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WHO Collaborating Center Global Consultation on Equity Models for a Pandemic Agreement in support of the World Health Organization and the Intergovernmental Negotiating Body

ADVANCING A WORLD TOGETHER EQUITABLY







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UNAIDS, a joint program of 11 UN agencies, is leading the global effort to end AIDS as a public health threat by 2030 as part of the Sustainable Development Goals. Since the first cases of HIV were reported more than 35 years ago, 78 million people have become infected with HIV and 35 million have died from AIDS-related illnesses. Since it started operations in 1996, UNAIDS has led and inspired global, regional, national and local leadership, innovation and partnership to ultimately consign HIV to history. UNAIDS generates strategic information and analysis that increases the understanding of the state of the AIDS epidemic and progress made at the local, national, regional and global levels. It leads the world's most extensive data collection on HIV epidemiology, programme coverage and finance and publishes the most authoritative and up-to-date information on the HIV epidemic—vital for an effective AIDS response. UNAIDS produces data for impact—no major report, speech or policy initiative on HIV has been launched or made without referring to data collected and released by UNAIDS.

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National Sovereignty Implications of a Pandemic Instrument THE O'NEILL INSTITUTE (A WHO COLLABORATING CENTER) AND FNIH convened a global consultation at UNAIDS headquarters in Geneva on equity models for a pandemic agreement on 16-17 January 2023. Experts from more than 20 disciplines and 30 organisations from across the globe met to develop the content and scope of "equity" in the context of a new international agreement on pandemic preparedness, prevention, response, and recovery. In attendance was the co-chair of the Intergovernmental Negotiating Body (INB), which is tasked with crafting the instrument, along with senior observers from the World Health Organization who are assisting the INB in that effort. This report summarises the major themes that emerged for policymakers to contemplate as they consider how to create a fairer and more equitable world that is able to address pandemic threats. This report is not meant as a consensus document, but as a compilation of the ideas and diverse perspectives offered. All sessions proceeded under Chatham House rules. The O'Neill Institute, FNIH, and UNAIDS facilitated the discussions. The O'Neill Institute drafted these findings with input from the FNIH and the expert participants. 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, FNIH, or UNAIDS. In addition, it should not be construed that participants or their institutions agree with every assertion made herein.

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INTRODUCTION: ADVANCING A WORLD TOGETHER EQUITABLY

The vision presented in the draft WHO convention, agreement, or other international instrument (CA+) on pandemic prevention, preparedness, response, and recovery "aims for a world where pandemics are effectively controlled" and "to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and international cooperation." As negotiations progressed on the new instrument, equity has emerged and been reinforced as its cornerstone principle. Delayed and inadequate access to equipment, diagnostics, and vaccines; export and trade measures that disproportionately burdened the vulnerable; and other circumstances prompted the World Health Assembly (WHA) to elevate equity as an explicit and fundamental objective of a future accord. Despite consensus around the moral value of equitable access, there has been much debate around what equity entails and how it may be actioned in the new instrument. Without these, it may be difficult for the public to judge whether any global regime can meaningfully provide new protection to all people from epidemic or pandemic pathogens.

To lead this effort, the WHA established an Intergovernmental Negotiating Body (INB) in December 2021.² The WHA emphasised:

the need for a comprehensive and coherent approach to strengthen the global health architecture, and recogniz[ed] the commitment of Member States to develop a new instrument for pandemic prevention, preparedness and response with a whole-of-government and whole-of-society approach, *prioritizing the need for equity.*³

Chaired by Precious Matsoso of South Africa and Roland Driece of the Netherlands, the INB was "to define and agree on its working methods and timelines...based on the principles of inclusiveness, transparency, efficiency, Member State leadership and consensus" with a process "informed by evidence". It would "identify the substantive elements of the instrument", "begin the development of a working draft", and eventually "submit its outcome for consideration by the Seventy-seventh World Health Assembly" in May 2024.⁴

The INB undertook extensive negotiations to develop a "conceptual zero draft", a document meant less as a working draft of the instrument than a basis from which to begin substantive negotiations.⁵ Released in November 2022, the conceptual zero draft proposed that member states consider global supply chain and logistics networks, the WHO's regulatory role, health systems recovery, and financing as important elements for promoting equitable outcomes. It also referenced rights enshrined in other agreements, aiming to be coherent with the greater multilateral regime. The INB signalled its intent to undertake an inclusive process to gather stakeholder views. This convening was designed to support its deliberations.

The O'Neill Institute for National and Global Health Law at Georgetown University, the Foundation for the National Institutes of Health (FNIH), and the Joint United Nations Programme on HIV/AIDS (UNAIDS) convened an expert group representing every WHO region in disciplines as diverse as global health, law, human rights, biomedical science, financial services, civil society, humanitarian aid, charitable fundraising, government, patient advocacy, academia, and health equity to consider existing models that assert equity as a priority and analyse them for possible inclusion in a new pandemic instrument. In attendance were the INB co-chair and senior WHO observers who are assisting the INB. The meeting took place from 16-17 January 2023 at UNAIDS headquarters in Geneva and this report summarises the reflections and contributions considered there for the benefit of WHO policymakers, member states, and the public.

In early February 2023, the INB released a "zero draft" based on the conceptual zero draft and consultations hosted by the INB in December 2022. It will serve as the basis for negotiations at subsequent INB meetings. Experts who are closely monitoring the negotiations stipulated that while these early drafts acknowledge the suboptimal experience of populations living in low- and middle-income countries during the COVID-19 pandemic's acute phase, they believe more imaginative and dynamic approaches are needed to make good on the promise of a more equitable world together.



EQUITY: WHAT IT IS, HOW IT HAS BEEN APPLIED, WHY IT IS CRITICAL HERE

EQUITY IS AN ANCIENT MORAL CONCEPT often embedded in statutory, traditional, and customary legal sources. However, despite widespread usage of the term, there is not a commonly accepted definition. The INB is not the first body to grapple with this challenge and so as it attempts to drive consensus around this most core of principles, it is helpful to provide an overview of what equity means in a variety of relevant contexts.

Definitions Used by Implementing Institutions

The WHO defines health equity as "the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality." As an objective, this definition does not necessarily mean that all people need access to the same type and number of resources. Often, it means addressing underlying challenges and the individual needs of underserved and vulnerable populations in a manner specific to their well-being.

Regional and national governmental bodies employ several related definitions. For instance, the Africa Centres for Disease Control's equity commitment states that it:

will treat all stakeholders with fairness and without discrimination or partiality. All resources, including technical, material, financial, etc. required to maintain a healthy continent must be judiciously used based on evidence and without any discrimination. All forms of public health support and response by Africa CDC must be based on reliable data, evidence and science; no special consideration, advantage or attention will be given to any party based on their place of origin, religion, gender, ethnicity, ideology, economy, individual opinions, or other similar prejudice. Africa CDC staff shall demonstrate the principle of justice, fairness and rationality and shall not participate in decision-making on matters that they have vested interest and/or conflict of interest in.⁷

In this spirit, Africa CDC recently called for increased local agency participation and a more active role for regional coordinating public health institutes, arguing this would ensure strategies are more context and equity sensitive. The National Cancer Institute in the United States defines health equity as a "situation in which all people are given the chance to live as healthy a life as possible regardless of their race, ethnicity, sex, gender identity, sexual orientation, disability, education, job, religion, language, where they live, or other factors." The Philippines' Department of Health describes it as that state of everyone being able to "attain their full health potential and that no one should be disadvantaged from achieving this potential because of their social position or other socially determined circumstance."

