United States Government Accountability Office

Report to Congressional Requesters

April 2024

PUBLIC HEALTH PREPAREDNESS

Mpox Response Highlights Need for HHS to Address Recurring Challenges

GAO-24-106276

GAO Highlights

Highlights of GAO-24-106276, a report to congressional requesters

April 2024

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Mpox Response Highlights Need for HHS to Address Recurring Challenges

Why GAO Did This Study

State and local jurisdictions are often first to detect and respond to public health events. However, if their public health and medical capabilities need support, as with mpox, HHS is charged with coordinating federal assistance to supplement the response.

GAO was asked to review the federal response to the mpox public health emergency. In this report, GAO (1) describes the federal response to the mpox outbreak, (2) assesses the extent to which the federal mpox response presented challenges similar to those experienced in past public health emergencies, and (3) assesses federal efforts to address recurring public health emergency challenges.

GAO reviewed HHS documents and mpox infection data from May 18, 2022, to January 31, 2023. GAO interviewed officials from the Department of Homeland Security, HHS, and 14 selected jurisdictions (six states, the District of Columbia, and seven localities), chosen based on case rates and demographic and geographic diversity. GAO received written responses from the White House mpox response team. GAO also reviewed HHS after-action processes and documents.

What GAO Recommends

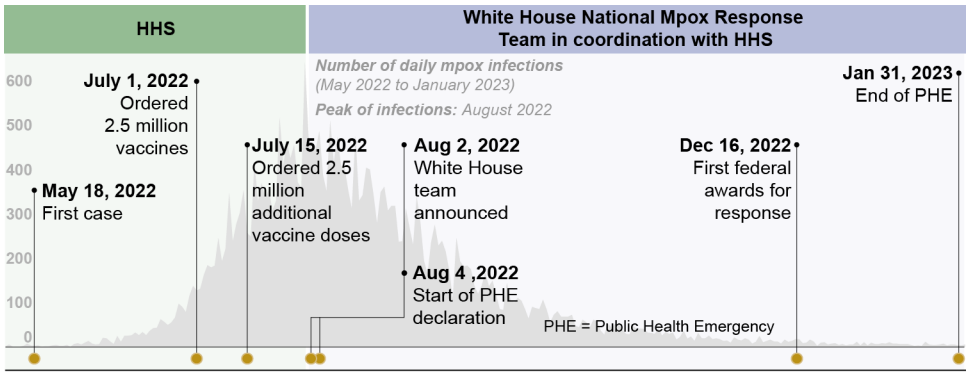
GAO is making two recommendations to HHS: to develop and implement a coordinated, department-wide after-action program that (1) encourages after-action collaboration across HHS component agencies, and (2) includes relevant external stakeholders involved in each response when identifying challenges and associated solutions. HHS concurred with both recommendations.

View GAO-24-106276. For more information, contact Mary Denigan-Macauley at (202) 512-7114 or Deniganmacauleym@gao.gov.

What GAO Found

Mpox, a serious infectious disease caused by a virus in the same family as smallpox, experienced an unprecedented global outbreak in 2022. The Department of Health and Human Services (HHS) led the initial federal response in the U.S., beginning in May 2022. According to a White House press release, a White House mpox response team was established and assumed leadership of the federal response, and the Secretary of Health and Human Services declared mpox a public health emergency in early August 2022. The federal mpox response included providing vaccines to jurisdictions for the prevention of mpox, among other efforts.

Timeline of Selected Mpox Response Activities and Number of Mpox Infections[a]



Source: GAO analysis of Department of Health and Human Services (HHS) information. | GAO-24-106276

[a]The decline in daily mpox cases was likely due to the combined effect of events in figure above.

The six states, the District of Columbia, and seven local jurisdictions GAO interviewed described challenges with HHS's initial response to mpox that were similar to those GAO identified in HHS's response to past emergencies. For example, jurisdictions noted challenges with communication and the availability of vaccines, tests, and treatments, among other problems. Similar persistent and recurring deficiencies led GAO to add HHS's leadership and coordination of public health emergencies to its High-Risk List in January 2022, calling for an HHS leadership commitment to transform its efforts.

HHS—as the designated lead for the federal public health and medical response to emergencies—does not have a coordinated, department-wide after-action program to identify and resolve recurring emergency response challenges. While some component agencies within HHS have after-action programs, these agencies work independently without coordinating with each other, and do not always engage relevant external stakeholders in identifying challenges and associated solutions. GAO's past work has shown the benefits of coordination and including stakeholders when addressing challenges. Embracing a coordinated, department-wide after-action program for each response that includes external stakeholders would help HHS develop informed and comprehensive solutions. Such solutions should, in turn, strengthen HHS's ability to respond to future emergencies, including those that could be more infectious and lethal than mpox.

Contents

Abbreviations

ASPR	Administration for Strategic Preparedness and Response
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
LGBTQ	lesbian, gay, bisexual, transgender, and queer
NIH	National Institutes of Health
WHO	World Health Organization

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April 18, 2024

The Honorable Bennie G. Thompson
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Troy A. Carter, Sr.
Ranking Member
Subcommittee on Emergency Management and Technology
Committee on Homeland Security
House of Representatives

The Honorable Ritchie Torres
House of Representatives

On July 23, 2022, the World Health Organization (WHO) declared mpox (then referred to as monkeypox) a public health emergency of international concern.[1] The Secretary of Health and Human Services subsequently declared mpox a public health emergency in the U.S. on August 4, 2022. The declaration remained in place until January 31, 2023.[2] According to the Centers for Disease Control and Prevention (CDC), mpox is an infectious disease caused by a virus, in the same family of viruses that causes smallpox. It can cause a painful rash, enlarged lymph nodes and fever. Most people fully recover, but some get

[1]A public health emergency of international concern is an extraordinary event in one country that constitutes a public health risk to other countries through international spread of disease and potentially requires a coordinated international response. All WHO member countries are required to notify WHO of such emergencies. WHO makes the final determination about the existence of a public health emergency of international concern. Following the declaration for mpox, the Director-General of WHO provided a number of recommendations to stop transmission, enhance surveillance, and develop clinical management and infection prevention research into the use of vaccines, therapeutics, and other tools. On May 11, 2023, WHO ended the global health emergency for mpox.

[2]A declaration of a public health emergency triggers the availability of certain authorities under federal law that allow the federal government to take appropriate action to respond to the emergency, including making grants, entering into contracts, and conducting and supporting investigations into the cause, treatment, or prevention of the disease. 42 U.S.C. § 247d(a). For more details, see GAO, *Opioid Crisis: Status of Public Health Emergency Authorities*, GAO-18-685R (Washington, D.C.: Sept. 26, 2018).

very sick. Anyone can get mpox and it is transmitted largely through skin-to-skin contact.[3]

The first human cases of mpox were identified on the continent of Africa in 1970, and there have been limited outbreaks in countries outside of Africa since 2003. Starting in early May 2022, mpox cases were reported in the United Kingdom. On May 18, 2022, the first domestic case of an unprecedented global outbreak was reported in Massachusetts; mpox then spread to other parts of the U.S. as the country was still grappling with the COVID-19 pandemic.[4] As of November 2023, a total of 31,277 U.S. cases (92,432 global cases as of December 2023) and 55 mpox-associated U.S. deaths were reported to CDC. Experts and stakeholders raised concerns about the slow initial pace of the federal response to the mpox outbreak, coming on the heels of the COVID-19 pandemic.

State and local public health entities are often the first to detect and respond to public health events. However, when there is a public health emergency that exceeds state, local, tribal, or territorial resources, and there is a need for support, the federal government can provide resources to assist response efforts.[5] Under federal law, the Department of Health and Human Services (HHS) is charged with leading the federal public health and medical response to public health emergencies and incidents covered by the National Response Framework.[6] Within HHS, the Administration for Strategic Preparedness and Response (ASPR) has the

[3]Mpox typically presents as a rash, and sometimes, though less typically, with fever, chills, or swollen lymph nodes, among other symptoms. Transmission may also occur through direct contact with materials that were in contact with lesions or bodily fluids, and through exposure to large respiratory droplets from prolonged face-to-face contact.

[4]In 2003, 47 confirmed and probable cases of mpox were reported in six states. The people infected with mpox in that outbreak became ill after having contact with pet prairie dogs. This was the first time that human mpox was reported outside Africa.

