

Third World Network

Comments on the WHO Director-General's report on "The public health implications of implementation of the Nagoya Protocol" (EB 148/21)

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This short paper contains comments of Third World Network (TWN) on the report prepared by the World Health Organization (WHO) Director-General on the public health implications of implementation of the Nagoya Protocol, Agenda Item 14.4 for the 148th WHO Executive Board Meeting, beginning on 18 January 2021. The Executive Board is expected to adopt a recommendation on the item to the World Health Assembly, whose meeting is to begin in May.

These comments follow the organization of the Director-General's paper. In the interest of brevity, not every point of the WHO report is herein considered. This paper provides general comments and, where appropriate, specific observations on items in the WHO report.

Content

Opening Matters

Pages 1-2 of EB 148/21

Survey Results

- A. Current arrangements**
Pages 3-5 of EB 148/21
- B. Outcomes and implications**
Pages 6-7 of EB 148/21

Influenza virus sharing (WHA 72(12))

Page 8 of EB 148/21

Pathogen Access in the COVID-19 Context

Pages 9-10 of EB 148/21

Executive Board Action

Page 11 of EB 148/21

Opening Matters

Pages one and two of the DG's report introduce the topic of the public health implications of the Nagoya Protocol on Access and Benefit Sharing. Unfortunately, there are three foundational elements that are pivotal to a well-grounded discussion of this topic that are absent or inadequately reflected in this introductory section of the WHO paper. These are:

1. The relationship between the Nagoya Protocol and its parent agreement, the Convention on Biological Diversity (CBD) and, in turn, WHO Member States

Fundamental to discussing the Nagoya Protocol and its relationship to public health is recognizing the Protocol's relationship to the CBD and, in turn, how the membership of these two agreements overlaps with that of WHO.

The Nagoya Protocol is a supplementary agreement to the CBD. It was negotiated and adopted in 2011 at the prompting of many developing countries that sought to make fair and equitable benefit sharing, one of the CBD's three objectives, a more concrete reality.

Since the Nagoya Protocol merely "add meat to the bones" of the CBD, it is important to remember that the core principles and the essential obligation to share benefits arising from use of pathogens and other biodiversity apply not only to countries that have ratified the Nagoya Protocol (128 Parties, or 65% of WHO Member States),¹ but also all CBD Parties (196), who are slightly more numerous than WHO Member States (194).²

The key point is that nearly all WHO Member States are committed by a legally-binding treaty to fair and equitable benefit sharing for use of pathogens by virtue of the CBD, and two thirds of WHO Member States have to date undertaken the more specific obligations of the Nagoya Protocol. This means that ensuring fair and equitable benefit sharing is an obligation and objective of nearly all WHO Member States.

2. National sovereignty over genetic resources, including pathogens, is the law

WHO documents, including this report, have recently lamented alleged cases of so-called "delays" in sharing of pathogens, but these complaints should not overshadow the unequivocal fact that WHO Member States are under no obligation to share pathogens.

The CBD and Nagoya Protocol have enshrined national sovereignty over genetic resources in international law, and the important implications of this need to be squarely acknowledged at the outset of any discussion on pathogen sharing. WHO Member States may decide themselves if, how, and when to share pathogens (and their genetic sequences).³

¹ Turkmenistan's ratification of the CBD takes effect on 2 February, which will bring the number of Nagoya Parties to 129, or fully two thirds (66%) of the number of WHO Member States.

² The United States is the only large country that is a Member State of WHO but has not ratified CBD.

³ It should be further noted that the International Health Regulation (IHR) does not require sharing of pathogens or sequence information. The IHR further expressly states in its Article 57 (para 1) that "*The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.*"

By not clearly delineating this fact, the WHO paper fails to clearly reflect the legal rights of Member States, even as it berates some of them for alleged “delays”. In fact, any WHO Member State would be acting within its sovereign right to postpone sharing of pathogen samples, for example, for the purposes of securing benefit sharing.

The key observation is that countries are sovereign over their genetic resources, and while reliable systems to share pathogens are often in the interest of all, countries are within their rights to condition sharing on recipients making commitments for benefit sharing, as they have under the Pandemic Influenza Preparedness Framework (PIP Framework, see below).

