

**Standardized National Hypothesis Generating Questionnaire
Supporting Statement A**

**Request for OMB Approval
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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. Standardized National Hypothesis Generating Questionnaire
- D. Determination of Non-Applicability of Human Subjects Regulations

Standardized National Hypothesis Generating Questionnaire

This is a request for OMB approval of a questionnaire to facilitate the collection of standard data during multistate foodborne disease outbreak investigations.

A. Justification

1. Circumstances Making the Collection of Information Necessary

It is estimated that each year roughly 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. The Outbreak Response and Prevention Branch (ORPB) at the Centers for Disease Control and Prevention (CDC) works with local, state, and federal public health partners to ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Foodborne outbreak investigations have several steps or phases: detecting a possible outbreak, defining and finding cases, generating hypotheses about likely sources, testing the hypotheses, identifying the source of food and/or the point of contamination, taking steps to control an outbreak, and determining when an outbreak is over. During multistate investigations, state and local health departments frequently collect initial information from ill persons. As an investigation expands, CDC typically coordinates the investigation by ensuring that additional data are collected consistently across states and aggregating and analyzing those data to identify potential causes of the outbreak. Once sufficient epidemiologic data have been collected to identify a suspect vehicle for the outbreak, the appropriate regulatory agencies are involved to determine whether ill persons can be connected to a common source through product traceback. If a common source is identified, CDC, state and local health departments, and the appropriate regulatory agencies work collaboratively to control the outbreak. While investigations are dynamic and multiple steps may occur in parallel, initial hypothesis generation occurs early in an outbreak investigation after cases have been identified, but before a source for the outbreak has been found.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the U.S. state or local jurisdictions are responsible for the initial data collection, and there is not a standard, national form or data collection system for illnesses caused by enteric pathogens.

Because of this:

- Consistent exposures are not gathered across jurisdictions so existing data are often not comparable or compatible.
- Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.
- Many cases must be re-interviewed to determine exposure history to elements that were not evaluated during jurisdiction-specific interviews; this leads to additional investigative delays.

- For each cluster, data must be collated and evaluated centrally after hypothesis-generating interviews. Because data elements are determined for each outbreak, new databases must often be created for data entry and comparison.

The goal of the Standardized National Hypothesis Generating Questionnaire (SNHGQ) is to define a core set of data elements to be used for hypothesis generation once a given situation is determined to be a “multistate foodborne investigation”. The SNHGQ-defined elements would be used in the early phases of an outbreak investigation to generate hypotheses about the source(s) of infection and facilitate collaboration across jurisdictions. These data elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint the source of food contamination events. To the extent that a given state or local jurisdiction has already collected these elements during their initial investigation, the SNHGQ would be populated with that pre-existing data.

Once a leading hypothesis is identified during the hypothesis generation phase, typically after no more than 15 to 20 interviews, the investigation progresses to hypothesis testing. During these later phases of an outbreak investigation, the SNHGQ is no longer used; rather the initial data collected during the outbreak are utilized to tailor the next phase in the data collection process; to focus on hypothesis testing, often in localized illness clusters. Situations in which EIS officers are called in at this phase would typically be covered under the OMB number 0920-0008 (referred to as Epi-Aids).

In response to the need for standardized data elements during multistate foodborne disease outbreak investigations, the SNHGQ data elements were assembled and define the core elements for use when a multistate cluster of enteric disease infections is identified. The SNHGQ data elements were drafted with the intent that they would be administered over the phone by public health officials to case-patients or their proxies. State and local public health departments could use either SNHGQ form itself or submit data collected using local forms that contain SNHGQ data elements. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local and state health departments, as well as the Food and Drug Administration and the Department of Agriculture Food Safety Inspection Service. Informational sessions were held during three national OutbreakNet Annual Meetings during 2009-2011 that included participation from foodborne epidemiologists from throughout the United States. Engaged partners indicated a high level of consensus regarding the need and utility for these core elements and the SNHGQ.

The SNHGQ elements and form aim to improve the timeliness of hypothesis generating analyses during multistate investigations. This will be accomplished through the use of the SNHGQ to collect and submit common data elements that will be maintained centrally for rapid pooling and analysis (described in part B). In addition, interview data can be used to conduct comparisons of reported exposures between cases in a current investigation and cases who have been interviewed during previous investigations. These

comparisons, called case-case comparisons, use data from cases that are not associated with a specific investigation to determine reasonable expected rates of exposure.

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 Outbreak Response and Prevention Branch at CDC.

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

1.1 Privacy Impact Assessment

Overview of the Data Collection System

Collection of the SNHGQ data elements will employ quantitative and qualitative methods, including telephone interviews, designed to elicit core elements exposures from respondents. Interviewers will be able to probe further or deviate from the specific data elements to the extent that respondents reveal new information. There are no research questions addressed; standardized data will be compiled on recent food consumption history and other exposures related to enteric diseases in the context of responding to acute multistate infectious disease outbreaks.

Description of Information to be Collected

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

2. Purpose and Use of Information Collection

The SNHGQ will be used by federal, state, and local public health officials responsible for conducting interviews with reported cases of enteric disease in their jurisdiction. CDC's Outbreak Response and Prevention Branch has piloted the use of the SNHGQ during multistate cluster investigations as the form was being developed to finalize formatting and ensure utility. The data elements of the SNHGQ have been used voluntarily by OutbreakNet partners engaged in multistate cluster investigations.

