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Questions swirl about proposed WHO pathogen collection

Effort to "shortcut" the Nagoya Protocol raises fairness and equity and other issues

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In a brief announcement on 4 December 2020, World Health Organization (WHO) Director-General Dr. Tedros Adhanom Ghebreyesus revealed that WHO plans to create a new collection of viruses and other biological samples related to diseases outbreaks. Tedros noted that the initiative is supported by Switzerland, which has offered a biosafety level 4 (BSL-4) laboratory located in Geneva to physically host the collection.

Tedros' announcement came as a surprise to many health policy observers, as the move appears to pre-empt the discussion that WHO Member States plan on access and benefit sharing for pathogen samples to take place soon, at the WHO Executive Board on 18-26 January 2021 and the seventy-fourth World Health Assembly in May.

Details Unavailable

Late in December WHO reaffirmed its plan to create the collection, which it calls a "biobank". A 24 December WHO press release on "issues to track in 2021" states that "*We also plan to establish a Bio Bank – a globally agreed system for sharing pathogen materials and clinical samples to facilitate the rapid development of safe and effective vaccines and medicines.*"

No one would object to the rapid development of safe and effective treatments, but the biobank raises important policy questions about fairness and equity, and access to medicines, diagnostics and treatments. Will countries that deposit samples in this Swiss-located biobank have their interest in affordable medicines protected? Or will their deposits be passed on to private companies – vaccine, therapeutic, and diagnostic makers – without benefit sharing obligations? Such a bank would serve the interests of borrowers rather than depositors, and exacerbate the extreme inequities in access to medicine that have been laid bare by the COVID-19 pandemic.

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Also unexplained is why WHO is using the term "globally agreed" to describe the biobank when its Member States have yet to endorse the process or have any input into its creation. Who is developing the biobank's rules and procedures? How will the biobank protect the sovereign rights of its depositors? And how will it ensure consistency with the Nagoya Protocol on Access and Benefit Sharing, the global agreement which requires fair and equitable benefit sharing for use of genetic resources, including viruses, which the majority of WHO Member States have ratified?

The questions are many, but Director-General Tedros has not made any further public comment. Other WHO officials have declined to elaborate on the biobank, leaving WHO Member States and health policy experts guessing about what comes next.

Comments of one WHO official

One exception to WHO's silence is Dr. Mark Perkins, the WHO Lead for Laboratory Networks, who described the motivations behind the biobank in an online meeting organized by the Colorado School of Public Health (US) on 10 December. According to Perkins' statement, the biobank idea is "*to develop a specimen repository that could, early in outbreaks, receive things and send them on for research activities, support research activities, to identify the cause, the pathogen, etcetera, in a way that would facilitate exchange of information and not create complex legal situations.*"

Perkins didn't explain why existing networks cannot handle this task and a new repository is required. Perkins also did not draw any distinction between public health use and exploitation of the materials for the development of proprietary commercial products, leaving an unclear scope of "research activities" that the biobank is intended to support.

Perkins' reference to "complex legal situations" was initially unexplained, but he subsequently linked them to the Nagoya Protocol, stating that "*it is recognized that if we go down the Nagoya Protocol road, there is likely to be hesitation in sharing until there's confirmation in writing of what the benefits would be."* Perkins then implied that the Nagoya Protocol has been responsible for "*year long discussions*" on benefit sharing for pathogens, though he did not identify any specific cases.

Perkins linked the proposed biobank proposal to issues surrounding access to SARS-CoV-2 samples at the beginning of the present pandemic. While conceding that access to viruses has not been problematic since the pandemic took root, he said that at the outset of the outbreak "*There was a request that went out to countries to propose to share their specimens, their viruses early on, and many didn't want to do so*." He did not specify when this request was made, to what countries it was sent, nor which countries allegedly "didn't want" to cooperate.

Perkins' comments did not acknowledge that Member States are not under any obligation to share viruses, nor did he express sensitivity to the idea that countries may use their sovereign rights to genetic resources, including pathogens, to request fair and equitable sharing of benefits. In the context of pathogens, this likely means access to affordable medicines, diagnostics and treatments.

