

19-ID-08**Committee:** Infectious Disease**Title:** Revision to the Case Definition for National Pertussis Surveillance

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: 13-ID-15.

Synopsis:

This position statement updates the pertussis case definition (previous position statement 13-ID-15) by: classifying PCR-positive cases as Confirmed, regardless of cough duration and presence of pertussis symptoms; limiting Confirmed case classification to those with laboratory confirmation; and eliminating age-specific classifications.

I. Statement of the Problem

The current pertussis case definition (2014 CSTE Position Statement 13-ID-15) does not accurately reflect burden of disease among persons of all ages. This definition was implemented to better capture infant disease burden; revisions included classifying PCR-positive, or epi-linked, cases occurring among infants with cough of any duration, and one other clinical symptom, as Probable. While these changes improved the ability to identify infant cases, a complex case definition was the result, with age-specific classifications (<1 year vs. ≥1 year) and laboratory confirmation requirements in both Confirmed and Probable classifications. In addition, the updated definition did not accurately reflect the current state of pertussis testing practices in the U.S. Finally, the requirement to confirm ≥14 days of cough for most cases required an unrealistic degree of public health follow-up.

PCR is currently the primary diagnostic tool used to detect pertussis. Over time, there have been notable improvements in accuracy of the test, related to the transition from conventional to real-time PCR, and incorporation of multiple gene targets. However, PCR-positive cases have stringent clinical requirements in order to meet the Confirmed classification: ≥14 days of cough and presence of a pertussis clinical symptom. This is in contrast to the clinical requirements for the other confirmatory laboratory test: culture-positive cases only require cough to meet the Confirmed classification. The need to confirm ≥14 days of cough for PCR-positive cases places substantial burden on local and state health departments, especially in a setting of disease resurgence. In addition, PCR-positive cases may not meet the required clinical criteria for a variety of reasons, such as early intervention with antibiotics or loss of patient follow-up, yet still be true cases. Finally, the differences in Probable and Confirmed classifications by age and type of confirmatory laboratory test further encumbers local and state departments during case classification assessment.

II. Background and Justification

Bordetella pertussis is among the most poorly controlled bacterial vaccine-preventable diseases in the U.S. Pertussis vaccine was introduced in the 1940s, and the routine childhood immunization program has resulted in substantial reductions of disease. However, the number of reported pertussis cases has increased steadily since the late 1980s, with a considerable resurgence observed over the last 10 years. The most notable peak was in 2012 when more than 48,000 cases and 18 deaths were reported, the largest number of cases in the U.S. since the mid-1950s. Significant numbers of cases were also reported in 2004, 2010 and 2014, ranging from 25,000–32,000 cases. Reasons for the increase in reported disease are likely multifactorial, with improved provider recognition and reporting of pertussis disease, changing diagnostic practices, molecular changes in the organism, and waning immunity from acellular pertussis vaccines potentially responsible.

Diagnosis of pertussis is challenging: no single test is adequate to confirm the diagnosis throughout the course of illness. With its excellent specificity, culture is considered the gold standard. However, it is now used infrequently, given its variable sensitivity and long turnaround time. In contrast, PCR is rapid and highly sensitive. Significant improvements have been made in the quality of PCR testing performed in many public health, clinical and commercial laboratories over the last 20 years. For example, the overall transition from conventional to real-time-PCR has resulted in higher sensitivity. A reduction in the number of false-positive events via contamination was attained through improving specimen collection protocols and implementing changes in laboratory practices. In addition, the adoption of real-time-PCR protocols by public health, clinical and commercial laboratories that include multiple targets allowing for speciation of *Bordetella* species has greatly improved specificity. All of these factors have resulted in increased confidence in the accuracy of PCR testing, and it has become the most widely used test to diagnose pertussis. While serology can be a useful test for diagnosing pertussis late in the disease course, when culture and PCR are no longer able to detect infection, there are challenges to its use and it is not currently considered “confirmatory.”

Revision of the case definition will better capture pertussis disease across all age groups, not just infants. Classifying all PCR-positive cases as Confirmed, regardless of cough duration or presence of a pertussis symptom, will simplify classification and understanding: lab confirmation by either culture or PCR equals “Confirmed.” This change will more accurately reflect current diagnostic practices, with PCR as the test of choice, as well as decrease the investigative burden borne by state and local health departments. Restricting the Confirmed classification to cases with confirmatory laboratory testing and eliminating age-specific classifications will further streamline the case definition. The revised case definition will allow for more precise estimation of the disease burden across age groups.