[5]State, local, tribal, or territorial governments are hereafter referred to as “jurisdictions”. In sections of this report, we also use the term “jurisdiction” to refer to various subsets of these four governmental entities.

[6]42 U.S.C. § 300hh(a). The National Response Framework establishes an all-hazards response structure to coordinate federal resources during emergencies and disasters and is divided into 14 emergency support functions. Emergency Support Function #8 of the framework—Public Health and Medical Services—provides the mechanism for federal assistance to supplement local, state, tribal, territorial, and insular area resources in response to a disaster, emergency, or incident that may lead to a public health, medical, behavioral, or human service emergency, including those that have international implications. HHS is the lead agency for Emergency Support Function #8. See Federal Emergency Management Agency, *National Response Framework, Fourth Edition*. (Washington, D.C.: October 2019).

lead responsibility for public health emergency preparedness, including providing policy coordination and strategic direction before, during, and following a public health emergency.[7]

In January 2022, we added HHS's leadership and coordination of public health emergencies to our High-Risk List.[8] We have found persistent deficiencies in HHS's ability to lead and coordinate the nation's preparedness for and response to emergencies. HHS has consistently fallen short in five areas of an effective national response. Moreover, we have made more than 150 recommendations to HHS in this high-risk area. As of December 2023, 86 of these recommendations remain open. You asked us to review the federal response to the mpox public health emergency.

In this report, we

1. describe the federal response to the mpox outbreak,
2. assess the extent to which the federal mpox response presented challenges similar to past public health emergencies, and
3. assess federal efforts to address recurring public health emergency challenges.

To describe the federal response to the mpox outbreak, we reviewed HHS documents and interviewed officials from HHS and its component agencies involved in the mpox response: ASPR, CDC, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Health Resources and Services Administration (HRSA). We reviewed CDC's data on the number of mpox cases at the national level. To assess the reliability of these data we reviewed CDC documentation and CDC-published reports about mpox data, and interviewed agency officials. We looked at the extent of

[7]See 42 U.S.C. § 300hh-10.

[8]GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies.* GAO-22-105291. Washington, D.C.: Jan. 27, 2022.

undetected mpox cases for individuals infected with mpox.[9] We determined that the data we used were sufficiently reliable for the purpose of this report.

We interviewed and requested information about the federal mpox response from the Department of Homeland Security, including the Federal Emergency Management Agency (FEMA), as a FEMA official was appointed to lead a White House national mpox response team to coordinate a whole-of-government federal response effort. The department and FEMA referred our inquiries to the White House. We submitted questions to the White House about the actions they took during the mpox outbreak, which they answered in writing.

To assess the extent to which the federal mpox response presented challenges similar to past public health emergencies, we took the following actions:

- We reviewed results of a literature search on the mpox outbreak—including results about health equity.
- We selected and visited 14 jurisdictions to understand any challenges they experienced with the federal mpox response. The 14 jurisdictions selected were California (Los Angeles and San Francisco), District of Columbia, Florida (Miami Dade County), Georgia (Atlanta/Fulton County), Illinois (Chicago), New York (New York City), and Texas (Houston). We selected these jurisdictions based on their high number of per capita mpox cases, and to provide demographic and geographic diversity. We visited six of the 14 jurisdictions in person, and the other eight virtually.[10] The structure of local health departments may be centralized—led by employees of the state, or

[9]For example, we reviewed a CDC report regarding the prevalence of undetected mpox cases. Some mpox cases were among persons experiencing homelessness or accessing homeless services. Mpox infections may also go undetected due to barriers to seeking or accessing the health care system. See Centers for Disease Control and Prevention, "Possible Undetected Mpox Infection Among Persons Accessing Homeless Services and Staying in Encampments—San Francisco Calif., October-November 2022," *Morbidity and Mortality Weekly Report* (MMWR), 72, no. 9 (March 3, 2023): 227-231.

[10]The jurisdictions we selected represented the majority of mpox cases nationwide at the time we began our interviews in early 2023. The experiences of the selected jurisdictions are not generalizable. We report the information obtained in the interviews with these jurisdictions using the following classifications: "several jurisdictions" is defined as two jurisdictions, "some jurisdictions" is defined as three to six jurisdictions, and "most jurisdictions" is defined as seven or more jurisdictions.

decentralized—led by employees of local governments.[11] We interviewed representatives of the jurisdictions about various aspects of their response to mpox in five key areas: 1) communication, 2) coordination, 3) medical countermeasures, 4) workforce capacity and funding, and 5) data collection and reporting. We selected these key areas because they align with the key areas GAO identified in its high-risk designation as important to an effective national emergency response.[12]

- We interviewed representatives of 18 external stakeholders that were either in the emergency preparedness and public health field or community-based organizations (hereafter referred to as stakeholders). For example, we interviewed officials from the National Association of County and City Health Officials, the Association of State and Territorial Health Officials, the American Public Health Association, the American Clinical Laboratory Association, and the Association of Public Health Laboratories about their perspectives on the federal response to mpox. In addition, we interviewed national organizations that serve the lesbian, gay, bisexual, transgender, and queer (LGBTQ) community, including the National Coalition for LGBTQ Health, Human Rights Campaign, and the San Francisco AIDS Foundation. This demographic was selected because the outbreak disproportionately affected men who have sex with men.

  We interviewed the 18 selected stakeholders about their assessments of the federal response to mpox in the same five key areas and the extent to which challenges from prior public health emergencies in the key areas were repeated during the mpox response. We also obtained comments from the selected jurisdictions about their experience accessing mpox medical countermeasures through the Strategic National Stockpile.

- We also reviewed actions taken by HHS to address: 1) past GAO recommendations for improving its public health emergency response activities, and 2) the areas of concern regarding HHS leadership and

[11]See CDC, *Health Department Governance*, (Washington, D.C.: Nov. 25, 2022), accessed January 19, 2024, https://www.cdc.gov/publichealthgateway/sitesgovernance/index.html.

[12]GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023).

coordination of public health emergencies identified on the High-Risk List.[13]

To assess federal efforts to address recurring public health emergency challenges, we reviewed the lessons learned that HHS's component agencies documented in disease-related public health emergency after-action reports and internal reviews from 2005 to 2022. We also reviewed documentation from HHS component agencies describing the processes to implement their after-action programs.[14] These after-action reports and internal reviews covered public health emergencies such as Zika, Ebola, H1N1, and COVID-19, and the Crimson Contagion training exercise.[15] We interviewed HHS officials about the standards and guidance that component agencies use for their after-action programs, including the programs' process for tracking the implementation of corrective actions to lessons learned identified during the reviews. We also reviewed actions taken by HHS to address after-action programs at HHS and other federal agencies.[16]

We conducted this performance audit from October 2022 to April 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13]See GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO-22-105291 (Washington, D.C.: Jan. 27, 2022). In addition, multiple GAO reports during the COVID-19 pandemic made recommendations to HHS regarding various aspects of its public health emergency response activities. See GAO, *Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*, GAO-21-513 (Washington, D.C.: Aug. 4, 2021).

[14]Following emergency responses, some HHS component agencies, including ASPR, develop after-action reports, which identify strengths and areas for improvement. These after-action reports also identify priority observations to be addressed, set completion deadlines, and include an improvement plan.

[15]The Crimson Contagion 2019 Functional Exercise tested the nation's ability to respond to a large-scale outbreak of a novel avian influenza virus, that quickly spreads via human-to-human transmission across the U.S. and the world.

[16]For example, see GAO, *Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness,* GAO-21-513 (Washington, D.C.: Aug. 4, 2021).

Background

Overview of Mpox

Mpox is part of the family of orthopoxviruses and is endemic in parts of West and Central Africa. Cases of mpox during the most recent global outbreak involved small, localized skin lesions. The initial cases of mpox during the latest global outbreak were associated with international travel. Cases associated with domestic transmission were subsequently identified throughout all 50 states. Case numbers in the U.S. peaked in early August 2022 and declined thereafter. As of November 2023, a total of 31,277 U.S. cases (92,432 global cases) and 55 mpox-associated U.S. deaths had been reported to CDC.

