CONCLUSIONS AND RECOMMENDATIONS OF THE PROJECT ON THE WORLD HEALTH ORGANIZATION AND THE NEED FOR POST-COVID-19 REFORM*

I. INTRODUCTION

A new and deadly virus emerged in Wuhan, China, in late 2019. This easily transmissible novel coronavirus quickly spread throughout the region and, by mid-January 2020, the virus began to spread beyond its country of origin. The World Health Organization (WHO) was first informed of the illness on December 31, 2019. One month later, on January 30, the WHO declared a Public Health Emergency of International Concern (PHEIC) in response to what was known to be SAR-CoV-2, the virus which causes COVID-19. A PHEIC is the highest level of alert available under the International Health Regulations (IHR 2005), the WHO's framework for responding to emerging diseases.

Governments responded to this threat with varying degrees of seriousness and effectiveness. At the time of this writing, COVID-19 has been identified on every populated continent, resulting in more than 100 million infections and 2.1 million deaths.[1] International travel has been curtailed, millions of people continue to live under public health restrictions, and economic activity has dramatically slowed. Several vaccines have been developed in record time, but estimates indicate that worldwide inoculation will not reach levels sufficient to return to "normal life" until at least 2022.[2] The virus – and new variants – continue to spread with rapidity and morbidity, highlighting the need for international legal cooperation in the face of a common disaster.

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* These Conclusions and Recommendations were submitted to the World Health Organization's Independent Panel for Pandemic Preparedness and Response in April, 2021 by the participants in this Symposium, joined by other participants in the Project. Whitney R. Harris World Law Institute Senior Fellow Madaline George and Harris Institute Director Leila Nadya Sadat took the lead in preparing the conclusions and recommendations, as well as the White Paper submitted to the WHO from which these conclusions and recommendations were drawn, and they appear in the comprehensive White Paper submitted to the WHO in the Executive Summary. Student Researchers Madeleine Denny, Ali Petot and Christian Rose provided superb assistance and support, and the McDonnell International Scholars Academy provided a substantial grant supporting this research. We hope that these conclusions, the White Paper accompanying them, and this Symposium will influence the ongoing process of WHO reform. We are also grateful to the editors of the *Washington University Global Studies Law Review* for their superb editing and assistance with this volume.
The online submission is available at https://theindependentpanel.org/your-contributions/view-results/.

1 *Coronavirus World Map: Tracking the Global Outbreak*, N.Y. TIMES https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html (last visited Jan. 26, 2021).

2 Sofia Bettiza, *Covid Vaccines: Why Some Countries Will Have to Wait until 2022*, BBC (Jan. 25, 2020), https://www.bbc.com/news/av/health-55804788.

The WHO plays a critical role in how States and the international community handle global health emergencies. COVID-19 has tested the effectiveness of the IHR 2005, the only binding legal instrument regarding international disease prevention and control. The IHR 2005 were drafted in part as a response to the 2003 emergence of SARS and are generally agreed to be an improvement from their predecessor.[3] Yet while the IHR 2005 include a process for declaring a PHEIC and impose requirements upon States, their application and implementation are insufficiently robust. The coronavirus crisis and States' attacks on the WHO itself have compounded these challenges.

Under its Constitution, the WHO, representing its 194 member States, acts as "the directing and coordinating authority on international health work."[4] During a global health crisis, the WHO monitors and supplies information on the disease and its spread, helps countries prepare their health systems to identify, track, prevent, and treat the disease, and plays a key role in the search for a treatment or vaccine. It works in collaboration with its Member States and has little autonomous authority of its own, relying on national governments for funding, access, and implementation.

The IHR 2005 require States to cooperate with the WHO and with each other by tracking health events on their territories, notifying the WHO if they reach a certain threshold of seriousness, providing detailed information to each other and to the WHO, and implementing a range of responses, including achieving a core set of public-health capacities.

The IHR define a PHEIC 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."[5] The WHO Director-General and an Emergency Committee are responsible for declaring a PHEIC, which allows the WHO to issue "measures that can address travel, trade, quarantine, screening, [and] treatment," as well as determine best practices.[6] Six PHEICs were declared between 2009 and 2020, each accompanied by Temporary

3 *C.f.* Barbara von Tigerstrom, *The Revised International Health Regulations and Restraint of National Health Measures*, 13 HEALTH L.J. 35 (2005).

