World Health Organization

EXECUTIVE BOARD **EB148/21**
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The public health implications of implementation of the Nagoya Protocol

Report by the Director-General

1. This report is submitted pursuant to decision WHA72(13) (2019), in which the Seventy-second World Health Assembly requested the Director-General to broaden engagement with Member States, the Secretariat of the Convention on Biological Diversity,[1] relevant international organizations and relevant stakeholders: (1) to provide information on current pathogen-sharing[2] practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications; and (2) to provide a report to the Seventy-fourth World Health Assembly, through the Executive Board at its 148th session. The Executive Board considered an interim report on implementation of decision WHA72(13) at its 146th session.[3]

2. Insofar as the emergence and spread of the SARS-CoV-2 virus, which causes COVID-19, has highlighted the importance of rapid pathogen sharing in the context of public health emergencies, this report includes a section that focuses specifically on cooperation across countries in sharing the SARS-CoV-2 virus and the SARS-CoV-2 genetic sequence data, and the WHO COVID-19 Reference Laboratory Network.

BACKGROUND

3. Timely sharing of pathogens, their genetic sequence data and relevant metadata is of paramount importance in enabling early identification, sound risk assessment, initiation of evidence-based interventions and the subsequent development and deployment of countermeasures such as diagnostics, vaccines and therapeutics. Establishing mechanisms for fair and equitable sharing of the benefits arising from the utilization of the concerned resources has become a central element of ensuring expedited pathogen sharing.

4. The Nagoya Protocol to the Convention on Biological Diversity[4] is an international agreement whose objective is the fair and equitable sharing of the benefits arising from the utilization of genetic

[1] The WHO Secretariat has worked closely with the Secretariat of the Convention on Biological Diversity throughout the implementation of decision WHA72(13), including on developing the all-stakeholder survey, participation in joint stakeholder briefings, drafting the interim report and collaborative stakeholder outreach.

[2] For the purposes of this report, the term "pathogen sharing" refers specifically to physical sample sharing. Where the text discusses non-physical samples (i.e. genetic sequence data), this is noted explicitly.

[3] Document EB146/19.

[4] 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: text and annex. Montreal: Secretariat of the Convention on Biological Diversity; 2011 (https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf, accessed 27 October 2020).

resources. The Protocol aims, through the establishment of national legal frameworks, to create legal certainty and benefit-sharing mechanisms for the users and providers of genetic resources. Under the Protocol, genetic resources may be accessed subject to the "prior informed consent" of the country providing the resources and once "mutually agreed terms" have been reached that include the fair and equitable sharing of the benefits arising from the utilization of the concerned resources.

5. Under the Nagoya Protocol, the term "genetic resources" means "genetic material of actual or potential value". "Genetic material" in turn means "any material of plant, animal, microbial or other origin containing functional units of heredity", which has generally been understood to include human pathogens. Importantly, the Protocol in its Preamble recognizes the International Health Regulations (2005) and "the importance of ensuring access to human pathogens for public health preparedness and response purposes". Many WHO Member States have international and/or domestic obligations regarding access and benefit sharing, including under the Nagoya Protocol for those Member States that are also Parties to the Protocol.

APPROACH TO IMPLEMENTATION OF DECISION WHA72(13)

6. Following the adoption of decision WHA72(13) in May 2019, the WHO Secretariat took a coordinated approach across its divisions and sought input from all technical units that may have had experience with or knowledge of human pathogen sharing, including the Secretariat of the Pandemic Influenza Preparedness (PIP) Framework, focal points for the International Health Regulations (2005), and the food safety and communicable disease teams. The WHO Secretariat also contacted Member States, its partners and other stakeholders, including the Secretariat of the Convention on Biological Diversity, United Nations agencies, funds and programmes such as the FAO, other international agencies such as the OIE, and civil society and public sector entities. These engagements were both formal – including two all-stakeholder briefings in late 2019 – and informal, and continued throughout 2020.

