World Health Organization

WHO Technical Consultation Series – WHO BioHub System: Researchers' needs and contributions to the future pandemic system

I. Introduction

A new era of cooperation is needed for the urgent development of a globally agreed mechanism for sharing pathogens. The coronavirus disease (COVID-19) pandemic highlighted the shortcomings of the global health security architecture. Noting these shortcomings, the Director-General of the World Health Organization (WHO), Dr Tedros Adhanom Ghebreyesus, called for the development of an innovative approach to strengthen preparedness and response to infectious hazards through the establishment of the WHO BioHub System. The purpose of this system is not to replace existing structures, but rather to complement them. The aim is to encourage and support the rapid and broad sharing of biological materials with epidemic or pandemic potential (BMEPP) soon after the detection of unusual events. Overall, the system would allow the effective characterization and surveillance of those BMEPP, and the timely production of diagnostic products, devices, therapeutics and vaccines. The principles on which the WHO BioHub System is based include the equitable allocation of the benefits derived from the sharing of BMEPP for public health purposes.[1]

To fulfil its goals, the WHO BioHub System needs to be based on trust among all parties involved and built under pre-agreed conditions and a clear modus operandi. Hence, this initiative is set up as a **pathfinder project** to spark discussions on the further development of this global system, while better understanding the system's implications through the launch of a pilot testing phase until May 2022. Throughout the pilot testing phase, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) will be the sole pathogen shared with and from the WHO BioHub Facility, which is located in Spiez, Switzerland. Subsequently, the scope of BMEPP shared within the system will be broadened to potentially include those on the list of priority pathogens for research and development (R&D) in the WHO R&D Blueprint,[2] and additional facilities will reinforce the WHO BioHub System.

Within the WHO BioHub System, the laboratories (both those sharing BMEPP and those requesting them) will play a key role in supporting public health responses by rapidly analysing the BMEPP or developing research projects to expand knowledge and advance technical work on high-threat pathogens. Therefore, this consultation involves a wide range of stakeholders including laboratories, biorepositories, research entities, and health authorities from both the public and private sectors. The objective of this consultation is to start a conversation with those key stakeholders to gain their support in designing a WHO BioHub System that meets public health needs. The input of key stakeholders will ensure the viability of the guiding principles of the WHO BioHub System – especially "Acknowledgement, co-authorship and joint research" and "Collaboration and cooperation".

1 See the BioHub concept note at https://www.who.int/initiatives/who-biohub.

2 At present, the priority diseases are COVID-19, Crimean-Congo haemorrhagic fever, Ebola virus disease and Marburg virus disease, Lassa fever, Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome (SARS), Nipah and henipaviral diseases, Rift Valley fever, Zika and "Disease X" (see Prioritizing diseases for research and development in emergency contexts).

II. Topic statement

When new pathogens emerge and lead to outbreaks, it is critical to rapidly identify and characterize those pathogens, assess the risk posed by their emergence and, where appropriate, quickly develop countermeasures such as diagnostics, vaccines and therapeutics. In 2003, when China was experiencing a devastating outbreak of pneumonia of unknown origin, the rapid sharing of biological materials with a global laboratory network speeded up the discovery of the responsible pathogen: SARS-CoV. Similarly, the WHO BioHub System aims to provide a rapid, secure and inclusive approach to disseminating material – with a swift provision of information back to the originating laboratories – and to facilitate additional sophisticated analysis and research by qualified laboratories around the world.

This technical consultation will provide a forum for discussing the characteristics of a global system to ensure the rapid sharing of BMEPP, and for the rapid generation of knowledge (and related research benefits) arising from this sharing. This background paper provides indications of broad areas of motivations for and barriers to pathogen sharing, to help stakeholders to start thinking ahead of the meeting, and to serve as a basis for discussions during the technical consultation itself.

III. Factors impacting the sharing of BMEPP

This section provides a list of some of the factors that may motivate or discourage laboratories from joining the WHO BioHub System. The list will be discussed during the technical consultation, and the WHO Secretariat welcomes any comments and input from the participants.

A. Confidence and trust

Confidence and trust in various design and operational aspects of the system are foundational and critical factors; these will be built and maintained if the system implements and sustains international and national **biosafety and biosecurity** requirements. In addition, to uphold the objectives of **advancing global public health goals** while **promoting local researcher needs**, there must be an unwavering commitment to the **equitable sharing of benefits** arising from the use of the system.

