

Mpox

Multi-country External Situation Report n. 36, published 14 September 2024

KEY FIGURES		
Global – Laboratory confirmed	Reporting period: 1 January 2022 - 31 July 2024	
Cases	Deaths	Countries affected
103 048	229	121
Africa – Laboratory confirmed	Reporting period: 1 January 2024 – 8 September 2024 ¹	
Cases	Deaths	Countries affected
5759	32	15
Selected countries experiencing rapid	Reporting period: 1 January 2024 – 8 September 2024	
increases: all cases (suspected and		
tested cases) ²		
Burundi	Democratic Republic of the Congo	
1489	21 835	

Highlights

- On 14 August 2024, the WHO Director-General declared the resurgence of mpox to be a public health emergency of international concern (PHEIC), requiring a coordinated international response.
- This report focuses on the reporting period 1 January 8 September 2024, as the latest complete epidemiological week, for the African continent. Global updates will be included once a month.
- The number of suspected and confirmed mpox cases reported in Africa in 2024 continues to increase. The most affected countries currently are the Democratic Republic of the Congo and Burundi.
- Testing coverage in the Democratic Republic of the Congo remains low, due to limited testing capacity, and the number of suspected cases is around five times the number of laboratory-confirmed ones.
- Mpox case fatality ratio in the Democratic Republic of the Congo in 2024 is 0.5% among confirmed cases (25 deaths out of 5160 cases) and 3.3% among suspected cases (717 deaths among 21 835 cases).
- In Africa, the two monkeypox virus (MPXV) clades and their subclades circulate in different geographic
 areas and affecting different populations, therefore need tailored and locally-adapted outbreak
 responses.
- Clade Ib, in circulation for approximately one year, has been associated with sustained human-to-human transmission and a rising trend in reported cases in eastern Democratic Republic of the Congo. Clade Ib is also causing an ongoing outbreak in Burundi.
- Although genomic sequencing capacity is limited, clade Ib appears to be the predominant strain in the North and South Kivu provinces of the Democratic Republic of the Congo, Burundi, Rwanda, Kenya, and Uganda, and has been confirmed in imported cases in Sweden and Thailand, one case in each county.
- This report presents an overview of the epidemiological situation in three countries that have national declarations of mpox outbreaks (Democratic Republic of the Congo, Burundi and Central African Republic). Future reports will include overviews from more countries.
- Comprehensive <u>global</u>, <u>continental</u> and national planning to address the mpox situation are underway. This report provides an overview of WHO global mpox response activities.

¹ The slight differences in case counts, deaths and countries affected between this report and the regional mpox bulletin produced by the WHO Regional Office for Africa are explained by the different reporting periods of each report. Please find the latest regional mpox bulletin in the following link: Regional Mpox Bulletin: 6
September 2024 | WHO | Regional Office for Africa

² In some countries, suspected cases that undergo testing are not removed from the overall count of suspected cases, regardless of whether the test result is positive (confirmed case) or negative (discarded case).

- This report also includes two brief special focus sections providing updates on laboratory testing for clade Ib MPXV and the current global situation regarding vaccine availability and distribution.
- WHO has <u>announced on 13 September the prequalification of MVA-BN vaccine</u>, the first vaccine against mpox to be prequalified.

In this edition:

- Situation overview
- Epidemiological update
 - Global situation
 - Situation in Africa
 - Monkeypox virus distribution in Africa
 - Epidemiological focus on selected countries
- Global operational updates
- Special Focus
 - Laboratory testing for MPXV
- WHO mpox resources

Situation overview

This report provides a weekly overview of the mpox epidemiological situation in Africa (WHO African Region and part of WHO Eastern Mediterranean Region), as of 8 September 2024.

Most recent updates available on the global situation can be found on the WHO mpox surveillance report.

On 14 August 2024, under the International Health Regulations (2005), the WHO Director-General declared that the increase in mpox cases in the Democratic Republic of the Congo and its expansion to neighboring countries constitutes a <u>public health emergency of international concern</u> (PHEIC). This spread represents a public health risk to other Member States and requires a coordinated international response.

This increase in mpox cases, particularly in eastern Democratic Republic of the Congo, is associated with the emergence of clade Ib MPXV, which is spreading through sustained human-to-human transmission in the absence of zoonotic exposure. Although genomic sequencing capacity is low in these settings, clade Ib appears to be the predominant strain in the North and South Kivu provinces of the Democratic Republic of the Congo, Burundi, Rwanda, Kenya, and Uganda, and has been confirmed in imported cases in Sweden and Thailand.

