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

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Supporting Statement
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The National Disease Surveillance Program I. Case Reports is an ongoing surveillance activity of the Centers for Disease Control and Prevention (CDC), the Coordinating Center for Infectious Diseases (CCID). This request is a renewal of a previously approved data collection. Two new forms have been added, Invasive Methicillin-Resistant *Staphylococcus aureus* (MRSA) and tularemia. One form has been removed, Idiopathic CD4+ T-Lymphocytopenia (ICL).

A. Justification

1. Circumstances Making the Collection of Information Necessary

Surveillance of the incidence and distribution of disease has been an important function of the US Public Health Service (PHS) since an 1878 Act of Congress authorized PHS to collect morbidity reports. After the Malaria Control in War Areas Program had fulfilled its original 1942 objective of reducing malaria transmission, its basic tenets were carried forward and broadened by the formation of the Communicable Disease Center (CDC) in 1946. CDC was conceived of as a well-equipped, broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases and through field investigations.

It was soon recognized that control measures (such as the DDT spraying for malaria) did not alleviate the threat of disease reintroduction. In 1950, the Malaria Surveillance Program began and in 1952, the National Surveillance Program started. Both programs were based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. The original scope of the National Surveillance Program included the study of malaria, murine typhus, smallpox, psittacosis, diphtheria, leprosy, and sylvatic plague. Over the years, the mandate of CDC has broadened in preventive health activities and the surveillance systems maintained have expanded. This program is authorized under the Public Health Service Act, Section 301 and 306 (42 USC 241 and 242K) (Attachment A).

The surveillance emphasis has shifted as certain diseases have declined in incidence, national emergencies have prompted involvement in new areas, and other diseases have taken on new aspects. The following diseases/conditions are included in this program:

Active Bacterial Core (ABCs)
Creutzfeldt-Jakob Disease (CJD)
Cyclosporiasis cayetanensis
Dengue
Hantavirus pulmonary syndrome (HPS)
Invasive Methicillin-resistant Staphylococcus aureus (MRSA)
Kawasaki syndrome
Legionellosis
Lyme Disease (LD)
Malaria
Plague
Q Fever
Reye Syndrome
Tick-borne Rickettsial Disease
Trichinosis
Tularemia
Typhoid Fever
Viral Hepatitis

Attachment C contains descriptive summaries of each disease under surveillance, an explanation of significant revisions to the forms, and the impact on burden estimates.

2. **Purpose and Use of Information Collection**

CDC works with state health departments to propose, coordinate, and evaluate nationwide surveillance systems. State epidemiologists are responsible for the collection, interpretation, and transmission of medical/epidemiological information to CDC.

The original purpose for reporting communicable diseases was to determine the prevalence of diseases dangerous to public health. However, collecting data also provided the basis for planning and evaluating effective programs for prevention and control of infectious diseases. Current information on disease incidence is needed to study present and emerging disease problems. CDC coordination of nationwide reporting maintains uniformity so that comparisons can be made from state to state and year to year.

In addition to development of prevention and control programs, surveillance data serves as statistical material for those engaged in research or medical practice, aid to health education officials and students, and data for manufacturers of pharmaceutical products. For example, Active Bacterial Core Surveillance (ABCs) pneumococcal data has continued to be used in the introduction of pneumococcal vaccines in other countries. It was used extensively in a comprehensive report that reviewed all data from surveillance efforts following conjugate vaccine introduction for the GAVI Pneumococcal Advanced Development and Introduction Plan (PneumoADIP). As a result, GAVI plans are now shifting from data gathering to beginning demonstration projects in developing countries. Pneumococcal data is being used in cost effectiveness studies for conjugate vaccine. Analysis of 2004 ABCs data has shown sustained reductions in invasive pneumococcal infections among infants, young children and adults due to direct and indirect effects of the conjugate vaccine, despite replacement disease. Analysis of the pneumococcal conjugate vaccine effectiveness study is complete and a manuscript has been drafted.

