ABOUT THE O’NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW

The O’Neill Institute for National and Global Health Law (O’Neill Institute) was established in 2007 through the generous philanthropy of Linda and Timothy O’Neill to respond to the need for innovative solutions to the most pressing global health concerns. In bringing together experts from both the public health and legal fields, the O’Neill Institute reflects the importance of public and private law in health policy analysis. Housed at Georgetown University Law Center in Washington, D.C., the O’Neill Institute draws upon Georgetown’s considerable intellectual resources, and believes that the law is a fundamental tool for solving critical health problems. The O’Neill Institute sees national and global health law as a frontier for collaborative, international, and rights-based approaches to health and well-being for all.

ABOUT THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

The Foundation for the National Institutes of Health (FNIH) creates and leads alliances and public-private partnerships that advance breakthrough biomedical discoveries and improve the quality of people’s lives. The FNIH organizes and administers research programs; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health challenges. The FNIH was established by the United States Congress in 1990 as a not-for-profit 501(c)(3) charitable organization. The FNIH began its work in 1996 to facilitate groundbreaking research at the U.S. National Institutes of Health (NIH) and worldwide. As an independent organization, it raises private funds and creates public-private partnerships to support the mission of the NIH—making important discoveries that improve health and save lives.
SECTION 1

INTRODUCTION

On 1 December 2021, the World Health Assembly adopted a resolution establishing an Intergovernmental Negotiating Body (INB) to determine the content and form of a new pandemic agreement. Consultations over the course of the first half of 2022 have given rise to questions from Member States as to the content and form of a new instrument. During the INB’s first public hearings:

There were different views expressed in terms of the overall future governance mechanism of a new international instrument. Some participants advocated for the instrument to be non-binding and advisory in nature and for individual countries to be able to implement their own policies in order to respect national sovereignty. Other speakers stressed that nationalism should be prevented, with steps taken to monitor and enforce national compliance to the international instrument.

This means that the INB and country decision-makers will need to grapple with how the principle of national sovereignty, and the accompanying principle of non-interference, will be addressed with respect to the agreement’s content and form, including obligations to share data, resources, and personnel, and to relinquish control over certain aspects of national coordination and response. The INB will have to find a balanced path that contains meaningful norms and compliance while still respecting national sovereignty.

The O’Neill Institute for National and Global Health Law, a WHO Collaborating Center, in partnership with and supported by the Foundation for the National Institutes of Health (FNIH), in an effort to support the World Health Assembly and the INB, convened leading authorities on international agreements in trade, regional integration, public health emergency preparedness, finance, biomedical science, climate change, maritime affairs, tobacco control, and human rights. Through a series of written, bilateral, and group discussions, we sought to provide the INB with a learned analysis of the stringency and stickiness of international commitments and the often nonobvious relationship between norm-setting and regime compliance to inform its dialogue. We hope this offers technical assistance and support on the INB decisions regarding the modality of a possible pandemic instrument under WHO Constitution Article 19 (conventions), Article 21 (regulations), Article 23 (recommendations), or alternative vehicles. Our expert group is highly diverse in its experience and knowledge, and every WHO region is represented among its membership. Moreover, our experts do not share a uniform view as to the propriety of pursuing a new treaty: some accept that a new binding agreement is essential while others believe that attention should be more focused on reform of the International Health Regulations (IHR) and other existing mechanisms. However, all share a commitment to improved pandemic preparedness and response. The list of contributors is provided as Annex 1. The list of our guiding questions is provided as Annex 2.
Broadly, the experts often noted that whatever content and form are chosen for an agreement, stakeholder involvement will be critical. Intergovernmental agreements in recent years have been augmented, or even displaced, by solutions that are less government-centered and extend to the charitable and business sectors, as well as civil society. Prominent public-private partnership (PPP) models in global health include Gavi, the Vaccine Alliance; the Global Fund for AIDS, Tuberculosis, and Malaria; CEPI; and intergovernmental/inter-PPP initiatives such as the Access to COVID-19 Tools (ACT) Accelerator, including the COVAX Facility. Now that the ACT Accelerator may sunset by the end of 2022, finding new innovative equity models will be important. New partnerships focused on discrete areas of pandemic preparedness and response could be negotiated among member governments, industry, and international organisations before a new crisis sets in.

Just as important as an inclusive approach, an agreement with one or many binding legal obligations cannot rely predominantly on rulemaking and enforcement since many countries lack the technical and infrastructural capacity to achieve compliance. This has been a prominent shortcoming of the IHR, for example. Agreements that establish what in some contexts are described as “unfunded mandates” risk failure precisely because they do not account for critical components of sovereignty, particularly the power of the purse. Thus, compliance is not simply a matter of accountability mechanisms but also adequate and sustainable financing and an aligned incentive structure.

