WHO BioHub System

1 year progress report:
May 2021 – May 2022
Executive summary:

- Within the new era of cooperation, WHO, Member States and partners are co-developing the WHO BioHub System aimed to overcome existing barriers in international sharing of pathogens and address the call of Member States as expressed in World Health Assembly Resolution 74.7;

- The WHO BioHub System is an innovative, pathfinder project with the objectives of promoting rapid and timely sharing of biological materials with epidemic or pandemic potential (BMEPP), facilitating rapid access to such pathogens and their information by relevant, interested, and qualified entities for the development of effective and safe public health products including diagnostics, vaccines and therapeutics; and ensuring fair and equitable access to such products by all countries, based on public health needs;

- Sharing of BMEPP is facilitated through laboratories known as “WHO BioHub Facilities”, that operate under the WHO BioHub System’s Guiding Principles and standard Terms of References. Terms and conditions related to the onward sharing of BMEPP to public health and other entities are stipulated in Standard Material Transfer Agreements (SMTAs) which could be signed in advance of the actual sharing, therefore reducing timelines during emergency response;

- Developed through a phased and iterative approach, activities are organized into two streams of work: Stream 1: Pilot-Testing (operationalization); and Stream 2: System Design;

- During stream 1, the first WHO BioHub Facility was set up and operations were tested through a series of shipments. This allowed for refinement of documents and practices as well as identification of further needs;

- During stream 2, several key topics were discussed with relevant stakeholders to inform future Member States consultations. The topics related to researchers’ needs and contributions, genetic sequence data, intellectual property, and access and benefit sharing considerations;

- To advance this work elements of the WHO BioHub System may be further piloted, so that these can serve as building blocks of the new architecture for epidemic pandemic prevention and response, consistent with other ongoing Member State work;

- WHO will seek Member State input on engagement processes to support the system design elements and proposes a series of Member States specific consultations in 2022.
I. Background

Epidemics and pandemics can have catastrophic effects at individual and societal level, with the current COVID-19 pandemic serving as a reminder of such devastating impacts. This crisis has prompted calls for a new era of cooperation, to strengthen the global health architecture for a better global response including a more equitable allocation of countermeasures. As the world is looking forward the end of the acute phase of this pandemic, efforts to ensure greater preparedness for future ones need to remain steadfast. One key area of pandemic preparedness is ensuring rapid and efficient sharing of pathogens with epidemic or pandemic potential, and their relevant genetic sequence data. This is the first step towards epidemic containment - by swiftly identifying the causative agent and sharing it safely with research institutions and other relevant actors, so that necessary risk assessment can be done rapidly. The proper identification and characterisation of the pathogen is crucial for the development of medical countermeasures. Regardless of how sophisticated analysis methods become, access to the biological material with epidemic or pandemic potential (BMEPP) remains the starting point for any health emergency response. But there are numerous challenges to ensuring rapid sharing of pathogens at the global level. These include lack of national capacities to diagnose the pathogen or to perform international shipping, diverse national legal frameworks that require negotiation and agreement of sharing conditions, lack of clarity on handling research results and inconsistent recognition of scientific contributions, and unclear or non-existent access to benefits arising from sharing of BMEPP. To date these matters have not been addressed systematically, comprehensively and in a standardized manner.

The Director General of WHO decided at the end of 2020 to launch an innovative approach to address the issue of the rapid sharing of biological material and the related genetic sequence information for emerging pathogens with pandemic potential, including the access to benefits arising from this sharing. The initiative aiming at the multilateral sharing of BMEPP has been called the BioHub System.

In May 2021, the World Health Assembly (WHA) through resolution 74.7 called on the WHO Director General to ensure that WHO undertakes activities to advance preparedness in this area. Please see Box 1.

BOX 1: SEVENTY-FOURTH WORLD HEALTH ASSEMBLY WHA 74.7, AGENDA ITEM 17.3 31 MAY 2021 STRENGTHENING WHO PREPAREDNESS FOR AND RESPONSE TO HEALTH EMERGENCIES, PARAGRAPH 9(15):

The World Health Assembly requested the Director-General, as soon as practicably possible and in consultation with Member States “to work together with Member States, the medical and scientific community, and laboratory and surveillance networks, to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens of pandemic and epidemic, or other high-risk, potential, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the Pandemic Influenza Preparedness Framework and the importance of ensuring rapid access to human pathogens for public health preparedness and response purposes”.

