

Attachment C –Surveillance Summaries

National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Creutzfeldt-Jakob Disease Surveillance

Creutzfeldt-Jakob disease (CJD) is an invariably fatal neurodegenerative disease that occurs at about one case per million population per year. About 10% of CJD deaths occur in patients <55 years of age. Since 1996, a new variant form of CJD (vCJD) has been reported to occur among unusually young patients primarily in the United Kingdom but also other European countries. Most vCJD patients died at <55 years of age. Strong laboratory and epidemiologic evidence indicate that vCJD is causally linked with bovine spongiform encephalopathy (BSE). BSE is a disease in cattle that was first recognized in the United Kingdom in 1986 but has since been identified in many other European countries, Canada, Japan, Israel, and the United States. The first vCJD case in the United States was reported in a long-term U.S. resident who was born and raised in the United Kingdom during the height of the BSE epidemic there. CDC monitors the occurrence of CJD and vCJD in the United States by employing several CJD surveillance mechanisms. One of these mechanisms focuses on the striking difference in age distribution of CJD and vCJD cases and involves investigation of CJD decedents <55 years of age.

However, because the patients are deceased, IRB has not raised human subject concerns. HIPAA allows collection of data for public health surveillance purposes.

The occurrence of these diseases has been shown to differ among various racial groups, and certain racial/ethnic groups may be more at risk for certain disease complications. It is therefore important to collect race/ethnicity information.

Data collection methodology: Surveillance forms are completed by the state and submitted to CDC.

1Cyclosporiasis Surveillance Case Report Form (CDC 54.48)

Cyclosporiasis is caused by the parasite *Cyclospora cayetanensis*. Foodborne outbreaks of cyclosporiasis have been recognized and investigated in the United States almost every year since 1995. As a result of a large, multi-state outbreak in 1996, the Division of Parasitic Diseases (DPD) established a sentinel surveillance system for cases of cyclosporiasis. In 1998, the Council of State and Territorial Epidemiologists (CSTE) recommended that cyclosporiasis be made a nationally notifiable disease; to date (as of 2006), 37 states have made cyclosporiasis reportable. The primary method for states to report cases to CDC is through the National Electronic Telecommunications System for Surveillance (NETSS), an electronic disease reporting system that collects data on a limited number of variables, mostly demographic, that are not tailored to the disease being reported. The National Electronic Disease Surveillance System (NEDSS), which was launched in March 2006, allows states that have the necessary technology and support staff to submit more extensive epidemiologic and laboratory data about cases of various diseases, including cyclosporiasis. However, to date, relatively few states have this capability. To obtain additional data about cases that are reported through various means, DPD contacts health departments and provides the 2-page report form. This form continues to be needed/used to facilitate timely collection of data in a structured format and thereby to detect and prevent outbreaks.

Infection with *Cyclospora* involves symptoms associated with gastroenteritis, including watery diarrhea, with frequent, sometimes explosive stools; anorexia, nausea; vomiting; abdominal bloating and cramping; weightloss, which can be substantial; fatigue; and body aches (1). Onset of symptoms generally occurs an average of 7 days after exposure and illness can often be prolonged but ultimately self-limited. Infection is treatable with TMP-SMZ (1)

1. Herwaldt BL. *Cyclospora cayetanensis*: a review, focusing on the outbreaks of cyclosporiasis in the 1990s. Clin Infect Dis 2000;31:1040-57.

Dengue Case Investigation (CDC 56.31A-B)

Dengue and dengue hemorrhagic fever (DHF) are caused by one of four closely related, but antigenically distinct, virus serotypes (DEN-1, DEN-2, DEN-3, and DEN-4), of the genus *Flavivirus*. Dengue is primarily a disease of the tropics, and the viruses that cause it are maintained in a cycle that involves humans and *Aedes aegypti*, a domestic, day-biting mosquito that prefers to feed on humans. Infection with dengue viruses produces a spectrum of clinical illness ranging from a nonspecific viral syndrome to severe and fatal hemorrhagic disease. The first reported epidemics of dengue fever occurred in 1779-1780 in Asia, Africa, and North America; the near simultaneous occurrence of outbreaks on three continents indicates that these viruses and their mosquito vector have had a worldwide distribution in the tropics for more than 200 years.

