Policy Opportunities to Enhance Sharing for Pandemic Research
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COVID-19 reveals gaps in international law that can inhibit timely sharing of information, samples, and sequences

The coronavirus disease 2019 (COVID-19) pandemic has demonstrated the critical importance and persistent challenges of rapidly sharing public health and scientific information, biological samples, and genetic sequence data (GSD). Sharing these resources is crucial to characterizing the causative agent, understanding its spread, and developing diagnostics, antiviral treatments, and vaccines. But even though these resources are critical for the global health community, there is currently no legal obligation for countries to share physical pathogen samples or associated GSD. To date, researchers have often shared such resources in a spirit of scientific openness. Yet ongoing scientific cooperation has been insufficient (1) despite the scale of the pandemic threat. The lack of a clear legal obligation to share pathogens or associated GSD during a health emergency represents a blind spot in international law and governance, impeding pandemic response and scientific progress. We examine the sharing of public health information, biological samples, and GSD in the still early days of the COVID-19 pandemic, identify barriers to sharing under the current international legal system, and propose legal and policy reforms needed to enhance international scientific cooperation.

On 10 January, scientists in China publicly uploaded the first genetic sequence of severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2) (2). Two days later, China officially shared the viral GSD with the World Health Organization (WHO) (3). The WHO praised China for sharing GSD less than 2 weeks after the first case cluster was reported on 31 December 2019 (3). The early availability of GSD enabled laboratories around the world to rapidly begin developing diagnostic test kits and launching research into antiviral medications and vaccines.

Since that time, thousands of SARS-CoV-2 sequences from around the globe have been uploaded to online databases such as GenBank and the Global Initiative on the Sharing of All Influenza Data (GISAID). These genetic sequences have helped to track the spread of SARS-CoV-2, determine which containment strategies have been successful, and monitor the emergence of adaptive mutations in the viral genome (1). Physical samples of SARS-CoV-2 were, however, unavailable until researchers in Australia isolated the virus from a traveler from Wuhan on 29 January and sent the isolate to the WHO and other laboratories (4).
A Global Governance Patchwork

The WHO's International Health Regulations (IHR, 2005) require all 196 States Parties to notify the WHO within 24 hours of all relevant “public health information” on any event that may constitute a Public Health Emergency of International Concern (PHEIC). The reporting obligation includes case definitions, diagnostic results, risk assessments, and case fatality data, as well as information on containment and mitigation measures. Countries could broadly interpret “public health information” to include GSD; however, WHO policy does not classify GSD as health information under the IHR, and States Parties do not appear to interpret “public health information” to include GSD (5). Furthermore, physical pathogen samples are not regarded as “health information” that must be shared with the WHO.

The main international instruments governing access to human pathogens were primarily designed not for public health, but to prevent the exploitation of biodiverse countries' genetic resources, ensuring that the benefits of research and development are equitably shared. The United Nations Convention on Biological Diversity (CBD, 1992) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (NP, 2012) recognize Parties' sovereignty over genetic resources within their borders. The CBD defines “genetic resources” as “genetic material of actual or potential value.” Genetic material is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.” These broad definitions are generally accepted to capture pathogens, including human viruses such as SARS-CoV-2 (6). However, the definitional focus on “material” suggests that Parties could interpret the CBD and NP to exclude the associated pathogen GSD.

These legally binding agreements allow countries to enact laws regulating access to their genetic resources and obtain a share of the benefits associated with their use (“access and benefit sharing” or ABS). The CBD and NP state that access to genetic resources should occur with the country of origin's prior informed consent and that such access should be on mutually agreed terms. Mutually agreed terms can include benefit sharing, such as recognition in publications, capacity building, training, intellectual property, and royalties. The CBD and NP default to a bilateral contractual arrangement between the provider party and the user party, negotiated on a case-by-case basis. In practice, the parties often negotiate a material transfer agreement (a contract governing the transfer of research materials), unless a specialized ABS instrument such as a multilateral agreement or framework exists for a specific category of genetic resources.
Although equity and fairness are common goals, the CBD and NP objectives are not necessarily aligned with the WHO’s mission, especially during health emergencies where access to pathogen samples from multiple countries and for multiple users is time-sensitive. In these situations, negotiating a separate ABS agreement for each sample would result in high transaction costs and unacceptable delays. In December 2006, Indonesia refused to share H5N1 influenza virus samples with the WHO, claiming sovereign authority over these samples. Invoking the CBD, Indonesia argued for fairer distribution of vaccines and antivirals during influenza pandemics (7). In response, WHO Member States adopted the Pandemic Influenza Preparedness Framework (PIP Framework, 2011), a multilateral instrument that regulates access to influenza viruses with human pandemic potential and shares the benefits associated with their use, including diagnostics, vaccines, and antivirals. The PIP Framework was adopted as a nonbinding resolution, but provider and user parties agree to ABS terms through the use of standard material transfer agreements among provider nations, the WHO, and pharmaceutical companies and other users. The adoption of the PIP Framework meant that the ABS transaction cemented its place in global public health governance. Rather than treating these as separate issues, the PIP Framework has now linked access to pathogen samples to the reciprocal sharing of vital medicines and vaccines. Like the CBD and NP, the PIP Framework focuses on the sharing of physical samples. During negotiation of the PIP Framework, Member States specifically deferred consideration of GSD, and they have yet to reach consensus on how, if at all, GSD should interact with the Framework.

