



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-0997]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Standardized National Hypothesis Generating Questionnaire” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on March 10, 2023 to obtain comments from the public and affected agencies. CDC received two non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g.,
permitting electronic submission of responses; and
(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Standard National Hypothesis Generating Questionnaire (OMB Control No. 0920-0997) - Reinstatement – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly one in six Americans get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of these illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the United States there is not a

standard, national form or data collection system for illnesses caused by many enteric pathogens. 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.

CDC requests a Reinstatement of this project, called the Standardized National Hypothesis-Generating Questionnaire, to collect standardized information from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent 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 to shorten the time to pinpoint how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire (SNHGQ) was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to collect core elements data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Since the last revision of the SNHGQ in 2019, CDC has investigated over 470 possible multistate foodborne and enteric clusters of infection involving over 26,000 ill people. Of which, an outbreak vehicle has been identified in 199 of these investigations. These outbreaks have led to many recalls and countless regulatory actions that have removed millions of pounds of

contaminated vehicles out of commerce. In almost all instances, the SNHGQ or iterations of the SNHGQ have been instrumental in the successful investigation of these outbreaks. The questionnaire has allowed investigators to more efficiently and effectively interview ill persons as they are identified. Because these exposures are captured in a common, standard format, we have been able to share and analyze data rapidly across jurisdictional lines. Faster interview response and analysis times have allowed for more rapid epidemiologic investigation and quicker regulatory action, thus helping to prevent thousands of additional illnesses from occurring and spurring industry to adopt and implement new food safety measures in an effort to prevent future outbreaks.

The total estimated annualized burden requested is 3,000 hours (approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak investigations with 45 minutes/response). There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Ill individuals identified as part of an outbreak investigation	Standardized National Hypothesis Generating Questionnaire	4,000	1	45/60

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.