The emergence of dengue/DHF as a major public health problem has been most dramatic in the

American region. Each year, tens of millions of cases of dengue fever occur and, depending on the year, up to hundreds of thousands of cases of DHF. The case-fatality rate of DHF in most countries is about 5%; most fatal cases are among children and young adults.

The reasons for this dramatic global emergence of dengue/DHF as a major public health problem are complex and not well understood. However, several important factors can be identified. First, effective mosquito control is virtually nonexistent in most dengue-endemic countries. Second, major global demographic changes have occurred, the most important of which have been uncontrolled urbanization and concurrent population growth. Third, increased travel by airplane provides the ideal mechanism for transporting dengue viruses between population centers of the tropics, resulting in a constant exchange of dengue viruses and other pathogens.

The CDC Dengue Branch's surveillance system is a passive (i.e., voluntary), laboratory-based system. And as such, personal identifiers are needed in order to inform healthcare providers about the laboratory results of their patients. CDC provides this service to the general public at no cost to the consumer. However in order to perform this function, CDC, like any other laboratory, needs personal identifiers. We have a number of physical security measures for data storage in place. Data contained on the forms are entered into a CDC electronic database by three CDC employees. Data entry takes place in one room located in a high security CDC facility. This room has a lock on the door and no other activities are conducted in this room. After the data is entered into the database, the forms are sorted in a locked cabinet that is located in this same room. Data are not electronically transmitted outside of the CDC Dengue Branch. Both physical (i.e., the case investigation form) and electronic data is held within CDC. Case investigation forms are brought to the CDC on a weekly basis. No data are collected electronically.

Most case investigation forms are collected by Puerto Rican Department of Health officials. Occasionally a healthcare provider or family member will drop off a blood sample to be tested for dengue at the CDC's Dengue Branch. In order for a specimen to be processed, a case investigation form is required.

CDC's Dengue Branch has taken measures to safeguard data collection. As stated above, the CDC Dengue Branch's surveillance system is a passive (i.e., voluntary), laboratory-based system. And as such, personal identifiers are needed in order to inform healthcare providers about the laboratory results of their patients. CDC provides this service to the general public at no cost to the consumer. However in order to perform this function, CDC, like any other laboratory, needs personal identifiers.

We have a number of physical security measures for data storage in place. Data contained on the forms are entered into a CDC electronic database by three CDC employees. Data entry takes place in one room located in a high security CDC facility. This room has a lock on the door and no other activities are conducted in this room. After the data is entered into the database, the forms are sorted in a locked cabinet that is located in this same room. Data are not electronically transmitted outside of the CDC Dengue Branch. Both physical (i.e., the case investigation form) and electronic data is held within CDC.

Case investigation forms are brought to the CDC on a weekly basis. Most case investigation forms are collected by Puerto Rican Department of Health officials. Occasionally a healthcare provider or family member will drop off a blood sample to be tested for dengue at the CDC's Dengue Branch. In order for a specimen to be processed, a case investigation form is required. No data are collected electronically. CDC assigns a case number to the form. The Department of Health does not keep a copy of the forms and they do not have access to CDC's electronic database.

Our surveillance system was established for public health purposes and because of this, IRB clearance was not obtained for the case investigation form.

Justification of Sensitive Questions.

The CDC Dengue Case Investigation Form does not contain any sensitive data. For example, we do not collect information about race/ethnicity, sexual orientation, salary, drug use, or history of disease such as HIV/AIDS or other sexually transmitted diseases. Infection with dengue is not associated with any social stigma. The topic of dengue is freely discussed in Puerto Rican society.

