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Can We even Define What WHO Member States Are Voting for?

REPPARE

April 2024

With Member States of the World Health Organization (WHO) negotiating new agreements to centralize management of pandemics with an annual budget of over \$31.5 billion, it would be reasonable to assume that everyone was clear on what a pandemic actually is. Surprisingly, this is not the case. Although countries will be voting in two months on a new Pandemic Agreement and amendments to the International Health Regulations (IHR) to grant the WHO wide authority over pandemic management, there is no universally-agreed definition of "pandemic."

What degree of severity is required? How widespread must it be? What proportion of the population must be at risk?

An outbreak of common cold crossing borders fits many pandemic definitions, as does a repeat of the medieval Black Death. International agreements are normally formed around a definable problem, but the world is about to invest tens of billions without a solid basis to predict costs and benefits. In other words, there is no clear agreement on what the World Health Assembly is actually agreeing to.

A History of Pandemics

When we now speak of a pandemic, we usually mean the global spread of SARS-CoV-2 that began in 2019. The word evokes images of empty streets and closed markets, of masked faces and silent people standing 6 feet apart. This drives the sense of urgency that policy makers are currently responding to through the design of new pandemic documents. Many pandemic prevention, preparedness and response (PPPR) documents suggest that these policies are an essential response by claiming a 50% chance of a Covid-19-like pandemic in the next 25 years or referring to the economic costs of Covid-19 to support claims of return on investment. This approach is problematic as it fails to distinguish between the direct costs of the disease and the effects of the very unusual response.

The etymology of the word "pandemic" comes from the ancient Greek root dêmos $(\delta \tilde{\eta} \mu o \varsigma, people, populace)$ with the related "epidemic" and "pandemic." The prefix pan-(ancient Greek $\pi \acute{\alpha} v$) generally means all or every; thus, pandemic is derived from the ancient Greek concept $\pi \acute{\alpha} v \delta \eta \mu o \varsigma$ (of or

belonging to the whole people, public). The term usually refers to infectious diseases, although some use of pandemic can be more broadly colloquial, for example speaking of a "pandemic of obesity." What distinguishes pandemics (and epidemics) from endemic diseases is that they affect a large number of people in a relatively short time span and in excess of normal expectancy. What sets pandemics apart from epidemics in people's minds is a wider geographic spread across national borders.

Some of the worst pandemics recorded in history followed the European conquest of the Americas, bringing new pathogens to an immunologically naïve population. Such conditions do not exist in today's globalized world. Other devastating pandemics were caused by bacteria like cholera or the plague, the latter being responsible for the Black Death in the 14th century that wiped out perhaps a third of the European population. Improved sanitation and the discovery of antibiotics has since fundamentally reduced the threat of bacterial infections, once the main driver of pandemics. The last major

pandemic the world faced prior to Covid-19 was the Spanish flu of 1918. Accordingly, up until the Covid-19 pandemic, "pandemic preparedness" almost universally referred to influenza pandemics. The WHO published their first influenza pandemic plan in 1999, motivated by the first recorded human

infections with avian flu H₅N₁. The plan was updated several times, the <u>last time</u> in 2009 and defines several "pandemic phases." These constitute the only pandemic definitions the WHO has published in official guidance and remain specific to influenza.

The Swine Flu Controversy

When the WHO declared the H₁N₁ Swine flu a pandemic in 2009, despite it being no more severe than normal seasonal influenza. a controversy erupted over what defines a "pandemic." While the WHO's pandemic plan had always focused on the spread of a novel subtype of influenza without requiring it to be extraordinarily severe, a definition on the WHO's website read for six years: "An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in several simultaneous epidemics worldwide with enormous numbers of deaths and illness." In response to a query by a CNN journalist questioning the need for a condition of "enormous" severity, the definition of pandemic influenza on the WHO homepage was changed in May 2009, removing the phrase "with enormous numbers of deaths and illness." Instead, the new definition clarified that "pandemics can be either mild or severe in the illness and death they cause, and the severity of a pandemic can change over the course of that pandemic."

Although the definition on the website had no practical effects, the fact that the change happened shortly before declaring Swine flu a pandemic <u>raised suspicion</u>. In March 2011, the European Parliament adopted a resolution on the evaluation of the

management of H1N1 influenza in 2009-2010 in the European Union. The <u>resolution</u> "urges the WHO to revise the definition of a pandemic, taking into consideration not only its geographical spread but also its severity."

