. The original estimate of total time per response was 45 minutes, which included additional time for the collection of laboratory information, data entry, and submission of information to CDC. Because we expect an increase of ~1 minute per response, the total time burden per response is now expected to be 46 minutes; this is reflected in the burden tables below.

The 2018 CNHGQ is provided as **Attachment 1. CNHGQ 2018 Revisions**.

Changes from the 2017 version of the questionnaire are summarized in **Attachment 2. Crosswalk of Non-substantive changes to 2018 CNHGQ**.

Note, because of the time required to develop the web version of the questionnaire, the revised Epi Info survey is still in production; the web survey will be completed upon approval of the proposed content changes to the PDF version. The Epi Info version will precisely mirror the content of the attached PDF version of the questionnaire.

Burden

The annualized burden hours and cost to reporting jurisdictions to submit these data to CDC increased by 1 minute per response compared with the original estimates in the “Estimates of Annual Burden Hours and Cost Burden to Respondents” sections in 12 A. and 12 B. of OMB No. 0920-1198. We still expect the same number of respondents. The total estimated annualized burden hours are 767 (an increase of 17 hours compared to the previously approved estimate of 750 hours). The revised burden tables are provided below.

A. 12A. Estimated Annual Burden Hours (Revised)

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	1,000	1	46/60	767
Total					767

B. 12B. Estimates of Annualized Cost Burden to Respondents (Revised)

Respondent Category	Average Hourly Wage	Burden (in hours)	Cost Burden
All occupations in the United States	\$23.23	767	\$17,817.41

Total		750	\$17,817.41
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Requested OMB approval date and rationale

OMB approval is requested by 4/6/2018. Approval by this date will allow for the survey collection instrument to be disseminated to state public health partners in preparation for the 2018 cyclosporiasis outbreak season (typically, May–August). Lead time is requested so that we can finish building the Epi Info web version of the questionnaire, and so that state partners can become familiar with the revised format of the CNHGQ before use in May.

Estimated timeline

- 4/6/2018 Target date for receipt of OMB change request approval
- 4/15/2018 Complete building of web version of information collection instrument
- 4/15/2018 Disseminate CNHGQ to state public health partners in preparation for the 2018 outbreak season
- 5/1/2018 State public health partners begin administering CNHGQ to cyclosporiasis case-patients