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Pandemic Treaty Negotiations after COVID-19: Issues and Challenges Toward a Pathogen Access and Benefit-Sharing System

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In the wake of the COVID-19 pandemic, the international community recognized the need to strengthen international health security systems to prevent, prepare for, and respond to the spread of infectious diseases, with the result that negotiations for a pandemic treaty are underway. A major focus of these negotiations is the establishment of a system of pathogen access and benefit-sharing, in connection with which discussions have been ongoing, informed by assessments of COVID-19 situations, about the need to ensure equitable access to vaccines. While several frameworks exist regarding access to genetic resources and the sharing of benefits derived from their use—including the Convention on Biological Diversity, the Nagoya Protocol on Access to Genetic Resources, and the Pandemic Influenza Preparedness Framework (PIP Framework)—no system is in place for sharing non-influenza pathogen samples, related genetic sequence data, and benefits arising from their use. Such a system could be modeled on the genetic sequence sharing mechanism used during the COVID-19 pandemic or the PIP Framework's Standard Material Transfer Agreements (SMTA). However, further discussions are likely needed before the international community can implement this system.

Introduction

During the COVID-19 pandemic, the world recognized the critical role of the global health security system in preventing, preparing for, and responding to infectious disease threats. This recognition led the international community to begin negotiations for amendments to the International Health Regulations (IHR) and the introduction of a pandemic treaty as an international framework to address areas not covered by the IHR. An example of these efforts can be found in the World Health Assembly[1] held during the COVID-19 pandemic, where members of the World Health Organization (WHO) agreed on two key points: to adopt amendments to the IHR and to draft a legally binding pandemic agreement to be presented for a vote at the 77th World Health Assembly in May 2024 (Kim, S. et al., 2022). Although the proposed IHR amendments were adopted at the 77th World Health Assembly, the draft pandemic accord failed to reach a conclusion, delaying the chance of its adoption by six months until a special session of the Assembly scheduled for mid-December 2024, or even by a full year until the 78th Assembly.

One key issue in the pandemic accord negotiations concerns 'pathogen access and benefit-sharing' (PABS), which, in light of the challenges caused by the excessive hoarding of vaccines by wealthy countries, focuses on ensuring equitable access to health products, including vaccines. This entails enabling access to genetic sequence data (GSD)[2] and a fair distribution of benefits resulting from their utilization. Genetic sequence data, used to identify causative agents and understand pathogen-spread pathways, are essential for global infectious disease surveillance and research and development. In this context, the proposed PABS system is seen as a necessary mechanism for achieving equitable access to vaccines and related health products (WHO, 2017a; Strobeyko, 2024). Ensuring equitable vaccine access is regarded as a particularly pressing concern, given that, during the pandemic—with vaccines already researched, developed, and manufactured through prompt sharing of SARS-CoV-2 GSP and unprecedented support from both public and private organizations—while wealthier nations were moving on toward booster injections, most people in developing countries, including healthcare workers, lacked access even to initial doses (Rizk et al., 2022).[3]

There are several international mechanisms for accessing genetic resources and sharing benefits derived from their use. However, there is currently no system in place for the international sharing of pathogen sequence data. For example, the IHR stipulates the sharing of public health information but does not include GSD. In recent discussions on IHR amendments, several developed countries emphasized the need for international pathogen GSD sharing, while the IHR Review Committee recommended addressing the benefit-sharing aspect of GSD sharing (WHO, 2023).[4] The UN Convention on Biological Diversity (CBD), established grounded on recognition of biodiversity's value for current and

1) WHO's highest decision-making body; attended by all WHO member countries

2) While physical pathogen samples can only be shared between laboratories, GSD can be easily shared via email or publication. Although some regulations require the use of physical pathogen samples, vaccine development is often achieved without them. (WHO, 2017a)

3) This is a longstanding issue–the need for a system of pathogen sample sharing and equitable benefit division has been raised time and again since before COVID-19, from the times of the Ebola crisis (2014–2016) and the MERS outbreak (2013) [Moorthy, 2022; Piselli, 2022; Rourke et al., 2020]

4) To view written comments from each country, refer to https://apps.who.int/gb/wgihr/.

future generations and with the backing of the United Nations Environment Program (UNEP), is another case in point, to which the Nagoya Protocol on Access and Benefit Sharing was supplemented in 2011 to advance its goal toward fair use of genetic resources and equitable benefit distribution (Secretariat of CBD, 2011). WHO's Pandemic Influenza Preparedness (PIP) framework, yet another example of a mechanism created to ensure access to pathogen samples and benefits-sharing, applies only to influenza viruses with human pandemic potential, leaving non-influenza pathogens outside its scope.

