

Coronavirus Disease Case Definitions, Diagnostic Testing Criteria, and Surveillance in 25 Countries with Highest Reported Case Counts

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We compared case definitions for suspected, probable, and confirmed coronavirus disease (COVID-19), as well as diagnostic testing criteria, used in the 25 countries with the highest reported case counts as of October 1, 2020. Of the identified countries, 56% followed World Health Organization (WHO) recommendations for using a combination of clinical and epidemiologic criteria as part of the suspected case definition. A total of 75% of identified countries followed WHO recommendations on using clinical, epidemiologic, and diagnostic criteria for probable cases; 72% followed WHO recommendations to use PCR testing to confirm COVID-19. Finally, 64% of countries used testing eligibility criteria at least as permissive as WHO. We observed marked heterogeneity in testing eligibility requirements and in how countries define a COVID-19 case. This heterogeneity affects the ability to compare case counts, transmission, and vaccine effectiveness, as well as estimates derived from case surveillance data across countries.

Novel infectious pathogens can pose major challenges to global health and security. Tracking the geography, demographics, and suspected mode of transmission of these pathogens by using a standardized case definition remains the foundation for infectious disease surveillance (1). Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease (COVID-19), was first characterized in December 2019 (2). By January 2020, the first national case definition was developed (3) and the World Health Organization (WHO) declared a public health emergency of international concern (4). WHO's interim

guidance for global COVID-19 surveillance, released on January 31, 2020, provided a hierarchy of confirmed, probable, and suspected case definitions (5). This guidance encouraged the use of all available clinical, epidemiologic, and laboratory evidence for case classification purposes and noted that countries might need to adapt these definitions to their unique epidemiologic situations. Recommendations for testing suspected cases and widespread testing on the basis of transmission intensity, number of cases, and available resources were included.

Both WHO and national case definitions have evolved as knowledge about COVID-19 etiology and the myriad of ways the disease manifests after infection has grown (5–7). Early on, surveillance emphasized a travel history to Wuhan, China, where the initial outbreak occurred, and a narrowly defined set of symptoms. However, the virus rapidly spread to other provinces in China and then internationally, and reports of patients who experienced new symptoms or remained asymptomatic increased (8). Confirming a COVID-19 case relies on diagnostic testing; therefore, testing capacity has played a vital role in COVID-19 surveillance efforts. The types of tests available have expanded to include molecular and antigen tests to detect the presence of the SARS-CoV-2 virus and serologic tests to detect antibodies produced from previous SARS-CoV-2 infection (9,10). However, the availability of these tests and the resources needed to collect, handle, and process clinical specimens have varied widely across nations (11). Shortages of test kits and reagents and lack of laboratory capacity have forced officials in many locations to make difficult decisions about testing eligibility (12).

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Differences in testing eligibility criteria and case definitions pose a challenge not only to detecting the actual number of cases within countries, but also to understanding the global burden of disease and adequately responding to pandemics. Global guidelines have been developed for testing eligibility criteria and case definitions but are usually reviewed at a national level and are subject to adaptation on the basis of laboratory and health system considerations. Earlier evaluations of global COVID-19 case definitions do not reflect the latest changes to national case definitions and testing eligibility criteria and do not target the full range of countries with the highest number of reported COVID-19 cases (13–15). We analyzed national COVID-19 case definitions from the 25 countries with the largest number of reported COVID-19 cases as of October 1, 2020 (collectively representing ≈85% of the global cases at that time), and the specific criteria used to determine eligibility for diagnostic testing. We also determined the implications of intercountry differences on ongoing efforts to understand global disease burden and control the pandemic.

Methods

Design

We identified the 25 countries with the highest number of reported COVID-19 cases from WHO COVID-19 cumulative case counts as of October 1, 2020 (16). We extracted surveillance case definitions and official testing policies from official government Web sites for the respective countries. If definitions were not available on government Web sites, we extracted definitions from personal communication with Centers for Disease Control and Prevention field staff.

To find these data, we searched government Web sites using these keywords: case definition, suspect case, confirmed case, COVID-19, case criteria, surveillance, testing criteria, guidelines, laboratory, reverse transcription PCR (RT-PCR), and asymptomatic. All surveillance definitions and testing criteria were verified current as of January 1, 2021. Several official policies were not available in English. For these documents, we used Google Translate (<https://translate.google.com>) to identify definitions and testing policies.

Data Management and Analysis

To compare case definitions across countries, we classified the components of each definition into 3 parts: diagnostic components including a laboratory test or radiographic imagery; clinical signs and symptoms,

such as cough, fever, and severe acute respiratory infection; and epidemiologic criteria, including travel to a high-burden region or contact with a confirmed or suspected case. For each country's testing policy, we reviewed which persons were eligible for diagnostic testing. Countries were classified as testing asymptomatic persons without any additional criteria; testing asymptomatic persons with some epidemiologic criteria, such as contact with a confirmed case; or recommending testing exclusively for symptomatic persons. These analyses were based solely on diagnostic testing eligibility criteria and did not consider exceptions, such as testing asymptomatic persons before travel, asymptomatic testing through the private sector, or local-level mass testing. Exceptions to national testing policies varied on a local level and frequently changed, which made data difficult to procure and unreliable. We compared elements of national case definitions and testing criteria against global norms from WHO.

Source Assessment

To assess sources, we extracted information on their origin (government source or personal communication) and timeliness (date of publication). We compiled the date of publication and presumed implementation of each country's most recent case definition as verified on January 1, 2021 (Appendix Table 1, <https://wwwnc.cdc.gov/EID/article/28/1/21-1082-App1.pdf>). Publication dates range from March 27, 2020, to December 18, 2020, for case definitions and July 6, 2020, to January 1, 2021, for testing policies.

Results

Suspected Case Definitions

We identified suspected case definitions in 24 (96%) of 25 countries (Table 1; Appendix Tables 2,3). Although Israel does not have an official suspected case definition, persons are considered suspected on the basis of contact with confirmed cases, which is determined by digital surveillance of cellphones. We interpreted Israel's suspected contact determined by cellphones to be an epidemiologic criterion. The 3 most common criteria in suspected case definitions were fever (reported in 92% of countries), cough (reported in 84% of countries), and labored breathing (reported in 84% of countries). In 7 countries (28%), other criteria were used in addition to common criteria (Table 1). The WHO suspected case definition relies on clinical symptoms, including the 3 most common, and epidemiologic criteria. A total of 14 (56%) countries followed this guidance broadly by using clinical and

Table 1. Selected suspected case definition criteria across 25 countries with the highest COVID-19 case counts, current as of January 1, 2021*

Country	Diagnostic testing/laboratory evidence†	Clinical symptoms							Epidemiologic criteria, any	
		Cough	Fever	SARI	Labored breathing	Headache	Muscle pain	Loss of taste or smell		
WHO definition (reference)		X	X	X	X	X	X	X	X	
Argentina		X	X	X	X	X	X	X	X	
Bangladesh‡		X	X	X	X	X	X	X	X	
Brazil		X	X	X	X	X	X	X	X	
Chile		X	X	X	X	X	X	X	X	
Colombia	X	X	X	X	X	X	X	X	X	
France§¶		X	X	X	X	X	X	X	X	
Germany§¶		X	X	X	X	X	X	X	X	
India#		X	X	X	X	X	X	X	X	
Indonesia			X	X	X	X	X	X	X	
Iran			X	X	X	X	X	X	X	
Iraq‡		X	X	X	X	X	X	X	X	
Israel**									X	
Italy§¶		X	X	X	X	X	X	X	X	
Mexico		X	X	X	X	X	X	X	X	
Pakistan#		X	X	X	X	X	X	X	X	
Peru		X	X	X	X	X	X	X	X	
Philippines‡		X	X	X	X	X	X	X	X	
Russia		X	X	X	X	X	X	X	X	
Saudi Arabia		X	X	X	X	X	X	X	X	
South Africa		X	X	X	X	X	X	X	X	
Spain		X	X	X	X	X	X	X	X	
Turkey		X	X	X	X	X	X	X	X	
Ukraine		X	X	X	X	X	X	X	X	
United Kingdom¶		X	X	X	X	X	X	X	X	
United States	X									
No. (%) countries including criterion††	2 (8)	21 (84)	23 (92)	16 (64)	21 (84)	15 (60)	14 (56)	14 (56)	15 (60)	16 (64)

*Complete data are available in Appendix Table 3 (<https://wwwnc.cdc.gov/EID/article/28/1/21-1082-App1.pdf>). X indicates the criterion was sufficient for, or a potential component of, the suspected case definition requirement(s). COVID-19, coronavirus disease; SARI, severe acute respiratory infection; WHO, World Health Organization.