Implementation of this WHA request is unfolding in an evolving global health landscape. Any approach to address the needs identified by Member States, must respond to and anticipate the accelerated pace of technological transformations, and take into consideration the implications of internationally adopted agreements such as 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. Considerable work remains to be done to ensure that the WHO BioHub System
provisions allow countries to engage in the sharing of novel pathogens in a trusted, transparent and efficient way while promoting equitable access to benefits arising from such sharing.

To date there is only one global health specific access and benefit sharing mechanism— the Pandemic Influenza Preparedness (PIP) Framework, which applies solely to pandemic influenza. The PIP Framework has two main objectives, that are pursued on an equal footing: 1) improve the sharing of influenza viruses with pandemic potential with the Global Influenza Surveillance and Response System (GISRS) by strengthening GISRS, and 2) achieve more predictable, efficient, and equitable access to benefits arising from the sharing of such viruses, notably vaccines and antiviral medicines. The PIP Framework offers numerous best practices to inform developments in the area of access and benefit sharing, but also has specificities that pertain to the influenza viruses and existing infrastructure (GISRS).

To heed the WHA 74.7 call, and mindful of all these contextual details, WHO has pursued the development of the WHO BioHub System, an innovative, pathfinder project aimed to offer a functional, trusted, and scalable system to enable the rapid sharing of BMEPP. It also endeavours to increase the availability of health information and knowledge related to the BMEPP, and, in due course, medical countermeasures needed to respond to outbreaks of disease due to BMEPP. The impetus for developing the System at this time, is also represented by the numerous lessons learned from the current COVID-19 pandemic, the opportunity to capitalize on the existing momentum and recognition of the needs that this System should urgently address and the possibility to pilot test operational approaches through the sharing of SARS-CoV-2 variants which are still emerging. In recognition of the numerous engagements and discussions that need to take place, WHO is following an iterative design approach where elements are sequentially established, piloted and refined.

This report presents the conceptual approach that underpins the WHO BioHub System, the progress achieved to date and considerations on potential next steps.

II. WHO BioHub System objectives, guiding principles and conceptual approach

The BioHub System has the following objectives:

- Promote rapid and timely sharing of biological materials with epidemic or pandemic potential;
- Facilitate rapid access to such pathogens and their information by relevant, interested, and qualified entities for the development of effective and safe public health products including diagnostics, vaccines and therapeutics; and
- Ensure fair and equitable access to such products by all countries, based on public health needs.

A set of 10 Guiding Principles have been proposed to steer the activities foreseen under the umbrella of the WHO BioHub System. These are described in Box 2.
**BOX 2: WHO BIOHUB SYSTEM GUIDING PRINCIPLES**

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

2. **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.

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

4. **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 to receive BMEPP.

5. **Acknowledgement and co-authorship**
   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 laboratory or countries and make efforts to engage them in preparation of manuscripts for presentation and publication.

6. **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 or 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.

7. **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.

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

9. **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 legal rules and regulations as well as national and international law.

10. **Consistency with applicable ethical regulations, norms, and standards 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.
The aim of the WHO BioHub System is to facilitate sharing of BMEPP through WHO BioHub Facilities, that are laboratories operating under the WHO BioHub System's Guiding Principles and standard Terms of Reference. These Facilities are responsible for receiving, storing, growing, sequencing, and preparing BMEPP for distribution to Qualified Entities (QE) or other Facilities. This approach aims to ensure that many laboratories around the world have access to BMEPP rapidly in order to start research faster.

The conditions for countries to share BMEPP with Facilities are contained in Standard Material Transfer Agreements (SMTAs) which may be signed in advance of any actual sharing, in order to reduce sharing timelines during emergency response. Thus, if an SMTA is already in place with a Provider country at the time of the emergence of a BMEPP, only a checklist needs to be filled-in for the shipment of the new BMEPP. The checklist would specify the Provider country’s details and permissions regarding use of that particular BMEPP. Provider countries would be able to select whether they allow the BMEPP to be used for non-commercial, commercial, or both purposes.

Entities requesting BMEPP, referred to as Qualified Entities (QEs), would be able to solicit BMEPP, knowing in advance their obligations with respect to the BMEPP requested. They too would be able to sign SMTAs in advance of making any requests, so that at the time of the emergency, they would only fill in a checklist with details applicable to that particular BMEPP. This approach should reduce transactional timelines and offer procedural and legal certainty and predictability. This conceptual approach is presented in Figure 1.