This article reviews the background, objectives, and scope of key frameworks concerning access to genetic resources and pathogens and the sharing of benefits arising from their use, and discusses their relationship to and implications for the proposed pandemic treaty.

Existing systems for pathogen access and benefit-sharing

◆ *The CBD (1992) and the Nagoya Protocol (2010)*

The CBD came into effect in 1993, aiming for three objectives: (1) conservation of biodiversity, (2) sustainable use of its components, and (3) fair and equitable sharing of benefits arising from the use of genetic resources (Secretariat of CBD, 2011).[5] The Nagoya Protocol,[6] implemented with the goal of advancing the third of the CBD objectives, established a transparent and predictable framework that governs access to genetic resources and ensures the fair sharing of benefits resulting from their use (Secretariat of CBD, 2011).[7]

As to whether digital sequence information (DSI) or GSD[8] should be considered a type of genetic resource subject to the CBD and the Nagoya Protocol, a question taken up for some time at international dialogues (CBD/COP/DEC/14/20), the state parties to the CBD concluded at a meeting in December 2022 that they would establish a multilateral instrument for sharing DSI, including GSD on pathogens (CBD/COP/DEC/15/9). If established,[9] this mechanism will apply to DSI on all pathogens not subject to the PABS system (Article 4, CBD).[10]

5) The CBD acknowledges the sovereign rights of a state over its natural resources and requires other state parties that use its genetic resources to share the benefits derived from such use with the state of origin. (Secretariat of CBD, 2011).

6) The Nagoya Protocol is a supplement to the Convention on Biological Diversity, adopted at the 10th Conference of the Parties held in Nagoya, Japan, on October 29, 2010. As of August 2024, 141 parties participated.

7) The Nagoya Protocol in its Annex lists monetary and non-monetary benefits that are subject to sharing.

8) In the field of environmental affairs, DSI is primarily used. Compared to GSD, DSI is broader in scope, encompassing all types of digital information derived from genetic resources. It has been argued that DSI, rather than GSD, should be included in the pandemic treaty, as it is more comprehensive and could better support future developments in science (WHO, September 3, 2024).

9) The decisions of specific details on access to genetic resources and related benefit-sharing were scheduled for the 16th UN CBD (October 21, 2024 – November 1, 2024) (CBD/COP/DEC/15/9).

10) If the parties in the pandemic treaty negotiations decide not to adopt a PABS system, pathogen GSD and DSI will be subject to the multilateral access and benefit-sharing system under the CBD. However, concerns have been raised that the CBD, in light of the emphasis it places on the preservation of biodiversity, may not be as effective in ensuring risk assessment for infectious diseases, rapid access to data, and the swift development of pandemic-related products. adequately addressed (Strobeyko, 2024).

◆ *PIP framework: background and functions*

In 2007, Indonesia declared that, in protest of the restrictions imposed on access to a vaccine developed elsewhere by using samples from a case originated from within its land and in defense of its national sovereignty over biological resources as affirmed in the CBD, it would stop sharing its H5N1 virus samples with the global community (Sedyaningsih et al., 2008). This action triggered negotiations on ways to share influenza viruses of pandemic potential and to facilitate access to vaccines and sharing of other benefits. As a result, the World Health Assembly in 2011 adopted the PIP framework (WHO, 2021), according to which member states would share influenza viruses promptly and systematically through the existing Global Influenza Surveillance and Response System (GISRS) and commit, drawing on the Standard Material Transfer Agreement (SMTA), to sharing benefits arising from their use (WHO, 2021).[11] Limited though its application is to influenza viruses, the PIP Framework may nevertheless be the only multilateral framework in place to govern the sharing of pathogen access and related benefits.