†See suspected case definition for applicable country (Appendix Table 2).

‡World Health Organization definition (updated August 2020).

§European Centre for Disease Prevention and Control definition.

¶These countries consider these definitions as possible not suspected cases; because of the comparability between possible and suspected, we treated these definitions as a suspected definition.

#World Health Organization definition (updated March 2020).

**Israel does not have an official suspect case definition; persons are considered suspected on the basis of contact with confirmed cases determined by digital surveillance of cellphones.

††Denominator is 24 countries with suspected case definition.

epidemiologic criteria, 10 (40%) countries required clinical symptoms alone for the suspected case definition, and 2 countries (8%) also incorporated diagnostic testing. The United States relies on laboratory evidence, including antibody or antigen positivity, without any clinical symptoms or epidemiologic criteria, whereas Colombia primarily relies on epidemiologic criteria and clinical symptoms but includes laboratory and radiologic tests as part of their definition to assist with diagnoses (17,18).

Probable Case Definitions

We identified probable case definitions in 16 (64%) of 25 countries (Table 2; Appendix Tables 4,5). The remaining 9 (36%) countries chose not to use a probable case definition and instead use only suspected

and confirmed case definitions. The WHO probable case definition includes criteria from all 3 categories: diagnostic testing (chest imaging), clinical symptoms, and epidemiologic criteria. Of the 16 countries, 12 (75%) were consistent with WHO and included criteria from all 3 categories. The number of required criteria across countries was heterogeneous. The 3 most common criteria in probable case definitions were fever (reported in 94% of 16 countries), labored breathing (reported in 88% of 16 countries), and confirmed contact with a probable or confirmed case (reported in 81% of 16 countries). Fourteen (88%) countries included diagnostic testing for the probable case definition, 15 (94%) included clinical symptoms in their definitions, and 14 (88%) included epidemiologic criteria.

Confirmed Case Definitions

We identified confirmed case definitions in all 25 countries (100%) (Table 3; Appendix Tables 6,7). All confirmed case definitions required diagnostic testing. A total of 18 (72%) countries were consistent with WHO’s recommendations and specified RT-PCR tests in their case definition. Of these countries, 10 (40%) also included antigen or antibody tests in their definition. In 7 (28%) countries, the type of diagnostic test was not specified. Reference to the suspected case definition within the confirmed case definition was included in 7 (28%) of countries. Of these, Mexico, Saudi Arabia, and Turkey required that a person meet the suspected case definition in addition to diagnostic testing criteria. In addition to confirming cases on the basis of diagnostic testing, 6 (24%) countries confirmed cases exclusively on the basis of loss of taste or smell (anosmia or ageusia). Overall, 8 countries (32%) included clinical symptoms as part of their confirmed case definition.

Testing Eligibility Criteria

We identified testing criteria in all 25 countries (100%) (Appendix Table 8). Of those, 8 (32%) countries had no symptom requirements for testing, 8 (32%) had no symptom requirements for testing but required epidemiologic criteria (i.e., exposure to a confirmed or probable case), and 9 (36%) countries required symptoms. Of the 8 countries requiring epidemiologic criteria, 5 (63%) also allowed testing for asymptomatic healthcare workers (Appendix Table 8). Policies from Saudi Arabia and the United Kingdom specified not to test asymptomatic persons but included an exception for healthcare workers (Appendix Table 8). WHO recommends testing asymptomatic persons who have had contact with a confirmed case; 64% of countries used eligibility criteria at least as permissive as WHO.

Source Assessment

We found 92% of case definitions on government Web sites, and 72% were published or included in

Table 2. Selected probable case definition criteria across 25 countries with the highest COVID-19 case counts, current as of January 1, 2021*

Country	Diagnostic testing			Clinical symptoms					Epidemiologic criteria		
	Inconcl. test	Antigen test	Radiograph imaging	Cough	Fever	SARI	Labored breathing	Loss of taste or smell	Travel history	Hosp.	Confirmed contact
WHO definition (reference)			X	X	X	X	X	X	X	X	X
Argentina											
Bangladesh†			X	X	X	X	X	X	X	X	X
Brazil											
Chile	X	X	X	X	X	X	X	X		X	X
Colombia	X			X	X		X	X	X		X
France‡			X	X	X		X	X			X
Germany‡			X	X	X		X	X			X
India§	X			X	X	X	X		X	X	X
Indonesia					X	X	X				
Iran			X		X	X		X	X		X
Iraq†			X	X	X	X	X	X	X	X	X
Israel											
Italy‡			X	X	X		X	X			X
Mexico											
Pakistan§	X			X	X	X	X		X	X	X
Peru											
Philippines†			X	X	X	X	X	X	X	X	X
Russia				X	X	X	X	X	X		X
Saudi Arabia											
South Africa											
Spain	X		X	X	X	X	X	X			
Turkey											
Ukraine	X										
United Kingdom											
United States		X	X	X	X	X	X	X			X
No. (%) countries including criterion¶	6 (38)	2 (13)	10 (63)	13 (81)	15 (94)	11 (69)	14 (88)	12 (75)	8 (50)	6 (38)	13 (81)

*Complete data are available in Appendix Table 5 (<https://wwwnc.cdc.gov/EID/article/28/1/21-1082-App1.pdf>); full probable case definitions are shown in Appendix Table 4. X indicates the criterion was sufficient for, or a potential component of, the probable case definition requirement(s). COVID-19, coronavirus disease; hosp., hospitalized; inconcl., inconclusive; SARI, severe acute respiratory infection; WHO, World Health Organization.

†World Health Organization definition (updated August 2020).

‡European Centre for Disease Prevention and Control definition.

§World Health Organization definition (updated March 2020).

¶Denominator is 16 countries with probable case definition.

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Table 3. Selected confirmed case definition criteria across 25 countries with the highest COVID-19 case counts, current as of January 1, 2021*

Country	Diagnostic testing					Clinical symptoms		Epidemiologic criteria		
	PCR test	Antigen test	Ab test	Positive test (NS)	Radiograph imaging	Meet suspected case definition	Loss of taste or smell	Travel history	Hosp.	Confirmed contact
WHO definition (reference)	X									
Argentina	X	X				X	X			X
Bangladesh†	X									
Brazil	X	X	X		X		X			X
Chile	X					X	X		X	
Colombia	X	X								
France‡	X	X								
Germany‡	X	X								
India†				X						
Indonesia	X			X						
Iran				X						
Iraq†	X									
Israel				X						
Italy‡	X	X								
Mexico				X		X	X			X
Pakistan †				X						
Peru	X	X				X		X	X	X
Philippines†	X	X								
Russia	X	X	X							
Saudi Arabia	X					X		X	X	X
South Africa	X									
Spain	X	X				X	X			
Turkey	X					X	X	X	X	X
Ukraine				X						
United Kingdom				X						
United States	X									
No. (%) countries§	18 (72)	10 (40)	2 (8)	7 (28)	1 (4)	7 (28)	6 (24)	3 (12)	4 (16)	6 (24)

*Complete data are available in Appendix Table 7 (<https://wwwnc.cdc.gov/EID/article/28/1/21-1082-App1.pdf>); X indicates the criterion was sufficient for, or a potential component of, the confirmed case definition requirement(s). Full confirmed case definitions can be found in Appendix Table 6. Ab, antibody; hosp., hospitalized; NS, not specified; WHO, World Health Organization.

†World Health Organization definition (confirmed case definition did not change between March 2020 and August 2020 update).

‡European Centre for Disease Prevention and Control definition.

