How do we get out of another epidemic?

What’s going on?

Here we go again

HMPXV

Davey Smith, MD, MAS
Professor of Medicine
UC San Diego
TikTok & Twitter @DaveySmithMD

September 8, 2022
Smith Disclosures

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 Strathdee, PhD
- Rehan Syed, MD
- Tim Wilkin, MD
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

https://www.poz.com/blog/cdcs-daskalakis-monkeypox-stigma-gay-room
Governor Newsom Proclaims State of Emergency to Support State’s Response to Monkeypox
Published: Aug 01, 2022

San Diego County follows state’s lead, declares local monkeypox state of emergency
AUG. 2, 2022 5:39 PM PT

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?
2022 outbreak detected in 110 countries with 53,446 confirmed and 3,163 suspected cases (as of 2022-09-06).

Since 2022-09-02, 497 new confirmed cases have been reported.
Where

U.S.

U.S. Cases | California
---|---
19,962 | 3,897
When

data as of 04 Sep 2022 17:00 CEST

World

U.S.

S.D.

Source: WHO
Who: U.S.

Monkeypox cases reported to CDC: Race/Ethnicity by Week

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<tr>
<td>Multiple Races</td>
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<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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</table>
Who: U.S.

Monkeypox cases reported to CDC: Race/Ethnicity by Week

Race / Ethnicity
- American Indian/Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Multiple Races
- Native Hawaiian or Other Pacific Islander
- White
<table>
<thead>
<tr>
<th>Age</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
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<td></td>
<td>35</td>
<td>20</td>
<td>65</td>
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<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>116</td>
<td>44%</td>
</tr>
<tr>
<td>White</td>
<td>110</td>
<td>42%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>22</td>
<td>8%</td>
</tr>
<tr>
<td>Asian</td>
<td>6</td>
<td>2%</td>
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<tr>
<td>Other/Multiple Race</td>
<td>3</td>
<td>1%</td>
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<tr>
<td>American Indian or Alaska Native</td>
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<td>Native Hawaiian or Other Pacific Islander</td>
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<td>1%</td>
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<tr>
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<td>51</td>
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<td>Central</td>
<td>173</td>
<td>56%</td>
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<td>North Central</td>
<td>52</td>
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<td>South</td>
<td>27</td>
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<td>North Coastal</td>
<td>27</td>
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<tr>
<td>East</td>
<td>15</td>
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<tr>
<td>North Inland</td>
<td>15</td>
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<td>4</td>
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<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Persons Experiencing Homelessness</td>
<td>12</td>
<td>4%</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>10</td>
<td>3%</td>
</tr>
<tr>
<td>Deaths</td>
<td>0</td>
<td>0%</td>
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### Reported values

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

1. Note given true proportions of variables, yes reporting may be common than no reporting
2. May be hospitalised for isolation or medical treatment
### San Diego County Confirmed and Probable Cases*
#### Updated Weekly
#### Data Through 9/3/2022, Updated 9/6/2022

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Percent†</th>
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<tr>
<td><strong>Total</strong></td>
<td>313</td>
<td>100%</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
<td>308</td>
<td>98%</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>1%</td>
</tr>
<tr>
<td>Transgender female</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Transgender male</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Genderqueer or non-binary</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Identity not listed</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Declined to answer</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Unknown or missing</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Sexual Orientation</strong></td>
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</tr>
<tr>
<td>Gay, lesbian, or same-gender loving</td>
<td>210</td>
<td>85%</td>
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<tr>
<td>Bisexual</td>
<td>19</td>
<td>8%</td>
</tr>
<tr>
<td>Heterosexual or straight</td>
<td>13</td>
<td>5%</td>
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<tr>
<td>Declined to answer</td>
<td>4</td>
<td>2%</td>
</tr>
<tr>
<td>Orientation not listed</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Questioning/unsure/patient does not know</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Unknown or missing</td>
<td>67</td>
<td></td>
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</table>
2003 Midwest monkeypox outbreak - Wikipedia

Update: Multistate Outbreak of Monkeypox --- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003 (cdc.gov)
What is the difference now?

