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## **Sovereignty, sanctions, and data sharing under international law**

Pathogen samples and scientific data are bargaining chips in a global argument about who gets what in a pandemic

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In September 2021, after inaugurating the Berlin-based World Health Organization (WHO) Hub for Pandemic and Epidemic Intelligence, German Health Minister Jens Spahn indicated that sanctions might be an appropriate tool to deal with WHO member states that do not cooperate on data sharing during disease outbreaks. Tedros Adhanom Ghebreyesus, director general of the WHO, affirmed this, stating that “exploring the [idea of] sanctions may be important” in cases where collaboration fails (1). Such comments indicate that the WHO Hub has been designed without much consideration of data sovereignty and “access and benefit sharing” (ABS) debates occurring across multiple United Nations (UN) bodies, including the WHO. Threats of sanctions do little to promote the ideals of equity and solidarity often touted as foundational to global health governance. They entrench the idea that pathogen samples and associated data are “bargaining chips” rather than vital inputs to public health research and pandemic response.

## Access and Benefit Sharing

The informal sharing of scientific samples and associated data between researchers is largely over, due in part to developments in international law in the early 1990s that saw genetic resources change status from the common heritage of humankind (essentially public domain resources) to sovereign resources of the country of origin. Under the UN's 1992 Convention on Biological Diversity (CBD), states have sovereign rights over their genetic resources and can regulate access to them in accordance with their domestic laws and policies. Under the CBD and its associated Nagoya Protocol, the use of sovereign genetic resources requires the prior informed consent of the originating state. Then the provider and user must come to mutually agreed terms, which can include the sharing of benefits associated with the use of the genetic resources in research and development, but can also include conditions about sample collection, storage, and destruction, for example.

The ABS transactional mechanism was designed to generate benefits for countries providing samples so as to incentivize their conservation of biological diversity and the sustainable use of its components. At the very heart of ABS lie questions of power differentials between nations of the Global North and South, and the fair and equitable sharing of the benefits of scientific research and development. Unfortunately, despite laudable principles, ABS has in practice failed to generate the quantum of benefits required to make an impact on biodiversity conservation, as the world continues to deal with an unprecedented ecological crisis and species loss. Furthermore, every nation can implement ABS rules in their domestic laws, so the process of obtaining prior informed consent and coming to mutually agreed terms is different in every country and has resulted in onerous bureaucratic processes for scientists engaging in research on genetic resources from around the globe. Nevertheless, despite such challenges, the ABS concept now applies to other areas of international law, including global health security.

On the issue of pathogenic genetic resources, the ABS debate has largely centered around the WHO's Pandemic Influenza Preparedness (PIP) Framework (2011), a nonbinding instrument that asks WHO member states to share influenza virus samples of human pandemic potential with the WHO. The WHO can then provide those samples to pharmaceutical companies that use them to make influenza vaccines. The pharmaceutical companies are asked to share associated benefits (including vaccine doses) with the WHO for distribution to countries in need during an influenza pandemic. This is an example of the ABS transaction in action: sharing samples in exchange for vaccines, or other future benefits. Notably, the PIP Framework is not underpinned by the threat of

sanctions but rather was designed to place sample sharing on an “equal footing” with the sharing of benefits such as vaccines.

The PIP Framework applies only to influenza viruses with human pandemic potential, not seasonal influenza viruses. But the PIP Framework as a piece of WHO policy is built around the Global Influenza Surveillance and Response System: infrastructure that exists to constantly monitor seasonal influenza and update the virus strains used to develop a new seasonal influenza vaccine each year. The PIP Framework’s ability to generate and deliver pandemic influenza vaccine doses has not yet been tested in an actual influenza pandemic.

Furthermore, it has a substantial blind spot: genetic sequence data (GSD). The PIP Framework encourages (but does not require) the sharing of GSD on publicly accessible sequence repositories like GenBank. Increasingly, synthetic genetic resources, created using open-access GSD and sourced from commercial providers, are sufficient for some research and development that previously required physical virus samples. This approach might thus avoid the requirement to share the benefits associated with the use of physical virus samples sourced through the PIP Framework. Countries from the Global South that depend on the benefits promised through the PIP Framework for their national influenza pandemic preparedness plans are concerned that the increasing use of synthetic biology techniques will lead to the PIP Framework’s obsolescence, cutting them out of any benefit sharing and minimizing the incentives to share virus samples in the first place (2).

