



World Health
Organization

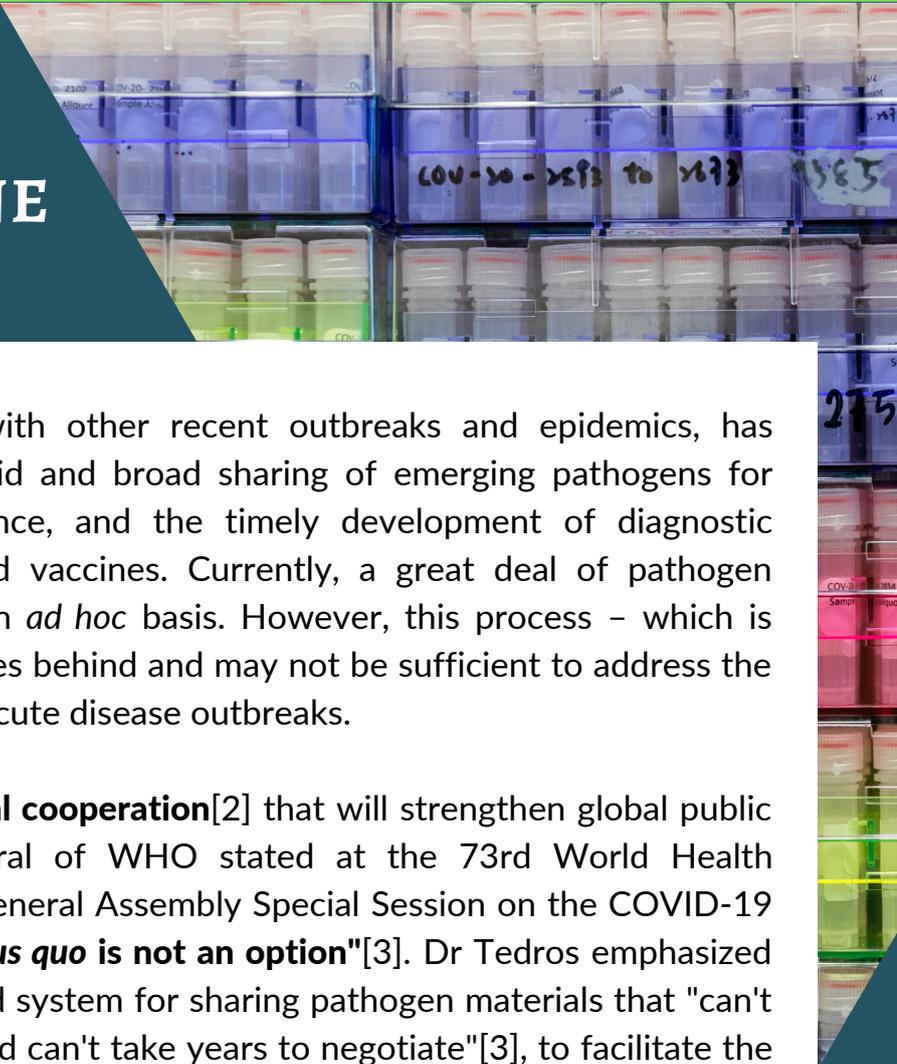
The WHO BioHub

The WHO BioHub System for Preparedness and Response to Epidemics and Pandemics

Proposed approach

The World Health Organization (WHO) proposes to develop a new, fast, and complementary system with global reach: the **WHO BioHub System**. This System will allow Member States to share biological materials with epidemic or pandemic potential[1] (BMEPP) on a **voluntary basis** with one of the trusted WHO BioHub Facilities under pre-agreed conditions. The WHO BioHub System will not replace or interfere with existing or future bilateral sharing of pathogens.

The goal of the WHO BioHub System is to encourage the sharing of BMEPP soon after the detection of a pathogen with epidemic or pandemic potential in order to characterize it, provide informed review of the risk under the International Health Regulations (2005) (IHR), and foster greater international cooperation for health emergency preparedness and response. Overall, the WHO BioHub System will contribute to expand knowledge and advance technical work on high-threat pathogens.



Sample sharing

SETTING THE SCENE

The COVID-19 pandemic, along with other recent outbreaks and epidemics, has underscored the importance of rapid and broad sharing of emerging pathogens for effective characterization, surveillance, and the timely development of diagnostic products, devices, therapeutics, and vaccines. Currently, a great deal of pathogen sharing is done bilaterally and on an *ad hoc* basis. However, this process – which is often slow – is leaving some countries behind and may not be sufficient to address the global needs that are arising during acute disease outbreaks.

Calling for a **new era of international cooperation**[2] that will strengthen global public health security, the Director-General of WHO stated at the 73rd World Health Assembly and the United Nations General Assembly Special Session on the COVID-19 response that "**returning to the status quo is not an option**"[3]. Dr Tedros emphasized the urgent need for a globally agreed system for sharing pathogen materials that "can't be based on bilateral agreements, and can't take years to negotiate"[3], to facilitate the rapid development of medical countermeasures as global public goods.

