Monkeypox Outbreak: Updates on the Epidemiology, Testing, Treatment, and Vaccination

Clinician Outreach and Communication Activity (COCA) Call

Tuesday, July 26, 2022

Free Continuing Education

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Today's Presenters

Jennifer McQuiston, DVM, MS (Opening Remarks) (no slides)
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Incident Manager
2022 Multinational Monkeypox Response
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Monkeypox Response Update

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CAPT Jennifer McQuiston, DVM, MS

Incident Manager

CDC Multi-National Monkeypox Response 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/index

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Monkeypox cases in the United States (Official counts as of July 25, 2022, at 2pm EST)

- Total: 3,487 cases among U.S. residents
- 45 states, District of Columbia, and Puerto Rico
    - 3 cases in people residing outside of U.S.

Top jurisdictions reporting cases:

STATE	CASE COUNT
NEW YOK	990
CALIFORNIA*	356
ILLIONOIS	344
FLORIDA	273
GEORGIA	268
TEXAS	220

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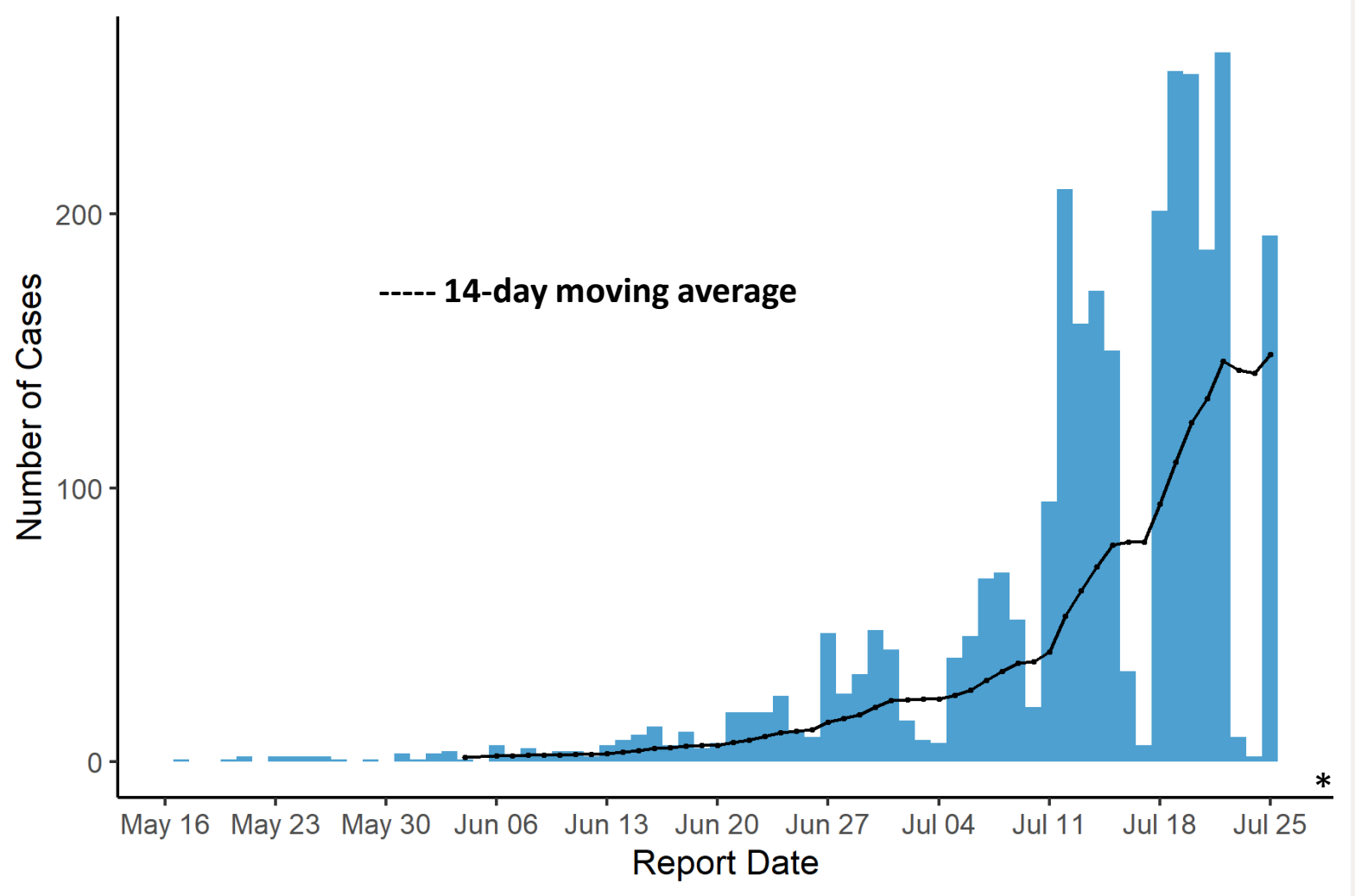
Monkeypox cases reported to CDC: Epi Curve and 14-day Moving Average (Official counts as of July 25, 2022, at 2pm EST)