Figure 1: WHO BioHub System: Concept and elements

![Diagram of WHO BioHub System: Concept and elements](image-url)

*Standard Material Transfer Agreement

**Biological materials with epidemic or pandemic potential
III. BioHub System development

The WHO BioHub System is being developed in phased manner to allow broad and meaningful consultation with Member States and relevant stakeholders. The current phase of development follows a two-stream approach:

- Stream 1: Pilot-Testing (operationalization) and
- Stream 2: System Design.

Stream 1 focuses on Member States sharing SARS-COV-2 and its variants to test the feasibility and operational arrangements. This stream is demonstrating the feasibility of signing Standard Material Transfer Agreements between Member States and the WHO BioHub Facility in Switzerland, for the sharing of BMEPP into and out of the Facility. Stream 2 is under way through an iterative and broad consultative process to allow WHO Member States and relevant stakeholders to discuss and provide input on elements pertinent to the further design of the System. It includes a series of engagements and technical consultations with various stakeholders including Member States, public health organizations, civil society organizations, research institutes, biorepositories and industry.

IV. Progress achieved to date

Stream 1 – Pilot-testing operational update

To operationalize stream 1, WHO signed a Memorandum of Understanding in May 2021 with the Swiss Confederation to designate the Spiez Laboratory as the first WHO BioHub Facility. The following activities were undertaken for the pilot phase:

- **Operationalization of the WHO BioHub Facility** – consisted of an assessment visit to Spiez Laboratory and exchanges at different levels to set a framework for collaboration that could serve as a model for setting up other BioHub Facilities. Formalization of collaboration with the WHO BioHub was done through signing a Letter of Agreement enclosing the Terms of Reference for a WHO BioHub Facility.

- **Processes and supporting documentation** – were established and refined building on best practices and continuous feedback from volunteering Member States. Numerous meetings and exchanges with the volunteering Member States allowed the development of the Standard Material Transfer Agreement (SMTA) Package for the sharing of BMEPP by Member States, for non-commercial purposes as part of the pilot phase. The SMTAs are therefore reflecting of the best practices from the SMTAs used for the Pandemic Influenza Framework (PIP) and the feedback received from the volunteering Member States. To facilitate operational processes Standard Operating Procedures (SOPs), one-pagers and explanatory slide-sets were developed.

- **Tools to facilitate operations** such as dedicated webpage and tracking tools to enable transparent and real-time monitoring of BMEPP consisting of databases and dashboard. Current tracking tools need to be further transformed to allow for greater functionalities based on the feedback received from the pilot-testing operations.

To date, a total of 11 countries – Egypt, El Salvador, Italy, Japan, Luxembourg, Peru, Portugal, South Africa, Switzerland, Thailand, the United Kingdom – have joined the pilot phase in some capacity (e.g. signing SMTA, signing agreement for designation of a BioHub Facility, shipping BMEPP).

As of March 2022, six shipments of SARS-COV-2 samples have been made, involving four countries. Table 1 presents the available BMEPP in the WHO BioHub Facility. Two outbound shipments in Table 2 took place with the South Africa Omicron variant that was available in the Facility to Portugal and Luxembourg.
Table 1: BMEPP provided into the WHO BioHub System Facility in Spiez, Switzerland

<table>
<thead>
<tr>
<th>Provider Member State</th>
<th>Variant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luxembourg</td>
<td>Alpha, Beta, Gamma, Delta</td>
</tr>
<tr>
<td>South Africa</td>
<td>Omicron (B.1.1.529)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Omicron (B.1.1.529)</td>
</tr>
</tbody>
</table>

Table 2: BMEPP sent out of the WHO BioHub System in Spiez, Switzerland

<table>
<thead>
<tr>
<th>Recipient Member State</th>
<th>Variant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luxembourg</td>
<td>Omicron (B.1.1.529)</td>
</tr>
<tr>
<td>Portugal</td>
<td>Omicron (B.1.1.529)</td>
</tr>
</tbody>
</table>

With the shipment of the Omicron variant from South Africa, the WHO BioHub System was able to demonstrate the timeline for sharing when a new BMEPP emerges, and enabled WHO to analyse the process with a view to finding ways to improve its efficiency. Some notable highlights of the pilot include: 1) the South African Omicron sample (BMEPP) arrived at the WHO BioHub Facility within two weeks after the first case was reported globally; BMEPP was further shared in less than a week with the first requesting Qualified Entity (Luxembourg). This QE reported that it received the BMEPP and performed preparedness activities using it, before the first Omicron case was detected in their country. Upon review of the process, it was highlighted that the timelines could have been further reduced by: i) WHO more broadly informing Member States of the option of sharing COVID-19 variants through the WHO BioHub System (the Provider laboratory was not aware of this initiative); and ii) having the SMTAs signed in advance.

