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

**OMB Control Number 0920-0009**

**Expiration Date 06/30/2019**

**Program Contact**

**Ansley Hynes**

**National Center for Immunizations and Respiratory Diseases**

**1600 Clifton Rd, C-12**

**Atlanta GA 30333**

**Submission Date: January 25, 2019**

**Circumstances of Change Request for OMB 0920-0009**

CDC requests approval for a non-substantive change to OMB Control No. 0920-0009

National Disease Surveillance Program - I. Case Reports

Expiration Date 06/30/2019

Form Name: Acute Flaccid Myelitis: Patient Summary Form

***Background:*** Acute flaccid myelitis (AFM) is a rare but serious condition that affects the nervous system, specifically the spinal cord, which can cause the muscles and reflexes in the body not to work normally.  AFM is characterized by sudden onset of limb weakness and sometimes accompanied by cranial nerve dysfunction such as facial drooping or difficulty speaking. In many cases, distinctive lesions in the gray matter (nerve cells) of the spinal cord may be seen on neuroimaging. CDC does not yet know the cause of these AFM cases and it is unclear what pathogen or immune response is causing the weakness and paralysis. CDC has not yet determined who is at higher risk for developing AFM, or the reasons why they may be at higher risk. However, what we know about the AFM cases for which CDC has received information is that most patients are children and the patients’ symptoms have been most similar to complications of infection with certain viruses, including poliovirus, non-polio enteroviruses, adenoviruses, and West Nile virus. AFM is diagnosed based on a combination of clinical symptoms and specific MRI findings or results from testing of cerebrospinal fluid.

***Overall Collection Activity:*** Information about cases is collected from state health departments, in consultation with clinicians, using a national case report form. The national rollout for requesting case reporting is ongoing.State and Local health departments are notified of the need to fill out the case report form through various communications, including a health advisory, communications through the ELC project, and a request to the Council of State and Territorial Epidemiologists (CSTE). Case report forms are sent from the state health department to CDC and will be analyzed to determine any geographic and temporal commonalities among cases and identify the etiology, mode of transmission, and risk factors for disease. The geographic location of cases are not known until case report forms are submitted by states. This information will be used to directly inform control measures to prevent additional cases. Specifically, CDC will use this information to describe the illness, identify etiology, modes of transmission, risk factors, and geographic distribution of the neurologic illness. The data will also help inform the baseline rate of AFM in the United States, which is currently unknown.

***Non-Substantive Change*:** Since 2014, state and local health departments, in consultation with clinicians, have submitted information about suspected cases and outcomes to CDC. Recently, CDC has received feedback from the state and local health departments that the patient summary form does not sufficiently capture the range of possible outcomes in the follow up section. In an effort to make questions clear and useful, CDC deleted two broad questions that request the site of the paralysis and added 6 questions that are more specific in nature. Because there is no specific treatment for acute flaccid myelitis, detailed information on the clinical status of cases, including follow-up, is important for providing a more complete clinical description of the illness and improving our understanding of the overall burden of illness beyond the acute period. The data will be used for planning and evaluating effective programs for secondary prevention.

### Estimates of Annualized Burden Hours

The Acute Flaccid Myelitis: Patient Summary Form changes increase the total burden hours from 33 to 50 hours because the average burden per response to complete the form increased from 20 minutes to 30 minutes. The total annualized number of approved burden hours currently is 173 and approval of this request would increase annualized burden to 190.

There is no change in burden for CJD, Kawasaki syndrome, Reye Syndrome since the last submission.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hours) | Total Burden Hours |
| Epidemiologist | CJD | 20 | 2 | 20/60 | 13 |
| Epidemiologist | Kawasaki Syndrome | 55 | 8 | 15/60 | 110 |
| Epidemiologist | Reye Syndrome | 50 | 1 | 20/60 | 17 |
| Epidemiologist | Acute Flaccid Myelitis  | 100 | 1 | 30/60 | 50 |
| Total |  |  |  |  | 190 |

***Privacy Act Determination:*** The NCIRD Information Systems Security Officer reviewed the changes to the Acute Flaccid Myelitis: Patient Summary Form and determined that the information collected is not applicable to the Privacy Act. 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.

***Description of Changes***

The changes to form are as follows:

1. Acute Flaccid Myelitis Outcome Section was modified to “Follow-Up (completed at least 60 days after onset of limb weakness)”
2. Question #34, #35, #37 have been deleted.
3. Renumbered the remaining questions after deleting the original #34, #35 and #37.
4. Question 34 has been simplified to “Impairment” instead of “60 day residual”
5. Date of Death has been included with Question 34 for clarity.
6. Question 35 was added to understand the overall physical condition and reliance on medical care of AFM cases
7. Question 36 was added to specifically understand upper limb function following a case of AFM
8. Question 37 was added to specifically understand lower limb function following a case of AFM
9. Question 38 was added to understand if speech and hearing impairments are present following a case of AFM
10. Question 39 was added to understand if bowel and bladder impairments are present following a case of AFM
11. Question 40 was added to understand general functioning and the need for support following a case of AFM