

IMPLEMENTATION OF THE NAGOYA PROTOCOL AND PATHOGEN SHARING: PUBLIC HEALTH IMPLICATIONS

Study by the Secretariat

Contents

Acknowledgments.....	3
Table of Abbreviations	3
Executive summary.....	4
I. Introduction.....	10
a. Background.....	10
b. Questions.....	10
c. Methodology	10
d. Report Outline.....	10
II. Overview of access and benefit-sharing principles under the Nagoya Protocol.....	11
a. Scope of the Nagoya Protocol, prior informed consent and mutually agreed terms.....	11
b. Public health implications of the Nagoya Protocol.....	14
III. The Nagoya Protocol and the sharing of influenza viruses.....	15
a. Influenza virus sharing system.....	15
b. The implications of the Nagoya Protocol on the influenza virus sharing system	17
IV. The Nagoya Protocol and the sharing of non-influenza pathogens	19
a. Pathogen sharing.....	19
b. The implications of the Nagoya Protocol on the sharing of non-influenza pathogens	22
V. Possible paths forward	23
a. Recognition of “specialized international instruments” under the Nagoya Protocol.....	23
b. Developing implementing legislation that supports public health	25
1. Article 8b: Special consideration during health emergencies	26
2. Model contractual clauses, codes of conduct, guidelines, best practices and standards	26
a. Consultations.....	27
Annex 1 - Methodology	29

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Table of Abbreviations

ABS	Access and benefit sharing
AFP	Acute flaccid paralysis
CBD	Convention on Biological Diversity
COP-MOP	Conference of the Parties Serving as the Meeting of the Parties to the Nagoya Protocol
CVV	Candidate vaccine virus
FAO	Food and Agriculture Organization
GISRS	Global Influenza Surveillance and Response System
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
GSD	Genetic sequence data
IHR	International Health Regulations (2005)
IVPP	Influenza viruses with human pandemic potential
MAT	Mutually agreed terms
MOU	Memorandum of understanding
MTA	Material transfer agreements
NIC	National Influenza Centre
PHEIC	Public Health Emergency of International Concern
PIC	Prior informed consent
PIP BM	PIP Biological Materials
TORs	Terms of reference
WHO CC	WHO Collaborating Centre
WHO ERL	WHO Essential Regulatory Laboratory

Executive summary

1. The Executive Board at its 138th session in January 2016 considered the report of the First Meeting of the Review Committee on the Role of the International Health Regulations (2005).¹ During the discussions,² it was agreed that the Secretariat would prepare a study, for presentation to the Board at its 140th session, in order to analyse how the implementation of the Nagoya Protocol might affect the sharing of pathogens, and the potential public health implications. The full report by the Secretariat will be made available in due course, in all six official languages, on the WHO website.³

2. The present summary contains the following: a brief statement of the methodology employed; background information; key findings; and main considerations raised and options proposed by Member States and stakeholders. It is intended as an aid to Member States in their consideration of the full report.

Methodology

3. This analysis was prepared using a multi-pronged approach to information-gathering, which included a call to Member States, through their health and environmental sectors, and to stakeholders, for written responses to key questions, as well as in-person and telephone interviews with relevant stakeholders and experts. In addition to relevant internal units of the Secretariat, various international organizations, including the secretariat of the Convention on Biological Diversity and FAO, were also consulted.

Background information

4. The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity, which has as one of its main goals the fair and equitable sharing of the benefits derived from the use of genetic resources.⁴ The Protocol expands on the Convention's access and benefit-sharing provisions, with the aim of creating a global framework for the development of access and benefit-sharing instruments for genetic resources.

5. The Nagoya Protocol applies to genetic resources, and traditional knowledge associated thereto, that are covered by the Convention on Biological Diversity, and to the benefits arising from their utilization. Under the Protocol, genetic resources may be accessed subject to the "prior informed consent" of the country of origin and once "mutually agreed terms" have been reached that include

¹ Document EB138/20.

² See document EB138/2016/REC/3, summary record of the second meeting, section 1.

³ The relevant section can be found at www.who.int/influenza/pip/2016-review/en

⁴ Convention on Biological Diversity Art. 1, entered into force 29 December 1993, 1760 UNTS 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-01>, accessed 5 December 2016.

the fair and equitable sharing of benefits arising from the utilization of the concerned genetic resources.⁵

6. The Nagoya Protocol lists in its annex many benefits supportive of public health, such as technology transfers and collaboration in scientific research, which could be implemented by Parties through mutually agreed terms.

7. Although the Nagoya Protocol sets out broad principles, many details are left to domestic jurisdictions, including how to address pathogens in implementing legislation and how to implement health emergency measures. These decisions will have an impact on public health.

8. The public health response to infectious disease relies on ongoing surveillance, timely risk assessment, implementation of public health control measures, and access to medical interventions, such as vaccines and medicines.

9. In the context of influenza, for example, monitoring the evolution and spread of viruses, and responding to outbreaks, is a continuous process, requiring constant access to samples of circulating influenza viruses. This involves the sharing of thousands of influenza virus samples every year, from as many countries as possible, with the Global Influenza Surveillance and Response System, a WHO-coordinated global network of laboratories. Based on these samples, laboratories of the Global Influenza Surveillance and Response System can then conduct risk assessment, monitor the evolution of seasonal influenza activity as well as the pandemic potential of novel influenza viruses, and recommend risk management measures, including vaccines. Vaccine manufacturers use materials and information developed by the Global Influenza Surveillance and Response System to produce influenza vaccines.

10. Further, the Pandemic Influenza Preparedness Framework, adopted in 2011 by the Health Assembly in resolution WHA64.5, aims to improve pandemic influenza preparedness and response and strengthen the Global Influenza Surveillance and Response System, “with the objective of a fair, transparent, equitable, efficient, and effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits, such as diagnostics and antivirals.”⁶

11. For non-influenza pathogens, sharing occurs in various ways: ad hoc, bilaterally, as the need arises, or through existing networks of institutions and researchers. Such networks share pathogen

⁵ Convention on Biological Diversity Art. 5, entered into force 29 December 1993, 1760 UNTS 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-05>, accessed 5 December 2016.

⁶ See Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: Section 2 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 15 November 2016).

samples for surveillance and diagnostic activities, in order to determine, for example, epidemiological changes or the development of resistance.

12. In the context of polio eradication for instance, laboratories in the Global Polio Laboratory Network share samples from suspected polio cases for the purpose of rapid detection and in order to ensure rapid containment and response through the monitoring of polio virus transmission patterns.

Key findings

13. A central conclusion of the study is that: (1) the Nagoya Protocol has implications for the public health response to infectious diseases, including influenza; and (2) these implications include opportunities to advance both public health and principles of fair and equitable sharing of benefits.

14. The responses to the questions provided to Member States and stakeholders also clarified a number of issues.

-- Infectious disease response relies on ongoing surveillance, timely risk assessment, public health control measures, and access to diagnostics, vaccines and treatments. This requires both rapid and comprehensive sharing of pathogens and fair and equitable access to diagnostics, vaccines and treatments.