A rapid review of the process was conducted by WHO following the shipments to identify areas for improvement. WHO is using lessons learned to revise relevant tools and processes. This experience enabled reflections on ensuring timeliness of operations through tracking various key performance indicators such as days between request and pickup of samples, SMTA/shipment form signing, obtaining national authorizations, days between pickup and delivery of samples, total transport days of samples, total days from request to delivery. The average total days from request to delivery was 8.75 days (not including the data from shipments that were delayed at the request of countries due to the holiday season) of which transport timelines represent approximately 1.83 days. These KPI are reflecting of challenging times with several airlines having cancelled flights from one of the sending country. However more pilot-testing shipments need to be performed before establishing a final KPI target. This is due to many factors impacting international shipment. For example, a 3 year pre-pandemic overview of yellow fever operations in 7 countries showed that in particular for certain settings, transport KPIs can vary between approximated averages of minimum 12 days up to maximums of 167 days, with some of the labs consistently having difficulties in shipping out samples internationally. Therefore it is important to engage as many countries as possible to continue pilot-testing operations, so that realistic KPIs can be set. At the WHO BioHub Facility level the following KPIs have been tracked: days/hours between reception and culturing (ready to ship), days between reception and titration, days/hours between reception and sequencing and data analysis, days between reception and shipping and days from sample receipt to sequence upload.
Figure 2: Overview of first Omicron shipments into and out of the WHO BioHub Facility

South Africa Omicron Shipments Timeline  
(two shipments into the WHO BioHub Facility)

- **Omicron first reported to WHO from South Africa**  
  Wednesday – 24 November 2021

- **WHO is notified by SA about intention to send BMEPP through the BioHub**  
  Monday – 29 November 2021

- **WHO BioHub SMTA related materials signed**  
  Saturday 4 December 2021

- **Booking form received from Provider**  
  Monday and Tuesday – 6, 7 December 2021

- **Courier pick up from Provider**  
  Wednesday and Thursday – 8 & 9 December 2021

- **BMEPP arrival in WHO BioHub Facility**  
  Thursday and Friday – 9 & 10 December 2021

- **WHO is notified by LU about intention to receive BMEPP through the BioHub**  
  Saturday – 18 December 2021

- **WHO BioHub SMTA related materials signed**  
  Wednesday – 22 December 2021

- **Booking form received WHO BioHub Facility**  
  Wednesday – 22 December 2021

- **Courier pick up from WHO BioHub Facility**  
  Thursday – 23 December 2021

- **BMEPP arrival in Qualified Entity**  
  Thursday – 23 December 2021

Luxembourg Shipment Timeline  
(shipment out of the WHO BioHub Facility)

- **WHO is notified by LU about intention to receive BMEPP through the BioHub**  
  Saturday – 18 December 2021

- **WHO BioHub SMTA related materials signed**  
  Wednesday – 22 December 2021

- **Booking form received WHO BioHub Facility**  
  Wednesday – 22 December 2021

- **Courier pick up from WHO BioHub Facility**  
  Thursday – 23 December 2021

- **BMEPP arrival in Qualified Entity**  
  Thursday – 23 December 2021
Processes and documentation were also reviewed and several changes were proposed to bring greater clarity on operational processes. The documentation that was developed and updated consisted of SOPs, one pagers, slides and operation templates (booking form, proforma invoices for different categories of shipments and packing list).

Tools to ensure traceability and transparency were developed building on in-house existing databases and dashboards. To enable operations at scale and ensure greater user functionalities (including for scenarios when more WHO BioHub Facilities will participate in operations) further development of the prototype of tracking tool associated databases and monitoring dashboard is ongoing. The tool is envisaged to power the BMEPP catalogue with technical details, enable secure log-in functionalities for participating entities to facilitate data entry and visibility, automatic notifications and facilitation of documents exchange which could be signed electronically in addition to paper based approaches. It will also inform information dashboards that will ensure visibility on BMEPP exchanged through the WHO BioHub System.

Box 3 presents a selection of key findings and related activities to improve the sharing processes.

