

# Controlling the 2022 Monkeypox Virus Outbreak in the United States: Action Needed

*This brief was developed by a working group convened by the National Coalition of STD Directors to collaborate on a comprehensive and effective response to the 2022 monkeypox virus (MPV) outbreak. Questions? Contact Rachel Deitch at [rdeitch@ncsddc.org](mailto:rdeitch@ncsddc.org) or Andrea Weddle at [aweddle@hivma.org](mailto:aweddle@hivma.org).*

The 2022 MPV outbreak is [the largest](#) that has occurred in the United States and globally. [MPV cases](#) have been identified in all 50 states, the District of Columbia and Puerto Rico. During the current phase of the outbreak, a [majority of cases](#) have occurred among gay and bisexual men and men who have sex with men, but anyone – regardless of their sexual orientation and gender identity – can be affected by MPV. Black/African American and Hispanic/Latino individuals have represented nearly 70% of cases.

The virus is spread between humans by direct contact with infected lesions or fluids or contact with contaminated materials like clothing or bedding. Although vaccines, tests and treatment are available to control the spread of MPV, a limited supply of vaccines and administrative and procedural barriers to accessing testing and treatment have impeded the national response. A timely, robust public health response implemented in partnership with affected communities and frontline health care providers and researchers is critical to controlling the outbreak.

## **WHAT'S NEEDED**

MPV is a rare disease that, prior to the current outbreak, was largely limited to the African continent. Most health care providers and public health officials in the United States do not have experience with MPV, and clinics/health systems do not have protocols in place to facilitate infection prevention, evaluation and care delivery. MPV diagnosis/testing, vaccination and treatment are labor and time intensive, due in part to the regulatory safeguards in place given the limited study of MPV in humans. The ability to deliver MPV services is further complicated by a public health and infectious diseases workforce already depleted by the COVID-19 pandemic and by the need to ensure affordable access to MPV testing for individuals who are uninsured or underinsured. **Emergency supplemental funding and other policy actions are urgently needed.**

**COMMUNITY ENGAGEMENT AND EDUCATION:** An effective response requires meaningful engagement with the populations most heavily impacted by the MPV outbreak in addition to clear and concise MPV information for disproportionately affected communities, the general public, health care providers and public health professionals. In addition to the recommendations below, we urge support for changing the name to reduce stigma.

Recommendations:

- Increase resources to build capacity for outreach, prevention and treatment within clinics and community-based organizations serving heavily impacted populations.
- Provide funding to support a multifaceted public education campaign to reduce the stigma associated with MPV and provide science-based information that dispels myths about prevention, diagnosis and treatment.

**DIAGNOSIS/TESTING:** Testing is available through public health laboratories and five commercial laboratories. Other commercial laboratories and hospitals have also developed laboratory tests. The testing protocols differ for public health and commercial laboratories, with each having different requirements for specimen collection and for how specimens are transported to the lab for testing.

The addition of five commercial laboratories for MPV testing helped to address access to testing but did not alleviate the time required to conduct MPV specimen collection and test ordering. Providers report that, due to administrative hurdles and filling out test requisitions, it can take up to **one to two hours per patient to submit a specimen for an MPV test**. In addition, for some facilities, including public health clinics, the costs and billing requirements associated with using commercial labs are barriers to their use. **Most sexual health clinics report that they are unable to use commercial labs because of billing and funding issues and because their patients are unable to afford the cost sharing.**

#### Recommendations:

- Provide emergency supplemental funding for uncompensated workforce needs, including a mechanism for health care providers to be reimbursed for additional work associated with the outbreak response.
- Provide funding to ensure testing is available without cost sharing, regardless of insurance status.
- Fund research to examine the use of other specimen types such as blood, urine or oral swabs. Further, incentivize and fund the development of easier to use point-of-care diagnostics.
- Prioritize communities that have been disproportionately impacted by the outbreak with increased access to testing and testing capacity.
- Facilitate and support health care institutions' creation and use of laboratory-developed tests as permitted under FDA policy for MPV tests.
- Fund health care provider training and education.
- Create a centralized list of tests offered by various laboratories as well as acceptable specimen types and submission information links.

**VACCINATION:** Vaccination is recommended for people at risk for MPV. The preferred vaccine for MPV, JYNNEOS, is currently in very short supply in the United States. FDA recommends that two doses of the vaccine be administered 28 days apart for maximum protection. FDA granted an emergency use authorization to allow for intradermal administration (an injection into the upper layer of the skin) of JYNNEOS, with a lower dose injection, to stretch the limited supply. The demographic data available on the individuals who have received the MPV vaccine is limited, but [available data suggests](#) that Black and Hispanic people are receiving smaller shares of the vaccine although they account for a larger percentage of cases. With the limited supply, resources to ensure equitable access to the vaccine for communities and populations most affected by MPV are urgently needed.

#### Recommendations:

- Provide emergency funding to support provider training and vaccination scale up, including sufficient vaccination supplies, with a focus on clinics and community-based organizations serving populations at higher risk for MPV, and funding to support administration costs.
- Provide resources and guidance to ensure equitable distribution of the available supply.
- Incentivize complete data reporting on MPV cases and vaccinations.
- Continue to seek innovative strategies to rapidly scale up the available supply of the JYNNEOS vaccine.

**TREATMENT:** No treatments are approved for MPV, but given the similarity to smallpox, tecovirimat (TPOXX), a treatment approved for smallpox based upon animal data, may be used to treat MPV. A randomized, controlled trial is planned to evaluate the use of tecovirimat for the treatment of MPV, which is expected to provide important data to inform optimal use of tecovirimat. Until clinical trial data is available, tecovirimat is only available through an expanded access investigational new drug (IND) protocol held by CDC. Steps have been taken to reduce the administrative burden to access tecovirimat, including reducing the forms and the reporting required, but it still requires between 30 minutes and **two hours per patient to procure treatment, depending on available resources and staff capacity**. Community-based clinics continue to report not having the capacity to obtain treatment.

#### Recommendations:

- Increase reimbursement to adequately cover health care providers' effort and time.
- Provide funding to health care systems to serve as test and treat centers and to support partnerships with community-based clinics and practices within communities.
- Support research and community engagement in clinical trials to study tecovirimat and other potential new treatments.

**PUBLIC HEALTH & WORKFORCE CAPACITY:** The public health officials, clinicians and researchers leading the MPV response have been on the frontlines of the COVID-19 response for more than two and half years. Many health care systems and community health centers and clinics have not recovered from staffing losses during the COVID-19 pandemic. They do not have capacity to levy the response necessary to manage and control MPV in their community **without relying on volunteer or overtime service from an already strained workforce.**

Recommendations:

- Adequately fund and sustain funding for HHS, including for sexual health clinics.
- Pass the PREVENT Pandemics Act, which includes loan repayment for infectious diseases and bio preparedness health care professionals.
- Pass Outbreak Activation legislation to authorize the Secretary for Health and Human Services to increase reimbursement for services related to communicable disease prevention and treatment during a public health emergency.