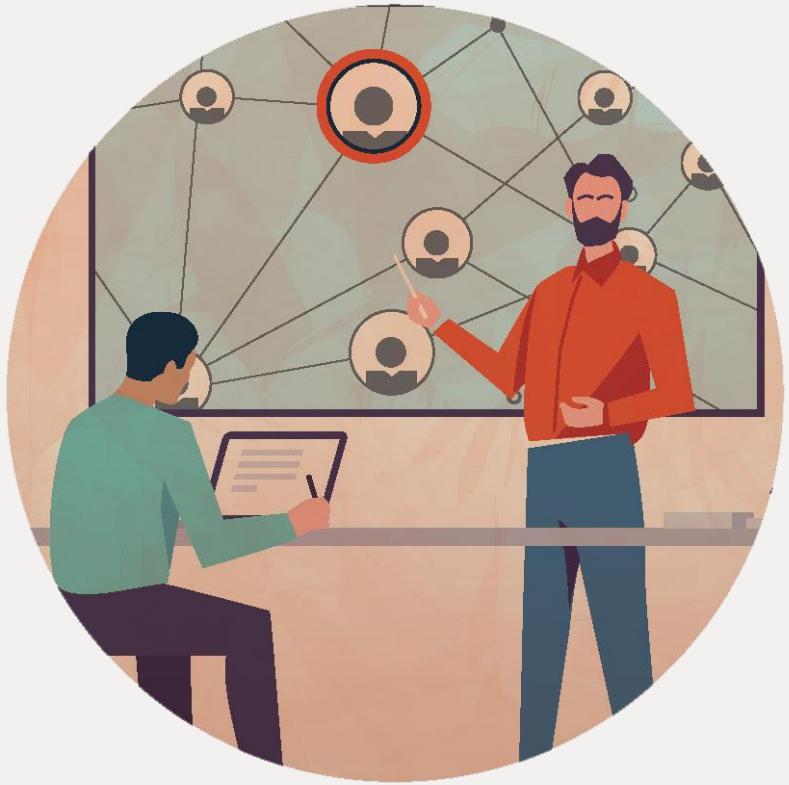
MONKEYPOX

Monkeypox Response Update

MONKEYPOX

Monkeypox Response Update



Melanie Taylor MD, MPH

CDC/NCHHSTP/DHP

July 21, 2022

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

MONKEYPOX

Monkeypox: Updates about Clinical Diagnosis and Treatment

Pre-2022 U.S. cases

- 2003: Outbreak linked to small mammals imported from Ghana
  - Cases: 47, multistate involving upper Midwest United States
  - Cause was traced to spread of Monkeypox virus from: imported African rodents → pet prairie dogs → people who had contact with pet prairie dogs

- 2021: 2 unrelated cases in travelers from Nigeria
  - July (Texas) and November (Maryland)
  - Similar to imported cases during 2018-2021 reported in travelers to United Kingdom (U.K.) (4), Singapore (1), Israel (1)

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Monkeypox: Updates about Clinical Diagnosis and Treatment

May 2022

- United Kingdom: cases in 3 distinct clusters announced May 7, 14, and 16
  - Travel-associated: 1
  - Family cluster of unknown etiology: 3
  - Cases identified at sexual health clinics among gay, bisexual, or other men who have sex with men (MSM): 4

- United States: first suspected case identified on May 17
  - Resident of Massachusetts who had traveled to Canada
  - Began as anogenital rash (vesicles, pustules) and spread to face and trunk
  - Tested positive by the OPX generic test at Massachusetts Laboratory Response Network laboratory

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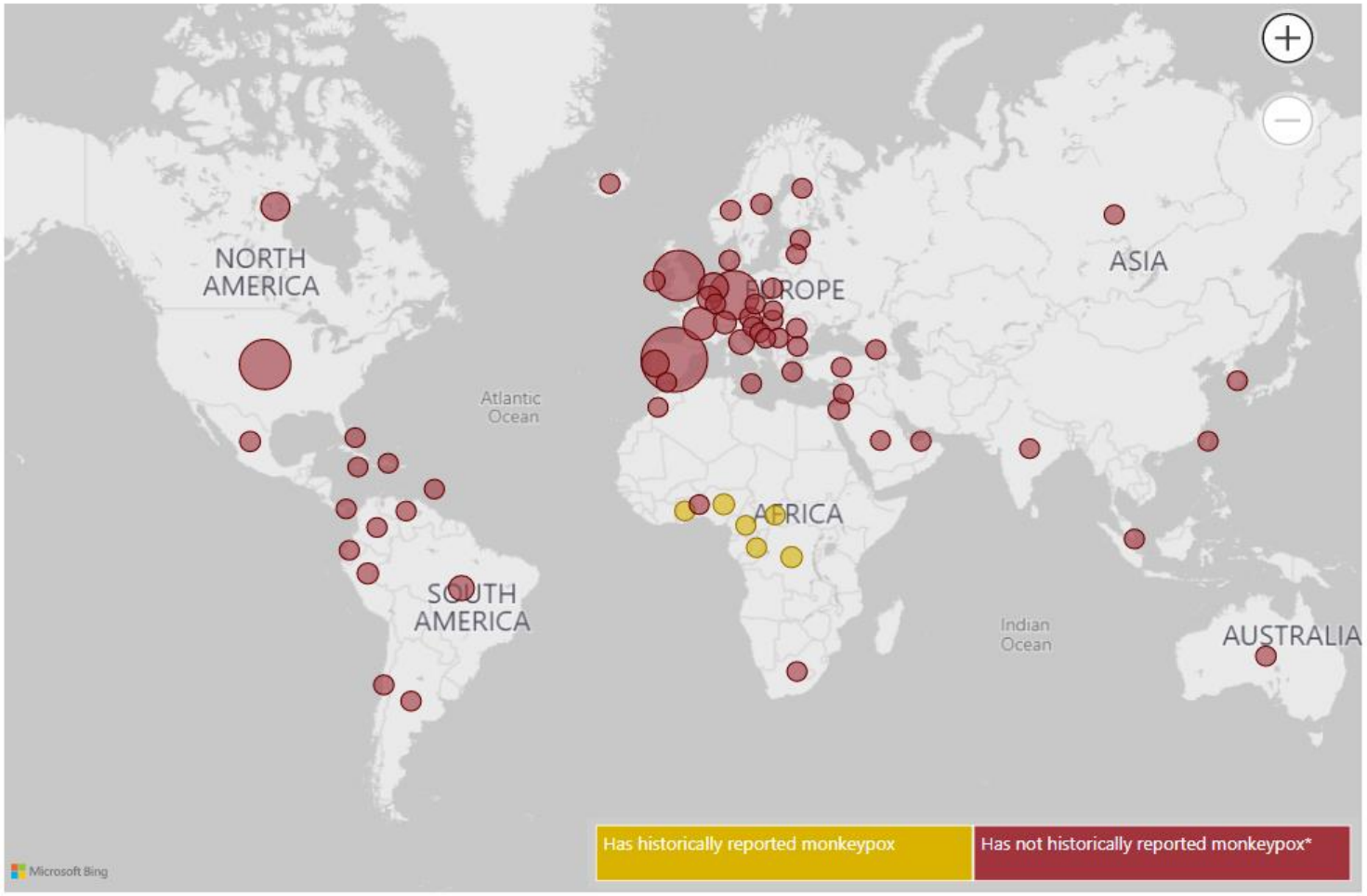
2022 Monkeypox Outbreak Global Map



Data as of 19 Jul 2022 5:00 PM EDT

	Total Confirmed Cases	Number of Locations
Has historically reported monkeypox	243	6
Has not historically reported monkeypox*	14268	64
Total	**14511**	**70**

Location	Total Confirmed Cases
Has not historically reported monkeypox*	**14268**
Spain	3125
United Kingdom	2137
United States	2107
Germany	2033
France	912
Netherlands	656
Canada	596
Portugal	515
Brazil	384
Italy	374
Belgium	311
Switzerland	213
Israel	102
Peru	95
Austria	88
Sweden	71
Total	**14511**

[2022 Monkeypox Outbreak Global Map | Monkeypox | Poxvirus | CDC]

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Monkeypox: Updates about Clinical Diagnosis and Treatment

Demographics of U.S. cases*, N=305

- Median age: 36 years (range 20-76 years)
- Male sex at birth: 271
  - All for whom gender identity was reported, are cisgender men
  - MMSC†: 193/195(99%)
    Unknown: 76
- Female sex at birth: 5
  - Some cisgender women
  - Some transgender men
- No cases in children
- No deaths; some hospitalizations primarily for pain control

Any person, regardless of gender identity or sexual orientation, can acquire and spread monkeypox

