UPDATING THE INTERNATIONAL HEALTH REGULATIONS: REVISING IHR DECISION INSTRUMENTS AND THE BINARY PHEIC DECLARATION SYSTEM

RUPA R. PATEL[*]

MADALINE GEORGE[**]

I. AN INCREASINGLY URGENT NEED FOR REFORM

In 2005, in response to the 2002–2003 Severe Acute Respiratory Syndrome (SARS) pandemic, the World Health Assembly[1] adopted the International Health Regulations (IHR 2005).[2] The Regulations, which replace their predecessor from 1969, aimed to modernize global health threat monitoring, reporting, and response with the hopes of reducing morbidity, mortality, and socioeconomic repercussions. The IHR 2005 require its 196 States Parties to notify the World Health Organization (WHO) of "all events which may constitute a public health emergency of international concern."[3] To accomplish this goal, the IHR include two key components, Annex 1 and Annex 2, which rely sequentially on each other, to calculate a potential global health threat. Annex 1 obligates States Parties to have the capacity for disease surveillance, to conduct urgent report assessment within forty-eight hours, and to effectively minimize spread. Annex 2 is a decision instrument for States' National Focal Points (NFP)[4] to determine if an event is required to be reported to the WHO (*i.e.*, is "notifiable"). All notifiable events must be reported within twenty-four hours if the threat meets two of four criteria. Once an event is reported, an Emergency Committee and the Director-General may declare a Public Health Emergency of International Concern (PHEIC), initiating a coordinated international response, including temporary recommendations

* Dr. Rupa Patel is an Assistant Professor in the Division of Infectious Diseases at Washington University School of Medicine in Saint Louis, Missouri. That authors would like to extend their deep gratitude to Madeleine Denny for her superb research assistance throughout the course of this project.

** Madaline George is the Senior Research Fellow at the Whitney R. Harris World Law Institute at Washington University School of Law in Saint Louis, Missouri. She is also the Membership and Program Office at the International Law Association (American Branch).

1 The World Health Assembly is the decision-making body of the World Health Organization ("WHO").

2 World Health Org., 2005 International Health Regulations (3d ed. 2016), https://www.who.int/publications/i/item/9789241580496 [hereinafter IHR].

3 IHR, *supra* note 2, art. 6(1).

4 "Under the IHR, each State Party is required to designate or establish a NFP, a national office or center (not individual person) that is accessible at all times for IHR-related communications with WHO and relevant sectors within the country." *See Strengthening health security by implementing the International Health Regulations (2005): National IHR Focal Point*, WORLD HEALTH ORG., https://www.who.int/ihr/nfp/en/.

such as trade travel restrictions to prevent international spread. Since 2009, the WHO has declared six PHEICs.[5]

As the only legally binding instrument regarding international disease prevention and control, the IHR play a key role in global health security. When the IHR 2005 came into effect in June 2007, it was widely hoped that this new document would remedy some of the problems its predecessor encountered. The IHR 1969 was unable to account for emerging infectious diseases which spanned beyond the six quarantinable diseases it was bound to, nor did it adequately define a process for global action to minimize spread.[6] Yet less than two years after its adoption, the ineffectiveness of the IHR has been demonstrated by miscalculations during the Ebola and swine flu pandemics, as well as the current COVID-19 pandemic. These failures reveal similar limitations of the IHR 2005 to its predecessor in its inability to keep up with a dynamically changing environment, population growth and migration, emerging diseases, natural disasters, and other unpredictable situations.[7]

The novel coronavirus, SARS-CoV-2, which causes COVID-19, has claimed over 2.5 million lives worldwide since December 2019.[8] The estimated death toll, thus far, is more than three thousand times higher than that of the SARS pandemic,[9] and is expected to grow in the face of continued poor pandemic control and the development of several viral variants. It is widely accepted that the WHO's declaration of a PHEIC on January 30, 2020, was a delayed response and resulted in valuable time lost to prevent international spread, deaths, and economic loss.[10] Many reasons have been cited for this delay, but noteworthy concerns directly tied to the IHR include: (1) unsatisfied and difficult to attain core capacity

5 Lucia Mullen, Christina Potter, Lawrence O. Gostin, Anita Cicero & Jennifer B. Nuzzo, *An analysis of International Health Regulations Emergency Committees and Public Health Emergency of International Concern Designations*, 5 BMJ GLOB. HEALTH (2020).

6 IHR, *supra* note 2.

7 *See generally* Lawrence O. Gostin, Roojin Habibi & Benjamin Mason Meier, *Has Global Health Law Risen to Meet the COVID-19 Challenge? Revising the International Health Regulations to Prepare for Future Future Threats*, 48 J.L. MED. & ETHICS 376 (2020).

8 *COVID-19 Dashboard*, JOHNS HOPKINS UNIV. MED., https://coronavirus.jhu.edu/map.html (last accessed Feb. 18, 2021).

9 The SARS pandemic claimed 774 lives. *Summary of probable SARS cases with onset of illness from 1 November 2002 to 31 July 2003*, WORLD HEALTH ORG. (July 24, 2015), https://www.who.int/publications/m/item/summary-of-probable-sars-cases-with-onset-of-illness-from-1-november-2002-to-31-july-2003.

10 *See The Global Economic Outlook During the COVID-19 Pandemic: A Changed World*, WORLD BANK (June 8, 2020), https://www.worldbank.org/en/news/feature/2020/06/08/the-global-economic-outlook-during-the-covid-19-pandemic-a-changed-world; *see also* David M. Cutler & Lawrence H. Summers, *The COVID-19 Pandemic and the $16 Trillion Virus*, 324 JAMA 1495 (2020).

requirements for surveillance and response (Annex 1); (2) a lack of clarity within the health threat notification decision instrument (Annex 2); and (3) the binary nature of PHEIC declarations. This paper will focus on each concern in turn.

The urgent need for IHR reform is evidenced by the expected annual increase in both the number and variety of threats requiring different detection system and responses. There is a roughly three percent chance that a pandemic could take place in any given year.[11] In 2015, the WHO established a priority list for which diseases could become the next pandemic and required more research.[12] Dozens of diseases have been identified as threats over the last thirty years.[13] At least ten emerging and re-emerging infectious diseases[14] (the majority of which have no efficacious curative or preventive solutions) are on the horizon and have the characteristics to result in outbreaks[15] with serious global consequences, potentially wreaking more havoc than COVID-19.[16] In evaluating the severity of these potentially catastrophic diseases, analysts must look not only to the number of possible deaths, but also to the socioeconomic

11 Nita Madhav, Ben Oppenheim, Mark Gallivan, Prime Mulembakani, Edward Rubin & Nathan Wolfe, *Pandemics: Risks, Impacts, and Mitigation*, *in* DISEASE CONTROL PRIORITIES: IMPROVING HEALTH AND REDUCING POVERTY (Dean T. Jamison, Hellen Gelband, Susan Horton, Prabhat Jha, Ramanan Laxminarayan, Charles N. Mock & Rachel Nugent eds., 3d ed. 2017). Of note, between 1940 and 2004 there were more than 335 emerging infectious diseases reported. Kate E. Jones, Nikkita G. Patel, Marc A. Levy, Adam Storeygard, Deborah Balk, John L. Gittleman & Peter Daszak, *Global trends in emerging infectious diseases*, 451 NATURE 990 (2008).

12 *Emerging Infectious Diseases*, CTRS. DISEASE CONTROL, https://www.cdc.gov/niosh/topics/emerginfectdiseases/default.html#:~:text=Emerging%20infectious%20diseases%20are%20those,increase%20in%20the%20near%20future (last visited Mar. 15, 2021).

13 *See* Catharine I. Paules, Robert W. Eisinger, Hilary D. Marston & Anthony S. Fauci, *What Recent History Has Taught Us About Responding to Emerging Infectious Disease Threats*, 167 ANNALS INTERN. MED. 805 (2017) (including a figure of emerging diseases).

