Evolving global and national criteria for identifying a suspected case of COVID-19

Amporn Atsawarungruangkit[1] (iD)**, Jin Yuan[2],
Takamitsu Kodama[3], Ming-Tai Cheng[4],
Mohammad Mansouri[5], Boram Han[6,7],
Jarinrat Kongkamnerd[8], Fabian Riegg[1,9],
Anupama Menon[1] and Steven F. Moss[1]**

Abstract

Background: The outbreak of coronavirus disease 2019 (COVID-19) began in December 2019 and continues to spread worldwide. Rapid and accurate identification of suspected cases is critical in slowing spread of the virus that causes the disease. We aimed to highlight discrepancies in the various criteria used by international agencies and highly impacted individual countries around the world.

Methods: We reviewed the criteria for identifying a suspected case of COVID-19 used by two international public health agencies and 10 countries across Asia, Europe, and North America. The criteria included information on the clinical causes of illness and epidemiological risk factors. Non-English language guidelines were translated into English by a co-author who is fluent in that particular language.

Results: Although most criteria are modifications of World Health Organization recommendations, the specific clinical features and epidemiological risks for triggering evaluation of patients with suspected COVID-19 differed widely among countries. The rationale for these differences may be related to each country's resources, politics, experience with previous outbreaks or

[1]Warren Alpert Medical School of Brown University, Providence, Rhode Island, United States
[2]Boston University School of Medicine, Boston, Massachusetts, United States
[3]Tajimi City Hospital, Gifu, Japan
[4]National Taiwan University Hospital, Taipei, Taiwan
[5]Montefiore Medical Center, New York, New York, United States
[6]East Boston Neighborhood Health Center, Boston, Massachusetts, United States
[7]Boston Medical Center, Boston, Massachusetts, United States
[8]Farmacia, Chiangmai, Thailand
[9]University of Tübingen, Tübingen, Germany

Corresponding author:
Amporn Atsawarungruangkit, Rhode Island Hospital, 593 Eddy Street, POB 240, Providence, Rhode Island 02903, United States.
Email: amporn_atsawarungruangkit@brown.edu

pandemics, health insurance system, COVID-19 outbreak severity, and other undetermined factors.
Conclusion: We found no consensus regarding the best diagnostic criteria for identifying a suspected case of COVID-19.

Introduction

The outbreak of coronavirus disease 2019 (COVID-19) was first identified in December 2019.[1] On 11 February 2020, the virus that causes COVID-19 was officially named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2] On 11 March 2020, the World Health Organization (WHO) declared that COVID-19 can be characterized as a pandemic.[3] The clinical spectrum of COVID-19 is still evolving and is far from complete. Therefore, one of the most challenging tasks for health care providers is early recognition of COVID-19, to mitigate community spread and manage affected patients.

Respiratory droplets and direct contact are considered the primary routes of transmission for other respiratory viruses, including SARS-CoV, Middle East respiratory syndrome coronavirus (MERS-CoV), and influenza.[4] Case reports from China have described that most non-residents of Wuhan who developed COVID-19 had visited Wuhan (the epicenter of this pandemic) prior to symptom onset,[4,5] had contact with Wuhan residents,[4] or had close contact with confirmed cases.[5] For this reason, the transmission of SARS-CoV-2 is very likely to follow the same pattern as other coronaviruses.

Fever and dry cough are the two most commonly reported symptoms of COVID-19.[4–6] The WHO has recommended using these symptoms to identify a suspected case of COVID-19 since the very beginning of the outbreak (Table 1).[7–9]

As the emergence and spread of COVID-19 in different countries have been evolving rapidly, the reporting of cases varies widely among countries. This has resulted in what appears to be large variation in the total number of cases in different countries. However, the number of confirmed cases reported by a specific country may not provide an accurate estimate of the actual number of infected patients because many factors, such as a limited supply of testing kits, government policies, and criteria for identifying a suspected case, can potentially distort the data. Our objective was to analyze the criteria used in different countries for identifying a suspected case of COVID-19. For comparative analysis, we translated these criteria into English when necessary (i.e., criteria from China, Germany, Iran, Italy, Japan, South Korea, and Thailand).

Methods

We reviewed publicly available information regarding COVID-19 from 1 January 2020 to 14 March 2020 issued by various public health organizations around the world, including international agencies (the WHO and European Centre for Disease

Table 1. Criteria for identifying a suspected case of COVID-19 according to the WHO and ECDC.

Organization/ Issue date	Main criteria		Remarks
	Clinical course of illness	Epidemiological risk	
WHO[7] 27 February 2020	Acute respiratory illness (fever **AND** at least one sign/symptom of respiratory disease (e.g., cough, shortness of breath)) **AND** no other etiology that fully explains the clinical presentation.	**AND** A history of travel to or residence in a country/area or territory reporting local transmission of COVID-19 during the 14 days prior to symptom onset.	
	Any acute respiratory illness.	**AND** Having been in contact with a confirmed or probable COVID-19 case in the 14 days prior to onset of symptoms.	
	Severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g., cough shortness breath) **AND** requiring hospitalization **AND** no other etiology that fully explains the clinical presentation.		
ECDC[31] 2 March 2020	Acute respiratory tract infection (sudden onset of at least one of the following: cough, fever, shortness of breath) **AND** with no other etiology that fully explains the clinical presentation.	**AND** A history of travel to or residence in a country/area or territory reporting local transmission of COVID-19 during the 14 days prior to symptom onset.	Once local or community transmission has been reported in the country or area, all patients presenting with symptoms of acute respiratory infection in primary care or the emergency department of a hospital (first contact with the health care system) will be considered suspected cases.
	Any acute respiratory illness.	**AND** Having been in close contact with a confirmed or probable COVID-19 case in the 14 days prior to onset of symptoms.	
	Severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g., cough, fever, shortness breath) **AND** requiring hospitalization **AND** with no other etiology that fully explains the clinical presentation.		