Our collaborators often noted that national sovereignty should be considered in relation to shared risks and common security challenges, particularly when political boundaries cannot contain the effects of the threats. Given this, many saw the value in emulating existing agreements that demonstrate where national outcomes have been enhanced by eschewing the instinct to go it alone.

International law is vitally important but limited in the obligations it can impose by decree. It is traditionally difficult to create international norms, to persuade governments to give up aspects of sovereignty, and even more difficult to ensure compliance using the methods that work in domestic systems. Moreover, identifying and reckoning with the barriers to entering a new international agreement is a threshold challenge. Therefore, flexibility in approach and implementation must be considered at the outset, along with opportunities to build confidence. Because most states follow most of their international obligations most of the time, a new instrument could over time positively affect people’s lives in a cognizable way.
SECTION 2

BINDING OBLIGATIONS UNDER INTERNATIONAL LAW

A TREATY IS

an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.\(^5\)

The bedrock principle of treaty law is *pacta sunt servanda*, a concept of legendary normative import that was succinctly defined in Article 26 of the Vienna Convention on the Law of Treaties: “Every treaty in force is binding upon the parties to it and must be performed by them in good faith.” Moreover, state parties are “obliged to refrain from acts which would defeat the object and purpose of a treaty” (art. 18).
The WHO Constitution is itself a treaty, originally adopted in 1946 and now accepted by 193 nations. Article 19 of the Constitution is the mechanism most closely associated with creating new binding commitments in international health. It states that the World Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

It is important to emphasize that while an Article 19 convention can be adopted over the dissent of multiple Member States, the dissenters are not obligated to join the agreement. Each country retains sole authority over whether to ratify the instrument and to determine the processes by which to make that decision. The WHO has negotiated only one instrument under Article 19, the Framework Convention on Tobacco Control (FCTC), which has been transformative in some respects and limited in others (more on this below).

Consistent with Article 19, the Vienna Convention states that a “treaty does not create either obligations or rights for a third State without its consent” (art. 34) though as is the case with every other maturing area of international law, an obligation may over time become “binding upon a third State as a customary rule of international law, recognized as such” (art. 38). For a rule to have reached the status of “customary international law,” it requires a high degree of evidence that “the acts concerned amount to a settled practice” and “the States concerned must feel that they are conforming to what amounts to a legal obligation.”

In addition, a country that has entered into a treaty may elect to announce reservations, understandings, and declarations, which provide notice to fellow parties on how it intends to interpret the instrument. Unlike in common law contracting where multiple interpretations of key terms can void the agreement, the absence of a meeting of the minds is more readily tolerated but it makes accountability and enforcement that much more tenuous. Still, the opportunity to announce reservations lessens the barriers to entry and should trust and confidence arise over time the reward may be worth the risk.

The high bar for a country to be bound to a new obligation under international law, whether by treaty or custom, ensures that a country’s right to self-determination is protected from accidental or negligent waiver. In short, nations have to make a deliberate choice as to when they voluntarily agree that collective problems require collective decision-making, realizing that rights also come with obligations. Moreover, there must be clarity as to how these obligations flow—from state to state, from state to international organisations, some combination of these, or other possibilities.
CONVENTIONS CHARACTERIZED BY BINDING LEGAL COMMITMENTS

The experts analysed a bevy of conventions in diverse areas of international activity to outline the kinds of obligations countries have made and the extent to which these commitments are followed.

A. Framework Convention on Tobacco Control

As stated above, the only Article 19 treaty the Health Assembly has concluded is the FCTC, designed to establish a regulatory pathway for countries to adopt strong tobacco control measures in the face of a globally coordinated industry incentivised to proliferate it. It translated evidence-based public health measures into legally binding obligations; addressed the multiple sectors affected by tobacco consumption, including agriculture; and successfully laid the groundwork to adopt further measures at regular meetings of a standing decision-making body.

The framework convention approach offers important possibilities for a pandemic agreement. While provisions of the FCTC address problems that are international in character (e.g., transborder advertising, promotion, and marketing), the treaty mostly operates by establishing broad categories of regulatory action that parties may or must take. At the country level this allows for an accompanying approach rather than constraining parties to take all the same specific measures. Moreover, the FCTC’s governing body, the Conference of the Parties, has issued guidelines under relevant provisions that not only guide countries with respect to implementation but also provide the basis for domestic legislation where it is relevant and link its countermeasures to other human rights.

