Mpox Research and Innovation

Aligning Mpox Research Response with Outbreak Goals

Scientific conference
Version 3.0

AfricaCDC Centres for Disease Control and Prevention
CEPI
NIH National Institute of Allergy and Infectious Diseases
World Health Organization

This Research 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 a prioritized research agenda aligned with emergency response goals.

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.

Key Principles Guiding the Conference

Collaborative and Open Approach: We emphasize the importance of collaboration across various areas of expertise, including public health officials, researchers, funders, regulators, and ethics bodies. By working together, we can ensure that our research response efforts are comprehensive and inclusive, leveraging diverse expertise to tackle the complexities of this mpox outbreak.

Leadership from Affected Regions: This conference places the Ministry of Health (MOH) and researchers from countries most affected by mpox at the forefront. Their insights and experiences are invaluable in driving research priorities that are contextually relevant and impactful.

Alignment with Outbreak Response Goals: Research initiatives must be closely aligned with the overarching goals of the outbreak response. This includes efforts to reduce disease transmission, improve patient outcomes, and enhance public health preparedness through the evaluation of candidate medical interventions.

People-Centered Focus: At the heart of all research efforts there should be a commitment to people-centered research. We strive to ensure that the needs and well-being of affected populations are prioritized in all research activities, recognizing the human impact of the disease. Therefore, the research response will integrate good participatory practices ensuring dialogue with affected communities. In doing so, the uptake of research results will be more impactful.

Timely Integration of Research and Response: To maximize the effectiveness of research efforts, it is crucial that research activities are integrated into the outbreak response in a timely manner. This ensures that findings can be rapidly translated into actionable strategies that benefit public health.

Commitment to Ethically Sound and Scientifically Robust Research: Despite the commitment to urgency, all clinical research must respect international guidance for human subject protections and clinical trials must be robust resulting in reliable actionable evidence.

As we embark on this conference, we invite all stakeholders from the African continent and globally to engage actively and constructively in discussions, share insights, and collaborate on proposing innovative solutions. Together, we can advance our understanding of the mpox virus and contribute to a coordinated international response to the mpox outbreak that safeguards global health.

OBJECTIVES

- **Review Current Disease Transmission Dynamics**

Evaluate evidence and identify knowledge gaps on disease surveillance, the dynamics of mpox transmission, and clinical characteristics of various circulating clades, and what data are critical to interventions that can stop transmission and facilitate the optimal deployment and evaluation of medical countermeasures (MCMs).

- **Assess Therapeutics, Diagnostics, and Vaccines**

Review updated evidence regarding therapeutics, diagnostics, and vaccines, both licensed and under development, and strategize on deployment approaches for maximizing public health impact during the outbreak.

- **Explore Novel Evaluation Approaches for MCMs**

Investigate innovative methods for evaluating mpox therapeutics and vaccines, integrating them into the outbreak response. Identify methods for evaluating safety and effectiveness, and the types of clinical trials needed to assess efficacy in various populations.

- **Incorporate Good Participatory Practices**

Identify actions to ensure that research responses include good participatory practices, enhancing community engagement and adhere to ethical standards.

- **Enhance Scientific and Ethical Capacity**

Ensure that the mpox research response strengthens collaborative, scientific, regulatory, and ethical capacity across continental Africa.

- **Review Regulatory and Ethics Frameworks**

Examine the regulatory, ethics, and sample-sharing frameworks within the African research ecosystem to facilitate effective and ethical research that complies with international regulatory standards.

- **Identify Research Priorities and Opportunities**

Gather perspectives from various countries on research priorities and opportunities, aiming to reach a consensus on a prioritized research agenda, including regulatory and ethics convergence inclusive of timelines.

- **Ensure coordination of Studies in Africa**

Review the landscape of ongoing and planned studies in Africa, identifying opportunities for coordination and collaboration, with affected countries' Ministries of Health and researchers taking the lead.

- **Promote Multi-Country Trial Collaboration**

Encourage collaboration on multi-country trials, focusing on key actions to expedite these trials and promote research that addresses public health questions that support outbreak control.