**BOX 3: HIGHLIGHTS OF THE PILOT-TESTING ACTIVITIES**

**Timeliness:**
- The average total days from request to delivery was 8.75 days (not including the data from shipments that were delayed at the request of countries due to the holiday season);

**Processes and documentation to enable operational processes:**
- Documentation containing explanation on roles and responsibilities, communication pathway and exchange of information have been updated to reflect suggested improvements by participating stakeholders;

**Tools to ensure traceability and transparency:**
Prototype of tracking tool and monitoring dashboard is under further development.

**Operationalization of the WHO BioHub Facility:**
- The WHO BioHub Facility has reviewed their full-time equivalent (FTEs) needs and undertaken investments into new personnel to ensure additional support and back-up;

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**Stream 2 – System design update**

To enable the iterative design of the System to progress, and mindful of the WHA 74.7 request as well as feedback received from Member States, WHO conducted a series of technical consultations with a wide range of stakeholders to prepare and facilitate Member State discussions on key topics.

As of April 2022 the following activities have been undertaken in the past year:
- Six Member State Briefings were organized either as part of the WHO COVID-19 Information Sessions or as stand-alone sessions;
- Several bilateral engagements with Member States and other actors ranging from academia, biorepositories, civil society and industry occurred;
- A series of four technical thematic consultations* with various stakeholders were organized to enable System design. Invitations were disseminated through WHO networks and notifications about these events were also posted in advance on the WHO BioHub System
website. The consultations had the following participation (please see Figure 3 for the geographical distribution of participants).

- Theme 1: Research (28 October 2021) – 499 participants
- Theme 2: Sharing of Genetic Sequence Data (19 November 2021) – 399 participants
- Theme 3: Intellectual Property (9 December 2021) - 274 participants
- Theme 4: Access and benefit sharing (22 March 2022) – 331 participants.

* All meeting materials including background papers, recordings & slides are available at: https://www.who.int/initiatives/who-biohub.

The technical consultations followed the same format of benefiting from opening remarks and presentation on the WHO BioHub System concept from WHO senior leadership, followed by a facilitated discussion based on pre-circulated questions. Prior to each of the consultations a background document was prepared and made publicly available to enable discussions. This document contained technical details on the particular theme as well as the questions proposed to steer the discussions. Recordings, presentations and documents are available on WHO BioHub System’s webpage. In this report we briefly summarize the main themes as they were put forward by participants (these do not represent WHO’s views on these topics; for a more detailed overview please see the above mentioned resources on the initiative’s webpage).

During the first technical consultation on Researchers’ needs and contributions, participants expressed feedback on a range of topics:

- clarify which pathogens are expected to be shared through this System,
- ensure that providers of BMEPP receive both attribution and co-authorship, where relevant, in publications or presentations,
- protect personal data in BMEPP analysis and processing
- ensure operational processes are predictable, efficient and non-duplicative, existing alongside and building upon other infectious disease platforms.

Furthermore, according to participants, the System’s design needs to consider the balance between rapid access to BMEPP by many entities and targeted, early-stage access for a limited set of stakeholders that may be instrumental at the onset of the emergency response. Participants also mentioned that the WHO BioHub System could support the development of analytical tools to increase research capacity and improve the interoperability of various data streams. These research advancements and capacity-building efforts should be sustainable over the long term. Some participants also voiced that the system design should provide clarification on the implications of intellectual property over BMEPP samples; namely, whether the provider has the capacity to use the samples to develop their own medical countermeasures domestically. Participants also inquired whether the System could also provide benefits of enabling shared technology platforms and common practices which would accelerate research.

The second technical consultation on Approaches to handling genetic sequence data (GSD), gathered diverse views on how to consider GSD within the WHO BioHub System. There seemed to be agreement among participants on the need for rapid sharing of and access to GSD to enable public health responses during an outbreak. It was flagged that the value of GSD is cumulative and dependent on additional contextual information, which may not come from individual sequences. Participants flagged challenges with operationalizing the concept of commercial and non-commercial use of GSD and with the tracking of GSD use within the context of designing access and benefit-sharing (ABS) schemes. Diverse opinions were expressed on GSD access - with some participants advocating for open access to GSD, others for restricting it and other voices proposing an in-between model of sharing early data under one set of terms and then after a set timeframe, for this to migrate into a second set of more permissive provisions. Concerns were raised about existing GSD databases and technology platforms and potential disruptions to their functioning as a result of the WHO BioHub System. Some participants called for a WHO platform to host and track GSD utilization. National implementation of ABS rules under the Convention on Biological
Figure 3: Geographical distribution of participants in each of the technical consultations

**Theme 1: Research**

Geographical location of participants

Participants distribution according to WHO regions:
AFRO 5.6%, AMRO 37.7%, EMRO 2.6%, EURO 33.7%, SEARO 9.1%, WPRO 11.3%.