An overwhelming majority of mpox cases occurred among adult men who have sex with men and persons aged 21–55 years. The outbreak disproportionately affected persons with human immunodeficiency virus.[17] During the outbreak, health disparities were observed among racial and ethnic minority groups, including for Black and Hispanic persons.

Federal Health and Medical Response to Public Health Emergencies

The Secretary of Health and Human Services is responsible for leading the federal public health and medical response to public health emergencies. Within HHS, ASPR is the lead agency for public health emergency preparedness and response, policy coordination, and strategic direction. According to ASPR's strategic plan, its preparedness process involves a continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action to ensure an effective response. CDC also is to play a key role in the epidemiology and surveillance of diseases during a public health emergency. HHS component agencies, such as the Centers for Medicare & Medicaid

[17]The relationship between mpox and human immunodeficiency virus is known as a syndemic or synergistic epidemic. A syndemic or synergistic epidemic is the aggregation of two or more concurrent or sequential epidemics or disease clusters in a population with biological interactions, which exacerbate the prognosis and burden of disease.

Services, FDA, NIH, HRSA, and IHS, may also be involved in public health emergency response activities.[18]

The Secretary of Health and Human Services may declare a public health emergency upon a determination that (a) a disease or disorder presents a public health emergency; or (b) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.[19] The declaration of a public health emergency triggers the availability of certain authorities, such as the availability of certain emergency funds, the authority to temporarily reassign state and local personnel whose positions are funded under certain federal programs, and to waive some program requirements.

The Strategic National Stockpile and Medical Countermeasures

The Strategic National Stockpile is the national repository of medical countermeasures (such as vaccines and antivirals) that can be used to respond to a broad range of emergencies.[20] Items from its inventory may be provided to jurisdictions—state, local, tribal, and territorial entities—if their supplies are depleted or when the necessary countermeasures are not commercially available. In 2018, HHS shifted the oversight and operational control of the Strategic National Stockpile from CDC to ASPR.

Existing medical countermeasures were used for the mpox outbreak. For example, when the first U.S. case of mpox was reported on May 18, 2022, 2,400 doses of JYNNEOS were available in the Strategic National Stockpile to protect and vaccinate laboratory workers and CDC personnel. JYNNEOS was licensed for prevention of smallpox and mpox in individuals ages 18 years and older at high risk for infection. For these individuals, JYNNEOS is licensed for subcutaneous injection—injection beneath all layers of the skin. In addition, the antiviral drug TPOXX, stored in the Strategic National Stockpile, was made available for the

[18]The Centers for Medicare & Medicaid Services may waive or modify certain federal health care program requirements to increase access to medical services when both a public health emergency and a disaster or national emergency have been declared. FDA may provide recommendations, regulatory information, guidance, and technical assistance during a public health emergency. NIH may support research, including to develop medical countermeasures, to better understand and mitigate a public health threat. During a public health emergency, HRSA may provide grantees flexibility within the limits of statute. IHS is responsible for providing federal health services to American Indians and Alaska Natives.

[19]42 U.S.C. § 247d(a).

[20]See 42 U.S.C. § 247d-6b.

treatment of mpox under an expanded access investigational new drug protocol held by CDC.[21]

HHS Led the Initial Federal Response, with the White House National Mpox Response Team Assuming Leadership

HHS and its component agencies took several actions in leading the response to the mpox outbreak when the first cases were detected in May 2022. In August 2022, the Secretary of Health and Human Services declared mpox a public health emergency, and a White House National Mpox Response Team (White House team) assumed leadership of the response.

HHS's ASPR Led the Initial Mpox Response

HHS and its component agencies took actions to respond to the mpox outbreak beginning in May 2022, when the first mpox case was detected in the U.S. According to HHS officials, in early June 2022, ASPR stood up the Disaster Leadership Group to identify and recommend actions to the Secretary.[22] HHS's initial mpox response, led by ASPR, included the following actions, according to HHS officials:

- Coordinating response activities such as delivery of vaccines and antivirals, developing and implementing guidance on testing, and data gathering and disease surveillance among jurisdictional governments;
- Communicating information to jurisdictional governments about at-risk populations and the mode of transmission of the mpox virus;

[21]Expanded access is the use of investigational medical products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. See 21 U.S.C. § 360bbb(c) and 21 C.F.R. Part 312, Subpart I (2023). According to officials, the expanded access protocol for TPOXX was put in place prior to the mpox emergency, which allowed for access to the drug from the beginning of the outbreak.

At the time of the global mpox outbreak in 2022, there were no medical products approved for the treatment of mpox. TPOXX (also known as tecovirimat or ST-246) was approved for the treatment of smallpox.

[22]The Disaster Leadership Group hosted daily meetings and brought together leadership from across the federal government.

- Sharing information and creating opportunities for feedback (e.g., listening sessions) with key partner groups;[23]
- Acquiring, distributing, and facilitating access to medical countermeasures in the Strategic National Stockpile, including vaccines and antivirals to jurisdictional governments;[24]
- Supporting the deployment of jurisdictional and federal emergency workers; and
- Collecting, analyzing, and disseminating data about the number of mpox cases and administration of vaccines, and conducting surveillance activities using these data.

HHS's mpox response was conducted through multiple HHS component agencies including ASPR, CDC, FDA, NIH, IHS, and HRSA. See figure 1 for selected mpox response activities conducted by HHS component agencies in five key areas of public health emergency response.

[23]ASPR officials conducted joint calls with CDC and other stakeholder groups, including the Association of State and Territorial Health Officials and the Council of State and Territorial Epidemiologists about communications and messaging. According to officials, ASPR's regional staff located in all 10 FEMA regions collaborated with state and local health officials before, during, and after the emergency.

[24]According to officials, NIH also supports and conducts biomedical research for the development and clinical evaluation of medical countermeasures for orthopoxviruses including smallpox and mpox.

Figure 1: Selected Mpox Response Activities by HHS Component Agencies in Five Key Areas of Public Health Emergency Response

Response activities	Administration for Strategic Preparedness and Response (ASPR)	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)[b]	National Institutes of Health (NIH)[c]	Indian Health Services (IHS)	Health Resources and Services Administration (HRSA)[d]
Communicating information to jurisdictions about at-risk populations and the mode of transmission of virus	●	●	—	—	●	●
Coordination of response activities among federal entities and jurisdictions[a]	●	●	—	—	●	—
Acquiring, distributing, and facilitating the availability of vaccines, anti-viral medications, and issuing guidance on mpox testing	●	●	●	●	●	●
Deployment of local and federal PHE workers and providing funding to jurisdictions	—	●	—	—	—	—
Collecting, analyzing, and disseminating data about mpox cases and conducting surveillance activities	—	●	—	—	●	—

● Includes a role in a part of, or all of a response activity.

— No role in a response activity.

Source: Department of Health and Human Services. | GAO-24-106276

[a]From May 18, 2022, through August 2, 2022, ASPR, within the Department of Health and Human Services (HHS) was responsible for coordinating the federal public health and medical response to the mpox outbreak. On July 23, 2022, the World Health Organization declared mpox a public health emergency of international concern. In August 2022, the Secretary of Health and Human Services declared mpox a public health emergency, and the White House set up a response team to coordinate and manage the federal mpox response across the White House and all federal departments and agencies.

[b]According to officials, FDA issued guidance and regulatory decisions on the safety and effectiveness of vaccines, drugs, and devices intended for prevention, treatment, or diagnosis of mpox, reviewed mpox tests to determine if they met criteria to receive emergency use authorizations, and supported test developers.

[c]According to officials, NIH's role in the distribution of vaccine and anti-viral medications was limited to those vaccines and treatments distributed through clinical trials conducted or supported by NIH.