-- The two elements, which are equally important, are both promoted by the Nagoya Protocol, which clarifies and harmonizes legal obligations regarding access to genetic resources, and establishes a more equitable approach for sharing the benefits derived from their use.

-- In this way, the Nagoya Protocol can be supportive of pathogen-sharing. It can promote trust and encourage more countries to share pathogens, and it provides a normative basis for addressing the equitable sharing of benefits arising from their use.

Considerations and options

15. The Nagoya Protocol's provision of a foundation for a normative approach to accessing pathogens and sharing benefits arising from their use is based on core principles such as fairness, equity and the protection of global public health.

16. By clarifying and harmonizing access and benefit-sharing obligations associated with the sharing of pathogens, the Nagoya Protocol can support the promotion of timely sharing and speed up risk assessment as well as the development of disease countermeasures. In addition, predictable sharing of benefits can improve access to affordable treatments and help developing countries to build capacities in such areas as disease surveillance and research and development. Accordingly, the Nagoya Protocol provides an opportunity for Member States to establish pathogen-sharing systems that support global health equity.

17. For example, in the context of influenza, some respondents highlighted that the Protocol could help to bolster support for the Pandemic Influenza Preparedness Framework, encourage more participation in the influenza virus-sharing system and provide an opportunity to consider the equitable sharing of benefits arising from the use of seasonal influenza viruses.

18. In the context of non-influenza pathogens, some respondents highlighted that the Nagoya Protocol provides an opportunity for Member States to establish clear, pre-arranged benefit-sharing expectations for access to pathogens that will contribute to the public health response to infectious disease outbreaks.

19. At the same time, concerns have been voiced that implementation of the Nagoya Protocol could slow or limit the sharing of pathogens owing to: (1) uncertainty regarding the scope and implementation of the Nagoya Protocol, (2) the high transactional cost of implementing a bilateral system for access and benefit sharing and (3) the complexity of varying domestic access and benefit-sharing legislations. Such factors could have an impact on the comprehensiveness and speed of risk assessment as well as the timely development of vaccines, diagnostics and other medical countermeasures.

20. In the context of influenza, for instance, some respondents have mentioned that, with thousands of viruses shared with the laboratories of the Global Influenza Surveillance and Response System each year, the procedures for individual negotiations for Prior Informed Consent and Mutually Agreed Terms could increase the complexity of virus sharing and could make significant demands on both resources and time. This could slow down or limit virus sharing, posing a challenge to a public health response to influenza. Similarly, for non-influenza pathogens, it was highlighted that bilateral agreements may not always be supportive of a common approach to handling a public health threat.

21. As noted by respondents to this study, there are tools under the Nagoya Protocol that address these concerns. The manner in which the Nagoya Protocol is implemented – both collectively through the Protocol’s Meeting of the Parties, and by individual Parties through their domestic legislation – will be vital to ensuring that the Nagoya Protocol supports public health.

22. Respondents to this study therefore proposed a number of options for advancing public health and for improving harmonization between the Nagoya Protocol and existing pathogen-sharing systems. These included: (a) establishing new, or identifying existing “specialised international access and benefit-sharing instruments” under Nagoya Protocol Article 4.4; (b) suggestions to ensure that implementing legislation is supportive of public health; and (c) consultation, dialogue, public awareness and international collaboration.

23. Many respondents expressed the view that the Pandemic Influenza Preparedness (PIP) Framework for virus and benefit sharing is or should be considered an Article 4.4 specialized international access and benefit-sharing instrument. Such recognition would mean that the Nagoya Protocol's requirements for case-by-case Prior Informed Consent and Mutually Agreed Terms would not apply with respect to influenza viruses with human pandemic potential. This could promote 'legal certainty' with respect to such pathogens, strengthening the mechanisms of the PIP Framework.

24. Further, Article 8(b) of the Nagoya Protocol requires Parties to pay due regard to "present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally" when developing legislation on access and benefit sharing. Many respondents therefore focused on operationalising Article 8(b) in their implementing legislations in order to facilitate rapid access to pathogens that threaten public health while ensuring equitable benefit sharing.

25. Other proposals discussed by respondents included the development of a code of conduct for pathogen sharing to promote access to pathogens used for public health purposes, particularly when such use was non-commercial. The idea of developing simplified and accelerated processes to obtain Prior Informed Consent and Mutually Agreed Terms for pathogens with a significant public health impact was also suggested, including through the use of standard contractual templates, as encouraged under Article 19 of the Protocol.

26. Many respondents suggested that the Secretariat and Member States promote dialogue, consultation and public awareness of the issues relating to the Nagoya Protocol and pathogen sharing. They also called for international coordination on the implementation of the Nagoya Protocol and suggested a WHO-led effort to harmonize national implementing legislations to ensure that such laws are consistent with public health.

27. Lastly, a few respondents suggested adding agenda items to future WHO meetings to allow further discussion of the public health implications of the Nagoya Protocol.

28. Taken as a whole, responses to this study reflect a view that access to pathogens should be governed by an approach that promotes the rapid sharing of pathogens for global health purposes and the fair and equitable sharing of the resulting benefits. Consistent with this view, the Nagoya Protocol provides normative tools to promote efficient and equitable international access and benefit-sharing arrangements for pathogens, including through the development of specialized instruments, the recognition of emergencies that threaten human health, and the promotion of international collaboration.

29. Member States may wish to consider the feasibility of such tools, as well as the next steps for addressing the public health implications of the Nagoya Protocol, including opportunities to advance both public health and the principle of equitable sharing of benefits.

I. Introduction

a. Background

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol), which entered into force in 2014, is a supplementary agreement to the Convention on Biological Diversity (CBD). Its main goal is the fair and equitable sharing of the benefits derived from the use of genetic resources.⁷

The Executive Board at its 138th session in January 2016 considered the report of the First Meeting of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. During the discussions, it was agreed that the Secretariat would prepare a study, for presentation to the Board at its 140th session, in order to analyse how the implementation of the Nagoya Protocol might affect the sharing of pathogens, and the potential public health implications.⁸ The Secretariat provides this report in response to that decision.

b. Questions

This paper explores three key questions:

1. How the Nagoya Protocol might affect the sharing of pathogens, including seasonal and pandemic influenza;
2. The potential public health implications of this sharing, and;
3. Possible options for advancing public health, supporting the objective of a fair and equitable sharing of benefits.

c. Methodology

Preparation of this analysis involved a multi-pronged approach to gather information, which included a call for written responses to key questions by Member States, through their health and environmental sectors and to Global Influenza Surveillance and Response System (GISRS) laboratories. The Secretariat also conducted in-person and telephone interviews with relevant stakeholders and experts. In addition to relevant internal units of the Secretariat, various international organizations, including the secretariat of the CBD and Food and Agriculture Organization (FAO), were also consulted. Annex 1 contains a full description of methodology.

d. Report Outline

Following this introduction, the report begins with an overview of the access and benefit sharing principles laid out in the Nagoya Protocol, followed by a discussion of how the Nagoya

⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 1, entered into force 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>, accessed 23 November 2016

⁸ See document EB138/2016/REC/3, summary record of the second meeting, section 1.

