



# HMPXV

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**September 8, 2022**



# Smith Disclosures

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## Consultant for

- AstraZeneca
- Bayer
- Evidera
- Model Medicines
- Vx Biosciences

## Scientific Advisory Board

- FluxErgy
- Linear Therapies
- Pharma Holdings

# Slides From

Ankita Kadakia, MD

Susan Little, MD

Christine Johnson, MD

Steffanie Stratthdee, PhD

Rehan Syed, MD

Tim Wilkin, MD

# Outline

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Outbreak

Virology

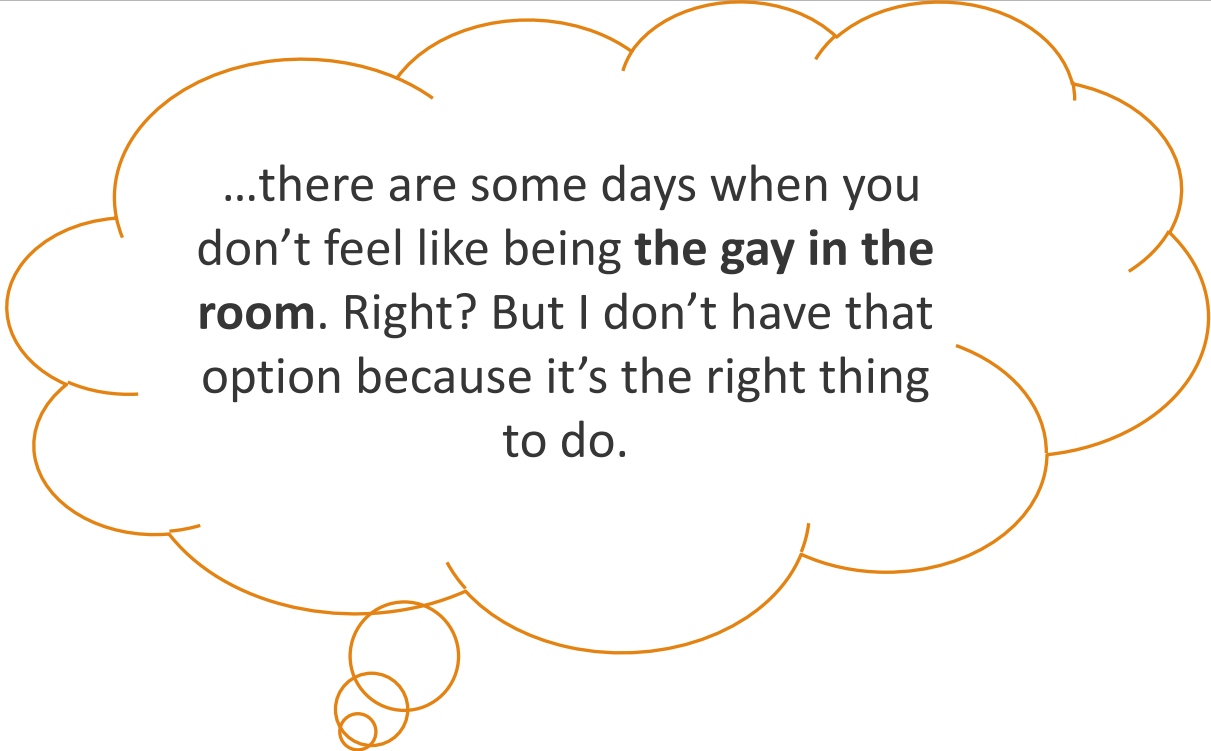
Transmission

Disease

Treatment

Vaccination

Research



...there are some days when you don't feel like being **the gay in the room**. Right? But I don't have that option because it's the right thing to do.

[Dr. Demetre Daskalakis](#)

# Outbreak

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## Governor Newsom Proclaims State of Emergency to Support State's Response to Monkeypox

Published: Aug 01, 2022

*The San Diego Union-Tribune*

## San Diego County follows state's lead, declares local monkeypox state of emergency

AUG. 2, 2022 5:39 PM PT

*The New York Times*

## ***As Monkeypox Spreads, U.S. Declares a Health Emergency***

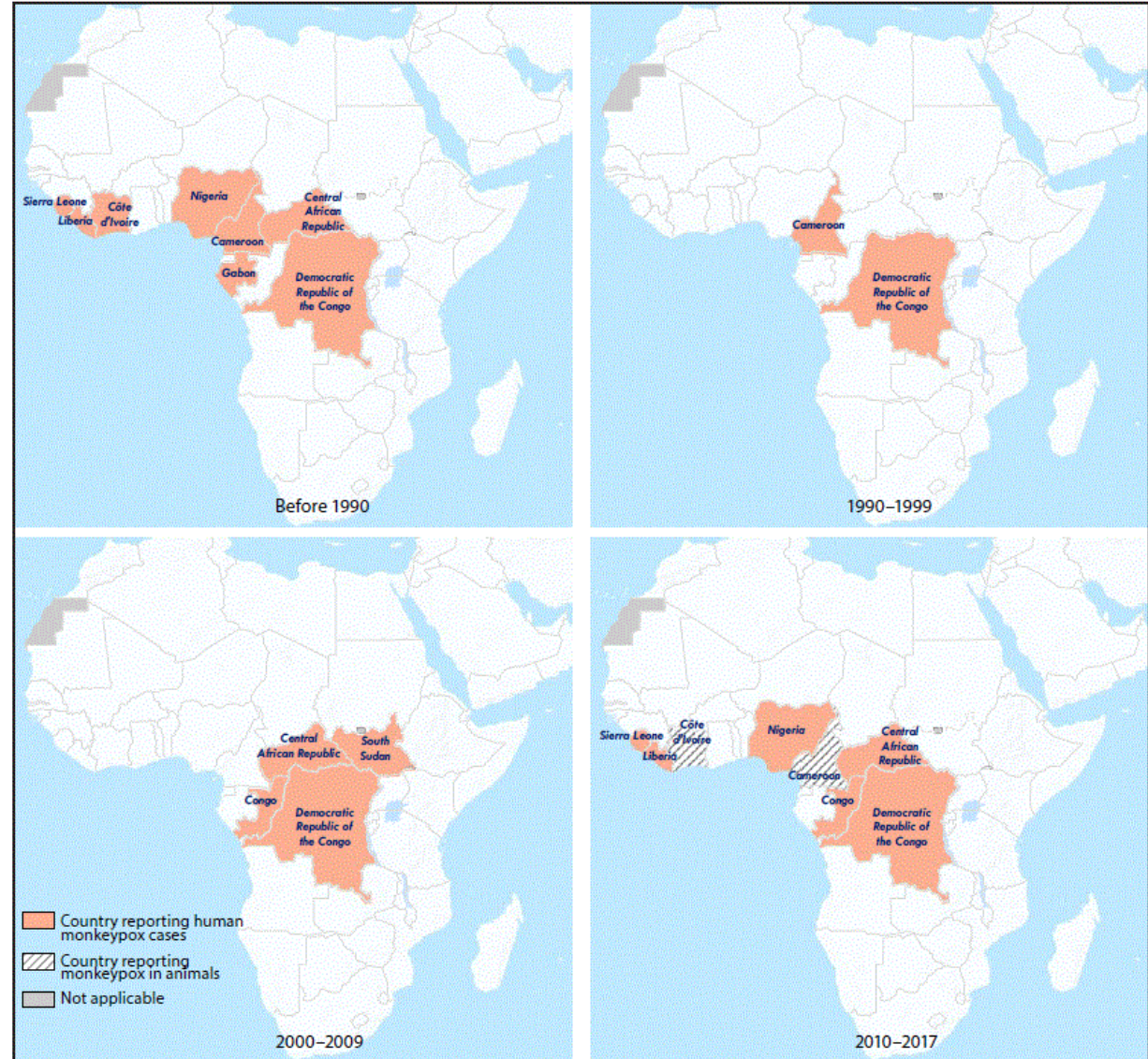
Aug. 4, 2022 Updated 2:42 p.m. ET

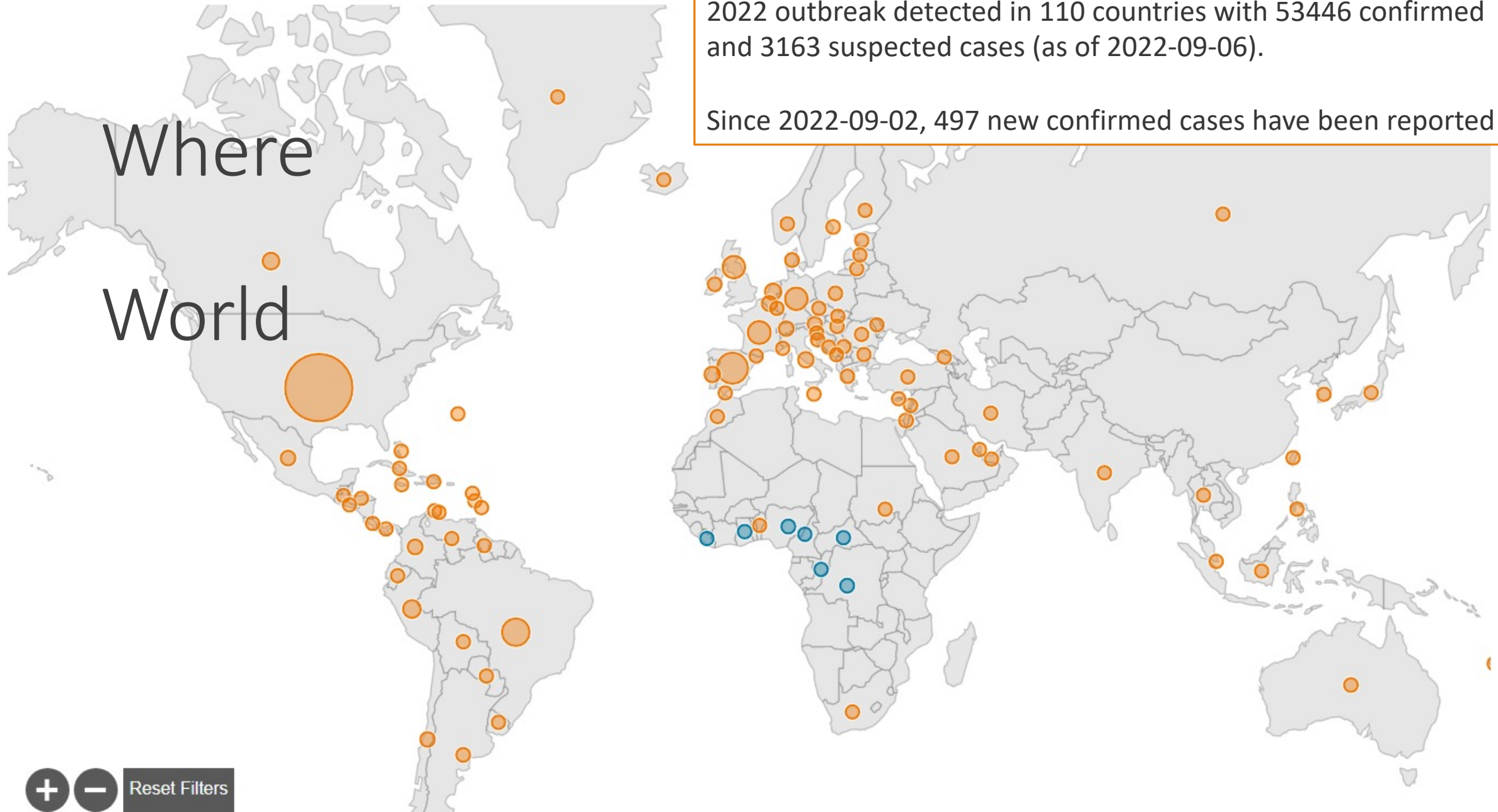


# When and Where

- HMPXV first discovered in lab monkeys in 1958, the primary carriers of monkeypox today are rodents.
  - New name coming! (Orthopox 4?)
- Endemic in Western and Central Africa 1970-2017
- We had HMPXV in US in 2003
  - 71 people infected from pet prairie dogs who got it from a pet rat from Ghana

Why have we not learned?

