A Global Health Law Trilogy: Transformational Reforms to Strengthen Pandemic Prevention, Preparedness, and Response

Benjamin Mason Meier, Roojin Habibi & Lawrence O. Gostin

Journal of Law, Medicine & Ethics (forthcoming September 2022)

This is a pivotal moment in the global governance response to COVID-19, with crucial global health law reforms being undertaken simultaneously in the coming years: the revision of the International Health Regulations, the implementation of the GHSA Legal Preparedness Action Package, and the negotiation of a new Pandemic Treaty. Rather than looking at these reforms in isolation, it will be necessary to examine how they fit together, considering: how these reforms can complement each other to support pandemic prevention, preparedness, and response; what financing mechanisms are necessary to ensure sustainable health governance; and why vital norms of equity, social justice, and human rights must underpin this new global health system.

Keywords: International Health Regulations, Global Health Security Agenda, Pandemic Treaty, World Health Organization, COVID-19

The COVID-19 pandemic has been the greatest health crisis of our lifetimes, but the glaring limitations of the public health response offer a unique opportunity to launch transformational reforms in global health governance. In reshaping global health governance to prepare for future threats, international initiatives in the coming years will give rise to sweeping reforms of global health law. The international community is simultaneously undertaking three transformational legal reforms: the revision of the International Health Regulations (IHR), the implementation of a Legal Preparedness Action Package under the Global Health Security Agenda (GHSA), and the negotiation of a new Pandemic Treaty. Taken together, these reforms could transform pandemic prevention, preparedness, and response, but it will be crucial to harmonize these legal initiatives, recognizing interconnections across the global health law landscape.

Limitations of Global Health Law in the COVID-19 Response

The COVID-19 pandemic has exposed fundamental gaps in global health law and governance. Revealing weaknesses in the foundations of pandemic preparedness and response, the IHR have proven ineffective in shaping national actions, with governments ignoring public health evidence, violating IHR standards, and undermining international health cooperation. The World Health Organization (WHO), which oversees IHR implementation, became embroiled in political controversy, keeping the Organization from holding governments to account for clear neglect of health recommendations and legal obligations. Despite fundamental IHR reforms in 2005 in the wake of the SARS epidemic, responses to COVID-19 have revealed continuing legal limitations in: notifying WHO rapidly of novel outbreaks, adhering to WHO recommendations, and realizing global solidarity in confronting a common threat.¹ In the absence of international legal obligations, essential medical countermeasures such as diagnostics, personal protective equipment, vaccines, and therapeutics remain inequitably allocated. Without innovative reforms in global health law and governance, the same inadequate, ineffective, and unjust response is likely to occur when the next health crisis occurs – a crisis could be even more catastrophic than the COVID-19 pandemic.

Reforming Global Health Law to Prepare for Future Challenges

This is a pivotal moment for the future of global public health, with the coming months holding the potential for a trilogy of crucial global health law reforms:

IHR Amendments

The IHR has near-universal adherence as the governing international legal instrument for responding to globalized infectious disease threats. IHR (2005) codified interlocking obligations to (1) alert the world rapidly to the emergence of a potential Public Health Emergency of International Concern (PHEIC), (2) encourage evidence-based public health interventions, while avoiding undue burdens on human rights or international trade and travel, and (3) ensure core national public health capacities to prevent, protect against, control, and provide a public health response to infectious disease outbreaks.² However, recent PHEICs have highlighted systemic failures to implement these obligations, undermining the effectiveness of the IHR.³ In response to IHR failures in the COVID-19 response, WHO member states have proposed targeted amendments to the IHR, including prompt and transparent reporting of PHEICs, sharing of scientific data and pathogen sequencing, and evidence-informed and rights-based public health measures.⁴ The May 2022 World Health Assembly has laid the foundation for member state negotiations over the next two years, culminating in revisions at the May 2024 Assembly. Should these reforms be adopted, they would automatically enter into force for all WHO member states within a prescribed period, unless a state explicitly rejects the amendments or submits a reservation to them.

GHSA Legal Preparedness Action Package

Building from national limitations in IHR implementation, states first came together in 2014 to launch the GHSA, creating a non-binding framework of "Action Packages" to support states in

preventing, detecting, and responding to public health emergencies.⁵ These GHSA Action Packages sought to build national core capacities for public health—refocusing international collaboration on public health as a security threat—but it has long been clear that states lack the legal authorities and legal competencies necessary to achieve GHSA targets.⁶ Recognizing these gaps in national legal capacities, states worked together amid the COVID-19 pandemic to establish a new GHSA Action Package on "legal preparedness." In developing a foundation and common understanding of the competencies necessary for public health emergency legal preparedness, this new GHSA Legal Preparedness Action Package seeks to develop technical tools to guide and support countries in strengthening national laws to realize global health security.⁷ Launched in March 2022, the implementation of this Action Package will be bringing together state and non-state actors over the next three years to build a strong advocacy platform for legal preparedness as well as develop technical resources for countries to review and strengthen legal preparedness capacities to respond to future public health emergencies.