It was also highlighted that the WHO has sophisticated rules concerning non-state interaction but that its Constitution pre-authorizes it to interface with entities of its own creation. The FCTC Secretariat, which is governed independently from of the WHO, therefore has a built-in structural advantage to allow it to fulfill the Convention’s aims with the support and partnership of the WHO. If a new pandemic agreement is crafted under Article 19, similar bodies will have comparable structural access.

To be sure, the FCTC has meaningful drawbacks, not least of which are that it took over a decade to negotiate and conclude and it is very hard to update as the external environment evolves. In addition, not all signatories of the Convention ratified the agreement, and one expert emphasised that a key signatory (the United States) faces nearly insuperable domestic political obstacles to securing the 67 Senate votes necessary for ratification anytime soon. It also contains a “no reservations” clause (art. 30) meaning the barrier to entry was higher than it might otherwise have been. That only one Article 19 treaty has even been concluded in the nearly 80-year history of the WHO is further evidence that Member States have some reluctance to use this mechanism and the reasons for that need to be explored, as they will have implications for any obligations that are included in an agreement of any nature.
B. Convention on Biological Diversity

The Convention on Biological Diversity (CBD) aims to conserve the “variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part” (arts. 1-2). In addition to conservation, the CBD supports the sustainable use of biological resources, along with fair and equitable sharing and technology transfer. Unsurprisingly, its crafters had to make choices to balance competing aims. For example, Article 3 of the CBD declares that:

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

The CBD’s Nagoya Protocol on Access and Benefit Sharing reinforces this principle by stating that pathogens and other genetic resources are owned by the country in which they are found. These provisions support sovereign interests and are meant to advance health equity, the latter of which is the principle that the World Health Assembly has set at the heart of any new pandemic agreement. At the same time, some experts reflected that “the sovereign right to exploit their own resources” runs counter to the concept of conservation of biodiversity overall. Strictly read, a nation could use its treaty-based monopoly on its own pathogens to engage in vaccine nationalism, even when those pathogens have contributed to a PHEIC or pandemic. So another lesson of the CBD experience is that negotiators will have to make trade-offs among important principles in the obligations and expectations they wish to place on the community of nations.
C. The U.N. Charter and Security Council

In many ways, the establishment of the Security Council by the United Nations Charter represented a tremendous willingness of governments to relinquish some sovereignty after the devastation of World War II. The Security Council can maintain or restore international peace and security through legally binding resolutions adopted pursuant to the Charter. It can identify “the existence of any threat to the peace” and “make recommendations” (art. 39), call for compliance with provisional measures (art. 40), take non-military action (art. 41), or take “such action by air, sea, or land forces as may be necessary to maintain or restore international peace and security” (art. 42). The stratifying of these articles may be a model to emulate in calibrating a response to pandemic threats.

Certainly, the binding character of Security Council resolutions has not insulated them from compliance challenges and allegations of ineffectiveness or overreach. For example, the Council may not recognize an obvious breach of peace and security in the first place or the peacekeeping forces it deploys to conflict zones may be ultimately unsuccessful in their efforts. There are also instances in which it has intervened in intra-country conflicts; those who are concerned about the potential of a pandemic instrument impinging on national sovereignty may wish to understand whether the INB intends to consider obligations that would unnecessarily intrude on intra-country affairs.

D. Human Rights Treaties

The major international human rights treaties, including the International Covenant on Civil and Political Rights; the International Covenant on Social, Cultural, and Economic Rights; the Convention on the Rights of the Child; the Convention on the Elimination of All Forms of Discrimination against Women; the Convention on the Elimination of All Forms of Racial Discrimination; the Convention on the Rights of Persons with Disabilities; and others, are operationalised through periodic reporting to authorised monitoring committees, and some of the experts reflected that constructive dialogues with state representatives have resulted. These instruments, along with global compacts on burden-sharing and cooperation, are bridging the gaps in formal treaty structures that cannot be fulfilled through amendments, particularly in the context of the U.N. Human Rights Council’s Universal Periodic Review (UPR).
Nongovernmental organizations (NGOs) monitor these interactions carefully, amplify their outcomes, and often issue shadow reports that incorporate their own independently driven observations. This increases public discourse and awareness and drives inclusion and transparency. For example, one expert highlighted the degree to which NGOs interfaced with the Helsinki Accords process, notably Helsinki Watch, which monitored the Soviet Union’s compliance with its treaty obligations and later evolved into Human Rights Watch, which advocates for human rights more generally. NGOs have also been credited with boosting state compliance with the FCTC and the International Code on the Marketing of Breast-milk Substitutes, among others.