Non-governmental public health organisations often build their strategies and decide their activities based on a definition of equity as they conceive it. For instance, the Center for Health, Human Rights, and Development (CEHURD)¹¹ in Uganda argues that equity requires that all people have access to the health care services they need irrespective of their social status, age, location, and sexual orientation, among others. It also means that those with the greatest need are prioritised when planning for and implementing healthcare interventions. CEHURD promotes this objective through, among other things, supporting public interest litigation aimed at getting the state to respect, protect, and fulfil its obligations under national and international human rights law. Likewise, Pro-Health International¹² in Nigeria, which provides health care services in rural and underprivileged populations, makes equity a cornerstone of its strategic planning. For example, it brings together community members and subject matter experts to evaluate service delivery and correct potential discriminatory practices.

Equitable standards have also been applied in clinical and teaching settings. For instance, at Hanoi Medical University¹³ in Vietnam, equity principles are integrated into its governance, requiring leaders to work in small teams, furthering collective accountability for attaining institutional goals. The university requires that members of its governing body possess a multitude of backgrounds and maintain a practice of ensuring members are given equal opportunity for input no matter what background they bring. In the hospital context, care is delivered based on diagnosis and need, and not ability to pay.

Equity in International Law

Almost all domestic legal systems and many areas of international law support using equity as an interpretive tool in applying the law, particularly when other rules of interpretation are less persuasive or lead to an unjust outcome.¹⁴ This, of course, cannot serve as an open invitation to override the law where it is clear, and particularly when it has been properly and legitimately decided by a legislative body. Rather it permits the exercise and application of judgment when the rules do not provide finality. The International Law Commission (ILC) called it a "balancing element", a "corrective factor", and one that is "designed to preserve reasonableness".¹⁵

For example, the International Court of Justice (ICJ), the UN organ that settles disputes between state parties, permits the litigants to request the court to decide their cases according to the ICJ's own sense of "what is right and good". However, the ICJ admits that it cannot apply this principle on its own accord, though it can craft "an equitable solution derived from the applicable law". To

Sometimes international legislation itself will instruct adjudicators to decide cases based on equity. For instance, the UN Convention on the Law of the Sea (UNCLOS) declares that under certain conditions disputes "should be resolved on the basis of equity and in the light of all the relevant circumstances, taking into account the respective importance of the interests involved to the parties as well as to the international community as a whole". In a similar vein, the UN/WHO Protocol on Water and Health states that "equitable access to water, adequate in terms both of quantity and of quality, should be provided for all members of the population, especially those who suffer a disadvantage or social exclusion". In the Common Market for East and Central Africa (COMESA) was created in 1994 "as an organisation of free independent sovereign states which have agreed to co-operate in developing their natural and human resources for the good of all their people" and was premised on the conclusion that joint governance would lead to mutually beneficial outcomes. The Escazú Agreement, a Latin American and Caribbean environmental treaty, was cited by UN Secretary General António

Guterres as operating as a "human rights treaty [benefiting] the most vulnerable groups and communities" because it enshrines "the right of all persons to have access to information in a timely and appropriate manner, to participate significantly in making the decisions that affect their lives and their environment, and to access justice when those rights have been infringed".²¹

Still, while equity is envisaged as a critical component of international law, states frequently prioritise other principles in the midst of crisis, such as a democratic, even fiduciary, duty owed to their own citizenry or the preservation of their own natural and scientific resources. For example, many high-income states entered pre-purchase agreements for COVID-19 vaccines early in the pandemic, which resulted in global supply shortages. Faced with a global health crisis, extant multilateral regimes were unable to push the world towards greater equity, including the International Health Regulations (2005) (IHR),²² despite IHR provisions that require collaboration, cooperation, and assistance. Therefore, if equity is a principle that states truly believe should sit at the centre of a new regime, how it is actualised requires urgent rethinking.

Conceptions of Justice and Differentiation

Some experts view equity as encompassing diverse approaches to "justice". These include substantial justice (that justice is delivered through the fair application of substantive law), distributive justice (that there should exist a fair disbursement of common advantages and the sharing of common burdens),²³ and corrective justice (the restoration of a form of equality required due to one party's ill-gotten gain). It includes possibilities for differentiated rights and obligations even among subjects that are nominally equal, like sovereign governments.

High-income and low-income countries are differentiated under legal regimes dedicated to addressing climate change, access to international finance mechanisms, and regulating trade and investment. For example, the Convention on Biological Diversity imposes certain conditions on all states, but it accounts for the wide range of economic resources and biodiversity richness among them, declaring that "each Contracting Party undertakes to provide, *in accordance with its capabilities*, financial support and incentives in respect of those national activities...".²⁴

Equity in health has sometimes meant an aspiration that everyone has equal opportunities to be healthy when controlling for identified social or economic factors and so some should have access to higher levels of support. Needless to say, what those factors are is a matter of great public debate and often controversy. Taking note of the principle of common but differentiated responsibilities (CBDR) acknowledges that all states have a shared obligation to address negative impacts but denies equal responsibility of all states with regard to protection. It has been proposed that international solidarity—collective action responding to adverse threats and the realisation that some nations do not possess the resources to respond effectively—is a key prerequisite and was sorely missing during COVID-19's acute pandemic phase. Differentiation may be on the table for the pandemic instrument, but how these mechanisms are marketed to governments and the public is critical.

Actioning a Definition of Equity and Identifying Key Results with Specificity

Coalescing around a definition is a threshold challenge for the INB and there is evidence that this has been a matter of considerable reflection. The conceptual zero draft provided a short definition that focused principally on response:

An effective response to pandemics requires ensuring fair, equitable and timely access to affordable, safe and efficacious pandemic response products, among and within countries, including between groups of people irrespective of their social or economic status.²⁶

The definition proposed in the subsequent zero draft is more expansive and aligned with the notions outlined by the expert group:

The absence of unfair, avoidable or remediable differences, including in their capacities, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of inequality, is central to equity. Effective pandemic prevention, preparedness, response and recovery cannot be achieved without political will and commitments in addressing the structural challenges in inequitable access to fair, equitable and timely access to affordable, safe and efficacious pandemic-related products and services, essential health services, information and social support, as well as tackling the inequities in terms of technology, health workforce, infrastructure and financing, among other aspects.²⁷

It will be an achievement in and of itself for the member states to unite around this definition or another one like it. The possibility exists that some signatories may elect to issue a reservation, or a "unilateral statement" when signing on to the agreement that purports "to exclude or to modify the legal effect of certain provisions of the treaty in their application to that State". The current draft does not generally permit reservations, but if consensus around the definition or other elements of the instrument do not materialise, some countries may make reservations a condition of their participation.

It is important therefore that the INB consider developing specific, measurable key results and metrics that directly implicate equity. Having these would allow the public to evaluate whether a more equitable system is emerging through this new regime. The INB has already incorporated an evaluation mechanism³⁰ and has set some input targets,³¹ but the results metrics are what really require identifying. The agreement could specifically instruct the Conference of the Parties (COP) (the anticipated supreme governing organ of the instrument)³²—and not just the member states on their own initiative³³—to determine, evaluate, and evolve key results metrics on an ongoing basis, as this will drive collective accountability for delivering.

Moreover, the agreement could provide room to integrate locally crafted regional preparedness and response protocols that are specifically tailored to those countries. While global coordination is essential, a one-size-fits-all approach may not be optimal in every instance. Providing a mechanism to integrate regionally crafted instruments could permit a more coherent international system and promote actions that are bespoke to the needs of every population.³⁴



A group photo at the third meeting of the Intergovernmental Negotiating Body (INB) at WHO headquarters in Geneva on 6 December 2022.

