Mpox Updates

Jan 2023

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Conflict of interest

- None

Outline

- Epidemiology
- Prevention
  - PEP
  - PrEP
- Clinical spectrum
- Management

CDC Changes Monkeypox Terminology to Mpox

Print

November 28, 2022

Dear Colleagues:

In support of the November 28, 2022 recommendation by the World Health Organization (WHO) and Health and Human Services (HHS), CDC will adopt "Mpox" as the term used to refer to monkeypox disease.

Mpox in US

2022 Outbreak Cases and Data

Data as of January 20 2023 at 2:00 pm EDT

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Beginning Monday, December 5, 2022, the data below will be updated once per week on Wednesdays.

U.S. Cases

Total Cases
30,061

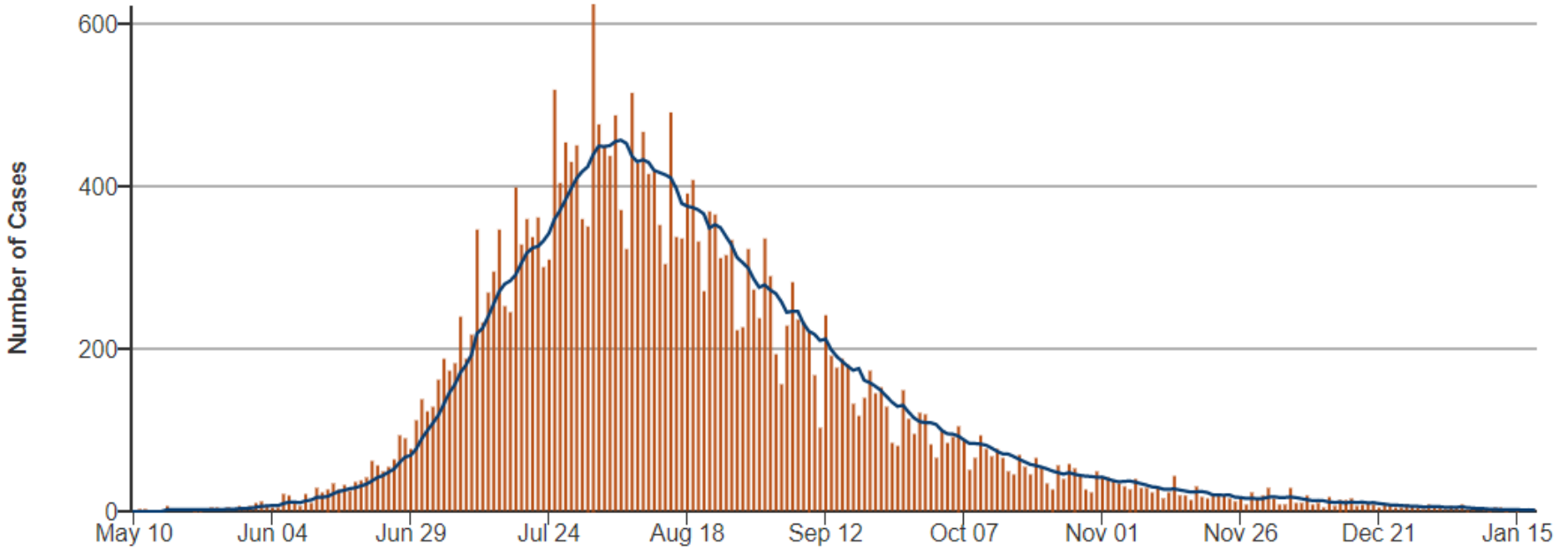
U.S. Deaths

Total Deaths
23

Global Cases

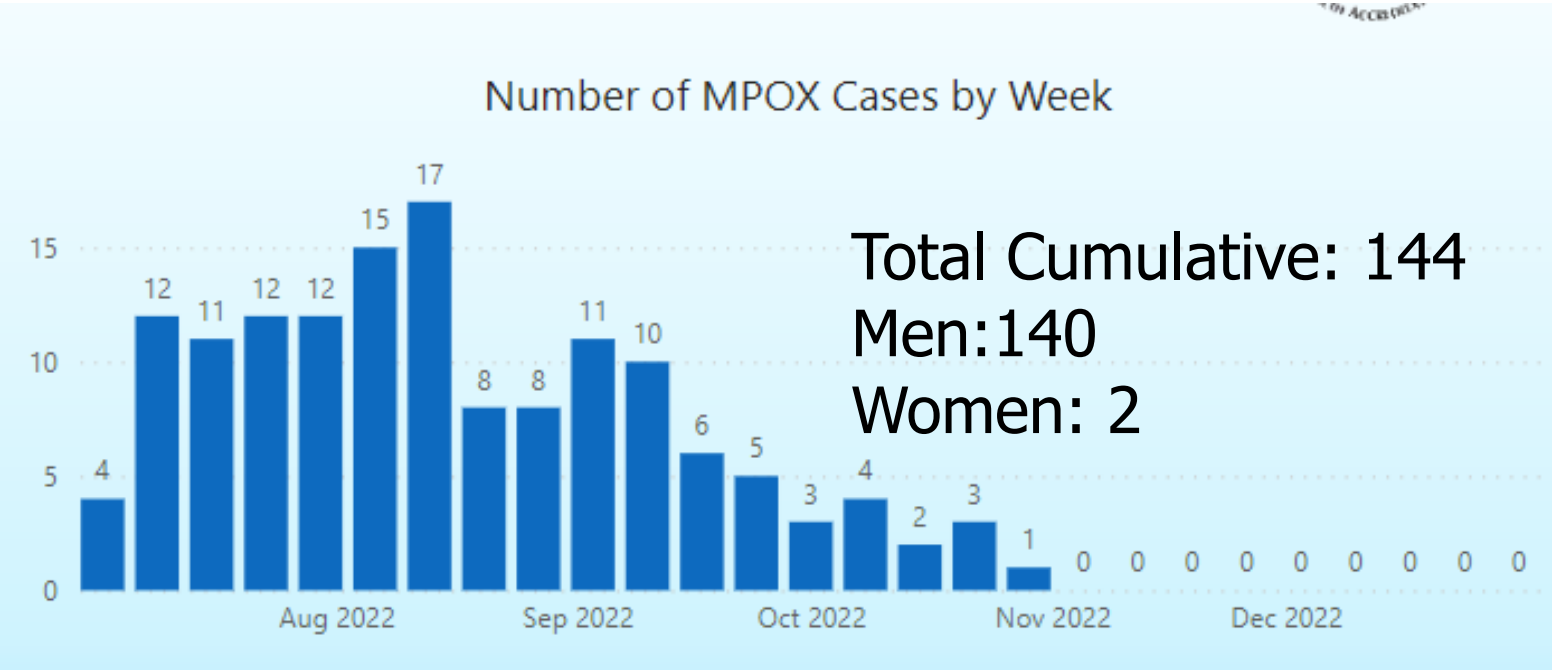
Total Cases
85,115

Mpox in US



- Gay, bisexual and other men who have sex with men (MSM) made up the majority
- Note: Testing also substantially declined

Mpox in CT



One case detected in Jan 2023!!

Mpox Epidemiology

- Approx what percent of all Mpox diagnosed people in US were also living with HIV?