WHO conducted the latest global mpox rapid risk assessment at the beginning of August 2024. Based on the available information, the mpox risk was assessed as follows:

- In eastern Democratic Republic of the Congo and neighbouring countries: high.
- In areas of the Democratic Republic of the Congo where mpox is endemic: high.
- In Nigeria and other countries of West, Central and East Africa where mpox is endemic: moderate.
- In all other countries in Africa and around the world: moderate.

Individual-level risk is largely dependent on individual factors such as exposure risk and immune status, regardless of geographic area, epidemiological context, biological sex, gender identity or sexual orientation.

This report, adapted from its previous versions, presents confirmed mpox cases and deaths,³ as described in the WHO case definitions published in the <u>Surveillance</u>, <u>case investigation and contact tracing for mpox interim guidance</u>, as well as suspected mpox cases, as defined by the national surveillance systems of the countries that have reported them. The rationale for presenting these cases is to allow the reader a better understanding of mpox epidemiological trends in countries with suboptimal access to testing, such as the Democratic Republic of the Congo. In 2024, the country tested around 40% of suspected cases overall, and among those, around 55% were positive.

Note: The indicator of suspected cases should be interpreted with caution, as these are recorded according to varying national case definitions, and in some countries, suspected cases that undergo testing are not removed from the overall count of suspected cases, regardless of whether the test result is positive (confirmed case) or negative (discarded case). In absence of more detailed information, it is currently not possible to correctly subtract confirmed cases from the total suspected cases reported, therefore, the confirmed cases are a subset of suspected cases.

³ For the WHO European region, both confirmed and probable cases are included within confirmed case counts and detailed case data.

Epidemiological update

For latest available data, please consult the mpox global surveillance report, updated weekly: <u>2022-24 Mpox</u> (Monkeypox) Outbreak: Global Trends

Global situation

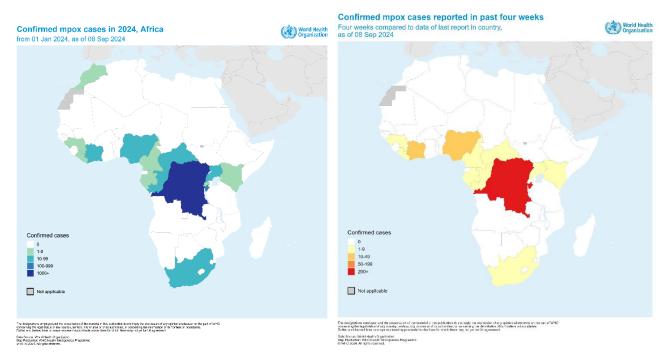
Mpox surveillance reporting, outside of Africa, continues on a monthly basis. The most recent complete data is from July 2024, as described in the mpox global surveillance report. Global updates will be provided only on a monthly basis. Once the August data is finalized, it will be included in next week's report.

Situation in Africa4

In 2024, as of 8 September 2024, 15 countries in Africa have reported 5759 confirmed mpox cases (Figure 1, left), including 32 deaths (Case Fatality Ratio [CFR] of 0.6%). The three countries reporting the most cases in 2024 are the Democratic Republic of the Congo, (5160 confirmed cases, 25 deaths), Burundi, (385 confirmed cases, no deaths), and Nigeria (55 confirmed cases, no deaths). Burundi reported mpox for the first time in 2024 and is currently experiencing sustained community transmission.

Among the countries reporting mpox in 2024, 12 countries have reported new confirmed cases within the past four weeks (see Figure 1, right).

Figure 1. Geographical distribution of confirmed mpox cases, by country, in Africa, in 2024 (left, 1 January – 8 September) and the last four weeks (right, 12 August – 8 September).



From 1 January to 8 September 2024, a total of 25 093 suspected mpox cases, including both tested and untested cases, and 723 deaths among suspected cases, were reported in Africa. The three countries reporting the most suspected mpox cases in 2024 are the Democratic Republic of the Congo (21 835 suspected cases, 717 deaths), Burundi (1489 suspected cases, no deaths), and Nigeria (935 suspected cases, no deaths).

