

July 22, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

We, the undersigned organizations representing clinicians, medical microbiologists, public health officials and epidemiologists, scientists, patients, and advocates, write to highlight challenges impeding our nation's response to the current monkeypox virus (MPV) outbreak and to offer policy recommendations to improve patient outcomes and stop the spread of the virus. We appreciate the Administration's response efforts thus far and call on the Administration to move swiftly to strengthen the response and hope that our perspectives will inform your strategies.

Regulatory hurdles combined with insufficient health care and public health resources, personnel and infrastructure already strained by the ongoing COVID-19 pandemic present substantial barriers to patient access to MPV vaccination, diagnostics and treatment. Without timely and effective health care and public health approaches to combat this virus, we will lose more ground, the outbreak will be unnecessarily prolonged (with both human and economic costs) and we risk establishing animal reservoirs in the U.S. This is a global outbreak, and U.S. leadership and coordination with other countries is important to prevent further transmission. We must immediately apply lessons learned from the COVID-19 and HIV pandemics to ensure a more equitable, rapid and well-coordinated MPV response.

Like the early days of HIV and other infectious diseases outbreaks, the MPV outbreak is currently disproportionately impacting a population that has long experienced stigma and discrimination — gay and bisexual men and other men who have sex with men.¹ In addition, data as of July 13, 2022 from the World Health Organization (WHO) and the European Centre for Disease Prevention and Control (ECDC) found that, among those with MPV for whom HIV status was known, 42.7% had coinfection with HIV.² In addition, like COVID-19, early MPV data from some states indicate racial disparities (57% of people with MPV in Georgia were Black as of July 12, 2022.)³ The Administration's commitment to health equity must be a guiding force in this response.

As such, individuals who are uninsured and/or underinsured are particularly vulnerable and face significant barriers to health care. Funding is needed to ensure access to vaccines, testing and treatment for uninsured and/or underinsured individuals. Safety net clinics also need additional resources to evaluate and treat patients with suspected or confirmed MPV.

Nearly two and half years into the COVID-19 pandemic, state and local health departments are severely strained and understaffed, which complicates their response to the MPV outbreak. Case investigations

¹ Because of inadequate data collection, the impact on transgender and gender diverse persons is yet unknown.

² Joint ECDC – WHO Regional Office for Europe Monkeypox Surveillance Bulletin. July 13, 2022. Available online at <https://monkeypoxreport.ecdc.europa.eu>.

³ Georgia Board of Public Health Meeting. July 12, 2022. Available online at <https://dph.georgia.gov/about-dph/board-public-health/board-public-health-meetings/2022-board-public-health-meetings>

and contact tracing for monkeypox and connecting contacts with post exposure prophylaxis are very time intensive activities that are critical to reduce the spread of infection. Greater flexibility is needed to allow staff and resources to be more easily reassigned. In addition to supplemental MPV funding, sustained funding for public health infrastructure is needed to bolster the workforce, efficiently collect and share data, rapidly analyze and summarize information to develop effective control measures and establish vaccination campaigns, address stigma and promote health equity and ensure that a baseline of public health support is available in all communities.

Additionally, many acute healthcare facilities are tasked with assessing possible MPV cases in their emergency departments as health department resources are stretched thin. The healthcare personnel dedicated to preventing the spread of COVID, multidrug-resistant organisms, and other healthcare-associated infections in healthcare facilities must now address the challenge of preventing transmission of MPV to patients, visitors, and staff. Infection prevention and control personnel face the same staffing crisis that is afflicting the rest of healthcare, resulting in a smaller, overtaxed workforce serving a role that is critical for patient and employee safety.

Below we have provided specific recommendations to support the MPV outbreak response. We recognize that some of the recommendations below will require resources to support implementation. We urge the Administration to work with Congress to secure the necessary funding to support the MPV response and end this outbreak and recommend that Congress include a minimum of \$100 million in the FY'23 Labor, Health and Human Services and Education appropriations bill.

Challenges and Policy Recommendations

Vaccination: We welcome the Administration's recently announced plans to expand US supply of JYNNEOS vaccine and we appreciate federal, state and local efforts to get shots in arms. However, we remain concerned that the current supply is inadequate and that the vaccine rollout is disadvantaging individuals who do not have the resources, including internet access and transportation, to secure vaccination appointments. Based on lessons learned from COVID-19, the federal government should provide state and local public health jurisdictions, clinical and community partners, including sexual health clinics, and the public with the information and guidance to ensure that the limited supply of JYNNEOS vaccines is equitably distributed and reaches those at greatest risk of serious illness.

