

Form Description for the Information Collection “National Disease Surveillance Program - II. Disease Summaries,” OMB No. 0920-0004

OVERVIEW OF CDC INFLUENZA SURVEILLANCE

The Centers for Disease Control and Prevention has the responsibility 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 is an acute respiratory disease caused by infection with influenza viruses. 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. Although the highest rates of illness occur among school-aged children, the highest rates of hospitalizations from influenza-related causes occur among infants and young children, persons of any age with certain chronic medical conditions (including chronic pulmonary (including asthma), cardiovascular, renal, hepatic, neurologic hematologic, or metabolic disorders (including diabetes mellitus), and among those ≥ 65 years of age. 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. During seasonal influenza epidemics from 1979-1980 through 2000-2001, the estimated annual overall number of influenza-associated hospitalizations in the United States ranged from approximately 55,000 to 431,000 per annual epidemic. Influenza-related deaths can result from pneumonia, exacerbations of existing cardiopulmonary conditions, or exacerbations of other chronic conditions. Over a period of 31 seasons between 1976 and 2007, estimates of influenza-associated deaths in the United States range from a low of about 3,000 to a high of about 49,000 deaths. The continuing emergence of new strains of influenza, such as influenza A (H1N1)pdm09 virus, influenza A variant viruses, and influenza A (H7N9) virus, necessitates annual virologic and epidemiologic surveillance.

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 vaccine. 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.

WHO Collaborating Center for Influenza Surveillance, Influenza Virus Surveillance CDC 55.31- Attachment E

Form CDC 55.31 is used to collect summary influenza virus data from World Health Organization (WHO) collaborating laboratories in the United States who report their data using over the Internet. For laboratories that utilize the electronic method of reporting data, there is no reporting form since a connection is established between the laboratory and a CDC server.

State, county, city, or university laboratories that collaborate with the U.S. WHO Influenza Surveillance Program report the number of respiratory specimens submitted for influenza diagnosis and the number positive for influenza by type and subtype. All laboratories report these data each week throughout the year. These reports are used to assess and report the distribution of influenza virus strains throughout the United States.

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U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment – Attachment F

At the beginning of each influenza season, a survey is sent to each participating U.S. WHO collaborating laboratory to obtain information used in the analysis and interpretation of data obtained from year-to-year.

U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly, CDC 55.20 – Attachment G

Form CDC 55.20 is a single form used to collect summary influenza-like illness data from healthcare providers participating in ILINet. Providers have the option of faxing this data via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form. The workfolder (CDC 55.20E) is used by the provider to track their own data submitted throughout the season.

Because state health department morbidity estimates are imprecise and generally untimely, a system was developed in 1982 to collect influenza-like illness data directly from practicing family physicians who voluntarily participated without remuneration. Prior to 1997, CDC and state health departments’ maintained separate influenza sentinel provider surveillance systems. In 1997, CDC collaborated with state health departments to reduce duplication of efforts and allow resources to be focused on expanding the number of providers reporting in order to improve the geographic representation and completeness of the data. Over the years, the system has continued to evolve and expand. For the 2016-2017 season, approximately 1,800 health care providers in all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands regularly reported to CDC.

Participating providers report the following data each week of the year: influenza-like illnesses by age group (0-4 years, 5-24 years, 25-49 years, 50-64 years, and >64 years) and the total number of patients seen for any reason. These data are shared by CDC and state health departments. Year-round influenza surveillance data typically provides a baseline level of influenza activity during the summer months and are essential components of seasonal and pandemic influenza surveillance and are used to detect other unusual occurrences of influenza-like illness. A minor revision to the ILINet weekly report (CDC 55.20) is requested. Participating providers will have the option to report the total number of patients seen for any reason by influenza-like illness age group. This information will be invaluable in calculating age-group specific impact of circulating influenza viruses on outpatient visits for influenza-like illness.

The primary method of reporting is Internet (97%) using form 55.20E as a work folder. A few providers still prefer to transmit their data via facsimile (3%) (CDC55.20). The facsimile form is part of the work folder.

