

Mpox: Transparency and Accountability for the Global Response

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COVID Collaborative

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Latest Mpox Response Insights

The highlights and latest updates sections below contain our latest analysis and most recent updates across all topic areas since the <u>last edition</u> of the report. The updates since the last edition are also written in red in the body of the report.

In the wake of the U.S. health agencies' communications and foreign aid freezes, we hope to serve as a resource for transparency on emerging outbreaks globally while continuing to provide in-depth analysis of the mpox response. We will provide brief updates on emerging outbreaks with the state of available medical countermeasures and diagnostics needed to effectively respond.

Highlights:

Over 50% of pledged doses have been delivered to 11 countries, with reports of high vaccine acceptance in the 7 countries vaccinating: Nearly 3 million doses of mpox vaccines have been delivered across the DRC, Uganda, Sierra Leone, Angola, Rwanda, Nigeria, Cote d'Ivoire, the Central African Republic, Liberia, Kenya, and South Africa. Seven of these countries (DRC, Uganda, Sierra Leone, Rwanda, Liberia, Central African Republic and Nigeria) have started vaccination campaigns. The remaining four countries have not yet been able to deploy vaccines either due to funding constraints or case load (e.g. South Africa has not reported a case since February 2025). More than 698,000 people have been vaccinated with at least one dose with children aged 1-17 accounting for 22% of the total vaccinated. Additional vaccine doses are still needed to reach the 6.4 million doses needed for this phase of the response. 568,520 doses are available from Unicef and the USG based on prior agreements, but the doses from Unicef require funding to deploy and those from the USG require authorization to deploy. 104,000 of these doses (18.3%) have been allocated to Uganda and the DRC, but the DRC may not accept the USG vaccines due to short shelf-life (11-12 months).

Latest updates at a glance:

- On June 9th, the World Health Organization <u>announced</u> that the mpox outbreak continues to meet the criteria of a public health emergency of international concern (PHEIC).
- The Democratic Republic of Congo <u>received</u> 100,000 doses of the MVA-BN vaccine from France on May 30th, and 1.5 million doses of the LC-16 vaccine from Japan on May 31st.
- Sierra Leone <u>received</u> 20,000 doses of the MVA-BN vaccine from the UAE on June 9rd.
- Gavi and Unicef have funded a shipment of 97,660 doses to be delivered to Uganda in June.
- Africa CDC's incident support management team (IMST) leads visited Sierra Leone to provide support for the mpox response including: financial support; deployments of community health workers for surveillance, infection prevention and control, and risk communication and community engagement; laboratory reinforcement; data harmonization and health system digitalization.
- Vaccination started in Kinshasha using the LC16 vaccine on June 14th.
- The DRC, Uganda, and Sierra Leone accounted for 91% of all confirmed cases on the continent over the last 6 weeks and a consistent downward trend in the number of cases has been observed in all three countries.











- The US reported a new case of clade I mpox on June 17th. The individual recently traveled to a region experiencing active clade I transmission.
- Bavarian Nordic <u>has begun</u> a clinical trial evaluating the safety and immunogenicity of the MVA-BN vaccine in infants and children under 2 years old, and pregnant or breastfeeding women.

Emerging outbreaks:

Cholera: There is an active cholera outbreak in 21 member states and cumulatively in 2025 there have been 168,975 cases and 3,378 deaths reported. Four member states (Angola, DRC, Sudan, and South Sudan) contributed to 85% of all cases and 92% of all deaths in 2025. Children continue to bear a high burden of infection with up to 47% of all cases and 37% of deaths. In all four countries, the case fatality rate is high with all countries reporting close to 2% and above highlighting the need for accelerated response. Other public health outbreaks in the continent include measles, dengue and lassa fever.

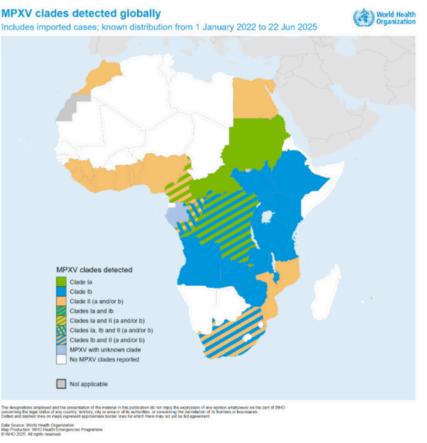
Introduction

The COVID-19 pandemic exposed significant global inequities in the access to therapeutics, vaccines, testing, and other medical interventions that could limit the range and impact of the disease. These global inequities are not limited to the COVID-19 pandemic and need to be critically addressed in the ongoing mpox outbreak. Through our QuickStart newsletter updates, we aim to serve as an external, independent source for tracking actions to meet commitments, catalyzing additional commitments to meet the need, and holding the world to account for the mpox response.

