

**NATIONAL DISEASE SURVEILLANCE PROGRAM - II.
DISEASE SUMMARIES**

OMB 0920-0004

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Supporting Statement B

OMB 0920-0004 — Foodborne, Person-to-Person, Animal Contact, Environmental, and Unknown Outbreaks

1. Respondent Universe and Sampling Methods

The surveillance report forms and instructions are available to all states and territories of the United States. State and local health department staff submit these reports to CDC on an ongoing basis using the National Outbreak Reporting System (NORS). Participation in NORS is voluntary; however, NORS provides the mechanism for reporting nationally notifiable foodborne outbreaks. State and territorial public health departments that choose to participate in NORS will be responsible for the collection, interpretation, and transmission of NORS data elements by logging into a password-protected, web-based reporting system. CDC publishes an annual report, providing the states with yearly aggregates of their submissions. This is a nationally-available system, so no sample selection is required.

2. Procedures for Collection of Information

NORS Foodborne, person-to-person, animal contact, environmental, and unknown mode of transmission outbreak data will be collected electronically from participating state and territorial health departments. Paper forms will not be collected by CDC. NORS uses a password-protected, web-based surveillance platform hosted at CDC (ITSO/AHB) that is designed to support reporting to CDC from state and territorial public health departments. NORS is a shared access point that collects information for foodborne, person-to-person, animal contact, environmental, and unknown mode of transmission outbreak data, as well as data on waterborne disease outbreaks (see section on “Waterborne Disease Outbreaks,” below). The data collected in NORS does not include personally identifiable information. Respondents submit information such as the reporting date of the outbreak, the dates of exposure, and etiology.

3. Methods to Maximize Response Rates and Deal with Non-response

Foodborne, person-to-person, animal contact, environmental, and unknown mode of transmission outbreak data are collected as passive surveillance with voluntary participation from state and territorial public health departments. These data are available to all participating states and territories through the web-based reporting platform. State agencies are able to submit, review, and edit data in an ongoing basis, thus encouraging timely data submission to NORS. Foodborne and waterborne outbreaks are nationally notifiable and are reported to CDC through NORS.

4. Test of Procedures or Methods to be Undertaken

This is a revision of a previously approved data collection; only minor changes to the data collection instrument were made. No other test of procedures was performed.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

State and territorial public health departments that collect NORS data elements may voluntarily report those data to NORS. CDC will consult on statistical aspects of NORS analyses and seek input from internal statisticians as needed on projects involving NORS data. Individual states and territories will have access to NORS data in accordance with established data-use guidelines and user permissions.

OMB 0920-0004 -- Calicivirus

- 1. Respondent Universe and Sampling Methods** – CaliciNet is a national network of public health laboratories that contribute to a database of genetic sequences from noroviruses identified in outbreaks. As more states participate, CaliciNet may find links to help identify multistate outbreaks, detect potential norovirus-contaminated food before preparation and serving, and identify the emergence of new norovirus strains. This network compares norovirus sequences to

be able to rapidly link norovirus outbreaks with a common food source as well as to identify emerging norovirus strains. CaliciNet went live in March 2009 and currently has 24 states certified for participation.

- 2. Procedures for Collection of Information** – Certified participants gain access to CaliciNet via a two-part process: 1. CDC access via a secure CDC website using an assigned key fob and 2. Server access with an assigned user login and password. Participants upload on a monthly basis (biweekly during September – May). Electronic uploading allows immediate processing and analysis of national trends and allows for data correction by participating centers. The data collected in this surveillance system contain unique specimen identifiers that allow for tracking at the outbreak level, not specimen level. No person identifiable data are collected. The respondents submit molecular results and genotype data on specimens positive for norovirus. Once entry is complete, the data are stored on a secure SQL server, accessible only by the CaliciNet information Technology staff and the database administrator.
- 3. Methods to Maximize Response Rates and Deal with Non-response** – There are currently 24 laboratories participating in CaliciNet. CaliciNet is a passive surveillance system and participation is voluntary. Approximately 30% of laboratories report in a timely manner every two weeks during the high norovirus season, based on which genotype trends can be estimated. The remaining 70% labs report the information late, and this information is incorporated into later summaries of the data. CaliciNet actively encourages participating laboratories to increase uploads during the norovirus season, but norovirus season also coincides with influenza season testing of which has priority over norovirus in most of the participating laboratories.
- 4. Test of Procedures or Methods to be Undertaken** - Participating laboratories report nucleic acid detection and genotyping results for norovirus.
- 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data** - The following individuals are involved in analysis and management of the data:

- CaliciNet Administrator: experienced, bachelor-level microbiologist, manages data, performs quality assurance, analyzes on weekly basis
- CaliciNet Team Lead: available for consultation on more complex analysis of data
- State Public Health Laboratories: manages data entry

OMB 0920-0004 — Enterovirus

1. **Respondent Universe and Sampling Methods** – The National Enterovirus Surveillance System (NESS) is a laboratory-based system that monitors temporal and geographic patterns in the occurrence of enteroviruses and human parechoviruses. Data are collected from state public health laboratories and commercial laboratories.
2. **Procedures for Collection of Information-** In order to submit reports electronically to NESS, each laboratory is required to register via the SAMS Public Health Partner Portal. Information may also be submitted via e-mail by sending a formatted Excel spreadsheet to the NESS coordinator. Laboratories are encouraged to report enterovirus detections by serotype, specimen type, collection date, age of patient, and sex of patient to CDC monthly. Electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating laboratories. The data collected are of individual line listings, but no identifiers or distinguishable personal-level data are included in this surveillance system. Once entry is complete, the data are housed on a secure SQL server, accessible only by the Office of Informatics technical developer and the NESS coordinator.
3. **Methods to Maximize Response Rates and Deal with Non-response** – There are currently approximately 10-20 labs participating in NESS. NESS is a passive surveillance system and participation is voluntary. Participating laboratories are encouraged to report enterovirus and parechoviruses detections to CDC monthly. Most laboratories do not respond on a monthly basis but more on a quarterly basis since there are only a few detections to report each month, if any. NESS could be improved with more regular reporting by current laboratories and by increasing

the number of participating laboratories. Non-response is not a significant issue with NESS; however, summary reports are usually published every two years giving laboratories enough time to submit data.

4. **Test of Procedures or Methods to be Undertaken** - Laboratories are encouraged to report enterovirus detections by serotype and specimen type.

5. **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing**

Data - The following individuals are involved in analysis and management of the data:

NESS coordinator: masters-level epidemiologist, manages data, analyzes on weekly basis

Backup coordinator: experienced, masters-level epidemiologist who assists with coordination

Branch statistical team: masters- or doctoral-level statisticians available for consultation on more complex analysis of data

Agency informatics staff: manage data entry and storage system

OMB 0920-0004 -- Respiratory and Enteric Viruses

1. **Respondent Universe and Sampling Methods** – The National Respiratory and Enteric Virus Surveillance System (NREVSS) is a laboratory-based system that monitors temporal and geographic patterns in the occurrence of several respiratory and enteric viruses, including respiratory syncytial virus (RSV), human parainfluenza viruses (HPIV), human metapneumovirus, respiratory and enteric adenoviruses, human coronaviruses and rotavirus. Data are collected from collaborating university and community hospital laboratories, selected state and county public health laboratories, military laboratories, and commercial laboratories. These participating laboratories report virus antigen detections, isolations and electron microscopy results on a weekly basis.

The National Adenovirus Type Reporting System (NATRS) is a laboratory-based system that monitors temporal and geographic patterns in the occurrence of human adenoviruses. Data are collected from state public health, academic, military, hospital, and commercial laboratories.

The Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form and instructions are distributed to all states and territories in the United States. States, select local health departments, and less frequently, healthcare facility staff submit these reports to CDC when investigating a patient for possible MERS-CoV infection.

The newly created Suspect Respiratory Virus Patient form will be used by health departments and health care facilities to provide epidemiologic and clinical information when they submit a specimen to a CDC lab for testing in situations where they suspect an unusual cluster and/or potential outbreak of a respiratory virus. The information provided will be used to help characterize the reported clusters and to assess the likelihood of an outbreak.

2. Procedures for Collection of Information -

Reporting for NREVSS is conducted weekly using a secure CDC website. Electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating centers. The weekly reports collected via NREVSS are analyzed by CDC staff and the results are immediately updated on a public CDC website. The data collected are in aggregate form and no identifiers are included in this surveillance system. The respondents only submit the total number of tests performed for each virus and the total number of positive results. No person-level data is collected. Once entry is complete, the data are housed on a secure SQL server, accessible only by the Office of Informatics technical developer and the NREVSS coordinator. Graphs are updated weekly on the CDC's public website for NREVSS. In addition, MMWR reports of viral activity are published each year for RSV, and occasionally for other viruses included in the surveillance system. Reports are also periodically published in peer-reviewed journals.

