



Meeting Summary

Joint Coordination Group (JCG)

Date	Time	Location
Friday, 17 June 2022	14:00 – 16:00 GMT	Virtual (Zoom)

Participants

JCG Members

Peggy Hamburg, Chair
DCVMN/Instituto Butantan – Alexander Preciosio
EMA – Marco Cavaleri
FDA – Peter Marks
FIND – Bill Rodriguez
GAVI – Sophie Mathewson
GAVI – Marta Tufet
IPMFA/Sanofi – Isabelle Deschamps
IFRC – Petra Khoury
MSF – Sidney Wong
UNICEF – Andrew Owain Jones
Wellcome Trust – Charlie Weller
WHO – Deus Mubangizi
WHO – Ana Maria Henao Restrepo
WHO – Chikwe Ihekweazu
WHO – Tim Nguyen
WHO – Rosamund Lewis

Non-JCG Members

Africa CDC – Merawi Aragaw
DRC INRB – Jean-Jacques Muyembe
Global Fund – Harley Feldbaum
Nigeria CDC – Ifedayo Adetifa
Nigeria CDC – Lateefat Amao
Nigeria CDC – Oluwatoni Akinola

CEPI

Frederik Kristensen
Nicole Lurie
Gwen Tobert
Elizabeth Rinaldi
Adam Hacker
Ankur Mutreja
Barbara Ngouyombo
Debra Yeskey
Elen Høeg
Ingrid Kromann
Joseph Simmonds-Issler
Khadimul Mazhar
Oyeronke Oyebanji
Paul Kristiansen
Bill Dowling
Kristine Rose
Alexandru Rotar
Ranna Eardley-Patel
Tiana Carstairs

Item 1: Welcome and Introductions

CEPI Deputy CEO Frederik Kristensen explained that CEPI convened this meeting because CEPI's mission is not only to accelerate R&D, but also to enable access. He highlighted the need to learn from collective failures of enabling access to vaccines and other lifesaving tools during the COVID-19 pandemic.

JCG Chair Peggy Hamburg framed the purpose of this meeting, noting that it is important to establish an “ecosystem” of partners and stakeholders around monkeypox preparedness and response. She encouraged participants to address issues of equity at this early stage as we utilise existing products and think about how to ensure we have the tools we need for the future under different potential scenarios. She also flagged the opportunity to build preparedness for future outbreaks of other epidemic diseases. [Note: This JCG meeting was held on 17 June 2022. On 25 June, WHO Director – General Tedros determined that the current monkeypox outbreak does not constitute a Public Health Emergency of International Concern (PHEIC) at this time.¹]

Item 2: Updates and Follow-up from March 18 JCG Meeting

Nicole Lurie, CEPI Executive Director for Preparedness and Response, emphasised that the role of the JCG is to prompt action. She therefore briefly summarised CEPI's actions following the March JCG discussion on Chikungunya vaccines nearing licensure and considerations for country access to them. CEPI has been reaching out to WHO and regional regulators to look at potential regulatory pathways, as well as to UNICEF and Gavi to discuss next steps. CEPI intends to provide further updates at the next JCG meeting in the Autumn.

Item 3: Conclusions of the June 2-3 WHO consultation on monkeypox research priorities and knowledge gaps

Ana Maria Henao-Restrepo, Co-lead of the WHO R&D Blueprint for Epidemics, provided an overview of the conclusions and priorities coming out of the consultation her Team held on 2-3 June 2022. These included:

- To take a broad view in the context of other infectious diseases, collaborate across borders and disciplines, document and share best practices, optimise the standard of care, and ensure infrastructure for addressing these needs persists beyond the current epidemic.
- Global studies organised as partnerships to enhance equity, speed, generalisability, and local capacity.
- A need to determine the best diagnostic testing strategies to effectively find cases and a need for lab-based studies.
- Existing data for antivirals is currently only available from preclinical models, with continued uncertainties about their efficacy – especially against monkeypox. Randomised trials with standard-of-care (SOC) control can be done ethically.
- Vaccine research priorities include placebo-controlled studies and characterisation of immune responses to identify biomarkers that predict protection.