14 An emerging infectious disease is a disease whose rate of new infection has increased in the past two decades and could increase in the future. Some infectious diseases can reemerge, such as when there is acquired drug resistance and a lack of prevention control measures (*e.g.*, drug resistant tuberculosis, measles).

15 The CDC has several terms used to classify the spread of diseases. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, PRINCIPLES OF EPIDEMIOLOGY IN PUBLIC HEALTH PRACTICE: AN INTRODUCTION TO APPLIED EPIDEMIOLOGY AND BIOSTATISTICS 72 (3d ed. 2012), https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html ("Occasionally, the amount of disease in a community rises above the expected level. Epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. Outbreak carries the same definition of epidemic, but is often used for a more limited geographic area. Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known. Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people.").

16 World Health Org., 2018 Annual Review of Diseases Prioritized Under the Research and Development Blueprint (2018), https://www.who.int/docs/default-source/blue-print/2018-annual-review-of-diseases-prioritized-under-the-research-and-development-blueprint.pdf?sfvrsn=4c22e36_2.

repercussions posed by an outbreak, which can be devastating and long-lasting.[17] One potential pandemic disease has been labeled as "Disease X" to signify that scientists anticipate not knowing all the specific diseases that are to come. As the volume of threats to evaluate increases, it is increasingly important that the IHR have a high statistical probability of accurately identifying true threats to global health security, as well as identifying events which do *not* pose a global risk.

Emerging infectious diseases are fostered by close interactions between (1) infectious agents or pathogens, (2) animal hosts and humans, and (3) the environment. They are increasingly driven by today's global urbanization, animal habitat encroachment, and the effects of climate change.[18] SARS, H1N1 influenza, and the novel coronavirus, classified as zoonotic diseases, are examples of how pathogens emerged from animal reservoirs to cause human catastrophe. These pandemics and several historical disease outbreaks emphasize how the equilibrium of these factors directly impacts future global health security. Climate change's impact on health can be seen in disturbances in the seasonal patterns and geographic locations of disease-carrying insects (*e.g.*, mosquitoes, ticks, and flies). These vectors have caused unusual patterns of Zika, dengue, malaria, West Nile, and other emerging diseases worldwide requiring state-of-the-art surveillance systems and response capacities.[19] Lastly, antimicrobial resistance, a byproduct of human behavior and our interconnectedness with animals and the environment, threatens our wellbeing in the context of a non-innovative antimicrobial development pipeline. The former remains absent from the IHR, further rendering the IHR insufficient to safeguard future international health security. Reforms must acknowledge the varied global health threats knocking at today's doorstop and the pace that they are arriving.

The One Health Approach acknowledges the transdisciplinary view – the interconnectedness of humans, pathogens, animals, and the shared environment have a role in instigating emerging public health threats – and,

17 Deaths and economic damage are not always positively correlated, and we have seen instances with the economic toll has been high even though deaths have been low. Anas El Turabi & Philip Saynisch, *Appendix C: Modeling the Economic Threat of Pandemics*, *in* THE NEGLECTED DIMENSION OF GLOBAL SECURITY: A FRAMEWORK TO COUNTER INFECTIOUS DISEASE CRISES (2016), https://www.ncbi.nlm.nih.gov/books/NBK368393/.

18 David M. Morens & Anthony S. Fauci, *Emerging Pandemic Diseases: How We Got to COVID-19*, 182 CELL 1077 (2020), https://www.cell.com/cell/pdf/S0092-8674(20)31012-6.pdf.

19 Felicia Keesing, *Impacts of biodiversity on the emergence and transmission of infectious diseases*, NATURE (2010), https://www.nature.com/articles/nature09575?page=12#auth-1; Anthony S. Fauci & David M. Morens, *Zika Virus in the Americas—Yet Another Arbovirus Threat*, 374 NEW ENG. J. MED. 601 (2016).

thus, promotes linked disease surveillance and prevention efforts within these three areas.[20] One Health more precisely addresses prevention of zoonotic disease, antimicrobial resistance, effects of climate change, food safety, environmental contamination, and a wide-range of other public health threats. One Health's integration into IHR's components, such as national core capacity requirements for surveillance and response, would be beneficial to global health security.[21] Efforts have begun to include One Health approaches in pandemic response,[22] but further effort should be made to ensure this practice is commonplace, including by directly incorporating it into the IHR.

II. AN OVERARCHING OBSTACLE TO IHR COMPLIANCE – MEETING ANNEX 1 STANDARDS

A key aspect of the IHR 2005 is the requirement that member countries meet certain domestic benchmarks regarding their healthcare capacity. Though sanitary conventions have long required that nations maintain certain disease monitoring capabilities at ports of entry, the IHR 2005 were innovative in obligating nations to meet minimum standards for domestic healthcare and health infrastructure. Annex 1 provides "minimum requirements" that States must meet in order to effectively detect and analyze possible health threats. Among these requirements are that the State "establish, operate and maintain a national public health emergency response plan" and "determine rapidly the control measures required to prevent domestic and international spread [of disease]."[23]

Annex 1's minimum standards are designed to ensure that every WHO Member State has the basic operational capacity to fulfil its obligations

20 CTRS. DISEASE CONTROL, A CDC FRAMEWORK FOR PREVENTING INFECTIOUS DISEASES: SUSTAINING THE ESSENTIALS AND INNOVATING FOR THE FUTURE (Oct. 2011), https://www.cdc.gov/ddid/docs/ID-Framework.pdf; *One Health,* CTRS. DISEASE CONTROL, https://www.cdc.gov/onehealth/basics/index.html#:~:text=One%20Health%20is%20a%20collaborative,plants%2C%20and%20their%20shared%20environment (last visited Mar. 15, 2021).

21 Lawrence O. Gostin & Rebecca Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 MILBANK Q. 264 (2016).

22 For example, in the third Emergency Committee meeting for COVID-19, the Committee called for coordination with World Organisation for Animal Health (OIE), Food and Agriculture Organization of the United Nations (FAO), and WHO Member States to identify zoonotic virus sources and prevent transmission. Statement, World Health Org., Statement on the Third Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Coronavirus Disease (COVID-19) (May 1, 2020), https://www.who.int/news/item/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19).

23 IHR, *supra* note 2, at annex 1.

toward its own people and toward the international community.[24] The IHR 2005 envisioned the attainment of minimum standards for domestic health systems in all Member States by 2016 at the latest.[25] Despite these aspirations, the most recent survey of State compliance showed that two-thirds failed to meet their Annex 1 obligations.[26] A recent review of 182 countries and their ability to respond to the COVID-19 pandemic revealed that countries' capacities to prevent, detect, and respond to outbreaks varied widely. Only half of the countries reviewed had adequate operational readiness or adequate response enabling functions (resources and coordination aptitude).[27]

Failures to meet capacity benchmarks by States Parties are not indicative of widespread indifference toward global health security. Instead, it should be seen as a consequence of a lack of necessary funding to meet IHR requirements in many low-income nations – creating weak links in the global system.[28] When national funding for new projects is available, immediate concerns often take precedent over long-term projects to

24 *See* Lawrence O. Gostin & Ana Ayala, *Global Health Security in an Era of Explosive Pandemic Potential*, 9 J. NAT'L SEC. L. & POL'Y 53, 65 (2018). "Although the IHR is designed to build and maintain capacities to detect, assess, report, and respond to a potential PHEIC [public health emergency of international concern], the core capacity obligation also indirectly strengthens national public healthcare systems and, ultimately, the global health risk framework." *Id.*

25 Gostin & Katz, *supra* note 21, at 270 ("State Parties were required to develop and maintain core capacities by 2012, with a possible extension to 2014, and an additional extension to 2016.").