Since the beginning of 2024, the number of confirmed mpox cases in Africa has been steadily rising, mainly driven by the outbreaks in the Democratic Republic of the Congo (see Figure 2), which account for around 90% (5160 of 5759 cases) of confirmed cases on the continent.

⁴ On the African continent there are 47 Member States in the WHO African Region and seven in the Eastern Mediterranean Region.

Similarly, the number of suspected mpox cases, including untested and tested cases, on the continent have been increasing in 2024 (see Figure 3), also driven by transmission in the Democratic Republic of the Congo. In both epidemic curves, the number of cases reported in Burundi has also been increasing.

Please note that the confirmed cases in Figure 2 are a subset of all cases shown in Figure 3, and the number of suspected cases is around five times the number of confirmed ones.

Figure 2. Epidemic curve of confirmed mpox cases in Africa, by reporting country, 1 January – 8 September 2024

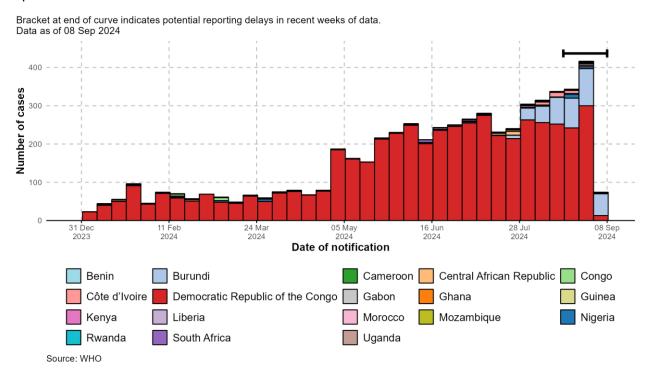
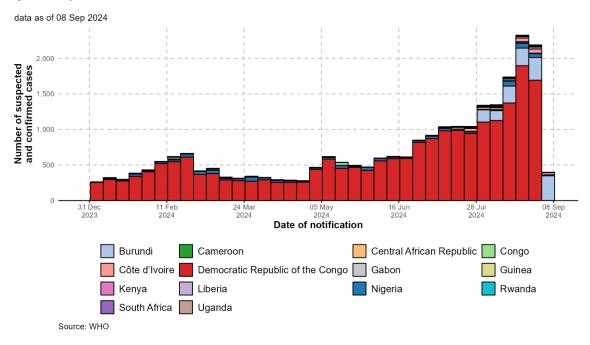


Figure 3. Epidemic curve of suspected mpox cases (tested and untested) in Africa, by reporting country, 1 January – 8 September 2024



Monkeypox virus distribution in Africa

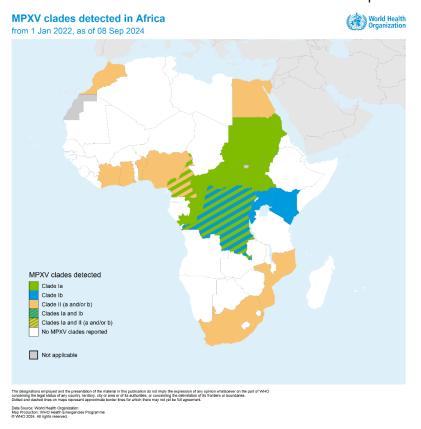
As of 8 September 2024, the distribution of reported MPXV clades in Africa is as shown in the map below (Figure 4). This information is compiled from sequencing conducted and shared via different sources including open access databases, peer-reviewed publications, reports, as well as direct communication to WHO, including through its Technical Advisory Group on Virus Evolution.

To date, countries in West Africa, northern and southern Africa have reported clade II MPXV. Countries in central and eastern Africa have reported clade I MPXV. Cameroon is the only country where both MPXV clades are found, clade I in the eastern part of the country and clade II in the west bordering Nigeria.

To date, clade lb MPXV in Africa has been detected in the Democratic Republic of the Congo (in South Kivu, North Kivu and Kinshasa provinces), Burundi, Kenya, Rwanda and Uganda. Additionally, two cases have also been detected in Sweden and Thailand, one case respectively.

The geographic distribution presented below may not fully capture all clades in any given geographic location.

Figure 4. Geographic distribution of MPXV clades detected in Africa as of 8 September 2024.



