Monkeypox Update -- July 20, 2022

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Texas Department of State Health Services
The information presented today is based on CDC’s recent guidance and MAY change.

July 20, 2022
Agenda

• Monkeypox Virus and Disease Overview – Dr. Shuford
• Monkeypox Treatments – Dr. Shuford
• Diagnostic Consults and Testing – Imelda Garcia
• Vaccine and Therapeutic Ordering – Imelda Garcia
• Question and Answers
Monkeypox: Global Situational Update

Available at: https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html. Accessed 7/19/2022.
# Monkeypox: Texas Situational Update

## Reported Monkeypox Cases in Texas by Public Health Region

<table>
<thead>
<tr>
<th>Public Health Region</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHR 1</td>
<td>1</td>
</tr>
<tr>
<td>PHR 2/3</td>
<td>42</td>
</tr>
<tr>
<td>PHR 4/5N</td>
<td>0</td>
</tr>
<tr>
<td>PHR 6/5S</td>
<td>34</td>
</tr>
<tr>
<td>PHR 7</td>
<td>27</td>
</tr>
<tr>
<td>PHR 8</td>
<td>6</td>
</tr>
<tr>
<td>PHR 9/10</td>
<td>0</td>
</tr>
<tr>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110</strong></td>
</tr>
</tbody>
</table>

## Reported Monkeypox Cases in Texas by Case Age at Time of Illness

<table>
<thead>
<tr>
<th>Age Category</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;21 Years</td>
<td>0</td>
</tr>
<tr>
<td>21-29 Years</td>
<td>36</td>
</tr>
<tr>
<td>30-39 Years</td>
<td>44</td>
</tr>
<tr>
<td>40-49 Years</td>
<td>22</td>
</tr>
<tr>
<td>50-59 Years</td>
<td>6</td>
</tr>
<tr>
<td>60+ Years</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110</strong></td>
</tr>
</tbody>
</table>

## Reported Monkeypox Cases in Texas by Type of Travel

<table>
<thead>
<tr>
<th>Travel Type</th>
<th># of Cases</th>
<th>% of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign Travel</td>
<td>13</td>
<td>12%</td>
</tr>
<tr>
<td>Domestic Travel</td>
<td>35</td>
<td>32%</td>
</tr>
<tr>
<td>No Travel</td>
<td>37</td>
<td>34%</td>
</tr>
<tr>
<td>Unknown Travel</td>
<td>25</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

As of July 18, 2022
Monkeypox: Basic Facts

- Monkeypox is caused by the monkeypox virus
- Monkeypox virus is an orthopoxvirus
  - Same virus family as variola virus (smallpox) and vaccinia
  - Different virus family than varicella virus (chickenpox)
- Two types of monkeypox
  - West African and Central African (aka Congo Basin)
  - Current outbreak is due to West African clade
- Discovered in 1958, but first human case identified in 1970
- African rodents and non-human primates are thought to harbor the virus

Available at: [https://www.cdc.gov/poxvirus/monkeypox/faq.html](https://www.cdc.gov/poxvirus/monkeypox/faq.html). Accessed 7/19/2022.
Monkeypox: Transmission

- Person-to-person spread is driving the current global outbreak
  - Direct contact with the infectious rash, scabs, or body fluids
  - Exposure to respiratory secretions during prolonged, face-to-face contact
  - Contact with items that previously touched the infectious rash or body fluids
  - Vertical transmission to a fetus through the placenta

- Can also become infected by being scratched or bitten by an infected animal or by preparing or eating meat or using products from an infected animal

Available at: https://www.cdc.gov/poxvirus/monkeypox/transmission.html. Accessed 7/19/2022.
**Monkepox: Clinical Course**

