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

DIARRHEAL DISEASE SURVEILLANCE

The three most common bacterial causes of diarrhea in the United States are *Salmonella*, *Campylobacter*, and *Shigella*. The Council of State and Territorial Epidemiologists has endorsed the need for CDC to maintain surveillance for all three infections. The data are essential to measure trends, recognize multi-state or international outbreaks, and evaluate effectiveness of prevention efforts.

The surveillance system involves entry of data into an electronic reporting system which was implemented in 1990, the Public Health Laboratory Information System (PHLIS) by State Health Departments. PHLIS is a PC-based reporting system for local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. PHLIS was developed by CDC, and is potentially capable of handling any data types (epidemiologic, laboratory, hospital, special studies, etc.). The laboratories are asked to enter information on human and nonhuman isolates. Data requested include: species/serotype, patient's name (which are encrypted prior to coming to CDC, see justification below), age, sex, county of residence, residence type at onset, and specimen from which isolate was obtained (stool, blood, other). Cooperating State Health Departments report to CDC, by phone if there is something felt to be urgent. Currently, information concerning isolates is electronically reported each week through PHLIS from all 50 states and selected territories. Patient name or other identifiers are maintained at the state health department and are stripped electronically before information is transmitted to CDC. The switch to electronic entry and reporting also improved the function of the systems in other ways, reducing time needed for data entry and transmission and analysis, and giving the participants more ready access to the data.

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OVERVIEW OF CDC RABIES SURVEILLANCE
New formats introduced for electronic reporting of animal rabies cases and new forms introduced for human rabies diagnosis.

This group contains descriptions of the following:
Monthly Report of Laboratory Confirmed Cases of Rabies: CDC 55.28
Enhanced Animal Rabies Surveillance (electronic)
Possible Human Rabies Patient Information (paper)

The Centers for Disease Control and Prevention has responsibility for national surveillance of human and animal rabies with the goal of determining the circulation of rabies in animal reservoir populations, human exposure and impact of the disease on the U.S. population, and providing critical information necessary for ongoing control measures (Such as oral vaccination of wildlife in collaboration with the US Department of Agriculture). While on average 2-3 human cases of rabies are reported each year, approximately 25,000 – 35,000 persons require rabies postexposure prophylaxis (PEP) each year due to potential rabies exposures. Also primary diagnosis of animals involved in human exposures by state health, university, and agricultural laboratories provides critical information on the rabies status of those animals preventing an additional 60,000-100,000 persons from requiring rabies PEP each year.

Surveillance data are used to provide information on the circulation of rabies virus in animal populations regionally and locally. This information is frequently of a critical nature for treatment decisions in situations where an animal is not available for diagnostic testing after an animal exposure. Animal rabies surveillance has also provided information necessary to document the recent elimination of canine rabies virus variants (responsible for dog-to-dog rabies transmission) in the US and ongoing surveillance is critical to ensure canine rabies has not been reintroduced into the US. Clinical information provided on human rabies cases is used to record the occurrence of human rabies cases and provide historical and prospective information on the clinical course of rabies and may provide important information for evaluating new biologics and potential human rabies treatment protocols.

In addition to monitoring annual circulation of rabies in animal populations and the occurrence of rabies in humans, these systems are in place to detect novel viruses or host shifts of rabies virus variant between reservoir species which could result in new focuses of rabies in regions previously unaffected by rabies in carnivore species with a subsequent increase in risk to humans.

Monthly Report of Laboratory Confirmed Cases of Rabies: CDC 55.28

For the reporting of animal rabies, most respondents have converted from the hard-copy aggregate reporting form to electronic reporting of enhanced animal rabies surveillance data. Aggregate case reporting continues to be used by a few respondents that have not yet moved to electronic reporting.

Enhanced Animal Rabies Surveillance (electronic)

Enhanced animal rabies surveillance consists of additional information on all animals tested for rabies by state public health, state agricultural, and university laboratories. This information, beyond aggregate number of cases collected in form CDC 55.28, is critical for determining fluctuations in rabies incidence in animal populations while controlling for testing bias. Enhanced information also includes human and animal exposures, animal rabies vaccination status, detailed animal collection locations, and rabies virus variant information which are critical in further determining the burden of animal rabies on human populations. The Rabies Surveillance Network involves 100% electronic reporting of national animal rabies data, with no forms. Requested data elements for reporting are specified and data is provided in various formats (either automated through PHLIS-PHINMS or periodic email submission of data exported from state surveillance databases). Frequency of enhanced rabies testing data is variable ranging from weekly to monthly depending on submission rates of animals for rabies testing at state laboratories. More real-time data collection allows for better situational awareness for state and federal partners performing oral rabies vaccination of wildlife populations and otherwise response and direct communications to public in areas where epizootics of rabies are occurring. Animal rabies data is routinely available ad hoc for participating state and federal partners via the Rabies Surveillance Network web-based application in addition to an annual summary available publicly in September issue of the Journal of the American Veterinary Medicine Association.

