

Interim-20-ID-01**Committee:** Infectious Disease**Title:** Standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19)

☐ 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: N/A.

Synopsis: This position statement creates a standardized case definition for 2019 novel coronavirus disease (COVID-19) including asymptomatic infections caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) and adds COVID-19 to the list of nationally notifiable conditions.

I. Statement of the Problem

Introduction of SARS-CoV-2, the virus that causes 2019 novel coronavirus disease (COVID-19), into the United States has resulted in the need for standardized surveillance to assist in understanding the transmission and epidemiology of the disease in U.S. jurisdictions. Public health agencies are investigating reported respiratory illnesses and identifying infected people (cases) through laboratory testing. Nationwide standardized surveillance is necessary to provide consistent case identification and classification, measure the potential burden of illness, characterize the epidemiology of medically attended and moderate to severe COVID-19 in the United States, detect community transmission, and inform public health response to clusters of illness and efficacy of population-based non-pharmaceutical interventions on the epidemic.

II. Background and Justification

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 SARS-CoV and 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. SARS-CoV-2 is a newly identified pathogen and it is assumed there is no existing human immunity to the virus. Everyone is assumed to be susceptible, although there may be risk factors that increase an individual's illness severity.

Based on epidemiologic reports of the outbreak in China, those at highest risk for severe disease and death include people aged over 60 years and those with underlying conditions such as hypertension, diabetes, cardiovascular disease, chronic respiratory disease, and cancer. Disease in children appears to be relatively mild, and 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 have been clustered. Most cases in China occurred in households and in Washington, for example, a significant cluster was associated with a long-term care facility. However, cases have been reported in the United States with no direct epidemiologic link to confirmed cases. Ongoing surveillance of illness, risk factors, and epidemiologic linkage is needed to characterize the disease transmission in the United States, and to inform intervention and mitigation strategies.

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^{4, 5}. CSTE realizes that field investigations will involve evaluations of persons with no symptoms and these individuals will need to be counted as cases.

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

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for COVID-19.
 - A. Utilize standard sources (e.g. reporting*) for case ascertainment for COVID-19. Surveillance for COVID-19 should use the recommended sources of data to the extent of coverage presented in Section V.
 - B. Utilize standardized criteria for case ascertainment for COVID-19 presented in Section VI and Table VI in Technical Supplement.
 - C. Utilize standardized criteria for case classification for COVID-19 presented in Sections 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 **COVID-19** and **add** COVID-19 to 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 COVID-19 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 COVID-19 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 to conduct public health surveillance follow the recommended methods outlined in this recommendation and in the accompanying 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

Surveillance of COVID-19 is necessary to characterize the epidemiology of the disease in the United States, to measure the burden of disease in the United States health system, and to inform public health action.

V. Methods for Surveillance: Surveillance for COVID-19 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 COVID-19

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

As commercial laboratories implement testing for SARS-CoV-2, laboratory reporting will be the most common source of data. Healthcare providers and facilities who diagnose or become aware of clinically compatible COVID-19 cases should report them to public health authorities.

VI. Criteria for case ascertainment

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

Symptoms of COVID-19 are non-specific and the disease presentation can range from no symptoms (asymptomatic) to severe pneumonia and death. COVID-19 is a mild to moderate illness for approximately 80% of individuals evaluated with the disease; 15% are severe infection requiring supplemental oxygen; and 5% are critical infections requiring mechanical ventilation.² People with COVID-19 generally develop signs and symptoms, including mild respiratory symptoms and fever ~5 days after infection (mean incubation period 5-6 days, range 1-14 days).³

A1. Clinical Criteria for Reporting

In outpatient or telehealth settings at least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

- at least one of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:

- Clinical or radiographic evidence of pneumonia, or
- Acute respiratory distress syndrome (ARDS).

AND

No alternative more likely diagnosis

A2. Laboratory Criteria for Reporting

- Detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test.
- Detection of specific antigen in a clinical specimen.

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- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection.*

**serologic methods for diagnosis are currently being defined*

A3. Epidemiologic Linkage Criteria for Reporting

- In a person with clinically compatible symptoms with one or more of the following exposures in the 14 days before onset of symptoms:
 - Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2; OR
 - Close contact** with a person diagnosed with COVID-19; OR
 - Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

A4. Vital Records Criteria for Reporting

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

A5. Other Criteria for Reporting

Autopsy findings consistent with pneumonia or acute respiratory distress syndrome without an identifiable cause.

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

In addition to patient demographics, the following disease-specific data elements are expected to be included in all reports to public health agencies:

Laboratory Information:

- Specimen type
- Collection date
- Laboratory test performed
- Results

Clinical Information

- Description of clinical symptoms and signs of illness, or if asymptomatic
- Date of illness onset
- Hospitalization
- Underlying diseases or co-infections

Epidemiologic Information

- Known contact or linkage to COVID-19 cases
- Recent travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2
- Member of a risk cohort as defined by public health authorities during an outbreak

VII. Case Definition for Case Classification

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

A1. Clinical Criteria

At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

At least one of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:

- Clinical or radiographic evidence of pneumonia, or
- Acute respiratory distress syndrome (ARDS).

