Strategic Preparedness, Readiness and Response Plan

MONKEYPOX



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Strategic Preparedness, Readiness and Response Plan: Monkeypox

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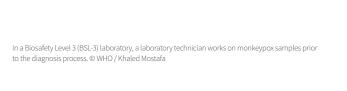
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Contents



Foreword from the Director-General	1
Part I. Overview and objectives	2
Introduction	2
Situation overview	4
Temporary recommendations of the Emergency Committee	6
Strategic objectives	7
Part II. A targeted response to stop the monkeypox outbreak	9
An integrated plan – the 5Cs	9
C1 Emergency coordination	10
C2 Collaborative surveillance	11
C3 Community protection	13
C4 Safe and scalable care	17
C5 Countermeasures and research	18
Next steps: Implementation and mutual support	20

Foreword from the Director-General





Since monkeypox was first identified in 1958, few people outside of Africa and the public health community had ever heard of the virus. That changed dramatically in 2022. Already this year, the number of monkeypox cases reported to WHO has surpassed the total number reported in all previous years combined. The current outbreak has spread around the world and requires a coordinated global response.

This Strategic Preparedness, Readiness and Response Plan (SPRP) outlines the priority actions needed to stop human-to-human transmission of monkeypox, minimize animal-human transmission of the virus in affected countries, and protect vulnerable groups at risk of severe disease.

With enhanced disease surveillance, laboratory testing, contact tracing, risk communication and risk reduction measures, this monkeypox outbreak can be stopped. And in regions that do not have animal-to-human transmission, this virus can be eliminated. Vaccination must be part of a comprehensive approach, but will not by itself bring the outbreak to an end,

and inequities in access to vaccines, treatments and tests must be urgently addressed.

To change the course of this monkeypox outbreak and advance the state of global health security, we must act on the lessons learned from the COVID-19 pandemic. In particular, we must urgently strengthen the systems and tools for epidemic and pandemic preparedness and response in countries, regions, and globally.

For these systems and tools to be effective, community engagement is essential. Groups that are disproportionately affected, particularly men who have sex with men, face stigma and discrimination in many countries. This undermines prevention and response efforts and will only prolong the outbreak by creating barriers to testing and treatment for those most at risk.

Ultimately, to stop monkeypox transmission and protect vulnerable groups, we need a strong commitment in affected countries to implement effective and evidence-based public health measures in a way that safeguards the dignity and human rights of all individuals and communities. We trust that countries will use this SPRP to do just that.

Dr Tedros Adhanom Ghebreyesus

Director-General World Health Organization

Introduction



This Strategic Preparedness, Readiness and Response Plan (SPRP) is intended to help guide coordinated public health action to stop the monkeypox outbreak.

On 23 July 2022, the World Health Organization (WHO) Director-General declared the escalating monkeypox outbreak a Public Health Emergency of International Concern (PHEIC), WHO's highest level of alarm under international law. As of 4 October 2022, 68 900 laboratory confirmed cases of monkeypox have been reported to WHO from 106 Member States in all six WHO regions, reflecting an unusually high number of cases and a wide geographical spread of the virus. Most cases are being reported from Europe and the Americas, with the majority occurring among men who have sex with men. However, the outbreak continues to spread in all WHO regions and in all demographic groups, underscoring the need for all countries to design and deliver information and services tailored to all at-risk communities at the same time as ensuring human rights and dignity.

Monkeypox can infect anyone and is of particular concern for vulnerable groups at higher risk of severe disease, including people with suppressed immune systems, people who are pregnant, and young children. In addition, uncontrolled transmission provides the virus with more opportunities to adapt, potentially resulting in strains that are more challenging to control or treat. In the medium term, there is a risk that monkeypox will become entrenched across multiple settings, particularly as it could exploit the ecological niche left by the eradication of smallpox.

Therefore, the primary focus for all countries must be to ensure that they are prepared to detect and stop the outbreak of monkeypox using effective public health measures, including enhanced disease surveillance, careful contact tracing, tailored risk communication and community engagement, and riskreduction measures, including where exposure to infected animals is possible. There is a window of opportunity to intensify collective efforts to achieve the goal of stopping the monkeypox outbreak.

Figure 1. Core components, objectives, and goal

WHO drafted this SPRP with the input of partners and public health experts. It is based on WHO's current global risk assessment and will be adjusted as the situation evolves. In addition, the SPRP will be complemented by forthcoming Operational Planning Guidelines and a Monitoring and Evaluation Framework.

CORE COMPONENTS

C1| Emergency coordination:

➤ Strengthen emergency operations and foster coordination between Member States and key stakeholders for responsive public health and adaptive key health services.



C2 Collaborative surveillance:

Monitor and share information to improve the collective understanding of how this outbreak is evolving, identify specific risks, and inform response measures.



C3 Community protection:

Raise awareness and empower communities to adopt protective measures.



C4 | Safe and scalable care:

Provide safe and quality clinical care for individuals and prevent infections in health and community settings.



C5 Countermeasures and research:

Improve access to effective medical products for monkeypox and drive the cross-cutting research agenda.

OBJECTIVES

Interrupt human-tohuman transmission of monkeypox, with a focus on groups at high risk of exposure.

Protect vulnerable groups at risk of severe monkeypox disease.

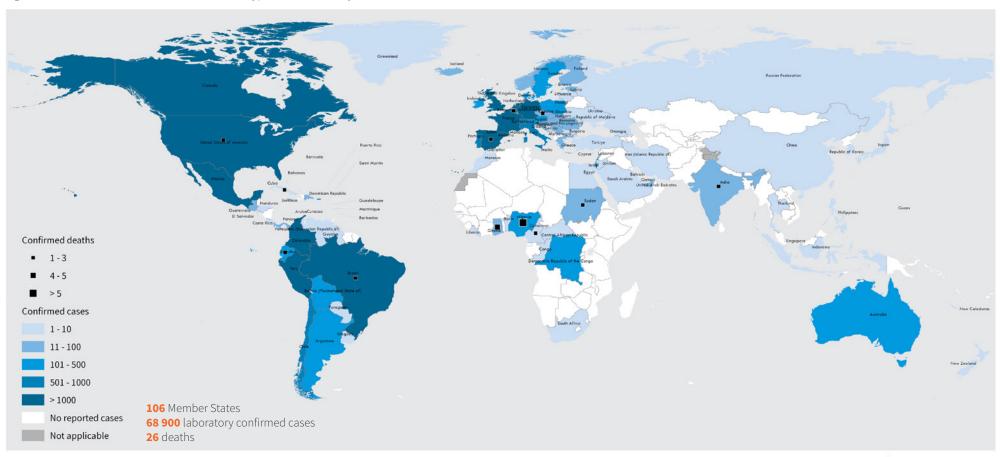
Minimize zoonotic transmission of monkeypox virus.