7. To ensure a broad reach in collecting data on current human pathogen-sharing practices and arrangements and implementation of access and benefit-sharing measures, as well as opinions on the public health implications of both, the WHO Secretariat, in consultation with its partners, developed a survey, open to all stakeholders. The survey was designed to collect quantitative and qualitative data through a multiple choice questionnaire and written responses. In addition to relevant internal units of the WHO Secretariat, the Secretariat of the Convention on Biological Diversity provided input to the survey, while various international organizations, including the FAO and the OIE, and external experts, including members of the Pandemic Influenza Preparedness Framework Advisory Group, were consulted.

8. The survey was made available on the WHO website to all stakeholders in English, French and Spanish; the English version was posted on 10 December 2019, the other languages on 20 December 2019. WHO contacted Member States, WHO collaborating centres, non-State actors in official relations with WHO, partner agencies, laboratories and laboratory networks, and private sector stakeholders to alert them to the opening of the survey. The Secretariat of the Convention on Biological Diversity issued a notification to all Parties to the Convention to encourage them to participate.[1] Stakeholders were reminded of deadlines and, following an extension, were given until 13 March 2020 to submit answers.

[1] Notification – Survey on pathogen sharing, including for influenza, and access and benefit-sharing arrangements. Montreal: Secretariat of the Convention on Biological Diversity; 27 January 2020 (SCBD/NPU/DC/WY/BG/RKi/88360; https://www.cbd.int/doc/notifications/2020/ntf-2020-012-abs-en.pdf, accessed 30 November 2020).

RESULTS OF THE ALL-STAKEHOLDER SURVEY

9. WHO received 118 complete and 3133 incomplete responses to the survey, for a total of 3251 responses. In addition to the quantitative questions, respondents submitted over 300 pages of text containing additional information. Of the more than 3000 responses, 353 submissions contained information on the identity of the respondent; these included 81 responding as countries, 46 as non-State entities, 174 as individuals and 52 as "others" (laboratories, international organizations, or individuals). The survey was a qualified success – qualified because, while it is clear from the thousands of responses that many stakeholders were aware of and interested in the survey, only 118 completed the process. This may partly be due to the fact that the COVID-19 crisis emerged in January 2020, mid-way through the survey process, resulting in competing priorities for all stakeholders.

10. With such a small sample size, it is difficult to draw broad conclusions from the quantitative data. However, the qualitative replies provide a snapshot of experiences and from these it is possible to garner a greater understanding of the landscape of pathogen sharing and access and benefit-sharing arrangements, and some of the implications for public health.

Current pathogen-sharing practices and arrangements

11. There are various pathogen-sharing arrangements, as noted by partners working across the range of human pathogens. The questionnaire requested information on bilateral arrangements, formal professional networks, formal academic networks, informal networks and laboratory-to-laboratory sharing, as well as providing the opportunity to identify other mechanisms. The present report focuses on human pathogen sharing, although numerous examples were provided of non-human (both animal and plant) pathogen-sharing arrangements. Where respondents provided information on the sharing of genetic sequence data, the report also includes a summary of this information.

12. Survey respondents noted that bilateral pathogen sharing for research and development cooperation includes access to specific strains for quality control or for research or assay validation activities. The entities involved include academic institutions, reference laboratory networks, national public health agencies, and international or intergovernmental agencies. Arrangements may involve partnerships between research institutions for specific projects or requests for sharing by an agency such as WHO or its regional offices. Collaborative research agreements exist between government agencies both within countries (such as between the Public Health Agency of Canada and the Canadian Food Inspection Agency) or between countries (such as Porton Down in the United Kingdom of Great Britain and Northern Ireland and the United States Army Medical Research Institute of Infectious Diseases). Many of these approaches include a bilateral material transfer agreement and/or collaboration agreement establishing the terms for pathogen sharing. Some countries indicated that they share materials under the International Health Regulations (2005).