States rarely relinquish control to intergovernmental decision-making bodies through human rights treaties. Normally, they only require governments to consider domestic action to support their treaty obligations. One exception, however, is that some human rights treaties allow individuals to seek a remedy of a human rights violation from a regional body. For example, the American Convention on Human Rights of 1969 established the Inter-American Court on Human Rights (art. 33), and a “State Party may...declare that it recognizes as binding...the jurisdiction of the Court on all matters relating to the interpretation or application of this Convention (art. 62). Another prominent illustration is the European Convention on Human Rights (ECHR), which is enforced by the European Court of Human Rights in Strasbourg. However, even when these organs exist, state compliance with them can be tenuous. While most parties to the ECHR do comply with it, some states grant ultimate decision-making to their apex judicial authorities, while others disregard rulings and withdraw from the mechanism.

E. Global Trade Agreements

Trade liberalisation provisions under World Trade Organization (WTO) agreements concerning non-discrimination, market access, and national treatment obligations represent legal duties enforced through a dispute resolution mechanism that states have found to be credible and that is carefully tailored to the scope of each dispute. WTO members can also negotiate exceptions to binding rules in public health emergencies, such as TRIPS Agreement Flexibilities or the recent IP temporary waiver for COVID-19 vaccines.

Specialized agreements like the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) provide guidance to governments on compliance measures and organise the adoption of technical guidance by expert bodies like the Codex Alimentarius Commission and the International Organization for Standardization. An Article 19 instrument could attempt to create mechanisms that mimic these relatively successful apparatuses, it being understood that the incentive structure to comply with trade obligations is much different than that underpinning public health. Even when incentives to comply are apparent, some experts expressed that sovereignty concerns still pervade the WTO’s relatively successful system.

F. International Environmental Law

Some experts suggested that sovereignty and collective interests had aligned in certain environmental agreements. For example, the Vienna Convention for the Protection of the Ozone Layer is a highly flexible instrument that created a forum for discussion and ideation that could lead to conversation and swift action on discrete issues as they arise. As the science evolved, state parties had momentum to craft and conclude the Montreal Protocol on Substances that Deplete the Ozone Layer only two years after Vienna, which introduced...
what remains the standard approach to compliance in environmental governance; a major treaty-specific environmental fund; and provisions on trade measures, market mechanisms and technology transfer. This was cited as a model for initiating the kinds of conversations that build confidence and trust and lead to durable results.

The Convention on Nuclear Safety\textsuperscript{27} codified International Atomic Energy Agency (IAEA) standards and introduced a peer-review system for implementation. In the nuclear energy space, the work of the IAEA under the Non-Proliferation Treaty and bilateral safeguard agreements has been essential in addressing the improper diversion of nuclear technology to military use. While national regulators are ultimately responsible for the safety of material within their borders, the regulators have agreed to peer-review each other, understanding that a nuclear catastrophe in one nation may not be confined within political borders. In other words, to ensure nuclear safety within one’s own territory, it is necessary to have some influence over the practices of one’s neighbors and to apply their learnings to one’s own context. The IAEA/NPT system of inspections based on safeguard agreements is idiosyncratic and linked to the nature of the dual use of nuclear technology, but the principle could be applied to any number of pandemic preparedness measures, including peer assessments of outbreak assessments, core capacities, and service delivery. The Convention, and the IAEA specifically, are generally regarded to have worked well (with some exceptions) as a result of the international consensus on the issue, and the IAEA’s expertise in implementing its mandate.

A series of conventions concerning the movement and disposal of hazardous material was also cited as containing examples of multilateral agreements where countries had calculated that collective action merited a degree of joint decision-making. The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal,\textsuperscript{28} the
Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemical and Pesticides in International Trade, and the Stockholm Convention on Persistent Organic Pollutants created expert committees to identify and regulate hazardous chemicals and instituted notification and prior informed consent processes for when covered materials are produced or transported. Understanding how the parties have built confidence in this system over time can provide a roadmap to generating trust in a new pandemic regime.

However, the cautionary tale concerning environmental treaties is there is little appetite from countries to cede regulatory intervention to international technocrats. State delegations desire to stay in the mix and to delegate work to their own regulatory bodies (the IAEA/NPT system being a relevant example). Countries have chosen to reimagine other regimes in this manner too. In the climate change space, the pressure was so strong to devolve power that the Kyoto Protocol’s centralised, top-down approach evolved into the more distributed and disbursed system found in the Paris Agreement. (This latter mindset is also driving the post-2020 Global Biodiversity Framework.)

