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When does a major outbreak become a Public Health Emergency of International Concern?

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Could the pandemic of the century have been averted? The process by which WHO decides whether to declare a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations has drawn criticism. Reports have condemned the 4-month delay by WHO after the international spread of Ebola in west Africa before declaring a PHEIC.[1] The Democratic Republic of the Congo, now experiencing the second largest Ebola outbreak in recorded history, notified WHO of the outbreak on Aug 1, 2018, but WHO required four Emergency Committee meetings, including on Oct 17, 2018 (216 confirmed cases, 139 deaths, and 64% case fatality ratio), and April 12 and June 14, 2019 (four confirmed cases in Uganda). Justifying their response, the Emergency Committee said that "the cluster of cases in Uganda is not unexpected".[2] A PHEIC was finally declared at the fourth Emergency Committee meeting on July 17, 2019 (2501 cases and 1668 deaths), almost a year after initial notification. The International Health Regulations[3] do not require actual international spread, only a high potential for that spread, and thus the criteria for a PHEIC had already been met by the second Emergency Committee meeting.[4] Notably, the PHEIC declaration coincided with increased resourcing and international focus, leading to a major reduction in Ebola cases.

Global health scholars have criticised the Emergency Committee process as lacking transparency, using "irrelevant considerations, undue influence and political interference",[5] and delaying declaration when International Health Regulations criteria have been met.

The coronavirus disease 2019 (COVID-19) outbreak originating in China and reported to WHO on Dec 31, 2019, suggests that little has changed. The PHEIC declaration for COVID-19 occurred well after most public health experts had concluded that this outbreak posed a major international threat. At the first Emergency Committee meeting on Jan 22, 2020 (309 cases and six deaths reported in mainland China; five confirmed cases in four countries or territories), the Emergency Committee said it did not have key facts from China. It extended the meeting to the next day, when cases had risen to 571, with 17 deaths and ten cases in seven other countries or territories. Yet, the Emergency Committee could not achieve consensus, and the Director-General concluded that the outbreak was "an emergency in China, but it had not yet become a global health emergency".[6]

Again, the process appeared "more political than technical", as a *Lancet* Editorial described Ebola in the Democratic Republic of Congo, adding that "the committee seems to have favoured local protectiveness over global galvanising".[7] By the time the Emergency Committee declared a PHEIC for COVID-19 on Jan 30, 2020, 7736 cases and 179 deaths had been confirmed in mainland China, with 107 cases confirmed in 21 other countries.

Delays in declaring a PHEIC could have serious detrimental consequences, lulling governments and donors into a false sense of security, because they could reason that if WHO does not consider the situation an international emergency, then it does not require a surge response.

The legal definition of a PHEIC is clear, as "an extraordinary event that may constitute a public health risk to other countries through international spread of disease and may require an international coordinated response."[3] The purpose of the declaration is to focus international attention on acute public health risks that "require coordinated mobilisation of extraordinary resources by the international community" for prevention and response.[3]

The PHEIC process requires urgent reform. First, the all-or-nothing nature of the assessment generates confusion. We therefore propose a multilevel PHEIC process with each level defined by objective epidemiological criteria and paired with specific readiness actions. Level 1 PHEIC alert should indicate a high risk outbreak in a single country, with the potential for international spread requiring concerted public health efforts to contain and manage it locally. Level 2 PHEIC should imply that multiple countries have had importations and that limited spread has occurred in those countries. Level 3 PHEIC would indicate large clusters in multiple countries, with evidence of ongoing local transmission. This tiering would provide less ambiguous risk signalling, while also encouraging

For the **London School of Hygiene & Tropical Medicine's COVID-19 tracker** see https://vac-lshtm.shinyapps.io/ncov_tracker/

For the **situation reports on Ebola in the Democratic Republic of the Congo** see https://www.who.int/emergencies/diseases/ebola/drc-2019/situation-reports

earlier, proportionate public health measures when they are most effective.

Second, WHO should convene an expert consensus meeting to establish objective, evidence-based epidemiological and containment criteria to transparently guide its decision making processes. The draft algorithm under Annex 2 of the International Health Regulations[8] (appendix) already includes critical elements, but there are also subjective considerations, such as restraints on international travel and trade. The algorithm contains perverse relative weightings, treating the five categories as equivalent.

See Online for appendix

The clear purpose of a PHEIC declaration is to catalyse timely evidence-based action, to spur increased international funding and support, and to limit the public health and societal impacts of emerging and re-emerging disease risks. In the aftermath of the COVID-19 pandemic, International Health Regulation reform must be an ethical imperative for more rapid and effective responses to novel infectious diseases.

We declare no competing interests.

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