4 Constitution of the World Health Organization, July 22, 1946, 4 Bevans 119, 14 U.N.T.S. 185.

5 *IHR Procedures concerning public health emergencies of international concern (PHEIC)*, WORLD HEALTH ORG., https://www.who.int/ihr/procedures/pheic/en/ (last visited March 5, 2021).

6 World Health Organization (@WHO), TWITTER (Jan. 30, 2020, 2:01 PM), https://twitter.com/who/status/1222973217435987970?lang=en.

Recommendations.[7] There is "no mathematical formula [or] algorithm" for a pandemic declaration,[8] nor does this declaration trigger new funding, protocols, or regulations.[9]

Throughout the COVID-19 pandemic, the WHO has faced criticism for its handling of the outbreak. Critics argue that the WHO was too late in declaring a PHEIC and too lenient in its dealings with Chinese authorities.[10] Many scholars of international law and global health pointed to systemic weaknesses in the IHR 2005.[11] Criticisms range from a lack of funding to vague language in the IHR and WHO Constitution, and many experts suggest that the IHR needs improvement if they are to adequately protect against future pandemics. As Professor Gian Luca Burci, former legal counsel to the WHO, has noted, the "criteria [for a PHEIC] are open ended and difficult to be framed in purely legal terms,"[12] suggesting that more precise regulations are required. Likewise, in the second meeting of the IHR Emergency Committee regarding the outbreak of COVID-19, the Committee advised that the "WHO should continue to explore the advisability of creating an intermediate level of alert between the binary

7 Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. TRAVEL MED. 1 (2020).

8 As explained by Michael Ryan, WHO director for health emergencies. *See* William Wan, *WHO declares a pandemic of coronavirus disease covid-19*, WASH. POST (Mar. 11, 2020), https://www.washingtonpost.com/health/2020/03/11/who-declares-pandemic-coronavirus-disease-covid-19/.

9 Previously, the WHO utilized a six-stage classification for declaring a disease a pandemic, with a disease being classified as a pandemic when stage six was reached. This process was abandoned following H1N1. *See* Stephanie Debehay, *WHO says it no longer uses 'pandemic' category, but virus still emergency*, REUTERS (Feb. 24, 2020), https://www.reuters.com/article/uk-china-health-who-idUKKCN20I0PD.

10 *See, e.g.*, 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 (2020).

11 *See, e.g.*, Alison Agnew, *A Combative Disease: The Ebola Epidemic in International Law*, 39 B.C. INT'L & COMPAR. L. REV. 97 (2016); 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); Monica Rull, Ilona Kickbusch & Helen Lauer, *International Responses to Global Epidemics: Ebola and Beyond*, 6 INT'L DEV. POL'Y (2015), https://journals.openedition.org/poldev/2178#quotation.

12 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.

possibilities of PHEIC or no PHEIC, in a way that does not require reopening negotiations on the text of the IHR (2005)."[13]

The WHO's effectiveness requires it to be perceived as legitimate, reliable, and credible. Attacks on its authority and budget[14] threaten its ability to effectively fulfil its mandate. The WHO and the IHR 2005 have been challenged by COVID-19, raising questions of fundamental and necessary technical reform, as the WHO Assembly of May 18–19, 2020 noted.[15] They have also been subjected to a broader, ideological challenge, especially by the Trump administration, similar to the criticisms levelled at other international institutions such as the International Criminal Court, the World Trade Organization, UNESCO, and the U.N. Human Rights Council.

Recognizing the need and potential opportunity for WHO reform in light of the pandemic, the Whitney R. Harris World Law Institute at Washington University School of Law, led by Professor Leila Nadya Sadat, launched a research project on *Global Governance: The World Health Organization (WHO) and the Need for Post-COVID-19 Reform* with support from the University's McDonnell Scholars Academy. This project resulted in the collaboration of partners at Florida State University College of Law, Washington University Institute for Public Health, the National University of Singapore, Melbourne Law School and the Melbourne School of Population and Global Health, and the Max Planck Institute for Comparative Public Law and International Law. The goal was to undertake an examination of the International Health Regulations (IHR 2005) and to produce and disseminate a report with recommendations for constructive reform. The research project held a series of meetings between August 2020 and February 2021. Several partners contributed essays which analyzed specific aspects of the IHR 2005 and shed light on the possibility for improvement. These articles were debated and revised following feedback

13 Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), World Health Organization, Jan. 30, 2020, https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

14 *See, e.g.*, Michael D. Shear & Donald G. McNeil Jr., *Criticized for Pandemic Response, Trump Tries Shifting Blame to the W.H.O.*, N.Y. TIMES (Apr. 14, 2020), https://www.nytimes.com/2020/04/14/us/politics/coronavirus-trump-who-funding.html.