26 Adam Kamradt-Scott, *Achieving Global Health Security: The Implementation of International Health Regulations*, GENEVA CTR. FOR SEC. POL'Y (2016). Reliable and detailed data about IHR compliance is difficult to obtain, as compliance is measured via self-assessments by Member States. These assessments do not use quantitative metrics and, as such, have been criticized as unreliable. Gostin & Katz, *supra* note 21, at 278. Nonetheless, it is widely agreed that most States do not have sufficient domestic systems to comply with their surveillance and mitigation responsibilities. A 2014 study, for example, found that only 64 of 194 Member States had achieved IHR's obligations for essential surveillance, laboratory, data management, and other services as of 2014. WORLD HEALTH ORG., ONE YEAR INTO THE EBOLA EPIDEMIC, at ch. 13 (2015) (chapter title: "The Warnings the World Did Not Heed").

27 Nirmal Kandel, Stella Chungong, Abbas Omaar & Jun Xing, *Health Security Capacities in the Context Of COVID-19 Outbreak: An Analysis of International Health Regulations Annual Report Data from 182 Countries*, 395 LANCET 1047 (2020).

28 There is a general consensus that low-income regions face greater challenges in obtaining IHR compliance than those with greater income. *See, e.g.*, Craig Murray, *Implementing the New International Health Regulations: The Role of the WTO's Sanitary and Phytosanitary Agreement*, 40 GEO. J. INT'L L. 625, 641 (2009); Gostin & Katz, *supra* note 21; *see also WHO – World Bank Strategic Partnership Financing Preparedness*, WORLD HEALTH ORG. (2019), https://extranet.who.int/sph/news/who-%E2%80%93-world-bank-strategic-partnership-financing-preparedness ("Health security threats have an especially destructive impact on development investment and GDP in low-income and lower-middle income countries.").

improve healthcare infrastructure.[29] In some instances, corruption and mismanagement worsen shortages.[30] The result is felt both at home and on the international stage. Domestically, residents of countries that fall below IHR standards are less likely to receive adequate healthcare.[31] Internationally, the lack of infrastructure causes gaps in global health monitoring and increases the risk that a novel disease may develop and spread before it is detected.[32]

Although funding is not the focus of this Essay, it is a key obstacle to IHR compliance for developing and maintaining core capacity. No matter what changes are made to Annex 2's algorithm for notification, financial reform to ensure that all Member States have the capacity to comply with Annex 1 and are therefore able to identify health events that may give rise to a notification under Annex 2 will be a necessary hurdle that the international community must address.[33]

Even with financial reform, it is likely that resources – both financial and otherwise – will continue to fall short given the scale of the problem. Priority should be given to States with inadequate domestic capacity, which are also in geographic areas where future disease outbreaks are predicted, or which are emerging disease hotspots.[34] A data visualization platform containing national preparedness core capacities is being developed and has the potential to overlay these characteristics to identify the regions where such a targeted approach could have the greatest impact.[35] While bolstering individual national capacity is important to achieve the IHR's goals, emphasis should also be placed on simultaneously building up inter-country

29 *See* David Bishop, *Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT'L L. 1173 (2005); Murray, *supra* note 28 ("[C]ountries may be forced to decide between dedicating resources to the IHR or to more urgent public health crises, such as malaria.").

30 *See, e.g.*, Laurie Garrett, *Ebola's Lessons: How the WHO Mishandled the Crisis*, 94 FOREIGN AFFS. 80, 86–87 (2015).

31 *See generally id.* (describing the domestic effects of the 2014 Ebola outbreak on countries with weak healthcare systems).

32 *See, e.g.*, Monica Rull, Ilona Kickbusch & Helen Lauer, *International Responses to Global Epidemics: Ebola and Beyond*, 6 INT'L DEV. POL'Y (2015) (detailing how Ebola spread undetected due to poor healthcare infrastructure).

33 This essay does not seek to delve into the pros and cons of proposed financial reforms, but acknowledges that several ideas have been proposed. These reforms generally fall into three different categories: (1) those seeking increased contributions from wealthy Member States, *e.g.*, Bishop, *supra* note 28; (2) those looking to create collaborations with other non-governmental organizations (NGOs), see Murray, *supra* note 28; and (3) those proposing new mechanisms for resource distribution, *see* Lawrence O. Gostin, Mary C. DeBartolo, & Eric A Friedman, *The International Health Regulations 10 years on: the governing framework for global health security*, 386 LANCET (2015).

34 Jones et al., *supra* note 11.

35 Kandel, *supra* note 27.

and regional collaborations to achieve goals of global preparedness to prevent disease spread.

The global community is only as strong as its weakest partner; yet even those who technically met their Annex 1 competencies have struggled with COVID-19, suggesting it is time to rethink competency and preparedness.[36] The resources and know-how for detection, assessment, and response is complex. Detection involves modernized surveillance or disease monitoring systems, epidemiologic investigation, laboratory-based pathogen identification, scientific data documentation, and a specialized and sustained workforce with regular trainings.[37] Building external workforces to assist States Parties and their local stakeholders will continue to be important as the number of threats to assess grows. In turn, national players should strengthen reporting processes among local frontline workers who will likely witness unexpected or unusual clinical situations first. A recent report suggests that operational readiness capacity, enabling functions, emergency supply chain logistical management, and maintenance of essential health services during crises should be prioritized. Multidisciplinary teams are also crucial to pandemic response, and as such, investments should be made in garnering local expertise among epidemiologists, anthropologists, communication specialists, social behavioral experts, economists, and others so that disease spread is prevented to safeguard global health security.[38]

Core capacity building must also acknowledge the wide ecosystem of actors who have potential to partake in the identification and notification processes. The current notification system within Annexes 1 and 2 only allows State actors to report events and does not permit external actors (such as NGOs) nor the WHO to assist with outbreak investigation without permission. This seems to have played a role in the delayed notification of COVID-19.[39] The IHR should make room for non-State actors to play a larger role in real-time detection, assessment, reporting, and response of

36 Tess Aitken, Ken Lee Chin, Danny Liew & Richard Ofori-Asenso, *Rethinking Pandemic Preparation: Global Health Security Index (GHSI) is predictive of COVID-19 burden, but in the opposite direction*, 81 J. INFECTION 318 (2020); *Global Health Security Index*, NUCLEAR THREAT INITIATIVE & JOHNS HOPKINS CRT. FOR HEALTH SEC., https://www.ghsindex.org/ (last visited Mar. 15, 2021).

37 *Infectious Disease Framework*, CTRS. DISEASE CONTROL, https://www.cdc.gov/ddid/docs/ID-Framework-2pageoverview.pdf (last visited Mar. 15, 2021).

38 Kandel, *supra* note 27.

39 *See* Allyn L. Taylor, Roojin Habibi, Gian Luca Burci, Stephanie Dagron, Mark Eccleston-Turner, Lawrence O. Gostin, Benjamin Mason Meier, Alexandra Phelan, Pedro A. Villareal, Alicia Ely Yamin, Danwood Chirwa, Lisa Forman, Gorik Ooms, Sharifah Sekalala, Steven J. Hoffman, *Solidarity in the Wake of COVID-19: Reimagining the International Health Regulations*, 396 LANCET 82 (2020).

events.[40] Although the IHR 2005's reporting time of forty-eight hours in Annex 1 and twenty-four hours in Annex 2 are already unrealistic in most instances, including more actors in the IHR reporting process would help, especially as we brace for a growing number of both infectious and non-infectious disease threats The WHO should embrace and better train non-State actors to play a larger role in detection and monitoring.