As, within the PIP Framework, all parties involved in the sharing of influenza virus samples—including providers (including laboratories), the WHO, and recipients (including pharmaceutical manufacturers)—are legally bound by SMTAs, the user must contribute a portion of benefits to the WHO from the use of biological resources (WHO, 2021). Manufacturers' benefit-sharing obligations are listed in Table 1.

[Table 1] PABS within the PIP Framework

	Scope	Obligations or benefit-sharing
Within GISRS	Parties to the Agreement (Laboratories), WHO	(General provisions) The provider or recipient will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries
Outside GISRS	A: For manufacturers of vaccines and/or antivirals	(Commit to two of the following options) - Donate at least 10% of real time pandemic vaccine production to WHO - Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices. - Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO. - Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices. - Grant to manufacturers in developing countries licenses on mutually agreed terms - Grant royalty-free licenses to manufacturers in developing countries or to WHO
	B: Manufacturers of products relevant to pandemic influenza preparedness and response	(Commit to one of the following options) - Donate to WHO at least X2 diagnostic kits needed for pandemics. - Reserve for WHO at least X2 diagnostic kits needed for pandemics, at affordable prices. - Support, in coordination with WHO, the strengthening of influenza specific laboratory and surveillance capacity in developing countries. - Support, in coordination with WHO, transfer of technology, know-how and/or processes for pandemic influenza preparedness and response in developing countries.
	C: Other entities	(Consider contributing to the measures listed below) Donation of vaccines; donation of antivirals; donation of medical devices; donation of diagnostic kits; affordable pricing; transfer of technology and processes; granting of sublicenses to WHO; laboratory and surveillance capacity building

Source: "Framework for the sharing of influenza viruses and access to vaccines and other benefits (second edition)," Pandemic Influenza Preparedness (PIP), 2021, pp. 29–35, WHO.

11) The movement of pathogens within the GISRS or to outside locations is monitored through the Influenza Virus Traceability Mechanism (IVTM).

GISRS participants are required to contribute either financially or non-financially to the operation of the system, with manufacturers who use the system responsible for contributing 50 percent of its running costs (WHO, 2021, pp. 21-22).[12]

Responses to the COVID-19 pandemic

◆ *GSD sharing during the COVID-19 pandemic*

The IHR in Article 6.1 requires that state parties notify WHO "of all events which may constitute a Public Health Emergency of International Concern" within 24 hours of assessment of relevant public health information. Pathogen data and GSD, though they may in a broad sense be treated as part of public health information, are not classified as such by the IHR.

With no internationally agreed-upon regulations in place on access to GSD and the sharing of related benefits,[13] such data have been shared, following scientific cooperation norms, through digital platforms like the Global Initiative on Sharing All Influenza Data and the International Nucleotide Sequence Database Collaboration, with WHO's laboratory network facilitating the international sharing of pathogens (Moorthy, 2022). During the COVID-19 pandemic, data on thousands of its vital sequences were uploaded from around the world onto these online platforms.[14] These efforts helped to track the spread of the virus, identify effective containment strategies, and monitor the emergence of mutations, expediting, as a result, the development of countermeasures—diagnostic test kits, medications, and vaccines (Rourke et al., 2020). However, not all previous health emergencies, including the Ebola crisis, saw GSD shared as successfully (Moorthy, 2022). As pointed out by some commentators, the absence of a legally-binding instrument enforcing the sharing of pathogen GSD impedes scientific progress as well as pandemic response (Rourke et al., 2020).

◆ *Access to medical countermeasures during the COVID-19 pandemic*

The Access to COVID-19 Tools Accelerator (ACT-A), launched in April 2020 as part of a global collaboration to "accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines," was "organized in four pillars: diagnostics, treatment, vaccines, and health

12) Each manufacturer is required to pay an annual contribution, with the amount determined through consultations with the PIP Framework expert group, based on the nature and capabilities of the manufacturer. The WHO uses the contributions from manufacturers to build influenza pandemic response funding or to strengthen the capabilities of countries that lack the necessary capacity. Countries with sufficient capacity are requested to help strengthen the national laboratories and influenza surveillance capabilities of WHO and member countries, particularly those in developing nations (WHO, 2021, pp. 21–22).