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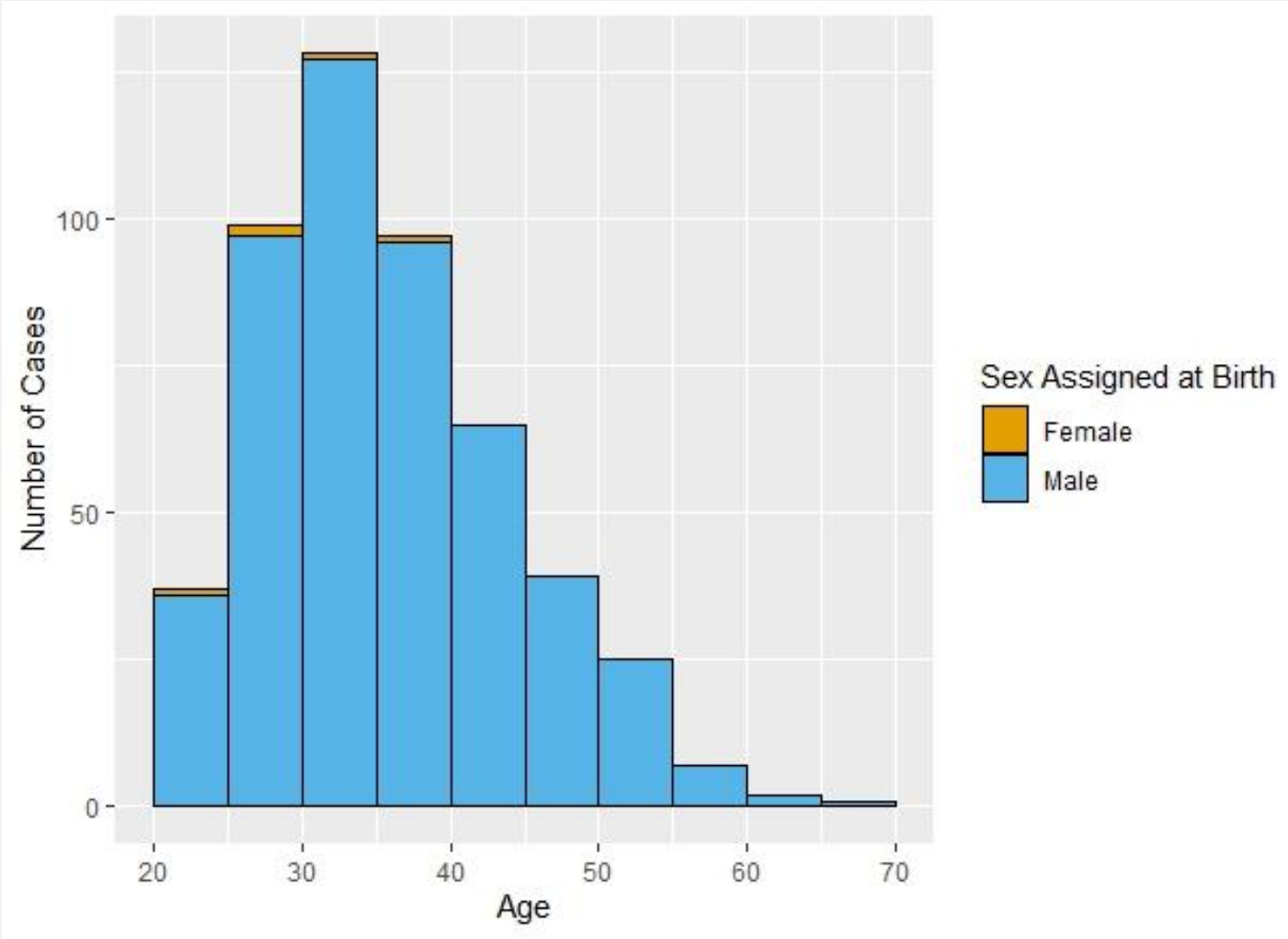
Monkeypox cases reported to CDC: Demographics (Official counts as of July 25, 2022, at 2pm EST)