Peter Doshi pointed out in a 2009 article "the elusive definition of pandemic influenza" that the earlier definition on the WHO website is illustrative of a wider perception of pandemics as catastrophic in nature. He points to another text on the WHO website, where it was stated that even in a best-case scenario of an influenza pandemic, it would lead to 4 to 30 times more deaths than seasonal influenza. At the same time, the WHO also refers to the Asian flu of 1957-1959 and the Hong Kong flu of 1968-1970 as being pandemics, although they were not extraordinarily severe. Doshi further argued that "we must remember the purpose of "pandemic preparedness," which was fundamentally predicated on the assumption that pandemic influenza requires a different policy response than does annual, seasonal influenza. As a result, Doshi and others argued that the "pandemic" label must of necessity carry a notion of severity, for otherwise the rationale behind the original policy of having "pandemic plans" distinct from ongoing public health programmes would be called into question.

This tension of definitional appropriateness remains today. On the one hand, pandemics are portrayed as catastrophic events or even an existential threat. On the other, Swine flu is mentioned as an example of a pandemic despite causing fewer deaths than a typical influenza season. Alongside Swine flu, diseases such as SARS-I, MERS, Zika,

and/or Ebola are often used as examples to illustrate a perceived increase in <u>pandemic risk</u>, although <u>SARS-I</u>, <u>MERS</u>, and <u>Zika</u> each have less than I,000 deaths recorded globally, ever, and Ebola is zoonotically confined to central and western regions of Africa.

Pandemic or PHEIC?

In an earlier draft of the Pandemic Agreement, the Intergovernmental Negotiating Body (INB) presented a notably specific definition of a pandemic: "the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality, and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control." This definition is more restrictive than most existing definitions of pandemics, as it requires a pathogen to cause severe morbidity and mortality and to spread globally. This might be widely considered to justify unusual measures of intervention. However, the INB discarded its pandemic definition in the latest draft of the Pandemic Agreement without replacement.

The INB's discarded, and highly specific, definition stood in contrast to the definition used by the World Bank in the <u>establishing document</u> of the Financial Intermediary Fund for PPPR (now known as The Pandemic Fund). There, a pandemic is defined as "an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and

usually affecting a large number of people." The new draft of the Pandemic Agreement now includes the following definition of a "pathogen with pandemic potential," namely "any pathogen that has been identified to infect a human and that is: novel (not yet characterized) or known (including a variant of a known pathogen), potentially highly transmissible and/or highly virulent with the potential to cause a public health emergency of international concern." It does not *actually* have to make anyone sick.

Unlike the term pandemic, a Public Health **Emergency of International Concern** (PHEIC) is defined in the IHR (2005) as "an extraordinary event which is determined ... to constitute a public health risk to other states through the international spread of disease and to potentially require a coordinated international response." PHEICs are not limited to infectious disease outbreaks but can extend to health risks from chemical or nuclear contamination. Member States are required to notify the WHO about events that may result in a PHEIC, presumably determining "extraordinary" and "potentially" in some generally accepted context.

Once an alert is made, an ad-hoc emergency committee is convened at the WHO to consult the Director-General about the

determination and termination of a PHEIC as well as issuing temporary recommendations to affected States. Although an emergency committee consults, including a member from the affected State(s), all decision-making power lies with the Director-General and it is at their discretion whether and to what degree the committee's recommendations are used. This political aspect is important, as the new Amendments proposed for the IHR would make WHO recommendations during a PHEIC, such as border closures and mandatory vaccinations, binding for member States.

Defining pandemics as potential PHEICs harmonizes the two ongoing negotiations

for the Pandemic Agreement and IHR amendments. Many critics claim that the IHR amendments would give the WHO Director-General the power to unilaterally declare a pandemic. Yet, the Director-General already has the power to declare a PHEIC under the existing regulations (although the IHR amendments may make such a declaration more consequential). Currently the proposed amendments do not define pandemics. While it seems logical to harmonize both policies, it is important to remember that the IHR are broader in scope, and not all PHEICs are pandemics. The WHO Director-General declared six PHEICs for infectious disease outbreaks in the last ten years, the latest being Mpox (monkeypox) in 2022.

Disease Burden of Pandemics

Covid-19 was the pandemic with the highest recorded death toll since the Spanish flu. The official number of seven million represents the equivalent of around five years of deaths from tuberculosis, but occurred in a far older age group. Given that the burden of tuberculosis had been stable or decreasing prior to the Covid-19 pandemic, as has the burden of HIV/AIDS and malaria (they are now rising again), these diseases are not usually referred to as pandemics.

