STATE CAPITOL
P.O. BOX 942849
SACRAMENTO, CA 94249-0115

California Legislature

Senate Select Committee on Monkeypox

Briefing Paper and Summary Report – 8/9/22 Hearing

Introduction

Monkeypox is a viral disease caused by infection with the monkeypox virus. The disease's characteristic symptom is a rash with lesions that can be very painful. The monkeypox virus is an orthopoxvirus. Other orthopoxviruses include smallpox and cowpox. Monkeypox is significantly less severe than smallpox.[1] Contrary to its name's implication, while it is true that monkeys can be viral hosts, the most common natural monkeypox hosts are thought to be small rodents, such as various rat and squirrel species.[2] There are two genetic groups, or clades, of the virus – Clade I, the clade originating from the Congo Basin, and Clade II (composed of 2 subgroups, Clade IIa and IIb), originating from West Africa. Clade IIb consists of the group of strains circulating in the current global outbreak. Clade II strains are generally considered to be less severe and lethal than Clade I.[3][4] The monkeypox incubation period is typically 1-2 weeks, and the illness itself normally lasts 2-4 weeks. Early prodromal symptoms include fever, chills, and headache, among others. In the current outbreak, lesions often occur in the mouth, genital, and anorectal areas. Also in the current outbreak, only a few lesions or a single lesion may constitute the entire rash.

Monkeypox was first identified in animals in 1958, and in humans in 1970, respectively. Since then, it has primarily spread through Central and Western Africa, becoming endemic in those regions.[5] There has previously been a monkeypox outbreak, albeit a much smaller one, in the United States. In 2003, 47 confirmed and probable cases were reported in the Midwest. All cases were traced to contact with infected pet prairie dogs imported from Ghana. Since then, there have been a few isolated travel-associated monkeypox cases in the United States.[6]

[1] https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/smallpox-and-other-orthopoxvirus-associated-infections
[2] https://www.who.int/news-room/fact-sheets/detail/monkeypox
[3] https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html
[4] https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names
[5] https://www.who.int/news-room/fact-sheets/detail/monkeypox
[6] https://www.cdc.gov/poxvirus/monkeypox/outbreak/us-outbreaks.html