The PIP Framework and NP were negotiated concurrently by separate UN bodies—the World Health Assembly and the CBD’s Conference of the Parties, respectively—but each influenced the other. The PIP Framework recognizes “the sovereign right of States over their biological resources,” using language influenced by the CBD. Despite contested negotiations, the NP did not explicitly address whether pathogens should be included within its scope, leaving it to countries to make future determinations. It did, however, include a special provision on “expeditious” ABS during “present or imminent emergencies that threaten or damage human, animal or plant health.” The NP Parties can determine whether and how to implement this special consideration in domestic legislation, such as delaying ABS documentation requirements during a PHEIC.

The WHO declared COVID-19 a PHEIC on 30 January. As a PHEIC, and potential PHEIC prior to the declaration, the IHR governs the sharing of public health information. Yet physical samples of SARS-CoV-2 would be regulated by domestic ABS laws implemented under the CBD and NP. The PIP Framework is not directly relevant because it applies only to influenza viruses with human pandemic potential. All this creates a complicated and confusing global patchwork of pathogen ABS
laws. Global governance is further complicated because the extent to which any of these legal instruments apply to GSD is unclear.

**Samples Without Samples: Dematerialization and Rematerialization of Pathogens**

With the rapid improvement and decreasing costs of DNA synthesis, the international scientific and ABS communities must find solutions to governing GSD, recognizing that extant ABS policies focus on physical genetic materials (8). This is especially pertinent for viruses that are relatively easy to synthesize from GSD. Researchers could decide to circumvent existing ABS rules by synthesizing a virus, thus avoiding benefit-sharing obligations and undermining global efforts to more equitably distribute the benefits of research and development.

In 2017, a Canadian research team synthesized the horsepox virus using GSD that was openly accessible on GenBank (9). The team could have accessed a physical sample of horsepox virus from the U.S. Centers for Disease Control and Prevention, but this would have required signing a material transfer agreement, with potential limits on commercializing future products. There is evidence that the Canadian team decided to synthesize the virus to avoid these legal obligations (10). The synthesis of viruses demonstrates how openly accessible GSD creates a major gap in global ABS governance.

On 21 February, a Swiss lab announced that it had synthesized the SARS-CoV-2 genome from synthetic DNA constructs ordered on 14 January using publicly available GSD. In their preprint published on the bioRxiv server, the research team detailed the synthesis of multiple RNA viruses, including SARS-CoV-2, using their yeast-based reverse genetics platform (11). The team reported difficulties in creating two of the 14 synthetic DNA fragments to synthesize SARS-CoV-2, requiring a physical virus sample isolated from a COVID-19 patient in Germany in order to recover infectious virus particles (11). Even though the first SARS-CoV-2 genetic sequence was shared early, it is clear that these developments in synthetic biology could make governments reluctant to share GSD on openly accessible databases if it means they could miss out on benefits that might otherwise be gained by enforcing their domestic ABS laws. Any delay in sharing pathogen GSD during a potential PHEIC could be catastrophic.
Proposed Legal Obligations

There is currently no international legal instrument that can compel countries to share either physical pathogen samples or GSD during a public health emergency. The recognition of sovereignty in the CBD and NP, affirmed by the PIP Framework, means that countries determine how viruses isolated in their country are shared. At present, scientific courtesy and norms drive continued sharing, but without a legal obligation to share, it is difficult to induce formal sharing or sanction those countries that choose not to. It must also be remembered that in a health emergency, limiting access to these resources on the basis of state sovereignty may be one of the few points of leverage available to developing countries hoping to negotiate fair and equitable access to benefits from research and development, such as diagnostics, treatments, and vaccines. As the situation stands, inconsistent and often conflicting legal regimes are creating confusion about countries' rights and obligations surrounding sample and GSD sharing, potentially impeding pandemic preparedness and response [e.g., (12)].

The legal uncertainty surrounding who has the authority to grant access to samples and GSD, who can use those resources, and on what terms, caused access problems during the 2012 Middle East respiratory syndrome–coronavirus (MERS-CoV), 2014–2016 West African Ebola virus disease (EVD), and 2016 Zika virus outbreaks (13). If countries limit access to physical pathogen samples, they would be acting within their sovereign rights under the CBD and NP, but they would breach scientific norms and international expectations. Moreover, if countries withhold pathogen GSD, the international community has no legal tool to encourage compliance—only traditional diplomatic and economic protocols such as that of the media pressure on India after its perceived delay in posting SARS-CoV-2 sequences online (14).

