

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

OMB 0920-0004

Reinstatement with Change

January 2023

Point of Contact:
Lazenia Harris, DHSc, MPH
CDR, U.S. Public Health Service
Deputy Associate Director for Epidemiologic Science
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases
1600 Clifton Road, NE, Mailstop D76
Atlanta, GA 30333

National Disease Surveillance Program- II. Disease Summaries
OMB 0920-0004- Request for Reinstatement with Change

Table of Contents

- A. Justification**
 - 1. Circumstances Making the Collection of Information Necessary**
 - 2. Purpose and Use of Information Collection**
 - 3. Use of Improved Information Technology and Burden Reduction**
 - 4. Efforts to Identify Duplication and Use of Similar Information**
 - 5. Impact on Small Businesses or Other Small Entities**
 - 6. Consequences of Collecting the Information Less Frequently**
 - 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**
 - 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**
 - 9. Explanation of Any Payment or Gift to Respondents**
 - 10. Protection of the Privacy and Confidentiality of Information Provided to Respondents**
 - 11. Institutional Review Board (IRB) and Justification for Sensitive Questions**
 - 12. Estimates of Annualized Burden Hours and Costs**
 - 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**
 - 14. Annualized Cost to the Government**
 - 15. Explanation for Program Changes or Adjustments**
 - 16. Plans for Tabulation and Publication and Project Time Schedule**
 - 17. Reason(s) Display of OMB Expiration Date is Inappropriate**
 - 18. Exceptions to Certification for Paperwork Reduction Act Submissions**

List of Attachments

Attachment A, Authorizing Legislation: Section 301 of the Public Health Service Act (42 USC 241)
Attachment B, 60 Day Federal Register Notice
Attachment C, Disease Summaries
Attachment E, WHO Collaborating Center for Influenza - Influenza Virus Surveillance (CDC 55.31)
Attachment F, U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment
Attachment H, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder (CDC 55.20E)
Attachment J, Influenza-Associated Pediatric Mortality Case Report Form
Attachment K, Human Infection with Novel Influenza A Virus Case Report Form
Attachment M, Human Infection with Novel Influenza A Virus Severe Outcomes
Attachment P, Novel Influenza A Virus Case Screening Form
Attachment T, Antiviral Resistant Influenza Infection Case Report Form
Attachment U1, NREVSS Antigen Detection Worksheet (CDC 55.83A) (electronic)
Attachment U2, NREVSS Virus Isolation (Culture) Worksheet (CDC 55.83B) (electronic)
Attachment U3, NREVSS Polymerase Chain Reaction (PCR) Worksheet (CDC 55.83D) (electronic)
Attachment V, National Enterovirus Surveillance System (NESS) Report (CDC 55.9) (electronic)
Attachment W, National Adenovirus Type Reporting System (NATRS) Form
Attachment X, Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form
Attachment Y, Viral Gastroenteritis Outbreak Submission Form
Attachment AA, Influenza Virus (Electronic, year round), PHLIP_HL7 messaging Data Elements
Attachment BB, Influenza virus (electronic, year round) (PHIN-MS)
Attachment CC, Suspect Respiratory Virus Patient Form
Attachment DD, Human Subjects Determination
Attachment EE, Aggregate case counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI)
Attachment FF, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Short Form
Attachment GG, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF)
Attachment HH, Arthropod (Vector)-Borne Diseases (Non-Human Data)

- Reinstatement includes 4 new forms, minor revisions to reinstated forms, and the discontinuation of several previously approved forms.
- The data will be used to determine the prevalence of disease and planning and evaluating programs for prevention and control of infectious diseases. Disease incidence is needed to study present and emerging disease problems.
- The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures.
- The subpopulation is anyone who meets the criteria or case definitions for these diseases.
- Data collected as part of the CDC surveillance activities are published frequently in the *MMWR* and in the Surveillance Summaries published periodically as part of the *MMWR*. In addition, the data are included in the *MMWR* Annual Summary, in individual surveillance reports prepared on individual diseases under surveillance, and in journals related to individual diseases.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a three-year approval for National Disease Surveillance Program - II. Disease Summaries, OMB Control Number 0920-0004. Expiration Date 10-31-2020. This is a reinstatement with change of a previously approved information collection request.

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. This surveillance program is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241) (Attachment A).

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 these reports to CDC on variable frequencies; weekly, monthly, or quarterly. CDC then calculates and publishes weekly statistics via the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with timely aggregates of their submissions.

Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments must be able to share data on certain conditions across jurisdictions and to coordinate program activities to prevent and control the conditions.

The following diseases/conditions are included in this program:

- Influenza Virus
- Caliciviruses
- Respiratory and Enteric Viruses
- Arthropod-Borne Diseases (Non-Human Data)
- Enteric Outbreaks with Unknown Mode
- Enteroviruses
- Parechoviruses

Attachment C contains descriptive summaries of each disease under surveillance.

2. Purpose and Use of Information Collection

State and Territorial Epidemiologists are responsible for the collection, interpretation, and transmission of medical and epidemiologic information at the state level. State Health Departments submit the disease summaries to CDC and CDC tabulates, analyzes the data for trends, publishes, and distributes within the health community. By coordinating nationwide collection of epidemiological data, CDC is able to calculate annual between-state comparisons of diseases covered under this request.

As with the previous approval, these data are essential for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need to modify current preventive measures. Diseases included in this surveillance program are Influenza Virus, Caliciviruses, Respiratory and Enteric Viruses, Enteroviruses and Parechoviruses. Proposed reinstatements with change include 8 influenza forms, Suspect Respiratory Virus Patient Form, Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form, Viral Gastroenteritis Outbreak Submission Form, National Respiratory and Enteric Virus Surveillance System (NREVSS) Laboratory Assessment and National Enterovirus Surveillance Report. These forms have minor edits with minor burden change from last approval OMB approval. 4 new forms have

been added and include Attachment EE Aggregate count of persons exposed to Highly Pathogenic Avian Influenza (HPAI), Attachment GG Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF), Attachment FF Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction short form version and Attachment HH Arthropod-Borne Diseases (Non-Human Data). The data from the new forms will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens. Attachment D NORS Foodborne Disease Transmission and Attachment Z Waterborne Diseases Transmission are discontinued in this package because they have been moved to OMB approved Control # 0920-1304. Additionally, Attachment G U.S. Outpatient Influenza-Like Illness Surveillance Network (ILINet) Weekly is discontinued and is no longer needed. The frequency of response for each form included in the package will depend on the disease and surveillance need. The total burden estimate for all collection instruments in this reinstatement request is 27,458. There are no costs to the respondents other than their time.

3. Use of Improved Information Technology and Burden Reduction

The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures. For example, the reporting of the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form is reported as needed via facsimile transmission, email, or direct data entry via the Internet.

The National Enterovirus Surveillance System (NESS) uses an MS Excel spreadsheet to list each detection report. The report is completed either on a monthly or a quarterly basis by the respondents, and then emailed to the coordinator for entry into an MS Access database. The same data may also be reported through a secure web-based platform called NESSweb.

The National Respiratory and Enteric Virus Surveillance System (NREVSS) reporting is conducted weekly using a secure CDC website. Staff report that electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating centers.

Attachment H - U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder no longer accepts reporting via facsimile and is reported only via the internet using a secure password-protected CDC website.

For virologic surveillance data collected through the U.S. World Health Organization (WHO) Collaborating Laboratories system, data is transmitted from participating laboratories using S3, SFTP, PHIN-MS, or a secure password-protected CDC website. For data collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), reporting is conducted by enrolled healthcare providers each week using a secure password-protected CDC website. This electronic reporting allows for immediate processing and analysis of virologic and ILINet surveillance data. Less than 3% of enrolled ILINet providers submit their weekly data to CDC via facsimile transmission. Individual case report forms for human infections with novel influenza A viruses, also including a separate report form for cases with severe outcomes, and for influenza-associated pediatric deaths are submitted on the CDC Secure Access Management System (SAMS) from state and select local health departments. Data collected on the Antiviral Resistant Influenza Infection Case Report Form and the U.S. WHO Collaborating Laboratories Testing Methods Assessment are submitted to the domestic surveillance team or email. Data collected on the Aggregate counts of person exposed to highly pathogenic avian influenza (HPAI) form will be completed by state health department staff through a Microsoft Word form and emailed to fluvIEWSupport@cdc.gov

Data for the surveillance of pediatric hepatitis of unknown etiology will be collected from participating jurisdictions 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.