Protocol might affect the sharing of influenza pathogens and other pathogens. The report concludes with a summary of input received from Member States and stakeholders on potential paths forward.

II. Overview of access and benefit-sharing principles under the Nagoya Protocol

The Nagoya Protocol entered into force on 12 October 2014 and as of November 2016 there were 84 Parties to the Protocol.⁹ Implementation of the Nagoya Protocol is at an early stage; many Parties have yet to adopt legislative, administrative or policy implementing measures at the domestic level.¹⁰

The Nagoya Protocol expands on the CBD's access and benefit sharing (ABS) provisions, aiming to create a global framework for the development of ABS instruments for genetic resources. The CBD Secretariat considers that the Nagoya Protocol is important because

[it] plays an important role in creating greater legal certainty and transparency for both providers and users of genetic resources by:

- Establishing more predictable conditions for access to genetic resources;
- Helping to ensure benefit-sharing when genetic resources leave the providing country.

By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.¹¹

a. Scope of the Nagoya Protocol, prior informed consent and mutually agreed terms

The Nagoya Protocol applies to genetic resources, and traditional knowledge associated therewith, that are covered by the CBD, and to the benefits arising from their utilization.¹² Genetic resources, as defined by the CBD, are “material of plant, animal, microbial or other origin containing functional units of heredity”¹³ “of actual or potential value”,¹⁴ but not human genetic resources.¹⁵

⁹ Parties to the Nagoya Protocol. In: Convention on Biological Diversity [website]. Montreal: CBD; 2016 (<https://www.cbd.int/abs/nagoya-protocol/signatories/>, accessed 29 November 2016).

¹⁰ Based on publicly available information, at least 28 Parties have adopted implementing measures on access and benefit sharing as of November 2016. The Access and Benefit-Sharing Clearing-House. In: Convention on Biological Diversity [website]. Montreal: CBD; 2016 (<https://absch.cbd.int/>, accessed 23 November 2016).

¹¹ About the Nagoya Protocol. In: Convention on Biological Diversity [website]. Montreal: CBD; 2016 (<https://www.cbd.int/abs/about/default.shtml>, accessed 26 August 2016).

¹² Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 3, entered into force 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>, accessed 23 November 2016.

¹³ Convention on Biological Diversity art. 2, *entered into force* 29 December 1993, 1760 U.N.T.S. 79. Text available at: <https://www.cbd.int/convention/articles/default.shtml?a=cbd-02>

¹⁴ *Ibid*

¹⁵ Although not expressly excluded in the text, CBD Parties recognized in COP 10 Decision X/1, which adopts the Protocol, that “human genetic resources are not included within the framework of the Protocol”. Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Montreal: CBD; 2010 (UNEP/CBD/COP/DEC/X/1; <https://www.cbd.int/decision/cop/?id=12267>, accessed 31 October 2016)

A few respondents to this study expressed views about whether pathogens are included in the scope of the Nagoya Protocol.¹⁶ This was extensively debated during negotiations of the Protocol.¹⁷ “Negotiators finally decided against a specific inclusion or exclusion of pathogens in the Protocol, in favour of the general provisions under Articles 3-4 and the special consideration under Article 8(b).”¹⁸ The only explicit mention of pathogens is found in the Protocol’s preamble, which declares that Parties are: “Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes”.¹⁹

States Parties may determine the legal status of pathogens in their implementing legislation. While few implementing laws and measures explicitly address pathogens and access to them, or public health in general,²⁰ European Union Regulation 511/2014,²¹ applicable and in force for all of the European Union’s 28 Member States, clearly states that pathogens fall within the scope of the Protocol.

An important but currently unresolved question is whether genetic sequence data (GSD) are included under the scope of Nagoya.²² This is likely to be discussed at the next meeting of the Conference of the Parties to the CBD in December 2016.²³

¹⁶ Although the majority of submissions and interviews did not directly address the question of whether pathogens were included within the scope of the Nagoya Protocol, a few respondents expressed the view that pathogens were included under the Protocol, while a few others expressed the opposing perspective. Given the Nagoya Protocol’s objective to preserve biodiversity, some believed that pathogens should be excluded as the primary aim is to destroy rather than conserve them. In addition, others suggested that the PIC and MAT system was poorly adapted to pathogens given their wide and rapid transfer between humans and the difficulty, in some cases, of identifying the country of origin. On the other hand, several Member States considered that “the Nagoya Protocol clearly includes pathogens” considering they “contain functional units of heredity and are replicable” and the fact that Article 8(b) includes reference to pathogens.

¹⁷ Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing. Montreal: Convention on Biological Diversity; 2010 (UNEP/CBD/WG-ABS/9/ING/2, <https://www.cbd.int/doc/meetings/abs/abswg-ing-02/official/abswg-ing-02-abswg-09-ing-02-en.pdf>, accessed 31 October 2016), art. 3(f), 6(b).

¹⁸ Morgera E, Tsoumani E, Buck M. Unraveling the Nagoya Protocol : A commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity. Leiden : Brill; 2014 : 104.

¹⁹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity preamble, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁰ The Access and Benefit-Sharing Clearing-House. In : Convention on Biological Diversity [website]. Montreal : CBD; 2016 (<https://absch.cbd.int/countries>, accessed 31 October 2016).

²¹ Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014 OJ L 150.

²² Genetic sequence data (GSD) are the genetic code for a specific genetic resource; GSD that provide the ‘instructions’ for how organisms are built and function. Each molecule of DNA or RNA is composed of four different nucleotides, or building blocks (adenine, cytosine, guanine and thymine in DNA and adenine, cytosine, guanine and uracil in RNA) that line up to form genes, which determine the structure of proteins. The order of these nucleotides – the sequence – is critical because genetic sequences contain information about the structure and specific properties of an organism.

²³ The CBD’s Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) has recommended that the Conference of the Parties to the Convention on Biological Diversity (CBD COP) adopt a decision “invit[ing] the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol to clarify, if and how, the use of digital sequence information on genetic resources relates to access and benefit-sharing.” Subsidiary Body on Scientific, Technical and Technological Advice, Twentieth Meeting. Synthetic Biology. Montreal: CBD; 2016 (UNEP/CBD/SBSTTA/20/16, Resolution XX/8; <https://www.cbd.int/doc/meetings/cop/cop-13/official/cop-13-05-en.pdf>, accessed 31 October 2016).