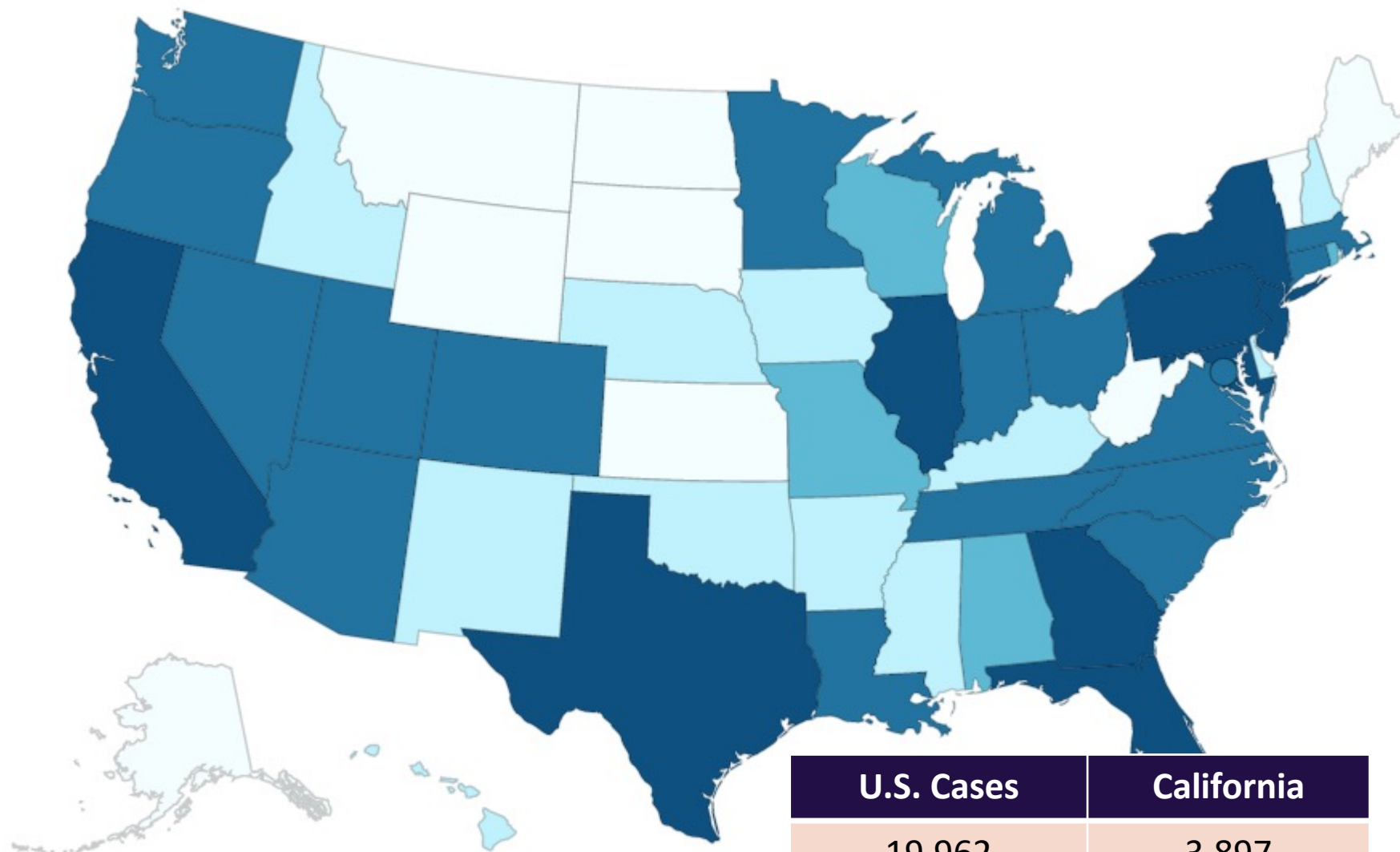






# Where

# U.S.

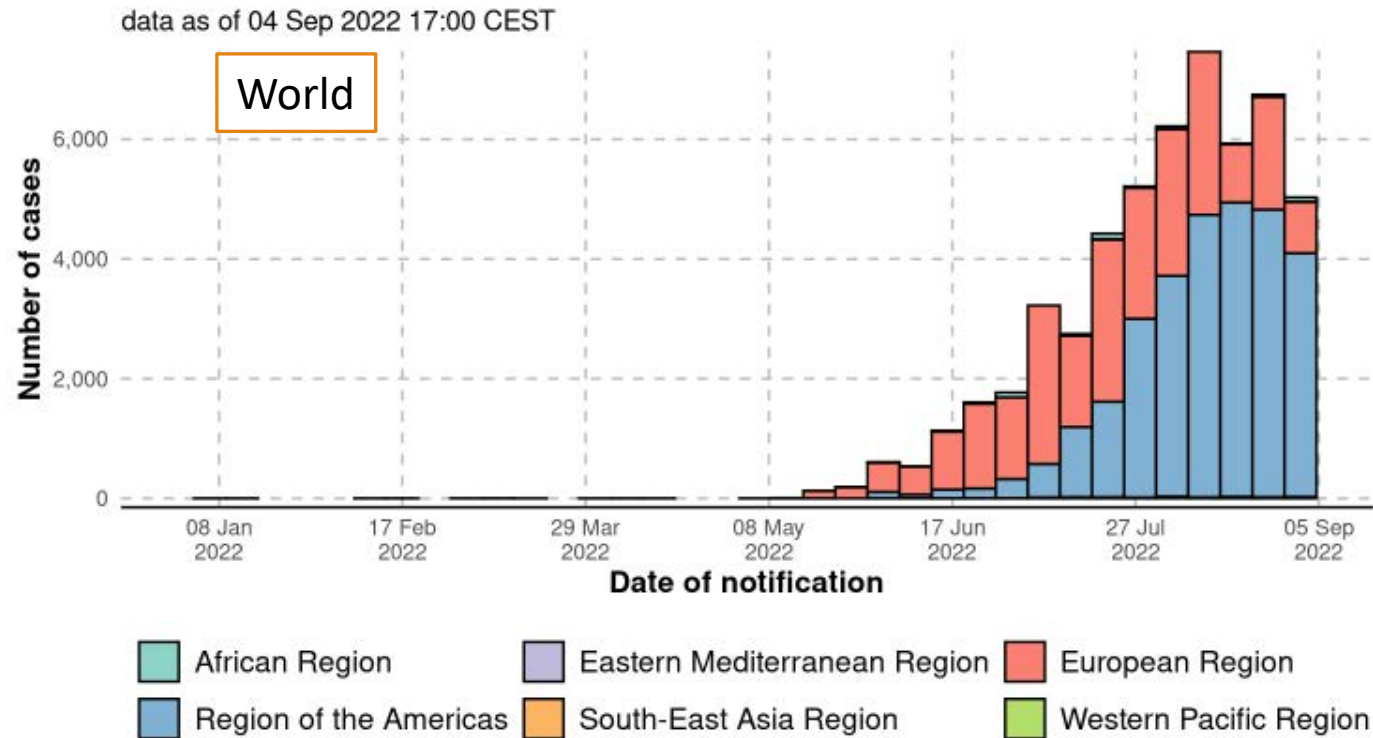


U.S. Cases	California
19,962	3,897

Territories **PR**

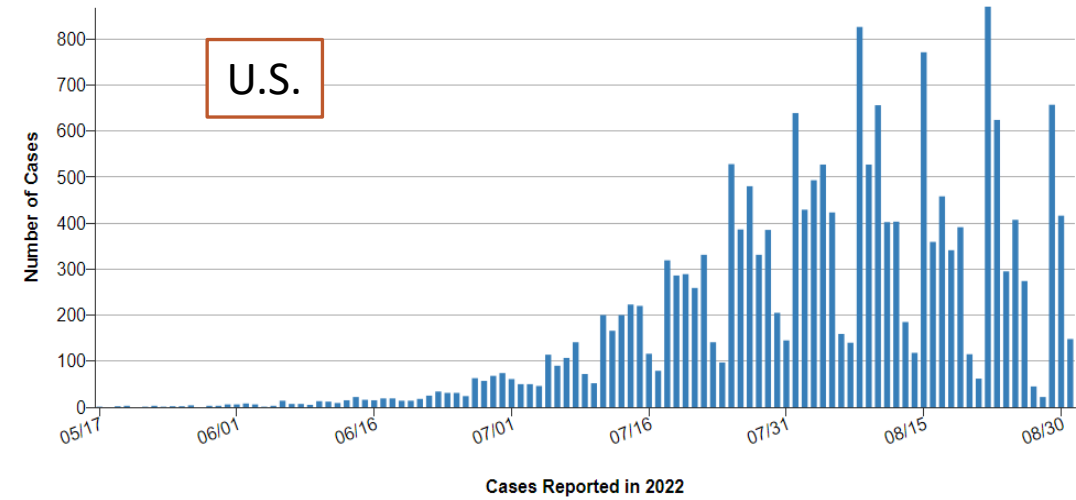


# When



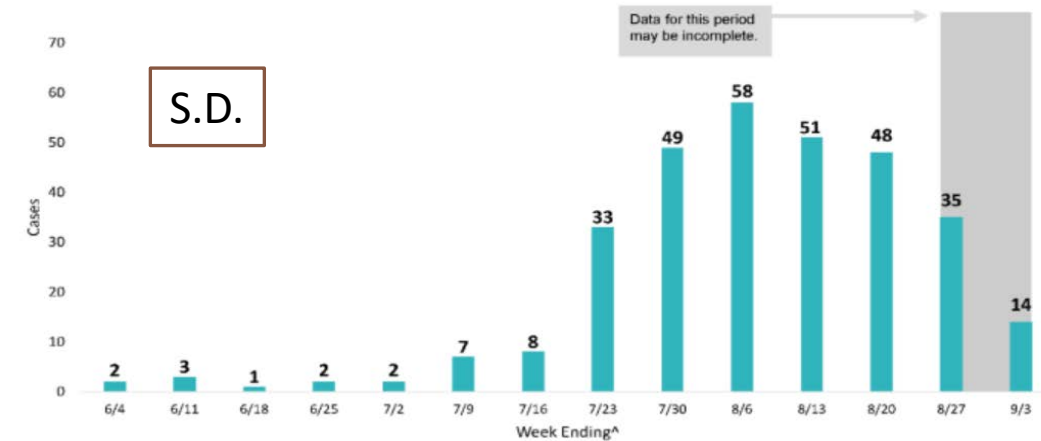
Source: WHO

## U.S. Monkeypox Case Trends Reported to CDC



## MPOX CASES BY EPISODE DATE Updated Weekly (Tuesday) Data Through 9/3/2022

Confirmed and Probable MPOX Cases\* by Episode Date †  
San Diego County Residents, N=313

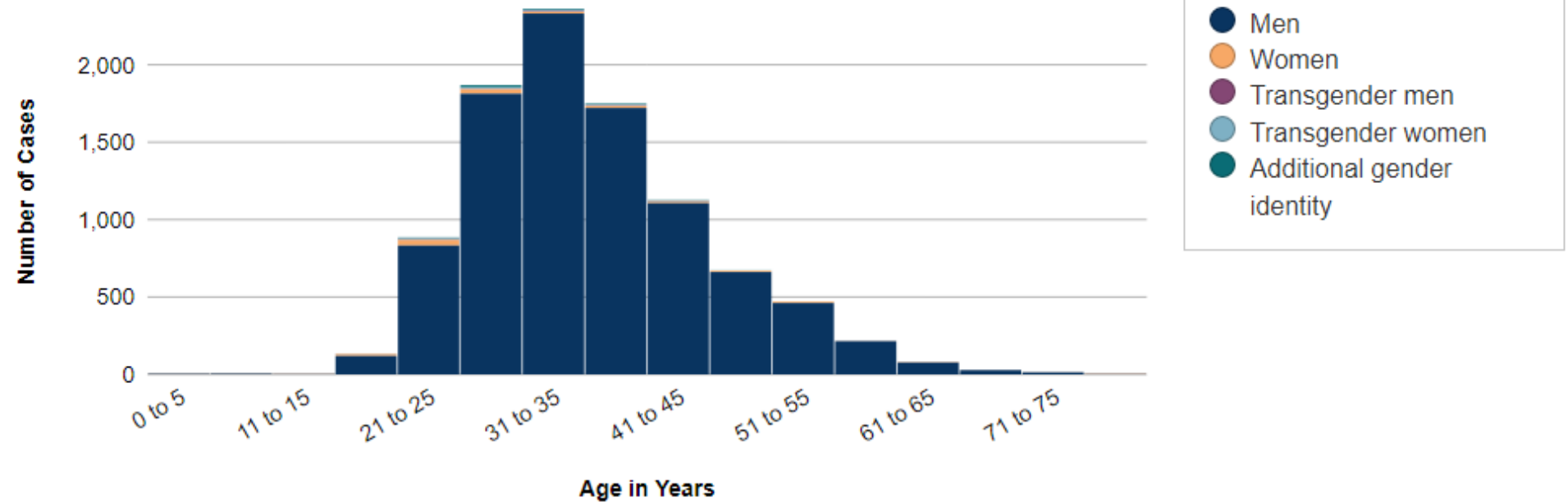




# Who

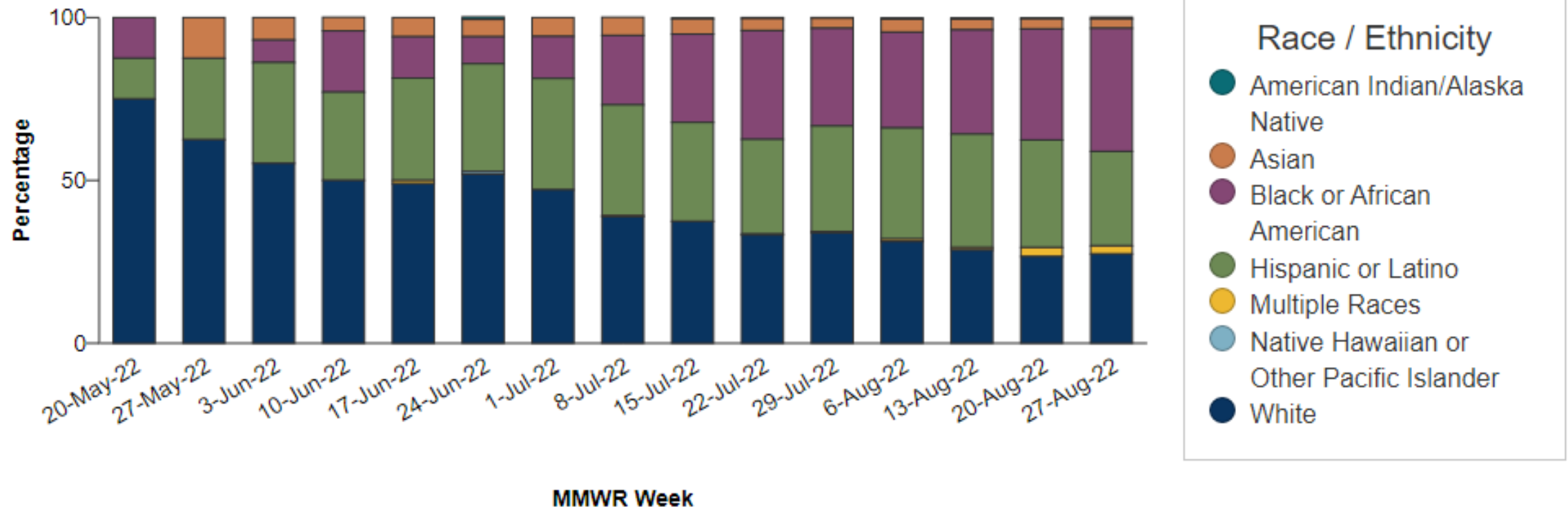
# U.S.

Monkeypox cases reported to CDC: Age and Gender



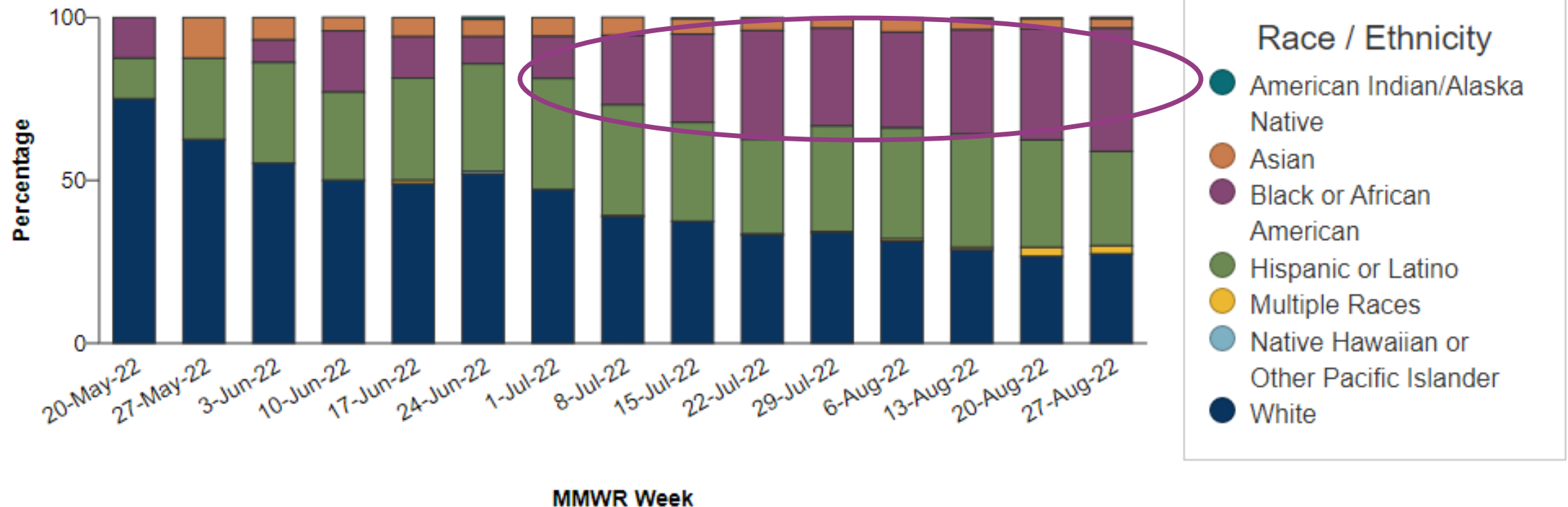
# Who: U.S.