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. ArboNET involves 100% electronic reporting of non-human arthropod-borne disease surveillance data, with no paper forms. Jurisdictions transmit data to ArboNET using one or more of three standardized methods developed and supported by the National Center for Emerging and Zoonotic Infectious Diseases, 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. Any jurisdiction may enter records manually using a Web-based form. Interactive maps of arboviral surveillance data for non-human activity are publicly available. Descriptive maps generated from tick surveillance data are available to the public. This information is updated regularly and provides data to a county level. These real-time data allow physicians and public health officials to make more informed decisions about patient care and vector control operations based on the most up-to-date information.

The information requested is the minimum amount required to maintain surveillance of these selected diseases.

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 disease-specific surveillance system. While similar information may be collected from limited geographic areas or collected in one-time studies, for most diseases, sampling would not be sufficient for the states' need of conducting prevention or control programs. The surveillance systems in this request collect data from all states and territories of the U.S. in a uniform manner.

5. Impact on Small Businesses and Other Small Entities

This collection of information will not involve small businesses or other small entities.

6. Consequences of Collecting Information Less Frequently

Disease reporting varies to the extent that diseases 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 disease is its rapid identification followed by notification to the local health authority that a case of disease exists within a particular jurisdiction. Prompt notification to CDC allows for identification of epidemics and outbreaks so that immediate prevention and control measures can be taken. Therefore, collecting less frequently would negatively impact the identification and notification of the disease reporting. The submission frequency requested in this package is dependent on the epidemiology of the disease in question and is addressed individually for each form.

For example, CDC is responsible for surveillance of influenza with the goal of determining the impact of the disease on the U.S. population and developing improved prevention and control measures. Influenza types A and B viruses are responsible for epidemics of respiratory illness that occur almost every winter in temperate climates and are often associated with increased rates of hospitalization and death. The estimated rates of influenza-associated hospitalizations and influenza-related deaths vary substantially from one influenza season to the next, depending, in part, on the characteristics of the circulating influenza virus strains. The emergence of new strains of influenza, such as influenza A (H1N1) pdm09 virus, influenza A (H3N2) variant virus, and influenza A (H7N9) virus necessitate annual virologic and epidemiologic surveillance.

Influenza surveillance data are used to determine influenza vaccine composition for the following year and permits rapid detection of influenza virus circulation and the degree to which vaccine virus strains match circulating wild type virus strains. It provides data used in determining influenza-associated morbidity, mortality, and economic loss. Furthermore, it may assist in the control of the disease by affording the opportunity for rapid preventive action, for example, by chemoprophylaxis of high-risk persons who have not received the vaccine. Circulating influenza viruses are constantly changing and annual monitoring for antiviral resistant influenza viruses is needed as this information is critical to antiviral recommendations and guidance. In addition to

monitoring annual influenza epidemics, this system is in place to detect viruses with pandemic potential and track the course of the next influenza pandemic.

CDC is also responsible for surveillance of arthropod-borne diseases with the goal of assessing risks of these diseases for the U.S. population and developing improved prevention and control measures. ArboNET, the national arboviral surveillance system, was developed by CDC and state health departments in 2000 in response to the emergence of West Nile virus in 1999. In 2003, the system was expanded to include other domestic and imported arboviruses of public health significance. In addition to human disease cases, ArboNET maintains data on arboviral infections among non-human mammals, sentinel animals, dead birds, and mosquitoes. Variables collected for non-human infections include arbovirus, species, state and county, and date of specimen collection or symptom onset. The total number of mosquitoes or birds tested weekly can also be reported. In 2018, a new Tick Module was added to ArboNET to allow jurisdictions to report their data on tick presence and abundance and tickborne pathogen presence and prevalence. The non-human data are collected to better understand when and where Americans are at risk for exposure to vectors and their associated human pathogens.

Monthly or quarterly reports of enterovirus and parechovirus detections in the US via the National Enterovirus Surveillance System (NESS) aids in establishing seasonal trends. Enteroviruses are detected year-round but tend to peak in the summer and fall months. However, varying types of enteroviruses in a given year may result in earlier or later peak activity.

The weekly reports collected via National Respiratory and Enteric Virus Surveillance System (NREVSS) are analyzed by CDC staff and the results are immediately updated on a public CDC website. Real-time data allow physicians and public health officials to make decisions based on the most up to date surveillance reports of viral activity in their area.

