



UK Health
Security
Agency

Protocol for the case note review of Acute Flaccid Paralysis reported cases

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Executive summary

In October 2018, there was a noted increase in reports of unexplained acute neurological symptom presentations, particularly Acute Flaccid Paralysis (AFP) and Acute Flaccid Myelitis (AFM). Since the beginning of 2018, 70 suspected AFP cases have been reported in the UK (49 in 2018, 18 in 2019, 1 in 2020 and 2¹ in 2021). Cases were reported throughout the UK with a median age of 6.5 years. Enhanced surveillance was established and all reported cases were investigated to exclude polio and identify other potential infectious causes, including non-polio enteroviral infection. Enterovirus D68 was detected in eleven of the reported cases, primarily from respiratory samples. Increases in AFP or AFM linked to enterovirus infection have also been reported in Europe and the USA.

Whilst AFP or AFM are not on the list of notifiable diseases in the UK, health professionals are encouraged to report cases as part of national surveillance for polio. This is a World Health Organization requirement to demonstrate that the UK continues to be free of wild poliovirus infection. UKHSA is gathering information on clinical history, possible risk factors and outcomes for reported cases.

Health professionals are requested to report all cases of AFP or AFM that meet the case definition below.

“Acute flaccid paralysis/myelitis, not explained by a non-infectious cause”

AFP or AFM is characterised by rapid onset of weakness of an individual's extremities, often including weakness of the muscles of respiration and swallowing, progressing to maximum severity within 10 days. The term 'flaccid' indicates weakness accompanied by hyporeflexia or areflexia in the affected limb(s).

¹ 2021 data are provisional.

The purpose of the AFP surveillance is as follows:

- to investigate and exclude poliovirus infection
- to investigate the potential contribution of other enteroviruses, especially enterovirus D68
- to systematically characterise the illness and document long-term sequelae
- to increase awareness of guidance on the investigation and management of such cases
- to advocate for further research and identify potential research
- to act as a focus for national and international collaboration

Case definition

Any case of acute flaccid paralysis in England not explained by a non-infectious cause.

WHO defines AFP syndrome as "characterised by rapid onset of weakness of an individual's extremities, often including weakness of the muscles of respiration and swallowing, progressing to maximum severity within 1 and 10 days. The term 'flaccid' indicates the absence of spasticity or other signs of disordered central nervous system (CNS) motor tracts such as hyperflexia, clonus, or extensor plantar responses".

Purpose of case note review

The purpose of the case note review:

- to systematically characterise the illness, including radiological results and document the long-term sequelae
- to characterise the clinical interventions undertaken and their outcomes
- ensure completeness of clinical information so far reported
- gather key results and information to present at the expert panel

Study population to review

Cases reported through UKHSA's AFP surveillance with a classification of acute flaccid paralysis not explained by a non-infectious cause

Period for case ascertainment

Cases from January 2018 onwards.

Case note review

Case note review:

- all clinical electronic and paper records relevant to the AFP case will be sought and reviewed including relevant radiology
- key data items which were not in the initial AFP report to UKHSA will be highlighted and sought for each case
- data will be held on a UKHSA encrypted laptop in password protected Excel or Access files
- Data will be saved to the C drive of the laptop while working at the hospital and then transferred to the UKHSA network server and deleted from the C drive
- If needed documents such as discharge summaries and clinic letters will be copied but names and NHS numbers removed and a study number allocated

MRI scan review

Anonymised MRI scans will be requested on CD in DICOM format and collected when the clinical case note review takes place. No names, NHS or hospital numbers will be attached to the MRI scan and the study number will be used to identify the scan.

The scans will be reviewed centrally at UKHSA and via Skype on a shared desktop during the Expert Review Panel meeting. If it is decided that a more detailed review is needed the PACS system at St Thomas' will be used.

Expert review panel

An expert panel will review all cases and relevant information including MRI scans and classify cases as:

Acute flaccid paralysis (AFP)	Clinical	Any person with symptoms of acute flaccid paralysis not explained by a non-infectious cause
Polio status	Discarded	Not AFP or AFP explained by a non-infectious cause
	Polio-confirmed	AFP case in whom polio-virus detected
	Pending	AFP case with inadequate specimens or samples not yet tested and/or 60 day follow-up not completed
	Polio-discarded	AFP case where polio-virus infection unlikely after expert review based on clinical, epidemiological, and virological information
Acute flaccid myelitis (AFM)	Probable	Any person with symptoms of acute flaccid limb paralysis AND CSF showing pleocytosis (5 WCC > 5 cells/mm ³)
	Confirmed	Any person with symptoms of acute flaccid limb paralysis AND an MRI showing a spinal cord lesion largely restricted to grey matter spanning ≥ 1 spinal segment
	Pending	Any person with symptoms of acute flaccid limb paralysis AND an MRI unavailable or results need clarification
	Discarded	Any person with symptoms of acute flaccid limb paralysis AND an MRI findings inconsistent with AFM
Non-polio enteroviral associated AFP	Confirmed	AFP case where non-polio enterovirus was detected in appropriately timed samples (respiratory, stool, CSF taken within 14 days of illness onset)
	Negative	AFP case where non-polio enterovirus was NOT detected in appropriately timed samples (respiratory, stool, CSF taken within 14 days of illness onset)
	Pending	AFP case where specimens not taken or samples not yet tested
	Unexplained	AFP case where inadequate specimens available

Data security

This surveillance and proposed data collection has approval from the UKHSA Caldicott panel which has confirmed that it is covered under the subsection of regulation 3 of section 251:

- diagnosing communicable diseases and other risks to public health
- recognising trends in such diseases and risks
- controlling and preventing the spread of such diseases and risks

The study will comply with the 6 Caldicott principles governing the use of personally identifiable information. UKHSA has had systems in place for several years to show compliance with Caldicott principles. The immunisation department has a Caldicott monitor which carries out monthly audits and the site has an overall Caldicott audit, all of which are monitored by the Health Care Commission.

The information collected will be put into a password protected Access database which will be in a restricted access folder on the UKHSA network. The UKHSA network is protected by a secure firewall to prevent outside access to the organisations network.

Identifiers (NHS number or case note number) taken to hospitals to carry out case note review will be held in a password protected excel file on the encrypted laptop transfers of patient data outside the secure area will be encrypted in line with Cabinet Office requirements.

UKHSA laptops used to access the data employ full disk encryption using McAfee Endpoint Encryption, managed by UKHSA IT. See: UKHSA SQL Database Servers (including Porton SQL Clusters) & RID_Fileshare_SLSP.

Electronic media will be erased using a software package. If the equipment is to be discarded, storage media such as fixed disks will be removed from computers and rendered unreadable by destruction.

The study is under the National Information Governance Board for Health and Social Care (NIGB) to process confidential patient information for the surveillance and analysis of health and disease (NIGB ref: PIAG 03-(c)/2001).

UKHSA does have stringent data security measures in place and are registered under the Data Protection Act (registration number: Z7749250) and UKHSA has a [Personal Information Charter](#) which outline how personal information is protected:

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About the UK Health Security Agency

The [UK Health Security Agency](#) is an executive agency, sponsored by the [Department of Health and Social Care](#).

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Prepared by: Immunisation and Vaccine Preventable Diseases Division
For queries relating to this document, please contact: immunisation@phe.gov.uk

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