

21-ID-01**Committee:** Infectious Disease**Title:** Update to the 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: Interim-20-ID-02

Synopsis: This position statement updates the standardized case definition for 2019 novel coronavirus disease (COVID-19), including asymptomatic infection caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), and adds COVID-19 as a nationally notifiable condition. Updates clarify clinical, laboratory, and epidemiologic linkage criteria, and add specificity for enumerating reinfections.

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 COVID-19-like illnesses and identifying infected people (cases) through laboratory testing, provider reporting, and through monitoring of contacts who develop COVID-like illness. 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, inform public health response to clusters of illness, and monitor the effectiveness of COVID-19 vaccinations as well as 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 although closely related to both SARS-CoV and MERS-CoV. 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 was no pre-existing human immunity to the virus. 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, including but not limited to obesity, hypertension, diabetes, cardiovascular disease, chronic respiratory or kidney disease, immunosuppression from solid organ transplant, and sickle cell disease. A complete list can be found at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Disease in children mostly appears to be relatively mild, and there is evidence that a significant proportion of infections across all age groups are asymptomatic, or presymptomatic at the time of testing.

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 March 2021, widespread community transmission of SARS-CoV-2 has been documented throughout the United States, and globally, and virus variants are circulating widely.

Because of the rapid advancement in the science of COVID-19 disease and SARS-CoV-2 infection, CSTE is revising this position statement to update clinical criteria determined to be indicative of infection, refine laboratory criteria to include genomic sequencing and acknowledge testing performed in non-traditional settings such as work sites, temporary testing sites, at-home tests, and others. Updated criteria for enumerating a case of reinfection is

included based on recent studies indicating different sequenced SARS-CoV-2 strains can be detected at different time points from weeks to months after initial diagnosis.²

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

Note: Given the ongoing nature of the COVID-19 pandemic and the continued evolution of the science behind the disease, jurisdictions should treat COVID-19 cases as “immediately notifiable, urgent (within 24 hours)” when voluntarily notifying the CDC. However, the widespread impact of the pandemic on state, local, and national public health responses may result in adjustments to notification processes, i.e., electronic notification of a confirmed or probable case of COVID-19 does not necessitate a follow-up phone call to the CDC Emergency Operations Center (EOC) within 24 hours. Jurisdictions should refer to CDC guidance on COVID-19 case notification methods. Jurisdictions may consider contacting the CDC EOC regarding unusual clusters or cases.

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 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.*

***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, including monitoring the impact of vaccination and assessing for waning immunity and vaccine breakthroughs.

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, at-home testing (optional)	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, respiratory failure, and death. COVID-19 is a mild to moderate illness for approximately 80% of individuals evaluated with the disease; 15% have severe infection requiring supplemental oxygen; and 5% of individuals have critical infections requiring mechanical ventilation.⁵ 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).⁶ In exposed populations such as nursing home residents, half of all infections detected during cohort screening may be presymptomatic or asymptomatic.⁷

A1. Clinical Criteria for Reporting

In the absence of a more likely diagnosis, any medically-attended (including symptoms ascertained telephonically by public health staff, e.g., contact tracers) person with:

- Acute onset or worsening of at least two of the following symptoms or signs:
 - fever (measured or subjective),
 - chills,
 - rigors,
 - myalgia,
 - headache,
 - sore throat,
 - nausea or vomiting,
 - diarrhea,
 - fatigue,
 - congestion or runny nose

OR

- Acute onset or worsening of any one of the following symptoms or signs:
 - cough,
 - shortness of breath,
 - difficulty breathing,
 - olfactory disorder,
 - taste disorder,
 - confusion or change in mental status,
 - persistent pain or pressure in the chest,
 - pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone,
 - inability to wake or stay awake

OR

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

A2. Laboratory Criteria for Reporting

- Detection of SARS-CoV-2 RNA in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider, OR
- Detection of SARS-CoV-2 genomic sequence, OR
- Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test performed by a CLIA-certified provider, OR
- Detection of SARS-CoV-2 nucleocapsid and spike protein receptor binding domain (RBD) specific antibodies in serum, plasma, or whole blood by a CLIA-certified provider.

NOTE: Some jurisdictions may opt to include testing performed by individuals at home using over-the-counter test kits. In Section VII, this is supportive laboratory evidence.

