

# **National Disease Surveillance Program - I. Case Reports**

**0920-0009**

Request for OMB approval of a Revision ICR

Expiration Date: 08/31/2022

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**Supporting Statement A**

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## Table of Contents

|  |    |
|--|----|
| 1. Circumstances Making the Collection of Information Necessary                                  | 3  |
| 2. Purpose and Use of Information Collection   | 4  |
| 3. Use of Improved Information Technology and Burden Reduction                                   | 6  |
| 4. Efforts to Identify Duplication and Use of Similar Information                                | 6  |
| 5. Impact on Small Businesses or Other Small Entities  | 6  |
| 6. Consequences of Collecting the Information Less Frequently                                    | 6  |
| 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5                              | 6  |
| 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency | 7  |
| 9. Explanation of Any Payment or Gift to Respondents   | 7  |
| 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents         | 7  |
| 11. Institutional Review Board (IRB) and Justification for Sensitive Questions                   | 8  |
| 12. Estimates of Annualized Burden Hours and Costs   | 8  |
| 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers                 | 9  |
| 14. Annualized Cost to the Government  | 9  |
| 15. Explanation for Program Changes or Adjustments   | 9  |
| 16. Plans for Tabulation and Publication and Project Time Schedule                               | 10 |
| 17. Reason(s) Display of OMB Expiration Date is Inappropriate                                    | 10 |
| 18. Exceptions to Certification for Paperwork Reduction Act Submissions                          | 10 |
| Attachments  | 10 |

- A. The goal of this study is to collect disease specific surveillance reports of rare, uncommon or infrequent disease.
- B. The data will be used to determine the prevalence of diseases dangerous to public health. The data will also be used for planning and evaluating effective programs for prevention and control of infectious diseases. Disease incidence is needed to study present and emerging disease problems.
- C. Case data will be transmitted to CDC electronically or hard copy from State and Local Health Departments.
- D. The subpopulation is anyone with one of these diseases: CJD, Kawasaki disease, Reye Syndrome, or Acute Flaccid Myelitis
- E. 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.

CDC is requesting a three-year revision of OMB Control Number 0920-0009 (exp. date: 8/31/2022). This Revision ICR includes reductions in the burden hours for Reye Syndrome and Kawasaki Syndrome. Changes to the Acute Flaccid Myelitis Patient Summary Form, including the addition of travel history and polio vaccination questions, were approved via a non-substantive change request 8/1/22.

**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 the 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).

This ICR covers surveillance activities for these four, rare diseases:

- 1. Creutzfeldt-Jakob Disease (CJD)
- 2. Reye Syndrome
- 3. Kawasaki syndrome
- 4. Acute Flaccid Myelitis

Attachment C contains descriptive summaries of each disease under surveillance.

## 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 and epidemiological information to CDC.

The original and continued purpose for reporting communicable diseases is to determine the prevalence of diseases dangerous to public health. Collecting this data has also provided the basis for planning and evaluating effective programs for prevention and control of infectious diseases. Although the collection activities in this request may be infrequent, the information submitted on the disease incidence is needed to identify and study present and emerging disease problems. CDC's coordination of nationwide reporting maintains uniformity so that comparisons can be made from state to state and year to year.

For new diseases such as Acute Flaccid Myelitis (a relatively uncommon syndrome among children that presents a sudden onset of weakness in one or more arms or legs with MRI scans that show inflammation of the gray matter, nerve cells, in the spinal cord), the data collected from the case reports found that the majority of these cases were associated with the acute onset of areflexic limb weakness, often following a febrile or respiratory illness; cerebrospinal fluid (CSF) was characterized by pleocytosis (increase in inflammatory white blood cells) and normal or mildly elevated CSF protein levels. However, a cause for the 2014 acute flaccid myelitis cases has not been determined.

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. Annual surveillance data are published in the MMWR Surveillance Summary.

Since the last approval (June, 2019), updates include:

1. **CJD:** CJD continues to occur in the United States at a rate of approximately 1 to 1.5 cases per 1 million population per year. The age-adjusted incidence was calculated to be 1.3 cases per million for 2020, the most recent year with complete data available. Studying the potential for an animal prion disease, chronic wasting disease (CWD) of deer and elk, to transmit to humans is a Prion and Public Health Office priority as CWD continues to be found in new parts of the country. Part of this focus involves the review of very young cases, for which the CJD form is a tool. The estimated burden of this form will be low, as it will primarily be used for very young, non-familial, suspected human prion disease cases.