GOAL

Stop the monkeypox outbreak.



Figure 2. Distribution of cases and deaths of monkeypox, from 1 January until 4 October 2022



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Data Source: World Health Organization Map Production: WHO Health Emergencies Programme Map Date: 4 October 2022



Situation overview



Outbreak detection and epidemiology

On 7 May 2022, WHO was informed of a confirmed case of monkeypox in an individual who returned to the United Kingdom of Great Britain and Northern Ireland following travel to the Federal Republic of Nigeria. This was the tenth documented, laboratory-confirmed case of monkeypox in a person travelling from Nigeria since an outbreak of monkeypox began there in 2017. A few days later, an unrelated family cluster of cases with no link to travel and a cluster of cases in men who have sex with men were also confirmed in the United Kingdom. Meanwhile, Portugal alerted other Member States of the European Union about cases of an unidentified illness causing rash and rapidly confirmed this to be due to monkeypox. These events marked the start of a multi-country outbreak of monkeypox and suggested there had been undetected spread.

As of <u>4 October</u>, a total of 68 900 laboratory confirmed cases, including 26 deaths have been reported to WHO from 106 Member States across all six WHO regions. The 10 countries with the highest burden of confirmed cases are: United States of America (n= 25 672), Brazil (n= 7869), Spain (n= 7188), France (n= 3999), The United Kingdom of Great Britain and Northern Ireland (n= 3635), Germany (n= 3625), Peru (n= 2587), Colombia (n= 2042), Mexico (n= 1627), and Canada (n= 1400). Together, these countries account for 86.6% of the cases reported globally.

Monkeypox is caused by the monkeypox virus, which is closely related to the variola virus that caused smallpox. Current evidence suggests that monkeypox virus can be transmitted from animal-to-human (zoonotic), from human-to-human, and from contaminated environments to humans (fomite) (Table 1). In countries currently experiencing infections, transmission appears to be occurring primarily through close physical contact, including sexual contact. Due to the global eradication of smallpox and the cessation of national smallpox vaccination programmes in 1980, there is likely to be little immunity to monkeypox, particularly among people living in urban areas or countries that do not typically report cases of monkeypox.

There are two known clades of the monkeypox virus: Clade I (formally Congo Basin or Central African) and Clade II (formally West African). Closely related strains of Clade II have been identified in most cases occurring during this outbreak. The cause of the outbreak remains unclear and under investigation, but the sudden and unexpected appearance of large numbers of monkeypox cases and the rapid global spread (Figure 2) of the disease suggest that human-to-human transmission of monkeypox virus had gone undetected for some time. It is also possible that the high rate of infection and rapid geographical spread of the virus has been augmented by viral adaptation to aid human-to-human transmission. This and other potential contributing factors to the outbreak remain the subject of research by WHO and partners.

The signs and symptoms of monkeypox present similar to those of smallpox, but monkeypox is less contagious and clinically less severe than smallpox. However, monkeypox can lead to complications, such as secondary bacterial infections of the skin or eyes, compromised ability to swallow or breathe due to enlarged lymph nodes, blindness, scarring, and in rare cases encephalitis or sepsis. Notably, while many monkeypox cases in areas with only human-to-human transmission are occurring with the clinical presentation of fever, swollen lymph nodes and rash, approximately half are reported to have lesions, often in the anogenital area, which may appear before the onset of systemic symptoms such as fever. In the context of this global outbreak, new clinical symptoms are appearing, such as severe inflammation of the urethra (urethritis) or rectum (proctitis), severe pain, myocarditis and encephalitis.

Diagnostics, therapeutics and vaccines

The two WHO collaborating centres on smallpox and other orthopoxviruses have developed countermeasures against smallpox. The global scientific community is collaborating to evaluate and accelerate the use of these countermeasures for monkeypox prevention and clinical care in response to the ongoing outbreak. WHO recommends that every effort be made to use these countermeasures in the context of collaborative research protocols with standardized data collection.

The recommended diagnostic test for monkeypox is based on nucleic amplification testing (NAAT), using real-time or conventional polymerase chain reaction (PCR). WHO is supporting efforts to rapidly scale up testing capacity across all six WHO regions. The overall goal of laboratory testing in this context is to enable timely and accurate confirmation of infection to support the breaking of chains of transmission, to stop the outbreak. Interim laboratory testing guidance has been developed.

Optimal supportive <u>care</u> is recommended for the management of symptoms and the prevention of complications from monkeypox. Two antiviral therapeutics have currently been approved for treatment of smallpox, and of these, one (tecovirimat) has been approved by the European Medicines Agency (EMA) for the treatment of monkeypox. A global collaborative <u>clinical trial protocol</u> to assess the efficacy of tecovirimat for improving clinical outcomes during this outbreak of monkeypox has been developed. Other clinical studies are underway.

There are three <u>smallpox vaccines</u> recommended for consideration by national authorities during this monkeypox outbreak for targeted vaccination of persons at risk of infection. Of these, one vaccine (MVA-BN) has been approved in Canada, Europe and the United States of America, and one vaccine (LC16) has been approved in Japan.



Table 1. Known modes of mokeypox virus transmission

Animal-to-human

Initial "spillover" from animals-to-humans (zoonotic transmission) is thought to be the most common trigger for outbreaks, although the animal reservoir of monkeypox virus has not yet been identified. Different animal species, mainly rodents and non-human primates, are known to have been infected. Animal-to-human transmission may occur by direct inoculation via bites, scratches or by direct contact with the body fluids and/or the meat of an infected animal during hunting and other activities involving susceptible animal species.

Human-to-human

Human-to-human transmission may occur following close contact with an infected and symptomatic patient, including face-to-face, skin-to-skin, mouth-to-mouth and mouth-to-skin contact. Transmission typically involves direct contact with skin or mucocutaneous lesions, and may be amplified by direct mucocutaneous contact, which can occur during sexual activity. Inhalation of respiratory droplets (and possibly short-range aerosols) may also contribute to infection. People with monkeypox are infectious until their rash has completely healed (which normally takes between two and four weeks). The rash, bodily fluids (such as fluid or pus from lesions) and scabs are particularly infectious, as are lesions in the mouth or anus.