Ideally, all emerging pathogens that cause a risk to public health security should be rapidly shared with a global, trusted, and transparent end-to-end system[4] that works across laboratories and partners to quickly characterize, sequence, and carry out necessary and useful public health risk assessments. This System would work to ensure the rapid implementation of response interventions and the development of products such as diagnostics, treatments, and vaccines that can be made available to all countries based on public health needs and equitable access principles.

[1] For purposes of the WHO BioHub System, BMEPPs include clinical samples, specimens, isolates, and cultures –either original or processed of a novel pathogen. This term does not include influenza viruses that may be contained in clinical samples or specimens shared under the WHO BioHub System.

[2] See <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-world-health-assembly---9-november-2020>.

[3] See <https://www.who.int/director-general/speeches/detail/who-director-general-s-closing-remarks-at-the-world-health-assembly---13-november-2020>.

[4] Such a system currently exists (only) for influenza viruses with human pandemic potential (the Global Influenza Surveillance and Response System). Influenza virus will not be considered in the WHO BioHub System and will continue to be shared through GISRS.

Process

The **WHO BioHub Facilities** will share BMEPP with **qualified entities** that meet relevant and applicable WHO and other national or international regulations and standards. At an initial stage, these qualified entities will receive BMEPP for non-commercial purposes. In parallel, the WHO Secretariat will work on a proposal to broaden the WHO BioHub System for the use of BMEPP by qualified entities – such as manufacturers – for commercial purposes including the development of by-products, as well as their fair and equitable allocation to countries in need.

It is proposed to use a stepwise, phased approach to build the new System. Given the appearance of several variants of SARS-CoV-2, and following proposals from several WHO Member States, **the first WHO BioHub Facility will be set up in 2021** to receive, store, grow, sequence, and share SARS-CoV-2 BMEPP. This **first pilot phase** will allow the rapid operationalization of the WHO BioHub System. Subsequently, in a second phase, the aim will be to expand the scope and user base of the WHO BioHub System to other pathogens and commercial qualified entities, as well as to connect the System with existing repositories or laboratory networks by the end of 2022.

Numerous factors need to be considered by Member States, in consultation with stakeholders, for the development of the WHO BioHub System. They include strategic, operational, and procedural matters which will be addressed in a transparent and inclusive manner, with full engagement of Member States and in consultation with stakeholders.

Objectives

The objectives of the WHO BioHub System will be to:

1. **Promote** rapid and timely sharing of BMEPP;
2. **Facilitate** the rapid characterization of such pathogens and related risk assessment;
3. **Facilitate** the development of safe, protective countermeasures and other public health products; and
4. **Ensure** fair and equitable access to such products by all countries based on public health needs.

GUIDING PRINCIPLES

The WHO BioHub System will be guided by the following principles:



A voluntary system for the global public health

All contributions of BMEPP to the WHO BioHub System will be entirely voluntary, based on the desire for rapid generation of information and other resources for global public health.



Timeliness

To enable an effective public health response, the end-to-end system from sample collection to shipping and generation of scientific information must function with urgency. Data and analyses will be made publicly available in a timely manner, while respecting all applicable WHO, international, and national regulations and standards, and communicated promptly to decision-makers in the affected countries as well as more broadly to all WHO Member States to support effective and timely response measures.



Equity & Fairness

Equity and fairness, as well as public health risk and needs, will govern access to BMEPP contributed to the WHO BioHub System, and the research, data, and other materials resulting from the WHO BioHub System.



Transparency

Terms and conditions with respect to the use of BMEPP, sequence data and information from the WHO BioHub System will be made publicly available, as will criteria for entities to receive BMEPP.



Acknowledgment, co-authorship and joint research

The contributions of collaborators to the WHO BioHub System, including laboratories providing BMEPP or genetic sequence data, will be appropriately acknowledged in presentations and publications, using guidelines such as those outlined by the International Committee of Medical Journal Editors. To the extent possible, entities using BMEPP in scientific research projects will seek the participation of scientists from the originating laboratories or countries and make efforts to engage them in preparation of manuscripts for presentations and publications.

GUIDING PRINCIPLES

The WHO BioHub System will be guided by the following principles:



Sustainability and maximal preservation

The BMEPP and associated data (e.g. epidemiological information) available through the WHO BioHub System will be critical for understanding diseases with epidemic and pandemic potential and developing tools to combat them. These important resources will need to be maintained and managed over the longer term. The WHO BioHub System will therefore be established and managed with longer term sustainability and maximal preservation in mind.



Collaboration & Cooperation

The WHO BioHub System will promote collaboration and cooperation with existing networks, repositories, and scientific groups to strengthen knowledge and contribute to the advancement of effective, efficient, fair and equitable response to epidemic or pandemic public health events.