Another proposal to strengthen national capacity seeks to engage frontline workers (ranging from health workers to laboratory staff responsible for reporting events to government officials) in capacity building efforts and developing country specific tools.[41] Toolkits should be tailored to each country's epidemiology and event reporting processes to assist the local public health workforce to more accurately comply with Annex 1 and to aid in implementing Annex 2's protocols. The utility of this approach was demonstrated in a 2011 assessment of European countries which determined that local communication improvements and infrastructure changes were needed to facilitate compliance with Annex 2 reporting.[42] This resulted in the development of several country-specific tools for patient-facing and diagnostic laboratory staff on what to report, the reporting process, and follow-up procedures. The toolkit included a corresponding guidance document for the relevant NFP and was accompanied by education and implementation plans. Scaling up and maintaining these country-specific initiatives should be prioritized when strengthening core capacities.

Core capacity requirements for surveillance and response should also incorporate the One Health Approach and transdisciplinary view of emerging threats. This would translate to linking several surveillance systems, laboratory detection modalities, transdisciplinary experts, and response programs attuned to arising public health dangers shared among animals, humans, and the environment. Incorporating this approach explicitly within Annex 1 requirements will ensure that a varied number of threats, ranging from environmental contamination to emerging zoonotic diseases, are accounted for within national and global detection and response capabilities. Furthermore, the One Health Approach potentially aids NFPs to accurately define potential threats as "unusual and unexpected

40 The Ebola pandemic highlights the importance of this, as it was a non-State actor who sounded the alarm for a developing outbreak.

41 Emily MacDonald, Preben Aavitsland, Dounia Bitar & Katrine Borgen, *Detection of Events of Public Health Importance Under the International Health Regulations: A Toolkit to Improve Reporting of Unusual Events by Frontline Healthcare Workers*, 11 BMC PUB. HEALTH 713 (2011).

42 *Id.*

events" as required in Annex 2. Coordination mechanisms for surveillance and response should be strengthened with the WHO, World Organization for Animal Health and the United Nations Food and Agriculture Organization to control disease spread among animal sources, which could worsen outbreaks and perpetuate transmission across borders.[43]

III. ANNEX 2'S LIMITATIONS AS A TOOL FOR IDENTIFYING AND RESPONDING TO GLOBAL PUBLIC HEALTH THREATS AND PROPOSED REVISIONS

Having acknowledged the challenges posed by Member States in complying with Annex 1, it is nonetheless critical to focus on the tools countries use to determine if an event must be reported to the WHO under Annex 2, as well as the method of declaring health emergencies that pose a multinational threat. Despite its faults, the IHR 2005 did make some important changes from its predecessor. For example, it moved away from "disease specific" notifications to that of "any event," which is broad enough to capture significant infectious or non-infectious health events. Yet while this revision permits the IHR 2005's relevancy to future non-infectious public health threats, it also generated rather vague criteria for the four components[44] of a notifiable threat as outlined in Annex 2.[45] Annex 2 contains a flowchart to guide States Parties in determining when a health event has reached a level of threat severe enough to justify notification (within twenty-four hours) to the WHO.

Yet despite the importance of this algorithm, Annex 2 has been criticized as a decision-making tool for identifying notifiable threats. Tools such as this should have high sensitivity and positive predictive value, *i.e.*, they should allow NFPs to successfully use the tool to identify events that

43 Gostin & Katz, *supra* note 21.

44 The four components are: Is this public health impact of the event serious?; Is the event unusual or unexpected?; Is there a significant risk of international spread?; Is there a significant risk of international travel or trade restrictions?

45 Thomas Haustein, Helge Hollmeyer, Max Hardiman, Stephan Harbarth & Didier Pittet, *Should this event be notified to the World Health Organization? Reliability of the International Health Regulations notification assessment process*, 89 BULL. WORLD HEALTH ORG. 269 (2011), https://www.who.int/bulletin/volumes/89/4/10-083154/en/; Michael Edelstein, David L. Heymann, Johan Giesecke & Julius Weinberg, *Validity of International Health Regulations in Reporting Emerging Infectious Diseases*, 18 EMERGING INFECTIOUS DISEASES 1115 (2012); Aranka Anema, Eric Druyts, Helge G. Hollmeyer, Maxwell C. Hardiman & Kumanan Wilson, *Descriptive review and evaluation of the functioning of the International Health Regulations (IHR) Annex 2*, GLOB. HEALTH (2012), https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-8-1.pdf.

warrant notification to the WHO a possible PHEIC declaration.[46] If a large volume of threats is evaluated, as is anticipated in the future, then the tool should also have high specificity and negative predictive value (*i.e.* the ability to identify events that do *not* require notification), to avoid overburdening the system.

46 Michael G. Baker & David P. Fidler, *Global Public Health Surveillance Under New International Health Regulations*, 12 EMERGING INFECTIOUS DISEASES 1058 (2006).

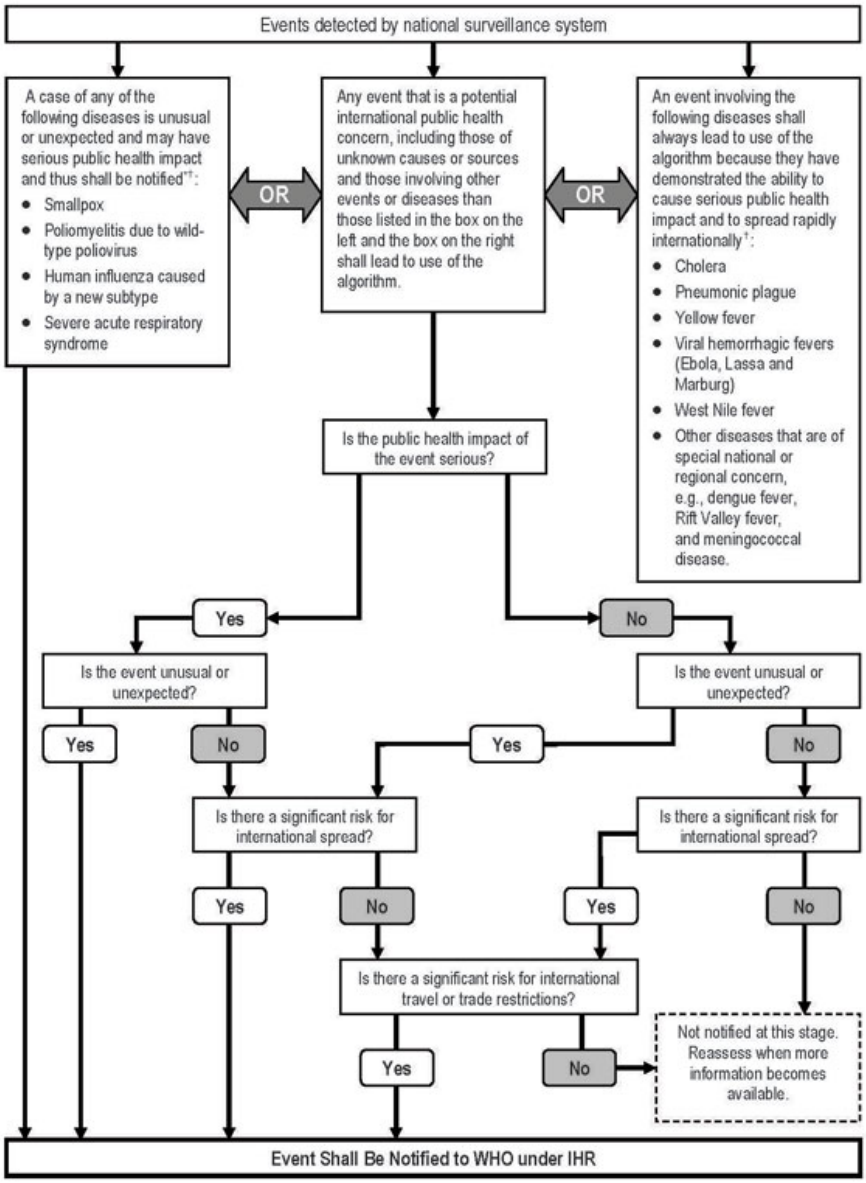

Figure 1: IHR Annex 2[47]

