

# Technical Brief Prevent, Detect and Respond to Mpox

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#### **Contents**

Introduction	3
Epidemiological characteristics	3
WHO Guidelines	4
Global Fund Financing through C19RM and HIV, TB and Malaria Investments	5
Resilient and Sustainable Systems for Health	6
Disease surveillance	6
Laboratory system strengthening	7
Human resources for health	7
Targeted Programming	8
Mpox community-based prevention	8
Community engagement	8
Community system strengthening	8
Health Equity, Gender Equality and Human Rights	9
Infection Prevention and Control (including Personal Protective Equipment)	10
Diagnostics and Therapeutics	11
Targeted Support to Vaccine Service Delivery	11
Annex 1. List of interventions and activities that can be supported through C19RN funds or HIV, TB, malaria and RSSH grants	M 13
Annex 2. MPXV molecular tests which are currently compliant with Global Fund Quality Assurance standards	16
Annex 3. Laboratory testing algorithm for mpox testing: positive results (WHO)	18

#### Introduction

Discovered in 1958, the first human case of "mpox" (formerly named "monkeypox")<sup>1</sup> was recorded in 1970. Despite its name, the source of the disease remains unknown. Nonhuman primates (like monkeys) might harbor the virus and infect people. Historically, mpox has been a viral zoonosis with symptoms similar to those seen in smallpox patients, although it is clinically less severe. With the eradication of smallpox in 1980 and subsequent cessation of smallpox vaccination, mpox has emerged as the most important orthopoxvirus for public health.

In July 2022, <u>WHO declared</u> the multicountry outbreak of mpox to be a Public Health Emergency of International Concern (PHEIC).<sup>2</sup> This technical guidance was subsequently produced to guide implementers on the use of Global Fund financing to support mpox prevention, preparedness and response. The PHEIC was declared over in July 2023. Differential investments in response efforts and related effectiveness were noted between global North and South regions, notably the lack of vaccines deployed in the WHO African Region (WHO AFRO) despite persistent transmission and associated morbidity and mortality.

Since January 2024, the AFRO region has seen increasing case rates<sup>3</sup> (WHO Sitrep #35) of mpox, with an overall tripling of case rates compared with the 2022 period that prompted the initial PHEIC. AFRO is the only region which has seen an increasing trend in mpox cases during the last two reporting periods, and cases have been reported in several new countries in East-Central Africa, including in Burundi, Kenya, Rwanda and Uganda.

In response to the evolving epidemiology and risk analysis, the <u>Director General of the Africa Centers for Disease Control and Prevention (Africa CDC) declared</u> a Public Health Emergency of Continental Security (PHECS) on 13 August 2024 and the WHO redesignated the <u>mpox epidemic a Public Health Emergency of International Concern (PHEIC)</u> on 14 August 2024. This technical brief has been updated to align with current guidance from WHO and Africa CDC.

#### **Epidemiological characteristics**

The epidemiology of mpox has continued to evolve in complex ways which have important implications for prevention, preparedness and response. Currently there are clades I and II, with Ia, Ib, IIa, and IIb sub-lineages, each with different transmission and geographic

<sup>&</sup>lt;sup>1</sup> World Health Organization. "WHO Recommends New Name for Monkeypox Disease." *WHO*, November 28, 2022. https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

<sup>&</sup>lt;sup>2</sup> World Health Organization. "WHO Director-General's Statement on the Press Conference Following IHR Emergency Committee Regarding the Multi-Country Outbreak of Monkeypox, 23 July 2022." WHO, July 23, 2022. <a href="https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-the-press-conference-following-IHR-emergency-committee-regarding-the-multi--country-outbreak-of-monkeypox--23-july-2022." World Health Organization. Multi-Country Outbreak of Mpox: External Situation Report 35, 12 August 2024. Geneva: World Health

<sup>&</sup>lt;sup>3</sup> World Health Organization. *Multi-Country Outbreak of Mpox: External Situation Report 35, 12 August 2024.* Geneva: World Health Organization, 2024. <a href="https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox-external-situation-report-35--12-august-2024">https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox-external-situation-report-35--12-august-2024</a>.

patterns (see <u>WHO SitRep #35</u> for details). Clade Ib is the newest variant having emerged during epi week 16 (14 to 20 April) in 2024. Below is a summary of the main global epidemiological characteristics of mpox cases based on a detailed case-based data shared by WHO Member States through the global mpox disease surveillance system from 1 January 2022 to 30 June 2024:

- Globally, 96.4% (87,189 of 90,410 cases) of confirmed cases with available data are male, with a median age of 34 years (interquartile range: 29 41 years). However, misdiagnosis and delayed diagnosis, and differences in signs and symptoms have been noted among cis women and gender diverse populations compared to men, requiring a gender, rights and equity approach in the response.<sup>4</sup>
- Among modes of transmission, sexual contact is the most commonly reported (19,102 of 22,801 cases, 83.8%), followed by person-to-person non-sexual contact.
- Among cases where at least one symptom is reported (n = 36,085), the most common symptom is any rash (88.6% of cases), followed by fever (58.0%), and systemic rash or genital rash (54.8% and 49.5%, respectively). The symptomatology of cases has been very consistent over time (WHO SitRep #33).
- Around half (18,628 of 35,861 cases, 51.9%) of cases with available information on their HIV status are reported to be in persons living with HIV. This proportion approximates that reported during January to June 2024 (237 of 543 cases; 43.6%) and is related to the common risk factor of sexual exposure between the two conditions.

#### **WHO Guidelines**

Guidelines on the <u>clinical management and infection prevention and control for mpox</u> were released on 10 June 2022. New interim guidance on <u>surveillance</u>, <u>case investigation and contact tracing for mpox</u> and on diagnostic testing for the monkeypox virus (MPXV) was issued in March and May 2024<sup>5</sup>, respectively, including a new chapter on mpox reinfection and reinfection definitions, and more considerations relevant to endemic contexts in the African region.

The documents outline components of a comprehensive package to prevent, detect and respond to mpox outbreaks, including via:

- Event-based and indicator-based (case surveillance).
- Event verification and investigation (rapid response, case finding and contact tracing).
- Laboratory diagnostics, including confirmatory testing and sequencing.

<sup>&</sup>lt;sup>4</sup> "Monkeypox Virus Infection in Humans across 16 Countries — April–June 2022." *The Lancet* 400, no. 10347 (2022): 641–649. https://doi.org/10.1016/S0140-6736(22)02187-0.

<sup>&</sup>lt;sup>5</sup> World Health Organization. Laboratory Testing for the Monkeypox Virus: Interim Guidance, 2024. Geneva: World Health Organization, 2024. https://www.who.int/publications/i/item/WHO-MPX-Laboratory-2024.1.

- Laboratory systems strengthening, including strengthening sample referral and reporting systems.
- Infection prevention and control (IPC), including personal protective equipment (PPE).
- Clinical management and isolation with supportive care.
- Preventive vaccination of high-risk groups and post-exposure vaccination of contacts.

Additional guidance on risk communication and community engagement and vaccination are also available.<sup>6</sup>

### Global Fund Financing through C19RM and HIV, TB and Malaria Investments

Global Fund financing can be used to fund activities and interventions that help prevent, detect and/or respond to mpox outbreaks in Global Fund-eligible countries and includes:

- Systems strengthening of core prevention, detection and response functions, such as disease surveillance, laboratory capacity, surge workforce, case management and other capacities essential for early detection and response to outbreaks.
- **Targeted programming,** such as mpox prevention communication and information, and community engagement activities.
- Maximizing health equity, gender equality and human rights interventions to address inequitable outcomes, minimize stigma and discrimination, address harmful gender norms and practices that serve as a barrier to seeking care and increase vulnerability, and promote community led/peer outreach and access to justice.
- **IPC** including screening/triage, system strengthening, training and **PPE**, if meeting Quality Assurance (QA) requirements.
- **Diagnostic kits**, if meeting QA requirements.
- Multi-use therapeutics, if meeting QA requirements.

Funding for these activities/interventions can be applied from either the HIV, TB, malaria or RSSH grants and/or COVID-19 Response Mechanism (C19RM). To be eligible for funding, the interventions selected are required to:

<sup>&</sup>lt;sup>6</sup> World Health Organization. Surveillance, Case Investigation and Contact Tracing for Mpox (Monkeypox): Interim Guidance. Geneva: World Health Organization, 20 March 2024. <a href="https://iris.who.int/bitstream/handle/10665/376306/WHO-MPX-Surveillance-2024.1-eng.pdf?sequence=1">https://iris.who.int/bitstream/handle/10665/376306/WHO-MPX-Surveillance-2024.1-eng.pdf?sequence=1</a>.