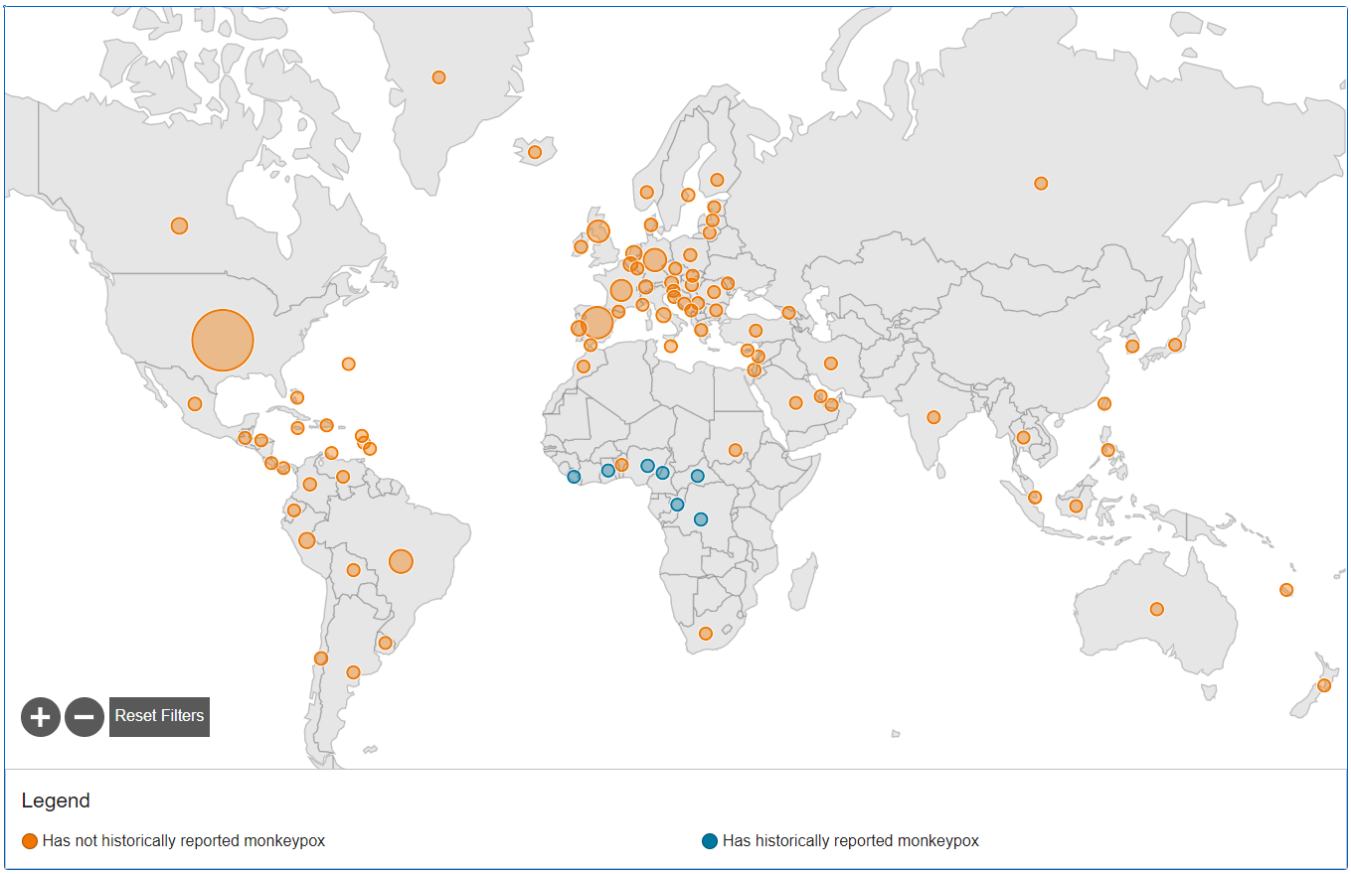

Figure 1: Global 2022 Monkeypox Outbreak Case Map: As of 8-22-22[7]

As of August 22, 2022, the current global monkeypox outbreak has seen 42,954 reported cases across 95 countries – most of which have not historically reported monkeypox cases. 9 countries have reported over 1,000 cases. The United States has reported 15,432 cases, the most of any country in the current outbreak.[8] There have been 12 deaths globally, and 0 deaths in the United States. California, with 2,663 reported cases, has seen the second-largest outbreak (based on reported cases), after New York, with 2,910 reported cases.[9] As of August 18, 2022, in California, there have been 62 hospitalizations. The majority of the cases have been reported in Los Angeles County (936 cases) and San Francisco county (614 cases). The vast majority of cases have been reported in gay and bisexual men, with white and latino men disproportionately constituting the infected individuals.[10]

[7] https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html
[8] Ibid
[9] https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html
[10] https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Monkeypox-Data.aspx

After persistent advocacy by numerous elected officials, the LGBTQ+ community, the medical community, and others, multiple local jurisdictions, the state of California and eventually, the federal government – issued declarations of emergency related to monkeypox. San Francisco declared a state of emergency on July 28th, 2022, followed by Los Angeles County and the State of California on August 1, 2022, and the federal government on August 4th, 2022.[11][12][13][14]

