

## **International Sharing of Human Pathogens to Promote Global Health Security—Still a Work in Progress**

### **Introduction**

Human pathogens are shared globally among research institutions and public agencies through international networks to safeguard global public health. Sharing samples and related data is necessary to enable researchers to identify and understand pathogens and to develop diagnostic tests and medical countermeasures. Without rapid human pathogen sharing, risk assessment and risk management cannot be carried out to prevent or respond to outbreaks caused by known and unknown diseases. This *Insight* examines the progress and limitations of the international framework on sharing human pathogens, examining its history, the legal instruments applicable to pathogenic genetic material, the question of genetic sequence data/“digital sequence information,” and future avenues for global governance.

Human pathogen sharing became an issue of international contention in 2006, when Indonesia declined to share H5N1 pandemic influenza samples due to perceived inequities in the global influenza surveillance system. This was reportedly a reaction to the development of a vaccine against H5N1 by an Australian company, based on Indonesian samples shared through the global network of laboratories coordinated by the World Health Organization (WHO) and known today as the Global Influenza Surveillance and Response System (GISRS)—without Indonesia’s prior informed consent. The WHO’s acknowledgement that patents were sought over modified GISRS samples further compounded the issue. Indonesia thus invoked the principle of sovereignty over biological resources under the Convention on Biological Diversity (CBD), including genetic

resources, and the consequent requirement for fair and equitable access to benefits resulting from their utilization.<sup>1</sup>

The World Health Assembly (WHA) responded to this incident in 2007 with the launch of prolonged and complex negotiations that led to the adoption in May 2011 of the Pandemic Influenza Preparedness (PIP) Framework, a landmark, innovative arrangement to increase global preparedness against the ever-present risk of an influenza pandemic. It is a non-legally binding instrument bringing together WHO, its 194 member states, manufacturers involved in influenza preparedness and response, research institutions and universities, and other stakeholders, to implement a global and multilateral approach to preparedness and response.<sup>2</sup>

The PIP Framework is founded on two equal pillars: the need to ensure timely and systematic sharing of influenza viruses with pandemic potential (PIP Biological Material) and the need to ensure that benefits are equitably shared with all countries depending on their needs. One innovative feature is the requirement to use standard material transfer agreements (SMTA) annexed to the Framework as legal instruments to transfer PIP Biological Material within and outside the GISRS. In the latter case, the SMTA is concluded between the WHO—as the steward and trustee of the system—and the institutions (usually research centres or pharmaceutical companies) receiving samples. The recipient commits itself to providing certain benefits through the WHO in case of an outbreak of pandemic influenza, with the benefits depending on its classification: a) vaccine manufacturers, b) diagnostics manufacturers, or c) research centres and academia. This places access to benefits on a multilateral basis rather than a bilateral and purely transactional one.

### **Pathogen Sharing and the Nagoya Protocol**

The CBD confirms national sovereignty over biological and genetic resources, establishing that access to those resources must be based on the prior informed consent of the provider, and subject to mutually agreed terms for the fair and equitable sharing of benefits arising out of their utilization. The provisions on access and benefit sharing (ABS) were elaborated in the 2010 Nagoya Protocol to the CBD, which entered into force in 2014.<sup>3</sup>

The Protocol does not contain specific rules addressing pathogen sharing arrangements despite pathogens ostensibly falling within its definition of “genetic resources.”<sup>4</sup> Yet, it does recognize its possible impact on public health in its preamble and substantive provisions. Parties agreed to the Protocol mindful of the 2005 WHO International Health

Regulations and the importance of ensuring access to human pathogens for public health preparedness and response purposes, and proposed the taking into consideration of human health emergencies in national ABS measures (Article 8(b)).

Although not aimed at public health, the Protocol's provisions on its relationship with other international treaties and instruments (Article 4) are important for establishing unhindered global pathogen sharing arrangements and represent important principles for global health security. Most importantly, the Protocol does not apply to genetic resources covered by specialized international instruments (SII) that are consistent with/do not run counter to CBD and Protocol objectives (Article 4.4). This is a narrow exemption, as it only applies to parties to the SII, to the specific types of genetic resources covered by the SII, and pursuant to its purpose. It was likely included to protect the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, but also generated a discussion on whether the PIP Framework qualifies as an SII notwithstanding its non-legally binding status and the consequent difficulty of identifying its parties. Second, parties can develop and implement other relevant international instruments (including ABS instruments) and should pay due regard to "useful and relevant ongoing work or practices" under relevant instruments and international organizations, like the WHO (Article 4.3).

