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

**OMB 0920-0004**

Revision with Minimal Modification
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Supporting Statement B

**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 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, who assists with coordination, data entry, and analyzes data on a monthly basis

   Data Manager: manages data and performs quality assurance

   NESS team: masters- or doctoral-level epidemiologists available for consultation on more complex analysis of data

   Agency informatics staff: manage system access 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, rhinovirus, enterovirus, human

coronaviruses, severe acute respiratory syndrome coronavirus 2, norovirus and rotavirus. Data are collected from collaborating university and community hospital laboratories, select state and county public health laboratories, military laboratories, and commercial laboratories. These participating laboratories report results from three diagnostic categories: antigen, virus isolations and polymerase chain reaction 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 complete these forms and submit to jurisdictional state health departments. State health departments may share these forms with CDC if/when they reach out for consultation or in any situation where PUIs become lab-confirmed MERS-CoV cases. These forms may be used more broadly for public health responses should there ever be a US case of lab-confirmed MERS-CoV (e.g. for contact tracing and/or outbreak investigations).

The 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. A public-facing dashboard is 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.

For NATRS, adenovirus typing information is submitted through either the Public Health Laboratory Interoperability Project or 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 currently no longer shared systematically with CDC. This would change should

there ever be a US patient with lab-confirmed MERS-CoV. If this occurred, this form would be used to support subsequent public health response (e.g. contact tracing and outbreak response). 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 (labeled as PCR), 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 Coronavirus and Other Respiratory Viruses Division, 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 – Influenza Virus**

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 seven surveillance forms, minor revisions were done to three surveillance forms, and one forms was removed and one form was added. 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

**OMB 0920-0004 – Pediatric Hepatitis of Unknown Etiology**

1. **Respondent Universe and Sampling Methods -** Forms for surveillance for pediatric acute hepatitis of unknown etiology and instructions are distributed to all states and territories in the United States. State, territorial, and select local health department staff submit the forms to CDC on a rolling basis as persons under investigation (PUIs) for pediatric hepatitis of unknown etiology are identified by jurisdictions. Respondents acting in their official capacities include public health officials from state, territorial, and select local health departments, who will work with clinicians, infection preventionists, and other hospital staff to complete the standardized data collection instrument. Participation in surveillance of pediatric hepatitis of unknown etiology is

voluntary. This is a nationally available surveillance system, so no sampling or site selection is required.

2. **Procedures for Collection of Information** - Surveillance for pediatric hepatitis of unknown etiology is a collaborative effort between CDC and partners at state, local, and territorial health departments, public health and clinical laboratories, and healthcare providers. Forms will be completed on PUIs for pediatric hepatitis of unknown etiology and transmitted to CDC via secure ShareFile, after which data will be entered by CDC staff into an established REDCap database. ShareFile is a file sharing and uploading service for CDC staff to securely share files and folders with each other and external partners. Alternatively, jurisdiction public health officials may enter data directly into the REDCap database should they choose to do so.

3. **Methods to Maximize Response Rates and Deal with Non-response -** Surveillance for pediatric hepatitis of unknown etiology is voluntary. State and territorial health departments are reminded at monthly calls between public health officials and CDC about the importance of participation in this surveillance system. As of 21 October 2024, 47 jurisdictions reported at least one PUI to CDC.

4. **Test of Procedures or Methods to be Undertaken -** This data collection is a continuation of the initial investigation into PUIs for pediatric hepatitis of unknown etiology that began in April 2022 under Emergency Epidemic Investigations (EEI) Generic ICR (OMB No. 0920-1011). The information collection instruments are based on the data collection instruments utilized for the initial emergency response investigation but have been refined over time with feedback from jurisdictions and to address evolving investigation and data collection needs. 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 Viral Gastroenteritis Branch staff at CDC to compile, manage, and analyze data collected through the surveillance of pediatric hepatitis of unknown etiology.

CDC will consult on statistical aspects of analyses and seek input from internal statisticians as needed on projects involving data from the surveillance of pediatric hepatitis of unknown etiology.

**OMB 0920-0004 –** Arthropod-Borne Diseases (Non-Human Data)

1. **Respondent Universe and Sampling Methods-** ArboNET is a passive electronic surveillance system administered by CDC's Division of Vector-Borne Diseases in Fort Collins, Colorado. Respondents include state, local or territorial health departments.
2. **Procedures for Collection of Information-** ArboNET involves 100% electronic reporting of non-human arbovirus surveillance data, with no paper forms. Jurisdictions transmit data to ArboNET using one or more of three standardized methods developed and supported by the Division of Vector-Borne Diseases. Jurisdictions that already have an electronic surveillance system can upload multiple records from their system using an Extensible Markup Language (XML) message; jurisdictions without an electronic surveillance system can upload multiple records from a Microsoft Access database using an XML message; or any jurisdiction may enter records manually using a Web-based form
3. **Methods to Maximize Response Rates and Deal with Non-response-** Since ArboNET is a passive surveillance system, no specific measures are taken to maximize response rates and/or deal with non-response. Participation in this enhanced surveillance is voluntary because not all states routinely collect these data. A voluntary system allows states collecting data a mechanism to report them while not requiring states that have not been routinely collecting such data to report. Data reported to ArboNET are received and analyzed by the Division of Vector-Borne Diseases in Fort Collins, Colorado. Division statisticians are available for support as needed.
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**

Division of Vector-Borne Disease statisticians are available for support analysis of ArboNET data, as needed.