23-ID-07

Committee: Infectious Disease

Title: Update to Public Health Reporting and National Notification for Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection

☒Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 09-ID-53

Synopsis:

- This position statement updates the standardized case definition for Paralytic Poliomyelitis to simplify reporting and clarify the difference between non-poliovirus-associated acute flaccid myelitis (AFM) and paralytic poliomyelitis by adding a laboratory component for the confirmed classification. No updates are made to Nonparalytic Poliovirus Infection.
- Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection should remain as nationally notifiable conditions; however, the CDC notification timeframe has been updated from within 4 hours to within 24 hours.

I. Statement of the Problem

Wild-type poliovirus was eliminated from circulation in the United States (U.S.) in 1979 after introduction of poliovirus vaccine (1). The Global Polio Eradication Program has helped decrease wild-type poliovirus transmission worldwide, leading to eradication of types 2 and 3, and persistence of type 1 wild-type poliovirus in only 2 countries (2). Internationally, low poliovirus vaccination coverage and challenges with vaccination campaigns have led to a reemergence of type 2 vaccine derived poliovirus (VDPV) (3) and an increased risk for importation into the U.S. In July 2022, a case of polio in an unvaccinated young adult from New York was identified, representing only the second instance of community transmission in the U.S. since 1979 (4). The case, which was caused by VDPV type 2 (VDPV2), was genetically linked to a case in Israel. VDPV2 was also detected in wastewater samples in several counties in New York.

Rapid identification and investigation of potential poliomyelitis cases is critical for preventing further poliovirus transmission, particularly in communities with low poliovirus vaccine coverage. Collection of specimens for poliovirus detection is important to determine whether a case of paralytic poliomyelitis is categorized as being due to wild-type or vaccine-related virus infection and understand chains of transmission.

II. Background and Justification

Poliomyelitis is characterized by the acute onset of flaccid paralysis caused by one of the 3 types of polioviruses, whether wild-type or vaccine-associated. Paralysis is typically asymmetrical, often affecting the lower limbs. The majority of poliovirus infections are asymptomatic or subclinical, and fewer than 1% are paralytic. The onset of paralysis is rapid, and usually does not progress after 3 days. Transmission of poliovirus occurs primarily through the fecal-oral route.

Starting in 1988, the World Health Organization (WHO) has targeted poliomyelitis for eradication. Two types of vaccines are available for preventing polio, inactivated polio vaccine (IPV) and oral polio vaccine (OPV). The introduction of these vaccines has led to a dramatic decrease in wild-type poliovirus transmission globally and led to the elimination from the Americas since 1991 (5). OPV contains live, attenuated poliovirus, which on rare occasions, can cause paralysis. If there are communities with low coverage, vaccine virus can circulate and mutate over time to regain neurovirulence. Vaccine-associated paralytic poliomyelitis can occur in both OPV recipients and their contacts. OPV has not been recommended in the U.S. since 2000. The U.S. and most industrialized countries

are now using only inactivated poliovirus vaccine (IPV). Two doses of IPV are up to 90% effective and 3 doses are estimated to be 99-100% effective in preventing paralytic disease (5). Non-immune persons traveling to areas with circulating wild-type or vaccine-derived polioviruses are at risk of being infected with either wild-type or vaccine-derived polioviruses. Until polio is eradicated and oral poliovirus vaccine use has ended worldwide, there is a risk that imported polioviruses will continue to circulate and cause disease in populations with low immunization rates. Wild-type polio is currently endemic in only 2 countries, Pakistan and Afghanistan (2).

Two polio-related conditions are nationally notifiable: "paralytic poliomyelitis," in which clinical criteria for the disease have been met; and "non-paralytic poliovirus infection," in which the case-patient is asymptomatic or mildly ill without paralysis (6). Suspected cases of paralytic poliomyelitis or non-paralytic poliovirus infection should be reported to public health immediately, regardless of whether the virus is suspected to be wild poliovirus or vaccine-derived poliovirus.

Although surveillance for acute flaccid paralysis (AFP) has not been routinely conducted in the U.S. since polio was eradicated, the appearance of a condition with a similar clinical presentation in 2014 led to the development of a standardized case definition for surveillance of acute flaccid myelitis (AFM), which is a subtype of AFP (7). AFM is characterized by rapid onset of flaccid weakness in one or more limbs and distinct abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI). To date, all stool specimens from AFM patients tested at CDC have been negative for poliovirus except for the patient from New York in 2022, who initially came to the attention of public health as a suspect AFM patient (4). The previous definition for a confirmed paralytic poliomyelitis case does not include a laboratory component (6), thus AFM cases can technically be considered confirmed cases of paralytic poliomyelitis. Therefore, to help simplify reporting and clarify the difference between AFM and paralytic poliomyelitis, a revision to the Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection case definition is being proposed.