47 IHR, *supra* note 2, at annex 2.

At least three studies have assessed Annex 2 by studying the agreement of NFPs and experts when using Annex 2 on fictitious cases to determine if the event was notifiable.[48] Another report assessed Annex 2's language among States Parties and WHO regional offices.[49] Further studies are lacking on the robust validation of the decision instrument.[50]

One study revealed there was (median) 81% agreement among NFPs and experts for the fictitious cases that required notification. However, agreement was low (median 55%) for the non-notifiable cases.[51] The study's authors recommended that to improve the reliability of case assessments by NFPs, Annex 2 needs further guidance on its use and clearer definitions of terms used to evaluate each criterion. The authors also suggested that the criterion, themselves, be revised. While acknowledging that the IHR 2005 is intentionally broad, "the lack of specificity of the decision instrument in Annex 2 leaves considerable room for users' perceptions, experience and knowledge to have an influence."[52] Another study explained that "low specificity would result in an increase in false-positives results and increased costs associated with the notification process and determination of serious events."[53] In other words, Annex 2, as designed, opens the door for over-reporting cases, which can burden State Parties and the WHO, especially as the number of threats to review increases. This instrument would benefit from improved sensitivity in the detection of notifiable cases.

A second study, by Edelstein et al., compared an investigator's assessment of an event using Annex 2 with that of experts' analysis and found that a small number of assessed events missed the classification for notification, reflecting "challenges of predicting [the] evolution of an event as it occurs and [the] potential for human error."[54] This is concerning, as any instrument to be used in the IHR for identifying events with potential global consequences should *minimize* the chances of a Member State missing a reportable event. As the study's authors put it, "[a]lthough a

48 Anema et al., *supra* note 45; Edelstein et al., *supra* note 45; Haustein et al., *supra* note 45.

49 *WHO Technical Consultation on the Implementation and Evaluation of Annex 2 of the International Health Regulations (2005)*, WORLD HEALTH ORG. (2009), https://www.who.int/ihr/summary_report_annex2.pdf (WHO/HSE/IHR/2009.10).

50 Internal actors have recommended revisions to this instrument, but as of this writing, none have been adopted. *E.g.* World Health Org., Report of the Ad Hoc Expert Group on Annex 2, Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern, Doc. A/IHR/IGWG/2/INF.DOC./4 (Feb. 22, 2005), https://apps.who.int/gb/ghs/pdf/IHR_IGWG2_ID4-en.pdf.

51 Haustein et al., *supra* note 45.

52 *Id.*

53 Edelstein et al., *supra* note 45.

54 *Id.*

sensitivity of 100% would be difficult to attain, maintaining the number of missed events at an absolute minimum should be a priority when the instrument is revised or evaluated."[55]

A WHO technical consultation identified other challenges and misunderstandings related to Annex 2, especially as regards the time frames in which events needed to be assessed and notified.[56] There was also a lack of clarity among States Parties on whether notification required a laboratory-confirmed diagnosis (if so, it would likely result in States surpassing the established forty-eight hour limit for surveillance assessment and twenty-four hour timeframe for notification). The inclusion of criteria that meets benchmarks for data quality regarding detection, assessment, and reporting (*i.e.*, disease diagnostic criteria, laboratory-based identification) contribute to the gray areas of Annex 2's criteria. To foster the intended sensitivity of Annex 2 and facilitate early identification and assessment, the technical consultation called for some sort of early warning system and the establishment of a communication system where States Parties could alert the WHO of unusual situations.

These studies revealed that Annex 2's criteria lack clarity, creating the potential for missing notifiable cases and also over-reporting non-notifiable cases. Concrete solutions are needed to address this identified gap in Annex 2's accuracy. Edelstein et al. concluded that the first two criteria (*i.e.*, if the public health impact of the event is serious and if the event is unusual or unexpected) require more specificity and could benefit from clear definitions.[57] Guiding benchmarks for epidemiological concepts (such as "is the number of cases and/or number of deaths for this type of event large for the given place, time, or population?") could prove beneficial. Durrheim et al. point to Annex 2's "subjective considerations, such as restraints on international travel and trade" and the equal weight with which each criteria is considered, and instead recommend the establishment of "objective, evidence-based epidemiological and containment criteria."[58] A third study, by Anema et al., found that the NFPs surveyed considered Annex 2 to be

55 *Id.*

56 *WHO Technical Consultation on the Implementation and Evaluation of Annex 2*, *supra* note 49.

57 Edelstein et al., *supra* note 45, at 1120 (finding that more specificity was needed "about what makes an event serious or unusual" and recommending "setting more prescriptive seriousness and unusualness criteria"). The authors note that these steps "would improve specificity without decreasing sensitivity and in turn increasing PPV." They also reinforce that "focus should be placed on keeping the number of missed events to a minimum." *Id.*

58 David N. Durrheim, Lawrence O. Gostin & Keymanthri Moodley, *When does a major outbreak become a Public Health Emergency of International Concern*, 20 LANCET 887 (2020).

restrictive to a narrow topic of infectious diseases threats,[59] thereby suggesting that other public health threats may not be captured by NFPs using the framework. Regular training of NFP staff is needed,[60] but even more so, this highlights that integrating the One Health Approach into Annex 2 would prove beneficial and could help the IHR 2005 maintain relevancy in the future. Of course, any reform to Annex 2 must ensure that the criteria does not become too vague or nondescriptive, thereby replicating existing problems and leading to over- or underreporting of potential threats.

IV. LIMITATIONS TO THE PHIEC DECLARATION SYSTEM AND PROPOSED REFORMS

The WHO has two options when evaluating events reported by NFPs – either declare a Public Health Emergency of International Concern (PHEIC) or do not. Under the current governance of the WHO and IHR 2005, the PHEIC is the only threat level for health emergencies.[61] Under Article 1 of the IHR, PHEICs have three criteria: (1) the event is considered extraordinary, (2) there is a risk to other states by international spread,[62] and (3) international coordination is needed to control the outbreak. The WHO Director-General determines whether an event constitutes a PHEIC having considered information provided by the State Party where the event is occurring, advice from the Emergency Committee, "scientific principles as well as the available scientific evidence and other relevant information," and "an assessment of the risk to human health, of the risk of international spread, and of the risk of interference with international traffic."[63] Despite the IHR 2005's attempt to systematize the PHEIC declaration process, the WHO has faced criticism on a variety of fronts each of the six times that a

59 Anema et al., *supra* note 45.

60 *See, e.g.*, Edelstein et al., *supra* note 45, at 1120.

61 *See* Barbara von Tigerstrom, *The Revised International Health Regulations and Restraint of National Health Measures*, 13 HEALTH L.J. 35, 39 (2005). Although the WHO has also declared severe outbreaks to be "pandemics" in the past, a pandemic declaration creates a semantic, not legal, distinction. Pedro A. Villarreal, *Pandemic Declarations of the World Health Organization as an Exercise of International Public Authority: The Possible Legal Answers to Frictions Between Legitimacies*, 7 GOETTINGEN J. INT'L L. 95, 122-23 (2016). *See also* Pedro Villarreal's essay in this volume. Pedro Villarreal, *Towards a Timeless Legal Definition of a Pandemic*, 20 Wash. U. Global Stud. L. Rev. 611 (2021).

62 This is broadly defined as "any illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans." IHR, *supra* note 2, art. 1.

63 IHR, *supra* note 2, art. 12; *see* von Tigerstrom, *supra* note 61, at 39.

PHEIC has been declared.[64] A common complaint is that the all-or-nothing nature of the PHEIC declaration is problematic, resulting in several issues, including delayed and premature declarations.