- Age:
  - Median: 35 years
  - Range: 18 – 76 years[1]
- Male sex at birth: 1,373 (99.1%)
- Female sex at birth: 13
- MMSC[2]: 304/309 (98.4%)

[1]Pediatric cases not reflected here
[2]Male-to-male sexual contact



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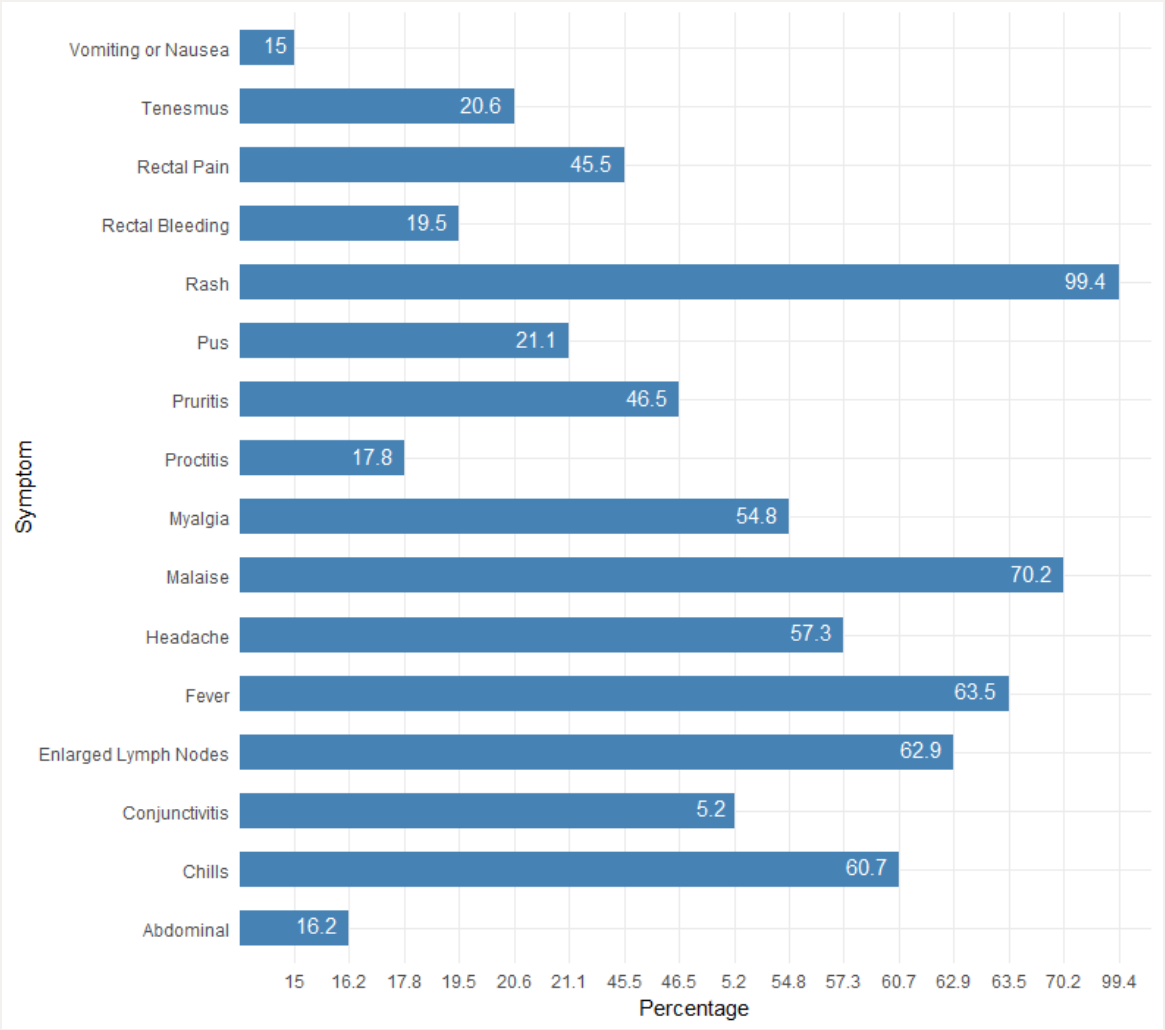
Monkeypox cases reported to CDC: Symptoms (Official counts as of July 25, 2022, at 2pm EST)

