BIG IDEAS

ENDING THE HIV EPIDEMIC — SUPPORTING ALL PEOPLE LIVING WITH HIV AND REDUCING NEW TRANSMISSIONS

MONKEYPOX AND MENINGOCOCCAL DISEASE OUTBREAKS SIGNAL NEW HEALTH THREATS FOR COMMUNITIES HEAVILY IMPACTED BY HIV AND DEMAND IMMEDIATE ACTION

IN APRIL 2022, A NEW VARIANT OF MONKEYPOX virus infection was identified in the United Kingdom that has exploded into a global outbreak. The first case was diagnosed in the United States in May, and as of July 15th, 1,814 cases have been reported, with 12,556 cases worldwide. In June 2022, the Centers for Disease Control and Prevention (CDC) also announced that they were working with Florida public health authorities on a large and growing outbreak of meningococcal disease. Both outbreaks are currently concentrated among gay and bisexual men and other men who have sex with men (MSM). Beyond adversely affecting the health and well-being of MSM, these crises are sentinels of a growing threat of infectious diseases, and if they are not effectively contained, they could spread to broader populations, similar to HIV. In recent years, there has been an increasing drumbeat to scale back infectious disease funding, with the World Health Organization (WHO) and other global health institutions calling for shifting more resources to fight noncommunicable diseases (NCDs).

The last two years demonstrate that infectious diseases remain a public health threat. The COVID-19 pandemic, which has eclipsed the 1918 Flu in severity, was the third leading cause of death worldwide in 2021 and the third leading cause of death in the U.S. in both 2020 and 2021, and there have been documented increases in influenza, adenovirus, and tuberculosis. The U.S. remains unprepared for future plagues. While the Biden-Harris Administration has moved with remarkable speed to respond to the monkeypox outbreak and has issued alerts to the risk of meningococcal disease, in both cases, not enough is being done. Concerted action is needed right away to attempt to contain these outbreaks as

EXPONENTIAL GROWTH: PROJECTED U.S. MONKEYPOX DIAGNOSES AS EARLIEST GROUP OF GAY MEN BECOMES FULLY VACCINATED

By July 15th, diagnoses increased to 1,814 cases

0 2,000 4,000 6,000 8,000 10,000 12,000
6/1/22 Flat trend in monkeypox diagnoses 6/23/22 Start of U.S. community vaccinations in NYC 7/8/22 Cumulative diagnoses by analysis date 8/4/22 6 weeks after launch of NYC vaccinations campaign (projected)

SOURCE: amfAR analysis using data downloaded from Our World in Data, July 10th, 2022 based on current guidelines indicating that it takes six weeks from first dose of vaccine to achieve full protection. Analysis: Log-linear regression: log(cumm_cases) = B_0 + B_1*t; t is days since June 1 (t>=0). Resulting output used to estimate projected cases by August 4, 2022. Projected number of diagnoses will be affected by: 1. Proportion of population vaccinated by August 4th; 2. Whether diagnoses begin to reflect the actual number of cases; 3. Behaviors that facilitate transmission.
Policy action is needed to:

**1. BOLSTER THE OUTBREAK RESPONSE**

The predominant circulating monkeypox variant is spreading rapidly within certain populations. At present, nearly all cases are in men, principally MSM. Of all confirmed U.S. diagnoses, New York has the most, followed by California, Illinois, Florida, and the District of Columbia. These diagnoses potentially underestimate the true number of cases. If other infectious diseases are any guide (e.g., HIV, COVID-19), infections could take hold first in coastal states and then move to the interior U.S. We must act quickly.

An early problem with the initial outbreak response has been inadequate surveillance and difficulties for suspected exposures to be tested. Initially, testing was confined to public health laboratories. There has been an increase from 69 to 78 labs to increase capacity across the nation in the Laboratory Response Network that had a reported capacity initially to test 6,000 to 8,000 specimens per week.7,8 The process for ordering tests is cumbersome. Some critics have suggested also that there was a bottleneck9 and that steps should be taken to ramp up testing capacity.10 On July 6th, Labcorp, the nation’s largest commercial laboratory, announced that it was beginning to test for orthopox viruses with the capacity to test 10,000 specimens per week, doubling the prior national testing capacity.11 And on July 11th, the Mayo Clinic announced its capacity to test 10,000 specimens per week, tripling the prior testing capacity.12 Other commercial laboratories are also expected to come online in the near future, which marks an exceptionally rapid response.