People who closely interact with someone who is infectious, including health workers, household members and sexual partners, are at greater risk of infection. Vertical transmission (mother-to-child) can occur during pregnancy via the placenta or from an infected parent-to-child through skin-to-skin contact, skin-to-mouth contact or inhalation of respiratory droplets.

While it is known that close physical contact, including contact during sexual activity, can lead to transmission, it is still unclear whether transmission through sexual fluids can occur. Research is underway to investigate this further.

Contaminated environments

Transmission of monkeypox virus via contact with contaminated surfaces, objects or materials (fomites) can occur. This mode of transmission may have played a role in the small number of cases linked to transmission within households and not linked to sexual contact. Research is ongoing into the role of fomite transmission in the current outbreak.



A sexual health worker's first-hand experience with monkeypox. He said, "I want people to watch out for themselves. Be considerate, kind, and isolate if you have symptoms. Be alert and watch out for symptoms such as rashes, fever and muscle ache. Also, be your own health advocate and know your rights."
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Temporary recommendations of the Emergency Committee



The International Health Regulations (2005) Emergency Committee regarding the multi-country outbreak of monkeypox was first convened on 23 June 2022. At that meeting, although differing views were expressed, the Committee resolved by consensus that the outbreak did not represent a PHEIC. In light of new developments in the outbreak, the WHO Director-General reconvened the Committee on 21 July 2022. On this occasion, although the Committee was unable to reach a consensus, having considered the views of Committee Members and Advisors as well as other factors in line with the International Health Regulations, the WHO Director-General declared on 23 July 2022 that the global monkeypox outbreak represents a PHEIC.

The WHO Director-General also issued <u>Temporary</u> <u>Recommendations</u> (Figure 3), which take into account the views expressed by the Committee. These Temporary Recommendations, summarized below, apply to different groups of countries based on their epidemiological situation, patterns of transmission and capacities. All Temporary Recommendations are expected to be implemented in full respect of established principles of human rights, inclusion and the dignity of all individuals and communities.

Figure 3. Emergency Committee Temporary Recommendations according to outbreak status*

Group 1. Countries that have not yet reported a case of monkeypox or have not reported a case for more than 21 days. Recommendations for these countries include strengthening all aspects of readiness; to plan for and implement interventions to avoid stigmatization and discrimination to establish and intensify epidemiological disease surveillance; to raise awareness and intensify detection capacity; to engage key communities, sexual health networks and civil society networks; to focus risk communication and community support efforts; and to immediately report to WHO probable and confirmed cases of monkeypox.

Group 2. Countries with recently imported cases of monkeypox, and which are experiencing human-to-human transmission. Recommendations for this roup of countries include implementing a coordinated response to stop transmission and protect vulnerable groups; to engage and protect affected communities; to intensify surveillance and public health measures; to strengthen clinical management and IPC in hospitals and clinics; to accelerate research into the use of vaccines, therapeutics and other tools; and recommendations on international travel.

Group 3. Countries with transmission of monkeypox between animals and humans. Recommendations for this group of countries include establishing or activating collaborative One Health coordination, and undertaking detailed case investigations and studies to characterize transmission patterns.

Group 4. Countries with manufacturing capacity for diagnostics, vaccines and therapeutics. Recommendations for countries in this group include raising production and the availability of medical countermeasures, and working with WHO to ensure necessary supplies are made available based on public health needs, on solidarity, and at reasonable cost to countries.

* All countries belong to more than one group



Emergency Committee Chair Dr Jean-Marie Okwo-Bele (right) speaks during the first meeting of the International Health Regulations (2005) Emergency Committee regarding the multi-country monkeypox outbreak, held at WHO Headquarters in Geneva, Switzerland on 23 June 2022.

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Strategic objectives



Only together can we **stop the monkeypox outbreak.**

To achieve this goal, we must meet three strategic objectives: (Figure 4.)

- Interrupt human-to-human transmission of monkeypox, with a focus on population groups at high risk of exposure.*
- 2 Protect vulnerable groups at risk of severe monkeypox disease.**
- 3 Minimize zoonotic transmission of monkeypox virus.

*Population groups at high risk of exposure: At the time of publication, in many settings the primary population group at high risk of exposure was men who have sex with men, particularly those who have multiple partners. In other settings, heterosexual exposure is also emerging as an important risk in this outbreak. Some communities may be at risk of zoonotic transmission. It remains critical to appreciate that other population groups may also be at risk of exposure as the outbreak evolves.

**Vulnerable groups at risk of severe monkeypox disease:
At the time of publication, this includes people with immune suppression (such as those on immunosuppressive therapy or living with poorly controlled HIV), people who are pregnant, and children.

Our way of working matters. The public health response to monkeypox in all countries should uphold the principles for equity, inclusion and human rights. Four imperatives, informed by the latest understanding and research of the outbreak, should underpin our collective approach:

- Information: Information and communication are at the heart of the global response to monkeypox. We should support and use innovative, tailored risk communications, co-created through community engagement and partnerships with those who are most at risk, particularly in addressing stigma in population groups most affected by the outbreak.
- Action: Emergency response to an outbreak requires rapid and effective action be taken by individuals, communities and health authorities to prevent spread, mitigate risk and stop transmission.
- Evidence: Effective response requires public heath action informed by evidence. We should generate scientific evidence through forward-looking clinical and public health research and use this evidence to support response strategies and efforts.
- Equity: All stakeholders should strive for equity in access to diagnostic and testing and enhancing laboratory capacity, personal protective equipment (PPE), vaccines and therapeutics based on public health needs.

To achieve these strategic objectives, the SPRP outlines an integrated approach within five core components (5Cs) of preparedness, readiness and response. This provides a framework for international and national strategies to be calibrated and optimized, and to strengthen operational readiness for emergence of new threats.

