National Disease Surveillance Program - I. Case Reports

OMB No. 0920-0009

Revision

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Supporting Statement
National Disease Surveillance Program - I. Case Reports
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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). This request is a revision of a previously approved data collection. Two Active Bacterial Surveillance (ABCs) forms have been removed and approved as separate documents under OMB # 0920-0802. CDC is requesting approval also of minor changes to the Malaria Case Surveillance Report form, CDC 54.1.

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:

Creutzfeldt-Jakob Disease (CJD)
Cyclosporiasis cayetanensis
Dengue
Hantavirus pulmonary syndrome (HPS)
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.

Privacy Impact Assessment

Overview of the Data Collection System

Data are collected on standard case report forms that are completed by the State or local health department or, in some cases, by CDC field workers. Data for some case reports may be transmitted electronically to CDC by the National Electronic Telecommunications Systems for Surveillance (NETSS), the National Notifiable Diseases Surveillance System (NNDSS), or by hard copy for other case reports. Data may be collected by personal interview, telephone interview, through medical records review, or by electronic means.

Items of Information to be Collected

Information is collected that allows the case to be evaluated against an established case definition. In addition, information is collected that allows tracing of cases, contacts, travel, or other linkages necessary to evaluate and resolve an outbreak. If personal information is necessary to be collected, the IRB has approved its collection and the data are held securely at CDC until destroyed. For five of the Case Reports in this ICR, no personal identifiable information is collected. For others, it is necessary to collect sensitive data such as name, address, race/ethnicity, or medical history that are collected per HHS policy only for epidemiologic analysis. In most cases, these data are not transmitted to CDC but rather held at the local level for direct response. All data stored at CDC are in locked offices, requiring card key access to a secure building.

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

There is no website associated with this ICR that is directed at children under 13 years of age.

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. One example in 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.

Privacy Impact Assessment Information

Information in identifiable form (IIF) is necessary for 12 of 16 case reports since the information is used to follow up on case patients, to trace patients and contacts, to determine exposures and risks, and to attempt to attribute a cause and source so the outbreak can be eliminated as quickly as possible. The information collected is used solely to assess the presence and scope of an outbreak or to contact specific patients if necessary to ensure appropriate medical response. No identifiable information is collected on the forms for Creutzfeldt-Jakob Disease (all patients are already dead), Kawaskai Syndrome, Reye Syndrome, or Typhoid fever. For eight of the eleven forms where IIF is collected, the personal identifying data are not submitted to CDC, but is kept at the local health department for local follow-up.

Information on the Case Report forms are shared with State and Local public health officials in the process of outbreak response.

The proposed collection of information will have minimal impact on privacy since virtually all of these individuals will have already visited a physician where a full medical record is known, but held securely. In all cases where CDC is responsible for storage of IIF, the records and information are held in locked offices in secure buildings accessed only by secure card key.

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 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 17, 2009, Volume 74, No. 241, pp. 66975-76 (see Attachment B). One comment was received which discussed the mis-treatment of food animals as the cause of disease..

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: Robert Rolff
Utah State Epidemiologist
rrolff@utah.gov
801-538-6386

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, Malaria, Q Fever, Tick-borne Rickettsial Disease, Tularemia, 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.

Privacy Impact Assessment Information

The information collected is used solely to assess the presence and scope of an outbreak or to contact specific patients if necessary to ensure appropriate medical response. For eight of the eleven forms where IIF is collected, the personal identifying data are not submitted to CDC, but is kept at the local health department for local follow-up. In all cases where CDC is responsible for storage of IIF, the records and information are held in locked offices in secure buildings accessed only by secure card key.

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 13,368 hours. This collection requests an estimate of 11,441 hours. This reduction is the result of removal of the ABCs forms and rounding the number of responses for other forms.

Table 1

Estimated Annualized Burden Hours

Type of Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Epidemiologist	Tyhphoid fever	55	6	20/60	110
	Viral hepatitis	55	200	25/60	4583
	CJD	20	2	20/60	13
	Cyclosporiasis	55	10	15/60	138
	Dengue	55	182	15/60	2503
	Hantavirus	40	3	20/60	40
	Kawasaki Syndrome	55	8	15/60	110
	Legionellosis	23	12	20/60	92
	Lyme Disease	52	385	10/60	3337
	Malaria	55	20	15/60	275
	Plague	11	1	20/60	4
	Q Fever	55	1	10/60	9
	Reye Syndrome	50	1	20/60	17
	Tick-borne Rickettsia	55	18	10/60	165
	Trichinosis	25	1	20/60	8
	Tularemia	55	2	20/60	37
Total					11,441

B. The estimated total cost to respondents is $360,375. This assumes an average value per burden hour based on 2008 data from the Bureau of Labor Statistics for state Epidemiologists with an average salary of $31.50 per hour. The burden estimate is based on the time required to complete the forms.

Estimated Annualized Burden Costs

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Health Departments	11450	31.50	$360,391.50
Total			$360,391.50

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**

The requested total burden is 11,441 hours, which represents a decrease in burden hours due to the removal of the ABCs forms and rounding of responses previously submitted with decimals.

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 submit 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**

No method is needed 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 were made to one data collection instrument and two others were removed. 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 Surveillance Summaries