

SUMMARY REPORT | NOVEMBER 2021

APPROACHES FOR A NEW PANDEMIC AGREEMENT

LEGAL TOOLS FOR PANDEMIC PREPAREDNESS

WHO COLLABORATING
CENTER SUPPORT FOR NEW
COORDINATING MECHANISMS

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.

ABOUT THIS DOCUMENT

On May 25, 2021, the World Health Assembly (WHA) of the World Health Organization (WHO) called for a Special Session to be convened in late November to consider developing a convention, agreement, or other international instrument on pandemic preparedness and response. On September 8-9, the O'Neill Institute and FNIH convened 30 of the world's leading authorities on global health law, financing, biomedical science, implementation, and emergency response along with leaders from prominent international organizations involved in defeating the pandemic. The high-level experts had in-depth discussions on the weaknesses and persisting gaps in global pandemic preparedness and what a new international agreement might include to address them. This meeting was followed by regional consultations convened in Africa, Latin America-Caribbean, and Southeast Asia. This report summarizes the major themes that arose across the listening sessions, along with specific project or program proposals, potential avenues of international collaboration, and operational considerations for use by policymakers and the international community as they consider how to move forward. This summary report is not meant as a consensus document, but a compilation of the ideas and diverse perspectives offered.

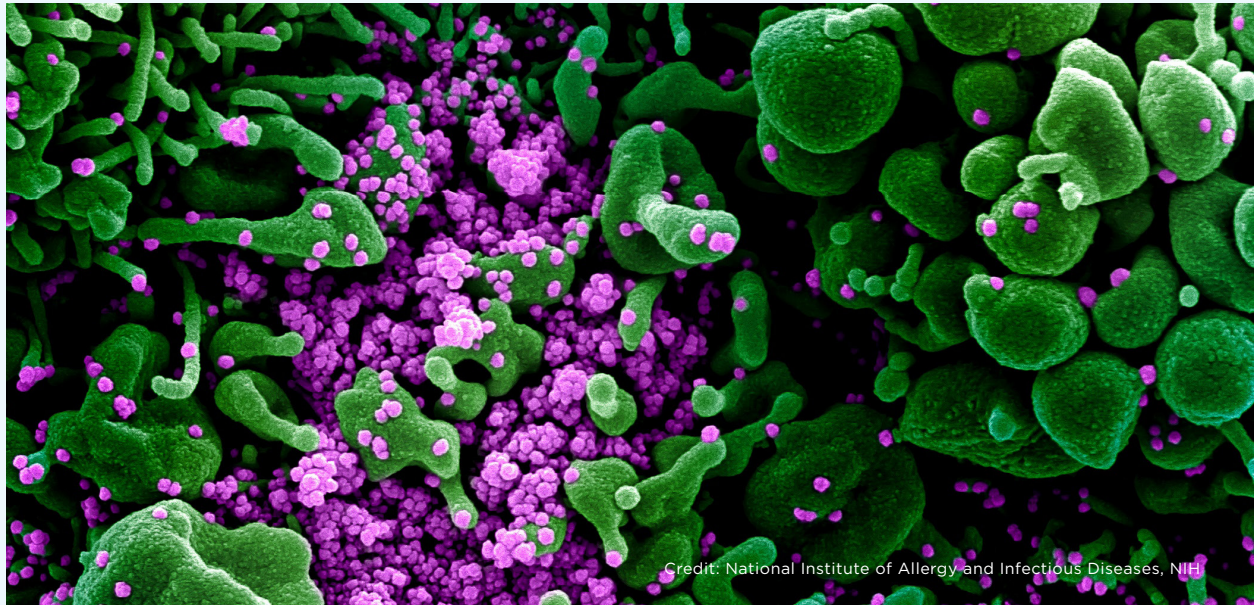
All sessions proceeded under Chatham House rules. The O'Neill Institute and FNIH facilitated the discussions. The O'Neill Institute drafted these findings with input from the FNIH and the listening session experts. A portion of the project was funded by a grant from the FNIH's Pandemic Relief Fund.

This summary does not necessarily reflect the views or positions of the participants, their institutions, the O'Neill Institute, or FNIH. In addition, it should not be construed that participants or their institutions agree with every assertion made herein.

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BACKGROUND



THE COVID-19 PANDEMIC REVEALED THE FRACTURED AND INADEQUATE STATE OF GLOBAL HEALTH LAW INFRASTRUCTURE AND ITS DEEPLY EMBEDDED INEQUALITIES. The most important infectious disease preparedness and response accord, the International Health Regulations (IHR), has not reliably galvanized governments to collect crucial information on emerging disease threats or share data. Although the IHR requires all states parties to establish and maintain core health system capacities, the regulations do not provide incentives for investment in national capacities to prepare for, and respond to, infectious disease threats. Importantly, the IHR does not govern fair and equitable access to medical innovations and countermeasures, including life-saving medicines, vaccines, or medical supplies. Overall, the pandemic has revealed gaping inequities whereby key medical resources developed in one area of the world do not accrue to the benefit of all peoples. Vaccine inequities represent a major moral failure, but also a failure of global governance.

On 30 March 2021, the heads of state of 26 nations, joined by the Director-General of the WHO and the President of the European Council, called for an international treaty on pandemic prevention and preparedness—the highest level of political action to avert and respond to future health crises. In an historic action, 194 countries adopted a WHA resolution to host a special session devoted solely to an international pandemic agreement, now scheduled for 29 November 2021.

The WHA special session will explore several vehicles, including political statements and resolutions, revision of the IHR, and an intergovernmental process to negotiate a new, legally binding international agreement, achieved through the exercise of the WHO's constitutional authority. None of these ideas precludes additional approaches, such as negotiating “soft” or non-binding instruments, forming or improving global public-private partnerships, and institutional modernization, including, most importantly, strengthening of the WHO. These may be achieved along parallel tracks of negotiation and may ultimately be realized in combination.

ADDRESSING GAPS IN SURVEILLANCE, DATA, AND PREPAREDNESS

ATYPICAL CASES OF PNEUMONIA LATER IDENTIFIED AS SARS-COV-2 CIRCULATED IN THE CITY OF WUHAN IN THE HUBEI PROVINCE OF CHINA IN LATE 2019. Under the IHR, those cases should have been detected through surveillance systems monitoring both animal and human populations, reported promptly to the responsible National Focal Point, and then rapidly forwarded to the WHO, which would coordinate an evidence-based global response. Instead, city and provincial officials struggled with how to manage the novel pathogen and whether and how to report it to national authorities. Subsequently, national authorities did not effectively report the urgency and impact of the virus.

Although almost the entire genome of the virus was sequenced by 2 January 2020, and diagnostics were developed soon thereafter, the virus rapidly spread worldwide, while WHO and national governments operated with incomplete information.

