Mpox Member States Briefing

23 August 2024

Public Health Emergency of International Concern for the upsurge of mpox

- On 14 August 2024 the WHO Director-General declared a **Public Health Emergency of International Concern for the upsurge of mpox** under IHR
- The Director General issued mpox temporary recommendations for IHR States Parties
- **Standing recommendations** issued in August 2023 and **extended** for another year until August 2025

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Director-General Temporary recommendations

Key Actions for States Parties experiencing the upsurge of mpox

- **Emergency Coordination**
  - ➢ Establish or enhance coordination and partner engagement.
- **Surveillance & Diagnostics**
  - ➢ Enhance surveillance, diagnostics, and contact tracing.
- **Clinical Care**
  - ➢ Expand patient support and strengthen healthcare capacity.
- **Travel & trade**
  - ➢ Increase cross-border collaboration and avoid restrictions.
- **Vaccination**
  - ➢ Prepare for targeted vaccination of high-risk groups.
- **Communication & Engagement**
  - ➢ Strengthen risk communication and counter misinformation.
- **Governance & Financing**
  - ➢ Secure funding and integrate mpox response into health programs.
- **Reporting**
  - ➢ Quarterly updates to WHO on progress and challenges.

First meeting of the International Health Regulations (2005) Emergency Committee regarding the upsurge of mpox 2024

19 August 2024 | Statement |Reading time: 18 min (4760 words)

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 (DRC) and in a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC) under the provisions of the Regulations. The communication of the Director-General regarding the determination of the above-mentioned PHEIC on 14 August 2024 is available here.

Principle: Respect human rights and dignity in all measures

Health Emergency Prevention, Preparedness, Response and Resilience (HEPR) Framework

Emergency coordination

Strengthened **workforce capacity** for health emergencies

Strengthening health emergency preparedness, readiness, and resilience

Health emergency **alert and response coordination**

Collaborative surveillance

Strong national integrated disease, threat, and vulnerability **surveillance**

Effective diagnostics and **laboratory** capacity for pathogen and genomic surveillance

Collaborative approaches for event detection, risk assessment, and response monitoring