Similar discussions about the ability of synthetic biology to undercut the ABS transactional mechanism are taking place under the placeholder term “Digital Sequence Information” (DSI) at the CBD, the UN’s Food and Agriculture Organization (FAO), and in negotiations for the new international legally binding instrument under the UN Convention on the Law of the Seas (UNCLOS). The contention of some, particularly nations of the Global South, is that the use of DSI for research and development is equivalent to the use of physical genetic resources for the purposes of ABS. This potentially represents a major regulatory burden for nations of the Global North who have grown accustomed to open-access DSI. Negotiations to resolve this issue are ongoing, focusing on the CBD as the main international ABS convention covering most genetic resources, including pathogens.

This is the international legal context that was either missed or dismissed during the announcement of the new WHO Hub. Supported in part by the German Government, the WHO Hub will collate epidemiological, social, and environmental data from both formal and informal sources, analyze that

data for insights into disease detection and response strategies, and have a strong focus on global collaboration and data sharing (3). However, there was no discussion of benefit sharing at the WHO Hub's announcement. Although an accompanying strategy paper mentions benefit sharing, it was linked to sharing the benefits of data insights rather than more holistic notions of benefit sharing embraced by other UN institutions. Benefit sharing was instead presented in the strategy paper in the same sentence as the notion of participation, underlying the clear expectation that WHO member states would share their data "for the common good" (4) and seemingly, based upon the comments at the Hub's inauguration, if such lofty cosmopolitan ideals were ineffective, member states would share under threat of sanction.

## **Sanctions**

This is not the first time that the WHO has floated the idea of sanctions on nation states that fail to live up to their international public health obligations, including data sharing. The closest thing to an existing international legal obligation to share pathogen sequence data is found in the WHO's 2005 International Health Regulations (IHR). Member states are required to notify the WHO of all events within a state's territory that may constitute a public health emergency of international concern, together with provision of all relevant public health information. The term "public health information" has been interpreted by some to mean pathogen sequence data, but this is not specified in the IHR, and it clearly does not include pathogen samples.

In 2011, the Review Committee on the Functioning of the IHR during the 2009 H1N1 influenza pandemic lamented the "lack of enforceable sanctions" as the "most important structural shortcoming of the IHR" (5). Similarly, the report of the Ebola Interim Assessment Panel requested the IHR Review Committee to "examine options for sanctions for inappropriate and unjustified actions under the Regulations" (6). Although the subsequent IHR Review Committee on Ebola did not ultimately recommend a sanctions regime, more recently, in the midst of the COVID-19 pandemic, the Report of the Review Committee on the Functioning of the IHR during the COVID-19 response listed "sanctions for non-compliance" as part of the "[p]ossible contents of a future global convention on pandemic preparedness and response" (7).

In floating the idea of sanctions at the announcement of the WHO Hub, Minister Spahn stated that the WHO should look to the World Trade Organization (WTO), a non-UN agency, as an example of how the WHO could impose state sanctions. The WTO has 164 members, and its Dispute Settlement

Body can authorize trade sanctions—so-called suspension of concessions or other obligations—if a WTO member is found in breach of its multilateral trade obligations or has nullified or impaired the trading situation of another WTO member.

The problem with sanctions in the context of global public health is that the WHO is not a policing or enforcement body (8) and it is not, nor should it be anything like, the WTO. Indeed, using the WTO as a potential model for the imposition of sanctions within the global health arena represents a fundamental misunderstanding of how WTO sanctions work. The WTO as an institution does not itself have the authority or capacity to impose sanctions. It has “no enforcement power to speak of... [it] cannot force compliance; it cannot punish violators” (9). Rather, sanctions—or suspension of concessions or other obligations, to use WTO parlance—may only be instituted by an individual member of the WTO following a successful dispute before its dispute settlement system.

Although the WTO Dispute Settlement Body may grant the authorization, it is individual members that actually institute the sanctions. “Collective” sanctions are not permitted and because sanctions reduce trade and hence are economically harmful (in that they involve the erection of trade barriers to, in theory at least, “rebalance” trade relations between the disputing members), smaller countries have tended to avoid imposing them as they generally lack the economic capacity to retaliate. It is also of note that the WTO dispute settlement system is not at present functioning as intended, owing to the refusal by the United States to agree to the appointment of new members to the WTO’s Appellate Body, which hears appeals from first-instance WTO dispute settlement panels.