§Denominator is 25 countries with confirmed case definitions.

documents published after the most recent WHO definition was published (August 7, 2020) (Appendix Table 1). India and Pakistan used the previous WHO definition (dated March 2020); we could not confirm that these countries updated their definition on the basis of the newest WHO definitions. We could not locate definitions on government Web sites for Israel, Iraq, and Iran; for these countries, we obtained definitions from personnel involved in the country's COVID-19 response. Of 25 countries, 23 (92%) had an official government source for diagnostic testing criteria. In total, 88% of testing criteria were published after September 1, 2020. The policies for Philippines, Brazil, and Pakistan were updated in July and August 2020.

Discussion

All iterations of WHO's global COVID-19 surveillance guidance state that countries might need to adapt case definitions to their specific circumstances (5–7,19). Beginning with the March 20, 2020, version,

WHO also encouraged countries to publish their adapted versions online and in periodic situation reports (6,7). Nearly all countries (92%) in this analysis chose to deviate from WHO case definitions; 92% of countries posted their case definition on a government Web site. Suspected and confirmed case classifications were found for nearly all countries, but 36% excluded the probable case classification. In addition, we observed substantial variation among testing criteria used in national case definitions. Although WHO reserved the use of laboratory testing for confirmed cases only, 2 (8%) countries included laboratory evidence for suspected cases and 14 (88%) for probable cases; 32% included nonlaboratory criteria for confirmed cases. Laboratory evidence in some countries was not restricted to RT-PCR and included increasingly available antigen and antibody tests. Testing eligibility criteria also differed widely; many countries either excluded asymptomatic persons from routine testing (36%) or only included them under certain conditions (32%).

Differences in case definitions and testing eligibility can affect efforts to monitor disease trends and determine the impact and effectiveness of vaccines across countries and over different periods. As knowledge of a novel disease increases, the sensitivity and specificity of the case definition changes over time, ultimately affecting the number of cases identified (20). For example, during the 2002–2003 severe acute respiratory syndrome outbreak, several iterations of case definitions in the Netherlands diverged from the more sensitive and less specific WHO case definition. When all cases were reevaluated, 21 cases were classified as suspected and 2 as probable according to the latest WHO case definition, as opposed to 9 suspected and zero probable cases according to the Netherlands case definitions (21). As the COVID-19 pandemic emerged in China, a February 12, 2020, change to the case definition to include clinically diagnosed mild cases resulted in identification of >15,000 cases (22). A study of successive case definitions in China, each with gradually increasing sensitivity, also yielded higher detection of cases (15). During January 15–March 3, 2020, the National Health Commission of China used 7 versions of the case definition for COVID-19; the study estimates that the proportion of cases detected increased by 7 times after the first change, 3 times from change 2 to 4, and 4 times after change 5. The authors estimated that if the fifth version of the case definition had been applied throughout the outbreak, 4.2 times more confirmed cases would have been identified in China by February 20, 2020 (232,000 vs. 55,508). A more recent study benefitting from the availability of the complete genome sequence for SARS-CoV-2 and access to respiratory specimens collected early for retrospective analysis perhaps best demonstrates the effect of a restrictive case definition (23). Those authors identified multiple early cases of SARS-CoV-2 infection in Nottingham, UK, that, despite demonstrating symptoms consistent with COVID-19, did not meet case definition criteria used for diagnostic testing referral in place at the time because of lack of travel history or contact with an infected person. Genomic sequencing of these undetected cases revealed that most were acquired locally by community spread before widespread mitigation measures were adopted. These findings suggest that countries that used less sensitive case definitions, particularly at the start of the pandemic, might have grossly underestimated the true burden of disease, which affected decisions about the need for and timing of infection control measures. Changes in case definitions, both across and within countries, might also need to be

considered when analyzing an epidemic curve for COVID-19 or other novel diseases.

The wide variation we found in suspected and probable case criteria and the complete omission of the probable case classification in some nations is of particular interest. WHO indicated that suspected and probable case definitions were revised to reflect increased knowledge of the clinical spectrum of COVID-19 signs and symptoms, especially the most common and predictive. These updates informed global and national surveillance because some symptoms have limited predictive value for surveillance purposes despite their frequent inclusion in case identification procedures (24–27). In its August 7, 2020, guidance, WHO delineated recommendations for handling each case classification. These recommendations included investigating suspected and probable cases for the presence of SARS-CoV-2 by using available laboratory tests, conducting contact tracing with persons with eligible exposure to probable and confirmed cases, and providing specific types of notifications within 24 hours of identifying probable and confirmed cases (8). This guidance also included a new request for countries to include counts of probable cases and confirmed cases in weekly aggregate reports.

WHO case definition guidance does not explicitly state a type of test for diagnostic confirmatory testing but references laboratory guidance that recommend nucleic acid amplification tests (NAATs), such as RT-PCR (28). Many countries might not have considered the laboratory guidance and used the WHO confirmed case definition verbatim. Indeed, we found that 7 countries did not specify a type of test for confirmatory testing. Results indicating some countries' use of alternatives to NAAT as laboratory evidence is another key finding. Antigen tests, particularly point-of-care tests, have been promoted as a tool for early detection and preventing asymptomatic spread (10). However, their sensitivity is generally lower than NAATs, leading to false negatives (29). Antibody tests have typically been recommended as a surveillance assay rather than a standalone diagnostic tool (12,30). Despite the limitations of NAAT alternatives, their increasing availability in many areas and benefits such as lower overall cost, simplified logistics and supply chain management, and faster turnaround of results for rapid versions could explain their integration in some confirmed case definitions.

In all 25 countries, confirmed cases relied on diagnostic testing. Characterizing differences in eligibility for diagnostic testing across countries helps determine whether different persons are being diagnosed

and designated as a confirmed case. For example, a country that requires symptoms and epidemiologic transmission to be eligible for diagnostic testing might have fewer cases detected than if they permitted testing to all persons in a country regardless of clinical or epidemiologic criteria. Early testing strategies targeted segments of the population believed to be at greatest risk for exposure to SARS-CoV-2. For example, national testing policy in Australia emphasized defining and targeting high-risk settings, such as residential care facilities or correctional facilities (31). In May 2020, the European Centre for Disease Prevention and Control expanded the pool of persons eligible for laboratory testing, resources permitting, to include asymptomatic persons in healthcare settings and long-term care facilities to identify potential sources of infection and protect vulnerable persons (14). WHO recommendations for laboratory testing also evolved over time and acknowledged that testing priorities would depend on intensity of transmission, number of cases, and laboratory capacity. On June 25, 2021, WHO released updated guidance that called on member states to create a national testing strategy that adapts to these changes and to implement public health actions that break transmission chains (32). Specific strategies for different SARS-CoV-2 transmission scenarios might include testing more persons than those who meet the latest suspected and probable case definitions, such as patients with unexpected clinical manifestations, asymptomatic contacts, and samples from existing sentinel surveillance sites. In addition, the guidance includes alternative testing strategies when laboratory capacity is low or overstretched.

Because of the large proportion of asymptomatic or mildly symptomatic COVID-19 cases, detecting both symptomatic and asymptomatic cases is necessary to ensure accurate case counts (33). Including asymptomatic cases also affects key epidemiologic metrics, such as incidence and case-fatality ratio. Although expansive testing criteria would increase the likelihood of detecting asymptomatic infections, this benefit should be weighed against the effect tracing and testing these eligible persons would have on the public health system (31). For example, broadening testing eligibility criteria might overload the healthcare system with persons who have low probability of infection or disease progression. Furthermore, many settings might not have adequate resources to test all eligible persons (33). Although WHO provides harmonious global testing criteria and case definitions, our findings suggest heterogeneity in how these aspects were adapted; it might be necessary to account

for these deviations when comparing and collating COVID-19 case counts across countries.

