



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-25-24EE]

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 “Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) National Hypothesis Generation and Investigation Module” 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 April 5, 2024 to obtain comments from the public and affected agencies. CDC received two 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

Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) National Hypothesis Generation and Investigation Module – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) at the Centers for Disease Control and Prevention (CDC) aims to protect public health through the prevention and control of disease, disability, and death caused by foodborne, enteric, waterborne, and environmentally transmitted infections. To overcome challenges presented by the changing landscape of enteric diseases, the need for comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are essential to guide prevention and control activities. The submitted forms standardize hypothesis generating instruments used during enteric disease outbreak investigations and surveillance. This includes foodborne, waterborne, and zoonotic disease surveillance and outbreak investigations. In addition, enhanced surveillance for antibiotic resistant isolates is also included in this package.

Form 1. National Hypothesis Generation Questionnaire (NHGQ) defines a core set of data elements to be used for hypothesis generation once a given situation is determined to be a multistate foodborne or zoonotic enteric disease investigation. NHGQ-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. This form is currently approved under OMB Control Number 0920-0997 but will be moved to this ICR upon OMB approval.

Form 2. Foodborne Focus Questionnaire – Once a leading hypothesis is identified during the hypothesis generation phase, typically after no more than 15 to 20 interviews using the NHGQ, a leading hypothesis is often identified and more specific information needs to be collected, such as type, variety, brand, and purchase location, to confirm the hypothesis. During these later phases of an outbreak investigation, the NHGQ is no longer used. Data collected through the Foodborne Focus Questionnaire are utilized to tailor the next phase of the outbreak investigation and guide potential public health action, such as a product recall or public health alert.

Form 3. Animal Contact Focus Questionnaire – this questionnaire will be deployed once a suspected vehicle is identified either via the Hypothesis Generating Questionnaire or via epidemiologic data collected in initial STLT patient interviews. DFWED would only deploy sections relevant to the species identified as the potential outbreak vehicle. This questionnaire would be used to confirm the hypothesized animal vehicle, to collect information needed to take public health action including animal contact settings, purchase locations, and pet food brands and lot numbers, and to identify risk communication priorities so we can instruct the public how to prevent further illnesses.

Form 4. Shigella National Hypothesis Generation Questionnaire – Questionnaire is used for multistate outbreaks of Shigellosis. Shigellosis is highly contagious, and as person-to-person transmission is coming, it can be challenging to identify how individuals could have become ill.

As a result, a comprehensive hypothesis generating questionnaire focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities. This form is currently approved under OMB Control Number 0920-1307 but will be moved to this ICR upon OMB approval.

Form 5. NARMS SIRI Module 1 (nontyphoidal Salmonella, STEC, Vibrio, or Campylobacter) – this questionnaire module includes questions that will be asked of patients with nontyphoidal Salmonella, STEC, Vibrio, or Campylobacter isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 6. NARMS SIRI Questionnaire Module 2 (nontyphoidal Salmonella except multidrug-resistant Newport, STEC, or Vibrio) – this questionnaire module includes questions that will be asked of patients with nontyphoidal Salmonella (except serovar Newport), STEC or Vibrio isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 7. NARMS SIRI Questionnaire Module 3 (multidrug-resistant Salmonella Newport) – this questionnaire module includes questions that will be asked of patients with multidrug-resistant Salmonella Newport isolates. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 8. NARMS SIRI Questionnaire Module 4 (Campylobacter) – this questionnaire module includes questions that will be asked of patients with Campylobacter isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 9. NARMS SIRI Questionnaire Module 5 (Typhoid or Paratyphoid) – this questionnaire module will be asked of patients with *Salmonella* Typhi or Paratyphi isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

CDC requests OMB approval for an estimated 5,850 annualized burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Cluster and outbreak case patients	National Hypothesis Generating Questionnaire	4,000	1	45/60
Cluster and outbreak case patients	Foodborne Focus Questionnaire	4,000	1	20/60
Cluster and outbreak case patients	Animal Contact Focus Questionnaire	450	1	30/60
Shigellosis case patients	Shigella Hypothesis Generating Questionnaire	1500	1	45/60
Nontyphoidal <i>Salmonella</i> , STEC, <i>Vibrio</i> , or <i>Campylobacter</i> case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 1	305	1	15/60
Nontyphoidal <i>Salmonella</i> (except Newport strain), STEC, or <i>Vibrio</i> case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 2	130	1	10/60
Multidrug-resistant <i>Salmonella</i> Newport case patients	NARMS SIRI Questionnaire Module 3	125	1	15/60
<i>Campylobacter</i> case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 4	50	1	25/60

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
<i>Salmonella</i> Typhi or Paratyphi case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 5	50	1	20/60

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