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Diagnosis for all

Policy brief

Diagnostics & the Nagoya Protocol

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Relevance of the Nagoya Protocol to diagnostics

The Nagoya protocol is an international agreement, supplementary to the United Nations Convention on Biological Diversity.[1] It provides a legal framework designed to ensure that the benefits arising from the utilization of genetic resources and associated traditional knowledge are shared in a fair and equitable way with the contributor. The Nagoya Protocol was adopted in 2010 and entered into force in 2014. However, the Nagoya protocol itself does not have the force of law; each nation retains the authority to determine the legal obligations of parties to genetic resource access, irrespective of their endorsement of the Nagoya Protocol.

Although there is no established definition of genetic resources, they can be considered to be any plant, animal or microbial materials, excluding human genetic material, that have value for research and development across any sector, including medical and public health innovation. Genetic resources can include samples of a pathogen from infected individuals or environmental sources, which can directly inform the design and improvement of diagnostics for that pathogen. Biobanks of high-quality, well-characterized biological samples play an important role in the development and validation of diagnostic tools.

Benefits from the use of genetic resources can arise when research results in the development of a product for commercial use, such as a diagnostic assay. Countries have a right to regulate access to their genetic resources by requiring users to negotiate mutually agreed terms for sharing of advantages or profits derived from their use, prior to access. This concept is known as 'access and benefit sharing'. Benefit sharing can be monetary, such as provision of royalties or supplies of commercialized product, or non-monetary, such as the sharing of research results. FIND is committed to full compliance with national benefit sharing legislation in the countries where our biobanking activities are conducted.*

Access to diagnostics in LMICs is severely limited, with only 19% of populations having access to the simplest diagnostic tests beyond HIV and malaria at the primary care level.[2] Ensuring that low- and middle-income countries (LMICs) that contribute genetic resources share in the benefits of subsequent commercialization could contribute to greater availability of diagnostics, leading to improved patient and public health outcomes.

Digital sequence information and the Nagoya Protocol

Unlike other genetic resources, digital sequence information (DSI) is typically held in online open-access databases, disconnecting use from physical access. Because of this, DSI represents a loophole in the Nagoya Protocol. Many countries understand that DSI downloaded from public databases is not subject to the Nagoya Protocol, while many LMICs believe their sovereign rights have been undermined, as potential monetary gains from DSI through commercialization have not been shared with them, as they would have been with other genetic resources.[3,4]

DSI is essential to research and development, and to fulfilling the aims of global public health targets such as the United Nations Sustainable Development Goals. For example, access to SARS-CoV-2 viral genome sequences, primarily from the GISAID (Global Initiative on Sharing All Influenza Data) initiative, which now contains over 16 million SARS-CoV-2 genomes, enabled the rapid development of diagnostic PCR assays and subsequently PCR kits for large scale testing during the COVID-19 pandemic. GISAID has developed a Database Access Agreement (DAA) that issues licenses for the use of data and includes benefit sharing, including acknowledgement of the source of data.[5] Collection of DSI is also used to inform public health surveillance on variants of concern or drug resistance, making it critical for preventing, detecting, and responding to disease outbreaks. As such, the World Health Organization (WHO) encourages the sharing of pathogen genome data to protect global public health.[6] The WHO principles for sharing pathogen genome data focus on collaboration between contributors and researchers, acknowledgement and intellectual credit, and equitable access to health technologies as a benefit.

*To ensure this, we rigorously analyze the access and benefit sharing legislation of each host country through the Access and Benefit-Sharing Clearing-House, and in cases of uncertainty, we proactively engage with the access and benefit sharing focal point of the respective country.

What has been the impact of the Nagoya protocol?

While well-intentioned, the Nagoya Protocol has unfortunately proven not only to be inefficient but also to have encouraged unreasonable expectations on the part of certain providers and created obstacles to research.[7] Despite being over 12 years old, many countries still have not introduced an operational infrastructure to support benefit sharing. Additionally, while 140 countries are official Parties to the protocol, notable absences include the United States, Russia, Australia, Canada, and New Zealand.[8] There remains a need for increased international efforts to ensure that the benefits of genetic resource and DSI research are shared fairly with providers.

SUMMARY

Sharing of genetic resources and DSI is vital to the development of new and improved diagnostic tools and to the control and prevention of disease. Mechanisms to allow access to biological samples and data to support scientific research must ensure that benefits are shared in an equitable manner with contributing countries. FIND therefore calls for the inclusion of DSI into the protocol as well as ratification by additional Parties.

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References

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ABOUT THIS POLICY BRIEF

FIND accelerates equitable access to reliable diagnosis around the world. We are working to close critical testing gaps that leave people at risk from preventable and treatable illnesses, enable effective disease surveillance, and build sustainable, resilient health systems. In partnership with countries, WHO, and other global health agencies, we are driving progress towards global health security and universal health coverage. We are a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

From time to time, FIND publishes technical briefs and policy briefs on issues relevant to the diagnostics equity agenda. All briefs, including this one, are prepared by FIND staff and reflect FIND's view at the time of publication. Further information on this and other technical briefs and policy briefs can be found on our website at **www.finddx.org**. We also welcome feedback on this and other briefs at **info@finddx.org**.

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