Community protection

Community **engagement**, **risk communication** and **infodemic management**

Population and environmental **public health interventions**

Multisectoral action for **social and economic protection**

Safe and scalable care

Scalable clinical care during emergencies

Protection of health workers and patients

Maintenance of **essential health services**

Access to countermeasures

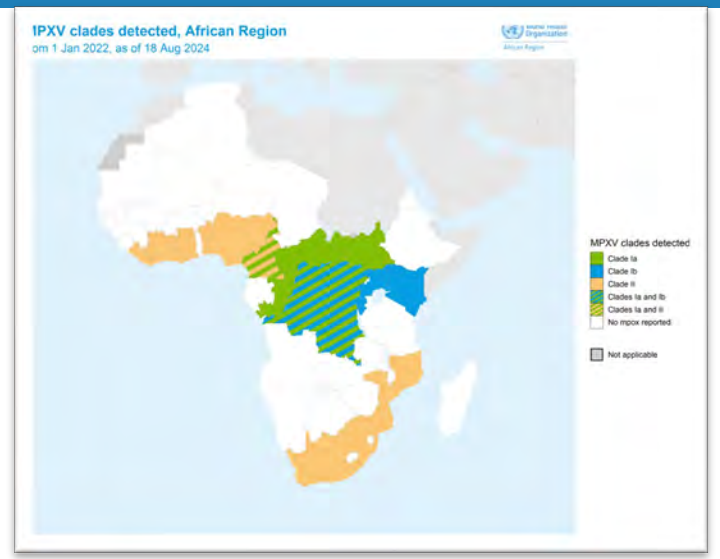
Fast tracked **R&D**

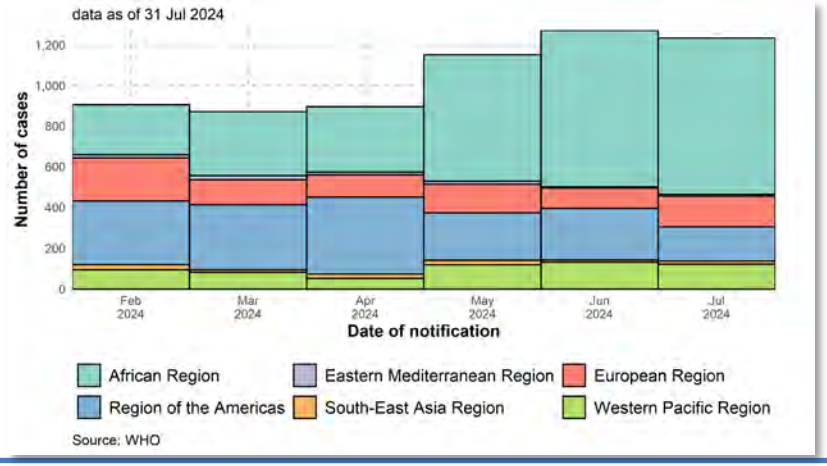
Scalable **manufacturing platforms**

Coordinated **supply chains** & emergency distribution

Collaborative surveillance critical activities

- Continuing **global mpox surveillance**
- Strengthening the surveillance in the **African continent** with **weekly** and subregional data **reporting**
- Publishing regular **epidemiological trends updates**
- Supporting countries with **testing** and **sequencing** capacities
- Providing **technical support and guidance** on surveillance, case investigation, testing and data analysis standards
- Conducting **rapid risk assessments** of the evolving situation
- Finalizing mpox **transmission protocol** for MS to implement





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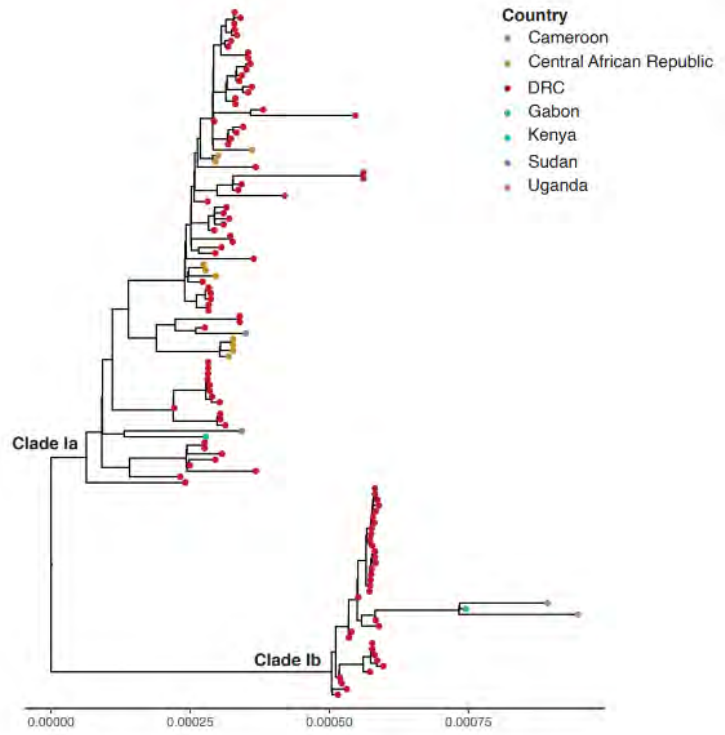
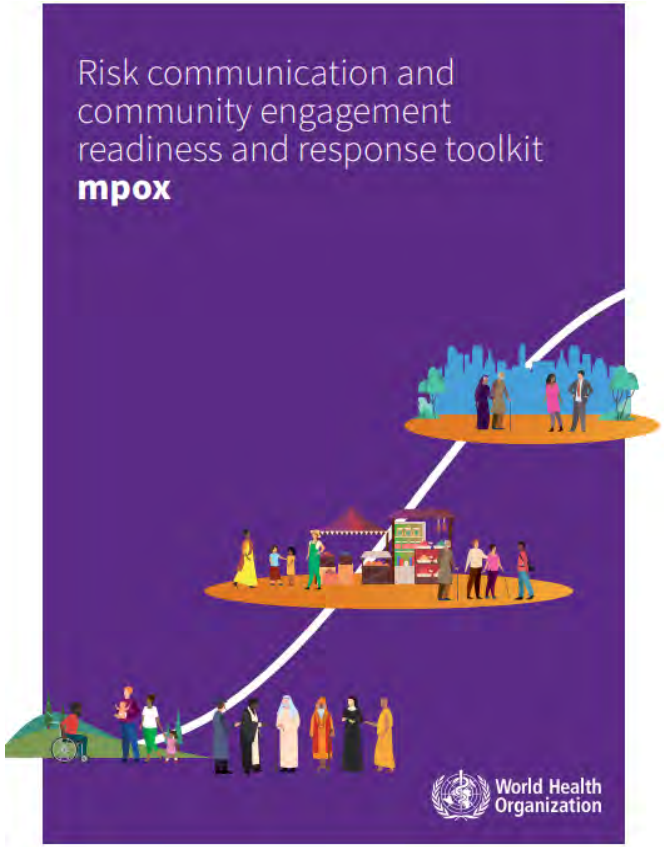
Collaborative surveillance: Lab/Diagnostics activities

