

National Outbreak Reporting System: An Evaluation of Foodborne Disease Outbreak Surveillance and Technical Requirements for Reporting

OSTLTS Generic Information Collection Request

OMB No. 0920-0879

Supporting Statement - Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

Foodborne illnesses represent a significant public health burden in the United States. It is estimated that each year, 48 million Americans (1 in 6) become ill, 128,000 are hospitalized, and 3,000 die as the result of a foodborne illness [1]. Norovirus and *Salmonella*, which are the two leading causes of foodborne disease, are estimated to cost over \$5 billion annually due to healthcare costs and lost productivity [2]. Reducing foodborne illnesses by only 10% would prevent 5 million people from getting sick [1]. Because foodborne illness poses a substantial public health challenge, food safety has been identified as one of CDC's ten "winnable battles," public health priorities with large-scale impact on health and with known, effective strategies to address them [3] (**See Attachment A – Letter from CDC Director on food safety and Attachment B – CDC's Winnable Battle website on food safety**).

CDC has maintained a collaborative surveillance program, the Foodborne Disease Outbreak Surveillance System, for collection and reporting of data on the occurrence and causes of foodborne disease outbreaks in the United States since 1973 (OMB No. 0920-0004 "The National Disease Surveillance Program - II. Disease Summaries"), but data on foodborne outbreaks has been at the core of public health surveillance efforts for many years. Beginning in 1925, the Public Health Service published summaries of outbreaks of gastrointestinal illness attributed to milk and in 1938, it added summaries of outbreaks caused by all foods. Over the years the system has evolved and is now the primary source of national data describing the numbers of illnesses, hospitalizations, and deaths; the etiologic agents; the implicated foods; the contributing factors; and the settings of food preparation and consumption associated with outbreaks in the United States. From 1973-1997, the reporting system was paper based, referred to as pFORS (paper-based Foodborne Outbreak Reporting System). During this era, states mailed or faxed in outbreak reports to CDC. The outbreak reports were reviewed by CDC and the data analysis was verified before manual data entry. In 1998, the reporting system became web-based and health departments began transitioning away from the paper reporting. The system is referred to as eFORS (electronic Foodborne Outbreak Reporting System). The National Outbreak Reporting System (NORS) was launched in 2009 and replaced eFORS, which had been used for electronic reporting of foodborne outbreaks until 2008 (**See Attachment C – NORS interface screenshot**). One of the major enhancements with the advent of NORS was the ability to report outbreaks due to food, as well as other modes of transmission, including water, person-to-person, animal contact, and environmental contamination. NORS has improved the ability to describe and prevent foodborne disease outbreaks at national and state levels through the collection of detailed information about the foods and pathogens that pose the biggest risk to human health. Routine data collection by NORS is covered under OMB No. 0920-0004 "The

National Disease Surveillance Program - II. Disease Summaries.” For this current OMB application, we plan to conduct a one-time survey of NORS users about their experience with NORS.

NORS data, along with historical outbreak report data transferred into NORS, are readily available for review and analysis by stakeholders. Stakeholders include federal agencies with jurisdiction over the food supply, state, local and federal public health agencies, consumer interest groups, industry, physicians and other medical practitioners, academic researchers, and the public. Data collected by NORS are also disseminated by CDC in several forms. Annual summary data are published in MMWR reports (**See Attachment D – MMWR Report Sample**). Data are also used to produce peer-reviewed publications on specific foods and settings of public health importance and to inform current and future outbreak investigation efforts. NORS data are also made publicly available through the Foodborne Outbreak Online Database (**see Attachment E – Foodborne Outbreak Online Database**). This should enable foodborne disease outbreak investigators, researchers, and health policy makers to evaluate and implement effective measures designed to prevent illness and reduce the burden of foodborne diseases in the United States.