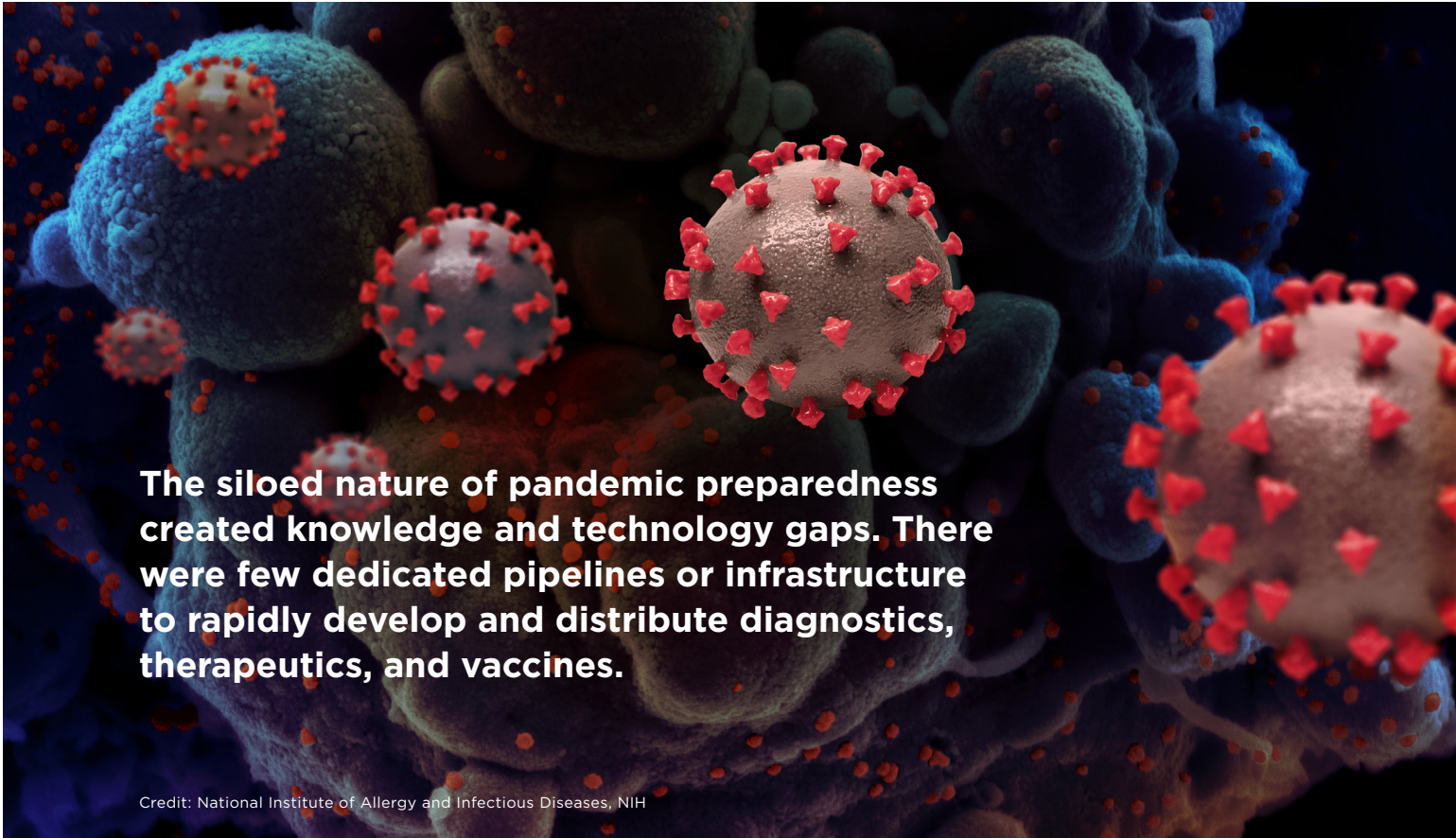
Investment in Global Surveillance and Enhanced Use of Technological Tools

In January 2021, the Independent Panel for Pandemic Preparedness and Response established by the WHO Director-General responding to WHA resolution 73.1 condemned the WHO's existing pandemic alert system, stating it "is not fit for purpose" and called for "a new global framework...to support prevention and protection from pandemics."

Part of the IHR's inadequacy in this respect is that many low- and middle-income countries need significant support if they are to reach the objectives set forth in global preparedness mechanisms like the IHR. Only one-third of IHR States Parties reached established targets for adequate health system capacities. For the two-thirds that did not, most faced resource constraints. National Focal Points, which should have served as the backbone of the communication system, have lacked the resources and technologies to gather necessary information from within their territories and have been stymied by misunderstanding and less than full cooperation by ministries of finance and trade, among others. While many of these professionals understand their functions and obligations, they are constrained in their ability to collect the data necessary to identify unknown viruses and to determine if a cognizable threat is emerging.

Effective Surveillance, Data, and Preparedness Require Multisectoral Approaches

With respect to the COVID-19 pandemic, inaction across government ministries in high-, middle-, and low-income countries hindered the initial response during February 2020. Therefore, the countries most immediately affected, like the Republic of Korea, Italy, and the



The siloed nature of pandemic preparedness created knowledge and technology gaps. There were few dedicated pipelines or infrastructure to rapidly develop and distribute diagnostics, therapeutics, and vaccines.

Credit: National Institute of Allergy and Infectious Diseases, NIH

U.S., and eventually many more, lost the most important opportunity to contain what became a declared pandemic the following month. The siloed nature of pandemic preparedness created knowledge and technology gaps. There were few dedicated pipelines or infrastructure to rapidly develop and distribute diagnostics, therapeutics, and vaccines. Prevention, preparedness, and response should have been implemented across government ministries.

Pandemic preparedness training and education provided by the WHO tends to be offered to ministries of health even though finance, defense, and interior ministries (among others) are often better positioned and resourced to respond. Those ministries are extraordinarily sensitive to the negative economic and cultural impacts of pandemic non-pharmaceutical interventions and so their deeper engagement prior to and during a pandemic is critical. Instead, many of them underestimated the severity of the situation.

WHO undertakes daily, weekly, monthly, and annual simulation exercises all over the world, which could be broadened to reach a wider range of ministerial officials. This training of leaders, in turn, must be translated into broader national and pan-national planning efforts. The structure and sustainability of the lay and health workforce is essential. For instance, there should be a minimum number of workers trained in so-called “One Health” methodologies: collaborative, multisectoral, and transdisciplinary approaches working at the sub-national, national, regional, and global levels with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.

Just as One Health methodologies are needed for enhanced multisectoral surveillance, data collection and analysis should be integrated across health systems. Many public health emergencies have demonstrated that data and information concerning outbreak origin, migration, hospital training, and public health message penetration are critical. Data should be collected at all levels, in line with well-developed ethical guidelines for data privacy and protection, particularly individually identifiable health information. For example, the Global Health Security Agenda Legal Preparedness Action Package is aggregating and synthesizing public health legal preparedness efforts advanced at the U.S. Centers for Disease Control

and Prevention, the Food and Agriculture Organization, the International Federation of Red Cross and Red Crescent Societies, and WHO as well as a number of specialized non-governmental organizations.