Adenovirus typing information submitted via email by sending a formatted Excel spreadsheet to the surveillance coordinator. Laboratories report patient-level adenovirus detections by type, with limited laboratory, demographic, and clinical information including specimen type, collection date, age of patient, and sex of patient to CDC on a quarterly basis. The data collected are of individual line listings, but no identifiers or distinguishable personal-level data are included in this surveillance. Once entry is complete, the data is housed in a secure Access database accessible only by the Office of Informatics technical developer and the surveillance coordinator.

The MERS-CoV PUI short form and investigation procedures are a collaborative effort between CDC and its partners in state, local, and territorial health departments. Modifications to the form and procedures are done in collaboration with the Council of State and Territorial Epidemiologists (CSTE). The short form is used to collect limited demographic, clinical, laboratory, and exposure information/travel history for patients meeting the PUI case definition and for whom MERS-CoV testing using the CDC-developed assay is conducted. The data collected are housed in a secure SQL database which is also available via online portal for participants to enter data directly, accessible only by the Office of Informatics technical developer and the surveillance coordinator.

The new Suspect Respiratory Virus Patient Form will be requested from health departments and clinical sites when submitting specimens to the CDC lab for viral pathogen identification. The data will be entered into the report form and either included in the package that is mailed to the appropriate laboratory along with specimens submitted for testing or faxed or emailed separately to a subject matter expert in the Division of Viral Diseases.

3. Methods to Maximize Response Rates and Deal with Non-response-

There are currently approximately 550 labs participating in NREVSS, though not all laboratories submit results for all the listed pathogens or all the test methods. NREVSS is a passive surveillance system and participation is voluntary. Nonetheless, approximately 85% of laboratories report in a

timely manner each week during the high respiratory season, which allows an accurate determination of trends. In addition, many of the 15% of the other labs report the information late, and this information is incorporated in later summaries of the data. So non-response is not a significant issue with NREVSS.

There are currently 13 labs participating in the National Adenovirus Type Reporting System (NATRS). It is a passive laboratory-based surveillance system with voluntary participation. Participating laboratories are asked to report type specific adenovirus detections to CDC on a quarterly basis. Non-response is not a significant issue with this surveillance.

The MERS-CoV PUI form is completed in conjunction with CDC's consultation with state, local, and territorial health departments evaluating individuals for potential MERS-CoV infection.

Reporting of a MERS-CoV PUI is strongly encouraged for laboratories using the CDC MERS-CoV testing assay. Many partners in state, local, and territorial health departments submit short forms as part of their job to perform a public health service. If follow up is necessary, a Division of Viral Diseases staff member will contact the appropriate public health partner.

Submission of the Suspect Respiratory Virus Patient Form will be completely voluntary.

Provision of such information in some form would be deemed very beneficial when a public health jurisdiction requests CDC consultation regarding a potential cluster of illnesses of particular concern for more public health in general.

4. Test of Procedures or Methods to be Undertaken-

Participating NREVSS laboratories report testing and detection results for virus antigen, nucleic acid amplification, and viral isolations for the pathogens under surveillance. These results are reported in aggregate (i.e., the number of tests performed and the number of tests positive in the prior week).

Laboratories participating in NATRS are asked to report detections by adenovirus type and specimen type by typing method, with limited demographic and clinical information, on the patient level. Laboratories can report multiple types detected in individual patients.

Due to emergence of MERS-CoV in 2012, the MERS-CoV PUI was created to augment domestic preparedness for a newly identified pathogen that has had several imported cases identified in the United States. The short form collects limited demographic and clinical information, exposure and travel history, and concomitant respiratory viral pathogen testing results.

The Suspect Respiratory Virus Patient Form was based upon forms that have been used for outbreak responses in the past. It is designed to collect information that may be useful and relevant for respiratory outbreak investigations of unknown origin in a standardized format.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data -

The following individuals are involved in analysis and management of the data:

- NREVSS coordinator: masters-level epidemiologist, manages data, analyzes on weekly basis
- Backup coordinator: experienced, masters-level epidemiologist who assists with coordination
- National Adenovirus Type Reporting System coordinator: masters-level epidemiologist, manages data, analyzes on a monthly basis
- National Enterovirus Surveillance System coordinator: masters-level epidemiologist, manages data, analyzes on a monthly basis
- MERS-CoV coordinator: masters-level epidemiologist, manages data, analyzes on a regular basis.
- Subject matter experts in the Respiratory and Picornavirus Team, including in particular medical epidemiologists and masters-level surveillance coordinators, routinely assess reports regarding potential clusters of unusual illness and respond to public and health department inquiries.
- Branch statistical team: available for consultation on more complex analysis of data
- Agency informatics staff: manage data entry and storage system