- **Diagnostic procurement** of validated PCR kits → WHO EUL for in vitro diagnostics will open
- **WHO Global EQA**: should start shipping panels in few weeks time
- Ongoing **Lab evaluations of POC tests** with various stakeholders (e.g. FIND)
- **Availability of clade Ia and Ib isolates in the WHO Biohub** (live viruses or PCR control material) for all countries (**non-commercial purpose**) who wish to access such material
- Coordinated functional characterization of clade Ib



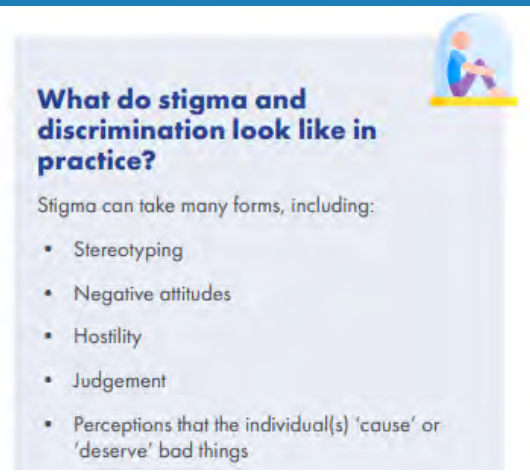
Community protection critical activities (1)

- **Engage affected communities**, in design, implementation, and evaluation of mpox prevention and control interventions. Establish mechanisms for ongoing dialogue and feedback. Support and empower community-led initiatives.
- Gather and utilize data on at-risk groups, knowledge gaps, risk perceptions, behaviors, social norms and the prevalence of stigma and discrimination to guide the development of evidence-based **risk communication strategies.** Implement strategies to counter **stigma, discrimination and counter mis- and dis-information.**
- Empower **community volunteers and health workers** to identify suspected cases early and report them promptly to the national mpox surveillance system. Train the community health workforce on case definitions and home care practices to contain and control outbreaks at the earliest stage.
- Ensure optimal deployment of **mpox vaccines**, prioritizing people at high risk of infection & healthcare/frontline workers; address vaccine hesitancy



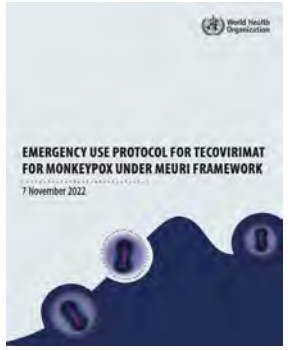
Community protection critical activities (2)

- Apply evidence-informed, equitable, and context-specific **Public Health and Social Measures** and continuously monitor and adjust PHSM policies, while minimizing unintended negative consequences.
- Implement **community IPC measures** and ensure **basic WASH services i**n high-risk settings. Ensure continuity of school services by providing guidance and supporting compliance with IPC standards.
- Strengthen cross-border surveillance and management of suspected cases in the context of international travel, including at **points of entry and during mass gatherings**. Apply a risk-based approach to travel and mass gatherings and implementing appropriate public health measures to mitigate mpox transmission risks, while avoiding unnecessary restrictions on travel and trade.
- Implement measures to prevent **zoonotic transmission** by educating communities on the risks of wildlife interactions, promoting safe practices and avoiding contact with potentially infected animals.