Epidemiological focus on selected countries

Burundi

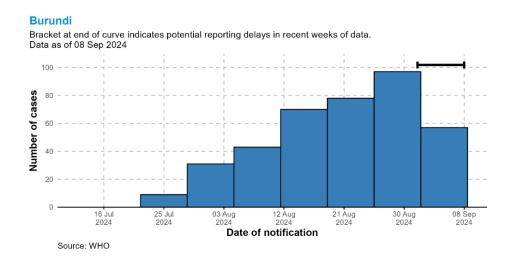
On 25 July 2024, the Ministry of Health of Burundi declared an outbreak of mpox following confirmation of three cases by the National Reference Laboratory of the Institut National de Santé Publique (INSP). These are the first confirmed mpox cases identified in Burundi.

Epidemiological investigations and genomic sequencing linked confirmed cases, due to clade lb MPXV infection, in Burundi to the province of South in the Democratic Republic of the Congo.

The number of alerts, investigations and confirmed mpox cases in the country has rapidly increased. As of 8 September 2024, 385 cases in 30 of the 49 health districts have been confirmed (see Figure 5). No mpox deaths had been documented at the time of reporting. Mpox case definitions used in Burundi can be found here.

The most affected health district is Bujumbura Nord, reporting around 47% of the total national confirmed cases. Approximately half of the cases are male and children under five years of age are the most reported age group among confirmed cases. Transmission dynamics in the country are currently being investigated by the Ministry of Health. While not fully understood, both community transmission and household transmission among close contacts is believed to be taking place.

Figure 5. Epidemic curve of confirmed mpox cases by week in Burundi as of 8 September 2024



Central African Republic

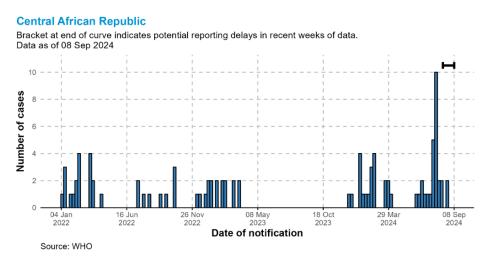
On 17 July 2024, the Ministry of Health and Population of the Central African Republic confirmed mpox cases detected in the health district of the capital Bangui, and on 20 July 2024, a national mpox outbreak was declared. The country is considered historically endemic for mpox, and from 2021 to 2023 around 40 outbreaks were detected. Before the cases in Bangui, all previous mpox outbreaks were in rural, forested areas in the south.

From 1 January to 31 August 2024, the country has recorded 278 suspected mpox cases, of which 47 have been confirmed (see Figure 6), including one death (CFR of 2.1%). Sequenced samples have shown the presence of clade Ia MPXV infection.

Confirmed cases range from 7 months to 42 years of age, with 25% of confirmed cases being under 4 years of age and 75% under 25 years of age. Currently, five health districts are experiencing outbreaks, while eleven districts have reported at least one confirmed case in 2024.

A national mpox response, led by the Ministry of Health, is ongoing in the country.

Figure 6. Epidemic curve of confirmed mpox cases by week, the Central African Republic, 8 September 2024



Democratic Republic of the Congo

From 1 January to 8 September 2024, 5160 confirmed mpox cases (Figure 7) across 23 of the 26 provinces have been reported in the Democratic Republic of the Congo, including 25 deaths (CFR of 0.5%). Over 21 835 suspected cases (both tested and untested) (Figure 8), including 717 deaths (CFR 3.3%), have been registered since the beginning of 2024. Due to limited access to laboratory testing in remote areas, only about 40% of all suspected cases have been tested in 2024 (up from 9% in 2023), and among these, around 55% tested positive. The mpox case definitions used in the Democratic Republic of the Congo can be found here.

Based on currently available information, the spread of mpox in the Democratic Republic of the Congo is attributed to two distinct main outbreaks - spread of MPXV clade Ia in Equateur and other provinces of the country where mpox is endemic, including spread to and outbreaks in Kinshasa, and the spread of clade Ib MPXV in the provinces of North and South Kivu, which also includes a few cases in Kinshasa. Current sequencing capacity in the country is limited and clade distribution might be broader than what is currently known.

The number of reported suspected and confirmed cases in the country has continued to rise in recent weeks. The top five provinces with the highest number of cases in the last four weeks are Sud-Kivu, Sankuru, Equateur, Sud-Ubangi and Tshopo. Among these only South Kivu is not considered endemic for mpox.