Best practices to develop legal infrastructure could also be advanced. For example, a model pandemic preparedness statute developed by WHO or with WHO as a major technical partner could assist national governments in framing their domestic legal frameworks.

Generation, Measurement, Analysis, and Sharing of Data Must Be Robust and Transparent

Gaps in surveillance and data collection are directly related to the lack of accountability and transparency mechanisms in the IHR. The 2005 IHR revision was prompted by the failure of countries to rapidly report a disease outbreak with pandemic potential (SARS) and WHO's lack of legal authority to demand information or investigate origins to support its response mandate. Like many international regimes proceeding under "trust but verify" approaches, the IHR needed, but never possessed, sufficient accountability and transparency mechanisms. Indeed, the IHR gives states significant flexibility to shape their information sharing with WHO. To generate better outcomes, surveillance data must be distributed, and compliance mechanisms should be crafted within WHO based on internationally agreed-upon criteria since pathogens do not respect political boundaries.

Those criteria, in turn, must reflect evidence-based relationships between data, implementation, and outcomes. There has been no significant correlation between the measures used to gauge preparedness leading up to COVID-19 and the success of any given country's response. For example, some of the countries at the top of the 2019 Global Health Security Index pandemic preparedness rankings had less optimal responses to the current pandemic in terms of contact tracing, distribution of PPE, and morbidity and mortality outcomes than others seemingly less well situated. The Global Health Security Index will release new preparedness rankings on 8 December 2021. More importantly, new mechanisms to turn 'preparedness on paper' into reality needs to be designed and implemented.

Similarly, there are technologies that could be mobilized to gather and share disease data, such as those used to surveil seasonal influenza. Yet, data-sharing systems are disaggregated with incompatible strategies deployed among countries and international institutions, including WHO. Surveillance could be significantly improved using systems already in place. ProMED, for example, has played a key role in detection and response and there are lessons to be learned from its system of reporting.

The relationship between the public and private sectors can also be optimized to address gaps. For example, mobile phone, wastewater sampling, and related technology companies could be engaged to determine where outbreaks are occurring or how infections may be spreading. Much of that information may be provided in a secure or anonymized way that respects privacy rights.

Private sector actors are often thought of as part of the response—companies that produce diagnostics, equipment, therapeutics, and vaccines; clinics and hospitals that provide care; airline and logistics firms that transport people and products; insurers that cover loss; and, certainly, financial institutions that lend and support procurement of goods and services. But this situates many of the actors needed for effective planning and response peripherally, and consequently private-sector capabilities remain un- or under-mobilized.

INTRA- AND INTERNATIONAL COMMUNICATION AND COORDINATION AFTER THE PANDEMIC DECLARATION

WHO DECLARED COVID-19 A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN ON 30 JANUARY 2020, AND A GLOBAL PANDEMIC ON 11 MARCH 2020 (the latter is not a formal legal power given to WHO, and its clear legal definition will play an important part in future preparedness and response). Under the IHR, WHO recommended standard travel precautions and issued no new guidance between March and July 2020. With respect to masks, its guidance was unclear, on the one hand stating that masks alone were insufficient, on the other stating that unnecessary use of masks created procurement burdens and a false sense of security. The U.S. imposed a broad travel ban the same day the pandemic was declared, and many countries and regional organizations followed suit.

Internationally, the pandemic declaration established an emergency of the highest order, but other than triggering national emergency plans where they existed, the legal obligations to coordinate the response were unclear. Instead, mistrust became rampant and thwarted effective global coordination. In addition, the WHO was caught in the middle of diplomatic posturing among powerful member states and its own investigation into the origins of SARS-CoV-2 appeared compromised.

Within societies, the ways in which the origin, infectiousness, and severity of COVID-19 was communicated bred suspicion and complacency. The messaging around mask wearing, aerosolized spread, social distancing, and therapeutics or vaccines became subjects of confusion, in some cases because there had been little investment in developing tenable communication strategies. In some countries, political leaders undercut scientific guidance further confusing the public. Complete lockdowns, like those implemented in Wuhan and subsequently adopted in many urban centers, limited transmission, but were often misunderstood. Concurrently, social media platforms perpetuated the spread of unscientific perspectives.

Relatedly, communication concerning risks and benefits was often vague and not grounded in emerging evidence. For example, decisions to close schools, while justified in the pandemic's early days, required more nuanced balancing against the clear social, developmental, and economic costs once it became evident that lower disease severity among children coupled with other public health measures could be a more targeted strategy.

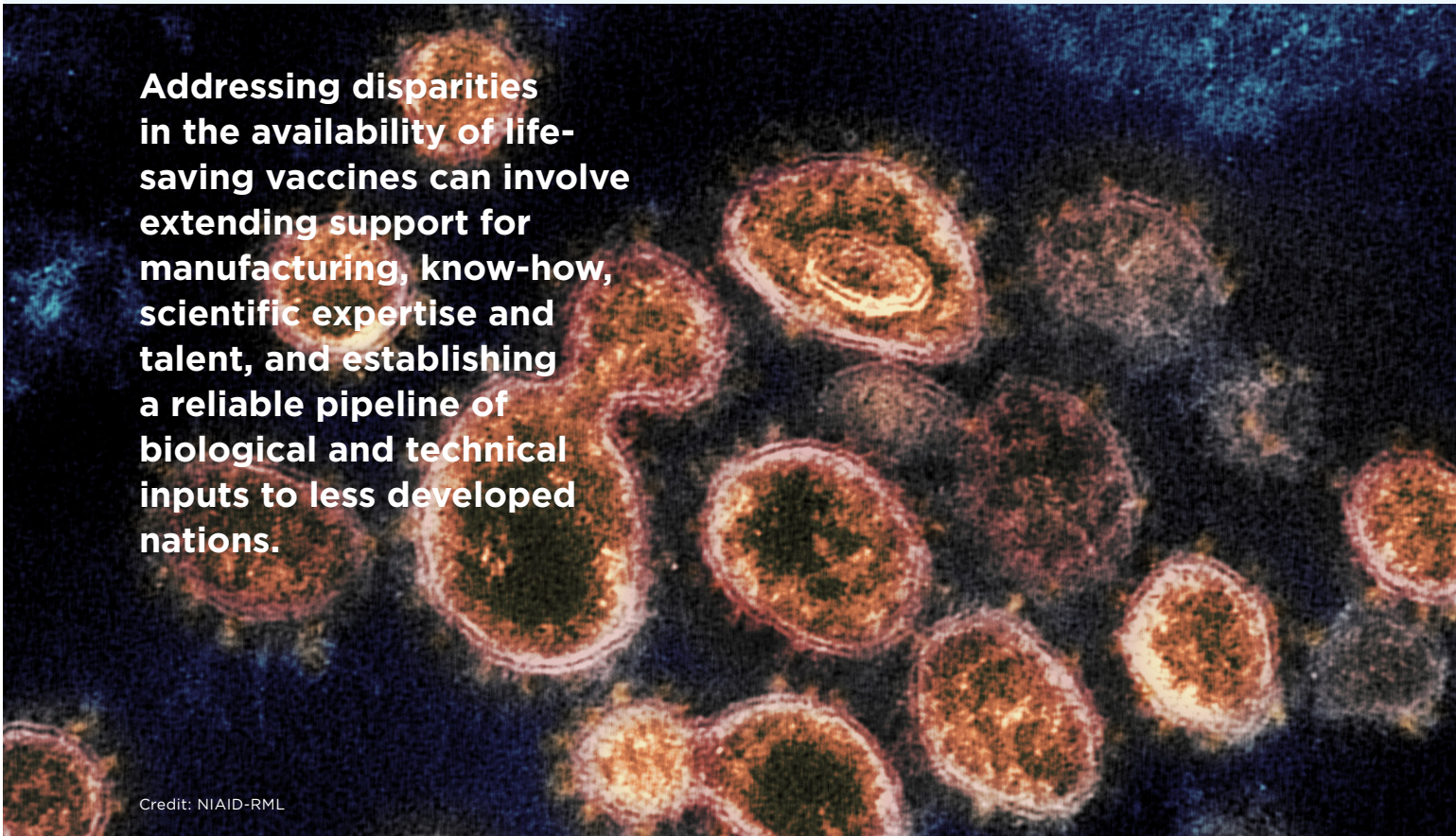
Also, early in the pandemic there were hundreds of therapeutic compounds chasing very little clinical trial capacity. Reporting results out of insufficiently powered trials gave the public false hopes about the safety and effectiveness of several putative countermeasures, thus costing precious time, resources, and public patience.