As testing capacity grows, however, a greater focus will need to be placed on educating providers and the public about testing options and ensuring reimbursement is available, including for persons without health insurance.

Immediate supplies of the preferred monkeypox vaccine (JYNNEOS) are limited (see text box on page 5), and distribution and deployment of the available vaccine supply is not meeting the urgency of the moment. In recent weeks, HHS has released nearly 200,000 doses of the JYNNEOS vaccine from the Strategic National Stockpile (SNS),13 but demand is high. We recognize that making resource allocation decisions in times of scarcity is a thankless task, and federal policymakers may be seeking to triage vaccine distribution to avoid future stockouts before more supplies become available. At the same time, there may be an opportunity cost for not immediately
surging more vaccines to geographic areas reporting the largest outbreaks. The population of the District of Columbia, for example, is 0.2% of U.S. population. As of July 11th, it contained 7.9% of diagnosed monkeypox cases, yet in the original (July 1st) vaccine distribution, it received only 1,706 (4.1%) doses. Other urban centers like New York City have also been disproportionately impacted. More aggressive and focused vaccination and outreach in these communities may be beneficial to the overall response.

**POLICY ACTION: Increase Testing and Surveillance for Monkeypox**

As we applaud the rapid scale-up of testing capacity, continued focus is needed to further expand the actual tests performed and to conduct more surveillance. New and innovative testing methods have been proposed, such as the saliva-based tests, with a purported potential to test as many as 20,000 specimens per day. Every effort should be made to encourage appropriate testing and to remove barriers to testing. CDC also should be working with health departments and clinical providers to conduct sentinel studies and other surveillance activities to create a more informed picture of unfolding trends.

**POLICY ACTION: Expand Vaccine Access to Achieve Herd Immunity as Early as Possible**

There are a number of actions that the CDC should consider to extend the impact of current monkeypox vaccine supplies. This includes a greater focus on containment of the outbreak within MSM communities and related communities, including people who engage in sex work and networks of people who use drugs. Although not definitive, early evidence suggests that a heightened focus on vaccinating and treating people living with HIV is warranted. According to the July 13th monkeypox surveillance report of the World Health Organization and European Centre for Disease Prevention and Control, 43% of those diagnosed with monkeypox in Europe are people living with HIV. The District of Columbia Department of Health reported, however, that only 11% of its cases were among people living with HIV. There are no conclusive data showing that monkeypox severity is greater for people living with HIV, but there is a possibility that we may see worse outcomes among people with HIV if transmission shifts from more affluent MSM with the means to travel extensively to communities of MSM who have fewer resources and are less likely to be HIV virally suppressed.

By seeking to saturate such early hotspots with vaccines, it may be possible to curb or slow the spread of monkeypox to other areas and to other

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**U.S. GOVERNMENT EFFORTS TO ADDRESS MONKEYPOX**

**MAY 18TH**
First case detected in U.S. in Massachusetts

**MAY 19TH**
U.S. places $119 million order with Bavarian Nordic for vaccine with an option to buy $180 million’s worth more vaccines

**MAY 27TH**
CDC recommends monkeypox vaccine to people with high risk occupational exposures

**JUNE 7TH**
CDC posts harm reduction sexual health guidance to reduce Monkeypox exposure

**JUNE 10TH**
CDC documents community spread of monkeypox among people who have not traveled overseas

**JUNE 10TH**
CDC estimates existing total testing capacity at 8,000 specimens per week

**JUNE 13TH**
CDC targets monkeypox epidemic social marketing materials for Pride festival organizers and attendees

**JUNE 14TH**
CDC updates monkeypox case definition

**JUNE 22ND**
HHS supports expansion of monkeypox testing capacity to five commercial laboratory companies: Aegis Science, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics and Sonic Healthcare

**JUNE 23RD**
The first monkeypox vaccination clinic in the U.S. opens in NYC

**JUNE 23RD**
CDC distributes a Dear Colleague Letter for clinicians from CDC Director Dr. Walensky providing critical monkeypox information.

