Committee: World Health Assembly (WHA)

Issue: Devising Action Plans for Pathogen Access and Benefit-Sharing (P-ABS)

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Introduction

Recent public health emergencies of international concern (PHEICs) have highlighted the importance of sharing pathogen genome data, as well as the benefits of its utilization in strengthening global health security. During the COVID-19 pandemic, it was pathogen research, more specifically, the rapid sequencing of the SARS-COV-2 genome, that expedited the creation of effective vaccines. Thanks to pathogen sharing, possible variants were identified quickly as well.

In the current status quo, however, international discussion on pathogen access and benefit-sharing is decreasing. Against the uncertainty of an emerging global health crisis, member states are choosing to withhold their pathogen data and resources or only utilize them for domestic gain.

One of the biggest challenges is the continuous politicization of pathogens. Instead of promoting global health, countries are incentivized to utilize pathogens as a mode of value. This hinders free, open, and transparent information sharing and further creates a clash of interest between developed, high-income nations and nations under challenging development contexts. As for benefit-sharing, there has yet to be a ubiquitous definition and extent set, given the different stances of stakeholders.

It's essential to remember that global health crises are a transborder challenge. With far and wide-reaching consequences, every nation has witnessed the effects of such crises, whether directly or indirectly, across political, economic, and ecological sectors. If this phenomenon of passivity persists, global health will only weaken further. Therefore, collective and collaborative action is absolutely crucial to constructively prevent, prepare, and respond to future health crises. Promoting pathogen access and sharing data, practices, and breakthroughs will be integral in devising a comprehensive framework for global health surveillance to be better equipped to prevent and prepare for future health crises. Additionally, this will aid governments in making better-informed decisions in responding to outbreaks.

Definition of Key Terms

Pathogens

A pathogen is defined as an organism causing disease to its host. About one in a billion pathogens affect human health, and through genetic mutations, pathogens may gain new functions or enhance existing characteristics.

Potential Pandemic Pathogen (PPP)

Potential Pandemic Pathogens are bacteria, viruses, and other microorganisms that are highly transmissible and highly virulent. PPPs are capable of wide, uncontrollable spread in human populations, likely to cause significant morbidity and/or mortality in humans. Some examples include the H5N1 influenza viruses (bird or avian influenza), SARS-CoV, Middle East respiratory syndrome (MERS), and SARS-CoV-2 (COVID-19). Any unknown pathogen that could cause a future outbreak is referred to as 'Disease X.' The World Health Organization (WHO) has a list of priority pathogens, which serves as a reference point for future research.

Access

Access refers to the rapid and systemic sharing of biological materials with pandemic and epidemic potential, along with relevant information and data such as genetic sequences.

Benefit-Sharing

Benefit Sharing refers to the distribution of benefits derived from pathogen research to all stakeholders, especially active contributors. Within the context of this agenda, benefit-sharing encompasses both financial benefits, such as royalties from products developed, or non-financial benefits, like resilience, healthcare systems, or the availability of necessary resources like vaccines, therapeutics, and diagnostics.

Genetic Resources

Genetic Resources refer to genetic material of actual or potential value. In this instance, genetic material refers to any material of plant, animal, microbial, or other origin containing functional units of heredity, such as nucleotide and amino-acid sequence information. The 'value' of genetic resources can be realized through the development of vaccines and pharmaceutical products.

Enhanced Potential Pandemic Pathogen Research (ePPP Research)

Enhanced Potential Pandemic Pathogen Research (ePPP Research) refers to research that may be reasonably anticipated to create, transfer, or use potential pandemic pathogens resulting from the enhancement of a pathogen's transmissibility and/or virulence in humans. ePPP Research has been subjected to much controversy, with many experts believing that the possible risks of 'gain-of-function'

research, such as spillover events, outweigh the benefits. Gain-of-function research further refers to the genetic alteration of an organism to enhance its biological functions.

Material Transfer Agreement (MTA)

A Material Transfer Agreement (MTA) is a contract governing the transfer of materials between two parties. It defines the rights of the provider and the recipient with respect to the materials and any derivatives. MTAs are regularly used to govern the transfer of biological materials, such as samples, but can also cover associated data, such as metadata or the clinical state of the donor.

