

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
<b>Total .....</b>	.....	.....	.....	.....	<b>3,000</b>

**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](mailto: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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