A3. Epidemiologic Linkage Criteria for Reporting

A person meeting the clinical reporting criteria with 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
- Member of an exposed risk cohort as defined by public health authorities during an outbreak or during high community transmission.

**Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). 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.*

A4. Vital Records Criteria for Reporting

A person whose death certificate lists COVID-19 disease or SARS-CoV-2 or an equivalent term as an underlying 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
- COVID-19 vaccination history

Epidemiologic Information

- Known contact or linkage to COVID-19 cases
- Member of a risk cohort as defined by public health authorities during an outbreak

VII. Case Definition for Case Classification

This CSTE case definition is intended solely for public health surveillance purposes and does not recommend criteria for clinical partners to utilize in diagnosing patients with potential COVID-19 disease or potential SARS-CoV-2 infection. See Section IX for information regarding which classifications of cases of COVID-19 should be publicly released by a public health department.

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

A1. Clinical Criteria

In the absence of a more likely diagnosis:

- Acute onset or worsening of at least two of the following symptoms or signs:
 - fever (measured or subjective),
 - chills,
 - rigors,
 - myalgia,
 - headache,
 - sore throat,
 - nausea or vomiting,
 - diarrhea,
 - fatigue,
 - congestion or runny nose

OR

- Acute onset or worsening of any one of the following symptoms or signs:
 - cough,
 - shortness of breath,
 - difficulty breathing,

- olfactory disorder,
- taste disorder,
- confusion or change in mental status,
- persistent pain or pressure in the chest,
- pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone,
- inability to wake or stay awake

OR

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

A2. Laboratory Criteria

Laboratory evidence using a method approved or authorized by the FDA⁸ or designated authority*:

*Confirmatory** laboratory evidence:*

- Detection of SARS-CoV-2 RNA in a post-mortem respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider, OR
- Detection of SARS-CoV-2 by genomic sequencing***.

*Presumptive** laboratory evidence:*

- Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test performed by a CLIA-certified provider.

*Supportive** laboratory evidence:*

- Detection of antibody in serum, plasma, or whole blood specific to natural infection with SARS-CoV-2 (antibody to nucleocapsid protein), OR
- Detection of SARS-CoV-2 specific antigen by immunocytochemistry in an autopsy specimen, OR
- Detection of SARS-CoV-2 RNA or specific antigen using a test performed without CLIA oversight.

**On March 13, 2020, the President issued a Memorandum on Expanding State-Approved Diagnostic Tests: "Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request."*

***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.*

****Some genomic sequencing tests that have been authorized for emergency use by the FDA do not require an initial PCR result to be generated. Genomic sequencing results may be all the public health agency receives.*

A3. 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; OR
- Member of an exposed risk cohort as defined by public health authorities during an outbreak or during high community transmission.

[†]Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). However, it depends on the exposure level and setting; for example, in the setting of an aerosol-generating procedure in healthcare settings without proper PPE, this may be defined as any duration.

A4. Vital Records Criteria

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

A5. Case Classifications

Confirmed:

- Meets confirmatory laboratory evidence.

Probable:

- Meets clinical criteria AND epidemiologic linkage with no confirmatory or presumptive laboratory evidence for SARS-CoV-2, OR
- Meets presumptive laboratory evidence, OR
- Meets vital records criteria with no confirmatory laboratory evidence for SARS-CoV-2.

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.

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

The following should be enumerated as a new case:

- SARS-CoV-2 sequencing results from the new positive specimen and a positive specimen from the most recent previous case demonstrate a different lineage,
OR
- person was most recently enumerated as a confirmed or probable case with onset date (if available) or first positive specimen collection date for that classification >90 days prior[‡],
OR
- person was previously reported but not enumerated as a confirmed or probable case (i.e., suspect)^{††}, but now meets the criteria for a confirmed or probable case.

[‡]Some individuals, e.g., severely immunocompromised persons, can shed SARS-CoV-2 detected by molecular amplification tests >90 days after infection. For severely immunocompromised individuals, clinical judgment should be used to determine if a repeat positive test is likely to result from long term shedding and therefore not be enumerated as a new case. CDC defines severe immunocompromise as certain conditions, such as being on chemotherapy for cancer, untreated HIV infection with CD4 T lymphocyte count <200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days.

^{††}Repeat suspect cases should not be enumerated.

Note: See Appendix 1 for supplemental operational information.