Access to genetic resources under the Nagoya Protocol

Access to genetic resources under the Nagoya Protocol is subject to two basic requirements: prior informed consent (PIC) and mutually agreed terms (MAT). Under the CBD and the Nagoya Protocol, States have sovereignty over natural resources.²⁴ Those who wish to access genetic resources may do so subject to the “prior informed consent” of the country of origin and once “mutually agreed terms” are reached.²⁵ For instance, a research institute wishing to access a genetic resource that is from another jurisdiction must meet the obligations set by that jurisdiction’s ABS legislation. In practice, this could mean establishing contact with the local CBD National Focal Point on Access and Benefit Sharing or other competent authority responsible for granting access to the specific genetic resource; and applying for the necessary permits and entering into a bilateral agreement on mutually agreed terms that would specify the terms and conditions for, in particular, equitable sharing of benefits. Parties in which a genetic resource is utilized must make sure that due diligence is exercised, ensuring that anyone using genetic resources in their jurisdiction follows proper PIC and MAT procedures.²⁶

The Nagoya Protocol suggests in its annex a non-exhaustive list of monetary and non-monetary benefits that can be implemented by Parties, including many benefits supportive of public health, such as: research funding; joint ownership of intellectual property rights; sharing of research and development results; collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities; technology transfers; and capacity building. In the context of health emergencies, the Nagoya Protocol recommends that domestic legislations include provisions on access to affordable treatments by those in need, especially in developing countries.²⁷

While the Nagoya Protocol sets out broad principles, such as PIC²⁸ and MAT²⁹, the details of implementing them are left to domestic legislation. In that implementation, it will be important for Nagoya States Parties to consider how to address access to pathogens, especially during public health emergencies. These decisions taken by Parties on their implementing legislation for the Protocol may, individually and in the aggregate, have an impact on public health.

²⁴ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 6, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁵ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 5 and 6, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁶ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 15, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 8(b), *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁸ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 6, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

²⁹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 5, *entered into force* 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>

b. Public health implications of the Nagoya Protocol

The public health response to infectious disease relies on on-going surveillance, timely risk assessment, implementation of public health control measures, and broad access to medical interventions, such as vaccines and medicines. This requires both rapid and comprehensive sharing of pathogens and fair and equitable access to medical interventions by all countries in need in order to protect against and respond to the threat of infectious diseases.

The Nagoya Protocol provides a foundation, based on core principles, such as fairness and equity, for a global common approach to accessing pathogens, and sharing benefits arising from their use. As suggested by several respondents to this study, implementation of the Nagoya Protocol in the context of infectious diseases could help to (1) clarify and harmonize the ABS obligations associated with access to pathogens and (2) establish a fairer and more equitable approach for sharing the benefits derived from their use.

Increased clarity, fairness and equity could encourage timely sharing, which would support risk assessment and the development of medical countermeasures. In addition, predictable sharing of benefits could improve access to affordable treatments and help build capacities, such as disease surveillance, and research and development, particularly in developing countries. Through the sharing of benefits such as joint ownership of intellectual property, collaboration and acknowledgment of contributions, the Nagoya Protocol provides an opportunity for Member States to establish pathogen-sharing systems that support global health equity.

Concerns have been voiced that implementation of the Nagoya Protocol could slow or limit the sharing of pathogens due to: (1) the current uncertainty regarding the scope and implementation of the Nagoya Protocol, (2) the high transactional cost of concluding bilateral ABS agreements and (3) the potential complexity of varying domestic ABS legislation. This in turn could impact the comprehensiveness and speed of risk assessment as well as the timely development of vaccines, diagnostics and other medical countermeasures.

As noted by respondents to this study, there are tools under the Nagoya Protocol that address these concerns. The manner in which the Nagoya Protocol is implemented – both collectively through the Protocol’s Meeting of the Parties, and by individual Parties through their domestic legislation – will be vital to ensuring that the Nagoya Protocol supports public health.

This study has highlighted that Member States and stakeholders share the common view that the sharing of pathogens should be governed by effective and efficient approaches and instruments that balance the public health need for rapid access to pathogens with the essential goal of ensuring

that the benefits that result from this sharing are equitably distributed. Given this, the Nagoya Protocol presents an important normative basis to further promote international collaboration towards pathogen sharing to better protect the world's health.

III. The Nagoya Protocol and the sharing of influenza viruses

a. Influenza virus sharing system

Influenza poses a particular threat to global public health. Worldwide, annual outbreaks of seasonal influenza are estimated to result in about 3 to 5 million cases of severe illness, and about 250 000 to 500 000 deaths.³⁰ Influenza viruses are constantly evolving and, occasionally, a new virus emerges against which most people do not have immunity. These novel viruses can spread across the world causing a pandemic. Such a pandemic can have a devastating economic and public health impact—the 1918 outbreak is estimated to have caused 50 million deaths worldwide.³¹

Monitoring the evolution and spread of influenza viruses, and responding to epidemics is a continuous process, requiring constant access to samples of currently circulating influenza viruses. The sharing of influenza viruses has occurred for almost 65 years through a WHO-coordinated global network of laboratories known as GISRS.³² GISRS comprises four different types of laboratories: National Influenza Centres (NICs), WHO Collaborating Centres (WHO CCs), WHO Essential Regulatory Laboratories (WHO ERLs), and WHO H5 Reference Laboratories, all of which operate under WHO Terms of Reference (TORs).

NICs collect and process more than 2 million clinical specimens globally every year and act as the reference laboratory in their country. They must immediately send clinical specimens and viruses that cannot be readily identified to a WHO CC or H5 Reference Laboratory. Viruses shared with GISRS are used for assessment of associated risks and development of risk countermeasures³³.

Through the use of genetic sequencing and antigenic assays, GISRS laboratories conduct risk assessments, monitor the evolution of seasonal influenza viruses, follow the epidemic spread of viruses, or evaluate the pandemic potential of novel influenza viruses. Based on these analyses, GISRS can recommend risk management measures including supporting the development of vaccines. Meaningful risk assessment depends heavily on timely virus sharing, the quality of virus samples, and

³⁰ See Influenza (Seasonal) Fact Sheet No 211. In: World Health Organization [website]. Geneva: WHO; March 2014 (<http://www.who.int/mediacentre/factsheets/fs211/en/>, accessed 28 November 2016).

³¹ Taubenberger T, Morens DM. 1918 Influenza: The mother of all pandemics. *Emerg Infect Dis.* 2006;12. doi: 10.3201/eid1201.050979.

³² Prior to 2011 and the introduction of the PIP Framework, GISRS was known as the Global Influenza Surveillance Network.

³³ Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: annex 4 “Guiding Principles for the development of Terms of Reference for current and potential future WHO global influenza surveillance and response system (GISRS) laboratories for H5N1 and other human pandemic influenza viruses (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 31 October 2016).

their associated GSD, as well as the representativeness of the viruses shared, with regard to their characteristics, epidemiological context and geographic distribution.

Vaccination is the most effective way to prevent influenza and to lessen severe outcomes from the illness. Twice a year WHO, in close collaboration with GISRS laboratories, makes a recommendation on the composition of seasonal influenza vaccines. This involves receiving and testing thousands of influenza virus samples from as many countries as possible and selecting the most representative influenza viruses to be included in vaccines. Candidate vaccine viruses (CVVs) are then prepared for each of the recommended influenza virus strains. These CVVs are available to vaccine manufacturers, public health laboratories or academic research institutions. Vaccine manufacturers use them to produce influenza vaccines. Because it takes at least six months for manufacturers to produce vaccines using current technologies, it is essential that influenza viruses be shared with GISRS in a systematic and timely manner well in advance of the vaccine composition meetings.

GISRS laboratories also develop and update the reagents necessary for detecting newly circulating influenza viruses. In addition, GISRS also reports on the genetic and antigenic characteristics of influenza viruses, provides situation analysis and assessment, and contributes to WHO publications on regional and global influenza activity. All of these are available to all Member States, industry and other stakeholders.