Credit: WHO / Pierre Albouy

EQUITY AND ONE HEALTH

A "ONE HEALTH" APPROACH TO HEALTH POLICY emphasises the relationship between animals, humans, and their environment, recognising that the care of one is essential to the care of all. Given the likely zoonotic origin of SARS-CoV-2, as well as recent outbreaks of Ebola, MERS-CoV, and Zika, One Health has gained traction as an important approach to pandemic prevention.

Like equity, One Health has not been well defined. In 2021, the One Health High Level Expert Panel, formed by the WHO and other intergovernmental organisations, developed a holistic and comprehensive definition of One Health, which served as a basis for their One Health Joint Plan of Action.³⁵ In general, a One Health approach calls for multisectoral and multi-institutional cooperation across the interfaces of human, animal, and ecosystem health risks. Actions taken in one sphere do not occur in isolation; they reverberate to other aspects of society. For example, farming practices related to antibiotic use may be intended solely to address animal health but may also contribute to an increase in antimicrobial resistance, which has implications for human health.

Strategies to address environmental, human health, and animal health issues should ideally be developed collaboratively with all relevant stakeholders, particularly local communities, and across sectors. Likewise, legal measures adopted to address one area can affect international commitments in other spheres. It has been noted that mechanisms to improve health need to maintain coherence with the existing multilateral regime. Some institutions may have a comparative advantage, such as existing expertise and resources, in addressing particular matters. The current draft aims to "promote and implement a One Health approach that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives". It is critically important that this ethos is maintained; asking the WHO to develop new regimes when it is underresourced to fully handle its existing mandate would be a major risk.

It was suggested that the principle of equity should not be restricted to post-outbreak inequities, such as unequal global vaccine distribution and other gaps in the IHR, but should also address inequities with respect to the communities that suffer disproportionately from zoonotic outbreaks before they become global pandemics. Indeed, some have argued that for vulnerable communities at the frontlines of the animal-environment interface, equity can only be ensured if zoonotic disease outbreaks are prevented from happening.³⁷ It was also suggested that the pandemic instrument should support those communities at the highest risk of spillover, so that they can protect themselves and transition away from high-risk practices without jeopardising their food security and livelihoods.

Notably, implementing a One Health approach can itself be a burden for countries that lack adequate financial and human resources. The early drafts recognise the disparities in burdens and resources across countries, specifically for developing countries that are particularly vulnerable to the adverse effects of pandemics, do not have adequate capacities to respond to outbreaks, and would have to bear a disproportionate or abnormal burden.³⁸

To be sure, the conceptual zero draft articulates, and the zero draft further expands upon,

equity with respect to One Health as both a principle and an outcome, and they include extensive references to the One Health approach.³⁹ The instrument could protect the rights of agricultural and factory farm workers, promote gender equity, and improve equity in access to food and quality of food products—something the negotiators appear willing to address.⁴⁰

Both drafts also mention the importance of working with other relevant areas under a One Health approach and cites antimicrobial resistance as a silent pandemic and a possible aggravating factor in other catastrophic health events. Given the all-of-society implications of a post-antibiotic world, and the potentially disproportionate impact on marginalised communities, this issue may be particularly ripe for an intergovernmental solution.

One model that was highlighted was the One Health Workforce-Next Generation⁴¹ project, which aims to share information and resources about training One Health workers across Southeast Asia. This project involves universities and ministries of agriculture, education, and others assisting health leaders adequately coordinate and develop their One Health workforces.

Another consideration for the pandemic instrument is community engagement. Building rapport and credibility between communities and scientists may be facilitated by a national One Health strategy and a national focal point or committee for One Health, which is similar to the approach taken in other international legal regimes. Should policymakers take this path, they should be sure such focal points coordinate with, and are not isolated from, those other regimes' focal points.

It was also noted that incorporating a One Health approach provided an important opportunity to put in place missing governance at the international level between regimes that oversee human, animal, and ecosystem health. Without those connections, there will be gaps in nations' capacities to prevent, detect, and respond to emerging and persisting public health threats. The institutions that play a leading role in animal and ecosystem health should be engaged without delay.

Strengthening One Health in the Pandemic Instrument

Several of the matters reviewed above could be expanded upon in the main instrument, in a subsequent protocol, or through a COP-led mechanism. The expert group identified agricultural and factory farm workers as being a particularly vulnerable population. They are, for instance, at a higher risk of contracting highly pathogenic avian influenza (HPAI) compared to others. To enable mitigation, the instrument could coordinate country programmes to disburse efficacious and safe doses of H5N1 vaccine from stockpiles during their replenishment, which could be offered to these workers with their support and informed consent. This has the potential of preventing outbreaks within human populations, providing important protection to an exposed group, and reducing wastage.

Strengthening the prompt sharing of data on drivers and occurrences of outbreaks among animal, human, and environmental sectors is critical to pre-empting zoonotic risks. Capacity building, technology transfer, and financing would also be needed to implement these measures along with the support of UN agencies. Farm workers are likely to be the first people to observe or experience a possible epidemic event, and so helping them improve the conditions of their animals on their farms to reduce risk of disease emergence and spread among their animals and having systems in place to transmit their warnings are in the interest of all of society. Farm workers and other vulnerable communities must be involved in the whole-of-society, whole-of-government efforts so that the measures developed are effective and implemented.

In addition, the INB could identify climate change, wildlife, antimicrobial resistance, and land use partners with whom the instrument must integrate. This would provide important and specific signalling to the public and expedite the process of defining roles and mutual objectives.

THE FINANCING ELEMENTS OF SUPPORTING EQUITY

MOBILISING ADEQUATE FINANCE TO MEET THE MANDATE HAS BEEN ELUSIVE. As stated in *Legal Tools for Pandemic Preparedness*, the report of the first O'Neill-FNIH expert convening:

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.⁴²

The World Bank's pandemic financing facility ran out mere months into a years-long pandemic. The IHR places an unfunded mandate on countries and perhaps a perverse economic incentive not to comply with reporting obligations. During the acute phase, most countries found themselves scrambling to establish social support and income loss programmes while also endeavouring to procure equipment, diagnostics, and vaccines. Of course, addressing equity requires adequate financing, but how to do it is a real challenge.

Gavi, the Vaccine Alliance⁴³ pioneered a number of models that could be considered. With a mission to save lives and protect people's health by increasing equitable and sustainable use of vaccines in the world's poorest countries, Gavi has a remarkable track record of success.

First, Gavi served as the implementing agency for the International Finance Facility for Immunisation (IFFIm), a multilateral development institution created to accelerate the availability of predictable, long-term funds.⁴⁴ IFFIm frontloads funding for Gavi's vaccine programmes by issuing Vaccine Bonds on the capital markets that are backed by the legally binding commitments of sovereign donors (whose funding pays back the investors). This enables donor pledges to go to work immediately.

The legally binding nature of the sovereign donor commitments is what gives IFFIm its power. IFFIm is held together not by treaty but by a Finance Framework Agreement the parties to which are the sovereign donors, the World Bank, Gavi, and the IFFIm Company (an English charity governed by an independent board of directors). Unlike pledges of traditional official development assistance, which are difficult to enforce, there are two practical reasons for IFFIm's donors to make good on their pledge payments. First, the sovereign donors agreed to waive immunity in their own countries for failure to pay their pledges on time. For IFFIm to make sense financially, it needed to borrow in the capital markets at competitive rates, and the sovereign donors understood that the credit rating agencies would not consider giving any borrower a high rating without an enforceable promise to pay. Secondly, the credit rating agencies could threaten to downgrade a donor's own rating for missing payments, regardless of whether IFFIm itself sued. Both of these factors provided real incentives, even during austerity.