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

Position Statement	Section of Document	Revision Description
Interim-20-ID-02	Synopsis	Updated synopsis based final ratification of position statement.
Interim-20-ID-02	I. Statement of the Problem	Updated surveillance methods to include provider reporting and contact tracing and updated necessity of nationwide standardized surveillance to include monitoring effectiveness of COVID-19 vaccinations.
Interim-20-ID-02	II. Background and Justification	<ul style="list-style-type: none"> • Removed out-of-date information based on evolving science around immunity and reinfection. • Added reference link to complete list of underlying conditions that increase risk of severe COVID-19 disease. • Clarified that significant portion of children infected with SARS-CoV-2 may be asymptomatic OR presymptomatic. • Added brief information about SARS-CoV-2 variants. • Added explanation for updating the case definition before ratification.
Interim-20-ID-02	III. Desired Actions to be Taken	Retained recommendation to add COVID-19 to the NNC List and retained notification timeframe of “immediately notifiable, urgent (within 24 hours); however, added footnote explaining rationale behind retained notification timeframe.
Interim-20-ID-02	IV. Goals of Surveillance	Added examples to goal of informing public health action. Examples included monitoring impact of vaccination; assessing waning immunity and vaccine breakthroughs.
Interim-20-ID-02	V. Methods for Surveillance, Table V	Added optional at-home testing as an other source of data for case ascertainment.
Interim-20-ID-02	VI. Criteria for case ascertainment	<p>A1. Clinical Criteria for Reporting:</p> <ul style="list-style-type: none"> • Clarified that medically-attended includes a person whose symptoms were ascertained telephonically by public health staff, e.g., contact tracers. • Specified that symptoms and signs must be newly acute or worsening. • Added the following to “any one” symptoms or signs list: <ul style="list-style-type: none"> ○ confusion of change in mental status, ○ persistent pain or pressure in the chest, ○ pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone, ○ inability to wake or stay awake. <p>A2. Laboratory Criteria for Reporting</p> <ul style="list-style-type: none"> • Clarified specimen types for detection of SARS-CoV-2 RNA and specific antigen. • Specified that molecular amplification test must be diagnostic and performed by a CLIA-certified provider.

		<ul style="list-style-type: none"> • Added SARS-CoV-2 genomic sequence as a new criterion. • Clarified that SARS-CoV-2 specific antigen must be detected using a diagnostic test performed by a CLIA-certified provider. • Specified SARS-CoV-2 antibodies should be nucleocapsid and spike protein receptor binding domain (RBD) specific antibodies. • Clarified SARS-CoV-2 antibodies must be detected by a CLIA-certified provider. • Added footnote related to jurisdictions opting to include testing performed by individuals at home using over-the-counter test kits as laboratory criteria for reporting. <p>A3. Epidemiologic Linkage Criteria for Reporting</p> <ul style="list-style-type: none"> • Updated member of exposed risk cohort can be defined by public health during either an outbreak OR during high community transmission. • Updated close contact definition to be within 6 feet for at least 15 minutes cumulatively over a 24-hour period. <p>A4. Vital Records Criteria for Reporting</p> <ul style="list-style-type: none"> • Clarified that a death certificate could list “an equivalent term” to COVID-19 disease or SARS-CoV-2 as an underlying cause of death or significant condition contributing to death.
Interim-20-ID-02	VI. Criteria for case ascertainment	<p>B. Disease-specific data elements to be included in the initial report</p> <ul style="list-style-type: none"> • Added COVID-19 vaccination history as a clinical data element to be included.
Interim-20-ID-02	VII. Case Definition for Case Classification	<p>A1. Clinical Criteria:</p> <ul style="list-style-type: none"> • Specified that symptoms and signs must be newly acute or worsening. • Added the following to “any one” symptoms or signs list: <ul style="list-style-type: none"> ○ confusion of change in mental status, ○ persistent pain or pressure in the chest, ○ pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone, ○ inability to wake or stay awake. <p>A2. Laboratory Criteria</p> <ul style="list-style-type: none"> • Added footnote to define “designated authority” for laboratory evidence approval or authorization. • Clarified specimen types for detection of SARS-CoV-2 RNA and specific antigen in confirmatory and presumptive laboratory evidence. • Specified that molecular amplification test must be diagnostic and performed by a CLIA-certified provider in confirmatory laboratory evidence. • Added detection of SARS-CoV-2 by genomic sequencing as new confirmatory laboratory evidence, accompanied by footnote to explain that some genomic sequencing tests that have been authorized for emergency use by the FDA do not require an initial PCR result and therefore genomic sequencing results may be the only results a public health agency may receive. • Clarified that SARS-CoV-2 specific antigen must be detected using a diagnostic test performed by a CLIA-certified provider in presumptive laboratory evidence. • Specified SARS-CoV-2 antibodies should be specific to natural infection (antibody to nucleocapsid protein) in supportive laboratory evidence. • Added detection of SARS-CoV-2 RNA or specific antigen using a test performed without CLIA oversight to supportive laboratory evidence.