COVID-19, coronavirus disease 2019; WHO, World Health Organization; ECDC, European Centre for Disease Prevention and Control.

Prevention and Control (ECDC)) and public health organizations in 10 countries or regions, namely, China, Germany, Iran, Italy, Japan, South Korea, Taiwan, Thailand, the United Kingdom (UK), and United States of America (US). For non-English documents, one co-author who is fluent in the relevant language translated the information into English.

We focused on criteria for identifying a suspected case of COVID-19 and summarized the criteria in the form of clinical course of illness and epidemiological risk. This study is solely a qualitative analysis; no statistical analysis was undertaken.

Owing to the nature of the present study, the requirements for ethics approval and informed consent were not applicable.

Results

The criteria according to the two international public health agencies and 10 countries (listed in alphabetical order) are summarized below.

International agencies

A summary of criteria of the WHO and ECDC is listed in Table 1. We also searched the Africa Centers for Disease Control and Prevention (Africa CDC) website. The Africa CDC is currently using the WHO criteria and has not released any continent-specific criteria.

The criteria of the ECDC are nearly identical to the WHO criteria, except that epidemiological risk is waived once there is a local or community outbreak.

China

As part of the effort to slow the spread of SARS-CoV-2 and reduce mortality, the National Health Commission released the first version of its diagnosis and treatment protocol for novel coronavirus pneumonia on 16 January 2020. During the subsequent 2 weeks, this protocol was frequently updated owing to rapid nationwide spread of COVID-9 and emerging data. By the end of January, the fourth version of the protocol was released.[10] The newest version of this protocol was published on 3 March 2020 (Table 2),[11] with the recommendation to use clinical manifestations and epidemiological risks to define suspected cases of COVID-19. Clinical manifestations consist of symptoms, radiographic features, and complete blood count; epidemiological risks mainly focus on the hot zone (Hubei Province, especially Wuhan), exposure to patients with confirmed COVID-19, and evidence of community spread. Although the seventh version of this protocol is similar to prior versions, there are several key differences. The seventh version includes fever and/or respiratory symptoms in identifying a suspected case; respiratory symptoms were not included in the fourth version (Table 3). In the fourth version of the protocol, epidemiological risk factors were considered mandatory but this requirement was loosened in the seventh version, with individuals considered suspected cases without any epidemiological risks as long as all three clinical manifestations were met.

The Chinese protocol also emphasizes the utility of chest imaging and complete blood count when evaluating a suspected case. The imaging findings in COVID-19 vary from localized pure ground-glass opacities to consolidated lesions to lung whiteout. Based on chest imaging alone, COVID-19 is difficult to distinguish from other viral pneumonia.[12] However, when the outbreak erupted in Hubei Province, the demand for testing kits dramatically exceeded the supply; as a result, National Health Commission revised its recommendations in the fifth version of the Chinese protocol and allowed the diagnosis of COVID-19 to be based on clinical manifestations and characteristic chest imaging

Table 2. Criteria of 10 countries for identifying a suspected case of COVID-19.

Country/ Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
China[11] Seventh version 3 March 2020	Two of the following features are required: (1) Fever **AND/OR** respiratory symptoms (2) Radiographic features suggesting COVID-19[a] (3) In early phase, WBCs normal **or** mildly decreased **OR** lymphocyte count normal **or** decreased	**AND**	One of the following risks are required:[b] (1) Travel to/living in Wuhan or adjacent areas, or other areas with confirmed COVID-19 cases within 14 days of symptom onset (2) Close contact with a laboratory-confirmed COVID-19 case within 14 days of symptom onset (3) Close contact with an individual who has fever or respiratory symptoms, coming from Wuhan or adjacent areas, or from other areas with confirmed COVID-19 cases within 14 days of symptom onset (4) Cluster cases with fever **AND/OR** respiratory symptoms (occurring within a family, workplace, or school within a period of 2 weeks)	
Germany[14] 5 March 2020	Non-specific general symptoms **OR** acute respiratory symptoms of any severity	**AND**	Contact with confirmed cases within 14 days prior to the onset of disease.	Well-founded suspicion.
	Acute respiratory symptoms of any severity **with or without** fever	**AND**	A stay in high-risk areas within 14 days prior to the onset of disease.	
	Acute respiratory symptoms of any severity **with or without** fever	**AND**	A stay in regions with confirmed cases within 14 days prior to the onset of disease.	Case under differential diagnostic clarification.

(continued)

Table 2. Continued.

Country/Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
	Clinical or radiological indications of viral pneumonia **without** alternative diagnosis	**AND**	No measurable epidemiological risks.	
Iran[32] 27 February 2020	Chills, dry cough, sore throat with or without fever **AND** shortness of breath or hypoxia (oxygen saturation <93%)	**AND**	(1) Any person who had close contact with a laboratory-confirmed COVID-19 case within 14 days of symptom onset	
	(1) Fever with above symptoms without hypoxia **AND** (2) in a high-risk group^c with positive CT scan or chest x-ray	**AND**	(2) A history of travel in affected geographic areas within 14 days of symptom onset	
Japan[33] 4 March 2020	Non-vulnerable person: Fever (≥37.5°C) **OR** respiratory symptoms for more 4 days.	**AND**	Potential exposure to COVID-19	Consider nucleic acid amplification (such as PCR), when criteria are met. A vulnerable person is defined as: (1) advanced age; (2) a person with diabetes, chronic heart failure, chronic obstructive pulmonary disease, or chronic kidney disease with dialysis; and (3) a person who is on immunosuppressants or receiving chemotherapy.
	Vulnerable person: Fever (≥37.5°C) **OR** respiratory symptoms for more 2 days.	**AND**		
Italy[34] 9 March 2020 (This version is the same as the ECDC	Acute respiratory tract infection (sudden onset of at least one of the following: cough, fever, shortness of breath) **AND** with no other etiology that fully explains the clinical presentation.	**AND**	A history of travel to or residence in a country/area or territory reporting local transmission of COVID-19 during the 14 days prior to symptom onset.	Once local or community transmission has been reported in the country or area, all patients presenting with symptoms of acute respiratory infection to primary care or

(continued)

Table 2. Continued.