Another model that Gavi pioneered was the Advance Market Commitment (AMC), which was built to ensure a stable market for vaccines designed for the developing world. According to Gavi:

By agreeing to buy large quantities of vaccines at established prices once the vaccine was licensed, the mechanism effectively created healthy market dynamics, providing pharmaceutical companies with an incentive to develop and produce suitable vaccines and guaranteeing a sustainable price to provide coverage for anyone that needed it.⁴⁵

As with the COMESA example presented above, the AMC pools the demand of dozens of countries. In doing so, Gavi can de-risk the market for vaccines designed for the developing world, drive cost savings, and save lives. The AMC model also served as the basis for the COVAX AMC, aimed to accelerate the introduction of COVID-19 vaccines in low- and lower middle-income countries (LMICs).⁴⁶

UNAIDS has recently bolstered efforts "to identify and promote strategies to increase and expand the options for the equitable and sustainable financing of the HIV response, its integration in health systems, and as a building block of pandemic preparedness" ⁴⁷. Its strategy seeks to generate new resources through taxes, debt, blended and private finance, and using purchasing strategies to drive fair pricing. In this way, it is working to set in place a wide variety of financing streams that will help navigate different circumstances. UNAIDS supplements this work with advocacy to generate support in the public and private sectors. Several experts noted throughout the consultation that the costs of prevention are far lower than the costs to respond to pandemics, and so this is an apt area for advocacy, particularly since many governments often let health financing atrophy.

The Framework Convention on Tobacco Control (FCTC)⁴⁸—the only other accord completed under the WHO's general treatymaking power—has equity as a key principle and requires its state parties to provide sufficient financial support to achieve its objectives. Notably, its COP partnered with the World Bank to create a capital investment fund to support its implementation.⁴⁹

There is also a need to explore innovative engagement mechanisms for finance, bringing together various stakeholders including healthcare professionals, governments, research bodies, civil society organisations, the private sector, and others in an atmosphere of trust to help generate ideas, actionable data, and ultimately, additional finance. Inclusivity in these conversations can only help to diversify perspective and develop non-obvious solutions. There is emerging interest in leveraging private capital in support of vulnerable populations and fragile communities, but getting the capital markets to invest in these projects will require the kind of granular project data that facilitates investments.

Innovative engagement mechanisms for biomedical discovery are also important. The FNIH's model brings together U.S. government agencies, the life sciences industry, academia, and increasingly the patient community to approach vexing questions in biomedical health.⁵⁰ These partnerships marshal many kinds of valuable resources in addition to money such as scientific creativity, technical expertise, and political will. Central to that value proposition is that all parties are treated, and are expected to behave, as partners to a common venture that, if successful, will accelerate scientific discovery without providing any partner a preferential economic benefit. These partnerships tend to de-silo information and often work in the pre-competitive space where new knowledge can be put in the public domain. The zero draft does "encourage non-State actors to participate in and accelerate innovative research and development for addressing novel pathogens"⁵¹ although the implementation of the partnership model here requires a deeper sharing of the design of research, the implementation of research plans, and accountability for the results.

Liability for failure to comply with the convention's obligations may be another area for consideration. Environmental treaties often incorporate a "polluter pays" concept in apportioning costs; this could be piloted in the health context for failure to report a potential outbreak or, in more egregious cases, suppression of that information. Major questions include whether a new international dispute mechanism would have the power to enforce judgments or whether state parties would be willing to give effect to these provisions in their domestic law.

The zero draft's financing section was strengthened from the previous draft that merely stated countries should prioritise pandemic financing⁵² to requiring that countries allocate 5% or more of their annual health budget spend on pandemic prevention, preparedness, response, and health systems recovery.⁵³ Including a clear metric is helpful to judge commitment and performance, so long as it is evidence based.

For reimagining health financing in a post-COVID-19 world, one needs to address critical questions such as the value of differentiated financing responsibilities for groups of countries, associated benchmarks, concrete roles for designated leaders at the national/international nexus, sharing of experiences, preventing corruption, minimising wastage of valuable resources, and accountability. For an effective pandemic preparedness and response financing model, one needs to incentivise governments to fully engage them.

Case Study

There is a national agreement on healthcare financing in Vietnam that imposes obligations shaped by conceptions of equity. In Vietnam, it is a mixed public-private provider system organised at three levels: centrally, provincially, and by the district. Vietnam uses three funding mechanisms to finance its health system: National expenditures for health facilities and personnel, nationally funded health insurance, and private payments by individuals for health services.

A higher share of private health expenditure can exacerbate inequity because, without assistance from the state, people who cannot afford care cannot access services and will run the risk of impoverishment when paying for health care costs. Therefore, Vietnam has increased the state budget for health to cover recurrent health expenditures and it continues to subsidise health insurance for the poor and children

under six years of age. It has also invested in the upgrading of district hospitals, commune health centres, and provincial hospitals.

Vietnam has also made significant progress in the area of national health insurance, an important step in reaching heightened equity. Introduced in 1992, Vietnam has two insurance plans: a compulsory plan for the unemployed and poor and a voluntary plan targeting students and families of those covered by the compulsory plan. However, many out-of-pocket payments in Vietnam are made on over-the-counter drugs, while insurance covers only approved drugs used during treatment. Minimising out-of-pocket payments remains a key priority.

Possible Innovative Finance Options

The instrument could create a mechanism similar to IFFIm designed to underwrite the costs of emergency vaccine development, particularly work done by innovators such as the inventors of the patent-free Corbevax vaccine. This model incorporates an equity objective with a meaningful compliance mechanism. However, achieving this would require the personal involvement of high-profile domestic champions to communicate the importance of, and lobby for, donor governments making commitments to pandemic-related spending that a domestic court would enforce and a credit agency would rate. In many countries, incorporating treaty commitments into national law is a major hurdle. Alternatively, the INB could specifically set the stage to work with IFFIm, which has a nearly two-decade track record in the capital markets and immunisation as part of its existing mandate.

A pandemic accord could contemplate the establishment of a COVAX-like facility but it would need to apply learnings from the prototype. Notably, by the time COVAX was organised, many industrialised countries had completed supply agreements with manufacturers, thus relegating COVAX to the back of the queue. To mitigate this, the facility would need to be established now so that it is ready to go. In other words, equity requires preparation. In addition, COVAX was highly dependent on supply from one particular manufacturer, and the country where the manufacturer was domiciled prohibited export of vaccine when it experienced a surge. To lower this risk, the facility would need to be ready to procure vaccine from multiple sources. A stronger commitment would be for states to legislate domestically that they would not prohibit export of countermeasures to such a facility (a commitment not dissimilar to the one made by IFFIm's donors). If they are not willing to do this between pandemics, then scepticism should abound about the durability of any commitment during a crisis.

Not to be forgotten is that an instrument might also contemplate mechanisms for post-pandemic recovery, particularly concerning healthcare infrastructure. A protocol developed in concert with and harmonised with other international and regional mechanisms could help ensure that the health sector is as adequately supported as other parts of the economy during periods of recovery.

Also, the Conference of the Parties could have a standing committee on sustainable financing to regularly ideate and propose to member states emerging opportunities to finance the global pandemic preparedness and response regime. Critically, it needs to be an inclusive group involving representatives of ministries of finance and treasuries, along with others who are conversant in economics, financial services, donor and investor relations, and capital markets, as the proposition of advocating for more official development assistance alone is unlikely to be successful. Inclusiveness also means involving private sector voices who while not accountable to member state capitals, can provide perspectives and opportunities for member state consideration. It will be tempting for countries to take the same conservative fiscal orientation they often have with their multilateral initiatives, but they also cannot create a set of expectations for the public that the treaty will do something for them and couple that with little financing and no pathway to success.