The Nagoya Protocol, with 131 parties as of July 2021, has raised challenges and concerns for public health, and is the object of discussions within the WHO, so far without a concrete outcome. The transactional and bilateral approach of the CBD and the Nagoya Protocol is seen by many as incompatible with the need for timely and unimpeded multilateral pathogen sharing for public health purposes, especially for pandemic prevention and response. Moreover, the implementation of the Protocol in national laws has created a patchwork of at times inconsistent approaches that generate uncertainties, red tape, and delays. The WHO has expressed concern at recent instances of delays in obtaining candidate strains for the composition of the seasonal influenza vaccines.<sup>5</sup> Concurrently, a number of developing countries and civil society organizations emphasize the importance of the Protocol for translating principles of equity and redressing power imbalances into enforceable provisions.

### **Genetic Sequence Data/Digital Sequence Information**

An important lacuna in the Nagoya Protocol is its failure to directly address genetic and biochemical information and associated data. One aspect is addressed in the PIP Framework—genetic sequence data (GSD)—i.e., the mapping of a genome in digital form that can be exchanged and downloaded through the web and later used to reconstruct

up to the whole pathogen using synthetic biology techniques. The PIP Framework does not regulate GSD sharing, limiting itself to suggesting that member states share GSD in a timely manner, given the important public health interests at stake.

The legal vacuum surrounding the legal status of GSD is largely due to the increasing spread of this previously sophisticated and relatively inaccessible technology, which risks side-lining the bargain for ABS established by the PIP Framework and CBD/Nagoya Protocol, and is the object of on-going negotiations within the latter under the placeholder term “digital sequence information.”<sup>6</sup>

While awaiting a multilateral resolution of this issue, the void has been filled by privately-run databases such as the International Nucleotide Sequence Database Collaboration (consisting of GenBank, the DNA Data Bank of Japan and European Nucleotide Archive)<sup>7</sup> and the Global Initiative on Sharing All Influenza Data (GISAID),<sup>8</sup> a private initiative supported by donors, governments, and non-profits, where public and private actors can upload GSD that is then freely accessible to anyone, subject to conditions barring commercial exploitation or requiring acknowledgment of the providing party. GISAID, even though in principle focusing on influenza strains, has become the repository of choice for SARS-CoV-2 GSD since the first gene sequence was uploaded to GenBank by Chinese scientists on January 5, 2020.<sup>9</sup>

### **Future Avenues for the Global Governance of Pathogens**

Global pathogen governance is uncertain and shifting, driven both by immediate pandemic-related concerns and longer-term trends in related fora. The public health community is concerned by delays in pathogen sharing linked to haziness in the implementation of the Nagoya Protocol, such as delays in the sharing of seasonal influenza viruses as well as hurdles for risk assessment and risk management. The pharmaceutical industry is concerned by uncertainties surrounding access to pathogens and the risk of breaching national and international rules. They are also apprehensive about the potential for further regulation, including over the utilization of GSD/DSI, which is playing an increasing role for research—as demonstrated by the breakthrough success of mRNA vaccines for SARS-CoV-2.

In 2019, the WHA requested the Director-General for a report on pathogen-sharing practices and arrangements, the implementation of ABS measures, and potential public health outcomes and other implications.<sup>10</sup> The mandate ended with the Secretariat presenting its final report to the 74<sup>th</sup> WHA in May 2021. No decision was adopted, but it is expected that the Secretariat will continue to monitor developments and facilitate

discussions and capacity-building at the national level. The apparent lack of urgency is puzzling given the documented chilling effect of the Nagoya Protocol on human pathogen sharing.