Another example of the significance of continuous surveillance and reporting is in the case of Trichinellosis, an infection that occurs worldwide, but is most common in areas where raw or undercooked pork, such as ham or sausage, is consumed. Cases of trichinellosis have documented the decline of this meat-borne infection from 400-500 cases in the 1950s to less than 10 cases per year in the most recent years. Surveillance has kept the pressure on the pork industry to prevent transmission in pig farms and maintained awareness of the public concerning the potential risks. Annual surveillance data are published in the MMWR Surveillance Summary. The most recent trichinellosis summary publication based on the surveillance data include: Trichinellosis Surveillance- United States, 1997-2001. MMWR 2003; 52 (SS6): 1- 8.

CDC currently collects data for certain diseases in summary form under OMB No. 0920-0004. These disease summaries are for important, yet different types of infections from those covered in this disease case reports request. The diseases contained in this request require more frequent monitoring than those in the disease summaries package. Maintaining separate OMB numbers for these two types of data collections assists CDC in managing the two surveillance activities.

Following the October 2001 anthrax attacks, it is critical now more than ever, for states to report diseases and illnesses to CDC. Health departments now are defining their roles to respond effectively to an intentional release of biological organisms. Three of these biological organisms on the list for potential terrorist agents, tularemia, plague and Q fever, are covered in this OMB package.

3. Use of Improved Information Technology and Burden Reduction

In general, most case report forms are mailed to CDC through appropriate state health departments. In certain circumstances, such as outbreak situations, reports are first made by telephone, then followed by a written report. Information on ABCs, Invasive MRSA, CJD, Hepatitis, Kawasaki Syndrome, Lyme Disease, Plague, Reye Syndrome, and Tularemia may be submitted by hard copy or electronically. As state health departments develop computer capabilities, additional report formats are being developed for electronic transmission.

The National Electronic Disease Surveillance System (NEDSS) is a broad initiative at CDC that uses national data and information system standards for developing efficient, integrated, and interoperable surveillance systems at the state and local levels. It includes tools for electronic data transfer to health departments from health care systems. There are security standards in place to maintain the public health track record of protecting sensitive data.

CDC originally thought NEDSS would have been implemented fully by now but there have been delays in the development of the database, changes in the performance engineering, and delays with development to insure integration into state's existing systems. Therefore until CDC can fund all states and territories, we need to renew this OMB package to maintain complete infectious disease reporting.

4. Efforts to Identify Duplication and Use of Similar Information

No other nationwide surveillance systems which monitor these diseases exists. While similar information may be collected on a sample basis or from a particular area of the country, for most diseases, sampling would not be sufficient for the states' need of conducting prevention or control programs. The surveillance systems in this request collect data from all states and territories of the U.S. in a uniform manner.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting Information Less Frequently

Disease reporting varies to the extent that diseases differ in occurrence, modes of transmission, infectious agents, patient's susceptibility and resistance, control of patient's contacts and the immediate environment, and epidemiologic measures. In general, case reports are submitted as soon as possible after the investigation of a case. The first step in the control of a given disease is its rapid identification followed by notification to the local health authority that a case of disease exists within a particular jurisdiction. Prompt notification to CDC allows for

identification of epidemics and outbreaks, so that immediate prevention measures can be taken. There are no legal obstacles to reduce the burden.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

Depending on disease occurrence and other variables as described in A.6. above, respondents may be required to report information more often than quarterly. Surveillance reports are submitted as soon as possible after an epidemiologic investigation. This permits rapid response to public health problems and prompt initiation of prevention and control measures. There are no other special circumstances.

8. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. A 60-day Federal Register Notice was published in the *Federal Register* on December 8, 2005, Volume 70, No. 235, pp. 73006-73007 (see Attachment B). No public comments were received.

B. The Council of State and Territorial Epidemiologists (CSTE) are routinely consulted regarding the availability of data, the frequency of collection, and the revisions of any forms. The Executive Director of CSTE is Patrick McConnon, (770) 458-3811.