**JUNE 28TH**
HHS releases 56,000 doses of monkeypox vaccine

**JUNE 28TH**
CDC recommends vaccine access for gay and bisexual men at high risk of monkeypox exposure.

**JULY 1ST**
White House releases monkeypox outbreak strategy

**JULY 6TH**
Labcorp begins monkeypox testing nationally adding capability of additional 10,000 specimens to be tested weekly

**JULY 7TH**
HHS releases another 144,000 doses of monkeypox vaccine

**JULY 11TH**
Mayo Clinic Laboratories begin monkeypox testing increasing cumulative nationwide testing capacity to 30,000 tests weekly

**JULY 13TH**
HHS procures additional 800,000 vaccine doses

**JULY 14TH**
Aegis Sciences announced that it will begin testing for MPX, increasing cumulative nationwide testing capacity to 40,000 tests weekly

**JULY 15TH**
U.S. weekly testing capacity rises to 70,000 tests per week
non-MSM communities. A recently reported additional 800,000 doses of vaccines will be available as early as the end of July. Although this could greatly reduce the current vaccine crunch, there remain arguments to get as much current supply of vaccine into arms now via a one-dose regimen of the JYNNEOS vaccine for the current crisis period. Clinical experts have suggested prioritizing the first dose of JYNNEOS to the largest population feasible and delaying the second dose because the monkeypox vaccine can help prevent disease or reduce symptoms even if taken after exposure. Moreover, a recent New England Journal of Medicine analysis suggests that a single shot of the JYNNEOS vaccine produces a robust enough immune response that can be sustained for as long as two years before taking the second dose. Recently, Mayor Eric Adams of New York City endorsed the one-dose solution to increase vaccine coverage. This is akin to the United Kingdom delaying second mRNA COVID-19 doses for months in order to vaccinate a greater proportion of the population in a shorter period of time, an approach that was ultimately validated by studies showing the presence of greater neutralizing antibodies among those whose dosages were delayed rather than the standard shorter interval. There is understandably an innate conservatism of not wanting to depart from the proven efficacy of a two-shot regimen.

The current moment, however, represents a crisis because the two-dose regimen takes six weeks for full vaccination. We estimate there will be 11,000 diagnosed cases in the U.S. alone (see figure on page 1) on August 4th, which will mark six weeks after the first mass vaccination campaigns began in the U.S., amidst a projected 100,000 cases globally.

Additionally, CDC should elevate its focus on meningococcal disease (see text box on page 5) and integrate communications to MSM about both conditions and the need for individual and community action. At a time of vaccine fatigue resulting from COVID-19, it is understandable that many may seek to minimize additional vaccination recommendations, but the current meningococcal disease outbreak among MSM is growing. While we are not equipped to make vaccination guideline recommendations, given that the MenACWY vaccine is safe and widely available, CDC should consider expanding its recommendation to cover all MSM in the country, not only those living in or traveling to Florida. Further, a recent study of people living with HIV found that vaccination rates are poor. Only 16% of patients in this study of claims data received their first MenACWY vaccine in the first two years following their HIV diagnosis, and only 66% of those received their second dose within a year of the first dose. CDC and HRSA should consider additional provider guidance, as well as educational campaigns to affected communities. Taking these actions provides an opportunity to effectively contain the current meningococcal outbreak.