The National Adenovirus Type Reporting System (NATRS) is a passive surveillance mechanism to collect adenovirus typing data on a quarterly basis from laboratories in the US. When available, this granular data enhances adenovirus circulation data already collected by NREVSS. The objective is to document the types of adenovirus circulating in the US and identify any emergent or severe adenovirus infections by using a simple, voluntary reporting mechanism. Transmission, seasonality, and clinical course vary greatly according to the specific types of adenovirus that may cause infection in humans. A vaccine that protects against several adenovirus types is currently available to US military recruits. The effect of this vaccine on overall circulation of adenovirus types in specific settings is unknown and warrants monitoring.

There is a need for real-time monitoring for the emergence of MERS-CoV in the US due to the uncertainty and threat to human health. Less frequent data collection could result in missing the initial cases of MERS-CoV occurring in the US delaying the public health response to this emerging virus in the human population.

The Suspect Respiratory Virus Patient Form will be made available to health departments and clinical sites when they submit specimens to the CDC lab for viral pathogen identification. Submission of specimens is typically only done for severe cases of unknown etiology, particularly when a cluster of similar cases are noted, requiring further investigation. The data provided will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens.

Data for pediatric hepatitis of unknown etiology are collected as Patients Under Investigation (PUIs) are identified by jurisdictions. Surveillance for pediatric hepatitis of unknown etiology was not routinely conducted in the United States prior to April 2022, and as such, data to understand the epidemiology of this condition are limited. Additional data collected on PUIs in a standardized manner will inform the public health response to pediatric hepatitis of unknown etiology in the United States.

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, to permit rapid response to public health problems and prompt initiation of prevention and control measures, respondents may be required to report information more often than quarterly. Surveillance reports are submitted as soon as possible after an epidemiologic investigation and delays in reporting could 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 60-day Federal Register Notice (Attachment B) was published in the Federal Register on September 16, 2022 Vol. 87, No. 179, pp. 56955-56956. CDC received two public comments related to this notice.

A. Consult Outside the Agency: 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 a regular basis throughout the year. Janet Hamilton is the Executive Director.

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 to 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. However, personally identifiable information (PII) is collected on some of the forms.

For the diarrheal disease case surveillance, identifiers are maintained at the state or local health department, and information is encrypted before data are transmitted to CDC. CDC does not have the capability of un-encrypting identifiers.

NREVSS data are collected through a secure website within the CDC. No identifiers or demographics 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 each week. 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.

Data collection for NATRS, the Suspect Respiratory Virus Patient Form, the National Enterovirus Surveillance System, and the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form includes age, gender, state of residence, and optional information on broad clinical outcomes. A locally assigned patient ID and/or specimen ID may be submitted for NATRS, the Suspect Respiratory Virus Patient Form, and the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form. This number, typically assigned by a state or local health department or possibly by a hospital, may be used by CDC to group results together that were submitted for a single person or to report test results for a specific specimen back to the health department or submitting laboratory which will maintain the link to personal identifiers as needed. The data for NESS are not identifiable and does not include any identifier that could be traced back to the patient.

Data collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) do not involve the collection of individually identifiable information. Submission of data through PHLIP_HL7 messaging and PHLIS-2 submit the influenza laboratory results of testing on the patient level, and submitting laboratories have the option of including information on age, gender, and state of residence. Case report forms for influenza-associated pediatric deaths and human infections with novel influenza A viruses are collected through the CDC

Secure Access Management System (SAMS) from state and select local health departments. Data collection for influenza-associated pediatric deaths and human infections with novel influenza A viruses will include age, gender, race, ethnicity, state and county of residence, date of birth, and date of death. Data collection for antiviral-resistant influenza infections will include age, gender, race, ethnicity, and state and county of residence. This data will be faxed or emailed to the influenza antiviral resistance coordinator. Data for the Aggregate Counts of Persons Exposed to Highly Pathogenic Avian Influenza (HPAI) form are aggregate and no patient identifiers are collected. Once submitted data from all surveillance systems are received at CDC, the data is stored on secure SQL servers or excel files and access to databases/files are limited to select domestic influenza surveillance staff.

Data collected for pediatric hepatitis of unknown etiology are de-identified and personally identifiable information (PII) are only collected where necessary for public health response (e.g., date of birth). All data are submitted to CDC via secure ShareFile or via direct entry into the CDC instance of REDCap, which is behind the SAMS authenticated firewall and only accessible to project team members via SmartCard. Data collected will be tabulated and shared only in aggregated form; no personally identifiable information will be shared. Analysis results from these data will be published in peer-reviewed journals and presented to public health partners and others in medical and public health fields (e.g., conferences).