2003 Midwest monkeypox outbreak - Wikipedia

Update: Multistate Outbreak of Monkeypox --- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003 (cdc.gov)
Why do we not learn? Shigella

Did you know the diarrhea germ Shigella can be spread through sexual activity?

Washing your hands and using condoms are key to staying healthy.

UPDATE: SHigellosis among Men in Southern California

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

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

To: CAHAN San Diego Participants
Date: October 11, 2021
From: EISB, Public Health Services
Why do we not learn?

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

- 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

Sometimes you gotta be the ‘gay in the room’.
Virology
HMPXV Virology

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?
Fig. 1: Phylogenetic analysis of MPXV viral sequences associated with the 2022 worldwide outbreak. | Nature Medicine
181 participants in Spain
- 99% PCR of skin swab positive
- 70% PCR of throat swab positive
- 78% PCR of anal swab positive
Transmission
Transmission

2022 outbreak*: most common transmission mode
2003 US outbreak: most common transmission mode

Most commonly observed mode of transmission
Less commonly observed mode of transmission
Hypothesized mode of transmission

*The HMPXV which circulated in 2003 is a different variant of the West African clade than observed in the 2022 outbreak.
Three reasons monkeypox outbreak seems to be driven by sexual transmission in MSM

- **98%** MSM or bisexual men suspected for 95% of all cases
- **91%** Seminal fluid samples positive for monkeypox DNA
- **73%** Patients reported anogenital lesions
Disease
HMPXV Infection

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/m.px_global/

Proportion of cases with reported symptom*

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

Source: WHO
Disease process

A  Evolution of Cutaneous Lesions

Day 0  Single genital lesion treated with IM penicillin as suspected syphilis
Day 4  Condomless sexual contact in MSM
Days 4–6  Feeling unwell; additional lesions develop
Day 11  Confirmed monkeypox: facial and genital lesions PCR positive
Day 21  Follow-up 1: facial lesions PCR negative, genital lesions PCR positive
Day 28  Follow-up 2: genital lesions PCR negative

Another reason not touch a rash

Disease process

B  Oral and Perioral Lesions

Disease process

C Perianal, Anal, and Rectal Lesions
## Fatality Rate

<table>
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<tr>
<th>Countries/Clade</th>
<th>Case Fatality Rate</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>All countries^2</td>
<td>78/892 = 8.7%</td>
<td>7.0%– 10.8%</td>
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<tr>
<td>Clade 1^3</td>
<td>68/640 = 10.6%</td>
<td>8.4%– 13.3%</td>
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<tr>
<td>Clade 3^4</td>
<td>9/247 = 3.6%</td>
<td>1.7%– 6.8%</td>
</tr>
<tr>
<td>Clade 3, African countries only</td>
<td>9/195 = 4.6%</td>
<td>2.1%– 8.6%</td>
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### 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” (?)

[www.ncbi.nlm.nih.gov/pmc/articles/PMC8870502/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC8870502/)


Potential Treatments

Vaccinia Immune Globulin, Cidofovir, Brincidofovir, and Tecrovirimat
Brincidofovir

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

Clinical features and management of human monkeypox: The Lancet Infectious Diseases
Tecovirimat

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

https://jamanetwork.com/journals/jama/fullarticle/2795743
Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

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<th>Patient</th>
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<th>4</th>
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<td>Fever, fatigue</td>
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<td>Lymphadenopathy</td>
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<td>None</td>
<td>None</td>
<td>Inguinal and neck</td>
<td>Inguinal and neck</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
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<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
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<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td>Necker and unguinal</td>
<td></td>
</tr>
<tr>
<td>Genital lesions</td>
<td>Perianal</td>
<td>Perianal</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
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<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td>Genital</td>
<td></td>
</tr>
<tr>
<td>No. of lesions</td>
<td>10-100</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>10-100</td>
<td>&lt;10</td>
<td>10-100</td>
<td>10-100</td>
<td>10-100</td>
<td>&gt;100</td>
<td>10-100</td>
<td>&lt;10</td>
<td>10-100</td>
<td>&lt;10</td>
<td>10-100</td>
<td>&lt;10</td>
<td>10-100</td>
<td>&lt;10</td>
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<td>&lt;10</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>10-100</td>
<td>&lt;10</td>
<td>10-100</td>
</tr>
</tbody>
</table>