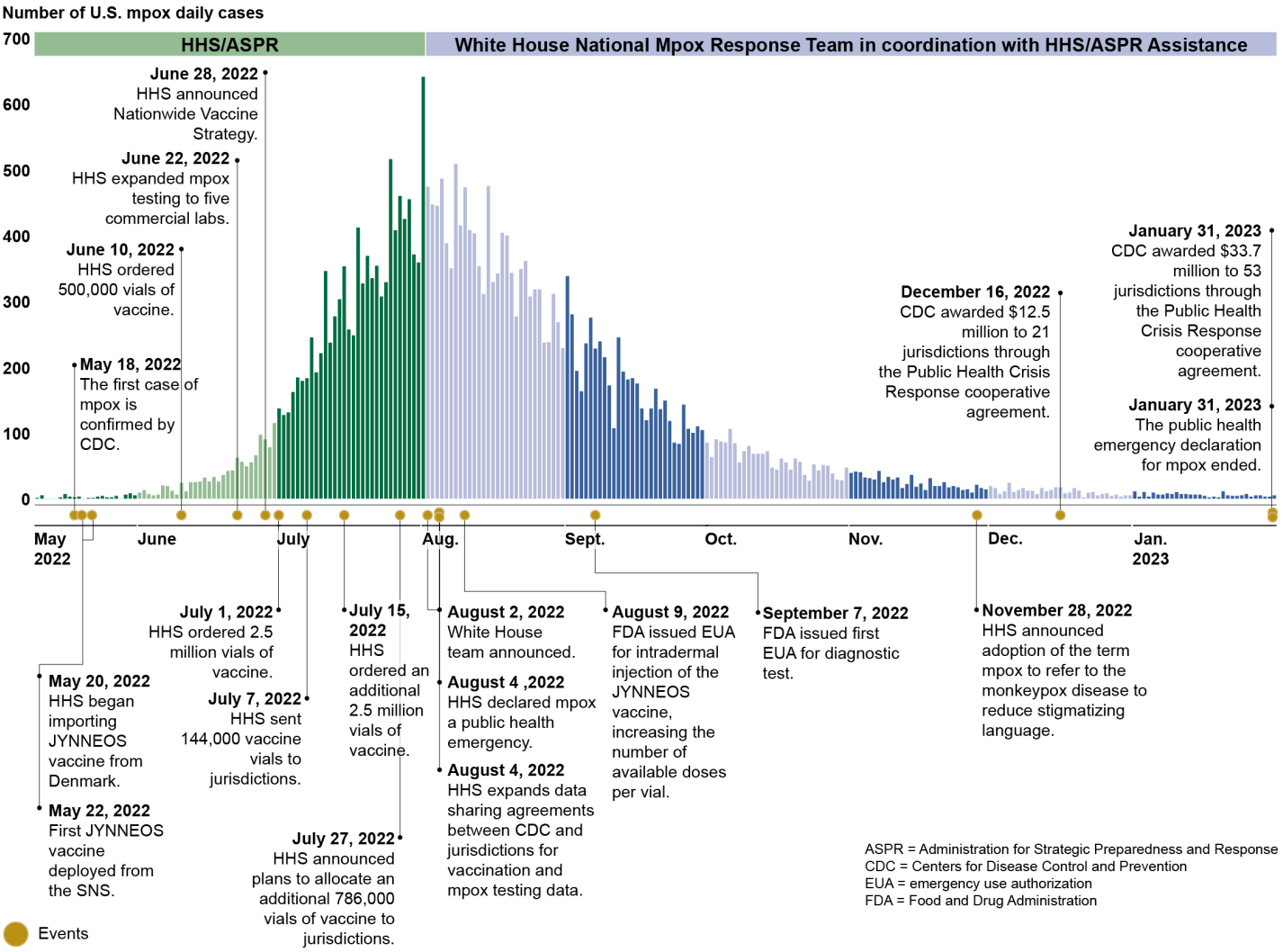
[d]During the course of the mpox outbreak, one of the approaches taken by HHS was to prioritize men who have sex with men to receive mpox vaccines. According to ASPR officials, HRSA was allocated vaccine to reach low-income people with human immunodeficiency virus via the Ryan White HIV/AIDS Program sites. HRSA permitted health centers to use existing HRSA grant funding to support mpox testing and treatment, and vaccine administration cost for uninsured patients.

A White House Team Assumed Leadership of the Federal Response during the Peak of the Mpox Outbreak

In August 2022, with rapid transmission of mpox in the U.S. (peaking in August 2022), the Secretary of Health and Human Services declared mpox a public health emergency, and a White House team was established to coordinate and manage the response. According to a White House press release, the White House team assumed leadership of the federal response to further accelerate and strengthen the mpox response through equitably increasing the availability of tests, vaccinations, and treatments at that point in time.

Moreover, according to the White House team, the mpox response required a level of coordination above any one department, and having the White House team involved was critical for this coordination. The President selected officials from FEMA and CDC to serve as the coordinator and deputy coordinator, respectively, of the White House team. The team led the response from that point forward, according to the White House team. (See Figure 2 for details on the timeline of selected federal mpox response activities and the daily number of national mpox cases.) According to HHS officials, after the White House team assumed leadership of the federal response, ASPR continued to execute its role as the lead for the public health and medical services response under the National Response Framework.

Figure 2: Timeline of Selected Federal Mpox Response Activities and Daily Number of Mpox Infections, May 2022 through January 2023[a]



Source: GAO analysis of Department of Health and Human Services (HHS) information. | GAO-24-106276

[a]The decline in daily mpox cases was likely due to a variety of factors that may have included but not limited to the establishment of the White House National Mpox Response Team.

The Secretary's declaration of a public health emergency provided for more capabilities to accelerate and strengthen overall government response efforts to meet the rapid transmission of mpox in the U.S., according to HHS press releases. For example, according to CDC officials, a few jurisdictions were reluctant to share data and required that there be a federal emergency declaration in place before they would sign

data use agreements with CDC and share data related to vaccinations and mpox testing with CDC.[25] These agreements provided CDC with more complete data from jurisdictions needed to track the spread and treatment of mpox.

After the White House team assumed leadership of the mpox response, HHS announced additional actions. For example:

- In coordination with the White House, the Secretary of Health and Human Services declared on August 9, 2022, that circumstances existed justifying the authorization of emergency use of intradermal vaccines. Subsequently, FDA issued an emergency use authorization allowing intradermal injection of the JYNNEOS vaccine in individuals ages 18 years and older at high risk of infection.[26] This had the effect of increasing vaccine dose availability.[27] FDA also authorized JYNNEOS for subcutaneous injection in individuals younger than 18 years of age at high risk of infection.

- In addition, on September 7, 2022, the Secretary declared that circumstances existed justifying the authorization of emergency use of *in vitro* diagnostic tests for mpox.[28] As of March 2024, FDA had authorized eight diagnostic tests for the detection and diagnosis of mpox infection.

[25]Although the public health emergency declaration was not needed to provide CDC authority to collect these data, CDC officials explained that it provided necessary justification to certain jurisdictions to share the data with CDC. Officials noted that CDC was collecting mpox data from the majority of jurisdictions before the public health emergency declaration.

[26]FDA may issue an emergency use authorization to temporarily allow the use of an unapproved medical product, or the unapproved use of an approved product, provided certain statutory criteria are met. For example, it must be reasonable to believe that the product may be effective and that the known and potential benefits of the product outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3.

[27]Intradermal injection of JYNNEOS requires a 0.1mL dose, whereas subcutaneous injection requires a 0.5mL dose.

[28]*In vitro* diagnostic tests are performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick.

HHS's Initial Mpox Response Presented Challenges Similar to Prior Public Health Emergencies

Jurisdictional officials and other stakeholders we interviewed described challenges with HHS's initial response to the mpox outbreak in areas aligned with those we have identified in our high-risk designation as key to an effective response. These key areas included communication; leadership and coordination; obtaining and deploying medical countermeasures; funding and workforce capacity; and data collection, reporting, and disease surveillance.

These challenges were also similar to those HHS identified in six after-action reports and other internal reviews from past public health emergencies between 2009 and 2022.[29] According to officials from several jurisdictions we interviewed, coordination and execution of the federal response to the mpox outbreak improved once the White House team took the lead.

Communication

HHS did not effectively communicate to the public the significantly increased risk of mpox for certain individuals during the initial stages of the outbreak, according to some jurisdictional officials we interviewed. Some officials said CDC's risk communication at the beginning of the mpox outbreak did not clearly identify the individuals who were most at-risk for mpox (men who have sex with men) and the most common mode of transmission (sexual contact). This information would have allowed such individuals to take preventative steps, according to one stakeholder we interviewed. Conversely, some individuals were at a very low risk for mpox, such as school- and day-care-aged children. Some parents of such children were unduly concerned because they did not know that young children were at a very low risk for mpox and were not part of the most at-risk group, according to officials from one jurisdiction.