Item 4: Monkeypox Overview and Activities of the WHO Health Emergencies

¹ [https://www.who.int/news/item/25-06-2022-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee--regarding-the-multi-country-monkeypox-outbreak](https://www.who.int/news/item/25-06-2022-meeting-of-the-international-health-regulations-(2005)-emergency-committee--regarding-the-multi-country-monkeypox-outbreak)

Tim Nguyen, Unit Head for High Impact Events Preparedness in the WHO Health Emergencies Programme, gave an overview of the current monkeypox situation in non-endemic countries and the WHO response. As of 16 June, 42 countries had reported about 2,100 cases, with the majority in the European Union. While the disease can affect anyone, nearly all the current cases are male, and mostly men who have sex with men. The WHO response has five pillars: protection of communities from further spread, collective intelligence, emergency coordination, clinical care, and medical countermeasures (MCMs). The goals of the response are to raise awareness, empower at-risk populations, and stop spread in unexpected geographical locations. The primary approach is surveillance, detection, and isolation. The WHO recently issued interim guidance documents on clinical management and infection prevention and control (IPC)² as well as on immunisation³. The WHO is not recommending mass vaccination at this time.

As part of its response, the WHO is examining options for enabling access to MCMs during the current outbreak and has ongoing engagement with smallpox countermeasure manufacturers, holders, and partners. Nguyen noted that these MCMs were developed for a possible smallpox resurgence and are in limited supply and highly priced because they are only produced on a contractual basis. Access options include direct procurement from the manufacturer, pooled procurement (e.g., HERA, WHO global access and allocation initiative) from the manufacturer, bilateral donation from countries, and multilateral donations via WHO. Nguyen shared WHO's thinking on what a potential WHO global access and allocation mechanism for monkeypox MCMs could look like, based on the model of the International Coordinating Group (ICG) on Vaccine Provision.

Item 5: Endemic Country Perspectives and Concerns

JCG Chair Peggy Hamburg moderated this panel discussion among Dr. Aragaw (Head of the Division of Emergency Preparedness and Response, Africa CDC) and Dr. Amao (National Monkeypox Technical Working Group Team Lead, Nigeria CDC). Drs. Muyembe (DRC INRB) and Adetifa (Nigeria CDC) were unfortunately called into other urgent meetings and were unable to participate.

The panelists were asked for their perspectives on (1) evolving country/regional needs with regards to monkeypox control over the long term; (2) the role of countries, regions, and international organisations in supporting procurement, stockpiling, and deployment of MCMs; and (3) ways the response to the current global outbreak could be leveraged to better support efforts in endemic countries in the long-term.

Highlights:

- One of the key differences between the outbreaks in endemic and non-endemic countries is that the transmission context is mainly animal-to-human in the former and human-to-human in the latter; though recent cases in Nigeria with no known animal contact highlights the need for further research.
- Preparedness is essential, including the ability to jumpstart research when future outbreaks occur. This requires pre-positioned clinical trial material, improved surveillance, expanded lab capacity, and workforce and infrastructure preparedness.
- JCG members were encouraged to take a wider point of view and consider not just monkeypox, but other diseases that could expand beyond current endemic zones.
- The current response strategy in the region is mainly palliative because the region does not have access to prophylactics, like vaccines. As monkeypox will continue to be a threat to the region, JCG members were encouraged to find a mechanism for equitable access to MCMs and pooled procurement to avoid unnecessary competition across economies.

² <https://www.who.int/publications/i/item/WHO-MPX-Clinical-and-IPC-2022.1>

³ <https://www.who.int/publications/i/item/who-mpx-immunization-2022.1>

Item 6: Regulatory

Participants discussed several regulatory issues related to monkeypox MCMs and enabling equitable access including how WHO Prequalification (PQ) / Emergency Use Listing (EUL) factor in and whether PQ/EUL can be based on existing stringent regulatory authority (SRA) licensure with monkeypox indications.

Highlights:

- The African Medicines Agency has great potential to harmonise regulatory approaches across the continent and thereby accelerate access. While local regulatory decision making supports pharmacovigilance, it can also slow access.
- If we wish to collect more data on MCMs in this outbreak, then the nature of their deployment should enable that to happen. First the public health community needs to agree upon what we hope to achieve in response to this outbreak.
- A Public Health Emergency of International Concern (PHEIC) declaration or other extenuating circumstances is required to trigger an EUL.⁴
- It was noted that access is not equitable if some countries can only get access through participation in clinical trials (and only some countries are prepared to host clinical trials).
- How might we leverage a SRA approval based on immunogenicity to enable access in future epidemics? Even if outbreaks do not reach PHEIC status or global impact, can we have mechanisms like EUL to address demand and urgent need at the local/regional level? How can we think beyond efficacy studies to other forms of data (e.g., observational studies) that can inform the data package?