The quality of NORS data is dependent on outbreak investigations conducted by state and local health departments, the usability of the reporting system, and the resources available to each state and local health department to investigate and report outbreaks. CDC epidemiologists conduct annual data quality checks and communicate closely with the states to address any data issues. To maximize the number and the quality of foodborne disease outbreak reports, issues with the reporting system, both technical and non-technical, need to be promptly identified and addressed. Preliminary analysis of the 2009 data showed a large drop in the number of reported foodborne disease outbreaks, from 1034 in 2008 to 681 in 2009, a decrease of almost half of the previous five-year average (**see Attachment F – NORS foodborne outbreak data**). We hypothesize that this may have been caused by 1) technical issues associated with the introduction of the new system, 2) reassignment of types of outbreaks previously reported as foodborne to another mode of transmission, 3) staffing and budgetary issues, especially because of the resources required to respond to the 2009 H1N1 influenza outbreak, or 4) other, unidentified reasons. While the number of outbreaks reported in 2010 and 2011 has increased again, the number of outbreaks reported each year remains below the pre-2009 average. An understanding of how changes to NORS may have impacted foodborne disease outbreak reporting will help the CDC surveillance team to interpret the 2009 surveillance data as well as data from subsequent years, to continue to improve NORS-Foodborne surveillance and reporting, and to draw accurate conclusions about trends in foodborne disease outbreaks and the foods that cause them.

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from Reporting Site Administrator (RSA) who is responsible for entering foodborne disease outbreak data into the NORS at state or local health departments in all states, the District of Columbia, and US territories who report foodborne disease outbreaks, acting in their official capacities.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

Privacy Impact Assessment

Overview of the Data Collection System – The data collection system consists of a SurveyMonkey® web-based questionnaire (**see Attachment G- Survey Instrument -Word version and Attachment H - Survey Instrument – Online version**) designed to survey RSA who is responsible for entering foodborne disease outbreak data into NORS at state or local health departments in all states, the District of Columbia, and US territories who report foodborne disease outbreaks. RSA are foodborne epidemiologists responsible for creating NORS users, reviewing and cleaning foodborne outbreak reports that local users have entered within their respective site. Some RSAs may also be responsible for entering outbreak reports. Each reporting site will have at least one RSA. The survey will ask about foodborne outbreak surveillance and problems with the current reporting system in order to improve foodborne disease outbreak reporting and to understand factors that affect reporting of foodborne disease outbreaks. Examples of questions to be asked include any technical problems experienced while entering the data, and how the mode of transmission for each outbreak is determined.

The SurveyMonkey® instrument was pilot tested by eight public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the survey.

Items of Information to be Collected –

The survey instrument consists of four parts and 33 questions: 1) five general questions about the reporting agency and use of NORS, 2) 17 questions about the NORS interface, 3) six questions that address data quality and completeness of data reported to NORS, and 4) five questions on modes of transmission for reported outbreak. The final question asks for any additional feedback. Five questions have skip patterns. The most common question type is multiple choice with one or multiple answers; four questions involve rating scale and two are text questions. The survey is designed to take approximately 15 minutes to complete.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age –

The data collection system involves using a web-based survey. Respondents will be sent a link directing them to the online survey only (i.e., not a website). No website content will be directed at children.

2. Purpose and Use of the Information Collection

The objectives of the survey are:

- To identify barriers to foodborne disease outbreak surveillance and reporting and ways to improve the reporting system.
- To understand technical problems encountered by NORS users and determine strategy to improve the NORS interface and outbreak reporting
- To identify possible reason(s) for an initial large drop in the number of foodborne disease outbreaks reported in 2009 following the transition to NORS and subsequent fluctuations in the number of foodborne disease outbreaks.

At CDC, the results of the evaluation will be used:

- To improve the NORS program by addressing barriers to food borne disease surveillance and reporting e.g., lack of personnel or funding
- To improve the NORS interface
- To improve the support provided to the NORS users by CDC
- To improve the quality of analysis of NORS data, by understanding factors that affect reporting and identifying reporting gaps
- To update reporting guidance documents

The results of the evaluation will be shared with the participating state and local public health agencies via email/written report and in a webinar. The improvement in the interface and reporting guidance documents would mean that state and local health departments will have enhanced resources for outbreak reporting. The results may also be shared with other CDC groups conducting outbreak surveillance to improve their systems.