CDC officials told us that early in the outbreak, the agency acted based on the information that was available at the time. CDC noted that the agency's earliest risk communications did include information on men who have sex with men and sexual contact. Moreover, when jurisdictions asked them about the risk to school children, CDC officials told us they were transparent and communicated the epidemiological information on that risk and other risks that was available at the time.

[29]We reviewed six HHS after-action reports and other internal reviews from past public health emergencies between 2009 and 2022 and identified similar lessons learned that HHS has identified across multiple emergencies.

Two-Spirit Populations

According to the Indian Health Service, the term "two-spirit" does not simply mean someone who is an Indigenous person from North America identifying as gay. However, two-spirit individuals may be included in the umbrella of LGBTQ. Traditionally, American Indian/Alaska Native two-spirit people are individuals who combine activities of both men and women with traits unique to their status as two-spirit people.

Source: Indian Health Service. | GAO-24-106276

Additionally, some stakeholders raised concerns about the inclusiveness of HHS's mpox communication. A stakeholder group representing tribal governments said CDC's risk communication was not adapted for tribal communities, and that additional cultural sensitivity was needed. For example, CDC messaging directed to men who have sex with men may not have been appropriate for two-spirit individuals. (See box, left.) CDC officials agreed that risk communication should be inclusive, and based on data that are available. They added that improvement in data collection and analysis during a response would likely result in improved risk communication.

According to officials, CDC initiated webinars and emails immediately after the first case of mpox was identified in May 2022, and external communications clearly stated what the agency knew, including that men who have sex with men were at greater risk for mpox. They described a number of additional mpox communication activities.[30] These included the release of a Health Alert Network memo on May 20, 2022. CDC began holding routine calls for clinicians and other partners on May 24, 2022. In addition, according to officials, CDC published a fact sheet for the public, which described the potential for mpox transmission through intimate and sexual contact, and that CDC disseminated the fact sheet to jurisdictional health departments and community partners.

CDC tailored communications to avoid stigma and discrimination among affected audiences, according to officials. Several jurisdictional officials we spoke with acknowledged the challenge both they and federal officials faced in providing accurate risk communication to the communities at highest risk of mpox without stigmatizing them. They also said risk communication improved as HHS incorporated community input.

One jurisdiction and one stakeholder group noted challenges with translation of CDC materials. For example, one jurisdiction said materials excluded individuals who needed certain translations, such as in indigenous languages from South American or West African countries. Officials from the jurisdiction said questions on case identification forms regarding sexual orientation and gender identity were sometimes hard to translate because some languages do not include equivalent terms. This

[30]According to CDC officials, within a week of the first mpox case CDC issued a press release, launched a webpage specifically for mpox, held calls with global public health partners, and conducted outreach to national organizations including national LGBTQ+ organizations and key opinion leaders.

could have affected the way patient demographic data was entered on those forms.

These communication challenges are similar to those we identified in past work leading, in part, to our decision to place HHS's leadership and coordination of public health emergencies on our High-Risk List. For example, we reported on communication concerns throughout the COVID-19 pandemic. To illustrate, in June and September 2020 we reported that uncoordinated communication between the federal government and jurisdictions, and with providers and the general public, could contribute to confusion and frustration.[31] We found other communication problems with the 2016 Zika and 2009 H1N1 responses.[32] In the midst of a public health emergency, clear and consistent communication—among all levels of government, with health care providers, and to the public—is paramount.[33] As such, we have made recommendations over the years aimed at improving communication, some of which HHS agreed with and is working to implement.

Further, an independent panel convened by HHS on its 2014 Ebola response also cited challenges with communication. It recommended that HHS clarify its strategy for communicating risk-related information to the public, Congress, and other key stakeholders during responses to urgent public health threats.[34]

Leadership and Coordination

Because the mpox response was spread across multiple HHS component agencies, there did not appear to be a central point of coordination until the White House team was stood up, according to several jurisdictional officials we interviewed, potentially slowing the response. For example, officials from several jurisdictions talked about challenges working with

[31]GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625 (Washington, D.C., June 25, 2020); and *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, GAO-20-701 (Washington, D.C., Sept. 21, 2020).

[32]GAO, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, GAO-17-445 (Washington, D.C., May 23, 2017), and GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C., June 27, 2011).

[33]GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO-22-105291 (Washington, D.C.: Jan. 27, 2022); GAO-20-625; and GAO-20-701.

[34]Fielding, J., Allen, T., Chu, B., *et al.*, *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response*, June 2016.

CDC and ASPR, and said the two agencies regularly directed questions or requests from jurisdictions to the other agency. HHS could have responded to questions and requests from jurisdictions more quickly had there been increased coordination across all HHS agencies.

Officials from some jurisdictions emphasized the importance of coordinating with Black, Latinx/Hispanic, and LGBTQ populations, as the outbreak disproportionately affected those communities. For example, one jurisdiction said that early in the outbreak HHS did not use trusted messengers that represent the communities disproportionately affected as effectively as possible.

According to HHS officials, HHS's response was centrally coordinated by ASPR for certain response activities. For example, early in the response, ASPR coordinated with interagency and jurisdictional partners, specifically in its efforts to procure and distribute vaccines to jurisdictions.

Several jurisdictional officials emphasized that leadership and coordination improved once the White House team was stood up. Several jurisdictions and stakeholder groups we spoke with noted that the White House team included trusted leaders from the LGBTQ community. This intentional staffing improved coordination because it allowed trusted leadership to facilitate often difficult and complex conversations and communicate decisions to public and private stakeholders across government, academia, industry, and affected communities, according to the White House team.

We have found it is key in emergencies to establish clear roles and responsibilities for the wide range of key federal, jurisdictional, and nongovernmental partners. We have found in numerous instances that HHS's public health emergency response has not done this. For example, in 2022, we recommended that HHS prioritize the development of a public health situational awareness network by designating a lead operating division and clearly defining the division's roles and responsibilities to ensure that HHS and the federal government have the comprehensive capabilities needed to allow for a timely response to infectious disease outbreaks. These recommendations remained open as of February 2023.[35]

[35]GAO, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network,* GAO-22-104600 (Washington, D.C.: June 23, 2022).

Moreover, in its after-action report for the 2016 Zika emergency response, CDC found no consistent, centralized role or system to coordinate and track engagement and communication with various partners. The agency noted that one was needed, as the absence of such clear central points of communication sometimes prevented timely information exchange and response.[36]

Obtaining and Deploying Medical Countermeasures

Many individuals in need of medical countermeasures (such as vaccines, tests, and antivirals) did not receive them promptly in the initial mpox response, according to jurisdictional officials and stakeholders.

Vaccines. Limited vaccine supply and other logistical barriers initially prevented many individuals that wanted to be vaccinated from being vaccinated, according to most jurisdictions and stakeholder groups we spoke with. For example:

- Officials from several jurisdictions noted that early in the response, limited vaccination appointments filled so quickly that individuals who were working or otherwise unable to access technology during the times appointments were available online were not able to book appointments. These officials said this limited availability led to inequitable outcomes, as the most connected, mobile, and resourced communities were able to get vaccinated first. Officials from some jurisdictions told us they were not able to provide individuals with their second dose of vaccines at the recommended 4-week interval due to limited supply.[37]

  HHS provided vaccines to jurisdictions in phases. According to HHS, jurisdictions were instructed to use doses made available in the first phase immediately. HHS published guidance in early July 2022 that reminded jurisdictions that providers would be responsible for managing inventory in the second phase to ensure availability of second doses for individuals vaccinated in both the first and second phase.[38] However, officials from several jurisdictions told us there was

[36]Centers for Disease Control and Prevention, *2016 Zika Virus Response: CDC After-Action Report/Improvement Plan*, Dec. 22, 2017.

[37]The JYNNEOS vaccine is licensed and available under an emergency use authorization as a series of two doses administered 4 weeks apart. CDC recommends a 4-week interval between the first and second doses.

[38]HHS officials told us that early in the mpox response, stakeholders, and public health partners requested that HHS make vials of the JYNNEOS vaccine available to jurisdictions and not “hold back” inventory to supply second doses.

not sufficient inventory to both meet demand for first doses and provide second doses at the recommended intervals.