### **The Pandemic Treaty**

It is difficult, if not impossible, to see how the imposition of sanctions could effectively work in the global health arena, particularly a system modeled on the multilateral trade regime. It would require, at the bare minimum, an adversarial system of dispute settlement to be introduced, with compliance tied to specific legal obligations that do not yet exist. Perhaps such obligatory norms might be introduced through a Pandemic Treaty, first touted by the European Union (EU) Council President Charles Michel in November 2020 at the Paris Peace Forum. The idea for a Pandemic Treaty gained further support from a range of actors, including the public endorsement by 26 world leaders and Tedros, with the current tools for pandemic preparedness noted as being insufficient to such a degree that “a treaty is the best thing that we can do that can bring the political commitment of member states” (10). On 1 December 2021, a special session of the World Health Assembly, the decision-

making body of the WHO, adopted a consensus decision to start the negotiation process for a “convention, agreement, or other international instrument” on pandemic prevention, preparedness, and response (11).

There are legitimate concerns that the proposed pandemic instrument merely represents another example of rich nations imposing their will on the poorest nations, including by disregarding their sovereign rights over pathogens and associated data. Indeed, the limited substantive content available has focused mainly on the sharing of data and samples, health system strengthening, and One Health (integration of human, animal, and environmental health), with only limited reference to concerns regarding vaccine nationalism, and equitable access to vaccines (12). The fact that the pandemic instrument is being proposed by the very nations that engaged so proactively in rampant vaccine nationalism during COVID-19 raises questions about the extent to which these nations are actually willing to solve problems in equitable access to vaccine through a pandemic instrument, particularly when the current situation works so well for these wealthy states (13).

To bolster this concern, the WHO has not only proposed the pandemic instrument and inaugurated the WHO Hub in Berlin that is focused on information sharing, but also launched a new (and separate) “WHO BioHub Facility” focused on pathogen sample sharing. Announced in May 2021 by the Swiss Confederation and the WHO, the WHO BioHub Facility is based in Spiez, Switzerland, and is intended as an “international exchange system for [samples of] SARS-CoV-2 and other emerging pathogens” (14). These initiatives have been announced in quick succession and without much by way of member state consultation.

Through initiatives such as the Hub in Germany, the BioHub in Switzerland, and wider initiatives at the WHO, there is a growing sense that rich countries are building a global pandemic infrastructure that prioritizes their access to information and samples over developing nations’ access to vaccines and other countermeasures. These initiatives not only bypass formal modes of governance within the WHO but also result in the further “decentraliz[ation]” of the WHO, all “paid by and in favour of rich countries” [comments by M. Voss in (15)]. In addition, the comments from Tedros and Minister Spahn imply that what are at present voluntary initiatives in respect of information and pathogen sharing might not stay voluntary for long.

Clearly, the introduction of an international legal obligation—backed by sanctions—to share pathogen samples and associated sequence data would change the legal and normative underpinnings of global health research and governance, but for whose benefit? Such a model would see sanctions

for those nations that do not share their samples and data, but would there be sanctions for countries that fail to share associated benefits such as vaccines and other medical countermeasures during a pandemic? And if so, would the ability to sanction be out of reach for smaller countries, as it often is at the WTO, given the limited capacity of smaller economies to retaliate? Even if the WHO were capable of imposing sanctions, private entities like pharmaceutical companies would be out of their jurisdictional reach. The WHO would only be able to rule to sanction member states. And how would a punitive system secure the much-needed trust required to make global health governance function? Can solidarity and equity, mentioned countless times in discussions on the Pandemic Treaty, be achieved by a one-sided system that seemingly privileges concerns of richer countries?

International sharing of pathogen samples and scientific data is essential to epidemic and pandemic response, but the adoption of ABS terms for the sharing of pandemic influenza samples through the WHO's PIP Framework in 2011 cemented the legal status of pathogens as resources that poorer countries can trade for much needed medical countermeasures. The ABS transaction, previously embraced by the WHO, cannot now be ignored by deciding that pathogen samples and GSD or DSI should be shared by nations out of some lofty commitment to the common good, while the benefits generated from research and development on those very resources remain private goods to be sold to the highest bidders (13).

Countries that have been denied adequate access to COVID-19 vaccines during this pandemic are highly unlikely to give up one of their few bargaining chips and agree to share pathogen samples and associated data without some meaningful guarantees that they will receive vaccines and other benefits in return during the next pandemic, as per their rights under the CBD and Nagoya Protocol. The threat of sanctions is only going to entrench this transactional attitude further. If rich countries want samples and data from developing nations, they need to start treating those nations as equals—partners in a joint scientific endeavor. And that means not leaving them to fend for themselves while the developed world sets up its own early warning system, complete with sanctions to threaten and punish the noncompliant poor.



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