Viral Sovereignty

Viral sovereignty is the concept that virus samples isolated within the territorial boundaries of a nation-state are the sovereign property of that state. The term was first established in the Nagoya protocol with the purpose of securing biodiversity. When states exercise their viral sovereignty, it could deter pathogen sharing.

History

In 1952, the WHO established the Global Influenza Surveillance Network (GISN) (renamed the Global Influenza Surveillance and Response System (GISRS)), a global network of more than one hundred influenza laboratories to monitor the spread of influenza. To properly track influenza and detect possible pandemic strains, the GISRS was reliant on the open sharing of influenza viruses.

Fast forward to the Influenza Outbreak in 2011, when the Indonesian government claimed sovereignty over H5N1 influenza virus samples under the Nagoya Protocol. The Indonesian government's refusal to share samples was spurred by the WHO's distribution of Indonesia's virus strains to private companies. The vaccines developed by these companies were unaffordable to many lower and middle-income countries, including Indonesia. As a result of Indonesia's actions, the WHO initiated the Pandemic Influenza Preparedness Framework (PIP Framework) in an attempt to ensure equitable distribution of benefits derived from pathogen use.

Prior to this occurrence, there had been several other instances of information withholding under similar diplomatic contexts. In West Africa, during the 2014 Ebola virus outbreak, foreign agencies arrived to test patients for Ebola. In the process, they took biological specimens and samples from patients. During the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, the WHO instructed Taiwanese epidemiologists to approach the People's Republic of China directly for Chinese SARS virus samples and data. While some, considering the politically sensitive relationship of the two countries,

defended the WHO's actions, others pointed out that the WHO did have the requested samples. In another case, Russian and Chinese public health ministries shared virus samples to study infectious diseases. In these instances, there is an underlying implication of pathogen data as belonging to a sovereign state.

Key Issues

Lack of Transparent and Open Data Sharing

The Politicization of Pathogen Access

Under the conditions of 'viral sovereignty' covered by international legal frameworks like the Nagoya Protocol, which allows countries to determine the use of biological material accessed within their territory, countries are increasingly restricting access to pathogen data. This can be attributed to the politicization of pathogens, which occurs as countries designate substantial value to the data itself rather than prioritizing the long-term goal of securing global health. Naturally, this phenomenon undermines global health security by limiting the scope of available information. A report by the Covington & Burling LLP found that the lack of data led to (i) sub-optimal vaccine composition, including lack of regional representativeness; (ii) diagnostics that were not tailored or tested against original or new variants of pathogens; and (iii) skewed and non-representative epidemiology in genomic surveillance. Balancing open and equitable pathogen access with viral sovereignty and domestic interests remains a fundamental challenge for the UN.

Intellectual and Other Property Rights

Concerns over property rights, especially intellectual property rights, are a contributing factor to lackluster pathogen access. Intellectual property encompasses every intangible creation of the human intellect, whether it be through patents or copyrights. There have been numerous cases in which third parties utilized pathogen data for commercial benefit without the permission of the 'provider.' As a result, researchers are reluctant to contribute their findings and knowledge. This phenomenon is especially prevalent among researchers and scientists, especially those who seek academic accolades and recognition. Hence, it is vital that the sources from which clinical samples or pathogen isolates have originated be appropriately acknowledged in presentations and publications.

Inefficient Data Sharing Process

In a global health crisis, a timely assessment and response is critical. However, the existing processes for pathogen data sharing require the parties involved to renegotiate terms every time a user requests access to genetic resources. This results in delays in procuring access to pathogens and puts the

timely development of medical countermeasures during health crises at risk. There needs to be an accelerated and flexible response system to PHEICs.

Benefit Distribution

Inequities in Countries with Challenging Developing contexts

The recent COVID-19 pandemic was marked by numerous instances of health inequity, such as the unequal distribution of vaccines and other necessary resources. This phenomenon was especially prevalent in least-developed countries (LDCs), least economically developed countries (LEDCs), low-income countries (LICs), and Small Island Developing States (SIDs) with challenging development contexts. Although the WHO, along with several other organizations, has worked to procure basic aid to these countries, it is evident that some underrepresented regions still lack both the data and necessary resources when it comes to predicting and responding to health crises.

Even in the case of countries that have provided significant data, they often have difficulty reaping the benefits of their information. During the pandemic, South Africa criticized that it had no access to updated vaccines against the Omicron variant, even though South Africa's researchers were among the first to identify and publish information on the new variant of SARS-CoV-2. As high-income countries (HIC) with greater buying power sign advance purchase agreements to obtain vaccines, medicines, diagnostics, and personal protective equipment, the limited supply is diminished.