- Officials from several jurisdictions told us intradermal administration of vaccines was challenging because ancillary supplies, such as specific syringes and needles required for this route of administration, were not provided with the vaccines. According to HHS officials, HHS did not have the capacity or mechanism to provide ancillary supplies. However, according to HHS officials, jurisdictions may have expected to receive such supplies because ASPR distributed COVID-19 vaccine ancillary supplies to states during the COVID-19 response. In the case of mpox, however, the Strategic National Stockpile provided technical assistance to jurisdictions that requested ancillary supplies, according to HHS officials.

Access to vaccines improved after FDA authorized the JYNNEOS vaccine for intradermal administration, according to some jurisdictional officials. The limited quantities of JYNNEOS vaccine in the Strategic National Stockpile were intended to be used in response to a national security incident, such as a bioterrorist attack, or for certain high-risk individuals, according to HHS officials. HHS told us that this contributed to delays in the deployment of the JYNNEOS vaccine, for the mpox response, as there was initially limited readily accessible supply. HHS officials also stated that some of the local challenges with vaccine access were the result of "mismanagement" that occurred at the local level in jurisdictions. HHS officials cited examples of local jurisdictions using pre-positioned vaccines in a manner that conflicted with HHS vaccine guidelines.

Diagnostic testing. Mpox diagnostic testing was challenging early in the mpox response due to administrative hurdles, according to most jurisdictional officials.[39] According to HHS officials, there was also a lack of access to adequate testing capacity in some areas. Sufficient testing is required to obtain an accurate understanding of disease trends and to treat cases. According to HHS officials, at the start of the mpox outbreak, the U.S. already had testing capacity with a specific CDC developed test. The CDC test kit was originally cleared by FDA prior to the 2022 outbreak. Officials told us this was sufficient to meet testing needs during the early stages of the mpox outbreak. According to officials, although

[39]Initially, testing was only available through Laboratory Response Network labs, and specimens had to also be sent to CDC for confirmatory testing. This required providers to collect two samples from multiple lesions for both the Laboratory Response Network lab and CDC.

national testing capacity in June 2022 exceeded the national mpox testing demand overall, access to testing in some areas was challenging, leading CDC and FDA to take action to increase access to diagnostic testing nationally through commercial labs. This greatly expanded capacity and alleviated testing shortages. FDA also worked with CDC throughout the outbreak to update the CDC test kit to increase testing capacity. In addition, the availability of laboratory developed tests—diagnostic tests designed, manufactured, and used in a single lab—added to testing capacity according to HHS.[40]

Antivirals. Initially, it was very challenging to prescribe antivirals for mpox due to the amount of paperwork required, according to most jurisdictional officials. For example, the expanded access protocol for TPOXX required providers and affiliated facilities to register as participating providers/sites with CDC to prescribe TPOXX. To dispense TPOXX, providers had to fill out a patient intake form, among other forms, for each patient.

The volume of paperwork sometimes led to submission of incomplete information or served as a barrier to providing care to mpox patients, according to one jurisdiction. Following the receipt of provider input, CDC, in partnership with FDA, reduced the number of forms to two forms totaling six pages, which helped reduce the administrative burden on providers prescribing TPOXX, according to HHS officials.

We have previously reported that HHS experienced similar challenges setting and meeting expectations about the availability of medical countermeasures during prior public health emergencies. For example:

- In April 2021, we reported that some stakeholders said states often did not have information critical to COVID-19 vaccine distribution at the local level, such as how many doses they would receive and when.[41] We re-emphasized our recommendation from a September 2020 report that HHS, along with the Department of Defense, should establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccines, including an

[40]According to agency guidance, FDA is exercising its enforcement discretion with respect to certain laboratory developed test for mpox—that is, FDA does not intend to object to laboratories' use of these tests before the agency has cleared or authorized them. See FDA, *Policy for Monkeypox [mpox] Tests to Address the Public Health Emergency*, FDA-2022-D-1908 (Sept. 7, 2022).

[41]GAO, *COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation*, GAO-21-443 (Washington, D.C.: Apr. 14, 2021).

approach for coordinating across federal agencies and nonfederal entities. This recommendation was not implemented but was closed in April 2022 because the time frame for its implementation had passed, due to widespread distribution and administration of COVID-19 vaccines.

- In June 2011, we reported that the credibility of all levels of government was diminished when the initial supply of the H1N1 vaccine available during the 2009 H1N1 pandemic did not meet expectations HHS conveyed to the public.[42] Moreover, in its own review of the H1N1 pandemic response, HHS found it should develop a process to provide transparent and realistic vaccine output range projections, in conjunction with vaccine manufacturers, for federal officials, vaccine planners in jurisdictions, and the public.[43]

In our past work, we have found that setting the right expectations and meeting them during a public health emergency is important to build public trust.

Funding and Workforce Capacity

Most jurisdictions told us they did not have adequate funding or staff capacity to respond to the mpox emergency. The Secretary of Health and Human Services may take a number of actions involving funding and staffing to support jurisdictions during a public health emergency. These actions include using several funding sources to respond to immediate needs that may arise, making temporary appointments of personnel, and authorizing temporary reassignment of federally funded jurisdiction staff to assist with a response. HHS officials noted that such actions are dependent on jurisdictions issuing a request for assistance, and that jurisdictions are aware of the request process for accessing and utilizing these authorities.

Some federal awards came to jurisdictions 4 to 5 months after the peak in mpox infections. For example, CDC awarded funds to jurisdictional partners in December 2022 and January 2023 to aid in the mpox response through its Public Health Crisis Response Cooperative

[42]GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C.: June 27, 2011).

[43]HHS, *2009 H1N1 Influenza Improvement Plan,* May 29, 2012.

Agreement.[44] Several jurisdictional officials said this timing inhibited immediate response.

Some jurisdictional officials also said they were initially unable to use existing funds awarded for COVID-19 response activities for mpox response activities. However, once the public health emergency was declared in August 2022, jurisdictions were notified that they could use funds initially awarded for COVID-19 in limited situations if the mpox response activities were also delivered in conjunction with COVID-19 response activities.

Most jurisdictional officials and stakeholder groups said that they initially did not have access to sufficient federal support for the necessary workforce and supplies for the mpox response. Moreover, some of these officials said they initially had to shift staff from other local health programs, such as those for responding to outbreaks of sexually transmitted infections, to respond to mpox, which put a strain on the other health programs.

We previously reported that HHS officials described challenges funding immediate needs during public health emergencies.[45] Officials told us that redirecting funds may be subject to limitations and may affect other programs, and funding for some immediate needs may be insufficient or restricted. We also reported on challenges building a public health workforce with temporary funding and supplemental appropriations as well as challenges in ensuring the availability of a sufficient public health workforce, due to burnout and other factors.

Jurisdictions are key partners in preparing for and responding to public health threats. The workforce and funding challenges they face can impact how quickly and effectively HHS and other response partners are able to contain infectious disease threats, as was demonstrated during the COVID-19 pandemic. In our past work we found that it is important to

[44]CDC established the Public Health Crisis Response Cooperative Agreement in October 2017. This cooperative agreement is designed to support the surge needs of existing state, local, tribal, and territorial public health programs responding to a significant public health emergency. Through this funding mechanism, CDC establishes an “approved but unfunded” roster of recipients that submit timely funding applications in response to a notice of funding opportunity.

[45]GAO, *Public Health Preparedness: Building and Maintaining Infrastructure beyond the COVID-19 Pandemic*, GAO-24-105891 (Washington, D.C.: Nov 7, 2023). GAO, *Public Health Preparedness: HHS Reserve Funding for Emergencies*, GAO-23-106102 (Washington, D.C.: Aug. 15, 2023).

understand key partners' capabilities and limitations. Through its role leading and coordinating the medical response under the National Response Framework, HHS is responsible for assisting jurisdictional governments when they need help during public health emergencies.[46] It is important for ASPR, the entity that leads HHS's public health emergency response efforts, to understand these jurisdictional capabilities and their limitations and incorporate this information in its emergency preparedness and response efforts.

Further, in its own review of the H1N1 emergency, HHS found a need to quickly increase federal and jurisdictional staffing levels during an emergency and provide respite opportunities to staff.[47]

Data Collection, Reporting, and Disease Surveillance

Most jurisdictional officials we spoke with described challenges reporting and submitting data to CDC. For example, several jurisdictional officials said that early in the response they had to manually upload case report data, which was time intensive. In July 2022, CDC provided jurisdictions with a means for bulk upload of case report data, helping to expedite data-sharing from jurisdictions to CDC, according to CDC officials.

