

# **National Outbreak Reporting System**

Request for OMB approval of a New Information Collection

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## **Supporting Statement A**

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- **Goal of the study:** The National Outbreak Reporting System (NORS) is a web-based platform that is used by local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to CDC.
- **Intended use of the resulting data:** CDC analyzes outbreak data to determine trends and develop and refine recommendations for prevention and control of foodborne, waterborne, and enteric disease outbreaks.
- **Methods to be used to collect:** State, local, and territorial health departments in the US submit data on outbreaks to CDC through NORS on an ongoing basis, as the outbreaks occur.
- **The subpopulation to be studied:** All state, local, and territorial health departments in the US can submit data to CDC on waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission, that occur in the United States.
- **How data will be analyzed:** Data are cleaned and aggregated annually and included in surveillance summaries, scientific publications, as well as made publicly available on the NORS Dashboard website.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for the National Outbreak Reporting System (NORS) for 3 years. Data collection through this surveillance system was originally approved as part of OMB Control Number 0920-0004, National Disease Surveillance Program - II, Disease Summaries, and is being moved into a new information collection package to allow for more timely updates to information collection instruments as necessary. Data collection through NORS is being removed from 0920-0004 during its upcoming renewal.

Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service since 1878. Through the years, PHS/CDC has formulated practical methods of disease control through field investigations. The CDC surveillance program is based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. Over the years CDC's mandate has broadened to include preventive health activities thus expanding surveillance systems.

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologists (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. In 1968, at the beginning of this surveillance program, CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health. Surveillance forms are distributed to state and local health department staff who voluntarily submit reports to CDC. Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments must

be able to share data on certain diseases across jurisdictions and to coordinate program activities to prevent and control illness. NORS collects data on all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. Though reporting to NORS is voluntary, NORS serves as the platform by which state, local, and territorial health departments submit data on foodborne and waterborne disease outbreaks, which are nationally notifiable. By analyzing data reported through NORS, CDC can better characterize such outbreaks and develop recommendations for prevention and control. Attachment 6 contains descriptive summaries of the components of NORS. This surveillance program is authorized by Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

## **2. Purpose and Use of Information Collection**

State, local, and territorial epidemiologists are responsible for the collection, interpretation, and transmission of epidemiologic information at the state level. Health departments submit data collected through routine outbreak investigations to CDC, and CDC tabulates, analyzes the data for trends, publishes, and distributes the data both publicly and through analyses within the scientific community. By coordinating nationwide collection of epidemiological data, CDC can determine both national and state-specific estimates and comparisons of foodborne, waterborne, and enteric disease outbreaks.

NORS data are collected electronically, through a password-protected, web-based platform hosted by CDC. Attachment 3 is the data dictionary for the NORS platform. Attachments 4 and 5 are the reference tools for NORS. Attachment 4 references the data elements collected for investigations of all foodborne disease outbreaks, as well as enteric disease outbreaks caused person-to-person transmission, animal contact, environmental contamination, and those that were spread by an unknown mode of transmission. Attachment 5 references the data elements collection for investigations of all waterborne disease outbreaks.

Data collected through NORS are essential for measuring trends in foodborne, waterborne, and enteric disease outbreaks, evaluating the effectiveness of current preventive strategies, and determining the need to modify current preventive measures. Data on outbreaks for which NORS reporting is applicable can be transmitted to CDC at any time. Rapid reporting is encouraged as soon as officials are notified of the outbreak, as this timely reporting is helpful for control of outbreaks, understanding of any pathogen-specific trends, and development of recommendations for prevention. NORS data may thus enable rapid detection and characterization of outbreak-associated pathogens and vehicles of transmission.

As previously indicated in OMB Control No. 0920-0004, the burden for data collected through NORS is estimated at 20 minutes per form or approximately 747 burden hours. There are no costs to the respondents other than their time.