**Theme 2: Sharing of Genetic Sequence Data**

Geographical location of participants

Participants distribution according to WHO regions:
AFRO 7.5%, AMRO 30.6%, EMRO 2.8%, EURO 40.1%, SEARO 6.5%, WPRO 12.5%.

**Theme 3: Intellectual Property**

Geographical location of participants

Participants distribution according to WHO regions:
AFRO 2.2%, AMRO 39.4%, EMRO 1.8%, EURO 33.2%, SEARO 10.9%, WPRO 12.4%.

**Theme 4: Access and Benefit sharing**

Geographical location of participants

Participants distribution according to WHO regions:
AFRO 3.6%, AMRO 39.3%, EMRO 2.1%, EURO 35.3%, SEARO 6.6%, WPRO 13%.
Diversity (CBD) and its Nagoya Protocol was mentioned to affect access to and the use of BMEPP and of GSD, with some voices stating that these may hinder research and development of medical countermeasures. Others stressed that upholding benefit-sharing from the utilization of genetic resources—including human and animal pathogens—is an obligation for countries who are Parties to the CBD and the Nagoya Protocol (currently 133 WHO Member States). No consensus existed on whether the same benefit-sharing obligations should apply to BMEPP and GSD. Lastly numerous voiced stressed the importance of non-monetary benefits by developing capacity through the WHO BioHub System for both sequencing and bioinformatics so that Member States can analyse and use GSD.

The third technical consultation on Intellectual Property (IP), similarly brought forward different perspectives from participants. While some called for a stable, predictable, and effective IP framework, other voices mentioned the WHO BioHub System should not address IP as it will lead to disagreement and delay the development of a functioning, trusted system. Similarly there were different views on the level of standardization of agreements and allowing for customizable approaches. Some participants argued for full standardization, to avoid any uncertainty and mitigate against unequal negotiations, undue influence or unhelpful competition, while others called for some level of customization with WHO overseeing related negotiations. In respect to application of IP provisions, some participants mentioned that differentiation must be made between IP based on industries, as BMEPP and GSD use may vary among different stakeholders. Other participants stated that the use of GSD and BMEPP are converging, and both need to be treated equally, including on IP-related aspects. Other suggestions were to link commercialization and benefit-sharing at a regulatory or policy level, by relying on tracking such commercialization through voluntary declarations to the Ministries of Health in countries where the products would be sold. Participants interventions further highlighted issues that may need to be addressed when it comes to IP such as bring clarity on commitment to benefit sharing, means of participation in product development and clinical trials, contributions to surge capacity during pandemics for product manufacturing, ways to advance transparency on use of shared data and process for appeals in cases where IP-related terms are not being met. One respondent proposed positioning IP handling based on different epidemiological stages. These span scenarios with no outbreaks, situations with local or regional outbreaks of high public health importance and lastly an unfolding pandemic, with each situation being determined by WHO. The proposal was to increase benefit-sharing obligations on IP based on a deterioration of the epidemiological situation and that benefits should be distributed to Member States that are in most need, regardless of contribution, under the WHO’s supervision. Other proposals to govern IP consisted of assigning IP resulting from research on BMEPP and/or GSD to WHO, and therefore to the multilateral mechanism designed by Member States. Another approach was to not regulate IP and solicit contributions into a fund. Benefits arising from these contributions would be distributed to the providers based on an evaluation of the relative importance of the shared materials. Another participant also mentioned the potential for establishing a central fund, where different stakeholders may contribute, and which should assists Member States in obtaining priority access to vaccines and research from manufacturers. This fund was proposed to also finance clinical trials, help provide support for fast-track regulatory approvals, or for covering fees for international IP applications. Another participant suggested exploring joint IP rights or non-exclusive licensing agreements as part of benefit-sharing arrangements.