The sharing of seasonal influenza viruses and influenza viruses with human pandemic potential (IVPP) is governed by two different but mutually reinforcing and supportive regimes: the GISRS seasonal influenza terms of reference and the WHO Pandemic Influenza Preparedness Framework (PIP Framework), respectively. Under those regimes, NICs are designated by the health ministry of the country concerned and are recognized by WHO. Designation requires formally agreeing to comply with the GISRS seasonal influenza TORs and the PIP Framework, under which NICs agree, *inter alia*, to share influenza virus samples with other GISRS and non-GISRS laboratories.

Sharing of influenza viruses with human pandemic potential: PIP Framework

While the GISRS seasonal influenza TORs detail expectations in regard to the sharing of seasonal influenza viruses and describe the seasonal influenza activities carried out by the different GISRS laboratories³⁴, the sharing of influenza viruses with human pandemic potential (IVPP) within GISRS and outside of GISRS (to vaccine, diagnostic, and antiviral manufacturers as well as non-

³⁴ See Global Influenza Surveillance and Response System. In: World Health Organization [website]. Geneva: WHO; 2016 (http://www.who.int/influenza/gisrs_laboratory/en/, accessed 31 October 2016).

GISRS research institutions) is governed by the PIP Framework. The PIP Framework, adopted in 2011 by the Health Assembly in resolution WHA64.5, aims

to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system (“WHO GISRS”), with the objective of a fair, transparent, equitable, efficient, and effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits, such as diagnostics and antivirals.³⁵

Under the PIP Framework, Member States agree to rapidly share PIP Biological Materials (PIP BM)³⁶ through their NICs with all GISRS laboratories³⁷. When PIP BM are shared outside of GISRS, the entity receiving the materials must conclude with WHO a legally binding contract known as a Standard Material Transfer Agreement 2. Under this agreement, in exchange for receiving PIP BM, influenza product manufacturers must select among specific benefit-sharing options, such as donation of vaccines or technology transfer.³⁸ In addition, influenza vaccine, diagnostic and pharmaceutical manufacturers who use GISRS provide an annual financial contribution to WHO, the ‘Partnership Contribution’, which WHO uses to improve pandemic preparedness and response. Since 2011, WHO has secured access to over 350 million doses of pandemic influenza vaccines and has received more than US\$ 100 million from manufacturers that is being used to strengthen pandemic preparedness and response capacities in countries where they are weak.

b. The implications of the Nagoya Protocol on the influenza virus sharing system

On the one hand, the Nagoya Protocol has the potential to strengthen GISRS and the PIP Framework by raising awareness of its core principles, notably “the importance of ensuring access to human pathogens for public health preparedness and response purposes,”³⁹ taking into consideration the need for “expeditious fair and equitable sharing of benefits arising from the use of such genetic resources, including access to affordable treatments by those in need, especially in developing

³⁵ See Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: Section 2 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 15 November 2016).

³⁶ The PIP Framework defines PIP Biological Materials to include: “human clinical specimens, virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment.” Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: section 4.1 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 31 October 2016).

³⁷ Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: sections 5.1.1 and 5.1.2 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 31 October 2016).

³⁸ Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011: Annex 2, art. 4 (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 31 October 2016).

³⁹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity preamble, entered into force 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

countries”⁴⁰. The Nagoya Protocol may help to highlight the fundamental importance of GISRS as a global public health good and the innovative nature of the PIP Framework. This could, in turn, help to bolster support for the PIP Framework and encourage more participation in the influenza virus sharing system. By improving fairness and equity the Nagoya Protocol may promote trust and encourage more countries to share seasonal influenza viruses. In addition, when properly implemented, it provides an opportunity to promote the equitable sharing of benefits arising from the use of seasonal influenza viruses.

This could create opportunities for public health. Increased virus sharing due to greater trust and more equitable sharing of benefits would potentially improve risk assessment, facilitate the production of laboratory products (such as reagents and CVVs) and ultimately allow for the production of more optimal vaccines, antivirals and diagnostics.

On the other hand, implementation of the Nagoya Protocol may pose challenges to the influenza virus sharing system. First, a majority of submissions to this study expressed concern over legal uncertainty and lack of clarity in regard to the interaction between the Nagoya Protocol and the current influenza virus sharing system. More specifically, the Nagoya Protocol sets out broad principles, leaving a great deal of discretion to implementing Parties; therefore, with the Protocol in its early stages, the lack of clarity about how the Nagoya Protocol applies to both seasonal and pandemic influenza viruses is perhaps inevitable. However, many respondents encouraged Parties to the Nagoya Protocol to clarify key issues, such as whether special rules apply to certain classes of pathogens and the relationship between the PIP Framework’s existing ABS system and the Nagoya Protocol. Such clarity would help to avoid potential disruption to virus sharing.

Depending on how the Nagoya Protocol is implemented, there could be two other significant impacts on influenza virus sharing. First, as highlighted in section II.b, the diversity of implementing legislation may render access to viruses more complex for laboratories and companies needing these viruses for risk assessment, research and product development. Second, given the large volume of viruses shared through GISRS, the procedures for bilateral PIC and MAT negotiations for each virus would be resource- and time-consuming. These issues could affect GISRS laboratories’ capacity to comply with their terms of reference.

These elements could potentially slow or limit influenza virus sharing and delay or hinder the development of comprehensive and effective vaccines and other medical countermeasures. For

⁴⁰ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 8(b), entered into force 12 October 2014. Text available at: <https://www.cbd.int/abs/text/default.shtml>.

seasonal influenza, given the need to update vaccines seasonally to match currently circulating seasonal viruses, it is essential that laboratories have access to as many influenza viruses as possible, and that manufacturers have access to the “best matched” CVVs in order to develop optimal vaccines and other medical countermeasures. As highlighted in section V however, several approaches suggested by respondents may offer solutions to facilitate or streamline the process to access influenza viruses.

IV. The Nagoya Protocol and the sharing of non-influenza pathogens

a. Pathogen sharing

International sharing of non-influenza pathogens may occur when countries with an outbreak of a disease do not have the capacity to isolate and identify pathogens from samples or are unable to conduct more advanced analyses such as genetic sequencing. Pathogens may also be shared for public health research and the development of vaccines, diagnostics and treatments.

Historically, the global sharing of pathogens was primarily done informally. In many instances, pathogens were shared without formal permission from national authorities, written agreement, or ongoing research collaborations between provider and recipient countries. Recipients often failed to acknowledge the contributions of provider countries or to share other benefits derived from the use of pathogens. Over the last few years, sharing practices appear to have improved due to a global awareness of provider countries’ rights and concerns.

The sharing of pathogens may occur on an *ad hoc*, bilateral basis, as the need arises, or through an existing network of institutions and researchers. In an *ad hoc*, bilateral system, a researcher may, for example, contact a researcher in another institution to request access to a pathogen for research purposes. Conditions of access are then agreed to by the two researchers and sometimes involve a formalized agreement.