Possible Human Rabies Patient Information (paper)

The Possible Human Rabies Patient Information form, a standardized questionnaire which contains detailed questions on relevant clinical and epidemiologic features of possible human rabies cases, was developed by CDC to collect important information on potential human rabies cases that submit samples to the CDC rabies laboratory for diagnostic testing. This information is submitted ad hoc by physicians when submitting samples for rabies diagnosis accounting for approximately 50 submissions each year. Collection on all cases submitted for diagnosis allows for collection of information on non-rabies encephalitis cases which are periodically used in cross-sectional analysis to identify risk factors that may be associated with human rabies versus other unknown encephalitis. Because of the relatively rare occurrence of human rabies these cases are presented on an individual basis as case reports in MMWR. Reviews of overall trends in

human rabies cases are tabulated and published on a semi-decadal basis. A hospital provided identification of patient and physician contact information is collected to facilitate communication of diagnostic results with hospitals and physicians, but CDC does not directly collect or store personally identifiable information for possible human rabies patient submissions.

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NATIONAL RESPIRATORY AND ENTERIC VIRUS SURVEILLANCE SYSTEM (NREVSS) - Forms 55.83A-D

Respiratory viruses reported using this form include RSV, PIV, Res. Adenovirus and influenza, and Enteric viruses include Rotatvirus 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.

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/ncidod/dvrd/revb/nrevss/index.htm).

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NATIONAL ENTEROVIRUS SURVEILLANCE SYSTEM (CDC 55.9)

Since 1964, state health departments have reported to CDC all enteroviruses isolated in their laboratories, regardless of clinical syndrome. This project, known as the Enterovirus Surveillance Program, was initially undertaken through the auspices of the Joint Committee of the Conference of State and Territorial Public Health Laboratory Directors. Reports are generally sent directly from the laboratory to CDC. Information solicited on the previously approved reported form (CDC 55.9) included demographic data (age, sex, state, year); clinical data (date of onset, syndrome, outcome); and laboratory data (enterovirus type isolated, anatomic source(s) if isolation) on all cases with one or more enterovirus isolated.

The present reporting form has been developed in Microsoft Excel to reduce the reporting burden. Clinical data is not requested, 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.

The purpose to undertaking national enteroviral surveillance was to monitor trends in the circulation of these viral agents, many of which are associated with severe clinical illness. Through analysis of the national database, one may approach more immediate problems of outbreak recognition and etiologic diagnosis. Ultimately, these data may provide insight leading to better control and prevention practices. Results of these reports are published periodically in the *MMWR* and peer-reviewed journals.

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

INVESTIGATION OF A FOODBORNE OUTBREAK (CDC 52.13)

This report provides for the systematic entry of basic data from an epidemiologic investigation of an acute foodborne disease outbreak of any etiology, including bacterial, parasitic, viral or chemical causes. 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 foodborne outbreaks. State and local health departments send completed reports on outbreaks they have investigated to CDC to be tabulated and analyzed and summarized. Data are published periodically in the *MMWR* and the *Foodborne Disease Surveillance Report*. Historically, use of data collected by this system had been slowed because of the long time required for data entry and coding once the forms are received. In 2001, CDC introduced electronic reporting of foodborne outbreak data through the Electronic Foodborne Outbreak Reporting System (EFORS). EFORS is a web-based reporting system that collects the same information as the paper forms, and can be used by local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. All reports beginning with 2001 data are entered into EFORS. Instructions for completing the form and posted on the internet. The form includes the OMB approval number and the burden advisement. EFORS ended and the National Outbreak Reporting System (NORS) began in 2009. NORS will allow the continual reporting of foodborne-associated illnesses, in addition to the following modes of transmission: person-to-person, animal contact, and envrironmental contamination other than food/water. The burden increased slightly due to the number of responses per respondent increasing and a slight increase in time for the response.