The fourth technical consultation on Access and Benefits Sharing focused on the potential arrangements around provision of benefits through the WHO BioHub System. In preparation for discussion, a list of potential benefits was prepared and these are listed in Figure 4.
Participants singled out benefits such as offering laboratory and capacity strengthening support including offering technical assistance to analyze pathogens. However as the BioHub develops and new actors come into play, one participant stressed the increasing need to manage biosafety and biosecurity risks. Linked to the development and growing of the System, one participant suggested to employ a distributed laboratory infrastructure by leveraging existing networks and biorepositories and stressed the importance of using standardized terms and conditions. Another participant mentioned the importance of ensuring provision of longer term capacity support as this leads to trusted partnerships and ultimately incentivizes rapid sharing of pathogens.

Participants commented chiefly on benefits such as equitable access to medical and other products, as this was seen, through the COVID-19 lens, as a major benefit that should be addressed during a pandemic. One participant mentioned recent academic research which found that there is particular difficulty in securing access to benefits that require significant financial resources and where intellectual property was involved, naming specifically efforts to ensure access to technologies. The participant also mentioned difficulties linked to power imbalances in negotiating such benefits and stressed the value of having pre-agreed conditions. Another intervention flagged that technology transfer is more complex compared to granting royalty-free products. One other suggestion was to link the triggering of the technology transfer support to situations where there is an inability to provide timely and equitable access to medical products in real time. In addition to facilitating transfer of technology and sharing of know-how other options mentioned as types of benefits included limiting applicability of IP to certain products and ensuring subsidies to purchase medical products or direct cash monetary sharing, justified by the extreme profitability of products during a pandemic. However, there were also voices that called for a delimitation between core benefits of the WHO BioHub System which in their view pertain solely to access to BMEPP, and the profit sharing aspect that should be subject to de-linked arrangements. Concerns were voiced around ensuring that the design is mindful of other initiatives that exist or may be developed, as well as of the emergence of other actors within the global health architecture. These aspects were feared to lead to additional burdens on certain categories of stakeholders and may raise questions on the comparative advantage of the Biohub Initiative. While there seemed to be consensus that the users of the System should be the providers of benefits, there were different views on the extent of contributions. Suggestions were that academia, laboratories and research institutions could provide

**Figure 4: Overview of potential benefits which may be provided through access and benefits sharing arrangements**

<table>
<thead>
<tr>
<th><strong>Public health tools and information</strong></th>
<th><strong>Laboratory and capacity strengthening support</strong></th>
<th><strong>Medical and other products</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Public health information and tools to perform risk assessment</td>
<td>• Reagents and reference biological materials</td>
<td>• Access to medical and non-medical countermeasures or products (through donation tier pricing or normal pricing)</td>
</tr>
<tr>
<td>• Regular and timely surveillance updates and situation reports</td>
<td>• Training, mentoring and capacity strengthening (funds or in-kind training towards building laboratory and/or surveillance capacities in developing countries)</td>
<td>• Grant to manufacturers in developing countries licenses on mutually agreed terms on technology, know-how, products and processes for which it holds IPR for the production BMEPP medical products.</td>
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<tr>
<td>• Access to genetic sequence data (GSD) through one or more relevant, publicly accessible databases</td>
<td>• Research – participation and acknowledgement of Provider scientists, especially those from developing countries, in scientific projects</td>
<td>• Grant royalty-free licenses to interested manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of BMEPP medical products.</td>
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<tr>
<td>• Timely updated and evidence-based vaccine recommendations</td>
<td></td>
<td>• Transfer of technology, know-how and/or processes for production of BMEPP medical products.</td>
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benefits that pertain more to public health tools and information and laboratory and capacity building support, while product developers could provide monetary contributions and/or medical product related support. Member States were also seen as users of the System and therefore providers/contributors of benefits.

These technical consultations provide a foundational understanding of the different stakeholders’ views and solutions that could be envisaged as access and benefit sharing options. Table 3 presents selected consolidated opinions, as expressed by different stakeholders. They are compiled with the view of synthesizing key ‘umbrella’ points that have system design implications. To advance the work on access and benefits sharing, Member States would need to consider a set of choices in the design of the system. These include, but are not limited to giving direction on whether BMEPP and GSD should be treated similarly, whether access to BMEPP and/ or GSD should be linked to provision of benefits or a separate stand-alone benefit arrangement should be enacted, and questions around ensuring sustainability of funding streams dependent on the type of benefits the System should offer. To fully prepare for a pandemic situation, there needs to be a recognition that benefits span both interpandemic (preparedness) and pandemic (emergency response) stages. Therefore, access to certain benefits may be conditioned by certain epidemiological categorizations along the emergency continuum. However, while recognizing this, some benefits will never be attained at the optimal speed and quantity without investments in preparedness activities. Another key consideration that emerged throughout all consultations was the need to ensure that the proposed solutions are not overcome by events and technological progress. Therefore, the access and benefit sharing modalities should anticipate the shifts in data analysis and production of medical countermeasures. Lastly, while the WHO BioHub System is a voluntary service, it aims to have global applicability so that each country that may want to use it, can engage with it. Therefore, system design efforts need to seek consistency between international legal arrangements.
### Table 3: Consolidated feedback on selected key topics related to the design of the WHO BioHub System as mentioned by stakeholders