13. Examples of pathogen sharing for research and development cooperation include: live Zika virus sent from the Centers for Disease Control and Prevention (United States of America) to the Robert Koch Institute (Germany), applying the material transfer agreement developed by the Global Health Security Action Group Sample Sharing Task Group; sharing of all available information on analyses of wild birds (more than 15 000) with the WHO Regional Office for the Eastern Mediterranean during the avian influenza outbreak in Egypt, under the International Health Regulations (2005); bilateral sharing of human pathogens with the reference laboratory for invasive infection control in the Korea Centers for Disease Control and Prevention in the Republic of Korea to detect serotyping between 2009 and 2016; and sharing by the Central Public Health Laboratory (a WHO-accredited national reference laboratory

and the national influenza centre for Afghanistan) of pathogen samples to support a surveillance programme for confirmation of suspected outbreaks across Afghanistan.

14. Respondents noted that professional networks, such as the European Culture Collections' Organisation and the World Federation for Culture Collections, play an important role in providing overarching infrastructure and standards for (primarily microbial) biological material exchange, including of pathogens. Proficiency testing schemes (such as the national external quality assessment scheme in the United Kingdom) were also cited. Examples of academic and non-profit networks that facilitate human pathogen sharing include the European Virus Archive network; phylogenetic analysis in research programmes; multilateral, multi-facility surveillance studies of multidrug-resistant bacteria; and studies on extended-spectrum beta-lactamase producing *E.coli* (such as the one between Mauritius and the Centre Hospitalier Universitaire de La Réunion).

15. In general, pathogen sharing takes place between laboratories of similar diagnostic background or biosafety level in a network. One of the most prominent of these, the WHO-coordinated Global Influenza Surveillance and Response System (GISRS), was mentioned several times. Several similar networks were also highlighted, such as the Emerging Viral Diseases-Expert Laboratory Network; the WHO Measles and Rubella laboratory network; the Administración Nacional de Laboratorios e Institutos de Salud in Argentina; the East Central Southern African Health Community regional tuberculosis laboratory network; the Biosafety Level 4 Zoonotic Laboratory Network and the European Network of Biosafety-Level-4 laboratories; the Arbovirus Diagnosis Laboratory Network of the Americas; the Latin American quality control programmes in bacteriology, tuberculosis, microbiology and antimicrobial resistance; and the European Non-Polio Enterovirus Network.

16. Databases that store and make genetic sequencing data available were also identified as being sharing mechanisms. The GISAID Initiative, originally known as the Global Initiative on Sharing All Influenza Data, was mentioned several times, as was GenBank. Genetic sequence data for foodborne pathogens are routinely shared through the International Nucleotide Sequence Database Collaboration and the Pathogen Detection Reference Gene Catalog, which links large member networks (the European Molecular Biology Laboratory, the DNA Data Bank of Japan and the United States National Center for Biotechnology Information), enabling them to share their data. The National Center for Biotechnology Information hosts the Pathogen Detection website, which is a freely available repository for the genetic sequence data of foodborne pathogens and their associated metadata.

17. Regarding informal mechanisms, comments by respondents to the survey referenced global initiatives such as the Global Microbial Identifier pathogen-tracking initiative, and pathogen sharing via colleagues working in the medical, laboratory and microbiology fields. It was emphasized that the distinction between informal networks and laboratory-to-laboratory sharing is blurred as pathogens and other biological materials are routinely shared between academic, public, and private sector laboratories as a result of personal and/or professional relationships, research collaborations, and so on. This sharing typically takes place under a material transfer agreement that addresses the terms and conditions for sample transfer.

Implementation of access and benefit-sharing measures

18. Though the numbers were small (n=21), the majority of responding Member States indicated that they have access and benefit-sharing legislation and/or regulations; of these, 11 specifically include

pathogens.[1] There was a split between countries whose legislation includes both physical samples and genetic sequence data and those whose legislation applies only to physical samples. Some countries indicated that they had received benefits from sharing pathogens, while others indicated that they had not.