In response to the COVID-19 pandemic, the WHO Secretariat developed a voluntary global BioHub initiative allowing member states to share biological materials under pre-agreed conditions, including compliance with biosafety, biosecurity, and other applicable regulations.<sup>11</sup> The Secretariat intends to make the initiative compliant with the Nagoya Protocol and to use best practices developed under the PIP Framework. The pilot phase is using SARS-CoV-2 and variants to test feasibility and operational modalities, but will expand to include other pathogens. Switzerland signed the first agreement with the WHO, making available a specialized laboratory as a repository for SARS-CoV-2 viruses or other pathogens with epidemic or pandemic potential as the first step in setting up an international system for the voluntary exchange of novel pathogens.

The WHA will hold a special session in November 2021 to discuss the possible negotiation of a treaty on pandemic preparedness and response, where ABS rules applicable to all human pathogens of pandemic potential could be discussed. The first part of the 15<sup>th</sup> Conference of the Parties to the CBD and 4<sup>th</sup> Meeting of the Parties to the Nagoya Protocol will be convened in October 2021 to adopt a roadmap for completing the negotiation of the post-2020 global biodiversity framework, to be adopted at a resumed session in May 2022. The first draft was released on July 5, 2021,<sup>12</sup> with Goal C focusing on substantially increasing the benefits shared from the utilization of genetic resources. This would be applicable to all CBD parties, not just the two-thirds that are Parties to the Nagoya Protocol. The agenda of the resumed session of the 4<sup>th</sup> Meeting includes the adoption of indicative criteria for SII,<sup>13</sup> and the question of a global multilateral benefit-sharing mechanism that addresses DSI.<sup>14</sup>

**About the authors:** Gian Luca Burci is Adjunct Professor of International Law at the Graduate Institute of International and Development Studies.

Frederic Perron-Welch is a Doctoral Fellow at the Grotius Centre for International Legal Studies, Leiden University.

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<sup>1</sup> David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy* 14 EMERGING INFECTIOUS DISEASES 88 (2008).

<sup>2</sup> For more information on the PIP, see [who.int/initiatives/pandemic-influenza-preparedness-framework](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework).

<sup>3</sup> See [cbd.int/abs](https://www.cbd.int/abs).

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<sup>4</sup> Convention on Biological Diversity, art 2, “‘Genetic material’ means any material of plant, animal, microbial or other origin containing functional units of heredity. ‘Genetic resources’ means genetic material of actual or potential value.”

<sup>5</sup> *The Public Health Implications of Implementation of the Nagoya Protocol*, Report by the Director General, WHO Doc. EB/148/21 (Jan. 6, 2021), ¶¶ 33-35.

<sup>6</sup> The 2020 Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources established that the placeholder term ‘digital sequence information’ could broadly include DNA, RNA, proteins, epigenetic modifications, metabolites, and other macromolecules.

<sup>7</sup> See [insdc.org](https://www.insdc.org).

<sup>8</sup> See [gisaid.org](https://gisaid.org).

<sup>9</sup> See, e.g., Lucy van Dorp et al., *Emergence of Genomic Diversity and Recurrent Mutations in SARS-CoV-2*, 83 INFECTION, GENETICS AND EVOLUTION 104351 (2020).

<sup>10</sup> WHA Decision WHA72(13).

<sup>11</sup> See [who.int/initiatives/who-biohub](https://www.who.int/initiatives/who-biohub).

<sup>12</sup> CBD/WG2020/3/3, <https://www.cbd.int/conferences/post2020/wg2020-03/documents>.

<sup>13</sup> See Indicative Criteria for Specialized International Access and Benefit Sharing Instruments in the Context of Article 4, Paragraph 4, of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization, U.N. Doc. CBD/SBI/3/CRP.11 (May 30, 2021), <https://www.cbd.int/doc/c/004d/4de2/ee9e126ce821459844c45c3c/sbi-03-crp-11-en.pdf>.

<sup>14</sup> Global Multilateral Benefit-sharing Mechanism (Article 10 Of The Nagoya Protocol), U.N. Doc. CBD/SBI/3/CRP.12 (June 2, 2021), <https://www.cbd.int/doc/c/0115/f139/a03cdb0ace728a1fc12eca40/sbi-03-crp-12-en.pdf>.