- **Incubation period:** 1-3 weeks
- **Clinical presentation**
  - Often starts with a prodrome of fever, malaise, headache, lymphadenopathy
  - Rash usually follows prodrome, though some people lack prodrome in current outbreak
    - Lesions progress through different phases: enanthem, macules, papules, vesicles, pustules, and then scabs
    - Takes about 2-4 weeks to progress through all stages
    - Infectious until scabs have fallen off and fresh skin is evident
- **Diagnosis:** Nucleic acid amplification test
- **Fatality rate** 1-10% in previous outbreaks, but lower with current outbreak

Available at: [https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html](https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html). Accessed 7/19/2022.
Monkepox: Medical Countermeasures

Medical countermeasures can be used for:

- Pre-exposure prophylaxis
- Post-exposure prophylaxis
- Treatment

JYNNEOS
Tecovirimat (TPOXX)
Vaccinia immune globulin
ACAM2000
Cidofovir
Brincidofovir
Medical countermeasures: JYNNEOS vaccine

- Live, non-replicating vaccine
- Licensed by FDA in 2019 for prevention of smallpox and monkeypox disease in adults at least 18 years old
  - PrEP or PEP
- Administered as subcutaneous injection in 2 doses at least 4 weeks apart
Medical countermeasures: JYNNEOS vaccine

- Efficacy
  - Animal data, immunogenicity studies support efficacy as PrEP
  - Very limited evidence for efficacy as PEP
- Safety and side effects
  - Safe for use in immunocompromised, atopic dermatitis
  - Safety not established in pregnancy, breastfeeding, pediatrics; use might still be considered
Medical countermeasures: ACAM2000 vaccine

- Live, *replicating* vaccine
- Licensed by FDA in 2007 for active immunization against smallpox in adults at least 18 years old
- CDC holds expanded access investigational new drug (EA IND) protocol allowing use to prevent non-smallpox orthopoxviruses during an outbreak, including use as PEP
- Administered percutaneously using a multiple puncture “scarification” technique
Medical countermeasures: ACAM2000 vaccine

- Efficacy to prevent monkeypox infection
  - PrEP: likely similar to other live smallpox vaccines (>85%) in endemic countries (Fine et al 1988)
  - Efficacy as PEP uncertain
- Safety and side effects
  - Significant side effect profile: myo/pericarditis (1 in 175), progressive vaccinia, eczema vaccinatum, postvaccinal encephalitis, fetal vaccinia, inadvertent inoculation or autoinoculation
  - Risk of severe side effects: pregnancy, young children, immunocompromised, exfoliative skin condition
Medical countermeasures: ACAM2000 vaccine
Vaccine for Pre-Exposure Prophylaxis

**TABLE 1. Recommendations for ACAM2000 and JYNNEOS vaccines for persons at occupational risk for exposure to orthopoxviruses — Advisory Committee of Immunization Practices, United States, 2022**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Vaccine product</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACAM2000</td>
</tr>
<tr>
<td>Who should receive the vaccine?</td>
<td>Persons at risk for occupational exposure to orthopoxviruses*</td>
</tr>
<tr>
<td>Who should be offered the vaccine?</td>
<td>Persons who administer ACAM2000 or care for patients with infection with replication-competent viruses</td>
</tr>
<tr>
<td>Populations for whom booster vaccination is recommended at specific intervals</td>
<td>Persons who are at ongoing risk for occupational exposure to orthopoxviruses</td>
</tr>
<tr>
<td>Booster frequency⁴</td>
<td></td>
</tr>
<tr>
<td>Persons working with more virulent orthopoxviruses (e.g., Variola virus or Monkeypox virus)</td>
<td>Every 3 years</td>
</tr>
<tr>
<td>Persons working with less virulent orthopoxviruses (e.g., Vaccinia virus or Cowpox virus)</td>
<td>At least every 10 years</td>
</tr>
<tr>
<td></td>
<td>JYNNEOS</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Research laboratory personnel working with orthopoxviruses, clinical laboratory personnel performing diagnostic testing for orthopoxviruses, and orthopoxvirus and health care worker response teams designated by appropriate public health and antiterror authorities.

⁴ Ongoing risk due to occupational work performed; response personnel are not considered at “sustained risk” for orthopoxvirus infections.