III. Statement of the desired action(s) to be taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for pertussis.
 - A. Utilize standard sources (e.g. reporting*) for case ascertainment for pertussis. Surveillance for pertussis should use the recommended sources of data to the extent of coverage presented in Section V.
 - B. Utilize standardized criteria for case ascertainment for pertussis presented in Section VI and Table VI in Technical Supplement.
 - C. Utilize standardized criteria for case classification for pertussis presented in Sections VII and Table VII in Technical Supplement.
 - D. Eliminate age-specific clinical criteria (e.g., apnea) and age-specific case classifications (i.e., infants and non-infants will have the same clinical presentation requirements and classifications).
2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for pertussis and retain pertussis on the *Nationally Notifiable Condition List*
 - 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) is transitioning to 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 MMGs.
5. CDC should publish data on pertussis as appropriate (see Section IX for additional information).

NNC data sharing/release and print criteria

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 to conduct public health surveillance follow the recommended methods outlined in the standardized surveillance position statement.

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local, state, or territorial public health. Note: notification is addressed in a Nationally Notifiable Conditions Recommendation Statement and is the process of a local, state, or territorial public health authority submitting a report (case information) of a condition on the *Nationally Notifiable Conditions List* TO CDC.

**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 provide information regarding the epidemiology of pertussis in order to facilitate prevention and control efforts, to identify outbreaks for public-health response, and to monitor the effects of vaccination efforts.

V. Methods for Surveillance: Surveillance for pertussis should use the recommended sources of data and the extent of coverage listed in Table V.

Table V. Recommended sources of data and extent of coverage for ascertainment of cases of pertussis.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	x	
Laboratory reporting	x	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers), specify:	x	

Death certificates	X	
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone survey		
School-based survey		
Other, specify:		

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VI. Criteria for case ascertainment

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

A1. Clinical Criteria for Reporting

- An acute cough illness of any duration with inspiratory whoop or paroxysmal cough or post-tussive vomiting or apnea.

A2. Laboratory Criteria for Reporting

- Any person with isolation of *B. pertussis* from a clinical specimen or a positive PCR test for pertussis.

A3. Epidemiologic Linkage Criteria for Reporting

- An acute cough illness of any duration in a person who is a contact of a laboratory-confirmed pertussis case.
- An acute cough illness of any duration in a person who is a member of a defined risk group during an outbreak.

A4. Vital Records Criteria for Reporting

- A person whose death certificate lists pertussis as a cause of death or a significant condition contributing to death.

A5. Other Criteria for Reporting

- A person whose healthcare record contains a diagnosis of pertussis.

B. Disease-specific data elements to be included in the initial report

Clinical Findings

Presence of cough

Epidemiologic risk factors

Immunization history

Number of doses of DTaP received

Date of last DTaP vaccination

Whether a dose of Tdap vaccine was given to a patient ≥ 10 years of age

Date of Tdap vaccination

Contact with a known or suspected pertussis case

Contact with a high-risk individual (e.g., infant or pregnant woman)

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

A1. Clinical Criteria

In the absence of a more likely diagnosis, a cough illness lasting ≥ 2 weeks, with at least one of the following signs or symptoms:

- Paroxysms of coughing; OR
- Inspiratory whoop; OR
- Post-tussive vomiting; OR
- Apnea (with or without cyanosis)

A2. Laboratory Criteria

Confirmatory laboratory evidence:

- Isolation of *B. pertussis* from a clinical specimen
- Positive PCR for *B. pertussis*

Presumptive laboratory evidence:

N/A

Supportive laboratory evidence:

N/A

A3. Epidemiologic Linkage

- Contact with a laboratory-confirmed case of pertussis

A4. Case Classifications

Confirmed:

- Acute cough illness of any duration, with
 - Isolation of *B. pertussis* from a clinical specimenOR
 - Polymerase chain reaction (PCR) positive for *B. pertussis*

Probable:

- In the absence of a more likely diagnosis, illness meeting the clinical criteria
- OR
- Illness with cough of any duration, with
 - At least one of the following signs or symptoms:
 - Paroxysms of coughing; *or*
 - Inspiratory whoop; *or*
 - Post-tussive vomiting; *or*
 - Apnea (with or without cyanosis)

AND

- Contact with a laboratory confirmed case (epidemiologic linkage)

Suspect: N/A

B. Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

Non-applicable (N/A)

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data sharing/release and print criteria

1. 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 the case counts constitute the "print criteria."

2. 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.

