

BRIEFER

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100 Days of Monkeypox: Evaluating the U.S. Response to the Emerging Global Outbreak

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INTRODUCTION

As Dr. Jay Varma, Director of the Cornell Center for Pandemic Prevention and Response, stated to John Oliver on August 8th, “...monkeypox was the perfect stress test.” The United States already had the tests, the vaccines, and the therapeutics to combat monkeypox because of its biodefense strategy to respond to a weaponized use of smallpox.¹ Yet, the early response has faced challenges.

August 15, 2022, marked the 100th day since the first case of monkeypox was reported in the United Kingdom, the first appearance of the disease’s spread in non-endemic areas. Since the first case was reported in the United Kingdom on May 7th, the virus has been confirmed in over 90 countries.² As of August 15th, there were 38,452 cases across the globe, with 12,636 in the United States alone.³ Simply put, the spread of the virus outpaced the public health messaging and activation of the medical countermeasures available.

1 [Monkeypox: Last Week Tonight with John Oliver \(HBO\)](#). YouTube. 2022.

2 [“Monkeypox 2022 Global Epidemiology; Report 2022-08-15.”](#) *Global.health*, August 15, 2022.

3 [“Map.”](#) *Global.health*. Accessed August 16, 2022.

To understand how the virus has spread despite U.S. preparations, it is important to examine the key response efforts tailored to the monkeypox outbreak.

EARLY DYNAMICS OF THE OUTBREAK

As highlighted during the rise of COVID-19, effective public health messaging and community engagement efforts are important to gaining control over an emerging infectious disease outbreak. Early reports indicated that this outbreak of monkeypox was atypical. Initial indicators like fatigue were less common than is often the case for victims of this virus, and the lesions associated with monkeypox also presented in lower numbers and more discrete regions of victims' bodies.⁴

These differences in how infections were driving symptoms meant that many individuals did not fall into the case definition for monkeypox and were either misdiagnosed or undiagnosed. After June 24th, the U.S. Centers for Disease Control and Prevention updated its guidance to clinicians to detail the new information and examples to compare similarly-presenting diseases.⁵

Prolonged skin-to-skin contact has emerged as the primary transmission route,⁶ and exposure to contaminated porous surfaces⁷ are ways monkeypox is spreading. These means of spread result in dense social and sexual networks being particularly vulnerable to viral exposure and spread.⁸

While the initial spread has disproportionately affected the community of gay and bisexual men who have sex with multiple partners,⁹ the virus is affecting the entire population and its jump within another dense social network is only a matter of time.^{10,11} However, the early messaging emphasis on the men who have sex with men has many in the LGBTQIA+ community concerned that the same bias-driven mistakes from the HIV/AIDS epidemic are being repeated.¹² Further, public health experts are already concerned that testing and treatment are not reaching at-risk and potentially positive individuals due to the outbreak's stigmatization.¹³

4 Girometti, Nicolò, Ruth Byrne, Margherita Bracchi, Joseph Heskin, Alan McOwan, Victoria Tittle, Keerti Gedela, et al. [“Demographic and Clinical Characteristics of Confirmed Human Monkeypox Virus Cases in Individuals Attending a Sexual Health Centre in London, UK: An Observational Analysis.”](#) *The Lancet Infectious Diseases* 22, no. 9 (2022): 1321–28.

5 [“Monkeypox in the United States: What Clinicians Need to Know.”](#) *Centers for Disease Control and Prevention*, June 21, 2022.

6 Kozlov, Max. [“How Does Monkeypox Spread? What Scientists Know.”](#) *Nature News*. Nature Publishing Group, August 11, 2022.

7 [“How It Spreads.”](#) Monkeypox. Centers for Disease Control and Prevention, July 29, 2022.

8 Roland, Denise. [“Monkeypox Likely Spread for Years Before Outbreak, Scientists Say.”](#) MSN. *The Wall Street Journal*, August 9, 2022.