13) The PIP framework requires the sharing of both physical samples and GSD, but the actual system focuses on physical samples, raising the need for further discussion on the sharing of GSD (WHO, 2021, pp. 8–13). The SMTA is also limited to physical samples (WHO, 2021, pp. 29–36). A group of experts reviewing the PIP framework recommended modifying the definition of the framework to include GSD (WHO, 2017a). However, during the 70th World Health Assembly, some countries called for postponing the inclusion of GSD in the PIP framework until a full evaluation is completed (WHO, 2017b).

14) Chinese scientists publicly uploaded the first genetic sequencing of the SARS-CoV-2 virus on January 10, 2020, and two days later officially shared the virus's GSD with the WHO (WHO, 2020). With early access to the GSD, laboratories worldwide were able to rapidly develop diagnostic test kits and begin research on antiviral drugs and vaccines (Rourke et al., 2020).

system strengthening" (WHO, 2022). Of these, the vaccine pillar was taken on by the COVID-19 Vaccines Global Access Facility (COVAX), through which governments, scientists, corporations, civil groups, and international health organizations collaborated to ensure low- and middle-income countries could access COVID-19 response products. However, as COVID-19 is not an influenza virus, securing a reserve of 10 percent of real-time vaccine production, as specified in the PIP Framework, was impossible during the pandemic. As a result, the COVAX reserve barely reached 3 percent of real-time vaccine production (Moorthy, 2022).

The PABS system as part of the Pandemic Treaty

In these circumstances, a PABS system may be created within the framework of the Pandemic Treaty. As to the scope of pathogens, it would be preferable to limit the PABS system's applicability to those with pandemic potential, as in the PIP Framework. A wider scope of application may lead to additional challenges in data management, delaying the development of diagnostics, medications, and vaccines, hindering the timely use of these countermeasures (Rizk et al., 2022).

In this case, the WHO's international network of laboratories can facilitate the sharing of pathogen samples. Meanwhile, pathogen GSD can be shared through existing international online databases, such as GISAID and INSDC, as it is essential to use public-domain or public-access databases to ensure timely surveillance and research by prompt GSD sharing (PIP Framework Advisory Group-Technical Working Group on the Sharing of Influenza GSD).[15] Pathogen sharing and the utilization of provided pathogens—both commercial and non-commercial—could be regulated through SMTA contracts. This could, after the manner of the PIP Framework's SMTAs, allow for sharing pathogen samples for such non-commercial purposes as surveillance, while imposing legally binding obligations on commercial utilization, such as the donation of part of reserve stockpiles and technological transfer. Details would need further negotiation.[16]

Given that no global system has been built that covers all pathogens, and considering the various issues raised, implementing the proposed PABS system may require a considerable amount of time[17]. Using existing systems for sharing of DSI and GSD is one thing; however, the question of how to track and identify pathogen utilization may emerge as a contentious issue. Linking GSD access to benefit sharing requires an agreement to adopt a tracing mechanism for monitoring GSD utilization, one like the PIP

15) At the Stakeholder Dialogue Session on the Pandemic Treaty, held on September 3–4, 2024, many participants agreed on the need for benefit-sharing but also emphasized that benefit-sharing should not hinder the rapid sharing of GSD (WHO, September 3, 2024).

16) For example, the pharmaceutical industry sees tiered pricing, such as supplying vaccines to developing countries at lower prices, as one example. However, developing countries raise the concern that the prices offered by the pharmaceutical industry are not affordable (WHO, September 3, 2024).

17) The Pandemic Treaty was initially set to be adopted at the World Health Assembly in May 2024, with the idea of supporting it with the political momentum created by the COVID-19 pandemic. However, as no agreement was reached at the May 2024 World Health Assembly, the adoption of the treaty was put off to the end of this year or the World Health Assembly in May next year. Despite this delay, there has been growing pressure, especially from developing countries, to reach an agreement as soon as possible. Also, since the PABS system is expected to be larger in scope than the existing PIP Framework and other pathogen-sharing systems, more time may be needed to gather input from individual countries when designing it. In light of this, it might be more effective to include the PABS system in the Pandemic Treaty and also develop a separate document with specific details through an intergovernmental meeting after the treaty's adoption.