The SNHGQ is needed to fill the identified gap of no standardized method of ascertaining core exposures elements among cases of enteric disease during multistate investigations. Without the SNHGQ, hypothesis-generating data collection instruments must be designed for each investigation. This results in delayed data collection and analysis, which in turn, delays outbreak investigations and limits the ability of public health officials to take necessary public health actions. Use of the SNHGQ will improve timeliness during the hypothesis-generating phase of investigations, thereby shortening the time to pinpoint how and where contamination events occurred.

2.1 Privacy Impact Assessment

No individually identifiable information will be collected.

The proposed data collection will likely have little or no effect on respondents' privacy.

3. Use of Improved Information Technology and Burden Reduction

The SNHGQ data elements and form were designed administration via telephone interviews with cases of enteric disease or their proxy. The SNHGQ is available in a fill-able PDF format that allows the interviewer to submit completed interview data via e-mail as an XML file format. The use of the fill-able PDF questionnaire limits the burden of needing to enter data from a paper-based form submitted via facsimile into an electronic format. However, the SNHGQ is available for use in a non-fillable format for those who choose to not submit data electronically. In this case, data will be submitted via facsimile to CDC where ORPB epidemiologists transcribe the data into the fill-able PDF to obtain the XML file format of the submitted data. There is no effective difference in the time it takes the interviewer to fill in the SNHGQ form as the fill-able electronic version, or by hand on the non-fillable form. The use of the fill-able form will be encouraged to limit data entry burden and it is expected that the majority of interviews will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has conferred with internal and external staff through various workgroups and meetings. There is currently no national, standardized hypothesis generating interview data collection instrument for use during multistate enteric disease outbreak investigations for most enteric disease pathogens. The SNHGQ should not generally lead to collection of duplicate information: the SNHGQ can be populated with any data elements routinely collected by the state or local jurisdiction on standardized infectious disease case report forms during their initial investigation. The *Listeria* Initiative Case Report Form provides a similar function, but is designed for use for all cases of listeriosis and as such, only collects data specific to the unique exposures of importance for infection with *Listeria monocytogenes*. The SNHGQ does not duplicate or replicate the *Listeria* Initiative Case Report Form (OMB No. 0920-0004). Instead, it provides data for the vast array of potential exposures of importance for investigating multistate outbreaks of various enteric disease pathogens.

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 consistent data slows down the epidemic investigation process.

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 Tuesday, July 24, 2012: Vol. 77, No.142, pages 43285-43286.

B. OutbreakNet is the national voluntary network of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States. OutbreakNet members include local, state, federal, and regulatory partners. During the 2009, 2010, and 2011 OutbreakNet Annual Conferences, breakout sessions were convened to discuss the core elements project and the subsequent development of the SNHGQ. Public health partners from across the U.S., both internal and external to CDC, participated in the development process, including the Food and Drug Administration and the Department of Agriculture. Additionally, following the 6th OutbreakNet Annual Conference held during 2010, OutbreakNet members volunteered to participate in a working group, led by CDC, to determine the format and final layout of the SNHGQ. This data collection instrument is a direct result of these collaborations.

9. Explanations of Any Payment or Gift to Respondents

There will be no remuneration to respondents.

10. Assurance of Privacy of Data Provided to Respondents

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.

These data elements and collection tool will ascertain information from respondents about exposures (food and other) preceding an onset of illness. It 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 be not be included in the data collection tool and no identifying information will be transmitted to CDC.

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

Privacy Impact Assessment Information

No individually identifiable information is being collected.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

A. Interviews will be conducted with cases of enteric disease identified as part of a multistate outbreak investigation. Based on the estimated number of cases of foodborne disease in the U.S. and the proportion of those cases that are outbreak associated, it is estimated that the SNHGQ would be administered to approximately 4,000 individual respondents across all jurisdictions each year.

B. We used the 2011 mean average hourly wage for all occupations in the United States. This wage of \$21.74 was obtained from the Bureau of Labor Statistics (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 3,000 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	Standardized National Hypothesis Generating Questionnaire (Core Elements)	4,000	1	45/60	3,000
Total					3,000

Exhibit 2 shows the estimated annual cost burden associated with individual’s time to participate. We used the 2011 mean average hourly wage for all occupations in the United States. This wage of \$21.74 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 \$65,220.00.

Exhibit 2. Estimated Annual Cost Burden to Respondents

Respondent Category	Average Hourly Wage	Burden (in hours)	Cost Burden
All occupations in the United States	\$21.74	3000	\$65,220.00
TOTAL		3000	\$65,220.00

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 \$3,564.00 over the one year period of data collection. Exhibit 3 provides a breakdown of the estimated total costs.

Exhibit 3. Estimated Costs to Federal Government

Cost Component*	Total Cost (in dollars)
Project Development and Project Management (including CDC staff time)	2,376
Data Collection Activities	0
Data Analysis	1,188
Publication and Dissemination of Results	0
Total	3,564

*Costs based on 2011 General Schedule Pay Tables for Atlanta, hourly rate, GS9-1.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This new data collection will use qualitative methods, including telephone interviews guided by semi-structured protocols designed to elicit core elements exposures from respondents. Interviewers will be able to probe further or deviate from protocols to the extent that respondents reveal new information. There are no specific research questions addressed, but instead, will ascertain standardized data across jurisdictions during multiple multistate investigations.

Activity	Estimated time schedule following OMB clearance
Utilize the SNHGQ to conduct interviews during multistate outbreak investigations	Months 1-36
Ongoing data analysis	Months 1-36

The analysis plan for data collected using the SNHGQ is to conduct descriptive analyses and primarily univariate analyses of food exposures among cases interviewed as part of multistate cluster investigations (further description of analyses is provided in part B). SAS will be used to determine the proportion of cases reporting consumption of specific food items to generate hypotheses about potential food vehicles during an outbreak investigation

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.