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WATERBORNE DISEASES OUTBREAK REPORT FORM (CDC 52.12)

The Waterborne Disease Outbreak Surveillance System is a collaboration between CDC, the Council of State and Territorial Epidemiologists, and the Environmental Protection Agency (EPA). This system is the only surveillance system for tracking and analyzing waterborne disease outbreaks in the United States and it has compiled data on over 1300 outbreaks since 1971. The data are used routinely to inform CDC recommendations and the system supplies critical data for EPA decision-making regarding existing and new regulations related to drinking water safety.

This form is used to summarize the data collected in investigations of waterborne disease outbreaks caused by drinking water or recreational water. The form captures the etiologic agents responsible for the outbreaks and identifies the water system deficiencies associated with outbreaks in order to improve prevention efforts. Data collected include: type of exposure, location of outbreak, date of outbreak, number of persons exposed and ill, symptoms, incubation period, duration of illness, etiologic agent, epidemiologic results such as attack rates, laboratory results of human specimens and water samples, characteristics of the water system and its deficiencies, and factors contributing to the contamination of the water. The form ensures the systematic collection of data by state and local health departments, which routinely investigate these outbreaks. No personally identifiable data are collected on this form. The data collected on this form are maintained in a database which resides on a CDC server and access is restricted.

Data on reported waterborne outbreaks are analyzed and published every two years in the Morbidity and Mortality Weekly Report Surveillance Summaries (MMWR-SS). These Surveillance Summaries are the most comprehensive account of waterborne disease outbreaks in the United States and have been cited in scientific publications more than 450 times over the past 15 years.

This has also been included in the National Outbreak Reporting System (NORS). This will simplify data collection and entry for state partners. Many of the waterborne outbreak disease coordinators already report foodborne disease outbreaks to CDC. It has been possible to develop a shared section of common outbreak questions. NORS has improved the quality of the data and its usability by local, state, and national partners.

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OVERVIEW OF CDC INFLUENZA SURVEILLANCE
Increase in burden due to increase in cases. New formats introduced for Internet reporting.

This group contains descriptions of the following thirteen forms:
WHO Collaborating Center for Influenza Surveillance, Influenza Virus Surveillance: CDC 55.31 (facsimile/internet), US WHO Influenza Collaboration Laboratories Address Update CDC 55.31A (annual survey)
U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet): CDC 55.20E (work folder), ILINet Reports of Influenza-Like Illness (ILI) CDC 55.20 (facsimile), daily ILINet Reports of Influenza-like Illness (ILI)
Influenza-Associated Pediatric Mortality (case report form)
Aggregate Hospitalization and Death Reporting Activity (Aggregate Hospitalization and Death Reporting Activity Weekly Report form)
Human Infection with Novel Influenza A Virus (Novel and Pandemic Influenza A Virus Infection Case Investigation Form, Novel and Pandemic Influenza A Virus Infection Contact Trace Back Form, Novel and Pandemic Influenza A Virus Infection Contact Trace Forward Form, Novel Human Influenza A Virus Infection Case Report Form, Daily Novel and Pandemic Influenza A Virus State Case Status Summary Update)
122 Cities Mortality Reporting System: CDC 43.5 (facsimile/internet). Daily Mortality Report (facsimile/internet)

The Centers for Disease Control and Prevention has responsibility for surveillance of influenza with the goal of determining the impact of the disease on the U.S. population and developing improved control measures. It has been estimated that influenza is responsible for approximately 36,000 deaths and more than 200,000 hospitalizations during an average influenza season. The continuing emergence of new strains of influenza, such as 2009 influenza A (H1N1) virus, necessitates annual virologic and epidemiologic surveillance.

Surveillance data are used to determine influenza vaccine composition for the following year. Influenza virus type A (H3N2), A (H1N1), and B circulate worldwide, but with differing intensities each year. Influenza virus type A (H3N2) infections have been associated with reports of outbreaks among all age groups. Influenza A (H1N1) infections have been recognized predominately among children and young adults and are associated with school outbreaks. Influenza type B virus has caused outbreaks of influenza in schools as well as other institutions, such as nursing homes. In April 2009, 2009 influenza A (H1N1) virus was identified in the United States and virus infections has been reported worldwide. 2009 influenza A (H1N1) virus infections have been associated with reports of illnesses and outbreaks in all age categories. Surveillance 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.

