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

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Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ)

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe consists of residents of the 57 jurisdictions that voluntarily submit case notifications for nationally notifiable conditions to the Centers for Disease Control and Prevention (CDC): health departments in every U.S. state, New York City, Washington DC, and 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands). Cyclosporiasis is a reportable condition in 44 of the 57 jurisdictions; health departments in those jurisdictions notify CDC of diagnosed and reported cases. However, even states in which cyclosporiasis is not a reportable condition may utilize the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) to investigate reported cases during an outbreak. No statistical sampling methods will be used. State and local public health officials will interview persons who have cases of cyclosporiasis (including persons who have laboratory-confirmed cases and persons who have clinically compatible illness who are epidemiologically linked to a person who has a confirmed case) identified as potentially part of an outbreak. Persons are identified based on reporting of diagnosis by healthcare providers or laboratories. State/local health departments will then interview the case patient to obtain their exposure history (using the Cyclosporiasis National Hypothesis Generating Questionnaire). Based on this exposure history the case patient may be identified as part of an outbreak. During the interview, respondents are asked if they know anyone else who is/has experienced a similar illness: question 17 asks if the case patient knows anyone else with similar illness and question 17b asks about the other ill persons, including the number and their relationship (e.g., son, mother, neighbor, friend, etc.) to the case patient. Question 17b explicitly states “Do not enter names or other personally identifiable information” and instructs health departments to enter only the state case ID of the ill contact(s), if known; thus, no PII is collected. The number of reported cases (both confirmed and probable) of cyclosporiasis has been increasing in recent years, potentially due in part to changes in the use and availability of diagnostic tests or greater awareness by healthcare providers. 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. It is unknown what effects the COVID-19 pandemic may have on the number of cyclosporiasis cases identified.

2. Procedures for the Collection of Information

Participant Recruitment. Respondents will be case-patients identified (e.g., through routine disease reporting) as potentially part of an outbreak. Officials in state and local public health departments will contact case-patients, or their proxies, to conduct the interviews.

Interviews. The CNHGQ has been designed for administration by public health officials via telephone interviews with persons who have reported cases of cyclosporiasis (or their proxies). Data collection will be guided by semi-structured protocols designed to elicit core element exposures from respondents. The CNHGQ has been designed to facilitate additional probing by the interviewer regarding particular food or other exposures reported by the interviewee. For example, if an ill person reports having eaten food outside the home, the interviewer would collect the name and location of the pertinent establishment (e.g., restaurant), as well as when and what the person recalls having eaten there. The burden associated with answering these open-ended elements of the CNHGQ was accounted for in the burden estimates provided in Supporting Statement A. 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.

The CNHGQ will collect data about exposures of potential relevance that the person had during the period of interest (typically, for ill persons, the 2-week period before onset of symptoms), as well as about other factors that may be pertinent to investigations of multistate outbreaks of cyclosporiasis, including:

1. Demographic data (without individually identifiable information)
2. Travel history
3. Illness information (e.g., onset, duration, hospitalization status, laboratory date)
4. Points of service for purchasing food items/ingredients eaten at home and foods eaten away from home (e.g., grocery stores, restaurants)
5. Fresh (raw/uncooked) produce (e.g., fruits, herbs, vegetables)

The CNHGQ will be available in an electronic format that allows the interviewer to submit completed interview data using a web survey tool (Attachment D. Cyclosporiasis National Hypothesis Generating Questionnaire - Epi Info Survey). Data will be written directly to a secure database server. 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. The CNHGQ will also be available in a fillable format for those who choose not to submit data electronically. In this scenario, data will be submitted via facsimile to CDC, where epidemiologists in the Parasitic Diseases Branch will transcribe the data into an electronic format (Attachment E. Cyclosporiasis National Hypothesis Generating Questionnaire - PDF fillable).

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

In general, state and local public health officials will make every effort (as resources allow) to contact case-patients identified as potentially part of an outbreak. Policies vary, but many jurisdictions attempt to contact a case-patient at least three times before classifying the patient as “lost to follow-up.” The CNHGQ has been designed so that the

telephone interview typically can be completed in ≤45 minutes; therefore, the burden on case-patients should be sufficiently low to maximize response rates.

4. Tests of Procedures or Methods to be Undertaken

The CNHGQ has been developed collaboratively with public health officials, who will conduct the interviews. On the basis of voluntary use of CNHGQ data elements by some state and local public health officials, the Parasitic Diseases Branch has received positive feedback regarding the content of the CHNGQ.

Because information collected regarding the CNHGQ data elements is intended for hypothesis generation in multistate outbreak investigations, analytic work will focus on obtaining frequency distributions (e.g., using SAS) for demographic variables, as well as for food and other exposure variables addressed in the CNHGQ. Such frequency distributions also will be stratified by various demographic and exposure variables. The primary objectives of the descriptive analyses are to identify food and other exposures with high reported frequencies and to describe the demographic characteristics of case-patients.

In general, once exposure variables of potential interest are identified via descriptive analyses, the exposure data for case-patients may be compared with data obtained from other sources, to assess whether the exposures of interest occurred more frequently than expected among case-patients. For example, exposure data for case-patients and the general population could be compared (e.g., by using data from the FoodNet survey, a population-based survey of food consumption history among healthy persons in 10 states). The comparison of reported exposures among case-patients and the general population makes it possible to estimate the probability of observing a particular exposure frequency (proportion) among case-patients by chance alone, given the population exposure data. As CDC receives more CNHGQ data over time, analyses may be performed comparing “current” outbreak-related exposures with those reported for prior outbreaks. Additional analyses needed to understand the relationship between exposures and illness may be beyond the scope of the CNHGQ.

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

Epidemiologists from federal and state agencies have been involved in developing the CNHGQ.

The Parasitic Diseases Branch will be responsible for managing and reviewing submitted data. The principal investigator and project director is Anne Straily.