Furthermore, CDC's data systems for disease surveillance could be better integrated, which would help support more efficient reporting and submission of data, according to some jurisdictional officials. For example, one jurisdiction said that there is a need for investments to ensure that CDC's data systems allow for the integration of electronic health and lab records, as well as efficient data transfer from state health departments.

HHS officials noted that CDC is leading a Data Modernization Initiative aimed at modernizing public health data systems and infrastructure. This initiative encompasses various projects intended to enhance data collection, streamline data exchange, improve data management, strengthen data analysis, and broaden infrastructure of public health data systems.

However, according to officials, HHS has yet to establish a formal national public health situational awareness network with a standardized data format to ensure that information can be consistently reported,

[46]Federal Emergency Management Administration, *National Response Framework, Fourth Edition*. (Washington, D.C.: October 2019).

[47]HHS, *2009 H1N1 Influenza Improvement Plan,* May 29, 2012.

compared, and analyzed across jurisdictions, though it has been required by federal law for more than 15 years.[48] This network was intended to provide secure, near real-time information to facilitate early detection of and rapid response to infectious diseases.

The federal government still lacks this needed network and has not yet overcome the challenges identified in previous GAO reviews. Having near real-time access to these data could significantly improve our nation's preparedness for public health emergencies and potentially save lives. We have found that, without it, HHS has relied on incomplete and inconsistent data during multiple public health emergencies.[49] In 2022, we recommended that CDC define specific action steps and time frames for the agency's data modernization efforts.[50] However, as of April 2023, CDC had only partially addressed this recommendation. While CDC has identified a 2-year time frame to implement a Public Health Data Strategy, it has not defined when it will meet specific milestones within that time frame. In addition, while CDC's strategy outlines broad actions it plans to take, it does not define the specific steps needed to achieve these actions.

Our past work has shown that it is key to a public health emergency response to collect and analyze complete and consistent data to inform decision-making—including any necessary midcourse changes, as well as future preparedness. We have previously raised concerns about CDC's ability to quickly collect and analyze complete and consistent data to gain a national picture. Furthermore, we have found that development of an integrated situational awareness network could enable quicker identification of emerging disease trends and patterns during the course of public health emergencies.

Further, HHS identified similar challenges and has made related recommendations in past after-action reports. For example, in its after-action report on the 2016 Zika response, CDC identified the need for rapid development of data transfer agreements. These agreements

[48]See Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, § 202, 120 Stat. 2831, 2845-48 (2006) (codified as amended at 42 U.S.C. § 247d-4).

[49]GAO, COVID-19: *Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO-22-105291 (Washington, D.C.: Jan 27, 2022).

[50]GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments*, GAO-22-105397 (Washington, D.C.: Apr 27, 2022).

outline data use and sharing expectations between reporting entities and CDC, and more rapid development would allow jurisdictional partners to share health data more quickly with CDC during a public health emergency or outbreak.[51] In addition, in its review of the H1N1 response, HHS identified a need for expanded and automated clinical surveillance such as by improving the use of electronic health records.[52]

HHS Does Not Have a Coordinated, Department-Wide Approach Involving External Stakeholders to Identify and Resolve Past Challenges

HHS does not have a coordinated, department-wide approach to identify and resolve past challenges after a response. This has contributed to the recurrence of those challenges during the mpox emergency and raises concerns for HHS's ability to lead and respond to future emergencies. Moreover, existing efforts within HHS to identify and resolve past challenges do not always engage external stakeholders who have been part of response teams. Embracing a coordinated, department-wide approach could help HHS reduce the likelihood of repeating past mistakes by developing informed and comprehensive solutions.

HHS Does Not Have a Coordinated, Department-Wide After-Action Program

We found that there is no department-wide mechanism within HHS that coordinates the identification and resolution of challenges from past public health emergencies. Although HHS component agencies must coordinate during their response to these emergencies, they do not coordinate their efforts to learn from past emergencies to prepare for future ones. The lack of such a coordinated approach can lead to less effective piecemeal efforts to identify and resolve past challenges. This, in turn, can lead to challenges that are recurring, such as those HHS experienced during the recent mpox outbreak.

Of the six component agencies involved in public health emergency responses, three—ASPR, CDC, and FDA—carry out their own after-action programs to identify challenges from past public health emergencies. According to documents we reviewed and interviews with agency officials, each component agency works independently, focusing on its own ability to improve how it prepares for, and responds to, public

[51]CDC, *2016 Zika Virus Response: CDC After-Action Report/Improvement Plan*, Dec. 22, 2017.

[52]HHS, *2009 H1N1 Influenza Improvement Plan,* May 29, 2012.

health emergencies, without consideration of lessons learned at the HHS level.

- ASPR and CDC use their own internal processes to identify and implement solutions for issues found following an emergency response, including during the mpox response. Their internal processes include identifying and tracking the implementation of solutions.
- FDA follows its internal processes for identifying improvements and modifications but does not have a process for tracking the implementation of solutions, according to FDA officials.

Of the other three component agencies involved in public health emergency responses, HRSA has identified lessons learned related to the agency's COVID-19 vaccine program. According to agency officials, HRSA plans to develop a standard operating procedure to inform future responses. IHS officials stated that while the agency does not have an after-action program, it plans to develop one. Lastly, NIH participates in planning activities, such as the Testing and Diagnostics Working Group and the National Biodefense Strategy and Implementation Plan efforts, that include an emphasis on lessons learned from recent disease threats, according to its officials.

Coordination between the existing after-action programs with other HHS component agencies is rare. For example, the scope of ASPR's after-action program is limited to examining ASPR's ability to respond and does not extend to the abilities of other HHS component agencies, according to ASPR officials. According to these ASPR officials, if the root cause of a corrective action identified by ASPR is found to be within a different HHS component agency, ASPR might inform the other agency of the issue via a memo. However, officials noted that even this limited sharing is rare.

Over the course of our review, HHS officials stated that HHS does not have a coordinated, department-wide approach to identify and resolve past challenges. Instead, HHS component agencies might conduct after-action reviews, according to these officials, who noted that these voluntary efforts inform HHS's broader efforts to coordinate and respond effectively to any future public health emergency. In December 2023, HHS officials told us that HHS intends to develop a coordinated, department-wide approach to identify and resolve past challenges but has not yet done so due to resource constraints. HHS had not provided any documentation or other information on the development of a coordinated,

department-wide after-action program, including an outline of planned efforts or time frame for implementing its plan, as of December 2023.

HHS's fragmented approach to identifying lessons learned is part of a larger HHS approach to public health emergencies where multiple HHS component agencies are involved in the same areas of preparation and response, making coordination crucial. We have reported in past work that improved interagency coordination can help agencies better manage fragmented federal efforts and result in a more effective government.[53] For example, in August 2021, we recommended agencies work together to monitor the results of exercises designed to improve the government's response to biological threats.[54] We made this recommendation after we found such cross-government review of exercises and incidents lacking in ways that limited agencies' abilities to identify and address systemic challenges. Specifically, we found in that 2021 report, that the relevant agencies did not have the needed information to allow them to identify gaps and areas for improvement to ensure efficient and effective preparedness for nationally significant biological incidents.

Existing After-Action Efforts within HHS Do Not Always Include External Stakeholders When Identifying Solutions to Address Past Challenges

HHS's ability to learn from and apply lessons following an emergency response also is limited because component agencies' existing after-action programs do not always include all relevant stakeholders involved in public health emergency responses when identifying challenges and associated solutions. For example, ASPR's after-action program includes interviews with relevant jurisdictional partners when identifying challenges but not in identifying associated solutions. However, FDA's program includes only internal stakeholders in certain circumstances, according to agency officials. CDC's after-action program includes only interviews with its own staff on their experiences with external partners, according to CDC officials. CDC officials said that the agency plans to involve key external stakeholders beginning with the after-action process for the COVID-19 response and update its policy accordingly.

[53]GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO-22-105291 (Washington, D.C.: Jan. 27, 2022); GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*, GAO-23-105520. (Washington, D.C.: May 24, 2023).

