

ESTIMATED ANNUAL REPORTING BURDEN

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Adult Poison Center Callers	Call-back Questionnaire for Self	210	1	40/60	140
Adolescent Poison Center Callers	Call-back Questionnaire for Self	30	1	40/60	20
Parent or Guardian Poison Center Callers.	Call-back Questionnaire for Proxy ...	60	1	40/60	40
Total	200

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

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**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

**Centers for Disease Control and
 Prevention**

[60Day-16-0997; Docket No. CDC-2016-0054]

**Proposed Data Collection Submitted
 for Public Comment and
 Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Using the Standardized National Hypothesis Generating Questionnaire during Multistate Investigations of Foodborne Disease Clusters and Outbreaks.

DATES: Written comments must be received on or before August 22, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0054 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and

Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Standardized National Hypothesis Generating Questionnaire (0920-0997, Expiration Date 10/31/2016)—Revision—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 1 in 6 Americans gets 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 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 U.S. 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 revision to this project to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire, 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 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 how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire 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 implementation of the SNHGQ in 2013, ORPB has investigated over 700 multistate foodborne and enteric clusters of infection involving over 26,000 ill people. Of which, an outbreak vehicle has been identified in 200 of these investigations. These outbreaks have led to over 50 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 for the Standardized National Hypothesis Generating Questionnaire 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 hrs)	Total burden (in hrs)
Individuals	Standardized National Hypothesis Generating Questionnaire (Core Elements).	4,000	1	45/60	3,000
Total	3,000

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

Amendment: A notice of this meeting was published in the **Federal Register** on May 24, 2016, Volume 81, Number 100, Pages 32754-32755. The original notice is amended to include Matters for Discussion as follows:

Matters for Discussion: The agenda will include discussions on meningococcal vaccines; human papillomavirus vaccines; influenza; cholera vaccine; hepatitis vaccines; safety of maternal Tdap vaccination; Respiratory Syncytial Virus (RSV) and vaccine supply. A recommendation vote is scheduled for meningococcal vaccines, influenza vaccine, and cholera vaccine. A VFC vote is scheduled for meningococcal vaccines, and influenza.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Stephanie Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road NE., MS-A27, Atlanta, Georgia 30329, telephone 404/639-8836; Email ACIP@CDC.GOV.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of

meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

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