Chairman of the Surveillance Committee: Allen Craig
Tennessee State Epidemiologist
allen.craig@state.tn.us
(615) 741-7247

9. **Explanation of Any Payment or Gift to Respondents**

There are no provisions for payments or gifts to respondents.

10. **Assurance of Confidentiality Provided to Respondents**

The CDC Privacy Act Officer has determined that the Privacy Act is applicable to those forms in which full names are being collected. Names or other personal identifying information are not routinely collected by CDC on case reports. The exceptions are Cyclosporiasis, Dengue, Hantavirus, Kawasaki Syndrome, Malaria, Q Fever, Tick-borne Rickettsial Disease, and Viral Hepatitis. Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994.

11. **Justification for Sensitive Questions**

Epidemiological characteristics such as age, race, sex, geographic location, socioeconomic classification, religious affiliation, etc., are collected only when these factors may produce health

problems. Clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health.

12. **Estimates of Annualized Burden Hours and Costs**

A. The previously approved burden is 14,508 hours. This collection requests 13,368 hours. See Table 1. CDC program staff made the decision to remove the Idiopathic CD4+ T-Lymphocytopenia (ICL) form on 11/14/2006, after the 30-Day FRN was sent for publishing. Therefore, the burden posted in the 30-Day FRN is incorrect by an additional 3 burden hours.

Table 1
Estimated Annualized Burden Hours

Form	Number of Respondents	No. Responses/ Respondent	Total Responses	Hrs/ Response	Total Burden in hours
ABCs	329	21	6,909	10/60	1,152
ABCs Invasive MRSA	18	256	4,608	10/60	768
CJD	20	2	40	20/60	13
Cyclosporiasis	55	10	550	15/60	138
Dengue Case Investigation	55	182	10,010	15/60	2,503
Hantavirus Pulmonary Syndrome	46	3	138	20/60	46
Kawasaki Syndrome	55	8	440	15/60	110
Legionellosis Case Report	23	11.7	269	20/60	90
Lyme Disease Report	52	385	20,020	10/60	3,337
Malaria Case Surveillance Report	55	20	1,100	15/60	275
Plague Case Investigation Report	11	1	11	20/60	4
Q Fever	55	1	55	10/60	9
Reye Syndrome Case Surveillance Report	50	1	50	20/60	17
Tick-borne Rickettsial Disease Case Report	55	18	990	10/60	165
Trichinosis Surveillance Case Report	25	1	25	20/60	8
Tularemia	55	2.2	121	20/60	40
Typhoid Fever Surveillance Report	55	6	330	20/60	110
Viral Hepatitis Case Record	55	200	11,000	25/60	4,583
Total					13,368

B. The estimated total cost to respondents is $235,597. This assumes an average value of $17.62 per burden hour based on 2002 data from the Bureau of Labor Statistics for state workers with an average salary of $36,764. The burden estimate is based on the time required to complete the forms. The total annual burden for this request is 13,371 and is presented per case report form in Table 1.

Estimated Annualized Burden Costs

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Health Departments	13,371	17.62	$235,597
Total			$235,597

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

There are no capital and maintenance costs incurred by respondents.

14. Annualized Cost to the Government

Each data case report results in action taken by multiple programs in response to the required CDC mandate in maintaining preventive health activities and surveillance systems. The action taken will vary, depending on the specifics of the data reporting involving multiple staff. The cost of conducting the study to the government is estimated based on the expenses incurred in the following categories: salary, computer resources, printing, mailing, and miscellaneous, such as (telephone calls and stationary supplies). The estimated annual cost to the government is $80,000.

15. Explanation for Program Changes or Adjustments

See Table 2 (next page). The current burden for this project is 14,508. The requested total burden is 13,368 hours, which represents a decrease of 1140 hours. The difference is mainly due to a large decrease in viral hepatitis cases.