Indeed, early in the COVID-19 pandemic, WHO Director-General Dr. Tedros Adhanom Ghebreyesus criticized the rigid nature of the all-or-nothing PHEIC declaration process and recommended that reforms should be considered, including a multi-tiered declaration approach.[65] At its first meeting regarding the novel coronavirus outbreak, the Emergency Committee "expressed divergent views on whether this event constitutes a PHEIC or not."[66] The Committee did, however, acknowledge concerning information known about the virus that implied it could quickly have severe consequences in terms of morbidity and mortality for a large number of people when compared to other known viruses.[67] The Committee advised the Director-General that:

> In the face of an evolving epidemiological situation and the restrictive binary nature of declaring a PHEIC or not, WHO should consider a more nuanced system, which would allow an intermediate level of alert. Such a system would better reflect the severity of an outbreak, its impact, and the required measures, and would facilitate improved international coordination, including research efforts for developing medical counter measures.

Despite the constellation of known concerning information (*i.e.*, rapidly changing situation, epidemiology evidence of current and predicted spread, a potential for under-diagnosed cases, clinical disease severity, and high human-to-human transmissibility), the Emergency Committee waited until

64 David P. Fidler, *To Declare Or Not to Declare: The Controversy over Declaring a Public Health Emergency of International Concern for the Ebola Outbreak in the Democratic Republic of the Congo*, 14 ASIAN J. WTO & INT'L HEALTH L & POL'Y 287, 291–93 (2019); Chang-fa Lo, *The Missing Operational Components of the IHR (2005) from the Experience of Handling the Outbreak of COVID-19: Precaution, Independence, Transparency and Universality*, 15 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 1, 9–11 (2020) (criticizing PHEIC procedure in the early days of the COVID-19 pandemic).

65 Statement, World Health Org., Statement on the First Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV) (Jan. 23, 2020), https://www.who.int/news/item/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov) [hereinafter First Meeting of the IHR Emergency Committee].

66 First Meeting of the IHR Emergency Committee, *supra* note 65; *see also* Gostin et al., *supra* note 7.

67 The Committee acknowledged concerning information about the potential threat including that "human-to-human transmission is occurring" and that there was "a preliminary R0 estimate of 1.4-2.5," indicating exponential transmission that is several folds higher than influenza, as well as the fact that "25% [of confirmed cases] are reported to be severe." First Meeting of the IHR Emergency Committee, *supra* note 65.

the second meeting to declare a PHIEC. This decision (or lack thereof) led to a delay in mobilizing funds and preventing cross-border transmission. This situation is likely to reoccur and should be considered one of the highest priorities for IHR reform.

Under the existing system, declarations are seen as somewhat arbitrary and there is a lack of transparency in the decision to declare a PHEIC.[68] Not only are Article 1 criteria vague, but the process by which the WHO declares a PHEIC has been criticized for the use of "irrelevant considerations, undue influence and political interference,"[69] rather than strictly scientific determinations.[70] One of the first comprehensive analyses of sixty-six Emergency Committee statements for the rationale of their PHIEC decisions found inconsistent rationale and haphazard application of Article 1 criteria. It was also unclear, and not regularly reported, which criterion had or had not been met.[71]

A scoring system, or other type of instrument, should perhaps be developed for use by the Emergency Committee and Director-General when evaluating reported events. Such an instrument could ensure fidelity to Article 1 criteria and encourage uniform definitions, as well as allow for the transparent documentation of information supporting or negating each criterion. Emergency declarations should have epidemiological criteria that are both objective and evidence-based, thereby removing the potential for subjective considerations that currently exist.[72] Greater accuracy would also combat accusations of arbitrariness that have accompanied past PHEIC declarations. If the WHO could point to the ways which its system is backed

68 *See* Taylor et al., *supra* note 39; Mullen et al., *supra* note 5; Fidler, *supra* note 64.

69 Mark Eccleston-Turner & Adam Kamradt-Scott, *Transparency in IHR emergency committee decision making: the case for reform*, BMJ GLOB. HEALTH, at 3 (2019).

70 *See, e.g.*, *The Politics of PHEIC*, 292 LANCET 2470 (2019) ("The decision [for a third time of the EC to not declare a PHEIC in the DRC] appears more political than technical and that is a mistake. The committee seems to have favoured local protectiveness over global galvanising."); Garrett, *supra* note 30 (criticizing the politicized nature of the WHO response to the 2009 Ebola outbreak in the Democratic Republic of the Congo). Most academics agree that the WHO should be more readily able to declare a PHEIC and that such a declaration should be based on science, not politics. However, the WHO does not exist in a vacuum and the political realities of global health must be considered in any proposed modification to the IHR. *See* Villarreal, *supra* note 61; Fidler, *supra* note 64, at 292 ("[T]he PHEIC authority is not, and was not intended to be, merely an epidemiological exercise. It demands political leadership from the Director-General. . . .").

71 Mullen et al., *supra* note 5.

72 Durrheim et al., *supra* note 58; *see also* Mullen et al., *supra* note 5 (concluding that a "more standardised and transparent process for ECs is needed to assess the event and determine if a PHEIC declaration is warranted for the public health community to understand the decision-making process" and that "[g]uidelines that include the standardised definitions and how they should be assessed for each of the three core IHR criteria is necessary for future PHEIC declarations to ensure confidence in the IHR EC process remains").

by science, its declarations would gain greater credibility and legitimacy. Further transparency could be achieved through publishing meeting transcripts in a readily available public manner.[73] As the PHEIC process became less politicized and arbitrary, trust and compliance by member states may also increase.[74]

Another problem stemming from the PHEIC system results from the stigma and economic and social consequences countries involved in a PHEIC declaration face, in no small part due to WHO recommended trade and travel restrictions, or those imposed by States even against explicit WHO recommendations to the contrary.[75] Fear of these repercussions disincentivizes States from reporting the initial outbreak and dissuades the WHO from subsequently issuing a PHEIC. One study reported that as many as 20–30% of the NFPs questioned stated that they did not want to notify the WHO of events due to the risk of negative consequences often attached to PHEIC declarations.[76]

Many proposals to increase the accuracy of global health warnings, while decreasing the political risk of issuing them, center around implementing a tiered system of emergency declarations to replace the existing binary yes/no nature of PHEIC declarations. Although the number of tiers vary by proposal – with some envisioning only one level before a PHEIC and others proposing several tiers and a more nuanced warning system – they all aim to encourage early reporting of, and response to, serious disease outbreaks. These revisions may motivate more nations in the

---

73 Taylor et al., *supra* note 39.

74 Barna, *supra* note 78; *see also* Gian Luca Burci, *The Outbreak of COVID-19 Coronavirus: Are the International Health Regulations Fit For Purpose?*, EJIL:TALK! (Feb. 27, 2020), https://www.ejiltalk.org/the-outbreak-of-covid-19-coronavirus-are-the-international-health-regulations-fit-for-purpose/ (discussing the importance of credibility for the WHO).

75 *See, e.g.*, Arielle Silver, *Obstacles to Complying with the World Health Organization's 2005 International Health Regulations*, 26 WIS. INT'L L.J. 229 (2008) (detailing, among other examples, the harsh economic consequences experienced by Peru in response to its disclosure of a cholera outbreak to the WHO); Bradly J. Condon & Tapen Sinha, *The Effectiveness of Pandemic Preparations: Legal Lessons from the 2009 Influenza Epidemic*, 22 FLA. J. INT'L L. 1 (2010) (detailing harsh response to H1N1 in Mexico and noting the economic consequences); Barbara von Tigerstrom & Kumanan Wilson, *COVID-19 travel restrictions and the International Health Regulations (2005)*, 5 BMJ GLOB. HEALTH 2020 (documenting trade and travel restrictions and resulting economic consequences imposed during the COVID-19 pandemic against the advice of the WHO). The WHO Director-General has acknowledged the negative consequences that come from PHEIC declarations. *See, e.g.*, Statement, World Health Org., Statement on the Meeting of the International Health Regulations (2005) Emergency Committee for Ebola Virus Disease in the Democratic Republic of the Congo on 12 February 2020 (Feb. 12, 2020), https://www.who.int/news-room/detail/12-02-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo-on-12-february-2020.