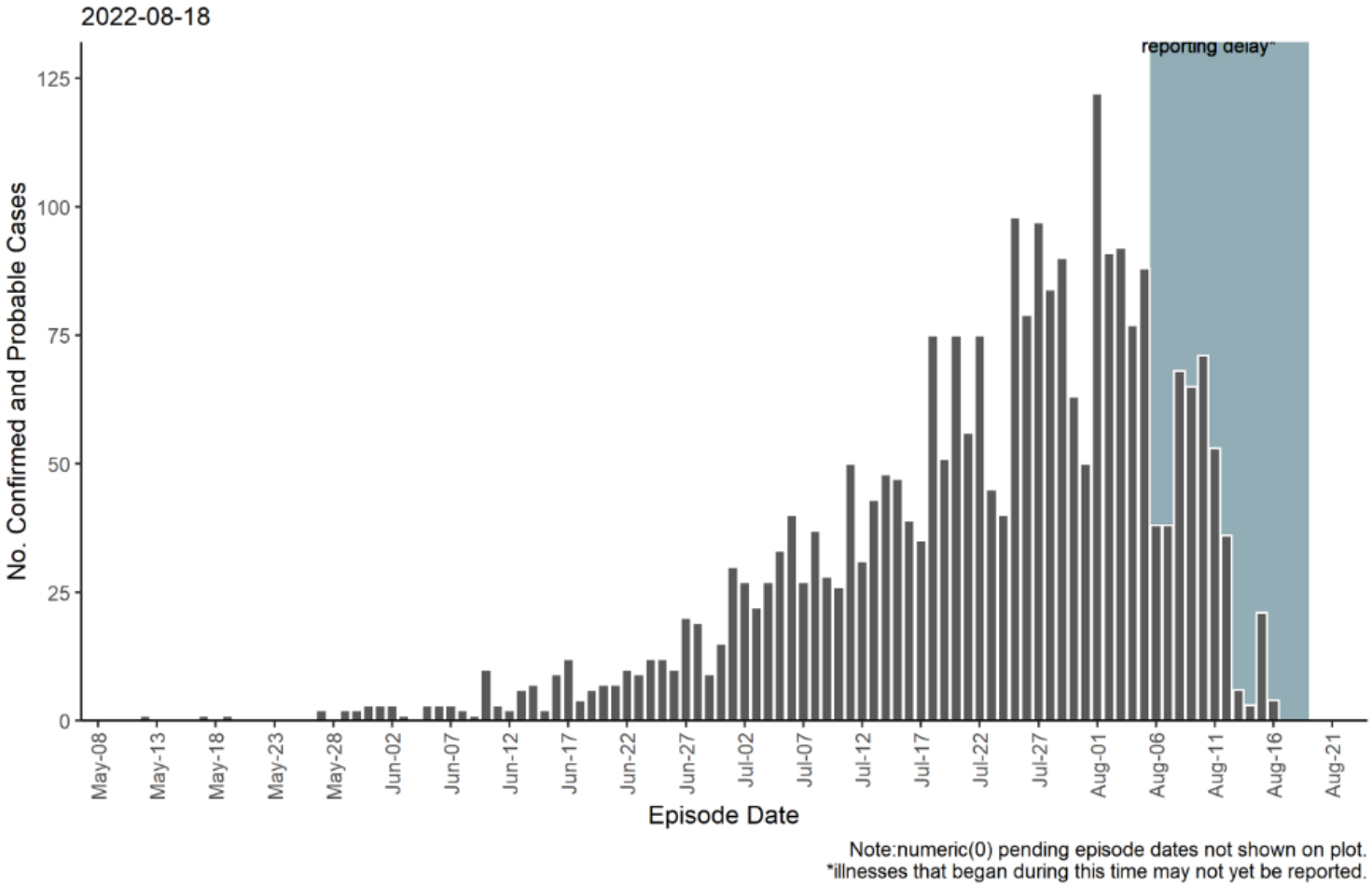

Figure 2: Monkeypox case by episode date - As of 8-18-22. "Episode date" refers to the date the event is estimated to have taken place.[15]

[11] https://sfmayor.org/article/san-francisco-declare-local-public-health-emergency-monkeypox
[12] https://www.dailynews.com/2022/08/02/mitchell-declares-la-county-state-of-emergency-for-monkeypox/
[13] https://www.gov.ca.gov/2022/08/01/74502/
[14] https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html
[15] https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Monkeypox-Data.aspx

Transmission

Monkeypox can be transmitted through close, skin-to-skin contact. This primarily includes direct contact with monkeypox rash, scabs, or body fluids from a person with monkeypox. Direct contact with someone with monkeypox can happen through intimate contact, such as oral, anal, and vaginal sex, touching the genitals, hugging, or kissing. While indirect contact with someone with monkeypox via shared surfaces such as towels and bedding can also result in transmission, indirect contact is much less likely to result in infection. Monkeypox can also spread through contact with respiratory secretions.[16]

Testing

Currently, the only FDA-approved monkeypox test is the CDC Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set. The FDA advises specimens to be collected by swabbing directly from a lesion, and says that using blood or saliva samples may result in false test results.[17] Testing capacity has been increased beyond the capacity of the public health Laboratory Response Network (LRN) by equipping commercial laboratory companies such as Labcorp and Quest Diagnostics with the approved test kits.[18] At least one small study has detected monkeypox viral DNA in saliva, semen, and other clinical samples, suggesting that testing could be made more widely accessible if a new sampling method is approved by the FDA.[19] Research universities such as Stanford University are working with philanthropic partners, life science companies, and other research universities to identify monkeypox and other pathogens such as Covid-19 at wastewater treatment plants across the country.[20] The early wastewater detection effort, called WastewaterSCAN, detects pathogens before conventional testing indicates that a pathogen is circulating in the population.[21]