World Health Organization. Risk Communication and Community Engagement (RCCE) for Monkeypox Outbreaks: Interim Guidance. Geneva: World Health Organization, 24 June 2022. https://www.who.int/publications/i/item/WHO-MPX-RCCE-2022.1.

World Health Organization. *Vaccines and Immunization for Monkeypox: Interim Guidance*. Geneva: World Health Organization, 24 August 2022. <a href="https://www.who.int/publications/i/item/WHO-MPX-Immunization-2022.2-eng">https://www.who.int/publications/i/item/WHO-MPX-Immunization-2022.2-eng</a>.

World Health Organization. *Diagnostic Testing for the Monkeypox Virus (MPXV): Interim Guidance*. Geneva: World Health Organization, May 2024. https://iris.who.int/bitstream/handle/10665/376952/WHO-MPX-Laboratory-2024.1-enq.pdf?sequence=1.

- Overlap with or contribute positively to HIV, TB, malaria, RSSH and/or C19RM objectives (including health and community systems).
- Align with Global Fund Board policies on C19RM and/or the <u>Global Fund Strategy</u>, as applicable. Note the Emergency Fund is not a viable route due to limited funding available.
- Follow the usual process per the Global Fund <u>Guidelines for Grant Budgeting</u>,
   Operational Policy Note on Revise Grants or the C19RM Guidelines, as relevant.

Additionally, the procurement of all pharmaceutical products and diagnostics must be compliant with the Global Fund's relevant QA policies.

A list of activities and interventions which currently meet these criteria can be found in Annex 1, based on the Global Fund Modular Framework Handbook for the 2023-2025 allocation period and the C19RM Modular Framework. The list may be updated occasionally as additional products, activities and/or interventions are determined by the Global Fund Secretariat to meet these criteria and will be communicated to Principal Recipients, accordingly.

#### **Resilient and Sustainable Systems for Health**

Support can be requested for systems strengthening of core prevention, detection and response functions, such as disease surveillance, laboratory capacity, a surge workforce and other functions for early detection and response to outbreaks. This can include policy development, regulation and strategies for prevention, detection and response.

#### **Disease surveillance**

Disease surveillance capacities can be improved by strengthening event- and indicator-based surveillance systems that can enable early detection and prompt reporting of mpox cases. Rapid sensitization of health facility- and community-based health workers to case definitions using available platforms, inclusion of case definitions and signals in existing surveillance platforms such as indicator-based surveillance and response (IDSR) and event-based surveillance are recommended (WHO AFRO and Africa CDC normative guidance). Support for event-based surveillance could include both health facility-based and community-based reporting including among key populations and other vulnerable groups. Strong preference for use of existing digital platforms to enhance rapid reporting of mpox cases/events, linking lab results to cases, provide feedback to stakeholders, as platforms to communicate and disseminate information about mpox should be considered.

Linking mpox surveillance to laboratory testing is a key consideration (see the <u>Laboratory</u> <u>systems strengthening</u> section below) to ensure cases are confirmed and response is appropriate. Response to mpox including case investigations, contact tracing and other

measures, enhancing public health emergency operations centers, capacity building for epidemic intelligence and decision making such as through Frontline and/or Intermediate Field Epidemiology Training Programs (FETP) should be prioritized. Consideration should be given to strengthen routine integrated HIV and sexually transmitted infection surveillance, including mpox, based on existing communicable disease surveillance platforms; and to ensure focus on gender equality, human rights and equitable approaches, and engagement of the populations most affected by the disease.

#### **Laboratory system strengthening**

Support to specimen transport networks, quality management systems, laboratory information systems, equipment management systems and biosafety practices (including biohazardous waste management) help strengthen laboratory systems. Biosafety practices are especially important for mpox sample transport and diagnostic systems.

Shortening the turnaround time for results is a key consideration to improve patient management and public health measures, which include clade-specific testing and sequencing. Therefore, mpox diagnostics may leverage existing multipathogen diagnostics equipment where appropriate, as well as integrated sample transportation and laboratory information systems to facilitate delivery of test results. Memorandum of understandings (MOUs) between countries for sample referrals can also be useful.