## Monkeypox cases reported to CDC: Race/Ethnicity by Week



# Who: U.S.

## Monkeypox cases reported to CDC: Race/Ethnicity by Week



Who

S.D.

Age		
Median	35	-
Minimum	20	-
Maximum	65	-
Race/Ethnicity*		
Hispanic or Latino	116	44%
White	110	42%
Black or African American	22	8%
Asian	6	2%
Other/Multiple Race	3	1%
American Indian or Alaska Native	3	1%
Native Hawaiian or Other Pacific Islander	2	1%
Unknown or missing	51	
HHSA Region		
Central	173	56%
North Central	52	17%
South	27	9%
North Coastal	27	9%
East	15	5%
North Inland	15	5%
Unknown or missing	4	
Persons Experiencing Homelessness	12	4%
Hospitalizations	10	3%
Deaths	0	0%



# Who

# World

As of September 05 2022

	Reported values <sup>1</sup>		Unknown or Missing Value
	Yes	No	
Men who have sex with men	11923 (95.2%)	607 (4.8%)	33442
HIV-Positive	5576 (44.9%)	6834 (55.1%)	33562
Health worker	313 (4.2%)	7070 (95.8%)	38589
Travel History	1213 (27.9%)	3127 (72.1%)	41632
Sexual Transmission	7822 (91.0%)	777 (9.0%)	37373
Hospitalised <sup>2</sup>	1550 (8.4%)	16928 (91.6%)	27494
ICU	9 (0.1%)	8072 (99.9%)	37891
Died	4 (0.0%)	19681 (100.0%)	26287

<sup>1</sup> Note given true proportions of variables, yes reporting may be common than no reporting

<sup>2</sup> May be hospitalised for isolation or medical treatment

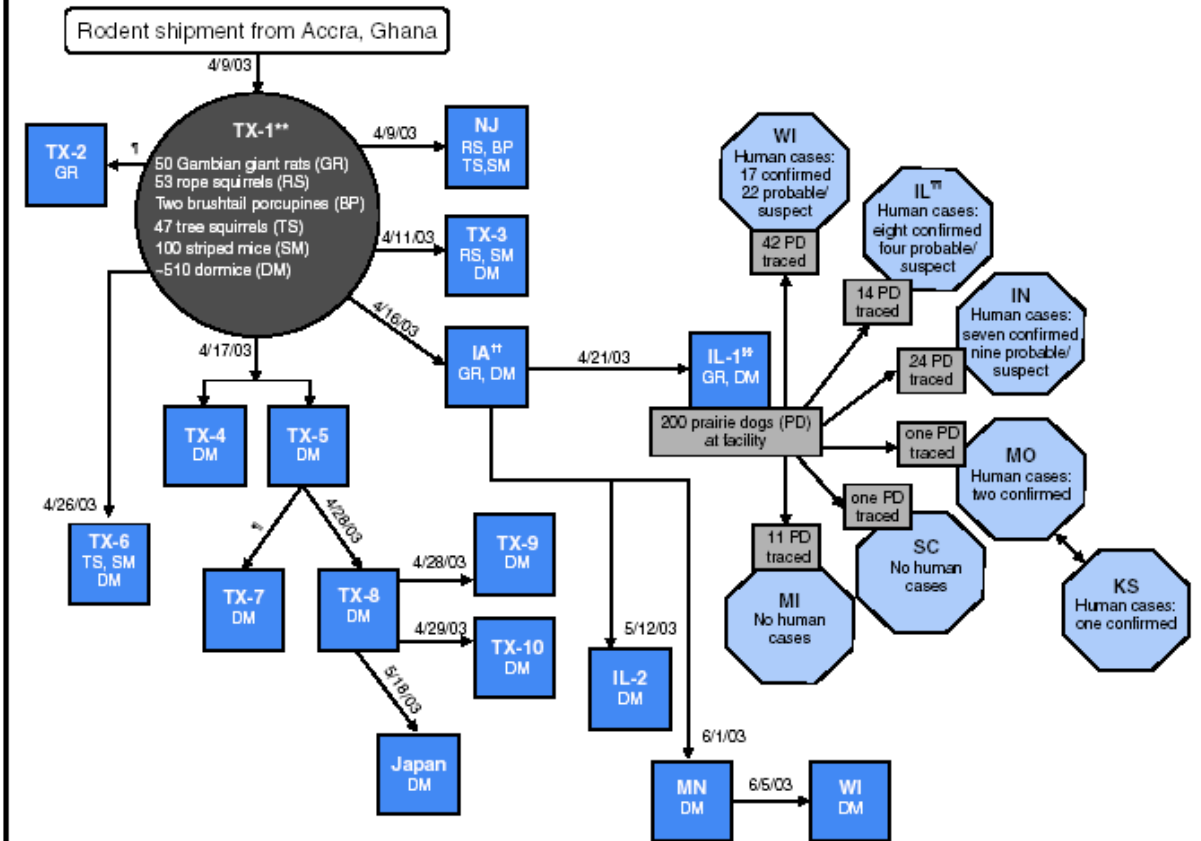
Who

S.D.

San Diego County Confirmed and Probable Cases* Updated Weekly Data Through 9/3/2022, Updated 9/6/2022		Percent <sup>†</sup>
Total	313	100%
Gender		
Male	308	98%
Female	3	1%
Transgender female	2	1%
Transgender male	0	0%
Genderqueer or non-binary	0	0%
Identity not listed	0	0%
Declined to answer	0	0%
Unknown or missing	0	
Sexual Orientation		
Gay, lesbian, or same-gender loving	210	85%
Bisexual	19	8%
Heterosexual or straight	13	5%
Declined to answer	4	2%
Orientation not listed	0	0%
Questioning/unsure/patient does not know	0	0%
Unknown or missing	67	



2003



[Update: Multistate Outbreak of Monkeypox --- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003 \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a1.htm)

2003 Midwest monkeypox outbreak - Wikipedia



2003

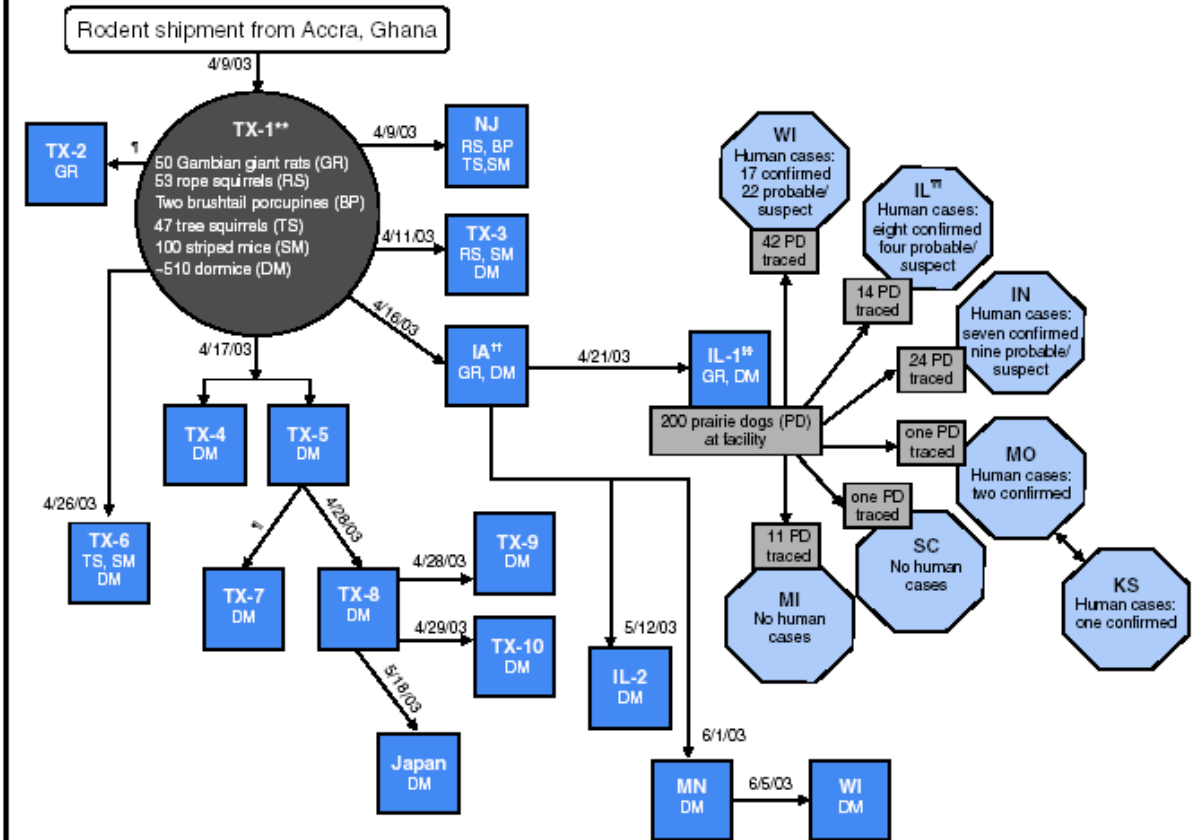
What is the difference now?



Disease	Monkeypox
Virus strain	"West African clade" <sup>[1]</sup>
Source	African rodents (Gambian pouched rat, dormice, rope squirrels) housed with prairie dogs
Location	Midwestern United States
Index case	May 15, 2003
Confirmed cases	71
Recovered	71
Deaths	0
Fatality rate	0%



2003 Midwest monkeypox outbreak - Wikipedia



[Update: Multistate Outbreak of Monkeypox --- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003 \(cdc.gov\)](https://www.cdc.gov/media/releases/2003/s030515mpo.html)



# Why do we not learn? Shigella



To: CAHAN San Diego Participants  
Date: January 17, 2017

**UPDATE: SHIGELLOSIS AMONG MEN IN SOUTHERN CALIFORNIA**



To: CAHAN San Diego Participants  
Date: October 11, 2021  
From: EISB, Public Health Services

Health Advisory: *Shigella sonnei* among persons experiencing homeless in San Diego County

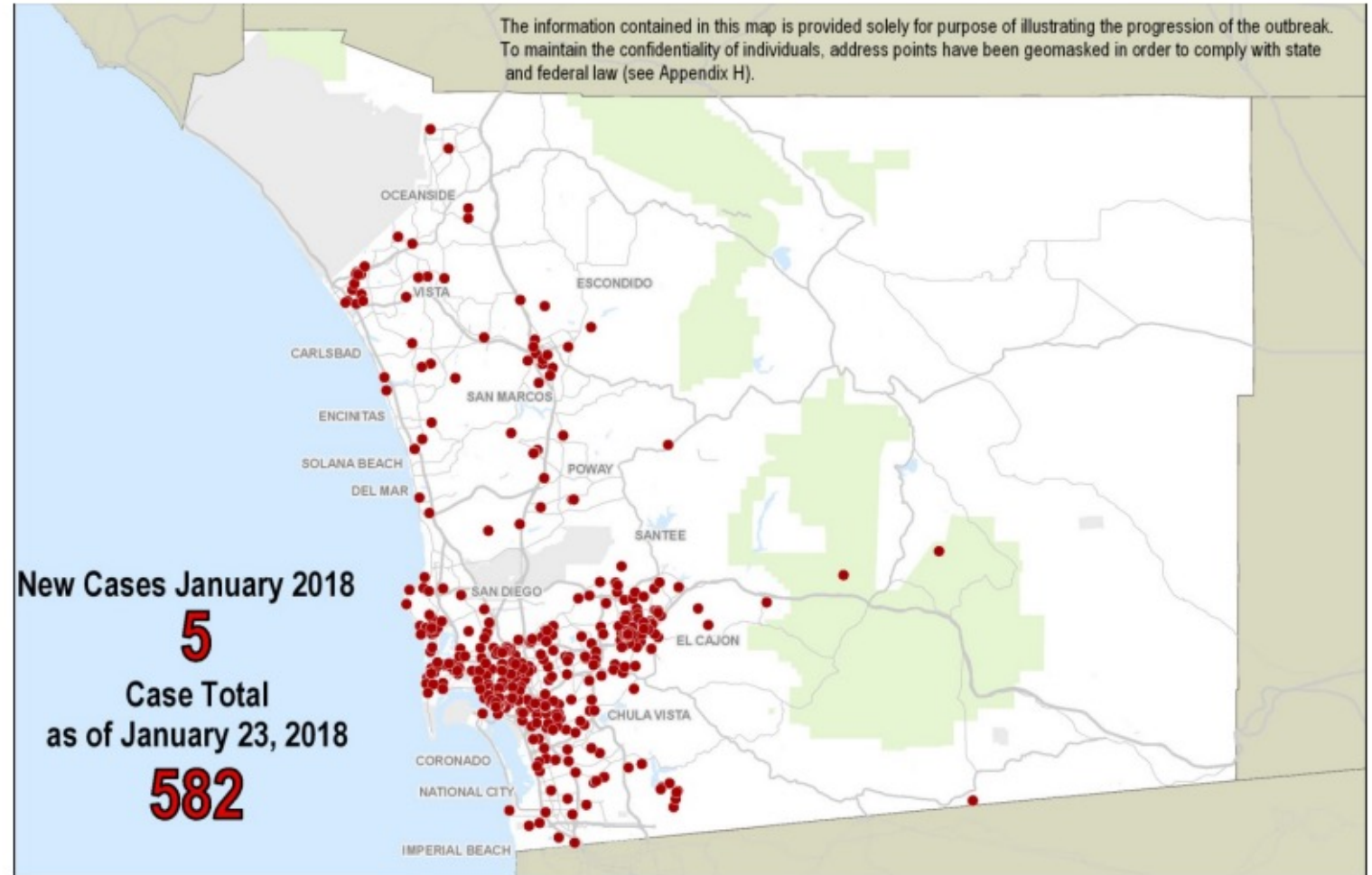
# Why do we not learn?

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## Hepatitis A

- Unstably housed
- MSM

- There are 582 cases associated with the HAV outbreak as of January 23, 2018, including 20 deaths.





It's 2022. Is  
stigma real for  
sexual and  
gender  
minorities?