		<p>A3. Epidemiologic Linkage</p> <ul style="list-style-type: none"> Updated member of exposed risk cohort can be defined by public health during either an outbreak OR during high community transmission. Updated close contact definition to be within 6 feet for at least 15 minutes cumulatively over a 24-hour period. <p>A4. Vital Records Criteria</p> <ul style="list-style-type: none"> Clarified that a death certificate could list “an equivalent term” to COVID-19 disease or SARS-CoV-2 as an underlying cause of death or significant condition contributing to death. <p>A5. Case Classifications</p> <ul style="list-style-type: none"> Specified that a probable case meets clinical criteria and epidemiologic linkage with no confirmatory OR presumptive laboratory evidence for SARS-CoV-2.
Interim-20-ID-02	VII. Case Definition for Case Classification	<p>B. Criteria to distinguish a new case of this disease or condition</p> <ul style="list-style-type: none"> Updated entire section and added related footnotes based on new data and evolving science.
Interim-20-ID-02	XII. Coordination	Removed Subject Matter Experts who rotated off of agency’s COVID-19 response efforts or who did not participate in the ratification of Interim-20-ID-02.

XI. References

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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		
<i>Clinical Criteria for Reporting</i>			
Patient medically attended	N	N	
At least <u>two</u> of the following symptoms or signs: <ul style="list-style-type: none"> • fever (measured or subjective) • chills • rigors • myalgia • headache • sore throat • nausea or vomiting • diarrhea • fatigue • congestion or runny nose 	O	O	
Any <u>one</u> of the following symptoms or signs: <ul style="list-style-type: none"> • cough • shortness of breath • difficulty breathing • olfactory disorder • taste disorder • confusion or change in mental status • persistent pain or pressure in the chest • pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone • inability to wake or stay awake 	O	O	
Clinical or radiographic evidence of pneumonia	O	O	
Acute respiratory distress syndrome (ARDS)	O	O	
No alternative more likely diagnosis	N	N	
Symptoms or signs must be acute or worsening	N	N	
<i>Laboratory Criteria for Reporting</i>			
Detection of SARS-CoV-2 RNA in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider			S
Detection of SARS-CoV-2 genomic sequence			S
Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test performed by a CLIA-certified provider			S
Detection of SARS-CoV-2 nucleocapsid and spike protein receptor binding domain (RBD) specific antibodies in serum, plasma, or whole blood by a CLIA-certified provider			S
<i>Epidemiological Linkage Criteria for Reporting</i>			
Close contact* in the 14 days before onset of symptoms with a confirmed or probable case of COVID-19 disease		O [‡]	

Member of an exposed risk cohort, as defined by public health authorities during an outbreak or during high community transmission, in the 14 days before onset of symptoms		O [‡]	
<i>Vital Records Criteria for Reporting</i>			
A person whose death certificate lists COVID-19 disease or SARS-CoV-2 or an equivalent term as an underlying cause of death or a significant condition contributing to death			S
<i>Other Criteria for Reporting</i>			
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.

*Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). 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.

[‡]Epidemiologic linkage criteria are considered with clinical evidence, but are not sufficient, in the absence of symptoms, to report to public health.