Determining the Scope of Benefits

Aside from the issue of developing countries, the specifics of benefit-sharing have yet to be established. Provider countries will, naturally, demand a quid pro quo or compensation for their data contributions. The majority of UN resolutions have worked to ensure benefit distribution. In the case of the recent Pandemic Accord, provider countries currently can seek financial benefits once their data is used in a commercial manner. During emergency PHEICs, however, countries, especially LMICs, will also require health-related resources such as vaccines.

Major Parties Involved and Their Views

The United States of America (USA)

As one of the world's leading countries in biological research, the USA has gathered extensive and valuable research on PPPs. Notably, the US has attempted to assess how to provide transparency, public engagement, and continued dialogue about enhanced PPP research, from publishing the HHIS Framework

for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework) to imposing limits on gain-of-function ePPP research.

Indonesia

During the H5N1 avian influenza outbreak, Indonesia shared major pandemic influenza samples through the WHO's global influenza laboratory network. However, Indonesia faced difficulty in securing access to vaccines developed from the H5N1 influenza samples it provided. In part, this was due to Advanced Purchase Agreements negotiated by other countries. From that point, Indonesia stopped sharing influenza samples until the equitable distribution of resulting resources was ensured, which led to the initiation of the PIP Framework. This is an instance of a country exercising its viral sovereignty.

Least Developing Countries (LDCs)
Least Economically Developed Countries (LEDCs)

Due to multiple factors, including financial circumstances, development contexts, and ongoing conflicts and disasters, it is extremely challenging for LDCs and LEDCs to prepare for potential health crises. Even in instances when LDCs and LEDCs contributed meaningful data, they rarely benefited from the commercialization of the provided data and could not secure necessary resources, partly due to the advance purchase agreements signed by high-income countries. For LDCs and LEDCs, a comprehensive and fair benefit-sharing system is a priority.

The Private Sector

The Private Sector includes relevant stakeholders working in the fields of therapeutics, medicines, vaccine manufacturing, diagnostics, and personal protective equipment. When it comes to discussing this agenda, the private sector has different stances on pathogen access and benefit sharing and seeks to separate the two. While they will greatly benefit from the increased scope of available data, those in the private sector are reluctant to share the benefits and resources that derive from the commercial utilization of this data. Due to past treaties such as the Nagoya protocol, the private sector was mandated to undergo a time-consuming process to access data. The International Federation of Pharmaceutical Manufacturers believes that the Nagoya Protocol hinders research collaboration in urgent situations. Hence, they will seek to increase the efficiency of pathogen data-sharing by revising current resolutions.

The International Pathogen Surveillance Network (IPSN)

The IPSN is a global network of pathogen genomic actors brought together by the WHO Hub for Pandemic and Epidemic Intelligence to accelerate progress in pathogen genomics and improve public health decision-making.

National Center for Biotechnology Information (NCBI)

A part of the United States National Library of Medicine, the NCBI seeks to advance science and health by providing information relevant to biotechnology, biomedicine, and genomics. It does so in the form of databases, such as the Genbank. The Genbank is a collection of all publicly available DNA sequences and is a part of the International Nucleotide Sequence Database Collaboration (INSDC) alongside the DNA Data Bank of Japan and the European Nucleotide Archive. The INSDC promotes open access to scientific knowledge.

Timeline of Relevant Resolutions, Treaties and Events

Date	Description of event
Dec 29, 1993	The Convention on Biological Diversity (CBD) enters into force. One of the CBD's foremost objectives is the fair and equitable sharing of benefits arising from genetic resources.
2005	The WHO releases the "Guidance for the timely sharing of influenza viruses/specimens with potential to cause human influenza pandemics", reiterating the importance of the permission of the originating country/laboratory for the distribution of viruses and specimens.
2005	The World Health Assembly Resolution 58.5 is adopted, calling for the rapid sharing of clinical specimens and viruses through the WHO GISRS https://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_5-en.pdf
June 15, 2007	The International Health Regulations (IHR) is adopted.
Oct 29, 2010	The Nagoya Protocol on Access and Benefit Sharing, a supplementary agreement to the CBD, provides a legal framework promoting fair and equitable sharing of benefits related to genetic resources.
May 24, 2011	Implementation of the 2011 Pandemic Influenza Preparedness Framework
Jan 1, 2016	UN Sustainable Development Goals (SDGs) #3 Good Health and Well-Being, and #17 Partnership for the goals emphasizes the importance of collaboration in enhancing global health security.
May 2016	WHO's Disease Research and Development (R&D) Blueprint is developed. It fast-tracks the availability of effective tests, vaccines and medicines to reduce the repercussions of large-scale health crises.