Influenza-Associated Pediatric Mortality Case Report Form- Attachment J

In 2004, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making influenza-associated deaths in children (persons less than 18 years) a nationally notifiable condition. The Influenza-associated Pediatric Mortality case report form, a

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standardized case questionnaire which contains detailed questions on relevant clinical and epidemiologic features of influenza, was developed by CSTE and CDC. State or territorial influenza surveillance epidemiologists report these data over the Internet on the Secure Access Management Services (SAMS). Each week, limited data on laboratory-confirmed influenza-associated deaths in children is transmitted from the CDC/Influenza Division to the Nationally Notifiable Disease Surveillance System (NNDSS). Data obtained from this form has led to the modification of influenza vaccine recommendations. Personal identifiers are collected by state or local public health officials; this information is removed from the form and maintained at the state or local health department before submission to CDC. A minor revision is requested for the Influenza-Associated Pediatric Mortality Case Report Form. One question was rephrased to better reflect recommendations made by the Advisory Committee on Advisory Practices (ACIP) and two questions were added regarding whether or not immunization records or information about influenza vaccination was available (and if so, the sources of information that were reviewed) was added to the case report form.

Human Infection with Novel Influenza A Virus Case Report Form - Attachment K Human Infection with Novel Influenza A Virus Severe Outcomes - Attachment M Novel Influenza A Virus Case Screening Form - Attachment P

In 2007, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making human infection with a novel influenza A virus a nationally notifiable condition. Novel influenza A virus infections include all human infections with influenza A viruses that are different from currently circulating human influenza H1 and H3 viruses. These viruses include those that are subtyped as nonhuman in origin and those that are unsubtypable with standard methods and reagents. Human infections with novel influenza A viruses that can be transmitted from person to person may signal the beginning of an influenza pandemic. Rapid detection and reporting of human infections with novel influenza A viruses – viruses against which there is little to no preexisting immunity – will facilitate prompt detection and characterization of influenza A viruses with pandemic potential and accelerate the implementation of effective public health responses.

From 2005 to early 2012, only 36 cases of variant (v) influenza virus infection were reported to the Centers for Disease Control and Prevention (CDC). From July–December 2012, however, 309 cases of H3N2v were reported in 11 states, representing the largest outbreak of human infections with a variant influenza virus since the 2009 H1N1 pandemic. From 2013 to 2017, 43 cases of H3N2v were reported from 8 states. A majority of cases had self-limited illness, but hospitalizations were more prevalent among those with young age and the presence of underlying medical conditions. Most cases reported prolonged and direct exposure to swine at an agricultural fair, suggesting that was the primary risk factor for illness. These outbreaks highlight the assertion that every case of variant influenza virus infection has epidemic potential and must be investigated thoroughly and rapidly.

The Human Infection with Novel Influenza A Virus Case Report Form should be used by state health departments to report cases of confirmed novel influenza A virus infection to CDC. This form will be critical to the collection of information from cases where swine or avian species are suspected as the source of their infection. The Novel Influenza A Virus Case Screening Form may be used by local or state health departments for cases under investigation for possible

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human infection with novel influenza A viruses. . The Human Infection with Novel Influenza A Virus Severe Outcomes form will be used on patients that became severely ill (i.e. hospitalized or died) after an infection with a novel influenza A virus. These forms contain detailed questions on relevant clinical and epidemiologic features of influenza, were developed by CSTE and CDC. The Novel Influenza A Virus Infection Contact Tracing Form and Novel Influenza A Virus Case Status Summary form were discontinued on October 2, 2016. State or territorial influenza surveillance epidemiologists report these data over the Internet on the Secure Access Management Services (SAMS). Each week, limited data on human infections with novel influenza A viruses is transmitted from the CDC/Influenza Division to the Nationally Notifiable Disease Surveillance System (NNDSS). Personal identifiers are collected by state or local public health officials and maintained at the state or local health department before submission to CDC.

Antiviral Resistant Influenza Infection Case Report Form - Attachment T

Antiviral drugs are the second line of defense against influenza viruses. Currently, influenza neuraminidase inhibitor antiviral medications oseltamivir, zanamivir, and peramivir are currently recommended for use against seasonal influenza. There are limited treatment options for an infection with an oseltamivir-resistant viruses, experimental drug use would be required; thus widespread circulation of resistant viruses is a public health emergency requiring special guidance and testing. After a resistant virus is identified by the laboratory, it is necessary to obtain key information from the infected patient to determine whether the resistant virus was circulating in the community or whether the resistant virus developed during treatment. This information is critical to antiviral recommendations and guidance. Over the past several seasons since the pandemic, a small but steady increase in the circulation of oseltamivir-resistant viruses has been reported. Any additional and significant increase will require new guidance and health alerts. This form, Antiviral Resistant Influenza Infection Case Report Form, will be critical to the collection of information that is essential to antiviral use guidance. Since circulating viruses are constantly changing, annual monitoring is needed. Personal identifiers are collected by state or local public health officials and maintained at the state or local health department before submission to CDC.

Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements – Attachment AA

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

Weekly data are transmitted to CDC throughout the year over the Internet (53 laboratories) or electronically using the Public Health Information Network – Messaging System (PHIN-MS) (3 laboratories) and Public Health Laboratory Interoperability Project (PHLIP) (57 laboratories). Transmission of data via PHIN-MS and PHLIP, electronic systems that can be corrected and updated with the latest, most accurate influenza isolate information, improves the timeliness and quality of the data. All of the 60 laboratories using PHIN-MS and PHLIP have elected to develop an interface between their laboratory computer and PHIN-MS and PHLIP to transmit their data. In these instances, their previous weekly burden of summarizing this information and transmitting it by facsimile has been eliminated and transmitting it by Internet has been reduced. No patient identifiers are received at CDC.

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OVERVIEW OF RESPIRATORY AND ENTERIC VIRUS SURVEILLANCE

National Respiratory and Enteric Virus Surveillance System (NREVSS) - Forms Antigen Detection Worksheet 55.83A, Virus Isolation (Culture) Worksheet 55.83B, Polymerase Chain Reaction (PCR) Worksheet 55.83D – Attachment U1, U2, U3

Respiratory viruses reported using these forms include respiratory syncytial virus, human parainfluenza viruses, respiratory adenovirus, rhinovirus, enterovirus, human metapneumovirus, human coronaviruses, and influenza, and enteric viruses include rotavirus, enterovirus, and adenoviruses 40 and 41. Respiratory syncytial virus (RSV) is the most important viral respiratory tract pathogen of infants and young children, and may cause serious disease in immunocompromised patients and the elderly. Annual epidemics are associated with increased rates of pneumonia and bronchiolitis hospitalization among infants and young children. The human parainfluenza viruses (HPIV) are also important respiratory pathogens in children, and epidemics are associated with increases in physician visits for bronchiolitis, croup, and pneumonia. RSV, HPIV, and adenoviruses are important causes of nosocomial pneumonia and other lower respiratory tract illness. Rotavirus is the most common cause of severe diarrhea in children in the United States, with an estimated 3 million cases and 70,000 hospitalizations per year.

Since January 1989, selected clinical and public health laboratories have reported to CDC the number of specimens tested and number of specimens positive for RSV, HPIV, adenovirus, and rotavirus. The purpose of this surveillance system is to track temporal and geographic trends for these viruses and to make the findings available to public health care professionals and health-care providers in a timely fashion. The primary objective of the system is to identify epidemics geographically, and not to enumerate cases.

In July 1990 the reporting was changed from monthly to weekly reporting with a computerized telephone polling system and results were collected by diagnostic testing method (antigen detection testing, virus isolation, electron microscopy and PCR added in 2004). In 2002, the system was changed again to transfer all data entry to the online system. Weekly electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating centers. Influenza data collection was added July 1997 to increase reporting to influenza surveillance systems, and allows the reporting of influenza during non-influenza surveillance season. To reflect ongoing technical developments and increasingly routine use of assays and multiplex PCR panels for detection of respiratory virus, in 2007, rhinovirus, human metapneumovirus, and enteric enteroviruses were added to the forms for data collection. In 2013, the electron microscopy form was removed since it had become obsolete as a method of routine viral detection, and a form for annual assessments of laboratory practices among participating laboratories was added. In 2014 human coronaviruses were added to the data collection for form PCR testing. Currently, only forms 55.83 A, B, and D are in use as form 55.83 was discontinued since it was rarely used.

