Centers for Disease Control and Prevention Center for Preparedness and Response



Situational Update for Clinicians about Severe Monkeypox Virus Infections

Clinician Outreach and Communication Activity (COCA) Call Thursday, October 6, 2022

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Today's Presenters

Agam Rao, MD, FIDSA

CAPT, U.S. Public Health Service
Subject Matter Expert, Vaccine Task Force
and Clinical Task Force
2022 Multinational Monkeypox Response
Centers for Disease Control and Prevention

Caroline Schrodt, MD, MSPH

LCDR, U.S. Public Health Service Lead, Clinical Escalations Team 2022 Multinational Monkeypox Response Centers for Disease Control and Prevention

Jemma Alarcón, MD, MPH

Los Angeles County
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Epidemic Intelligence Service Officer
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Centers for Disease Control and Prevention

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Adjunct Professor Infectious Diseases Emory University

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MONKEYPOX

Background and State of Outbreak

Agam Rao, MD CAPT, U.S. Public Health Service

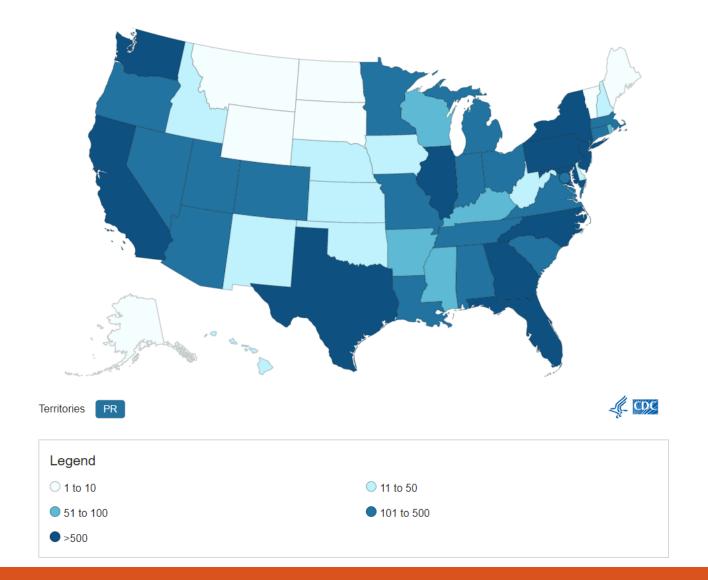
Monkeypox Subject Matter Expert, CDC



Situational update

- May 2022, cluster involving gay, bisexual or other men who have sex with men (MSM) reported in United Kingdom
- Initial U.S. cases believed to have originated from exposures during large gatherings associated with international PRIDE events
- Early cases predominantly among non-Hispanic white MSM
- Most cases self-limited but severe pain and proctitis reported; some patients with more severe manifestations
- As of September 30, globally 70,420 cases; majority of cases currently in the Americas

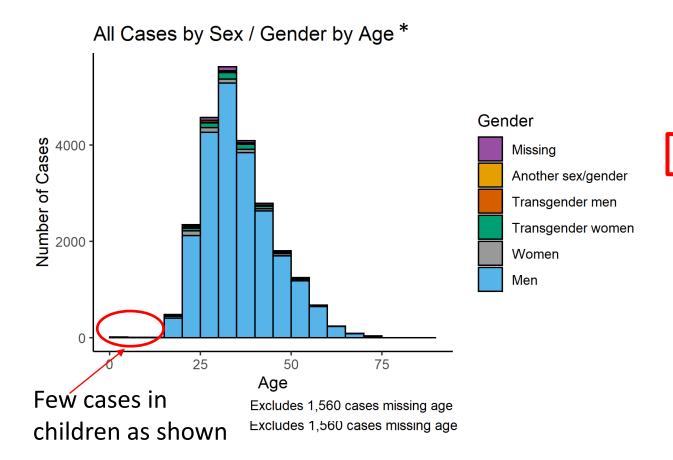
2022 cases (data as of 10/4/2022)



Highest number of reported cases:

- California
- New York
- Texas
- Florida
- Georgia
- Illinois

Sex and gender (data as of 9/29/2022)



Sex/gender*	Cases	Percent
Men	22,701	94.7%
Women	862	4.2%

- Most cases among men
- Some cases in women, transgender women, transgender men, and persons who report another sex or gender

^{*}Gender available for 94% of cases

Gender identity of affected men (data as of 9/29/2022)

Gender identify*	Cases	Percent
Men, recent MMSC reported [†]	8,844	73.0%
Men, no recent MMSC reported [†]	2,452	20.2%