MPOX: safe and scalable clinical care

Emerging evidence: Preliminary results from the PALM 007 evaluating tecovirimat in Clade I show no efficacy on primary endpoint of skin resolution. Both groups with mortality 1.7 % showing that standardized supportive care can reduce mortality. Other trials on tecovirimat in Clade II continue. WHO monitoring results for update on recommendation.

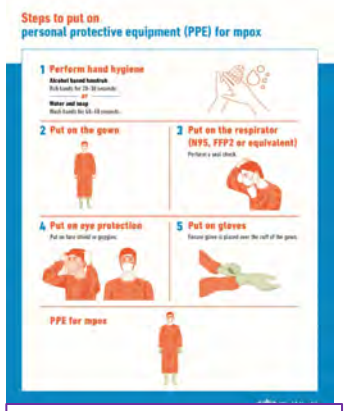


Emergency use access to tecovirimat V2.0 June 2024 patients with mpox while clinical trials cannot be immediately initiated, maintaining ethics and regulatory oversight; ensuring data monitoring for clinical characteristics and serious adverse events. 2nd EOI to launch to MS next week for those interested.

Treatment	Polyester				Cotton			
	Clean condition		Dirty condition		Clean condition		Dirty condition	
	Conc. (log_{10} PFU)	LRV	Conc. (log_{10} PFU)	LRV	Conc. (log_{10} PFU)	LRV	Conc. (log_{10} PFU)	LRV
Virus titer	4.5 ± 0.1	-	4.6 ± 0.2	-	4.0± 0.0	-	4.2 ± 0.1	-
Water at 22°C	3.3 ± 0.1	1.2	2.8 ± 0.2	1.9	2.6± 0.1	1.3	2.7 ± 0.0	1.5
Water at 70°C	≤1.0 ± 0.0	≥3.5	≤1.0 ± 0.0	≥3.6	≤1.0 ± 0.0	≥3.0	≤1.0 ± 0.0	≥3.2
Sodium hypochlorite 0.05%	≤1.0 ± 0.0	≥3.5	≤1.0 ± 0.0	≥3.6	≤1.0 ± 0.0	≥3.0	≤1.0 ± 0.0	≥3.2
Liquid disinfectant	≤1.0 ± 0.0	≥3.5	≤1.0 ± 0.0	≥3.6	≤1.0 ± 0.0	≥3.0	≤1.0 ± 0.0	≥3.2
Powder detergent 1	≤1.0 ± 0.0	≥3.5	≤1.0 ± 0.0	≥3.6	≤1.0 ± 0.0	≥3.0	≤1.0 ± 0.0	≥3.2
Powder detergent 2	≤1.0 ± 0.0	≥3.5	≤1.0 ± 0.0	≥3.6	≤1.0 ± 0.0	≥3.0	≤1.0 ± 0.0	≥3.2

Mpox inactivation study: preliminary findings show inactivation of MPXV virus on fabrics and pourous/non pourous surfaces with readily available disinfectants and detergents. Soon to be published

Collects patient-level anonymized clinical data to understand of clinical features and outcomes of mpox. Encourage MS to implement to **understand their own outbreaks/disease severity, risk factors** and to contribute to **global analysis**.