Figure 7. Epidemic curve of confirmed mpox cases by week, the Democratic Republic of the Congo, 8 September 2024

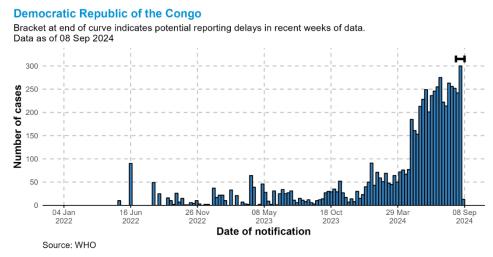
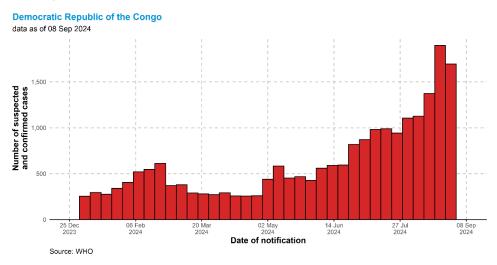


Figure 8. Epidemic curve of suspected mpox cases (tested and untested) by week, the Democratic Republic of the Congo, 8 September 2024



Global operational updates

The WHO <u>Global Strategic Preparedness and Response to mpox</u> (SPRP) outbreaks follows the health emergency prevention, preparedness, response and resilience (HEPR) framework, which provides a comprehensive approach to managing health emergencies. This framework focuses on strengthening five core health emergency components ('the 5Cs') with the aim to:

- 1. **Emergency coordination**: establish efficient coordination mechanisms across local, national, and global levels, to ensure that health crisis response is well-coordinated, timely and effective.
- 2. **Collaborative surveillance**: promote the integration of real-time data collection, sharing, and analysis across sectors to detect and monitor health threats early, ensuring rapid response.
- 3. **Community protection**: focus on building community resilience and ensuring that communities are engaged in efforts to prevent and mitigate the impact of health emergencies through vaccination, risk communication, and other public health measures.
- 4. **Safe and scalable care**: ensure health systems are equipped to provide essential and emergency care during crises, with scalable capacity to handle surges in demand while maintaining safety standards for patients and health workers.
- 5. Access to countermeasures: facilitate the availability and equitable distribution of medical countermeasures (vaccines, treatments, diagnostics, and personal protective equipment) to protect populations during health emergencies.

The HEPR framework above underpins the WHO Strategic Framework for enhancing prevention and control of mpox (2024-2027) (published May 2024) and also forms the basis for the current emergency response for the new Public Health Emergency of International Concern.

This section of the report provides an overview of the main global operational updates of the WHO mpox response in the acute response phase for the PHEIC. This is not an exhaustive list of activities, and more updates will follow in the coming weeks.

1. Emergency coordination

WHO Global Strategic Preparedness and Response Plan (SPRP)

On 6 September 2024, WHO published the <u>mpox global SPRP</u> incorporating inputs from WHO Member States, numerous partners including Africa Centres for Disease Control and Prevention (Africa CDC), and others. The global SPRP emphasizes the need for strengthened surveillance, research, equitable access to medical countermeasures, and community empowerment to respond to this global health emergency. The initial six-month timeframe for the SPRP aims to controlling acute outbreaks of human-to-human transmission.

Mpox Continental Preparedness and Response Plan for Africa

On 6 September 2024, WHO and Africa CDC published the joint <u>continental response plan</u> for the African continent to support countries' efforts to curb the spread of mpox. This continental response plan, which is fully aligned with the Global SPRP. WHO and Africa CDC are collaborating with numerous stakeholders, including governments, UN agencies, non-governmental organizations, and civil society.

Member States and partner briefings

To provide information on the evolving epidemiological situation, operational planning and implementation and to support coordination efforts, WHO has held briefings and consultations with partners, expert advisory groups and committees including: Member States through their representatives; the Standing Committee on Health Emergency Prevention, Preparedness and Response (SCHEPPR); the Smallpox and mpox vaccine working group of the Strategic Advisory Group of Experts on immunization (SAGE); the Strategic and Technical Advisory Group on Infectious Hazards with Pandemic and Epidemic Potential (STAG-IH); the

Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC); the Access to COVID-19 Tools Accelerator (ACT-A); the WHO Regional Committee for Africa; the Global Health Cluster, the Global Mpox Partnership; the i-MCM-Net partners forum, operational partners; civil society organizations (CSOs); donors; technical networks; communities of practice; and others. These briefings are critical for fostering alignment among diverse stakeholders, ensuring a coordinated and unified response.