9 Soucheray, Stephanie. [“Monkeypox Cases Reach 7,500 in US; 99% of Cases in Males.”](#) CIDRAP, August 8, 2022.

10 Thornhill, John P., Sapha Barkati, Sharon Walmsley, Juergen Rockstroh, Andrea Antinori, Luke B. Harrison, Romain Palich, et al. [“Monkeypox Virus Infection in Humans across 16 Countries — April–June 2022.”](#) *New England Journal of Medicine* 387, no. 8 (August 25, 2022): 679–91.

11 [“Technical Report 2: Multi-National Monkeypox Outbreak, United States, 2022.”](#) *Monkeypox*. Centers for Disease Control and Prevention, September 1, 2022.

12 Lewis-Thornton, Rae. [“Opinion | We’re Making the Same Mistake with Monkeypox That We Made with HIV/AIDS.”](#) *The Washington Post*, August 8, 2022.

13 Favro, Marianne. [“Monkeypox Stigma Leads to Low Demand for Testing, Experts Say.”](#) *NBC Bay Area*, August 4, 2022.

THE TESTING, VACCINATION, AND THERAPEUTIC ROLLOUT

Monkeypox is somewhat unique in U.S. preparedness for this virus, though the experience to date has made clear that putting that preparedness to use requires further improvements.

First, this case shows the importance of advance investments in research, development, acquisition, and stockpiling. Unlike other emerging infectious disease outbreaks, the United States had the toolkit to respond to the threat of monkeypox. As highlighted in CSR's previous piece on the initial response to the outbreak,¹⁴ biodefense strategies to combat smallpox led to the development of tests, vaccines, and therapeutics that are effective for monkeypox.

However, at the same time, several hurdles hampered the containment response during the first 100 days.

TESTING

From the onset of the outbreak, experts have warned that the rate of testing for monkeypox is insufficient. Back on June 23rd, the United States had 237 confirmed cases, but the CDC had only run 1,058 tests.¹⁵ By the end of July, testing capacity across public and private entities was up to 80,000 tests per day,¹⁶ yet many of the labs involved were receiving less than 100 samples to run per week.¹⁷

One complication contributing to the low testing rate is the current testing protocol, requiring a swab of a patient's lesions for PCR testing.¹⁸ This strategy is limiting for multiple reasons, including the delay between infection and the presentation of the lesion, the presence of positive patients who do not exhibit lesions, and the multi-day lag from sample to result. Another factor is that monkeypox was not one of the state-mandated notifiable diseases until the CDC recently required it starting on August 1st.¹⁹ This means that some positive cases that could have better-indicated actual trends may not have been on the government's radar.

14 Regan, Dan. "[As the World Health Organization Meets on the 2022 Monkeypox Outbreak, an Early Examination of U.S. Responses.](#)" Council on Strategic Risks, June 27, 2022.

15 Doucleff, Michael. "[Monkeypox Outbreak in U.S. Is Bigger than the CDC Reports. Testing Is 'Abysmal.'](#)" *NPR*, June 25, 2022.

16 "[HHS Expanding Monkeypox Testing Capacity to Five Commercial Laboratory Companies.](#)" *HHS.gov*, June 22, 2022.

17 Cohen, Elizabeth. "[Testing Is Crucial to Getting Monkeypox under Control, but There's a 'Shocking' Lack of Demand.](#)" *CMN*, August 1, 2022.

18 "[For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results: FDA Safety Communication.](#)" U.S. Food and Drug Administration, July 15, 2022.

19 Soucheray, Stephanie. "[HHS Promises 1.1 Million Monkeypox Vaccines in Coming Weeks.](#)" *CIDRAP*, July 28, 2022.

VACCINATION

At the onset of the outbreak, the majority of the vaccines in the Strategic National Stockpile (SNS) were the ACAM2000 vaccine,²⁰ which has a higher risk of side effects compared to the JYNNEOS two-dose vaccine. In May, the SNS only had 2,400 doses of JYNNEOS on hand.²¹ On August 4th, Health and Human Services detailed the shipment of 602,000 JYNNEOS doses to states and jurisdictions.²² However, estimates on July 31st put the U.S. population eligible for the two-dose vaccine at 1.5 million.²³

One ongoing hurdle is the lack of data-sharing agreements between local health systems and the CDC.²⁴ This is impacting the ability to track the testing at local levels, the logistics of doses administered, and monitoring the effectiveness of the current vaccination strategy.