ADDRESSING GLOBAL DISPARITIES AND PROMOTING EQUITY

HIGHLY SAFE AND EFFECTIVE COVID-19 VACCINES WERE DEVELOPED WITHIN A YEAR OF THE INITIAL OUTBREAK—AN UNPRECEDENTED SCIENTIFIC ACHIEVEMENT.

Sadly, vaccine development capacity is severely limited to countries that have the capital to support research and manufacturing. As a result, populations in countries without this ecosystem often have had to wait to benefit from essential vaccines and treatments.

Addressing disparities in the availability of life-saving vaccines can involve extending support for manufacturing, know-how, scientific expertise and talent, and establishing a reliable pipeline of biological and technical inputs to less developed nations. For example, mRNA is an exciting vaccine technology because it provides a broadly effective technique for addressing a number of infectious diseases that can be duplicated across many different geographies with the right resources. Making simple, flexible platforms such as mRNA more widely available allows new vaccines to be designed quickly, which in turn means they may be less expensive to produce, and their development and manufacture can take advantage of existing infrastructure. WHO and partners from COVAX, have set-up a technology transfer hub for mRNA vaccines in South Africa to help boost and scale up vaccine production in Africa.

A microscopic image showing numerous spherical virus particles, likely coronaviruses, with a distinct outer membrane and internal structure. The particles are illuminated with a mix of orange, red, and blue light, giving them a textured, almost crystalline appearance. They are scattered across the frame, with some appearing more prominent than others.

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Disparities could also be addressed through multilateral access-and-benefit sharing mechanisms whereby governments share, or allow the sharing of, biological materials and related genetic sequence information and, in turn, receive benefits like access to technology and know-how that are developed using those resources. This is how WHO's Global Influenza Surveillance and Response System currently operates, allowing access to information about circulating strains of influenza in return for defined benefits should an influenza pandemic arise.

Some advocate rethinking the global intellectual property regime, largely governed by the World Trade Organization (WTO) TRIPS Agreement, and further managed through bilateral and multilateral trade and investment agreements. Some have also argued that the waiver of those protections for COVID-19 related interventions introduced by India and South Africa may lower barriers while others contend the existing regime is critical for innovation and that 2021 vaccine supply issues have been a function of the availability of raw material and domestically-driven export prohibitions.

Within societies, COVID-19 exacerbated already significant gaps between haves and have-nots. Access to remote learning allowed children in wealthier families to largely maintain education and instruction while children with less access may face permanent gaps. Many women bore the brunt of a lack of childcare as schools closed or switched to remote learning; some were compelled to leave the workforce. Access to sexual and reproductive health services was interrupted and gender-based violence increased. Similarly, persons with disabilities were deprived of access to rehabilitative services, physical work accommodations, and the support communities they rely upon.

The most important effort toward equity over the course of the COVID-19 pandemic, the ACT Accelerator, brought together governments, scientists, businesses, civil society, philanthropists, and global health organizations to facilitate access to COVID-19 diagnostics, therapeutics, and vaccines for low- and middle-income countries. However, there is no plan to establish a permanent organization to continue the collaboration. COVAX, the vaccine pillar of the ACT Accelerator, is co-led by CEPI, Gavi and WHO, alongside key delivery partners UNICEF and the PAHO Revolving Fund. It had distributed some 350 million doses of COVID-19 vaccines to the world's poorest countries by late September 2021—an important contribution, but it is in serious jeopardy of missing its commitment to distribute 2 billion doses by year-end 2021.

COVAX faced several challenges, especially the refusal of specific companies to commit meaningful amounts of vaccines to it and supply disruptions caused by export restrictions. With some difficulty, COVAX also addressed the liability concerns expressed by companies for serious adverse events that might follow immunizations authorized through emergency use in certain procurement agreements with governments. The liability question remains complex and unresolved in the context of humanitarian agency procurement. According to many participants, the global system developed for vaccine equity was undermined by governments entering bilateral deals with companies as well as donations directly to governments tainted by politics and geopolitical preferences.

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RESILIENT HEALTH SYSTEMS AND SUSTAINABLE FINANCING

THE UNIVERSAL HEALTH COVERAGE (UHC) AGENDA CANNOT BE SEPARATED FROM THE GAPS MENTIONED IN MORE DISCRETE AREAS. COVID-19 is a public health, development and mobility crisis. It has had a severe impact on poor populations and other vulnerable groups. Many people working in agricultural and informal sectors do not have social security nets, and therefore lack access to preventative and acute forms of care that form a first line of defense against pandemic emergence. Most countries lack a nationwide network of laboratories to analyze and share analyses from collected samples.

The lessons of robust health systems were learned long before COVID-19. The 2009 H1N1 public health emergency is an example of strong health systems in Mexico and the United States reacting nimbly in response to good information while the 2014 Ebola public health emergency in West Africa demonstrated how weak or non-existent health systems could facilitate disease spread. Sustainable financing may be accomplished through framework-type commitments in the near-term, but robust support from OECD countries will be required over the longer term.