2. Collaborative surveillance

Updated surveillance tools

The mpox Case Investigation Form (CIF) and minimum dataset Case Reporting Form (CRF) have been reviewed and updated to enable countries to better describe the current phase of mpox outbreaks. The updated CIF and CRF can be accessed here.

Epidemiological data on mpox are updated weekly, and the latest data can be accessed on the WHO mpox surveillance report here.

Diagnostics

WHO is working with experts and partners to explore additional near-point-of-care solutions for mpox diagnostics. Since the 2022 PHEIC declaration, WHO has delivered laboratory reagents, PCR kits, point-of-care specimen collection kits or a combination thereof to 46 of 47 African countries. Since the 2024 PHEIC declaration, WHO is delivering a further 63 450 PCR kits and 26 600 specimen collection kits to 13 priority African countries.

Functional characterization of MPXV clade Ib genome samples through the <u>Biohub</u> is underway through coordination led by WHO. Clade Ia and clade Ib material (live virus or DNA) is being distributed to laboratories around the world for comparative characterization to begin.

Special studies

An mpox transmission study protocol under development by WHO and partners is being finalized. The objective of this WHO protocol is to provide a template to stakeholders to better understand and quantify risk and characteristics of mpox transmission and better document risk factors for severe disease, focusing on case and contact ascertainment.

3. Community protection

Partner coordination and engagements

Partner mechanisms have been active throughout the reporting period. In August 2024, these mechanisms were strengthened and new mechanisms set up through:

- Briefings provided by WHO and other partners through the WHO global mpox partnership and coordination through its working groups (January – August 2024).
- Coordination of Community Protection global partners, including UNICEF, the International Federation
 of Red Cross and Red Crescent Societies (IFRC), Civil Society Organizations to strengthen multisectoral
 action in the mpox response.
- Coordination of the <u>Collective Service</u> partners for risk communication and community engagement (RCCE) action.
- Establishment of a Community Advisory Group of community researchers, community academics, community experts and community leaders from affected countries to inform response.
- Briefing of CSOs and partners through <u>EPI-WIN</u>, and civil society networks, such as the World of World network and faith networks.

Community protection technical briefs

Effective response to health emergencies provides protection for those affected or at risk. An extensive collection of guidance materials and resources is available on the WHO website. These have been updated as needed since 2022. Local-level community and civil society engagement is key to driving impact. To complement existing materials which will be further updated and contextualized, a series of short operationally focused technical briefs for various audiences is in development. These briefs will provide practical information on how to plan and deliver a comprehensive package of actions for community protection. They include how to set up a community reference group, key considerations for community infection prevention and control (IPC) and water, sanitation, and hygiene (WASH), what to include in training for community workers (including on protection against infection and mental health impacts), top tips for home-based care, how to plan and deliver localised and context specific public health and social measures (PHSM), and multisectoral action to protect against social and economic impacts.

Available tools and products

The following tools and products have been developed or updated:

- RCCE Readiness and Response <u>toolkit</u> for mpox
- Mpox Fact Sheet
- Mpox Q&A web page
- Public health advice as below:
 - RCCE messages tailored for priority audiences have been updated and shared through WHO and partner networks.
 - o RCCE messages for new target audiences like children, breastfeeding mothers, pregnant women and caregivers are nearing finalization.
 - Updated Public Health Advice series for sex workers, camps and internally displaced persons, mass gatherings, border health, and home-based care are being reviewed and updated. This series of papers is available in the WHO mpox outbreak toolkit, along with other resources.

Support to countries hosting mass gatherings and event organizers

Technical assistance and advice tailored to context has been provided to countries and event organizers hosting mass gatherings, including the Africa Cup of Nations, Inter-Parliamentary Union, and the Indonesia-Africa Forum.