Influenza Virus Surveillance (Form CDC 55.31)

Form CDC 55.31 is a single fax form used to collect summary influenza virus data from collaborating laboratories around the country. The web interface for labs that choose to report their data over the Internet is identical to the paper fax form. 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 World Health Organization (WHO) Influenza Surveillance Program report numbers of throat or nasopharyngeal swab specimens submitted for influenza diagnosis and the number positive for influenza. All laboratories report these data weekly from October through mid-May and the majority of these laboratories are reporting these data all year. These reports are used to assess and report the distribution of influenza virus strains throughout the United States.

Weekly data are transmitted to CDC by facsimile (26 laboratories), over the Internet (38 laboratories), or electronically using the Public Health Information Network – Messaging System (PHIN-MS) (17 laboratories) and Public Health Laboratory Interoperability Project (PHLIP) (5 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. Most of the 20 state 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 or Internet has been reduced. Data collection through the Public Health Laboratory Information System (PHLIS) ended in September 2008. No patient identifiers are received at CDC.

Changes to the form 55.31 include:

- Correction of the OMB approval number
- Addition of number of 2009 influenza A (H1N1) isolates collected and number of influenza A (unable to be subtyped) isolates collected (by age group)

Influenza Virus Surveillance Survey (Form CDC 55.31A)

Once a year a survey is sent to each participating laboratory to obtain information used in analyzing and interpreting data obtained from year-to-year.

U.S. Outpatient Influenza-like Illness Surveillance Network (CDC 55.20)

Form CDC 55.31 is a single fax form used to collect summary influenza-like illness data from participating healthcare providers. Providers have the option of faxing this data in 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 2008-09 season, approximately 1,800 health care providers in all 50 states regularly reported to CDC.

Participating providers report the following data each week from October through mid-May: influenza-like illnesses by age group, and the total number of patients seen for any reason. These data are shared by CDC and state health departments. A subset of healthcare providers has volunteered to report these data year round. Year-round influenza surveillance data typically provides a baseline level of influenza activity during the summer months and is proving to be extremely helpful in monitoring the course of the 2009 influenza A (H1N1) virus activity during the summer of 2009. Weekly ILI data are essential components of seasonal and pandemic influenza surveillance and are used to detect other unusual occurrences of influenza-like illness.

The primary method of reporting is Internet (87%) using form 55.20E as a work folder. A few providers still prefer to transmit their data via facsimile (13%) (CDC55.20). The facsimile form is part of the work folder. No patient identifiers are received at CDC.

In 2009, enhanced surveillance efforts were recommended by CDC in response to the emergence of the 2009 influenza A (H1N1) virus in the United States. The CDC pandemic surveillance plan calls for increasing the frequency of surveillance reporting from weekly to daily in sites where that is feasible. Daily influenza-like illness reporting will result in more timely data collection and accelerate the implementation of public health responses.

The daily ILINet Reports of Influenza-like Illness (ILI) is a single fax form used to collect daily summary influenza-like illness data from participating healthcare providers. Providers have the option of faxing this daily ILI data in via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form. No patient identifiers are received at CDC.

Changes to the form 55.20E and 55.31 include:

- Correction of the OMB approval number
- The U.S. Influenza Sentinel Provider Surveillance Network was renamed to the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) to more accurately reflect CDC's increasing use and inclusion of electronic influenza-like illness data.
- Added in two new influenza-like illness age groups (25-49 years and 50-64 years), splitting the existing 25-64 year age group, to help inform vaccine policy decisions

Influenza-Associated Pediatric Mortality (case report form)

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 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 Data Network (SDN) or HL7 messaging system. Laboratory-confirmed influenza-associated deaths in children are reported through the Nationally Notifiable Disease Surveillance System (NNDSS). Data obtained from this form has lead 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.

Changes to the form include:

- Currently, only limited data on pediatric influenza-associated deaths is collected through NNDSS. The expanded case report form will provide additional data elements that will be used to monitor severe outcomes in pediatric patients.

Aggregate Hospitalization and Death Reporting Activity

The Aggregate Hospitalization and Death Reporting Activity Weekly Report Form is a single form used to collect summary data from the New York City, state, and territorial health departments regarding influenza-associated hospitalizations and deaths. State or territorial influenza surveillance epidemiologists report these data over the Internet on the Secure Data Network (SDN).

