Non-Substantive Change Request to OMB Control Number 0920-0009; National Disease Surveillance Program - I. Case Reports

Program Contact
Amy H. McMillen, MPH
National Center for Emerging and Zoonotic Infectious Diseases
Office of Policy, Analysis, and Strategy
1600 Clifton Rd, C-12
Atlanta GA 30333

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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; National Disease Surveillance Program - I. Case Reports

Form Name: Acute Neurological Illness with Limb Weakness in Children

Acute Neurological Illness with Limb Weakness in Children

In response to a larger than expected increase in the number of children presenting with acute neurological illness with limb weakness, CDC initiated an investigation to determine the etiology of the illness. As the investigation transitions, collecting more detailed information on the clinical status of cases after a longer period of follow-up will be important for providing a more complete clinical description of the illness as well as a further understanding of the overall burden of illness beyond the acute period. Overall, these changes include adding, deleting and reformatting. Estimates of annualized burden hours for this change request remain the same. The total burden estimate for the form included in OMB Control No. 0920-0009 is 30 minutes.

Description of Changes

The changes to form are as follows:

1) Divided approved form into Part I and Part II, specifically, the *Confirmation of Case Information* was moved under heading Part I of the new version of the form. They are still used together.
2) Part I, under *Confirmation of Case Information* Question B: now includes (Terms in the spinal cord MRI report such as “affecting mostly gray matter,” “affecting the anterior horn or anterior horn cells,” “affecting the central cord,” “anterior myelitis,” or “poliomyelitis” would all be consistent with this. If still unsure if this criterion is met, consider asking the radiologist directly.)
3) Under PART II. Acute Neurologic Illness with Limb Weakness in Children: Patient Summary Form
    a) Modified State ID so that it represents standalone Question #10 in new format. Previously it was included in Question 9 as Patient ID___State ID____.
    b) Removed instructions on how to assign a State ID: (HD to assign using State abbrev, then number: aa--##, use leading zero) to reduce confusion.

c) Question #10 on currently approved form asks for both Patient Sex and Patient Age in the same question. Modified so that Patient Sex is Question #11 in new format and Patient Age is Question #12 in new format. **As a consequence the form has been re-numbered.**

d) Added question #18; Was patient admitted to a hospital: yes, no, unknown

e) Modified question about clinical status to focus on patient outcome: Question 21 states: At the time of last / most recent follow-up, how would you best characterize the patient's outcome, in terms of affected limb strength:

- Completely recovered; back to baseline strength with no residual sequelae
- Partially recovered; some improvement in limb strength, but with ongoing weakness compared to initial presentation
- No demonstrable improvement in limb strength; essentially as weak as at time of first presentation
- Decline in limb strength; weaker in affected limbs than at time of first presentation
- Unknown / unable to comment

a. Deceased

f) Question 22 is a standalone question referring to question 21 – Date of Death __/__/__

g) Added Question 23. At the time of last / most recent follow-up, how would you best characterize the patient's functional outcome, in terms of effect of limb weakness on activities of daily living? (Not applicable if Q21 is 'deceased')

- Completely functionally recovered; able to do all activities as prior to acute illness
- Somewhat functionally impaired; able to do some activities on own, but needs caregiver assistance with other things (dressing, tying shoes, feeding, etc.)
- Completely dependent on caregiver for basic daily functions.

Under Signs/Symptoms Conditions at ANY time during the illness:

h) Modified Question 18 that previously identified the *number* of limbs with acute weakness to be more specific by asking *which* limbs have been acutely weak. Must indicate yes- no –unknown; for each limb (right arm, left arm, right leg, left leg).

i) Added Question: Date of neurological exam (recorded at worst weakness thus far) MM/DD/YYYY.

j) Removed Question: Grade of Motor Weakness, of most affected muscle group: At Peak Severity 0/5 – 1/5 – 2/5 -3/5 -4/5 – 5/5.

k) Removed Question: Date for Peak Severity 0/5 – 1/5 – 2/5 -3/5 -4/5 – 5/5.

l) Removed Question: Grade of Motor Weakness, of most affected muscle group: At Most Recent Examination 0/5 – 1/5 – 2/5 -3/5 -4/5 – 5/5.

m) Removed Question: Date for At Most Recent Examination 0/5 – 1/5 – 2/5 -3/5 -4/5 – 5/5.

n) Added Question 26: Reflexes in the affected limb(s): areflexic/hyporeflexic (0-1), Normal (2), Hyperreflexic (3-4+).

o) Modified sensory loss/numbness question to include "in the affected limb(s), at any time during the illness? (Paresthesias should not be considered here) Yes – No- Unknown."

p) Added Question 28: Any pain or burning in the affected limb(s) at any time during illness. Yes – No – Unknown.
q) Modified clinical involvement in cranial nerve question to focus on cranial nerve signs and include options: diplopia/double vision – loss of sensation in face – facial droop – hearing loss-dysphagia – dysarthria for clarification.
r) Modified questions 31-37 to include examples and "at any time during illness" for clarification.
s) Added **Other Patient Information** section; questions 38 – 49.

Under Polio Vaccination History:

t) Removed alphabetical lettering a./a./c. section. Now represented by Questions 50-52
u) Removed question: Were any of these doses administered outside of the US? Yes – No - Unknown

Under Neuroradiographic Findings:

v) Removed question: Site of lesion(s) and options: mostly right side, mostly left side, both sides, unknown

Under MRI of brain

w) Added options (Question 67. And 68.) to Supratentorial question #66
x) Modified brainstem options from Ventral pons/dorsal pons to only pons.
y) Removed "deep nuclei" from question to 'Any lesions affecting the cerebellum?'
z) Modified cranial nerve lesions options to CN_ Unilateral _ Bilateral from CN_ R _ L _ both R and L.
aa) Under **CSF examination**; added question 78. "was a lumbar puncture performed; yes – no – unknown. If yes, complete 79".
bb) Modifications of questions under **Pathogens testing performance** section include reformatting to emphasize the type of specimen tested for/and the identification of that specific pathogen
cc) Added **Treatment** header and question #87; Were any of these therapies administered for the acute neurologic illness? A. Antibiotics B. Antivirals C. Corticosteroids D. IVIG E. Plasma exchange or Plasmapheresis F. Interferon G. Other immunosuppressive therapy