Epidemiology

On August 13th, 2024, the Africa CDC declared the mpox outbreak a Public Health Emergency of Continental Security (PHECS), which is the first time this designation has been used since the agency's inception. On August 14th, 2024, the World Health Organization declared the mpox outbreak a public health emergency of international concern (PHEIC). Mpox is an infectious disease that causes symptoms such as a painful rash, fever, muscle aches, and headaches. Symptoms can last 2-4 weeks, and the virus can be passed to others until all sores have healed and a new layer of skin has formed. Mpox spreads through close skin to skin contact with someone who has mpox, through contact with contaminated objects or needle injuries, during pregnancy or birth, or from exposure to an animal with mpox. Currently, the animal reservoir of mpox is unknown.

There are <u>two clades</u> of the virus: clade I (subclades la and Ib) and clade II (subclades IIa and IIb). Clade I is more likely to cause severe illness and death, and is currently spreading in Central and <u>Eastern Africa</u>. Historically clade I mpox cases typically resulted from contact with an infected animal, but subclade Ib cases appear to be <u>spreading</u> mostly through human-to-human contact.



Source: WHO 2022-2024 Mpox Outbreak: Global Trends







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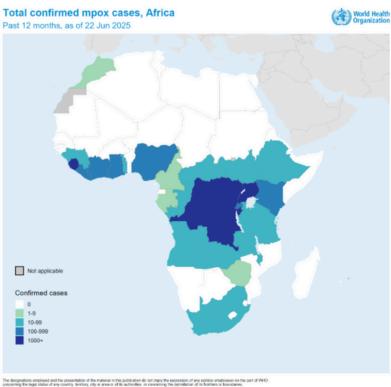
Subclade Ib is a newer subclade and its spread from the Democratic Republic of Congo (DRC) to surrounding countries (Burundi, Kenya, Rwanda, Uganda) is partly what triggered the PHEIC declaration. Recently, a new variant of clade Ia (APOBEC3) has been detected in the DRC with potentially higher transmissibility. The APOBEC3 mutation is also seen in novel clade Ib and is a factor associated with its increased transmissibility. Clade II was the cause of the 2022 outbreak and usually causes less severe illness, and is endemic to West Africa.

In 2025 alone (as of June 27th), a total of 73,071 suspected mpox cases were reported across 26 countries, with 21,554 (29.5%) confirmed cases. As of June 26, 2025, the number of suspected mpox cases across the continent have reached 94% of the number of cases in 2024, signifying a higher disease burden higher in 2025 when compared to 2024. In Africa, 17 countries are currently in the active phase of the mpox outbreak: DRC, Burundi, Nigeria, Rwanda, Uganda, Kenya, Republic of Congo, Zambia, Liberia, Sierra Leone, Angola, South Sudan, Tanzania, Malawi, Togo, Ghana, and Ethiopia. On May 25th, Ethiopia reported the country's first confirmed case of mpox in a 21-day old infant. As of June 4th, 17 mpox cases have been confirmed with 1 death reported. As of June 4th, Togo notified 22 new cases of which 5 were confirmed (21.6%). DRC, Uganda & Sierra Leone accounted for 87% of all the new confirmed cases with Sierra Leone accounting for 40% of confirmed cases. In Uganda, over half of all mpox deaths have occurred in people living with HIV leading the country to prioritize vaccinations in this population. As of epi week 24, 3,113 cases have been notified, 679 of those were confirmed (21.8%), and 25 deaths were reported among suspected cases (case fatality rate: 0.80%). Among total confirmed cases in the DRC, clade la and Ib are co-circulating, and the APOBEC3 mutation in clade la has been reported in Kinshasa. The situation in Kivu, DRC is stabilizing which has allowed vaccination activities to resume and enabled the deployment of epidemiologists to intensify the response.

Outside the African region, 15 countries have reported cases of clade I mpox: Belgium, France, China, the United Kingdom, Canada, Germany, Sweden, Thailand, Pakistan, Nepal, the United States, the United Arab Emirates, Brazil, and Switzerland. In early April, Switzerland <u>reported</u> the first case of clade Ib mpox in a traveler returning from Africa. The case is currently isolating and risk of spread to the public is low. As of May 31st, the UK has <u>reported</u> 12 cases of clade Ib mpox. On June 22nd, Nepal <u>reported</u> its fourth confirmed case of mpox in an adult with recent travel to Saudi Arabia. On June 17th, the US <u>reported</u> a new case of clade I mpox in an individual with recent travel to a region experiencing active clade I transmission.