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

Criterion	Confirmed	Probable			Suspect
Clinical Evidence					
At least <u>two</u> of the following symptoms: <ul style="list-style-type: none"> • fever (measured or subjective) • chills • rigors • myalgia • headache • sore throat • nausea or vomiting • diarrhea • fatigue • congestion or runny nose 		O			
Any <u>one</u> of the following symptoms or signs: <ul style="list-style-type: none"> • Cough • Shortness of breath • Difficulty breathing • Olfactory disorder • Taste disorder • Confusion or change in mental status • Persistent pain or pressure in the chest • Pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone • Inability to wake or stay awake 		O			
Clinical or radiographic evidence of pneumonia		O			
Acute respiratory distress syndrome (ARDS)		O			
No alternative more likely diagnosis		N			
Symptoms or signs must be acute or worsening		N			
Laboratory Evidence					
Detection of SARS-CoV-2 RNA in a post-mortem respiratory swab or clinical specimen using a diagnostic molecular amplification test* performed by a CLIA-certified provider	S				
Detection of SARS-CoV-2 by genomic sequencing**	S				
Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test* performed by a CLIA-certified provider			S		
Detection of antibody*** in serum, plasma, or whole blood* specific to natural infection with SARS-CoV-2 (antibody to nucleocapsid protein)					O
Detection of SARS-CoV-2 specific antigen by immunocytochemistry* in an autopsy specimen					O
Detection of SARS-CoV-2 RNA or specific antigen using a test* performed without CLIA oversight					O
Absence of diagnostic molecular amplification detection of SARS-CoV-2 RNA		N	N	N	N

Absence of genomic sequencing detection of SARS-CoV-2		N	N	N	N
Absence of SARS-CoV-2 specific antigen detection		N			N
Epidemiologic Linkage Evidence					
Close contact [^] with a confirmed or probable case of COVID-19 disease in the prior 14 days		O			
Member of an exposed risk cohort, as defined by public health authorities during an outbreak or during high community transmission, in the prior 14 days		O			
Vital Records Evidence					
A death certificate that lists COVID-19 disease or SARS-CoV-2 or an equivalent term as an underlying cause of death or a significant condition contributing to death				N	
Other Evidence					
No prior history of being a confirmed or probable case					N
Criteria to distinguish a new case:					
SARS-CoV-2 sequencing results from the new positive specimen and a positive specimen from the most recent previous case demonstrate a different lineage	O	N/A	N/A	N/A	N/A
Person was most recently enumerated as a confirmed or probable case with onset date (if available) or first positive specimen collection date for that classification >90 days prior	O	O	O	O	N/A
Person was previously reported but not enumerated as a confirmed or probable case (i.e., suspect) ^{^^} but now meets the criteria of a confirmed or probable case	O	O	O	O	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.

**Test must be approved or authorized by the FDA or designated authority. Note: On March 13, 2020, the President issued a Memorandum on Expanding State-Approved Diagnostic Tests: "Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request."*

*** Some genomic sequencing tests that have been authorized for emergency use by the FDA do not require an initial PCR result to be generated. Genomic sequencing results may be all the public health agency receives.*

**** 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.*

[^]Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). However, it depends on the exposure level and setting; for example, in the setting of an aerosol-generating procedure in healthcare settings without proper PPE, this may be defined as any duration.

^{^^}Repeat suspect cases should not be enumerated.

Appendix 1. Operational Guidance for Enumeration of New Cases of COVID-19

Note: This appendix is currently in development as of July 2021 and will be updated as soon as possible.

Appendix 2 Epidemiological Classification of Work-Relatedness

The Epidemiological Classification of Work-Relatedness Appendix is a product of the CSTE Occupational Health Subcommittee. Please direct any questions or comments about the appendix to the Subcommittee co-chairs: Ken Rosenman (MI): rosenman@msu.edu and Sara Wuellner (WA): wues235@lni.wa.gov.

Background:

The CSTE Occupational Health Subcommittee created a workgroup to develop standardized surveillance guidance to improve exposure-associated classifications of confirmed or probable COVID-19 cases. This workgroup, representing state and federal occupational health specialists, had weekly conference calls with the goal of supporting identification of work-related COVID-19 transmission to better identify and control workplace clusters, provide critical information about patterns of disease among workers, better understand COVID-19 health disparities, and inform prevention and intervention efforts.

This guidance applies to cases that are classified as confirmed or probable according to the CSTE surveillance case definition for COVID-19.

The classification for work-related cases of COVID-19 may evolve as the epidemiology of and risk factors for SARS-CoV-2 are better understood. How sensitive or specific to make the work-related classification was considered. A more sensitive case-definition is more inclusive and allows employers to implement workplace intervention and prevention strategies, which are more likely to be successful than interventions outside the workplace, for example to address crowded housing. A second concern was that information on non-work contacts may be unknown and to require the exclusion of non-work contacts for a case to be classified as likely work-related may be overly specific and exclude work-related cases. For example, given a cluster of cases in a meat packing facility, it would be reasonable to call these cases likely work-related although for any given individual in that cluster an exposure outside of work may have been the actual source of infection.