1. 5%
2. 10%
3. 20%
4. 40%

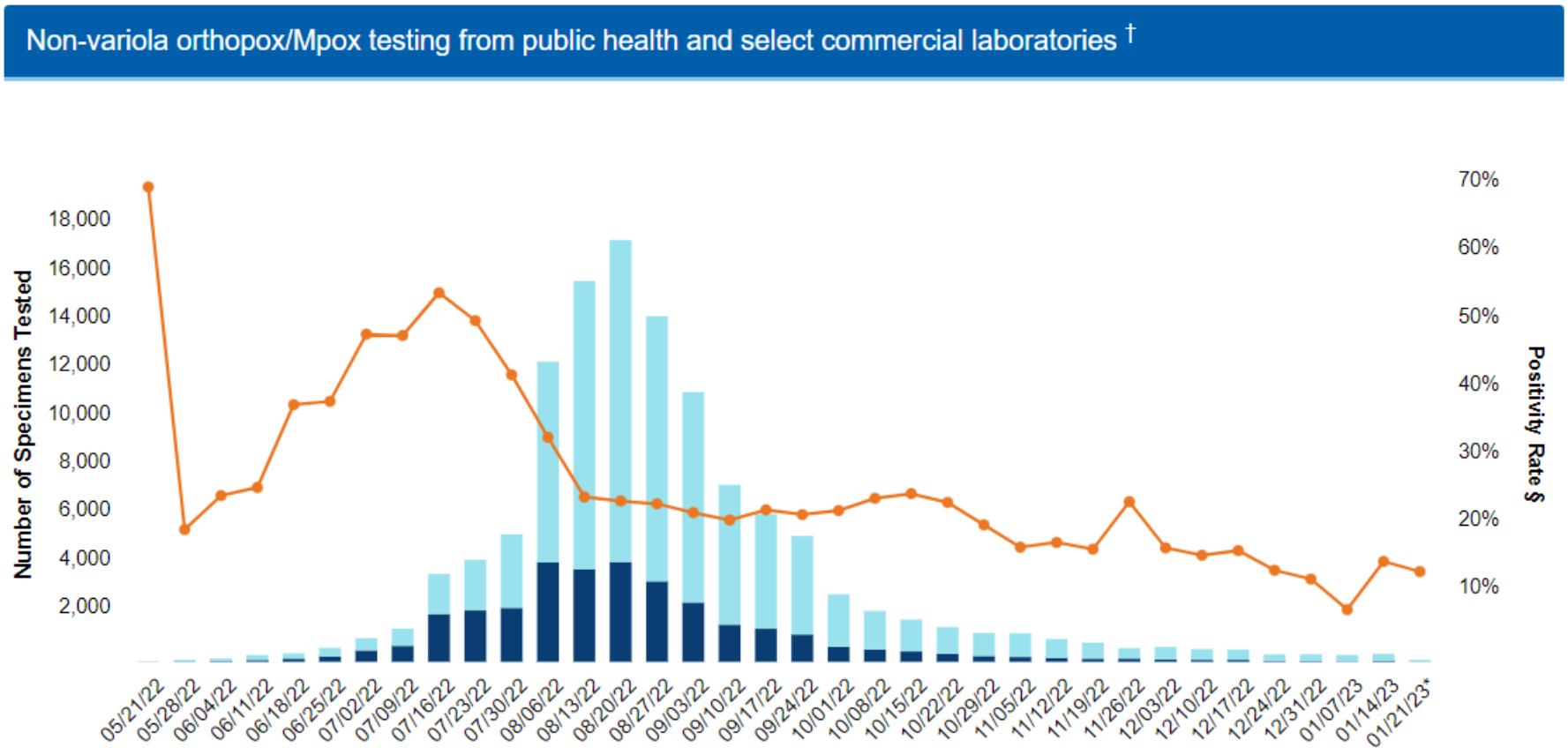
High prevalence (35-45%) of HIV co-infection.
High STI rates (41%) in preceding year

Implications:

✓ Test for HIV
✓ Test for other STIs
✓ Discuss **HIV PrEP** if HIV-ve

MMWR September 9, 2022 / 71(36);1141–1147

Testing also going down!