Table 2
Program Change in Burden Since Previous Report

Form	Currently Requested Burden	Previous Burden	Change
ABCs	1152	78	+1074
ABCs Invasive MRSA	768	0	+768
CJD	13	13	0
Cyclosporiasis	138	138	0
Dengue Case Investigation	2,503	2,503	0
Hantavirus Pulmonary Syndrome	46	40	+6
Idiopathic CD4+T-lymphocytopenia	0	3	-3
Kawasaki syndrome	110	110	0
Legionellosis Case Report	90	86	+4
Lyme Disease Report	3,337	1131	+2,206
Malaria Case Surveillance Report	275	275	0
Plague Case Investigation Report	4	7	- 3
Q Fever	9	5	+ 4
Reye Syndrome Case Surveillance Report	17	17	0
Tick-borne Rickettsial Disease Case Report	165	165	0
Trichinosis Surveillance Case Report	8	13	-5
Tularemia	40	0	+40
Typhoid Fever Surveillance Report	110	128	-18
Viral Hepatitis Case Record	4,583	9740	- 5,157
Total			- 1,084

16. **Plans for Tabulation and Publication and Project Time Schedule**

Data collected as a result of surveillance activities are published by CDC in the surveillance report for the respective condition or in the Morbidity and Mortality Weekly Report (MMWR), and CDC Surveillance Summaries. Most reports are issued on an annual basis; others are issued frequently during a season of high incidence and intermittently during the remainder of the year. Summaries of data are often published in the MMWR and in the annual summary, Reported Morbidity and Mortality in the United States.

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

We request that the expiration date not be printed on the surveillance reports. Many of these reports are rarely revised, and have been in continuous use for several years. Because they are printed in large quantities and distributed to all states, many forms are in stock at the time of the routine expiration date. The most current statement will be added to each form upon OMB approval of the current package and reprinting of the forms.

18. **Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

1. **Respondent Universe and Sampling Methods**

No sample selection is involved in this surveillance study. The surveillance report forms and instructions are distributed to all States and Territories of the United States. State and local health department staff submits these reports to CDC on variable frequencies ---- weekly, monthly, or quarterly. In certain circumstances, such as outbreak situations, reports are first made by telephone, and then followed by a written report.

2. **Procedures for Collection of Information**

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). Changes in the surveillance program and in reporting methods are affected in the same manner. 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.

3. **Methods to Maximize Response Rates and Deal with Non-response**

There is not a method to deal with non-response as the state public health laboratories submit the disease surveillance forms as a part of their job to perform a public health service. Therefore, the response rate is expected to be 100%.

4. **Test of Procedures or Methods to be Undertaken**

This is a revision of a previously approved data collection, only minor changes to the data collection instruments have been made. No other test of procedures has been performed.

5. **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Patrick McConnon
Council of State and Territorial Epidemiologists (CSTE)
Executive Director
(770) 458-3811

Attachments

Attachment A Public Health Service Act, Section 301 and 306 (42 USC 241 and 242K)
Attachment B 60-Day Federal Register Notice
Attachment C Forms

ATTACHMENT A

ATTACHMENT B

ATTACHMENT C

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

Active Bacterial Core surveillance (ABCs) (CDC 52.15A)

ABCs tracks invasive infections caused by five bacteria of public health importance: group A streptococcus, group B streptococcus, *Haemophilus influenzae, Neisseria meningitidis* and *Streptococcus pneumoniae*. (Invasive MRSA infections, also a part of ABCs, is described separately.) These ABCs pathogens are the major bacterial causes of meningitis, pneumonia, bacteremia and otitis media in the United States. The peak age groups affected are the very young and the elderly but persons of all ages acquire invasive infections due to ABCs pathogens. Approximately 76,950 invasive infections and 8025 deaths due to these five bacteria occur each year in the U.S. Vaccines are available for three ABCs pathogens: *H. influenzae, N. meningitidis* and *S. pneumoniae*.