Data will change pending ongoing investigations and additional cases*

†male to male sexual contact

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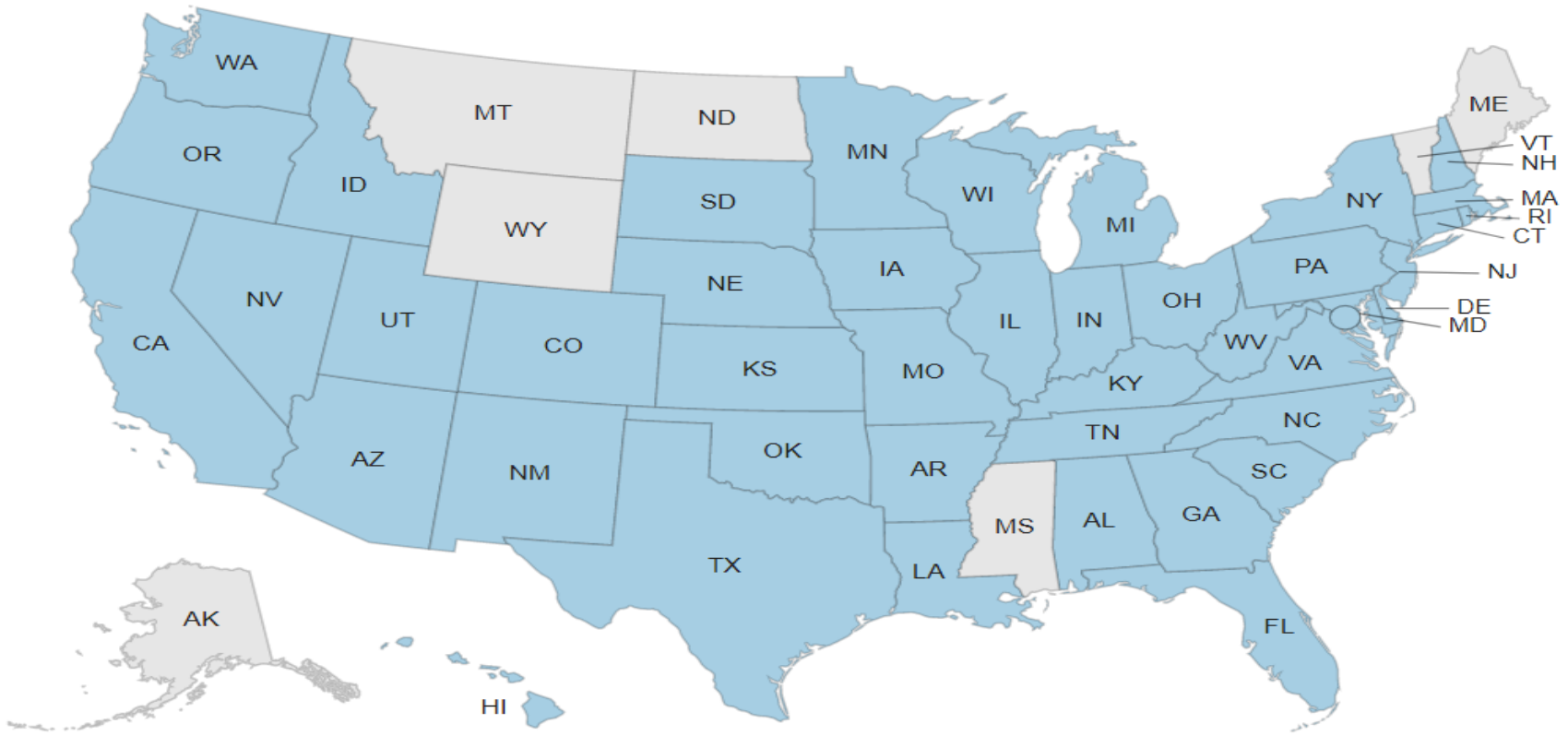
MONKEYPOX

2022 U.S. Map & Case Count

Updated July 19, 2022 Print

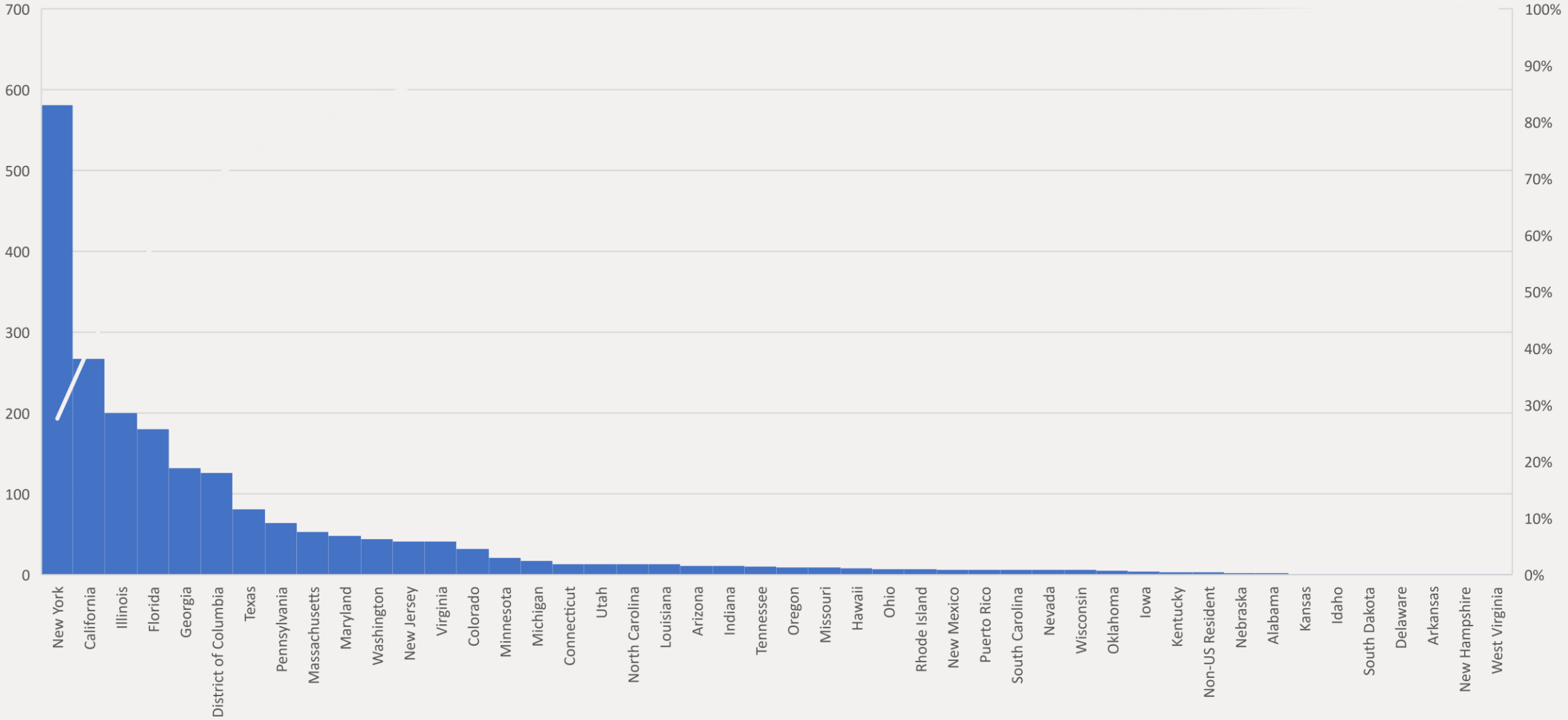


Territories PR

[2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC]

MONKEYPOX

Monkeypox Cases by Jurisdiction of Diagnosis as of July 19, 2022



2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC

MONKEYPOX

Transmission

1. Direct contact with the infectious rash, scabs, or body fluids
2. Respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
3. Touching items (such as clothing or linens) that previously touched the infectious rash or body fluids
4. Pregnant people can spread the virus to their fetus through the placenta
5. Being scratched or bitten by an infected animal or by preparing or eating meat or using products from an infected animal.

How it Spreads | Monkeypox | Poxvirus | CDC

MONKEYPOX

Transmission

- Monkeypox can spread from the time symptoms start until the rash has fully healed and a fresh layer of skin has formed.
- The illness typically lasts 2-4 weeks.
- There is no current evidence that people who do not have monkeypox symptoms can spread the virus to others.
- At this time, it is not known if monkeypox can spread through semen or vaginal fluids

How it Spreads | Monkeypox | Poxvirus | CDC

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Clinical Symptoms

- Skin rash or exanthem
- Lesions in different phases of development seen side-by-side
- Rash either scattered or diffuse; sometimes limited to one body site and mucosal area (e.g. anogenital regions or lips/face)
- Presenting complaint sometimes anorectal pain or tenesmus; physical examination notable for visible lesions and proctitis
- Prodromal symptoms mild or not occurring
- Fever, lymphadenopathy not occurring in all patients
- Co-infections with HIV and other sexually transmitted infections (STIs)

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

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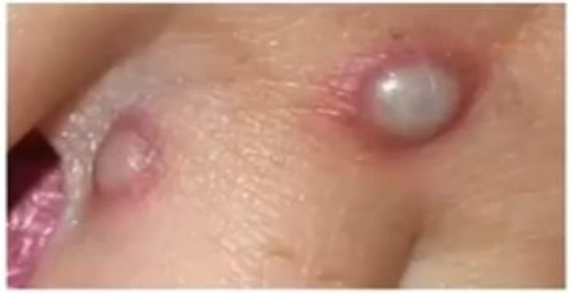
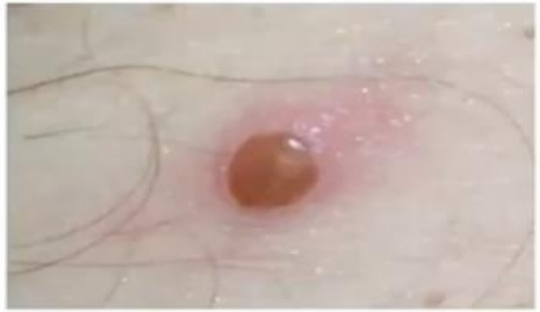
Monkeypox: Updates about Clinical Diagnosis and Treatment

Classic lesions: Firm, deep-seated, well circumscribed, painful, itchy, sometimes umbilicated



Lesions observed during 2003 U.S. monkeypox outbreak



Reed KD, Melski JW, Graham MB, Regnery RL, Sotir MJ, Wegner MV, Kazmierczak JJ, Stratman EJ, Li Y, Fairley JA, Swain GR, Olson VA, Sargent EK, Kehl SC, Frace MA, Kline R, Foldy SL, Davis JP, Damon IK. The detection of monkeypox in humans in the Western Hemisphere. N Engl J Med. 2004 Jan 22;350(4):342-50.

