



August 1, 2022

Alondra Nelson, Ph.D.  
Deputy Assistant to the President  
White House Office of Science and Technology Policy  
1650 Pennsylvania Avenue NW  
Washington, D.C. 20504

Dear Dr. Nelson:

The Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA) appreciate the opportunity to provide input on the U.S. monkeypox research priorities released by the White House Office of Science and Technology Policy (OSTP) on July 21, 2022. We agree with the research priorities identified by OSTP, and we hope our comments below will help you further develop and advance research ideas.

IDSA and HIVMA represent more than 12,000 infectious diseases physicians, scientists, and other healthcare and public health professionals who specialize in infectious diseases and HIV medicine. Our members are on the front lines of responding to the monkeypox (MPV) outbreak and work across a variety of healthcare settings, including hospitals, academic medical centers, long-term care facilities, public health departments, publicly funded clinics, and private practice. We appreciate the Administration's response efforts thus far to address the growing monkeypox virus outbreak and call on the Administration to move swiftly to strengthen the response and hope that our perspectives will inform your research strategies.

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.<sup>1</sup> In addition, data as of July 26, 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, 37% had coinfection with HIV.<sup>2</sup> 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.)<sup>3</sup> The Administration's commitment to health equity must be a guiding force in this response at every level: prevention/vaccination, testing/diagnostics and treatment.

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

<sup>2</sup> Joint ECDC – WHO Regional Office for Europe Monkeypox Surveillance Bulletin. July 26, 2022. Available online at <https://monkeypoxreport.ecdc.europa.eu>.

<sup>3</sup> 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>

The recommendations below provide details about necessary research to inform the monkeypox outbreak response, reduce the impact on at risk populations and stop the spread of the virus.

### **Health equity**

We appreciate the inclusion of research to improve equity and reduce stigma in the research areas identified by OSTP. We recommend that consideration of health inequities be woven into every research priority, as individual outcomes are likely to vary widely depending on race/ethnicity, socioeconomic status, geographic location and access to health care services in addition to HIV status and the presence of other coinfections.<sup>4</sup> We also agree with the importance of equitably balancing the response with endemic and non-endemic countries. Given the global nature of infectious diseases, global coordination is critical to a successful response.

### **Epidemiological, immunological, and clinical characteristics**

Research is needed to understand the natural history of the virus – how it progresses, how transmission aligns with the course of disease and specific transmission dynamics regarding lesions as compared to bodily secretions. As far as we know, individuals who are not symptomatic cannot spread MPV, but additional research to verify whether this holds true in the current outbreak is needed. In addition, given the high rates of co-infection with HIV and other sexually transmitted infections seen during the 2022 outbreak in the U.S., study is needed to understand the frequency and impact of coinfections with HIV and other sexually transmitted infections on transmissibility and clinical presentation and course.

We also suggest adding an additional research priority evaluating how best to keep clinicians up-to-date and help them to incorporate new disease knowledge and guidance into clinical practice more quickly as the outbreak is evolving rapidly.

### **Effectiveness, safety, and equitable distribution of vaccines and therapeutics**

Research is needed to determine whether drugs like tecovirimat or Brincidofovir that have been approved for treatment of smallpox are efficacious in the treatment of MPV and when in the course of the virus they should be given to patients. IDSA and HIVMA clinicians treating patients with monkeypox are doing so blindly as there is no available data that shows when treatment is efficacious, when treatment should be given, if treatment shortens the clinical course and infectiousness or if treatment should be considered primarily for pre-exposure or post-exposure prophylaxis in those with high-risk encounters including known exposure to another positive case. Both randomized clinical trials (RCT) and observational studies should be used to answer these questions.

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<sup>4</sup> *Washington Post*. July 27, 2022. "Struggle to protect gay, bisexual men from monkeypox exposes inequities," Available online at <https://www.washingtonpost.com/health/2022/07/27/monkeypox-gay-men-vaccine-treatment/>.

- 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 and should include input from the impacted communities.
- We are very encouraged that NIAID is working with the AIDS Clinical Trials Group to develop and quickly launch an RCT, and we are providing more specific feedback on the study design. 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. It will be important to ensure diverse enrollment in RCT.

Additionally, research should be supported to develop additional drugs for the treatment and prevention of monkeypox.

Vaccine studies should be conducted using both Jynneos and ACAM2000, mainly because of varying accessibility of Jynneos, particularly in low/moderate income countries. Dose sparing strategies should be studied to explore ways to stretch limited vaccine supply. Studies should include consideration of pediatric vaccination as well as adults. In addition, targeted studies are needed to understand the safety of vaccine and therapeutics in transplant and oncology patients and patients with HIV, as these individuals have specific characteristics and risks that must be considered.

We strongly urge the collection of demographic data for individuals who are vaccinated, tested and treated in order to evaluate access through an equity lens. Studies should identify the best strategies to foster equitable access to vaccination, testing and treatment.

### **Diagnostic tools and surveillance**

We agree with the priorities identified and the urgent need to expand testing capacity and surveillance. We appreciate that the National Institute of Standards and Technology has recently provided linearized plasmid DNA to assist in the development and validation of qPCR assays for MPV detection. We urge the further sharing of control materials, reagents and other supplies with hospital-based laboratories to facilitate the development of on-site testing options. We also encourage prioritization of developing rapid, point-of-care diagnostics and mechanisms to support testing of saliva, rectal swabs, blood and urine samples. Tests capable of detecting monkeypox in pre-symptomatic patients would also be valuable. Like we now have for COVID-19, home-based testing should be developed so that individuals can test themselves if they have a lesion rather than seeking testing every time at healthcare settings.

### **Environmental infection prevention and control**

We recommend study of effectiveness of personal protective equipment (PPE) in health care professionals and the most appropriate and effective environmental control efforts, e.g., type of disinfectant wipes and recommended time for closure of a room, if any, after a patient with monkeypox. Greater specificity is important for clinics and providers to be able to evaluate and plan for the resources required to protect patients and their staff. There also is a need to balance the need for PPE and environmental infection prevention with resource conservation, including the level of environmental waste globally.

### **Public health communication strategies**

Research on public health communication strategies should study different communication methods and modalities. Research should also consider strategies that are best suited to different population groups, especially with respect to groups that have historically experienced discrimination and stigma and who have been heavily impacted by the current outbreak, including sexual and gender minorities, people of color and people with HIV.

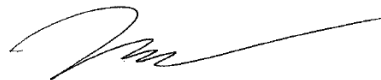
Communications directed to pregnant people, parents of young children and clinicians that care for these populations will be important to prepare for potential transmission in these populations that are at higher risk for serious disease.

Thank you for your leadership at this crucial time. IDSA and HIVMA and our members are committed to collaborating with you to inform a monkeypox response guided by equity, science and compassion. Please direct questions to Eli Briggs, Director of Public Policy for the Infectious Diseases Society of America ([ebiggs@idsociety.org](mailto:ebiggs@idsociety.org)) or Andrea Weddle, Executive Director of the HIV Medicine Association ([aweddle@hivma.org](mailto:aweddle@hivma.org)).

Sincerely,



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President, IDSA



Marwan Haddad, MD, MPH  
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