G. International Narcotics Control Law

Treaties governing and monitoring the production of legal and illicit drugs may provide lessons on how to develop an investigatory programme. The International Narcotics Control Board (INCB), originally created by the Single Convention on Narcotic Drugs, 1961, can investigate compliance with the Convention and its successor agreements and enjoys some limited sanctions authority. The INCB’s monitoring, reporting, and investigatory powers are viewed as its strengths, but experts cautioned that there is little appetite to aggressively pursue such an option under a pandemic convention at such an early stage. However, a pandemic agreement could specify a limited set of critical conditions with scalable consequences for a failure to comply.

H. International Health Regulations

Our collaborators turned, perhaps predictably, to the most important public health preparedness and response agreement in existence today: the International Health Regulations. The IHR were crafted under the WHO Constitution’s alternative international law-making power found in Articles 21–22:

*The Health Assembly shall have authority to adopt regulations concerning:*

- a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
- b) nomenclatures with respect to diseases, causes of death and public health practices;
- c) standards with respect to diagnostic procedures for international use;
- d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;
- e) advertising and labeling of biological, pharmaceutical and similar products moving in international commerce.

[Such] regulations...shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice.
As with Article 19 conventions, Article 21 regulations can be approved over the objection of WHO Member States, who are nevertheless not compelled to be bound by them. However, countries must opt-out of Article 21 regulations as opposed to exercising the opt-in mechanism associated with Article 19 conventions. Some experts highlighted evidence from behavioral science that an opt-out regime may result in more countries participating in an agreement due to the effort required to take affirmative steps to remove oneself from the instrument.

The IHR “provide an overarching legal framework that defines countries’ rights and obligations in handling public health events and emergencies that have the potential to cross borders and create rights and obligations for countries, including the requirement to report public health events. The Regulations also outline the criteria to determine whether or not a particular event constitutes a ‘public health emergency of international concern’.”

The IHR accommodate many aspects of national sovereignty, empowering the country-designated “National Focal Points,” and recognising the compliance challenges that states with complex federal systems would face with the notification requirement. In addition, parties are permitted to use their own domestic structures and resources to meet their IHR obligations, particularly with regard to surveillance, reporting, notification, verification, response, collaboration, and port of entry activities. As to be expected, such a philosophy can slow implementation and result in unaligned interpretations over requirements.

The 2005 revision of the IHR was designed to address such compliance gaps by boosting accountability and transparency, particularly concerning countries’ obligations to report emerging threats. Even then, the revision gave states significant agency to shape the information sent to the WHO and did not address the real adverse economic and political implications of proactively reporting potential pathogens. Some experts emphasised that surveillance data must be shared according to internationally agreed-upon criteria and that, to the extent that sovereign preferences inhibit such a regime, all populations will be threatened.

Resolving disputes has also been a challenging issue and there has been no standalone mechanism for compliance monitoring and evaluation. Some experts reinforced the need to address countries’ incentives to comply and were closely observing a newly initiated IHR reform negotiation that includes the formation of a committee to address country compliance.

I. Regional Multilateral Cooperation Treaties

In the 2021 high-level meetings that the O’Neill Institute and FNIH convened to analyse Legal Tools for Pandemic Preparedness:

Several regional leaders supportive of an Article 19 agreement generally cautioned that effective regional strategies should not be usurped by a one-size-fits-all approach. Common diseases will be endured differently due to seasonality, resourcing, and variations in immunological naivety. Deliberate choices as to what should be handled at the global, regional, national, and local levels; creating room to incorporate and harmonize regionally-developed protocols addressing local responses; and enhancing communication between and among regions are areas ripe for consideration.

Many regional institutions from the Organization of American States to the Nordic Council of Ministers are organised via treaty and tailored to address matters of particular importance to the region. For example, the Treaty Establishing the East African Community facilitated the negotiation and development of a regional intellectual property regime related to public
health. It is also incrementalist in that governments have only given limited powers to the East African Community but there is room to increase the areas that they can work on together as they build confidence and demonstrate positive results. Regional treaties can serve as the starting point for building collective consensus.

In addition, the Association of Southeast Asian Nations (ASEAN) adopted the Agreement on Disaster Management and Emergency Response (AADMER) to improve joint preparedness and response in the wake of the 2004 Indian Ocean Tsunami. Like other examples referenced in this report, AADMER serves as an overarching framework to encourage ongoing conversation and coordination as new threats are identified or realised. It recognises that, although a Country has the primary role to reduce disaster risk, responsibility should be shared with other stakeholders, including local government, the private sector, and others when it comes to aid, assistance, and international cooperation. It paved the way for the establishment of the ASEAN Coordinating Centre for Humanitarian Assistance (AHA Centre), which serves as the operational engine of AADMER and facilitates cooperation and coordination amongst ASEAN nations, and with relevant UN and international organisations.