Privacy Impact Assessment

Individuals asked to provide information for the survey used in this protocol will be informed of the reason for collecting the information and how the information will be used. Participants will be notified that their participation is voluntary through a written statement attached to the survey. All survey responses will be kept secure and IP addresses will not be collected. Names and identifiers will not be entered into computer records and will not be included in any published materials related to this study.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a SurveyMonkey[®] web-based questionnaire allowing respondents to complete and submit their responses electronically. Web surveys reduce respondent burden by enabling them to easily access the survey and complete it at a convenient time and location. The survey was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 33 survey questions).

4. Efforts to Identify Duplication and Use of Similar Information

NORS was launched in 2009, and this is the first survey to systematically evaluate the reporting through NORS. Therefore, the data collected are unique.

5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection.

The purpose of this survey is to collect data that is not otherwise available. Specifically, without this data there would be:

- Incomplete understanding of limitations and barriers to foodborne disease outbreak reporting, which in turn can impact the analysis and data-driven decision making
- Incomplete understanding of how changes to the surveillance system impact reporting, thus limiting ability to interpret trends in the number of foodborne disease outbreaks
- Incomplete understanding of the IT capacity and infrastructure at state, local and territorial agencies
- No timely feedback regarding usability of the NORS interface and technical assistance to public health agencies.
- Reduced ability to promote NORS to public health agencies

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This data collection is not research involving human subjects.

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the survey instrument by eight of public health professionals. In the pilot test, the average time to complete the survey including time for reviewing instructions, gathering needed information and completing the survey, was approximately 15 minutes. Based on these results, the estimated time range for actual respondents to complete the survey is 10-20 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$30.00 is estimated for all 130 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting Site Administrator (RSA)	130	1	20/60	43	\$30.00	\$1,290
TOTALS	130	1		43		\$1,290

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each survey.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks. Surveys will be prepared by CDC staff (FTE). A senior level FTE will review and approve the activities. The estimated cost to the federal government is \$5,661. Table A-14.1 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Epidemic Intelligence Service Officer (GS-12) Development of instrument, pilot testing, OMB package preparation, data collection, data analysis, report preparation	80	\$37.90	\$3,032
Senior Epidemiologist (GS-14) Review and approve the activities.	20	\$50.00	\$1,000
Surveillance Epidemiologist (GS-11) Development of instrument, pilot testing, OMB package preparation, data collection, control, data analysis, report preparation	50	\$32.58	\$1,629
Estimated Total Cost of Information Collection			\$5,661

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the results of this data collection. The results of the evaluation will be used to improve NORS interface, and technical and analytic support provided to users by CDC, as well as in the internal analysis of NORS data. The results of the evaluation will be shared with the participating state and local public health agencies via email/written report and in a webinar.

Analysis Plan

Data analysis will begin upon completion of data collection. The CDC evaluation team will perform the analysis using SAS 9.3. The analysis will consist of simple descriptive statistics to identify and highlight problems with the current system, and understand reporting patterns. In some cases, chi-square analysis may be conducted to test associations between some variables.

Project Time Schedule

- ✓ Design survey questionnaire.....(COMPLETE)
- ✓ Develop survey protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test survey questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- OMB approval.....(TBD)
- Conduct survey.....(Survey open 5 weeks)
 - Reminder email at two and four weeks
- Collect, code, quality control, and analyze data.....(2 weeks)
- Prepare report.....(2 weeks)
- Disseminate results/publication of findings.....(5 weeks)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

REFERENCES

[1] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, Griffin PM: Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis* 2011, 17:7-15.

[2] Batz MB, Hoffmann S, Morris JG, Jr. Ranking the risks: The 10 pathogen-food combinations with the greatest burden on public health: University of Florida; 2011.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- **Attachment A – Letter from CDC Director on Food Safety**
- **Attachment B – CDC’s Winnable Battle Website on Food Safety**
- **Attachment C – NORS interface screenshot**
- **Attachment D – MMWR Report sample**
- **Attachment E– Screenshot of CDC’s Foodborne Outbreak Online Database**
- **Attachment F – NORS Foodborne outbreak data**
- **Attachment G – Survey Instrument (word version)**
- **Attachment H – Survey Instrument (online version)**