19. Member States and non-State actors emphasized that access and benefit-sharing arrangements are common between collaborating laboratories, and may include access to high containment facilities; resultant data and materials are shared according to the terms of an agreement. Arrangements cover patents, technology transfers, shared publication authorship and ownership (arrangements regarding authorships in future publication are often established in material transfer agreements), and isolate sharing between institutes or networks with material transfer agreements in place. In one example, the material transfer agreements that facilitate the sharing of Nipah virus and hepatitis E virus samples include provisions stipulating that the centres concerned will use the viral strains to implement in-house diagnostic tests in symptomatic travellers returning from endemic areas. Respondents also noted that they understood seasonal and pandemic influenza vaccine distribution to qualify as benefit-sharing.

20. Responses to the survey indicated that networks often share isolates under terms that define access and benefit sharing. Here again, the GISRS was commonly cited. Other examples included the European Virus Archive Global Consortium laboratories, which share viral strains isolated from clinical samples in exchange for being supplied with other viral strains and reagents free of charge, and the Sierra Leone Ebola biobank established in partnership with Sierra Leone, which has as its overarching principle ensuring that the people of Sierra Leone benefit from the arrangement.

21. Most respondents indicated that different pathogens are treated differently, either under national legislation or in access and benefit-sharing arrangements. Arrangements may differ depending on the biohazard level of the pathogen and/or whether it is of human, animal, or plant origin. For instance, there are higher sensitivities with regard to the sharing of Ebola or influenza than the sharing of *E.coli*, campylobacter, listeria or salmonella, and therefore they are treated differently. In the United Kingdom, for example, some high-consequence pathogens can only be held by certain organizations under Advisory Committee on Dangerous Pathogens guidance and anti-terrorism legislation, and access/benefit sharing is usually on a case-by-case basis. The United States similarly categorizes pathogens according to their perceived level of threat; transfer of pathogens between laboratories can be made more restrictive according to categorization. Countries may also restrict export controls for higher-risk pathogens. Several respondents noted that as benefit-sharing provisions are often focused on non-monetary returns, capacity building, training, and information exchanges will be more or less important depending on the pathogen itself and on the needs of the different stakeholders.

22. Animal pathogens are often treated differently to human samples. Reponses indicated that it is easier to access samples from animals (non-human primates, for example) than those from humans, which are more strictly controlled. One example mentioned was the sylvatic yellow fever outbreak in Brazil, when obtaining access to human samples was challenging. This may also have an impact on which laboratories are used. For instance, information and material from some zoonotic pathogens (such as MERS-coronavirus) are sent to human medical reference laboratories, while material from some animal pathogens (such as foot-and-mouth disease virus) are sent to veterinary diagnostic laboratories.

[1] For additional information on relevant legislation, see the WHO study on legislative and regulatory measures related to influenza, prepared pursuant to decision WHA72(12) (operative paragraph 1(b)), available at https://www.who.int/influenza/pip/governance/wha72-12/en/ (accessed 27 October 2020).

23. Inactivation may also play a role in facilitating sharing: one respondent reported receiving vials of Nipah virus and hepatitis E virus samples in Virkon, a pathogen inactivation media used under Australian Department of Agriculture quarantine requirements.

Potential public health outcomes and other implications of pathogen-sharing arrangements and the implementation of access and benefit-sharing measures

24. Many respondents indicated that newly emerging pathogens have to be shared speedily to enable fast classification and characterization, and that minimizing the public health and economic risks associated with outbreaks is tied closely to transparency and timely pathogen sharing. There was an overall view in received responses that pathogen sharing is positive for public health if well-regulated and transparent, and if the benefits are agreed by and shared among both the data generators and receivers. Similarly, there was convergence that pathogen sharing enables multijurisdictional and international outbreak investigations and improves the quality of laboratory surveillance, which can provide immense benefits in relation to: research and development; validations of diagnostic tests in public health emergencies; transfer of technologies and expertise, including through opportunities for laboratories to work with pathogens to which they would not ordinarily have access; and due recognition and protections for the source provider. On the other hand, some respondents pointed out that barriers to rapid pathogen sharing can potentially have negative public health outcomes and implications.