Rather, Perkins set WHO's intent apart from that of the Nagoya Protocol, and said that WHO's wants to "shortcut" benefit sharing discussions. According to Perkins, "*we're trying to shortcut that … and we're now in the process of developing the rules for governance, etcetera.*" By "we" Perkins, who formerly was a senior figure at a diagnostics manufacturers trade association, appeared to be referring to an internal WHO staff group. He did not reply to a request for clarification.

Sovereignty: Relationship with the Nagoya Protocol

Few if any persons involved in health policy object to systems designed to facilitate rapid transfer of pathogens for public health purposes, particularly potentially pandemic pathogens. Yet, at the same time, the single greatest global challenge in public health is to address the huge disparities between wealthy and poorer

countries in their citizens' access to vaccines, therapeutics, and diagnostics. This disparity has played out in the disproportionately high human price many developing countries have paid with diseases including AIDS, hepatitis and, presently, COVID-19.

The Nagoya Protocol is designed to ensure that benefit sharing takes place, especially when biodiversity - including pathogens – is used commercially. Thus, application of the Nagoya Protocol to systems for the collection and use of pathogens is a potentially important way to improve fairness and equity in access to medicines.

The difficulty with WHO's biobank planning, as described by Perkins, is that WHO, or some of its leadership, appear to believe that requests for benefit sharing for pathogens are a problem that needs to be squelched, rather than an expression of the sovereign rights of WHO Member States that is intended to help resolve inequities in access to medicines.

The public health benefits of implementing the Nagoya Protocol have been made very clear by the successful WHO Pandemic Influenza Preparedness Framework (PIP Framework), which has raised US$200 million for public health, and which has obtained commitments to access to treatments for developing countries in the event of a new influenza pandemic. The PIP Framework was developed at the same time as the Nagoya Protocol, and embraces the Protocol's concepts, and operates in a manner that is consistent with it.

Complaints about the Nagoya Protocol such as Perkins' have become commonplace among representatives of the pharmaceutical industry, but these accusations are almost never backed up with verifiable details. For example, the vaccine industry has advanced such allegations about seasonal influenza viruses, but WHO research did not especially support those claims. WHO instead found that most laboratories were not affected by problems accessing viruses and that for the minority of laboratories that did have trouble, access and benefit sharing agreements were only one among several causes of delay. Other causes identified by WHO's draft report include phytosanitary laws, national security laws, data protection laws, and others.[1]

It should also be again noted that WHO Member States are within their rights to decide to postpone sharing pathogens, and may be more inclined to do so if no benefit sharing agreement exists. Indeed, in a world of health inequities, what is wrong with a Member State saying that it would be happy to share pathogen samples, but would like to do so based an agreement that, for example, provides for reduced cost of any resulting medicines in return?

As the PIP Framework and efforts outside of health have shown, the development of standard material transfer terms enables the rapid transfer of pathogens (and other materials) within a fair and equitable benefit sharing structure. What the COVID-19 pandemic, among other recent outbreaks, has shown is the importance that standard terms comply with the Nagoya Protocol and be hammered out in advance, so that countries can quickly reach for standard, and fair and equitable, agreements when speed is of the essence for public health.

Governance

There are obviously many difficult and delicate issues among the procedures under which the proposed WHO biobank would operate. These are presently being developed by WHO staff behind closed doors. And though no request for the creation of a biobank has been made by the World Health Assembly (WHA), pertinent issues are to be discussed by the Executive Board in January 2021 and the WHA later in the year (under the agenda item on the Nagoya Protocol).

[1] WHO 2020. Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (DRAFT). February.

Clearly, since shipments of pathogens and the sharing of benefits derived from them is a matter that invokes the sovereign interest of WHO Member States, the development of any WHO biobank (if Member States agree the effort should be undertaken) would be better led by Member States themselves in a process under their control.

Top among the issues to be considered in relation to any WHO biobank is defining specific benefit sharing obligations and making them enforceable. Before any samples are placed in the biobank, depositors would need assurance that the bank is able and willing to provide benefits to depositors and, if necessary, to stop borrowers from evading their obligations. And those obligations will necessarily include rules related to digital sequence information – gene and other sequences – and rules about subsequent recipients who obtain biobank materials or sequence information secondhand. This means WHO must be able to legally enforce the rules and collect damages if a biobank user that is a "borrower", such as a vaccine company, fails to comply with its obligations.