- Most common symptoms:
  - Rash (99%)
  - Malaise (70%)
  - Fever (64%)
  - Lymphadenopathy (63%)



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Testing for Suspect MPX Cases

- US Laboratory Response Network (LRN) labs (10,000 tests/week)
  - LRN labs (located within the state public health labs) perform CDC's FDA cleared non-variola Orthopoxvirus (NVO)-specific PCR test
  - Send samples to CDC for MPX-specific PCR and sequencing
- Commercial laboratory testing is now available (70,000 additional tests/week)
  - 40,000 testing capacity per week using CDC NVO test
  - 30,000 tests of commercial MPOX-specific laboratory test
- Current testing capacity is at least 80,000 tests per week

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Testing for Suspect MPX Cases

- **Specimen type**
  - Commercial and LRN labs-accepted specimen type is lesion material
  - Swab of lesion from any part of the body is acceptable
  - Approximately 3 lesion specimens per patient are suggested
  - CDC is evaluating other specimen types through a research protocol
- **Specifics on the acceptable lesion specimen type accepted within the LRN and commercial laboratories may vary (e.g., dry swab or swab in VTM or UTM)**
  - This is based on the laboratory's CLIA approval
  - Clinicians should initiate diagnostic testing for any suspect monkeypox patient
  - Based on clinical presentation and/or epidemiologic criteria
  - Testing of persons who belong to populations for which the incidence of monkeypox is expected to be very low decreases the positive predictive value of test results
  - Other differentials should also be considered if there are no known monkeypox epi links or risk factors

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Testing for Suspect MPX Cases

- Billing information (commercial labs)
  - No specific CPT codes for monkeypox testing is available at commercial labs yet
    - Each commercial lab performing testing may have their own CPT billing codes for monkeypox that can be accessed on their website by clinicians
  - The company performing the testing will bill private insurance, Medicaid, or Medicare
- Orthopoxvirus Results Interpretation
  - There are no other circulating orthopoxviruses within the United States that cause systemic disease
  - Clinical care such as isolation recommendations should begin based on the orthopoxvirus test result and should not wait on any additional viral characterization testing
    - Probable MPX: positive OPX PCR
    - Confirmed MPX: positive MPX-specific PCR or sequence analysis

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Update: Tecovirimat (TPOXX) Treatment for Monkeypox under Expanded Access Investigational New Drug Protocol

