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Understanding COVID-19 new diagnostic guidelines – a message of reassurance from an internal medicine doctor in Shanghai

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The change in diagnostic criteria for COVID-19 diagnosis in Hubei province, released on 12 February 2020 by the National Health Commission of Hubei Province, caused a shift in the numbers of total cases from ≈43,000 to ≈60,000 overnight.

Understandably, this has caused significant turmoil in the lay public, especially in western countries, as well as some confusion amongst specialists. The aim of this article is to explain the rationale for the choice of the new criteria and the meaning of the new data, from the perspective of the authors (EB, GC) based in Shanghai, China, both struck by the level of panic and emotional distress in many people that has been generated by the new data.

The COVID-19 virus causes a pneumonia syndrome, with specific and already well-described symptoms [1–3]. As in Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), because of the high infection rate, the new virus poses a risk of a global pandemic, and all measures must be taken to ensure control of infection spread [4]. In this context, timely diagnosis is a crucial element.

Initially, the diagnosis was based on real-time fluorescent RT-PCR or genetic sequencing of respiratory specimens or blood specimens, which required 1–2 days for completion (currently as rapid as 6 hours). The case numbers released up to 12 February referred to patients tested positive for the virus based on such techniques.

Based on the knowledge that accumulated over the weeks, though, the guidelines for COVID-19 diagnosis have been constantly updated; in addition, the diagnostic criteria and algorithm for patients in and outside of Hubei differ slightly. The changes introduced for Hubei province in the last version (the fifth, released on 12 February), added typical pneumonia findings on pulmonary computed tomography (CT) as one of the clinical diagnostic criteria, next to clinical symptoms (fever, cough) and history of travel in the Hubei region. With the new criteria, therefore, patients previously labelled as "suspected cases" shifted to "clinically diagnosed cases" (table 1).

Clinical diagnosis is the best option for identifying patients as it allows for quick and efficient case management. A similar, standard procedure was applied in the case of SARS and MERS too. A recent publication has supported the notion that bilateral ground-glass opacities in the posterior and peripheral lungs seen on a CT scan are associated with confirmed infection [5]. Clinically diagnosed patients have been receiving standardised treatment as soon as possible, without waiting for the genetic test to be completed. Thus, their official inclusion in the new criteria was a formal step rather than any change in the standard of care. Immediate treatment of each patient increases the success outcome rate, decreasing fatality, which is still difficult to estimate [6].

It is the responsibility of media and science communicators to ensure that a proper explanation of the new statistics is provided; one option might be to clearly separate in statistics the number of clinically vs genetically confirmed cases.

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Table 1: Diagnostic criteria for COVID-19 infection – development of version 4 to version 6. Version 5 implemented clinically diagnosed cases for Hubei province.