Regulatory

There are currently three vaccines for mpox on the market: MVA-BN (Bavarian Nordic), LC16-KMB (KM Biologics), and ACAM2000 (Emergent BioSolutions). MVA-BN was the first mpox vaccine to receive WHO prequalification (September 13th) and LC16-KMB was granted emergency use listing (EUL) on November 19th. ACAM2000 remains under consideration by the WHO for EUL. MVA-BN's pregualification has been extended for use in adolescents aged 12-17 (October 8th), and LC16-KMB is the only vaccine approved for use in children under the age of 12. On March 31st, the U.S. FDA approved a freeze-dried formulation of the MVA-BN vaccine, which provides advantages in transportation, storage conditions, and shelf-life. KEMRI, the Kenya Medical Research Institute, has partnered with Tonix Pharmaceuticals to conduct a phase 1 trial for TNX-801 (an investigational mpox vaccine). The DRC has granted emergency use authorization (EUA) (June 2024) for both MVA-BN and LC16-KMB vaccines. Nigeria has also granted emergency use authorization for MVA-BN.



Dotted and dashed lines on maps represent approximate bo Data Source: World Health Organization

Source: WHO 2022-2024 Mpox Outbreak: Global Trends







The WHO has granted EUL to three mpox diagnostics: The <u>Alinity m mpox assay</u> (Abbott – October 3rd), <u>Cobas</u> <u>MPXV</u> (Roche – October 14th), and <u>Xpert mpox</u> (Cepheid – October 25th). Both the Alinity m mpox assay and Cobas MPXV are able to deliver results in less than 2 hours and are considered lab-based, PCR diagnostics. **Cepheid's Xpert mpox**, compatible with Gene Xpert systems, is able to deliver results in under 40 minutes and **is the only near pointof-care diagnostic available at this time.** Africa CDC has <u>recommended</u> the use of a PCR test manufactured by Morocco-based Moldiag, which offers a lower price of around \$5-6 per test. On May 22, the South African Health Products Regulatory Authority (SAHPRA) has approved the Alinity m MPX assay under Emergency Use Listing.

The Africa CDC Diagnostic Advisory Committee is currently <u>evaluating</u> 2 rapid diagnostic tests (RDTs) at the National Institute of Biomedical Research in the DRC – one RDT from Conti Pharma and one RDT from Revital. Both of these RDTs were evaluated last year and found to have a sensitivity of 23%, but manufacturers have made improvements that will hopefully improve sensitivity of the tests. Results from the evaluation are expected in the second week of May 2025.

Summary of key regulatory dates:

Product Name	Regulatory Approval Type	Date
MVA-BN (Bavarian Nordic, vaccine)	WHO PQ	September 13, 2024; extended for use in adolescents 12-17 on October 8, 2024
LC16-KMB (KM Biologics, vaccine)	WHO EUL	November 19, 2024
Alinity m mpox assay (Abbot, diagnostic)	WHO EUL, South Africa EUL	October 3, 2024 (WHO PQ); May 22, 2025 (South Africa)
Cobas MPXV (Roche, diagnostic)	WHO EUL	October 14, 2024
Xpert Mpox (Cepheid, diagnostic)	WHO EUL	October 25, 2024

Vaccines

Supply:

The <u>estimated</u> need for vaccine doses is between 18-22 million doses to meet the Africa CDC's goal of vaccinating at least 10 million people in 6 months. There are three existing vaccines that are effective against mpox: MVA-BN (Bavarian Nordic), ACAM2000 (Emergent BioSolutions), and LC16-KMB (KM Biologics), but at the present time the WHO recommends use of MVA-BN or LC16-KMB during an outbreak. Many doses of all three available vaccines are within high-income countries' national stockpiles, and most countries have not disclosed the available quantity. The U.S. has over 100 million doses of ACAM2000, and an unknown quantity of MVA-BN doses. It is unclear if the U.S. pledged doses for donation will come from the U.S. stockpile of vaccines. Canada <u>may have</u> up to 2 million doses of MVA-BN in the national stockpile. Japan <u>may have</u> up to 200 million doses of LC16-KMB, of which up to 3 million have been pledged. Spain <u>has pledged</u> 500,000 doses, which is around 20% of its stockpiles, while Germany <u>has pledged</u> 100,000 doses from its total military stockpile of 117,000 doses

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Manufacturing capacity:

Bavarian Nordic, the manufacturer of the MVA-BN mpox vaccine, <u>estimates</u> **it can supply 13 million doses of the vaccine by the end of 2025**, and is exploring options to expand capacity. By the end of 2024, the company estimates 2 million doses could be supplied. Based on early discussions to <u>transfer manufacturing</u> to other companies there is the potential for **an additional 50 million doses to be supplied in the next 12-18 months.** With only 2 million doses that can be supplied by Bavarian Nordic by the end of 2024, **it will be critical for high-income countries with national stockpiles to donate doses to meet the estimated need.**

As part of efforts to address supply constraints, Bavarian Nordic <u>entered</u> into a licensing and manufacturing agreement with the Serum Institute of India (SII). The agreement includes technology transfer to enable supply for the Indian market where SII already has the licenses to sell and distribute the product. Additionally, Africa CDC has <u>announced</u> that a technology transfer agreement is close to being finalized between Bavarian Nordic and a local African manufacturer. The agreement is expected to be finalized and announced in the coming weeks, with the goal of building a stockpile of doses for the continent.

Procurement:

The European Health Emergency Response Authority <u>has negotiated</u> a joint contract to enable EU countries to access MVA-BN vaccines and tecovirimat for mpox. The exact cost of mpox vaccines is unclear, but it is estimated the <u>market</u> price of MVA-BN is around \$70-\$100 per dose, which would quickly deplete Gavi's \$500 million First Response Fund. Gavi has <u>announced</u> plans to purchase 500,000 doses of MVA-BN, using money from the First Response Fund to procure the doses and support the transportation, delivery, and costs of administering the vaccines. UNICEF has <u>announced</u> **an agreement to purchase 1 million doses of MVA-BN**, which includes the 500,000 doses that were committed by Gavi. Bavarian Nordic has stated **all 1 million doses will be made available for supply by the end of 2024**.

Donations:

In the last two weeks, there have been no new donations of mpox vaccines announced. Africa CDC has issued an urgent appeal for additional mpox vaccine donations as there is currently a shortage of vaccines to meet demand. Over 568,000 doses from both UNICEF and the U.S. government could be made quickly available, but UNICEF is looking for funding to be able to deliver vaccines while the U.S. government doses require authorization for release. Fewer than 5.6 million vaccine doses have <u>been pledged</u> for donation. On September 24th (2024), the United States announced a donation of 1 million doses of the MVA-BN vaccine to the international mpox response. This marks the largest donation of MVA-BN mpox vaccines to date. This donation is in addition to the combined 60,000 doses the U.S. donated and delivered to Nigeria (10,000 doses) and the DRC (50,000 doses). The European Commission has pledged 566,500 doses. Canada has also <u>pledged</u> to donate up to 200,000 doses, stating that the number of doses delivered will be dependent on the receiving countries' capacity for storage and administration. The available mpox vaccines have less strict cold-chain requirements compared to COVID-19 vaccines and many available mpox vaccines can be stored in a refrigerator (see table below). Japan <u>has pledged</u> up to 3 million doses of the LC16-KMB vaccine. The vaccine donations from Japan are expected by the end of 2024, but <u>challenges</u> have risen around liability issues and identifying an entity to take on the risk in case of adverse events. Nigeria <u>donated</u> 1,000 doses of mpox vaccines (from the 10,000 doses they received from the U.S.) to Rwanda.

The WHO and partners have <u>established</u> an **access and allocation mechanism (AAM) for mpox** medical countermeasures, including vaccines, treatments, and diagnostic tests. This mechanism was established as part of the interim Medical Countermeasures Network. The guiding principles for the mechanism are preventing illness and death, mitigating inequity, and ensuring transparency and flexibility. The AAM has <u>allocated</u> 899,000 mpox vaccines to 9 countries (Central African Republic, Cote d'Ivoire, the Democratic Republic of the Congo, Kenya, Liberia, Nigeria, Rwanda, South Africa and Uganda). 85% of these vaccines (765,200) will go to the Democratic Republic of the Congo which is currently the most affected country. The second-round <u>allocation</u> by the AAM consists of 238,000 vaccine doses that will be distributed across 4 countries: Angola, Guinea, Sierra Leone, and Uganda. Uganda and the DRC have <u>been approved</u> for a 3rd round allocation of 743,200 mpox doses.