ArboNET non-human data do not contain PII. No identifiers or human demographics are included in this component of the surveillance system.

All records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to use the records. Paper forms are kept in locked file cabinets in a locked room. Computer files are password protected. State health departments reporting patient names electronically encrypt identifiers before sending them to CDC.

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

IRB Approval

A CDC human subjects advisor has determined that the activities in 0920-0004 are considered Not Research - Public Health Surveillance under 45 CFR 46.102(l)(2). Consistent with current CDC policy, Public Health Surveillance activities do not meet the regulatory definition of research and are therefore outside the scope of IRB review requirements. (Attachment DD)

Sensitive Questions

Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. Some forms also include race and ethnicity data, which may be considered sensitive by some persons. If race/ethnicity is not an integral part of epidemiologic investigation, it is not collected. For example, CDC does not collect race/ethnicity on Attachment EE, Aggregate counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI) aggregated influenza surveillance or on Attachment Y, Viral Gastroenteritis Outbreak Submission Form because race/ethnicity are not key risk factors for contracting these diseases. Clinical laboratory data are collected and reported when that information is essential to proper identification and control of the particular health problem. Only the minimum data necessary is collected on all surveillance forms.

12. Estimates of Annualized Burden Hours and Costs

- A. The total burden estimate in Table 1 for all forms is 27,458. The frequency of response for each form will depend on the disease and surveillance need. This represents a 2,657 burden hour increase since last approval. The increase in burden hours is attributed to the addition of four new forms previously outlined less Attachment D NORS Foodborne Disease Transmission, Attachment Z Waterborne Diseases Transmission and Attachment G U.S. Outpatient Influenza-Like Illness Surveillance Network (ILINet) Weekly from the previous OMB approval. Current burden estimates are based on previous experience and feedback from stakeholders using these instruments.

Table 1 – Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Epidemiologist	Attachment E—WHO Collaborating center for Influenza-Influenza Virus Surveillance	47	52	10/60	407
Epidemiologist	Attachment F—U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	113	1	10/60	19
Epidemiologist	Attachment H—US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E	1800	52	10/60	15,600
Epidemiologist	Attachment J—Influenza-Associated Pediatric Mortality —Case Report Form	57	2	30/60	57
Epidemiologist	Attachment K—Human Infection with Novel Influenza A Virus Case Report Form	57	2	30/60	57
Epidemiologist	Attachment M—Human Infection with Novel Influenza A Virus Severe Outcomes	57	1	90/60	86

Epidemiologist	Attachment P— Novel Influenza A Virus Case Screening Form	57	1	15/60	14
Epidemiologist	Attachment T— Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86
Epidemiologist	Attachment U— National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic)	550	52	15/60	7150
Epidemiologist	Attachment V— National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	20	12	15/60	60
Epidemiologist	Attachment W— National Adenovirus Type Reporting System (NATRS)	13	4	15/60	13
Epidemiologist	Attachment X— Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form	57	3	25/60	71
Epidemiologist	Attachment Y— Viral Gastroenteritis Outbreak Submission Form	20	5	5/60	8
Epidemiologist	Attachment AA— Influenza Virus (Electronic, Year Round),	57	52	5/60	247

	PHLIP_HL7 messaging Data Elements				
Epidemiologist	Attachment BB— Influenza virus (electronic, year round) (PHIN-MS)	3	52	5/60	13
Epidemiologist	Attachment CC— Suspect Respiratory Virus Patient Form	10	5	30/60	25
Epidemiologist	Attachment EE, Aggregate counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI)	52	52	10/60	451
Epidemiologist	Attachment FF, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Short Form	52	4	15/60	52
Epidemiologist	Attachment GG, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF)	52	2	45/60	78
Epidemiologist	Attachment HH, Arthropod (Vector)- Borne Diseases (Non-Human Data)	57	52	60/60	2964
Total					27,458

B. The proposed estimated annual cost is \$1,040,771.54. This represents an increase from the previous submission and can be attributed primarily to increase in the 2021 median pay of \$37.90 for an epidemiologist. This

information is based on data from the Bureau of Labor Statistics website (see <https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>).