In addition, the ASEAN Secretariat administers a relief fund and facilitates the development of a five-yearly work programme. Despite having such a civil service, AADMER is clear that the “sovereignty, territorial integrity and national unity of the Parties shall be respected… in the implementation of this Agreement [and] each affected Party shall have the primary responsibility to respond to disasters occurring within its territory…” (art. 3).

**J. Maritime Treaties**

International maritime law is a body of international obligations concerning navigation, shipping, and shared waterways. Like infectious diseases, bodies of water do not recognise political borders, so the laws of nature often compel countries to work together to solve common challenges.

The Boundary Waters Treaty of 1909 was enacted to “prevent disputes regarding the use of boundary waters” between Canada and the United States. The treaty created the International Joint Commission comprising three US and three Canadian representatives, with decisions taken by majority. In the case of a tie, the Commission reports the outcome to their respective governments who together choose a neutral “umpire” to finally resolve the matter (art. 10). This method is commonly used in arbitration proceedings to solve any number of disputes and could be pertinent for a pandemic treaty because it lessens the barriers to entry by assuring parties that if a disagreement were to arise, they would retain some agency over who would ultimately get to determine an outcome. The International Convention for the Safety of Life at Sea (SOLAS) could also be a model for how to amend an international treaty expeditiously and to put in place critical information-sharing provisions.
SECTION 4

AGREEMENTS CHARACTERIZED BY NORM-SETTING OR SHARED INTERESTS IN OUTCOMES

The agreements outlined above analyse how reservations about participation based on principles of national sovereignty could be managed through monitoring committees, tailored forms of sanctions framework models, and dispute resolution mechanisms. Not all international agreements, however, operate through binding legal obligations. Many international agreements operate through the generation and perpetuation of norms that have significant effects on state behaviour. This section analyses those aspects of international agreements that have both binding and precatory provisions—like the FCTC—and those that operate entirely on a voluntary basis, like the Pandemic Influenza Preparedness Framework. For some aspects of a new pandemic agreement, norm-setting may serve as an effective alternative to binding obligations in furthering global preparedness to respond to the next pandemic. The WHO is a strong norm-setting organisation, but there are internationally regulated sectors where additional international organisations and voices will be necessary: food, animal health, trade, intellectual property, and transportation, among others.

A. Framework Convention on Tobacco Control’s Guidelines Issued by the Conference of the Parties

While the FCTC’s text has mandatory “shall” provisions for many of its evidence-based measures, it also includes precatory “should” language including obligations to inform individuals about tobacco’s health hazards, taxation policies, and the size of graphic warnings. While strengths of the FCTC include the empirical foundation of its measures, based on prospective studies of the health effects of tobacco use and synthesis of evidence, as well as the political momentum of successive WHA resolutions, it has also been successful through the norms it has generated. The WHO was effective at cultivating a global network of NGOs and media to build public support for the FCTC and its provisions. It successfully reframed public discussion on tobacco to emphasize the fundamental inconsistency between the sale and availability of tobacco products on the one hand and individual and public health on the other. Part of the successful messaging campaign was built on every individual being impacted by tobacco, similar to COVID-19.

These norms certainly have limits as to their effect. The FCTC has had marginal influence on important policy measures such as taxation and national smoking cessation programmes to buttress prevention efforts. This indicates the gradual, deliberative nature of absorbing treaty provisions into national legislative and programmatic reforms.
Additionally, the FCTC lacks a systemic means for implementation, unlike national legislation. Successful implementation requires parties to modify legal, administrative, and enforcement structures—often with limited understanding of treaty provisions. This is also true with respect to the FCTC’s Illicit Trade Protocol.

B. International Health Regulations’ Normative Provisions

Participants suggested that the normative force of the IHR had been largely neglected and whether in a new pandemic agreement or in targeted revisions to the IHR, norms had to be addressed. The incentive structure is misaligned with the legal obligations. For example, why should a low- or middle-income government addressing an infectious disease outbreak report to the WHO, thus inviting the real-world stigma and economic consequences attached unless absolutely necessary? Developing countries are often cautious about releasing data to a system run by developed countries. They weigh the risks of exclusion, trade, and travel restrictions.

Over the two declared pandemics, and most of the intermediate PHEICs, many countries ignored the WHO’s recommendations as to travel and trade measures and similarly gave short shrift to sharing data, equipment, medicines, personnel, or vaccines. Unless the damage to sovereignty and national interests can be addressed in a new pandemic agreement, it is likely to face the same or even more significant challenges than the IHR.