EQUITY CONSIDERATIONS FOR ACCESS TO MEDICINES AND TECHNOLOGY

EQUITABLE ACCESS TO MEDICAL COUNTERMEASURES HAS BEEN A VEXING, persistent, and pervasive challenge. It is a complex issue involving affordability, innovation, fiduciary duty, transparency, and public communication, and it cuts across multiple sectors, notably trade and intellectual property (IP). What occurred during the COVID-19 pandemic is a case in point: inequities in vaccine access manifested shortly after the first diagnostics and vaccines were authorised late in 2020. By mid-March 2022, almost 80% of the population of high-income countries had received a dose of vaccine while the rate in low-income countries hovered at 14%.⁵⁴

At issue is the tension between incentivising and speeding innovation with equitable distribution of the resulting benefits from that innovation. Providing inventors with time-limited monopolies on selling and reaping the benefits of their inventions—patents—has been the avenue through which governments have provided such incentives. Of course, there is significant debate concerning the extent to which existing IP regimes strike the appropriate balance. Some experts argued that existing protections for diagnostics and medicines excessively inflate prices and limit supply, thus creating a substantial burden, if not an outright barrier, for poorer communities to access essential diagnostics, therapies, and vaccines. Others argue that disrupting the current IP regime could devastate innovation, making industry investment in novel, unpredictable countermeasures too risky. What is essential is to

Concerning clinical trial enrolment, there are pervasive barriers to participation by underrepresented and marginalised communities as a result of outdated recruitment strategies, lack of trust in the research process, information-sharing challenges, and an often underdeveloped value proposition for participating.

find equity mechanisms that incentivise scientific sharing and innovation, while also ensuring equitable distribution and access to lifesaving medical resources.

The primary international regime governing IP rights for medicines (and all other inventions) is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁵⁵ It is generally considered to reflect a preference for strong IP but it contains a "compulsory licensing" provision that permits governments in certain circumstances to authorise the manufacture or import of on-patent medicines. The patent holder receives compensation but does not have the same pricing freedom to which it is normally entitled.⁵⁶

It was noted that research, development, and clinical trials cost an exorbitant amount of money, time, and resources, and that promising therapies fail more often than not for reasons ranging from toxicity to insufficient proof of efficacy. Under the domestic law of many countries, publicly traded companies owe fiduciary duties to their shareowners and other stakeholders that arguably require them to preserve the value of business assets, making waiving IP protection a problematic proposition both legally and commercially. Also, some manufacturers argued that their investments during the 2014 Ebola crisis were unjustified in retrospect, causing them to avoid markets for emergency products thereafter. At the same time, many argue that product pricing suffers from a lack of transparency at best and gouging at worst, and that many companies weaponize IP regimes to keep their monopolies far longer than public policy was meant to give them.

The pandemic instrument could also address investment in the entire lifecycle of product development, and in particular clinical trial enrolment. Clinical trials of course require the service and courage of potentially hundreds of human beings to test an unproven therapy in their own bodies. The life sciences industry has sometimes done a poor job of building a diverse participation base to ensure that all populations can have confidence in the safety and effectiveness of a new treatment. For example, Dr. Francis S. Collins, former director of the U.S. National Institutes of Health, publicly chastised one of NIH's industry partners for drastically underrecruiting persons of colour to its COVID-19 trial when those communities were disproportionally affected by the disease. There are pervasive barriers to participation by underrepresented and marginalised communities as a result of outdated recruitment strategies, lack of trust in the research process, information-sharing challenges, and an often underdeveloped value proposition for participating. Moreover, there is evidence that marginalised populations that do participate in trials may not have equitable access to vaccines and therapies that are ultimately authorised.

Governments around the world also heavily subsidised industry efforts through public support programmes like Operation Warp Speed in the U.S. and the multilaterally supported COVAX facility, even going so far as to take on the entire financial risk of vaccines that ended up worthless. Accelerating vaccine development was the priority and so it was natural to mobilise extraordinary amounts of public finance to "take many shots on goal". As a result, multiple viable vaccines were authorised within one year, an unprecedented scientific achievement. However, unlike other providers of company capital, taxpayers generally did not reap the financial rewards on their investment. Moreover, the success of several vaccine candidates obscures the fact that taxpayers bore the risk that *none* of them could have worked despite the investment. The current draft has set the stage for this discussion with potential provisions covering information disclosure on public funding for research and development⁵⁸ to more equitably shared risk when taxpayer funds are used.⁵⁹

As stated in the zero draft, the diversification of the global supply chain and logistics network is necessary to achieve equity. 60 Several experts believe that strengthening national and regional capacities, both in drug development and manufacturing, is critical to overcoming barriers to access and should be a focus of the convention. Having existing capacity in place rather than relying solely on imports from industrialised nations could give them more agency to respond and lower their risk. India, for example, has long used its IP law and domestic investments to supply its population and many others around the world. Its largest manufacturer was an early producer of Oxford-AstraZeneca's vaccine and is gearing up to produce future COVID-19 nasal vaccine modalities. Having domestic production meant India's population would have more assured access. On the other hand, countries relying on COVAX were also dependent on India's production capacity, so when the country experienced a surge and the government initiated an export ban, people in import-dependent countries experienced delayed access. 61

Furthering Access in the Agreement

The early pandemic treaty drafts support time-bound waivers of IP rights in the midst of a pandemic⁶² and it was suggested that the instrument must address how compulsory licensing and other flexibilities can be applied and structured when they have only been exercised predominantly to fight HIV. It was also noted that local communities and civil society organisations play an important role in the "last mile" of delivery to hard-to-reach and marginalised populations. The HIV/AIDS community has been extraordinarily successful in engaging local leaders, and case studies from its work could be examined and applied.

It was suggested that the pandemic instrument should include a new emergency model that delinks pandemic products from normal pricing approaches but doing so would require the input and partnership of a sceptical industry. This is not an exceptional suggestion however: two of the 28 seats on the Gavi board are allocated to representatives of the vaccine industry and this has been credited with propelling Gavi's equity goals and innovative mechanisms.

It was also contemplated whether industry has an obligation to ensure communities that participate in clinical trials have fair access to authorised treatments as part of their fiduciary duty to stakeholders in some domestic regimes. The instrument could lean heavily into this proposition, reminding innovators that they are dependent on the service of clinical trial participants to commercialise their inventions.



A healthy volunteer receives an experimental universal influenza vaccine as part of a Phase 1 clinical trial at the NIH Clinical Center in Bethesda, Maryland, USA.

Credit: National Institute of Allergy and Infectious Diseases/NIH

THE EQUITY DIMENSIONS OF TRUST AND PUBLIC HEALTH COMMUNICATION

THE CONCEPTUAL ZERO DRAFT AND THE ZERO DRAFT each contemplate significant member state efforts to improve public health communication and strengthen trust in public health experts and biomedical research, critical issues that came to the fore during the COVID-19 pandemic's acute phase. ⁶³ There is an urgent need to take a new approach to building public trust and addressing misinformation, and to seriously evaluate how to adjudicate information to help people make informed decisions.