Table 2- Estimated Annualized Burden Costs

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 E_WHO COLLABORATING CENTER FOR INFLUENZA Influenza Virus Surveillance	47	52	10/60	407	\$37.90	\$15,425.30
Epidemiologist	Att F_U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	113	1	10/60	19	\$37.90	\$720.10
Epidemiologist	Att H_US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E	1800	1	10/60	15,600	\$37.90	\$591,240.00
Epidemiologist	Att J_Influenza-Associated Pediatric Mortality_Case Report Form	57	2	30/60	57	\$37.90	\$2,160.30
Epidemiologist	Att K_Human Infection with Novel Influenza A Virus Case Report Form	57	2	30/60	57	\$37.90	\$2,160.30
Epidemiologist	Att M_Human Infection with Novel Influenza A Virus Severe Outcomes	57	1	1.5/60	86	\$37.90	\$3,259.40
Epidemiologist	Att P_Novel Influenza A Virus Case Screening Form	57	1	15/60	14	\$37.90	\$530.60
Epidemiologist	Att T_Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86	\$37.90	\$3,259.04
Epidemiologist	Att U_National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic)	550	52	15/60	7150	\$37.90	\$270,985.00

Epidemiologist	Att V_National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	20	12	15/60	60	\$37.90	\$2,274.00
Epidemiologist	Att W_National Adenovirus Type Reporting System (NATRS)	13	4	15/60	13	\$37.90	\$492.70
Epidemiologist	Att X_Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form	57	3	25/60	71	\$37.90	\$2,690.90
Epidemiologist	Att Y_Viral Gastroenteritis Outbreak Submission Form	20	5	5/60	8	\$37.90	\$303.20
Epidemiologist	Att AA_Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements	57	52	5/60	247	\$37.90	\$9,361.30
Epidemiologist	Att BB_Influenza virus (electronic, year round) (PHIN-MS)	3	52	5/60	13	\$37.90	\$492.70
Epidemiologist	Attachment CC_Suspect Respiratory Virus Patient Form	10	5	30/60	25	\$37.90	\$947.50
Epidemiologist	Attachment EE_Aggregate counts of persons exposed to highly pathogenic avian influenza (HPAI)	52	52	10/60	451	\$37.90	\$17,092.90
Epidemiologist	Attachment FF, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Short Form	52	4	15/60	52	\$37.90	\$1,970.80
Epidemiologist	Attachment GG, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF)	52	2	45/60	78	\$37.90	\$2,956.20
Epidemiologist	Attachment HH, Arthropod (Vector)-Borne Diseases (Non-Human Data)	574	52	60/60	2964	\$37.90	\$112,335.60

Total							\$1,040,657.84
-------	--	--	--	--	--	--	----------------

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

There are no capital and maintenance costs incurred by respondents

14. Annualized Cost to the Government

Each data case report results in action taken by multiple programs in response to the required CDC mandate in maintaining preventive health activities and surveillance systems. The action taken will vary, depending on the specifics of the data reporting involving multiple staff. Influenza activities estimate \$10,521,246.00 The influenza estimate includes \$9.4M for the Epidemiology and Laboratory Capacity (ELC) cooperative agreement to support epi and laboratory personnel in all 50 states, plus territories, Information Technology at \$346,000.00, additional personnel costs of \$765,746.00 and \$9,500.00 for computers, printing and phones. Arthropod-Borne (Non-Human Data) estimate for personnel is \$112,335.60. Activities associated with pediatric hepatitis of unknown case cost an estimated \$62,012.60 in staff time to refine data collection instruments, manage the database, enter data, and perform data analysis. NESS, NATRS, MERS and remaining collection activities estimate \$260,000.00. The overall incurred costs include staff support, platform maintenance and computer resources and miscellaneous expense. These costs more accurately reflect cooperative agreement funding and program costs to the federal government since the last revision. The estimated annual cost to the government is \$10,955,594.20

15. Explanation for Program Changes and Adjustments

This is a request for a reinstatement with change. Many of the collection activities remain the same, however, four new forms have been added including an Aggregate case counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI), Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF), Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction short form version and Arthropod (Vector)-Borne Diseases (Non-Human Data). The data from the new forms will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens. The following forms are removed from 0920-0004 and moved to OMB approved Control 0920-1304: Attachment D-NORS Foodborne Disease Transmission and Attachment Z - Waterborne Diseases Transmission.

Attachment G – U.S. Outpatient Influenza-Like Illness Surveillance Network (ILINet) Weekly is discontinued. The total burden estimate for all forms is 27,458 hours, this represents a 2,657 burden hour increase since last approval.