Some previous smallpox vaccinated and some with Jynneos vaccinated

https://jamanetwork.com/journals/jama/fullarticle/2795743
### Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox vaccination history</td>
<td>Unk</td>
<td>Unk</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Unk</td>
<td>Unk</td>
<td>Unk</td>
<td>Unk</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>HIV, hepatitis B, hepatitis C status</td>
<td>HIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>HIV</td>
<td>HIV</td>
<td>None</td>
<td>HIV</td>
<td>None</td>
<td>HIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

#### Systemic symptoms
- None
- Fever, backache, fatigue
- Fever, backache, headache, diarrhea, chills
- Fever, fatigue
- Fever, backache, headache, diarrhea, chills
- Malaise, 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, sore throat
- Fever, myalgia, headache, sore throat
- Fever, chills, urethritis
- Fever, sore throat, back pain
- Fever, sore throat
- Fever, chills, fatigue, painful bowel movements

#### Lymphadenopathy
- None
- Inguinal
- Inguinal and neck
- None
- Neck andinguinal
- Cervical
- Neck and inguinal
- Right inguinal
- None
- Inguinal
- Inguinal
- Inguinal
- Cervical, inguinal
- Cervical
- Inguinal
- None
- Inguinal
- None
- Inguinal

#### No. of lesions
- 10–100
- <10
- <10
- 10–100
- <10
- 10–100
- 10–100
- >100
- 10–100
- <10
- 10–100
- <10
- <10
- <10
- 10–100
- <10

#### Genital lesions
- Perianal
- Perianal
- Genital
- Genital
- Genital
- Perianal
- Perianal
- Genital
- Genital
- Perianal
- Genital
- Genital
- Perianal
- Genital
- Genital
- Genital
- Genital

[https://jamanetwork.com/journals/jama/fullarticle/2795743](https://jamanetwork.com/journals/jama/fullarticle/2795743)
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 | No | No | Unk | No | Unk | No | 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 | None | Fever, fatigue | Fever, backache, headache, diarrhea, chills | None | Malaise, fever | Fever, headache | Fever, sore throat, itching, fatigue | Fever, headache | Headache, shoulder and neck pain | Headache, hoarseness | Fever, fatigue, headache, constipation, sore throat | Fever, headache, nausea, fatigue | Fever, sore throat, back pain | Fever, sore throat | Fever, chills, fatigue, painful bowel movements | Fever, sore throat | Fever, chills, night sweats | Fever, chills, fatigue, painful bowel movements |
| Lymphadenopathy | None | None | None | None | Inguinal and neck | None | None | Neck and inguinal | Genital | Right | None | None | Inguinal and neck | None | None | None | Genital | Right | None | None | None | Genital | Right | None | None |

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

Why did this happen?

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8870502/
Prevention

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\textsuperscript{th} standard dose)
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

- 33,468 vials requested by the County.
- 7,917 vials received by the County.¹
- 5,755 vials allocated/distributed⁶
- 2,162 vials reserved for post-exposure prophylaxis.

¹ 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.

⁶ The number of vials distributed to healthcare systems, FQHC, and County clinics.

Data as of: September 5, 2022
Updated: September 6, 2022
Mpox vaccine appointments are available for high-risk clients at North County vaccination event this Thursday. Schedule now at 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.