Furthermore, the U.S. Food and Drug Administration's Emergency Use Authorization on August 9th²⁵ is aimed at tackling the disparity between the vaccine supply and demand by changing the injection to be released between the layers of the skin, using 20% of the dose compared to the standard vaccination into the muscle. This new vaccine administration strategy is intended to stretch the limited SNS JYNNEOS supply,²⁶ a move that has resulted in a clash between the vaccine's manufacturer and the Biden administration.²⁷

THERAPEUTICS

At the start of the outbreak, there were 1.7 million courses of TPOXX,²⁸ an antiviral cleared for use against smallpox in 2018,²⁹ available in the SNS. By July 22nd, when there were over 6,000 probable or confirmed cases in the United States, only 223 people were prescribed TPOXX courses.³⁰

20 Van Beusekom, Mary. "[Monkeypox Epidemic Control Hinging on Scarce Vaccines.](#)" CIDRAP, July 22, 2022.

21 "[Fact Sheet: U.S. Department of Health and Human Services Response to the Monkeypox Outbreak.](#)" HHS.gov, July 21, 2022.

22 "[Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency.](#)" HHS.gov, August 4, 2022.

23 Gupta, Sanjay. "[Dr. Sanjay Gupta: While Monkeypox Cases Rise, Why Are We Waiting for the Cavalry to Rescue Us?](#)" CNN, July 31, 2022.

24 Ibid.

25 "[Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply.](#)" U.S. Food and Drug Administration, August 9, 2022.

26 Soucheray, Stephanie. "[US to Begin Intradermal Injections of Jynneos, Stretching the Supply.](#)" CIDRAP, August 9, 2022.

27 Diamond, Dan, Fenit Nirappil, and Lena H. Sun. "[Inside America's Monkeypox Crisis - and the Mistakes That Made It Worse.](#)" *The Washington Post*, August 18, 2022.

28 Ibid, 21.

29 "[FDA Approves the First Drug with an Indication for Treatment of Smallpox.](#)" U.S. Food and Drug Administration, July 13, 2018.

30 Steenhuisen, Julie. "[U.S. Regulators Defend Requiring More Data on Monkeypox Drug.](#)" *Reuters*, August 3, 2022.

The prescription of TPOXX under the CDC's expanded access protocols is due to the drug's initial study against smallpox,³¹ a virus belonging to the same family as monkeypox. This regulatory process involves intensive paperwork to obtain permission for treatment by the CDC, with additional internal reviews within healthcare systems due to the experimental use of the drug specifically for monkeypox.³²

OUTLOOK AND ANALYSIS

On August 4th the U.S. Health and Human Services Secretary Xavier Becerra declared the ongoing monkeypox outbreak a Public Health Emergency.³³ The announcement came 12 days after the WHO designated monkeypox a public health emergency of international concern³⁴ and 2 days after the Biden administration chose Robert Fenton, Jr. (of the Federal Emergency Management Agency) and Dr. Demetre Daskalakis (of the CDC) to coordinate the U.S. federal monkeypox response.³⁵

In addition to improving public health messaging and the opening of federal resources for testing and vaccination, the emergency declaration could expand efforts like wastewater surveillance,³⁶ which already plays an important role in monitoring COVID-19.

Regarding TPOXX, the CDC took steps on August 8th to expedite its procurement.³⁷ The goal is a streamlined process for clinician requests and reducing the turnaround time from several days to delivering the medication from the SNS within 24 hours.