Country/ Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
definition of 2 March 2020)	Any acute respiratory illness.	**AND**	Having been in close contact with a confirmed or probable COVID-19 case in the 14 days prior to onset of symptoms.	the emergency department of a hospital (first contact with the health care system) will be considered a suspected case.
	Severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g., cough, fever shortness breath) **AND** requiring hospitalization **AND** with no other etiology that fully explains the clinical presentation.			
South Korea[35] (7-1 edition) 6 March 2020	Fever **OR** respiratory symptoms	**AND**	A history of contact with a symptomatic laboratory-confirmed COVID-19 case who develops symptoms within 14 days from contact.	
	Fever **OR** respiratory symptoms	**AND**	A history of travel to high-risk geographic areas within 14 days of symptom onset.	
	Fever **OR** respiratory symptoms	**AND**	Contact or association with a domestic collective outbreak according to the epidemiological database and developing symptoms within 14 days of contact.	
	Referred by a physician for coronavirus infection testing, such as presenting with pneumonia of unknown etiology.			

(continued)

Table 2. Continued.

Country/ Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
Taiwan[36] 1 March 2020	Fever $\geq$38°C **OR** acute upper airway symptoms **OR** Clinical, radiological or pathological diagnosis of pneumonia	**AND**	A history of travel from affected geographic areas, or in contact with people from affected areas who have fever or acute airway symptoms, within 14 days of symptom onset. **OR** Having been in close contact with highly probable case [c] or confirmed case, including providing care/living together without proper protective equipment **OR** direct contact with respiratory secretions/bodily fluids of such a person within 14 days of symptom onset.	Must report to Taiwan CDC within 24 hours if compatible with the criteria. Highly probable case: not laboratory confirmed, but compatible with clinical criteria **AND** contact with a confirmed case within 14 days of symptom onset.
	Clinical, radiological or pathological diagnosis of pneumonia. Diagnosis of community-acquired pneumonia without travel history of affected geographic areas, clinicians have ruled out possible causes and highly clinical suspicion of novel pathogens.	**AND**	Health care providers **OR** cluster cases within 14 days of symptom onset.	

(continued)

Table 2. Continued.

Country/ Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
Thailand[37] (Third version) 2 March 2020	Fever **AND** any symptoms of respiratory illness (e.g., cough, runny nose, sore throat, respiratory distress, or dyspnea)	**AND**	Any of the following conditions in the 14 days prior to onset of symptoms:	Criteria for airport health control.
	(1) Fever **AND** any symptoms of respiratory illness (e.g., cough, runny nose, sore throat, respiratory distress, or dyspnea) (2) Pneumonia	**AND**	(1) A history of travel in affected geographic areas (2) Living in the same household as any person with a history of travel as in (1) (3) Working in close contact with international tourists (4) Having been in contact with a confirmed or probable COVID-19 case (5) Being a health care provider involved with or having contact with a suspected case	Criteria for health care facility.
	Pneumonia with one of the following conditions: (1) Close contact with a confirmed or probable COVID-19 case in the 14 days prior to onset of symptoms (2) A health care provider (3) No improvement after treatment (4) Unexplained etiology (5) Severe case or death with unexplained etiology	**AND**	No need to consider the epidemiologic risk.	Criteria for health care facility.
	A cluster of patients with acute respiratory tract infection that have negative tests for influenza	**AND**	Meeting the cluster definition below: (1) For health care providers, having three people working in	Criteria for a cluster of patients.

(continued)

Table 2. Continued.

Country/Issue date	Main criteria		Remarks
	Clinical course of illness	Epidemiological risk	
	confirmed by rapid test or rapid thermocycling process.	the same department (same health care facility for small health care facilities) within a week (2) For non-health care providers, having five people working in the same department within a week	
United Kingdom [38] 13 March 2020	Patient requiring hospital admission with: (1) Either clinical **or** radiological evidence of pneumonia **OR** (2) Acute respiratory distress **OR** (3) Influenza like illness New continuous cough **and/or** high temperature		Inpatient definition. Patients who meet the following criteria and are well enough to remain in the community (stay at home).
United States [39] 4 March 2020	Fever **AND/OR** symptoms of acute respiratory illness. Health care providers can use their judgement to determine whether the patient should be tested.	**AND** (1) Any person, including health care workers, having close contact with a laboratory-confirmed COVID-19 case within 14 days of symptom onset **OR** (2) A history of travel from affected geographic areas within 14 days of symptom onset	Fever is either measured temperature $\geq 100.0°F$ ($37.78°C$) or subjective fever.

COVID-19, coronavirus disease 2019; ARDS, acute respiratory distress syndrome; CT, computed tomography; WBC, white blood cell; PCR, polymerase chain reaction.
aScattered small opacities and interstitial changes peripherally in the early phase; diffuse ground-glass opacities, infiltrates, or extensive consolidations in severe cases. Pleural effusions are uncommon
bIf no epidemiological risk identified, all three clinical features must be met.
cHigh-risk group is defined as: (1) immunodeficient patients (such as those taking corticosteroids or those with cancer, a history of transplant, and HIV-positive patients) or (2) patients with underlying diseases (such as cardiovascular disease, hypertension, diabetes, underlying respiratory disease, and body mass index >40).