This position statement proposes to:

- add a laboratory component to the confirmed classification for paralytic poliomyelitis; and
- remove the probable classification for paralytic poliomyelitis.

III. Statement of the Desired Action(s) to be Taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for **paralytic poliomyelitis and nonparalytic poliovirus infection**.
   A. Utilize standard sources (e.g., reporting*) for case ascertainment for **paralytic poliomyelitis and nonparalytic poliovirus infection**. Surveillance for **paralytic poliomyelitis and nonparalytic poliovirus infection** should use the recommended sources of data to the extent of coverage presented in Section V.
   B. Utilize standardized criteria for case ascertainment for **paralytic poliomyelitis and nonparalytic poliovirus infection** presented in Section VI and Table VI in Technical Supplement.
   C. Utilize standardized criteria for case classification for **paralytic poliomyelitis and nonparalytic poliovirus infection** presented in Section VII and Table VII in Technical Supplement.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for **paralytic poliomyelitis and nonparalytic poliovirus infection** and **update** paralytic poliomyelitis and nonparalytic poliovirus infection on the *Nationally Notifiable Condition List* using the following notification** timeframe:
   ☐ Immediately notifiable, extremely urgent (within 4 hours)
   ☒ Immediately notifiable, urgent (within 24 hours)
   ☐ Routinely notifiable
   ☐ No longer notifiable

3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g., States and Territories) conducting surveillance (according to these methods) should submit case notifications to CDC.

4. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) can receive HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease specific MMG for the new condition among other conditions waiting for MMG development.

5. CDC should publish data on Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
   - ☒Confirmed
   - ☐Probable
   - ☐Suspect
   - ☐Unknown

6. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority should conduct public health surveillance and use the case classifications included in this standardized surveillance position statement.

** Reporting: process of a healthcare provider, laboratory, or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.*

*** Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Conditions List to CDC.*

IV. Goals of Surveillance

To rapidly identify and contain any wild-type or vaccine-derived poliovirus imported into the U.S.

V. Recommended Data Sources and Methods for Surveillance

Surveillance for paralytic poliomyelitis and nonparalytic poliovirus infection should use the following recommended sources of data and/or methodologies and the extent of coverage listed in Table V.

Table V. Recommended Sources of Data, Surveillance Methods, and Extent of Coverage for Ascertainment of Cases of Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection.

Source of Data/Methodology for Case Ascertainment	Coverage	
	Population-Wide	Sentinel Sites
Clinician reporting, including hospitals, emergency departments, pathologists, medical examiners	X	
Laboratory reporting	X	
Reporting by other entities, specify: N/A		
Death certificates	X	
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone or online survey		
School-based survey		
Other, specify: N/A		

VI. Criteria for Case Ascertainment

Case ascertainment is the process through which public health identifies potential cases of a disease or condition using data reported or provided to public health by healthcare, laboratories, and other reporting entities. This public health reporting is triggered by the case ascertainment criteria (a single criterion or a combination of criteria) included in this position statement, and each initial report sent to public health should include common data elements and disease-specific data elements. Case ascertainment criteria are not intended to be used for clinical diagnosis purposes.

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition and recommended reporting procedures.

Report any illness to public health authorities that meets the following criteria.

Paralytic Poliomyelitis

A1. Clinical Criteria for Reporting
- A person with acute onset of flaccid paralysis with decreased or absent tendon reflexes in the affected limbs, in the absence of a more likely alternative diagnosis.

A2. Laboratory Criteria for Reporting
- Diagnostic test for poliovirus is ordered, **OR**
- Poliovirus detected in clinical specimen using a properly validated assay.^

^*The Global Polio Laboratory Network (GPLN) provides guidelines on acceptance of results from labs that are not in GPLN; assays would have to be validated and approved by GPLN. CDC is part of GPLN.*

A3. Epidemiologic Linkage Criteria for Reporting
N/A

Nonparalytic Poliovirus Infection

A1. Clinical Criteria for Reporting
N/A

A2. Laboratory Criteria for Reporting
- Diagnostic test for poliovirus is ordered, **OR**
- Poliovirus detected in clinical specimen using a properly validated assay.^

^*The Global Polio Laboratory Network (GPLN) provides guidelines on acceptance of results from labs that are not in GPLN; assays would have to be validated and approved by GPLN. CDC is part of GPLN.*

A3. Epidemiologic Linkage Criteria for Reporting
N/A

B. Disease-Specific Data Elements to be Included in the Initial Report

Disease-specific data elements should be included in addition to the common data elements that are to be reported for all initial individual case reports (see CSTE Position Statement 09-SI-01 “Common Core Data Elements for Case Reporting and Laboratory Result Reporting” https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS/09-SI-01.pdf). Public health authorities do not expect that an initial report will contain all the information necessary for case investigation and case classification.

