



Coronavirus Disease 2019 (COVID-19) 2020 Interim Case Definition, Approved August 5, 2020

NOTE: A surveillance case definition is a set of uniform criteria used to define a disease for public health surveillance. Surveillance case definitions enable public health officials to classify and count cases consistently across reporting jurisdictions. Surveillance case definitions are not intended to be used by healthcare providers for making a clinical diagnosis or determining how to meet an individual patient's health needs.

CSTE Position Statement(s)

Interim-20-ID-02

Background

In late December 2019, investigation of a cluster of pneumonia cases of unknown origin in Wuhan, China resulted in identification of a novel coronavirus. The virus is distinct from both severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV), although closely related. Early epidemiologic findings indicate COVID-19 may be less severe¹ than SARS or MERS, but evidence suggests that the virus is more contagious than its predecessors. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a newly identified pathogen and it is assumed there is no pre-existing human immunity to the virus. Initial seroconversion, including neutralizing antibodies, has been documented and there is some evidence that immunity to SARS-CoV-2 re-challenge during early convalescence is likely. The extent of long-term immunity from anamnestic responses is unknown currently. At the beginning of the pandemic, everyone was assumed to be susceptible; it is now known that there are risk factors that increase an individual's illness severity.

Those at highest risk for severe disease and death include people aged over 60 years (especially those 85 years and older) and those with underlying conditions such as obesity, hypertension, diabetes, cardiovascular disease, chronic respiratory or kidney disease, immunosuppression from solid organ transplant, and sickle cell disease. Disease in children mostly appears to be relatively mild, and there is growing evidence that a significant proportion of infections across all age groups are asymptomatic.

Cases of COVID-19 in China and the initial U.S. cases in early March 2020 were clustered. Most cases in China occurred in households and in Washington, for example, a significant cluster was associated with a long-term care facility. By mid-March, multiple areas in the United States reported cases with no direct

epidemiologic link to confirmed cases. As of July 2020, widespread community transmission of SARS-CoV-2 has been documented in geographically dispersed regions. Ongoing surveillance of illness, risk factors, and epidemiologic linkage is needed to characterize the disease transmission in the United States, to inform intervention and mitigation strategies, and to monitor and assess their impacts.

Epidemiological reports from the field are demonstrating a growing importance of presymptomatic and asymptomatic infections from two lines of evidence: the serial interval of COVID-19 appears to be close to or shorter than its median incubation period and clusters linked to presymptomatic and asymptomatic index cases^{2,3}. The Council of State and Territorial Epidemiologists (CSTE) realizes that field investigations will involve evaluations of persons with no symptoms and these individuals will need to be counted as cases.

Because of the rapid advancement in the science of COVID-19 disease and SARS-CoV-2 infection, CSTE is updating the COVID-19 position statement within four months of its first interim approval by the Executive Board on April 5, 2020. In these four months, CSTE has received feedback from members on implementation, and in addition, antigen detection tests and serologic tests have been developed and authorized for use by the U.S. Food and Drug Administration (FDA). This update clarifies interpretation of antigen detection tests and serologic test results within the case classification. CSTE acknowledges the dual utility of these tests for public health surveillance of COVID-19 and clinical diagnosis of COVID-19. Classifying a test as confirmatory, presumptive, or supportive laboratory evidence is intended solely to assist a public health agency with case investigation and case counting, in the context of population health, that will lead to public health action. A provider may order a test under a variety of circumstances ranging from a drive-through testing site in a minimally symptomatic or asymptomatic person where very little clinical or epidemiologic data will be collected, to an acutely ill person presenting in an emergency department for hospital admission. The provider will use the testing platform that best fits the clinical situation, testing availability, and diagnostic capability, which should not be influenced by CSTE position statement Interim-20-ID-02.

Clinical Criteria

In the absence of a more likely diagnosis:

- At least two of the following symptoms:
 - fever (measured or subjective),
 - chills,
 - rigors,
 - myalgia,
 - headache,
 - sore throat,
 - nausea or vomiting,
 - diarrhea,
 - fatigue,

- congestion or runny nose

OR

- Any one of the following symptoms:
 - cough,
 - shortness of breath,
 - difficulty breathing,
 - new olfactory disorder,
 - new taste disorder

OR

- Severe respiratory illness with at least one of the following:
 - Clinical or radiographic evidence of pneumonia,
 - Acute respiratory distress syndrome (ARDS).