In coordinated networks, members often agree to or are expected to share pathogens with other members on pre-arranged terms. These networks aim to share samples in a rapid manner for surveillance and diagnostic activities. For example, national public health laboratories that are part of a coordinated network may share specimens from certain cases with specialized laboratories able to perform more advanced testing in order to confirm diagnosis or for surveillance purposes. WHO may act as the coordinator of the network or simply provide support to countries in connecting the Ministry of Health or national laboratory with these specialized laboratories.⁴¹ There are a number of

⁴¹ During outbreaks, this coordination may be provided through the WHO’s Global Outbreak Alert and Response Network (GOARN) and the Emerging and Dangerous Pathogens Laboratory Network (EDPLN) for example.

successful models of laboratory networks co-ordinated by WHO.⁴² In general, these WHO co-ordinated networks place laboratories in categories according to their role - national, regional, or specialised (global) laboratories. This categorization allows for laboratories with differing capacities to be responsible for different functions within the network, such as national laboratories providing the initial confirmation of a pathogen and sharing it with regional laboratories that then sequence the pathogen.

In each of these situations, the provider and recipient parties will typically enter into a material transfer agreement (MTA) or memorandum of understanding (MOU), or agree to terms of reference. For national laboratories it is often the provider country's Ministry of Health that is responsible for negotiating these agreements, while for non-governmental institutions, technology transfer offices may be responsible. Although there are no globally accepted standard terms for the sharing of pathogens, there is now generally greater awareness of the importance of involving local researchers in collaborative research projects and recognizing their contributions⁴³. While WHO is often not directly involved in negotiations or typically party to MTAs or MOUs, individuals interviewed for this study have reported that WHO's involvement as a co-ordinator has led to an increased regard for equity in the negotiation of bilateral instruments, and inclusion of benefit-sharing terms. These terms can include a wide range of benefits, including acknowledgement and collaborations, technology transfer, joint ownership of intellectual property rights, capacity building and sometimes access to diagnostics, vaccines, and treatments.

Coordinated sharing of polioviruses under the Global Polio Eradication Initiative – a case study

Coordinated laboratory networks vary considerably in both structure and function. However, many networks follow a model similar to that of the WHO-coordinated poliovirus sharing system. A description of this system is provided below as an illustration.

In 1988, the World Health Assembly adopted resolution WHA41.28 committing to the global eradication of poliomyelitis.⁴⁴ At that time, polio paralysed more than 1000 children worldwide every day.⁴⁵ Following the Health Assembly, WHO, Rotary International, the US CDC, and UNICEF created the Global Polio Eradication Initiative (GPEI). “Since then, more than 2.5 billion children

⁴² In developing this study, the Secretariat examined materials and/or interviewed responsible officers for the following networks : WHO Emerging and Dangerous Pathogens Laboratory Network; WHO Global Influenza Surveillance and Response System; WHO Global Bacterial Vaccine Preventable Diseases Laboratory Network; WHO Global Polio Laboratory Network; WHO Global Task Force on Cholera Control; WHO HIV Drug Resistance Laboratory Network, WHO HPV Laboratory Network (LabNet); WHO Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) Laboratory Network; WHO Japanese Encephalitis Laboratory Network; WHO Measles and Rubella Laboratory Network; WHO Rotavirus Laboratory Network; WHO Tuberculosis Supranational Reference Laboratory Network; WHO Yellow Fever Laboratory Network.

⁴³ Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. Geneva: WHO; 2016 (http://www.who.int/csr/research-and-development/guidance_for_managing_ethical_issues.pdf?ua=1, accessed 24 November 2016).

⁴⁴ Resolution WHA41.28. Global eradication of poliomyelitis by the year 2000. In: Forty-first World Health Assembly, Geneva, 2-13 May 1988 (WHA41/1988/REC/28; http://apps.who.int/iris/bitstream/10665/164531/1/WHA41_R28_eng.pdf, accessed 31 October 2016).

⁴⁵ History of polio. In: Global Polio Eradication Initiative [website]. Geneva: GPEI; 2016 (<http://polioeradication.org/polio-today/history-of-polio/>, accessed 28 November 2016).

have been immunized against polio [...] backed by an international investment of more than US\$ 11 billion.”⁴⁶

“The most important strategies for eradication of polio are the immunization of every child under 5 years of age and having a strong surveillance system to rapidly detect cases of poliomyelitis when they arise.”⁴⁷ Established in 1990, the Global Polio Laboratory Network (GPLN) is primarily responsible for distinguishing “polio as a cause of acute flaccid paralysis (AFP) from diseases other than poliovirus”⁴⁸. In 2014, over 203 000 specimens were studied by laboratories in the GPLN, with more than 8500 poliovirus isolates characterized.⁴⁹

The GPLN consists of 146 laboratories within a three-tiered structure. Its primary purpose is to diagnose polio cases for rapid detection and response. The first tier, subnational and national laboratories, detect poliovirus in specimens collected from possible cases. Positive samples are then shared with the second tier, regional reference laboratories, that confirm whether the virus is type 1, 2 or 3, and differentiate wild-type and Sabin-like viruses. If the samples contain wild-type virus or have discordant results, they are sequenced to characterize and differentiate Sabin-like viruses from vaccine-derived polioviruses, where a vaccine virus has reverted to a virus that can cause paralysis. Some regional laboratories have this capacity; if not the sample is shared for sequencing and characterization with a third tier laboratory, one of seven global specialized laboratories based in the Finland, France, India, Japan, the Netherlands, United States, and the United Kingdom. Global specialized laboratories also prepare reference reagents, offer laboratory trainings and conduct research to support global polio eradication, among other activities.

Laboratories in the network are generally affiliated with either governmental or university institutions. Accreditation of the laboratories is done annually through a process of nomination, training and testing, and requires formal agreement by the national health authorities.⁵⁰ In order to be accredited, national polio laboratories must agree to send all poliovirus isolates from cases of AFP to regional reference laboratories for testing⁵¹. As all members of the network agree to share samples with each other, MTAs or MOUs are not used.

⁴⁶ History of Polio. In: Global Polio Eradication Initiative [website]. Geneva: GPEI; 2016 (<http://polioeradication.org/polio-today/history-of-polio/>, accessed 31 October 2016).

⁴⁷ Polio laboratory network. In: World Health Organization [website]. Geneva: WHO; 2016 (http://apps.who.int/immunization_monitoring/laboratory_polio/en/index.html, accessed 31 October 2016).

⁴⁸ The Global Polio Laboratory Network (GPLN). In: Global Polio Eradication Initiative [website]. Geneva: GPEI; 2016 (<http://polioeradication.org/polio-today/polio-now/surveillance-indicators/the-global-polio-laboratory-network-gpln/>, accessed 31 October 2016).

⁴⁹ Global Polio Eradication Initiative. The 21st Informal Consultation on the Global Polio Laboratory Network - Final report of recommendations. Geneva: GPEI; 2015 (http://polioeradication.org/wp-content/uploads/2016/07/GPLN_Meeting_recommendations_2015.pdf, accessed 31 October 2016).

⁵⁰ World Health Organization. National Polio Laboratory Check List for Annual WHO Accreditation. Geneva: WHO; 2003 (http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_ab_network_nationl_polio_labs_checklist.pdf, accessed 31 October 2016).