#### **Human resources for health**

The health workforce is critical for early detection and response to outbreaks, including mpox. Global Fund financing can be used to support health care workers, community health workers, and support staff that may be involved in surveillance (e.g. FETP), contact tracing, referrals, IPC, case management, vaccination and other functions. In addition to capacity building (see the *Disease surveillance* section above), support can include a temporary (surge) increase in the workforce to meet detection and response needs in quickly evolving situations, such as deployment of rapid response teams when supported by a strong justification on why external resources are required for temporary workforce deployment. Support can also be used for activities relating to human resources for health (HRH) planning that help strengthen HRH core capacities in the medium-term, in line with the most recent assessment report, such as state parties annual report, joint external evaluation, and others. <sup>7</sup> Safeguarding of front-line health workers is critically important through IPC measures including availability of IPC guidelines, training, PPE, IPC programs, amongst other interventions (per IPC section below).

<sup>&</sup>lt;sup>7</sup> For more information on SPAR, see: <a href="https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting">https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting</a>.

#### **Targeted Programming**

#### **Mpox community-based prevention**

Evidence-based information on mpox modes of transmission, prevention strategies, and symptoms, delivered by health care providers in community settings or peer outreach workers, can help increase awareness and knowledge of mpox, drive demand for mpox prevention, diagnosis and treatment services and empower community members to make decisions about their own heath.

Community-led and community-based organizations can play a key role in delivering mpox prevention and risk communication messages to their communities in a culturally appropriate way, facilitate linkage to diagnosis and treatment and address human rights-, gender- and other service delivery barriers to access. Where possible, mpox prevention messages should be integrated into existing prevention work, for instance in community outreach interventions targeting children and/or gay men and other men who have sex with men (MSM), depending on the epidemiologic context. WHO's strategic framework for enhancing prevention and control of mpox provides guidance to health authorities, communities and other stakeholders in preventing and controlling mpox outbreaks. Mpox literacy is key amongst the community and anticipates shifts in understanding, as new information emerges about modes of transmission, mpox reinfection and recrudescence, circumstances that put people at risk, and the effectiveness of public health measures in protecting people.

#### **Community engagement**

It is critical to involve communities in decision-making processes on the provision of mpox services in a timely and proactive manner. Based on context, community engagement activities such as strengthening mpox literacy, addressing harmful gender norms that might prevent health seeking, community consultations, rapid assessments and identification of needs can help inform design of service delivery modalities and build trust between communities and other actors in the health response.

#### **Community system strengthening**

An effective response to mpox, particularly when impacting marginalized and stigmatized populations, should also be delivered in community-based settings. Public health authorities should work with key populations and community groups to establish trust, convey accurate information in a culturally appropriate language, and create spaces for key populations to access safe, high-quality mpox prevention, vaccination, and care both in formal health settings and through community-led responses. This includes engaging community

<sup>&</sup>lt;sup>8</sup> World Health Organization. *Strategic Framework for Enhancing Prevention and Control of Mpox: 2024-2027.* 24 May 2024. https://www.who.int/publications/i/item/9789240092907.

members in the design and rollout of mpox programs, for example through community advisory panels. Community-led monitoring (CLM) is also key for generation and analysis of critical data to improve service delivery and access, particularly for the most marginalized populations who might otherwise avoid formal care.

However, many key populations community groups and organizations lack the resources and capacities needed to deliver and manage mpox prevention services. It is key to focus on strengthening community organizations and systems to be effective partners in national mpox responses. This includes dedicated trainings, adequate renumeration for peer health workers, support for community-led monitoring and analysis, and use of the produced community data for mpox service improvement. When communities are meaningfully engaged in program design, their perspective is included and helps build their technical capacity on issues related to mpox response. Interventions that are part of CSS include community-led monitoring, community-led research and advocacy, institutional capacity and leadership development and community engagement, linkages and coordination.

#### **Health Equity, Gender Equality and Human Rights**

Advancing health equity, gender equality, and human rights is crucial not only in reducing the heightened risks of mpox infection faced by specific marginalized and vulnerable communities, but also in shaping an effective and inclusive response to the disease. The integration of human rights norms and principles into the provision of mpox services supports the removal of structural barriers that prevent and discourage community members from accessing health care. Programs must recognize and appropriately address inequities in risk, vulnerability and access to services for the communities most impacted by mpox. This includes a greater focus on health equity, implementing targeted interventions that address the specific challenges and factors that exacerbate vulnerability. Some of these are age, poverty, social and economic marginalization, cultural and gender norms, stigma, discrimination, violence and criminalization (particularly in those contexts where communities of gay, bisexual men and other MSM are impacted by the disease).

Gender is a critical factor in risk for disease and people's ability to access and receive services. Mpox services must be designed, implemented and monitored in a way that recognizes and responds to gender-specific needs, gendered barriers to services and gender inequalities in health outcomes.