25. The survey asked respondents to comment on arrangements that eased or created challenges to pathogen sharing and tracking. Respondents in general noted that pathogen sharing is easier where bilateral agreements are already in place between institutions and the researchers know and trust each other. The Global Health Security Initiative has developed a voluntary material transfer agreement to facilitate the rapid sharing of non-influenza biological materials among members during a potential or actual public health emergency. This mechanism was used during the Zika outbreak and is being used for the sharing of physical samples of SARS-CoV-2.

26. Respondents noted other key aspects of efforts to ensure easier pathogen sharing, including clear communication and transparency between stakeholders in carrying out the transfer of materials; clear definition of roles and responsibilities; and specific regulatory frameworks or material transfer agreements affecting both parties involved in the transfer of the material. Transfers under the PIP Framework or transfers where laboratories take the time to understand and then follow national access and benefit-sharing legislation are generally considered to be successful. The use of courier companies was highly recommended.

27. Issues noted by respondents that make human pathogen sharing challenging include the absence of a harmonized system across countries and unclear domestic guidelines, exacerbated by recipient laboratories that are not aware of, do not have time to understand or do not comply with access and benefit sharing arrangements. Additionally, lack of awareness of the Nagoya Protocol and its requirements, and the individualized implementation mechanisms unique to each State Party to the Protocol, complicate the landscape.

28. More general concerns reported include bureaucratic delays; overlapping, conflicting or unclear processes for customs clearance and other regulatory requirements; lack of international couriers capable of handling shipments; multiple levels of approvals needed for sharing with external parties; lengthy

negotiations; lack of procedures for unified national biosafety regulations and related lack of harmonization across jurisdictions; language barriers; and restrictions regarding dual use.[1]

29. Some respondents noted that the ease or difficulty of accessing physical samples of pathogens in a given country – including the potential for delays and legal uncertainty associated with access and benefit-sharing compliance, and tracking use – may affect research, clinical trials, and other business and research choices.

30. The survey asked respondents to consider whether pathogen-sharing arrangements and access and benefit-sharing agreements should differentiate among pathogens. While a few respondents indicated that procedures should be the same for all pathogens, most agreed that approaches should be pathogen-specific to address the need for immediate sharing of pathogens which pose higher threats to public health. In regard to differentiating between pathogens, factors identified include: risk/benefit; biosafety or containment level; infectivity/ contagion/R_0; mode of transmission; rate of mutation; impact on/threat to public health, especially pandemic potential; and travel and trade restrictions or social, economic and environmental factors. It was noted, however, that classification is challenging: some pathogens occur in multiple different strains that change continuously over time and region by region; some may pose a higher threat to some regions than others; and some, like antibiotic-resistant bacteria, might have a relatively low biosafety level but still pose an urgent public health threat. Other respondents noted that classifying or separating pathogens by type would prove difficult, particularly considering the cases of emerging pathogens (such as SARS-CoV-2) whose characteristics are not fully known at the moment they cause an outbreak.

31. Nearly all responses indicated that genetic sequence data should be differentiated from physical sample sharing, noting that benefit to public health is linked to the ability to share sequences almost instantaneously across the world at no cost. Respondents particularly highlighted differences due to the risks of handling physical samples; the broader potential for sharing genetic sequence data; and the huge logistic differences (relating to biosafety and biosecurity, cold-chain storage equipment, qualified personnel, correct certificates and adequate transportation). Nonetheless, it was also noted that sharing gene sequences can be more complex than sharing physical samples because of the difference in scale and the ease and multiple ways of sharing, altering and re-sharing. With genetic sequence data, the implications for sharing or making that data publicly available are more to do with ensuring appropriate credit for the work and data privacy issues.