Table 3. Earlier versions of criteria for identifying a suspected case of COVID-19 in China, Japan, South Korea, and United States.

Country/ Issue date	Main criteria			Remarks
	Clinical course of illness		Epidemiological risk	
China[10] Fourth version 27 January 2020	Two of the following features are required: (1) Fever (2) Radiographic features suggesting COVID-19 (3) In early phase, WBCs normal or mildly decreased **OR** decreased lymphocyte count	**AND**	One of the following risks are required: (1) Travel to/living in Wuhan or other areas with community spread of COVID-19 within 14 days of symptom onset (2) Close contact with an individual who has fever or respiratory symptoms coming from Wuhan or other areas with community spread of COVID-19 within 14 days of symptom onset (3) Cluster cases or epidemiological link to a confirmed COVID-19 patient	Scattered small opacities and interstitial changes peripherally in the early phase; diffuse ground-glass opacities, infiltrates, or extensive consolidations in severe cases. Pleural effusions are uncommon.
Japan[40] 3 February 2020	Patient with fever **or** respiratory symptoms (mild to severe).	**AND**	A history of close contact with a confirmed novel coronavirus case	
	Patient with fever (≥37.5°C) **AND** respiratory symptoms.	**AND**	A history of travel to **or** residence near the outbreak area of novel coronavirus within 14 days before onset of symptoms.	
	Patient with fever ≥37.5°C) **AND** acute respiratory symptoms.	**AND**	A history of close contact with a person who traveled to **or** has residence near the outbreak area of novel coronavirus within 14 days before onset of symptoms.	

Table 3. Continued.

Country/ Issue date	Main criteria — Clinical course of illness	Epidemiological risk	Remarks
	Patient with severe fever **AND** respiratory symptoms that require ICU or ICU-like treatment, resulting in an unclear diagnosis.		Physicians should consider the patient a possible suspected case of coronavirus without laboratory confirmation.
United Kingdom[41] 10 March 2020	Patient requiring hospital admission with: (1) Either clinical **or** radiological evidence of pneumonia **OR** (2) Acute respiratory distress **OR** (3) Influenza like illness (1) Acute respiratory infection of any degree of severity, including at least one of the following: shortness of breath (difficulty breathing in children) **or** cough (**with or without** fever) **OR** (2) Fever with no other symptoms	**AND** In the 14 days before the onset of illness: (1) Travel to specified countries and areas. This includes transit, for any length of time, in these countries **OR** (2) Contact with a confirmed case of COVID-19	
United States[42] 28 February 2020	Fever **OR** symptoms of lower respiratory illness (e.g., cough or shortness of breath).	**AND** Any person, including health care workers, having contact with a laboratory-confirmed COVID-19 case within 14 days of symptom onset.	Fever is either measured temperature $\geq$100.0°F (37.78°C) or subjective fever.
	Fever **AND** symptoms of lower respiratory illness (e.g., cough or shortness of breath).	**AND** A history of travel from affected geographic areas within 14 days of symptom onset.	

Table 3. Continued.

Country/ Issue date	Main criteria		Remarks
	Clinical course of illness	Epidemiological risk	
	Fever with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without an alternative explanatory diagnosis (e.g., influenza).	**AND** No identified source of exposure.	
United States[16] 17 January 2020	Fever **AND** symptoms of lower respiratory illness (e.g., cough, shortness of breath)	**AND** In the last 14 days before symptom onset: (1) History of travel from Wuhan City, China **OR** (2) Close contact with a person who is under investigation for 2019-nCOV while that person was ill	
	Fever **OR** symptoms of lower respiratory illness (e.g., cough, shortness of breath)	**AND** In the last 14 days before symptom onset, close contact with a laboratory-confirmed 2019-nCoV case while that person was ill.	

COVID-19, coronavirus disease 2019; ICU, intensive care unit; nCOV, novel coronavirus.

findings, without requiring serological or polymerase chain reaction (PCR) confirmatory tests.[13] Whether this approach was cost-effective is debatable, but in that unique context, it facilitated the evaluation of suspected cases. Interestingly, the first published case series described clinical features of COVID-19 among hospitalized patients and highlighted that more than 50% of cases had normal white blood cell counts and lymphopenia.[6] Subsequent Chinese protocols quickly adopted and integrated these new data, to help improve accuracy in assessing suspected cases.

Germany

The Robert Koch Institute (Ministry of Health) set four criteria for identifying suspected cases of COVID-19, as presented in Table 2.[14] Every patient who fulfills criterion 1 or 2 is classified as a suspected case, which must be reported to the responsible public health department; the individual must also undergo laboratory diagnostic testing for COVID-19. Criteria 3 and 4 are cases under differential diagnostic clarification; these are tested for COVID-19 without reporting to the responsible public health department unless they have a positive test result. Criteria 3 and 4 show that the threshold of testing in Germany is set very low because there are only a few regions worldwide that have absolutely no COVID-19 cases, and every unclear case of pneumonia is tested in principle. To minimize the risk of spreading COVID-19 to other patients and health care providers, several hospitals have set up a separate specialized area in which patients are tested for COVID-19. Within the framework of influenza surveillance, samples from patients with acute respiratory diseases sent in by sentinel practices of the Working Group on Influenza have also been tested for SARS-CoV-2 at the Robert Koch Institute since 24 February 2020, to detect and monitor the circulation of SARS-CoV-2 at an early stage.[15]

Iran

On 19 February 2020, two people were reported positive for COVID-19 in Qom, a province considered a holy site located south of Tehran.[16] The disease spread dramatically thereafter. Within 3 days, COVID-19 was found in three other regions including Tehran, the capital, and the total number of confirmed cases and deaths increased dramatically. Iranian officials decided not to impose any quarantine, although the government did cancel cultural and sporting events, closed universities, schools, and offices, and placed restrictions on travel between cities. Officials asked everyone to stay at home, even those who were not symptomatic or were not in contact with any confirmed cases.