## **3. Use of Improved Information Technology and Burden Reduction**

Historically, use of outbreak data collected by the Foodborne Disease Outbreak Surveillance System and the Waterborne Disease and Outbreak Surveillance System were slowed because of the time required for data entry and analyses once the forms were received. In 1998, CDC introduced electronic reporting of

foodborne outbreak data through the electronic Foodborne Outbreak Reporting System (eFORS). eFORS was a web-based reporting system used by local, county, or state organizations to enter, edit, analyze, and transmit data electronically to other state or federal offices. Beginning in 1998, all foodborne outbreak reports were entered into eFORS. In 2009, this system was phased out in lieu of the National Outbreak Reporting System (NORS). NORS was designed to integrate the outbreak reporting systems and enhance national outbreak reporting by allowing for ongoing reporting of all foodborne and waterborne disease outbreaks, as well as enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. All data are collected electronically through the NORS web-based platform. Attachment 3 is the data dictionary for the NORS platform. Attachments 4 (NORS Foodborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.13) and 5 (NORS Waterborne Disease Transmission, Form 52.12) are the reference tools for NORS; state, local, and territorial health departments may use these forms to assist in gathering information for submission to NORS, however no data are submitted to CDC using paper forms; all data must be submitted electronically. The information requested is the minimum amount required to maintain surveillance for foodborne, waterborne, and enteric disease outbreaks.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The specific variables included in this information collection request are not included in any other nationwide outbreak-specific surveillance system. While similar information may be collected from limited geographic areas or collected in one-time studies, for most outbreaks, sampling would not be sufficient for state prevention and control programs. NORS collects outbreak data from all U.S. states and territories in a uniform manner.

#### **5. Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses or other small entities.

#### **6. Consequences of Collecting the Information Less Frequently**

Outbreak reporting varies to the extent that pathogens differ in occurrence, modes of transmission, infectious agents, patient's susceptibility and resistance, control of patient's contacts and the immediate environment, and epidemiologic measures. The first step in the control of a given outbreak is its rapid identification followed by notification to the local health authority. Prompt notification to CDC allows for further identification of any larger-scale outbreaks as well as any potential increase in pathogen prevalence during a given time period, so that prevention and control measures can be taken. Outbreaks caused by various pathogens are reported with varying frequency to CDC as they occur. Since NORS was established in 2009, approximately 2,000–4,500 outbreaks have been reported to CDC each year.

There are no legal obstacles to reduce the burden.

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

As described in section A.6, in order to permit rapid response to outbreaks and timely initiation of prevention and control measures, health departments are encouraged to report outbreak data to CDC as soon as possible after identification of the outbreak. As outbreaks may occur at any time, reporting may occur more or less frequently than once per quarter and outbreak investigations may take several weeks to months to finalize. Given this, reports may be entered into NORS and/or edited at any time in order to allow for all available information to be reported to CDC, and delays in reporting could potentially result in serious public health consequences. There are no other special circumstances. This request fully complies with regulation 5 CFR 1320.5 with the exception to quarterly reporting.

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

- A. A 60-day Federal Register Notice was published in the Federal Register on February 25, 2020 vol. 85, No. 37, pp. 10691 (Attachment 2). CDC received two non-substantive comments (Attachments 2a and 2c) and one substantive comment (Attachment 2b) and replied with a standard CDC response.
- B. The Council of State and Territorial Epidemiologists (CSTE) are routinely consulted regarding the availability of data, the frequency of collection, and the revisions of any forms. CDC has collaborated with CSTE since CSTE's inception in 1951, and it is through the CSTE annual conference that the cooperation of all states is maintained. Although formal CSTE meetings are usually held only once a year, communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis throughout the year. Jeff Engel is the Executive Director ([jengel@cste.org](mailto:jengel@cste.org)) of CSTE.

## **9. Explanation of Any Payment or Gift to Respondents**

There are no payments or gifts to respondents.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The NCIRD Information Systems Security Officer reviewed this submission and determined that it is not applicable to the Privacy Act because the information is not retrieved by personal identifiers. PII related to outbreak surveillance is not submitted to CDC. Non-personally identifiable data relating to foodborne, person-to-person, animal contact, environmental, unknown, and waterborne outbreaks are submitted in aggregate to CDC via NORS. The NORS platform is housed in a secure system; only those users with password-protected accounts may access and/or enter NORS data.

Records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to use the records. Any paper or computer files are stored according to state and local health department privacy standards; paper files are not submitted to CDC.

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

Institutional Review Board (IRB)

IRB Approval

A CDC human subjects advisor has determined that the activities in 0920-0004, including the National Outbreak Reporting System (Attachments 3, 4, 5) are considered routine public health surveillance activities. Consistent with current CDC policy, routine surveillance activities do not meet the regulatory definition of research and are therefore outside the scope of IRB review requirements.

Sensitive Questions

Epidemiologic characteristics such as age, sex, and geographic location, as well as clinical laboratory data are routinely collected because of their significance in resolving public health problems. All outbreak data are collected in aggregate, and only the minimum data necessary for public health surveillance are collected.

