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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 <u>last edition</u> are also written in red in the body of the report.

WHO Emergency Committee on Mpox to assess if mpox remains classified as a public health emergency of international concern (PHEIC), while Africa CDC's Emergency Consultative Group urges mpox is not under control:

Ahead of the WHO's meeting on November 22 to reassess mpox's classification as a PHEIC, the United States has reported the first case of clade 1 mpox (subclade unspecified). The index patient recently traveled to countries experiencing mpox transmission and there is limited concern for spread of mpox in the broader population at this time. The US is the seventh country outside of Africa to report a case of clade 1 mpox (UK, Sweden, Germany, Pakistan, India, Thailand). Cases continue to rise in Uganda, with 184 new cases (all clade 1b) notified in the last week. 100% of these cases were confirmed to be positive. There is rising concern of new clusters of cases among sex workers in the country.

Latest updates at a glance:

- Genomic <u>sequencing</u> of the cases in Zimbabwe and Zambia revealed clade 1b mpox, highlighting spread of this clade across the African region.
- The first African <u>manufactured</u> diagnostic for mpox, a PCR test kit produced by Moldiag (Morocco) was recommended for use by the Africa CDC. The test was approved after promising results when trialed in the Democratic Republic of Congo, and is a cheaper alternative to GeneXpert at an estimate cost of \$5-6/test depending on the quantities purchased.
- Africa CDC has released an updated recommended <u>Mpox Diagnostics List</u>, which includes the locally manufactured test kit.
- Africa CDC and the WHO have <u>released</u> the Mpox Testing Strategy to guide member states as they strengthen laboratory diagnostics and pathogen sequencing capabilities.
- The WHO has <u>added</u> the LC16 vaccine to emergency use listing (EUL).
- Japan's LC16 mpox vaccine is the only vaccine available for use in children under 12, but donated doses
 have yet to arrive on the continent amid liability challenges. Africa CDC believes doses will arrive by the
 end of 2024.
- The Africa CDC mpox <u>dashboard</u>, released 2 weeks ago, provides valuable data on the epidemiological situation on the continent and financial resources for the response. Additional data and transparency are needed on total response funding and allocation, vaccine access and delivery, and progress towards vaccination targets.











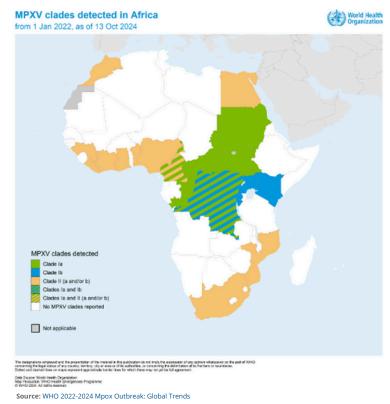
Introduction

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 Ia 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 appears to be <u>spreading</u> mostly through human-to-human contact. 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. Clade II was the cause of the 2022 outbreak and usually causes less severe illness, and is endemic to West Africa.

In 2024 alone, through 7 November 2024, there have been 55,413 suspected cases of mpox from 20 African Union member states. Out of the suspected cases, 12,162 (22.08%) have been confirmed and 1,142 deaths (Case fatality rate: 2.06%) were reported. In the last week, there were 1,501 new cases, 302 (20.12%) of those were confirmed, and there were 33 (Case fatality rate: 2.20%) deaths. Of all confirmed cases in 2024, 36.3% are in children under the age of 15 though some countries are reporting higher burden among children such as Burundi (48.4%), Central African Republic (50%), and Liberia (67%). Men represent 49.3% of the total confirmed cases. The disease has spread to all 5 regions of Africa. Angola recently reported the first case of mpox (clade not specified), becoming the 20th country on the continent to report an mpox case. Cases in the Democratic Republic of Congo appear to be stabilizing with confirmed cases dropping from around 400 a week in July to around 200-300 a week. Uganda continues to show a concerning rise in the number of mpox cases. In the last week, 184 new cases were notified and 184 were confirmed with 0 deaths reported. New clusters of cases among sex workers have been identified as a cause for concern in trying to contain the outbreak.







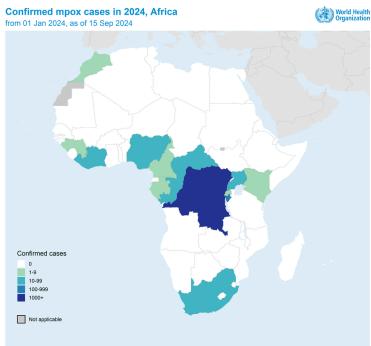




3 new cases were <u>identified</u> in Kenya (Mombasa, Nakuru, Nairobi) after nearly 1 month without new cases. Outside of the African region, the United Kingdom, Germany, Sweden, Pakistan, India, and Thailand are the only other nations with reported cases of clade Ib. The United States <u>reported</u> the first case of clade 1 mpox (subclade unspecified) on November 15th. The index case acquired mpox while traveling, and at this time there is low risk of spread to the general population.