The first official guideline for the diagnosis and treatment of COVID-19 was published on 27 February (Table 2). Based on this guideline, a suspected case is defined as someone who has a dry cough, chills, sore throat, with or without fever, or alternatively, upper/lower respiratory symptoms with positive imaging findings. A possible case is defined as an individual who meets the criteria of a suspected case and has had close contact with someone with confirmed COVID-19 infection in the past 14 days and who has recently traveled to a COVID-19 epidemic area in the past 14 days.

The Iranian guideline recommends anyone with sore throat and chills, with or without fever, to be evaluated for respiratory distress or hypoxia. If these are present, the patient should be referred to a designated medical center for further evaluation and testing. Febrile patients who are in a high-risk group (as defined in Table 2) without respiratory distress should undergo imaging tests; the recommended imaging modality is either chest radiograph or

computed tomography (CT) scan. If imaging findings are positive, the patient should be referred to a designated medical center. Febrile high-risk patients with normal imaging findings should be quarantined at home, may receive antibiotics, and should be followed daily by public health representatives. Febrile patients who are not in a high-risk group and have no respiratory distress should be quarantined at home. Febrile patients who are in a high-risk group but have a normal chest radiograph or CT scan should be quarantined at home and treated with hydroxychloroquine and oseltamivir.

According to the guideline, outpatients do not need to be tested for COVID-19. Patients with compatible clinical symptoms and radiologic findings are considered to have COVID-19, and treatment can be started in isolation at the designed medical centers. Confirmatory tests should be done only for patients with a positive initial test who require intubation; not all patients need confirmatory testing.

Italy

The first travel-related case of COVID-19 was confirmed in Rome on 30 January 2020.[17] On the same day, a Ministry of Health decree suspended flights from and to China for 90 days. On 31 January, the Italian government declared a state of emergency. However, the first case of secondary transmission was identified in the Lombardy region (northern Italy) on 18 February. After that, the number of confirmed COVID-19 cases increased dramatically in northern Italy. Five days later, on 23 February, the Council of Ministers closed regions with outbreaks (Lombardy and 14 nearby provinces). On 9 March, a Prime Ministerial decree limited the movement of all citizens throughout the entire country and suspended all sporting events and closed schools and universities through

3 April 2020. On the same day, the definition of a suspected case of COVID-19 was revised and the latest definition of the ECDC was fully adopted, as presented in Table 1 and Table 2 (Italy).

Japan

On 16 January 2020, the first confirmed case of a novel coronavirus was reported.[18] The basic policy for countermeasures related to the novel coronavirus was adopted at a ministerial meeting on 21 January.[19] These countermeasures include: (1) border quarantine measures, (2) identification of suspected patients in Japan, (3) establishing operations centers for clinical laboratory testing, (4) ensuring the safety of all Japanese citizens outside of Japan, and (5) providing prompt and accurate information.

Simultaneously, prophylactic countermeasures for viral infection, including safe coughing techniques and handwashing, were widely promoted.[20] Initially, the main testing targets were patients who had stayed in or traveled to Hubei Province, China within the past 14 days. However, human-to-human transmission within Japan was soon detected and as a result, screening targets were expanded to include four criteria (Table 3). However, the complexity of these criteria led to many other people requesting testing. Simpler screening criteria were published on 17 February, as shown in Table 2.

Around this time, the focus of countermeasures changed to attempting to suppress direct transmission via a national social distancing strategy, announced by Prime Minister Shinzo Abe on 29 February 2020. Schools were requested to close temporarily. In addition, mass gatherings and events were recommended to be canceled, postponed, or reduced in size. On 6 March, the restriction on medical insurance was lifted, which enabled health care facilities to use private laboratories for

COVID-19 testing directly, without going through public health centers.[21] Consequently, many more tests could be performed. Additionally, a 14 day quarantine was mandated for all visitors from China and South Korea.[21]

South Korea

The first confirmed case of COVID-19 was diagnosed in South Korea on 20 January 2020.[22] Since then, the number of patients has increased exponentially. The surveillance guidelines from the Korea Centers for Disease Control and Prevention have been revised several times, the most recent being the seventh edition. The guideline is as stated in Table 2, but asymptomatic patients have also been tested at the discretion of a physician, facilitated by the low cost of testing and the abundance of testing kits.

Easy access to testing in South Korea followed the decision of a Seoul-based company to develop test kits back in early January 2020, even before the first patient in the country was diagnosed with COVID-19. Test kits were quickly developed, emergently approved, and massive production was initiated. This response system was forged after the 2015 outbreak of MERS. The country's aggressive approach to diagnosis led to a high number of cases (more than 220,000 tests were performed as of 12 March[22]), and innovative drive-through clinics allowed for efficient and safe high-volume testing while limiting patient–provider contact. In addition, the government pays for the cost of testing if the patient is symptomatic or is referred by a physician. For asymptomatic patients or those not referred by a physician, testing can be performed at a cost to the patient of 140 USD.[22]

The general public also receive emergency text alerts when a positive COVID-19 result is confirmed, including information about the patient's recent travel history.

Although this has raised concerns about privacy, the technology has helped in surveillance of cases and has identified high-risk areas to avoid. It is likely that South Korea's proactive approach in testing a large number of people (by far the highest number outside of China) has resulted in a death rate among confirmed cases that is among the lowest worldwide.