Laboratory Criteria

Laboratory evidence using a method approved or authorized by the FDA⁴ or designated authority:

Confirmatory laboratory evidence:*

- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical or autopsy specimen using a molecular amplification test

Presumptive laboratory evidence:*

- Detection of SARS-CoV-2 by antigen test in a respiratory specimen

Supportive laboratory evidence:*

- Detection of specific antibody in serum, plasma, or whole blood
- Detection of specific antigen by immunocytochemistry in an autopsy specimen

**The terms confirmatory, presumptive, and supportive are categorical labels used here to standardize case classifications for public health surveillance. The terms should not be used to interpret the utility or validity of any laboratory test methodology.*

Epidemiologic Linkage

One or more of the following exposures in the prior 14 days:

- Close contact** with a confirmed or probable case of COVID-19 disease;
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is generally defined as being within 6 feet for at least 15 minutes. However, it depends on the exposure level and setting; for example, in the setting of an aerosol-generating procedure in healthcare settings without proper personal protective equipment (PPE), this may be defined as any duration. Data are*

insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.

Criteria to Distinguish a New Case from an Existing Case

A repeat positive test for SARS-CoV-2 RNA using a molecular amplification detection test within 3 months of the initial report should not be enumerated as a new case for surveillance purposes. To date, there has been minimal evidence of re-infection among persons with a prior confirmed COVID-19 infection and growing evidence that repeat positive RNA tests do not correlate with active infection when viral culture is performed. Similarly the experience with other coronaviruses is that reinfection is rare within the first year.^{5,6} NOTE: The time period of 3 months will be extended further when more data becomes available to show risk of reinfection remains low within one year of the initial report.

Case Classification

Suspect

- Meets supportive laboratory evidence*** with no prior history of being a confirmed or probable case.

**** For suspect cases (positive serology only), jurisdictions may opt to place them in a registry for other epidemiological analyses or investigate to determine probable or confirmed status.*

Probable

- Meets clinical criteria **AND** epidemiologic linkage with no confirmatory laboratory testing performed for SARS-CoV-2.
- Meets presumptive laboratory evidence.
- Meets vital records criteria with no confirmatory laboratory evidence for SARS-CoV-2.

Confirmed

- Meets confirmatory laboratory evidence.

Other Criteria

Vital Records Criteria

A death certificate that lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or a significant condition contributing to death.

Comments

CSTE approved interim position statement Interim-20-ID-02 on August 5, 2020. Interim-20-ID-02 supersedes the first CSTE COVID-19 interim position statement, Interim 20-ID-01, which was approved on April 5, 2020.

This position statement, Interim-20-ID-02, updates the standardized case definition for COVID-19, including asymptomatic infections caused by SARS-CoV-2, and retains COVID-19 as a nationally notifiable condition. The updates clarify clinical, laboratory, epidemiologic linkage, and vital records criteria for case ascertainment and case classification based on the continued evolution of the COVID-19 pandemic. In addition, the probable case classification is updated, and a suspected case classification is added.

Reference(s)

1. The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) in China. *Zhonghua Liu Xing Bing Xue Za Zhi*. 2020;41(2):145–151. DOI:10.3760/cma.j.issn.0254-6450.2020.02.003.
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4. FDA Emergency Use Authorizations <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations> and <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger>.
5. Korean “Re-Positives” Assessed as Not Infectious. https://www.cdc.go.kr/board/board.es?mid=a30402000000&bid=0030&act=view&list_no=367267&nPage=1 accessed July 10, 2020.
6. COVID-19: Ongoing viral detection and repeat positives. <https://www.publichealthontario.ca/-/media/documents/ncov/main/2020/06/covid-19-ongoing-viral-detection-repeat-positives.pdf?la=en> accessed July 13, 2020.

Related Case Definition(s)

- Coronavirus Disease 2019 (COVID-19) | 2020 Interim Case Definition, Approved April 5, 2020 (<https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/>)

Content source: Centers for Disease Control and Prevention (<http://www.cdc.gov/>)

Office of Public Health Scientific Services (OPHSS) (<http://www.cdc.gov/ophss/>)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) (<http://www.cdc.gov/ophss/csels/>)

Division of Health Informatics and Surveillance (DHIS) (<http://www.cdc.gov/ophss/csels/dhis/>)

National Notifiable Diseases Surveillance System (NNDSS) (<http://www.cdc.gov/nndss/>)