3. The Nagoya Protocol has created demonstrable public health benefits in WHO’s work

The purpose of the report is to illuminate the public health implications of the Nagoya Protocol, but it oddly does not highlight WHO’s work on the PIP Framework, which concretely demonstrates benefits of the Nagoya Protocol’s principles for public health through the Framework’s access and benefit sharing rules for potentially pandemic influenza strains. Yet, inexplicably, this highly relevant experience is entirely omitted from the introduction of the DG’s report, and almost altogether ignored in the remainder. It is as if WHO intends self-harm by ignoring its own successes.

Through the PIP Framework, WHO has raised US \$200 million in industry payments to support WHO programs for public health and pandemic preparedness, and secured important other benefits in the event of a new influenza pandemic, while sharing of potentially pandemic influenza viruses has improved.

Prominently citing the positive experience of the PIP Framework is an obviously important and germane starting point for the present discussion about additional pathogens, yet the report does not do so, potentially leaving Member States and their delegates who are less familiar with the PIP Framework in a state of ignorance.

Survey Results

The DG’s report initially notes the significant limitations on drawing conclusions from WHO’s “all-stakeholder survey”, which had a disappointingly small number of full respondents (118). These limitations are described and noted by WHO in paragraphs 9 and 10 of the report, and they cast substantial doubt on conclusions presented in entire remainder of the paper, which are paradoxically often based on assertions based on the survey results.

Further in relation to the limited sample, the report does not indicate the breakdown of the kinds of “all stakeholders” that did complete the survey except to note later that only 21 of the 118 were Member States, or less than one in five (17.8%) of the respondents. The North/South balance of the respondents is not noted, and it is unclear what proportion of the non-state respondents are companies, WHO-affiliated laboratories, civil society organizations, academics, or others. This unhelpful lack of data about the survey respondents makes it impossible to know clearly whose opinions are being summarized and presented in the bulk of the report, which further signals the need for caution in drawing conclusions.

It is further worth considering how, in so small a sample size, the balance of types of respondents might have changed the outcomes and impacted the overall appropriateness and validity of responses. It is clear, for instance, that the perspective and interests of a government ministry with respect to pathogen access and benefit sharing might be quite different than that of a company or a database operator.

For instance, asked to cite an instance of benefit sharing, a company might allege that selling vaccines is “benefit sharing” (e.g. in paragraph 19), whereas a government ministry, particularly in a developing country, would be very unlikely to describe the commercial vaccine market, which has failed in the case of the current COVID-19 pandemic, as “benefit sharing” in the sense of the Nagoya Protocol. And in the end, what constitutes appropriate benefit sharing for pathogens is a matter for governments to decide in their sovereign right.

Paragraphs on page 3 and 4 tell the reader what she is likely to already know - that pathogens are shared among laboratories in a variety of networks, and that a variety of databases host pathogen sequences and other information. While these paragraphs contain a number of examples of how and where pathogen samples move, they contain little to no specific information about benefit sharing.

The following section on “Implementation of access and benefit-sharing measures” mixes several issues together. A few examples of what one or maybe more survey respondents considered to be benefit-sharing are provided, but the significance of these is inconclusive and unexplained.

Oddly, but perhaps more importantly, questions related to sequence information and export controls are raised in this section about “benefit sharing”.

Sequence information: The issue of pathogen sequences (paras 16 and 18), is sometimes called “genetic sequence data” by WHO, though it is more often in the context of the Nagoya Protocol called “digital sequence information” (DSI). DSI is a critical issue for the future of access and benefit sharing for pathogens, and any WHO approach to benefit sharing for pathogens will need to squarely address the issue. DSI in this context has been previously discussed, and more information can be found in the following reports:

- TWN Briefing Paper

Ebola: Company avoids benefit-sharing obligation by using sequences

https://twon.my/title2/briefing_papers/No99.pdf

- TWN Briefing Paper

Access and benefit sharing for pathogens: An overview of the issues facing the 2021 World Health Assembly and WHO Executive Board

https://twon.my/title2/briefing_papers/twn/ABS%2opathogens%20TWNBP%20Dec2020%20Hammond.pdf

Export controls: Export controls (para 21) are a longstanding and non-Nagoya Protocol related issue in the movement of pathogen samples around the globe, particularly potentially pandemic pathogens. The purpose of pathogen export control laws, which are primarily used by developed countries, is to prevent certain viruses and bacteria, said to be potentially weaponized, from being transferred to other countries that are considered security threats.