⁴ Booster doses are recommended for response personnel only once an event is identified.

Available at: [https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm). Accessed 7/7/2022.
Vaccine for Post-Exposure Prophylaxis

• Priority 1: Standard post-exposure prophylaxis
  • Given after exposure to monkeypox to help prevent illness from monkeypox virus
  • Should be given within 4 days for the best chance to prevent onset of the disease
  • If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease

• Priority 2: Post-exposure prophylaxis ++
  • Given after presumed exposure to monkeypox
  • Aims to reach people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox

• DSHS recommending use for both of these priority populations

• Pre-exposure prophylaxis for individuals at risk for non-occupational exposure not currently recommended

Available at: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html. Accessed 7/19/2022
Medical countermeasures: Tecovirimat (TPOXX)

- Antiviral medication developed to treat smallpox
- Approved for treatment of smallpox in adults and children weighing at least 3kg
  - Oral capsule approved by FDA in 2018
  - IV formulation approved by FDA in May 2022
- CDC holds EA-IND allowing its use for other orthopoxviruses in adults and children
Persons who should be considered for treatment after CDC consultation

- Persons with severe disease (e.g., encephalitis)
- Persons who may be at high risk of severe disease: immunocompromised; pediatric patients, especially if ≤ 8 years of age; pregnant or breastfeeding people; persons with one or more complications)
- Persons with aberrant or complicated monkeypox infections, including accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)
Monkeypox: Other Treatments

- Cidofovir
  - FDA-approved for cytomegalovirus retinitis
  - In vitro data suggest efficacy against orthopoxviruses
  - Available from the Strategic National Stockpile (SNS)

- Brincidofovir
  - FDA-approved for treatment of smallpox in children of all ages and adults
  - In vitro data suggest efficacy against orthopoxviruses

- Limitations of cidofovir and brincidofovir
  - Uncertain efficacy for treatment of monkeypox
  - Use limited by renal and hepatic toxicity
  - Brincidofovir not available through SNS
• Vaccinia immune globulin (VIGIV)
  • FDA approved for treatment of complications due to vaccinia vaccination (e.g. ACAM2000)
  • CDC holds EA IND allowing for use for prevention and treatment of complications from infection with orthopoxviruses
  • Unknown efficacy as PrEP, PEP, or treatment for monkeypox

• Trifluridine (Viroptic)
  • Antiviral medication licensed for treatment of herpes keratoconjunctivitis/keratitis
  • In vitro evidence of activity against orthopoxviruses
Diagnostic Consults and Testing
• Send diagnostic questions and testing requests to the local and regional health departments
  • Please include photos of the rash, symptoms, demographic information, and any exposure histories.

• DSHS Emerging & Acute Infectious Disease Unit (EAIDU) is available to assist, as necessary
  EAIDUMonitoring@dshs.texas.gov
Clinicians interested in requesting medical countermeasures for treatment of monkeypox:

- Contact your local health department/public health region to request Tecovirimat, VIGIV, or cidofovir
- DSHS will work with the local/public health regions to coordinate CDC clinical consults and request medical countermeasures from the Strategic National Stockpile (SNS) on a case-by-case basis.
  - EAUDmonitoring@dshs.texas.gov
Lab Testing Guidance:

Texas LRNs and 5 specific commercial labs can perform orthopoxvirus-specific testing on **dry** lesion swab specimens. CDC performs confirmatory testing.