Estimates of Annualized Burden of Hours and Costs.

Whatever time (and cost) that it takes a healthcare provider, family member or public health nurse to (voluntarily) fill out the CDC Dengue Case Investigation Form is significantly outweighed by the cost of sample processing. CDC provides this service free of charge to the consumer. Alternatively, the consumer can choose to use one of the private laboratories in Puerto Rico and pay for the laboratory's diagnostic service while still completing the necessary paperwork.

Hantavirus pulmonary syndrome

Hantavirus pulmonary syndrome (HPS) is a deadly disease transmitted by infected rodents through urine, droppings, or saliva. Humans can contract the disease when they breathe in aerosolized virus. It has been recognized as a disease since 1993. It is uncommon and the chances of becoming infected are low. However, HPS has a high mortality rate and immediate intensive care is critical once symptoms appear. Rodent control in and around the home remains the primary strategy for preventing hantavirus infection. HPS is only one of a host of emerging or reemerging infectious diseases that are being more widely recognized every year.

The form is changed because some variables were difficult for the states to obtain the information, and other variables were removed because they were not being completely utilized in the surveillance process and did not have a direct impact on CDC hantavirus research. The burden is increased slightly because additional states will be completely the forms due to improved surveillance of the disease.

IRB approval has not been obtained, additionally it is not necessary for surveillance. Identifiable information is required for identification and meaningful interpretation of laboratory diagnostics results. HPS may not be confirmed without compatible clinical or exposure data. All case report forms are submitted to CDC and managed appropriately to prevent release of identifiable information. A separate fax machine is dedicated to receiving forms. Additionally, each case report form submission is given a patient identification number which is used by CDC staff and the states when discussing the patient via phone or e-mail. Once the ID number has been assigned it is the only method used for identification. This further ensures the security of confidential information.

1National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Kawasaki Syndrome (CDC 55.54)

Kawasaki syndrome is an acute febrile vasculitis of unknown etiology that primarily affects children <5 years of age. It is a leading cause of acquired heart disease of children in the United States. Kawasaki syndrome occurs in a winter-spring seasonality, male predominance, and occasional community-wide outbreaks. During non-outbreak years, the incidence of Kawasaki syndrome could range from 9-19 cases per 100,000 children <5 years of age. Kawasaki syndrome can result into various types of complications. Coronary artery ectasia, the most serious complication of Kawasaki syndrome, can occur in up to 20% of untreated patients. The mainstay treatment for Kawasaki syndrome is administration of intravenous immunoglobulin and long-term aspirin. The use of intravenous immunoglobulin within 10 days of Kawasaki syndrome onset has been shown to reduce the severity of the illness and the occurrence of cardiac complications.

Identifying information is not collected. IRB approvals are not required for these data collections. State/local health departments submit surveillance forms to CDC without

patient name. An assigned patient code number or other available data may be used by the state to identify the patient if necessary.

The occurrence of these diseases has been shown to differ among various racial groups, and certain racial/ethnic groups may be more at risk for certain disease complications. It is therefore important to collect race/ethnicity information. Much of our surveillance data are compared to hospital discharge data, death certificate data, and other data sources where only one race can be listed. For comparison purposes, it is best to allow for only one race to be selected; however, the “other” box may be used as an option for patients where more than one race cannot be specified.

Data collection methodology: Surveillance forms are completed by the state and submitted to CDC.

1 National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Legionellosis Case Report (CDC 52.56)

Legionellosis is an infection caused by the bacteria in the *Legionella* genus. The disease has two distinct forms: Legionnaires' disease, the more severe form of infection which includes pneumonia, and Pontiac fever, a milder illness. An estimated 8,000 to 18,000 persons get Legionnaires' disease in the United States each year. An additional unknown number are infected with the Legionella bacterium and have mild symptoms or no illness at all. Outbreaks are usually recognized in the summer and early fall, but cases may occur year-round. About 5% to 15% of known cases of Legionnaires' disease have been fatal.