Feb 1, 2023	The WHO Pandemic Prevention, Preparedness, and Response Accord is drafted. The accord seeks to strengthen pandemic-related health systems and suggests the initiation of a WHO Pathogen Access and Benefit-Sharing System.

Evaluation of Previous Attempts to Resolve the Issue

One of the first attempts to address access to scientific data and benefit-sharing was the Convention on Biological Diversity (CBD), with the goal of ensuring the fair and equitable sharing of benefits arising from genetic resources. Later on, the Nagoya Protocol came into action as a supplementary agreement to the CBD. The Nagoya Protocol introduced the concept of 'viral sovereignty,' essentially giving nations the ability to determine, control, and monitor the use of biological material accessed within their territory. Viral sovereignty is guaranteed through Material Transfer Agreements (MTAs), Prior Informed Consent (PIC), and Mutually Agreed Terms (MAT) between the Provider and the User. However, these agreements were conducted on a case-by-case basis for one health crisis at a time, resulting in counterproductivity. As individual stakeholders attempt to promote their own rights and interests, the negotiations increasingly become time-consuming.

Another framework was the Pandemic Influenza Preparedness (PIP) Framework, which focused on a global approach to pandemic influenza preparedness and response. One of its major objectives was to improve and strengthen the sharing of PIP Biological material, or H5N1, and other influenza viruses with human pandemic potential and increase the availability of the supplies invented from virus studies. The PIP Framework was applauded for securing samples and outlining a clear procedure on material transfer mechanisms, though it lacked both international consensus and a benefit-sharing guarantee system. It was also very controversial, as it seemingly endorsed negotiation between the WHO and private commercial entities. Additionally, requiring the private sector to provide financial contributions to the PIP Framework brought up concerns about transparency.

In February of 2023, the WHA Intergovernmental Negotiating Body drafted the WHO Pandemic Prevention, Preparedness, and Response Accord. The accord emphasizes the active involvement of the WHO in overseeing the implementation of the newly suggested WHO Pathogen Access and Benefit-Sharing System (PABS System) within the pandemic and inter-pandemic context. Although the final version has yet to be submitted, the accord proposes promising directions for equitable benefit-sharing. It is worth noting that the current version of the accord doesn't have compliance mechanisms; instead, it relies on the 'good faith' of its member states. Strengthening compliance and preventing circumvention remains an unsolved task.

Possible Solutions

The fundamental cause of the growing politicization of pathogen access lies in the ‘gray area’ of viral sovereignty. While the UN WHO’s stance on ensuring viral sovereignty is unwavering, it also has a responsibility to promote pathogen access and benefit-sharing. One of the ways to mediate politicization is to increase transparency in all steps of P-ABS to establish trust. For instance, the UN should always ask for the permission of the provider to utilize or share given data with third parties.

Decoupling, or the separation of pathogen access and benefit-sharing, can simultaneously address politicization and inefficient processes. Currently, the constant clash of interests and equity concerns hinders the rapid and efficient sharing of pathogen data. Therefore, addressing pathogen access first and then discussing the terms of benefit-sharing separately will greatly increase efficiency.
On the policy front, the CBD, the Nagoya Protocol, and the PIP Framework are the only substantial guidelines and frameworks in the status quo. And yet, the content is partially too vague and even contradictory. As for the PIP Framework, it is specialized towards influenza, which means it is less equipped to deal with other diseases. As viruses evolve and new health crises emerge, delegates could consider expanding policies to adopt specialized international ABS instruments consistent with the objectives of past protocols and frameworks.

In an age of individualism and nationalism, withholding valuable information might seem like the right course of action. However, regional representativeness is an integral part of health crisis response, something that can only be achieved through multilateral collaboration and cooperation. While deserving quid pro quo should be provided, it is important to keep the fundamental goal of global health in mind.

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