If physicians are considering testing they should:
• Recommend consult with their local or regional health department; and
• For LRN testing, send an email to EAIIDUMonitoring@dshs.texas.gov requesting testing at the LRN
• EAIDU will then send a Case ID for the suspected case

Specimen collection procedures for confirmatory testing
• Collect samples from more than one lesion, preferably from different locations on the body or from lesions with differing appearances.
• Vigorously swab or brush lesion with two separate sterile dry polyester or Dacron swabs.
• Break off end of applicator of each swab into a 1.5- or 2-mL screw-capped tube with O-ring or place each entire swab in a separate sterile container.
• Ship samples to the LRN in their region.
• Case ID should be included in the specimen collection
Labs currently testing/reporting Monkeypox results

- 10 public health Laboratory Response Network labs
- 5 commercial labs
- 1 hospital system

- Receiving both positive and negative lab results in NEDSS
# Laboratories reporting to NEDSS

Onboarded for Electronic Lab Reporting for MonkeyPox

<table>
<thead>
<tr>
<th>Lab Name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>City of Houston</td>
<td>7/1/22</td>
</tr>
<tr>
<td>LabCorp</td>
<td>7/5/22</td>
</tr>
<tr>
<td>Mayo Clinic Laboratories</td>
<td>7/8/22</td>
</tr>
<tr>
<td>Quest Diagnostics</td>
<td>7/13/22</td>
</tr>
<tr>
<td>DSHS Lab</td>
<td>7/14/22</td>
</tr>
<tr>
<td>Aegis Science</td>
<td>7/13/22</td>
</tr>
<tr>
<td>Baylor Scott &amp; White</td>
<td>Pending</td>
</tr>
<tr>
<td>Sonic Healthcare</td>
<td>Pending</td>
</tr>
</tbody>
</table>
## Public Health Laboratories reporting to NEDSS

<table>
<thead>
<tr>
<th>LRN Name</th>
<th>NEDSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lubbock</td>
<td>Yes</td>
</tr>
<tr>
<td>El Paso</td>
<td>No</td>
</tr>
<tr>
<td>Fort Worth/Tarrant</td>
<td>No</td>
</tr>
<tr>
<td>Dallas</td>
<td>No</td>
</tr>
<tr>
<td>Tyler</td>
<td>No</td>
</tr>
<tr>
<td>Austin</td>
<td>Yes</td>
</tr>
<tr>
<td>Houston</td>
<td>Yes</td>
</tr>
<tr>
<td>San Antonio</td>
<td>Yes</td>
</tr>
<tr>
<td>Corpus Christi</td>
<td>No</td>
</tr>
<tr>
<td>Harlingen</td>
<td>No</td>
</tr>
</tbody>
</table>
Monitoring

- 21-day monitoring
- Monitoring based on exposure risk level
  - For High and Intermediate Risk exposures:
    - Twice daily temperature checks, once daily contact with public health
  - For Low Risk exposures:
    - Initial contact by public health and self-monitoring for the remainder
    - HCWs can self-monitor through their infection prevention department
- Monitoring logs for community and flight exposures -> DSHS Central Office
- DSHS Central Office will send out contacts identified by CDC’s DGMQ or through Epi-X
Vaccine & Therapeutic Ordering
JYNNEOS™
(Smallpox and Monkeypox Vaccine, Live, Non-replicating)
## Overview of JYNNEOS Vaccine

<table>
<thead>
<tr>
<th><strong>JYNNEOS: FDA approved in 2019</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viral strain</strong></td>
</tr>
<tr>
<td><strong>Indication/Usage</strong></td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
</tr>
<tr>
<td><strong>Maximum Immunity</strong></td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
</tr>
<tr>
<td><strong>How supplied</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Storage Conditions</strong></td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Preparation and Administration</strong></td>
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<tr>
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<tr>
<td><strong>Expiration Date</strong></td>
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</table>

*JYNNEOS Package Insert*
Package insert states the vaccine can be stored under refrigerated temperatures for up to 12 hours, but unopened vaccine vials can be stored up to 8 weeks under refrigerated conditions.
Total available JYNNEOS doses to Texas is 20,104
• Houston/Harris County receives its own allocation of 5,324 doses.
• Remaining state allocation is 14,780.
Current Texas Vaccine Ordering Process

Current limit of 10 Vaccine Drop Sites for TX
  • Dallas County HHS
  • San Antonio Metro
  • Austin Public Health
  • Tarrant County Public Health
  • Cold Chain
  • Five sites for Houston and Harris county
JYNNEOS Ordering Process (available starting 7/22/22)