⁵¹ World Health Organization. National Polio Laboratory Check List for Annual WHO Accreditation. Geneva: WHO; 2003 (http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_ab_network_nationl_polio_labs_checklist.pdf, accessed 31 October 2016); criteria 4.

The ultimate benefit of GPEI is global eradication of polio. Therefore, countries participating in the initiative are provided with the necessary tools and support to achieve this goal. In addition to laboratory and surveillance support, GPEI supports thousands of polio workers worldwide; provides funds for vaccine procurement; works to ensure vaccine supply security; and provides support and technical assistance to Member States.⁵²

b. The implications of the Nagoya Protocol on the sharing of non-influenza pathogens

By defining requirements for access and benefit sharing, the Nagoya Protocol can provide a more structured framework for the sharing of pathogens. Interviews conducted during this study have highlighted current uncertainty with respect to legal terms for accessing pathogens, which has affected sharing of pathogens, as evidenced in recent outbreaks.⁵³ For instance, during recent public health emergencies of international concern (PHEICs), the international response was impacted by a lack of clarity over such questions as: which government entity could grant access to the pathogens, which entity became the custodian of the pathogens after transfer, whether intellectual property rights could be sought over the pathogens and whether benefit-sharing obligations were linked to access. The Nagoya Protocol encourages countries to answer those questions in advance and to involve the whole of government in creating laws, policies and strategies that address public health – including for the sharing of pathogens and access to benefits.

By promoting a more structured approach to pathogen sharing, the Nagoya Protocol has the potential to lead to the creation of more coordinated networks that share common public health goals and approaches, such as GISRS and GPLN. Over time, it has the potential to contribute to legal certainty regarding pathogen sharing.⁵⁴

By reinforcing principles of fairness and equity, the Nagoya Protocol also provides an opportunity for Member States to establish clear, pre-arranged benefit-sharing expectations arising from access to pathogens that will, in turn, contribute to strengthening public health response to infectious disease outbreaks. Negotiation of benefit sharing terms could result in improved access to affordable medicines and enhanced research capacities in developing countries, including the development of research projects that are better targeted to national priorities. Other public health benefits could include the development of a more robust pharmaceutical sector in developing countries and support for the education and training of technical staff. This in turn could strengthen public health systems in developing countries.

⁵² Global Polio Eradication Initiative. Financial Resource Requirements: 2013-2019. Geneva: GPEI; 2016 (http://polioeradication.org/wp-content/uploads/2016/10/FRR2013-2019_April2016_EN_A4.pdf, accessed 31 October 2016)

⁵³ World Health Organization. Information note on sample sharing, biobanking and material transfer agreements, Geneva: WHO (http://www.who.int/csr/research-and-development/information_note_on_sample_sharing.pdf?ua=1, accessed on 24 November 2016.)

⁵⁴ For instance, article 6(3) of the Nagoya Protocol states that “each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements; (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;”.

The Nagoya Protocol could, however, also pose challenges to pathogen sharing. As described above, *ad hoc*, bilateral sharing is currently informal. Thus a concern raised by some respondents is that the implementation of the Nagoya Protocol, and the resulting diversity of implementing legislations, could risk slowing or discouraging some sharing, if public health needs are not taken into account.

For coordinated networks, such as the poliovirus sharing system, implementation of the Nagoya Protocol could prove challenging to the already established multilateral pathogen sharing processes. The volume of sharing within certain coordinated networks may make it difficult and time-consuming to negotiate bilateral agreements for each specimen, thus potentially slowing the public health response.

Moreover, it was highlighted that bilateral agreements may not always be supportive of a common approach to handling a public health threat. For example, to support the common goal of global polio eradication, a country sharing a poliovirus sample might derive greater benefit from ensuring access to polio vaccines by polio-endemic countries rather than receiving a direct benefit, such as royalties. This was raised in several submissions, and respondents suggested a number of ways to promote public health while ensuring adequate benefit sharing in the context of global public health responses and goals. These are discussed in the following section.

V. Possible paths forward

Respondents proposed a number of options for advancing public health and for improving harmonization between the Nagoya Protocol and existing pathogen sharing systems. In this section we describe three types of proposals: a) establishing new “specialized international access and benefit-sharing instruments” under Article 4.4 of the Nagoya Protocol, or designating existing instruments as such; b) ensuring that implementing legislation is supportive of global public health; and c) promoting consultation, dialogue, public awareness and international collaboration. These proposals are summarized and presented below. It is expected that considerations of feasibility of these proposals will be the subject of discussions at the Executive Board.

a. Recognition of “specialized international instruments” under the Nagoya Protocol

Article 4 of the Nagoya Protocol covers the relationship between the protocol and other international agreements. Of particular relevance are Articles 4.3 and 4.4, which state:

Article 4.3: This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and

relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

Article 4.4: Where a specialized international access and benefit-sharing instrument applies that is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Under Article 4, the Nagoya Protocol will not apply to certain genetic resources, as long as they are covered by another specialized international instrument that is consistent with, and does not run counter to, the objectives of the CBD and the Nagoya Protocol. In other words, Article 4.4 can be understood as a recognition that Parties may enter into Nagoya-consistent international arrangements to facilitate access and benefit sharing on a large scale for specific classes of genetic resource.

The Nagoya Protocol does not list existing specialized international instruments, nor does it provide any details on the elements of such instruments or the process to recognize them. The FAO *International Treaty on Plant Genetic Resources for Food and Agriculture* (“Plant Treaty”)⁵⁵ is one instrument that is widely considered to fall under Article 4.4. Several Parties to both the Nagoya Protocol and the Plant Treaty have recognized the status of the Plant Treaty as a specialized international ABS instrument in their domestic implementing legislation or biodiversity laws.⁵⁶

Most submissions received during this study stated that the PIP Framework is consistent with the Nagoya Protocol. Many respondents also expressed the view that the PIP Framework is or should be considered an Article 4.4 specialized international ABS instrument. Recognition of the PIP Framework under Article 4.4 would clarify that the Nagoya Protocol’s requirements for bilateral *ad-hoc* access and benefit-sharing negotiation would not apply to IVPP shared through GISRS. This could promote ‘legal certainty’ with respect to such pathogens, strengthening the PIP Framework

⁵⁵ The Plant Treaty establishes a multilateral access and benefit-sharing system, which covers the “plant genetic resources for food and agriculture listed in Annex I, established according to criteria of food security and interdependence”. *International Treaty on Plant Genetic Resources for Food and Agriculture* art. 11.1, *entered into force* 29 June 2004, 2400 U.N.T.S. 43345. Text available at: <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>.

The preamble of the Nagoya Protocol clearly recognizes the fundamental role of the Plant Treaty in relation to the interdependence of all countries with regard to plant genetic resources for food and agriculture, their special nature and importance for achieving food security worldwide. The preamble also considers the multilateral ABS system established under the Plant Treaty to be in harmony with the CBD. Furthermore, decision 10/1 (2010) of the CBD COP, which adopted the text of the Nagoya Protocol, recognized that the Plant Treaty is one of the “complementary instruments” that constitutes the ABS regime along with the CBD, the Nagoya Protocol and the Bonn Guidelines. In addition, the Plant Treaty states that the objectives of the treaty are “in harmony with Convention on Biological Diversity”. *International Treaty on Plant Genetic Resources for Food and Agriculture* art. 1.1, *entered into force* 29 June 2004, 2400 U.N.T.S. 43345. Text available at: <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>.