This is not a common form, information obtained is voluntary, reported monthly by hardcopy, 0% electronic, identifiable data are collected and not sent to CDC, privacy system of records does not apply because CDC does not receive personal identifiers, affected public is state, local, tribal governments

11 National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Lyme Disease Surveillance (CDC 52.60)

Lyme Disease (LD) is an infection caused by the spirochete *Borrelia burgdorferi*, which is transmitted to humans through the bite of infected deer (*Ixodes scapularis*) or western black-legged (*I. pacificus*) ticks. Ticks become infected after feeding on an animal, such as white-footed mice, squirrels, chipmunks, other small mammals, or birds, which harbors the spirochete and acts as a reservoir. The deer tick transmits LD in the northeastern, mid-Atlantic, and north central United States while the western black-legged tick does so on the Pacific Coast.

LD is the most commonly reported vector-borne disease in the United States. A mean of approximately 20,000 cases annually were reported by states to the CDC during 2001-2004. Over the past 10 years, approximately 95% of cases have been annually reported

from 12 northeastern, mid-Atlantic, and north central states. Surveillance for cases of LD can be complicated by another rash illness that can occur following the bite of the Lone Star tick (*Amblyomma americanum*) and that might be diagnosed as Lyme disease. However, these ticks, which are common human-biting ticks in the southern and southeastern United States, do not transmit the Lyme disease bacterium.

Individual identifying data are collected by local and/or state health departments in a header on the case report form. The individual identifying patient data are retained at the local and/or state health department and are not transmitted to CDC. Data are transmitted electronically to CDC on a weekly basis via the National Electronic Telecommunications System for Surveillance (NETSS). Institutional Review Board (IRB) approval is not required for this data collection. The only sensitive data collected are that of race/ethnicity which are collected per HHS policy for epidemiologic analysis.

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). 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.

1National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Malaria Case Surveillance (CDC 54.1)

Malaria is caused by a parasite that is transmitted from person to person by the bite of an infected Anopheles mosquito. These mosquitoes are present in almost all countries in the tropics and subtropics. Anopheles mosquitoes bite during nighttime hours, from dusk to dawn. Therefore, antimalarial drugs are only recommended for travelers who will have exposure during evening and nighttime hours in malaria risk areas.

Malaria was endemic throughout much of the United States in the late 19th and early 20th centuries. Interrupted human-vector contact, decreased anopheline populations, and effective treatment contributed to a decline in transmission and to subsequent eradication. However, environmental changes, the spread of drug resistance, and increased air travel could lead to the re-emergence of malaria as a serious public health problem. The potential for the reintroduction of malaria into the United States has been demonstrated by recent outbreaks of mosquito borne transmission in densely populated areas of New Jersey, New York, Texas, and Florida.

Surveillance activities include identifying outbreaks of local malaria transmission, identifying other cases acquired in the United States (for example, transfusion-induced cases) and monitoring trends in imported cases that guide CDC prevention recommendations.

Data containing identifiers is collected and submitted to the CDC, annually. In order to ensure adequate security provisions for identifiable data, records are maintained in the

office of the records keeper, which is housed in a locked office within the card-access only secured building.

Plague Case Investigation Report (CDC 56.37)

We are submitting a revised Plague Case Investigation Report form for OMB review and clearance. In general, the overall content of the Plague Case Investigation Report form has not changed; most of the modifications are formatting changes. However, there are a few additions and deletions to the form. Explanations for all changes follow this summary page. The overall time to complete the form remains the same.

Plague is an infectious disease of animals and humans caused by the bacterium *Yersinia pestis*. Typically, humans get plague by handling an infected animal or by being bitten by a rodent flea that is carrying the plague bacterium. Today, modern antibiotics are effective against plague, but if an infected person is not treated promptly, the disease is likely to cause illness or death. Outbreaks in people still occur in rural communities or in cities. In the United States, plague is geographically limited to the southwestern section of the country and typically occurs in rural areas with an average of 10 to 15 cases being reported each year. Globally, the World Health Organization reports 1,000 to 3,000 cases of plague every year.