There are no requested changes to the form.

2. **Reye Syndrome:** There have been no documented cases of Reye syndrome reported to us since June 2016. As part of influenza surveillance, deaths related to influenza in children are monitored. No Reye syndrome has been identified from among these decedents. It appears that prevention efforts have successfully gotten the message out to not treat influenza-like

illness or chickenpox in children with aspirin or other salicylates that the incidence of Reye syndrome is below that which we can detect. We do not know whether any new treatments may come along in the future that, like salicylates, might increase the risk for Reye syndrome.

There are no requested changes to the form.

3. **Kawasaki Syndrome:** KD continues to occur in the United States, and the cause of this disease is still unknown. Hospitalization data from the Kids' Inpatient Database can be used to estimate KD incidence – for 2016, the most recent year available, incidence was calculated to be 19.8 cases per 100,000 children <5 years of age. This incidence finding is consistent with previous years, in contrast to a steadily increasing KD incidence reported in Japan. The CDC KD form has been used as part of a passive national surveillance system to collect additional case information, including data on cardiac complications and treatment.

There are no changes to the form.

4. **Acute Flaccid Myelitis:** Since 2014, state and local health departments, in consultation with clinicians, have submitted information about suspected cases and outcomes to CDC. In 2022, CDC submitted a non-substantive change request to OMB that was approved 8/01/2022.

The enteroviruses responsible for acute flaccid myelitis (AFM) are different from poliovirus but are within the same virus family (*Picornaviridae*). Both AFM and polio can cause acute flaccid weakness that appears clinically similar and initially hard to distinguish without the additional data such as travel and polio vaccination history and testing of clinical specimens.

Minor changes to the form include the addition of patient travel history 30 days before the onset of limb weakness and patient polio vaccination history. The instructions on the follow-up form have changed to reflect that the form is to be completed only at 60 days. The 6-month and 12-month follow up instructions have been removed.

The burden estimate for the Acute Flaccid Myelitis (AFM) Patient Summary Form remains at 80 hours.

### 3. Use of Improved Information Technology and Burden Reduction

The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures. The reporting of all four diseases in this submission are reported as needed via facsimile transmission or email.

OMB Control No. 0920-0728 incorporated thirteen diseases/conditions that were previously included in 0920-0009. This was an important step in implementing CDC's longer-term strategy of developing a more coordinated and integrated infectious diseases surveillance system that reduces overlap and duplication; increases interoperability, integration and efficiency; and thereby reduces burden to state, territorial and local health departments that report infectious disease data to CDC.

The focus of 0920-0009 is on non-nationally notifiable infrequent diseases and conditions not

covered in any other OMB approved package. The information requested is the minimum amount required to maintain surveillance of these selected diseases.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The specific variables included in this information collection request are not included in any other nationwide surveillance system. 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.

Currently, acute flaccid myelitis is not a nationally notifiable disease. However, CSTE released a position statement specifying a standardized case definition for Acute Flaccid Myelitis in 2015.

#### **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., 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 May 23, 2022, Vol. 87, No. 99, p. 31237. (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. 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 ([jengle@cste.org](mailto:jengle@cste.org)).

Due to a 2014 increase in acute neurological illness with limb weakness in children, now known as Acute Flaccid Myelitis, CSTE Infectious Disease Committee published a position statement during the 2015 CSTE annual meeting that includes a standardized case definition for Acute Flaccid Myelitis. It was coordinated through the CDC Director and authored by Colorado Department of Public Health and Environment, Lisa Miller, MD, MSPH, State Epidemiologist, 4300 Cherry Creek Drive South Denver, CO 80246, 303-692-2663, [Lisa.miller@state.co.us](mailto:Lisa.miller@state.co.us).

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

There are no gifts of payment to respondents.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

### Creutzfeldt-Jakob Disease (CJD), Reye Syndrome, Kawasaki syndrome

NCEZID's Information Systems Security Officer and CDC's Senior Official for Privacy reviewed the submission and determined that the Privacy Act does not apply since information is not retrieved by personal identifiers. However, personally identifiable information (PII) is collected.