Figure 4. Strategic objectives





Figure 5. WHO's response to the monkeypox emergency

WHO's response

WHO and partners continue to provide support to countries, through five interdependent core components (5Cs) of preparedness, readiness, and response. Key activities and mechanisms of WHO support within each core component include, but are not limited to the following:

C1| Emergency coordination



- Providing emergency response support at global, regional and country levels through technical guidance, surge support and mobilization of resources
- Supporting national authorities with establishing or enhancing coordination mechanisms and public health capacities at national and sub-national levels employing a One Health approach

C2 Collaborative surveillance



- Supporting national authorities to ensure surveillance, epidemiological investigation and contact tracing which is inclusive of affected communities, animal contacts, and leverages approaches and lessons learned from the COVID-19 pandemic
- Supporting the genomic sequencing of the monkeypox virus found in the current outbreak and scale-up of testing across all six WHO regions; providing diagnostic capacity and trainings, and ensuring centralised procurement and shipment of diagnostic kits

C3| Community protection



- Working closely with affected communities to develop risk communication and community engagement (RCCE) strategies for preventive, risk-reduction, and other social measures. Ensuring evidence-based information for prevention efforts, enhanced case identification, contact tracing, testing and treatment
- Utilizing the WHO Information Network for Epidemics (EPI-WIN) for working
 with global communities of practice to inform stakeholders and the general
 population; providing real-time intelligence on challenges and best practices
 in monkeypox prevention, testing and treatment

C4| Safe and scalable care



- Supporting coordination and effective implementation of case/clinical
 management for monkeypox and regularly monitoring health service
 availability and capacity, particularly for primary care, sexual health services,
 and appropriate intensive care support where needed
- Supporting countries to implement appropriate IPC measures to mitigate and control transmission of the disease in health care and community settings and providing capacity-building for countries through the development and delivery of training to health workers

C5 Countermeasures and research



- Working with scientists, partners, and manufacturers of medical countermeasures (MCM) to assess global supply and demand and encourage scaling up of vaccine production and supporting equitable access
- Supporting countries with MCM rollout through guidance, training and capacity-building measures, procurement of vaccines and therapeutics; working with countries to support integration of vaccines and therapeutics research with ongoing public health response

An integrated plan – the 5Cs



The ability to effectively stop the monkeypox outbreak depends on public health actions that are implemented and facilitated in a coordinated way through a multidisciplinary global, national and subnational response. Outbreak response should be led by national authorities, involve communities, leverage local resources and capacities, and be supported by WHO and partners.

Conceptually, these activities can be grouped into five interdependent <u>core components</u> (5Cs) of preparedness, readiness and response (Figure 6). These components must be integrated horizontally at local, national and regional/global levels and vertically between each geographical level of organization. All five components are essential to an effective response and must be grounded in the principles of equity and inclusiveness.

Part II of this document sets out key public health actions based on existing capabilities and capacities of current systems, required within each of these five components at the global and national levels, and outlines the role of WHO and its partners in supporting countries to stop the monkeypox outbreak.

Figure 6. Core components of preparedness, readiness and response.



coordination. Strengthen emergency operations and foster coordination between Member States and key stakeholders for responsive public health action and

C2| Collaborative surveillance. Monitor and share information to improve the collective understanding of how this outbreak is evolving, identify specific risks, and inform response measures

adaptive key health services

C3| Community
protection. Raise
awareness and empower
communities to adopt
protective measures

C4| Safe and scalable care. Provide safe and quality clinical care for individuals and prevent infections in health and community settings

c5| Countermeasures
and research. Improve
access to effective medical
products for monkeypox
and drive the cross-cutting
research agenda

☼ C1 Emergency coordination



Strengthen emergency operations and foster coordination between Member States and stakeholders for responsive public health and adaptive health services

To achieve the objectives and stop the monkeypox outbreak in all affected countries, close collaboration and partnerships will be needed at the global, regional, national and subnational levels. This will include cooperation among national authorities, across sectors and with a wide variety of partners for the continuous gathering, evaluation and interpretation of data, risk assessment of the epidemiological situation, and prioritization of critical functions and interventions. Global support and cooperation will also be needed to identify research gaps, advance scientific understanding, and facilitate the use of public health interventions for monkeypox, including the deployment of diagnostic tests and laboratory supplies, vaccines, and therapeutics, based on needs.

It is vital to ensure that there is timely and transparent information sharing across national, regional and global levels, that operational priorities are aligned, and that duplication of effort is minimized. Additionally, it is critical to be agile, so that rapid tactical and strategic adjustments can be made in response to feedback from communities, the evolving epidemiological situation, and other public health intelligence.



Leadership, coordination, planning, financing and monitoring

Inclusive multisectoral, multi-partner mechanisms for coordination, planning, financing and monitoring at global, regional, national and subnational levels based on incident management principles should be rapidly established in all countries, leveraging existing coordination through emergency operations centres (EOCs) to ensure engagement of all relevant partners in HIV prevention and care networks and sexual health services. National authorities should lead coordination with support from the three levels of WHO and other partners. Due to the zoonotic nature of the virus, good coordination and communication between wildlife services, veterinary services and public health services should be ensured, using a One Health approach.

Key partners should be engaged early to inform planning. These include: nongovernmental, civil society and community-based organizations, particularly those representing the health interests of men who have sex with men, primary care and sexual health services and associations supporting affected communities; regional and national public health agencies and associations; global laboratory networks; WHO collaborating centres; research collaborations; and relevant UN agencies and partnerships, including UNAIDS, the Global Outbreak Alert and Response Network, Risk Communications and Community Engagement (RCCE) experts and others. Affected communities are key stakeholders for monkeypox emergency response and should be engaged to inform decision-making and implementation for all workstreams.

Emergency response strategies, plans and budgets should be developed, implemented, monitored and updated in accordance with the latest available information. Public health measures should be adapted based on the evolving situation and local context. All related processes, including the products and services generated, should be well-documented to facilitate After Action Review.

A technical briefing about the multi-country monkeypox outbreak held during the 75th World Health Assembly on 27 May 2022. © WHO / Pierre Albouy

Operations in all at-risk and affected countries should be informed by key performance indicators, including epidemiological and response indicators. The combination of these indicators integrated with social scientific and anthropological analyses of health care-seeking behaviour, health services utilization, community feedback and perceptions should drive the evolution of response operations and inform possible adaptation of interventions to improve community uptake.

Countries are encouraged to use monitoring, standardized data collection and key performance indicators to better support implementation and inform decision-making in real-time. Wherever possible, data should be stratified by sex, age, sexual orientation as appropriate for this outbreak, pregnancy status and other important factors that are critical to identify trends, gaps and disparities. Collection and analysis of disaggregated data is central to a Human Rights-Based Approach to Data, and necessary in order to adjust public health and social measures and adapt essential health services to respond appropriately.

In line with existing accountability frameworks, and demonstrating commitment to gender equality, health equity and human rights, WHO recommends that all countries undertake a substantive gender, equity and inclusion analysis to inform coordination and response planning. These dimensions should be incorporated into all operations from the outset of the response, including baseline assessment, design, planning and implementation of response measures, to ensure gender-responsive and equity-oriented interventions, monitoring, impact assessment and reporting.

Successful implementation of response measures also depends on meaningful participation, collaboration and consultation with groups experiencing social exclusion, vulnerability, discrimination and additional barriers to access services.