Taiwan

Taiwanese officials began to take action against the novel disease on 31 December 2019, when the WHO was notified about a new type of pneumonia with unknown etiology in Wuhan, China.[23] On 15 January 2020, the government listed this disease, "Severe Pneumonia with Novel Pathogens," as a Category 5 notifiable disease (the same level as MERS-CoV and Ebola virus infection) and mandated that cases be reported within 24 hours.[24] The initial criteria were fever and acute upper airway symptoms with travel or a contact history with people from affected geographical areas (initially only Wuhan and the surrounding area). Indeed, travel history was more strongly emphasized than the clinical condition. However, after a few locally confirmed cases without a definite travel or contact history were identified, the criteria were modified. To prevent underestimating possible community transmission and nosocomial infections, pneumonia together with a high clinical suspicion of infection with a novel pathogen and occupation as a health care provider were added to the modified criteria on 28 February.

Thailand

On 13 January 2020, Thailand was the first country outside of China to report a case of COVID-19.[25] At the end of January, Thailand still had the highest number of confirmed cases outside of China and

remained among the five most affected countries until 23 February. The total number of confirmed cases has increased more slowly in Thailand than in many other countries, and Thailand dropped out of the 10 most affected countries on 1 March. The third version of the criteria used for identifying a suspected case in Thailand was updated on 2 March and is summarized in Table 2. The criteria are very stringent relative to those of other countries, requiring patients to present with both symptoms (fever and any symptoms of respiratory illness) and an epidemiological risk factor to qualify for free testing. Physicians do not advise testing for symptoms alone owing to concerns about the cost of testing.[26]

United Kingdom

Based on the WHO declaration of 30 January 2020 that the novel coronavirus outbreak was a public health emergency of international concern, chief medical officers in the UK promptly raised the risk level of COVID-19 from low to moderate in the country.[27] One day later, the first two cases of COVID-19 were confirmed. Since then, the definition of a suspected case, along with other guidance in the UK, has been updated frequently. Earlier versions of the UK criteria, updated on 10 March (Table 3), seem to be a simplified version of the WHO guidelines as there are two main conditions: clinical cause of illness with epidemiological risk and clinical cause of illness without epidemiological risk. One thing that is explicitly specified as a risk factor is transit in an affected country for any length of time. The initial clinical threshold for patients with epidemiological risk factors was very low because it included patients with a fever but with no other conditions. Nevertheless, 3 days later (13 March), the definition was updated to focus only on the clinical course of illness

and defined two types of suspected cases: those that qualified for hospital admission and those that should stay at home. This change in definition is likely to be the result of a rapid increase in the number of patients presenting to a hospital (Table 2).

United States

On 17 January 2020, the Centers for Disease and Controls (CDC) issued the first guideline for identifying a suspected case of COVID-19.[28] Four days later, the first travel-related case of COVID-19 in the US was reported. Before the end of January, the first case of human-to-human transmission in the US was confirmed. As in many other countries, the situation has been evolving rapidly. On 28 February, the CDC announced an updated version of the diagnostic criteria, with the following major changes, apart from expanding the list of affected geographic areas. First, testing should be considered for the scenario of severe unexplained clinical presentation without epidemiological risk; second, fever can be either subjective or confirmed. In fact, the first condition is aligned with the WHO guideline; the other conditions are proactive measures established by the CDC. On 29 February, the US Food and Drug Administration (FDA) issued a new policy that allowed certain laboratories to use diagnostic tests for COVID-19 before receiving FDA approval.[29] On 4 March, CDC again updated the criteria to include a wider group of symptomatic patients. The new criteria dropped the specific condition of no epidemiologic risk but also emphasized that physicians should use their judgment to determine whether a suspected case requires further investigation.

Discussion

The COVID-19 situation varies from country to country. Effective responses or

countermeasures need the coordinated efforts of not only public health organizations but also governmental and private sectors, including health care systems and the insurance industry, and most importantly, citizens themselves. To better understand the risk of spreading SARS-CoV-2 globally, all countries should ideally have the same criteria for identifying suspected cases. However, in practice, there is no one-size-fits-all guideline in this pandemic and no best or practice criteria have yet been defined. Every country has set its own criteria based on the principle of ALARA (as low as reasonably achievable) given the available resources and the situation of the country, including budget, economic impact, insurance coverage, and so forth.

Based on all the criteria that we have reviewed, most criteria are similar to and appear to be adapted from the WHO criteria, focusing on specific symptoms and epidemiological risk assessment. However, depending on resource allocation, these criteria may fail to capture or may severely underrepresent certain populations including: (1) asymptomatic cases, (2) patients with a financial barrier to accessing laboratory tests (owing to a lack of insurance coverage and high testing costs) and (3) patients with a legal barrier to accessing the health care system (including undocumented immigrants and homeless individuals). The proportion of cases in the latter two groups is dictated to a large extent by the government policies of individual countries.

It is notable that although the WHO advises against people who are not sick wearing a mask in community settings owing to a lack of evidence, the global shortage of disposable surgical masks is a growing problem owing to massive mask use.[30] Therefore, mask policies should be carefully implemented in conjunction with diagnostic criteria and other measures, to prevent a supply shortage and ensuing panic.

Our study has several limitations. First, at the time of writing, the COVID-19 pandemic is ongoing; therefore, the criteria are being updated frequently. However, we do not anticipate dramatic changes in the present criteria. Nevertheless, it is important to review these criteria in real-time at this point in the pandemic, so as to critically assess countermeasures. Second, non-English documents were translated by the co-authors, who are not certified medical translators. However, the authors' medical knowledge and professional background should ensure a high degree of translation accuracy.

Conclusions

Some governments may initially have had political incentives to report a low number of cases of COVID-19 infection. As the virus spreads widely and death tolls rise, governments must appreciate the need for transparency and cooperation. Although the idea of universal testing is attractive, the cost, supply, and availability are currently limiting its widespread implementation in many areas. Adapting updated criteria and other countermeasures will contribute to flattening the curve of infection in this novel global pandemic. According to our findings, there is currently no consensus as to the best diagnostic criteria for identifying a suspected case of COVID-19.