Y. pestis is considered a Category A bioterrorism agent that could be used for intentional release. Used in an aerosol attack, cases of the pneumonic form of plague could occur. In such a scenario, people would develop symptoms consistent with a severe pneumonia (e.g. fever, cough, shortness of breath, chest pain) one to six days after becoming infected. People infected with plague could then potentially spread the bacteria to others who have close contact with them. Controlling the spread of the disease would be difficult because of the delay between being exposed to the bacteria and becoming ill. A bioweapon carrying *Y. pestis* is possible because the bacterium occurs in nature and could be isolated and grown in quantity in a laboratory.

Individual identifying data are collected by local and/or state health departments in a header on the case report form. The individual identifying patient data are retained at the local and/or state health department and are not transmitted to CDC. Data are transmitted electronically to CDC on a weekly basis via the National Electronic Telecommunications System for Surveillance (NETSS). Institutional Review Board (IRB) approval is not required for this data collection.

- Race/ethnicity is collected per HHS policy for epidemiologic analysis. In addition, collection of medical history is proposed as a change for this report form (please see Additions, B below). The reason to collect this sensitive information is because patients with pre-existing medical conditions have historically had a poorer prognosis. Therefore, we would like to capture this information in a systematic manner for further analysis to better delineate risk factors for developing complications of plague so that prevention and education efforts and can be better targeted and treatment interventions can be better utilized.

Q Fever – (form CDC 55.1)

Q fever is a zoonotic disease caused by *Coxiella burnetii*. It occurs worldwide, and is common in cattle, sheep, and goats throughout the United States. Human infection most commonly results from contact with these animals while they are giving birth; however cats, wild mammals, some birds, ticks, and contact with unpasteurized dairy products may serve as a source of infection as well. People may also become infected after exposure to wind-borne spread of the agent, up to several miles downwind of farms.

C. burnetii has the ability to withstand harsh environmental conditions, and persists for a long time in contaminated environments. Because of the bacteria's highly infectious nature and ability to withstand harsh conditions, *C. burnetii* has long been considered a potential bioterrorist agent. Although it does not cause significant fatalities, it can cause illness in large numbers of people, and poses a serious long-term health risk for endocarditis to some. A vaccine is available in Australia, but is not commercially available in the United States except under an investigational new drug license.

No patient identifiers are included with the data collected and all Case Report forms are kept in a locked office at CDC. The Tick-Borne Rickettsial and Q Fever Case Reports demonstrate a de-identification process implemented through use of a 3-part form. The first page and the third page, which are used by the state and local health departments, include the patient's name, the reporting physician's name, identifier codes, and other information relevant to the identity of the case patient. State and local health departments require the identifying information for their disease control efforts. However, the patient's name and contact information are not included (ie, they are blacked out) on the second page of the Case Report which is transmitted to CDC. Forms are reported quarterly.

1Reye Syndrome Case Surveillance Report (CDC 55.8)

Reye syndrome is an acute illness characterized by encephalopathy and fatty degeneration of the liver, and it occurs almost exclusively in children. In about one-third of patients, Reye syndrome results into death or severe, long-term neurologic complications. The occurrence of Reye syndrome is associated with the use of aspirin during viral infections such as influenza-like illness and varicella. Beginning in 1980, CDC cautioned physicians and parents not to use aspirin during these viral diseases. Labeling of aspirin-containing medications was required since 1986. As a result of these preventive measures, there has been a dramatic decline in the occurrence of Reye syndrome in the United States. However, rare preventable cases of Reye syndrome continue to occur. Continuous surveillance of Reye syndrome is required to monitor a possible resurgence of Reye syndrome with an increased use of aspirin or other new medications that are being introduced into the U.S. market.