Why export controls are discussed in this report's section on implementation of access and benefit sharing mechanisms is difficult to understand. Export control laws are not "access" laws in the sense of the Nagoya Protocol, as they stem from national security concerns and not questions of fair and equitable benefit sharing, and the two should obviously not be conflated.

While illuminating the impact of export control laws on pathogen sharing may be an interesting and worthwhile exercise in understanding important reasons why some pathogens are not shared, particularly by developed countries, this discussion is quite separate from Nagoya Protocol-related discussions that this section of the WHO report purports to address.

Nevertheless, in considering potential development of WHO approaches for pathogen sharing, it is important for Member States, especially developing countries, to contemplate how export control laws - which some countries cite as justification to refuse to share pathogens - may frustrate the fairness and equity of any benefit sharing plan. In the context of the WHO DG's proposed pathogen biobank, TWN has recently described this issue in more detail here:

- TWN Briefing Paper

Proposed WHO pathogen collection raises questions on fairness & equity

https://twn.my/title2/briefing_papers/twn/Questions%20about%20proposed%20WHO%20pathogen%20collection%20Jan2021%20Hammond.pdf

This portion of the DG's report concludes (paras 22 and 23) with obvious observations about handling of pathogens by different laboratories that, like the issue of export controls, are completely unrelated to the purported subject of this section of the report and which have little or no practical relevance to implementation of the Nagoya Protocol.

Outcomes and Implications

The report's subsequent pages (6 and 7) contain a number of disparate observations that are drawn from the submissions of the survey respondents. Many are not particularly germane to the question of the implications of the Nagoya Protocol for public health, but rather speak to generalities about successful human cooperation, such as the need for clear communication, developing agreements, and trust.

In one unclear passage (para 24), the paper makes reference to benefits "agreed by and shared among both the data generators and receivers" an odd phrase whose meaning is unclear. Of course, as previously noted, defining terms and conditions for adequate and acceptable benefit sharing under the Protocol is, in general, a matter of national law and policy. While those laws and policies may be implemented at the level of individual laboratories, the major parameters are generally not a question left to individual scientists to wholly decide.

A somewhat generic observation is made in this section (para 27) that laboratories may not comply with access and benefit sharing arrangements due to ignorance of national laws and policy. This of course may be true at times and is a matter that Member States should take up with their national institutions, rather than a matter for WHO *per se*. Notably, the Nagoya Protocol's obligations include obligations on

user countries to ensure that their laboratories and industry have obtained proper permissions for use of pathogens from their country of origin.

Salted in the same paragraph is a distinct and important issue - namely that varying procedures in different national laws can be difficult to negotiate. Of course this is a problem that is hardly unique to pathogens and which also occurs for many other materials and goods (as suggested by paragraph 28). Differences in national laws are unsurprising and practically unavoidable. In the interest of rapid and reliable sharing of pathogens, however, this issue may be a reason for the adoption of standardized approaches, provided those approaches ensure benefit sharing.

Page 7 of the report contains some longer and confusing observations about “whether pathogen-sharing arrangements and access and benefit-sharing agreements should differentiate among pathogens”. And, in addition, if such arrangements should similarly differ for sequence information.

This discussion is rather convoluted because it muddles practical considerations with legal ones in a manner that borders on nonsense. It goes without saying, for example, that as a practical matter sequence information is treated differently than pathogen samples. Everyone knows, or should know, that sequence information can be sent safely by electronic means and does not need to be put on a thumb drive and packed in dry ice in a biosecure shipping container. It should be similarly obvious the clinical sample of an ulcer patient whose condition may be caused by *Helicobacter pylori*, a risk group 2 pathogen, is treated quite differently and less stringently than a sample from a patient thought to be infected with H5N1 influenza virus.