⊕ C2 Collaborative surveillance



Monitor and share information to improve the collective understanding of how this outbreak is evolving, identify specific risks, and inform response measures

Pertaining to objectives 1 (interrupt human-to-human transmission) and 3 (minimize zoonotic transmission), the rapid investigation, detection and isolation of new cases of monkeypox are key to preventing onward transmission. These measures require heightened awareness and engagement among communities and frontline health care workers, along with robust surveillance and reporting mechanisms supported by diagnostic capacities that provide rapid, safe and accurate testing of samples.

Surveillance, epidemiological investigation and contact tracing

Epidemiological surveillance, investigation and contact tracing are essential to effective outbreak response. Early identification, treatment and isolation helps improve clinical care and minimizes further transmission. The success of these public health interventions is highly dependent on building trust between health authorities or intermediaries and affected communities. Inclusion of affected communities in planning a public health response is therefore essential to support contact tracing efforts. If a zoonotic transmission is suspected, good coordination between wildlife services, veterinary services and public health services is needed.

To address the many unknowns regarding the epidemiology of monkeypox, Member States should formally report cases using the WHO case report form. Member States with the capacity to do so are also encouraged to undertake in-depth investigation using the WHO-provided case investigation form, including use of Go.Data or other compatible tools available. Countries are also encouraged to report cases of monkeypox in animals to the World Organisation for Animal Health (WOAH) as significant animal health information. To better contextualize the reported number of cases, Member States are also encouraged to provide information on the public health measures put in place.

Crucial to these efforts are strengthened collaborative approaches for risk forecasting and disease monitoring. This includes the need to cultivate a better understanding of the factors that may contribute to the spread of the monkeypox virus, such as the reported number of sexual partners, the different types of events and gatherings, and animal contacts.

Regular social listening is another source of intelligence that should be incorporated into a multisource surveillance system. Online and community listening, as well as reviews of social science data, can serve to help identify and detect suspected cases of monkeypox.

The capacity to rapidly detect, verify, investigate and assess signals is essential for all countries responding to or preparing for the monkeypox outbreak. The timely detection of new alerts or changes in the situation should rely on response teams that are trained, equipped and rapidly deployable.

It is also critically important to better understand zoonotic transmission, with a One Health approach to reduce the risk of additional spillover events.



With three African countries with no previous history of human monkeypox transmission reporting cases, WHO is working with national health authorities in the region to bolster surveillance and laboratory diagnosis to detect cases and deter a silent spread of the virus. © WHO



Laboratories and diagnostics

Every effort should be made to ensure optimal laboratory testing capacity for confirmation of all suspected cases of monkeypox, and integrate laboratory reporting within surveillance and epidemiological systems. Diagnostic testing also means cases can be linked to care and treatment where appropriate.

Confirmation of monkeypox virus infection is based on nucleic acid amplification testing (NAAT) using real-time or conventional polymerase chain reaction (PCR) for detection of unique sequences of viral DNA. Laboratory capacity for diagnostic testing and surveillance for monkeypox virus infection using PCR must be expanded to facilitate early detection of monkeypox cases. Sequencing of samples from infected humans and animals is also encouraged to understand virus evolution and the clade(s) involved, especially to determine if cases represent a continuation of human-to-human transmission or new introductions, and to monitor mutations in the genome. WHO strongly encourages the sharing of genetic sequence data through publicly accessible databases.

A number of primer and probe sequence sets for PCR assays for orthopoxviruses and monkeypox viruses have been published, and can be adapted in laboratories with appropriate capacities; PCR kits detecting orthopoxviruses and monkeypox viruses are also becoming commercially available. However, because there is limited data on their accuracy, WHO is working with technical partners to validate available assays. In places where there is limited or no testing capacity, arrangements to ship samples to recognized reference laboratories should be made. There is currently very limited data on the use and accuracy of other test types, including rapid antigen tests, and further studies are needed to understand the role they may play in the future. WHO has also developed interim testing guidance for monkeypox virus. WOAH has published guidance for animal health professionals.

All laboratories handling samples that are known or suspected to be from patients or animals with monkeypox should carry out a local risk assessment and put appropriate control measures in place, including the use of a class I or class II biosafety cabinet or higher, and use of appropriate PPE by laboratory personnel. More information can be found in the <a href="https://www.who.asses.com/who-ses.co

WHO has been supporting the scale-up of testing access across all six WHO regions. This has included <u>shipment of samples</u> to referral laboratories, procurement of commercial kits and primer/probe and positive control materials, and sharing of testing protocols. Regional and national trainings have been organized to ensure capacity-building for safe, appropriate and accurate sample collection, handling and testing.



Before the diagnosis of the samples, a laboratory technician in Portugal mixes monkeypox samples with stocks inside the biosafety cabinets to inactivate and then extract the monkeypox virus in the samples collected from individuals who are suspected to have monkeypox. © WHO / Khaled Mostafa

C3 Community protection

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Delivery of preventive measures and empowerment of communities

Risk communication and community engagement (RCCE) measures are central to empowering and protecting communities, and are therefore key to achieving all objectives. Risk communication is intended to supply a specific audience with the information they need to make informed, independent judgements about risks to their health and safety and how to reduce those risks. This involves diverse strategies based on socio-behavioural science and community-led approaches.

In response to the monkeypox outbreak, RCCE guidance has been developed, and messages have been tailored for groups at risk and directed through specific channels to reach them. It is important to build trust and communicate that as scientists learn more, advice on how to protect oneself may change because of new knowledge. In order to build trust, communities need to be involved in all components of the response as partners and co-develop solutions that are relevant, acceptable and actionable by community members.

RCCE and infodemic management

To address objective 1 (interrupting human-to-human transmission), targeted, clear and explicit health education should be available. All work should be conducted with and through existing community networks and HIV technical units, as these represent organized, trusted, open and accessible means to provide information and interventions. Strategies, materials and activities should be co-developed with community representatives to ensure interventions are relevant and actionable, to help avoid stigmatization, and to identify communication channels that will reach those who need information without putting them at additional risk.

Health workers must be provided with information on the atypical presentation of symptoms specific to this outbreak. This information should include guidance on accessible care and non-stigmatizing patient care pathways. Clinical care and contact tracing efforts should be co-designed with affected populations to ensure these interventions do not stigmatize individuals. Clear and actionable <a href="https://docs.py.nonec.google.googl

To support objective 2 (protecting vulnerable groups), persons who have been or may be in contact with someone who has monkeypox should be given clear and explicit health education. Tailored content should also be made available through health care and other trusted networks for people who are pregnant. Again, clear and actionable homecare guidance to reduce household transmission should be made available.