32. It was also noted that so far it has not been possible to identify a feasible way of tracking genetic sequence data, as current audit systems do not allow monitoring of the uses made of sequence data downloaded from public databases. In addition, genetic sequence data cannot completely replace physical material, which is needed for assay validations and comparisons. Genetic sequence data and physical pathogen samples can serve quite different functions for public health: genetic sequence data form the bases of rapid response surveillance tools that can provide a high-resolution view of pathogen evolution, which is particularly important in outbreak situations, while physical pathogen samples may be essential for assessing the potential of any medical products for pathogen outbreaks.

[1] Dual use research of concern is life sciences research that is intended for benefit, but which might easily be misapplied to do harm.

CONNECTIONS WITH THE IMPLEMENTATION OF WHA72(12)

33. In addition to adopting decision WHA72(13), the Seventy-second World Health Assembly also considered the Nagoya Protocol and its public health implications in decision WHA72(12). The decision focused on two aspects of influenza virus sharing and associated public health considerations: influenza virus sharing through the GISRS,[1] on the one hand, and the treatment of influenza virus sharing in existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol,[2] on the other. In implementing decision WHA72(12), WHO gathered data from GISRS and non-GISRS laboratories (including private sector entities) to enable a deeper understanding of the challenges, opportunities and implications for public health associated with influenza virus sharing. This process included identifying specific instances in which influenza virus sharing was hindered and seeking ideas on how to mitigate delays in virus sharing. WHO produced a report on influenza virus sharing that specifically addressed the request made in paragraph 1(a) of decision WHA72(12).[3]

34. It is worth noting that, like many of the respondents to the survey developed as part of the implementation of decision WHA72(13), respondents to the survey on pandemic influenza sample sharing also noted that implementation of access and benefit-sharing legislation, such as that on the Nagoya Protocol, has slowed sample sharing between GISRS laboratories and some countries and WHO collaborating centres in the past two years. Most cases required lengthy bilateral negotiation of a material transfer agreement between a national influenza centre and a WHO collaborating centre. New legislation created uncertainty for national influenza centres and national focal points due to a lack of clarity about access and benefit-sharing or Nagoya Protocol requirements. The report noted that delays in virus sharing caused by new legislation and regulations took six to nine months to resolve or remained unresolved as of December 2019 (paragraph 15). There have also been delays in the case of non-GISRS laboratories. For vaccine producers, recent legislation implementing the Nagoya Protocol has posed a challenge for the timely receipt and use of candidate vaccine viruses (paragraph 19).

35. In the influenza context, lengthy delays in virus sharing due to national access and benefit-sharing and Nagoya Protocol requirements have implications for public health because they jeopardize the vaccine virus selection process, the timely development of candidate vaccine viruses and access to vaccines. Navigating a system in which each country has different access and benefit-sharing requirements that must be negotiated bilaterally is burdensome and inefficient, and could cause inequities in benefit sharing and limit virus access for research and development of improved influenza vaccines.

36. As part of its work to implement decision WHA72(12), the WHO Secretariat also conducted a systematic review of all laws and policy documents that deal with influenza virus sharing and that were available in the Convention on Biological Diversity Access and Benefit-Sharing Clearing-House.[4] For each WHO Member State and the European Union entries tagged in the Clearing-House as "legislative, administrative, or policy measures" (instruments) were reviewed. Each instrument was then coded to identify if and how genetic resources were defined in the law or policy instrument. This analysis covered express consideration of pathogens, influenza viruses (both seasonal and those with human pandemic

[1] See paragraph 1(a) of decision WHA72(12).

[2] See paragraph 1(b) of decision WHA72(12).

[3] See paragraph 7 of the report, which is available at https://www.who.int/influenza/pip/governance/WHA72-12-OP1a-Report-Edited_EN.pdf?ua=1 (accessed 27 October 2020).

[4] The Access and Benefit-Sharing Clearing-House. Montreal: Convention on Biological Diversity; 2020 (https://absch.cbd.int/, accessed 27 October 2020).

potential) and genetic sequence data. Each instrument was also coded to determine whether it made reference to instruments relevant to influenza virus sharing and public health, including the PIP Framework and the International Health Regulations (2005), as well as whether the instrument incorporated relevant provisions under the Nagoya Protocol, including recognition of specialized international access and benefit-sharing instruments (pursuant to Article 4(4) of the Nagoya Protocol) and special considerations (Article 8(b)).