Regulatory

On September 13, the WHO granted prequalification to Bavarian Nordic's mpox vaccine (MVA-BN). This is the first mpox vaccine to receive prequalification. Two ACAM2000 other mpox vaccines, (Emergent BioSolutions) and LC16-KMB (KM Biologics), are also consideration. October On prequalification for MVA-BN was extended for use in adolescents aged 12-17. Pregualification is often a prerequisite for organizations such as Gavi and UNICEF to begin procuring and distributing vaccines in LMICs. The Democratic Republic of Congo granted emergency use authorization in June for both MVA-BN and LC16-KMB vaccines. Nigeria has also granted emergency use authorization for the MVA-BN vaccine. The WHO announced that the LC16 mpox vaccine has been granted emergency use listing (EUL) on November 19th. This is the first available vaccine that is approved for use in children under the age of 12. The designations employed and the committing the legislation of early considerable the committee of the commi KEMRI, the Kenya Medical Research Institute, has Werden with Charles and Control of the Control Source: WHO 2022 partnered with Tonix Pharmaceuticals to conduct a



phase 1 trial for TNX-801 (investigational mpox vaccine). On October 3rd, the Alinity m mpox assay was the first in vitro diagnostic to receive emergency use listing by the WHO. The Alinity m mpox assay is a PCR test that is able to provide a result in less than 2 hours. The Alinity m mpox assay is not considered a point of care or near of care PCR platform, but a lab-based diagnostic platform. The WHO has listed two additional mpox diagnostics under emergency use listing (EUL). EUL has been granted to Cepheid's Xpert Mpox (Oct. 28) and Roche's cobas MPXV assay (Oct. 14), both of which are PCR-based diagnostic. Cobas MPXV can deliver results in less than 2 hours, and must be used on cobas systems. Xpert Mpox is compatible with GeneXpert systems, delivers results in under 40 minutes, and is the only near point-of-care diagnostic available for mpox at this time. Africa CDC has recommended the use of a PCR test manufactured by Morocco-based Moldiag, which offers a lower price of around \$5-6/test

Vaccines

compared to other available test.

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. <u>has over</u> 100 million doses of ACAM2000[GE2], 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.











Manufacturing capacity:

Bavarian Nordic, the manufacturer of the MVA-BN mpox vaccine, estimates 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 transfer manufacturing to other companies there is the potential for an additional 50 million doses to be supplied in the next 12-18 months. African vaccine manufacturers, Aspen Pharmacare and the Biovac Institute, have been in exploratory discussions with Bavarian Nordic about vaccine production. The potential for increasing manufacturing capacity is dependent on regulatory approvals and vaccine demand. 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.

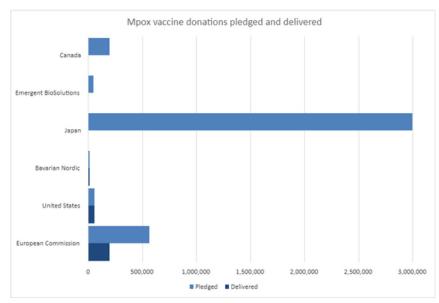
Procurement:

The European Health Emergency Response Authority has.negotiated 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 market price of MVA-BN is around \$70-\$100 per dose, which would quickly deplete Gavi's \$500 million First Response Fund. Gavi has announced 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 announced 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. Fewer than 5.6 million vaccine doses have been pledged for donation. On September 24th, 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 pledged 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 has pledged up to 3 million doses of the LC16-KMB vaccine. The vaccine donations from Japan are expected by the end of 2024, but challenges have risen around liability issues and identifying an entity to take on the risk in case of adverse events. Nigeria donated 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) mpox medical countermeasures, including vaccines, treatments, diagnostic tests. This mechanism was established as part of the interim Medical Countermeasures Network. The guiding principles for the mechanism preventing illness and death, mitigating inequity, and ensuring transparency and flexibility. The AAM has allocated 899,000 mpox vaccines to 9 countries (Central Republic, Cote d'Ivoire, 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



Source: Publicly available data compiled by the COVID QuickStart team, last updated November 19, 2024











Congo which is currently the most affected country. 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. These doses are expected to be delivered starting this week, and 975,700 doses will be the next batch of vaccines to be allocated and delivered in December. The AAM webpage has yet to be updated with information on the updated vaccine allocation or any subsequent deliveries outside of the press release announcing the allocation of 899,000 doses.