OMB 0920-0004 -- Waterborne Disease Outbreaks

1. Respondent Universe and Sampling Methods - The surveillance report forms and instructions are available to all states and territories of the United States. State and local health department staff submit these data to CDC on an ongoing basis using the National Outbreak Reporting System (NORS). Participation in NORS is voluntary. NORS provides the mechanism for reporting nationally notifiable waterborne disease outbreaks. State and territorial public health departments that choose to participate in NORS will be responsible for the collection, interpretation, and transmission of NORS data elements by logging into a password-protected, web-based reporting system. CDC publishes two-year reports of these data in the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with aggregates of their submissions. This is a nationally-available system, so no sample selection is required.

2. Procedures for Collection of Information - Since 2009, waterborne disease outbreaks have been reported to CDC through the National Outbreak Reporting System (NORS). Primary contacts for reporting to NORS are at the state and territory level. At the request of current state or territorial contacts, CDC may also contact local public health staff regarding data collection. Waterborne disease outbreak data will be collected electronically from participating state and territorial health departments. Paper forms will not be collected by CDC. NORS uses a password-protected, web-based surveillance platform hosted at CDC (ITSO/AHB) that is designed to support reporting to CDC from state and territorial public health departments. NORS is a shared access point that collects information for waterborne disease outbreaks, as well as foodborne, person-to-person, animal contact, environmental, and unknown mode of transmission outbreaks (see section on “Foodborne, Person-to-Person, Animal Contact, Environmental, and Unknown Outbreaks”, above) The data collected in NORS does not include personally identifiable information. Respondents submit information such as the reporting date of the outbreak, the dates of exposure, and outbreak etiology.

3. Methods to Maximize Response Rates and Deal with Non-response - Waterborne disease outbreak data are collected as passive surveillance with voluntary participation from state and territorial public health departments. These data are available to all participating states and

territories through NORS. State agencies are able to submit, review, and edit data in an ongoing basis, thus encouraging timely data submission to NORS. Since 1990, waterborne outbreaks have been nationally notifiable and are reported to CDC through NORS.

4. Test of Procedures or Methods to be Undertaken- No test of procedures has been performed.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data - State and territorial public health departments that collect NORS data elements may voluntarily report those data to NORS. CDC will consult on statistical aspects of NORS analyses and seek input from internal statisticians as needed on projects involving NORS data. Individual states and territories will have access to NORS data in accordance with established data-use guidelines and user permissions

OMB 0920-0004 – Influenza

1. Respondent Universe and Sampling Methods - The influenza surveillance forms and instructions are distributed to all states and territories in the United States. State, territorial, and select local health department staff, volunteer healthcare providers, laboratories, and other appropriate public health partners submit these reports to CDC on a weekly basis. Statistical calculations are made on all influenza surveillance data collected through the U.S. influenza surveillance system. Data is published in a weekly influenza surveillance report (FluView) and FluView Interactive throughout the year, in periodic *Morbidity and Mortality Weekly Report (MMWR)* influenza activity summaries, and peer-reviewed articles.

2. Procedures for Collection of Information - The Influenza Division at CDC collects, compiles and analyzes information on influenza activity each week in the United States and produces FluView, a weekly influenza surveillance report, and FluView Interactive, which allows for more in-depth exploration of influenza surveillance data, year-round. The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in state, local, and territorial health departments, public health and clinical laboratories, healthcare providers, clinics, and emergency departments. Any modifications to surveillance systems or reporting methods are done in collaboration with the Council of State and Territorial Epidemiologists (CSTE).

3. Methods to Maximize Response Rates and Deal with Non-response-

Reporting of weekly surveillance reports is done on a voluntary basis. Many partners in state, local, and territorial health departments, volunteer healthcare providers, public health and clinical laboratories and other appropriate public health partners submit surveillance forms as part of their job to perform a public health service. If follow up is necessary, an Influenza Division staff member will contact the appropriate public health partner.

4. Test of Procedures or Methods to be Undertaken - This is a renewal of a previously approved data collection. There are no modifications made to five surveillance forms, minor revisions were done to six surveillance forms, and seven forms were removed. The modifications were necessary to reflect enhanced data collection. No other test of procedures has been performed.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing

Data - It is the responsibility of the Influenza Division/Epidemiology and Prevention Branch staff to compile, manage, and analyze data collected through the U.S. influenza surveillance system