- Most cases for which gender identity was reported to CDC, are among men who report recent MMSC[†]
- Investigations ongoing to understand source of infection among men who not report recent MMSC but also those who report recent MMSC

^{*}Includes data for the ~ 11,500 men for whom gender identity was reported

[†]Male-to-male sexual contact

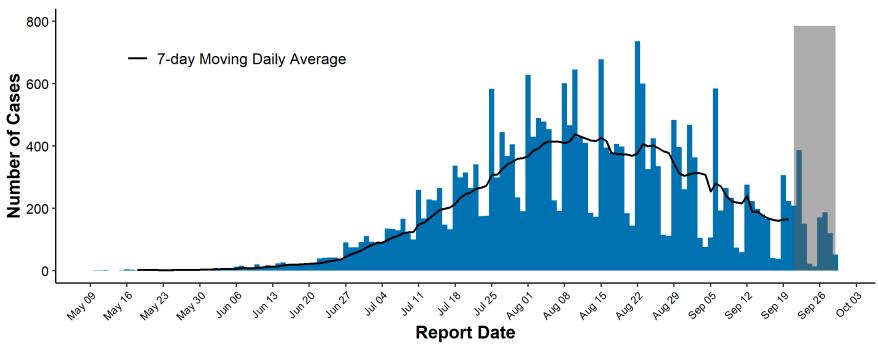
Spread to others

- Direct contact with infectious lesion(s), scab(s), saliva, and potentially other bodily fluids of a patient with monkeypox
- Respiratory secretions during prolonged face-to-face contact, or during intimate physical contact such as kissing, cuddling, or sex
- Touching items (such as clothing or linens) that previously touched the infectious rash or bodily fluids of a patient
- Placenta when a patient develops monkeypox virus infection while pregnant
- Patients are infectious once symptoms begin (whether prodromal or rash symptoms) and remain infectious until scabbed lesions fall off and a fresh layer of health tissue forms below

What we know about spread during this outbreak

- Spread is not limited to contact during sex; sex involves close skin-to-skin contact but is not inclusive of all potential skin-to-skin contact
- Few cases in some populations
 - Children, pregnant women, and healthcare personnel
 - Persons who are incarcerated (e.g., in jails)
 - Persons experiencing homelessness
- At this time, no sustained spread outside of MSM networks
- No sustained spread reported in congregate settings (e.g., college dormitories, long-term care facilities)
- Greater understanding of transmission dynamics is underway
- Recommended infection control practices and prevention education is essential, regardless of case counts

Trends in case counts



Data from recent days, shown shaded, are incomplete

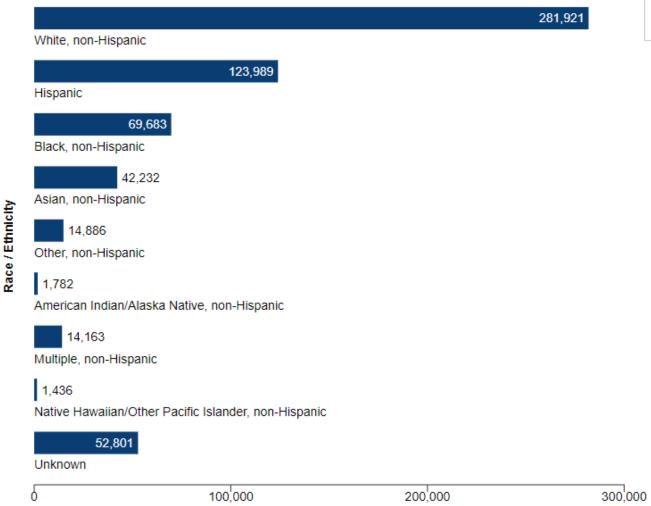
- Case counts have decreased
- Peak case counts around August 9th

Race / Ethnicity (as of 9/29/2022)

Race / Ethnicity*	Cases	Percent
Black or African American	6,523	33.2%
Hispanic or Latino	6,132	31.2%
White	5,833	29.7%
Asian	596	3.0%
American Indian or Alaska Native	63	0.3%
Native Hawaiian or Other Pacific Islander	56	0.3%
Other race	432	0.1%
Multiple races	28	0.1%