Resource scarcity is also a priority for understanding current and future pandemics. At the global level, there is next to no infrastructure for reliable pandemic funding and support while the need is vast—consider that the World Bank committed US \$200 million in pandemic emergency funds in September 2020 while some estimates at that point put the cost of a comprehensive response at US \$11 trillion.* It is the perpetual quandary facing many global development ambitions: where to find the capital to meet the need. Categories of funding necessary for pandemic preparedness include but are not limited to surveillance, detection and monitoring capacities, legal preparedness for emergencies and simulation exercises that accompany them, community health and primary health care systems, and risk communication and community engagement capacities necessary to build trust between public authorities and citizens. Effective planning and response likely requires additional support for surveillance and manufacturing capacity in the regions that need it, sufficient funding for WHO to meet its broad mandate, more direct aid for countries with stretched national budgets, and the ensured financing from reliable sources.

Commercial actors derive enormous benefit from stable markets and a more secure, pandemic- prepared world. Airlines, hospitality, entertainment, logistics, and utilities companies have been strained by the effects of the current pandemic. Companies should have a voice in preparedness and response but with corresponding financial responsibility that will de-risk the potential collapse of their industries. Some pharmaceutical companies acknowledge they have a unique and special responsibility during public health emergencies with respect to the medical countermeasures they produce. One model for incorporating that

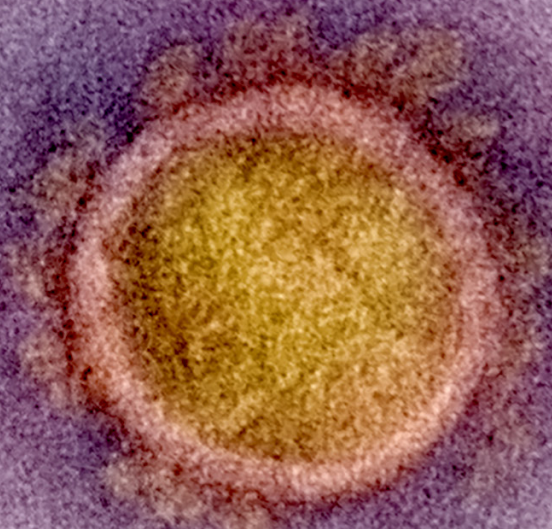
*Harry Kretchmer, 5 Urgent Actions to Stop Future Pandemics from Crushing the Global Economy, <https://www.weforum.org/agenda/2020/10/economic-cost-covid-global-preparedness-monitoring-board/>

unique role is WHO's Pandemic Influenza Preparedness (PIP) Framework, where companies contribute financially to pandemic preparedness and enter into agreements with WHO as to how they will contribute when flu pandemics arise.

Multilateral financial institutions are critical too. Regional intergovernmental organizations like PAHO and ASEAN work closely with related multilateral development banks like IDB and ADB to develop financial instruments that can smooth systemic economic disruption. During the COVID-19 pandemic, regional central banks such as the Bank of Central African States took action to increase liquidity and refinance loans. The International Finance Facility for Immunisation (IFFIm) issued a US \$750 million Vaccine Bond to accelerate the availability of funding for the Gavi COVAX Advance Market Commitment and is a model for specific kinds of financing for discrete aspects of pandemic preparedness.

Sustainable financing is essential not only to procure diagnostics, therapeutics, and vaccines, but to enable broader technology sharing. Low- and middle-income countries generally lack the resources to invest in biomedical discovery. Regional centers of research and manufacturing excellence, with dedicated financial and technical support provided on a bilateral and multilateral basis, offer a strong front line for producing medicines and vaccines rapidly during a pandemic.

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LEGAL POSSIBILITIES FOR REFORM

THERE ARE THREE POTENTIAL TRACKS BASED IN INTERNATIONAL LAW AT THE GLOBAL “ALL OF HUMANITY” LEVEL THAT COULD BE CATALYZED OUT OF THE WHA SPECIAL SESSION: 1) CHANGES ADVANCED THROUGH POLITICAL STATEMENTS AND RESOLUTIONS; 2) revision of the IHR; and/or 3) a new, legally binding international agreement, achieved through the exercise of the WHO’s constitutional authority. The content of such an instrument is likely to fall under two rubrics: preventing or managing emerging threats to prevent outbreaks of novel pathogens and effectively responding once outbreaks have occurred.

A. Recommendations and Political Commitments

Political statements have a useful signaling effect, but do not contain binding action requirements. Many of our experts believed that political statements in isolation were unlikely to make meaningful progress. One public health leader demurred that he “gets paid to do, not to talk.”

Some progress may be made through political commitments and instruments that are soft (i.e., technically informal) but with clear provisions for performance. Compliance is rooted in the commitment to test a mechanism and evaluate whether it has been useful to all parties and is sustainable. For example, the PIP Framework was achieved through the WHO’s Article 23 recommendation process. Under the PIP Framework, private companies contribute to the cost of running the system and, should an influenza pandemic be declared, commit to contributions of real-time production of vaccines for the benefit of poorer countries. Yet the mechanism is fragile: many of the agreements may be circumvented and the system remains untested. When it comes to non-legally binding instruments, the same low barriers to entry provide low barriers for exit too.

B. New Article 21 Regulations or a Revised IHR

Article 21 of the WHO Constitution permits the WHA to “adopt regulations” concerning several enumerated matters; the IHR is based on such constitutional authority and its reform and revision is a viable possibility. It has already established broad areas of consensus for pandemic prevention and response and calls for its reform signal a commitment to find a way to make it work. The United States has preliminarily supported this option, stating that amendments should improve information sharing and establish a system of intermediate health alerts prior to determination of a public health emergency of international concern.

Article 55 of the IHR provides broad contours for amendment of the Regulations while Article 57 provides similarly wide authority with respect to specialized agreements in furtherance of

its goals. These Articles may be used to address targeted aspects of pandemic preparedness and response, which may be achieved through Annexes to the IHR. For example, an Annex was concluded to extend the duration that a person's yellow fever vaccination would be considered valid for purposes of international travel.

On the other hand, the IHR is a product of its time. It was designed to do no harm to international commerce, crafted prior to modern movements of people, capital, and goods, and did not benefit from a maturing international human rights regime. Even when emergencies have been declared, countries have largely ignored WHO's recommendations for travel and trade measures and similarly have given short shrift to sharing data, equipment, medicines, personnel, and vaccines. In fact, it could be argued that the IHR disincentivizes reporting, given the collateral consequences to national economies. Overall, closing these clear gaps in the IHR could improve pandemic preparedness, even if it addresses only part of the problem.

C. An Article 19 Convention or Other Treaties

In theory, an international pandemic treaty could address the aforementioned failures in comprehensive form. Under Article 19 of the WHO Constitution, the WHA “shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization.” Article 2 allows WHO to engage many actors including those it has created (e.g., the FCTC, explained below), entities with which WHO has a formal relationship (e.g., Gavi, Global Fund), WHO hosted networks, and others.

