NATIONAL DISEASE SURVEILLANCE PROGRAM - II.
DISEASE SUMMARIES

OMB 0920-0004

Revision
July 23, 2014

Point of Contact:
Candice KJ Swartwood
chj8@cdc.gov
(404) 639-8897
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases
1600 Clifton Road, NE, Mailstop D76
Atlanta, GA 30333

Supporting Statement B

OMB 0920-0004 –- Foodborne Outbreaks

1. **Respondent Universe and Sampling Methods -** No sample selection is involved in this surveillance study. The surveillance report forms and instructions are distributed to all States and Territories of the United States. State and local health department staff submits these reports to CDC on variable frequencies ---- weekly, monthly, or quarterly. In certain circumstances, such as outbreak situations, reports are first made by telephone, and then followed by a written report. CDC then calculates and publishes weekly statistics via the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with timely aggregates of their submissions.

2. **Procedures for Collection of Information -**Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. 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.

3. **Methods to Maximize Response Rates and Deal with Non-response-** There is not a method to deal with non-response as the state public health laboratories submit the disease surveillance forms as a part of their job to perform a public health service.

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 instruments have been made. No other test of procedures has been performed.

5. **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data -** The Biostatistics and Information Management Branch, Division of Foodborne, Waterborne, and Environmental Diseases.

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 adminstrator.

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, and commercial laboratories. These participating laboratories report virus antigen detections, isolations and electron microscopy results on a weekly basis.

Adenovirus Typing Surveillance is a laboratory-based system that monitors temporal and geographic patterns in the occurrence of human adenoviruses. Data are collected from state public health laboratories and commercial laboratories.

The Middle East Respiratory Coronavirus Patient Under Investigation (MERS-CoV PUI) form and instructions are distributed to all states and territories in the United States. States and select local health department staff submit these reports to CDC when investigation a patient under investigation for possible MERS-CoV infection.

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 will be submitted via fax or email by sending a formatted Excel spreadsheet to the surveillance coordinator. Laboratories will report adenovirus detections by type, specimen type, collection date, age of patient, and sex of patient to CDC monthly. 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 will be housed on a secure Access or SQL server, accessible only by the Office of Informatics technical developer and the surveillance coordinator.
The MERS-CoV surveillance system is a collaborative effort between CDC and its partners in state, local, and territorial health departments. Modifications to the surveillance system are done in collaboration with the Council of State and Territorial Epidemiologists (CSTE).

3. **Methods to Maximize Response Rates and Deal with Non-response-** There are currently approximately 300 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.

It is estimated that approximately 10-20 labs will eventually participate in Adenovirus Typing Surveillance. It is being designed as a passive surveillance system with voluntary participation. Participating laboratories will be asked to report type specific adenovirus detections to CDC monthly or on a quarterly basis when there are only a few detections to report each month. Non-response is unlikely to be 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 a requirement for laboratories using the CDC MERS-CoV testing assay. Many partners in state, local, and territorial health departments submit surveillance 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.

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). In addition, an assessment of laboratory testing and reporting practices will be conducted up to one time per year per participant. This assessment is typically conducted over the telephone, but responses may also be written and returned by fax or e-mail when the participant is not available to respond by telephone.

Laboratories participating in adenovirus typing surveillance are asked to report detections by adenovirus type and specimen type.

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 yet to be identified in the United States.

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

Adenovirus Typing coordinator: masters-level epidemiologist, manages data, analyzes on a monthly basis

MERS-CoV coordinator: masters-level epidemiologist, manages data, analyzes on a regular basis.

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 - No sample selection is involved in waterborne disease outbreak reporting. The surveillance report forms and instructions are distributed to all States and Territories of the United States. State and territorial health department staff submits these reports to CDC on variable frequencies ---- weekly, monthly, or quarterly. For some waterborne disease outbreaks, reports are first made by telephone, and

then followed by a written report. CDC calculates and publishes biennial surveillance summaries via the Morbidity and Mortality Weekly Report (MMWR), providing the states with aggregates of their submissions.

2. Procedures for Collection of Information - Data on waterborne disease outbreaks are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. Beginning in 2009, waterborne disease outbreaks are reported to CDC through the National Outbreak Reporting System (NORS). Primary contacts for CDC 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.

3. **Methods to Maximize Response Rates and Deal with Non-response -** There is not a method to deal with non-response as state and territorial public health departments submit waterborne disease outbreak reports as a part of their job to perform a public health service.

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 - The Biostatistics and Information Management Branch, Division of Foodborne, Waterborne, and Environmental Diseases, CDC.

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. States and select local health department staff, volunteer healthcare providers, laboratories, vital statistics registrars, 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) 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 year round in the United States and produces FluView, a weekly influenza surveillance report, 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, vital statistics offices, 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, laboratories, vital statistics registrars, 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 six surveillance forms, minor revisions were done to eight surveillance forms, and two forms are new. 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.