 At this time, a disproportionate number of cases among Black and Hispanic people

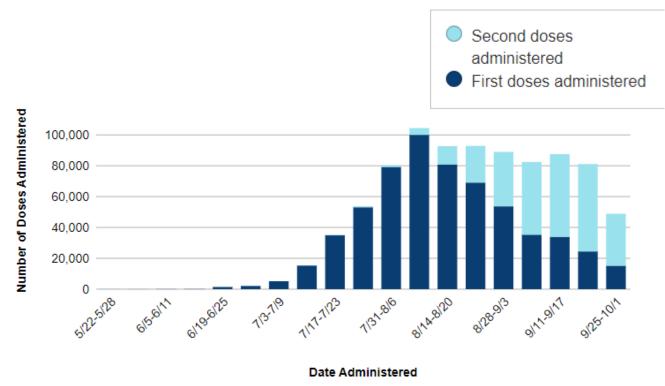
Vaccinations by race / ethnicity



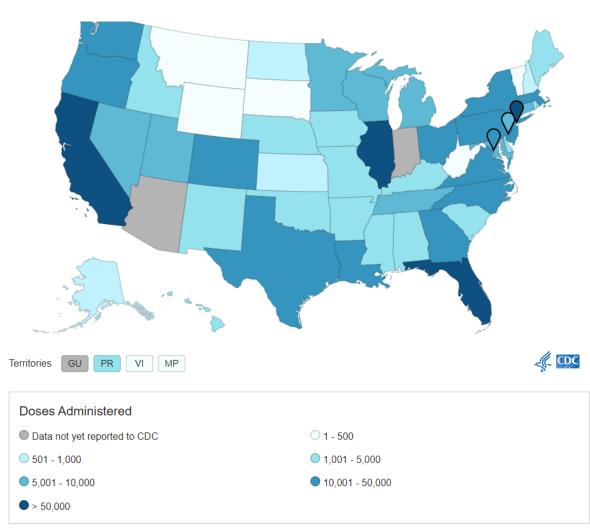
- First doses administered
 - Populations that comprise the highest proportion of cases received fewer vaccine doses
 - Vaccinating Black populations is critical
 - New guidance allows for intradermal administration of JYNNEOS vaccine in the deltoid area or sub-scapular region if the forearm is not feasible (e.g., strong patient preference for a discreet site due to stigma of visible wheal)

Total vaccine doses administered (includes PEP, PEP++, and PrEP):

873,552 doses as of 10/4



Most vaccinated persons are men but some recipients are women and children



Management of most patients

- Most immunocompetent patients recover with pain management* and other supportive care
- Tecovirimat should be considered for some conditions[†]
 - Severe disease: hemorrhagic disease, large number of lesions, sepsis, encephalitis, ocular or periorbital infections, other conditions requiring hospitalization
 - Lesions involving anatomic areas that could cause severe infection (such as, pharynx, penile foreskin, vulva, vagina, urethra, anus)
 - Lesions in persons who are at high risk for severe disease
 - Immunocompromise
 - Pediatric populations
 - Pregnant or breastfeeding
 - Condition affecting skin integrity

^{*}https://www.cdc.gov/poxvirus/monkeypox/clinicians/pain-management.html

[†]https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

Resources for severe cases

- Therapeutics
 - Tecovirimat (oral or intravenous)
 - Cidofovir
 - Vaccinia immune globulin intravenous (VIGIV)
 - Brincidofovir

- CDC is updating websites and soliciting individual input from physician experts in ophthalmology, neurologic infections, and immunocompromising conditions (among other specialties) to facilitate development of clinical guidance
- CDC clinical consultation staff available 24/7 to provide case-specific consultations

Examples of types of questions CDC has received during consultations

- Interpretation of unexpected orthopoxvirus positive PCR test result
- Use of tecovirimat in patients with renal insufficiency
- Suspicion for recurrent monkeypox
- Advice about treatment of unusual clinical presentations (e.g., ocular lesions)
- Role of CDC testing of pathology specimens for orthopoxvirus infections and other causes of observed pathology
- When to use specific therapeutics
- Management of severe illness in severely immunocompromised patients

Summary

- Case counts decreasing in the United States and worldwide
- Shift in cases from white non-Hispanic MSM to Hispanic and Black MSM
- Concurrent to this shift, increasing numbers of severe cases
 - Persons with severe immunocompromise, mostly MSM with newly diagnosed
 HIV that is advanced
 - Initial high demand for vaccination has leveled off; most administered vaccines at this time are 2nd doses and in white non-Hispanic men
- Important updates for clinicians in next presentation

Severe Manifestations

Caroline Schrodt, MD, MSPH
LCDR, U.S. Public Health Service
Lead, Clinical Escalations Team
2022 Multinational Monkeypox Response
Centers for Disease Control and Prevention

Severe manifestations of monkeypox

- Atypical or persistent rash with coalescing or necrotic lesions, or both
- Lesions on a significant proportion of the total body surface area
- Certain lesions in sensitive areas (such as face, genitalia, bowel, urethra)
- Lesions associated with edema and secondary bacterial or fungal infections
- Severe lymphadenopathy
- Lesions leading to stricture, scar formation, obstruction

Severe manifestations of monkeypox, continued

- Involvement of multiple organ systems and associated comorbidities, including:
 - Oropharyngeal lesions inhibiting oral intake
 - Pulmonary involvement with nodular lesions
 - Neurologic conditions including encephalitis and transverse myelitis
 - Cardiac complications including myocarditis and pericardial disease
 - Ocular conditions including severe conjunctivitis and sightthreatening corneal ulcerations
 - Urologic involvement including urethritis and penile necrosis

Who might be at risk for severe monkeypox?