Authors' contributions

AA: Study design and planning; AA, AM, BH, FR, JK, JY, MM, MTC, SFM, and TK: data analyses, interpretation, writing.

Availability of data and materials

The data used in this article are cited in the reference list.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Authors' contributions

AA: Study design and planning; AA, AM, BH, FR, JK, JY, MM, MTC, SFM, and TK: data analyses, interpretation, writing.

ORCID iD

Amporn Atsawarungruangkit https://orcid. org/0000-0003-0622-6839

References

1. Today. Novel coronavirus named 'Covid-19': WHO: Today. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www. todayonline.com/world/wuhan-novel-coro navirus-named-covid-19-who
2. Coronaviridae Study Group of the International Committee on Taxonomy of V. The species severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2. *Nat Microbiol* 2020; 5: 536–544.
3. World Health Organization. *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*. World Health Organization [Internet]. 2020 [cited Mar 10, 2020]. Available from: https: //www.who.int/dg/speeches/detail/who-direc tor-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020
4. Guan WJ, Ni ZY, Hu Y, et al. Clinical Characteristics of Coronavirus Disease 2019 in China. *N Engl J Med* 2020; 382: 1708–1720.
5. Tian S, Hu N, Lou J, et al. Characteristics of COVID-19 infection in Beijing. *J Infect* 2020; 80: 401–406.
6. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet* 2020; 395: 497–506.
7. World Health Organization. *Global surveillance for COVID-19 disease caused by human infection with novel coronavirus (COVID-19): interim guidance, 27 February 2020*. World Health Organization [Internet]. 2020 [cited Mar 10, 2020]. Available from: https: //apps.who.int/iris/handle/10665/331231
8. World Health Organization. *Global Surveillance for human infection with novel coronavirus (2019-nCoV): interim guidance, 31 January 2020*. World Health Organization [Internet]. 2020 [cited Mar 10, 2020]. Available from: https: //apps.who.int/ iris/handle/10665/330857
9. World Health Organization. *Surveillance case definitions for human infection with novel coronavirus (nCoV): interim guidance v1, January 2020*. World Health Organization [Internet]. 2020 [cited Mar 10, 2020]. Available from: https: //apps.who.int/ iris/handle/10665/330376
10. National Health Commission (China). Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 4): National Health Commission (China). 2020 [cited Mar 10, 2020]. Available from: http: //sn.chineseembassy. org/chn/sgdt/P020200130058289681646.pdf
11. National Health Commission (China). Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7): National Health Commission (China). 2020 [cited Mar 10, 2020]. Available from: http: //www.nhc.gov.cn/ yzygj/s7653p/202003/46c9294a7dfe4 cef80dc7f5912eb1989.shtml
12. Dai WC, Zhang HW, Yu J, et al. CT Imaging and Differential Diagnosis of COVID-19. *Can Assoc Radiol J* 2020; 71: 195–200.

13. National Health Commission (China). Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 5): National Health Commission (China). 2020 [cited Mar 10, 2020]. Available from: http: //www.chinacdc.cn/jkzt/crb/xcrxjb/202002/t20200205_212256.html

14. Robert Koch Institute (Germany). *COVID-19: Suspicion Clarification and Measures - Orientation Guide for Physicians (as of March 12, 2020)*. Robert Koch Institute (Germany) [Internet]. 2020 [cited Mar 12, 2020]. Available from: https: //www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Massnahmen_Verdachtsfall_Infografik_Tab.html

15. Robert Koch Institute (Germany). *Epidemiological bulletin 09/2020*. Robert Koch Institute (Germany) [Internet]. 2020 [cited Mar 13, 2020]. Available from: https: //www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2020/Ausgaben/09_20.pdf

16. Abdi M. Coronavirus disease 2019 (COVID-19) outbreak in Iran: actions and problems. *Infect Control Hosp Epidemiol* 2020; 41: 754–755.

17. Ministry of Health (Italy). *Covid-19 - Situation in Italy*. Ministry of Health (Italy) [Internet]. 2020 [cited Mar 12, 2020]. Available from: http: //www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus.jsp?lingua = italiano&id = 5351&area = nuovoCoronavirus&menu = vuoto

18. World Health Organization. *Novel Coronavirus – Japan (ex-China): Disease outbreak news*. World Health Organization [Internet]. 2020 [cited Mar 11, 2020]. Available from: https: //www.who.int/csr/don/16-january-2020-novel-coronavirus-japan-ex-china/en

19. Prime Minister's Office in Japan. *Ministerial Meeting on Countermeasures Related to the Novel Coronavirus: January 24, 2020*. Prime Minister's Office in Japan [Internet]. 2020 [cited Mar 11, 2020]. Available from: http: //japan.kantei.go.jp/98_abe/actions/202001/_00024.html

20. Ministry of Health, Labour and Welfare (Japan). *Q & A on Coronavirus Disease 2019 (COVID-19)*. Ministry of Health, Labour and Welfare (Japan) [Internet]. 2020 [cited Mar 11, 2020]. Available from: https: //www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/dengue_fever_qa_00014.html

21. Ministry of Health, Labour and Welfare (Japan). *About Coronavirus Disease 2019 (COVID-19)*. Ministry of Health, Labour and Welfare (Japan) [Internet]. 2020 [cited Mar 11, 2020]. Available from: https: //www.mhlw.go.jp/stf/seisakunitsuite/bunya/newpage_00032.html

22. Parodi E, Jewkes S, Cha S, et al. Special Report: Italy and South Korea virus outbreaks reveal disparity in deaths and tactics. Reuters. 2020 [cited Mar 12, 2020]. Available from: https://www.reuters.com/article/health-coronavirus-response/rpt-special-report-italy-and-south-korea-virus-outbreaks-reveal-disparity-in-deaths-and-tactics-idUSL4N2B55E0

23. Wang CJ, Ng CY and Brook RH. Response to COVID-19 in Taiwan: big Data Analytics, New Technology, and Proactive Testing. *JAMA* 2020; 323: 1341–1342.