ABCs surveillance staff at state health departments and academic institutions conducts medical record review on identified cases and complete a hard copy version of our two-page ABCs case report form. Data from the case report form is entered into databases at the ABCs sites and is transported monthly without identifiers (e.g., name, address, phone number, medical chart number) to CDC in a password protected zip file via an FTP site. Hard copy case report forms are stored at the ABCs sites in locked cabinets. All ABCs cases are assigned a unique identifier at the ABCs site before transmission of data to CDC. Linkage of the case report form data to personal identifying information can only be done at the ABCs sites.

Justification of the collection of sensitive data (e.g., underlying condition information)

The collection of underlying conditions is important as it allows us to monitor risk factors for infection due to the ABCs pathogens under surveillance.

Discussion of code number for question 11.b, Race

This is a multi-select field and more than one race can be indicated. Each race category is a separate variable and will be coded as “1” if that racial category applies to the case.

IRB Approval Status

The ABCs system conducts public health surveillance and is not considered research. Therefore, IRB approval is not required for ABCs data collections.

Changes to the form

- Question 11.a, option 2 will change from “Non-Hispanic or Latino” to “Not Hispanic or Latino”
- Question 11.b, third option will change from “American Indian/Alaskan Native” to “American Indian or Alaska Native”
- Question 11.b, fifth option will change from “Native Hawaiian/Pacific Islander” to “Native Hawaiian or Other Pacific Islander”
- In the OMB footer, “Project Clearance Officer” will change to “CDC/ATSDR Reports Clearance Officer”
- Increase font size on burden statement

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
ABCs case report form	329	21	10/60	1152

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Active Bacterial Core Surveillance (ABCs) (CDC 52.15A): Invasive Methicillin-resistant Staphylococcus aureus (MRSA) surveillance

Invasive MRSA surveillance is added to ABCs surveillance in order to collect information specific to invasive MRSA. The MRSA form was added originally under the ABCs form which was approved by OMB in 2003. The MRSA form is being presented as a separate form from the ABC form in this clearance package. Collaborating sites will enter and send data electronically. In addition to invasive MRSA, ABCs tracks invasive infections caused by five bacteria of public health importance: group A streptococcus, group B streptococcus, *Haemophilus influenzae*, *Neisseria meningitidis* and *Streptococcus pneumoniae*. Invasive MRSA disease can result in a variety of clinical syndromes including osteomyelitis, meningitis, endocarditis, pneumonia, septic arthritis, cellulitis, and bacteremia. Mortality is high (19%) among patients with invasive MRSA.

By tracking the incidence of invasive MRSA disease, it will be possible to identify community strains entering the healthcare setting as well as to measure the success of prevention efforts.

ABCs surveillance staff at state health departments and academic institutions conducts medical record review on identified cases and complete a hard copy version of our two-page ABCs case report form. Data from the case report form is entered into databases at the ABCs sites and is transported monthly without identifiers (e.g., name, address, phone number, medical chart number) to CDC in a password protected zip file via an FTP site. Hard copy case report forms are stored at the ABCs sites in locked cabinets. All MRSA cases are assigned a unique identifier at the ABCs site before transmission of data to CDC. Linkage of the case report form data to personal identifying information can only be done at the ABCs sites.

Justification of the collection of sensitive data (e.g., underlying condition information)

The collection of underlying conditions is important as it allows us to monitor risk factors for infection due to MRSA.

IRB Approval Status

The ABCs system conducts public health surveillance and is not considered research. Therefore, IRB approval is not required for ABCs data collections.

Discussion of code number for question 11.b, Race

This is a multi-select field and more than one race can be indicated. Each race category is a separate variable and will be coded as “1” if that racial category applies to the case.

Changes to the form

- 7.c, first option will change from ”American Indian or Alaskan Native” to “American Indian or Alaska Native” -
- Increase font size on burden statement
- Will add “Surveillance Office Use Only” statement.

Form Name	# of Respondents	# of Responses	Avg. Burden in hours	Total Burden in hours
Invasive MRSA form	18	256	10/60	768

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.