- Might be more severe among
 - People who are immunocompromised
 - People who are pregnant
 - People with atopic dermatitis or eczema
 - Young children (under 8 years of age)
- CDC is still researching who is at most risk

Immunosuppression and Monkeypox

- Most people with severe manifestations of monkeypox for whom CDC has been consulted are immunosuppressed
 - The majority with advanced HIV disease, not virally suppressed and with a low CD4 cell count (e.g., <100-200)

HIV and Monkeypox

- The HIV status of all sexually active adults and adolescents with suspected or confirmed monkeypox should be determined
- Treatment should include optimizing immune function
 - Limiting immunosuppressive medications if not otherwise indicated
 - Providing antiretroviral therapy for people with HIV

CDC Clinical Consultations

- Available 24/7 through health departments
- Can facilitate
 - Treatment with stockpiled VIGIV, IV TPOXX, and in the future, brincidofovir
 - Determination of antibody response (i.e., serology)
 - Evaluation of certain biopsy and autopsy specimens for orthopoxviruses
 - Genome sequencing, including to evaluate for tecovirimat resistance
 - Case specific advice based on accumulated clinical knowledge
 - >175 case specific consultations
- Learn together about clinical manifestations so that national guidance about use of stockpiled therapeutics and other countermeasures can be made accordingly
- Consider consultation with CDC Monkeypox Response Clinical Escalations Team (email <u>eocevent482@cdc.gov</u> or healthcare providers may contact the CDC Emergency Operations Center at (770) 488-7100)

CDC Clinical Consultations: Severe infections

- Demographics of affected patients
 - 100% male
 - Most immunocompromised due to advanced HIV
 - 2 patients receiving chemotherapy for cancer
- Progressive illness
 - >100 lesions; new lesions despite treatment
 - Coalesced lesions and necrosis
 - Significant lymphadenopathy
 - Hemodynamic instability requiring vasopressors
 - Sepsis and secondary infections
 - Intubation

Treating patients with severe monkeypox

- Oral or Intravenous (IV) TPOXX
 - Continue > 14 days and up to 90 days
 - Decreases viral replication
- Cidofovir or Brincidofovir (soon to be available from Strategic National Stockpile)
- Vaccinia Immune Globulin Intravenous (VIGIV)
- No data on effectiveness, use determined on case-by-case basis

Worsening, non-healing, recurrent, and new skin lesions while receiving antiviral treatment

- Repeat lesion swabs to assess for persistent monkeypox DNA
- Continue tecovirimat (oral or intravenous) beyond 14 days, until there is clinical improvement (no more than 90 days)
- Modifications to the dose, frequency, and duration may be necessary depending on the individual patient's clinical condition, disease progression, therapeutic response, or clinical judgement in consultation with CDC and FDA
- CDC encourages clinicians to submit specimens for further monkeypox virus characterization through genetic sequencing to identify mutations that could potentially result in resistance to antiviral therapy

Next steps, CDC

- Continue to answer clinical inquiries and provide clinical consultations, therapeutics, and laboratory testing
- Gather information about patient outcomes, including severely ill patients with monkeypox
- Develop interim guidance about use of stockpiled therapeutics (informed by input from clinical experts)
- Promote assistance provided by CDC for management of severe cases
- Increase clinician awareness of severe cases

Case Presentation

Jemma Alarcón, MD, MPH
Los Angeles County Department of Public Health
Epidemic Intelligence Service Officer
2022 Multinational Monkeypox Response
Centers for Disease Control and Prevention