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https://www.cdc.gov/poxvirus/monkeypox/response/2022/index

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Tecovirimat

- Tecovirimat (TPOXX or ST-246) is an antiviral medication developed for smallpox and is available from the Strategic National Stockpile

- Oral capsule and IV formulations approved by FDA for the treatment of human smallpox disease in adults and pediatric patients under Animal Rule
  - Efficacy based on studies of non-human primates infected with monkeypox and rabbits infected with rabbitpox
  - Safety evaluation in 359 healthy adults (18-79 years)

- Tecovirimat use for unapproved indications (i.e., uses not covered by the FDA-approved labeling) requires an alternative regulatory mechanism (e.g., Expanded Access Investigational New Drug (EA-IND) or Emergency Use Authorization)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208627s000lbl.pdf

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Tecovirimat EA-IND (also known as compassionate use)

- CDC holds an EA-IND to provide an umbrella regulatory coverage
  - Allow use of tecovirimat for non-variola orthopoxvirus infection (e.g., monkeypox, complications from replication-competent vaccinia virus vaccine)
  - CDC IRB serves as central IRB for review and approval
    - Non-research determination and that federal-wide assurance requirements do not apply
    - CDC IRB will provide a reliance agreement for facilities that elect to rely on CDC IRB approval
  - Clinicians and facilities do not need to request and obtain their own INDs
  - Provides liability coverage under the Public Readiness and Emergency Preparedness (PREP) Act for healthcare providers prescribing, administering, or dispensing the drug and for patients to seek compensation if they are seriously injured by the medication via the Countermeasure Injury Compensation Program

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

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Summary of Revised Tecovirimat EA-IND Protocol

- Recently updated to make it easier for providing tecovirimat treatment
- Streamlined and substantially reduces the number of patient visits and required forms
  - All patient visits can be conducted via **telemedicine**
  - All laboratory testing is **optional**
  - Required safety reporting on **serious adverse events only**
  - No pre-registration is required for clinicians and healthcare facilities to begin providing tecovirimat treatment
  - Forms required under the EA-IND can all be returned to CDC after treatment begins

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

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Revised Tecovirimat EA-IND Protocol

- Required
  - Obtain Informed Consent prior to treatment
  - Conduct a baseline assessment and complete the Patient Intake Form
  - Document progress once during and once after treatment on the Clinical Outcome Form
  - Report life-threatening or serious adverse events associated with tecovirimat by completing a PDF MedWatch Form and returning it to CDC
  - FDA Form 1572: One signed 1572 per facility

- Optional
  - Photos of lesions
  - Pharmacokinetic samples for testing
  - Clinical laboratory parameters (hematology, chemistry, and urinalysis parameters)
  - Lesion samples for resistance testing, if feasible, on new onset of lesions during and after completion of treatment
  - Patient Diary, if feasible, give the form for patient to complete and voluntarily return it directly to CDC

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

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Revised Tecovirimat EA-IND Protocol – additional clarification

- Primary tecovirimat use under the IND remains for **treatment** of laboratory confirmed or suspected OPXV infection based on known exposure and compatible clinical symptoms
- Post-exposure prophylaxis (PEP) on **individual case-by-case basis** for certain individuals for whom an alternative to PEP vaccination may be clinically necessary
  - Added in anticipation of potential PEP considerations for certain individuals while keeping the IND protocol evergreen
  - Any PEP use must be in clinical consultation with CDC
- Refer to CDC's Interim Clinical Considerations for the treatment of monkeypox for most up to date guidance regarding patients who should be considered for treatment
- No lower weight cap for use of IV tecovirimat. Allowed use in neonates under the IND protocol
- Includes explanation on IV administration over 6 hours and administration through syringe pumps

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

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Tecovirimat Availability for Treatment

- CDC is committed to ensuring that healthcare providers are able to readily access TPOXX for patient care.
- Based on early feedback from several providers, healthcare facilities, and academic centers, we feel optimistic that the revised protocol will help to lessen the burden and facilitate access to treatment for monkeypox.
- To request TPOXX, clinicians and care facility pharmacists should contact their state/territorial health department. To reach the CDC on-call clinical staff, contact the Emergency Operations Center 770-488-7100 or Poxvirus@cdc.gov.
- Greatly appreciate timely return of patient intake and clinical outcome forms by providers and healthcare facilities as they enable CDC to monitor clinically appropriate and safe use of tecovirimat.