Pandemic Treaty

With limitations of global health law hindering national and global responses during the COVID-19 pandemic, state and non-state actors have called for the development of a new convention, agreement, or other international instrument, codifying through WHO what has come to be known as the "pandemic treaty." Advocates see this new treaty as a means to ensure international coordination in a pandemic response, a "deep prevention" approach to preparedness (addressing upstream factors that could prevent disease outbreaks), and novel mechanisms to provide "universal and equitable access to safe, efficacious and affordable vaccines, medicines

and diagnostics for this and future pandemics." This pandemic treaty would seek to complement, rather than replace, the IHR, with the treaty detailing additional provisions to address limitations in the scope and content of existing legal instruments, thereby advancing legal authorities that would be more effective, equitable, and enforceable. Drawing from this call for a pandemic legal instrument, the World Health Assembly held a November 2021 special session, resolving to develop this new treaty under WHO authority. While the pandemic treaty was not a scheduled point of discussion in the May 2022 World Health Assembly, it was raised frequently during the discussion of WHO's preparedness and response to public health emergencies, with state and non-state actors looking to this treaty to support new global norms for information sharing and capacity building. With an Intergovernmental Negotiating Body empaneled to consider prospective treaty provisions, WHO member states have begun a multi-year negotiating process, with several state meetings, public hearings, and regional consultations scheduled in the coming months, to develop a draft agreement for consideration by the World Health Assembly in May 2024.

A Changing Landscape for Global Health Law

These reforms of global health law must be considered as interconnected instruments across an expansive legal landscape. Rather than developing these reforms in isolation, it will be crucial to examine how these sweeping reforms complement each other, recognizing:

- how these reforms align to support health system capacities understanding what
 each reform accomplishes (and leaves out) in realizing interconnected purposes
 toward the larger goal of legal preparedness.¹²
- what funding mechanisms are necessary to ensure effective health governance –
 recognizing how sustainable financing can strengthen leadership across
 governance institutions and support implementation of legal reforms.¹³
- why common norms are necessary across reforms examining how harmonized normative frameworks can shape common purpose across legal instruments, advancing equity, social justice, and human rights as a vital normative foundation of global health governance.¹⁴

This trilogy of global health law reforms could support global solidarity in the face of common threats, but public health leaders must align diplomacy across these simultaneous reforms to ensure the comprehensive legal architecture commensurate with emerging governance challenges. COVID-19 is an unprecedented crisis, but it offers a unique opportunity to reform global health law to effectively coordinate pandemic prevention, preparedness, and response – establishing transformational governance to overcome the limitations of the COVID-19 response and strengthen legal authorities to advance global health.

Note

The authors are grateful to Sonam Shah, Jacquelyn Bedingham, and Alessandro Figueroa for their research support in detailing these rapidly evolving advancements across the global health law landscape.

References

- 1. Gostin LO, Habibi R, Meier BM. Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats. *J Law Med Ethics*. 2020;48(2):376-381.
- 2. Villarreal PA, Habibi R, Taylor A. Strengthening the Monitoring of States' Compliance with the International Health Regulations. *Int Organ Law Rev.* 2022; 19(1): 215-240.
- 3. Singh S, McNab C, Olson RM, et al. How an outbreak became a pandemic: a chronological analysis of crucial junctures and international obligations in the early months of the COVID-19 pandemic. *The Lancet*. 2021;398(10316):2109-2124.
- 4. The Lancet Global Health. (2022). The future of the International Health Regulations. The Lancet Global Health, 10(7), e927.
- 5. Katz R, Sorrell EM, Kornblet SA, Fischer JE. Global Health Security Agenda and the International Health Regulations: Moving Forward. *Biosecurity and Bioterrorism:*Biodefense Strategy, Practice, and Science. 2014;12(5):231-238.
- 6. Meier BM, Tureski K, Bockh E, et al. Examining National Public Health Law to Realize the Global Health Security Agenda. *Medical Law Review*. 2017;25(2):240-269.
- 7. Ayala A, Brush A, Chai S, et al. Advancing Legal Preparedness through the Global Health Security Agenda. *J Law Med Ethics*. 2022;50(1):200-203.
- 8. Gostin LO, Meier BM, Stocking B. Developing an Innovative Pandemic Treaty to Advance Global Health Security. *J Law Med Ethics*. 2021;49(3):503-508.
- 9. Vinuales J, Moon S, Le Moli G, Burci GL. A global pandemic treaty should aim for deep prevention. *The Lancet*. 2021;397(10287):1791-1792.
- 10. World Health Organization. Special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response. Accessed April 9, 2022. https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74(16)-en.pdf
- 11. Gostin LO. COVID Pushed Global Health Institutions to Their Limits. *Sci Am*. 2022;326(3):46-49.
- 12. Burci G-L. A New Pandemic Treaty, Revised International Health Regulations, Or Both? What Is The Actual Roadmap? Health Policy Watch. February 2021. https://healthpolicywatch.news/a-new-pandemic-treaty-revised-international-health-regulations-or-both-what-is-the-actual-roadmap/. Accessed June 10, 2022.
- 13. Gostin LO, Klock KA, Clark H, et al. Financing the future of WHO. *The Lancet*. Published online March 2022:S0140673622005335.

14. Habibi R, Hodgson TM, Meier BM, Seiderman I, Hoffman S. Reshaping Global Health Law in the Wake of COVID-19 to Uphold Human Rights. Health and Human Rights Journal. June 1, 2021. https://www.hhrjournal.org/2021/06/reshaping-global-health-law-in-the-wake-of-covid-19-to-uphold-human-rights/. Accessed April 9, 2022.