Center for Surveillance, Epidemiology, and Laboratory Services



Monkeypox death in the United States

Jemma Alarcón, MD, MPH

Epidemic Intelligence Service Officer 2022

Assigned to: Los Angeles County Department of Public Health

Outline

- Hospital Course
- Results
- Discussion
- Conclusion

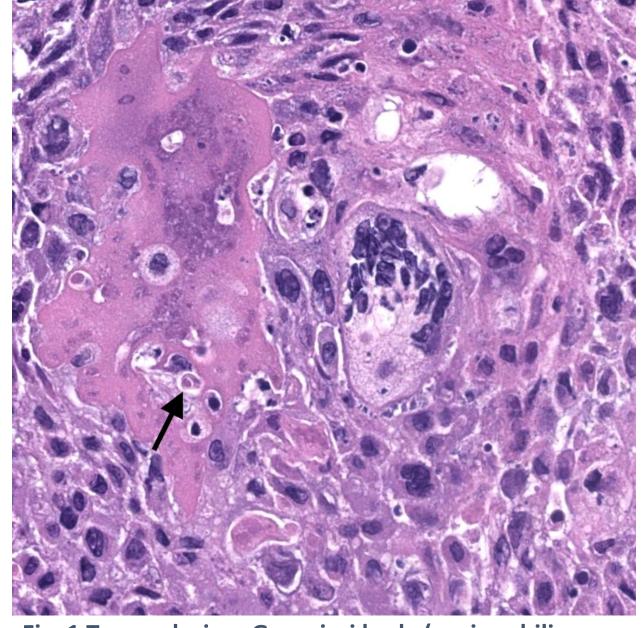


Fig. 1 Tongue lesion: Guarnieri body (eosinophilic inclusions)

Patient history

- 33 year old man with HIV/AIDS (Type 1, diagnosed 06/2011, CD4+ nadir 03/2018, <35cells/mm), recently treated syphilis, and gunshot wound to the abdomen (status, post-exploratory laparotomy) in 2015
- No Orthopoxvirus vaccine received
- Stopped taking bictegravir, emtricitabine, and tenofovir-alafenamide for at least one year before presentation
- Social history: denied drug use, smoking, but did report occasional alcohol use

Patient history

- On July 16, experienced prodromal fever and chills followed by skin lesions on his face, mouth, trunk, arms, legs, genitals, and perianal area beginning July 20.
- On July 31, he was diagnosed with monkeypox and prescribed oral tecovirimat on August 5.
- On August 9, he presented to the hospital with worsening skin lesions, oral pain, and inability to tolerate oral intake.

On Admission

 The patient noted watery diarrhea since exploratory laparotomy (2015), constipation for the past week and intermittent confusion in the past month.

Vitals:

T: 36.8°C

HR: 68 BPM

RR: 18

BP: 152/102 mmHg

Oxygen saturation of 100% on room air

On Admission

Physical exam:

HEENT: dry mucous membranes, hyperplasia, diffuse inflammation, a gingival exophytic lesion, and plaque-like lesions on the tongue and mucosal surfaces with yellow-white color.

Skin: facial pustular lesions including erosion to the right nostril and scattered lesions in different stages, including open sores with serous drainage. The perirectal area had areas of erythema and excoriations.

Abdomen: diffuse, mild, abdominal tenderness to palpation.

Notable hospital course events

Notable hospital course events

- Initially treated for Clostridium difficile
- Microbiology notable for 1 day of Staphylococcus epidermidis
- Patient had severe proctitis leading to large bowel obstruction (rectal tube in and out), difficulty with oral intake due to pain, abdominal distension, PPN then TPN
- Hospital day 16- had sepsis, right sided exudative pleural effusion, chest tube was placed, started to develop anasarca
- Hospital day 22- had severe facial swelling leading to concern for airway compromised, stepped up to ICU
- Hospital day 25- was intubated due hypoxic respiratory failure
- Hospital day 26- had septic shock with multiorgan failure. Significant leukemoid reaction with WBC up to 126 x 10³/μL
- Hospital day 27- transitioned to comfort care and passed

Results

Results

- Autopsy confirmed the patient's cause of death was disseminated Monkeypox disease.
- Histology samples were negative for malignancy or other infectious process.
- All lesion samples were positive for Orthopoxvirus PCR including:
 - Brain
 - Bone marrow
 - Lymph nodes (lung and inguinal),

- Lung
- Heart
- Liver
- Spleen
- Adrenal glands
- Kidney
- Gastrointestinal tract
- Testicles



Fig.2 Left hand, multiple lesions including coalescing lesions



Fig.3 Epiglottis with scattered ulcerative lesions



Fig.4 Esophagus with ulcerative and exudative lesions

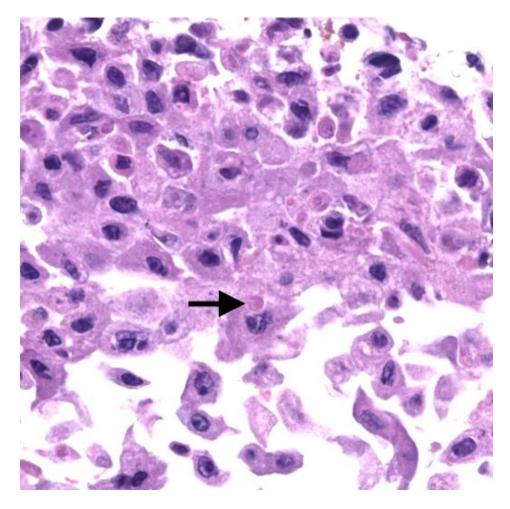


Fig.5 Histopathology of the esophagus (H&E 40X) mucosa showing an epithelial cell with an intracellular eosinophilic inclusion, consistent with a Guarnieri body (arrow)