15 *See* COVID-19 Response, Draft Resolution, Doc. No. A73/CONF./1 Rev.1, May 18, 2020, https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf (calling for "a stepwise process of impartial, independent and comprehensive evaluation, including using existing mechanisms, as appropriate, to review experience gained and lessons learned from the WHO-coordinated international health response to COVID-19").

from other members of the research project. The resulting papers are contained in this publication.

CONCLUDING OBSERVATIONS

Participants in the project offer the following ten recommendations and observations.

The Global Health Ecosystem

(1) The success and failures of certain States in containing the virus must be placed within a broad social and political context.

Singapore is often cited as an example of a successful State response to the COVID-19 pandemic, as it quickly contained the local pandemic situation to zero- or single-digit transmissions daily. Singapore's success was a result of its extensive pre-pandemic preparations, and the swift and coordinated government response. Nevertheless, Singapore's response was not perfect, particularly with respect to the spread of the virus in migrant workers' dormitories. The case study of Singapore demonstrates that the successes and failures of many countries in managing COVID-19 are attributable to social and political factors that facilitate or impede effective governmental decision-making and cooperation from the citizenry.

(2) Structural obstacles to health care reform and improvement have delayed low-income nations' ability to comply with the minimum standards for domestic health infrastructure established in IHR Annex 1, which has in turn caused delays in the monitoring and reporting of potential global health threats.

IHR Annex 1 requires all Member States to attain minimum standards of healthcare infrastructure so that they can accurately assess and identify threats to global public health. However, many nations lack the funding and resources to achieve these standards, and more than half of all Member States have fallen short. These nations weaken global health for everyone, as they do not have the capacity to accurately identify emerging threats before they spread internationally or to minimize the effects of those threats. Any plan to improve the notification structures of the IHR must recognize that even the best-designed systems rest on domestic capacity and that creating a strong heath threat identification system will depend on improving the health systems of nations with the lowest degree of investment.

Legal Reform and Reinterpretation

(3) The development of a legally cognizable definition of "pandemic" would provide an important public health tool for the international community of States.

The distinction between a PHEIC and a pandemic is unclear under existing law. This largely reflects a lack of scientific consensus. Yet during the onset of the COVID-19 crisis, there was confusion regarding the scope of the event. National governments often refer to the WHO Director-General's statement of March 11, 2020 declaring a pandemic, even though a PHEIC had been declared earlier on January 30, 2020. Moreover, no specific course of action follows from a pandemic declaration. In its current use, it does not mark a 'before and after' for states. Consequently, framing a legal definition of 'pandemic' would contribute to distinguishing it from a PHEIC. It would be equally useful in devising consequences of these declarations for the international community. Input from the medical and public health community will be decisive for properly framing the definition.

(4) The public health emergency of international concern (PHIEC) declaration system should be reformed with a tiered alert system, as a more nuanced system would better reflect the dynamic nature of pandemics and global health. A tiered system must establish clear criteria for each stage, which in turn must be accompanied by clear operational protocols, strategies for response cooperation, and financing mechanisms.

Under the current system of global health governance, only one level of alert exists: the Public Health Emergency of International Concern (PHEIC). The binary nature of this system has caused hesitancy among some NFPs to involve the WHO early in the disease-detection process, as they face serious socioeconomic repercussions if a PHEIC is declared. The WHO has itself been reluctant to declare PHEICs for this same reason. A tiered system of alert could include lower levels of disease detection, lessening the political repercussions for disease notification and for WHO involvement. This more nuanced system would be better able to capture the dynamic and ever-evolving landscape of global health, as it would give a more detailed assessment of any given threat. In addition to incentivizing early 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 poses at different stages of progression. A scoring

system, or other type of instrument, should be developed for use by the Emergency Committee and Director-General when evaluating reported events, and decisions should be made in a transparent manner.

(5) Strong monitoring mechanisms are necessary to avoid and manage the next pandemic and to improve IHR core capacity implementation. The WHO could draw from the experiences of other treaties and international organizations.

Currently, only one-third of countries have implemented their core capacity obligations under the IHR. The failure to meet IHR minimum requirements has been a persistent obstacle to achieving pandemic preparedness. However, the IHR mechanisms for monitoring and encouraging compliance from Member States are weak, as they rely on self-monitoring and self-reporting. This weakness is not inevitable; other treaty systems exhibit a spectrum of monitoring methods. Independent external review and standing monitoring bodies, like those found in the Nuclear Non-Proliferation Treaty and the 1961 United Nations Single Convention on Narcotic Drugs, create greater incentives for compliance. An analogous system is necessary in the context of global health in order to prevent future outbreaks of pandemic disease.