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 and opportunities for research, regulatory, and ethical collaboration, 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

Day 1
August 29
Co-Chairs: Jean-Marie Okwo-Bele, DRC and Jean-Jacques Muyembe, INRB, DRC

Time	Topic	Speakers
INTRODUCTION		
13:00 -13:15	Welcoming remarks	Dr. Dieudonne Mwamba Kazadi, Director General, INSP Dr. Jean Kaseya, Director General, Africa CDC Dr Michael J Ryan, Executive Director of WHE and Deputy Director General of WHO
13:15 -13:25	Objectives and expected outcomes	Chairpersons
13:25 -13:30	Official Opening of the Meeting	The Honorable Minister of Health of the Democratic Republic of Congo
Deliberating on current Disease Transmission Dynamics & Clinical Course		
13:30 -13:40	Overview of the epidemiology of mpox in DRC and globally	Brian Ajong, WHO
13:40 -13:50	Overview of clinical characteristics of various clades	Lorenzo Subissi, WHO
13:50 -14:00	Overview of the virologic characteristics of various clades	Jason Kindrachuk, University of Manitoba, Canada
14:00 -15:00	What are the main knowledge gaps? o What are the main knowledge gaps on the transmission dynamics and surveillance 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)? How can research address identified knowledge gaps? 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?	Panel discussion Moderated by Peter J Figueroa, University of the West Indies, Jamaica Jacqueline Weyer, National Institute for Communicable Diseases, South Africa Syndou Méité, Institut Pasteur, Côte d'Ivoire Olivier Le Polain, WHO Placide Mbala Kingebeni, INRB, DRC Dimie Ogoina, Nigerian Infectious Disease Society, Nigeria Richard Njouom Centre Pasteur, Cameroun Mulangu Sabue, INRB, DRC Emmanuel Nakouné, Institut Pasteur, Central African Republic

Time	Topic	Speakers
Assessing Vaccines: Integrating into the Outbreak Response		
15:00 -15:15	TPPs and overview of data and recommendations on mpox vaccines	Helen Rees, University of Wits, South Africa
15:15 -15:30	Deployment of limited vaccine supply to high-risk populations: opportunities for generation of randomized evidence	Richard Peto, University of Oxford, UK
15:30 - 16:10	What are the main knowledge gaps? o What studies are needed to assess safety, effectiveness, and efficacy of available vaccines in the context of the outbreak (age groups, special populations, routes of administration, schedule)? o How can evaluation of novel candidate vaccines be integrated into the outbreak response? o How can we generate robust evidence on optimal deployment strategies for maximizing public health impact of vaccination efforts during this outbreak? o How can other gaps be addressed?	Panel discussion Moderated by Phil Krause, WHO consultant Nicaise Ndembi, Africa CDC Tambe Elvis Akem, MSF/Epicentre, Liberia Bruce Kirenga, Makerere University, Uganda Francine Ntoumi, Congolese Foundation for Medical Research, Congo Andy Stergachis, Safety Platform for Emergency Vaccines (SPEAC), USA John Beigel, NIAID, USA Richard Peto, University of Oxford, UK
Converging on Vaccine Regulatory and Ethics Frameworks		
16:10 -16:30	Overview of vaccine regulatory and sample-sharing within the research ecosystem	Marco Cavaleri, EMA Kwasi Nyarko, AVAREF Secretariat
16:30 -17:00	How can regulators contribute to ensure research during outbreaks becomes an integral part of the regulatory framework in every outbreak response: o What are the major challenges towards regulatory convergence? o What actions are needed by national NRAs and economic regional communities to facilitate effective research that complies with international regulatory standards? o How can others contribute?	Panel discussion Moderated by Marco Cavaleri, EMA Anderson Montai, ANVISA, Brazil Brenda Valente, ANVISA, Brazil Rubina Bose, Central Drugs Standard Control Organization India Shinichi Okudaira, PMDA, Japan Donatien Kabamb Kabey, Acorep, DRC Beno Yakubu, National Agency for Food and Drugs Administration, Nigeria Tohlang Sehloho, SAHPRA, South Africa

Time	Topic	Speakers
		Peter Marks, FDA, USA or David Kaslow, FDA, USA
Assessing Diagnostics integrated into the outbreak response		
17:00 -17:10	Overview of available diagnostic tools and candidate tests in the pipeline with potential to facilitate diagnostics and outbreak response in the context of the TPP	Daniel Bausch, FIND
17:10 -17:20	Integrating research on unbiased diagnostics tools into the outbreak response	Ian Lipkin, Columbia University, USA
17:20 - 17:30	Enabling insights from Mpox data	Sebastian Maurer-Stroh, GISAID Initiative
17:30 -18:00	What research can help to scale up the access to tests with good sensitivity and specificity? o Is scaling up POC solutions (PCR based) possible? o What additional RDTs should be assessed? o Can reference labs be set up on the continent to support conduct and interpretation of serology studies?	Panel discussion Moderated by Miles Carroll, University of Oxford, UK Misaki Wayengera, Makerere University, Uganda Dougbeh Chris Nyan, National Public Health Institute of Liberia, Liberia Amadou Sall, Institut Pasteur Dakar, Senegal Eric D Laing, Uniformed Service University, USA Andreas Nitsche, RKI, The Netherlands Christina Hutson, CDC, USA Yenew Kebede, Africa CDC Félix Koukouikila, NHPL, Congo Christian Happi, Redeemers University, Nigeria
18:00	Adjourn	