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Tecovirimat-Treated Patients per Patient Intake Forms*

*As of July 22, 2022

Demographics (N=233)	N (%)
Age	37.0 (median)
Sex at birth	
Male	229 (98.3%)
Female	3(1.3%)
Not reported/declined	2 (0.4%)
Race	
American Indian or Alaskan Native	0
Asian	8 (3.4%)
Black	39 (16.7%)
Native Hawaiian or Other Pacific Islander	0
White	127(54.5%)
Other	29(12.5%)
Not Reported	30(12.9%)
Ethnicity	
Hispanic or Latino	75 (35.7%)
Non-Hispanic or Latino	135 (64.3%)
Other or unknown	23

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Tecovirimat-Treated Patients per Patient Intake Forms*

*As of July 22, 2022

Characteristic	N (%)
Underlying medical conditions	n=233
HIV	90 (38.6%)
Maligancy	1 (0.4%)
Solid organ transplantation	2 (0.9%)
Immunosuppressants or immunomodulators	1 (0.4%)
Other immunosuppressed conditions	5 (2.2%)
Pregnancy	0
History of atopic dermatitis or exfoliative skin condition	1 (0.4%)
Exposure to symptom onset and symptom onset to tecovirimat treatment timelines	
Median time from exposure to symptom onset (days)	6 (0-21)
Median time from symptom onset to tecovirimat administration (days)	8 (1-36)

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Tecovirimat-Treated Patients per Patient Intake Forms*

*As of July 22, 2022

Route of Tecovirimat administration	N=233
Oral	208 (89.3%)
IV	1 (0.5%)
Unk/Not reported	24 (10.2%)
Number of lesions at start of tecovirimat	N=233
Less than 10	95 (40.8%)
10-100	119 (51.1%)
Great than 100	13 (5.6%)
Unk/Not reported	6 (2.6%)
Signs/symptoms during course of illness	N=233
Fever	80 (34.3%)
Lymphadenopathy	47 (20.2%)
Malaise	14 (6.0%)
Headache	14 (6.0%)
Weakness	0
Proctitis	14 (6.0%)
Genital lesion(s)	13 (5.6%)
Anal lesion(s)	82 (35.2%)
Facial lesion(s)	42 (18.0%)

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Update on the National Monkeypox Vaccine Strategy

Steve Flores, PhD

Vaccine Team Co-Lead

Clinical Task Force

CDC 2022 Multi-National Monkeypox Response

Centers for Disease Control and Prevention

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Current National Vaccine Strategy

- **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)**
  - For the current outbreak, this approach can be considered as “standard PEP” for monkeypox
  - People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus
    - **High degree of exposure:** PEP recommended
    - **Intermediate degree of exposure:** Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks
    - Brief interactions and those conducted using appropriate PPE in accordance with Standard Precautions are not high risk and generally do not warrant PEP

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure
https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Considerations for PEP

- CDC recommends that the vaccine series be initiated within 4 days from the date of exposure for the best chance to prevent onset of the disease
- If initiated between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease
- However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox

https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Current National Vaccine Strategy, cont.