Changes to the form

- CDC will add a line to the end of the form requesting patient name to be redacted on neuropathology reports sent to us.
- Change the OMB number from “0920-009” to “0920-0009”
- Add a CDC contact name and address to the form for submission purpose
- Change “pacific islander” to “Pacific Islander”

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Creutzfeldt-Jakob disease	20	2	20/60	13

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Cyclosporiasis 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.

Changes to the form

- We revised the form, such that we no longer collect the patient's full name (only first 4 letters of last name) or date of birth (only month and year).
- We changed the ethnicity/race questions and asked Ethnicity prior to race.
- We added "snow peas" to the list of pertinent food items on p. 2 of the form.
- We also made some minor editorial changes in the form and clarified the meaning/intent of some of the questions.

Other issues re the form:
-- currently, "fax" is the primary means by which completed forms are returned to us

-- we manage the data in accordance with privacy considerations (e.g., the forms are kept in a locked cabinet)

This is not a common form, information obtained is voluntary, reported occasionally,

Form Name	# of Respondents	# of Responses	Average burden in hours	Total Burden in hours
Cyclosporiasis	55	10	15/60	138

affected public is state, local, tribal governments

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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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**

Dengue Case Investigation	55	182	15/60	2,503

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

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.

Changes to the form

- The following variables will be deleted from the form: "Was patient hospitalized?", "Number of times hospitalized since onset of illness?", "Name of hospital?", "Location of hospital?", "Record number?", "Did patient have any of the following?", "Has the patient received ribavirin?", "History of any relevant underlying medical conditions (i.e. COPD, malignancy, immunosuppression, diabetes)?", "Other explanations for acute illness (i.e. sepsis, burns, trauma)?", "If yes, was exam compatible with non-cardiogenic pulmonary edema?", "Are tissue specimens (fresh-frozen or paraffin blocks) available for testing?", "Is serum/blood specimens available for testing hantavirus infection?"
- The following variables will be added to the form: "Specimen acquisition date?" and "Signs and Symptoms"

Form Name	# of Respondents	# of Responses	Avg. Burden in hours	Total Burden in hours
Hantavirus Pulmonary Syndrome	46	3	20/60	46

National 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.

Changes to the form

Change "Alaskan Native" to "Alaska Native"

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Kawasaki Syndrome	55	8	15/60	110

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.

Changes to form

- "Alaskan Native" will be changed to "Alaska Native"
- add CDC/ATSDR Reports Clearance officer to burden statement

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

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Legionellosis Case Report	23	11.7	20/60	90

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.

Changes to the form

- Correct typo regarding OMB approval number by changing "0920-0004" to "0920-0009".
- In the race/ethnicity section, change "Native Hawaiian or Pacific Islander" to "Native Hawaiian or Other Pacific Islander."
- In the race/ethnicity section, insure that multiple selections can be chosen
- In the Symptoms and Signs section/Cardiologic, correct typo to read "atrioventricular."
- In the burden statement on the footer, change contact person to "CDC/ATSDR Reports Clearance Officer" and the subsequent attention to "ATTN: PRA (0920-0009)."

Form Name	# of Respondents	# of Responses	Avg. Burden in hours	Total Burden in hours
Lyme Disease Report	52	385	10/60	3,337

National 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.

The following addresses the changes to the Malaria Case Surveillance Report form.

(1) **Was malaria chemoprophylaxis taken?** – This question has been changed to ***"Did the traveler take drugs to prevent malaria?"*** This change was made in order to decrease error in confusing drugs taken for chemoprophylaxis as opposed to drugs taken for treatment.
(2) **If doses were missed, what was the reason? –** This question as been changed to ***"If doses were missed or not taken for prevention, what was the reason?"*** This change was made to better capture information on why one would choose not to take any chemoprophylaxis for prevention.
(3) **Website: http://www.cdc.gov/malaria/clinicians.htm#case –** A web address link to the CDC Malaria website was added to the form so a PDF version of the Malaria Case Surveillance Report Form could be readily accessible.
(4) PCR results box – This section within the laboratory results section was added in order to capture whether a PCR test was performed in order to determine parasite speciation.
(5) "Specimen sent to SHD for confirmation?" – This was a request from one of the State Health Department whereby to assist in their tracking for follow-up.