# 'Don't say gay' bill passes in Tennessee Senate, would ban teachers from discussing homosexuality

By ALIYAH SHAHID  
DAILY NEWS STAFF WRITER • May 21, 2011 at 11:43 am



## Alabama governor signs into law two bills limiting transgender youth protections

By Steve Almasy and Amanda Musa, CNN

🕒 Updated 4:50 PM ET, Fri April 8, 2022

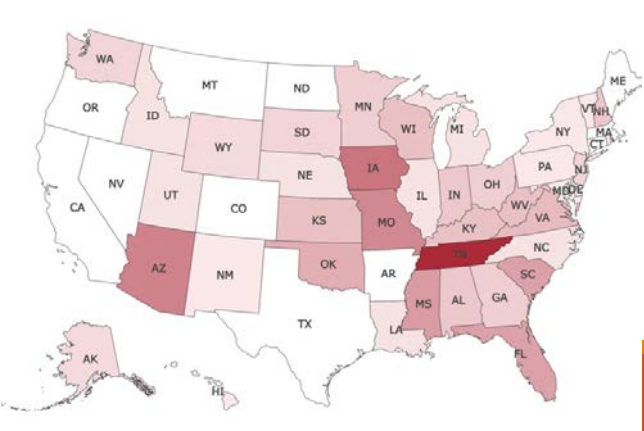
## Texas judge blocks Obamacare rule on free HIV drugs claiming they violate religious liberties

Josh Marcus · 9h ago

### These anti-LGBTQ laws go into effect today

*Most anti-LGBTQ bills will be implemented today. Is your state on the list?*

By John Russell   Friday, July 1, 2022





# Take Away's

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- Infectious diseases spread in vulnerable communities.
  - Already stigmatized
  - Already hidden (must disclose to get services)
  - Close knit for survival
- Stigma is real
  - Internal and External
- Devote resources to communities that are being hit.
- Be prepared, not surprised
- Sustain public health resources for vulnerable communities
  - even when there isn't a public health emergency



# Virology

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# HMPXV Virology

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Enveloped double-stranded DNA virus that belongs to the Orthopoxvirus genus of the Poxviridae family.

Two distinct genetic clades:

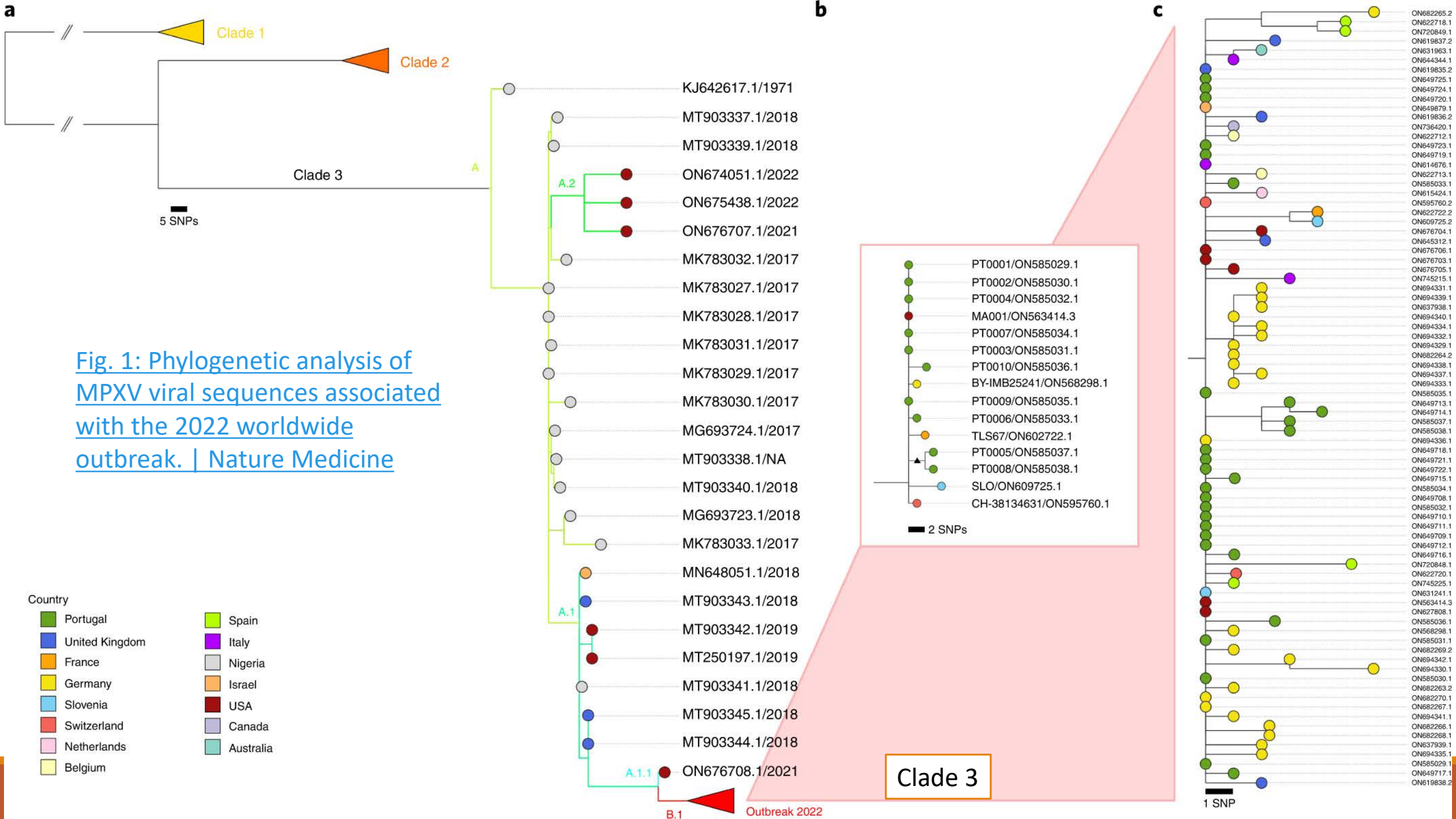
- Central African (Congo Basin) clade 1
- West African clade 3.

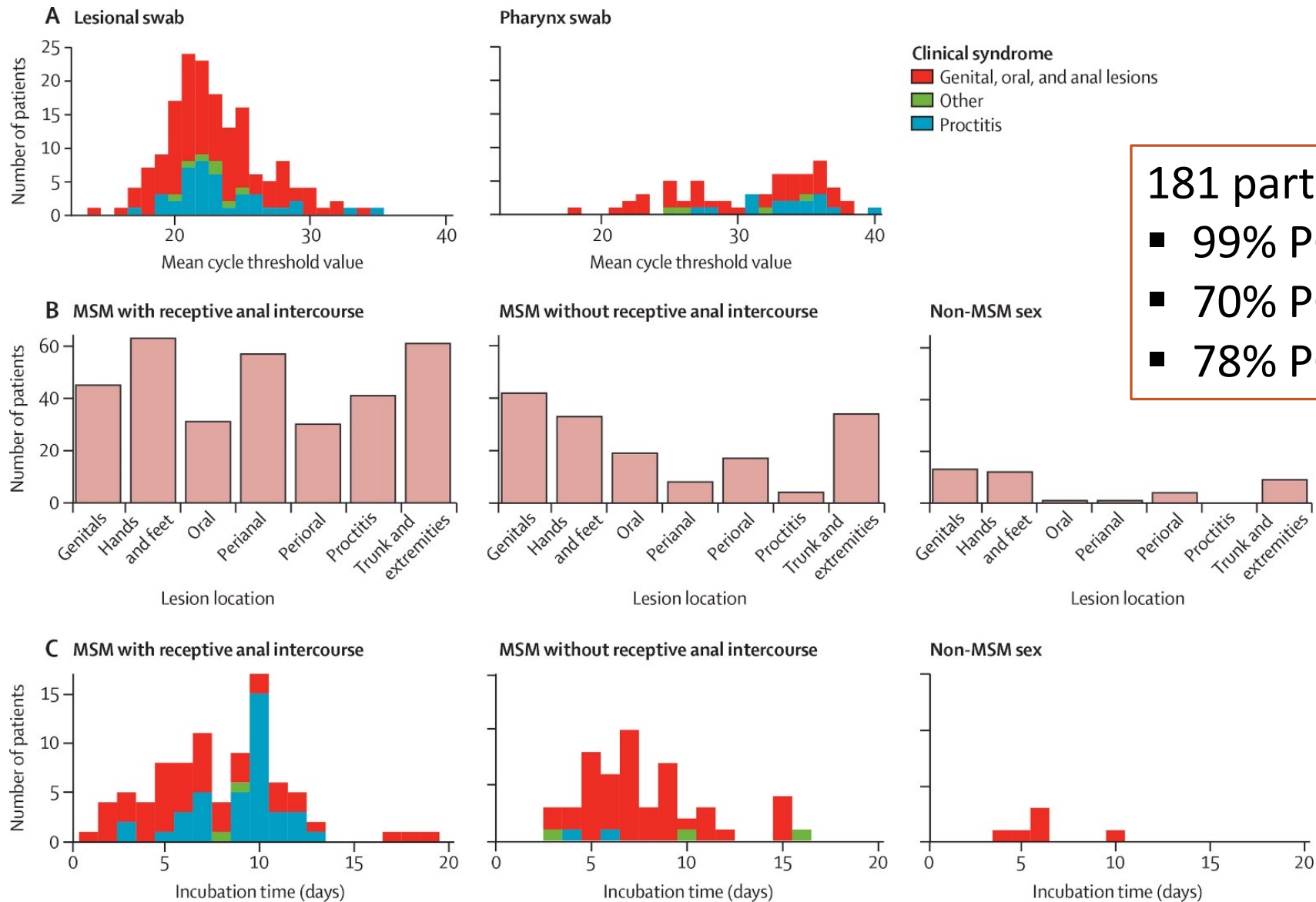
Clade 3 causes a less severe disease than Clade 1. (for now)

Isolates from the 2022 outbreak shared **40 mutations** that distinguish it from its closest variant.



Increased transmissibility?





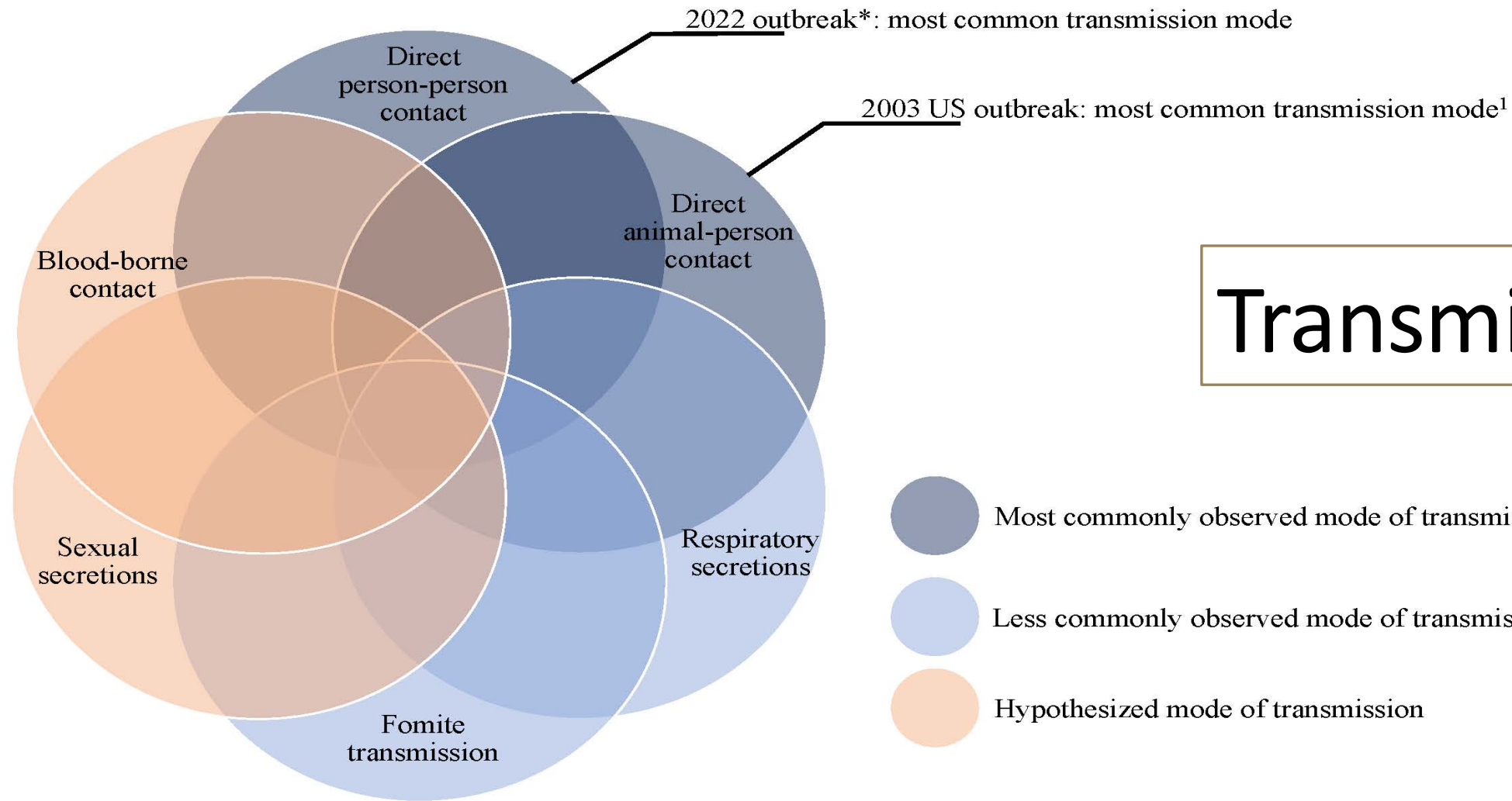
181 participants in Spain

- 99% PCR of skin swab positive
- 70% PCR of throat swab positive
- 78% PCR of anal swab positive



# Transmission

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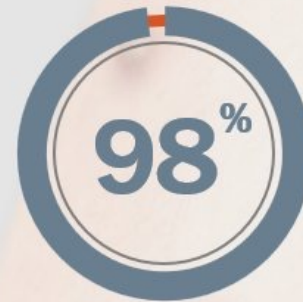


\*The HMPXV which circulated in 2003 is a different variant of the West African clade than observed in the 2022 outbreak.

1. Reynolds, M. G., Davidson, W. B., Curns, A. T., Conover, C. S., Huhn, G., Davis, J. P., ... & Damon, I. K. (2007). Spectrum of infection and risk factors for human monkeypox, United States, 2003. *Emerging infectious diseases*, 13(9), 1332. doi: 10.3201/eid1309.070175

MSM

## Three reasons monkeypox outbreak seems to be driven by sexual transmission in MSM



**MSM or bisexual men**  
Sexual transmission suspected for 95% of all cases



**Seminal fluid samples positive for monkeypox DNA**



**Patients reported anogenital lesions**

# Disease

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# HMPXV Infection

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The time from exposure to onset of symptoms from 5 to 21 days.

Replicates at the inoculation site then spreads to regional lymph nodes.