Personally Identifiable Information (PII) will be secured both physically and electronically. Physical surveillance forms will be stored in locked cabinets within employee badge-secured facilities; electronic data will be saved in folders restricted to non-users, within password-protected computer systems.

The information that will be collected includes patient's DOB, Age, First three letters of Patient's last name, Patient's initials, Patients Date of Death, State of Death, Ethnicity/Race, Patient's State, Patient's County, Patient's Sex and Physician contact info. This information is pulled from multiple forms.

At time of sample collection individuals are notified their information is being sent to the CDC by state health department staff. Individuals can choose not to write their address or their full name with the state.

### Acute Flaccid Myelitis: Patient Summary Form

The NCIRD Information Systems Security Officer and CDC Senior Official for Privacy reviewed the Acute Flaccid Myelitis: Patient Summary Form and determined that it is not applicable to the Privacy Act. While the Privacy Act is not applicable, the appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and PII. Procedural Safeguards assure that PII will be secured both physically and electronically. Physical surveillance forms will be stored in locked cabinets within employee badge-secured facilities; electronic data will be saved in folders restricted to non-users, within password-protected computer systems.

The Approved Records Control Schedule (N1-442-09-1, Item 2)

Authorized Disposition: Maintain at least eleven years, but no longer than twenty years, after the retirement of the records depending upon program need for scientific, legal, or business reference. Transfer to FRC is authorized in accordance with applicable storage regulations of electronic records.

Privacy impact assessments are attached for both systems (attachments G and H).

**11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

IRB Approval

These surveillance systems have been reviewed by IRB and a non-research determination was made (Attachment E)

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 98 hours, which is a decrease in 69 hours since the last request of 167 hours. Estimated burden is being adjusted to more closely match actual, experienced burden.

| Type of Respondent | Form Name              | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs) | Total Burden Hours |
|--------------------|------------------------|--------------------|---------------------------------|-----------------------------------|--------------------|
| Epidemiologist     | CJD                    | 10                 | 2                               | 20/60                             | 7                  |
|                    | Kawasaki Syndrome      | 20                 | 2                               | 15/60                             | 10                 |
|                    | Reye Syndrome          | 1                  | 1                               | 20/60                             | 1                  |
|                    | Acute Flaccid Myelitis | 100                | 4                               | 12/60                             | 80                 |
| Total              |                        |                    |                                 |                                   | 98                 |

B. Estimated Annualized Burden Costs

The Department of Labor website ([https://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](https://www.bls.gov/oes/current/oes_nat.htm#00-0000)) shows that the mean hourly rate for a State Epidemiologist has increased to \$37.90. The total requested is \$3,714.20, a decrease from \$5,592.83 of \$1,878.63



| Type of Respondent | Form Name                           | Total burden hours | Hourly Wage Rate | Total Respondent Costs |
|--------------------|-------------------------------------|--------------------|------------------|------------------------|
| Epidemiologist     | CJD                                 | 7                  | 37.90            | 265.30                 |
|                    | Kawasaki Syndrome                   | 10                 | 37.90            | 379.00                 |
|                    | Reye Syndrome                       | 1                  | 37.90            | 37.90                  |
|                    | Acute Flaccid Myelitis Summary Form | 80                 | 37.90            | 3032.00                |
| Total              |                                     |                    |                  | \$3714.20              |

### **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 \$10,000.

### **15. Explanation for Program Changes or Adjustments**

A non-substantive change request to the AFM form was approved in August 2022.

There are no changes to the CJD, Reye Syndrome, or Kawasaki forms.

For this current revision ICR, we are updating the burden hours for Kawasaki and Reye Syndromes following a decrease in experienced/expected collection. CJD burden remains the same.

All cost burdens have been updated to reflect current DOL Epidemiologist wage rates.

### **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.

**Attachments**

- A. Authorizing Legislation
- B. 60 Day Federal Register Notice
- C. Disease Summaries
- D. Surveillance Forms
  - 1. CJD
  - 2. Kawasaki Syndrome
  - 3. Reye Syndrome
  - 4. Acute Flaccid Myelitis
- E. IRB determination
- F. CSTE Infectious Disease, Standardized Case Definition for Acute Flaccid Myelitis
- G. PIA – AFM
- H. PIA – CJD, Reye Syndrome, Kawasaki syndrome