FRAMEWORK CONVENTION APPROACH

The only Article 19 Convention that WHO has negotiated and implemented to date is the Framework Convention on Tobacco Control (FCTC). It established a regulatory pathway for countries to adopt strong tobacco control measures “in response to the globalization of the tobacco epidemic.” It translated evidence-based public health measures into legally binding obligations, addressed the multiple sectors affected by tobacco consumption, including agriculture, advertising, marketing, and promotion as well as a mechanism for concluding subsequent measures. The FCTC set norms that have been adopted in ratifying and non-ratifying states but it has a mixed record overall.

Although other specialized UN agencies, as well as the UN itself, may ultimately serve as the home of such a convention, WHO is a strong norm-setting organization, and it is well-positioned to coordinate internationally regulated sectors: food, animal health, trade, intellectual property and transportation, among others. Coordination will also depend heavily on the willingness of those other sectors to be coordinated through WHO. The initial instrument could establish broad areas for coordination and regulation and leave detail to later protocols and guidelines. 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.

In short, a framework convention possesses a potential to achieve:

- an all-of-government and all-of-society approach that facilitates the coordination and participation of all relevant actors and stakeholders, including local communities;
- a One Health approach that facilitates information sharing and coordination of activities between the human health, animal health, plant health and environmental sectors;
- domestic legal preparedness for public health emergencies through a continuous process of developing, reviewing and updating laws, policies, and contingency plans;
- addressing many facets of risk management from risk mitigation measures to post-pandemic recovery; and
- adopting the risk communication and community engagement (RCCE) approach to the delivery of public health information, diagnostics, and treatments in the context of pandemics and epidemics.

This potential is necessarily limited by national sovereignty, prioritization of activities, and tailored responses fit to particularized contexts.

HARMONIZATION WITH RELATED TREATIES AND INTERNATIONAL INSTRUMENTS

A new international agreement will necessarily affect key aspects of human life governed by other treaties including the UN Framework Convention on Climate Change, the UN Convention on the Law of the Sea, the Convention on Biological Diversity and its implementing Nagoya Protocol, human rights treaties, and others. There is a growing view that digital sequencing information (DSI) and genetic sequencing data (GSD), which are key to biodiversity management as well as pandemic preparedness, will be discussed in the next meeting of the Conference of the Parties to the Convention on Biological Diversity. In addition, a new international agreement could touch upon the mandates of other intergovernmental organizations from the WTO to UNICEF.

Any instrument considered at the Special Session must have a dedicated team focused on these areas of overlapping authority. The IHR and the Nagoya Protocol, for example, have specific provisions that contemplate additional or special international agreements, and those provisions must guide negotiations for a new pandemic instrument. Moreover, an already stretched WHO should not be burdened with new tasks when other IGOs are mandated, and better situated, to deliver on their comparative advantages. However, a strong coordination between UN agencies and bodies is needed. Importantly, any new international instrument must be harmonized with existing legal obligations, including those under the IHR.

DRAWBACKS

Unsurprisingly, the major drawback to this mechanism is its barrier to entry. There is an inverse relationship between the rigor of substance and enforcement provisions and countries' willingness to accede without significant reservations, understandings, and declarations. WHA passage does not preclude domestic ratification procedures. Treaties take time to negotiate, leave supportive private sector partners at the periphery of discussions, and fall out of date. Also, a framework convention approach would require countries to reach consensus on short, definite timelines for negotiating later protocols, and to do so in light of the priority likely to be given to national interests. Political and economic national priorities will be inclined to be put forward first, as has occurred during this pandemic.

THE POTENTIAL COMPONENTS OF A NEW OR REVISED INTERNATIONAL INSTRUMENT

THE FORM, WHETHER A NEW TREATY OR AMENDMENT TO AN EXISTING INSTRUMENT, ESPECIALLY THE IHR, THAT FUTURE GLOBAL PREPAREDNESS WILL TAKE IS ULTIMATELY UP TO THE DELEGATIONS REPRESENTING COUNTRIES AT THE WORLD HEALTH ASSEMBLY. Those delegations in turn represent constituencies ranging from the families of COVID-19 patients and healthcare workers to researchers and multinational corporations with fiduciary duties to their investors. Civil society must also play a major role, as it does addressing the AIDS pandemic. Negotiations must involve multiple sectors, which gives legitimacy to the process. For any agreement, four components appear critical: workable incentives, feasible sanctions, sustained financing, and a cohesive, consensus-based narrative as to the instrument's necessity, importance, and continued support.

Surveillance, Data, and Preparedness for Zoonotic Spillovers

The IHR focuses on response to novel outbreaks after they occur. A new instrument could incorporate the One Health approach and the prevention of naturally occurring zoonoses, which contribute to an estimated 75% of emerging infectious diseases. Separating animal and human populations could lessen spillovers, such as through improved land management, reforestation, and the effective regulation of wild animal trade and markets; researchers have already generated predictive models to identify where spillovers are likely. A proposal from the United Kingdom envisions regional zoonotic biohubs that may achieve early detection and response to novel pathogens and WHO is beginning to establish similar biohubs to share pathogen samples. Other UN agencies and legal instruments are relevant for regulating animal trade and forestry management.

To be effective, National Focal Points must be given the resources, technology, and training to effectively execute their functions. These offices may be restructured along the lines used by the IAEA, with a dedicated corps of expert inspectors who may investigate and report without interference if specified objective criteria are met.

Biosecurity and Biosafety

The two leading (and not mutually exclusive) theories as to COVID-19's origin are a spillover event from one mammalian species through another to humans and a leak from a biomedical research facility. H1N1 and Ebola likely originated from mammalian spillover. Likely places of spillover events are relatively predictable and are interwoven with the habitat-destroying and climate-change fueling practices of human beings. A multidisciplinary and multisectoral

One Health approach offers an opportunity for synergistic expertise to explore and address the complex linkages among humans, animals, plants, and the environment in relation to health and addressing spillover events. Similarly, there are published international guidance documents governing biosafety practices including inspection and early warning technologies, which could be optimized to account for this risk.

In addition, an international regime to monitor BSL-3 and 4 labs to help mitigate leaks would be useful and is ripe for rulemaking at the global level. Rigorous regulation and inspection of laboratory safety, as well as international regulation of gain-of-function research, could help prevent unintentional or deliberate release of pathogens. WHO has issued international guidance on biosafety that could be incorporated into a new agreement. Indeed, there is already a similar kind of regime for the two known laboratories that maintain live variola (smallpox) samples. In addition, a model safety statute could be crafted as a starting point for countries to develop their domestic regulatory regimes.

Monitoring, Inspection, Compliance, and Enforcement

The Review Committee on the Functioning on the International Health Regulations during the COVID-19 Response published a report discussing the IHR's lack of a standalone mechanism for monitoring and evaluation of compliance. Crafting such a mechanism may be elusive but it is critical to ensuring an international agreement is followed.