Recommendations

- The Centers for Disease Control and Prevention (CDC) should issue clearer messaging on prioritization of vaccination, and options for vaccinating laboratory personnel, and work with state and local health departments, clinicians, safety-net clinics, and community-based organizations (CBOs) to educate the public about vaccination. This should include creation of MPV Vaccine Information Sheets (VIS) at accessible reading levels and in multiple languages.
- The Food and Drug Administration (FDA) and CDC should prioritize facilitating the importing of JYNNEOS vaccine from Bavarian Nordic in Denmark to the U.S. to address the unmet demand.
- CDC should partner with safety-net clinics (community health centers, Ryan White Program clinics and other sexual health clinics), local health departments and CBOs to support equitable vaccine administration strategies, including utilization of mobile vaccine clinics.
- CDC and the Office of the Assistant Secretary for Preparedness and Response (ASPR) should instruct states to ensure that adequate supply from state allocations is reaching local communities, particularly large, urban population centers, that are hardest hit or at risk.

- As supply increases, ASPR should increase the number of vaccine-dispersing sites in each state (or local jurisdiction where applicable) that receive vaccines, enabling vaccine to get to more people in need more quickly.
- CDC should recommend that vaccination programs track and report demographic data, including location, race and ethnicity, sexual orientation, and gender identify and provide funding to facilitate this data collection.
- Information about the supply of available vaccines should be available in a transparent manner accessible to clinicians and the public.
- Current CDC recommendations for vaccination should be expanded to recommend vaccine use by laboratory personnel handling infectious samples for diagnostic testing (already permitted under CDC Advisory Committee for Immunization Practices recommendations.)

Testing: We appreciate the steps taken by the Administration to boost testing capacity, including expanding testing to large commercial laboratories, scaling testing capacity at public health laboratories, CDC publication of its protocol from its FDA-cleared test, and FDA authorization of additional reagents and automation to increase the capacity of laboratories using the CDC test. These steps should help expand access to testing, but some challenges and gaps will persist as noted below. Swift testing is especially crucial since administration of vaccine as post-exposure prophylaxis is only successful to prevent illness when administered within 4 days from the date of exposure.

Efforts must be made to continue to increase testing capacity and accessibility so that patients and providers are not discouraged from seeking testing. Some clinicians have reported taking the better part of a day to obtain approval for testing, which cannot be sustained. These challenges underscore the need to expand testing options.

Cost of testing should not be a barrier for patients: during this growing public health threat – fair pricing should be strongly encouraged and costs and fees should not be a barrier for uninsured and underinsured patients. Further, public programs such as Medicare and Medicaid, along with private insurers, should provide robust coverage of MPV testing.

Turnaround Time and Additional Test Options: The original CDC nonvariola orthopox test kit is a non-automated, manual kit, which considerably hampers delivering quick turnaround times for test results. We appreciate the Administration’s collaboration with clinical laboratories to validate additional automated platforms to expand capacity. Not all hospital laboratories have the necessary platforms to automate the CDC test, and manual testing procedures present risk to laboratory workers. The Administration should build upon existing efforts to continue expanding testing options so that all health care facilities, regardless of geographic location, can access a testing option that meets their unique needs and the needs of the patients they serve.

Test Orders: Many processes to submit orders for laboratory tests do not capture necessary basic demographic or contact information necessary for public health professionals to locate patients. Further, collecting and reporting the critical, expanded data is time consuming for ordering providers. Thus, when laboratory test results are received by public health departments delays occur in reaching individuals. Lack of demographic data also limits our ability to identify and address health inequities.

Biosafety guidance: Current laboratory biosafety recommendations lack sufficient clarity. It is not realistic in most laboratories to implement BSL-3 recommendations, and the guidance incorrectly assumes equivalency among laboratories.