Identifying information is not collected. IRB approvals are not required for these data collections. State/local health departments submit surveillance forms to CDC without patient name. An assigned patient code number or other available data may be used by the state to identify the patient if necessary.

The occurrence of these diseases has been shown to differ among various racial groups, and certain racial/ethnic groups may be more at risk for certain disease complications. It is therefore important to collect race/ethnicity information.

Data collection methodology: Surveillance forms are completed by the state and submitted to CDC.

Tick-borne Rickettsial Disease Case Report (CDC 55.1)

Rocky Mountain spotted fever (RMSF) and Ehrlichiosis (including human monocytic ehrlichiosis (HME) and human granulocytic anaplasmosis (HGA)) are tick-borne diseases that occur throughout much of the United States. RMSF, caused by *Rickettsia rickettsii*, is transmitted by *Dermacentor variabilis* (the American dog tick), *Dermacentor andersonii* (the Rocky Mountain wood tick), and in some cases *Rhipicephalus sanguineus* (the brown dog tick). HME, caused by *Ehrlichia chaffeensis*, is transmitted by *Amblyomma americanum* ticks (the lone star tick). HGA, caused by *Anaplasma phagocytophilum*, is transmitted by *Ixodes scapularis* (the black-legged tick) and *Ixodes pacificus* (the western black-legged tick).

These diseases are most commonly seen from April through September but can occur anytime during the year when there is warm weather, corresponding with times of

increased tick activity. These diseases cause moderate to severe illness characterized by fever, headache, body aches, and fatigue. A widespread rash, which is often present on the palms and soles as well, is usually seen with RMSF. A rash may also be seen with HME, but is less common with HGA infection. Because these diseases have similar clinical presentations, similar modes of transmission, and in many cases overlapping geographic boundaries, differentiation of the cause of infection may be difficult without accompanying laboratory tests.

No patient identifiers are included with the data collected and all Case Report forms are kept in a locked office at CDC. The Tick-Borne Rickettsial and Q Fever Case Reports demonstrate a de-identification process implemented through use of a 3-part form. The first page and the third page, which are used by the state and local health departments, include the patient's name, the reporting physician's name, identifier codes, and other information relevant to the identity of the case patient. State and local health departments require the identifying information for their disease control efforts. However, the patient's name and contact information are not included (ie, they are blacked out) on the second page of the Case Report which is transmitted to CDC.

1

1National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Trichinosis Surveillance Case Report (CDC 54.7)

Trichinosis, also called trichinellosis, is caused by eating raw or undercooked pork and wild game products infected with the larvae of a species of worm called *Trichinella*. Infection occurs worldwide, but is most common in areas where raw or undercooked pork, such as ham or sausage, is eaten. Nausea, diarrhea, vomiting, fatigue, fever, and abdominal discomfort are the first symptoms of trichinosis. Headaches, fevers, chills, cough, eye swelling, aching joints and muscle pains, itchy skin, diarrhea, or constipation follow the first symptoms. If the infection is heavy, patients may experience difficulty coordinating movements, and have heart and breathing problems. In severe cases, death can occur. For mild to moderate infections, most symptoms subside within a few months. Fatigue, weakness, and diarrhea may last for months.

Infection was once very common in the U.S. (annual average of 211 reported cases 1947-1982); however, infection is now relatively rare (5 cases reported in 2004). From 1983-2001, an average of 39 cases per year were reported. The dramatic decrease in reported cases is the result of legislation prohibiting the feeding of raw meat garbage to hogs, commercial and home freezing of pork, and the public awareness of the danger of eating raw or undercooked pork products. Cases are less commonly associated with pork products and more often associated with eating raw or undercooked wild game meats, particularly bear meat.

This is not a common form, information obtained is voluntary, reported occasionally as cases occur, and the affected public is state, local, tribal governments. 70-80% of the forms are reported electronically, the secondary method is by fax.