In an emergency on the scale of the COVID-19 pandemic, the usual social, political, and economic systems start to fray. International scientific cooperation is increasingly imperiled when countries prioritize their own interests, contrary to the international cooperation and openness that responding to the pandemic requires. The sharing of information, samples, and GSD in the COVID-19 pandemic has been inconsistent and highlights the urgent need to address gaps in international law and governance. International adherence to vital scientific norms is not assured in this or future outbreaks.

The international community must therefore start to consider how best to close this gap, and through which international forum(s). One option is for Parties to the CBD and NP to adopt a decision expanding the scope of these agreements to include GSD, thereby recognizing the potential to extract tangible benefits from GSD alone, and ensuring that some of those benefits flow back to the country
of origin. However, applying the same inefficient ABS regime that is currently applicable to physical
genetic resources (8) could simply slow the rapid sharing of GSD during a public health emergency,
and would therefore require Parties to commit to adopting domestic legislation that expressly considers
the NP's special provision on the need for “expeditious” ABS during health emergencies. Given that
this provision is couched in the same vague language as the rest of the NP, and that countries have
been slow to implement such measures, we remain skeptical about its effectiveness during a health
emergency. Furthermore, dealing with pathogen GSD through the CBD/NP forum would place this
issue primarily in the hands of domestic environmental ministries rather than public health
departments.

We feel that as the primary normative, technical, and legal body for global health, the World Health
Assembly is the logical venue for negotiating a comprehensive policy for international pathogen
sample and GSD sharing during public health emergencies. The WHO could design a pathogen-
specific specialized ABS instrument in harmony with the NP, with the WHO coordinating multilateral
access to pathogen samples and GSD from Member States and the distribution of benefits from
governments, pharmaceutical companies, and other users of those resources. The PIP Framework
could serve as a guide for determining how this might work, with the recognition that the PIP
Framework relies heavily on existing virus-sharing infrastructure for its implementation and that the
full range of benefit-sharing provisions remains untested. Any such pathogen-specific ABS instrument
should explicitly encompass both biological material and GSD sharing for all novel pathogens.
Although WHO Member States might be able to harness the momentum created by the COVID-19
pandemic to negotiate a specialized ABS instrument, they may not get support from non-state actors
(e.g., pharmaceutical companies) for anything other than a nonbinding resolution. The WHO has
already seen a decline in sample sharing through the PIP Framework, and there are no direct legal
ramifications for countries that do not share influenza samples with the WHO (13). This option
therefore lacks the legal and normative power of the IHR.

For these reasons, our preferred option would be for pathogen sharing to be reinforced by the IHR.
Procedurally, WHO Member States have been hesitant to reopen the IHR for negotiation. However, in
light of the COVID-19 pandemic, WHO Member States could take the opportunity to establish an IHR
Review Conference (15) to discuss how the IHR has been used during this pandemic, issue interpretive
guidance to inform WHO and Member States' actions in the lead up to and during the next PHEIC,
and rapidly consider pathogen sample and GSD sharing issues. This would provide an opportunity to
discuss the suitability of a specialized ABS instrument connected to the IHR, tailored to sharing
pathogens and GSD during potential and actual PHEICs. The text of the IHR need not be rewritten for
Member States to negotiate its implementation and come to understandings on aspects of the IHR and its operation, such as the PHEIC declaration process and the potential inclusion of GSD as “public health information” that is to be shared with the WHO during a potential or declared PHEIC.

Whatever path is chosen, WHO Member States and CBD (and NP) Parties could mobilize to advance international scientific cooperation, and there are multiple ways to foster trust and better collaborative relationships between providers and users of pathogen samples and GSD. The ABS transactional mechanism that reinforces state sovereignty over these resources and calls for prior informed consent and mutually agreed terms is not conducive to dealing with a PHEIC. We acknowledge that ABS, as a policy option for dealing with issues of equity and fairness in science and technology, has become entrenched in the United Nations’ policy space (8), so any reformed governance systems for ABS would therefore need to advance data sharing and global health equity while promoting badly needed consistency in the ABS regimes of the CBD, NP, and PIP Framework. The COVID-19 situation has demonstrated positive examples of rapid sharing, but it has also highlighted the reality that countries may not readily relinquish their sovereignty over pathogenic genetic resources and associated GSD. We must ensure that there is an adequate legal framework in place that engenders mutual trust and equitable scientific collaboration and makes these critical resources available for rapid research and development into much-needed diagnostics, vaccines, and treatments.
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