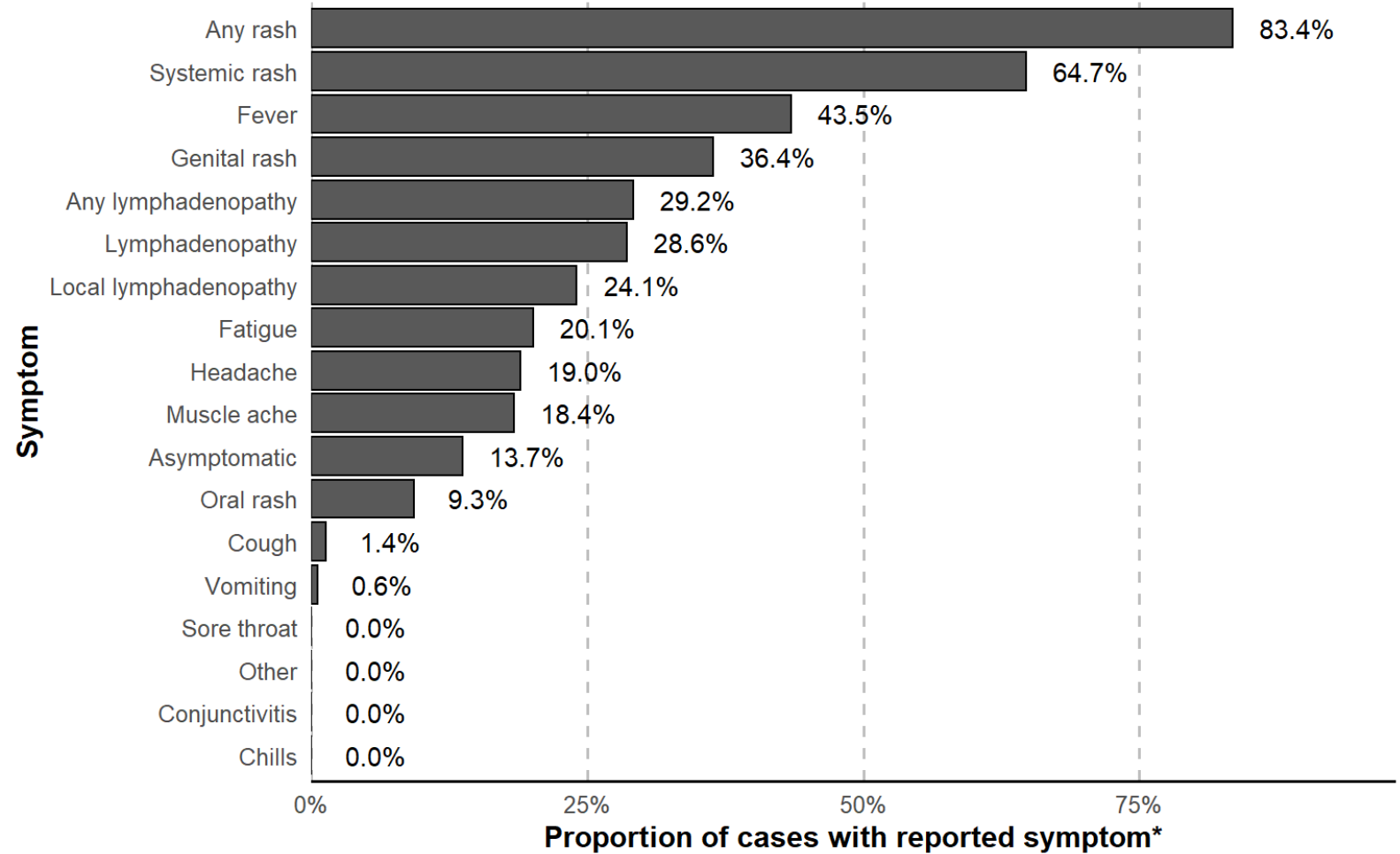
Following a period of initial viremia, the virus spreads to other body organs.

Duration of symptoms is typically 2 to 4 week.



# Disease process

[https://worldhealthorg.shinyapps.io/mpx\\_global/](https://worldhealthorg.shinyapps.io/mpx_global/)



Source: WHO

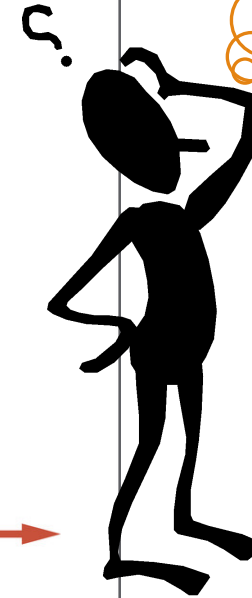
\*12811 cases with at least one reported symptom from a country where at least two unique symptoms reported used as denominator

# Disease process

## A Evolution of Cutaneous Lesions

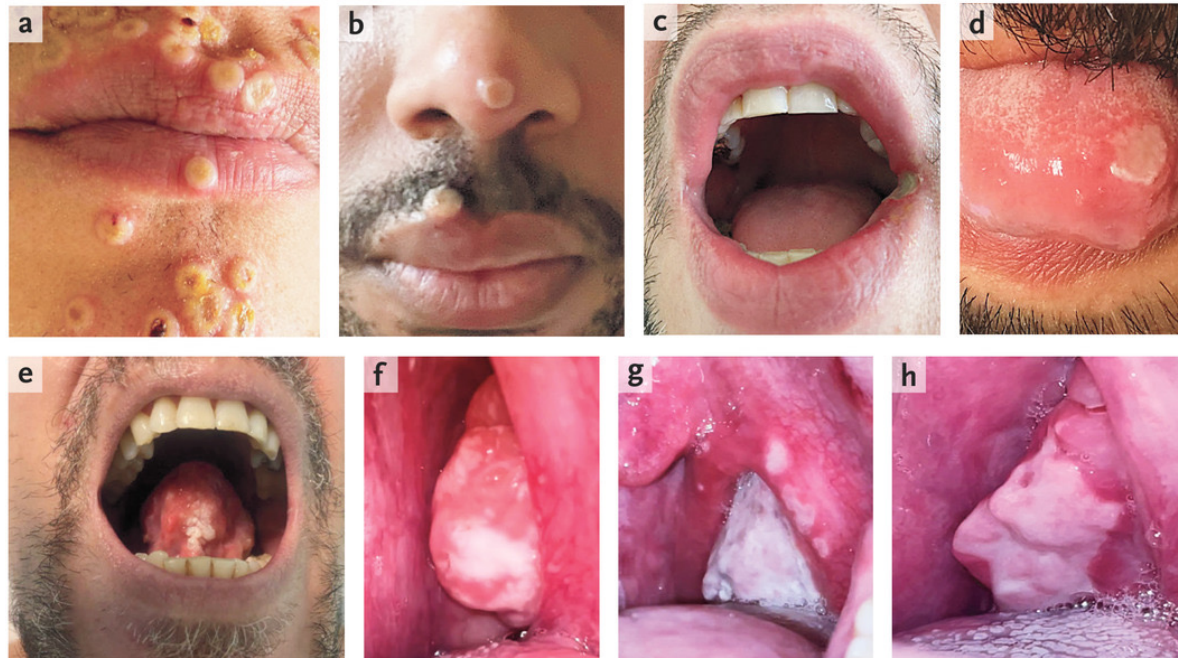


Another reason  
not touch a  
rash



# Disease process

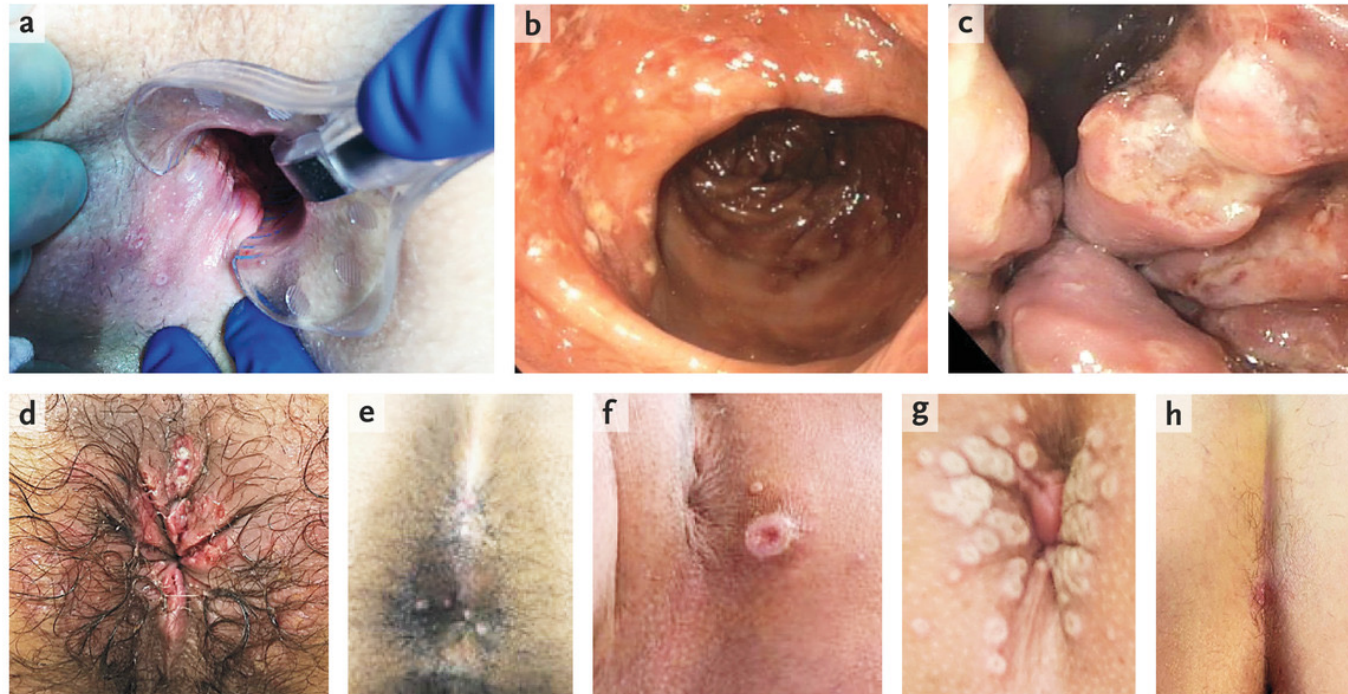
## B Oral and Perioral Lesions





# Disease process

## C Perianal, Anal, and Rectal Lesions



# Fatality Rate

Countries/Clade	Case Fatality Rate	95% CI <sup>1</sup>
All countries <sup>2</sup>	78/892 = 8.7%	7.0%– 10.8%
Clade 1 <sup>3</sup>	68/640 = 10.6%	8.4%– 13.3%
Clade 3 <sup>4</sup>	9/247 = 3.6%	1.7%– 6.8%
Clade 3, African countries only	9/195 = 4.6%	2.1%– 8.6%

## Clade 3, non-Africa Countries

1. Spain, male 40 yo “brain inflammation”
2. Spain male 31 yo “brain inflammation”
3. Brazil male 41 yo lymphoma on treatment (immunocompromised)
4. India male 22 yo “brain inflammation”
5. Ghana – no information
6. Texas– “immunosuppressed” (?)

[seekingalpha.com/news/3877939-texas-reports-first-us-death-linked-to-monkeypox](https://seekingalpha.com/news/3877939-texas-reports-first-us-death-linked-to-monkeypox)



# Potential Treatments

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Vaccinia Immune Globulin, Cidofovir, **Brincidofovir**, and **Tecrovirimat**

# Brincidofovir

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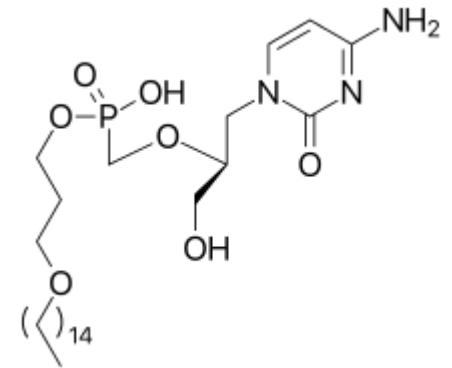
Brincidofovir FDA approved to treat smallpox

Prodrug of Cidofovir (conjugated with a lipid molecule)

Inhibits viral DNA polymerase and acyclic nucleotide incorporating into viral DNA chain

Safety and efficacy data are lacking for HMPXV

Brincidofovir is not available through the US CDC eIND



# Brincidofovir

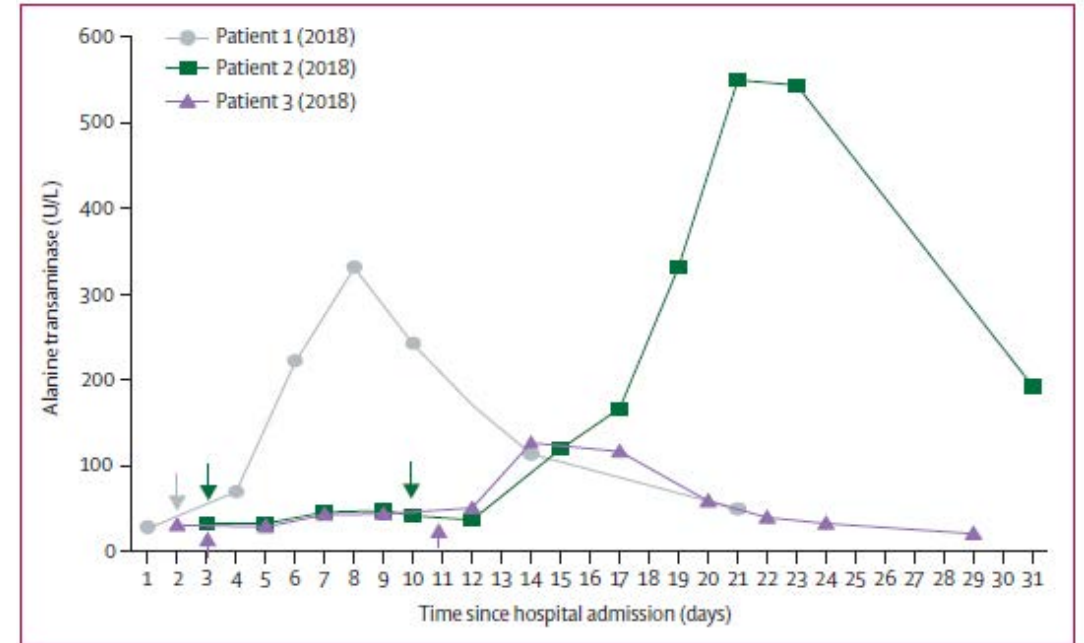
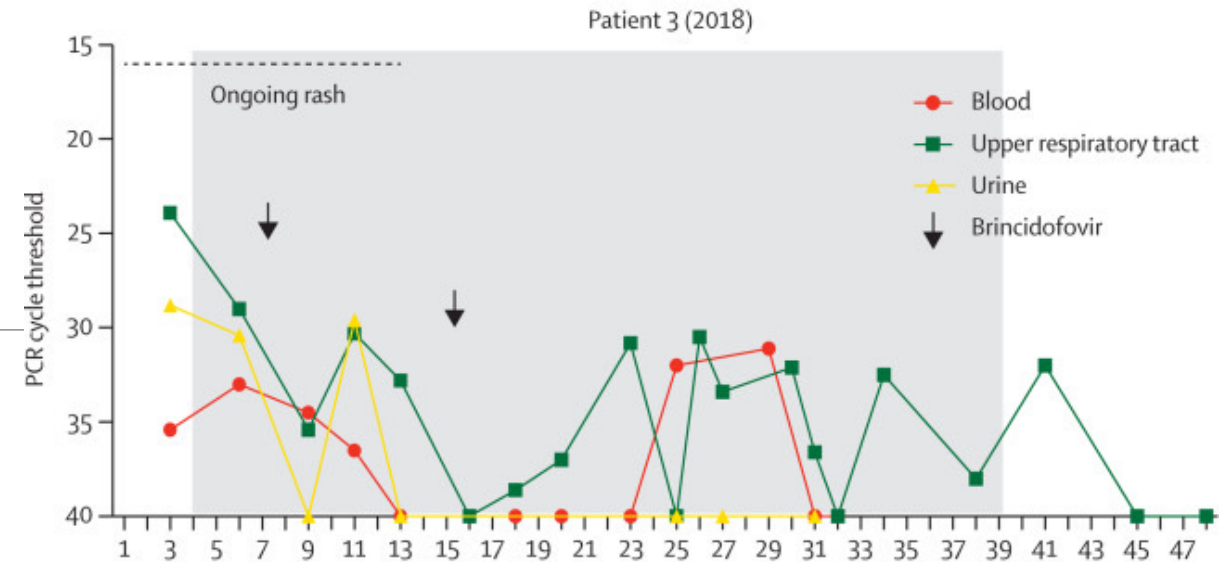
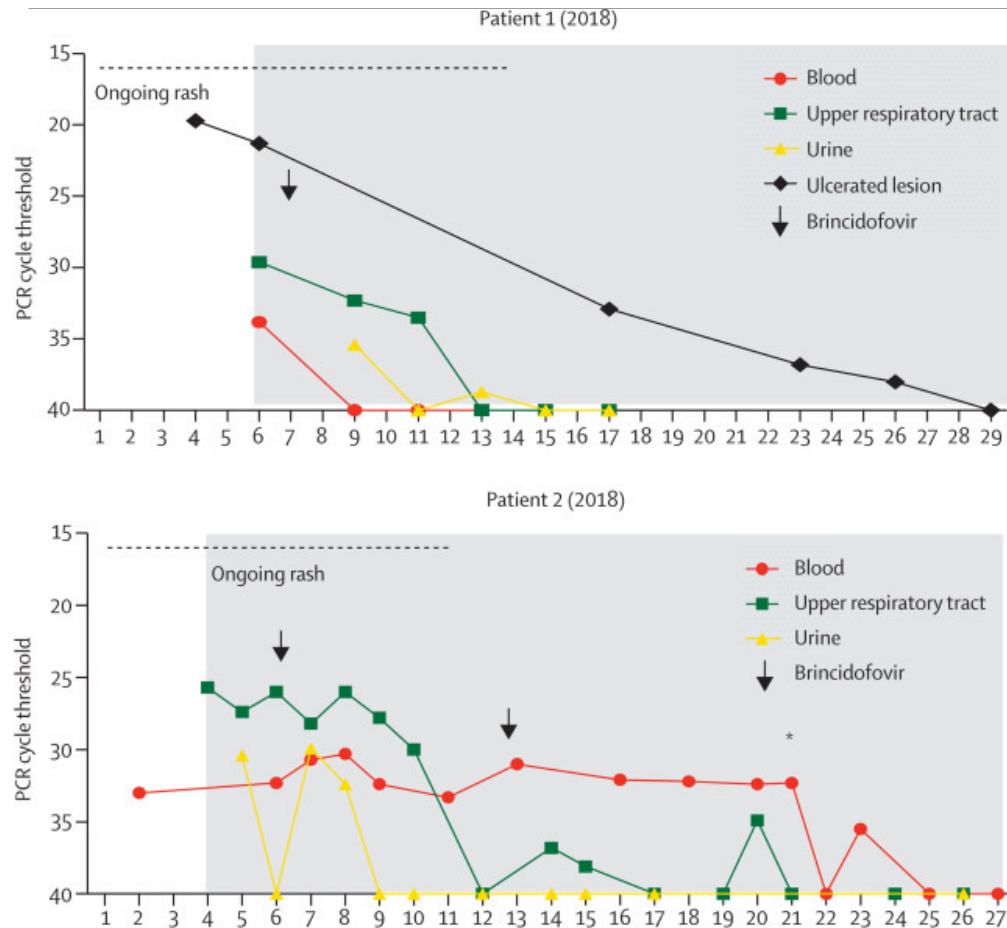