In response to the novelty of the monkeypox outbreak, HHS launched several new studies. In early July, the CDC stated that it will explore testing saliva, blood samples, and throat swabs.³⁸ International studies have found monkeypox in saliva, blood, urine, and rectal samples before the onset of lesions.³⁹ Additionally, the National Institutes of Health is conducting several studies to understand TPOXX's clinical efficacy on monkeypox in human populations, as well as understanding co-treatments with both vaccines.⁴⁰

31 [“SNS Products: Vaccines and Treatment Available for Use in Monkeypox Response,”](#) August 11, 2022.

32 Patel, Neeraj G., and Nadia Kounang. [“Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say.”](#) *CNN*. Cable News Network, August 2, 2022.

33 *Ibid*, 22.

34 Grover, Natalie, John Revill Natalie Grover, and Jennifer Rigby. [“Who Declares Global Health Emergency over Monkeypox Outbreak.”](#) *Reuters*, July 23, 2022.

35 [“President Biden Announces Team to Lead Monkeypox Response.”](#) The White House, August 2, 2022.

36 Kreidler, Mark. [“COVID Sewage Surveillance Labs Join the Hunt for Monkeypox.”](#) *NPR*, August 8, 2022.

37 [“Information for Healthcare Providers on Obtaining and Using TPOXX \(TECOVIRIMAT\) for Treatment of Monkeypox.”](#) Centers for Disease Control and Prevention, August 18, 2022.

38 Weintraub, Karen. [“As Monkeypox Outbreak Spreads, CDC Pledges More Vaccines. Here’s What to Know.”](#) *USA Today*, July 22, 2022.

39 Mazer, Benjamin. [“We’re Testing for Monkeypox the Wrong Way.”](#) *The Atlantic*, July 21, 2022.

40 Park, Alice. [“What to Know About the Monkeypox Drug TPOXX—And Why It’s So Hard to Get.”](#) *Time*, August 9, 2022.

The ongoing monkeypox outbreak is a considerable threat to the public health and national security of the United States. With K–12 schools and colleges resuming in-person sessions,⁴¹ it will be imperative to expedite messaging, testing, and vaccination efforts. Growing concern about the outbreak’s trajectory is that it may establish itself with an animal vector, most likely a rodent, within the United States and become endemic.⁴² With the decline in smallpox vaccination, models have indicated that a monkeypox outbreak fits the potential to become endemic.⁴³

As the virus has not been contained within the initial 100 days of the outbreak, the United States should take concrete steps across the entirety of the monkeypox response effort to get a firm handle on this infectious disease event. Detailed below are CSR’s recommendations for addressing the ongoing monkeypox Public Health Emergency.

- Public health experts need to build upon inclusive messaging regarding the spread and prevention of monkeypox⁴⁴ while building a dialogue with the LGBTQIA+ community on what they are experiencing, how to help stop the spread, and how to find support.⁴⁵
- The CDC should expand its funding on wastewater surveillance to include monkeypox,⁴⁶ to help provide new avenues of information on at-risk populations and viral load to get ahead of clinical testing-related lags.
- Strategic resources and authorities like data sharing agreements should be prioritized to ensure every opportunity for the CDC’s Center for Forecasting and Outbreak Analytics⁴⁷ to be successful in contributing to the biosurveillance landscape.
- The National Institutes of Health should consider ramping up the RADx Initiative⁴⁸ with the goal of developing rapid monkeypox tests, an important step toward increased community engagement and reducing barriers to care.
- With their recent elevation to an operational division,⁴⁹ the Administration of Strategic Preparedness and Response in HHS is facing its first national emergency under this new structure.

41 Salhotra, Pooja. “[How Colleges Are Preparing for a New Public Health Threat: Monkeypox.](#)” *NPR*, August 6, 2022.

42 Cohen, Jon. “[Concern Grows That Human Monkeypox Outbreak Will Establish Virus in Animals Outside Africa.](#)” *Science*, June 8, 2022.

43 Grant, Rebecca, Liem-Binh Luong Nguyen, and Romulus Breban. “[Modelling Human-to-Human Transmission of Monkeypox.](#)” *Bulletin of the World Health Organization* 98, no. 9 (September 1, 2020): 638–40.

44 Gilyard, Katherine. “[A Health Equity Expert on Making Monkeypox Messaging More Inclusive.](#)” *STAT*, August 5, 2022.