Additionally, to support objective 3 (minimize zoonotic transmission), information provided in enzoonotic areas should include how to reduce risks related to handling susceptible animals, including wildlife and handling or consumption of bushmeat. WOAH has published messages for at-risk communities to reduce risk of spillover events.



Health authorities communicate the risks of monekypox in advance of Berlin Pride. © WHO / Europe



In all circumstances, stigmatization of any population group must be avoided as it will reduce access to appropriate testing and treatment, thereby allowing further undetected transmission. Moreover, effective communication requires intentional and careful use of language, as well as community engagement and digital social listening analysis of community concerns. Rumours and misinformation also affect communities' ability to distinguish facts from mistruths and undermine their ability to protect themselves. It is critically important to rapidly identify and manage misinformation, and instead amplify facts in a manner that resonates with the community through credible and trusted sources. Engagement is needed with traditional media, social media influencers and trusted figures to disseminate the facts and help prevent the spread of misinformation. Responsible reporting through the media is also needed to increase awareness about the disease and available prevention measures and reduce stigma.

Engagement with communities offers insight into best practices, barriers and social norms that need to be addressed to encourage protective and health-care-seeking behaviours. Continuous, multi-directional communication with community leaders, influencers, health workers, media and local decision-makers should be established to build and maintain trust and confidence for readiness and response actions. Key tools include accountability mechanisms and feedback channels to ensure that community concerns are rapidly addressed and successes are documented, replicated and built upon.

WHO has released multilingual general public health advice for people organizing smaller gatherings or attending gatherings of any size and type, as well as information specifically designed for gay, bisexual and other men who have sex with men. Social gatherings that might involve sexual contact provide opportunities for information outreach and for RCCE activities; these should also address individual activities associated with side gatherings and unplanned congregations in public or private spaces.

WHO will continue to share simple scientific updates in an accessible way to enable decision-makers and the public to understand the facts about monkeypox. A <u>series of webinars</u> have helped share and interpret the latest information with the public. EPI-WIN Communities of Practice have been engaged and briefed. Significant outreach at global and regional levels with representatives from communities of gay, bisexual and other men who have sex with men, as well as sex worker communities, have taken place to help inform strategy and guidance. Additionally, risk perception surveys among key affected populations are planned.

The current monkeypox outbreak is being closely monitored by WHO, and additional guidance may be developed to address emerging community risks. The RCCE response involves a global network of WHO focal points and key representatives from national and supra-national centres for disease control to ensure consistent and informed communication and engagement interventions. WHO regional offices are tailoring approaches for affected populations within their regions.

STIGMA AND DISCRIMINATION ARE NEVER OK.

DISEASES CAN AFFECT ANYONE.

#SolidarityNotStigma

World Health Organization

Social media posts on Twitter. Credit: WHO





Points of entry, international travel and transport, mass gatherings and population movements

In countries with recently imported cases of monkeypox, or those that are otherwise experiencing human-to-human transmission, national authorities should establish risk-based policies and guidance related to border measures and international travel. These may include information at points of entry on signs and symptoms and advice for travellers, as well as information on how and where to seek health care services for monkeypox.

Strategies should be in line with the Temporary Recommendations issued by the WHO Director-General, and may be updated as appropriate to national and local circumstances.

Cross-border workers who are under health monitoring can continue their routine daily activities provided that health monitoring is duly coordinated by the jurisdictional health authorities from both/all sides of the border. In addition, communication between health and transportation authorities and points of entry should be established to facilitate international contact tracing, where needed. Unregulated trade in wildlife (including wildlife meat and products) and other mammals can potentially lead to the international spreadof diseases such as monkeypox.

WHO recommends that decisions related to the planning and organization of <u>large and small gatherings</u> be based on a risk-based approach consisting of three steps: risk evaluation, risk mitigation and risk communication. Planned events should be viewed as opportunities to share essential information on monkeypox and how people can protect themselves.

Health authorities and event organizers should facilitate the adoption of appropriate public health and social measures, including those aimed at informing attendees; reducing the frequency or intensity of physical contact; cleaning of venues, particularly where sex-on-premises may occur; and good ventilation of shared spaces to reduce the risk of transmission

of monkeypox during the event, as well as strategies to facilitate contact tracing afterwards. Important information will be gained from monitoring the impact of gatherings during the monkeypox outbreak and assessing epidemiological trends, event-based surveillance, and the public health and social measures implemented.



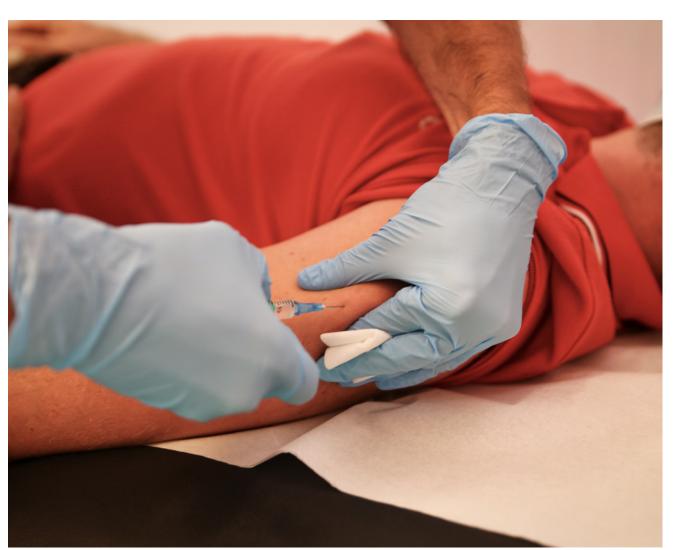
Festivals and gatherings across Europe bring together many hundreds of thousands of people from different countries. WHO Europe and the European Centre for Disease Prevention and Control created an resource toolkit for event organizers. © WHO / Europe



Vaccination

WHO has strongly encouraged Member States to convene their national immunization technical advisory groups (NITAGs) to review the evidence and develop policy recommendations for the use of vaccines for prevention of monkeypox as relevant to the national context. Prior experience with the use of smallpox vaccines and clinical immunogenicity and safety studies suggest that smallpox/monkeypox vaccines will have some protective effect against monkeypox. However, the potential level and duration of protection in the context of this outbreak are not known, and clinical correlates of protection have not been established. Therefore, WHO strongly encourages all countries to undertake vaccine effectiveness studies and participate in collaborative studies once they are established. At this time, two vaccines have received regulatory approval for prevention of monkeypox as well as smallpox.