Supported interventions in this program area include: encouraging leadership of women, gender diverse and key populations in community responses to the disease; promoting activities that reduce stigma, discrimination and violence (in health care and community settings); community consultations and empowerment initiatives such as legal literacy, access to justice and advocacy initiatives to reform harmful laws, policies and practices;

<sup>&</sup>lt;sup>9</sup> Cheyne, Ashleigh, et al. "Community Involvement in an Outbreak—One Year On for Mpox." *Clinical Infectious Diseases* 79, no. 1 (15 July 2024): 278–280. https://doi.org/10.1093/cid/ciad745.

engaging with community, religious and opinion leaders to question and transform gender-based violence, harmful gender norms and practices; engaging with men and boys in all their diversity to embrace positive masculinity and lead gender transformative initiatives; quantitative and qualitative analyses of gender-related barriers to accessing and using services, such as disability, mental health, social protection, human rights, and legal barriers. Support can also be requested for gender-focused interventions in human resources for health to ensure engagement of marginalized and affected populations in the surveillance, monitoring and response to mpox, and for other community engagement interventions that work to tackle structural factors and harmful gender norms that negatively affect risk, service access and health outcomes.

## Infection Prevention and Control (including Personal Protective Equipment)

IPC is critical in the mpox outbreak response, particularly in congregate settings, such as hospitals, home-based care settings, prisons and refugee camps. Ensuring compliance with minimum IPC standards, tailored to the specific risks of mpox, is essential for safeguarding health in both community and healthcare environments. Rapid identification of persons suspected with mpox infection should be emphasized, including screening/triage at health facilities followed by appropriate IPC. Contact and droplet precautions, such as gowns, gloves and face masks, are warranted for health care workers and others, including those supporting epidemiologic investigations of suspect cases and contacts, when in proximity to suspect or known cases. In addition, respirators are recommended for health care workers. Additional airborne precautions are also recommended for aerosol-generating procedures where applicable.

Supporting IPC, including screening/triage, and oversight and strengthening of IPC programs can greatly help to reduce the likelihood of unnecessary or unprotected health worker exposure. PPE is also effective but less effective than a systems-based approach to safety. A systems-based approach to IPC for mpox includes elimination controls (i.e., screening, triage and isolation to prevent exposure); and administrative controls (i.e., ensuring all health workers are trained to recognize and protect themselves from mpox exposure through training, supportive supervision and quality assurance/ improvement). PPE products supported by the Global Fund include gowns, gloves, eye protection (i.e., goggles or a face shield that covers the front and sides of the face), particulate respirator equipped with N95 filters or higher, surgical masks (for patients) and biosafety cabinets.

Prevention of mpox infection is focused on vaccination. Modes of transmission will inform further individual prevention measures that can be taken which are defined in WHO guidelines. In caring for sexually active populations and based on the precautionary principle, WHO suggests the use of condoms consistently during sexual activity (receptive

and insertive oral/anal/vaginal) for 12 weeks after recovery to prevent the potential transmission of mpox.<sup>10</sup>

Global Fund financing can be used for the procurement of PPE products which meet the applicable Global Fund's QA policy<sup>11</sup> and the <u>Guide to Global Fund Policies on Procurement and Supply Management of Health Products</u>.

#### **Diagnostics and Therapeutics**

In general, swab samples taken directly from a lesion or affected area are sent to a laboratory with established PCR capacity for endemic pathogens of public health importance where a PCR test is run to screen for Orthopoxvirus (OPXV) and/or confirm mpox with all results reported to WHO. In addition, consideration should be given to testing for HIV, TB and/or malaria among persons presenting with fever and depending on the broader clinical presentation and risk profile.

Clinical care for mpox should be fully optimized to alleviate symptoms, manage complications and prevent long-term sequelae. Patients should be offered fluids and food to maintain adequate nutritional status. Pain management should be optimal. Secondary bacterial infections should be treated as indicated. Specific treatments are under study but not validated yet.

C19RM funding can be used for the procurement of diagnostic tools which meet the <u>Global Fund's QA policies</u> and the reinvestment requirements under the <u>C19RM Guidelines</u>. HIV funding can also be used for the procurement of diagnostic tools pursuant to the criteria of the <u>Framework for Financing Co-infections and Co-Morbidities of HIV/AIDS</u>, <u>Tuberculosis and Malaria (COIM Framework)</u> and the Global Fund's QA policies. Please see Annex 2 for mpox molecular tests which are currently allowable for procurement and Annex 3 for the current WHO laboratory confirmatory testing algorithm.