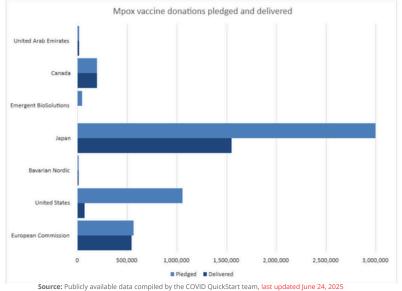


MPOX UPDATE: 6/27/2025



Delivery and uptake:

The first allocation of 899,000 vaccine doses have been accepted by all countries (Cote d'Ivoire, Nigeria, DRC, Liberia, CAR, Rwanda, Uganda, South Africa, and Kenya). It is not clear if all of these 899,000 vaccine doses have been delivered at this time. The European Commission delivered the first shipment of 100,000 doses (out of a total of 122,300 doses in the next tranche) on November 14th to the Africa CDC. The total 122,300 doses expected to arrive are comprised of donations from Belgium, Germany, and Portugal. An additional delivery of 765,200 vaccine doses is being planned for delivery to the DRC. Additionally, according to a statement from the Japanese government, 50,000 doses of the LC16 vaccine were expected to arrive in Kinshasa during the week of December 16, with an additional 3 million doses



scheduled for delivery in February. <u>The DRC's</u> Ministry of Health hosted Japanese experts and organized an LC16 workshop from December 16 to 19 to prepare for the vaccine's introduction and evaluation, as well as to focus on capacity building, training, and rollout planning. On May 10th, Angola <u>received</u> 67,000 doses of mpox vaccines from the EU. 1.5 million doses of the LC16 vaccine (from Japan) arrived in the DRC on May 31st, 100,000 doses of the MVA-BN vaccine (from France) arrived in the DRC on May 30th. 20,000 doses from United Arab Emirates were received by Sierra Leone on June 9th, 2025. A <u>bilateral donation</u> of 75,000 doses was shipped from the DRC to Sierra Leone on June 18th. A shipment of <u>97,660 doses</u>, funded by Gavi and Unicef, is expected to arrive in Uganda in June. **A total of 2,951,780 doses have been delivered (52.7% of pledged doses)** which consists of 1.4 million doses of MVA-BN and 1.55 million doses of LC16.

Countries that have started mpox vaccination campaigns:

Name	Vaccination campaign start date
Rwanda	September 17, 2024
Democratic Republic of Congo	October 5, 2024
Nigeria	November 18, 2024
Central African Republic	January 18, 2025
Uganda	February 1, 2025
Sierra Leone	March 27, 2025
Liberia	April 16, 2025









As of December 19, <u>4,278 doses</u> out of the allocated 9,000 vaccines have been used in Nigeria's vaccination campaign. This marks significant progress in covering the target groups, reflecting strong acceptance among communities and health workers. Nigeria is now preparing for the next phase of its vaccination campaign. As of November 14th, Rwanda has achieved 100% of the vaccination target and the eastern part of the DRC has achieved 103% of the vaccination target. The province of Kinshasa in the DRC has <u>launched</u> a vaccination campaign, achieving a coverage rate of 44.2%. The DRC is also preparing to extend vaccination efforts to the remaining 16 health zones in Kinshasa. In an effort to accelerate the uptake of the vaccines in the DRC, the new vaccination <u>approach</u> focuses on **sweeping hotspot catchment areas instead of solely vaccinating contacts**. Liberia is the most recent country <u>to launch</u> a vaccination campaign and is planning to distribute doses to high-risk areas. Sierra Leone has vaccinated over 30,000 people in two weeks. The vaccination campaign is targeting healthcare workers, contacts, and persons living in high-risk areas.

As of the end of December 2024, roughly 175,000 vaccines had been administered in the DRC. <u>Uganda</u> administered 9,000 vaccine doses donated by the European Commission in the first phase within seven days. The initial rollout prioritized sex workers, with young adults aged 20–49 accounting for 86% of the total vaccinated. Over 407,000 people (99% consumption rate) have been <u>vaccinated</u> within 14 days in Kinshasa. Children from the ages of 1-17 accounted for 39% of the total vaccinated. There is a current shortage of vaccines in the DRC as vaccination coverage stands at 70% of the target population. Across the 7 countries <u>vaccinating</u>, more than 763,000 doses have been <u>administered</u> (over 698,000 people with at least 1 dose). Children aged 1-17 account for 22% of the total number of people vaccinated. The DRC <u>accounts</u> for 80% of the total number of people vaccinated across the continent.

Cold-chain requirements for available vaccines:

<u>MVA-BN</u>	Shipped frozen (-20°C); can be stored frozen for long-term storage or refrigerated (2°C-8°C) and stored for 8 weeks.
<u>LC16-KMB</u>	Can be stored for 2 years in a refrigerator or for 4 weeks at room temperature (37°C or below).
<u>ACAM200</u> <u>0</u>	After reconstitution, can be stored in a refrigerator for 30 days. The antigen component is shipped frozen and can be stored frozen until expiry or refrigerated for up to 18 months or expiry. The diluent can be stored from 15°C-30°C.