IPC/WASH

- Coordination with key stakeholders (UNICEF and WASH cluster) for implementation of IPC and WASH measures in high-risk areas, congregate settings, schools, IDP and refugee camps.
- Development of operational guide on IPC and WASH measures for home care in resource limited settings to prevent and control community transmissions.
- Technical assistance and advice on IPC and WASH measures in schools and IDP/refugee camps. Reviewing the training package for community health care workers.
- Developed essential IPC and WASH supplies list for home care and community healthcare workers.
- Healthcare facilities rapid assessment tool for mpox has been developed and is currently being
 implemented in affected Member States to help identify key gaps to prioritize and address with the aim
 to ensure protection of health and care workers and patients while providing quality care. Posters on
 how to put on and remove personal protective equipment have been published and are being distributed
 to health facilities in affected areas.
- Tools and products that have been developed or under development:
 - o IPC & WASH measure for home care and isolation for mpox in resource limited setting.
 - Screening tool for health and care facilities.

Decision support for selection and implementation of public health and social measures

Support has been provided through WHO regional and country offices on the relevant public health and social measures as well as analysis of existing evidence on effective PHSM strategies for mpox.

4. Safe and scalable care

Clinical care and therapeutics

Preliminary results of the PALM 007 trial have shown that the antiviral tecovirimat did not improve time to resolution of mpox symptoms for a combined endpoint for all ages and for mild and severe disease. Other trials evaluating mpox (clade II) continue. However, these findings demonstrate that scaling clinical care should continue to strengthen and optimize safe and supportive standards of care in health facilities and at home, by ensuring that sufficient supplies and medicines to care for patients are available, and staff are trained in case management, IPC and WASH.

Monitored Emergency Use of Unregistered and Experimental Interventions (MEURI): WHO continues to provide access to tecovirimat under emergency use access protocols, with a Member States' briefing scheduled for 24 September 2024 to encourage new applications.

Direct in-country support to scaling the clinical response is provided by senior WHO staff working in collaboration with the Ministry of Health, case management colleagues and partner organizations. The primary objective is to ensure consistent high quality clinical care in health facilities, and at home. Underpinning this, support is provided for data collection to understand care quality and bed use.

Global Clinical Platform

The Global Clinical Platform has fully revised the electronic Case Report Form and is seeking partners to contribute data to enrich the global understanding of clinical phenotypes and outcomes, particularly in relation to the different clades.

The Global Clinical Platform Statistical Analysis Plan for mpox is being reviewed and updated. Version 1 of the Statistical Analysis Plan remains active. A Clinical Dashboard is being developed to allow direct visualization of the Global Clinical Platform data.

5. Access to and delivery of countermeasures

Coordination mechanisms

WHO and partners have set up the <u>Access and Allocation Mechanism (AAM)</u> with the Africa CDC, the Coalition for Epidemic Preparedness Innovations (CEPI), the Health Emergency Preparedness and Response Authority of the European Union (HERA), the Foundation for Innovative New Diagnostics (FIND), Gavi the vaccine alliance, the PAHO Revolving Fund, UNICEF, Unitaid and others, to coordinate available supplies, including donations, aggregate the demand from countries with outbreaks and strategically allocate available supplies to control the outbreaks.

The mechanism is designed to respond to the current upsurge of mpox by providing a structured approach to vaccine, therapeutics, and diagnostics access and allocation, and it is aimed at playing a central role in ensuring that the limited supplies available have the greatest public health impact in controlling and stopping moox outbreaks, particularly in the hardest-hit regions. It focuses on preventing illness, reducing inequities, ensuring transparency and helping countries with outbreaks by providing critical resources to control the spread of the disease.

The AAM has been established as a part of the interim Medical Countermeasures Network (i-MCM-Net). The i-MCM-Net brings together partners from around the world, including UN and other international agencies, health organizations, civil society organizations, industry and private sector to build an effective ecosystem for the development, manufacturing, allocation and delivery of medical countermeasures. The network was endorsed by WHO Member States as a mechanism to operate in the interim, as negotiations continue towards a pandemic agreement.

Prequalification and Emergency Use Listing of vaccines and diagnostics

To accelerate response to the current mpox outbreak, WHO issued calls for expression of interests for Prequalification (PQ) and Emergency Use Listing (EUL) assessment for mpox vaccines and diagnostics on 9 and 28 August respectively.

On 13 September, <u>WHO prequalified the MVA-BN vaccine</u>, making it the first mpox vaccine on its prequalification list. This decision aims to accelerate access to the vaccine, particularly in regions experiencing urgent outbreaks. WHO prequalification is based on data from the manufacturer, Bavarian Nordic A/S, and reviewed by the European Medicines Agency.