(6) Reinterpretation of existing WHO provisions may be a productive way to protect global health, as substantive reform to the WHO would be beneficial but may be difficult to achieve.

Global health governance relies on collaboration, as the system is only as strong as its weakest member. However, the most recent surge of nationalism, as exemplified by the U.S. and Chinese responses to COVID-19, undermine cooperation and threaten global efforts to contain this or future pandemics. In its current iteration, the WHO contains a number of structural weaknesses which restrict its ability to govern pandemic response and to ensure global health in the face of these nationalistic responses. Key changes to the WHO's architecture could address this, but may be difficult to achieve. A possible work around the challenges to substantive reform is to reinterpret existing provisions of the IHR using the precautionary principle.

(7) States should consider using the dispute settlement mechanisms in Article 75 of the WHO Constitution and Article 56 of the IHR to enforce State compliance with the obligations contain within these instruments.

Article 75 of the WHO Constitution provides for dispute resolution before the International Court of Justice, yet no State has ever employed this provision to ensure compliance with the IHR, perhaps due to jurisdictional and evidentiary difficulties. Disputes between States during the COVID-19 pandemic have demonstrated the need for a better resolution mechanism, both to resolve contention and to reinforce the power of the WHO.

(8) Annex 2 of the International Health Regulations, which governs when a Member States' National Focal Points (NFP) must report a potential health threat to the WHO, needs reform to more accurately and effectively detect threats to global health security.

Although Annex 2 of the IHR has improved upon its predecessor by moving away from the disease-specific model of threat notification, it continues to suffer shortcomings. Chief among these is the inability of Annex 2's decision-making algorithm to produce consensus about what constitutes a notifiable event. Several studies have demonstrated that Annex 2's decision instrument lacks specificity and requires improved sensitivity, which can result in missing reportable events and in false positives which threaten to overburden the reporting system, particularly as threats are predicted to increase in number in the future. Annex 2's criteria (particular the first two: *i.e.,* if the public health impact of the event is serious and if the event is unusual or unexpected) should be revised with clear definitions and should incorporate epidemiological criteria into the decision-making process so that States' National Focal Points (NFP) are able to make accurate and uniform decisions that are less dependent on subjective considerations. Finally, integrating the One Health Approach – which recognizes the interconnectedness of humans, pathogens, animals, and the shared environment in instigating health threats – into Annex 2 would help the IHR remain relevancy in the long-term.

The Need for New Legal Instruments

(9) It is worth considering whether a new comprehensive international treaty to prepare for and address future pandemic outbreaks should be negotiated. This could be done as a self-standing regime, or negotiated under the auspices of the United Nations.

The global response to the COVID-19 pandemic has been poorly designed and executed, with gaps in transparency, scientific understanding, and vaccine manufacturing capacity, as well as the lack of political cohesion. To avoid repetition of this scenario, consideration should be given to reconfigure the international framework for preparing and responding to pandemic outbreaks through an international treaty or convention defining obligations and rights sufficient to constrain arbitrary or destructive behavior by national political leaders. A comprehensive agreement might encompass the subject matter of the WHO (with its public health mandate) and also the World Bank and IMF (on the international financial side), as well as other subject matter actors, and might be negotiated under the umbrella of the United Nations. A key element to success would be an architecture that provides benefits to all States Parties – avoiding deprivation of Party A to benefit Party B. In principle an international agreement on pandemic preparedness and response could create benefits for all its participating members.

(10) States should consider the negotiation of a new treaty to ensure equitable access to vaccines, medicines, and diagnostics.

Calls for a new agreement on pandemic preparedness gained momentum on March 30, 2021 when leaders of the European Union, along with WHO Director General Dr Tedros Adhanom Ghebreyesus, called for the negotiation of a new international treaty to ensure "universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics."[16]

16 European Council, Press Release, *"COVID-19 shows why united action is needed for more robust international health architecture". Op-ed article by President Charles Michel, WHO Director General Dr Tedros Adhanom Ghebreyesus and more than 20 world leaders*, Mar. 30, 2021, https://www.consilium.europa.eu/en/press/press-releases/2021/03/30/pandemic-treaty-op-ed/.