Testing and therapeutics

In response to the surge in mpox cases in Sierra Leone, Africa CDC has provided laboratory support and training to the country. To date, testing is operational in 8 laboratories with 2 utilizing PCR and the first in-country genome sequencing has been completed. Africa CDC has also provided the sequencing platforms and reagents, 7,000 mpox PCR test kits (5,000 delivered, 2,000 en route), and training on PCR, sequencing and data analysis. In epi week 24, the DRC reported a 100% testing rate for samples that have arrived in the lab, however testing coverage is only 26% due to ongoing challenges in sample collection and transportation. The decrease in testing coverage over the last few weeks is believed to be directly the result of the stop of sample transport and sub-optimal sample collection due to the USG foreign aid pause. Africa CDC has succeeded in building decentralized laboratory capacity, increasing the number of laboratories with diagnostic capabilities for mpox from 2 in 2023 to 19 in February, 2025. An additional 3 GeneXpert testing laboratories have been activated in Nord Kivu, DRC, and there are now 26 testing laboratories with 3 capable of performing qPCR. The only WHO approved diagnostics use PCR or near point-of-care PCR. Contipharma's LAMPOX and Monkeypox Virus Antigen Rapid Test Kit both recently received market access authorization in the Democratic Republic of Congo. These are among the first rapid diagnostic tests that could improve testing, but further evaluation is needed to better understand performance and clade differentiation. It is important to note that at this time, the Africa CDC has emphasized no antigen rapid diagnostic test has demonstrated the minimum requirement for mpox testing. Morocco-based manufacturer, Moldiag, has delivered their mpox testing kits to Burundi, Uganda, Congo, Senegal, and Nigeria. The U.S. CDC has announced a donation of 300 mpox tests to Sierra Leone to help ensure timely diagnosis and intervention. Africa CDC has activated in Nord Kivu, DRC, and there are now 26 testing laboratories with 3 capable of performing qPCR. The only WHO approved diagnostics use PCR or near point-of-care PCR. Contipharma's LAMPOX and Monkeypox Virus Antigen Rapid Test

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The pause in USA government funding has severely impacted sample referrals on the ground, hindering the transportation of samples from various provinces to central laboratories and significantly reducing testing coverage. Compounding the situation, humanitarian crises—particularly armed conflict and mass displacement in Goma, North Kivu—have further challenged case confirmation and reporting, contributing to the decline in testing coverage.

There remains no therapeutic that has received WHO approval for mpox. Tecovirimat only has approval in the EU and US under animal rule and exceptional circumstances for mpox, and in South Africa for use in severe cases. On January 2nd, 2025, the Japan Ministry of Health, Labor and Welfare approved tecovirimat as the first antiviral treatment for orthopoxviruses despite results of the PALM007 and STOMP trials. Proper use of tecovirimat requires taking the medication within 30 minutes of eating a moderate or high fat meal for the full 14 day course of treatment. This may present difficulties for use in areas experiencing acute food insecurity such as the Democratic Republic of <u>Congo</u>. Results of the <u>PALM007 trial</u> for tecovirimat in the Democratic Republic of Congo showed the antiviral drug was safe but did not reduce the duration of mpox lesions in patients with clade I mpox. The study largely included participants under the age of 18 and limited representation of persons living with HIV. Results of the STOMP trial for tecovirimat in clade II mpox showed the antiviral drug was safe, but did not reduce the time to lesion resolution or have an impact on pain. Ongoing clinical trials aim to further understand why tecovirimat did not confer benefit, new approaches to treating mpox, and evaluating tecovirimat further in adults and people living with HIV infected with clade 2 mpox. SIGA has into an exclusive license agreement with Vanderbilt University for novel poxvirus monoclonal antibodies, though it will be critical to consider the potential downstream accessibility of this candidate.

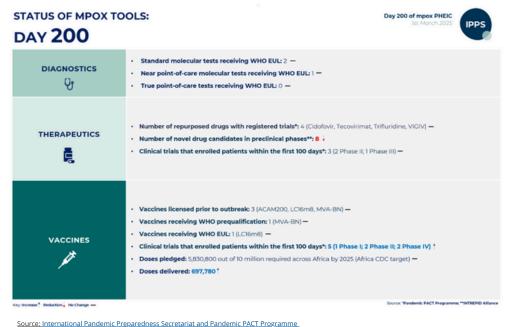
On January 15th, the Africa CDC announced the first patients had been enrolled in the MOSA trial which will be evaluating different antivirals for mpox either alone or in combination. The first antiviral that will be evaluated is brincidofovir (Emergent BioSolutions) which is currently only available in the U.S. under the emergency use investigational new drug designation for mpox.