Lesions observed in endemic countries

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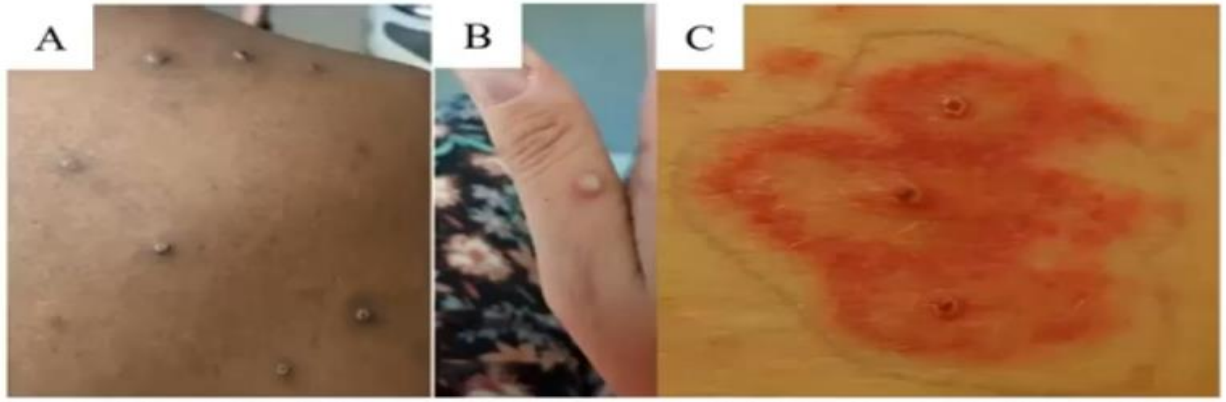
Monkeypox: Updates about Clinical Diagnosis and Treatment

Lesions observed during May and June 2022*

- Firm, deep-seated, well-circumscribed, painful, itchy, sometimes umbilicated
- Small lesions; often not distributed diffusely
- May rapidly progress through stages (papules, vesicles, pustules, and scabs)
- Papulovesicular and pustular lesions may be seen on same body site



Photos A and B from NHS England High Consequence Infectious Diseases Network; photo C from Reed KD, Melski JW, Graham MB et al. The detection of monkeypox in humans in the Western Hemisphere. Page 346. Copyright © 2004. Massachusetts Medical Society. Reprinted with permission

For additional images:

1) Ogoina D et al. Clinical course and outcome of human monkeypox in Nigeria. Clin Infect Dis. 2020; 71(8): 210-214
2) Antinori A et al. Epidemiological, clinical, and virological characteristics of four cases of monkeypox support transmission through sexual contact, Italy, May 2022. Euro Surveill. 2022 June; 27 (22).

*As data continues to be collected, what is known about the clinical presentation may change

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MONKEYPOX

Monkeypox: Updates about Clinical Diagnosis and Treatment

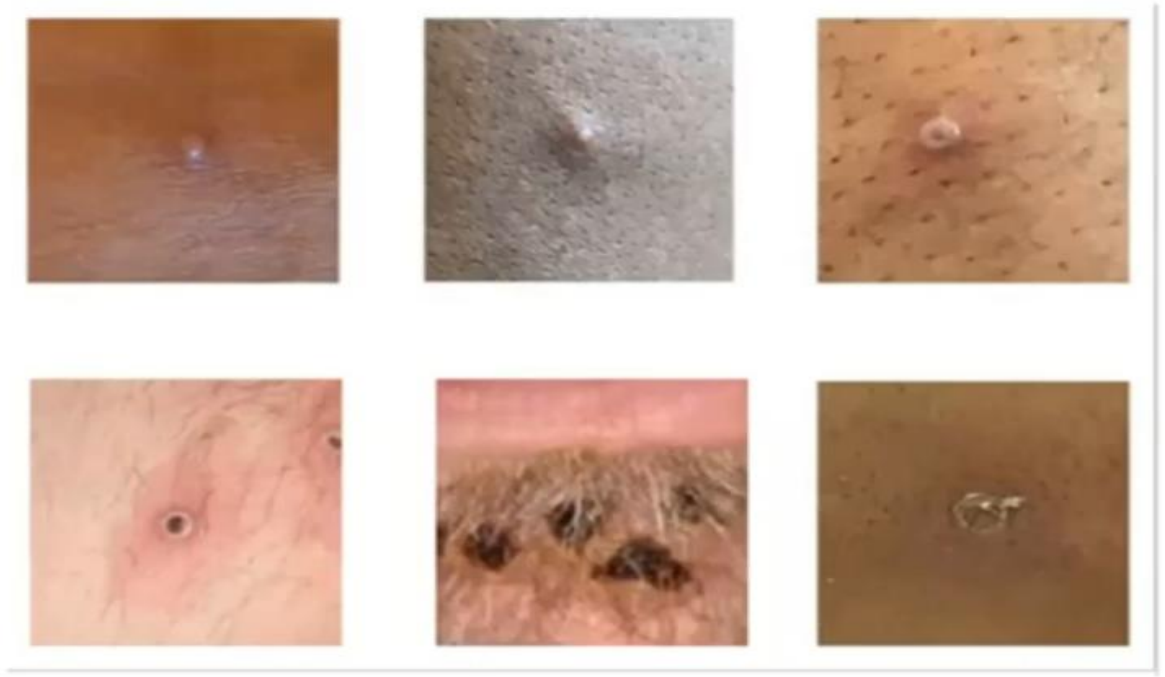
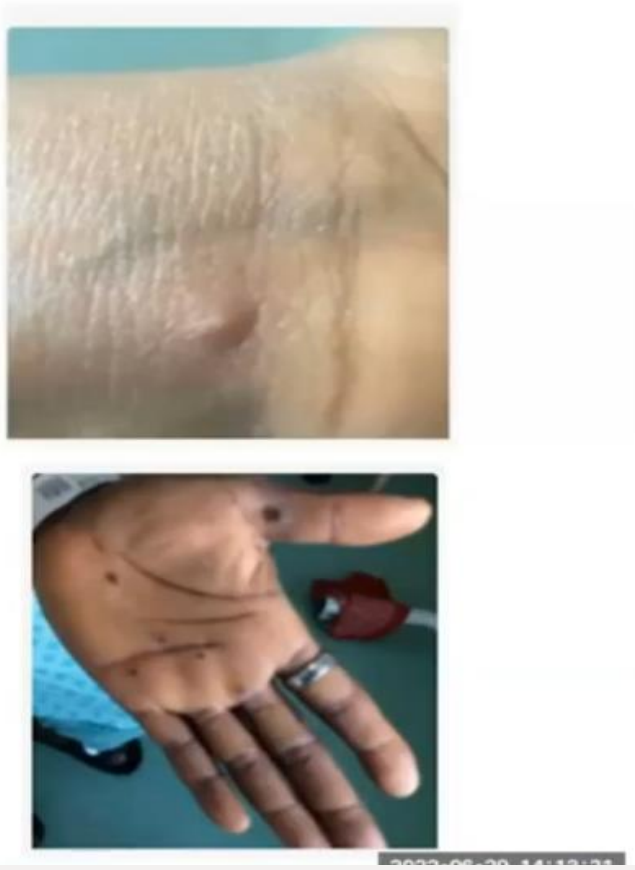