The controversies surrounding the transparency of WHO decision-making and the conduct of States Parties are subject to no meaningful form of dispute resolution. Even when the IHR worked fairly well in the context of Public Health Emergencies of International Concern, WHO's recommendations were often ignored or marginalized without scientific justification. As noted earlier, countries regularly flout their IHR responsibilities because the collateral consequences of compliance are severe and those for non-compliance are not. Similarly, the current response to the pandemic has been paralyzed by disputes that have arisen from the failure to provide avenues for dispute resolution. Many countries argued from the beginning that China had not fulfilled its obligations under the IHR and that a WHO fact-finding delegation was only authorized to visit well after evidence of the origins of the initial outbreak had dissipated.

Monitoring and compliance may be threaded through the broader international organizational infrastructure. For example, financial stability measures like those adopted by the IMF could include pandemic readiness. The WTO could oversee an intellectual property regime adapted for pandemic prevention. The World Bank and regional development banks may offer specialized loan products for health infrastructure strengthening.


Another option is for governments to make an international commitment to embed in their domestic law a commitment to non-interference with the export of vaccines, therapeutics, and PPE when the buyer is an institution such as WHO, UNICEF, Gavi, PAHO, COVAX, or an institution similarly fulfilling mandates to provide equitable access. One of the strengths of IFFIm is that country pledges are legally binding; states waived sovereign immunity and failure to make good on pledge commitments will adversely impact their credit ratings.

Inspection and monitoring bodies may also be structured as regional entities. Regional approaches to a monitoring board may strengthen the reliability of commitments if states in the same area are giving the same kinds of assurances.

Research, Scientific Sharing, and Transparency

Undoubtedly, the greatest success during the pandemic response was the rapid development of vaccines and therapeutics, including those that incorporate innovative mRNA and adapted adenovirus vector technologies. Yet open access and sharing of real-time virus samples, genomic sequencing, and clinical trial and other research data and tools were often lacking. A new legal instrument could channel significant research funding to infrastructures that facilitate sharing, while promoting open access, full transparency, public-private partnerships, and scientific cooperation.

Priorities for local and regional research initiatives include the following: (1) One Health surveillance research to identify potential pathogens and spillover risks and to establish an upstream alert system that a pathogen is circulating (2) rapid or high throughput sequencing for emerging pathogens with potential to leverage existing testing platforms for HIV, Tuberculosis, and Influenza, (3) integration of sequencing in patient care to detect novel mutations and connect broader international studies, (4) establishment of select networked sites for randomized clinical trials for therapeutics and vaccines as promising candidates emerge, (5) equity of access to research and development innovations through public-private partnerships, (6) broadening an LMIC network of vaccine production facilities and related training, so that once a microbial threat is identified and sequenced, sites in affected regions can manufacture vaccine with relative swiftness as part of a regional containment response, and (7) a global fund to facilitate initial research that could facilitate a faster response. In addition, the Accelerating COVID-19 Therapeutic Interventions and Vaccines public-private partnership demonstrated the power of identifying the most promising therapeutic candidates and getting them into fully powered clinical trials. A global mechanism to track emerging and spreading viral variants would also provide an early warning system for a pandemic's subsequent waves.



The most important way to address disparities globally is to ensure that there are enough diagnostics, equipment, medicines, and vaccines to reach critical thresholds in each country, indeed in every community.

Resilient Health Systems and Sustainable Financing

Rather than sector-by-sector or disease-by-disease approaches, programs to strengthen health systems that could effectively address a pandemic should be comprehensive and informed by principles of universal health coverage. Universal health coverage investments avoid many of the political and populist barriers to more targeted pandemic preparedness initiatives and are politically popular in many places; they are also no more expensive than some surveillance and response alternatives under consideration. While there exist some international and development funding streams for specific illnesses, especially HIV, they are frequently cordoned off from investments across health sectors. Those constraints could be lifted in emergencies, particularly if objective criteria are met such as a formal pandemic declaration.

Correspondingly, the world must make a commitment to the financial stability and well-being of those countries that fulfill their legal obligations by prioritizing the distribution to them of appropriate financial support and medical supplies. In 2009, Mexico did all that was expected of it during the early days of the influenza pandemic, and nevertheless found it difficult to procure lifesaving vaccines, and suffered punitive trade and travel measures. The incentives must work for, and not against, compliance.

Part of sustainable financing includes corporate contributions proportionate to the benefit commercial enterprises derive from operating in markets not destabilized by catastrophic health emergencies. Hospitality companies and airlines suffered significantly. Even those organizations that persisted or benefited economically from the pandemic have an enlightened self-interest to prevent huge epidemics so more lucrative business opportunities are not interrupted.

Domestic and International Equity

While an international agreement is unlikely to address intra-societal inequities directly, the ways in which decision-making is reached can be informed through internationally guided practice. The decision to close schools, for example, required very careful risk-benefit analysis of a kind that was not effectively or widely deployed and was subject to significant distortion based on misinformation. Similarly, vaccine hesitancy and public health measure resistance overlapped in many countries with socioeconomic, racial, and ethnic disparities that suggested little trust in official messaging about the pandemic or the measures needed to address it. Those aspects of intra-societal disparities can be addressed in several ways.

The most important way to address disparities globally is to ensure that there are enough diagnostics, equipment, medicines, and vaccines to reach critical thresholds in each country, indeed in every community. An international agreement may address some of the most essential features of equality: governance and access to intellectual property, technology, know-how, and data. An international agreement may also, crucially, address how governments procure these essential components of response, and what the relationship between governments and companies looks like, or should look like, as pandemic planning becomes a global endeavor.

An international agreement could address the stability of the global system and the challenges encountered by COVAX; the PIP Framework provides a potential model for such an approach. COVAX has been less successful as measured against its ambition, but not for lack of trying or consultations with LMICs. It took into account previous experience and learnings to rapidly stand-up vaccine procurement and distribution, but any regime will be limited by adverse systemic challenges.

Technology Transfer

Global efforts to create an international agreement on technology transfer are more than 40 years old, the most important led by the UN Conference on Trade and Development (UNCTAD) over the course of the 1960s and 1970s. There are important lessons in those negotiating histories for how technology transfer may proceed as part of pandemic prevention and planning while also meeting the general interests of companies, governments, and people.

Currently, there are few sustained efforts to intentionally transfer technologies needed for small-molecule drugs, biologics and vaccines, and advanced medical devices. But there are promising models including a vast, decades-long effort to boost influenza vaccine manufacturing capacity in LMICs.

The TRIPS regime may not yet provide a cognizable pathway for solving this challenge. TRIPS-complaint compulsory licenses, for example, may work for small molecule drugs but not vaccines: the licensing arrangement does not reach the additional IP rights covered by the proposed waiver including confidential information and trade secrets and regulatory data. This effectively inhibits local production of IP-protected vaccine technologies. To date, no vaccine company has joined the COVID-19 Technology Access Pool (C-TAP), launched by WHO with the support of Costa Rica and 40 member state cosponsors.