Attachment D, NORS Foodborne Disease Transmission Person to Person Disease Transmission Animal Contact Environmental Contamination Unknown Transmission Mode (CDC52.13)

This form is discontinued from use in 0920-0004 because it is now approved under 0920-1304.

Attachment E, WHO COLLABORATING CENTER FOR INFLUENZA Influenza Virus Surveillance

The respondents on this form changed from 53 to 47 due to laboratories reporting via a different mechanism or are no longer participating within the WHO Collaborating Centers.

Attachment H, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder; CDC 55.20E

CDC 55.20E form is used to collect data on influenza-like illness (ILI) by age group and the total number of patients seen for any reason from participating healthcare providers. These data are reported to CDC via internet weekly. The CDC 55.20E form also includes a tool that healthcare provider can use to track data that is submitted to CDC in the weekly ILI report throughout the entire season. Previously, providers were required to return this completed tool to CDC at the end of the season for data verification purposes, however, data verification now occurs using statistical methods therefore providers are no longer required to return the complete season tool to CDC. For this revision, there aren't any changes to the actual form however, CDC has adjusted the burden table to account for the fact that this form is now used for weekly reporting.

Attachment P, Novel Influenza A Virus Case Screening Form

For this revision, minor changes were made to the data elements being collected. The following questions were added: the person reporting and contact information, patient date of birth, state of residence, county and country residence, location of poultry or bird contact, if involved in depopulation of a known outbreak, if employed at a healthcare facility, and a notes field. Question about age (added days as a category), symptoms, and flu testing information were modified. Questions about how the case was identified, travel history, and PPE usage by healthcare personnel were removed.

Attachment U, National Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83) (electronic)

Attachment U1, NREVSS Antigen Detection Worksheet (CDC 55.83A) (electronic)

Revisions include calendar updates for the corresponding season. On the cover page, a previous gray scale image of the CDC building is replaced with a color image. No change to burden.

Attachment U2, NREVSS Virus Isolation (Culture) Worksheet (CDC 55.83B) (electronic)

Revisions include calendar updates for the corresponding season. On the cover sheet, a new graphic image for Participating Laboratories box and color image CDC building replaces a grayscale image from previous form. No change to burden.

Attachment U3, NREVSS Polymerase Chain Reaction (PCR) Worksheet (CDC 55.83D) (electronic)

Revisions include calendar updates for the corresponding season. On the cover page, a previous gray scale image of the CDC building is replaced with a color image. No change to burden.

Attachment V, National Enterovirus Surveillance System (NESS) Report (CDC 55.9) (electronic)

Revisions include the addition of options to select for enterovirus serial type, no change to the burden.

Attachment W, National Adenovirus Type Reporting System (NATRS) Form

Revisions include a minor name change from *Adenovirus Typing Form* to *National Adenovirus Type Reporting System (NATRS) Form*. Formatting has been changed and fields have been added to note unique patient and specimen IDs, and if the specimen was sent elsewhere for typing. Existing variables have been updated and/or reformatted to simplify data entry for the reporter. Changes include Date of report to CDC (col B) was previously called "Report Date" which was filled out by the submitter and will now be filled out by NATRS coordinator. For Specimen type (col J), added "serum", "urine", and "blood" to options, clarified NP/OP swab to "NP and/or OP swab", clarified NP/OP wash "NP and/or OP wash". Under AdV species (cols O and Q), program added "species G" to options, AdV type (cols P and R) was reformatted into a drop down with list of known types, including an option for "undetermined". For Outbreak type (col z), program added "community" to options. Footnotes were also added to provide additional clarification during data entry for the reporter, specifically Age type (col G): footnote added "if patient age is 0-2 years, please list age in months", Patient ID (col C) and Specimen ID (col D): footnote added "Please enter unique patient level identifier and laboratory specimen identifier(s). If entering >1 specimen per patient, epidemiologic and clinical data may be entered for the first line only."

Attachment X, Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form

Revision is limited to those related to the SARS-CoV-2 pandemic, mainly inclusion of respiratory specimen testing for SARS-CoV-2 (in addition to the other respiratory pathogens that were already previously listed).

Attachment Y, Viral Gastroenteritis Outbreak Submission Form

No changes have been made since last submission.

Attachment Z, NORS Waterborne Disease Transmission Form (CDC 52.12)

This form is discontinued from use in 0920-0004 because it is now approved under 0920-1304.