Outline

- Epidemiology
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  - PEP
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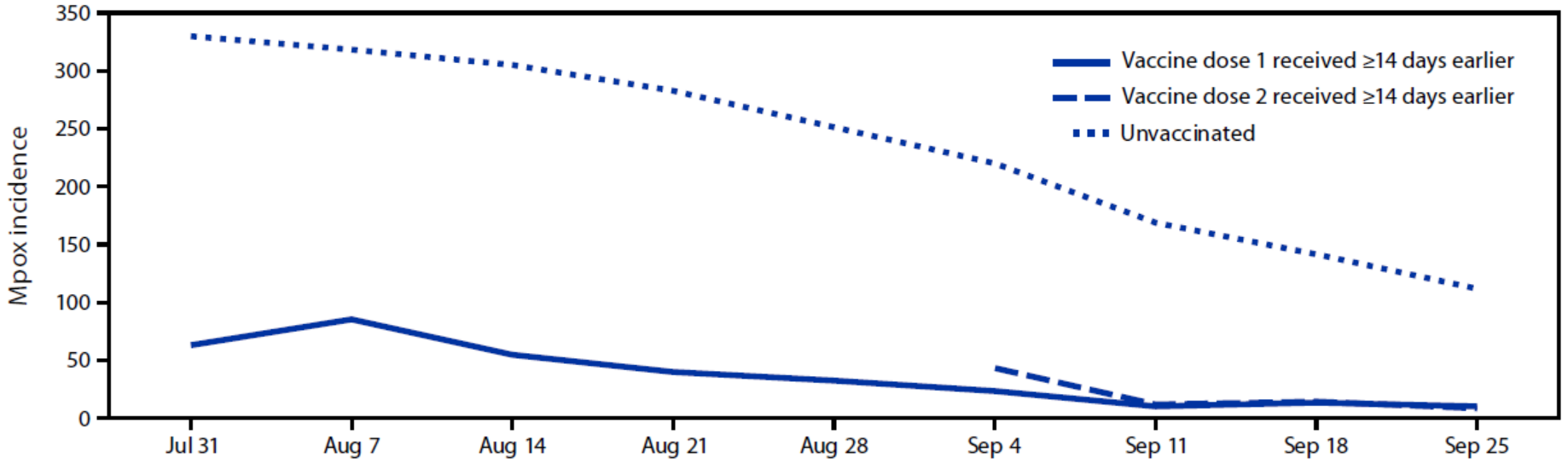
Vaccine: PEP and PrEP

- JYNNEOS vaccine is licensed as a series of two doses administered 28 days (4 weeks) apart
  - Min 24 days delay after 1st dose; ideally within 35 days
- Standard: sub-cutaneous, 0.5mL, also approved for age <18
- Aug-2022: Intradermal 0.1mL approved for adults (>=18 years)
- Antibody testing as immunity corelate is not available

Vaccine: How effective?

FIGURE. Weekly mpox incidence* among vaccine-eligible† men aged 18–49 years, by vaccination status§ — 43 U.S. jurisdictions,¶,** July 31–October 1, 2022



Relative risk unvaccinated vs 1 dose only: 7.4 (95% CI 6-9).
Relative risk unvaccinated vs both doses : 9.6 (95% CI 7-13).

VE two doses estimate per CDC (Dec-2022): 69% (higher in those without immunocomp)

Vaccine: Expanded PEP

Expanded Post-Exposure Prophylaxis (PEP++)	Vaccination **after known or presumed** exposure to mpox virus	• People who are known contacts to someone with mpox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment • People who are aware that a recent sex partner within the past 14 days was diagnosed with mpox • Gay, bisexual, and other men who have sex with men; and transgender, nonbinary, and gender-diverse people; who have had any of the following within the past 14 days: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex in association with an event, venue, or defined geographic area where mpox transmission is occurring

Timing:

Ideally within 4 days of exposure

Can give <=14 days but ?reduced efficacy

Immunocomp: can consider >=14 days

Do not give if already symptomatic with Mpox

CDC

Vaccine: PrEP

Pre-Exposure Prophylaxis (PrEP)	Vaccination **before exposure** to mpox virus	• People in certain occupational exposure risk groups*
		• Gay, bisexual, and other men who have sex with men; and transgender, nonbinary, and gender-diverse people; who in the past 6 months have had
		  ◦ At new diagnosis of one or more nationally reportable sexually transmitted diseases (i.e., HIV, chancroid, chlamydia, gonorrhea, or syphilis)
		  ◦ More than one sex partner
		• Gay, bisexual, and other men who have sex with men; and transgender, nonbinary, and gender-diverse people; who in the past 6 months have had
		• People who have had any of the following in the past 6 months:
		  ◦ Sex at a commercial sex venue
		  ◦ Sex in association with a large public event in a geographic area where mpox transmission is occurring
		• Sexual partners of people with the above risks
		• People who anticipate experiencing the above risks

Vaccine: remember Equity

Mpox Vaccine Equity Toolkit

Updated September 23, 2022 Español | Print

Who should use this toolkit? Health departments, public health partners, and groups working with populations most affected by mpox.