The first limitation of our study is that, although the included studies represented $\approx 85\%$ of reported cases globally, case definitions in the countries making up the remaining 15% of cases might differ. In addition, we chose to include the 25 countries with the highest number of reported cases, which might not represent the countries with the highest number of infections. Including countries on the basis of new infections from population-based serosurveillance or other sources merits future research. Second, although we identified suspected case definitions, confirmed case definitions, and testing criteria for most countries, we identified probable case definitions in only 16. This difference could be because of the lack of a probable case definition or its lack of availability in the public domain; regardless, the results of the probable case definition analyses might be less generalizable than the others. Third, we used Google Translate to translate definitions not in English in lieu of direct translation by native or bilingual speakers. Previous studies have used Google Translate for health-related text, including an analysis of national health agency mask guidance across multiple countries and regions during the COVID-19 pandemic (34). One study specifically compared the agreement between translations of abstracted data from published clinical trials between native speakers and Google Translate for 9 different languages and determined that agreement ranged from 85% to 97% (35). In our study, translation errors could have occurred for some languages and thus created discrepancies between the original policy intent and our interpretation of the translation. Fourth, our scope was limited to confirmed, probable, and suspected case definitions; other classifications, such as persons under investigation, might merit further research. Fifth, after extraction and analyses were completed, additional issues relating to case surveillance have emerged. These issues include cases amongst vaccinated persons, criteria for distinguishing a new case from an existing case (i.e., reinfection cases), as well as variants (17,36–39). Although these issues were not part of national case surveillance definitions, case surveillance amongst vaccinated persons can help inform stakeholders of changes in vaccine effectiveness, reinfection surveillance might provide further information on naturally acquired and vaccine-acquired immunity, whereas genomic surveillance could provide further insights on circulating strains. All three elements are vital to comprehensive national surveillance of COVID-19. Sixth, given the large number of possibilities, we chose not

to list every permutation of laboratory, clinical, and epidemiologic criteria for WHO and national suspected, probable, and confirmed case definitions. Finally, despite our analysis of each government's policies, these policies might not be implemented equally in various settings and could change over time. To continue to build on the implications of this study, further research should determine the programmatic implications of less sensitive case definitions, such as whether misclassifying cases leads to outbreaks and onward population transmission.

Case surveillance remains the foundation for national COVID-19 surveillance and plays a vital role in ongoing situational awareness, clarifying the impact and effectiveness of vaccines and informing other public health and social measures. We observed marked heterogeneity in testing eligibility requirements among countries and how countries define COVID-19 cases. Specifically, we observed heterogeneity in eligible clinical symptoms for suspected case definitions, laboratory and diagnostic requirements for probable case definitions, and eligible laboratory assays for confirmed case definitions. Testing eligibility criteria varied from being restricted to populations with exposure and symptoms to all populations being eligible, regardless of exposure and symptoms. Collectively, these issues suggest that efforts to compare and collate COVID-19 case counts across countries require careful interpretation. Improved harmonization of case definitions across countries prospectively for COVID-19, and for other novel infectious diseases that might emerge, warrants consideration.

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Coronavirus Disease Case Definitions, Diagnostic Testing Criteria, and Surveillance in 25 Countries with Highest Reported Case Counts

Appendix

Appendix Table 1. Assessment of sources for COVID-19 case definition and testing criteria across 25 countries with the highest case counts, current as of January 1, 2021*

Countries	Case definition source (date)†	Testing criteria source (date)†
WHO	WHO (1) (2020 Aug 7)	NA
Argentina	Government (2) (2020 Sep 11)	Government (3) (2020 Sep 23)
Bangladesh	Government (4) (2020 Nov 5)	Government (2020 Nov 5)
Brazil	Government (5) (2020 Aug 5)	Government (2020 Aug 5)
Chile	Government (6) (2020 Oct 1)	Government (7) (2020 Nov 18)‡
Colombia	Government (8) (2020 Oct 19)	Government (9) (2020 Oct)
France	ECDC (10) (2020 Dec 3)	Government (11) (2020 Oct 19)‡
Germany	ECDC (10) (2020 Dec 3)	Government (12) (2020 Dec 16)
India	Government (13) (2020 Jul 3)	Government (14) (2020 Sep 4)
Indonesia	Government (15) (2020 Jul 13)	Government (16) (2021 Jan 1)§
Iran	CDC contact (N. Farag, CDC, pers. comm., 2020 Sep 29)†	CDC contact (N. Farag, CDC, pers. comm., 2020 Sep 29)†
Iraq	CDC contact (Y.Y. Majeed, CDC, pers. comm., 2020 Oct 2)†	CDC contact (Y.Y. Majeed, CDC, pers. comm., 2020 Oct 2)†
Israel	CDC contact (H. Burke, CDC, pers. comm., 2020 Oct 7)†	Government (17) (2020 Dec 17)
Italy	ECDC (10) (2020 Dec 3)	Government (18) (2020 Oct 23)
Mexico	Government (19,20) (2020 Aug 25)	Government (21) (2020 Nov 11)
Pakistan	Government (22) (2020 Mar 27)	Government (23,24) (2020 Dec 2)
Peru	Government (25) (2020 Jul 10)	Government (26) (2020 Sep 30)
Philippines	Government (27) (2020 Nov 25)	Government (28) (2020 Jul 6)
Russia	Government (29) (2020 Oct 26)	Government (30) (2021 Jan 1)§**
Saudi Arabia	Government (31) (2020 Oct)	Government (31) (2020 Oct)
South Africa	Government (32) (2020 Aug 18)	Government (33) (2020 Sep 16)
Spain	Government (34) (2020 Dec 18)	Government (34) (2020 Dec 18)
Turkey	Government (35) (2020 Dec 7)	Government (35) (2020 Dec 7)
Ukraine	Government (36) (2020 Mar 28)	Government (37) (2021 Jan 1)§**
United Kingdom	Government (38) (2020 Sep 28)	Government (39) (2021 Jan 1)§**
United States	Government (40) (2020 Aug 5)	Government (41) (2020 Oct 21)

*CDC, Centers for Disease Control and Prevention; ECDC, European Centre for Disease Prevention and Control; NA, not applicable; WHO, World Health Organization.

†Date of Centers for Disease Control and Prevention contact communication.

‡Date the website was last updated.

§Date the source website was last verified in absence of website update date.

Appendix Table 2. Full suspected case definitions of COVID-19 in countries with highest reported case counts*