To supplement data from established influenza surveillance systems, improve surveillance timeliness, and expand geographic coverage to meet specific needs of the 2009 influenza A (H1N1) pandemic response, the Centers for Disease Control and Prevention (CDC) and the Council for State and Territorial Epidemiologists (CSTE) established the Aggregate Hospitalization and Death Reporting Activity (AHDRA) . AHDRA provides timely and representative notification of severe outcomes associated with influenza infection by providing CDC with the ability to: (i) track severe disease within states and territories in order to better capture the focal nature of the pandemic, (ii) track disease trends over brief periods of time in order to facilitate rapid public health responses to changes in influenza epidemiology, and (iii) accommodate variation in local resources by providing a simple, flexible method that allowed reliable reporting by all states and territories without overwhelming health departments during the course of the pandemic response.

Reporting jurisdictions are permitted to submit using a laboratory-confirmed or syndromic definition and are instructed to report aggregate counts for both outcomes on a weekly basis throughout the influenza season (October through mid-May of the following year). These data are shared by CDC and state health departments. The primary method of reporting is via a web-based data entry screen (100% of reporting jurisdictions). Only aggregate data are reported and no patient identifiers are received by CDC.

Changes to the form include:

- Additional data elements provide timely and representative notification of severe outcomes associated with influenza infection.

Human Infection with Novel Influenza A Virus

- Novel and Pandemic Influenza A Virus Infection Case Investigation Form, Novel and Pandemic Influenza A Virus Infection Contact Trace Back Form, Novel and Pandemic Influenza A Virus Infection Contact Trace Forward Form, Novel Human Influenza A Virus Infection Case Report Form, Daily Novel and Pandemic Influenza A Virus State Case Status Summary Update

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. Rapid reporting of human infections with novel influenza A viruses will facilitate prompt detection and characterization of influenza A viruses.

The Novel and Pandemic Influenza A Virus Infection Case Investigation Form should be used for investigation of suspected, probable, or confirmed cases of novel and pandemic influenza A virus infection. The Novel and Pandemic Influenza A Virus Infection Contact Trace Back Form should be used to determine the source of infection for suspected, probable, or confirmed cases of novel and pandemic influenza A virus infection. The Novel and Pandemic Influenza A Virus Infection Contact Trace Forward Form should be used to identify and follow contacts of persons with suspected, probable, or confirmed cases of novel and pandemic influenza A virus infection. The Novel Human Influenza A Virus Infection Case Report Form should be used by state health departments to report cases of confirmed novel and pandemic influenza A virus infection to CDC. The Daily Novel and Pandemic Influenza A Virus State Case Status Summary Update form should be used by state health departments to report aggregate numbers of suspected, probable, or confirmed cases of novel and pandemic influenza A virus infection to CDC. These forms contain detailed questions on relevant clinical and epidemiologic features of influenza, were developed by CSTE and CDC.

Core surveillance data will be reported to the National Notifiable Diseases Surveillance System (NNDSS) through the National Electronic Telecommunications System for Surveillance (NETSS) or the National Electronic Disease Surveillance System (NEDSS), as per state protocol.

Changes to the form include:

- Additional data elements will be instrumental in investigations of novel influenza A virus infections and will accelerate the implementation of effective public health responses.

122 Cities Mortality Reporting System Weekly Mortality Report (CDC 43.5)

The weekly mortality report is made by city health officers or vital statistics registrars from 122 major cities and metropolitan areas, using CDC 43.5. Reporters have the option of emailing or faxing this data in via a toll-free fax number, or the numbers reported by phone, or reporting data over the Internet. The web interface is identical to the fax form.

It is a report in which total deaths by age categories are cross-classified by number of deaths assigned to pneumonia and influenza. In preparing the report, the number of total deaths for all causes is entered for each age category: less than 28 days of age, 28 days to 1 year, and for succeeding age groupings; then the number of pneumonia and the number of influenza deaths are entered for each age category. Thus, the total number of deaths shown for any age category includes the number of deaths assigned to pneumonia and/or influenza. The weekly mortality report from 122 U.S. cities covers a period of 7 days.

The beginning and ending dates of the reporting week are established by the city or county health officer or vital statistics registrar, preferably dates which correspond with the usual work week. Their reporting period should be constant from week to week. The report should be received in Atlanta as soon as possible after the close of each weekly reporting period, and no later than noon on the following Tuesday. If a city's weekly mortality report is not received in Atlanta by Tuesday noon, a staff member from the Influenza Division (ID) in NCIRD telephones that city's reporter and collects the necessary data, as available. The data collected by Tuesday noon are published electronically on Thursday in the *Morbidity and Mortality Weekly Report (MMWR)* with a publication date of Friday and are available electronically through the Internet at *http://www.cdc.gov*.

