

National Disease Surveillance Program - I. Case Reports
OMB Control Number 0920-0009
Expiration Date 06/30/2019

Program Contact

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Circumstances of Change Request for OMB 0920-0009

CDC requests approval for a non-substantive change to OMB Control No. 0920-0009
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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 suspect cases to CDC. However, CDC has received feedback from the state and local health departments and clinicians about the feasibility of completing the requested information on the currently approved Acute Flaccid Myelitis Patient Summary Form. In order to decrease the overall burden to complete the form, CDC has deleted the clinical sections on the

form and in turn, requests the respondents supplement that clinical information with clinical notes, MRI reports, and images. CDC consulted with 26 state or local health departments about this new format submission and agreed that it would help ease the burden associated with completing the AFM patient summary form and reporting cases to CDC. Because there is no specific treatment for acute flaccid myelitis, detailed information on the clinical status of cases, including after a longer period of 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 requested information is used by CDC and external experts to make case determinations for suspect cases of AFM.

Estimates of Annualized Burden Hours

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

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 hrs)	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 20/60	50 33
Total					190 173

Privacy Act Determination: The NCIRD Information Systems Security Officer and CDC Senior Official for Privacy reviewed the changes to the Acute Flaccid Myelitis: Patient Summary Form and determined that the information collected is not applicable to the Privacy Act. Patient/participant names, while not actively collected in this project may be, in some instances, passively maintained as a result of the health facilities/study sites not removing them from MRI images or medical records. Names are neither used by nor necessary to the study. 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. PIA is attached.

Description of Changes

The changes to form are as follows:

- 1) Addition of a box under the title of the form for persons completing the form to indicate what supplemental information is being included with the form.
- 2) Question 15 has been simplified to help clarify and question 15a was added to include a question that will help determine whether the case meets the AFM case definition.
- 3) Questions 16-25 have been deleted.
- 4) Form renumbered to reflect Question 16, question has been modified to simplify the question about severity of illness. Now asks, *Was patient admitted to ICU?*
- 5) Questions 30-31, 34-35, and 40 have been deleted.
- 6) Sections on “Polio vaccination history”, “Neuroradiographic findings”, and “Pathogen testing performed” have been deleted.
- 7) New questions, (28-31) were added to simplify the “Neuroradiographic findings” section.
- 8) New questions (33-37) were added to collect information on outcomes after at least 60 days after onset of limb weakness.