NanoViricides has received approval from the Democratic Republic of Congo's National Ethics Committee for Health to move forward with a Phase II clinical trial of NV-387, a broad-spectrum antiviral drug. NanoViricides will now move forward with submitting a complete clinical trial application to initiate the trial

Candidate Manufacturer	WHO-listed authority approved for mpox	WHO EUL	Use in under- 18s	Ongoing [®] trials	Availability	Manufacturing capability	Comments
Tecovirimat* ⊖ Siga	✓ EMA†	×	×	6 9 Ph I 9 Ph II 9 Ph II 9 Ph II 9 Ph IV	South Africa; used under EA-IND for mpox in USA	Easily manufactured at scale	Primary endpoint not met in PALM007 (Clade I in DRC) PK/PD and resistance results awaited
Brincidofovir Emergent () BioSolutions	×	×	×	0 Ph I 0 Ph II 0 Ph II 0 Ph II 0 Ph II	Used under EIND for mpox in the USA	N/A	To be tested in the MOSA trial in DRC, Nigeria
/ICIV Emergent () BioSolutions	×	×	×	1 0 Ph II 0 Ph II 0 Ph II 0 Ph II 0 Ph II	N/A	N/A	Manufacturing/access at scale not currently feasible in LMICs
Cidofovir 🗘 Cilead	×	×	×	0 Ph I 0 Ph II 0 Ph II 0 Ph II 0 Ph IV	N/A	N/A	N/A
	lies (mAbs): 2 a urposed	nti-mpox i wailable for c nical trials in URI, but no mpleted an a	mAbs with o ompassionate u the DRC and CA African country opplication to M	ingoing preclinic: use in South Africe and AP or under application has applied for or EURI at this time.	for Approved under to animal rule / exceptional circumstances	iofactura) and JEPO r EIND: emergency in PK/PD: pharmacolo EA-IND: expanded a	ASCIO) -CBRND (Just Evotec)] restigational new drug netics / pharmacodynamics access investigational new dru sice PACT Programme



Below, is the status of vaccines, therapeutics, and diagnostics. Across all three categories progress has been made, but there is still a need for true point-of-care diagnostics, and more efficient and equitable vaccine allocation and delivery.



Financing

The incident management support team has completed the second phase of the <u>mpox response plan</u> which will be implemented from March 2025 to August 2025. This plan focuses on intensification, integration, and the legacy of the mpox response. The response strategy is

comprised of eight domains: communitycentered, multi-sectoral approach, strengthening of national and sub-national coordination, digitized surveillance, syndromic approach, decentralized laboratory testing, accelerated vaccination, and resilient health systems. This plan calls for a budget of USD \$429,595,970 with 70% of the budget to be spent within the first 3 months (March-May). 80% of the total budget has been allocated to intensification phase of the response, with the remaining 20% allocated to the integration and legacy phase (see allocation breakdown specific below). Approximately USD \$196 million remains from the first phase of the response and will be available to be carried over into phase 2.

Phases	Intensification	Integration and Legacy	Total	%
First 3 months	\$ 274,941,421	\$ 25,775,758	\$ 300,717,179	70%
Last 3 months	\$ 68,735,355	\$ 60,143,436	\$ 128,878,791	30%
Total	\$343,676,776	\$ 85,919,194	\$ 429,595,970	100%
% of total budget	80%	20%	100%	

Pillars	Amount	Allocation key
Coordination and Collaboration	\$ 17,183,839	4%
RCCE	\$ 51,551,516	12%
Surveillance and data	\$ 107,398,993	25%
Laboratory testing and sequencing	\$ 21,479,799	5%
Case Management (Medical, Nutrition & Mental Health)	\$ 42,959,597	10%
Infection Prevention and Control and WASH	\$ 51,551,516	12%
Vaccination and Logistics	\$ 111,694,952	26%
Research	\$ 17,183,839	4%
Continuity of essential services	\$ 8,591,919	2%
Total	\$ 429,595,970	100%

Source: Africa CDC Weekly Mpox Press Briefing 3/27

Combined with approximately USD \$9.6 million contributed from member states, this leaves a funding gap of USD \$224 million (currently the second phase is 47.9% funded).

The <u>Mpox Continental Preparedness and Response Plan for Africa</u> requested an **estimated budget of nearly \$600 million USD**, of which around \$329 million (55%) will be allocated for mpox response across 14 countries and mpox readiness in 15 additional countries. The other nearly \$270 million (45%) has been earmarked for operational and technical support through partners. The budget included in the Africa CDC and WHO Mpox Continental Preparedness and Response Plan for Africa does not include costs associated vaccine procurement, which is dependent on price negotiations with manufacturers and donated doses. **Africa CDC has reported they <u>received pledges</u> totaling \$1.3 billion USD from both international and domestic sources.** Publicly available pledges have been reported below.