Photo Credit: NHS England High Consequence Infectious Disease Network



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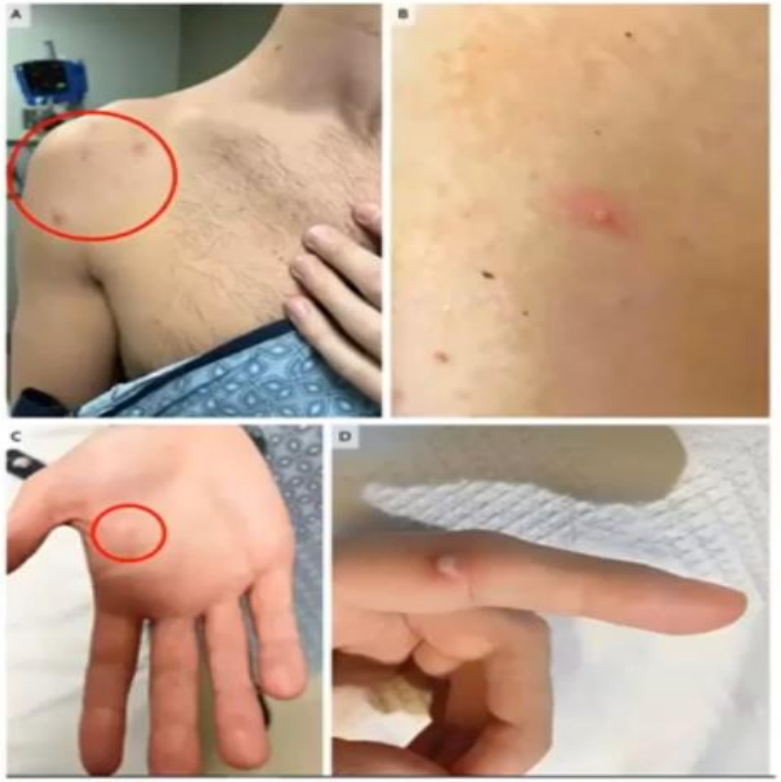
Monkeypox: Updates about Clinical Diagnosis and Treatment



From Basgoz N, Brown CM, Smole SC, et al. Case 24-2022: A 31-Year-Old Man with Perianal and Penile Ulcers, Rectal Pain, and Rash. Epub ahead of print. *Copyright* © Jun 15 2022. Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society

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Monkeypox: Updates about Clinical Diagnosis and Treatment

CDC guidance to clinicians

- Perform thorough skin and mucosal (e.g., anal, vaginal, oral) exam for rash
- Obtain swabs if
  - Observation of classic monkeypox rash OR
  - Observation of rash that could be consistent with monkeypox in persons with epidemiologic risk factors:
    - Contact with a person or people a) with similar appearing rash or b) with diagnosis of monkeypox
    - Close or intimate in-person contact with people in a social network experiencing monkeypox activity (e.g., men who have sex with men who meet partners through an online website, digital app or social event)
    - History of recent international travel to country currently with many cases
- Diagnosis of STI does not rule-out co-infection with monkeypox
- **Note:** any person, irrespective of gender identity or sexual orientation, can acquire and spread monkeypox.

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- Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

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Specimen Collection

- Use sterile synthetic swabs (including, but not limited to polyester, nylon, or Dacron) with a plastic, wood, or thin aluminum shaft,
- Swab the lesion vigorously to collect adequate DNA.
- *Do not use cotton swabs.*
- It is not necessary to de-roof the lesion before swabbing.
- Break off the end of each swab's applicator into a 1.5-or 2-mL screw-capped tube with O-ring or place the entire swab in a sterile container that has a gasket seal and is able to be shipped under the required conditions.
- Swabs from each lesion should be collected, preferably from different locations on the body or from lesions which differ in appearance.
- Two swabs and other specimens should each be placed in different containers. Only dry swabs or those in viral transport media (VTM) are acceptable for testing
- Commercial testing is now available through SonoraQuest, LabCorp and others

Preparation and Collection of Specimens | Monkeypox | Poxvirus | CDC

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2022 Monkeypox Case Study

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Thursday, June 2 – Day 1

- The patient, a 26-year-old Hispanic MSM and an established client at a publicly funded STI clinic, presented for a routine 3-month HIV PrEP Clinic visit via telehealth
- He had no concerns during his telehealth visit
- He was instructed to come to clinic for his routine testing the next day

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MSM: gay, bisexual, and other men who have sex with men; STI: sexually transmitted infection; HIV PrEP: HIV pre-exposure prophylaxis

Penile Lesions – Day 1

Of note: these lesions appeared after his morning telehealth visit

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Friday, June 3 – Day 2 – Patient History

- **While self-collecting specimens for STI testing, the patient mentioned a rash on his penis that had started late the day before but had worsened since that time**

- **Additional history:**
  - He had sex with 3 men at a sex party in New York City (NYC) on 05/29/2022
  - He did not know whether any of these partners had recent travel
  - No international travel
  - No fever, swollen glands, or fatigue

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Friday, June 3 – Day 2 – Patient Exam Findings

- **Genital exam**
  - Uncircumcised; multiple discrete small papules and macules on the glans penis, coronal sulcus, and distal penile shaft
  - Some skin lesions were flesh-colored and some were pale; no pustules
  - Lesions were firm and slightly rubbery; could not be unroofed
  - Lesions were painful
  - No inguinal lymphadenopathy

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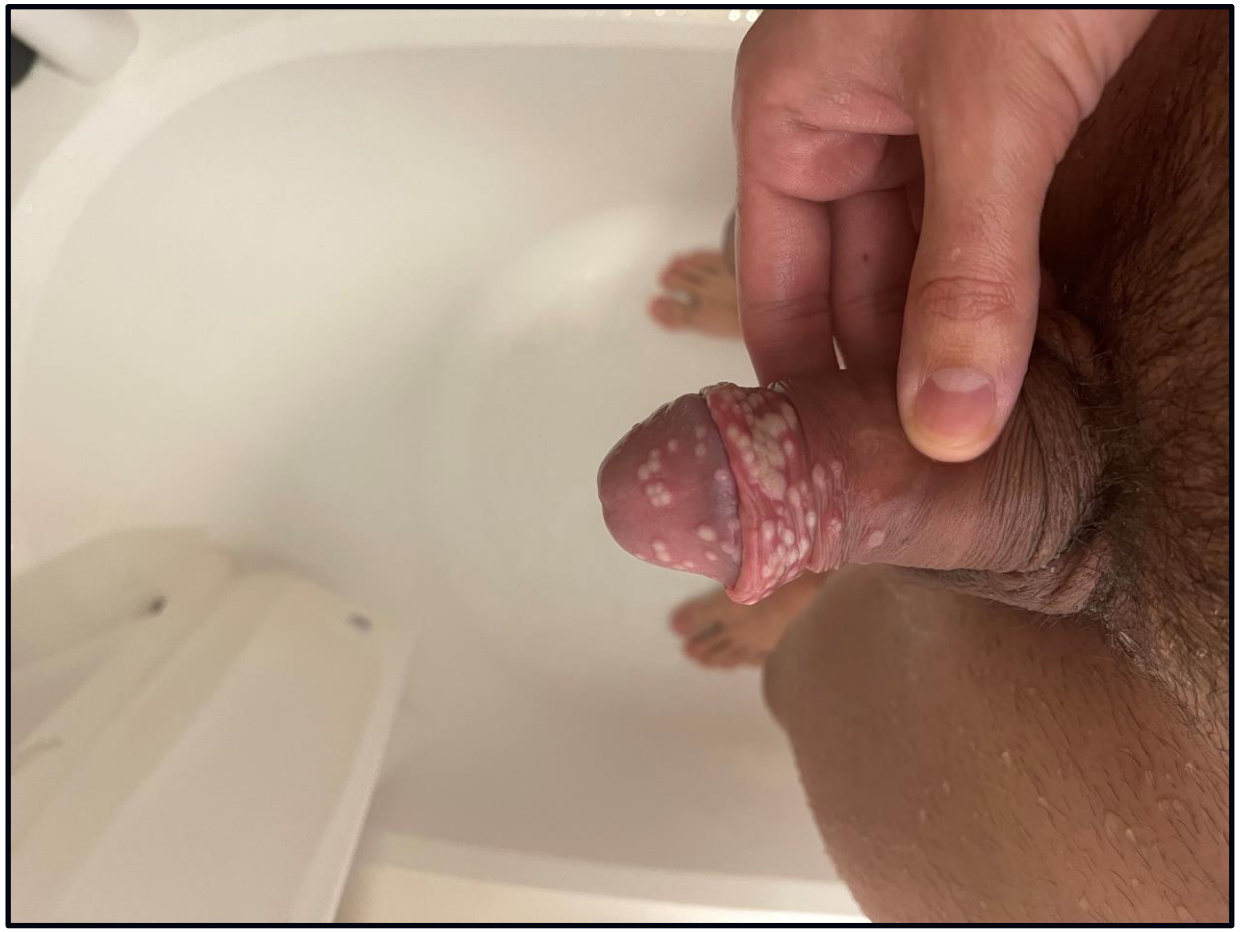
Friday, June 3 – Day 2 – Patient Testing and Treatment

- Routine PrEP Clinic HIV/STI testing was done – including an RPR test
  - An HSV culture was collected
- Empirically started on treatment for his first clinical episode of genital herpes
- Anticipatory guidance and counseling was provided for other possible diagnoses – including molluscum contagiosum and monkeypox
- Monkeypox swabbing was discussed but not done at that time because there were no prodromal symptoms and only 4 days had passed between the sex party and the onset of symptoms
- Plan to return to clinic next week to discuss results and reassess symptoms
- Patient agreed to sexual abstinence pending results and a definitive diagnosis