[54]GAO, *Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*, GAO-21-513 (Washington, D.C.: Aug. 4, 2021).

We have found in past work that it is important to include relevant stakeholders when addressing crosscutting challenges such as preparing for and responding to nationally significant public health emergencies. The ability to address such challenges often requires collaboration across the government and private sector, and the inclusion of relevant stakeholders is one of eight leading practices for enhancing interagency collaboration.[55] Our past work also has identified inclusion of relevant stakeholders as (1) a key practice to help effectively implement federal evidence-building and performance-management activities, and as (2) critical for an effective agency strategic review.[56] This is particularly true for public health emergency responses that require a whole-of-nation, multidisciplinary approach involving multiple federal agencies and coordination with nonfederal entities.[57]

While challenges identified during the mpox response are complex, without greater inclusion of relevant external stakeholders as part of a coordinated, department-wide after-action program, HHS is limiting its ability to learn and implement solutions identified during past public health emergencies to improve future responses. The effectiveness of future responses would be particularly important should HHS be faced with leading and coordinating a federal public health and medical response to an infectious disease more virulent and lethal than mpox or COVID-19, for which no medical countermeasures exist, or to a disease intentionally introduced into the population by a bad actor.

HHS—as the designated lead for the federal public health and medical response to public health emergencies—is missing an opportunity to improve its preparedness for future threats and to potentially save lives, because it has not developed and implemented a coordinated, department-wide after-action program that

1. encourages collaboration between its component agencies, including integrating the existing public health emergency after-action programs of these component agencies; and

[55]GAO-23-105520.

[56]GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, GAO-23-105460 (Washington, D.C.: Jul 12, 2023) and GAO, *Managing for Results: Practices for Effective Agency Strategic Reviews*, GAO-15-602 (Washington, D.C.: Jul 29, 2015).

[57]GAO-22-105291.

2. includes relevant external stakeholders involved in each public health emergency response—such as other federal agencies as well as jurisdictional, and nongovernment partners—when identifying challenges and associated solutions.

Office of Pandemic Preparedness and Response Policy

The Consolidated Appropriations Act, 2023, included a provision establishing the Office of Pandemic Preparedness and Response Policy within the Executive Office of the President. In July 2023, the White House stood up the new office, which is charged with leading, coordinating, and implementing actions related to preparedness for, and response to, known and unknown biological threats or pathogens that could lead to a pandemic or to significant public health-related disruptions in the United States.

Source: Consolidated Appropriations Act, 2023, and White House Fact Sheet. | GAO-24-106276

Such an approach will also better position HHS to support the Office of Pandemic Preparedness and Response Policy established in July 2023. Congress charged this office with coordinating federal activities to prepare for, and respond to, pandemic and other biological threats, including overseeing the development of federal after-action reports following a response to a pandemic or other biological threat.[58] Congress also authorized other agencies to support the office with information the new office determines is necessary to carry out its functions.

In addition, although the new office will provide strategic policy direction and engage in other activities such as clarifying roles and responsibilities, HHS, through ASPR, will continue to be responsible for coordinating the public health and medical response across applicable departments and agencies, according to White House officials. ASPR officials also acknowledged the agency's continued leadership role and noted that ASPR and the new office will work together to share information, implement national strategies, and coordinate response to public health emergencies.

Conclusions

HHS experienced challenges in its initial response to the mpox outbreak that were similar to those we identified in past HHS public health emergency responses and that led us to designate HHS's leadership and coordination of public health emergencies as a high-risk area. The challenges were also similar to those that HHS component agencies had previously identified in six after-action reports and internal reviews from 2005 to 2022.

Although HHS has said it intends to develop a coordinated, department-wide after-action program, the department has not provided any information on the development of such a program, including an outline of planned efforts or a time frame for implementing its plan to develop such a program. Until such a program is established, HHS is missing an opportunity to improve its preparedness for future threats because it does not have a coordinated, department-wide after-action program that specifically

[58]42 U.S.C. § 300hh-3.

1. encourages collaboration between its component agencies, including integrating the existing public health emergency after-action programs of these component agencies; and
2. includes relevant external stakeholders involved in each public health emergency response—such as other federal agencies as well as jurisdiction, and nongovernment partners—when identifying challenges and associated solutions.

Implementing such a program would also present new opportunities for HHS to support the Office of Pandemic Preparedness and Response Policy's charge to better protect our homeland from pandemic and other biological threats, some potentially more lethal than what the nation has seen thus far.

Recommendations for Executive Action

We are making the following two recommendations to HHS:

The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that encourages collaboration between HHS's component agencies, including integrating the existing public health emergency after-action programs of these component agencies. (Recommendation 1)

The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that includes relevant external stakeholders involved in each public health emergency response—such as other federal agencies, jurisdictions, and nongovernmental partners—when identifying challenges and associated solutions. (Recommendation 2)

Agency Comments

We provided a draft copy of this report to the Department of Homeland Security and HHS for review and comment. The Department of Homeland Security had no comments.

HHS concurred with both recommendations and provided technical comments, which we incorporated as appropriate. HHS's comments are reproduced in appendix I. In its general comments, HHS stated that it takes its role as the designated lead for the federal public health and medical response to public health emergencies seriously and is committed to coordination across the department and with external partners and stakeholders to continue to strengthen future response efforts. As such, HHS states that the department is already taking steps to implement GAO's recommendations, by designating ASPR as the lead to ensure swift identification and resolution of lessons learned for public

health emergencies through a centralized after-action review process that will include relevant stakeholders.

We are sending copies of this report to appropriate congressional committees, the Secretaries of Health and Human Services and Homeland Security, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or Deniganmacauleym@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Mary Denigan-Macauley
Director, Health Care

Appendix I: Comments from the Department of Health and Human Services (HHS)

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

April 1, 2024

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"PUBLIC HEALTH PREPAREDNESS: Mpox Response Highlights Need for HHS to Address Recurring Challenges" (GAO-24-106276).**

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT – PUBLIC HEALTH PREPAREDNESS: MPOX RESPONSE HIGHLIGHTS NEED FOR HHS TO ADDRESS RECURRING CHALLENGES (GAO-24-106276)

The Department of Health and Human Services (HHS or Department) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS takes its role as the designated lead for the federal public health and medical response to public health emergencies (PHE) seriously and is committed to coordination across the Department and with external partners and stakeholders to continue to strengthen future response efforts. The Department is already implementing GAO's recommendations to ensure swift identification and resolution of PHE lessons learned through a centralized after-action review process.

GAO Recommendation 1
The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that encourages collaboration between HHS's component agencies, including integrating the existing public health emergency after-action programs of these component agencies.

HHS Response
HHS concurs with this recommendation.

Through the Administration for Strategic Preparedness and Response (ASPR), HHS is establishing a centralized and coordinated, department-wide after-action approach, which will identify and address lessons learned from PHEs and other emergency responses and exercises. Currently, and as noted in this report, individual HHS Operating Divisions (OpDivs) including ASPR, the Centers for Disease Control and Prevention, and the Food and Drug Administration, have their own after-action programs. However, ASPR centralizing these efforts will enhance the Department's existing collection and analysis of critical data to inform decision-making to continuously improve the response to future PHEs. HHS will provide GAO and Congress an update on these efforts when it transmits its formal statement of action six months after the final issuance of this report.

GAO Recommendation 2
The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that includes relevant external stakeholders involved in each public health emergency response—such as other federal agencies, jurisdictions, and nongovernmental partners—when identifying challenges and associated solutions.

HHS Response
HHS concurs with this recommendation.

Various HHS OpDivs gather after-action information from relevant federal, jurisdictional and nonprofit partners and include their input in preparedness planning. However, as part of the Department's ongoing efforts to establish a centralized and coordinated, department-wide after-action approach, HHS, through ASPR, will ensure relevant external stakeholders continue to be included throughout the planning and implementation process. HHS will provide GAO and Congress an update on specific actions undertaken when it transmits its formal statement of action six months after the final issuance of this report.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley, (202) 512-7114 or DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the contact named above, Thomas Conahan (Assistant Director), N. Rotimi Adebonojo (Analyst-in-Charge), Jennie Apter, Xiaoyi Huang, Christian Perez, Lillian Riehl Schultze, Kaitlin Farquharson, and Joy Grossman made key contributions to this report. Also contributing was Roxanna Sun.

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