In addition to access, affordability, and availability challenges, there have also been acceptability issues, or the reluctance of some parts of the population to take a lifesaving vaccine or therapy when the opportunity is presented. Some research suggests the problem is less the existence of a knowledge gap that could be fixed by reinforcing accurate information than that human beings have evolved to take mental shortcuts when encountering new information as a way to cope with a complex world.⁶⁴ A person's mental shortcuts are generally a function of their own well entrenched personal values and are derived from their lived experience. They also tend to prioritise the input of close friends and community leaders over remote public health experts, even when the former figures do not possess accurate information. Overriding a mental shortcut requires a person to either conclude new information is absurd on its face, encounter information from a person known to them to lack credibility, or have the expertise and willingness to independently corroborate a new assertion. All of these are high hurdles to overcome and not easily addressed through international law making.

Trust is also a pervasive issue between some governments and their citizenries and so otherwise good health policy communication can go ignored. One expert cited an example of a sceptical populace believing that a government's free COVID-19 vaccine would be neither free, efficacious, nor safe. Another expert noted that some countries with strong lockdown measures had provided certain flexibilities to favoured industries to carry on their normal activities. Also cited were governments that tamped down on civil society organisations and journalists reporting on pandemic response and ones that refused to provide public health information in indigenous languages. These circumstances provide a ripe environment for suspicion and difficult-to-unwind conspiracy theories. It was suggested that opportunities for people from different cultural and socio-economic situations to congregate and solve joint challenges could provide an opportunity to discover common solutions.

There are also frequent calls for people to "trust science" but non-scientists do not have the knowledge and skill to critically evaluate the scientific conclusions they confront. Moreover, it was stated that hundreds of scientific papers related to COVID-19 research had been retracted during the pandemic, providing ample reason for some members of the public to be confused about whom to believe. It was argued that in a rush to disseminate scientific information,



some researchers had aggressively published "pre-prints" that, while nominally providing notice that their work had not been peer reviewed, were nonetheless picked up by media outlets and amplified regardless of quality. The conceptual zero draft contained an obligation seeking to foster "information sharing through open science approaches for rapid sharing of scientific findings and research results, *irrespective of the outcome*." Perhaps recognising the advisability of incorporating safeguards that balance rapid sharing with accuracy, the zero draft removed the last four words of that provision. 66

Whether the pandemic instrument could create gatekeeping mechanisms to amplify trustworthy information is unclear, but there are movements afoot to address the trust challenge and to the extent the convention can support those efforts, it could make a meaningful difference. For many people, the recent pandemic may harden their views on the credibility of authority figures, and it was claimed that to gain the trust of people whose dignity and rights were unrealised, it will require measures that genuinely convince them that the next time will be different.

Operationalising Improved Trust and Communication

It was acknowledged that trust is an attribute that is earned over time and that no matter what the pandemic accord ultimately says, it requires human beings to follow through on their commitments and be credible conveyors of information. Still there are tactical opportunities that the instrument could support. The accord or a future protocol could lay out a set of standards that underpin the "universal" peer review system that is contemplated by the negotiators, or a peer review system tailored for the pandemic context. It could craft new standards for publishing non-peer-reviewed pre-prints that preserve the opportunity to get new perspective into the public arena but would do so in a more responsible and less confusing manner. It could commit the WHO to crafting a very basic suite of pandemic-related public health information tools that could be translated without undue burden or cost into any language. It should also consider being prescriptive concerning the ethical obligations of persons appointed to the accord's governing bodies and secretariat to reinforce public confidence. Finally, an independent commission under the WHO's auspices or via a mechanism incorporated into the convention could be tasked with understanding and propagating trust in a holistic manner and provide learnings ahead of the inevitable next storm.

DATA SHARING AND ITS EQUITY IMPLICATIONS

AT THE ONSET OF THE COVID-19 PANDEMIC, researchers from the People's Republic of China shared genomic sequencing data (GSD) on SARS-CoV-2; as a result, a number of vaccine developers were able to adjust efforts that were under way against other infectious agents to address the new virus. It was noted, however, that the international regime governing and promoting the sharing of pathogen samples and sequenced data is weak and not shaped or informed by equity objectives, and that a convention could spur a multilateral system that can operate in an emergency, particularly if countries are willing to share technology in return for receiving GSD.

It was suggested that such a regime would require governments to obligate themselves to share both physical samples and GSD, share the benefits resulting from those samples and data, provide sufficient transparency to permit tracking of where samples and data are moving to and what is being done with them, broadcast who is accessing the benefits, and finance and strengthen their capacity to collect, store, sequence, and analyse their samples. Informed by similar models such as the Pandemic Influenza Preparedness Framework (PIP Framework), 68 a GSD and benefit-sharing regime could be founded through the pandemic accord and result in better global surveillance of disease with equity. Notably, the zero draft establishes a similar mechanism called the WHO Pathogen Access and Benefit-Sharing System. 69 It would cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits arising therefrom, and ensure that it operates synergistically with other relevant access and benefit-sharing instruments.

Governments are grappling with the competing and sometimes conflicting values of safeguarding individual data privacy and promoting open science and data sharing. Despite the public health rationales buttressing the latter values, states have taken steps to shore up personal privacy protection, with the European Union's General Data Protection Regulation (GDPR)⁷⁰ and the state of California's Consumer Privacy Act⁷¹ being prominent examples. These kinds of protections appear to have been developed without adequately addressing the public health and scientific research consequences, which include stifling the construction of global clinical trial networks to test new therapies. This reinforces the value of negotiating the pandemic instrument in the most inclusive manner possible.

Information collected at local health centres is often not captured in a digital repository and so cannot be aggregated with other data. There is often no impetus for local health workers to attempt to transmit it, and many of them feel that the benefits would be unlikely to accrue to their communities if they did so. They are the front line of surveillance and good information, and a regime that empowers them and can provide a real value proposition may be paid back many times over through timely warnings of emerging threats.

Though the possibility of crafting a pandemic convention was spurred by the emergence of SARS-CoV-2, the challenges in data sharing and analysis are similar to those identified in combatting tuberculosis, malaria, and any number of tropical diseases. It was acknowledged that this is a technically complex and politically delicate topic, but if it is successfully addressed in the pandemic instrument, it could pave the way for further protocols on other sensitive matters.

Improving Data Sharing and Governance Through the Pandemic Accord

The capacity of LMIC facilities to analyse GSD at the speed, efficiency, and cost of their high-income country counterparts has lagged despite investment. However, the Network for Genomics Surveillance in South Africa (NGS-SA) and Redeemer's University in Nigeria are viewed as success stories, so understanding their achievements and forming public-private partnerships to scale their models could be an avenue for closing the capability gap. The agreement could specifically request its COP to review these models and propagate their learnings.

As the treaty proposes to do to achieve its One Health objectives by working across regimes, the convention could support its data access and governance aspirations by working with officials responsible for GDPR and similar laws to try to strike a better balance.

Also, it was noted that fragmented and disbursed datasets have resulted from the lack of a coherent, intentionally built international data governance regime, and they are far less useful for research purposes than more integrated or linked datasets that combine the epidemiological, social, and immunological data needed to build good countermeasures. In addition, data from LMICs and smaller laboratories in high-income countries are critical for constructing comprehensive situational analyses and to design new medicines, and their contributions should be rewarded for reasons not dissimilar to why innovators are. A model public use agreement built using FAIR principles (findability, accessibility, interoperability, and reusability)⁷² could be helpful.



MORE ON OPERATIONALISING EQUITY

BY JANUARY 2022, THE INTERNATIONAL MONETARY FUND had estimated that the pandemic would cost over US \$12.5 trillion.⁷³ With only a small portion of that, preparedness and prevention measures could have averted countless deaths and misery and gone a long way towards addressing the vast disparities that emerged between the vulnerable and the privileged. In light of this realisation, and as a new pandemic agreement is being forged, what can actually be done now to operationalise equity? Doing this involves addressing issues such as how we make equity principles work in practice and measure their impact.