What is this toolkit about? This toolkit provides strategies, actions, and resources to increase vaccination among populations most affected by mpox but less likely to be vaccinated.

How should I use this toolkit? Use the resources and information below to address disparities and increase vaccine access for priority populations.

https://www.cdc.gov/poxvirus/monkeypox/resources/toolkits/vaccine-equity.html

Vaccine: safety

TABLE 2. Reporting rates for the 10 most frequently reported adverse health events* after JYNNEOS vaccine receipt, by route of administration† — Vaccine Adverse Event Reporting System, United States, May 22–October 21, 2022

Route of administration/ Health event	No. of reports	Reporting rate§ (95% CI)
Intradermal (n = 325)		
Injection site erythema	75	150 (118–188)
Dizziness	66	132 (102–168)
Urticaria	60	120 (91–154)
Injection site swelling	51	102 (76–134)
Syncope	43	86 (62–116)
Erythema	42	84 (60–113)
Loss of consciousness	41	82 (59–111)
Injection site pruritus	40	80 (57–109)
Hyperhidrosis	38	76 (54–104)
Pruritus	33	66 (45–92)
Subcutaneous (n = 212)		
Injection site erythema	36	107 (75–148)
Injection site swelling	36	107 (75–148)
Injection site pain	34	101 (70–141)
Pain	29	86 (57–123)
Erythema	28	83 (55–120)
Dizziness	27	80 (53–116)
Headache	26	77 (50–113)
Fatigue	25	74 (48–109)
Injection site pruritus	23	68 (43–102)
Pyrexia	23	68 (43–102)

- Myocarditis is known to be associated with ACAM2000 (live replication competent vaccine)
- "Current data **do not** suggest an increased risk for myocarditis after receipt of JYNNEOS, but the possibility of a small risk cannot be excluded."

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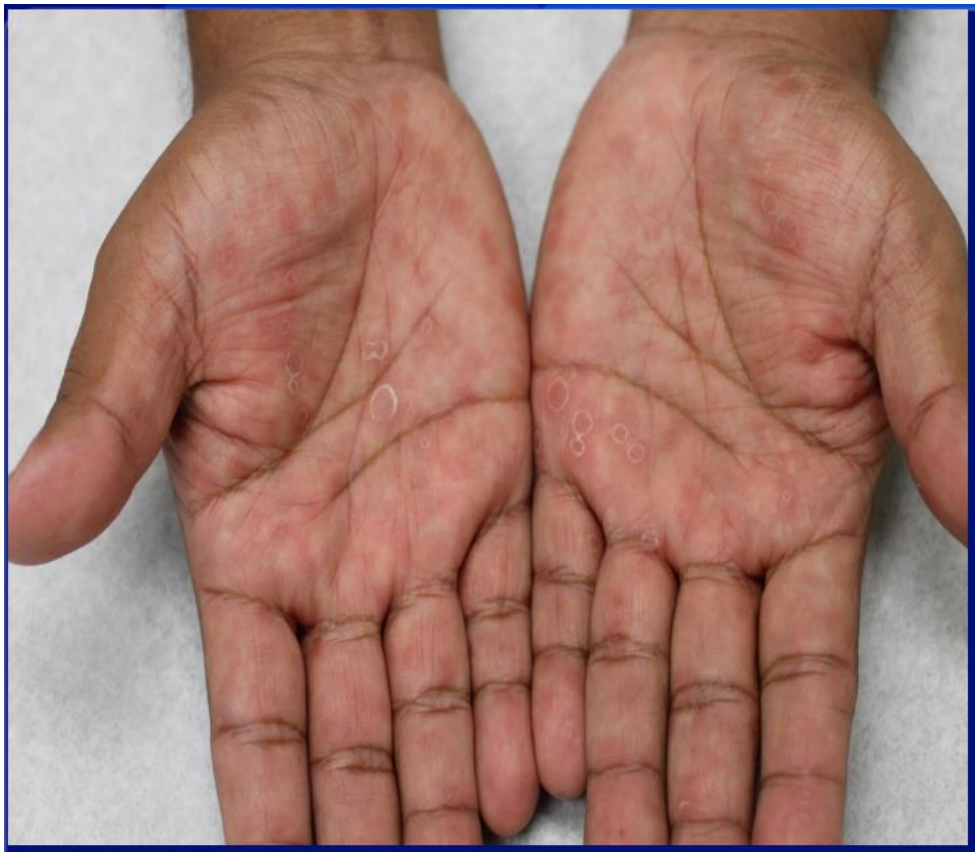
Clinical spectrum