#### **Targeted Support to Vaccine Service Delivery**

Global Fund-financing cannot be used for vaccines, but it can be used for selected crosscutting aspects of service delivery, such as non-health products. Mass vaccination for the general population, even in areas reporting outbreaks, is not recommended at this time. However, WHO now recommends preventive vaccination for high-risk groups and postexposure preventive vaccination for contacts.

Public health authorities are encouraged to put in place a robust surveillance and containment strategy to ensure detailed case investigation, contact tracing, monitoring, care,

<sup>&</sup>lt;sup>10</sup> World Health Organization. *Clinical Management and Infection Prevention and Control for Monkeypox: Interim Guidance, 2022.* Geneva: World Health Organization, 2022. <a href="https://www.who.int/publications/i/item/WHO-MPX-Clinical-and-IPC-2022.1">https://www.who.int/publications/i/item/WHO-MPX-Clinical-and-IPC-2022.1</a>.

<sup>11</sup> Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

and isolation protocols. This will help identify those populations at highest risk of infection <sup>12</sup> and who are top priority for vaccination. Given the emphasis on targeted vaccination by Africa CDC and WHO, risk communication, community engagement and related health education activities focused on addressing vaccine hesitancy should be considered.

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<sup>&</sup>lt;sup>12</sup> WHO recommends the use of primary preventive (pre-exposure) vaccination for individuals at risk of exposure. The group at the highest risk of exposure in the current multicountry outbreak is gay, bisexual or other MSM with multiple sexual partners. Others at risk may include individuals with multiple casual sexual partners, sex workers, health workers at risk of repeated exposure, laboratory personnel working with orthopoxviruses, clinical laboratory and health care personnel performing diagnostic testing for mpox and outbreak response team members. Post-exposure preventive vaccination is recommended for close contacts of cases, ideally within four days of first exposure (and up to 14 days in the absence of symptoms).

#### Annex 1. List of interventions and activities that can be supported through C19RM funds or HIV, TB, malaria and RSSH grants

Mpox supported interventions	Can be funded under HIV, TB, malaria and RSSH grants (refs. to 2023-2025 Allocation Period Modular Framework)	Can be funded under C19RM (refs. to C19RM Modular Framework)
Addressing national planning and	RSSH: Coordination and	Country-level
response management.	management of national disease	coordination and
	control programs (page 55).	planning (page 21).
Mpox community engagement	RSSH: Community systems	Risk communication
activities that support	strengthening (pages 13 to 16).	(page 23) and COVID-19
involvement of communities in		CSS: Social mobilization
decision-making processes:		(pages 13 to 14)
<ul> <li>rapid assessments;</li> </ul>		
<ul> <li>community consultations;</li> </ul>		
<ul> <li>identification of needs; and</li> </ul>		
<ul> <li>community mobilization.</li> </ul>		
Surveillance, including	RSSH: Routine reporting (page	Surveillance-
community-based and case-	44) and Surveillance for priority	epidemiological
based surveillance	epidemic-prone diseases and	investigation and contact
	events (page 48).	tracing (pages 22 to 23).
Mpox-specific diagnostics (see	HIV: Differentiated HIV testing	Laboratories and
Annex 2 and 3, below)	services, pg. 93 (under Co-	Diagnostics, pg. 7-9
	infection/Co-morbidity policy)	
Investigation, contact tracing to	RSSH: Surveillance for priority	Surveillance-
contain outbreaks	epidemic-prone diseases and	epidemiological
	events (page 48).	investigation and contact
	20011	tracing (page 4).
National reference laboratories	RSSH: Laboratory systems	COVID-19 diagnostics
testing capacity strengthening.	(including national	and testing (pages 22 to
For example, training, biosafety	and peripheral) (pages 37 to 42).	23).
(as sample handling will require		
use of class II biosafety cabinets)		
and waste management.  Surge workforce, including field	RSSH/PP: Human resources for	Surveillance systems
epidemiology training programs	health and quality of care (pages	(pages 5 to 7).
and rapid response teams.	28 to 36).	(pages o to 1).
Policy development and	RSSH: Laboratory systems	Country-level
regulation, strategies, algorithms	(including national	coordination and
and test validation.	and peripheral) (pages 37 to 42).	planning (page 21).
and test validation.	and penpheral) (pages 31 to 42).	pianing (page 21).