- Clinical Characteristics
  - Paralysis, date of onset
  - Asymmetric paralysis

  - Ascending paralysis
  - Immune deficiency (if any)
  - MRI results
- Epidemiological Risk Factors
  - Geographic area of residence (e.g., country, US county)
  - Geographic areas (e.g., countries, US counties) visited in last 30 days
  - Number of OPV doses received
  - Date of last OPV dose
  - Number of IPV doses received
  - Contact with a person who has received OPV in last 75 days
  - Contact with a person diagnosed with polio or poliovirus infection

VII. Case Definition for Case Classification

This case definition for case classification is intended solely for public health surveillance purposes and does not recommend criteria for clinical diagnosis purposes. Once a public health agency has ascertained data on potential cases of a disease or condition from reporting entities, the public health agency assigns case statuses based on the case classifications included within this position statement.

A. Narrative: A description of criteria to determine how public health should classify a case of Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection.

A1. Clinical Criteria

- Acute onset of flaccid paralysis with decreased or absent tendon reflexes in the affected limbs, in the absence of a more likely alternative diagnosis.

A2. Laboratory Criteria*

Confirmatory Laboratory Evidence:

- Poliovirus detected by sequencing of the capsid region of the genome by the CDC Poliovirus Laboratory, **OR**
- Poliovirus detected in an appropriate clinical specimen (e.g., stool [preferred], cerebrospinal fluid, oropharyngeal secretions) using a properly validated assay^, **AND** specimen is not available for sequencing by the CDC Poliovirus Laboratory.

** Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.*

^ The Global Polio Laboratory Network (GPLN) provides guidelines on acceptance of results from labs that are not in GPLN; assays would have to be validated and approved by GPLN. CDC is part of GPLN.

A3. Epidemiologic Linkage Criteria

N/A

A4. Case Classifications

Confirmed:

- Paralytic Poliomyelitis: Meets clinical criteria AND confirmatory laboratory evidence.
- Nonparalytic Poliovirus Infection: Meets confirmatory laboratory evidence.

B. Criteria to Distinguish a New Case of Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection from Reports or Notifications which Should Not be Enumerated as a New Case for Surveillance

Post-polio syndrome is a condition that can affect survivors of poliovirus infection decades after recovering from their initial infection. A person with post-polio syndrome should not be enumerated as a new case.

VIII. Period of Surveillance

All cases of paralytic poliomyelitis and nonparalytic poliovirus infection should be reported. Reporting should be on-going. Reporting should be immediate.

IX. Data Sharing/Release and Print Criteria

CSTE recommends the following case statuses* be included in the 'case' count released outside of the public health agency:

☒Confirmed
☐Probable
☐Suspect
☐Unknown

**Which case statuses are included in case counts constitute the "print criteria."*

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

X. Revision History

Position Statement ID	Section of Document	Revision Description
23-ID-07	Statement of the Problem	EDITED to provide context for proposed changes to reporting criteria and case definitions
23-ID-07	Background and Justification	EDITED to include recent data and justification
23-ID-07	Criteria for Case Ascertainment	EDITED "Recommended reporting procedures" to REMOVE "All suspected cases of paralytic poliomyelitis should be reviewed by a panel of expert consultants before final classification occurs" ADDED "A person with acute onset of flaccid paralysis with decreased or absent tendon reflexes in the affected limbs, in the absence of a more likely alternative diagnosis" as clinical criteria for reporting for Paralytic Poliomyelitis
23-ID-07	Disease-Specific Data Elements to be Included in the Initial Report	ADDED MRI results to Clinical Characteristics
23-ID-07	Case Definition for Case Classification (A2)	For Paralytic Poliomyelitis • ADDED Poliovirus detected by sequencing of the capsid region of the genome by the CDC Poliovirus Laboratory. OR