Signs and symptoms

- **Historically: characteristic rash preceded by prodromal symptoms (e.g., fever, lymphadenopathy, flu-like symptoms)**
- **Current cases: atypical features**
  - Rash still characteristic; but often starting in genital and perianal areas
  - Rash sometimes not disseminating to other parts of body
  - Being recognized at outpatient clinics because easily confused with sexually transmitted infections
  - Prodromal symptoms mild or not occurring
- **Reasons for unusual presentation unknown at this time**
- **Patient infectious once symptoms begin (whether prodromal or rash symptoms) until lesions scab and scabs fall off**

Clinical spectrum- remember differential diagnoses



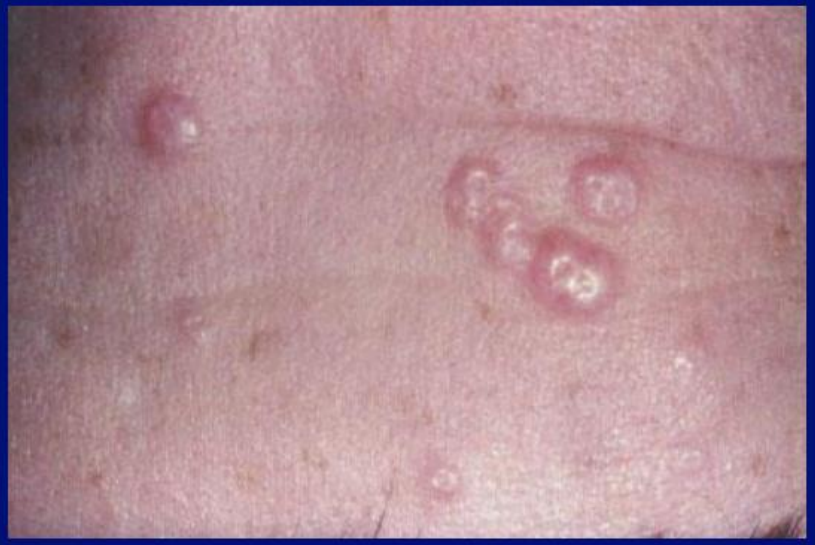
Secondary syphilis*

Monkeypox

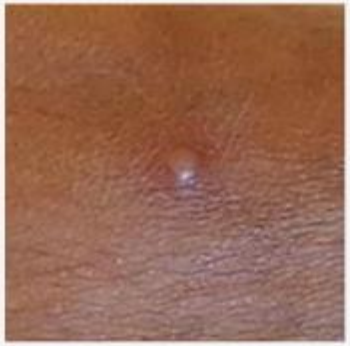
Clinical spectrum- remember differential diagnoses