<table>
<thead>
<tr>
<th>WHO BioHub System key value-added considerations</th>
<th>ABS considerations</th>
<th>Resource considerations for provision of benefits</th>
<th>Other topics</th>
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<tbody>
<tr>
<td>Ensuring rapid access for novel pathogens (no sharing pathway may exist);</td>
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<td>Involvement of other laboratory networks and biorepositories</td>
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<td>Avoid bilateral or ad-hoc arrangements;</td>
<td>• Will the legal obligations be the same for BMEPP and GSD?</td>
<td>• Different type of financing options for provision of benefits and running of the System:</td>
<td>Through using standardized terms and conditions – (Terms of Reference and SMTAs) employ a distributive network approach.</td>
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<td>Provide legal and operational predictability;</td>
<td>→ Proponents for equal handling raise the issue that in the near future medical countermeasures will be developed solely based on GSD information;</td>
<td>• Monetary contribution fees based on type of utilization into a contribution fund;</td>
<td>Governance</td>
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<tr>
<td>Ensure a transparent sharing process;</td>
<td>→ Opponents raised the worry that this may hinder product development, that traceability of GSD access and use is not feasible, and that a combination of GSD, likely obtained from different sources, will be needed to develop medical products).</td>
<td>• In-kind provision of benefits such as capacity support or different forms of technical assistance;</td>
<td>This aspect was less discussed, one input was received on a potential regional approach.</td>
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<td>Ensure equitable access to medical products based on public health needs.</td>
<td>• Will the access to BMEPP and/or GSD be linked to the provision of benefits?</td>
<td>• Commitment to donate or offer at cost, real-time access to medical products (based on epidemiological situation);</td>
<td>Process of development</td>
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<td>→ Proponents: this would be needed as this is a voluntary scheme and there may be an incentive to access the BMEPP and GSD but not contribute to the System;</td>
<td>• Solidarity donations into a humanitarian fund.</td>
<td>Member State driven process acknowledging discussions on global health instruments.</td>
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<td>→ Opponents: this should be decoupled as the incentive for stakeholders such as industry and others to contribute benefits would be that there is predictability and legal certainty that there will no additional national access and benefit sharing requirements applied to the shared BMEPP.</td>
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<td></td>
<td>• Access to BMEPP during an emergency (when demand exceeds supply) should be guided by the public health need and impact (prioritizing research needed for deciding on immediate public health measures).</td>
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<td>• Access to medical products should be based on public health need (guided by risk-assessment in the sense that if a country is at a more reduced risk-level it should be de-prioritized to access medical products during an emergency). The stakeholders that opinionated on this respect mentioned that this type of benefits should be offered regardless of whether Member State have provided BMEPP to the WHO BioHub System.</td>
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<td></td>
<td>• Technology transfer and (temporary) lifting of IP protection, are the most complex benefits to be potentially provided through the System. One proposal is to engage in these type of benefits based on the type of emergency and inability to provide timely and equitable access to medical products in real time.</td>
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V. Way forward

Progress on the development of the WHO BioHub System is being reported to WHO Member States through the report of the Director-General on implementation of resolution WHA 74.7. Certain Elements of the WHO BioHub System may be further piloted, so that they can serve as useful building blocks for the new architecture for epidemic and pandemic prevention, preparedness and response, consistent with ongoing Member State directions and decisions.

WHO will continue to seek Member State input on the WHO BioHub System design and is planning a series of Member States specific consultations in 2022 to discuss and gather input on elements of the access and benefit sharing mechanism.

WHO wishes to extend sincere thanks to all Member States and related authorities that have engaged in pilot testing operations, bilateral exchanges and technical consultations, to the Swiss Confederation and Spiez Laboratory for their commitment to this initiative, and to all the stakeholders that have offered constructive feedback to advance the WHO BioHub System design.