Item 7: Supporting Access

Participants were asked to consider the following questions:

- *What are JCG partners currently doing or planning with regards to research, securing supply, considering procurement, or other needs? What would you like to see from one another?*
- *Should there be global or regional stockpiles? If so, which entity should procure, maintain, and manage? In what time frame? What data are needed to inform such decisions?*
- *If research reveals that new or improved MCM tools are necessary, how should we be thinking, even now, about enabling equitable access to them?*
- *How will long-term access needs and demand be determined? When does this need to be completed?*
- *What needs to happen to sustainably match supply with that demand? In what time frame?*

Highlights:

- FIND is tracking 43 commercially available monkeypox tests, but none of them have had a formal performance evaluation.⁵ There is also no process or plan in place for a monkeypox diagnostics Emergency Use Authorisation. FIND does not have a monkeypox programme or financing to support evaluations; neither does WHO.
- This is a good test case for the 100 Days Mission and the ability to rapidly develop not just molecular tests, but also antigen/rapid diagnostic tests (RDTs), which would be especially helpful in endemic countries.

⁴ https://cdn.who.int/media/docs/default-source/medicines/eulprocedure_a63b659c-1cdc-4cee-aa2d-ef5dd9d94f0b.pdf?sfvrsn=55fe3ab8_7&download=true states that the EUL procedure “should be used primarily during a Public Health Emergency of International Concern (PHEIC), although the Director-General may authorize the use of this procedure for a public health emergency that does not meet the criteria of a PHEIC if/he determines that this is in the best interest of public health.”

⁵ FIND has a monkeypox test directory online, with the latest data on available tests: <https://www.finddx.org/mpx-test-directory>

- The JCG may have a role in convening a discussion around an outbreak for a pathogen that is not one of the members' identified "core" pathogens.
- CEPI is willing to connect the links in the chain if it receives a signal from the other members that this is desired.
- Given where we are in this outbreak, and the diagnostic gaps, CEPI asked the JCG members whether it would be helpful for CEPI to support monkeypox immunology and antibody standard development. FIND responded affirmatively. WHO representatives had left the call and will follow up separately.
- Gavi is conducting a "living assessment" to analyse the situation and examine tradeoffs in terms of other vaccines and priorities.
- Vaccine stockpiles need to be seen as insurance to ensure availability and prompt shipment of vaccines that are needed in emergencies. There are four elements that are important to take into account when establishing a stockpile: demand forecasting based on surveillance and epidemiological history; product characteristics; rotation options (e.g., what do we do with unused doses? Any program that doses could go to instead of wasting?); and risk-sharing. Long-term visibility and commitment is critical for manufacturers. Should stockpiles be maintained at the manufacturer for liability mitigation or regionally-based?
- How do we avoid a repeat performance of procurement decisions coming too late? Should there be a central or pooled procurement mechanism for monkeypox vaccines? Signs so far suggest a modest financial need, depending on how the situation evolves. Raising money up-front so that contracting can be done rapidly would be something to explore – for both Gavi and non-Gavi countries.

Item 8: Summary and Next Steps

In closing, Peggy Hamburg highlighted the importance of a broad research agenda – including clinical and epidemiological studies; rapid mobilisation of research opportunities; and building capabilities in endemic countries to manage cases, detect emerging outbreaks, provide quality care, and conduct clinical trials. Concerted efforts should be made to help strengthen key institutions and partners like the African Medicines Agency. It was also noted that:

- CEPI is willing to support development of an antibody standard and reagents useful for vaccine and diagnostics development.
- WHO Blueprint team can be expected to coordinate research related to generating new knowledge based on vaccine deployment in the current situation.
- FIND will continue to seek support for diagnostics development.
- If it is determined that a stockpile is needed to address future outbreaks, UNICEF may be well positioned to explore pooled procurement mechanisms.
- This group will reconvene if there is a need to do so.