C. Pandemic Influenza Preparedness Framework

Some progress may be made through political commitments and instruments that are soft (i.e., technically informal) but have hard, clear provisions for performance. The Pandemic Influenza Preparedness (PIP) Framework, a multilateral influenza sample and data sharing system, was achieved through the WHO’s Article 23 recommendation process. That system was established after the world’s first declared influenza pandemic resulted in the hoarding
of vaccines by rich countries. Under the PIP Framework, private companies contribute to the cost of running the system and, should an influenza pandemic be declared, they have committed to contributions of real-time production of vaccines for the benefit of poorer countries, or similar kinds of contributions to the global response. Most hard commitments are made via contract. Yet, the system is fragile: many of the agreements entered into by the companies may be easily circumvented, and the system remains untested. Data sharing goes one way—from the WHO collaborating laboratories to companies. Reform that depends on recommendations and political commitments is likely to be piecemeal, incremental, and weak. The PIP Framework, while non-binding under international law, nevertheless deeply affects the conduct of influenza therapy and vaccine manufacturers.

SECTION 5

NON-TREATY AGREEMENT WITH LEGALLY-BINDING OBLIGATIONS UNDER DOMESTIC LAW

The International Finance Facility for Immunisation Finance Framework Agreement

The International Finance Facility for Immunisation (IFFIm) accelerates Gavi’s ability to deliver vaccines to low-income countries. Many aid commitments from donor nations are disbursed to implementing agencies over many years, requiring the agencies to calibrate their activity to that cash flow. IFFIm accelerates that cash flow in the following manner: Based on the financial pledges it receives, it issues bonds in the capital markets, the proceeds of which are disbursed to Gavi to purchase vaccines. However, investors are not themselves donors; they are paid back over time as the government donors make their pledge payments. This “frontloading” effect has helped Gavi scale its activity and immunise children that would otherwise have had to wait years for basic life-saving countermeasures.
IFFIm’s master governing instrument is its Finance Framework Agreement (FFA), the parties to which are 10 sovereign nations, the World Bank, Gavi, and the IFFIm Company (a British charity). The FFA is not a treaty, yet it contains legally binding obligations on all parties, including the donor countries. In short, each of the donors has waived sovereign immunity, giving its domestic courts jurisdiction to rule on lawsuits alleging its government’s failure to pay its pledge obligations. This waiver is essential to the mechanism to achieve a high credit rating and provide the assurance that investors require to understand their investment risk and price the bonds appropriately. Moreover, the donors’ own sovereign credit ratings are linked to their reliability in making pledge payments. This incentive structure creates enormous confidence in the model, as the certainty of payment is much higher than with traditional aid pledges, which governments can elect to honour or not as priorities evolve.

Of course, of all the models reviewed in this report, IFFIm is the one that presents the highest sovereignty cost given the required waivers of immunity. In addition, despite its near-universal acclaim, IFFIm has been criticised for committing future governments to the decisions of current ones. A newly appointed international development minister may be surprised to learn that part of his or her budget has been legally committed to repaying bondholders. Still, IFFIm represents what can be achieved when obligations are binding in a domestic legal regime and the incentives to comply are palpable.

SECTION 6

RELATIONSHIP BETWEEN PUBLIC COMMUNICATION AND SOVEREIGNTY IMPLICATIONS

Because political leaders generally owe their first duty to their citizenry—and are politically incentivised to make good on that commitment—international instruments must be harmonised with those obligations to the extent possible. Global norms of transparency, monitoring, verification of facts, and accountability cannot be mere aspirations; they must have real cogency and be consistently practised and internalised. Many experts reflected that public communication should emphasise a two-way dialogue with citizens that generates genuine engagement and promotes understanding. NGOs are particularly important players as are government ministries when they are viewed as credible and provide timely and accurate information.

Broadly, the experts concluded that the public is not aware of what international law commitments are, what ones their governments have made, and the implications for their lives. This translates into real scepticism and distrust concerning how power is wielded and whether it is being ceded to remote unelected officials without proper public engagement.
Honest, deliberate, and open communication through traditional news outlets and social media can drive inclusivity and ownership. In addition, given the nature of public health communication and the evolution of scientific understanding, leaders must ensure they are transparent and clear about what they know about pandemic threats, what they do not yet know, and how they are going to try to figure out what is not known. Such communication philosophies concerning the development of an emerging pandemic instrument are likewise critical. Trust is difficult to win back once it is lost.

The experts also noted that discrete sectors of the public are likely to be more engaged with legal obligations that are specifically pertinent to them. If a person is engaged in reducing smoking (or in proliferating it), he or she is more likely to understand the obligations that the FCTC imposes than someone unaffected by it. Likewise, a Great Lakes shoreline resident or a shipping company transporting goods to Toronto is more likely to engage with the International Joint Commission than the average member of the public. However, pandemic preparedness touches everyone, so the need to communicate the implications of a global instrument is that much more important.