This classification has been developed for population-based epidemiological purposes and is not intended for use to determine an individual's eligibility for workers' compensation or to assist employers with Occupation Safety and Health Administration (OSHA) record keeping requirements.

Definitions:

“**Case**” refers to a confirmed or probable case of COVID-19 (see accompanying position statement, Section VII.)

“**Work-related**” means a case was infected with SARS-CoV-2 from an exposure at work.

Exposure outside of the workplace within 14 days of onset of symptoms or test result that meets confirmatory or presumptive laboratory criteria:

- Contact outside of work with a person that meets the definition of a confirmed or probable case.
- Participation in an event determined to be associated with a COVID-19 cluster (i.e. celebration, funeral)
- Travel on a cruise ship or airplane determined to be associated with a COVID-19 cluster

Face-to-Face Work with Public

This category includes all paid and unpaid workers who have face-to-face contact with the public (i.e. excludes persons who have contact with public only by phone or computer). It also excludes health care workers, who are defined in a separate section.

The US Department of Labor Occupational Information Network (O*NET) database (<https://www.onetonline.org>) was used to identify occupations with face-to-face public contact. We used O*NET survey measures regarding how important it is to work directly with the public or with customers and how closely people work to others in each occupation. We manually reviewed the list of occupations and selected occupations where face-to-face contact with public was expected. An additional O*NET measure on how physically close to other people one works in each

occupation was used for final selections. Since information about industry, but not occupation may only be available, criteria to identify industries where a high percentage of the occupations within the industry were identified using the O*NET data as having face-to-face contact. The final decision on face-to-face contact with the public should be made using all available information.

Health Care Worker

Health care personnel (HCP) include all paid and unpaid persons working in health care settings, home health care services, or health care occupations within other industries (e.g., school nurses) who have the potential for exposure to patients or infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP include, but are not limited to, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.

Cluster

A joint CDC/CSTE committee has developed a definition of an outbreak as part of the document title, "Proposed Investigation Criteria and Outbreak Definition for COVID-19 in Non-Residential, Non-Healthcare Workplace Settings. July 14, 2020," an excerpt from which is below. For the most up-to-date outbreak definition, please reference that document.

Outbreak definition:

Two or more¹ laboratory-confirmed² COVID-19 cases among workers at a facility with onset within a 14-day period³, who are epidemiologically linked⁴, do not share a household, and are not a close contact⁵ of each other outside of the workplace.

Work-Related Classification:

Work-related classifications are presented in three formats: 1) AND/OR logic statements, 2) a table, 3) and a flow diagram.

Work-Related Classification in AND/OR Logic Statement Format

Likely Work-Related:

- Worked outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection **AND**
- Is a health care worker or work includes face-to face contact with the public **AND**
- Is part of a cluster of COVID-19 illnesses among workers in a facility or has had contact with a co-worker, patient, resident, client, or customer classified as a confirmed or probable case.

OR

¹ Health departments may consider a higher threshold for defining an outbreak if there is a high case rate in the community (community transmission).

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

³ For onset, use symptom onset date whenever available. If symptom onset date is unknown or if a case is asymptomatic, use specimen collection date for the first specimen that tested positive. The 14-day period refers to the 14 days before the date of first symptom onset or first positive test sample.

⁴ Health departments should verify to the best extent possible that cases were present in the same setting during the same time period (e.g., same shift/department, same physical work area); that the timing fits with likely timing of exposure; and that there is no other more likely source of exposure for identified cases (e.g., household or close contact to a confirmed case outside of workplace setting).

⁵ Close contact is 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. For updated definition of a close contact please refer to CDC Contact Tracing Plan Appendices website at <https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact>

- Worked outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection **AND**
- Is a health care worker or work includes face-to face contact with the public **AND**
- Has had no known contact with a confirmed or probable case outside the workplace.

OR

- Worked outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection **AND**
- Is a non-health care worker and work does not include face-to-face contact with the public **AND**
- Is part of a cluster of COVID-19 illnesses among workers in a facility or has had contact with a co-worker classified as a confirmed or probable case.

Possibly Work-Related:

- Worked outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection **AND**
- Is a health care worker or work includes face-to face contact with the public **AND**
- Is not part of a cluster of COVID-19 illnesses among workers in a facility and has had no contact with a co-worker, patient, resident, client, or customer classified as a confirmed or probable case **AND**
- Has had contact with a confirmed or probable case outside the workplace.