Mpox supported interventions	Can be funded under HIV, TB, malaria and RSSH grants (refs. to 2023-2025 Allocation Period Modular Framework)	Can be funded under C19RM (refs. to C19RM Modular Framework)		
MOUs between member states for sample referrals.	RSSH: Laboratory systems (pages 37 to 42).	Surveillance systems (pages 5 to 7) and Laboratory systems (page 7 to 9).		
Strengthening sample handling, referral and reporting systems (sample transport and laboratory information systems).	RSSH: Laboratory systems (including national and peripheral) (pages 37 to 42).	Laboratories systems (page 7 to 9).		
Advocacy for development and availability of new IVDs, e.g., rapid antigen and molecular tests.	RSSH: National health sector strategy, policy & regulations (page 10).	Case management, clinical operations and therapeutics (pages 16 to 18).		
Select cross-cutting aspects of vaccine service delivery (e.g., vaccine deployment activities but not procurement of vaccines).	N/A	Surveillance systems (pages 5 to 7), Laboratory systems (pages 7 to 9), community system strengthening (pages 12 to 14), community health workers (pages 9 to 12) and health products and waste management systems (pages 18 to 21).		
IPC/PPE: Establishment of screening/triage sites; Strengthening of IPC programs to enable improved systems-based approach to IPC; Gowns, gloves, eye protection (i.e., goggles or a face shield that covers the front and sides of the face), particulate respirator equipped with N95 filters or higher, surgical masks (for patients) and biosafety cabinets.	RSSH/PP: Human resources for health and quality of care (pages 28 to 36) and TB/DR-TB Prevention - Infection prevention and control (IPC) (page 127), and DS. DR-TB prevention.	Infection prevention and control and protection of the health workforce (pages 14 to 16).		
<ul> <li>Mpox stigma and discrimination prevention and reduction activities in the following settings:</li> <li>Healthcare settings</li> <li>Individual (including internalized stigma),</li> </ul>	Reducing human rights-related barriers to HIV/TB services/Stigma and discrimination reduction (pages 63 to 112), community-led research and advocacy (page	Respond to human rights and gender related barriers to services (pages 24 to 25) and Mitigation for TB Programs (pages 26-27).		

Mpox supported interventions	Can be funded under HIV, TB, malaria and RSSH grants	Can be funded under C19RM	
	(refs. to 2023-2025 Allocation Period Modular Framework)	(refs. to C19RM Modular Framework)	
household and community settings.  Communication and information sector (journalists and other media professionals).	14), RSSH/PP: human resources for health (HRH) and quality of care (pages 29 and 31), eliminating TB-related stigma and discrimination (pages 137 and 138).		
Community-led and monitoring of episodes of stigma, discrimination and other rights violations related to mpox.	Reducing human rights-related barriers to HIV/TB services /Stigma and discrimination reduction (pages 63 to 112).	COVID-19 CSS: Community-led monitoring (pages 12 to 13).	
Community-led advocacy and research to support the development/improvement of and sustain access to mpox community-based interventions, particularly those targeting key populations.	Community-led research and advocacy (page 14).	COVID-19 CSS: Community-led advocacy and research (page 13).	
<ul> <li>Communication for prevention:</li> <li>Targeted information, education and communication activities including social media/web-based communication.</li> <li>Peer-led one-on-one and group communication for prevention section.</li> </ul>	RSSH: Community systems strengthening (pages 13 to 16).	Risk communication (page 23) and COVID-19 CSS: Social mobilization (pages 13 to 14).	
<ul> <li>Qualitative, quantitative and operational community-led research on health system preparedness and resilience in the context of disease outbreaks, including system capacities to assess and mitigate for potential human rights, health equity and gender related implications.</li> <li>Community-led mapping and</li> </ul>	RSSH: Community systems strengthening (pages 13 to 16).	COVID-19 CSS: Community-led advocacy and research (page 13) / health and community systems (page 13).	
analysis of legal, policy, harmful gender norms and other barriers that hinder/limit community-led and -based responses in disease outbreaks.			