Each week, the vital statistics offices of 122 cities report the total number of death certificates received and the number of those for which pneumonia or influenza was listed as the underlying or contributing cause of death by age group. The percentage of all deaths due to pneumonia and influenza (P&I) are compared with a seasonal baseline and epidemic threshold value calculated for each week. The seasonal baseline of P&I deaths is calculated using a periodic regression model that incorporates a robust regression procedure applied to data from the previous five years. An increase of 1.645 standard deviations above the seasonal baseline of P&I deaths is considered the "epidemic threshold," i.e., the point at which the observed proportion of deaths attributed to pneumonia or influenza was significantly higher than would be expected at that time of the year in the absence of substantial influenza-related mortality.

Weekly reporting of mortality data by health officers and vital registrars in 122 U.S. cities and metropolitan areas is used with data reported from collaborating laboratory and epidemiologic surveillance to identify national and regional influenza outbreaks.

The primary method of reporting is Internet (62%) using form CDC 43.5. Several city reporters prefer to transmit their data via facsimile (38%) (CDC 43.5). No patient identifiers are received at CDC.
In 2009, enhanced surveillance efforts were recommended by CDC in response to the emergence of the 2009 influenza A (H1N1) virus in the United States. The CDC pandemic surveillance plan calls for increasing the frequency of surveillance reporting from weekly to daily in sites where that is feasible. Daily mortality reporting will result in more timely data collection and accelerate the implementation of public health responses.

The daily mortality report is a single fax form used to collect the total deaths by age categories that are cross-classified by number of deaths assigned to pneumonia and influenza from participating city health officers or vital statistics registrars. Reporters have the option of faxing this daily ILI data in via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form. No patient identifiers are received at CDC.

Changes to the form 43.5 include:

- The Influenza Division/National Center for Immunization and Respiratory Diseases requests that the responsibility for data collection for 122 Cities Mortality System be transferred from OMB No. 0920-0007 to OMB number 0920-0004 to reflect the Influenza Division's administration and management of this surveillance system.

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Arboviral Diseases (including West Nile Virus) (100% electronic collection)

Prior to the first detection of West Nile virus (WNV) in the United States in September 1999, arboviral diseases - along with other nationally notifiable diseases - were electronically reported to the CDC through the National Electronic Telecommunications System for Surveillance (NETSS), whose publication of disease activity lags from several months to a year behind the date of disease reporting. No endemic arboviruses are currently reported through NETSS. At one time, reporting to NETSS was via the Human Arboviral Encephalitis Surveillance system on CDC form 55.3, which is now obsolete.

The public health concern over the anticipated geographic spread of WNV within in the United States led CDC in 2001 to begin accepting reports of WNV via ArboNET, an enhanced, web-based electronic reporting system for closely monitoring national WNV activity in humans, non-human mammals, birds and mosquitoes. The inclusion of other nationally notifiable arboviruses into ArboNET occurred in 2003**.** If needed, CDC ArboNET staff can also receive arboviral activity reports by telephone, fax, or e-mail. This unique, multi-faceted surveillance system has proven essential for the early detection of arboviral disease activity and for monitoring the spread of epidemic transmission of WNV. The arboviral transmission season begins in early summer with peak activity generally occurring in August-September when vector mosquito populations are at their peak. Information on nationwide transmission is disseminated weekly on electronic bulletin boards during the transmission season. In addition, periodic reports and an annual summary are published in the *MMWR*. Access to ArboNET requires a Digital Certificate to assure restricted access to sensitive data.

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Cholera and other *Vibrio* Illness Surveillance Report (CDC 52.79)

In 1988, Gulf Coast State Health Departments agreed to voluntarily report laboratory confirmed *Vibrio* illnesses to CDC. *Vibrio* species are naturally occurring marine bacteria and an important cause of seafood-borne and wound associated illnesses. Certain *Vibrio* species (e.g., *V. cholera, V. parahemolyticus*) cause dehydrating diarrheal illnesses. In addition to endemic cholera in the United States, illnesses caused by epidemic strains of cholera are reported among travelers returning from southern Asia and Latin America.

Other *Vibrio* species (e.g., *V. vulnificus*) result in septicemia and even death in individuals with underlying diseases such as liver disease or congestive heart failure. Since the 1970's, CDC has identified *V. vulnificus* as an emerging foodborne pathogen.