Results

- Bone marrow, spleen and lymph node histology showed features consistent with evidence of hemophagocytic lymphohistiocytosis (HLH) involving macrophages
- Whole genome sequencing confirmed monkeypox Clade IIb lineage B.1.2 (Nextclade) on fifteen postmortem specimens
- More analysis is being conducted at the CDC

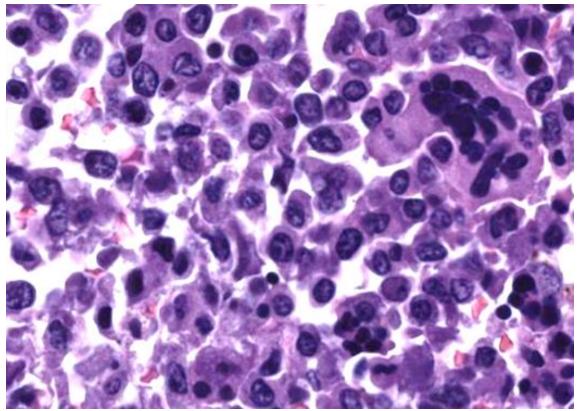


Fig.6 Markedly hypercellular bone marrow (99% cellular) (H&E 20X) with expanded trilineage hematopoiesis, including myeloid cell hyperplasia and hyperlobated megakaryocytes, occurring in a background of necrotic debris and high cell turnover. Occasional bone marrow macrophages demonstrate evidence of hemophagocytic lymphohistiocytosis (HLH)

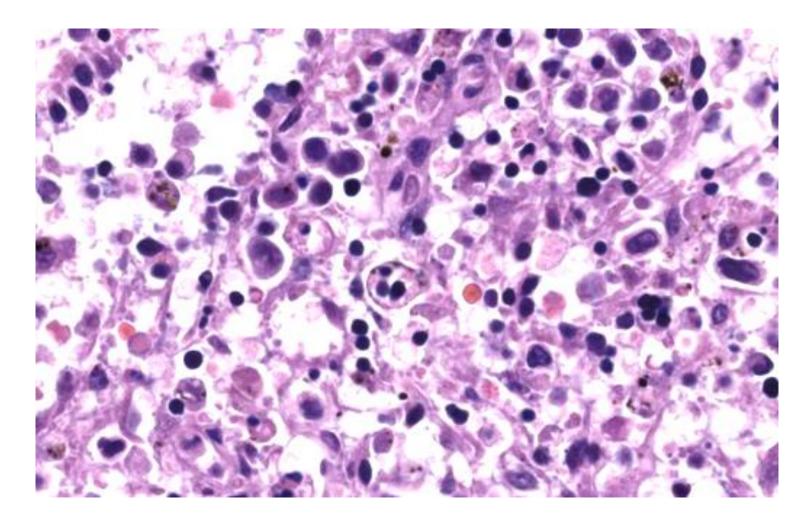


Fig.7 The spleen (H&E 20X) is notable for white pulp expansion by reactive lymphocytes, plasma cells, and histiocytes featuring prominent hemophagocytic lymphohistiocytosis (HLH)

Discussion

Discussion

- First confirmed monkeypox-related death in the United States, occurring in a 33 year old man a with HIV/AIDS (CD4,35 cells/mm) who died from disseminated monkeypox, despite treatment with 28 consecutive days of oral tecovirimat
- Although brain tissue was positive for monkeypox, no significant inflammation or viral cytopathic effects were observed

Discussion

- Bone marrow involvement by MPX has not been previously reported
- Until now, features of HLH had not been documented in disseminated MPX infection
- Was there any Immune Reconstitution Inflammatory Syndrome as part of the Systemic Inflammatory Response observed?

Conclusion

- Consider treatment with intravenous tecovirimat.
- Measuring therapeutic drug levels for tecovirimat.
- If specimens are obtained from individuals who received tecovirimat but continue to have new lesions form or have poor clinical or virologic response, consider sending specimens to CDC for resistance testing (non-CLIA).
- Second line therapies could be recommended including cidofovir or vaccinia immune globulin intravenous (VIGIV).
- Patients with HIV/AIDS, particularly those with low CD4+ counts, and infected with MPX should be closely monitored.
- Consultation regarding treatment options with local departments of health, and CDC, should take place early if hospitalized patients are not improving.