OR

- Worked outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection **AND**
- Is a non-health care worker and work does not include face-to-face contact with the public **AND**
- Is not part of a cluster of COVID-19 illnesses among workers in a facility **AND**
- Has had no contact with a co-worker classified as a confirmed or probable case.

Not Work-Related:

- A patient or resident in congregate care setting or a person incarcerated⁶ in the 14 days prior to onset of illness or date of specimen collection.

OR

- Did not work outside the home for any amount of time in the 14 days prior to onset of illness or date of specimen collection.

Unable to Classify:

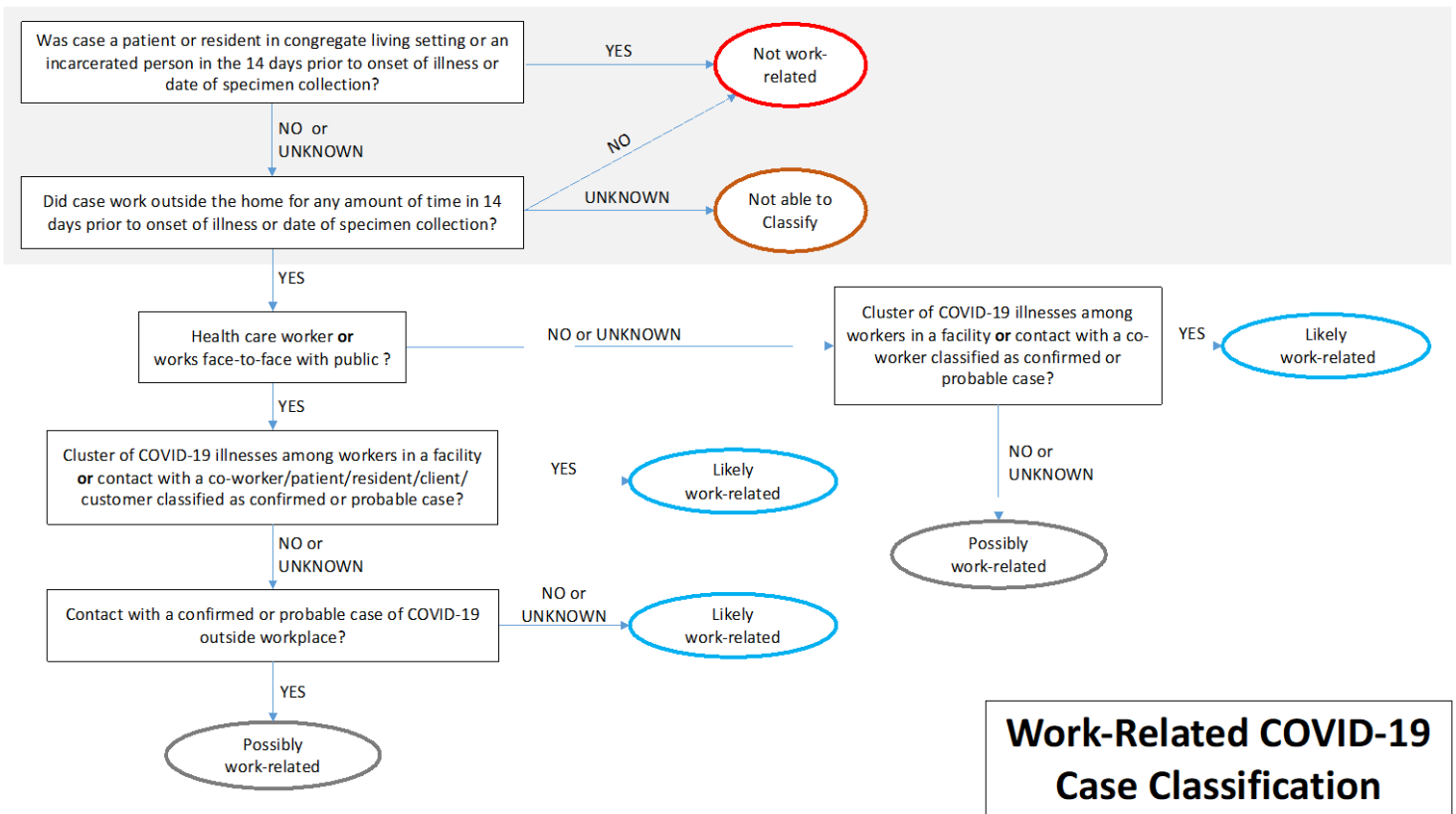
- Not a patient or resident in congregate care setting or an incarcerated⁶ person in the 14 days prior to onset of illness or specimen collection date **AND**
- Unknown if worked outside the home for any amount of time in the 14 days prior to onset of illness or specimen collection date.