PATHOGEN SHARING IN THE CONTEXT OF THE COVID-19 PANDEMIC

37. Following the detection of SARS-CoV-2 virus, which causes COVID-19, genetic sequence data were made available by being uploaded to the GISAID Initiative database and a number of other databases, including GenBank and virological.org. Large-scale, rapid, geographically dispersed sharing of SARS-CoV-2 sequences has generally occurred during the pandemic, with depositions into GISAID being made from laboratories in over 100 Member States.

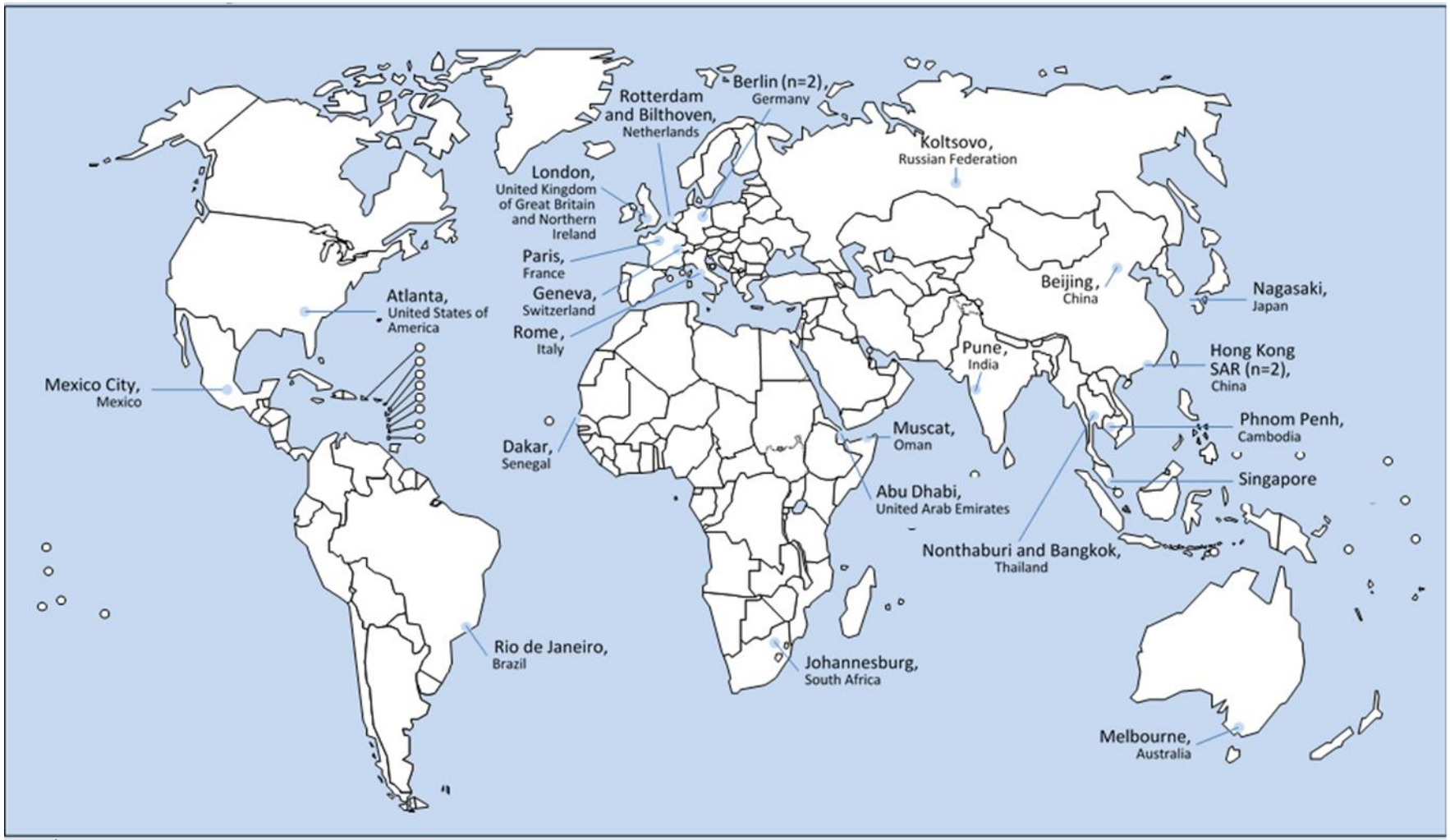
38. As an urgent response to the public health needs arising from the COVID-19 outbreak, WHO established the WHO COVID-19 Reference Laboratory Network (see Fig.). Each laboratory in the Network has agreed to: support capacity building of laboratories, particularly those in low- and middle-income countries, for diagnosis of COVID-19; provide a global reference resource of well-characterized viral strains and sequences; track the evolution of the virus causing COVID-19 and identify changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment; and develop and implement state-of-the art methods and develop assays to perform the laboratory's tasks arising from its participation in the Network. They also agree to limitations on the use of the virus and its sharing, to treating all virus materials and clinical samples as confidential and proprietary to the providing country, and to ensure that materials are not transferred or provided to any third party, unless clear standards are met.[1]