Additional guidance:

- Pertussis cases reported electronically through NNDSS are summarized weekly in the *MMWR* Notifiable Diseases tables and yearly in the *MMWR* Surveillance Summaries. Additional epidemiologic summaries may be published in the *MMWR* or peer-reviewed journals.
- State-specific compiled data will continue to be published in the weekly and annual *MMWR*. Twice annually, the National Center for Immunization and Respiratory Diseases (NCIRD) will send reports of state-level case counts, incidence, and fatalities to state and territorial partners to ensure the accuracy of case reports received at CDC.
- State-specific compiled data will continue to be published in the weekly reports and annual *MMWR* Surveillance Summaries. Aggregate data are included in PAHO and WHO annual reports. The frequency of additional publication of this data, in the *MMWR* and peer-reviewed journals, will be dependent on current epidemiology of disease at the national level.

- NCIRD currently reports aggregate data on cases of pertussis reported through NNDSS to PAHO on a yearly basis. No personal identifying or state specific information is re-released to PAHO, WHO, or other parties.

X. Revision History

Position Statement ID	Section of Document	Revision Description
13-ID-15	I,II, III, VI B, VII A	Classify all PCR-positive cases as Confirmed if cough is present, regardless of cough duration or presence of a pertussis symptom.
13-ID-15	I,II, III, VI B, VII A	Classify all epi-linked cases as Probable if cough and pertussis symptom is present, (eliminate requirement for cough duration).
13-ID-15	I,II, III, VI B, VII A	Eliminate age-specific clinical criteria (e.g., apnea) and age-specific case classifications (i.e., infants and non-infants will have the same clinical presentation requirements and classifications).

XI. References

1. Council of State and Territorial Epidemiologists (CSTE). Revision of the pertussis surveillance case definition to more accurately capture the burden of disease among infants <1 year of age 13-ID-015. CSTE June 2013. Available from: <http://www.cste.org>.
2. Faulkner AE, Skoff TH, Tondella ML, et al. Trends in pertussis diagnostic testing in the United States, 1990 to 2012. *Pediatr Infect Dis J*. 2016 Jan;35(1):39–4.
3. Tatti KM, Sparks KN, Boney KO, et al. Novel multitarget real-time PCR assay for rapid detection of *Bordetella* species in clinical specimens. *J Clin Microbiol*. 2011 Dec;49(12):4059–66.
4. Williams MM, Taylor TH Jr, Warshauer DM, et al. Harmonization of *Bordetella pertussis* real-time PCR diagnostics in the United States in 2012. *J Clin Microbiol*. 2015 Jan;53(1):118–23.
5. Loeffelholz M. Towards improved accuracy of *Bordetella pertussis* nucleic acid amplification tests. *J Clin Microbiol*. 2012 Jul;50(7):2186-90.

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Council of State and Territorial Epidemiologists Technical Supplement

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

Criterion	Pertussis	
<i>Clinical Criteria for Reporting</i>		
Cough (any duration)	N	N
Inspiratory whoop or paroxysmal cough or post-tussive vomiting or apnea	N	
<i>Laboratory Criteria for Reporting</i>		
Isolation of <i>B. pertussis</i> from a clinical specimen	S	
Positive PCR for <i>B. pertussis</i>	S	
<i>Epidemiological Linkage Criteria for Reporting</i>		
Contact with a lab-confirmed pertussis case		O
Member of a defined risk group during an outbreak		O
<i>Vital Records Criteria for Reporting</i>		
Death certificate lists pertussis as a cause of death or a significant condition contributing to death	S	
<i>Other Criteria for Reporting</i>		
Healthcare record contains diagnosis of pertussis	S	

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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.

O = At least one of these "O" (ONE OR MORE) criteria in **each category** (categories=clinical evidence, laboratory evidence, and epidemiological evidence) in the **same column**—in conjunction with all "N" criteria in the same column—is required to report a case.

Table VII. Classification Table: Criteria for defining a case of pertussis.

Criterion	Confirmed	Probable	Probable
<i>Clinical Evidence</i>			
Acute cough illness (any duration)	N		N
Cough ≥2 weeks duration		N	
Inspiratory whoop		O	O
Paroxysms of coughing		O	O
Post-tussive vomiting		O	O
Apnea (with or without cyanosis)		O	O
Absence of a more likely diagnosis		N	
<i>Laboratory Evidence</i>			
Isolation of <i>B. pertussis</i> from a clinical specimen	O		
Positive PCR for <i>B. pertussis</i>	O		
<i>Epidemiologic Linkage Evidence</i>			
Contact with a laboratory-confirmed case (classified as "confirmed")			N
<i>Criteria to distinguish a new case:</i>			
N/A			

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Notes:

N = All "N" criteria in the same column are NECESSARY to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.

O = At least one of these "O" (ONE OR MORE) criteria in **each category** (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the **same column**—in conjunction with all "N" criteria in the same column—is required to classify a case. A number following an "O" indicates that this criterion is only required for a specific disease/condition subtype.