Day 2

August 30

Co-Chairs: Dimie Ogoina, Niger Delta University, Nigeria and Samba Sow, CVD- Mali

Assessing Therapeutics integrated into the outbreak response		
13:00 -13:10	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	Janet Diaz, WHO
13:10 -13:20	Overview of candidate therapeutics and which ones could be considered in future clinical trials?	Karen Martins, BARDA, USA
13:20 -13:50	How can conducting research optimize clinical care? o How can the conduct of clinical trials improve the standard of supportive care? o How can clinical trials be embedded into outbreak response? o How can we overcome challenges in the conduct of clinical trials on mpox in high-risk patients including young children or PLHIV?	Panel discussion Moderated by Ian Crozier, NIH, USA Beno Yakubu, National Agency for Food and Drugs Administration, Nigeria Bernhards Ogutu, KEMRI, Kenya Jason Zucker, STOMP, USA Lucille Blumberg, National Institute for Communicable Diseases, South Africa Jean Luc Biampata, INRB, DRC Beatriz Grinsztejn, Fiocruz, Brazil Richard Kojan, ALIMA
Incorporating Good Participatory Practices in any research conducted in the context of this outbreak		
13:50 -14:00	Overview of available tools for community engagement and GPP	Julienne Anoko, WHO AFRO
14:00 -14:30	How can we ensure communities are at the center and contribute to guide research? o What actions are priorities to ensure that this research response includes good participatory practices? o What actions are priorities to ensure that this research response enhances community engagement? o What actions are priorities to ensure that this research response adheres to ethical standards?	Panel discussion Moderated by Nina Gobat, WHO Richard A Adegbola, Nigerian Institute of Medical Research, Nigeria N. Sam-Agudu, University of Minnesota, USA Hayley McGregor, University of Sussex, UK Elizabeth Serlemitsos, Johns Hopkins, USA Marie-Rose Bashwira, DRC

		Luke Bawo, Liberia Medicine Regulatory Agency, Liberia
Identifying the immediate Research Priorities and Opportunities		
14:30 -14:40	Overview of mpox studies of MCMs ongoing or planned	Kristine Rose, CEPI
14:40 - 15:10	What are the key actions to expedite these trials and promote collaboration to answer key public health questions? o CORE protocols? o Agreed endpoints to facilitate systematic review and synthesis o Platform trials? o Shared DSMBs or collaboration between DSMB? o Data sharing?	Panel discussion Moderated by Pontiano Kaleebu, UVRI/MRC, Uganda Yap Boum II, Pasteur Institut of Bangui, Central African Republic Mark Loeb, SMART, McMaster University, Canada Mayara Secco, Fiocruz, Brazil Carlos Alvarez, National University, Colombia Thomas Fleming, University of Washington, USA Alhassane Toure, WHO Abdourahamane Diallo, WHO Amanda Rojek, University of Oxford, UK Professor Christian Ngandu, INSP, DRC
15:10 -15:40	Research integrated into the outbreak response is needed and possible, what are the top 10 priorities? o What are the perspectives from various countries on ongoing research priorities and opportunities? o How can we promote consensus and collaboration around a common R&D Roadmap and on a prioritized research agenda? o What are the critical next steps?	Panel discussion Moderated by Marie-Paule Kieny, MPP, France Mosoka Fallah, Africa CDC Ian Crozier, NIH, USA Nina Gobat, WHO Pontiano Kaleebu, UVRI/MRC, Uganda Marie-Rose Bashwira, DRC Yap Boum II, Pasteur Institut of Bangui, Central African Republic Professor Christian Ngandu, INSP, DRC Peter J Figueroa, University of the West Indies, Jamaica Marco Cavaleri, EMA Miles Carroll, University of Oxford, UK Phil Krause, WHO consultant

Countries in the driving seat		
15:40 – 16:10	What can governments do to support national researchers and research institutions?	Panel discussion Moderated by Mosoka Fallah, Africa CDC Dougbeh Chris Nyan, National Public Health Institute of Liberia, Liberia Moses BF Massaquoi, CHAI, Liberia Helen Rees, University of Wits, South Africa Paula Reges, Fiocruz, Brazil Vedaste Ndahi, NEC, Rwanda Joseph Nyandwi, Institut National de Santé Publique, Burundi
Final conclusions and next steps		
16:10 -16:25	Summary of major conclusions & key messages	Chairpersons of day 1 and day 2
16:25 – 16:40	Next steps	WHO & Africa CDC
16:40 - 16:50	Closing remarks	Representatives of the meeting co-organizers
16:50	Adjourn	