Recommendations

- HHS should provide funding and a streamlined regulatory process for manufacturers and clinical laboratories to develop tests, including rapid diagnostic point of care tests and high throughput testing, to diversify testing options. Mechanisms to support testing of saliva, rectal swabs, blood and urine samples would greatly expand simple testing options.
- HHS should better leverage hospital laboratories with significant experience in outbreak detection and response to further augment testing capacity. This should include providing reagents, control materials, patient samples and other necessary supplies to hospital laboratories to support the development of laboratory developed tests and high throughput testing options.
- HHS should provide funding to cover the cost of testing for uninsured individuals.
- CDC should support efforts by clinical laboratories to enhance genomic surveillance by providing funding for sequencing and data submission. Recent investments to support genomic sequencing for COVID-19 could be a strong foundation for this effort.
- CMS should develop a mechanism through which providers can be reimbursed for provision of complete demographic and contact information at the time of test order.
- CMS should ensure robust coverage of testing through Medicare and Medicaid and work with private insurers to ensure coverage for all patients.
- CDC should provide more robust case reporting and surveillance, including race and ethnicity, sexual orientation, and gender identify data, to help guide the response, identify gaps, and ensure equitable access to testing.
- CDC should provide greater clarity for laboratories regarding practical and effective biosafety requirements and more details on how to handle waste.
- FDA should provide more uniform and defined guidance for specimen labeling.

Safe Isolation and Quarantine: As with COVID, patients with MPV need to isolate until declared non-infectious, which usually takes weeks. Until such time, crowded homes with shared bathrooms, potential contamination of linens and surfaces, and the practical difficulty of maintaining separation and cleaning all pose a transmission risk to household contacts. Currently, no funding from the Federal Emergency Management Administration (FEMA) or other sources is available to provide subsidized motel housing for isolation for MPV akin to COVID. The federal government should provide public health departments with funding to arrange for safe isolation housing for MPV patients.

Treatment: There is anecdotal evidence that tecovirimat (TPOXX) has reduces the length and severity of symptoms in patients with MPV. However, tecovirimat is currently only approved for smallpox treatment in the U.S. and is only available through the Strategic National Stockpile (SNS). Therefore, health care providers in the U.S. can only prescribe tecovirimat through the Centers for Disease Control and Prevention's (CDC) expanded access investigational new drug (IND) protocol which has been extremely labor intensive and time-consuming and unlikely to generate any meaningful data about the safety or effectiveness of tecovirimat. This protocol was not designed for clinical use in a rapidly expanding outbreak at the scale necessary to meet current needs. This approach is resulting in significant delays in treatment and preventing many patients from receiving tecovirimat due to the limited number of health systems and clinicians able to navigate the significant regulatory burden in addition to managing the increase in COVID-19 cases. This results in too many patients experiencing

MPV symptoms, including the prolonged severely painful skin rash, without relief, and continued spread of infection. In some cases, patients experience permanent damage including scarring and disfigurement.

While clinical trial data supporting the use of tecovirimat for MPV are lacking, cumulative experience of providers in Europe and the U.S. strongly suggest the drug is well tolerated and has benefits in reducing the duration and severity of MPV symptoms, including pain. The UK has approved, and the EU has authorized tecovirimat for treatment of MPV. A recently published UK study found that a patient treated with tecovirimat experienced no adverse effects and had a shorter duration of viral shedding and illness compared with the other six patients, suggesting that in addition to speeding symptom resolution, tecovirimat may also reduce the length of time for which an individual is contagious.⁴

Brincidofovir is an antiviral medication that was approved by the Food and Drug Administration (FDA) last year for the treatment of human smallpox disease in adult and pediatric patients, including neonates. This drug is currently not available commercially or through the SNS. We appreciate that CDC is developing an EA-IND to help facilitate use of Brincidofovir as a treatment for monkeypox, and urge streamlined, rapid access. Given the speed with which the outbreak is moving in the U.S., all additional avenues for treatment should be explored.

At this point in the current outbreak, patients are being harmed by the inability to access medications that could be beneficial, and we offer the following recommendations to expand access to treatment during the outbreak.

Recommendations

- CDC and FDA, with input from frontline clinicians and state and local health departments, should promptly develop a new compassionate use protocol to support streamlined, rapid access to tecovirimat for individuals with MPV as soon as possible, without waiting for clinical trial data. Slower, outdated communications, including faxes and physical mail, should not be required to prescribe tecovirimat.
- The National Institutes of Health (NIH), in collaboration with appropriate federal agencies, clinicians and scientists, should fund a registry and/or an observational study to gather data on the impact of tecovirimat prescribed via the new compassionate use protocol. Study design must not overburden clinicians or limit access to tecovirimat.
- NIH, in collaboration with appropriate federal agencies, clinicians and scientists, should fund randomized clinical trials (RCT) for individuals with MPV to assess progression to severe disease and A RCT can collect data to further inform use of tecovirimat. Research protocols should be pragmatic and include a rescue plan for patients who progress to severe disease to access treatment while also utilizing approaches from successful COVID-19 studies to provide clinically meaningful information. RCT should not interfere with access to tecovirimat through a new compassionate use protocol, as recommended above.