Case Presentation

Alexandra Dretler, MD Adjunct Professor Infectious Diseases Emory University

Case Presentation

Alexandra Dretler, MD

Case 2: Progressive Monkeypox

- Man in his 30's with known HIV, not on antiretroviral therapy (ART) for 6 months, previous CD4 <200
 - Reported recent sex with a man, after which he developed multiple penile and other scattered lesions consistent with monkeypox
 - Sought care at multiple facilities early July-Aug without diagnosis
 - Treated empirically for syphilis, GC/Ct and Herpes on multiple occasions in urgent care and ER without improvement
 - Restarted his ART about 2 weeks into illness
 - Developed phimosis and urinary retention saw urology outpatient who directly admitted him to hospital

Case 2: Progressive Monkeypox (slide2)

- ID consulted for penile lesions
- Clinically diagnosed with monkeypox based on physical exam finding and swab sent
- Started on oral tecovirimat inpatient and discharged with 14-day course
- CD4 <20, 1%
- Discharged with oral tecovirimat, ART and Bactrim (prophylaxis)
- Foley placed by urology for urinary retention
- Followed by Dept of Health and plan for follow up in ID office

Case 2: Progressive Monkeypox (slide 3)

- Returned to clinic on day 13 of oral tecovirimat
 - No new lesions in 4-5 days
 - Lesions were coalescing and with central eschars
 - Penile lesions had coalesced and began crusting
 - Foley remained in place and patient had planned urology follow up
- 1 week later he called office reporting a few scattered new lesions but otherwise stable

Case 2: Progressive Monkeypox (slide 4)

- 10 days post treatment ID follow up appointment
 - New lesions in multiple locations on body and specifically extending up shaft of penis
 - Reported ongoing weight loss, poor appetite and significant malaise and weakness
 - New eyelid lesion
 - Suprapubic foley placed for urinary retention and indwelling foley removed
 - Severe and persistent pain, most prominent from penile lesions
- Concern for secondary infections secondary to necrotic lesions
- Decision made after consult with CDC team to re-admit to hospital

Progressive Monkeypox-- Photos



Upon presentation



13 days of oral tecovirimat



2nd Admission

Case 2: Progressive Monkeypox (slide 5)

- Admitted to the hospital
 - Escalated to IV tecovirimat
 - Treated with broad spectrum antibiotics
- Additional medical counter measures
 - VIGIV discussed and ultimately given
 - Cidofovir- some concern for maintaining renal function
 - NOT given
 - Hydration (lactated ringers, based on % body surface area)
- Urology, Dermatology, Ophthalmology and Wound Care consulted

Case 2: Photos





Progressive Monkeypox-photos (2)



Case 2: Progressive Monkeypox (slide 6)

- Other hospital complications:
 - Methicillin-resistant staph aureus bloodstream and secondary skin infections
- Atrial fibrillation with rapid ventricular response developed
- CT PE protocol revealed pulmonary nodules concerning for pulmonary involvement
- Fortunately remained hemodynamically stable
- New lesions continued to arise
- Did repeat VIGIV
- Discharged from hospital on oral tecovirimat after 14 days of IV with plan to continue potentially until immune reconstitution

Case 2: Follow up

- Wound Care Follow up
 - Extensive lesions involving entire body but largely crusted or epithelializing
 - Back ulcer still with some central slough and necrosis but majority starting to epithelialize
 - Edges with persistent heaped lesions pox vs. inflammation
 - Penis with persistent eschar, thick slough but some healthy granulation tissue visualized along shaft
 - A few scattered active pox lesions visualized along base of penis
 - Remains on PO tecovirimat

Outpatient follow up (photos)





Thank You

Closing

Caroline Schrodt, MD, MSPH
LCDR, U.S. Public Health Service
Lead, Clinical Escalations Team
2022 Multinational Monkeypox Response
Centers for Disease Control and Prevention

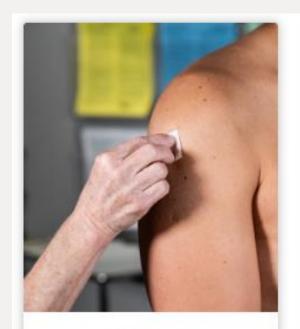
Final Reminders

- Upon initial presentation of signs and symptoms consistent with monkeypox:
 - Test for monkeypox
 - Test for HIV (including acute infection)
 - Test for other sexually transmitted infections
 - Assess for immunocompromising conditions
- Be familiar with severe manifestations of monkeypox and risk factors for severe disease.
- Contact local and state health departments or CDC early regarding severe manifestations of monkeypox for guidance on management and securing necessary resources for treatment.