Tularemia Case Investigation Form

Similar to plague, tularemia is a vector-borne infectious disease of animals and humans. Naturally occurring human cases have been reported from every state except Hawaii with approximately 120 cases being reported each year. In addition to causing endemic disease throughout the United States, *Francisella tularensis*, the causative agent of tularemia, is considered a Category A bioterrorism agent. Because of increased concern about bioterrorism, tularemia was designated as a nationally notifiable disease in 2000 and CDC has received numerous requests from state and local health departments for a standardized reporting form.

Tularemia is an infectious disease of animals and humans caused by the bacterium *F. tularensis*. Tularemia occurs throughout much of North America and Eurasia. In the United States, most human cases occur in the south-central and western states. *F. tularensis* is found in widely diverse animal hosts including rabbits, voles, water rats, and squirrels and can also be recovered from contaminated soil, water, and vegetation.

Humans become infected with *F. tularensis* through various modes including bites of infected ticks or biting flies, direct handling of infectious animal tissue (e.g. while hunting), contact with or ingestion of contaminated soil, water, or food, and inhalation of infectious aerosols. Recent noteworthy cases and outbreaks have occurred among landscapers on Martha's Vineyard, MA, researchers working with cultures contaminated with virulent *F. tularensis*, and pet hamster owners. Tularemia can cause a variety of illness in humans such as pneumonia, skin ulcers, glandular disease, and oropharyngeal disease. While tularemia can be successfully treated with antibiotics, 1-2% of cases are fatal. In the United States, approximately 120 cases are reported each year.

F. tularensis is considered a Category A bioterrorism agent that could be used for intentional release. *F. tularensis* is one of the most infectious pathogenic bacteria known requiring as few as 10 organisms to cause illness. If used in an aerosol release, the primary concern would be pneumonic disease in which people would develop symptoms consistent with a severe pneumonia (e.g. fever, cough, shortness of breath, chest pain) three to five days after becoming infected. Although people infected with tularemia can develop severe and sometimes fatal illness, the infection can not be spread from person to person. Therefore, the extent of a potential intentional release would be limited to those exposed to the actual release. A bioweapon carrying *F. tularensis* is possible because the bacterium occurs in nature and could be isolated and grown in quantity in a laboratory.

Individual identifying data are collected by local and/or state health departments in a header on the case report form. The individual identifying patient data are retained at the local and/or state health department and are not transmitted to CDC. Data are transmitted electronically to CDC on a weekly basis via the National Electronic Telecommunications

System for Surveillance (NETSS). Institutional Review Board (IRB) approval is not required for this data collection.

Race/ethnicity is collected per HHS policy for epidemiologic analysis. In addition, collection of medical history is proposed for this report form. The reason to collect this sensitive information is to better delineate risk factors for developing complications of tularemia so that prevention and education efforts and can be better targeted and treatment interventions can be better utilized.

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). 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.

11National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Typhoid Fever Surveillance Report (CDC 52.5)

In 2003, typhoid fever was diagnosed in approximately 360 persons in the United States. Despite the availability of two effective vaccines, NNDSS reports 300-400 cases each year. Approximately 75% of these cases occur among persons who report international travel during the preceding 4 weeks. Persons traveling to and from their country of origin appear to be at high risk.[1] In many areas of the world, *Salmonella* Typhi strains have acquired resistance to multiple antimicrobial agents, including ampicillin, chloramphenicol, and trimethoprim-sulfamethoxazole.[2]

None of the data are collected electronically. Data are collected by State and Local Health Departments and forwarded to CDC on the surveillance form with only the first three letters of the patient's last name. No sensitive information is collected. At CDC the forms are maintained in a cabinet in a room that has a lock. No Certificate or Assurance of Confidentiality is necessary. IRB approval is not required for this surveillance system since it is part of the routine practice of Public Health.

[1] Ackers ML, Puhr ND, Tauxe RV, Mintz ED. Laboratory-based surveillance of *Salmonella* Serotype Typhi infections in the United States: antimicrobial resistance on the rise. *JAMA* 2000;283:2668--73.