• Each Local and Regional Health Department (L/RHD) will place requests for vaccine through VAOS
  • Jynneos will only be able to be requested via one PIN per jurisdiction (PINs may be changed at Jurisdiction request)

• DSHS will review the request and will place the order based on vaccine availability and epidemiologic need

• The process for L/RHDs should not change, even if the process for Central Office placing orders does

• If there are questions regarding vaccine (clinical, requesting, shipping, etc.) please email: DSHSMPXVax@dshs.texas.gov
Reporting Monkeypox in ImmTrac2

- Immunization: Smallpox
- Trade Name: JYNNEOS-Monkeypox
- Lot: (enter as appropriate)
- Manufacturer: BN-Bavarian Nordic A/S
- Dose: Full
Currently Monkeypox is not disaster-related, so a standard (ImmTrac Adult or ImmTrac Child) consent is required.

Upon a public health disaster declaration, it is recommended that clients also sign a disaster consent form in the event there is a declared public health disaster in the future.

Consent forms can be found on our Forms & Publications webpage at [https://www.dshs.texas.gov/immunize/immtrac/forms.shtm](https://www.dshs.texas.gov/immunize/immtrac/forms.shtm)

After downloading a consent form(s),
  - Ask the client to sign it, save it at your office (paper or scanned)
  - Consent the client through ImmTrac2 or via affirmation in data exchange.
Consider Medical Countermeasure Treatments for Monkeypox:

_TPOXX, VIGIV, & Cidofovir_ may be considered for treatment in people infected with Monkeypox virus:

a) with severe disease  
b) who are at high risk for severe disease  
c) with aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where Monkeypox virus infection might constitute a special hazard

Request Medical Countermeasure Treatments from your jurisdiction’s health department.

- The Local/Regional Health Department  
  Email requests to: EAIDUMonitoring@dshs.Texas.gov
- DSHS will work with the local/regional health department and healthcare providers on a case-by-case basis to coordinate:
  - CDC clinical consults
  - Medical Countermeasure Treatment Requests from SNS

When requesting medical countermeasure treatments include the following:

**A. Case Description**

- **Age:**  
- **Sex:**  
- **Rash:**  
- **Fever:**  
- **Other symptoms:**  
- **Epi criteria:**

**Case Summary:**  
[provide as many details as you have and include any pictures that were sent with the consult]

**B. Ordering and Shipping Information:**

1) Shipping address for TECOVIRIMAT:  
2) Receiving POC #1 at shipping address (name, email, 24/7 monitored phone #):  
3) Receiving POC #2 at shipping address (name, email, 24/7 monitored phone #):  
4) Jurisdiction HD POC (name, email, 24/7 monitored phone #):  
5) Number of bottles of PO tecovirimat (1 full course = 2 bottles for people weighing 40–120kg, for other weight, see IND protocol page 6):  
6) If IV is requested, please specify number of days of therapy (for many patients, 14 vials [=7 days] of IV tecovirimat will be enough and the patient can be converted to PO tecovirimat; if the clinical picture does not improve after 7 days, additional IV doses can be ordered):  
7) Days/times the shipping address location is/is not available to receive a shipment:

**Example: Required Sections of the IND:**

1. FDA Form 1572. One signed 1572 per facility suffices for all tecovirimat treatments administered under the EA-IND at the same facility.  
3. Patient intake form.  
4. Adverse event form. Life-threatening or serious adverse events associated with TPOXX use should be reported to CDC (regaffairs@cdc.gov) within 24 hours of occurrence, or as soon as possible.  
5. Outpatient Case Report Form. Provides clinical progress of patients during TPOXX therapy (e.g., at Day 7). If the patient’s clinical condition necessitates performing clinical labs, please include a copy of the results.  
DISCLAIMER

The information presented today is based on CDC’s recent guidance and MAY change.

July 20, 2022
Questions?