PPE donning/doffing posters

Coming soon:

- IPC & WASH rapid health facilty assesment tool for mpox
- Optimised supportive care guidance and training package for mpox
- Essential items calculator for medicine, supplies, IPC for home and facilty based care
- **Home care** posters and tools for clinical care and IPC to stop onward transmission

Access to countermeasures critical activities

Vaccines

Therapeutics

Diagnostics

Other relevant health products

Guidelines & Policy

- Continued updating of WHO (interim) policies on the targeted use of MCMs based on latest available evidence, including SAGE recommendations , standard of care

Research & Development

- Global mpox R&D roadmap
- Operational research to evaluate the effectiveness and accessibility of mpox MCMs in diverse settings through :
  - Standardized research methods & mechanisms for data and information sharing
  - Use of CORE protocols for Clinical Trials

Manufacturing / Access & Allocation

- i-MCM-Net partnership
- Demand Forecasting & Planning
- Coordinated Dose sharing, Procurement, Negotiation, and Market Shaping
- Develop Transparent Needs-Based Allocation Framework

Supply Chain Management

- Disease Commodity Package Standards for mpox
- Dx pre-procurement and coordination
- Develop Vx phase 1 model donate/allocate
- Data sharing on finance demand, procurement and shipping processes
- Immediate focus on in-country delivery planning for Vx in hot-spot areas
- Supply Chain for Vx and Tx still in the R&D phase

Regulatory Approvals

- EUL process of Vx and Dx for the evaluation of dossiers and Prequalification of Tx
- Assist regulatory clearance / registration process in LMICs
- Technical support to LMICs for quality & safety monitoring and post-market surveillance (including substandard & falsified products)

R&D Blueprint for Epidemics- Research Agenda

Aligning research with outbreak response goals

- Updated understanding of current dynamics of mpox transmission and epidemiology
- Updated evidence regarding therapeutics, diagnostics and vaccines licensed and under development
- Novel approaches for evaluation of mpox therapeutics and vaccines integrated into outbreak response.
- Discuss countries perspectives in terms of ongoing research priorities
- Ensure research responds incorporates good participatory practices
- Landscape of ongoing and planned studies in Africa and opportunities for coordination and collaboration with the affected countries MOHs and researchers in the driving seat
- Discuss and promote collaboration on multi-country trials- including key actions to quickly advance such trials
- Ensure that mpox research response enhances collaborative scientific, regulatory, and ethical capacity in continental Africa.
- Review of regulatory, ethics, and sample sharing frameworks in the African ecosystem

EXPECTED OUTCOMES

Development of a Research Roadmap enumerating knowledge gaps, opportunities for research, regulatory & ethical collaboration, and outlining priority research

Facilitation of continental and international collaboration and partnerships regarding R&D of vaccines, therapeutics, and diagnostics related to Mpox

An outline of key steps and timelines to address the above

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CEPI

AfricaCDC Centres for Disease Control and Prevention

NIH National Institute of Allergy and Infectious Diseases

Vaccine deployment strategies to control the outbreak

Transmission via close contacts including sexual contacts

Incubation period about two weeks

Need to define hot spots

Limited number of doses, at least in the short to mid term

Phased Vaccination Strategies

Stop Outbreak: **To interrupt known chains of transmission** by targeting contacts of incident cases with onset in the previous 2-4 weeks, and healthcare workers/frontline workers (HCWs/FLWs) in areas with casesThey are the most likely to transmit the disease. It may help reduce transmission by breaking chains of infection, making it more efficient in preventing cases directly linked to known cases.

Expand Protection: To limit additional potential spread in affected communities (after phase), provided additional doses are available. It targets individuals at high risk of severe disease—based on local epidemiology—in affected areas. This strategy aims to reduce local transmission by vaccinating a larger portion of the target population (aiming at >90% coverage), providing wider community protection, though it requires additional doses, resources, and logistics.

Protect for the Future: **To increase levels of population immunity** in areas at risk of outbreak expansion and or future outbreaks. It targets all populations recommended by SAGE when and as doses become available.