AND

No alternative more likely diagnosis

A2. Laboratory Criteria

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

Confirmatory laboratory evidence:

- Detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test

Presumptive laboratory evidence:

- Detection of specific antigen in a clinical specimen
- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*

**serologic methods for diagnosis are currently being defined*

A3. Epidemiologic Linkage

One or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** with a confirmed or probable case of COVID-19 disease; or
- Close contact** with a person with:
 - clinically compatible illness AND
 - linkage to a confirmed case of COVID-19 disease.
- Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2.
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

A4. Vital Records Criteria

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

A5. Case Classifications

Confirmed:

- Meets confirmatory laboratory evidence.

Probable:

- Meets clinical criteria AND epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19.
- Meets presumptive laboratory evidence AND either clinical criteria OR epidemiologic evidence.
- Meets vital records criteria with no confirmatory laboratory testing performed for COVID-19.

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

N/A until more virologic data are available.

VIII. Period of Surveillance

Ongoing

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 the 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.
- In accordance with CSTE Position Statement 11-SI-04, CDC should apply the Revised Guidelines for Determining Residency for analyses and counting cases.

X. Revision History

This is the first standardized surveillance position statement for COVID-19 and SARS-CoV-2 infection.

XI. References

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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3. 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.
4. Serial interval of novel coronavirus (COVID-19) infections. Hiroshi Nishiura, Natalie M. Linton, Andrei R. Akhmetzhanov PII: S1201-9712(20)30119-3 DOI: <https://doi.org/10.1016/j.ijid.2020.02.060> Reference: IJID 4006 To appear in: *International Journal of Infectious Diseases*, Accepted Date: 27 February 2020
5. Presymptomatic Transmission of SARS-CoV-2 — Singapore, January 23–March 16, 2020. *Morbidity and Mortality Weekly Report Early Release* / Vol. 69 April 1, 2020 U.S. Department of Health and Human Services Centers for Disease Control and Prevention. Wycliffe E. Wei; Zongbin Li; Calvin J. Chiew; Sarah E. Yong; Matthias P. Toh; Vernon J. Lee

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Technical Supplement

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

Criterion	COVID-19				
Clinical Criteria for Reporting					
Patient seen in outpatient or telehealth setting	N		N		
At least <u>two</u> of the following symptoms: - Fever (measured or subjective) - Chills - Rigors - Myalgia - Headache - Sore throat - New olfactory and taste disorder(s)	O		O		
At least <u>one</u> of the following symptoms: - Cough - Shortness of breath - Difficulty breathing	O		O		
Clinical or radiographic evidence of pneumonia		O		O	
Acute respiratory distress syndrome (ARDS)		O		O	
No alternative more likely diagnosis	N	N	N	N	
Laboratory Criteria for Reporting					
Detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test					S
Detection of specific antigen in a clinical specimen					S
Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*					S
Epidemiological Linkage Criteria for Reporting					
Travel to an area with sustained, ongoing community transmission of SARS-CoV-2 in the 14 days prior to onset of symptoms			O	O	
Residence in an area with sustained, ongoing community transmission of SARS-CoV-2 in the 14 days prior to onset of symptoms			O	O	
Close contact** in the 14 days prior to onset of symptoms with a person diagnosed with COVID-19			O	O	
Member of a risk cohort group, as defined by public health authorities during an outbreak, in the 14 days prior to onset of symptoms			O	O	
Vital Records Criteria for Reporting					
A person whose death certificate lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death					S
Other Criteria for Reporting					
Autopsy findings consistent with pneumonia or acute respiratory distress syndrome without an identifiable cause					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.

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.

*Serologic methods for diagnosis are currently being defined.

**Close contact is defined as being within 6 feet for a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.

Table VII. Classification Table: Criteria for defining a case of COVID-19.

Criterion	Probable					Confirmed
Clinical Evidence						
At least <u>two</u> of the following symptoms: - Fever (measured or subjective) - Chills - Rigors - Myalgia - Headache - Sore throat - New olfactory and taste disorder(s)	O	O	O			
At least <u>one</u> of the following symptoms: - Cough - Shortness of breath - Difficulty breathing	O	O	O			
Clinical or radiographic evidence of pneumonia	O	O	O			
Acute respiratory distress syndrome (ARDS)	O	O	O			
No alternative more likely diagnosis	N	N	N			
Laboratory Evidence						
Detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test that has been approved or authorized by the FDA or designated authority						S
Detection of specific antigen in a clinical specimen using tests approved or authorized by the FDA or designated authority		O	O	O		
Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection* using tests approved or authorized by the FDA or designated authority		O	O	O		
Absence of molecular amplification detection test for SARS-CoV-2 RNA	N				N	
Epidemiologic Linkage Evidence						
Close contact** with a confirmed or probable case of COVID-19 disease in the 14 days before onset of symptoms	O	O		O		
Close contact** in the 14 days before onset of symptoms with a person with: - clinically compatible illness AND - linkage to a confirmed case of COVID-19 disease	O	O		O		
Travel to an area with sustained, ongoing community transmission of SARS-CoV-2 in the 14 days prior to onset of symptoms	O	O		O		
Residence in an area with sustained, ongoing community transmission of SARS-CoV-2 in the 14 days prior to onset of symptoms	O	O		O		
Member of a risk cohort, as defined by public health authorities during an outbreak, in the 14 days prior to onset of symptoms	O	O		O		
Vital Records Evidence						
A death certificate that lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death					N	
Criteria to distinguish a new case:						
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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. 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.

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**Close contact is defined as being within 6 feet for a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.