Best practices for safety and security

The WHO BioHub System will follow procedures that ensure that BMEPP which have been properly characterized, usually through culture and sequencing for pathogen materials. They will be prepared, dispatched, received, processed, stored, and shipped to qualified entities according to current, applicable national and international biosafety and biosecurity standards.



Consistency with applicable law

The WHO BioHub System will be established and operated in a manner consistent with applicable law, regulations, rules, and standards, including under national and international law.

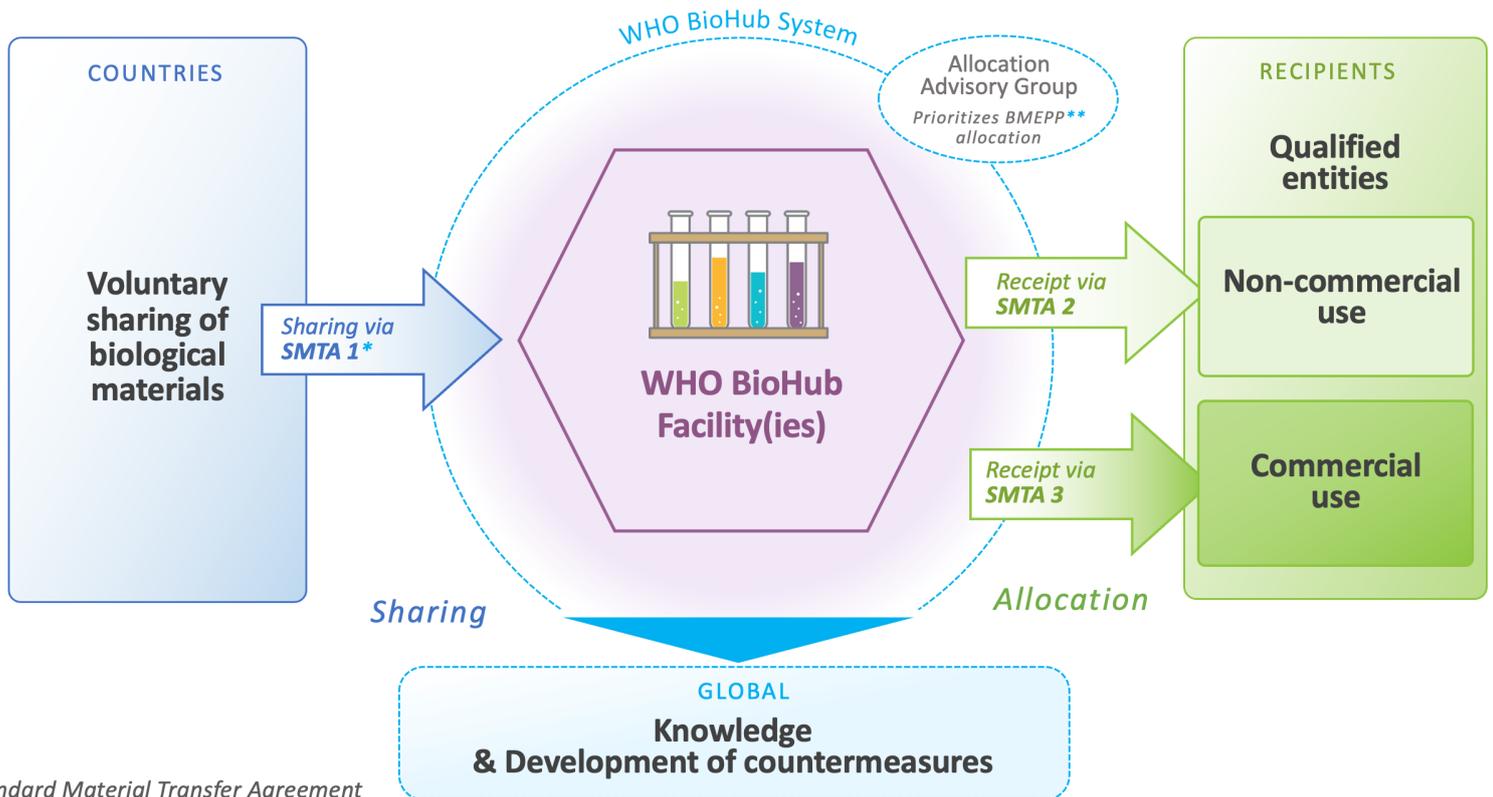


Consistency with applicable ethical requirements

The WHO BioHub System will be established and operated in a manner consistent with applicable WHO, international, and national ethical regulations, norms, and standards.

Figure 1

CONCEPTUAL MODEL OF THE WHO BIOHUB SYSTEM



* Standard Material Transfer Agreement

** Biological materials with epidemic or pandemic potential