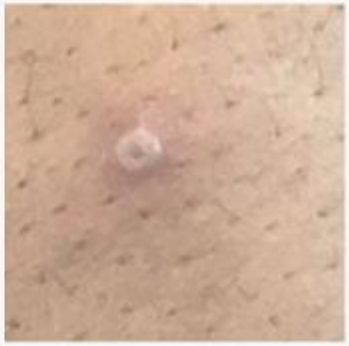
Monkeypox

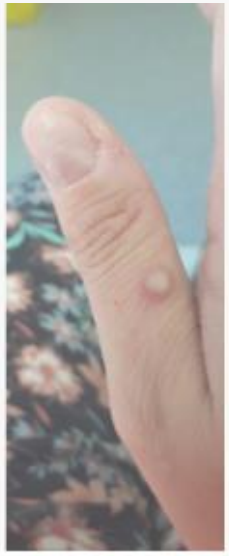
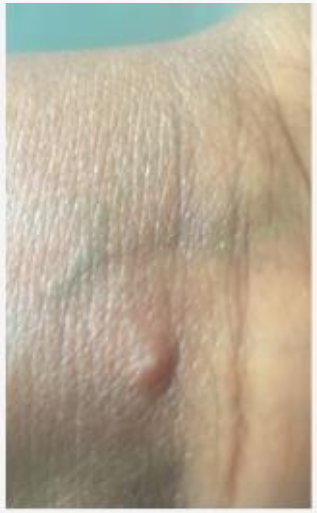
Molluscom contagiosum



Clinical spectrum- Mpox rash photos CDC library





CDC Advisory: Severe manifestation in immunocomp hosts

- Severe manifestations esp in immunocomp hosts such as HIV with CD4<200 and not on ART

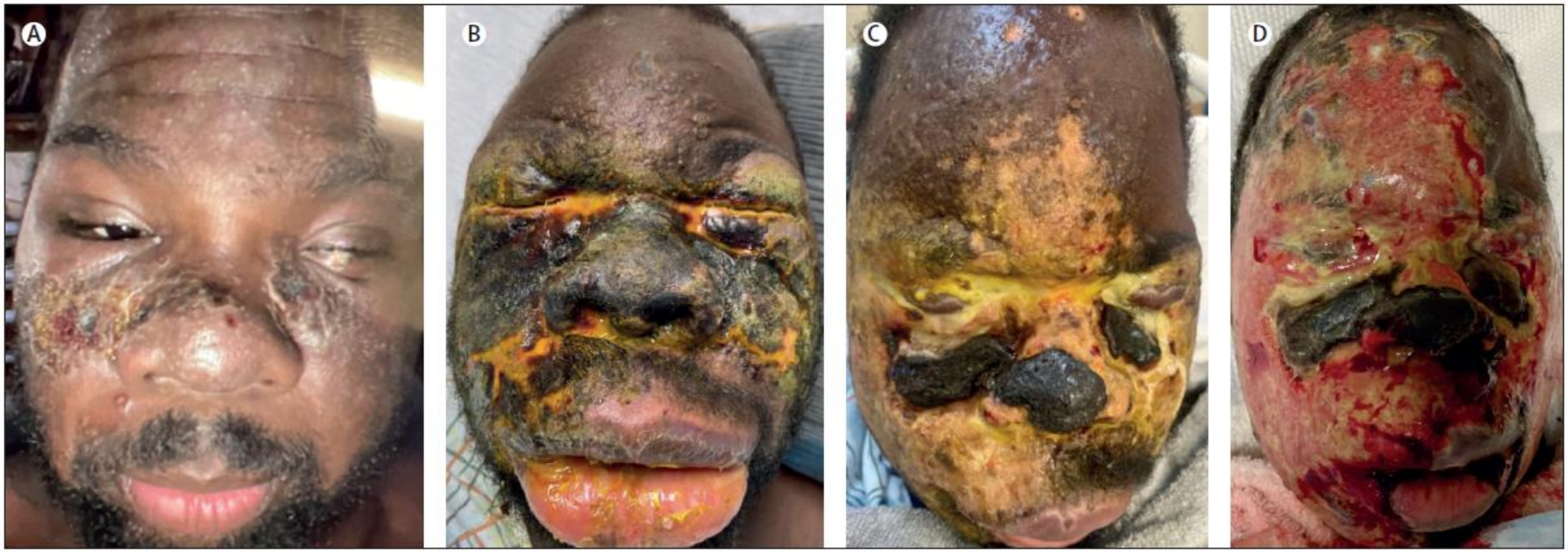


Figure 1: Chronological progression of mpox facial rash (patient one)

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Pain management

Pain Management in Monkeypox

- Monkeypox can cause severe pain and complications involving vulnerable anatomic sites
- Of the cases requiring hospitalization (13% of all cases), 30% required hospitalization for pain management
- Lesions involving anogenital/rectal and oropharyngeal mucosa and penis can cause pain out of proportion to their appearance
- Secondary bacterial infections can worsen pain