MCM-Net Mpox – ICG Mechanism

Establish International Coordination Group (ICG) on provision of mpox health products

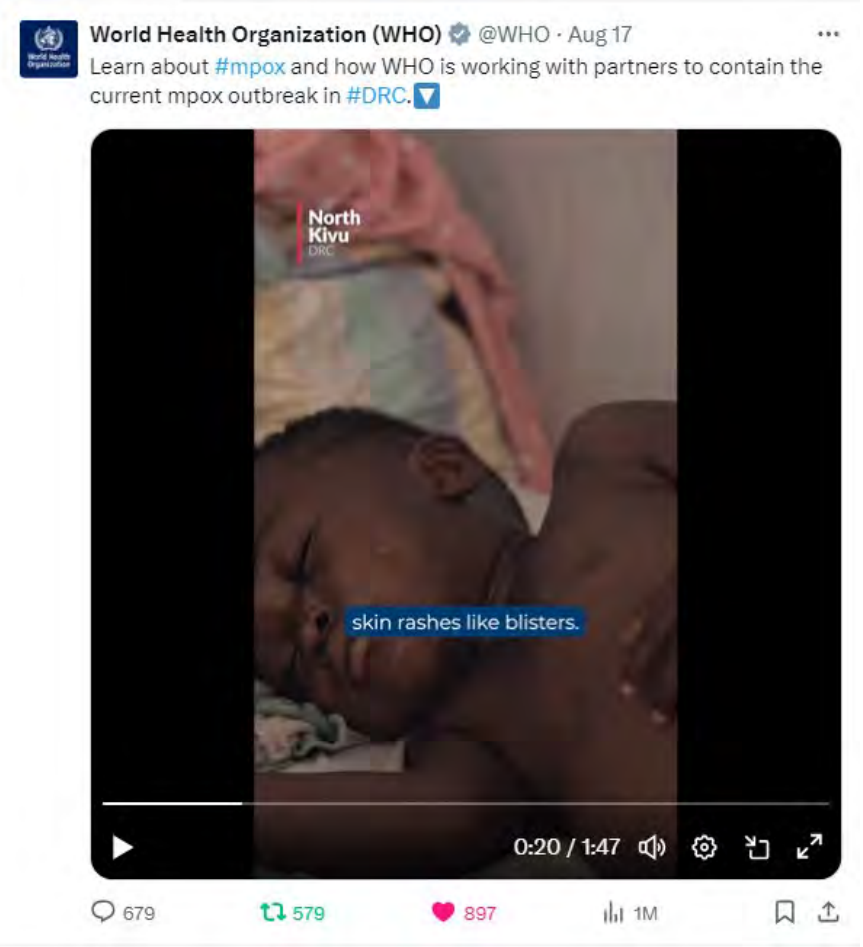
- ICG value for > 25 years in delivering equitable access to scares supplies of vaccines and therapeutics in epidemics and humanitarian emergencies for yellow fever, meningitis, cholera and ebola
- Trusted mechanism by countries through transparent review and timely decision-making based on impartiality and needs-based criteria's
- Multi-partner coordination and ownership based on accountability framework and principal oversight
- Key functions: Coordination, allocation, market-shaping/manufacturing, forecasting and procurement, financing, delivery and deployment, implementation

Member State engagement and partner coordination at global, regional and local levels is strong and needs to be strengthened

- We are in a concerning, evolving situation requiring further scale up in action
- Evidence based guidance; global and regional response plans
  - Addressing urgent needs of ramping up surveillance and sustaining lab capacities, addressing implementation of prevention interventions, advancing research and development and evaluation of PHSM, diagnostics, therapeutics and vaccines, providing protocols in development for field studies and interventions
- Engagement with Member States and partnerships regularly
  - Mpox partnership convened by WHO brings together major stakeholders worldwide monthly
  - WHO has operationalized iMCM Net Partnership
- Immediate actions to optimize prevention and response activities for access to countermeasures*
  - Establish SPRP with partners, August 2024
  - Advance R&D forum, 28 August 2024
  - Start vaccination
  - Establish mpox ICG mechanism to coordinate access and donation
- Extended Standing Recommendations and proposed temporary recommendations