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.

Form Name	# of Respondents	# of Responses	Avg. Burden in hours	Total Burden in hours
Malaria Case Surveillance Report	55	20	15/60	275

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

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.

Explanations for modifications (additions and deletions) to Plague Case Investigation Report form (OMB-CDC 56.37)

I. Justification for updated form

In general, the main content of the Plague Case Investigation Report form has remained the same; however, we have re-formatted sections to make the flow more logical and to simplify the form completion process. Examples of this include moving contact information to the top of page 1 and adding checkboxes in place of line listing for the symptoms in the Illness section on page 1. In addition, we have made a few modifications (both additions and deletions) which are described below.

II. Additions

A. Add "Occupation" to Patient Demographics section - "Occupation" is an important variable to collect to potentially identify at risk occupations that have not been previously identified.

B. Add "Medical History" section - Previously, information on pre-existing medical conditions was not collected. However, patients with pre-existing conditions, such as diabetes mellitus, have historically had a poorer prognosis. We would like to capture this data for further study and analysis. Additionally, the time between symptom onset and time first seen by medical personnel and location where first evaluated are predictors for health outcome and should be captured when possible.

C. Add "Clinical Course and Treatment" section – On the previous form, there was a small place to comment on antibiotics and (in the "illness" section) a small place to comment on current condition/prognosis and outcome. While the antibiotic section has been useful, the current condition/prognosis section was too general and did not provide useful information. Therefore, we modified the current condition/prognosis-outcome sections to better capture important data including complications, the type of plague diagnosed, and expanded choices for outcome.

D. Add two questions regarding associated plague illness or known secondary transmission to "Epidemiologic and Environmental Investigation" sections and add more room to make comments – We felt it was important to note if there was any epidemiologic link to other plague cases and if any secondary transmission had occurred, information which was not collected on the previous form. While there have not been any documented secondary cases of plague since 1929, it is important to monitor and document this finding. The addition of blank space to the form in the epidemiologic and environmental investigation section was the only consistent feedback/request from the state health departments who use the form.

E. Reformat form so that header and footer fit on the page

F. Change "Native Hawaiian or Pacific Islander" to "Native Hawaiian or Other Pacific Islander"

G. In the race/ethnicity section, insure that multiple selections can be chosen

H. In the Epidemiologic and Environmental Investigation section, correct the typo to "preceding"

III. Deletions

A. Delete "Community Contacts" page (#3) from old form – The state health departments who use the form commented that they rarely use this section when reporting. As a

compromise, we have attempted to provide room in the “Epi and Environmental Investigation” comments section for persons to report this information when appropriate.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Plague Case Investigation Report	55	0.2	20/60	4

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

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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Q fever	55	1	10/60	9

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

Reye 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.

Changes to the form

- Change “Alaskan Native” to “Alaska Native”
- Change “Hawaiian/Pacific Islander” to “Hawaiian or Other Pacific Islander”
- Add “Unknown” category box to 7. Patient’s Race

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Reye Syndrome Case Surveillance Report	50	1	20/60	17

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

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.

Changes to the form

Change "Alaskan Native' to "Alaska Native"
Change "Pacific Islander" to "Hawaiian or Other Pacific Islander"

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Tick-borne Rickettsial Disease Case Report	55	18	10/60	165

National 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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Trichinosis Surveillance Case Report	55	.45	20/60	8

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

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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Tularemia Case Investigation Report (New Form)	55	2.2	20/60	40

National 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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Typhoid Fever Surveillance Report	55	6	20/60	110

National 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 with in 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 many 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.

Form Name	**# of Respondents**	**# of Responses**	**Avg. Burden in hours**	**Total Burden in hours**
Viral Hepatitis Specific Screen in NETSS	55	200	25/60	4,583