**12. Estimates of Annualized Burden Hours and Costs**

A. Estimated Annualized Burden Hours

State, local, and territorial epidemiologists report data to CDC through NORS. The burden estimate for the NORS form, represented below, is 747 burden hours, based on an average response burden of 20 minutes per form. The frequency of response for the NORS form will vary depending on the pathogen and surveillance need but was estimated based on completion of the form for each mode of transmission at least three times. The average of each mode was weighed, based on the reporting frequency of each mode for the past three years. Attachments 4 and 5 are reference tools for attachment 3.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Epidemiologist	Attachment 3_National Outbreak Reporting System, Data Dictionary	59	38	20/60	747
	Attachment 4_ NORS Foodborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.13				
	Attachment 5_NORS Waterborne Disease Transmission, Form 52.12				
<b>Total</b>					747

B. Estimated Annualized Burden Costs

The proposed estimated annual cost for the NORS form is \$25,017.03. This is based on the 2018 median pay of \$33.49 for an epidemiologist, as indicated on the Bureau of Labor Statistics website (see

<https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>). Attachments 4 and 5 are reference tools for attachment 3 and reflect \$0 cost burden.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Epidemiologist	Attachment 3_National Outbreak Reporting System, Data Dictionary  Attachment 4_ NORS Foodborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.13  Attachment 5_ NORS Waterborne Disease Transmission, Form 52.12	59	38	20/60	747	\$33.49	\$25,017.03
Total							\$25,017.03

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

There are no capital and maintenance costs incurred by respondents other than their time to participate.

### 14. Annualized Cost to the Government



Outbreak reports submitted to CDC result in action taken by multiple programs in response to the required CDC mandate to maintain preventive health activities and surveillance systems. Actions taken in response to each report will vary, depending on the specifics of the outbreak. NORS activities (attachment 3, which encompasses activities in attachments 4 and 5) cost an estimated \$1,285,000.00. The foodborne and waterborne estimates include \$900,000.00 for personnel across two CIOs (NCIRD and NCEZID) and \$350,000.00 for Information Technology. The overall incurred costs include staff support, NORS platform maintenance, computer resources, and some printing and miscellaneous expense such as phone calls.

### **15. Explanation for Program Changes or Adjustments**

This is a request to move the NORS information collection instrument that was formerly approved as part of OMB Control No. 0920-0004 into its own information collection package. A revision to the collection instrument was last approved on 10/12/2017. The collection activities as previously approved in 0920-0004 remain the same, however, there are minor revisions including form consolidation, minor revised language, and rewording to improve clarity and readability of the data collection forms. Attachment 4, NORS Foodborne Disease Transmission, Person to Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode (CDC 52.13) and Attachment 5, NORS Waterborne Disease Transmission Form (CDC 52.12) are reference tools for Attachment 3, which is the data dictionary for NORS, and reflects the data collected in the web-based platform.

### **16. Plans for Tabulation and Publication and Project Time Schedule**

NORS data are collected on an ongoing basis and undergo a rigorous cleaning process with state submitters approximately once a year, per mode of transmission. Cleaned data are published periodically in surveillance summaries, as part of MMWR, and included in various program specific analyses. In addition, a subset of cleaned data are made available annually on the NORS Dashboard (<https://wwwn.cdc.gov/norsdashboard/>); larger datasets are available to the public upon request to CDC.

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

NORS data are collected through a web-based platform, for which Attachment 3 is the data dictionary, and Attachments 4 and 5 are the reference tools. Since Attachments 3, 4, and 5 were first approved as part of 0920-0004, minor modifications have been made to the information collection instrument. Because of their long period of use, printed paper forms are still in use at some health departments. No data are submitted to CDC using the paper forms; all data must be submitted electronically. As such, permission is requested to exclude the expiration date from the NORS forms.

### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

### **Attachments**

1. Authorizing legislation - Section 301 of the Public Health Service Act (42 USC 241)

2. Published 60-day FRN
  - a. Public Comment 1 (non-substantive)
  - b. Public Comment 2 (substantive)
  - c. Public Comment 3 (non-substantive)
3. Information Collection Instrument, Data dictionary for the National Outbreak Reporting System
4. Reference tool, NORS Foodborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.13
5. Reference tool, NORS Waterborne Disease Transmission, Form 52.12
6. Descriptive summaries for activities included in the National Outbreak Reporting System