Beginning with data collected in 1999, an annual summary of results has been provided to CSTE and distributed to all state epidemiologists and directors of state public health laboratories. The data provide important information on the public health impact of vibriosis in the Gulf Coast States.

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The paper form is necessary because public health nurses at the local level often perform initial data collection. Data collection is focused on relevant clinical and epidemiologic features of *Vibrio* illnesses. Use of the form is more efficient than the review of medical records to capture this information.

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

Outbreak Report of Suspected Viral Gastroenteritis

(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.

Data collected will include suspected source, setting, number exposed, and number of cases. This will allow CDC to link outbreaks together and assist in the development of control measures. This information will eventually be collected through a web-based reporting system which is being developed. The information will be accessible to states investigating outbreaks, initially by contact with the viral gastroenteritis section at CDC, and in the future via the Internet.

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

LISTERIA CASE FORM

Listeria monocytogenes is a facultative intracellular pathogen that causes serious illness among newborns, elder, and immunocompromised persons. It is usually acquired through ingestion of contaminated food, and it is a leading cause of death due to foodborne diseases in the United States. In 1999, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making listeriosis a nationally notifiable disease. The Listeria Case Form, a standardized case questionnaire which contains detailed questions on the consumption of high-risk foods, was developed by CSTE and CDC. Prompt interviewing of case patients using this form has lead to improvements in detecting and investigating listeriosis outbreaks, and the reduction of resources required to investigate listeriosis outbreaks. Data obtained from this form has lead to the timely identification and recall of contaminated foods.

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The paper form is necessary because public health nurses at the local level often perform initial data collection. Data collection is focused on relevant clinical and epidemiologic features of listeriosis collecting through medical chart review and patient interview.

Personal identifiers collected by state or local public health officials; this information is removed from the form and maintained at the state health department before submission to CDC. Data are reported to CDC monthly.

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

Harmful Algal Bloom-Related Illness Surveillance System (HABISS)

The extent of human illness caused by environmental exposure to algal toxins in drinking and recreational waters is an unknown, but emerging, public health concern. We do know that algal toxins include some of the most potent natural chemicals known and there is potential for exposure in any community using surface water for drinking or recreation. Harmful algal blooms (HABs) occur when an overgrowth of algae creates and environmental or health threat. Symptoms often occur from immersion, inhalation, and ingestion to water and/or food containing the toxin. The adverse health effects from HABs include the known shellfish poisonings, ciguatera fish poisoning, respiratory effects from aerosolized brevetoxins from Florida red tide, and other illnesses associated with exposure to the potent cyanobacterial (blue-green algal) toxins. There is evidence that the frequency and geographic distribution of HABs is increasing, and further increases in HABs are one of the most likely consequences of global climate change.

HABISS is a web-based surveillance system that allows collection of both human and animal health data as well as environmental data about the harmful algal blooms themselves. Data collection is organized in a modular format that can be expanded to suit the needs of state and local health and environmental protection agencies.

Public health agencies are provided with digital certificates that allow them to enter data into HABISS online. The system is presently being used in pilot programs by Florida, North Carolina, and Virginia.

Surveillance items to be collected include agency point of contact(s), geographic coordinates of algal event (s), laboratory algal identification results, time of algal events, time of human or animal exposure, case identifying information of those experiencing human illness (e.g. age/gender/mailing address/phone), route(s) of exposure, clinical signs and symptoms, medical review (s), clinical laboratory results, case definitions, case assessment, diagnosis, and follow-up data. Personal identifiers will be discussed in further detail, in Section A.10. CDC will ensure that several safeguards remain in effect throughout the duration of the surveillance system. These safeguards are also discussed in Section A.10. Screen shots of the web-based surveillance instrument can be found in Attachment 3 of this supporting statement.

Identification of Website and Website Content Directed at Children Under 13 Years of Age

This information collection will involve web-based data collection methods. Only state public health staff in the states who have successfully applied for and obtained funding from CDC and who have obtained digital certificates will be able to enter data into HABISS online. No content is directed to children under 13 years of age.

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

Babesiosis Case Surveillance

Babesiosis is caused by intraerythrocytic parasites of the genus *Babesia*, which are transmitted by infected ticks. In June 2010, due to public health concern over the increasing incidence of reported cases of babesiosis and the growing frequency of transfusion-associated cases, the Council of State and Territorial Epidemiologists voted to add babesiosis to the list of nationally notifiable conditions. CDC is responsible for the collection and publication of data regarding nationally notifiable conditions. Accurate surveillance data allow for the development and evaluation of public health prevention measures. Data on reported babesiosis cases will be published in the Morbidity and Mortality Weekly Report (MMWR).