In addition to direct support for technology transfer, current and future agreements between governments and vaccine companies may shape access. Contracts for new vaccines or advanced market commitments may include terms by which procuring governments may share know-how in preparation for pandemics. CEPI, for example, includes technology sharing terms in its contracts for vaccine candidates it supports. An international agreement may simply ask that governments not interfere in contracts where these terms have been put in place. Relatedly, companies generally are concerned with commercial terms, liability for negligence and adverse reactions, and intellectual property. Standardized or default provisions may be appended to an international agreement, much as they are for the PIP Framework.

Regulatory environments may also need to adapt to facilitate research, development, and technology transfer. Current frameworks are based on WHO, FDA, EMA and similar stringent regulatory authority review, which tolerates virtually no risk. For example, at least one regulator has suspended or withdrawn certain rotavirus vaccines, even in contexts where the data suggests that deaths from rotavirus far exceed vaccine risk. Risk-benefit analysis may need to adapt in the context of a pandemic where lower levels of efficacy may nevertheless provide an important part of the response.

Similarly, technological advances may make the large-scale administration and tracking of vaccines generated through technology transfer initiatives relatively inexpensive. Vaccine tracking systems should include booking, supply chain management, tracking at the individual level, and the ability to create real-time regional dashboards of coverage, safety and effectiveness, and information to individuals (including reminders). Vaccines are increasingly going to be the answer to pandemics so the world would benefit from having dependable systems in place. This could fit under Article 31 of the IHR, which already allows governments to require proof of prophylaxis for international travel. These systems could similarly be adapted for interoperability that may be addressed by an international agreement. Any such proposal, of course, must be balanced against potential inequities imposed by linking the ability to travel internationally with access to vaccines

Access-and-Benefit Sharing

Access-and-benefit sharing principles, which have steadily influenced a number of international regimes since 1992, may play a significant role in any international agreement dedicated to pandemic prevention and preparedness. Pandemics originate with pathogens, which are covered genetic resources under the Convention on Biological Diversity and its implementing Nagoya Protocol. There certainly is a topical and urgent need to improve global data accessibility to inform public health decisions on SARS-CoV-2 emerging variants and immunological strategies and create a responsible data sharing model for all pathogens with epidemic/pandemic potential. The access limitations on SARS-CoV-2 genomic data have meaningfully restricted global reporting and analysis capabilities. While the genetic sequence was shared in early 2020, biological samples were not available until later.

Looking to existing mechanisms, the PIP Framework provides a useful and replicable model. The PIP Framework is acknowledged by at least one competent authority as a specialized access-and-benefit international instrument under Article 4.4 of the Nagoya Protocol. The arrangement engages the private sector directly. It involves legally binding contracts requiring them to negotiate with WHO to provide antiviral medications, vaccines, and licensing of technologies in specified circumstances.

The current WHO-led biohub initiative has remained silent as to the benefits contributing parties may receive as a result of gaining access to pathogen samples and genetic sequence data. But the possibilities for providing meaningful benefit will almost certainly be addressed and could provide an important point to consider for an international agreement.

There certainly is a topical and urgent need to improve global data accessibility to inform public health decisions on SARS-CoV-2 emerging variants and immunological strategies and create a responsible data sharing model for all pathogens with epidemic/pandemic potential.

ALTERNATIVES AND COMPLEMENTS TO AN INTERNATIONAL AGREEMENT

THERE ARE ALTERNATIVES TO AN INTERNATIONAL AGREEMENT THAT MAY BE TAILORED TO ASPECTS OF PANDEMIC PREVENTION AND RESPONSE THAT AN INTERNATIONAL AGREEMENT MAY NOT OR SHOULD NOT COVER. Regional collaborations discussed throughout this report are a means. The Latin America-Caribbean region, for example, features PAHO working in close partnership with the Inter-American Development Bank as well as COVAX as part of a broader strategy toward vaccine access. Supporting the diversity of effective regional and local responses will require sophisticated framing of any global instrument.

Similarly, an international platform for emergency data sharing could be modeled on a number of mechanisms that were developed after the global experience with H1N1 and Ebola; GISAID is a notable example. Any platform developed or reformed should ensure that certain barriers to access that may be defensible in normal times are relaxed during an active pandemic.

Company law, or corporate law as it is known in many countries, may be adapted for vaccine companies. In many states of the U.S. for example, public benefit corporation forms of organization add layers of transparency and accountability. Certain emerging companies could be encouraged to adopt such corporate forms in certain circumstances, perhaps through access to otherwise unavailable pools of financing.

The success of global public-private partnerships such as the Global Fund and Gavi also provide models for collaboration and inclusion. They benefit from the deep engagement of government, civil society, companies, research institutions, and WHO and have served as models for new partnership endeavors such as the International Centre for Antimicrobial Resistance Solutions and a host of World Bank-supported partnerships.

The success of global public-private partnerships such as the Global Fund and Gavi also provide models for collaboration and inclusion.

CONCLUSION

The high-level listening sessions convened by the O'Neill Institute and FNIH identified critical gaps in global capacities for surveillance, data-collection and sharing, communication, coordination, and response. These gaps overwhelmed governments and those tasked with response and health care at every level. No country was able to escape the virus. Vaccination appears to be the most important intervention, aside from the hope that vaccine-resistant strains do not emerge, and less severe strains outcompete more severe ones.

This Special Session has been called historic; certainly, the challenges it seeks to address are. To make historic progress will require imagination and courage so that the global right to health can be truly realized. As WHO Director-General Tedros remarked in his opening statement to our consultation:

“The pandemic has taught us many lessons. The most important is we are one species, sharing one planet, and we have no future but a shared future.”

APPENDIX A

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APPENDIX B

ACRONYMS AND ABBREVIATED TERMS

ACT-Accelerator	Access to COVID-19 Tools Accelerator
ADB	Asian Development Bank
AIDS	Acquired Immunodeficiency Syndrome
ASEAN	Association of Southeast Asian Nations
BSL	Biosafety Level
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
C-TAP	COVID-19 Technology Access Pool
DSI	Digital Sequencing Information
EMA	European Medicines Agency
FCTC	Framework Convention on Tobacco Control
FDA	U.S. Food and Drug Administration
FNIH	Foundation for the National Institutes of Health
GISAID	Global Initiative on Sharing Avian Influenza Data
GSD	Genetic Sequencing Data
HIV	Human Immunodeficiency Virus
IAEA	International Atomic Energy Agency
IDB	Inter-American Development Bank
IFFIm	International Finance Facility for Immunisation
IGO	Intergovernmental Organization
IHR	International Health Regulations
IMF	International Monetary Fund
IP	Intellectual Property
LMIC	Low and Low Middle Income Countries
NIH	U.S. National Institutes of Health
OECD	Organization for Economic Co-operation and Development
PAHO	Pan American Health Organization
PIP Framework	Pandemic Influenza Preparedness Framework
PPE	Personal Protective Equipment
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
UNCTAD	UN Conference on Trade and Development
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization

APPENDIX C

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