Country	Definition
WHO (reference)	1. A person who meets the clinical AND epidemiologic criteria: Clinical Criteria: Acute onset of fever AND cough; OR Acute onset of ≥ 3 of the following signs or symptoms: fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnea, anorexia/nausea/vomiting, diarrhea, altered mental status.
Iraq†	Epidemiologic Criteria: Residing or working in an area with high risk for transmission of virus such as closed residential settings or humanitarian settings such as camp and camp-like settings for displaced persons,
Bangladesh†	anytime within the 14 days before symptom onset; OR Residing or travel to an area with community transmission anytime within the 14 days before symptom onset; OR Working in any healthcare setting, including within health facilities or within the community, anytime within the 14 days before symptom onset. 2. A patient with severe acute respiratory illness: acute respiratory infection with history of fever or measured fever of $\geq 38^{\circ}\text{C}$
Philippines†	and cough, with onset within the last 10 days and requiring hospitalization.
India	1. A patient with acute respiratory illness (fever and ≥ 1 sign/symptom of respiratory disease, such as cough or shortness of breath) AND a history of travel to or residence in a location reporting community transmission of COVID-19 during the 14 days before symptom onset. 2. A patient with any acute respiratory illness AND having been in contact with a confirmed or probable person with COVID-19 (see definition of contact) in the 14 days before symptom onset. 3. A patient with severe acute respiratory illness (fever and ≥ 1 sign/symptom of respiratory disease, such as cough or shortness of breath AND requiring hospitalization) AND in the absence of an alternative diagnosis that fully explains the clinical manifestation.
Pakistan	
United States	Meets supportive laboratory evidence with no previous history of being a confirmed or probable case. Supportive laboratory evidence: Detection of specific antibody in serum, plasma, or whole blood. Detection of specific antigen by immunocytochemistry in an autopsy specimen.
Italy‡§	Any person meeting clinical criteria: ≥ 1 of the following symptoms: cough, fever, shortness of breath, or sudden onset of anosmia, ageusia, or dysgeusia. Additional less specific symptoms include headache, chills, muscle pain, fatigue, vomiting, or diarrhea.
Germany‡§	
France‡§	
Brazil	1. Individual with acute respiratory condition, characterized by at ≥ 2 of the following signs and symptoms: fever (even if referred), chills, sore throat, headache, cough, runny nose, olfactory disorders or taste disorders. In children, nasal obstruction is also considered in addition to the previous symptoms, in the absence of another specific diagnosis. In the elderly, specific aggravation criteria such as syncope, mental confusion, excessive sleepiness, irritability, and inappetence should also be considered. If COVID-19 is suspected, fever might be absent and gastrointestinal symptoms (diarrhea) might be present. 2. Individual with Influenza-like illness who has dyspnea or respiratory discomfort OR persistent pressure in the chest OR O_2 saturation $< 95\%$ in room air OR bluish color of the lips or face. In children, in addition to the previous items, flapping of the nose, cyanosis, intercostal circulation, dehydration, and lack of appetite.
Russia	Clinical manifestations of acute respiratory infection: temperature $> 37.5^{\circ}\text{C}$ and ≥ 1 of the following: cough (dry or with scanty sputum), shortness of breath, feeling of congestion in the chest, satiety blood oxygen according to pulse oximetry (SpO_2) $\leq 95\%$, sore throat, nasal congestion or mild rhinorrhea, impaired or loss of smell (hyposmia or anosmia), loss of taste (dysgeusia), conjunctivitis, weakness, muscle pain, headache, vomiting, diarrhea, or skin rash in the absence of other known causes, which explain the clinical picture regardless of the epidemiologic anamnesis.
Colombia	Person with exposure because of having been in a place with community transmission or outbreak or contact with probable cases, and with respiratory OR nonrespiratory clinical manifestations of COVID-19 of any severity, clinical laboratory or radiologic findings belonging to groups of risk factors or vulnerability. Also, asymptomatic persons with exposure to probable or confirmed COVID-19 case-patients. Respiratory clinical manifestations: fever $> 38^{\circ}\text{C}$, cough, fatigue, expectoration, shortness of breath or dyspnea, sore throat, rhinorrhea, $\text{SpO}_2 < 93\%$. Nonrespiratory clinical manifestations: anosmia, hyposmia, ageusia, dysgeusia, diarrhea, anorexia, nausea and vomiting, abdominal pain or discomfort, acute conjunctivitis, seizures, vertigo, headache, myalgia, skeletal muscle injuries, altered consciousness, acute cerebrovascular disease, ataxia, seizures, meningoencephalitis, Guillain-Barre syndrome, mental status disorders, hepatic compromise due to elevated aminotransferases, erythematous rash, hive rash, vesicles, acral ischemia, unilateral transient livedo reticularis, acute cardiac injury, heart failure arrhythmia, shock, acute myocarditis, chest tightness, acute kidney injury, urinary symptoms or cystitis, coagulation disorders, thrombotic events, antiphospholipid antibodies, hearing loss, or hearing discomfort. Clinical laboratory and radiological findings: laboratory and nonetiologic clinical diagnostic tests: Albumin Decrease (81%), CRP increase (79%) (MIS-C 94%), LDH increase (69.3%), Thrombocytosis (61%), Lymphopenia (57.5%, 25%, 56.5%), Interleukin-6 increase (56%), AST increase (37%), Leukopenia (28%, 25%), Leukocytosis (18.3%), Neutrophilia (MIS-C 83%), Thrombocytopenia (13%, 16.4%–32.3%), Increase in D-dimer, Ferritin, Decrease in T3 and T 4 Troponin T (MIS-C 68%), pro BNP (MIS-C 77%). Pulmonary radiological findings Bilateral commitment (81%), Consolidation (73.5%), Ground Glass Opacity (73.5%), Abnormal echocardiogram (MIS-C 59%, 63%). Factors of vulnerability: healthcare workers, workers who serve in high volumes of public work in social protection, workers with high mobility because of occupational activity, and internal Colombian migrants.
Peru	Person with acute respiratory infection experiencing cough or pain from throat and ≥ 1 of the following signs / symptoms: general discomfort, fever, headache, difficulty breathing, nasal congestion.
Argentina	1. Anyone (of any age) who has ≥ 2 of the following symptoms: fever ($\geq 37.5^{\circ}\text{C}$), cough, odynophagia, shortness of breath, headache, myalgia, diarrhea, or vomiting, with no other etiology that fully explains the clinical manifestation. This criterion includes any severe acute respiratory infection. 2. Sudden loss of taste or smell, in the absence of any other identified cause. 3. Anyone who is a healthcare worker, resides or works in closed or long-term institutions, is essential personnel, lives in popular neighborhoods or native towns, or had close

Country	Definition
	contact with confirmed a COVID-19 case-patient within 14 days of contact AND has ≥ 1 of these symptoms: fever (37.5°C or higher), cough, odynophagia, shortness of breath, or sudden loss of taste or smell.
Spain	Anyone with a clinical picture of acute respiratory infection of sudden onset of any severity that occurs, among others, with fever, cough, or shortness of breath. Other symptoms such as odynophagia, anosmia, ageusia, muscle pain, diarrhea, chest pain, or headache, among others, might also be considered symptoms of suspected SARS-CoV-2 infection according to clinical judgment.
Mexico	Person of any age who has had ≥ 1 of the following signs and symptoms in the last 10 days: cough, fever, dyspnea (serious condition), or headache. In children < 5 years of age, irritability can replace headache. Accompanied by ≥ 1 of the following minor signs or symptoms: myalgia, arthralgias, odynophagia, chills, chest pain, rhinorrhea, anosmia, dysgeusia, or conjunctivitis.
South Africa	Any person presenting with an acute (≤ 10 days) respiratory tract infection or other clinical illness compatible with COVID-19, or an asymptomatic person who is a close contact a of a confirmed case-patient. Symptoms include ANY of the following respiratory symptoms: cough, sore throat, shortness of breath, anosmia (loss of sense of smell), or dysgeusia (alteration of the sense of taste), with or without other symptoms (which might include fever, weakness, myalgia, or diarrhea).
United Kingdom‡	New continuous cough or temperature $\geq 37.8^{\circ}\text{C}$ or loss of or change in normal sense of smell (anosmia) or taste (ageusia).
Iran	1. Acute onset of fever OR acute onset of ILI/ARI symptoms or nausea and vomiting AND epidemiologic criteria (residing/working/travel to high-risk settings or community transmission or health facilities within 14 days of symptom onset). 2. Severe acute respiratory infection.
Chile	1. Patient presenting an acute picture with ≥ 2 of the symptoms compatible with COVID-19: fever ($\geq 37.8^{\circ}\text{C}$), cough, dyspnea, chest pain, odynophagia, myalgia, chills, headache, diarrhea, or sudden loss or decrease of smell (anosmia or hyposmia) or taste (ageusia or dysgeusia). 2. Patient with severe acute respiratory infection requiring hospitalization.
Saudi Arabia	1. Patient with acute respiratory illness (sudden onset of ≥ 1 of the following: fever (measured or by history), cough, or shortness of breath. 2. Patient with sudden onset of ≥ 1 of the following: headache, sore throat, rhinorrhea, nausea, diarrhea, or loss of smell or taste AND in the 14 days before symptom onset, met ≥ 1 of the following criteria: contact with a confirmed COVID-19 case Or Working in or attended a healthcare facility where patients with confirmed COVID-19 were admitted. 3. Any admitted adult patient with unexplained severe acute respiratory illness (SARI), either community-acquired pneumonia or hospital-acquired pneumonia.
Turkey‡	1. At least 1 of the following signs and symptoms: fever, cough, shortness of breath, sore throat, headache, muscle aches, loss of taste and smell, diarrhea AND the clinical picture cannot be explained by another cause or disease AND 1 of the following within 14 days before the onset of symptoms: person or close contact has history of being in a high-risk area for the disease or person has confirmed contact with a COVID-19 case-patient. 2. At least 1 of the signs and symptoms of fever and severe acute respiratory infection (SARI) (cough and respiratory distress), requiring hospitalization, and the clinical picture cannot be explained by another cause or disease. SARI: The need for hospitalization because of fever, cough and dyspnea, tachypnea, hypoxemia, hypotension, diffuse radiological findings on lung imaging, and change in consciousness in a patient with acute respiratory tract infection that developed in the last 14 days. 3. Combination of ≥ 2 of the following signs and symptoms: fever, cough, shortness of breath, sore throat, headache, muscle aches, loss of taste and smell or diarrhea, and this situation cannot be explained by another cause or disease.
Indonesia	1. A person who has 1 of the following criteria: persons with acute respiratory infections (ARI) (namely fever ($\geq 38^{\circ}\text{C}$) or a history of fever and accompanied by any of the symptoms or signs of respiratory disease such as cough, shortness of breath, sore throat, runny nose, pneumonia from mild to severe AND in the last 14 days before symptoms appeared had a history of travel to or lives in a country or territory of Indonesia reporting local transmissions. 2. People with any of the symptoms or signs of ARI AND in the last 14 days before symptoms develop had a history of contact with a confirmed or probable COVID-19 case. 3. People with severe ARD or severe pneumonia requiring hospitalization AND no other cause based on a convincing clinical picture.
Israel	Israel does not have official surveillance case definitions; persons are considered suspect on the basis of contact with confirmed cases determined by digital surveillance of cellphones.
Ukraine	1. A patient with acute respiratory illness (sudden onset, fever, and ≥ 1 of the following symptoms: cough or difficulty breathing), regardless of the need for hospitalization, and who 14 days before the onset of symptoms meets ≥ 1 of the following epidemiologic criteria: contact with a confirmed or probable case of COVID-19 or visited or resided in a country or region with local transmission of the virus in the community according to WHO situation reports. 2. Patient with severe acute respiratory disease (body temperature $\geq 38^{\circ}\text{C}$ and ≥ 1 of the following symptoms: cough or difficulty breathing) requiring hospitalization and the absence of other reasons that fully explain the clinical picture.