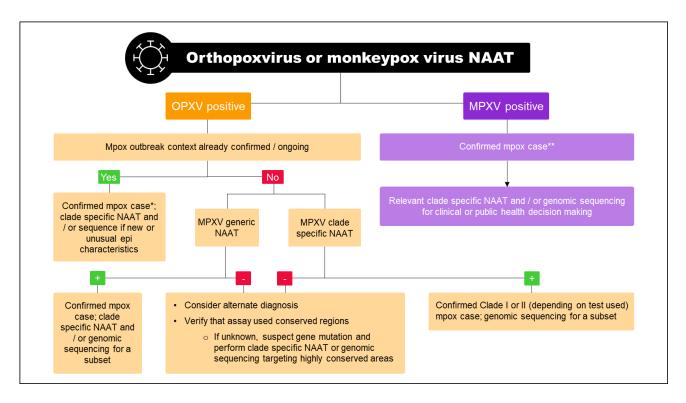
# Annex 2. MPXV molecular tests which are currently compliant with Global Fund Quality Assurance standards<sup>13</sup>

Supplier name	Test name	Shelf life (in months)	Storage conditions	Delivery lead-time (indicative)	Clade Targets	Remarks (equipment compatibility)
Abbott Laboratories	Alinity m MPXV AMP Kit (EUA)	12	-25°C to - 15°C	23 weeks	Detects clade I and II, but no differentiation in test result	Alinity m
Cepheid	Xpert Mpox	12	2°C to 28 °C	14 weeks	Detects non-variola Orthopoxvirus (OPXV) DNA and has a MPXV clade II specific call out	GeneXpert DX, Infinity DX system, GeneXpert Xpress system
Roche Molecular Systems`	cobas MPVX	12	2°C to 8°C	23-26 weeks	Detects clade I and II, but no differentiation in test result	cobas 6800 / 8800 systems
CERTEST BIOTEC SL	VIASURE Monkeypox Virus Real Time PCR Detection Kit	24	2°C to 40°C	11-15 weeks	Detects clade I and II, but no differentiation in test result	More information available here.
Guangzhou DaAn Gene Co., Ltd	Detection Kit for Monkeypox Virus DNA (PCR- Fluorescence Probing)	12	-20°C	12-14 weeks	No target information provided	ABI 7500 Roche LightCycler 480 DaAnGene AGS4800 or AGS8830-16
Wuxi Techstar Technology Co.,Ltd.	Monkeypox Nucleic Acid Detection Kit (Fluorescence PCR)	12	2-8°C away from light for 12 months 20-25°C away from light for 6 months	TBC	No target information provided	ABI 7500 ABI QuantStudio 5 Bio-Rad CFX96, LightCycler 480

<sup>&</sup>lt;sup>13</sup> The information listed in the table of Annex 2 was provided directly by the suppliers. The tests listed are considered consistent with current WHO guidance and meet the applicable quality standards from the <a href="Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics)">Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics)</a> and Core Personal Protective Equipment. In consequence, these products are considered eligible for procurement with The Global Fund resources and grant funds.

Supplier name	Test name	Shelf life (in months)	Storage conditions	Delivery lead-time (indicative)	Clade Targets	Remarks (equipment compatibility)
Jiangsu Bioperfectus Technologies Co., Ltd.	Monkeypox Virus (MPXV) Fast Real Time PCR Kit	12	-20°C	10-14 weeks	No target information provided	ABI 7500, ViiA 7, QuantStudio 5, QuantStudio 6/7, Bio-Rad CFX96, QIAGEN Rotor-Gene Q, Analytik Jena qTOWER3, Roche LightCycler 480, Bioperfectus STC-96A/96A PLUS and other applicable Bioperfectus machines.
	Monkeypox Virus and Orthopoxvirus Real Time PCR Kit	12	-20°C	10-14 weeks	No MPXV clade differentiation	Bioperfectus STC-96A, STC-96A PLUS, ABI 7500, QuantStudio 5, Roche LightCycler 480, Bio-Rad CFX96, QIAGEN Rotor-Gene Q, Analytik Jena qTOWER3 and other applicable Bioperfectus machines.
KH Medical Co., Ltd	RADI FAST Mpox Detection Kit	12	-25°C to - 15°C	10-14 weeks	Detects clade I and II	CFX96 Real-Time PCR Detection System, Bio-rad

# Annex 3. Laboratory testing algorithm for mpox testing: positive results (WHO)



<sup>\*</sup>This applies in resource-limited settings and provided that other orthopoxviruses do not co-circulate in humans; otherwise, a MPOX-specific or MPOX clade-specific test is required for confirmation.

Reference: Diagnostic testing for the monkeypox virus (MPXV) Interim guidance, WHO. 10 May 2024

<sup>\*\*</sup>If resources allow, sample should be further characterized in a reference laboratory.