39. Between 28 January and 11 June 2020, the reference laboratories in Abu Dhabi (United Arab Emirates), Atlanta (United States of America), Beijing (China), Berlin (Germany), Bilthoven (Netherlands), Dakar (Senegal), Geneva (Switzerland), Hong Kong SAR (China), Johannesburg (South Africa), Koltsovo (Russian Federation), London (United Kingdom), Melbourne (Australia), Mexico City (Mexico), Muscat (Oman), Nagasaki (Japan), Paris (France), Phnom Penh (Cambodia), Pune (India), Rio de Janeiro (Brazil), Rome (Italy), (Netherlands) and Singapore, received 100 shipments of specimens (multiple specimens per shipment) from the following 61 countries:

> Afghanistan, Albania, Algeria, Bahrain, Belarus, Belize, Bosnia and Herzegovina, Burkina Faso, Cameroon, Colombia, Comoros, Costa Rica, Côte d'Ivoire, Cyprus, Czech Republic, Democratic Republic of the Congo, Estonia, Eswatini, Ethiopia, Fiji, Guatemala, Iceland, India, Islamic Republic of Iran, Jamaica, Kazakhstan, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Liberia, Lithuania, Luxembourg, Mauritius, Mongolia, Mozambique, Nepal, New Zealand, Niger, Nigeria, North Macedonia, Pakistan, Paraguay, Qatar, Republic of Moldova, Romania, Serbia, Slovakia, South Africa, South Sudan, Sri Lanka, Sudan, Tajikistan, Timor-Leste, Tunisia, Uganda, Ukraine, Uzbekistan, Viet Nam and Zimbabwe.

[1] The terms of reference for WHO reference laboratories providing confirmatory testing for COVID-19 are available at https://www.who.int/publications/m/item/terms-of-reference-for-who-reference-laboratories-providing-confirmatory-testing-for-covid-19 (accessed 27 October 2020).

Fig. WHO COVID-19 reference laboratory network as of 29 April 2020 (n=26)



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Data source: **World Health Organization**
Map production: **WHO Health Emergencies Programme**

40. Details of the development of COVID-19 diagnostics, therapeutics and vaccines, all of which are driven by access to the SARS-CoV-2 virus, are available on the Access to COVID-19 Tools Accelerator website.[1]

ACTION BY THE EXECUTIVE BOARD

41. The Executive Board is invited to note this report and consider recommending that the Health Assembly request the Secretariat to 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.

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[1] See https://www.who.int/initiatives/act-accelerator (accessed 10 December 2020).