New financial pledges:

Donor	Recipient	Amount (USD)
USA	DRC and other AU member states and Multilateral Organizations	545,140,302
Coalition for Epidemic Preparedness Innovations (CEPI)	Vaccine development / BioNTech	72,000,000
Coalition for Epidemic Preparedness Innovations (CEPI)	Vaccine manufacturing capabilities (in Rwanda) / Bi	145,000,000
The Pandemic Fund	10 AU MS - WHO/UNICEF/FAO	129,000,000
Mastercard Foundation	UNICEF	35,000,000
Mastercard Foundation	WFP	15,000,000
European Union International Partnerships (EU INTPA)	UNICEF/WHO/Africa CDC	20,000,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	Burundi	140,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	Cote d'Ivoire	1,010,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	DRC	9,500,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	Ghana	1,500,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	Liberia	440,000
The Global Fund for HIV/AIDS, TB and Malaria (GFATM)	Rwanda	5,170,000



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UK Foreign, Commonwealth and Development Office (FCDO)	5 Standby Partners	440,000		
UK Foreign, Commonwealth and Development Office (FCDO)	IFRC	1,090,000		
UK Foreign, Commonwealth and Development Office (FCDO)	Rwanda, UNICEF DRC and other partners and countries	11,700,000		
UK Foreign, Commonwealth and Development Office (FCDO)	WHO AFRO	440,000		
AU-PRC (Covid response Fund),	Africa CDC	10,400,000		
Democratic Republic of Congo (DRC)	DRC	10,000,000		
European Union Health Emergency and Response Authority	Africa CDC	10,000,000		
African Development Bank (AfDB)	Africa CDC	3,700,000		
Cote d'Ivoire	Cote d'Ivoire	2,000,000		
The Bill and Melinda Gates Foundation (BMGF)	WHO-Africa CDC Joint Emergency Action Plan (JEAP)	1,600,000		
Denmark	WHO	1,400,000		
Republic of Korea	Republic of Korea	1,200,000		
World Bank	Africa CDC	1,050,000		
Burundi	Burundi	1,000,000		
Gavi, the Vaccine Alliance	Africa CDC	700,000		
Total: \$1,035,620,302				

Source: Africa CDC Event Dashboards

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The Pandemic Fund has decided, under the Fund's second call for proposals, **to fast-track US \$128.89 million to support 10 countries** in their response to mpox. This funding will go to projects that aim to enhance national and cross-border surveillance and early warning systems; strengthen laboratory capacities for disease detection, sequencing, and genomic surveillance; build a skilled workforce equipped to detect and rapidly respond to health threats and emergencies; and foster multisectoral coordination for pandemic prevention, preparedness, and response through a One Health approach. The 10 countries are: the DRC, Burundi, Rwanda, Uganda, Kenya, Sudan, Djibouti, Ethiopia, Somalia, and South Sudan.

In the news

Africa CDC mpox dashboard: https://dashboards.africacdc.org/

Trial of mpox vaccine begins in infants, toddlers, pregnant women: <u>https://www.cidrap.umn.edu/mpox/trial-jynneos-mpox-vaccine-begins-infants-toddlers-pregnant-women</u>

Mpox is still a health emergency, WHO says: <u>https://www.reuters.com/business/healthcare-pharmaceuticals/mpox-is-still-health-emergency-who-says-2025-06-09/</u>

Africa CDC and Fiocruz partner to strengthen health systems: https://africacdc.org/news-item/africa-cdc-and-fiocruz-partner-to-strengthen-health-systems/

Joint mpox continental activity report: <u>https://africacdc.org/download/outbreaks-response-in-africa-joint-mpox-</u> <u>continental-activity-report/</u>

Mpox Continental Response Plan 2.0: https://africacdc.org/download/mpox-continental-response-plan-2-0/

IPPS fourth implementation report: <u>https://d7npznmd5zvwd.cloudfront.net/prod/uploads/2025/01/IPPS_100-Days-Mission_2024_WEB_V2-1.pdf</u>

U.S. FDA approves freeze-dried formulation of Bavarian Nordic's mpox vaccine: <u>https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-freeze-dried-version-bavarian-nordics-mpox-smallpox-vaccine-2025-03-31/</u>

Understanding the resurgence of mpox: <u>https://tropmedhealth.biomedcentral.com/articles/10.1186/s41182-024-00678-1</u>

The first 100 days of the mpox response in Africa: <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)02681-3/fulltext</u>

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