



Mpox Research and Innovation

Aligning Research Response with Outbreak Goals

Scientific conference

Date: August 29-30th, 2024

Hybrid Meeting

Zoom link/Registration:

https://who.zoom.us/webinar/register/WN_YcYZItcJQrqUzQFLC1THWw

Live stream link: https://player.4am.ch/who/20240829_MpoxMC/index.html

Globally, the multi-country outbreak of mpox has led to 116 countries and territories in all WHO regions reporting 99 176 confirmed cases and 208 deaths (CFR 0.2%) between May 2022 and June 2024. The situation in the Democratic Republic of the Congo, linked to Clade I MPXV, has continued to evolve with cases rising steadily since late 2022 and has now become particularly concerning. This increased case reporting is driven by two concomitant outbreaks, including (1) outbreaks in historically endemic parts of the Democratic Republic of the Congo, affecting primarily children, and (2) a rapidly expanding outbreak of a new strain of MPXV clade I – named clade Ib – which like Ib appears to be spreading predominantly through sexual networks, expanding geographically in eastern provinces of the Democratic Republic of the Congo, and now also affecting neighbouring countries.

On August 13, 2024, Africa CDC's declared Mpox as a Public Health Emergency of Continental Security. This declaration aims to galvanize political leadership and engagement among AU Heads of State and Government, facilitating the rapid mobilisation of essential financial and technical resources to control the outbreak(link).

The Director-General of the World Health Organization (WHO), having concurred with the advice offered by the International Health Regulations (2005) (IHR or Regulations) Emergency Committee regarding the upsurge of mpox 2024 during its first meeting, held on 14 August 2024, has determined, on the same date, that the ongoing upsurge of mpox in the Democratic Republic of the Congo and a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC) under the provisions of the International Health Regulations (link).

This Research Response Conference is a pivotal gathering aimed at addressing the urgent global challenge posed by the mpox virus. This conference is designed to foster

a collaborative and open environment where researchers, public health officials, and stakeholders from affected countries can take the lead in shaping the research agenda.

Our collective goal is to align research efforts with outbreak response strategies to effectively mitigate morbidity and mortality, halt transmission, and advance the development of vaccines, diagnostics, and therapeutics to prevent future outbreaks.

OBJECTIVES

- **Review Current Disease Transmission Dynamics and Disease Surveillance**
- **Assess Therapeutics, Diagnostics, and Vaccines**
- **Explore Novel Evaluation Approaches for MCMs**
- **Incorporate Good Participatory Practices**
- **Enhance Scientific and Ethical Capacity**
- **Review Regulatory and Ethics Frameworks**
- **Identify Research Priorities and Opportunities**
- **Ensure coordination of Studies in Africa**
- **Promote Multi-Country Trial Collaboration**

EXPECTED OUTCOMES

- **Development of an emergency mpox research response:** Create a foundational document to guide the development of an mpox Research Response Agenda & Implementation Roadmap. This document will enumerate knowledge gaps information needed to end this epidemic, and identify opportunities for research, regulatory, and ethical convergence, while outlining priority research areas for this outbreak and for the African continent.
- **Enhanced Collaboration and Partnerships:** Outline approaches to further facilitate continental and international collaboration and partnerships focused on the research and development of vaccines, therapeutics, and diagnostics related to mpox.
- **Key Steps and Timelines:** Provide an outline of essential steps and timelines to address the identified research gaps and opportunities, ensuring a structured approach to advancing the research agenda.

DRAFT Agenda

Chairperson: XXXXX

Time	Topic	Speakers
INTRODUCTION		
	Welcoming remarks	Africa CDC WHO AFRO DG, INSP
	Objectives and expected outcomes	Chairperson-
	Official Opening	Honorable Minister of Health
Deliberating on current Disease Transmission Dynamics & Clinical Course		
10 mins	Overview of the epidemiology of clade 1 & clade 1b including high risk populations	
10 mins	Overview of the clade 1 clinical characteristics	
10 mins	Overview of the clinical and virologic characteristics of clade 1b	
30 mis	<p>What are the main knowledge in gaps?</p> <ul style="list-style-type: none"> o What are the main knowledge gaps on the transmission dynamics of clade 1 and clade 1b mpox transmission and on clinical characteristics? o What data is critical to facilitate the optimal deployment and evaluation of medical countermeasures (MCMs). 	<p>Panel discussion Moderated by XXXX</p> <p>Countries -response leaders and clinical management Other invited experts</p>
30 mins	<p>How can research address identified knowledge gaps?</p> <ul style="list-style-type: none"> o What studies could/should be integrated into the outbreak response? o How can they be coordinated across countries and what efforts from national researchers and others are needed for their timely implementation? o Can viral genomic sequencing be used to understand transmission dynamics drive targeted public health interventions? 	<p>Panel discussion Moderated by XXXX</p> <p>Countries Other invited experts</p>
Assessing Vaccines: Integrating into the Outbreak Response		
15 mins	Overview of data supporting the safety and efficacy of licensed and candidate vaccines for mpox for adult, pediatric, and special populations.	
20 mins	<p>What are the main knowledge gaps?</p> <ul style="list-style-type: none"> o What studies are needed to assess safety, effectiveness and efficacy of available 	<p>Panel discussion Moderated by XXXX</p>