Member States that are depositors, particularly developing countries whose samples are in demand from industry, need to consider and define what constitutes fair and equitable benefit sharing for their samples, and this is clearly another activity suited for Member States themselves rather than a WHO staff group.

Export Controls

The "complex legal situations" surrounding pathogens and an international biobank are not limited to access and benefit sharing issues. Unavoidably on the table for any international biobank are issues related to export controls, the national security laws that some countries use to impede rivals' access to pathogens that, it is claimed, might be used as weapons. Export controls are a long standing problem in transfers of potentially pandemic viruses between some countries, and for any WHO biobank to treat each Member State equally, a solution to the barriers created by these laws would be required.

Director-General Tedros has remarked that the Swiss Health Minister has offered use of a BSL-4 laboratory in Geneva to host the biobank. There is only one such laboratory known in Geneva, that of the Geneva University Hospitals,[2] which is operated in cooperation with virologists at the University of Geneva. The biobank would thus apparently be housed at a Swiss public institution.

While Switzerland is famed for its neutrality, it does not avoid all security cooperation. Since 1987, it has been a member of the Australia Group, a self-selected collection of mainly European and North American countries[3] that cooperatively develop rules designed to prevent transfer of biological materials (among other security-related items) to other countries that they deem to be a security threat. And some Australia Group members, such as the United States, impose export controls above and beyond the common approach of the Group. Many potentially pandemic viruses appear on the Australia Group's biological "common control list", and group members including Switzerland are expected to implement rules to prevent transfer of such viruses to a number of WHO Member States.

Presumably, if WHO established a biobank, samples from that biobank would need to be made available to authorized laboratories of any Member State, in keeping with the principles of WHO's establishment and operation. Yet doing so would potentially lead Switzerland to violate commitments to partners in the Australia Group and, perhaps even more importantly, the WHO biobank would be impaired as a centralized global resource because national security laws, especially in Australia Group countries, may prevent many Member States – mostly developed countries – from depositing materials in the WHO biobank. That's because they could not do so without WHO and/or Switzerland's commitment not to further transfer the materials to certain destinations. These destinations often include large and populous countries with domestic pharmaceutical industries.

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2 https://www.hug.ch/laboratoire-virologie/centre-national-reference-pour-infections-virales

3 Plus Japan, South Korea, Argentina, India, Turkey, and, of course, Australia itself. See: https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/index.html

Thus, the possibility exists that some Australia Group member states may obtain materials from a WHO biobank, and demand that all countries send pathogen samples to the biobank, even as they refuse to send samples themselves, or place restrictions on the distribution of samples, citing their own domestic law.

It is thus reasonable to be concerned that the WHO biobank would be used by many developed countries as a means by which to source other countries' genetic resources through a questionable use of the auspices of WHO while, at the same time, not fully participate in the global effort themselves due to their export control policies and laws.

Conclusion

With so many difficult and unanswered questions, it is hard to know if the WHO Director-General's proposed biobank will actually come into existence. It can be hoped that further information on WHO's activities will quickly come available, and that if the biobank is to proceed, that Member States will become involved.

The comments of WHO's Lead of Laboratory Networks on the impetus behind the biobank raise concern that WHO is moving in the wrong direction by seeking to evade ("shortcut"), rather than embrace, the legally binding Nagoya Protocol, an agreement that most of WHO's Members have ratified.

Further, it is clear that the development of the biobank's rules is taking place in the wrong environment, since the effort has strong national sovereignty implications for Member States, veritably demanding that any such biobank be developed not by an internal WHO team, but rather by an intergovernmental process aimed to ensure fair and equitable benefit sharing.

Everyone earnestly involved in global public health would like to see rapid transfer of potentially pandemic pathogens as well as fair and equitable access to the vaccines, therapeutics, and diagnostics that result from the use of those pathogens. Implementing the Nagoya Protocol through standardized terms and conditions for the exchange of pathogens, and their sequence information, would be a step forward for fairness and equity and access to medicines.

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