45 Kupferschmidt, Kai. “[Why the Monkeypox Outbreak Is Mostly Affecting Men Who Have Sex with Men.](#)” *Science*, June 20, 2022.

46 Parr, Lillian. “[Event Summary: COVID-19 Response Technologies & Their Future Role in Pathogen Early Warning.](#)” Council on Strategic Risks, March 17, 2022.

47 Duncombe, Ryan. “[The CDC Officially Launches the Center for Forecasting and Outbreak Analytics.](#)” Council on Strategic Risks, May 25, 2022.

48 Regan, Dan. “[Event Summary: RADx® Initiative & COVID-19 Solutions.](#)” Council on Strategic Risks, June 30, 2022.

49 Regan, Dan. “[U.S. Health and Human Services Secretary Beccera to Give Preparedness and Response Its Own Division.](#)” Council on Strategic Risks, July 26, 2022.

An internal study of the outbreak's first 100 days should be conducted to determine what actions need to be taken in future outbreaks based on new authorities, including evaluating the SNS.

- The Department of Defense (DoD) must always be a key player in improving preparedness and responses. It had great success in the U.S. response to the 2014-2016 Ebola outbreak,⁵⁰ being a critical member of Operation Warp Speed⁵¹ and the COVID-19 response, and expanding international partners' biosurveillance capacities through the Biological Threat Reduction Program.⁵² DoD and national security needs helped drive the development of smallpox diagnostics, vaccines, and treatments. Its partnerships in Africa contributed to bolstering epidemiological tools and sequencing from previous monkeypox outbreaks,⁵³ which provided insights relevant to the current monkeypox outbreak. Further, DoD has skills in international collaboration and emergency response contracting that may be used in the monkeypox outbreak.
- The combined U.S. response to COVID-19⁵⁴ and monkeypox⁵⁵ will surpass \$4.5 trillion in costs over a three-year span. It is critical to invest in our nation's capabilities to better anticipate, detect, and respond to emerging infectious diseases of the future. To achieve this goal, CSR continues to recommend *10 + 10 over 10*,⁵⁶ investing \$10 billion per year for biodefense and \$10 billion per year for health security, sustained over the next ten years.

The Biden administration has rightfully committed to action in preventing monkeypox from becoming endemic and stopping this outbreak. The ongoing responses to monkeypox and COVID-19 are yet another alarm bell that the United States must get far more serious about preventing and addressing biological threats.

ABOUT THE AUTHOR

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50 Parthemore, Christine, and Sherri Goodman. "[Let's Not Get Caught Flat-Footed on the Next Crisis: Coronavirus, Climate Change, and American Security.](#)" Council on Strategic Risks, May 19, 2020.

51 Parr, Lillian. "[CSR Webinar—Operation Warp Speed: The Interagency and Public-Private Collaborations That Drove It.](#)" Council on Strategic Risks, November 4, 2021.

52 Beaver, Bill, Christine Parthemore, and Nikki Teran. "[Key U.S. Initiatives for Addressing Biological Threats Part 3 – The Biological Threat Reduction Program.](#)" Council on Strategic Risks, August 10, 2021.

53 Kugelman, Jeffrey R., Sara C. Johnston, Prime M. Mulembakani, Neville Kisalu, Michael S. Lee, Galina Koroleva, Sarah E. McCarthy, et al. "[Genomic Variability of Monkeypox Virus among Humans, Democratic Republic of the Congo.](#)" *Emerging Infectious Diseases* 20, no. 2 (2014): 232–39.

54 [The Federal Response to COVID-19](#), July 31, 2022.

55 Diamond, Dan, and Tony Romm. "[U.S. may need \\$7 billion for monkeypox, Biden administration estimates.](#)" *The Washington Post*, July 26, 2022.

56 Weber, Andrew, and Yong-Bee Lim. "[10 + 10 Over 10: A Funding Vision for the U.S. Fight Against Biological Threats.](#)" Council on Strategic Risks, April 1, 2021.