Treatment

While most people with monkeypox have relatively mild symptoms and recover within 2-4 weeks, there is currently no FDA-approved treatment for monkeypox, and thus no over-the-counter medication that can be prescribed to specifically address more severe cases of the disease. Since monkeypox and smallpox are genetically similar, an antiviral called tecovirimat (TPOXX), approved to treat smallpox, has been recommended for immunocompromised individuals or individuals experiencing severe symptoms.[22] TPOXX is only available to treat monkeypox and other orthopoxviruses aside from smallpox through an Expanded Access Investigational New Drug (EA-IND) process.[23] In order to access the drug (only available from the Strategic National Stockpile), physicians must fill out the forms in the protocol (recently streamlined from 21 pages), provide follow-up information per patient, and provide other documentation.[24] While the CDC streamlining has helped reduce barriers to accessing TPOXX, the process has still been noted to take hours per patient, making it difficult for those with severe monkeypox symptoms to access the antiviral and obtain relief.

---

[16] https://www.cdc.gov/poxvirus/monkeypox/transmission.html
[17] https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response#:~:text=Q%3A%20Is%20there%20a%20saliva,lesion%20(rash%20or%20growth).
[18] https://www.hhs.gov/about/news/2022/06/22/hhs-expanding-monkeypox-testing-capacity-five-commercial-laboratory-companies.html
[19] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2022.27.28.2200503
[20] https://news.stanford.edu/2022/08/05/wastewaterscan-will-monitor-wastewater-covid-19-monkeypox-diseases/
[21] https://wastewaterscan.org/
[22] https://www.cdc.gov/poxvirus/monkeypox/treatment.html
[23] https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
[24] https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

Information regarding the efficacy of TPOXX for monkeypox in humans is mostly limited to case studies, including a case series that included one individual who received TPOXX and "…had a shorter duration of viral shedding and illness (10 days hospitalisation [sic]) compared with the other six patients."[25] In addition to this limited human data, animal studies of TPOXX have illustrated efficacy of the drug in combating orthopoxviruses.[26] Anecdotal physician reports of the efficacy and safety of the antiviral in monkeypox patients seem to support the oft-made assertion that because TPOXX is safe and effective for use on those with smallpox, it is also safe and effective with its less severe and less lethal viral relative. However, insufficient formalized research exists for the FDA to approve the drug for monkeypox, and TPOXX has been known to lead to rebound symptoms in individuals with monkeypox.

Clinical trials understanding the efficacy of TPOXX against monkeypox in humans are pending. Given the time constraints of clinical trials, enough information for the FDA to take action on changing the ability to access TPOXX could still be months away. In order to expedite access to TPOXX without issuing regular approval for the drug, the federal government could issue an emergency use authorization allowing for the administration of the antiviral for monkeypox. The federal government has yet to issue an emergency use authorization for TPOXX to be used for monkeypox.

Vaccination

Most major jurisdictions in California currently offer the Jynneos vaccine (approved for monkeypox) as post-exposure prophylaxis (PEP) for known close contacts of monkeypox cases and as pre-exposure prophylaxis (PrEP) for certain high-risk groups and individuals. As of August 12, 2022, a total of 43,222 vials of Jynneos had been shipped to Los Angeles County, and 66,309 vials to the rest of the state.[27] These figures include the first part of the phase 3 allocation, phase 3a. In total, phase 3 allocations include 48,120 vials for Los Angeles, and 72,520 vials for the rest of California. The California Department of Public Health (CDPH) determines how to distribute these allocations, and for phase 3a, among other qualifications, allocated jurisdictions with a formula that was 75% based on monkeypox cases in the 2 weeks preceding the allocation, and 25% based on early syphilis cases among men. CDPH has yet to announce its vaccine allocation formula for phases 3b and 3c.[28]

	Phase 0	Phase 1	Phase 2a	Phase 2b	Phase 3a	
Dates Received	**5/25-6/13**	**7/1/2022**	**7/14/2022**	**7/21/2022**	**8/1/2022**	**Total**
Los Angeles County	1,060	6,346	9,812	6,824	19,240	43,282
CA/CDPH	2,540	9,556	14,774	10,299	29,020	66,189
Total	3,600	15,902	24,586	17,123	48,260	109,471