76 Anema et al., *supra* note 45.

PHEIC identification and reporting process because they can potentially receive external assistance and related funding earlier in a crisis.[77]

Existing WHO systems, such as the Emergency Response Framework (ERF), which guides the WHO's approach to determining an outbreak's risk, and the Pandemic Influenza Preparedness Framework and Response Plan, might offer some solutions. The ERF, for example, involves three grades: (1) limited oversight managed by a country's health system, (2) moderate oversight and external support, and (3) major oversight and external support.[78] Likewise, the WHO created a six-phase schematic (later revised to four phases) depicting how a novel influenza virus grows from infecting a few humans to a global pandemic.[79] Each phase has a corresponding national program response and surveillance capacity goals, and defined the WHO's role for the specific stage.[80]

Unlike the binary PHEIC declaration, these existing systems are able to reflect the rapidly evolving nature of a situation and the corresponding response needed. The more nuanced tiered approaches can capture both the progression of, and recovery from, disease outbreak, especially as more epidemiological information becomes available. Integrating components of other pandemic control frameworks into the IHR could also provide greater uniformity across WHO alert systems and decrease confusion during disease outbreaks.[81]

---

77 *See generally* Bishop, *supra* note 28.

78 WORLD HEALTH ORG., ERF: EMERGENCY RESPONSE FRAMEWORK, (2d ed. 2017), https://apps.who.int/iris/bitstream/handle/10665/258604/9789241512299-eng.pdf?sequence=1; *see also* Mark Barna, *WHO process for declaring health emergencies scrutinized: COVID-19 response shows limitations*, NATION'S HEALTH (2020).

79 World Health Org., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS (2011), https://www.who.int/influenza/resources/pip_framework/en/; World Health Org., Guidance, Pandemic Influenza Preparedness and Response (2009), https://www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/. This six-phase system is designed to enhance surveillance and response given that "influenza pandemics are unpredictable, but recurring events that can have severe consequences on societies," which is similar to the situations the IHR is meant to manage.

80 The original six-phase pandemic paradigm was later revised to a four-phase influenza pandemic continuum that incorporated emergency risk management. *Pandemic Influenza Risk Management*, WORLD HEALTH ORG. (2017), https://apps.who.int/iris/bitstream/handle/10665/259893/WHO-WHE-IHM-GIP-2017.1-eng.pdf?sequence=1.

81 *See* Rachel Holloway, Sonja A. Rasmussen, Stephanie Zaza, Nancy J. Cox & Daniel B. Jernigan, *Updated Preparedness and Response Framework for Influenza Pandemics*, 63 CDC MORBIDITY & MORTALITY WKLY. REP. – REC. & REPS. 1 (2014), https://www.cdc.gov/flu/pandemic-resources/pdf/mmwr-rr6306.pdf; Noreen Quall, Alexandra Levitt, Neha Kanade, Narue Wright-Jegede, Stephanie Dopson, Matthew Biggerstaff, Carrie Reed & Amra Uzicanin, *Community Mitigation*

In the same light, a tiered alert system would benefit the global community by more accurately reflecting the status of global health.[82] By replacing the binary system with "an incremental mechanism that would enable intermediate stages for IHR-based alerts and guidance,"[83] the WHO could respond with more flexibility and coordination to novel or rapidly changing outbreaks. Outbreaks are rarely uniform across time or geographic region and a detailed, flexible system could more accurately capture the progression of a health threat.[84] For example, during the ongoing COVID-19 pandemic, the severity of the outbreak has varied greatly across geography and time; yet, the WHO's PHEIC declaration has remained unchanged.[85] With a tiered system, the global health community could better track whether a situation was improving, stagnating, or worsening, and coordinate an international response accordingly. A tiered system may allow countries to keep up with how data is gathered and take into account the delays in data gathering and surveillance and the often-underreported nature of emerging public health threats.

The 2015 Report of the Ebola Interim Assessment Panel has likewise weighed in on the reform question.[86] Noting that the existing PHEIC determination involved a "single binary decision," the Panel recommended "the possibility of an intermediate level that would alert and engage the wider international community at an earlier stage in a health crisis. This could facilitate preparedness, preventive action, and dedication of resources, which could avert an escalation of the situation."[87] This intermediate category would assist in defining a situation between an outbreak and a PHEIC declaration and could open the door to proper monitoring and mitigation activities without the full consequences of a

---

Guidelines to Prevent Pandemic Influenza – United States, 2017, 66 CDC MORBIDITY & MORTALITY WKLY. REP. – REC. & REPS. 1 (2017), https://www.cdc.gov/mmwr/volumes/66/rr/pdfs/rr6601.pdf. Maintaining several different WHO processes could cause confusion, as evidenced by the simultaneous use of multiple frameworks during the Ebola crisis and influenza pandemic. Gostin & Katz, *supra* note 21.

82 *See* Andra Le Roux-Kemp, *International and Operational Responses to Disease Control: Beyond Ebola and Epistemological Confines*, 15 IND. HEALTH L. REV. 247 (2018) (commenting on the assumptions about global health systems made by the IHR and the reality of those systems).

83 Taylor et al., *supra* note 39.

84 *Id.*

85 Lo, *supra* note 64.

86 World Health Org., Report of the Ebola Interim Assessment Panel (July 2015), https://www.who.int/csr/resources/publications/ebola/report-by-panel.pdf?ua=1.

87 *Id.* ¶ 23. The Report also documented stakeholder confusion regarding notification requirements, which supports the idea that the IHR requires more precise definitions for disease notification. Yet while the Report outlines several areas of improvement in the IHR process, it did not provide detail on what would constitute an intermediate level of warning nor what powers and next steps are triggered by such a declaration. Further efforts are needed to address these gaps.

PHEIC declaration.[88] Different categories could also enable responses tailored to the capacities of the countries involved. Whereas certain national health systems may have the ability to manage an outbreak with limited or no outside support, other, more vulnerable countries, may require significant external assistance. In the latter, the situation "may even trigger the need for an emergency response under the emergency response framework," which different response categories would permit.[89] A graded public health emergency notification system would consider the variations seen among different nations' systems to identify, investigate, and mitigate threats internally and determine when they would need external assistance at an earlier stage of outbreak progression.

Other proposals envision more gradation.[90] A recent article by David Durrheim et al. suggests a three-tier system.[91] In this model, a Level 1 PHEIC indicates outbreak in a single country with the potential to spread globally, requiring localized public health efforts to contain it. A Level 2 PHEIC involves limited spread in multiple countries, and a Level 3 PHEIC concerns ongoing transmission and non-limited spread in multiple countries. Each level is characterized by objective epidemiological criteria and a corresponding action plan.

The Berlin Institute of Global Health has proposed a "Scorecard for a Public Health Emergency of International Concern," which includes a five-tier alert system.[92] The scorecard itself is divided into three categories: (1) Detection and Surveillance, (2) Diagnostics and Treatment, and (3) Prevention, Preparedness, and Response. Each category has subcategories that are given a score of one through four. The overall score determines which of the five tiers is appropriate for the given situation: (1) national, (2) transnational (affected countries), (3) international (affected and neighboring countries), (4) global, or (5) global (more severe). In its effort to be objective, the scorecard defines and integrates disease characteristics into the level of PHIEC grade, such as diseases that are easily transmitted (*i.e.*, human-to-human asymptomatic transmission, high attack rate, high reproductive number) and potentially more fatal (*i.e.*, high case-fatality ratio). Importantly, it also takes into account if there are postulated or known

88 *Id*. ¶¶ 23–24.