The vaccine is approved for people over 18 years of age, with two doses to be administered four weeks apart. Although not licensed for those under 18, it may be used "off-label" in younger populations and other groups at risk with potential use of a single-dose option in areas with limited vaccine supplies in line with WHO SAGE recommendations as outlined in the WHO Smallpox and mpox (orthopoxviruses) vaccines position paper. WHO emphasizes continued data collection on safety and effectiveness as post-pregualification requirements.

This prequalification will enable faster procurement by governments and international agencies, ensuring that communities most affected by mpox can access the vaccine. The process may also help national regulators expedite approvals, increasing access to this vital tool in fighting the ongoing outbreak.

The WHO Prequalification program is reviewing the regulatory dossiers for the LC16 vaccine and discussing dossier submissions with the manufacturer of the ACAM2000 vaccine. As of 13 September, 6 expressions of interest have been submitted for the EUL assessment for diagnostics and WHO is awaiting product information submissions.

Global situation of vaccines availability and distribution

Currently, over 3.6 million vaccine doses have been pledged for the global mpox response. This includes over 620 000 doses of the MVA-BN vaccine pledged to affected countries by the European Commission, Austria, Belgium, Croatia, Cyprus, France, Germany, Luxembourg, Malta, Poland, Spain, and the United States of America, as well as vaccine manufacturer Bavarian Nordic. Japan has pledged 3 million doses of the LC16 vaccine, the largest number of doses pledged so far. To date, 265 000 doses of the MVA-BN vaccine were delivered to Kinshasa on 5, 8 and 10 September 2024 and 10 000 doses to Nigeria on 27 August. Delivery schedules span from September through the fourth quarter of 2024.

Mpox research and innovation: Aligning research response with outbreak goals

From 29 – 30 August 2024, WHO held a <u>scientific conference</u> aimed at aligning 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. It was designed to foster a collaborative and open environment where researchers, public health officials, and stakeholders from affected countries could take the lead in shaping the research agenda.

Special focus

Laboratory testing for MPXV

WHO currently recommends nucleic acid amplification testing (NAAT) on lesion material as the reference test for mpox. Some polymerase chain reaction (PCR)-based near-point-of-care solutions have been independently validated. The sensitivity of the antigen-detecting rapid diagnostic tests (RDTs) that have been evaluated so far has been insufficient (Please find the results here). A second round of evaluations is underway for additional near-point-of-care tests, including both PCR-based and antigen-detecting RDTs.

The choice of testing procedures should be adapted to the local context. It is critical that the NAATs employed be designed to target highly conserved regions of the viral genome, minimizing the risk of false negatives due to genomic deletions. Highly conserved NAATs may target generic orthopoxvirus (OPXV) or MPXV regions of the genome, with positive samples subjected to MPXV-specific or clade-specific NAATs for confirmation or epidemiological purposes. Since diagnostic failure among clade-specific NAATs has been associated with clade Ib MPXV, if clade-specific NAATs fail to detect MPXV, sequencing should be used for clade determination and genetic characterization to confirm/rule out clade Ib MPXV.

While distinguishing between clades Ia, Ib, IIa, and IIb is important for surveillance purposes, public health interventions aimed at interrupting transmission chains remain consistent across clades. These interventions include early case detection, case isolation, patient care, IPC measures, as well as contact tracing and monitoring.

Mpox resources

Strategic Planning and Global Support

- WHO Mpox global strategic preparedness and response plan. Updated 6 September 2024. Available at: https://www.who.int/publications/m/item/mpox-global-strategic-preparedness-and-response-plan
- Mpox Continental Preparedness and Response Plan for Africa: https://africacdc.org/download/mpox-continental-preparedness-and-response-plan-for-africa/
- WHO appeal: mpox public health emergency 2024, 27 August 2024. Available at: https://www.who.int/publications/m/item/who-appeal--mpox-public-health-emergency-2024
- Strategic framework for enhancing prevention and control of mpox- 2024-2027. May 2024. Available at: https://www.who.int/publications/i/item/9789240092907

International Health Regulations Emergency Committee, Review Committee and Recommendations of the Director-General

- First meeting of the International Health Regulations (2005) Emergency Committee regarding the
 upsurge of mpox 2024, 19 August 2024. Available at: https://www.who.int/news/item/19-08-2024-first-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-upsurge-of-mpox-2024
- Extension of the standing recommendations for mpox issued by the Director-General of the World
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