RPR: reactive plasma reagin; HSV: herpes simplex virus

Penile Lesions – Sunday, June 5 – Day 4



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Monday, June 6 – Day 5

- **Patient called the clinic to discuss lab results and provide update on symptoms**

- **Lab results**
  - RPR non-reactive, HSV culture negative
  - Pharyngeal and rectal NAAT were negative for both chlamydia and gonorrhea
  - Urine NAAT was positive for chlamydia (and negative for gonorrhea)

- **Symptom evolution**
  - Genital lesions had increased in size and number and had become more painful – in addition, his penis and foreskin had become more edematous
  - Additional lesions elsewhere on his body
  - Subjective fever for two nights associated with fatigue and decreased appetite

- **He learned that one of his partners at the NYC sex party lives in Toronto, was symptomatic, and was diagnosed with monkeypox**

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NAAT: nucleic acid amplification test

Tuesday, June 7 – Day 6 – Patient History

- **The patient returned to clinic (with his most recent sex partner)**

- **Pertinent index patient history:**
  - Reported 10 male sex partners in past the 90 days and 40 in the past year
  - Reported using the substances ecstasy and ketamine in the past 30 days
  - Sex with anonymous and pseudo-anonymous partners (i.e., only knew partners by their App profile name)
  - Engaged in receptive and insertive oral and anal intercourse; never used condoms
  - Prior history of chlamydia, gonorrhea, and syphilis infections

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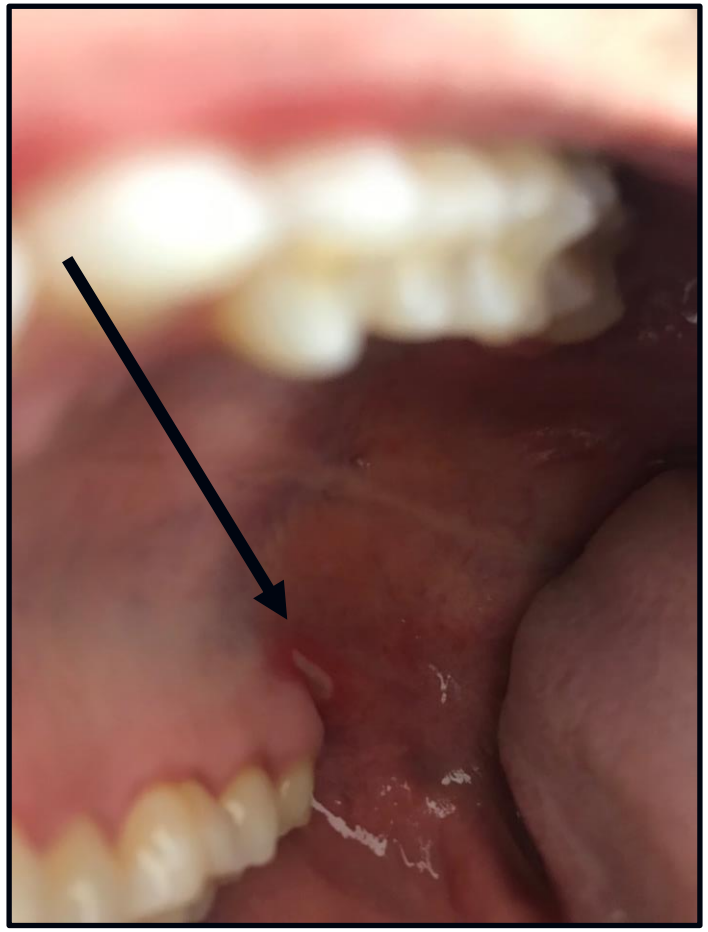
Tuesday, June 7 – Day 6 – Patient Exam Findings

- **Mouth with oral lesion**
  - Small ulcerated area in upper right rear oral cavity; painful when swabbed



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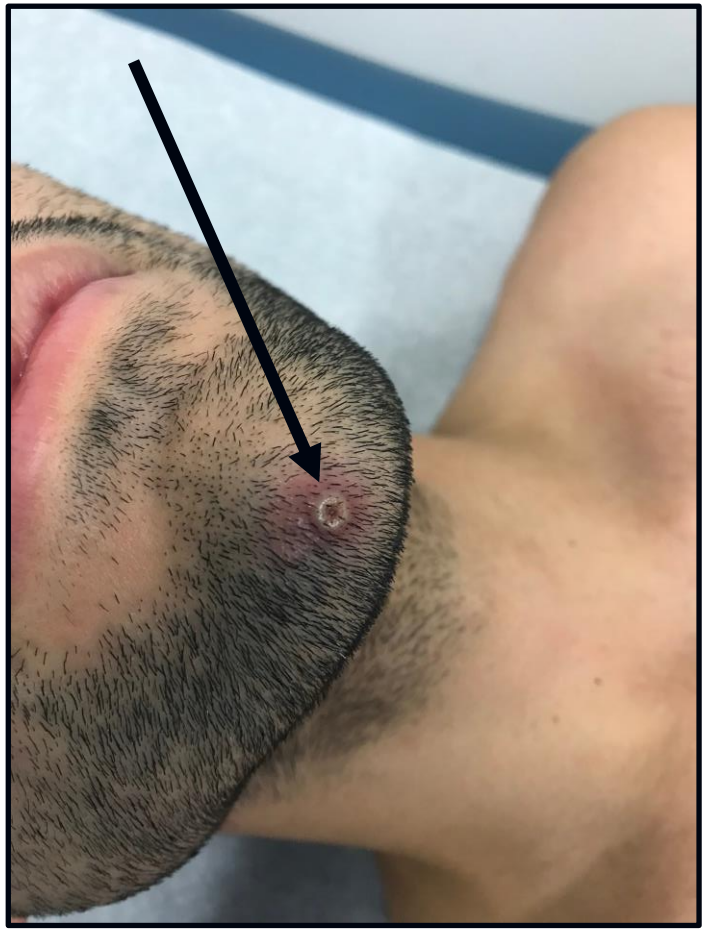
Tuesday, June 7 – Day 6 – Patient Exam Findings

- **Chin lesion**
  - One lesion with white rim, dark center, erythematous base



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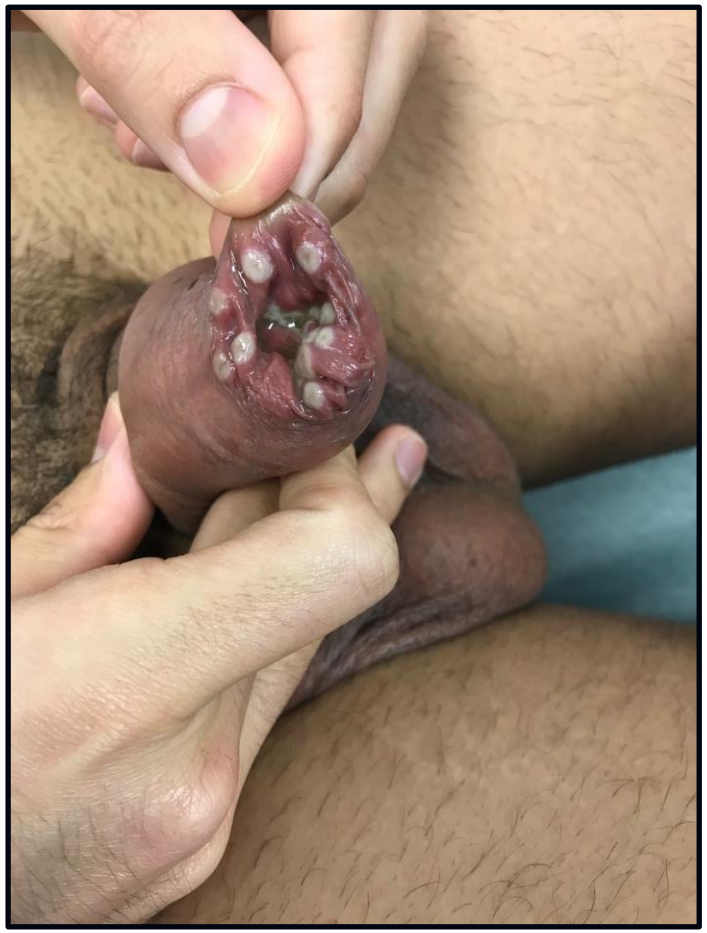
Tuesday, June 7 – Day 6 – Patient Exam Findings

- **Penis – uncircumcised with multiple white lesions with umbilicated center**
  - Edematous foreskin and distal end of penis
  - Patient unable to retract foreskin
  - Area generally painful
  - Possible white urethral discharge noted



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Tuesday, June 7 – Day 6 – Patient Testing and Treatment

- All three of the patient's lesions were swabbed for monkeypox testing
- The patient was started on doxycycline 100 mg by mouth twice a day for 7 days for urogenital chlamydia treatment
- The patient was instructed to call the clinic in the next day or two to discuss results and reassess symptoms