- **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++**
  - For the current outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox
  - Public health officials refer to it as “expanded PEP” or “PEP++”
  - People with certain risk factors are more likely to have been recently exposed to monkeypox; the PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox
- **Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP):** This approach refers to administering vaccine to someone at high risk for monkeypox (for example laboratory workers who handle specimens that might contain monkeypox virus)

https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Considerations for Monkeypox Vaccination

- No data are available yet on the effectiveness of these vaccines in the current outbreak
- People who get vaccinated should continue to take steps to protect themselves* from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox
- To better understand risks and benefits of these vaccines in the current outbreak, CDC is working with partners to collect data on vaccine safety and vaccine effectiveness

*https://www.cdc.gov/poxvirus/monkeypox/prevention.html
https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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JYNNEOS Allocations

- **Given the currently limited supply, JYNNEOS vaccine is being allocated to jurisdictions for use for the following individuals:**
  - Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
  - Presumed contacts who may meet the following criteria:
    - Know that a sex partner in the past 14 days was diagnosed with monkeypox
    - Had multiple sex partners in the past 14 days in a jurisdiction with known monkeypox
- **JYNNEOS doses should be prioritized for those people who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions)**

https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Vaccine Supply

- **JYNNEOS**
  - 56,000 doses in Phase 1 (June 28, 2022)
  - 240,000 doses across Phase 2a (July 8, 2022) Phase 2b (July 15, 2022)
  - >750,000 doses to be made available in Phase 3
  - HHS anticipates making ~1.9 million doses available in 2022, with an additional 2.2 million doses available during the first half of 2023

- **ACAM2000**
  - >100 million doses

https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/28/fact-sheet-biden-harris-administrations-monkeypox-outbreak-response/;
https://www.hhs.gov/about/news/2022/07/07/biden-harris-administration-make-additional-144000-doses-jynneos-vaccine-available-states-jurisdictions-for-monkeypox-response.html;
https://aspr.hhs.gov/ASPRBlog/Pages/BlogDetailView.aspx?ItemID=432

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Considerations for JYNNEOS

- **Two doses of JYNNEOS are required, as this is the FDA-approved dosing regimen**
  - Second dose should be administered 28 days after the first dose
- **JYNNEOS has been evaluated in clinical studies involving people with HIV infection** and atopic dermatitis and shown to be safe and effective in eliciting an immune response in these populations
- **People who receive JYNNEOS are considered to reach maximal immunity 14 days after their second dose**
- **We do not know if JYNNEOS will fully protect against monkeypox virus infection in this outbreak**
  - Individuals should take additional preventive measures and self-isolate as soon as they develop monkeypox symptoms, such as a rash
  - Infections despite vaccination may occur, and there are currently no data on effectiveness of JYNNEOS from the current outbreak

https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Upcoming Guidance Updates: JYNNEOS

- Interim clinical considerations on the use of the JYNNEOS vaccine
  - Exceptions to the two-dose vaccine series for people who have been diagnosed with monkeypox
  - Vaccine dosing interval clarifications (i.e., 7-day grace period)
  - Guidance about coadministration with other vaccines
  - Guidance for contraindications and precautions
- Storage and Handling
- Developing template standing orders

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Planning Considerations for Health Departments & Providers

- **Consider the following approaches to ensure equitable distribution:**
  - Engage diverse partners already working with special populations
  - Use non-stigmatizing language
  - Reiterate privacy of information and how data will be used
  - Bring vaccines to where people are through pop-up events and mobile outreach
  - Engage people from affected communities in planning and through peer education models

https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

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Resources

- **Smallpox vaccination information:** https://www.cdc.gov/smallpox/clinicians/vaccination.html
- **JYNNEOS**
  - 2022 ACIP Recommendations: https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
  - Package insert: https://www.fda.gov/media/131078/download
  - VIS (English): https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf
  - VIS (Spanish): https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf
- **ACAM2000**
  - 2016 ACIP Recommendations: https://www.cdc.gov/mmwr/volumes/65/wr/mm6510a2.htm
  - Package insert: https://www.fda.gov/media/75792/download
  - Medication guide: https://www.fda.gov/media/75800/download
  - CDC videos on administering ACAM2000: https://www.cdc.gov/smallpox/clinicians/administering-acam2000.html
  - Smallpox vaccination and adverse reactions, guidance for clinicians: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2022/callinfo_072622.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

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