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Annual summaries and alerts are published periodically in the *MMWR* and in medical journals. NREVSS data have been used to better define the epidemiology of RSV, HPIV, and rotavirus. Compiled data are made available over the Internet for infection control practitioners and other health care providers to use in planning and implementing effective control measures, and for researchers to assess in the effectiveness of new vaccines. (URL: <http://www.cdc.gov/surveillance/nrevss/>)

National Enterovirus Surveillance System (CDC 55.9) – Attachment V

Since 1964, participating public and private laboratories have reported to CDC enteroviruses that they isolate. This project, known as the National Enterovirus Surveillance System (NESS), was initially under the auspices of the Joint Committee of the Conference of State and Territorial Public Health Laboratory Directors. Reports are sent directly from the laboratories to CDC. Information solicited on the previously approved reported form (CDC 55.9) include demographic data (age, sex, state); clinical data (outcome); and laboratory data (specimen collection date, enterovirus type isolated, specimen type tested) on all cases with one or more enterovirus isolated.

The present reporting form has been developed in Microsoft Excel to reduce the reporting burden. These same data may also be reported through a secure web-based platform, NESSweb.

Enteroviruses are associated with a wide spectrum of disease, including severe clinical illness. NESS allows CDC to better characterize temporal and geographic trends in enterovirus activity, assess and monitor epidemics, guide in outbreak investigations, and identify targets for developing diagnostic assays and antivirals.

Findings from NESS are published periodically in the *MMWR* and peer-reviewed journals. Compiled data are also made available over the Internet for public health workers, infection control practitioners, and other health care providers to use in planning and implementing effective control measures. (URL: <https://www.cdc.gov/surveillance/ness/index.html>).

National Adenovirus Type Reporting System (NATRS) Report Form- Attachment W

In 2014, CDC, NCIRD, Division of Viral Diseases began developing a passive surveillance mechanism in the US to enhance adenovirus circulation data already being collected by NREVSS. Previously no national adenovirus typing surveillance system existed to monitor both civilian and military populations. Adenoviruses are important causes of pneumonia and other lower respiratory tract illness in children, the immunocompromised and military recruits. The majority of adenovirus epidemiological studies were conducted over 30 years ago. Since then, new molecular methods for adenoviral identification and genetic characterization have been developed to give epidemiologists better tools to identify outbreaks or emergent and more virulent strains. Our 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. This reporting mechanism previously called the Adenovirus Report Form has been renamed the National Adenovirus Type Reporting System (NATRS) Report Form.

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Reports are generally sent directly from the laboratory to CDC by e-mail. Information solicited on the report form includes demographic data (age, sex, state, year); laboratory data (adenovirus group or type, specimen type, specimen collection data, coinfection detections); and optional clinical data (hospitalization, outcome, part of an outbreak).

The present reporting form has been developed in Microsoft Excel to reduce the reporting burden. Clinical data are optional, because in most cases this information is not available to the reporting laboratories, and the date of specimen collection is requested in lieu of onset date. Ultimately, these data may provide insight leading to better control and prevention practices. Results of these reports may be published periodically in the *MMWR* and peer-reviewed journals.

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

Due to the emergence of a novel coronavirus associated with severe acute respiratory illness and death among individuals in the Middle East in 2012, the Middle East Respiratory Coronavirus Patient Under Investigation (MERS-CoV PUI) form was developed. This form is now called the Middle East Respiratory Syndrome (MERS) Patient Under Investigation Short Form. This form gathers basic demographic, clinical laboratory, and possible exposure information on individuals under investigation for possible MERS-CoV infection. In conjunction with use of the CDC’s MERS-CoV testing assay, state, local, and territorial public health departments are encouraged to consult with the CDC on MERS-CoV PUI and send the MERS-CoV PUI form to CDC. Partners have the option of faxing or emailing this form to the CDC’s Emergency Operations Center or reporting data over the Internet. The web interface is identical to the fax form.

Suspect Respiratory Virus Patient Form- Attachment CC

The Suspect Respiratory Virus Patient Form will be used to collect information when state or local health departments request laboratory testing or subject matter expert assistance for unusual cases, clusters, or outbreaks of respiratory illness that appears to have a viral cause. Upon receipt of this form, demographic, clinical, and epidemiologic data 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. Since this data will typically accompany a specimen sent to CDC for testing, a local specimen ID is required in order to report the test results back to the health department or submitting laboratory. 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 member of the NCIRD, Respiratory and Picornavirus Team.