Figure 3: Alanine transaminase values of the three patients who received therapy with brincidofovir

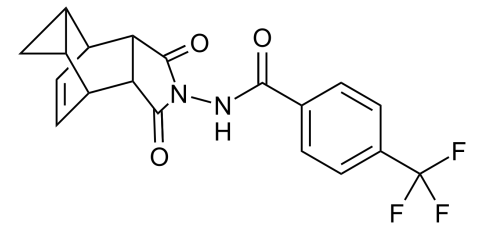
# Tecovirimat

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Tecovirimat is a promising treatment for HMPXV disease

- Indicated for the treatment of human smallpox disease
- Works by inhibiting viral p37 protein (highly conserved in orthopoxviruses) and blocks its interaction with cellular Rab9 GTPase and TIP47, preventing the formation of egress-competent enveloped virions
- Safety and efficacy data are lacking for HMPXV

Tecovirimat is being used through CDC EA-IND and community demand for treatment is high





# Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

**Table. Clinical Characteristics of Patients With Monkeypox Infection Treated With Tecovirimat**

Patient	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Smallpox vaccination history	Unk	Unk	No	No	No	No	No	Unk	Unk	Unk	Unk	No	No	No	Unk	No	Unk	Jynneos	Jynneos	No	Jynneos	Remote	No	Jynneos	Unk
HIV, <sup>a</sup> hepatitis B, hepatitis C status	HIV	None	None	None	None	HIV	HIV	HIV	None	HIV	HIV	None	HIV	None	None	HIV	None	None	None	None	None	None	None	None	HIV
Systemic symptoms	None	Fever, back-ache, fatigue	Nausea, chills, myalgias	Fever	Fatigue	Fever, fatigue	Fever, backache, headache, diarrhea, chills	None	Malaise, fever	Fever	Fever, sore throat, itching, fatigue	Fever, headache	Fever, headache	Head-ache, shoulder and neck pain	Head-ache, hoarseness	Fever, fatigue, head-ache, constipation, sore throat	Fever, head-ache, nausea, fatigue	Fever, myalgia, head-ache, sore throat	Fever, chills, urethritis	Fever	Fever, sore throat, back pain	Fever, sore throat	Fever, chills, night sweats	Fever, chills, fatigue, painful bowel movements	Fever
Lymphadenopathy	None	None	None	None	In-guinal	In-guinal and neck	None	None	Neck and in-guinal	Cervical	Neck and in-guinal	Right in-guinal	None	None	In-guinal	In-guinal	None	In-guinal	None	In-guinal	Cer-vical, inguinal	Cer-vical	None	In-guinal	None
No. of lesions	10-100	<10	<10	10-100	<10	10-100	10-100	<10	10-100	10-100	10-100	10-100	>100	10-100	<10	<10	10-100	<10	<10	<10	<10	<10	<10	10-100	<10
Genital lesions	Pe-rianal	Pe-rianal	Gen-ital	Gen-ital	Gen-ital	Pe-rianal	Pe-rianal	Gen-ital	Genital	No	Gen-ital	No	Pe-rianal and genital	Gen-ital	Gen-ital	Pe-rianal	Gen-ital	Gen-ital	Pe-rianal	Gen-ital	Pe-rianal and genital	Gen-ital	Gen-ital	Gen-ital	Pe-rianal

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Smallpox vaccination history	Unk	Unk	No	No	No	No	No	Unk	Unk	Unk	Unk	No	No	No	Unk	No	Unk	Jynneos	Jynneos	No	Jynneos	Remote	No	Jynneos	Unk
HIV, hepatitis B, hepatitis C status	HIV	None	None	None	None	HIV	HIV	HIV	None	HIV	HIV	None	HIV	None	None	HIV	None	None	None	None	None	None	None	None	HIV
Systemic symptoms	None	Fever, backache, fatigue	Nausea, chills, myalgias	Fever	Fatigue	Fever, fatigue	Fever, backache, headache, diarrhea, chills	None	Malaise, fever	Fever	Fever, sore throat, itching, fatigue	Fever, headache	Fever, headache	Headache, shoulder and neck pain	Headache, hoarseness	Fever, fatigue, headache, constipation, sore throat	Fever, headache, nausea, fatigue	Fever, myalgia, headache, sore throat	Fever, chills, urethritis	Fever	Fever, sore throat, back pain	Fever, sore throat	Fever, chills, night sweats	Fever, chills, fatigue, painful bowel movements	Fever
Lymphadenopathy	None	None	None	None	Inguinal	Inguinal and neck	None	None	Neck and inguinal	Cervical	Neck and inguinal	Right inguinal	None	None	Inguinal	Inguinal	None	Inguinal	None	Inguinal	Cervical, inguinal	Cervical	None	Inguinal	None
No. of lesions	10-100	<10	<10	10-100	<10	10-100	10-100	<10	10-100	10-100	10-100	10-100	>100	10-100	<10	<10	10-100	<10	<10	<10	<10	<10	<10	10-100	<10
Genital lesions	Perianal	Perianal	Genital	Genital	Genital	Perianal	Perianal	Genital	Genital	No	Genital	No	Perianal and genital	Genital	Genital	Perianal	Genital	Genital	Perianal	Genital	Perianal and genital	Genital	Genital	Genital	Perianal

Some previous smallpox vaccinated and some with Jynneos vaccinated

# Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

Table. Clinical Characteristics of Patients With Monkeypox Infection Treated With Tecovirimat

Patient	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Many with HIV					19	20	21	22	23	24	25
Smallpox vaccination history	Unk	Unk	No	No	No	No	No	Unk	Unk	Unk	Unk	No	No	No					Jynneos	Jynneos	No	Jynneos	Remote	No	Jynneos	Unk
HIV, <sup>a</sup> hepatitis B, hepatitis C status	Hiv	None	None	None	None	HIV	HIV	HIV	None	HIV	HIV	None	HIV	None	None	HIV	None	None	None	None	None	None	None	None	None	HIV
Systemic symptoms	None	Fever, back-ache, fatigue	Nau- sea, chills, myalgias	Fever	Fa- tigue	Fever, fa- tigue	Fever, backache, headache, diarrhea, chills	None	Malaise, fever	Fever	Fever, sore throat, itching, fatigue	Fever, head- ache	Fever, head- ache	Head- ache, shoulder and neck pain	Head- ache, hoarse- ness	Fever, fatigue, head- ache, consti- pation, sore throat	Fever, head- ache, nausea, fatigue	Fever, myalgia, head- ache, sore throat	Fever, chills, urethritis	Fever	Fever, sore throat, back pain	Fever, sore throat	Fever, chills, night sweats	Fever, chills, fatigue, painful bowel movements	Fever	
Lymphade- nopathy	None	None	None	None	In- guinal	In- guinal and neck	None	None	Neck and in- guinal	Cervical	Neck and in- guinal	Right in- guinal	None	None	In- guinal	In- guinal	None	In- guinal	None	In- guinal	Cer- vical, inguinal	Cer- vical	None	In- guinal	None	
No. of lesions	10- 100	<10	<10	10- 100	<10	10- 100	10- 100	<10	10- 100	10- 100	10- 100	10- 100	>100	10- 100	<10	<10	10- 100	<10	<10	<10	<10	<10	<10	10- 100	<10	
Genital lesions	Pe- rianal	Pe- rianal	Gen- ital	Gen- ital	Gen- ital	Pe- rianal	Pe- rianal	Gen- ital	Genital	No	Gen- ital	No	Pe- rianal and genital	Gen- ital	Gen- ital	Pe- rianal	Gen- ital	Gen- ital	Pe- rianal	Gen- ital	Pe- rianal and genital	Gen- ital	Gen- ital	Gen- ital	Pe- rianal	

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Smallpox vaccination history	Unk	Unk	No	No	No	No	No	Unk	Unk	Unk	Unk	No	No	No	Unk	No	Unk	Jynneos	Jynneos	No	Jynneos	Remote	No	Jynneos	Unk
HIV, <sup>a</sup> hepatitis B, hepatitis C status	HIV	None	None	None	None	HIV	HIV	HIV	None	HIV	HIV	None	HIV	None	None	HIV	None	None	None	None	None	None	None	None	HIV
Systemic symptoms	None	Fever, back-ache, fatigue	Nausea, chills, myalgias	Fever	Fatigue	Fever, fatigue	Fever, backache, headache, diarrhea, chills	None	Malaise, fever	Fever	Fever, sore throat, itching, fatigue	Fever, headache	Fever, headache	Head-ache, shoulder and neck pain	Head-ache, hoarseness	Fever, fatigue, head-ache, nausea, constipation, sore throat	Fever, head-ache, fatigue	Fever, myalgia, head-ache, sore throat	Fever, chills, urethritis	Fever	Fever, sore throat, back pain	Fever, sore throat	Fever, chills, night sweats	Fever, chills, fatigue, painful bowel movements	Fever
Lymphadenopathy	None	None	None	None	In-guinal	In-guinal and neck	None	None	Neck and in-guinal	Genital	Neck	Right	None	None	None	None	None	None	None	None	Genital	Genital	None	None	None
No. of lesions	10-100	<10	<10	10-100	<10	10-100	10-100	<10	10-100	10-100	10-100	10-100	>100	10-100	<10	<10	10-100	<10	<10	<10	<10	<10	<10	10-100	<10
Genital lesions	Pe-ri-anal	Pe-ri-anal	Gen-ital	Gen-ital	Gen-ital	Pe-ri-anal	Pe-ri-anal	Gen-ital	Genital	No	Gen-ital	No	Pe-ri-anal and genital	Gen-ital	Gen-ital	Pe-ri-anal	Gen-ital	Gen-ital	Pe-ri-anal	Gen-ital	Pe-ri-anal and genital	Gen-ital	Gen-ital	Gen-ital	Pe-ri-anal

Almost all with genital or peri-anal lesions. Wide range of number of lesions



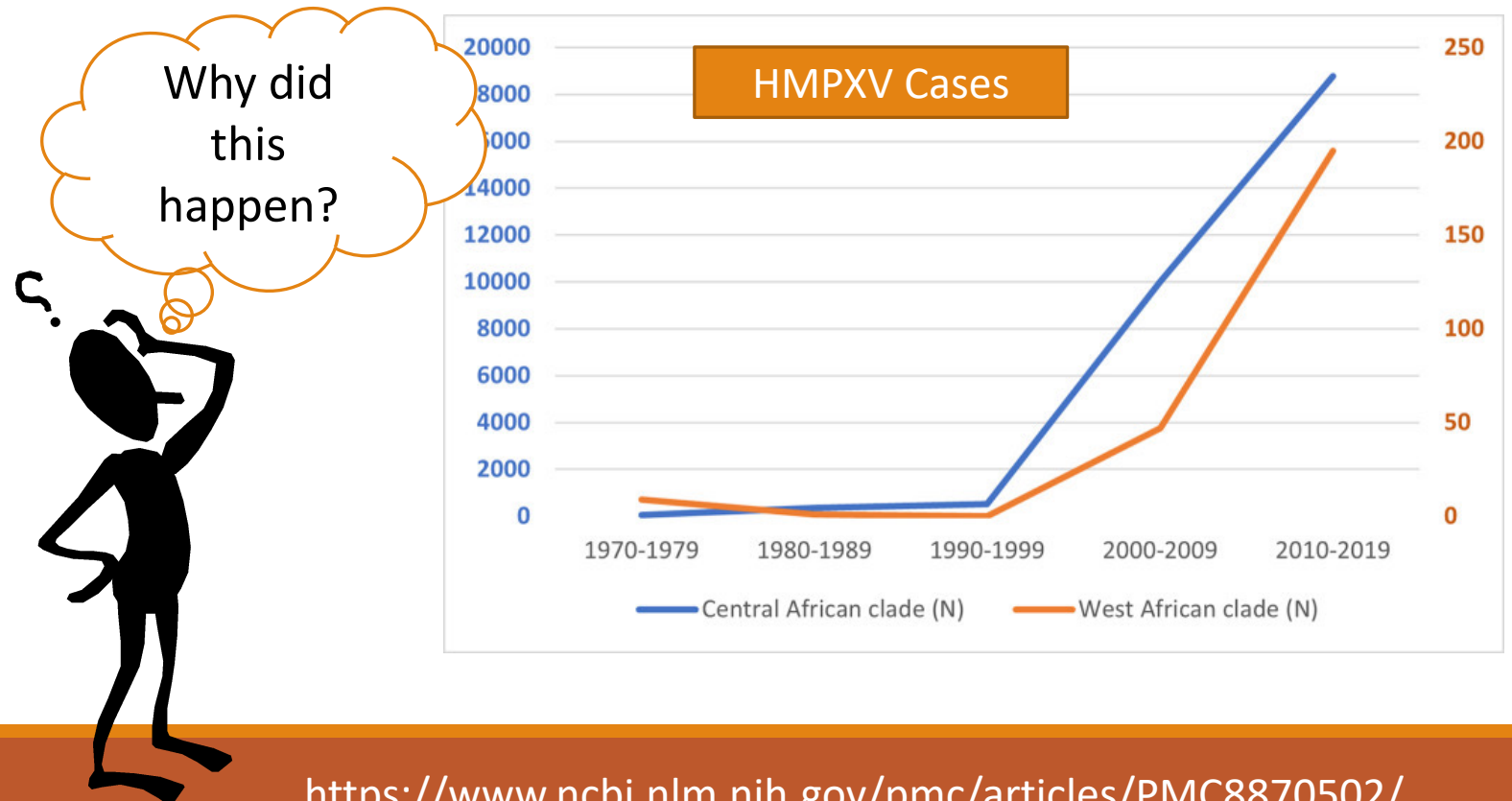
# Prevention

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# Will vaccines work?

