

National Disease Surveillance Program - I. Case Reports

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

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)	Q Fever
Cyclosporiasis cayetanensis	Reye Syndrome
Dengue	Tick-borne Rickettsial Disease
Hantavirus pulmonary syndrome (HPS)	Trichinosis
Kawasaki syndrome	Tularemia
Legionellosis	Typhoid Fever
Lyme Disease (LD)	Viral Hepatitis
Malaria	
Plague	

Attachment C contains descriptive summaries of each disease under surveillance. This is a request for a revision. The only change since the last submission is an updated cost to the respondent based on the Department of Labor Tables (A12. B) and some changes to the Legionellosis Surveillance Form (detailed in Attachment C).

1.1 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.

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 submission.

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), Kawasaki 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.

CDC is working to streamline efforts and reduce burden by combining all notifiable diseases into one OMB package, 0920-0728, National Notifiable Diseases Surveillance System (NNDSS). This is expected to happen in 2013-2014. At that time, all diseases in this submission will be rolled into 0920-0728 with the exception of CJD, Kawasaki Syndrome, and Reye Syndrome.

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 data collection.

6. Consequences of Collecting the 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.

This request fully complies with the regulation 5 CFR 1320.5.

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 12, 2012, Volume 77, No. 239, page 74017. (Attachment B). One comment was received from Tom Safranek, M.D., State Epidemiologist, Division of Public Health, Nebraska Dept. of Health & Human Services who is on the Council of State and Territorial Epidemiologist's Board. An explanation was provided to him with additional information about this project.

- 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. CDC has collaborated with CSTE since CSTE's inception in 1951, and it is through the CSTE annual conference that the cooperation of all states is maintained. Although formal CSTE meetings are usually held only once a year, communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis throughout the year. Jeff Engle is the Executive Director.

9. Explanation of Any Payment or Gift to Respondents

There are no gifts of payment to respondents.

10. Assurance of Confidentiality Provided to Respondents

10.1 Privacy Impact Assessment Information

These surveillance systems are not subject to IRB review and approval.

State participation in the surveillance collection is voluntary.

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 Estimated Annualized Burden Hours

This request is for 11,447 which is the same amount requested in the prior submission.

Form	Type of Respondent	No. of Respondents	No. of responses per respondent	Avg. Burden per response (in hrs)	Total burden hours
CJD	Epidemiologist	20	2	20/60	13
Cyclosporiasis	Epidemiologist	55	10	15/60	138
Dengue	Epidemiologist	55	182	15/60	2503
Hantavirus	Epidemiologist	46	3	20/60	46
Kawasaki Syndrome	Epidemiologist	55	8	15/60	110
Legionellosis	Epidemiologist	23	12	20/60	92
Lyme Disease	Epidemiologist	52	385	10/60	3337
Malaria	Epidemiologist	55	20	15/60	275
Plague	Epidemiologist	11	1	20/60	4
Q Fever	Epidemiologist	55	1	10/60	9
Reye Syndrome	Epidemiologist	50	1	20/60	17
Tick-borne Rickettsia	Epidemiologist	55	18	10/60	165
Trichinosis	Epidemiologist	25	1	20/60	8
Tularemia	Epidemiologist	55	2	20/60	37
Typhoid Fever	Epidemiologist	55	6	20/60	110
Viral hepatitis	Epidemiologist	55	200	25/60	4583

Total					11447

B: The Department of Labor website (<http://www.bls.gov/oes/current/oes191041.htm#nat>) shows that the mean hourly rate in 2012 for a State Epidemiologist is \$33.49. This is an increase since the last submission of \$31.50 hourly rate. The total requested is \$383,360 which is an increase in \$181,664. The previous submission was \$201,696

Estimated Annualized Burden Costs

Form	Type of Respondent	No. of Respondents	No. of responses per respondent	Avg. Burden per response (in hrs)	Total burden hours	Hourly Wage Rate	Total Respondent Costs
CJD	Epidemiologist	20	2	20/60	13	33.49	435
Cyclosporiasis	Epidemiologist	55	10	15/60	138	33.49	4,622
Dengue	Epidemiologist	55	182	15/60	2503	33.49	83,825
Hantavirus	Epidemiologist	46	3	20/60	46	33.49	1,541
Kawasaki Syndrome	Epidemiologist	55	8	15/60	110	33.49	3,684
Legionellosis	Epidemiologist	23	12	20/60	92	33.49	3,081
Lyme	Epidemiologist	52	385	10/60	3337	33.49	111,756

Disease	st						
Malaria	Epidemiologi st	55	20	15/60	275	33.49	9,210
Plague	Epidemiologi st	11	1	20/60	4	33.49	134
Q Fever	Epidemiologi st	55	1	10/60	9	33.49	301
Reye Syndrome	Epidemiologi st	50	1	20/60	17	33.49	569
Tick-borne Rickettsia	Epidemiologi st	55	18	10/60	165	33.49	5,526
Trichinosis	Epidemiologi st	25	1	20/60	8	33.49	268
Tularemia	Epidemiologi st	55	2	20/60	37	33.49	1,239
Typhoid Fever	Epidemiologi st	55	6	20/60	110	33.49	3,684
Viral hepatitis	Epidemiologi st	55	200	25/60	4583	33.49	153,485
Total					11447		383,360

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

There is an increased cost in burden to reflect the increase in the last 3 years. Also there are some changes to the Legionellosis form (explained in Attachment C). Specifically, the changes will allow the Legionella Program to better detect potential clusters and outbreaks of Legionnaires' disease and to monitor changing epidemiological trends by collecting a greater level of detail for each legionellosis case. The burden to the respondents should be minimally affected by these proposed changes.

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 Submissions

There are no exceptions to the certification.

List of Attachments

A. Authorizing Legislation

B. 60 Day Federal Register Notice

C. Disease Summaries

D. Surveillance Forms

1. CJD

2. Cyclosporiasis

3. Dengue (English version)

4. Hantavirus

5. Kawasaki Syndrome

6. Legionellosis

7. Lyme disease

8. Malaria

9. Plague

10. Q Fever

11. Reye Syndrome

12. Tick-borne Rickettsia

13. Trichinosis

14. Tularemia

15. Typhoid Fever

16. Viral Hepatitis

E. IRB determination