24. Taiwan Centers for Disease Control. Prevention and Control of COVID-19 in Taiwan: Taiwan Centers for Disease Control. 2020 [cited 2020 Jun 1, 2020]. Available from: https: //www.cdc.gov.tw/En/Category/Page/0vq8rsAob_9HCi5GQ5jH1Q

25. World Health Organization. Coronavirus disease 2019 (COVID-19) Situation Report: The World Health Organization. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

26. Matichon. The spokesman for the COVID-19 Center answers the question: Is the cost of the COVID-19 test expensive? Matichon. 2020 Mar 8, 2020. Available from: https://www.matichon.co.th/politics/news_2037371

27. Department of Health and Social Care and Public Health England. Number of coronavirus (COVID-19) cases and risk in the UK: Department of Health and Social Care and Public Health England. 2020 [cited 2020 Mar 10, 2020]. Available from: https:

//www.gov.uk/guidance/coronavirus-covid-19-information-for-the-public

28. Centers for Disease Control and Prevention (United States). Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV) in Wuhan, China: National Health Commission (China). 2020 [cited 2020 Mar 10, 2020]. Available from: https: //emergency.cdc. gov/han/HAN00426.asp

29. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics: U.S. Food and Drug Administration. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www.fda. gov/news-events/press-announcements/coro navirus-covid-19-update-fda-issues-new-poli cy-help-expedite-availability-diagnostics

30. Leung CC, Lam TH, and Cheng KK. Mass masking in the COVID-19 epidemic: people need guidance. *Lancet* 2020; 395: 945.

31. European Centre for Disease Prevention and Control. Case definition and European surveillance for COVID-19, as of 2 March 2020: European Centre for Disease Prevention and Control. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www.ecdc.europa.eu/en/case-definition-and-european-surveillance-human-infection-novel-coronavirus-2019-ncov

32. Ministry of Health and Medical Education of the Islamic Republic of Iran. Flowchart for Diagnosis and Treatment of COVID-19 at Outpatient and Inpatient Levels: Ministry of Health and Medical Education of Islamic Republic of Iran. 2020 [cited 2020 Mar 10, 2020]. Available from: http: //dme.behdasht. gov.ir/uploads/Felo_Tashkish.pdf

33. Ministry of Health, Labour and Welfare (Japan). Guideline for Consultation or Visiting Medical Institutions (as of Mar 4, 2020): Ministry of Health, Labour and Welfare. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www.mhlw.go.jp/ content/10900000/000597518.pdf

34. Ministry of Health (Italy). *Circular of the Ministry of Health. COVID-19, Update of the Case Definition.* Ministry of Health (Italy) [Internet]. 2020 [cited Mar 12, 2020]. Available from: http: //www.trovanorme.

salute.gov.it/norme/renderNormsanPdf? anno = 2020&codLeg = 73622&parte = 1% 20&serie = null

35. Korea Centers for Disease Control & Prevention. *Surveillance Guideline for COVID-19 Disease (7-1 edition).* Korea Centers for Disease Control & Prevention (KCDC) [Internet]. 2020 [cited Mar 14, 2020. Available from: https: //www.cdc.go. kr/gallery.es?mid = a20503010000&bid = 0002&list_no = 144644&act = view

36. Taiwan Centers for Disease Control. Severe Pneumonia with Novel Pathogens: Taiwan Centers for Disease Control. 2020 [cited 2020 Mar 11, 2020]. Available from: https: //www.cdc.gov.tw/File/Get/ I3mCSmJZjgHUTaGegZmfoA

37. Department of Disease Control of the Ministry of Public Health (Thailand). Definition of Suspected Case for COVID-19 (Mar 2, 2020): Department of Disease Control of the Ministry of Public Health (Thailand). 2020 [cited 2020 Mar 10, 2020]. Available from: https: //ddc.moph.go.th/vir alpneumonia/file/guidelines/G38_020363. pdf

38. Public Health England. COVID-19: investigation and initial clinical management of possible cases (Updated 13 March 2020): Public Health England. 2020 [cited 2020 Mar 14, 2020]. Available from: https: //www.gov.uk/government/publications/ wuhan-novel-coronavirus-initial-investiga tion-of-possible-cases/investigation-and-ini tial-clinical-management-of-possible-cases-of-wuhan-novel-coronavirus-wn-cov-infection

39. Centers for Disease Control and Prevention (United States). Evaluating and Reporting Persons Under Investigation (PUI): Centers for Disease Control and Prevention. 2020 [cited 2020 Mar 10, 2020]. Available from: https: //www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

40. National Institute of Infectious Diseases (Japan). *7th Designated Infectious Disease.* National Institute of Infectious Diseases (Japan) [Internet]. 2020 [cited Mar 11, 2020]. Available from: https://www.niid.go. jp/niid/images/epi/corona/2019nCoV-05-200209-2.pdf

41. Public Health England. COVID-19: investigation and initial clinical management of possible cases (Updated 10 March 2020): Public Health England. 2020 [cited 2020 Mar 10, 2020]. Available from: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-initial-investigation-of-possible-cases/investigation-and-initial-clinical-management-of-possible-cases-of-wuhan-novel-coronavirus-wn-cov-infection

42. Centers for Disease Control and Prevention (United States). Update and Interim Guidance on Outbreak of Coronavirus Disease 2019 (COVID-19): National Health Commission (China). 2020 [cited 2020 Mar 10, 2020]. Available from: https://emergency.cdc.gov/han/2020/HAN00428.asp