Such differences between how physical pathogen materials and information may be handled are obvious. But they are not especially important in the context of the Nagoya Protocol. The report thus unnecessarily complicates the question at hand, which is how to ensure fair and equitable sharing of benefits in all of these transfers. Once the principles are established at an intergovernmental level, then the application of those principles to the different ways in which pathogens are transferred becomes a matter of implementation. Sequence information databases can adopt updated terms and conditions, and paperwork associated with biological samples being shipped internationally can be updated to reflect the appropriate benefit sharing conditions.

The section concludes with an observation about tracking DSI, which WHO refers to as genetic sequence data. The paper asserts that DSI cannot be tracked, though it is unclear if WHO is making this statement or if it is repeating an observation by a survey respondent.⁴ The assertion may or may not be true and depends on a variety of factors, including the willingness of the database operator to cooperate with efforts to track users. In any event, the two important observations about this issue are that 1) the potential for tracking database users depends on the cooperation of database operators (most of whom are publicly funded), and 2) that for fair and equitable benefit sharing from use of sequence information, it is not necessarily a requirement to track each use of each sequence, as multilateral approaches and/or the incorporation of new terms and conditions for use of databases such

⁴ This paragraph also asserts that DSI and physical samples “can” serve different purposes. Of course this is true, but they can also serve the same purposes, and through reverse genetic and other techniques many pathogens can be physically recreated from sequence information. In some cases, such as influenza, this re-creation can take only a matter of hours. Recreated strains can and are being used in research and for the creation of vaccines.

as Genbank and GISAID may generate Nagoya Protocol compliant benefit sharing without need for comprehensive tracking.⁵

Influenza virus sharing: WHA 72(12)

This section (page 8-9) is perhaps the most surprising and concerning of the entire DG's report. Presenting the results of a questionnaire sent to influenza laboratories by the PIP Framework Secretariat, an alarming description of current influenza virus sharing is made, including claims of "lengthy delays" and other problems related to the Nagoya Protocol.

The problems with this characterization are two-fold. First, the description of the influenza virus sharing delays contained in the DG's report (paras 34 and 35) for EB148 in January 2021 sharply diverges from the report of the questionnaire itself, which was prepared by the PIP Secretariat and styled as a DG's report in February 2020. How and why the questionnaire results are portrayed so differently in two different DG reports is unclear and frankly raises concerns of the advancement of a particular agenda in the selective and radical re-characterization of the questionnaire results.

The second problem is another that has regrettably become endemic in WHO publications: the DG's report for EB148 fails to clearly differentiate between the applicable rules for sharing of potentially pandemic viruses, which is covered by the PIP Framework, and sharing of seasonal influenza viruses, which are not part of the PIP Framework. In the first case, for potentially pandemic viruses, a Nagoya Protocol compliant access and benefit sharing agreement exists, and in the second case, for seasonal viruses, there is no such agreement. This distinction is important but is not mentioned.

Thus paragraphs (34 and 35) render a misleading picture. Rather than an alarming situation of massive delays as portrayed by the DG's report, the questionnaire did not find any Nagoya Protocol related delays in sharing of potentially pandemic viruses.⁶ And for other viruses, it found that less than half of responding laboratories - both WHO affiliated and unaffiliated - reported any delays accessing seasonal influenza vaccine strains, and that these delays were for a variety of reasons, only one of which is related to the Nagoya Protocol.

To provide a more detailed, nuanced, and accurate depiction of the survey results, two pages consisting of summary tables from the February 2020 DG's report are reproduced in their entirety at the end of this TWN commentary. They paint a very different picture than the DG's report for EB 148.

Table 1 concerns access to seasonal candidate vaccine viruses, which are not covered by the PIP Framework. For these viruses, providing countries' sovereign rights means that they may require material transfer agreements and benefit sharing terms before transfer (as opposed to potentially pandemic strains under the PIP Framework, where transfer is expected under standard terms). The table indicates that only 39 of 119 responding laboratories, or less than a third, reported any delays at

⁵ Benefit sharing for use of DSI is a topic of intense negotiation by the Convention on Biological Diversity, with developing countries strongly supporting new measures to ensure that the sharing of DSI does not undermine benefit sharing obligations. Discussions have been delayed by the COVID-19 pandemic but can be expected to resume in earnest when the pandemic subsides.