Regarding vaccination for monkeypox, targeted immunization strategies for groups at high risk of infection are recommended. This includes specific strategies to reach gay, bisexual and other men who have sex with men and persons who have multiple sex partners, including sex workers. Post-exposure vaccination is recommended for contacts of cases, ideally within four days of first exposure (and up to 14 days in the absence of symptoms). Where contact tracing is challenged by a high number of reported contacts, other strategies to reach groups at risk of infection with pre-exposure immunization should be considered. Pre-exposure vaccination should also be considered for health workers at high risk of exposure, laboratory personnel working with orthopoxviruses, clinical laboratory personnel performing diagnostic testing for monkeypox and outbreak response team members designated by national public health authorities. All decisions around immunization with smallpox or monkeypox vaccines should be made through shared decision-making based on a joint assessment of risks and benefits, between a qualified health care provider and prospective vaccinee, on a case-by-case basis.



Monkeypox vaccine administered by a nurse. © WHO / Khaled Mostafa

R C4 Safe and scalable care



Provide safe and quality clinical care for individuals and prevent infections in health care settings

To achieve objectives 1 (interrupt human-to-human transmission) and 2 (protect vulnerable groups), policies and resources should be put in place to raise awareness and train health workers to provide optimal clinical care and implement infection prevention and control (IPC) measures for monkeypox. Caring for patients with suspected or confirmed monkeypox requires:

- early recognition through screening protocols adapted to local settings, isolation, triage and testing to diagnose cases and start monkeypox clinical care pathways;
- rapid implementation of appropriate IPC measures;
- symptom management for patients with mild or uncomplicated monkeypox for pain control, keeping lesions clean and maintaining adequate hydration and nutrition; these patients can be cared for in home settings;
- monitoring, identification and treatment of acute complications and provision of optimized supportive care as appropriate; and
- ensuring care through recovery to detect and manage any mid- or long-term sequalae.

Case management and clinical operations

High-quality care is a cornerstone of the monkeypox response that should be provided for every patient according to the severity of the disease. The clinical focus is symptom-based care, including lesion care, pain management, nutritional and hydration status maintenance and prevention of complications and sequelae, as appropriate. Some patients require hospitalization for pain management, treatment of secondary bacterial infections or abscesses, or intensive care support for severe disease, which may include encephalitis, sepsis, pneumonia or multi-organ failure. Particular attention must be given to ensure treatment of underlying conditions for those who are immunocompromised due to other illnesses, therapies or poorly controlled HIV.

In terms of specific antiviral treatments for monkeypox, since January 2022, tecovirimat has been approved by the European Medicines Agency (EMA) of the European Union (EU) and is authorized for the treatment of orthopoxvirus-associated infections (smallpox, monkeypox, cowpox, vaccinia virus) under exceptional circumstances. At present, countries are introducing the use of tecovirimat primarily for potential treatment of persons with severe illness or high levels of pain due to symptoms. Treatments should therefore be assessed through timely collaborative clinical trials and, when not possible, expanded or emergency use protocols under the MEURI framework and public health research.

Local response priorities should be guided by regular monitoring of health service availability, access barriers, health outcome disparities, health facility readiness and the use of primary health services at all levels of care. Plans to ensure adequate and appropriate health and social services to persons at risk, including support for isolation where needed, should be reviewed and adapted regularly. Special considerations should be made for population groups that are at high risk of exposure or those who are vulnerable to severe disease. This includes considerations at primary health level, and specific facilities for dermatology or sexually transmitted infections.

Health systems will face context-specific demands and challenges. A geographically widespread monkeypox outbreak may challenge the capacity of sexual health and immunization services and lead to an increase in indirect effects, such as difficulty securing appointments for routine preventive or urgent care. Stigma related to an infectious disease, such as monkeypox, can also influence health-seeking behaviour and inadvertently lead to lower levels of care. If access to services is compromised by capacity or by stigma and discrimination, infection due to other causes may spread, such as sexually transmitted infections. These effects can persist for some time after an outbreak is contained, including demand for public health support to achieve elimination of monkeypox.

Infection prevention and control (IPC)

Implementation of appropriate IPC measures in health care with engineering, administrative and PPE controls is essential to mitigate and control transmission of monkeypox. These measures include but are not limited to adequate space (for screening, isolation, donning/doffing), ventilation, triage of cases, hand hygiene, use of PPE, environmental cleaning and disinfection as well as safe management of health care waste. Health workers should apply standard precautions and perform a risk assessment to evaluate the need to use additional precautions. Both contact and droplet transmission-based precautions should be implemented for any suspected or confirmed case of monkeypox, including the use of respirators by health workers. Any staff with occupational exposure to monkeypox should have an appropriate assessment and management plan.

In addition, to prevent spill-back from infected patients to animals and potential reservoir formation in non-endemic areas, people who are suspected or confirmed to be infected with monkeypox virus should avoid close direct contact with animals, including domestic animals (such as cats, dogs, hamsters, ferrets, gerbils, etc.), livestock and other captive animals, as well as wildlife. People should be particularly vigilant around animals known to be susceptible to monkeypox, such as rodents and non-human primates.



Dr Cândida Fernandes is a sexually transmitted disease (STD) consultant and head of STD clinic, in the Department of Dermatology, Hospital de Santo António dos Capuchos in Lisbon, Portugal. © WHO / Khaled Mostafa

© C5 Countermeasures and research



Improve access to effective medical products for monkeypox and drive the cross-cutting research agenda

WHO calls on Member States and manufacturers to work together to achieve the global public health goal of ensuring that medical countermeasures for monkeypox are available to those who need them.

At present, a few diagnostic tests, vaccines and treatments have been approved by national regulatory authorities or are currently under development and approval to detect, prevent or treat monkeypox. However, there is limited data on the use of these products in the context of an outbreak of monkeypox, and it is important that the use of countermeasures is supported by enhanced data collection for pharmacovigilance surveillance, clinical effectiveness and safety and efficacy studies. Effective and equitable research means strengthening the global research and development infrastructure. Foremost is the need to resource regional research and develop infrastructure in low-income and middle-income countries. There is a vital need for sustainable and well-distributed global research capacity to ensure that all Member States are empowered to contribute to the global research effort

All stakeholders should strive for equity in access to diagnostics, vaccines, and therapeutics based on public health needs. During an emergency response, these medical products are allocated to countries at different times, and by different manufacturers or partners. Allocation of the limited supplies of medical products for monkeypox should be carefully coordinated amongst stakeholders to ensure that safe and effective products are supplied in a timely manner, where they can be used efficiently and expeditiously, and to the places where they are most needed. Additionally, appropriate tools and procedures to manage allocation and deployment operations should be in place.