Framework's Influenza Virus Traceability Mechanism (WHO, 2017a).[18]

Inasmuch as influenza response involves the production of seasonal vaccines, the GISRS's operational expenses have been covered in part by donations from pharmaceutical companies. When it comes to non-influenza pathogens in general, there is a need for further discussions to find means of securing the necessary funding, such as contributions from state parties (Rizk et al., 2022).[19]

Furthermore, given the differing particularities of various pathogens, including their varying rates of spread,[20] how the benefits gained from their use should be distributed may need to vary from one case to another. Since it is nearly impossible to predict in advance how these particulars will turn out, a flexible approach to benefit sharing is preferable (Rizk et al., 2022).

When to begin sharing benefits—whether from the point of accessing GSD or DSI, or from the onset of a PHEIC or pandemic—is still an open question that requires negotiation. In this regard, it has been noted that the proposed PABS system must include detailed guidelines to address scenarios where, should sharing of commercialized products (identified as benefits arising from accessing GSD or DSI) begins at the onset of a PHEIC or pandemic, the international export or supply of these products could be blocked if states during emergencies prohibit all exports and overseas distribution of related medical countermeasures (WHO, 2024. 9. 3.).

Concluding remarks

A multilateral framework is being developed to improve access to pathogens not covered by the existing system and to facilitate the sharing of benefits stemming from their use. In pandemic treaty negotiations, WHO member countries, acknowledging the state sovereignty over genetic resources and the critical role of international cooperation in mitigating public health threats, have agreed in principle on the prompt sharing of pathogens with pandemic potential and their DSI, as well as on the fair distribution of benefits arising from their use (WHO, 2024. 5. 24). Separately, outside the pandemic treaty negotiations, UN CBD state parties have agreed on the need to establish a multilateral system for sharing benefits arising from DSI utilization, with a meeting scheduled for the second half of 2024 to determine further details. If the proposed pandemic treaty and its PABS framework are adopted, only GSD outside this framework would remain under CBD jurisdiction (Article 4, CBD). The PABS system, with its mechanisms linking pathogen access to benefit sharing, would enable prompt, coordinated sharing of pandemic-potential pathogens, thereby helping countries worldwide, including Korea, strengthen

18) The PIP Framework Expert Group proposed an upstream approach where monitoring begins when data is downloaded from the database, as well as a downstream approach that monitors the final product stage, as a means of tracking the use of influenza GSD (WHO, 2017a). Considering the costs of establishing tracking mechanisms, it may be a more feasible to require commercial entities to disclose the information they use at the point of commercialization (WHO, September 3, 2024).

19) For example, the Food and Agriculture Organization (FAO) of the United Nations has discussed a system for accessing genetic resources and sharing benefits under the International Treaty on Plant Genetic Resources for Food and Agriculture. This system treats the subscription fees paid in advance as a form of benefit-sharing, as it takes time to derive commercial outcomes from genomic access (Kiene, 2022). Meanwhile, during a stakeholder consultation on the Pandemic Treaty held on September 3, 2024, the pharmaceutical industry argued that annual contributions discourage companies' participation in the system (WHO, 2024. 9. 3.)

20) There are pathogens that spread rapidly on a large scale, such as COVID-19, but there are also pathogens that do not spread in this way (Rizk et al., 2022).

preparedness, enhance response capabilities, and better protect public health from infectious disease threats. There is a clear need for an international instrument to ensure through international law prompt pathogen sharing and predictable benefit arrangements, which the current global health regime fails to guarantee despite their necessity for surveillance and the development of medical countermeasures like vaccines. The PABS system could also support developing countries in building capacity for sample collection and genetic sequencing, fostering surveillance and innovation. Costs would be partly covered by users of these genetic resources. The proposed system, if put in place, would expedite global inoculation by fair distribution of vaccines. This will help contain the spread of viral diseases and prevent them from evolving into novel variants.

It was unfortunately the case that when, during the COVID-19 pandemic, some high-income countries were gearing up to provide universal boosters, low-income countries had to do without so much as first doses even for healthcare workers. In a global pandemic emergency, achieving high vaccinations rates in only some countries has limited effect at best, as the virus may mutate into variants in under-vaccinated areas and in turn re-infect even fully-vaccinated countries. The discussion of the PABS system will continue as part of the ongoing process of pandemic treat negotiations. The discussion merits continued attention.

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