American Men's Internet Survey, 2022 Monkeypox Supplemental Survey. [https://emoryamis.org/](https://emoryamis.org/)
Research
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

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

Stigma is Real
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)

SPONSOR: NIH/AIDS CLINICAL TRIALS GROUP
Other tecovirimat studies for HMPXV

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

| **Design and Sample size** | 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) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Population</strong></td>
<td>Symptomatic HMPXV infection (greater than 3 kg)</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Superiority</td>
</tr>
<tr>
<td><strong>1^0 Outcome</strong></td>
<td>Time to clinical resolution</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>57 days</td>
</tr>
<tr>
<td><strong>Enrollment period</strong></td>
<td>8 weeks</td>
</tr>
<tr>
<td><strong>Agent</strong></td>
<td>Weight based oral Tecovirimat</td>
</tr>
</tbody>
</table>
Hypothesis

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

1<sup>st</sup> Objective and endpoint

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

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
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 ≤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

Arms A+B
- Tecovirimat or Placebo

Arm C
- Tecovirimat

Exam, Swabs, Blood
- d₁
- d₈
- d₁₅
- d₂₂
- d₂₉

STI Screen
- d₅₇

Study Diary every day thru Day 29
Lesion self-assessment, Pain Scale, Eq-5d-5L

Modified schedule for those <18 years of age

Randomized arm can move to open label tecovirimat for disease progression or severe pain (day 5 or later)

Daily reminder for diaries
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 $2 \times 10^7 \text{ TCID}_{50}$ 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 $1 \times 10^7 \text{ TCID}_{50}$ MVA-BN are non-inferior to the licensed regimen of $1 \times 10^8$ MVA-BN administered SC.

<table>
<thead>
<tr>
<th>Arm</th>
<th>Dose of JYNNEOS (MVA-BN)</th>
<th>Route of Administration</th>
<th>Vaccination Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$2 \times 10^7 \text{ TCID}_{50}$ (0.1 mL) – EUA regimen</td>
<td>Intradermal</td>
<td>X</td>
</tr>
<tr>
<td>2</td>
<td>$1 \times 10^7 \text{ TCID}_{50}$ (0.05 mL) – on-tenth dose</td>
<td>Intradermal</td>
<td>X</td>
</tr>
<tr>
<td>3</td>
<td>$1 \times 10^8 \text{ TCID}_{50}$ (0.5 mL) – licensed regimen</td>
<td>Subcutaneous</td>
<td>X</td>
</tr>
</tbody>
</table>
Phase 2 Randomized, Open-Label Multisite Trial to Evaluate the immunogenicity of Dose Reduction Strategies of the MVA-BN Vaccine

- 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
- visit lji.org/study
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

- Vaccination
- Previous infections
- Harm reduction

Rodent reservoirs likely mean no eradication
Is it safe to come out?

Any questions?
Resources and Information

WEBSITE & EDUCATIONAL MATERIALS

Human Monkeypox

Announcements
8/22/2022 1 NEW Vaccine Website
8/11/2022 Town Hall Recording

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

Local Cases
Cases and Test, Trace, and Treat (T3) dashboard

Vaccine
Vaccine eligibility, cumulative vaccine summary, and FAQs

Healthcare Professionals
Action items and resources

Local Health Emergency
Educational Materials
Events

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

Request a Monkeypox Presentation

Telebriefings

Telebriefings

Day and Time

Business Sector telebriefings will be held on their 2nd Wednesday of every other month from 9:30-10:30 AM. This meeting will be conducted completely online.

Join us for Business Sector telebriefings

Child Care Services
Child Care Sector telebriefings will be held on the 2nd Tuesday of the month at 1:00 PM.

This meeting will be conducted completely online.

Join us for Child Care Services telebriefings

Community- and Faith-Based Organizations
The Community and Faith-Based Organizations telebriefings will be held on quarterly on the 1st Wednesday of the month from 1:00-2:00 PM.

This meeting will be conducted completely online.

Join us for Community and Faith-Based Organizations telebriefings

NEWS ARTICLES

COUNTY NEWS CENTER
DIRECT TO YOU FROM THE COUNTY OF SAN DIEGO

Tag: monkeypox

County Distributing More Than 700 Vials Of Mpor Vaccine
Aug. 22, 2022 | 5:56 PM

The County of San Diego is distributing 700 vials of Mpor (monkeypox) vaccine this week to healthcare providers around the region.