2. EXPAND COMMUNITY RESPONSE CAPACITY

As we learned with COVID-19, it is essential to engage community stakeholders and community clinical providers in efforts to educate, screen, vaccinate, and treat people with a diagnosis or at a heightened risk of monkeypox. Similarly, broader community engagement can improve health department messaging and vaccination efforts for meningococcal disease. Although initial monkeypox vaccines and treatment efforts began with health departments, there are efforts to expand these services to community-based organizations trusted by affected populations. The constellation of HIV services organizations, networks of people living with HIV, LGBTQ+ services and advocacy organizations, as well as harm reduction, sex worker, reproductive justice, and racial and ethnic minority services and advocacy organizations have extensive trust, reach, and capacity. These organizations should be leveraged to have a maximal impact to provide education, interface between public health agencies and community members, and support vaccination and the delivery of other services. These organizations also could help ensure equity in vaccine distribution. Already there are concerns over the demographics of those receiving vaccine appointments, as well as reports of a disproportionate impact of monkeypox cases among communities of color. To achieve greater equity and effectiveness, the Administration must quickly identify and allocate resources for community responses. Priority should be given to existing funding mechanisms that do not require open competition and should require minimal supplemental reporting. Federal grant administrators also must build on lessons from emergency COVID-19 responses to expedite the awarding of funds to health departments and other grantees.

POLICY ACTION: Fund a diversity of organizations, including Black and Latinx, ballroom community, leather and other groups serving gay and bisexual men, transgender people and other affected communities, as well as networks of people living with HIV, people who use drugs, and people who engage in sex work to provide education, help with contact tracing, interface with researchers, government officials, and community members, and support the delivery of vaccination and other services with community-based clinical providers.

One especially important need for which community partners are critical is to ensure that all public health responses are grounded in a sexual health paradigm.
THE TOOLBOX FOR MONKEYPOX AND MENINGOCOCCAL DISEASE

MONKEYPOX

Monkeypox is a longstanding viral threat that has been endemic in parts of Africa, but it has not been an ongoing health threat in the U.S. The Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) maintains the Strategic National Stockpile (SNS) that is a national repository of antibiotics, vaccines, antidotes, and antitoxins that can be deployed in cases of a public health emergency.[1] Working with the CDC, the ASPR is deploying monkeypox vaccines and treatments to health departments. Vaccination is recommended for persons with suspected exposure to monkeypox and persons in groups at elevated risk for infection. Two vaccines and one antiviral treatment have been approved by the Food and Drug Administration (FDA) and are part of the SNS:

- The JYNNEOS vaccine was developed for monkeypox and smallpox and is the newest of the two vaccines, it is considered to have a better safety profile with fewer side-effects, and it is the only one recommended for people living with HIV. It is currently administered in two doses, spaced at least four weeks apart. This vaccine, however, is in short supply. On June 24th, the SNS had approximately 65,000 doses of the JYNNEOS vaccine, with an expected delivery of 300,000 doses within days of that date. On July 1st, the Administration ordered 2.5 million more doses. HHS anticipates making available 1.9 million doses in 2022, with an additional 2.2 million doses becoming available in the first half of 2023.[2,3]
- The ACAM2000 vaccine was developed for smallpox but can be used to prevent monkeypox. It is a one-dose vaccine administered with a special needle that requires training. The SNS has more than 100 million doses of the ACAM2000 vaccine and is currently permitting health departments to request deliveries of this vaccine.[2] Due to the potential for a higher rate of adverse reactions, contraindications in people with compromised immune systems, as well as possible transmissions to persons who have close contact with the vaccinee, federal and state health officials have expressed caution about widespread vaccination campaigns with ACAM2000, unless changing epidemic conditions warrant it.
- The SNS also maintains a supply of 1.7 million treatment doses of TPOXX (tecovirimat), an antiviral medication that has been approved to treat monkeypox.[2] Access to TPOXX, however, has been reported to be limited, suggesting the need for clearer provider guidance and easier methods for obtaining the medication.