Since HMPXV is closely related to smallpox, the smallpox vaccine works

Smallpox eradicated in 1980, and most worldwide vaccination campaigns wound down in 1970s





Strategic National Stockpile

# Prevention

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One FDA approved vaccine for HMPXV:

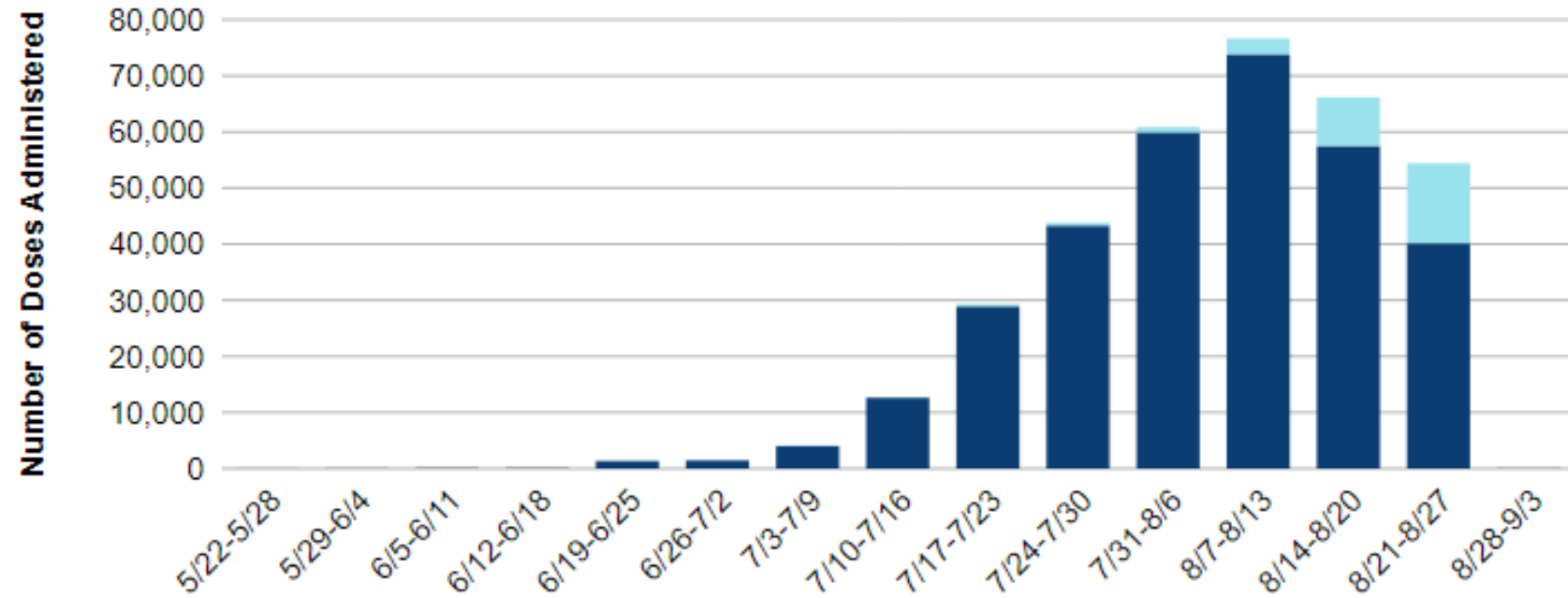
- JYNNEOS – live, **non-replicating** virus. Rec - 2 subcutaneous injections 4 weeks apart.
- PrEP and PEP

Although 20 million doses of Jynneos were stored in the SNS <10 years ago, all but 2,400 doses had expired by 2022.

- Sufficient vaccine for 1,200 people
- To date, almost 20,000 MPX cases in the US alone
- Additional Jynneos vaccine (other sources) allocated
- Emergency Use Authorization for Intradermal use (1/5<sup>th</sup> standard dose)

U.S.

## Total JYNNEOS Vaccine Doses Administered and Reported to CDC



**352,675**

Doses Administered in the 30 U.S. Jurisdictions Reporting Data as of August 30, 2022.

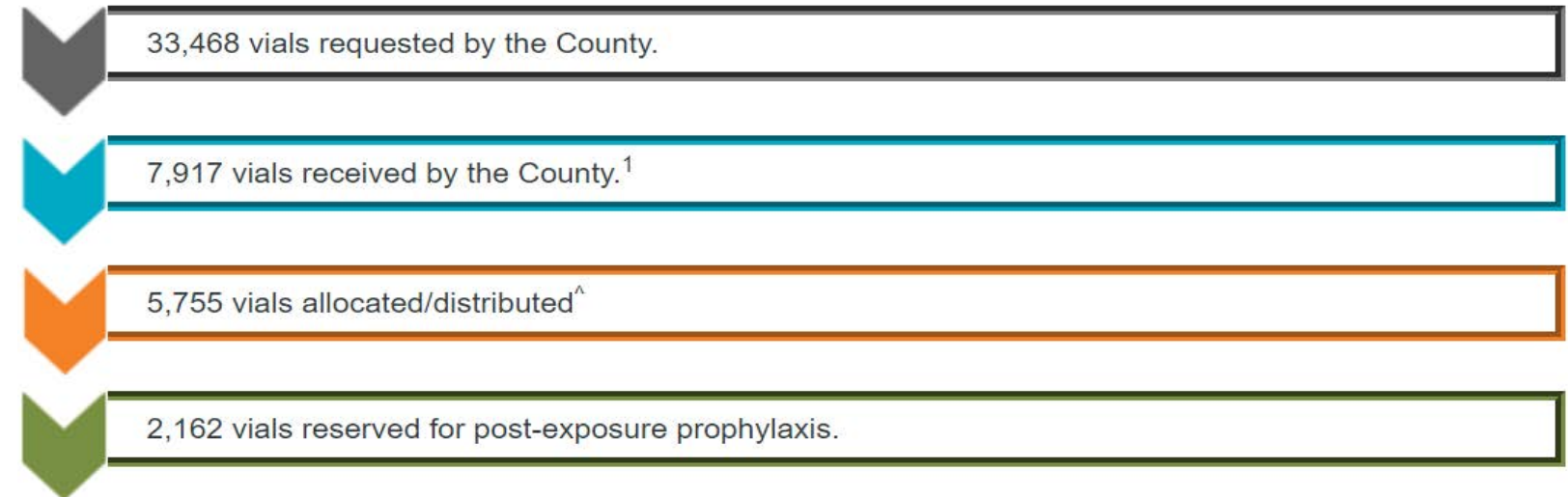
- Second doses administered
- First doses administered

# San Diego

## CUMULATIVE VACCINE SUMMARY Updated Weekly (Tuesday) Data Through 9/5/2022

**Note:** Effective 8/29/22, the Cumulative Vaccine Summary will be updated on Tuesdays, with data through the previous day.

Data are preliminary and subject to change



<sup>1</sup> The number of vials received was allocated from the California Department of Public Health (CDPH) to respond to the current MPOX outbreak. These vials are then distributed to public and community/hospital vaccination sites to administer.

<sup>^</sup>The number of vials distributed to healthcare systems, FQHC, and County clinics.

Data as of: September 5, 2022

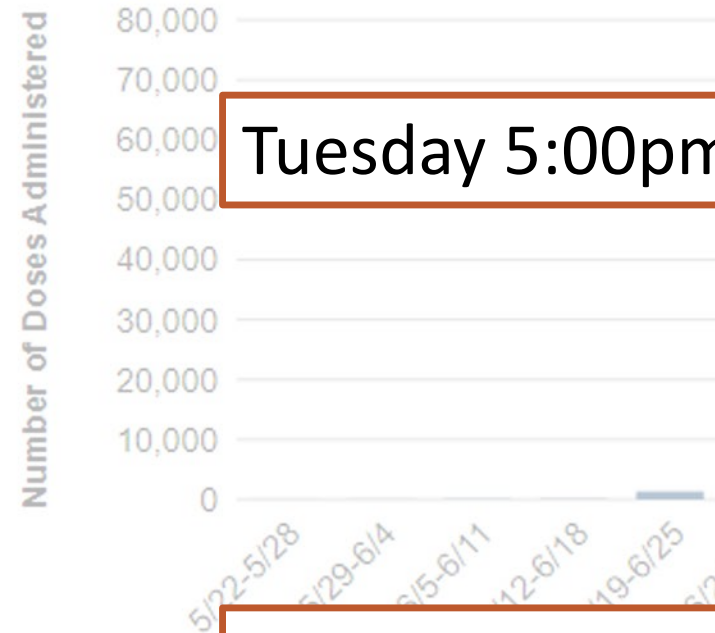
Updated: September 6, 2022



SMS

Text **COSD MONKEYPOX** to **468-311** to get text alert updates.

## Total JYNNEOS Vaccine Doses Administered



Tuesday 5:00pm

Tuesday 6:00pm

**352,675**

Doses Administered

Mpox vaccine appointments are available for high-risk clients at North County vaccination event this Thursday. Schedule now at [myturn.ca.gov](https://myturn.ca.gov)

All Mpox vaccination appts. are filled. Stay tuned for more. -  
Todas las citas de la vacuna contra Mpox se han llenado. Mantente al tanto para más información.



Gay, bisexual, and other men who have sex with men are taking steps to protect themselves and their partners from monkeypox.



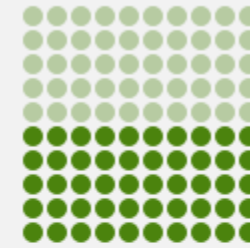
48%

reduced number of sex partners



50%

reduced one-time sexual encounters



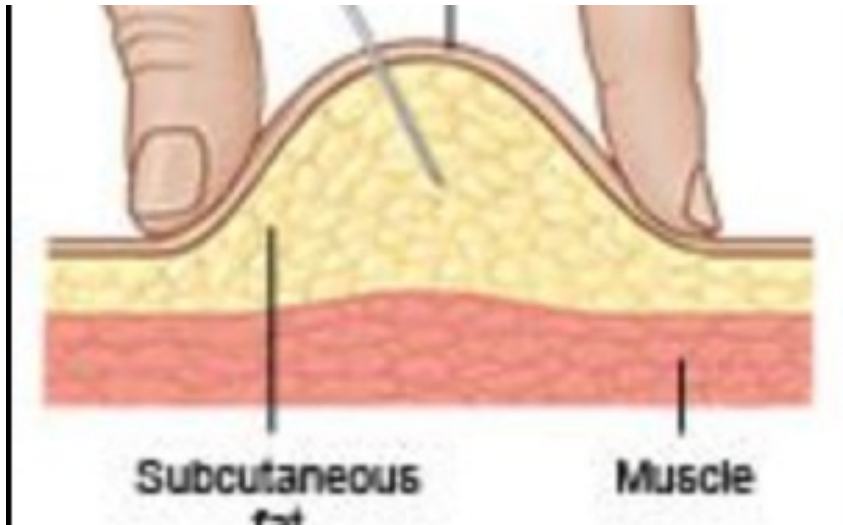
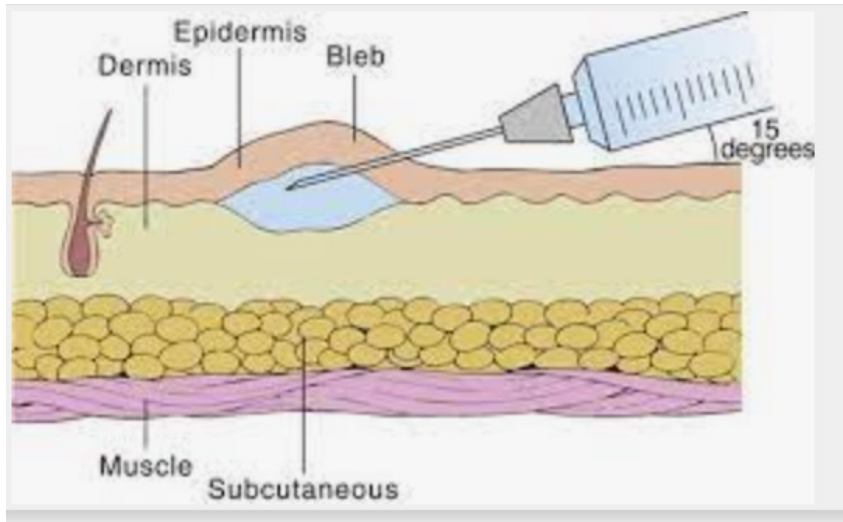
50%

reported reducing sex with partners met on dating apps or at sex venues

American Men's Internet Survey, 2022 Monkeypox Supplemental Survey. <https://emoryamis.org/>

# Research

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# NIH Multisite 22-0020 DoSES Clinical Trial

- Dose Reduction Strategies of the Jynneos Vaccine
  - To evaluate dose sparing strategies to extend the limited vaccine supply
  - To compare immune responses between current licensed dose and dose sparing vaccine strategies

USATODAY

**You have a lump on your arm weeks after monkeypox vaccine. Why it's a 'super common' side effect.**

Patrick Ryan, USA TODAY

August 25, 2022 · 5 min read

Stigma is Real

**A5418**

**A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Persons with Human Monkeypox Virus Disease**

**Study of Tecovirimat for Human Monkeypox Virus (STOMP)**

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SPONSOR: NIH/AIDS CLINICAL TRIALS GROUP



# Other tecovirimat studies for HMPXV

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PALM-007: randomized, double-blind, controlled trial of tecovirimat for HMPXV to be conducted in the Democratic Republic of Congo (n=450)

- Patients hospitalized for duration of treatment; different clade than current epidemic

PLATINUM: a randomized, double-blind controlled trial of tecovirimat for HMPXV to be conducted in the UK (n=500)

- Conducted remotely

Canadian trial (details unknown)

WHO/ANRS trial: 6 yrs and old; platform trial; time to complete resolution

All trials are evaluating same dose of tecovirimat, sampling of various compartments for HMPXV

- Unique features of A5418 rectal sampling, cross-over to tecovirimat for progression or severe pain, 2:1 allocation ratio, enrollment of presumptive HMPXV, earlier in course of disease, structure pain assessment

# Study Summary

<b>Design and Sample size</b>	2:1 Randomized, Blinded, Placebo-controlled (n=530) Intensively sampled subset (n=100) Open label for children, persons with pregnancy or severe disease, severe immune suppression or severe skin disease (n≅250)
<b>Study Population</b>	Symptomatic HMPXV infection (greater than 3 kg)
<b>Design</b>	Superiority
<b>1<sup>0</sup> Outcome</b>	Time to clinical resolution
<b>Duration</b>	57 days
<b>Enrollment period</b>	8 weeks
<b>Agent</b>	Weight based oral Tecovirimat

Hypothesis

Tecovirimat will lead to faster clinical resolution of HMPXV disease compared to placebo.