Factors that can damage confidence and trust are a **lack of transparency** on how the BMEPP will be used, a lack of **consistency**, and inadequate efforts to promote the contributions of laboratories in low- and middle-income countries (LMIC) to the system for international sharing of BMEPP.

B. Efficient processes

To maximize efficiency, end-to-end processes must be **simple but robust**. This includes the procedures to **request BMEPP** and **secure and manage the shipment** of samples. Shipment must be quick and **cost-effective** to enable rapid sharing. Once laboratories have received BMEPP, consideration must be given to the speed and ease with which **results and analyses can be shared**; for example, the implementation of user-friendly software in laboratories

that have received BMEPP that allows **timely prepublication access** to the results and **clarity on the timing of access** to the results for submitting parties (i.e. before public release). An additional opportunity to maximize efficiency is through the provision of **technical support** to make information on risk assessment and characterization rapidly available to national health authorities of originating countries, so that they can quickly implement the needed interventions to mitigate health impacts.

Processes are likely to be inefficient if there is a **lack of clarity** on how to access the system and how to identify contact points at relevant steps in the process. A **delay in providing information** to submitting parties, including on how the system would enable **access to medical countermeasures** developed as a result of sharing BMEPP, could both undermine trust and significantly disrupt the process. An additional important factor to avoid is **overlap with or duplication of existing systems** for the sharing of biological materials or biorepositories with the same public health objective. If participating in the WHO BioHub System carries a significant administrative and logistical burden, this will disincentivize LMIC laboratories and, more importantly, **hinder their ongoing efforts to address national priorities and needs**.

C. Research advancement and capacity-building

Fundamental to the establishment of the WHO BioHub System is the impact on and contributions to research advancement and capacity-building globally. Most simply, the system will support the **identification of new pathogens**. Beyond this lie significant **research and publication** opportunities (with appropriate acknowledgement, attribution and, where appropriate, co-authorship) in open access and high-impact scientific journals. As BMEPP research contributions increase, so will access to **potential grants** for research, which again will increase the number of research entities with the capacity to participate. Additional incentives for participating laboratories are the **training and capacity-building** opportunities; for example, in advanced research and analysis techniques, tools and approaches.

Subsequent to the research and analysis of BMEPP are the pathogen characterization and risk assessments that will be used to inform public health decision-making and contribute to protect global health. It is expected that all laboratories requesting BMEPP will share all the results of their analysis in a timely and transparent manner. A failure to do so may lead to potentially contradictory and confusing outputs as interested parties identify the findings haphazardly through disconnected publications in scientific journals.

D. Predictability

Predictability of the system is closely related to both trust and efficiency. In addition to the elements highlighted above, there is a need for early agreement on the **type of publications** and for consensus that publications will be in **open access** fora to maximize the scientific community's access to methods and results. In certain situations, it may be necessary for WHO to act as an interlocutor between laboratories that received BMEPP and those that submitted BMEPP in terms of co-authorship according to guidelines from the International Committee of Medical Journal Editors (ICMJE).

E. International collaboration

Intrinsic to the Director-General's request to strengthen global preparedness for infectious hazards through innovative initiatives is the request for **strengthened international collaboration**. The WHO BioHub System can therefore be viewed as a chance to contribute to global public health goods, a platform to access collaboration opportunities and new networks, and an opportunity to advance WHO's public health objectives in a fair and equitable manner. As national laboratories look to participate in the system, they will need the **support of national authorities**.

Desired deliverable from this workstream of the WHO BioHub System

A desired deliverable from this workstream is the development of a code of conduct – a written document that clarifies expected behaviours by submitting and receiving researchers and that is based on good practice examples from international collaborations.

IV. Questions

1) What is your opinion about the incentives and barriers for the sharing of biological materials with epidemic or pandemic potential?

2) Do you know good practices and solutions that could be part of the design of the WHO BioHub System, to help it to achieve its objectives and align with its principles?

3) What are the best ways for the WHO BioHub System to support global research advancement and capacity development (e.g. setting up networks or joining existing networks and supporting the transfer of skills and knowledge)?

4) Is there a need for a system to monitor or track acknowledgments and co-authorship? If so, what role should WHO and others play in such a system?