Communication and outreach critical activities

- Close coordination between communications teams at headquarters, region, country levels, risk communications
- Using all channels to reach different populations: Member States, Public Health Partners, NGOs, CSOs, expert and partner networks
- Huge surge in demand for information, especially from global media; concerning rise in mis- and dis-information.
- Actions have included: Member State information sessions, regular press conferences and media engagement, public advice on social media and website, social media LIVE, commissioning video and photos in DRC, disseminating content to media, engaging with tech and other partners, combatting mis- and disinformation, and more
- Ensuring content in multiple languages with appropriate visuals
- Additional resources needed to strengthen and sustain mpox communications while responding to multiple other emergencies

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Mpox strategic preparedness and response plan

August 2024

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Strategic Objectives

RESPONSE STRATEGY	OBJECTIVES	GOAL
C1 | Strengthened collaborative surveillance and detection Monitor and share information to improve collective understanding of how an outbreak is evolving, identify specific risk and inform response measures	**Rapidly Detect And Control Outbreaks**	**Stop Outbreaks of Mpox Transmission**
C2 | Enhanced community protection Raise awareness and empower communities to adopt protective measures		
C3 | Safe and scalable care Provide safe and quality clinical care for individuals and prevent infections in health settings	**Advance Mpox Research & Access to Countermeasures**	
C4 | Equitable access to medical countermeasures Ensure equitable access to effective diagnostics, vaccines and therapeutics for mpox response measures		
C5 | Emergency coordination Strengthen coordination between Member States and partners for public health response appropriate for the local context and risk	**Minimize Animal to Human Transmission**	

Guiding Principles

- Coordination & Coherence
- Equity & Solidarity
- Community Empowerment

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Concept of Operations

Global Level

- Global leadership and coordination
- Leverage emergency partners and networks
  - Act-A principles
  - SCHPERR
  - MCM-Net for mpox
  - R&D blueprint for epidemics
  - Other partner networks

Regional Level

- Joint Africa CDC and WHO coordination
- One plan - one budget
- Other regional coordination mechanisms
- Tailoring of strategic and operational guidance to the regional content
- Cross-border coordination

Country Level

- Countries with active outbreaks
- Countries with endemic transmission
- Countries at-risk of importation

Planning Assumptions

Establish joint Incident Management Support Teams (IMST's) across all levels:

- Global (WHO & partners)
- Africa Region (WHO, Africa CDC & partners)
- Countries with active outbreaks (DRC, Burundi)
  - Sub-national – active zone x 5
  - Sub-national – at-risk zone x 10
- Countries with endemic transmission (Nigeria, South Africa, Congo, Cameroon, Uganda, Cote d'Ivoire, Rwanda, CAR, Kenya, Liberia)
- Countries at risk of importation (Ghana, Angola, Zambia, South-Sudan, Tanzania, Eswatini, Lesotho, Namibia, Botswana, Mauritania, Mozambique, Zimbabwe)
- Other Regions (EURO, EMRO, PAHO, SEARO, WPRO)

Planning assumption for operations

- Current epi approx. 1,000 cases p/w
- @ 2 months cases increase to 2,000 p/w
- @ 4 months cases flatten to 2,000 p/w
- ➢ **Planning Estimate: 40K cases over 6 months**

Costing assumptions for 1,000 cases p/w

- # of tests PCR 500 p/w
- # of tests RDT 5,000 p/w
- # of vaccines 20,000 p/w
- # of treatments - home based 900 p/w
- # of treatments - hospital 100 p/w

Initial Budget Estimate for 6 Months Operation (Sep-24 to Feb-25)

Response Pillar	Technical Assistance	Operational Support	Total
Collaborative Surveillance	11.0	13.8	24.8
Community Protection	6.8	34.2	41.0
Safe and Scalable Care	7.1	12.7	19.8
Access to Countermeasure	14.9	-	14.9
Emergency Coordination	20.6	14.7	35.3
Total	**60.4**	**75.4**	**135.8**

*Excludes cost of vaccine purchase (approx. 2 million doses @ $50-$70 per dose)

Thank you

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