*ARD, acute respiratory distress; ARI, acute respiratory infection; AST, Aspartate Aminotransferase; BNP, B-type natriuretic peptide; COVID-19, coronavirus disease; CRP, C-reactive protein; ILI, influenza-like illness; LDH, Lactate Dehydrogenase; MIS-C, multisystem inflammatory syndrome-children; SARI, severe acute respiratory infection; SARS-CoV-2, severe acute respiratory infection coronavirus 2; SpO₂, blood oxygen saturation; WHO, World Health Organization.

‡World Health Organization definition.

‡These countries use a possible case definition in place of a suspected case definition.

§European Centre for Disease Prevention and Control definition.

Appendix Table 3. Full suspected COVID-19 case definition criteria across 25 countries with the highest case counts, current as of January 1, 2021*

Country	Diagnostic testing			Clinical symptoms													Epidemiologic criteria			Other				
	Laboratory evidence†	Cough	Fever	SARI	Labored breathing	Headache	Muscle pain	Sore throat or odynophagia	Chest pain or congestion	Runny nose or nasal congestion	Loss of taste or smell	Diarrhea	Nausea or vomiting	Joint pain	Chills	Rash	SPO ₂ Level	Conjunctivitis	Fatigue or weakness	Travel history	Hospitalized	Confirmed contact	Healthcare employee	Diagnostic, clinical, or EPI‡
WHO definition‡ (reference)		X	X	X	X	X	X	X	X	X	X	X	X						X	X	X		X	X
Argentina		X	X	X	X	X	X	X		X	X	X							X	X	X	X	X	X
Bangladesh‡		X	X	X	X	X	X	X		X	X	X							X	X	X	X	X	X
Brazil		X	X	X	X	X	X	X		X	X	X			X		X				X			X
Chile		X	X	X	X	X	X	X	X	X	X				X						X			X
Colombia	X	X	X		X	X	X	X		X	X	X	X	X		X	X	X	X	X		X	X	X
France§¶		X	X		X	X	X			X	X	X	X		X			X	X					
Germany§¶		X	X		X	X	X			X	X	X	X		X			X	X					
India#		X	X	X	X															X	X	X		
Indonesia			X	X	X			X		X										X	X	X		
Iran			X	X									X							X			X	
Iraq‡		X	X	X	X	X	X	X		X		X	X						X	X	X		X	X
Israel**																				X				
Italy§¶		X	X		X	X	X			X	X	X	X		X				X	X				
Mexico		X	X		X	X	X		X	X				X	X			X	X					
Pakistan#		X	X	X	X															X	X	X		
Peru		X	X	X	X	X			X											X	X	X		
Philippines‡		X	X	X	X	X	X	X		X	X	X	X						X	X	X		X	X
Russia		X	X		X	X	X	X	X	X	X	X	X			X	X	X	X					
Saudi Arabia		X	X	X	X	X	X	X		X	X	X	X								X	X	X	X
South Africa		X	X	X	X		X	X		X	X	X	X						X			X		
Spain		X	X	X	X	X	X	X	X	X	X	X	X											
Turkey		X	X	X	X	X	X			X	X									X	X	X		
Ukraine		X	X	X	X															X	X	X		
United Kingdom¶		X	X							X										X	X	X		
United States	X																							
No. countries including criterion	2	21	23	16	21	15	14	12	4	10	14	15	11	2	6	2	3	3	10	11	10	10	6	7
% of countries††	8%	84%	92%	64%	84%	60%	56%	48%	16%	40%	56%	60%	44%	8%	24%	8%	12%	12%	40%	44%	40%	40%	24%	28%

*X indicates the criterion was sufficient for, or a potential component of, the suspected case definition requirement(s). Full suspected case definitions can be found in Appendix Table 2. SARI, severe acute respiratory infection; SpO₂, blood oxygen saturation; WHO, World Health Organization.

†Refer to suspected case definition for applicable country (Appendix Table 2).

‡World Health Organization definition (updated August 2020).

§European Centre for Disease Prevention and Control definition.

¶These countries consider these definitions as possible not suspected cases; because of the comparability between possible and suspected, we treated these definitions as a suspected definition.

#World Health Organization definition (updated March 2020).

**Israel does not have official surveillance case definitions; persons are considered suspected on the basis of contact with confirmed cases determined by digital surveillance of cellphones.

††Denominator is 24 countries with suspected case definition.

Appendix Table 4. Probable case definitions of COVID-19 in countries with highest reported case counts*