MENINGOCOCCAL DISEASE

Meningococcal disease is a very serious infection that can quickly become deadly.[4]

- Vaccines are available that are distributed through health departments and regular health care channels (i.e., reimbursed by insurance and not available through the SNS). There are two different vaccines for meningococcal disease: one is for a strain that primarily impacts college-age young people, and another, MenACWY (sold under different brand names by different manufacturers), is recommended for the current outbreak among MSM. All people with HIV are recommended to be vaccinated for meningococcal disease on diagnosis.[5] Current CDC guidance is also for MSM living in Florida to receive the MenACWY vaccine and for MSM traveling to Florida to consult with their healthcare provider about being vaccinated.[4]
- Meningococcal disease is treated by a variety of antibiotics, and it is essential that treatment for suspected cases begin right away, even without a confirmatory diagnosis.

Despite significant progress on LGBTQIA+ civil rights, public dialogue and social messages toward MSM is often deeply rooted in shame over their sexuality. We welcome recent communications and educational materials from the CDC that may be groundbreaking for their affirming and stigma-free approach to sexual health.29 Especially at a time when transgender people are under attack in the public sphere and discussion of LGBTQIA+ issues is increasingly controversial, trusted community partners are needed more than ever to serve as a conduit of information about monkeypox, meningococcal disease, and other future infectious disease threats. This includes a forthright discussion of harm reduction that may encourage MSM and other communities to take steps to reduce their risk of infectious disease acquisition. There are a variety of strategies that MSM can discuss with each other to reduce risk, such as temporarily abstaining from sex, avoiding bathhouses and other public sex venues, reducing the number of sexual partners, and limiting partners to those within existing closed networks. Such messaging and open dialogue grounded in respect and community resiliency is critical, but may not be trusted when coming from governmental officials. More importantly, such messaging must remain non-stigmatizing and include as much of a harm reduction emphasis as possible. Potential controversy over frank public messages also could detract from the impact that can be achieved when such dialogues happen within communities themselves. The central focus should be placed on helping to stem these outbreaks, not fighting among ourselves.

3. IDENTIFY AND ALLOCATE EMERGENCY RESOURCES

To take many of the actions described above, resources are needed. The immediate needs described here must be followed by a sustained, long-term commitment to significantly greater funding to support sexual health clinics through the CDC Division of STD Prevention to build sustainable capacity to respond to a variety of sexually transmitted infections (STIs) including monkeypox, meningococcal disease, and other emergent or resurging infectious diseases. Congress holds the nation’s purse strings, and in normal circumstances, must appropriate funds for public health and other functions. Congress has delegated limited powers to the Executive Branch, however, to respond to urgent needs, including in cases of public health emergencies. The White House Domestic Policy Council should coordinate with the Office of Management and Budget (OMB) and HHS leadership to develop a transfer package of at least $100 million for monkeypox, meningococcal disease, and other infectious disease emergency responses with resources drawn from across HHS. The Administration also should assess its need for a supplemental funding request. HHS should use transferred funds to build on its cross departmental response in at least four areas:

- **Care and Services**: The Health Resources and Services Administration (HRSA) Bureau of Primary Health Care that administers the Health Centers Program and the HIV/AIDS Bureau that administers the Ryan White HIV/AIDS Programs, along with the CDC’s Division of STD Prevention (that funds sexual health clinics), should be given resources to expand access to community-based prevention, screening, and treatment services. Importantly, these programs must promise access to no-cost services so that persons who lack insurance have widely available access points; for these limited services, programs should not conduct eligibility screening and should serve all persons who seek services.

- **Testing and Surveillance**: As discussed, major steps have been taken to increase the capacity of public health and commercial laboratories to screen for monkeypox. Greater efforts are needed now to finance the availability and delivery of such tests and to expand testing for meningococcal disease. Additionally, new resources are needed for focused surveillance activities for both conditions.

- **Community Engagement**: We have already described the need for extensive community engagement and meaningful partnerships. Given the diversity of needed partners in many jurisdictions across the country, CDC, HRSA, SAMHSA, IHS, and other operating divisions should be enlisted in rapidly funding a multitude of community partners, with priority given to pass through funding to health departments or other approaches that can most expeditiously make awards to community partners.