First, there are already existing, evidence-based metrics and targets that are geared towards addressing equity and that coincide with pandemic preparedness and prevention. For example, UN Sustainable Development Goal 3, "Good Health and Well-Being", provides a 2030 target for universal health coverage "including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all". The International Covenant on Economic, Social, and Cultural Rights also addresses inequality, discrimination, and aid during times of public health emergencies. PEPFAR, the Global Fund, the Bill & Melinda Gates Foundation, the WHO, and others have created metrics in other epidemic contexts that could be readily adopted so that the public can track progress.

Second, some surmised that many inequities that developed over the course of the pandemic were a result of governments not extracting sufficient public benefit from the investments taxpayers made in private sector entities that were part of their response strategies. Governments, with broad authority to take measures to protect public health and address inequity, permitted certain corporations to enjoy abundant rewards while relieving them of much of the financial risk. This was vividly illustrated in the gaps in access to vaccines, but it also surfaced for diagnostics and personal protective equipment, which in some cases were needed to ensure a basic level of survival. Private sector actors are essential and important partners in pandemic response, but some questioned the balance of shared risk and reward that materialised. Operationalising equity could mean putting meaningful standards in the new agreement that specify what public authorities must do to ensure that the relationship with the commercial sector is healthy and serves the public interest.

Third, serious investment in manufacturing and development capacity in LMICs will be critical so that more of the global population lives in areas that do not need to rely on importing lifesaving countermeasures. These investments can be made at both the country and regional levels. Many industrialised nations and multinational corporations have an interest in creating and sustaining stable markets, and so might be willing to provide needed co-financing and to share technology.

Fourth, the INB should consider organising a comprehensive census, mapping, and analysis of vulnerable communities while negotiations are underway to inform how the pandemic accord may support or indeed prioritise their needs. This includes those suffering from non-communicable diseases like cancer who must continue to access treatment and care no matter the pandemic forecast. It means creating new domestic laws that eliminate point-of-service fees or payments, many of which are known to be corrupt, during pandemic emergencies when patients are at their most desperate. Pregnant women, breastfeeding mothers, and others faced a bevy of new challenges in accessing maternal care seemingly from a lack of pandemic preparation. For them and many vulnerable groups, provisions can be made for their care and comfort free from stigma.

Fifth, community participation must be adequately addressed, not just in Geneva where the agreement's negotiations take place, but in countries where implementation will occur and people's lives and livelihoods are at stake. Corruption in some countries' health systems was devastating to community participation and trust. People must have a say in what an equitable future looks like when their well-being and that of their families, neighbours, and communities are affected.

A comprehensive monitoring and evaluation framework—national, regional, and global—needs to be developed, financed, and maintained. Monitoring ensures that global regimes stay current, fit for purpose, and free of corruption so that they can fulfil their mandate and support a more prosperous future. The zero draft contemplates its creation⁷⁶ and should be a priority activity to build public trust.

And recognising that it is part of a global ecosystem of human interaction, it should be reiterated that a pandemic treaty should contain mechanisms to engage with other international, regional, and multilateral instruments and bodies. Principles such as accessibility, access, affordability, acceptability, equity, non-discrimination, access to information, and economic mobility are often adopted by those institutions, and they are key to sustaining a right to the highest attainable standard of health and for so many other human rights too.

CONCLUSION

The world has set out a lofty goal to make pandemic prevention, preparedness, and response more equitable. While the World Health Organization announced that the end of the emergency phase of the COVID-19 pandemic may be nearing, the only thing known for certain is that humanity will continue to confront epidemic diseases of novel origin. The reflections and insights presented here provide options for country leaders who have the solemn task of constructing a vanguard with the potential to better protect us and our children. It is a critical responsibility.

Nevertheless, our convening repeatedly felt a sense of optimism and movement, and that while one single international accord cannot solve every challenge identified and more, it could have a measurable impact if crafted and implemented well. As INB co-chair Precious Matsoso⁷⁷ stated in our meeting:

We need to recognise the vulnerabilities and fragility of the world we live in today, some of the difficulties that we have to deal with, and the gravity of these health threats. We *can* deal with this in our lifetime and ensure that we put measures in place where equity can be made a reality.



ENDNOTES

- 1 Zero Draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its Fourth Meeting, at 8, A/INB/4/3 (Feb. 1, 2023) [hereinafter CA+], available at https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf.
- The World Together: Establishment of an Intergovernmental Negotiating Body to Strengthen Pandemic Preparedness, Prevention, and Response, W.H.A. Res. SSA2(5) (Dec. 1, 2021), available at https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf.
- 3 *Id.* at 1 (emphasis added).
- 4 Id. art. 1.
- 5 See generally Conceptual Zero Draft for the Consideration of the Intergovernmental Negotiating Body at its Third Meeting, A/INB/3/3 (Nov. 25, 2022) [hereinafter CZD], available at https://apps.who.int/gb/inb/pdf_files/inb3/A_INB3 3-en.pdf.
- 6 Health Equity, WHO, https://www.who.int/health-topics/health-equity (last visited Feb. 4, 2023).
- 7 Our Values, AFRICA CTR. FOR DISEASE CONTROL & PREVENTION, https://africacdc.org/about-us/our-values/
- 8 See Press Release, African Union and Africa CDC Launches Partnerships for African Vaccine Manufacturing (PAVM), Framework to Achieve It and Signs 2 MoUs, (Apr. 12-13, 2021), https://africacdc.org/news-item/african-union-and-africa-cdc-launches-partnerships-for-african-vaccine-manufacturing-pavm-framework-to-achieve-it-and-signs-2-mous/.
- 9 Health Equity, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/health-equity (last visited Feb. 4. 2023).
- 10 Health Equity, REPUBLIC OF THE PHIL., DEP'T OF HEALTH, https://doh.gov.ph/blhsd/health-equity (last visited Feb. 4., 2023).
- 11 CTR. FOR HEALTH, HUMAN RIGHTS, & DEV. (Feb. 4, 2023), https://www.cehurd.org/.
- 12 PRO-HEALTH INT'L (Feb. 4, 2023), https://www.prohealthintl.org/.
- 13 HANOI MED. UNIV. (Feb. 4, 2023), https://en.hmu.edu.vn/.
- 14 See, e.g., ARISTOTLE, NICOMACHEAN ETHICS, V 312-17 (Harris Rackham trans., Loeb Classical Library 1926); John Tasioulas, *The Paradox of Equity*, 55 Cambridge L.J. 456 (1996).
- 15 Y.B. of the Int'l Law Comm'n 1976, Vol. II, Part 2, 132, U.N. Doc. A/CN.4/SER.4/1976/Add. 1 (Part 2) (1977) available at https://legal.un.org/ilc/publications/yearbooks/english/ilc_1976_v2_p2.pdf.
- 16 Statute of the International Court of Justice, art. 38.2.
- 17 Frontier Dispute (Burk. Faso v. Mali), 1986 I.C.J. 554, 567-568 (Dec. 22) (emphasis added).
- 18 U.N. Convention on the Law of the Sea, art. 59, Dec. 10, 1982, 1833 U.N.T.S. 3.
- 19 Protocol on Water and Health to the 1992 Convention on the Protection and Use of Transboundary Watercourses and International Lakes, art. 5(I), June 17, 1999, 2331 U.N.T.S. 202.
- 20 What is COMESA, THE COMMON MKT. FOR E. & S. AFR., https://www.comesa.int/what-is-comesa/ (last visited Feb. 4, 2023).
- 21 Regional Agreement on Access to Information, Public Participation and Justice in Environmental Matters in Latin America and the Caribbean, Mar. 4, 2018, U.N. Doc. LC/PUB.2018/8/.
- 22 May 23, 2005, 2509 U.N.T.S. 79.
- 23 LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW, 2d. 22.
- 24 Convention on Biological Diversity, art. 20, June 5, 1992, 1760 U.N.T.S. 79 (emphasis added).
- 25 For an explanation of CBDRs, see generally Matiangai Sirleaf, Responsibility for Epidemics, 97 TEX. L.J. 285, 314-354, available at https://texaslawreview.org/responsibility-for-epidemics/.
- 26 *CZD, supra* note 5, art. 4(4).
- 27 CA+, supra note 1, art. 4(4).
- 28 See, e.g., Vienna Convention on the Law of Treaties, arts. 1(d), 19-20, May 23, 1969, 1155 U.N.T.S. 331.
- 29 See CA+, supra note 1, art. 4(4).
- 30 See id., art. 23.