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Tuesday, June 7 – Day 6 – Partner History

- **The partner, a 23-year-old White MSM, presented for evaluation and reported onset of new rash**

- **Pertinent partner history:**
  - They were last together Wednesday, June 1 – one day before the index patient's symptoms started
  - Partner reported 3 male sex partners in the past 90 days and 10 in the last year
  - He reported sex with anonymous and pseudo-anonymous partners
  - He engaged in receptive and insertive oral and receptive anal intercourse; never used condoms
  - History of chlamydia and gonorrhea in the previous year

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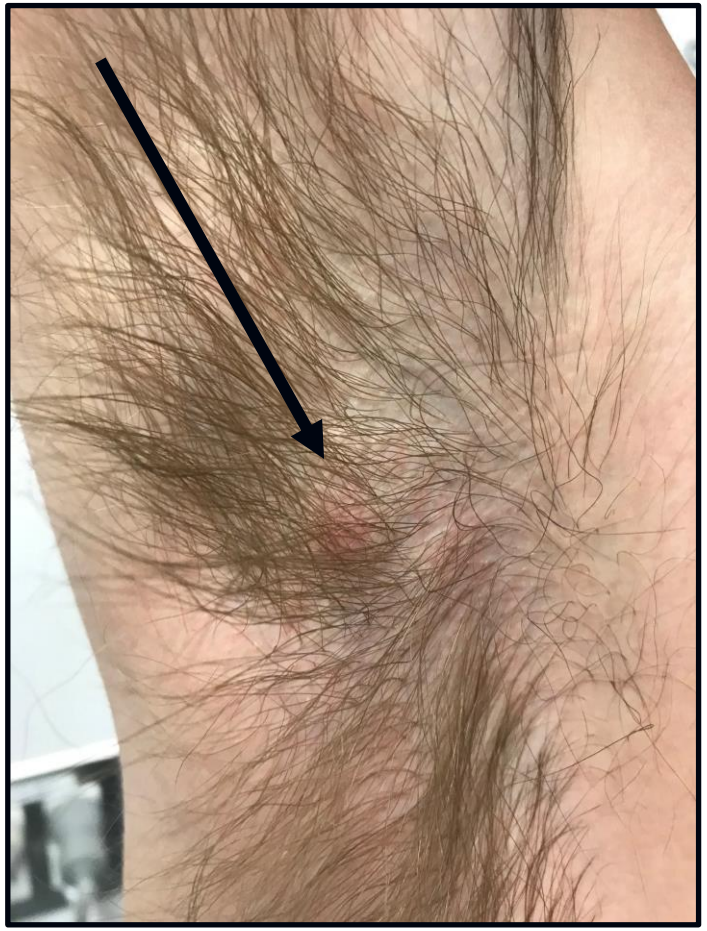
Tuesday, June 7 – Day 6 – Partner Exam Findings

- Skin of right axilla
  - One nodular firm papule (~0.5 cm) right axillae



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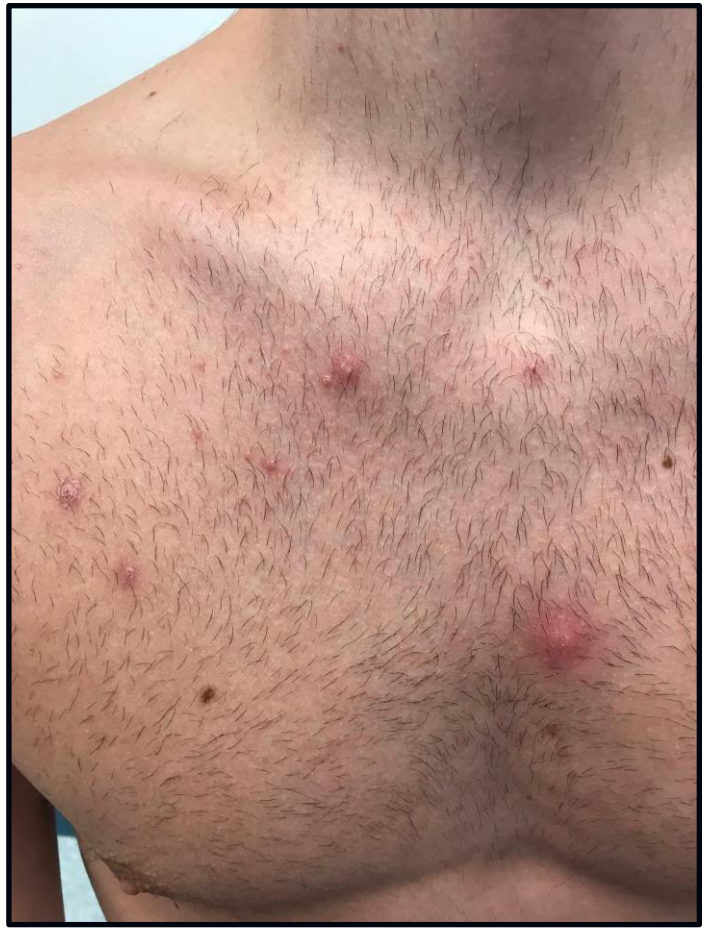
Tuesday, June 7 – Day 6 – Partner Exam Findings

- Chest
  - Five papular, mildly erythematous lesions across chest in varying sizes (largest ~0.5 cm)
  - One lesion with white rim, dark center, erythematous base



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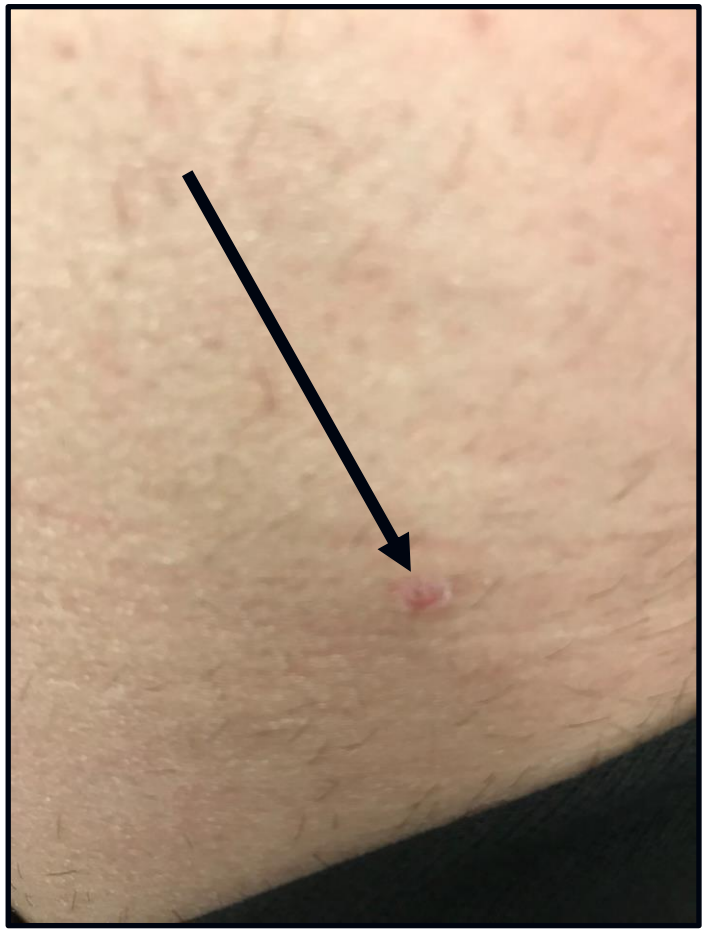
Tuesday, June 7 – Day 6 – Partner Exam Findings

- Buttocks
  - One very small papule on skin of left lower buttock



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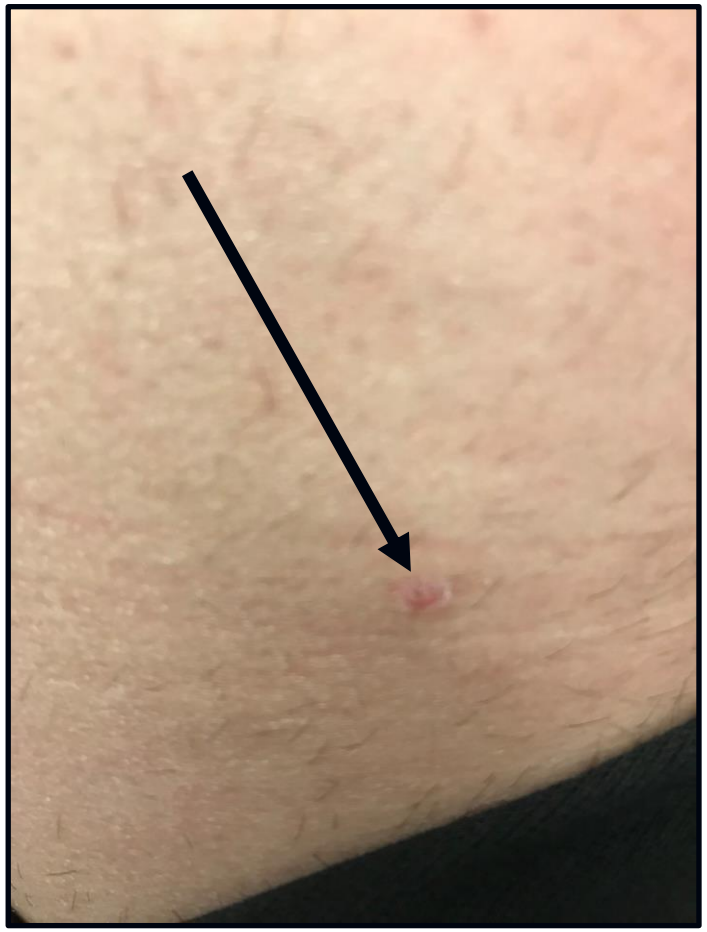
Tuesday, June 7 – Day 6 – Partner Exam Findings