⁵⁶ Examples of Parties that have recognized the Plant Treaty as a specialized instrument include: Australia, Ethiopia, France, India, Japan, Norway, Peru, Philippines, Switzerland, Uganda and the European Union.

mechanisms for virus and benefit sharing. Some respondents also stated the need for the PIP Framework to develop an ABS system for GSD to create ‘legal certainty’ around the sharing of this data. In addition, some suggested recognition of GISRS itself as an Article 4.4 specialised international instrument, pointing to the provision of risk assessment and laboratory products (such as CVVs) as benefits generated by the network. Submissions generally did not express a view on the method of recognition, although one Member State called for a formal designation by the Conference of the Parties Serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP).

Some submissions noted that implementation of the Nagoya Protocol is an opportunity to develop an agreement or framework for the sharing of pathogens that affect human health and the equitable distribution of benefits arising from their use, with the aim of having the agreement recognised as an Article 4.4 specialized instrument. Several submissions noted that such an agreement should be negotiated under the auspices of WHO.

In relation to this, the IHR Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response recommended in 2016 that the Secretariat and States Parties

consider using the PIP Framework or similar existing agreements as a template for creating new agreements for other infectious agents that have caused, or may potentially cause, PHEICs.⁵⁷ These agreements should be based on the principle of balancing the sharing of samples and data with benefit-sharing on an equal footing.⁵⁸

b. Developing implementing legislation that supports public health

Many respondents shared perspectives on how to develop domestic legislation that is supportive of public health.

First, some respondents set out general principles for developing implementing legislation. A few Member States highlighted the importance of ensuring that implementing legislation include full consultation and engagement with all stakeholders as well as better collaboration between relevant government ministries, such as health, environment, and agriculture. Key principles suggested for implementing legislation included: (1) legal clarity regarding scope and application, (2) timely access and benefit sharing for all, without preference for domestic users and (3) protection of public health initiatives.

⁵⁷ Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. Geneva: World Health Organization; 2016 (A69/21; http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf).

⁵⁸ Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. Geneva: World Health Organization; 2016 (A69/21; http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf): 31.

1. Article 8b: Special consideration during health emergencies

The Nagoya Protocol recognizes the need for special ABS processes in relation to health emergencies.

Article 8(b): In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: (b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.

Article 8(b) requires Parties to pay due regard to “present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally” when developing ABS legislation. Under this provision, Parties could, for example, develop special ABS measures for use during health emergencies in order to support timely and equitable public health responses, including access to affordable treatments to those in need, especially in developing countries.

Many respondents stated that implementing legislation should operationalise Article 8(b) to facilitate and ensure rapid access to pathogens that threaten public health in actual or likely emergency situations while ensuring equitable benefit sharing. It was mentioned that rules developed under Article 8(b) could also encompass pathogens outside of an acute emergency.

Under the principles of Article 8(b), respondents proposed various levels of exemption or special rules for pathogens. These ranged from a suggested “blanket exemption” for all pathogens that affect human health to a system in which decisions were made on a case-by-case basis, with rules based on the characteristics of each pathogen. To facilitate due diligence it was suggested that pathogens obtained from WHO be accompanied by assurances “that users are entitled to utilize the samples on acceptable terms”.

2. Model contractual clauses, codes of conduct, guidelines, best practices and standards

Article 20.1 of the Nagoya Protocol provides: “Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.”

Article 20.1 could further be used as the basis for developing a code of conduct for pathogen sharing; codifying some of the practice that WHO has been using in advising parties entering into bilateral MTAs or MOUs, as well as for the terms of operation of co-ordinated networks.

Several Member States suggested using Article 20 to promote access to pathogens used for public health purposes, particularly when such use was non-commercial. It was also suggested to develop simplified and accelerated processes to obtain PIC and MAT for pathogens with a significant public health impact, including the use of standard templates, as encouraged under Article 19 of the Protocol.

One Member State suggested the creation of a “fast track” or “exception committee” under the Nagoya Protocol “for specific scenarios regarding pathogenic diseases with severe public health implications”, which would balance global public health needs with appropriate benefit sharing.

a. Consultations

Finally, many respondents suggested that WHO and Member States promote dialogue, consultation and public awareness of the issues around the Nagoya Protocol and pathogen sharing. Such efforts could include the elaboration of possible new specialized international instruments for pathogens.

Several respondents called for international coordination on the implementation of the Nagoya Protocol, including the negotiation of pre-arranged terms for sharing with all parties, for instance through pre-drafted standard contractual templates for all transactions. Several respondents suggested a WHO-led effort to harmonize national implementing legislations to ensure that such laws are consistent with public health.

A few respondents suggested adding agenda items to future WHO meetings to further discuss the public health implications of the Nagoya Protocol. Others highlighted the importance of ensuring public health is a consideration at meetings of the COP-MOP. It was suggested that WHO liaise with Member States and other relevant entities to:

- build ties between public health entities and those involved in implementation of the Nagoya Protocol;
- raise public awareness of the PIP Framework and Nagoya Protocol;
- and resolve key issues in implementation, such as the handling of GSD and protection of intellectual property rights.

Taken as a whole, responses to this study reflect a view that access to pathogens should be governed by an approach that promotes the timely access to pathogens for global health purposes and the fair and equitable sharing of the resulting benefits. Consistent with this view, the Nagoya Protocol provides normative tools to promote efficient and equitable international access and benefit-sharing arrangements for pathogens, including through the development of specialized international instruments, the recognition of emergencies that threaten human health, and the promotion of international collaboration.

Member States may wish to consider the utility of such tools, as well as next steps for addressing the public health implications of the Nagoya Protocol, taking into account relevant developments, including the report of the 2016 PIP Framework Review Group⁵⁹.

⁵⁹ See document EB140/16.

Annex 1 - Methodology

Preparation of this analysis involved a multi-pronged approach to gather information. The preliminary stage involved a review of the Nagoya Protocol, existing pathogen sharing practices known to the Secretariat, as well as instruments that regulate or have a bearing on such practices, including WHO instruments such as the Pandemic Influenza Preparedness Framework (PIP Framework) and the International Health Regulations (2005) (IHR).

This was followed by a call to WHO and Convention on Biological Diversity (CBD) Member States for written responses to a set of broad questions, circulated to the permanent missions of WHO Member States in Geneva and, through the kind collaboration of the Secretariat of the CBD, to national focal points for the CBD and for the Nagoya Protocol. The questions sought Member States' opinions on the potential implications of the Nagoya Protocol on the sharing of pathogens and the possible actions that could be taken to address these implications. The questions were also circulated to laboratories in the Global Influenza Surveillance and Response System (GISRS), the primary global network for the sharing of influenza pathogens.

In parallel, in-person and telephone interviews were conducted with key stakeholders and experts. To facilitate discussion, these interviews were based on the same set of broad questions put to Member States.

The oral and written input received in response to these questions have been used throughout the report.