Country	Definition
WHO Definition Iraq† Bangladesh† Philippines†	1. A patient who meets clinical criteria AND is a contact of a probable or confirmed case, or epidemiologically linked to a cluster with ≥ 1 confirmed case. 2. A suspected case with chest imaging showing findings suggestive of COVID-19. Typical chest imaging findings suggestive of COVID-19 include the following chest radiography: hazy opacities, often rounded in morphology, with peripheral and lower lung distribution; chest CT: multiple bilateral ground glass opacities, often rounded in morphology, with peripheral and lower lung distribution; lung ultrasound: thickened pleural lines, B lines (multifocal, discrete, or confluent), consolidative patterns with or without air bronchograms. 3. A person with recent onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause. 4. Death, not otherwise explained, in an adult with respiratory distress preceding death AND was a contact of a probable or confirmed case or epidemiologically linked to a cluster with ≥ 1 confirmed case.
India Pakistan	1. A suspected case for whom testing for the COVID-19 virus is inconclusive. 2. A suspected case for whom testing could not be performed for any reason.
USA	1. Meets clinical criteria AND epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19. 2. Meets presumptive laboratory evidence (detection of SARS-CoV-2 by antigen test in a respiratory specimen). 3. Meets vital records criteria with no confirmatory laboratory evidence. Clinical criteria: ≥ 2 of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, nausea or vomiting, diarrhea, fatigue, congestion, or runny nose OR ≥ 1 of the following symptoms: cough, shortness of breath, difficulty breathing, new olfactory disorder, new taste disorder OR severe respiratory illness with ≥ 1 of the following: clinical or radiographic evidence of pneumonia, acute respiratory distress syndrome (ARDS). Epidemiologic criteria: ≥ 1 of the following exposures in the previous 14 days: close contact with a confirmed or probable case of COVID-19 OR member of a risk cohort as defined by public health authorities during an outbreak.
Italy‡ Germany‡ France‡	Any person meeting clinical criteria (≥ 1 of the following symptoms: cough, fever, shortness of breath, sudden onset of anosmia, ageusia or dysgeusia) with epidemiologic link (close contact with confirmed case within 14 days before onset or having been a resident or staff in an institution with ongoing transmission within 14 days before onset) OR any person meeting diagnostic criteria (radiological evidence showing lesions compatible with COVID-19).
Brazil	No probable case definition.
Russia	Same as suspected case AND ≥ 1 of the epidemiologic signs is present: return from a foreign trip 14 days before the onset of symptoms; having close contact in the last 14 days with a person under monitoring for COVID-19 who subsequently fell ill; having close contact in the last 14 days with a person with laboratory-confirmed diagnosis of COVID-19; availability of professional contacts with persons who have been identified as suspected or confirmed case of COVID-19.
Colombia	Person with any type of individual or multiple exposure to confirmed cases and with respiratory or nonrespiratory clinical manifestations of COVID-19, of any severity, and clinical or radiological laboratory findings. It also includes the person with doubtful etiologic laboratory results (RT-PCR) or laboratory testing is not feasible for some reason. Respiratory clinical manifestations: fever $>38^{\circ}\text{C}$, cough, fatigue, expectoration, shortness of breath or dyspnea, sore throat, rhinorrhea, SpO ₂ $<93\%$. Nonrespiratory clinical manifestations: anosmia, hyposmia, ageusia, dysgeusia, diarrhea, anorexia, nausea and vomiting, abdominal pain or discomfort, acute conjunctivitis, seizures, vertigo, headache, myalgia, skeletal muscle injuries, altered consciousness, acute cerebrovascular disease, ataxia, seizures, meningoencephalitis, Guillain-Barre syndrome, mental status disorders, hepatic compromise due to elevated aminotransferases, erythematous rash, hive rash, vesicles, acral ischemia, unilateral transient livedo reticularis, acute cardiac injury, heart failure arrhythmia, shock, acute myocarditis, chest tightness, acute kidney injury, urinary symptoms or cystitis, coagulation disorders, thrombotic events, antiphospholipid antibodies, hearing loss or hearing discomfort.
Peru	No probable case definition.
Argentina	No probable case definition.
Spain	1. Person with severe acute respiratory infection with clinical and radiological symptoms compatible with COVID-19 and negative diagnostic test results, or suspected cases with inconclusive diagnostic test. 2. Cases with high clinical-epidemiologic suspicion with repeatedly negative diagnostic test (≥ 1 PCR) and positive serologic testing for SARS-CoV-2 performed by high-throughput serologic techniques.
Mexico	No probable case definition.
South Africa	No probable case definition.
United Kingdom	No probable case definition.
Iran	1. Suspected case AND close contact with probable or confirmed case. 2. Suspected case AND positive imaging. 3. Acute onset of anosmia or ageusia without identified cause. 4. Death of a suspected case.
Chile	1. Probable case by laboratory result: patient who meets the definition of a suspected case in whom the PCR result is indeterminate or who has a positive antigenic test for SARS-CoV-2. 2. Probable case because of epidemiologic link: person who has been in close contact with a confirmed case and develops fever (axillary temperature $\approx 37.8^{\circ}\text{C}$) or ≥ 2 symptoms compatible with COVID-19 within 14 days of contact. The probable case because of an epidemiologic link does not require an RT-PCR test for SARS-CoV-2. If for any reason, a probable case-patient undergoes a confirmatory examination and it is positive, it will be considered as a confirmed case. On the contrary, if the result is negative or indeterminate, it will continue to be considered a probable case. 3. Probable case by imaging: suspicious case with negative RT-PCR result for SARS-CoV-2 but with a chest CT scan with characteristic images of COVID-19 according to the radiological report. 4. Probable case because of symptoms: person with sudden and complete loss of smell (anosmia) or taste (ageusia) without an explanation.

Country	Definition
Saudi Arabia	No probable case definition.
Turkey	No probable case definition.
Philippines	1. Suspected case whose testing for COVID-19 is inconclusive. 2. Suspected case who tested positive for COVID-19 but whose test was not conducted in a national or subnational reference laboratory or officially accredited laboratory for COVID-19 confirmatory testing. 3. Suspected case who died without undergoing any confirmatory testing.
Indonesia	1. Suspected cases with SARI. 2. Died with a convincing clinical picture of COVID-19 AND no RT-PCR laboratory results.
Israel	Israel does not have official surveillance case definitions; persons are considered suspected case-patients on the basis of contact with confirmed cases determined by digital surveillance of cellphones.
Ukraine	A suspected case for whom laboratory testing cannot be unambiguously interpreted.

*COVID-19, coronavirus disease; CT, computed tomography; RT-PCR, reverse transcription PCR; SARI, severe acute respiratory infection; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

†World Health Organization definition.

‡European Centre for Disease Prevention and Control definition.

Appendix Table 5. Full probable COVID-19 case definition criteria across 25 countries with the highest case counts, current as of January 1, 2021*

Country	Diagnostic testing				Clinical symptoms														Epidemiologic criteria			Other				
	Inconclusive test	Antigen test	Antibody test	Radiographic imagery	Cough	Fever	SARI	Labored breathing	Headache	Muscle pain	Sore throat or odynophagia	Chest pain or chest congestion	Runny nose or nasal congestion	Loss of taste or smell	Diarrhea	Nausea or vomiting	Chills	Rash	SPO ₂ level	Conjunctivitis	Fatigue or weakness	Travel history	Hospitalized	Confirmed contact	Diagnostic, clinical, or EPI†	
WHO definition (Reference)				X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	X	X	X	X
Argentina																										
Bangladesh‡				X	X	X	X	X	X	X			X	X	X	X					X	X	X	X	X	X
Brazil																										
Chile	X	X		X	X	X	X	X	X	X	X		X	X	X		X	X	X	X	X		X	X	X	X
Colombia	X				X	X		X	X	X			X	X	X	X			X	X	X			X	X	X
France§				X	X	X		X					X	X										X	X	X
Germany§				X	X	X		X					X	X										X	X	X
India¶	X				X	X	X	X														X	X	X	X	X
Indonesia						X	X	X					X										X	X	X	X
Iran				X	X	X							X	X		X						X	X	X	X	X
Iraq‡				X	X	X	X	X	X	X			X	X	X	X					X	X	X	X	X	X
Israel																									X	X
Italy§				X	X	X		X						X										X	X	X
Mexico																										
Pakistan¶	X				X	X	X	X														X	X	X		
Peru																										
Philippines‡				X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	X	X	X	X
Russia					X	X	X	X	X	X		X	X	X				X	X	X	X	X		X	X	X
Saudi Arabia																										
South Africa																										
Spain	X			X	X	X	X	X	X	X	X			X	X											
Turkey																										
Ukraine	X																									
United Kingdom																										
United States		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X
Country	6	2	0	10	13	15	11	14	8	8	9	3	7	12	7	6	2	2	2	2	6	8	6	13	10	
Totals																										
% of countries#	38%	13%	0%	63%	81%	94%	69%	88%	50%	50%	56%	19%	44%	75%	44%	38%	13%	13%	13%	13%	38%	50%	38%	81%	63%	

*X indicates the criterion was sufficient for, or a potential component of, the probable case definition requirement(s). Full probable case definitions can be found in Appendix Table 4. SARI, severe acute respiratory infection; SpO₂, blood oxygen saturation; WHO, World Health Organization.

†Refer to probable case definition for applicable country (Appendix Table 4).

‡World Health Organization definition (updated August 2020).

§European Centre for Disease Prevention and Control definition.

¶World Health Organization definition (updated March 2020).

#Denominator is 16 countries with probable case definition.