Time	Topic	Speakers
	vaccines in the context of the outbreak (age groups, special populations, routes of administration, schedule) <ul style="list-style-type: none"> o How can evaluation of novel candidate vaccines be integrated into the outbreak response? 	Countries Other invited experts
10 mins	Deployment of limited vaccine supply to high-risk populations and role of randomization in their assessments	
20 mins	What are the main knowledge gaps? <ul style="list-style-type: none"> o How to generate robust evidence on optimal deployment strategies for maximizing public health impact of vaccination efforts during this outbreak? 	Panel discussion Moderated by Jean-Marie Okwo-Bele Countries Other invited experts
Assessing Therapeutics integrated into the outbreak response		
10 mins	Data on the importance of optimizing standard of care and scaling up safe clinical supportive care for mpox patients: a basic approach to save lives	
10 mins	Overview of candidate therapeutics and what are the priority interventions to be studied in future clinical trials?	
30 mins	How can conducting research optimize clinical care? <ul style="list-style-type: none"> o How can conduct of clinical trials improve the standard of supportive care? o How clinical trials can be embedded into outbreak response? o How to overcome challenges in conduct of clinical trials on mpox in at risk patients such a young children or PLHIV? 	Panel discussion Moderated by XXXX Countries Other invited experts (Janet Diaz has suggestions)
Assessing Diagnostics integrated into the outbreak response		
10 mins	Overview of available diagnostics tool and candidate test in the pipeline with potential to facilitate diagnostics and outbreak response	
30 mins	What research can help to scale up the access to test with good sensistivity and specificity? <ul style="list-style-type: none"> o Is scaling up POC solutions (PCR based) possible? o What additional RDTs should be assessed? o Can reference labs be set up in the continent to support conduct and interpretation of serology studies? 	Panel discussion Moderated by XXXX Countries Other invited experts
Incorporating Good Participatory Practices in any research conducted in the context of this outbreak		

Time	Topic	Speakers
10 mins	Overview of available tools for community engagement and GPP	Dr. Mohammed Abdullaziz
20 mins	How can we ensure communities are at the center and contribute to guide research? <ul style="list-style-type: none"> ○ What actions are priority to ensure that this research response include good participatory practices? ○ What actions are priority to ensure that this research response enhances community engagement? ○ What actions are priority to ensure that this research response adheres to ethical standards. 	Panel discussion Moderated by XXXX Countries Other invited experts
Converging on Regulatory and Ethics Frameworks		
10 mins	Overview of regulatory, ethics, and sample-sharing frameworks within the African research ecosystem.	
30 mins	How can regulators and ethicists contribute to ensure research becomes an integral part of this and every outbreak response? <ul style="list-style-type: none"> ○ What are the major challenges towards regulatory convergence and ethical reliance in the African continent? ○ What actions are needed by national NRAs and ERCs to facilitate effective and ethical research that complies with international regulatory standards? ○ How can others contribute? 	Panel discussion Moderated by XXXX Countries Other invited experts
Identifying the immediate Research Priorities and Opportunities		
10 mins	Overview of mpox studies of MCMs ongoing or planned	Yap Boum
	What are the key actions to expedite these trials and promote collaboration to answer key public health questions? <ul style="list-style-type: none"> ○ CORE protocols? ○ Agreed endpoints to facilitate systematic review and synthesis ○ Platforms trials? ○ Shared DSMBs or collaboration between DSMB? ○ Data sharing? 	Panel discussion Moderated by XXXX Pis of each of some of the studies Other invited experts
10 mins	Summary of research priorities discussed during the meeting (in each precedent panel discussion)	

Time	Topic	Speakers
30 mins	<p>Research integrated into the outbreak response is needed and possible, what are the top 10 priorities?</p> <ul style="list-style-type: none"> ○ What are the perspectives from various countries on ongoing research priorities and opportunities, ○ How can we promote consensus and collaboration around a common R&D Roadmap and on a prioritized research agenda? ○ What are the critical next steps? 	<p>Panel discussion Moderated by XXXX</p> <p>Moderators of each of the precedent panel discussions</p> <p>Other invited experts</p>
Countries in the driving seat		
	<p>What can governments do to support national researchers and research institutions?</p>	<p>Panel discussion Panel discussion Moderated by XXXX</p> <p>Countries Other invited experts</p>
Final conclusions and next steps		
	Summary of major conclusions	
	Next steps & Timelines	Meeting organizers
	Closing remarks	