- **Research**: The National Institutes of Health (NIH) through the Centers for AIDS Research (CFAR) network should receive funds for supplemental research of existing MSM cohort studies (online and prospective) to understand the impact of the existing outbreaks and their overlap with HIV/STI risk, as well as research to determine whether testing or vaccine fatigue of these new viral threats affect HIV prevention and care adherence efforts among people at risk or living with HIV.
COVID-19 has shown that infectious diseases anywhere in the world can threaten the U.S. Oceans, entry restrictions, our country’s wealth and population characteristics and other factors do not offer effective protection from pandemic health threats. The United States believes that it holds unique responsibilities within the global community and in the area of health, it has often played THE essential leadership role:

- U.S. leadership on global HIV is unquestioned with bilateral support for PEPFAR, the President’s Emergency Plan for AIDS Relief, supporting lifesaving antiretroviral therapy (ART) for roughly 19 million people living with HIV around the world.[1] The U.S. is also the largest contributor to the Global Fund for AIDS, TB, and Malaria (Global Fund).[2]

- During the 2013-2016 West African Ebola outbreak, the global community’s moves were too tepid until the U.S. deployed its resources to assist affected nations to ultimately bring this outbreak to an end.

- No nation has done more to expand access to COVID-19 vaccinations in the global south than the U.S., having pledged to deliver 1.1 billion COVID-19 vaccine doses by the end of 2022 and having already delivered nearly 600 million doses. [3] Too frequently, however, our generosity has seemed begrudging, as vaccines were widely available in the U.S. long before they were broadly available around the world, and our own policy choices about recommending booster shots and other key decisions seemed to be made without due consideration of global concerns.

As with COVID-19, tools to fight many infectious diseases in resource-rich countries are not available in lower income countries. It is particularly galling that global attention on monkeypox—previously localized to certain African countries—was mobilized only after individuals in higher income countries were affected. No central or west African country has significant access to vaccines, despite endemic monkeypox. A 2020 paper predicted the potential of monkeypox outbreak, but it received little attention because the analysis focused on the Democratic Republic of the Congo.[4] The conditions the paper cites as giving rise to a monkeypox outbreak (i.e., the aging out of older cohorts fully vaccinated against Smallpox) is exactly why monkeypox is spreading so efficiently in resource-rich countries. The U.S. must actively work to counter global perceptions of selfishness that could undermine our diplomatic goals and weaken the bonds of friendship and openness to cooperation on which our country depends. To maximize global efforts at pandemic control, urgent action is also needed to:

- Robustly fund pandemic preparedness and biodefense.

- Even during domestic supply shortages, balance domestic needs with sharing vaccines, antiviral treatments, testing technology, surveillance, and technical capacity with other nations.

- Leverage PEPFAR’s and the Global Fund’s experience and trust in providing sensitive and quality services to key populations in low- and middle-income countries.


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**THE TIME IS NOW**

Many people have reflected on how the course of HIV could have been so much different had we had a government that cared about our communities and responded with urgency. We are very early in this new monkeypox crisis and likely early in an unfolding and growing threat of meningococcal and other infectious diseases. Time is of the essence to productively curb and limit these threats. Longer-term, we need to bolster funding for public health writ large. Success depends on trust of affected communities, yet in too many places, cooperation from stigmatized communities is threatened by the possibility that their aggregated data collected for public health purposes could expose them to harassment or discrimination from law enforcement or in accessing public services. We applaud the rapid response of the Biden-Harris Administration in many regards and are grateful for their commitment to our communities. Nonetheless, we need even more resources and more commitment of meaningful community partnerships to be successful at protecting the health of the American people.
ENDNOTES

8. Arielle Dreher, Testing squeeze keeps the scope of monkeypox a mystery, Axios (June 14, 2022), https://www.axios.com/2022/06/14/monkeypox-testing-needed.
25. Mangia, supra note 19.
26. onyx (@DreamStreet_ ), Primarily Black Harlem neighborhood sees huge number of white gay men and few Black gay men seeking monkeypox vaccine (Thread), Twitter (July 12, 2022, 12:17 PM), https://twitter.com/Dreamstreet_status/1546909219751923727?
text=YD124CCa4kkw4QJlab1TlQ.