Appendix Table 6. Confirmed case definitions of COVID-19 in countries with highest reported case counts*

Country	Definition
WHO	A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms.
Iraq†	
Bangladesh†	
Philippines†	1. Any person, irrespective of presence or absence of clinical signs and symptoms, who was laboratory confirmed for COVID-19 in a test conducted at the national reference laboratory, a subnational reference laboratory, or Department of Health-licensed COVID-19 testing laboratory. 2. Any suspected or probable COVID-19 cases who tested positive using antigen tests in areas without breaks or in remote settings where RT-PCR is not immediately available; provided that the antigen tests satisfy the recommended minimum regulatory, technical, and operational specifications set by the Health Technology Assessment.
India	A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms.
Pakistan	
USA	Meets confirmatory laboratory evidence (detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test).
Italy‡	Any person meeting laboratory criteria (detection of SARS-CoV-2 nucleic acid or antigen in a clinical specimen).
Germany‡	
France‡	
Brazil	1. Case of ILI or SARI with clinical confirmation associated with anosmia (olfactory dysfunction) OR ageusia (gustatory dysfunction) without any other previous cause. 2. Case of ILI or SARI with history of close or home contact, in the 14 days before appearance of signs and symptoms with confirmed case. 3. Case of ILI or SARI or death due to SARS that could not be confirmed by laboratory criteria AND that presents ≥ 1 of the following tomographic changes: peripheral, bilateral, frosted glass opacity, with or without consolidation or visible intralobular lines ("paving"), or multifocal matte glass opacity with rounded morphology with or without consolidation or visible intralobular lines ("paving"), or reverse halo sign or other findings of organizing pneumonia (seen later in the disease). 4. Case of ILI or SARI with test of positive result for SARS-CoV-2 performed by the RT-PCR method in real time or REAGENT result for IgM, IgA and / or IgG performed by the following methods: ELISA; immunochromatography (rapid test) for antibody detection; ECLIA; Or Antigen Search: reagent result for SARS-CoV-2 by the Immunochromatography method for antigen detection. 5. Asymptomatic persons with 1 of the following results: positive result for SARS-CoV-2 performed by the RT-PCR method in real time or immunological reagent result for IGM and/or IGA performed by the following methods: ELISA or immunochromatography (rapid test) for antibody detection.
Russia	1. A positive laboratory test result for the presence of RNA SARS-CoV-2 using NAAT or SARS-CoV-2 antigen using immunochromatographic analysis regardless of clinical manifestations. 2. Positive result for IgA, IgM and / or IgG antibodies in patients with a clinically confirmed COVID-19 infection.
Colombia	Person with laboratory (RT-PCR for SARS-CoV-2 (MIS-C 59%, 13%–69%) or Antigen detection test (alternative diagnosis. May change according to new evidence)) with positive results of active infection by the SARS-CoV-2 virus regardless of the presence or absence of clinical criteria, since the tests can be performed in asymptomatic, suspected or probable patients, with different prioritization.
Peru	1. Suspected case with a positive laboratory test for COVID 19, be it an RT-PCR test in respiratory samples and/or a rapid IgM, IgG, or IgG/IgM detection test. 2. Asymptomatic contact with a positive laboratory test for COVID-19.
Argentina	1. Confirmed by COVID-19 laboratory: any suspected cases with a detectable result for SARS-CoV-2 by molecular biology tests by RT-PCR, by molecular biology tests by loop-mediated isothermal amplification reaction (LAMP), or SARS-cov-2 antigens by non-molecular tests. Confirmatory diagnosis in suspected cases with mild or moderate symptoms, only during the first 7 days from the onset of symptoms. 2. Confirmed by clinical or epidemiologic criteria of COVID-19: in the last 14 days has been in close contact with a confirmed case OR Is part of a conglomerate of cases, with ≥ 1 case confirmed by laboratory, with no other defined diagnosis, and presenting ≥ 2 of the following symptoms: fever, cough, odynophagia, difficulty breathing, vomiting, diarrhea, headache, or myalgia. 3. Any person who, in the absence of any other identified cause, experiences sudden loss of taste or smell. 4. Any deceased person who does not have a defined etiologic diagnosis, has had a clinical picture compatible with COVID-19 (known by the certifying doctor or referred by third parties) regardless of previous health status and that has been close contact of a confirmed case or has been epidemiologically linked to a cluster of cases or to areas of sustained community transmission.
Spain	1. Person who meets clinical criteria for a suspected case and with a positive diagnostic test. 2. Asymptomatic person with positive diagnostic test with negative IgG or not performed.
Mexico	1. Person who meets the operational definition of suspected case and has a laboratory-confirmed diagnosis issued by Institute of Epidemiological Diagnosis and Reference. 2. Person who meets the operational definition of a suspected case, but who has been in contact with a laboratory confirmed case within the last 14 days from the date of onset of symptoms.
South Africa	A person with laboratory confirmation of SARS-CoV-2 infection (using an RT-PCR assay), irrespective of clinical signs and symptoms.
United Kingdom	Positive COVID-19 test result.
Iran	Laboratory confirmation with or without suspected or probable criteria.
Chile	1. Anyone who meets the definition of a suspected case in which the specific test for SARS-CoV-2 was positive (RT-PCR). 2. Any asymptomatic person identified through an active search strategy in which the specific test for SARS-CoV-2 was positive (RT-PCR).
Saudi Arabia	A person who meets the suspected case definition with laboratory confirmation of COVID-19 infection (PCR).

Country	Definition
Turkey	Cases in which SARS-CoV-2 is detected by molecular methods among the cases matching the possible case definition.
Indonesia	A person who has tested positive for the COVID-19 virus proven by the RT-PCR laboratory examination. Confirmation cases are divided into: confirmation case with symptoms (symptomatic), confirmation cases without symptoms (asymptomatic).
Israel	Positive COVID-19 test result.
Ukraine	A person with a laboratory-confirmed COVID-19 disease, regardless of clinical signs and symptoms.

*COVID-19, coronavirus disease; ECLIA, electrochemiluminescence immunoassay; ILI, influenza-like illness; MIS-C, multisystem inflammatory syndrome-children; NAAT, nucleic acid amplification technique; RT-PCR, reverse transcription PCR; SARS, severe acute respiratory syndrome; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

†World Health Organization definition.

‡European Centre for Disease Prevention and Control definition.

Appendix Table 7. Full confirmed COVID-19 case definition criteria across 25 countries with the highest case counts, current as of January 1, 2021*

Country	Diagnostic testing					Clinical symptoms					Epidemiologic criteria		Other†	
	PCR test	Antigen test	Antibody test	Positive test (nonspecified)	Radiographic imagery	Meet suspected case definition	Cough	Fever	SARI	Loss of taste or smell	Travel history	Hospitalized		Confirmed contact
WHO definition (reference)	X													
Argentina	X	X				X	X	X					X	X
Bangladesh‡	X													
Brazil	X	X	X		X				X				X	X
Chile	X					X				X		X		
Colombia	X	X												
France§	X	X												
Germany§	X	X												
India‡				X										
Indonesia	X													
Iran				X										
Iraq‡	X													
Israel				X										
Italy§	X	X												
Mexico				X		X				X			X	
Pakistan‡				X										
Peru	X	X				X					X	X	X	
Philippines‡	X	X												
Russia	X	X	X											
Saudi Arabia	X					X					X	X	X	
South Africa	X													
Spain	X	X				X				X				
Turkey	X					X				X	X	X	X	
Ukraine				X										
United Kingdom				X										
USA	X													
Totals	18	10	2	7	1	7	1	1	1	6	3	4	6	2
% of countries¶	72%	40%	8%	28%	4%	28%	4%	4%	4%	24%	12%	16%	24%	8%

*X indicates the criterion was sufficient for, or a potential component of, the confirmed case definition requirement(s). Full confirmed case definitions can be found in Appendix Table 6.

†Refer to probable case definition for applicable country (Appendix Table 6).

‡World Health Organization definition (confirmed case definition did not change between March 2020 and August 2020 update).

§European Centre for Disease Prevention and Control definition.

¶Denominator is 25 countries with confirmed case definitions.

Appendix Table 8. COVID-19 testing policies for asymptomatic persons in 25 countries with highest case counts as of January 1, 2021*

Countries	Asymptomatic testing	EPI Criteria: Confirmed contact	EPI Criteria: Healthcare employee
WHO	Yes with EPI Criteria	Yes	
Iraq	Yes with EPI Criteria	Yes	
Bangladesh	No		
Philippines	Yes		
India	Yes with EPI Criteria	Yes	Yes
Pakistan	Yes		
United States	Yes		
Italy	Yes		
Germany	Yes with EPI Criteria	Yes	Yes
France	Yes		
Brazil	Yes with EPI Criteria	Yes	Yes
Russia	Yes		
Colombia	No		
Peru	No		
Argentina	No		
Spain	Yes with EPI Criteria	Yes	Yes
Mexico	No		
South Africa	Yes with EPI Criteria	Yes	
United Kingdom	No		Yes
Iran	Yes with EPI Criteria	Yes	
Chile	Yes		
Saudi Arabia	No		Yes
Turkey	Yes with EPI Criteria	Yes	Yes
Indonesia	No		
Israel	Yes		
Ukraine	No		

*EPI, epidemiologic; WHO, World Health Organization.

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