Note: Doses for Los Angeles County are allocated separately by CDC

Figure 3: CDPH and LA County Vaccine Allocation by Phase[29]

[25] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00228-6/fulltext#%20
[26] https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
[27] https://aspr.hhs.gov/SNS/Pages/JYNNEOS-Distribution.aspx
[28] https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Monkeypox-Vaccine-Allocation-Process.aspx
[29] https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Monkeypox-Vaccines.aspx

The ACAM2000 vaccine, for which there is not a supply shortage, is approved for use against smallpox. It is also available under an EA-IND for monkeypox prevention, but is not recommended for all groups. ACAM2000 vaccine contains live virus, and can thus lead to more potential side-effects in individuals with certain medical conditions or history.[30]

In order to address an acute supply shortage of the Jynneos vaccine, on August 9, 2022, the federal government issued an emergency use authorization that allows for the intradermal (injection into the dermis) injection of the vaccine in order to increase supply as much as five-fold. A 2015 study of a two-dose intradermal series of Jynneos found that intradermal injection produced a similar immune response to the already-approved subcutaneous (below the skin) injection method.[31] The emergency use authorization that allowed for intradermal injection also allowed for the original administration method and dosage for individuals less than 18 years of age.

On August 15, 2022, the federal government announced that it would accelerate the schedule of the remaining phase 3 implementation. Both phases 3b and 3c were made available for ordering on August 15th under this accelerated timeline.[32]

State Budget Request

On July 20, 2022, Select Committee on Monkeypox Chair Senator Scott Wiener, along with 11 colleagues in the legislature, requested an emergency state budget appropriation to support county monkeypox efforts to expand testing, vaccination, treatment, and education/outreach.[33] The request emphasizes the funding need for CDPH to help local health jurisdictions with vaccination logistics, provide resources to treatment centers, provide emergency staffing for a variety of roles, expand testing, and provide funding to community-based organizations (CBOs) [34]

[30] https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/acam2000-vaccine.html
[31] https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-authorizes-emergency-use-jynneos-vaccine-increase-vaccine-supply
[32] https://www.hhs.gov/about/news/2022/08/15/biden-harris-administration-makes-hundreds-of-thousands-more-vaccine-doses-available-support-monkeypox-response.html#:~:text=FDA's%20Emergency%20Use%20Authorization%20of,end%20this%20national%20monkeypox%20outbreak.
[33] https://twitter.com/Scott_Wiener/status/1549811164346912768
[34] https://twitter.com/Scott_Wiener/status/1554240386947637249

8-9-22 Select Committee on Monkeypox Hearing

On Tuesday, August 9, 2022, Senator Wiener convened the first hearing of the Senate Select Committee on Monkeypox. During the hearing, the committee learned more about the clinical presentation of monkeypox and heard from a variety of state and local stakeholders. Panelists included the State Epidemiologist, Dr. Erica Pan, various county health authorities responding to outbreaks in their jurisdictions, leaders from various LGBTQ+ community-based organizations (CBOs), individuals who contracted monkeypox, and representatives from the labor and medical communities. The panelists outlined the response to the outbreak from state, local, and CBO perspectives, challenges faced, and resources needed to contain the outbreak.

Specific needs that arose from various voices in the hearing include:

- Allocating $38.5 million to CDPH to increase resources for vaccination, treatment centers, emergency staffing, expanded testing, and funding for CBOs directed through local health departments (LHDs)
- A drastic increase in vaccine supply
    - During the hearing, the federal government issued an emergency use authorization for intradermal administration of the Jynneos vaccine, increasing the number of doses that can be drawn from one vial by up to five-fold.
    - Even with this change, a vaccine supply shortage remains. Vaccinators also require training in many cases to administer the vaccine with this approach.
- Emergency use authorization of TPOXX to streamline access to the antiviral treatment
- Paid sick leave to help hourly and in-person workers at high risk of monkeypox to get vaccinated and recover safely if they contract monkeypox
- Reimbursement of Federally Qualified Health Centers for Jynneos administration
- Publicly available demographic data regarding access to vaccination and treatment
- Cultural competency in outreach to reach marginalized communities