⁴ Adler, H., Gould, S., Hine, P., Snell, L. B., Wong, W., Houlihan, C. F., Osborne, J. C., Rampling, T., Beadsworth, M. B., Duncan, C. J., Dunning, J., Fletcher, T. E., Hunter, E. R., Jacobs, M., Khoo, S. H., Newsholme, W., Porter, D., Porter, R. J., Ratcliffe, L., Schmid, M. L., ... NHS England High Consequence Infectious Diseases (Airborne) Network (2022). Clinical features and management of human monkeypox: a retrospective observational study in the UK. *The Lancet. Infectious diseases*, S1473-3099(22)00228-6. Advance online publication. [https://doi.org/10.1016/S1473-3099\(22\)00228-6](https://doi.org/10.1016/S1473-3099(22)00228-6)

- The Centers for Medicare and Medicaid Services (CMS) should develop a mechanism through which providers can be reimbursed for the more intensive procedures required in evaluating and treating a patient with MPV (including navigating regulatory pathways for testing and treatment as well as managing infection prevention). In addition, CMS should consider developing an “outbreak activation” modifier that can be used for future outbreaks—a new payment modifier that clinicians could append to current codes to provide increased resources/reimbursement for the additional time and work associated with patient care during an outbreak. A reimbursement or funding mechanism is critical to improving equitable access to treatment at community clinics and health centers and at safety-net academic sites.
- CDC and HRSA should immediately provide funding to sexual health clinics, local health departments, community health centers, Ryan White Clinics, and other providers who treat STIs and HIV to support access to rapid diagnosis and treatment for at risk populations.
- The CDC should develop an equitable priority algorithm for treatment therapeutics for MPV in case there are supply shortages.

Community Engagement: Ensuring people can make informed decisions requires providing key prevention information to the public and working with partners and trusted messengers to ensure information reaches impacted communities. Appropriate community engagement can help ensure equitable access to needed public health interventions for MPV, including testing, treatment, and vaccination. When communities receive accurate, timely information, they are empowered to take appropriate action, leading to long lasting, positive health outcomes.

Recommendations

- CDC and HHS should expand outreach to impacted communities through media campaigns, trusted messengers, and local community groups.
- CDC should work directly with community leaders, CBOs, and health departments to provide and disseminate educational materials and graphics. Outreach and postings should include social media, dating apps, and targeted media. These campaigns must be non-alarmist, non-stigmatizing, and fact-based.
- Engagement and communication materials should be sex-positive and focused on sexual health overall.
- CDC and HHS must ensure community engagement is continuous and evolves to adapt to community needs.
- CDC should develop a way to receive input and information directly from community partners.

Once again, we thank you for your leadership at this crucial time and we are committed to collaborating with you to inform and advance an MPV response guided by equity, science and compassion. Please contact Amanda Jezek, Senior Vice President of Public Policy and Government Relations for the Infectious Diseases Society of America, with any questions at ajezek@idsociety.org.

Sincerely,

AIDS Action Baltimore
 AIDS Alabama
 AIDS Foundation Chicago (AFC)
 AIDS United

American Academy of HIV Medicine
American College of Emergency Physicians
American Public Health Association
American Society for Microbiology
APLA Health
Association of Public Health Laboratories
AVAC
Big Cities Health Coalition
Black AIDS Institute
Community Education Group
Council of State and Territorial Epidemiologists
Equality California
Family Centers Inc.
Fast-Track Cities Institute
Fenway Health
GLMA: Health Professionals Advancing LGBTQ Equality
HealthHIV
HIV Dental Alliance
HIV Medicine Association
Howard Brown Health
Human Rights Campaign
Infectious Diseases Society of America
International Association of Providers of AIDS Care
Latino Commission on AIDS
NASTAD
National Coalition for LGBTQ Health
National Coalition of STD Directors
PCAF (formerly Pierce County AIDS Foundation)
Prevention Access Campaign
Project Weber/RENEW
Rhode Island Public Health Institute and Open Door Health
San Francisco Community Health Center
Silver State Equality
Society for Healthcare Epidemiology of America
The AIDS Institute
The Well Project
Treatment Action Group

cc:

Rochelle Walensky, MD, MPH; CDC Director
Robert M. Califf, MD; FDA Commissioner
Anthony Fauci, MD; NIAID Director
Dawn O'Connell, Assistant Secretary for Preparedness and Response