Delivery and uptake:

The European Commission <u>delivered</u> 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. This brings the total number of doses delivered to 380,880 (7.06% of pledged doses). The majority of doses (265,460) were delivered to the DRC where it is estimated 3 million doses are required to end the mpox outbreaks. Nigeria has received 10,000 doses, and Rwanda has received 6,420 doses. Five countries have developed or are in the process of developing vaccination plans for mpox. Nigeria began rolling out vaccinations on November 18th. Rwanda began <u>administering</u> mpox vaccinations to high-risk populations starting on September 17th. As of November 14th, Rwanda has achieved 100% of the vaccination target and the DRC has achieved 103% of the vaccination target. The DRC has <u>been unable</u> to start a vaccination campaign in Kinshasha due to a shortage of vaccine doses. The head of the DRC's mpox control program cited the need for at least 162,000 doses to start a campaign in Kinshasha, and currently only 53,921 (33.28%) doses are available.

Cold-chain requirements for available vaccines:

MVA-BN	Shipped frozen (-20°C); can be stored frozen for long-term storage or refrigerated (2°C-8°C) and stored for 8 weeks.
LC16-KMB	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

Testing capacity for mpox in the Democratic Republic of Congo remains low due to limited access to laboratory testing in remote areas. It is estimated only around 40-50% of suspected cases have been tested. The DRC is decentralizing laboratory services in an effort to improve diagnostic speed. 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. The WHO is in the process of reviewing additional requests for diagnostic manufacturing approvals for mpox. In response to rising cases of mpox in Uganda, the U.S. has donated 5,000 laboratory test kits (bringing the total donated to 10,000) to support testing efforts in the country. The Africa CDC and WHO have distributed 7,000 GeneXpert machines and cartridges to Burundi, Cameroon, the Central African Republic, Congo, Côte d'Ivoire, the Democratic Republic of Congo, Kenya, Liberia, Rwanda and Zambia alongside 11,000 tests. Additionally, the Africa CDC has provided 7 sets of sequencing equipment to Burundi, Ethiopia, Kenya, Mauritania, Sierra Leone, and Zimbabwe.











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. 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 Congo. Results of the PALM007 trial 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 1 mpox. The study largely included participants under the age of 18 and limited representation of persons living with HIV. 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. Some monoclonal antibodies (mAbs) are in preclinical development, though it will be critical to consider the potential downstream accessibility of these candidates. SIGA has entered 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.

Therape	utics 10	00 Da	ays Mis	sior	n mpo	ox tracker		npox PHEIC October 2024
Candidate Manufacturer	WHO-listed authority approved for mpox	WHO EUL	Use in under- 18s		going ⁰ rials	Availability	Manufacturing capability	Comments
Tecovirimat [®] () Siga	✓ EMA†	×	×	6	O Phi 2 Phii 4 Phiii O Phiv	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	O Phil O Phil O Phill O Phil	Used under EIND for mpox in the USA	N/A	To be tested in the MOSA trial in DRC, Nigeria
VIGIV Emergent () BioSolutions	×	×	×	1	O Phi 1 Phii O Phiii O Phiv	N/A	N/A	Manufacturing/acces at scale not currently feasible in LMICs
Cidofovir Gilead	×	X	×	0	0 Ph I 0 Ph II 0 Ph III 0 Ph IV	N/A	N/A	N/A
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Source: International Pandemic Preparedness Secretariat and Pandemic PACT Programme

This week marks day 100 of the mpox outbreak. To the right, 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.



Source: International Pandemic Preparedness Secretariat and Pandemic PACT Programme

Source: *Pandemic PACT Programme; **INTREPID Alliano











Financing

The Mpox Continental Preparedness and Response Plan for Africa 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 received pledges 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
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	Africa CDC	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

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/

KEMRI partners with Tonix Pharmaceuticals: https://www.kemri.go.ke/kemri-partners-withtonix-pharmaceuticals-to-develop-tnx-801-mpox-vaccine-in-kenya/

FIND mpox diagnostic landscape:

https://newsletter.finddx.org/t/ViewEmailArchive/d/185BA363900DF4722540EF23F30FEDED/C67FD2F38AC4859C/

Mpox vaccine generates robust response in adolescents: https://www.nih.gov/news-events/news-releases/mpox-vaccine-safe-generates-robust-antibody-response-adolescents

WHO lists LC16m8 mpox vaccine to EUL: <a href="https://www.who.int/news/item/19-11-2024-who-adds-lc16m8-mpox-vaccine-to-emergency-use-vaccine-to-e

listing#:~:text=The%20World%20Health%20Organization%20(WHO,PHEIC)%20on%2014%20August%202024

INTREPID Alliance releases antiviral landscape analysis: https://www.intrepidalliance.org/antiviral-pipeline/

Pandemic PACT mpox outbreak page: https://www.pandemicpact.org/outbreaks/mpox

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