	Version 4	Version 5		Version 6
Publication date	**27 Jan. 2020**	**5 Feb. 2020**		**18 Feb. 2020**
Suspected cases Any of the epidemiological history criteria plus any two of the clinical manifestations; OR three clinical manifestation criteria	**Epidemiological anamnesis**			
	Nationwide	**Hubei**	**Outside of Hubei**	**Nationwide**
	1. Travel history or residence in Wuhan or other areas with persistent local transmission within 14 days prior to onset of patient's symptoms 2. Exposure (14 days prior to the onset of the disease) to individuals with fever or respiratory symptoms from Wuhan or other areas with persistent local case transmission 3. Family clusters or epidemiological associations with novel coronavirus infections	1. Travel history or residence in Wuhan and its surrounding areas within 14 days before the onset of the disease, or in other communities where cases have been reported 2. Contact history with individuals tested positive for novel coronavirus infection within 14 days before the onset of patient's symptoms 3. Patient with fever or respiratory symptoms who came in contact with patients from Wuhan and surrounding areas or from communities with reported case within 14 days prior to the onset of patient's symptoms 4. Family clusters or epidemiological associations with novel coronavirus infections	1. Travel history or residence in Wuhan and its surrounding areas within 14 days before the onset of the disease, or in other communities where cases have been reported 2. Contact history with individuals tested positive for novel coronavirus infection within 14 days before the onset of patient's symptoms 3. Patient with fever or respiratory symptoms who came in contact with patients from Wuhan and surrounding areas or from communities with reported case within 14 days prior to the onset of patient's symptoms 4. Family clusters or epidemiological associations with novel coronavirus infections	1. Travel history or residence in Wuhan and its surrounding areas within 14 days before the onset of the disease, or in other communities where cases have been reported 2. Contact history with individuals tested positive for novel coronavirus infection within 14 days before the onset of patient's symptoms 3. Patient with fever or respiratory symptoms who came in contact with patients from Wuhan and surrounding areas or from communities with reported case within 14 days prior to the onset of patient's symptoms 4. Family clusters or epidemiological associations with novel coronavirus infections
	Clinical manifestations			
	1. Fever 2. Chest CT features of multiple small patchy shadows and interstitial changes, obvious extrapulmonary bands (early stage). Multiple ground-glass infiltration and infiltrates in both lungs (later stages). In severe cases, pulmonary consolidation and pleural effusion. 3. At an early stage of the disease, the total white blood cell count is normal or decreased, or the lymphocyte count is decreased.	1. Fever and/or respiratory symptoms 2. At an early stage of the disease, the total white blood cell count is normal or decreased, or the lymphocyte count is decreased.	1. Fever and/or respiratory symptoms 2. Chest CT features of multiple small patchy shadows and interstitial changes, obvious extrapulmonary bands (early stage). Multiple ground glass infiltration and infiltrates in both lungs (later stages). In severe cases, pulmonary consolidation and pleural effusion. 3. At an early stage of the disease, the total white blood cell count is normal or decreased, or the lymphocyte count is decreased.	1. Fever and/or respiratory symptoms 2. Chest CT features of multiple small patchy shadows and interstitial changes, obvious extrapulmonary bands (early stage). Multiple ground glass infiltration and infiltrates in both lungs (later stages). In severe cases, pulmonary consolidation and pleural effusion. 3. At an early stage of the disease, the total white blood cell count is normal or decreased, or the lymphocyte count is decreased.
Confirmed cases Suspected case with one item of aetiological evidence	1. Real-time fluorescent RT-PCR detected a nucleic acid of novel coronavirus in respiratory (sputum, pharyngeal swabs, and lower respiratory tract secretions) or blood samples OR 2. Sequencing of virus genes in respiratory or blood samples, highly homologous to 2019-nCoV	1. Real-time fluorescent RT-PCR detected a nucleic acid of novel coronavirus in respiratory (sputum, pharyngeal swabs, and lower respiratory tract secretions) or blood samples OR 2. Sequencing of virus genes in respiratory or blood samples, highly homologous with 2019-nCoV	1. Real-time fluorescent RT-PCR detected a nucleic acid of novel coronavirus in respiratory (sputum, pharyngeal swabs, and lower respiratory tract secretions) or blood samples OR 2. Sequencing of virus genes in respiratory or blood samples, highly homologous with SARS-CoV-2	1. Real-time fluorescent RT-PCR detected a nucleic ccid of novel Coronavirus in respiratory (sputum, pharyngeal swabs, and lower respiratory tract secretions) or blood samples OR 2. Sequencing of virus genes in respiratory or blood samples, highly homologous with SARS-CoV-2
Clinically diagnosed cases		Suspected cases with typical radiographic features		

Table based on officially available resources, translated by Dr Guoting Chen from: Diagnosis and treatment scheme of novel coronavirus pneumonia (Trial version 4th)., Diagnosis and treatment scheme of novel coronavirus pneumonia (Trial version 5th), Diagnosis and treatment scheme of novel coronavirus pneumonia (Trial version 6th).

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