- **Buttocks**
  - One very small papule on skin of left lower buttock

- **Lymph nodes**
  - No axillary, supraclavicular, or inguinal adenopathy



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Tuesday, June 7 – Day 6 – Partner Testing and Treatment

- All three of partner's anatomic sites with lesions (right axilla, chest, left buttock) were also swabbed for monkeypox testing

- The partner was started on doxycycline 100 mg by mouth twice a day for 7 days as a contact to chlamydia

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Wednesday, June 8 – Day 7 – Test Results

- All three sites of the patient's lesions tested Orthopoxvirus positive
- All three sites of the partner's lesions tested Orthopoxvirus negative*

*Specimen results were reported as: positive, negative, or QNS | TNP (meaning that there was not enough DNA material to run the test). The partner's specimen was adequate enough to report a negative result.

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Thursday, June 9 – Day 8

- The patient called the clinic with an update that the number and size of the lesions had continued to increase and that he was no longer able to urinate due to the pain and swelling
- The clinic staff communicated with a local emergency department to have the patient evaluated
- The patient was treated with oxycodone and phenazopyridine
- He was able to void spontaneously after the pain was controlled
- He was discharged home with pain management medication and an additional week of doxycycline – for “cellulitis” by the patient’s report

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Thursday, June 10 – Day 9

- The patient's partner returned to clinic for JYNNEOS post-exposure prophylaxis – 9 days after his last contact with the now confirmed case of monkeypox
- The partner's lesions had almost resolved – there was nothing present to re-swab for Orthopoxvirus
- Given the adequacy of the specimen collection, the negative Orthopoxvirus results, and the rapid resolution, the partner was given a diagnosis of folliculitis

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Lessons Learned

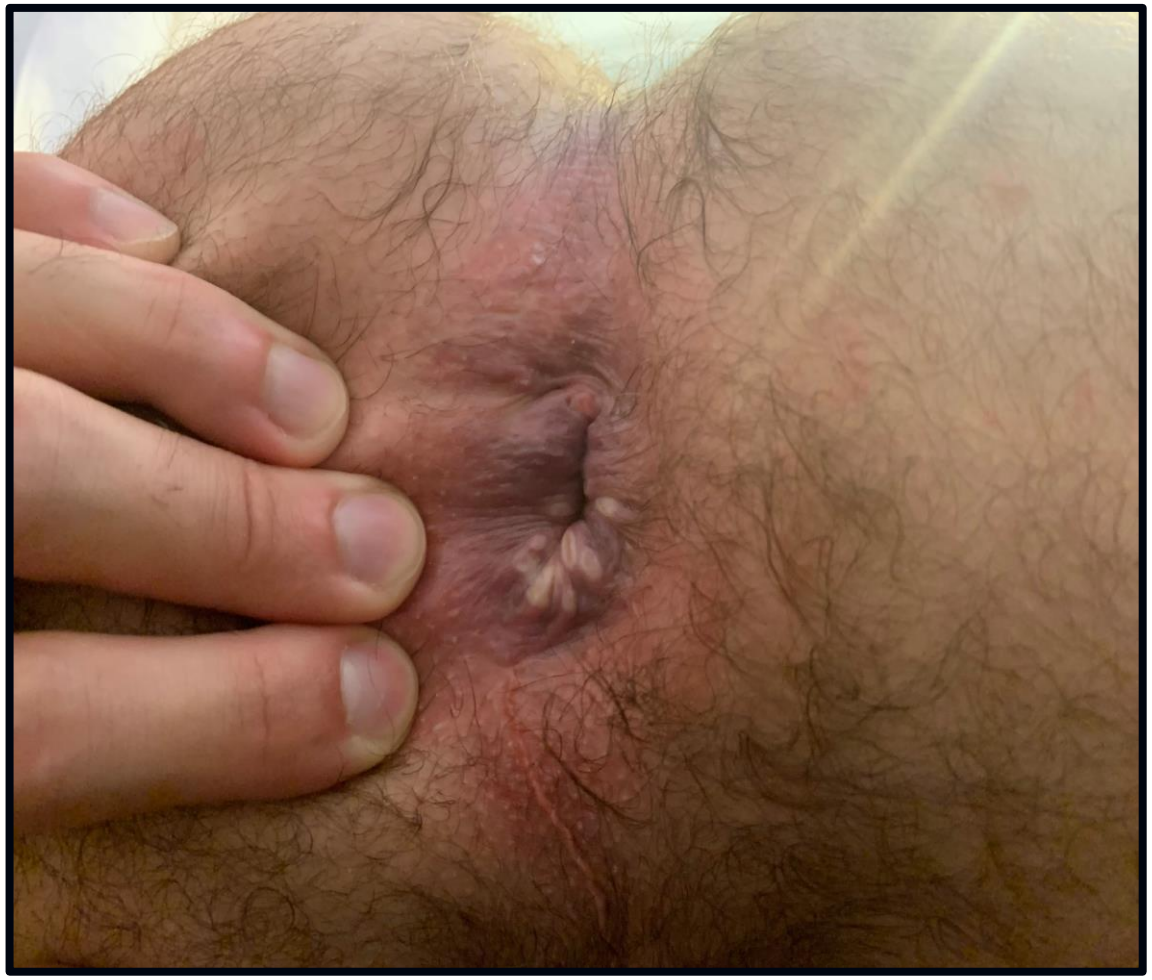
- **Complete sexual histories need to be taken especially in the presence of symptoms that suggest sexually transmitted infections**

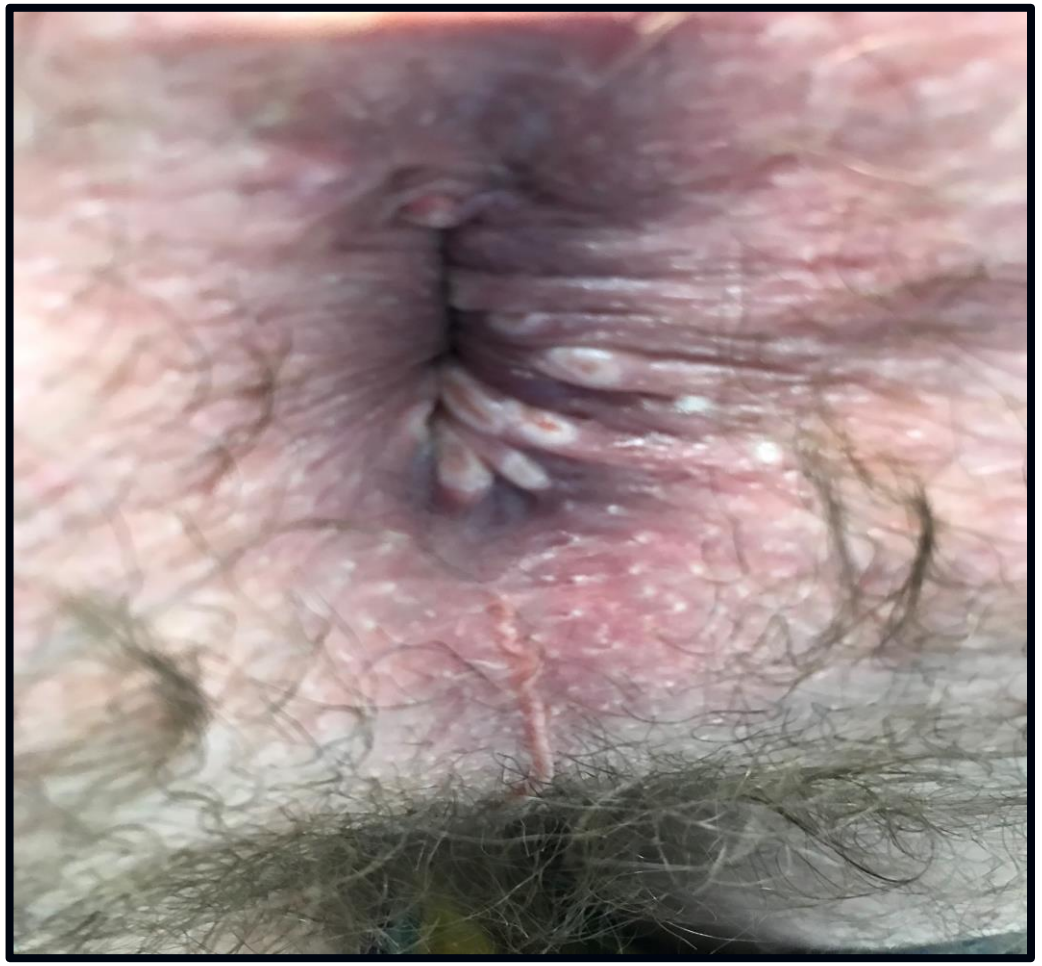
- **Clinical presentation**
  - Rash began in mucosal areas (genital, oral mucosa)
  - Clinic staff could not see the lesion umbilication in clinic on Day 2, but noticed it on photos the patient subsequently shared
  - The “prodromal syndrome” – the subjective fever, lethargy, and decreased appetite – began three days *after* the onset of penile lesions
  - The patient did not have lymphadenopathy