Slide courtesy Dr Paranandi DPH

Tecovirimat (TPOXX)

- FDA-approved for the treatment of smallpox
- **not** approved by FDA for MPox
- CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol ("compassionate use") that allows for the use of tecovirimat in Mpox
- The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs
- Tecovirimat use allowed under the EA-IND protocol is intended to be used in concert with CDC guidance for treatment of monkeypox

Tecovirimat (TPOXX) indications

- **Severe disease**, such as hemorrhagic disease, large number of lesions such that they are confluent, sepsis, encephalitis, ocular or periorbital infections,
- **Involvement of anatomic areas** which might result in serious sequelae that include scarring or strictures

- **High risk of progression** to severe disease:
  - o People with immunocompromising conditions
  - o Pediatric populations, particularly patients younger than 8 years of age
  - o Pregnant or breastfeeding people
  - o People with a condition affecting skin integrity — conditions such as atopic dermatitis, eczema, burns, etc

Prescribing TPOXX in Connecticut: **Required** Documentation

- Healthcare providers are required to complete and submit to CDC the following:
  - Informed Consent Form (English): Obtain prior to treatment
  - Patient Intake Form : Submitted within 7 days of starting treatment
  - FDA Form 1572: One form per facility for all TPOXX treatments administered at the same facility, submitted within 7 days of starting treatment
  - Serious Adverse Events: Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form and returning it to CDC within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the the FDA website send a copy to DPH at DPH.monkeypox@ct.gov

All submissions can be made via email (regaffairs@cdc.gov) or uploading to ShareFile

Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox.

DPH
Connecticut Department of Public Health

Prescribing TPOXX in Connecticut: Other Documentation

- Healthcare providers may also provide:
  - The clinical outcome form (progress information during and post treatment, optional photos of lesions at baseline and post treatment, lesion samples for resistance testing, plasma samples for pharmacokinetic testing, and patient diary (Optional Documentation)

All submissions can be made via email (regaffairs@cdc.gov**) or uploading to** ShareFile

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Prescribing TPOXX in Connecticut: Outpatient

- Documentation as previously described is **REQUIRED**
- A clinical suspicion of monkeypox plus a confirmatory or pending viral test
- Oral TPOXX is available at the University of Connecticut Health Pharmacy Services, Inc. (UHPSI)
  - Prescriptions may be sent M-F, 8 AM to 4:30 PM.
  - Once processed, TPOXX will be delivered from UHPSI on the next business day to the recipient (whether medical provider or directly to the patient).
- Please use one of the following options to prescribe tecovirimat for an outpatient:
  - Send UHPSI an **e-prescription** requesting the medication. In the "notes" section, please specify the delivery address.
  - **Fax** a prescription to 860-679-0303, and please include the delivery address
  - **Call in** the prescription to UCHC pharmacy at 860-679-4036 or 833-777-4276

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Tecovirimat (TPOXX) efficacy, safety and resistance

- Efficacy data not yet known: how effective? At what stage of disease?
  - Ongoing clinical trials (STOMP)

- No major safety signal
  - Oral: headache (12%), nausea (5%), abdominal pain (2%), and vomiting (2%). **Adherence issues : 3 pills BID x 14 days (84 pills)**
  - Intravenous: infusion site pain (73%), swelling (39%), erythema (23%), extravasation (19%), and headache (15%).

- Low barrier to resistance: concern for overuse causing resistance

Summary

- Mpox cases are down but NOT OVER yet!
- Testing rates are also down which is concerning
  - Part of all STI testing in cases with genital rash/ulcer/proctitis/urethritis?
- Don’t forget HIV and other STIs (and HIV PrEP if indicated)
- Jynneos vaccine seems to be effective, safe and now more available

Summary

- Jynnos vaccine: recognize who might benefit from PrEP and PEP++ for Mpox
  - Esp MSM with >1 sex partner or recent STIs
- Wide clinical spectrum of rash and clinical presentation
  - “test yourself out of it, don’t talk yourself out of it”!
- TPOXX is available for those with severe presentation or at risk of progression
  - Requires informed consent; efficacy unclear
  - Use wisely -potential for resistance