1<sup>o</sup> Objective

**To compare time to clinical resolution between people with HMPXV randomized to tecovirimat or placebo.**

and endpoint

Clinical resolution is when all skin lesions are scabbed over, desquamated, or healed and all visible mucosal lesions healed

Step 1: daily self skin checks and photographs

Step 2: participant reports clinical resolution

Step 3: video visit to confirm clinical resolution

Step 4: confirmation at in person visit

# A5418

## Population Eligibility

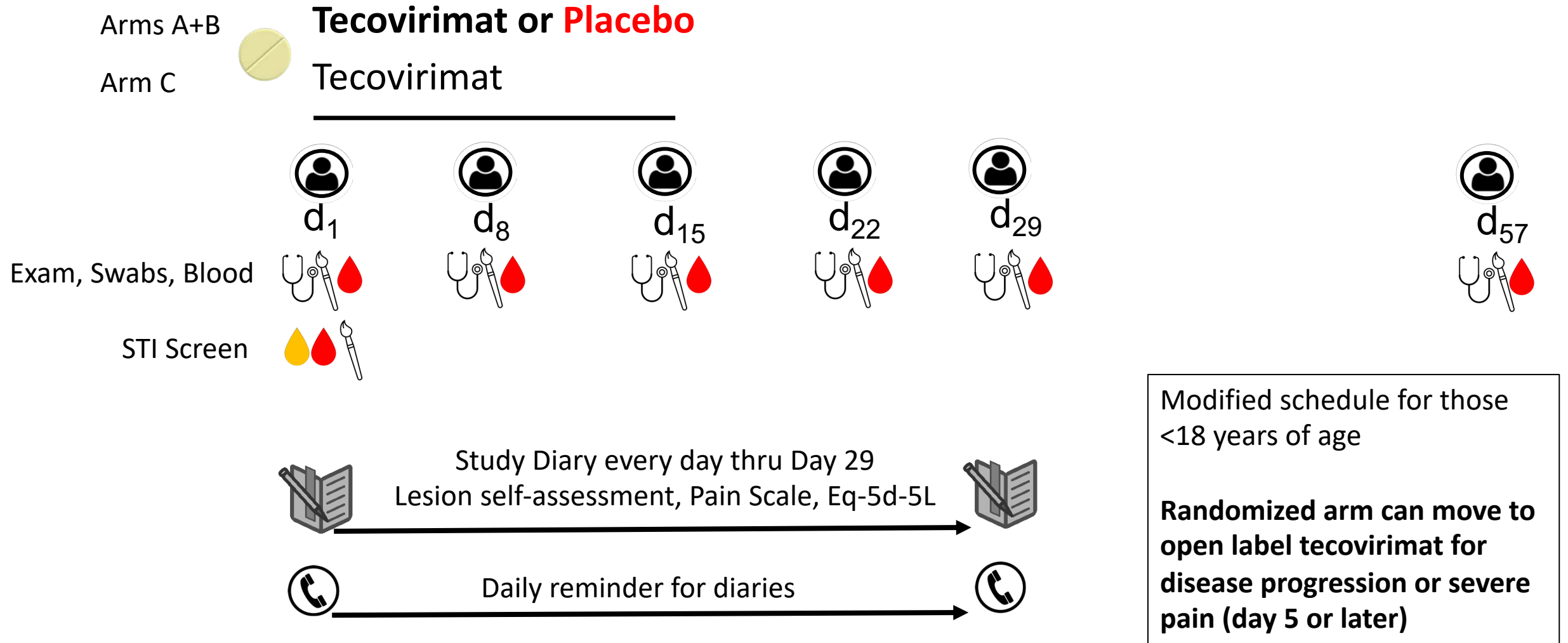
Outpatients (> 3 kg ) with:

- **Confirmed or presumptive** disease (oral, rectal, or skin lesion)
  - Laboratory-confirmed infection preferred
  - Presumptive diagnosis with compatible skin or mucosal lesions or proctitis in cisgender men or transgender women with sexual contact with 1 or more cismen or transwomen in 14 days prior to symptom onset or people with exposure to another person with known HMPXV.
- Onset of symptoms of HMPXV infection  $\leq 14$  days prior to randomization,
- At least one active, (not yet scabbed) skin lesion, mouth lesion or proctitis with or without visible ulcers

Randomization restricted to those 18 years or older without one of the following conditions

Those with severe disease (ocular involvement, hospitalization, deep lesions requiring surgical intervention, potentially disfiguring lesions on the face), pregnant and breastfeeding people, and those with severe immunodeficiency, severe inflammatory skin conditions, children are in open-label cohort.

# Schedule of Evaluations





# Phase 2 Randomized, Open-Label Multisite Trial to Evaluate the Immunogenicity of Dose Reduction Strategies of the MVA-BN Vaccine

## OBJECTIVES

### Primary

To determine if peak humoral immune responses following an ID regimen of  $2 \times 10^7$  TCID<sub>50</sub> MVA-BN are non-inferior to the licensed regimen of  $1 \times 10^8$  MVA-BN administered SC

To determine if peak humoral immune responses following an ID regimen of  $1 \times 10^7$  TCID<sub>50</sub> MVA-BN are non-inferior to the licensed regimen of  $1 \times 10^8$  MVA-BN administered SC

Arm	Dose of JYNNEOS (MVA-BN)	Route of Administration	Vaccination Day	
			Day 1	Day 29
1	$2 \times 10^7$ TCID <sub>50</sub> (0.1 mL) – EUA regimen	Intradermal	X	X
2	$1 \times 10^7$ TCID <sub>50</sub> (0.05 mL) – on-tenth dose	Intradermal	X	X
3	$1 \times 10^8$ TCID <sub>50</sub> (0.5 mL) – licensed regimen	Subcutaneous	X	X

# Phase 2 Randomized, Open-Label Multisite Trial to Evaluate the Immunogenicity of Dose Reduction Strategies of the MVA-BN Vaccine

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- **This study will enroll healthy, non-pregnant, non-breastfeeding adults 18 to 50 years old.**
- **Participants with stable medical conditions and well-controlled HIV infection, as determined by the investigator, can participate.**
- **Participant Inclusion and Exclusion Criteria must be confirmed by an investigator named on the delegation log. If there is any uncertainty, the PI should make the decision on whether a potential participant is eligible for study enrollment.**
- **No exemptions are granted on Inclusion/Exclusion Criteria.**

# Have you received the Monkeypox vaccine and/or been diagnosed or recovered from Monkeypox?

**La Jolla Institute is seeking participants to contribute to research on the human response by providing their blood for study.**

## ELIGIBILITY

- Volunteers received the Monkeypox vaccine and/or have been diagnosed or recovered from Monkeypox
- Over 18 years of age

- Financial compensation is up to \$500 for your time and effort

## PARTICIPATION

- Participation will consist of completing a brief study questionnaire + up to 5 blood draws

**For more information or how to get involved:**

- **call (858) 255-0680**
- **email [donors@lji.org](mailto:donors@lji.org)**
- **visit [lji.org/study](https://lji.org/study)**







# A GLOBAL LEADER IN PANDEMIC PREPAREDNESS

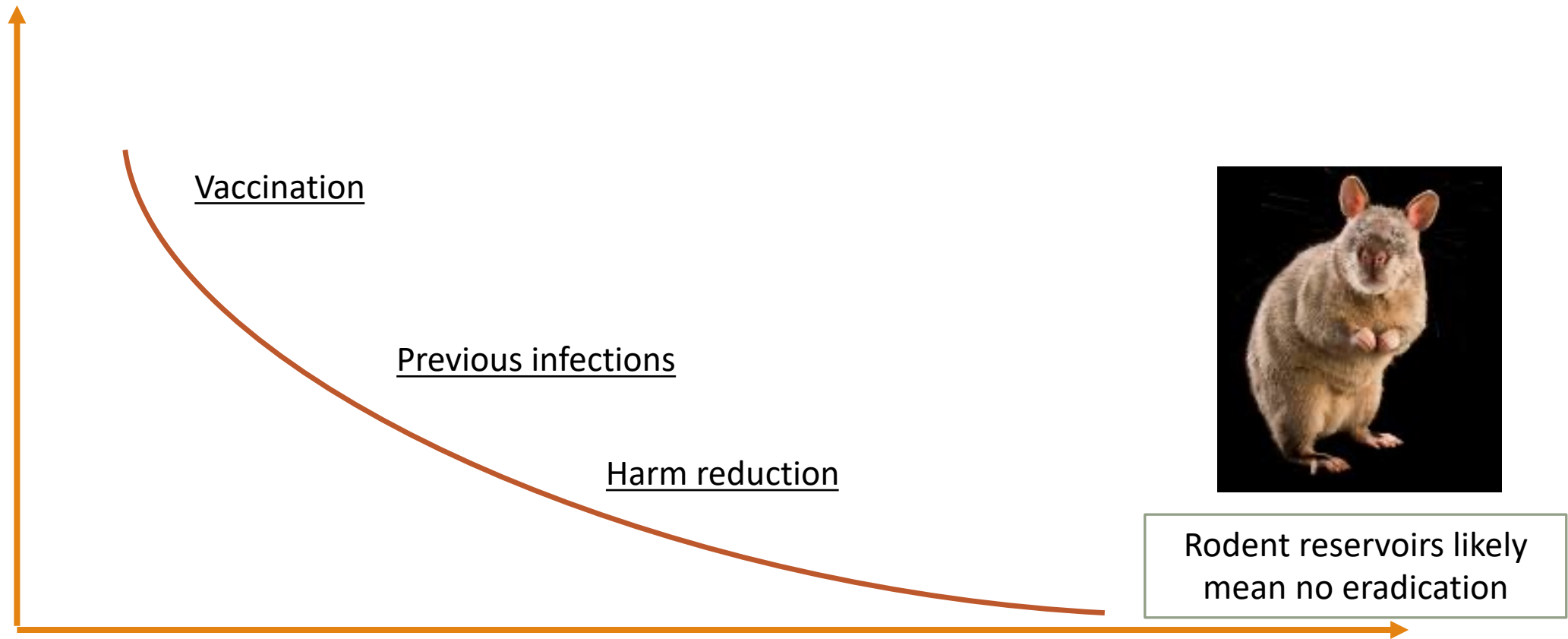
The way to create a Pandemic Response  
to Emerging Pathogens, Antimicrobial  
Resistance and Equity is to PREPARE.

*The joint SD CFAR & UC San Diego PREPARE Institute Developmental Grant in HIV/MPX is currently open.*

*This opportunity allows early stage (pre-R01) investigators who hold faculty appointments at an SD CFAR member institution to apply for up to \$50,000 in funding for a one-year project on MPX in the context of HIV risk, prevention, transmission, and/or treatment.*

# Getting to zero

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# Resources and Information

## WEBSITE & EDUCATIONAL MATERIALS

### Human Monkeypox

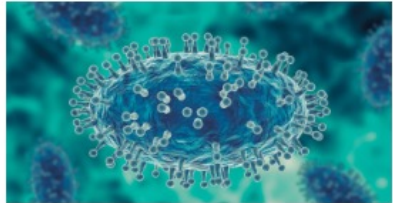


Announcements

8/22/2022 **\*\*NEW\*\* Vaccine Webpage**  
8/11/2022 **Town Hall Recording**

### About

Transmission, symptoms, treatment, exposure, prevention, and frequently asked questions (FAQs)



### Vaccine

Vaccine eligibility, cumulative vaccine summary, and FAQs



### Local Health Emergency

Multiple languages available

### Educational Materials

FAQs, flyers, and social media

### Events

Town halls and telebriefings



Text **COSD MONKEYPOX** to 468-311.

Get text updates about monkeypox from the County. Text COSD MONKEYPOX to 468-311. (Phone users: [tap to create the message](#))



Text **COSD MONKEYPOX** to **468-311** to get text alert updates.

## TELEBRIEFINGS

### Telebriefings

Request a  
Monkeypox  
Presentation

Request a [monkeypox presentation](#) from our *Live Well San Diego* Speaker's Bureau.

### Telebriefings

Sector	Day and Time
Businesses and Employers	Business Sector telebriefings will be held on then <b>2nd Wednesday of every other month from 9:30-10:30 AM</b> . This meeting will be conducted completely online. <a href="#">Join us for Business Sector telebriefings</a>
Child Care Services	Child Care Sector telebriefings will be held on the <b>2nd Tuesday of the month at 1:00 PM</b> . This meeting will be conducted completely online. <a href="#">Join us for Child Care Services telebriefings</a>
Community- and Faith-Based Organizations	The Community and Faith-Based Organizations telebriefings will be held on <b>quarterly on the 1st Wednesday of the month from 1:00-2:00 PM</b> . This meeting will be conducted completely online. <a href="#">Join us for Community and Faith-Based Organizations telebriefings</a>

## NEWS ARTICLES

### COUNTYNEWSCENTER

DIRECT TO YOU FROM THE COUNTY OF SAN DIEGO

HOME NEWS VIDEOS TOPICS PHOTOS BOARD MEETINGS COUNTY WEBSITE Q

### Tag: monkeypox

HEALTH

### County Distributing More Than 700 Vials Of Mpox Vaccine

Aug. 22, 2022 | 5:56 PM

The County of San Diego is distributing 705 vials of Mpox (monkeypox) vaccine this week to healthcare providers around the region.



For updates, text COSD MONKEYPOX to 468-311. For resources, visit:

[SanDiegoCounty.gov/monkeypoxSD](https://SanDiegoCounty.gov/monkeypoxSD)