Final Reminders, continued

- Consider treating immunocompromised people diagnosed with monkeypox with tecovirimat as early as possible in the course of disease and consider a prolonged course of tecovirimat for those with more refractory and severe monkeypox infection.
- Have a low threshold to use multiple medical countermeasures for people with severe manifestations of monkeypox or people who are at high risk of progression to severe manifestations.
- Optimize immune function among immunocompromised people with suspected or confirmed monkeypox.
- Ensure those with HIV are on effective antiretroviral therapy.

Update! New body sites for administration of intradermal vaccine



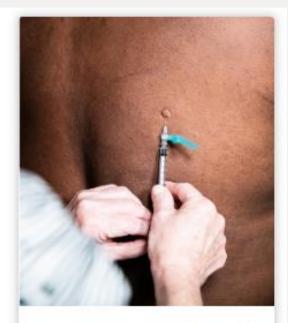
Example of locating and cleaning the site for intradermal administration at the deltoid.



Example of intradermal administration at the deltoid.



example of locating and cleaning the site for intradermal administration at the upper back below the scapula.



administration at the upper back below the scapula.

CDC Clinical Consultations

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 - Treatment with stockpiled VIGIV, IV TPOXX, and in the future, brincidofovir
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Acknowledgments

- Clinicians caring for patients with monkeypox
- Dr. Sapna Bamrah-Morris and others who helped plan and organize this call
- Health departments investigating cases
- CDC Multinational Monkeypox Outbreak Response
 - Clinical Consultations Team
 - Clinical Guidance Team
 - Vaccine Implementation Team
 - Worker Safety Team
 - Infection Prevention and Control Team
 - Special Case Investigations Team



For more information, contact CDC

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 www.cdc.gov

Or visit the 2022 U.S. Monkeypox Outbreak Response website:

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

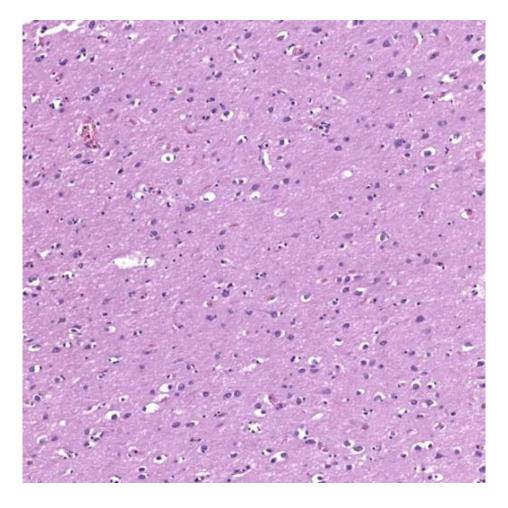


Fig.6 The brain (H&E 20X) is seen with no significant inflammation, the layers of the cerebral cortex are well-formed, triangular neurons and glial cells are not increased in number and are scattered in a background of pink neutrophils.

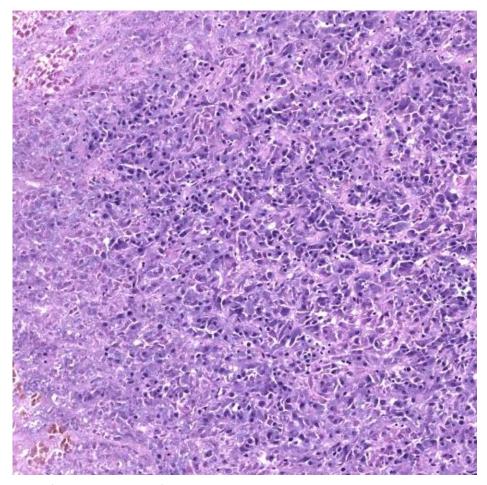


Fig.8 The adrenal gland (H&E 10X) demonstrates diffuse autolyzed parenchyma commonly seen in the post-mortem setting; some of the soft tissue around the right adrenal gland demonstrates mild chronic inflammation. There is no histomorphologic evidence of viral changes

Joining the Q&A Session

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Yon Yu, PharmD

Chief of Regulatory Affairs 2022 Multi-National Monkeypox Response Centers for Disease Control and Prevention

Today's COCA Call Will Be Available to View On-Demand

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 100622.asp

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

Upcoming COCA Call

Date: Thursday, October 13, 2022

Time: 2:00-3:00 P.M. ET

- Topic: Melioidosis in the United States: What Clinicians Need to Know Following Newly Discovered Endemicity
- Subscribe to COCA: https://emergency.cdc.gov/coca/subscribe.asp

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