⁶ It is possible for a person who is incarcerated and in a work-release program to be exposed to a confirmed or probable case of COVID-19 at their assigned work site, and after case investigation, may be considered likely or possibly work-related.

Work-Related Classification in Table Format

	Type of Work			
Work-Relatedness Classification	Health Care Worker who worked outside the home for any amount of time in the 14 days prior to onset of illness or specimen collection date	Worker with face-to-face public contact who worked outside the home for any amount of time in the 14 days prior to onset of illness or specimen collection date	All Other Workers who worked outside the home for any amount of time in the 14 days prior to onset of illness or specimen collection date	Not working outside the home in 14 days prior to onset of illness or date of specimen collection
Likely Work-Related	<p>Is part of a cluster of COVID-19 illnesses among workers in a facility OR Has had contact with a co-worker, patient, or resident classified as a confirmed or probable case OR Has had no known contact with a confirmed or probable case outside the workplace.</p>	<p>Is part of a cluster of COVID-19 illnesses among workers in a facility OR Has had contact with co-worker, client, or customer classified as a confirmed or probable case OR Has had no known contact with a confirmed or probable case outside the workplace.</p>	<p>Is part of a cluster of COVID-19 illnesses among workers in a facility OR Has had close contact with a co-worker classified as a confirmed or probable case.</p>	N/A
Possibly Work-Related	<p>Not part of a cluster of COVID-19 illnesses among workers in a facility AND Has had no contact with a co-worker, patient, or resident classified as a confirmed or probable case AND Has had contact with a confirmed or probable case outside the workplace.</p>	<p>Not part of a cluster of COVID-19 illnesses among workers in a facility AND Has had no contact with a co-worker, client, or customer classified as a confirmed or probable case AND Has had contact with a confirmed or probable case outside the workplace.</p>	<p>Not part of a cluster of COVID-19 illnesses among workers in a facility AND Has had no close contact with a co-worker classified as a confirmed or probable case</p>	N/A
Not Work-Related	<p>No work outside the home in the 14 days prior to onset of illness or date of specimen collection OR A patient or resident in congregate care setting or a person incarcerated in the 14 days prior to onset of illness or date of specimen collection.</p>	<p>No work outside the home in the 14 days prior to onset of illness (or date of specimen collection) OR A patient or resident in congregate care setting or a person incarcerated in the 14 days prior to onset of illness or date of specimen collection.</p>	<p>No work outside the home in the 14 days prior to onset of illness or date of specimen collection OR A patient or resident in congregate care setting or a person incarcerated in the 14 days prior to onset of illness or date of specimen collection.</p>	<p>No work outside the home in the 14 days prior to onset of illness or date of specimen collection</p>

Work-Related Classification in Flow Chart Format



**Work-Related COVID-19
Case Classification**

Use of Data on Death Certificates to Determine Possible Work Relatedness:

Death certificates contain the usual occupation and industry of the deceased. They are readily available in all jurisdictions and the occupation and industry information on the death certificate may be used to determine work-relatedness of COVID-19 deaths. However, the work-related classification states that when it is unknown whether a person worked outside the home in the 14 days prior to the onset of illness or date of specimen collection a case is “not able to be classified.”

Death certificates could be matched to cases to obtain information about recent work outside the home and the occurrence of a work-related cluster. In the absence of this matching, working-aged individuals (18-70 years of age) with a death certificate that meets the vital records criteria in the accompanying position statement whose occupation or industry is 1) health care, 2) requires face-to-face contact with public or are an essential worker, or 3) where case clusters have been identified should be evaluated for possible work-related classification. Describing the occupations and industries of all individuals between the ages of 18-70 who die and are confirmed or probable cases might identify work settings of concern.

Limitations include: It might not be known whether the decedent worked outside the home in the 14 days prior to onset of illness, death certificates list usual occupation and industry and not current occupation and industry at the time of death, the individual maybe retired or disabled at the time of the death, and occupation and industry are typically completed by funeral home staff without direct knowledge of the decedent’s occupational details.