		• Poliovirus detected in an appropriate clinical specimen (e.g., stool [preferred], cerebrospinal fluid, oropharyngeal secretions) using a properly validated assay AND specimen is not available for sequencing by the CDC Poliovirus Laboratory
23-ID-07	Case Definition for Case Classification (A2 – Laboratory Criteria)	For Nonparalytic Poliovirus Infection UPDATED wording for Confirmatory Laboratory Evidence – "Poliovirus detected by sequencing of the capsid region of the genome by the CDC Poliovirus Laboratory" OR "Poliovirus detected in an appropriate clinical specimen (e.g., stool [preferred], cerebrospinal fluid, oropharyngeal secretions) using a properly validated assay AND specimen is not available for sequencing by the CDC Poliovirus Laboratory."
23-ID-07	Case Definition for Case Classification (A4 – Case Classification)	For Paralytic Poliomyelitis EDITED definition for confirmed case to include laboratory criteria – "Meets clinical criteria AND confirmatory laboratory evidence" REMOVED definition for probable case For Nonparalytic Poliovirus Infection EDITED definition for confirmed case to conform with new format – "Meets confirmatory laboratory evidence" REMOVED Comment – "All suspected cases of paralytic poliomyelitis are reviewed by a panel of expert consultants before final classification occurs. Confirmed cases are then further classified based on epidemiologic and laboratory criteria (11). Only confirmed cases are included in Table I in the MMWR. Suspected cases are enumerated in a footnote to the MMWR table."
06-ID-15	09-ID-53	Transferred to new position statement format Added tables needed for electronic disease reporting.
N/A	06-ID-15	Established a CSTE standardized surveillance case definition for poliomyelitis, including poliovirus infections; made poliovirus infections nationally notifiable to CDC. Note: Paralytic poliomyelitis was previously nationally notifiable to CDC.

XI. References

1. Strebel PM, Sutter RW, Cochi SL, et al. Epidemiology of poliomyelitis in the United States one decade after the last reported case of indigenous wild virus-associated disease. Clin Infect Dis 1992; 14:568--79.
2. World Health Organization. Poliomyelitis (polio). https://www.who.int/health-topics/poliomyelitis/#tab=tab_1.
3. Estivariz CF, Link-Gelles R, Shimabukuro. Poliomyelitis. In: Hall E., Wodi A.P., Hamborsky J., et al., eds. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. 14th ed. Washington, D.C. Public Health Foundation, 2021.
4. Link-Gelles R, Lutterloh E, Schnabel Ruppert P, et al. Public Health Response to a Case of Paralytic Poliomyelitis in an Unvaccinated Person and Detection of Poliovirus in Wastewater - New York, June-August 2022. MMWR Morb Mortal Wkly Rep. 2022 Aug 19;71(33):1065-1068. doi: 10.15585/mmwr.mm7133e2. PMID: 35980868; PMCID: PMC9400530.
5. CDC. Poliomyelitis prevention in the United States: updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000;49(RR-5):1–22.
6. CSTE. National Surveillance for Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection. http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/09-ID-53.pdf.
7. CSTE. Revision to the Standardized Case Definition, Case Classification, and Public Health Reporting for Acute Flaccid Myelitis. https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2021/21-ID-02_AFM.pdf.

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Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	Paralytic Poliomyelitis		Nonparalytic Poliovirus Infection	
Clinical Criteria for Reporting				
A person with acute onset of flaccid paralysis with decreased or absent tendon reflexes in the affected limbs	N			
In the absence of a more likely alternative diagnosis	N			
Laboratory Criteria for Reporting				
Diagnostic test for poliovirus is ordered		S	S	
Poliovirus detected in clinical specimen using a properly validated assay*		S		S

Notes:
S = This criterion alone is SUFFICIENT to report a case.
N = All "N" criteria in the same column are NECESSARY to report a case.
* The Global Polio Laboratory Network (GPLN) provides guidelines on acceptance of results from labs that are not in GPLN; assays would have to be validated and approved by GPLN. CDC is part of GPLN.

Table VII.A. Classification Table: Criteria for defining a case of Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection.

Criterion	Paralytic Poliomyelitis		Nonparalytic Poliovirus Infection	
	Confirmed		Confirmed	
Clinical Evidence				
Acute onset of flaccid paralysis with decreased or absent tendon reflexes in the affected limbs	N	N		
In the absence of a more likely alternative diagnosis	N	N		
Laboratory Evidence				
Poliovirus detected by sequencing of the capsid region of the genome by the CDC Poliovirus Laboratory.	N		S	
Poliovirus detected in an appropriate clinical specimen (e.g., stool [preferred], cerebrospinal fluid, oropharyngeal secretions) using a properly validated assay		N		N
Specimen is not available for sequencing by the CDC Poliovirus Laboratory		N		N

Notes:
S = This criterion alone is SUFFICIENT to classify a case.
N = All "N" criteria in the same column are NECESSARY to classify a case.

Table VII.B. Classification Table: Criteria to distinguish a new case of Paralytic Poliomyelitis and Nonparalytic Poliovirus Infection from reports or notifications which should not be enumerated as a new case for surveillance.

Criterion	Paralytic Poliomyelitis	Nonparalytic Poliovirus Infection
	Confirmed	Confirmed
Criteria to distinguish a new case		
A person with post-polio syndrome should not be enumerated as a new case.	S	S

S = This criterion alone is SUFFICIENT to enumerate as a new case.