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FOODBORNE DISEASE TRANSMISSION (CDC 52.13) - Attachment D

This reporting form provides for the systematic entry of basic data from an epidemiologic investigation of an acute foodborne, enteric person-to-person, animal contact, enteric environmental, and enteric unknown outbreak. Foodborne illnesses are due to a multitude of pathogens, toxins, and chemicals that may contaminate food. Outbreaks occur in a variety of population groups such as schools, camps, general dining halls, institutions of various types, as well as in the general community. This report form also serves as a training device and a guide to health departments that routinely investigate outbreaks. State and local health departments send completed reports on outbreaks they have investigated to CDC to be tabulated, analyzed, and summarized. Historically, use of data collected by this system was slowed due to the time required for data entry and coding once the forms were received. In 1998, CDC introduced electronic reporting of foodborne outbreak data through the Electronic Foodborne Outbreak Reporting System (EFORS). EFORS was a web-based reporting system that collected the same information as the paper form, and was used by local, county, or state organizations to enter, edit and analyze data as well as transmit data electronically to other state or federal offices. In 2009, National Outbreak Reporting System (NORS) was established. NORS allows the continual electronic reporting of foodborne-associated outbreaks, in addition to the following modes of transmission: person-to-person, animal contact, and environmental contamination other than food/water/animal contact, and unknown mode. The burden did not change, based on the addition and removal of questions.

Data are published periodically in the *Surveillance for Foodborne Disease Outbreaks Annual Report*, as well as the MMWR, peer-reviewed journals, and an online tool.

WATERBORNE DISEASES OUTBREAK REPORT FORM (CDC 52.12) - Attachment Z

CDC has collaborated with the Council of State and Territorial Epidemiologists and the Environmental Protection Agency (EPA) on the Waterborne Disease and Outbreak Surveillance System since 1971. This report form provides for the systematic entry of epidemiologic, laboratory, and environmental health data collected during an epidemiologic investigation of an acute recreational water, drinking water, or other waterborne disease outbreak by public health departments in an individual state, territory, or Freely Associated State. This report form also serves as a training device and a guide to health departments that routinely investigate outbreaks. No personally identifiable data are collected on this form or submitted to the system. Since 2009, these data have been collected from the states through the National Outbreak Reporting System (NORS), a web-based reporting system that collects the same information as the paper form, and is used by local, county, or state organizations to enter, edit and analyze data as well as transmit data electronically to other state or federal offices, including CDC. The burden did not change based on the addition and removal of questions.

Data on reported waterborne disease outbreaks are analyzed and published as 2-year reports in the Morbidity and Mortality Weekly Report. Reports dating back to 1971 are available online at <http://www.cdc.gov/healthywater/surveillance/surveillance-reports.html>. The data are used routinely to inform CDC recommendations and to supply critical data for EPA decision-making regarding existing and new regulations related to drinking water safety.

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Viral Gastroenteritis Outbreak Submission Form– Attachment Y

Outbreaks of viral gastroenteritis are usually caused by norovirus or sapovirus which collectively are referred to as caliciviruses. Noroviruses are estimated to cause 23 million cases (33%) of all cases of gastroenteritis annually. Norovirus disease occurs as sporadic disease or as outbreaks of diarrhea and vomiting, in all age groups.

Noroviruses can be transmitted via contaminated food, contaminated water or directly from person to person. Many outbreaks involve several modes of transmission such as initial foodborne followed by person to person. In many cases the source of infection is unknown. The diverse modes of transmission are reflected in the diverse settings in which outbreaks occur such as restaurants, nursing homes, hospitals and schools. Historically however, diagnosis of noroviruses has been very difficult. Recent development of RT-PCR techniques has revolutionized the detection and characterization of norovirus strains, and testing for norovirus in outbreaks of gastroenteritis is gradually becoming more frequent.

CDC has been testing outbreaks for noroviruses for over 10 years, most recently using RT-PCR. Increasingly state public health laboratories have been testing for noroviruses and currently three quarters of all norovirus outbreaks are diagnosed by the states and a quarter by CDC. RT-PCR has allowed for norovirus strains to be sequenced and the development of CaliciNet, a nationwide database of norovirus sequences has allowed comparison of norovirus sequences from different outbreaks.

For effective interpretation of the significance of similar sequences, however, some epidemiological information is required. Currently, epidemiological information on norovirus outbreaks that are linked to food contamination is reported to the foodborne branch electronically via EFORS. However, there is no collection of epidemiological data of non-foodborne outbreaks of norovirus.