89 *Id.* ¶ 69.

90 *See, e.g.*, Gostin et al., *supra* note 7.

91 Durrheim et al., *supra* note 58.

92 Proposal for a Scorecard for a Public Health Emergency of International Concern, BERLIN INST. FOR GLOB. HEALTH, https://institut-fuer-globale-gesundheit.de/wp-content/uploads/2020/01/Final_Proposal_Scorecard_IGGB_310120.pdf (last visited Mar. 24, 2021).

disease countermeasures (*e.g.* disease treatment options and vaccines for disease prevention). The scorecard has yet to propose the corresponding operational protocol after a score is calculated and the category of PHIEC is determined.

Although no international organization can entirely escape politics, the declaration of a PHEIC is particularly fraught because it is a "point of no return" – once a PHEIC is issued, there is no further legal category of emergency. By adding more tiers, the WHO could decrease the resources required, political and social labeling, and financial costs associated with an emergency declaration. Key to this type of reform is that each tier must be accompanied by clear operational protocols, strategies for regional and international cooperation during the response, a clear explanation of the WHO's role and financing mechanisms. Lower-level tiers would be issued when an outbreak is relatively minor and could allow for the mobilization of financial and other resources, while typically not requiring trade or travel restrictions.[93] This would provide an incentive to work with the WHO and external partners early in a situation, and hopefully curtail a public health threat from progressing.[94] In addition to incentivizing reporting and cooperation, a tiered system has the benefit of appropriately distributing finite resources in a manner that reflects the level of threat an emergency pose at different stages of progression.[95]

Yet, the tiered system is not without potential drawbacks. Additional tiers would increase the complexity of the IHR system, which could lead to further confusion.[96] Confusion easily leads to distrust and accusations of arbitrary enforcement. A tiered approach may unintentionally burden the WHO's finite resources,[97] and domestic systems could become overburdened by a tiered reporting system in terms of costs, staffing requirements, and trainings to understand each tier's reporting requirements and subsequent protocols. There is also a possibility that countries could also politically manipulate the WHO warning system. If countries do not

93 *Cf.* Silver, *supra* note 67 (detailing how the current system leads to heavy economic consequences for compliance with the IHR, thereby disincentivizing disease reporting).

94 Gostin & Katz, *supra* note 21, at 305.

95 Alison Agnew, *A Combative Disease: The Ebola Epidemic in International Law*, 39 B.C. INT'L & COMPAR. L. REV. 97 (2016) (describing the need for the distribution of resources by the WHO to low-income countries in the context of Ebola).

96 J. Benton Heath, *Global Emergency Power in the Age of Ebola*, 57 HARV. INT'L L.J. 1 (2016) (discussing tensions which arise from complex national and international webs of decision-making).

97 Lawrence O. Gostin, *The World Health Organization's Historic Moment of Peril and Promise: Reimagining a Global Health Agency Fit for Purpose in the 21st Century*, 11 GLOB. HEALTH GOV. 57 (2017).

see the benefit or have a "buy in" for the low-level warnings, they may be hesitant to report disease outbreaks or threats that appear to be in the early stages.[98] Additionally, warnings could be misused as a justification for otherwise discriminatory trade or travel policies, although this is a problem already suffered by the current system. Finally, if warnings are issued for too many situations, they run the risk of becoming overly pedestrian and losing their impact.

Further research, including community and stakeholder participation, is needed to determine the best revision to the IHR 2005's binary PHEIC declaration system. Research should include but is not limited to: (1) how many tiers would improve the PHEIC declaration process *and* benefit the reporting process for member states, (2) what resources (*e.g.*, financial, staffing, trainings, etc.) would be required for successful implementation of a tiered PHEIC declaration approach, and (3) what are the distinct protocol pathways after a tier is defined? There needs to be a balance between the number of tiers added and the complexity and possible confusion each tier would bring. Cost-benefit analyses and modelling could be employed to understand the balance between overburdening the national and global system with early warning tiers versus reserving finite national and global resources for when a severe PHIEC is declared. The potential reduction or prevention in mortality and morbidity must be included in these calculations and estimations. Furthermore, estimations should account for the time until event notification with the goal that adding each tier should theoretically prevent delays in full or severe PHIEC declarations. Each tier may bring a burden to society (financial and non-financial) but the counterfactual is how many lives will be saved in the long run if there are no delays in a full or severe PHEIC declaration.

The question remains of how to revise the IHR to remove the binary system. Developing a new IHR Annex decision instrument to replace Annex 2 would be advisable. Direct changes to Annex 2's decision tree will likely: (1) minimize the overall confusion by NFPs and other parties during the switch to a multi-phase PHIEC system, (2) better delineate what criteria are needed for which phase and then which operation protocol to subsequently follow, (3) help streamline national core capacity surveillance and response goals outlined in Annex 1 on which Annex 2 is dependent, (4) set up the process for successful training, creation of tools and other education aids

98 Morten Broberg, *A Critical Appraisal of the World Health Organization's International Health Regulations (2005) in Times of Pandemic: It Is Time for Revision*, 11 EUR. J. RISK REGUL. 202 (2020) (commenting on lack of respect for WHO trade/travel restrictions among Member States).

(country-specific and generic), and implementation, and (5) establish accurate evaluation assessments regarding instrument reliability, sensitivity, and specificity. Developing an easy-to-follow decision instrument will accelerate State Party buy-in, field-level implementation among stakeholders, and reliable and consistent long-term use of the instrument as intended. Any revisions to the binary declaration system must be coupled with transparency, accountability, and flexibility for re-iterative revisions during the IHR process. Transparency and accountability should span the entire PHIEC declaration process – beginning from a State Party's detection of disease and activation of an early warning alert to the Emergency Committee's deliberations regarding which tier was decided upon and why.

V. CONCLUSION

The current COVID-19 pandemic has revealed shortcomings in the systems we rely upon for global health security. The many failures witnessed across the globe during this pandemic, coupled with the increasingly prevalent threat of future global health threats, has brought into sharp focus the urgent need to reform the existing mechanisms by which the global community monitors, evaluates, and responds to such threats in order to prevent large-scale death and human suffering. Two key reforms should be prioritized: (1) the development of a non-binary PHIEC declaration system and (2) clarification to Annex 2's criteria for the evaluation of threats to improve sensitivity and specificity for event notification.

It cannot be overlooked, however, that the use of Annex 2 as a decision instrument (as well as the State's ability to respond appropriately once a threat has progressed) depends on a Member State's core capacity for surveillance and response as outlined in Annex 1. Currently, far too many countries have weak public health systems that interfere with their ability to detect and assess emerging infectious and non-infectious disease events. Delays in detection result in the possibility that notifiable situations are not reported to the WHO in a timely fashion and hamper global responses to curb international spread. Non-State actors, frontline workers, and multidisciplinary teams should play a larger role to help Member States detect, assess, respond, and inform the WHO of developing crises through an established mechanism, accompanying training programs, and country-specific tools. Collective inter-State and regional cooperation to augment individual Member State surveillance and response capacities is paramount for sustained global health security.

The need to replace the all-or-nothing nature of PHEIC declarations has been well documented and offers several benefits. Such reform can make the IHR decision instruments and notification processes more closely align with the trajectory of infectious diseases outbreaks and the timeline in which information arises during international health crises. Creating a system that allows for an early alert – coupled with an early response – has great potential to prevent morbidity and mortality, and with it, the devastating social and economic consequences brought about by public health emergencies of this nature. The world is under constant and increasing threat of the next disruptive global disease outbreak, making reform increasingly urgent.