Samples were collected from individuals who are suspected to have the monkeypox virus for laboratory testing. A laboratory technician marks the samples of the monkeypox virus with internal codes prior to carrying out the laboratory diagnosis at the Biosafety Level 3 (BSL-3) laboratory.

Research and innovation

WHO has launched a global consultation on research and development for monkeypox to inform the response. The R&D Blueprint for Epidemics will continue to be the global mechanism to expedite research before and during epidemics to understand knowledge gaps and priority research questions for monkeypox, with the aim of fast-tracking the availability of effective tests, vaccines, medicines and social science that can be used to save lives.

Diagnostics

More research is crucial to improve existing diagnostics and to innovate new technologies. Point-of-care or near-patient tests, such as rapid antigen tests, could expand access to diagnostics and be a valuable tool for the early detection of monkeypox cases, as well as monitoring disease trends in populations. However, more evidence is urgently needed to understand their accuracy and use. Furthermore, data is needed to assess the accuracy of commercial PCR kits. Research on viral kinetics across different specimen types would also inform updates to future testing strategies and services.

Therapeutics

WHO is working with countries, manufacturers, research partners and other stakeholders to develop a framework for standardized research and data collection, that supports the use of antiviral and other potential therapeutics for further evaluation of their potential clinical efficacy and safety. Regarding existing or new therapeutics, WHO is recommending that Member States make all efforts to use these countermeasures against monkeypox within a framework of collaborative efficacy studies, using standardized design methods and data collection tools for clinical and outcome data that can rapidly increase evidence generation on efficacy and safety and collect data on effectiveness.

To enable reliable evaluations of interventions, randomized trials using standard protocols and study templates are the preferred approach, wherever possible. Unless there are compelling reasons not to do so, every effort should be made to implement randomized trial designs. It is feasible to conduct placebo-controlled studies, especially in individuals at low risk of severe disease and particularly for assessment of therapeutics. Harmonized data collection for safety and clinical outcomes using the WHO Global Clinical Platform for Monkeypox would represent a desirable minimum dataset in the context of an outbreak, including the current event.





Vaccines

Member States using vaccines against monkeypox are encouraged to do so within a framework of collaborative clinical studies using standardized design methods and data collection tools for clinical and outcome data to rapidly increase evidence generation, especially on vaccine efficacy and safety.

WHO will continue to engage with vaccine manufacturers to encourage scaling of vaccine production and with vaccine-procuring countries to equitably share vaccine supply for use in lower resource settings. WHO invites all partners to continue to explore and develop coordination mechanisms to support provision of vaccines according to public health need for the global outbreak of monkeypox. WHO strongly encourages all countries to undertake a range of vaccine effectiveness studies and participate in collaborative studies as they are established.

Other Research

Further research is needed to better understand the modes of transmission, including the role of droplets and aerosols (short-range and long-range). While studies are emerging showing significant environmental contamination in health care settings, the role of fomites in transmission in health care and community settings is unclear. We need to better understand viral kinetics, so we can improve diagnostic testing by knowing when and what to sample.

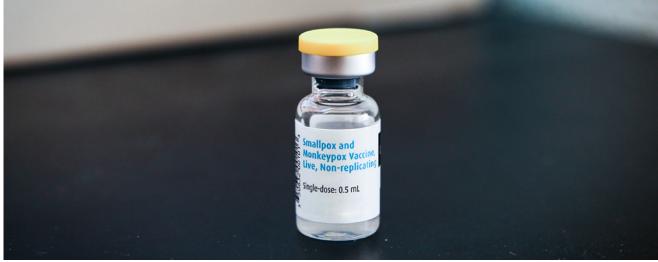
Human behaviour affects health outcomes, and this is also very true of how people respond during a health emergency, or how they seek health information and services. To support the monkeypox outbreak response, behavioural insights research will also serve to underpin innovative design of locally appropriate health information and interventions. Research is needed to better understand exposure risks and measures for health worker protection, including pre-exposure and post-exposure management.

Environmental surveillance in wastewater can potentially provide additional evidence on the virus in circulation at a population level, including the presence or absence and early warnings of increasing or decreasing trends. Additional research is needed in this regard. Finally ongoing research on zoonotic transmission of monkeypox will also be essential to mitigate risk at source and help prevent recurrent ongoing spillover events from becoming community or global outbreaks.

Finally, ongoing research on zoonotic transmission of monkeypox will be essential to develop risk reduction strategies at the human-animal-environment interface and prevent recurring spillover events with the potential with the potential to cause community or global outbreak. This would include the investigation of animal sources and routes of transmission, understanding viral circulation in animal populations, identifying Socio-economic and behavioural risk factors for spillover and spill back, as well as developing animal diagnostic capacity for monkeypox.

Operational support and logistics

The management of operations, support, logistics and deployment of essential supplies will be key for emergency response at every level. At the country level, logistical arrangements to support incident management and operations should be reviewed at regular intervals. Expedited procedures may be required in key areas, such as surge staff deployments, procurement of essential supplies, staff payments, and training.



A vial of the moneypox vaccine with one dose. © WHO



Next steps: Implementation and mutual support

WHO continues to work globally, regionally, and at country-level to provide the evidence, tools and support needed to protect and promote health. Drawing on the hard-won lessons from previous outbreaks such as COVID-19, there is no better time to advance towards a new era for emergency preparedness and response through community engagement and public health action. Confronting this global outbreak demands that we act swiftly and with vigilance to **stop the monkeypox outbreak**.

All WHO Member States, regional public health agencies, local authorities and relevant professional and civil society organizations and community groups are advised to develop a plan appropriate for their specific context, which will address and align to the overarching goal, three strategic objectives, and five core components of this SPRP. All WHO Member States and other entities are invited to state explicitly within their plan how they will collaborate directly with other entities to support the achievement of one or more of their objectives.

WHO is closely monitoring the latest available data, supporting international coordination, and enabling information sharing among Member States as well as other engaged partners. Ensuring that decision-making in all settings is informed by verified public health information and analysis continues to be a top priority for WHO. Collective commitment to timely and transparent information sharing across all levels is needed to ensure that operational priorities are aligned for appropriate, rapid response to the evolving epidemiological situation and, ultimately, for global health security.



LGBTQI+ march in Lisbon, Portugal. © Ricardo Fuertes



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