However, the Global Fund writes that these three diseases "shouldn't be labelled as 'just' epidemics or endemic. They are pandemics that have been beaten in rich countries." This is a critical point. The burden of any given pathogen is not exclusively determined by its biology but by the demographic, economical, and institutional context in which it spreads. If these long-term diseases

are actually the largest current pandemics, then is a rushed response in 2024 the best approach to them?

SARS-CoV-2 increased the risk of death and severe disease predominantly for people over 65 who constitute a large and growing fraction of populations in rich countries. However, the median age in Sub-Saharan Africa is 18 years and only three percent of the population is 65 or older. So, tuberculosis, malaria, and HIV/AIDS, affecting far younger populations in these countries, are their health priorities. Cholera was also regarded as a pandemic in the past when affecting wealthier populations and has now been largely forgotten in high- and middle-income countries. Meanwhile the cholera bacterium still causes outbreaks in places like Haiti where people have poor access to clean water and sanitation.

Getting this right is essential. By focusing on relatively low-burden pandemics that affect the whole planet, including wealthy populations, we unavoidably shift the focus from high-burden diseases afflicting low-income populations. This raises fairness concerns and contrasts the rhetoric on equity used in the draft Pandemic Agreement. It might therefore make sense to shift focus from pandemics to health emergencies of international concern, which may be geographically limited, as in the case of Ebola. Doing so may allow resources to be mobilised proportional to risk and need,

rather than investing vast amounts of money, time, and social capital into an obscure pandemic preparedness agenda that struggles to even define its aims.

Continuously conflating the concept of pandemic preparedness and PHEIC only creates confusion while obscuring the obvious political processes involved. If the WHO wants to convince the world to prepare for pandemics, and calm down fears of potential misuse of the pandemic label via a new governance process, then they need to provide clarity on what they are actually talking about.

REPPARE Team, University of Leeds. April 2024

<u>REPPARE</u> involves a multidisciplinary team convened by the University of Leeds, and led by two principal investigators.

Garret Wallace Brown

Garrett Wallace Brown is Chair of Global Health Policy at the University of Leeds. He is Co-Lead of the Global Health Research Unit and will be the Director of a new WHO Collaboration Centre for Health Systems and Health Security. His research focuses on global health governance, health financing, health system strengthening, health equity, and estimating the costs and funding feasibility of pandemic preparedness and response. He has conducted policy and research collaborations in global health for over 25 years and has worked with NGOs, governments in Africa, the DHSC, the FCDO, the UK Cabinet Office, WHO, G7, and G20.

David Bell

David Bell is a clinical and public health physician with a PhD in population health and background in internal medicine, modeling and epidemiology of infectious disease. Previously, he was Director of the Global Health Technologies at Intellectual Ventures Global Good Fund in the USA, Programme Head for Malaria and Acute Febrile Disease at the Foundation for Innovative New Diagnostics (FIND) in Geneva, and worked on infectious diseases and coordinated malaria diagnostics strategy at the World Health Organization. He has worked for 20 years in biotech and international public health, with over 120 research publications. David is based in Texas, USA.

Blagovesta Tacheva

Blagovesta Tacheva is a REPPARE Research Fellow in the School of Politics and International Studies at the University of Leeds. She has a PhD in International Relations with expertise in global institutional design, international law, human rights, and humanitarian response. Recently, she has conducted WHO collaborative research on pandemic preparedness and response cost estimates and the potential of innovative financing to meet a portion of that cost estimate. Her role on the REPPARE team will be to examine current institutional arrangements associated with the emerging pandemic preparedness and response agenda and to determine its appropriateness considering identified risk burden, opportunity costs and commitment to representative / equitable decision-making.

Jean Merlin von Agris

Jean Merlin von Agris is a REPPARE funded PhD student at the School of Politics and International Studies at the University of Leeds. He has a Masters of Science degree in development economics with a special interest in rural and agricultural development. Recently, he has focused on researching the effects of non-pharmaceutical interventions during the Covid-19 pandemic. Within the REPPARE project, Jean will focus on assessing the assumptions and the robustness of evidence-bases underpinning the global pandemic preparedness and response agenda, particularly assumed estimates regarding the frequency and severity of pandemics.