Attachment AA, Influenza Virus (Electronic, year round), PHLIP HL7 messaging Data Elements

Changes include the addition of HL7 2.5.1. message syntax and the addition of data element of interest for unsolicited reports. Additionally, respondents changed from 57 to 59 since last approval because 2 respondents began using this reporting mechanism.

Attachment BB, Influenza virus (electronic, year round) (PHIN-MS)

Changes include the addition of accepted values for test method and results.

Attachment CC, Suspect Respiratory Virus Patient Form

Changes include the addition respiratory specimen testing for SARS-CoV-2.

Attachment EE, Aggregate counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI)

This is a new form. USDA notifies CDC when H5N1 outbreaks among birds are detected in commercial or backyard farms. CDC works with state health departments to ensure that people who have been exposed to H5N1 are appropriately monitored for symptom development. Health departments typically monitor exposed people for symptoms for 10 days following their last exposure. CDC does not conduct the monitoring itself but will collect aggregate data from state health departments on the numbers of people who were exposed and who were monitored for symptoms on a weekly basis.

Attachment FF, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction short form version.

This is a new form.

Attachment GG, Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF)

This is a new form.

Attachment HH, Arthropod-Borne Diseases (Non-Human Data)

This is a new form.

16. Plan for Tabulation and Publication and Project Time Schedule

Data collected as part of the CDC surveillance activities are published frequently in the *MMWR* and in the Surveillance Summaries published periodically as part of the *MMWR*. In addition, the data are included in the *MMWR* Annual Summary, in individual surveillance reports prepared on individual diseases under surveillance, and in journals related to individual diseases.

Data collected through the influenza surveillance system are compiled and analyzed on a weekly basis and published in the weekly influenza surveillance report that is distributed to public health professionals, the media, as well as the general public. The report is available online. In addition, summaries of influenza activity in the United States are published in the *MMWR* periodically. Aggregated datasets for laboratory, influenza-like illness, and influenza-associated pediatric death data for each season are also made available via the FluView Interactive website. Influenza surveillance data are also periodically published in peer-reviewed journals.

Approximately every two years, a summary of enteroviral activity is reported in the *MMWR*. In years with a large burden of disease or with outbreaks of public interest, additional reports are published. Compiled data are also made available over the Internet (URL: <https://www.cdc.gov/surveillance/ness/index.html>).

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 data collected by NATRS will be compiled and analyzed on a quarterly basis and may result in annual summary reports in the *MMWR* or in a peer-reviewed journal.

Data collected using the MERS-CoV PUI short form are used to monitor patients with suspected MERS-CoV in the United States. Periodically, these data will be analyzed and summarized for publication and presentations that apprise the US public health community of the MERS-CoV PUI domestic surveillance activities.

Upon receipt, data collected using the new Suspect Respiratory Virus Patient Form will be assessed in real-time to inform situational awareness of subject matter experts and to support the rapid detection of potential new outbreaks which may require a public health response and/or notification.

Data collected for surveillance of pediatric acute hepatitis of unknown etiology will be compiled and periodically published on the CDC website. Data will also be analyzed in-depth for reports such as MMWR or published in peer-reviewed journals. Data on PUIs will also be analyzed in conjunction with detailed exposure data and data on matched controls collected as part of the in-depth evaluation that is approved under (CSTLTS Generic Information Collection Request OMB No. 0920-0879) to further understand causes and risk factors associated with pediatric hepatitis of unknown etiology.

CDC epidemiologists and entomologists routinely review and analyze ArboNET surveillance data and disseminate results to stakeholders via direct communication, descriptive summaries in *Morbidity and Mortality Weekly Reports*, DVBD's disease- or vector-specific websites and peer reviewed publications. Interactive maps of arboviral surveillance data for both human and non-human activity are available (https://wwwn.cdc.gov/arboNET/maps/ADB_Diseases_Map/index.html). Descriptive maps generated from tick surveillance data are available to the public (<https://www.cdc.gov/ticks/surveillance/index.html>). This information is updated regularly and provides data to a county level. CDC provides limited-use ArboNET data sets to the general public by formal request.

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

Many of the disease summary forms included in this request have required minor modifications since first approved, usually due to technology changes. Because of the long-term use, printed paper forms may still be in use or circulation. It is requested that permission be granted to exclude the expiration date from some disease summary forms included in this request.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.