[2] Steinberg EB, Bishop RB, Dempsey AF, Hoekstra RM, Nelson JM, Ackers M, Calugar A, Mintz ED. Typhoid fever in travelers: who should be targeted for prevention? *Clinical Infectious Diseases*. 2004; 39:186-191.

11National Disease Surveillance Program - I. Case Reports OMB No. 0920-0009

Viral Hepatitis Specific Screen in the National Electronic Telecommunication System for Surveillance (NETSS)

Viral Hepatitis surveillance covers all forms of Hepatitis (A - D).

Hepatitis A is an acute liver disease caused by the hepatitis A virus (HAV). The most common mode of HAV transmission is fecal-oral with the virus being transmitted from person-to-person between household contacts or sex partners, or by contaminated food or water. Good personal hygiene and proper sanitation can help prevent hepatitis A. Vaccines are available for long-term prevention of HAV infection in persons 1 year of age and older.

Hepatitis B is a liver disease that is caused by the hepatitis B virus (HBV). HBV is transmitted by contact with an infected person's blood or body fluids and also by sex with an infected person. HBV infection can cause an acute and a chronic illness. Chronic infection can lead to cirrhosis (scarring) of the liver, liver failure, liver cancer, and death. In the United States, an estimated 1.25 million people are chronically infected with HBV. Hepatitis B vaccine is available for all age groups to prevent HBV infection.

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). HCV is transmitted by contact with an infected person's blood or body fluids. HCV can cause acute and chronic infection of the liver. Chronic infection can lead to cirrhosis (scarring) of the liver, liver failure, liver cancer, and death. In the United States, an estimated 2.7 million people are chronically infected with HCV. There is no vaccine available against HCV infection.

Hepatitis D is a liver disease that is caused by the hepatitis D virus (HDV), but requires the presence of hepatitis B virus to cause infection. Modes of transmission are similar to those of HBV. HDV/HBV can cause an acute or chronic infection of the liver. Since hepatitis D virus needs hepatitis B virus to cause infection, hepatitis D virus infection can be prevented by preventing HBV infection by vaccination.

Collection of information about cases of viral hepatitis is done within the context of local communicable disease reporting laws and all data is transmitted to CDC via the National Notifiable Diseases Surveillance System (NNDSS) at the moment mostly using NETSS. CDC's National Notifiable Disease Surveillance System (NNDSS) is a mechanism used to monitor the occurrence of a variety of conditions (primarily infectious diseases) of public health significance. State and local health departments who collect data demographic, clinical, laboratory and risk factor data on persons reported with these conditions in their jurisdiction, send this data electronically to CDC weekly via the National Electronic Telecommunications System for Surveillance (NETSS).

NETSS is transmitted via SDN (Secure Data Network) which meets CDC policies for data transmission via internet. It is Web based and the states have access via PC using Internet Explorer. It contains tight security controls and uses Digital certificates and dynamic data encryption for faster more secure data transmission from the states to CDC. Information about cases of Viral Hepatitis may be collected differently by different state or local health departments. Some have developed paper forms that are based on the

Viral hepatitis specific screens within NETSS. Others may use the same case report form for any case of a reportable condition within the jurisdiction. Yet others, have no paper forms at all and collect data primarily electronically from health care providers or clinical labs. Regardless of which of these methods is used, generally identifying information is collected (including the patient's name, the reporting physician's name, date of birth and other information relevant to the identity of the case patient). State and local health departments require the identifying information for their disease control efforts. However, the patient's name and contact information are not included in viral hepatitis data that is transmitted to CDC.

The collection of data on cases of viral hepatitis is a public health surveillance function and is therefore not subjected to IRB review.

Information about risk behaviors that may facilitate transmission of viral hepatitis, such as use of injection drugs, is necessary in order to support disease control activities conducting by state and local health departments.