To prepare for national babesiosis surveillance, a babesiosis case report form was developed. This form facilitates the systematic collection of demographic data, clinical information, risk factors for infection, and laboratory testing results shared with CDC by state and local health departments. These data are maintained in a database which resides on a restricted-access CDC server. Personal identifiers collected by state or local public health officials are removed from the form before submission to CDC.

CDC is utilizing technology to minimize the buden associated with completing and submitting the babesiosis case report form. Data may be electronically transmitted through the National Electronic Telecommunications System for Surveillance (NETSS) or the National Electronic Disease Surveillance System (NEDSS), along with other nationally notifiable diseases. NEDSS (OMB 0920-0728) is an internet-based infrastructure for public health surveillance data exchange that uses specific Public Health Information Network (PHIN) and NEDSS electronic data and information standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state and local levels. Minimal case data will be reported electronically to CDC's Nationally Notifiable Disease Surveillance System on a weekly basis. States may develop an interface between their state surveillance system and CDC's NEDSS to improve the timeliness and quality of the data and to reduce the burden of summarizing this information and transmitting it by facsimile.

Burden estimates are based on CDC's prior experience conducting similar surveillance activities. There is no cost to respondents other than their time.

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

Brucellosis Case Report Form

Brucellosis, caused by *Brucella* spp., is a zoonotic disease that has been classified as a Nationally Notifiable Condition (NNC) and a Category B select agent. Brucellosis can cause a range of influenza-like signs and symptoms that may include fever, arthralgia, headache, myalgia, and weight loss. Later manifestations can include focal organ involvement (meningitis, endocarditis, hepatomegaly, orchitis/epididymitis, splenomegaly) and systemic symptoms such as arthritis/spondylitis, recurrent fevers, and fatigue.

Though brucellosis is a NNC, it is thought that cases are underreported due to its nonspecific symptoms and difficult clinical diagnosis. Based on data collected during outbreak investigations, it appears that the causative risk factors for brucellosis have been changing in the United States, but the *National Notifiable Diseases Surveillance System (***NNDSS)** does not collect sufficient information to capture the changes. Collecting more extensive information on *Brucella* species, risk factors, disease manifestations and/or links between cases can facilitate analyses of changes in risk factors and trends over time. The Brucellosis Case Report Form will collect additional detailed epidemiologic data.

Development and dissemination of an updated Case Report Form will allow the collection of information such as *Brucella* species, travel history, risk factors, and history of laboratory exposures. Variables developed for the collection of this information were approved by CSTE in the 2010 Brucellosis Position Statement (09-ID-14). The case data received from completed Case Report Forms will be used to gain a better understanding of risk factors associated with brucellosis, the *Brucella* species causing disease, and the burden of laboratory exposures and laboratory-acquired brucellosis.

Case confirmation is ascertained by definitive laboratory evidence, such as serology or culture and isolation. In the laboratory, *Brucella* spp. isolates are recommended to be manipulated under Biosafety Level 3 conditions because they are easily aerosolized. Brucellosis is one of the most commonly reported laboratory-acquired infections. Veterinary workers are also at risk of exposure to animal vaccines which can be infectious. The true burden of laboratory-acquired or vaccine-acquired brucellosis is unknown.

The Case Report Form will enhance brucellosis surveillance, simplify reporting of cases, and improve current treatment and laboratory-exposure prophylaxis recommendations. This ensures the systematic collection of data by state and local health departments, which routinely investigate cases. Many states that use the 1980 CDC Brucellosis Case Report Form (OMB 68-R3041) may wish to replace it with the updated form for state investigations as well as submission to CDC. Completion and submission of the Case Report Form will be requested by CDC on a voluntary basis for each brucellosis case. Those few states which experience a greater than average disease burden may submit

their own state case report form in place of the CDC Case Report Form.

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection methods. Personal identifying information collected by state or local public health officials is removed from the form and maintained at the state health department before submission to CDC. Transmittal to CDC will be via mail or facsimile. Data are reported to CDC by standard notification intervals as determined by CSTE. The data collected on this form are maintained in a database which resides on a CDC server and access is restricted. The forms will be stored in a locked cabinet in a locked office.