⁶ Some delays in sharing potentially pandemic viruses were found, but these primarily stem from national security measures such as export control laws and not access and benefit sharing in relation to the Nagoya Protocol.

all. Of those that reported delays, a number of reasons were cited, of which Nagoya Protocol-related concerns were only one. Other reasons include cost of courier services, permits unrelated to access and benefit sharing, and data policies. The table does not break out the reasons for delay into numbers, so it is not clear how many of the 39 laboratories reporting delays cited the Nagoya Protocol, nor how many of those laboratories were commercial users, or linked to commercial users, in which case provider countries delaying shipment in order to ensure benefit sharing might be more likely.

Table 2 concerns transfers covered by the PIP Framework, those for potentially pandemic strains and associated vaccine strains. In this case, only 18% of respondents reported delays (22/119), and none of them cited the Nagoya Protocol as a reason for those delays. Rather than the Nagoya Protocol, according to the report's conclusion, *"Biosafety and biosecurity issues are largely responsible for delays in the sharing of influenza viruses with pandemic potential"*.

The presentation of the questionnaire in the report for EB148 thus appears to mischaracterize the actual result. Member States may wish to question how this has come about and to refer to the actual data from the questionnaire.

Pathogen Sharing in the COVID-19 Context

The penultimate section provides a largely informational report on sharing of SARS-CoV-2 viruses since the outset of the present pandemic. There are two important omissions here:

First, the report mentions the widespread use of the GISAID database for SARS-CoV-2. Since this is a report on the implications of the Nagoya Protocol, the lack of mention of access and benefit sharing implications of use of this database is odd. In the present pandemic, GISAID and other databases have proven to be an effective means by which researchers can post and obtain viral sequences. Database sequences have also been used commercially to develop vaccines by, for example, the companies Moderna and Inovio, who incorporated materials synthesized from sequence data in their products.

At present the major databases used for SARS-CoV-2 (and, generally, other pathogens) do not have agreements that impose benefit sharing obligations on database users, meaning that Moderna, Inovio, and other companies obtained key inputs into their vaccines without undertaking any benefit sharing obligations. The importance and urgency of rectifying this problem - which is part of the digital sequence information / genetic sequence data issue - has become more as the COVID-19 pandemic progresses and so many countries are left without access to vaccines, or vaccines (as well as therapies and diagnostics) priced beyond their reach.

Secondly, the report's information on pathogen sharing in the context of the pandemic paints a picture of success, but that "success" is obviously for sharing viruses, and not a success for benefit sharing. A reference is made in paragraph 40 to the ACT Accelerator program, which developing country Member States will know is struggling to make vaccines, treatments, and diagnostics available affordably to much of the world. The depiction of virus sharing in the present pandemic as a success is thus a rather one-sided one: sharing of viruses has been a success, but sharing of benefits has not. Rectifying this problem is the goal of the Nagoya Protocol in public health, though the report oddly does not say as much.

Conclusion

The report concludes by proposing that the Executive Board recommends to the World Health Assembly that the Secretariat continue its work in this area, “with a specific focus on options to provide additional transparency, equity, clarity and consistency in pathogen-sharing practices globally, and to increase capacity worldwide for both the sequencing of pathogen genomes and the analysis of those genomes”.

Such a broad recommendation pre-empts a proper discussion by WHO Member States that should first focus on more clarity and understanding of the facts and issues, especially fair and equitable benefit sharing for public health objectives. Due to the flawed methodology of the survey and the unbalanced, even misleading, nature of the DG’s report, the way forward is a Member-State process and not a Secretariat-driven one.

One item of note with respect to the Secretariat’s work is how Member States will be involved in the development of the “bio-bank” for pathogens that has been proposed by the WHO DG. While this work is of relevance to the Nagoya Protocol and public health, many unanswered questions exist about it. Member States should take care to not accidentally endorse continued development of the “bio-bank” without new information on the plan and establishment of a clear guiding role of Member States in its possible creation. Consistency with the rights of Member States under the CBD and Nagoya Protocol also needs to be ensured. Questions related to the bio-bank have been elaborated in more detail in the bio-bank paper previously cited in this commentary.