Several additional strategies cited include regular awareness campaigns; crisp, memorable messages that can be transmitted through radio, SMS, news outlets, and social media platforms; and government engagement with academics, civil society organisations, and commercial enterprises that are going to be important partners during pandemic episodes. In some settings, national governments might consider allowing the citizenry itself to determine whether to accede to an agreement.
In the end, whether binding or non-binding, countries’ commitments to one another to address pandemic preparedness and response ought to be fulfilled in good faith. One way to think about it is that the most effective international instruments promote the value of global solidarity and mutual assurance over matters that are intuitively ripe for collaboration. It is what nations owe to their own residents, but also what they owe to each other.

An effective agreement will need to be carefully calibrated not only with international legal commitments in mind, but to align incentive structures that will build confidence and positively affect lives, mindful that the right of people to self-determination is also a deeply embedded principle and one that the public does not part with arbitrarily. International priorities must align with in-country realities, and the management of that messaging will be significant, whatever the content and form of a new instrument. International agreements in human rights, finance, and other areas provide examples for decision-makers to consider as they determine the modality of a potential pandemic instrument and the content it should contain. Its credibility, adherence, and effectiveness are all at stake.
ANNEX 1

PARTICIPANTS AND CONTRIBUTORS

CONVENORS

Lawrence O. Gostin, Founding O’Neill Chair in Global Health Law, Georgetown University Law Center, Director, WHO Collaborating Center on National and Global Health Law

Kevin A. Klock, Foundation for the National Institutes of Health, O’Neill Institute for National and Global Health Law

Sam Halabi, O’Neill Institute for National and Global Health Law, Colorado School of Public Health, and Colorado State University

Katie Gottschalk, O’Neill Institute for National and Global Health Law

Katherine Ginsbach, O’Neill Institute for National and Global Health Law

Kashish Aneja, O’Neill Institute for National and Global Health Law

EXPERT PARTICIPANTS

Alex Ansong, Ghana Institute of Management and Public Administration

Mely Caballero-Anthony, Nanyang Technological University

Brinda Dass, Foundation for the National Institutes of Health

Robert B. Eiss, Fogarty International Center, US National Institutes of Health

Maha El Rabbat, Former Minister of Health and Population, Egypt

Ngozi Erondu, Chatham House

Martín Hevia, Universidad Torcuato Di Tella

Dayanath Jayasuriya, President’s Counsel

Harold Hongju Koh, Yale University

Moses Mulumba, Center for Health, Human Rights and Development

Philippe Sands, University College London

Jorge E. Viñuales, University of Cambridge

WHO OBSERVERS

Abdou Salam Gueye, WHO Regional Office for Africa

Genevieve Howse, WHO Regional Office for the Western Pacific

Carla Saenz, Pan-American Health Organization
ANNEX 2

DISCUSSION QUESTIONS

1. Identify what you believe to be effective global or regional agreements that impose both binding obligations and advisory recommendations. These may, for example, include the Framework Convention on Tobacco Control, its implementing protocol on illicit trade, and guidelines issued to date by the Conference of the Parties, or the Bonn Guidelines issued pursuant to the Convention on Biological Diversity and the subsequent codification of some guidelines into the Nagoya Protocol. However, the agreements you identify need not be in the public health space. The convening will benefit from your insights from many areas of international activity from trade and finance to environment and security.

2. We encourage you to identify with specificity the legal obligation; its mandatory, precatory, or normative status; and reasons for its effectiveness or ineffectiveness.

3. What are (or have been) the implications (advantageous or adverse) to national sovereignty and self-governance of making those commitments?

4. To what extent do you believe the public is aware of those commitments? If it is aware, does it generally understand the rationale and accept them? If it is not, how should governments promote greater awareness?
ENDNOTES

3 "The right of a state to self-government; the supreme authority exercised by each state." Black’s Law Dictionary (11th ed. 2019).
4 One articulation reads “No state has the right to intervene in the internal or external affairs of another.” Montevideo Convention on the Rights and Duties of States, Dec. 26, 1933, art. 8, 165 L.N.T.S. 19.
10 U.N.E.P., Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Tenth Meeting, art.6, UNEP/CBD/COP/DEC/X/1 (Oct. 29, 2010).
19 W.H.A. Res. 34.22 (May 1981).
23 Id. at 1867 U.N.T.S. 493.
24 Id. at 1868 U.N.T.S. 120.
32 Dec. 12, 2015, 3156 U.N.T.S.
40 Jan. 11, 1909, TS No. 548.
42 W.H.A. Res. 64.5 (May 2011).