- 31 See, e.g., id., art. 19(1)(c).
- 32 See id., art. 20(2)(a).
- 33 See, e.g., id., art. 13(5).
- 34 See in Kevin A. Klock, Lawrence O. Gostin & Sam F. Halabi, Going Global, Acting Local: The International Pandemic Convention, 44 AFRICA HEALTH 11 (2022).
- 35 See Press Release, One Health Joint Plan of Action Launched to Address Health Threats to Humans, Animals, Plants and Environment, (Oct. 17, 2022), https://www.who.int/news/item/17-10-2022-one-health-joint-plan-of-action-launched-to-address-health-threats-to-humans--animals--plants-and-environment.
- 36 See CA+, supra note 1, art. 18(1); see also art. 18(5) (declaring its intention to commit to strengthen synergies with other existing relevant instruments that address the drivers of pandemics).
- 37 See Paula Braveman & Sofia Gruskin, Defining Equity in Health, 57 J. EPIDEMIOLOGY & CMTY. HEALTH 254 (2003).
- 38 See CZD, supra note 5, art. 4(8); CA+, supra note 1, art. 4(8).
- 39 See CZD, supra note 5, Preamble 22-25, arts. 4(14), (17); CA+, supra note 1, Preamble 23-26, arts. 4(14), (18).
- 40 See CZD, supra note 5, arts. 4(11-13), CA+, supra note 1, arts. 4(11-13) (in each draft, art. 4(11) refers to gender equality, art. 4(12) refers to non-discrimination and respect for diversity, and art. 4(13) refers to the rights of individuals and groups at higher risk and in vulnerable situations).
- 41 U.S. AGENCY FOR INT'L DEV., https://www.onehealthworkforce.org (last visited Feb. 4, 2023).
- 42 O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW & FOUND. FOR THE NAT'L INST. OF HEALTH, LEGAL TOOLS FOR PANDEMIC PREPAREDNESS 8 (2021). https://oneill.law.georgetown.edu/wp-content/uploads/2021/11/ONL_Pandemic_Prep_D1_P5.pdf (last visited Feb. 4. 2023).
- 43 GAVI, THE VACCINE ALLIANCE (Feb. 4, 2023), http://www.gavi.org.
- 44 INT'L FIN. FACILITY FOR IMMUNISATION (Feb. 4, 2023), https://www.iffim.org.
- 45 What is an Advance Market Commitment and How Could it Help Beat COVID-19?, GAVI, THE VACCINE ALLIANCE, https://www.gavi.org/vaccineswork/what-advance-market-commitment-and-how-could-it-help-beat-covid-19 (last visited Feb. 4, 2023).
- 46 See generally GAVI, THE VACCINE ALLIANCE, THE GAVI COVAX AMC: AN INVESTMENT OPPORTUNITY (2020). https://www.gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf.
- 47 JOINT U.N. PROGRAMME ON HIV/AIDS (Feb. 4, 2023), https://www.unaids.org.
- 48 May 21, 2003, 2302 U.N.T.S. 166.
- 49 WHO FCTC Investment Fund, WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, https://fctc.who.int/who-fctc/who-fctc-investment-fund (last visited Feb. 4, 2023).
- 50 FOUND. FOR THE NAT'L INST. OF HEALTH (Feb. 4, 2023), https://fnih.org/.
- 51 CA+, supra note 1, art. 9(4).
- 52 See CZD, supra note 5, art. 18.2(a).
- 53 See CA+, supra note 1, art. 19(1)(c).
- 54 See Gavi Yamey, et al., It is Not Too Late to Achieve Global Covid-19 Vaccine Equity, 376 BRIT. MED. J. (2022), citing Hannah Ritchie, et al., Coronavirus (COVID-19) Vaccinations, OUR WORLD IN DATA 2020, https://ourworldindata.org/covid-vaccinations.
- 55 Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1869 U.N.T.S. 299.
- 56 See generally id., art. 31.
- 57 Elizabeth Cohen & Dana Vigue, Covid-19 Vaccine Trials Have Been Slow to Recruit Black and Latino People and That Could Delay a Vaccine, CNN (Aug. 16, 2020, 5:53 PM EDT), https://www.cnn.com/2020/08/16/health/covid-19-vaccine-trial-black-minority-recruitment/index.html.
- 58 See CA+, supra note 1, art. 9(3)(a).
- 59 See id., art. 9(2)(c).
- 60 See id., art. 6.
- 61 See The Financing Elements of Supporting Equity section for a model on how to address export prohibitions.
- 62 See CZD, supra note 5, art. 7(2)(a)(iv); CA+, supra note 1, art. 7(4)(a).
- 63 See CZD, supra note 5, art. 16; CA+, supra note 1, art. 17.
- 64 See generally JESS BERENTSON-SHAW, A MATTER OF FACT: TALKING TRUTH IN A POST-TRUTH WORLD (Bridget Williams Books 2018).

- 65 See CZD, supra note 5, art. 8(2)(b).
- 66 See CA+, supra note 1, art. 9(1).
- 67 See id., art. 13(6).
- 68 W.H.A. Res. 64.5 (May 2011).
- 69 See CA+, supra note 1, art. 10.
- 70 2016 O.J. (L 119) 1, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?toc=OJ:L:2016:119:TOC&uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG.
- 71 Cal. Civ. Code § 1798.100-199, *available at* https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?divisio n=3.&part=4.&lawCode=CIV&title=1.81.5.
- 72 Mark D. Wilkinson, et al., *The FAIR Guiding Principles for Scientific Data Management and Stewardship*, 3 SCI. DATA (2016), *available at* https://doi.org/10.1038/sdata.2016.18.
- 73 IMF Sees Cost of COVID Pandemic Rising Beyond \$12.5 Trillion Estimate, REUTERS (Jan. 20, 2022, 11:29 AM EST), https://www.reuters.com/business/imf-sees-cost-covid-pandemic-rising-beyond-125-trillion-estimate-2022-01-20/.
- 74 SDG Target 3.8, WHO, https://www.who.int/data/gho/data/themes/topics/indicator-groups/indicator-group-details/GHO/sdg-target-3.8-achieve-universal-health-coverage-(uhc)-including-financial-risk-protection (last visited Feb. 4, 2023).
- 75 See, e.g., Jan. 3, 1976, 993 U.N.T.S. 3, General Comment No. 14.
- 76 See CA+, supra note 1, arts. 13(5), 16(3), 22(2), 23.
- 77 Permission to quote was authorised.

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