- **Considerations for concurrent STIs**
  - The patient was co-infected with urogenital chlamydia

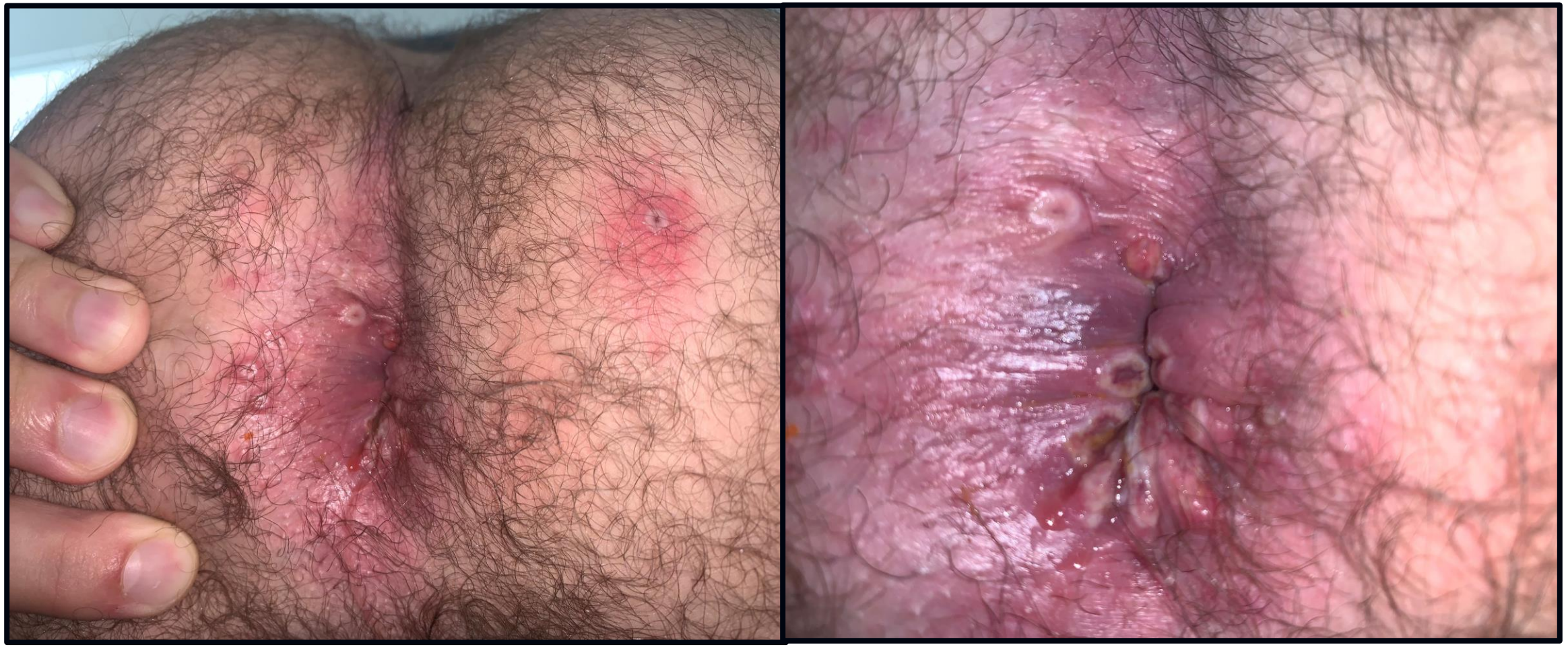
- **The patient had a sex partner one day before his monkeypox symptoms began who does not appear to have been infected**

Rectal Lesions – 06/22/2022





Rectal Lesions – 06/28/2022



MONKEYPOX

Medical Countermeasures

- Vaccines
  - JYNNEOS
  - ACAM2000
- Treatment
  - Tecovirimat
  - Vaccinia Immune Globulin Intravenous (VIGIV)
  - Cidofovir

- Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Vaccine Supply

- JYNNEOS
  - As of June 14, the SNS held more than 36,000 courses in its immediate inventory
  - ~150,000 courses to be delivered in the next few weeks
  - ~500,000 courses to be delivered this year
  - ~250,000 courses to be manufactured from existing bulk vaccine to be delivered later this year
  - ~7.9 million courses that could be filled and finished upon request by the government
- ACAM2000
  - >100 Million doses

- https://aspr.hhs.gov/ASPRBlog/Pages/BlogDetailView.aspx?ItemID=432
- https://www.bavarian-nordic.com/investor/news/news.aspx?news=6584

MONKEYPOX

ACAM2000 and JYNNEOS

	ACAM2000	JYNNEOS
Vaccine virus	Replication-competent vaccinia virus	Replication-deficient Modified vaccinia Ankara
"Take"	"Take" occurs	No "take" after vaccination
Inadvertent inoculation and autoinoculation	Risk exists	No risk
Serious adverse event	Risk exists	Fewer expected
Cardiac adverse events	Myopericarditis in 5.7 per 1,000 primary vaccinees	Risk believed to be lower than that for ACAM2000
Effectiveness	FDA assessed by comparing immunologic response and "take" rates to Dryvax*	FDA assessed by comparing immunologic response to ACAM2000 & animal studies
Administration	Percutaneously by multiple puncture technique in single dose	Subcutaneously in 2 doses, 28 days apart

*Both ACAM2000 and Dryvax are derived from the NYC Board of Health strain of vaccinia; ACAM2000 is a "second generation" smallpox vaccine derived from a clone of Dryvax, purified, and produced using modern cell culture technology.

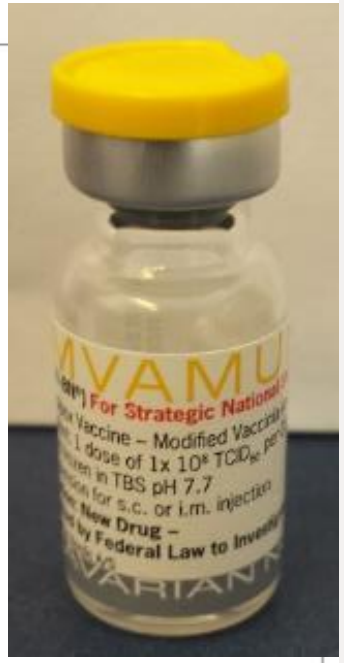
MONKEYPOX

Monkeypox: Updates about Clinical Diagnosis and Treatment

JYNNEOS

- **JYNNEOS is a live virus vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus**
  - Also known as IMVAMUNE, IMVANEX, MVA
- **Licensed by FDA in September 2019**
- **Indication**
  - JYNNEOS is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
  - CDC is developing an Expanded Access Investigational New Drug Protocol to allow the use of JYNNEOS for monkeypox in pediatric populations

https://www.fda.gov/vaccines-blood-biologics/jynneos



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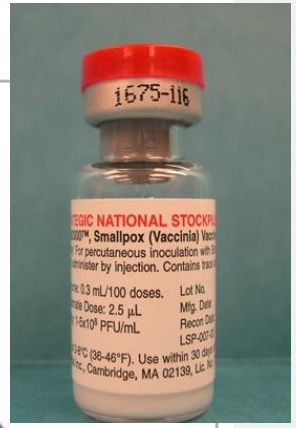
MONKEYPOX

Monkeypox: Updates about Clinical Diagnosis and Treatment

ACAM2000

- ACAM2000 is a live, replicating vaccinia virus vaccine
- Licensed by FDA in August 2007
- Replaced Dryvax - license withdrawn by manufacturer and remaining vaccine destroyed
- Indication
  - ACAM2000 is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection
  - CDC-held Expanded Access Investigational New Drug Protocol allows use for Non-Variola Orthopoxvirus Infection (e.g., monkeypox) during an outbreak



https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a6.htm
https://www.fda.gov/media/75792/download

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Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Pre-exposure Prophylaxis (PrEP)

- People who should get PrEP include:
  - Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including Monkeypox virus
  - Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
  - Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes

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MONKEYPOX

Pre-exposure Prophylaxis (PrEP)

- At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP
  - Laboratorians should consult with laboratory biosafety officers and supervisors to identify risks and precautions, depending on the type of work they are doing
  - Clinicians and laboratorians should use recommended infection control practices

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Vaccine Strategy Considerations

- Jurisdictions with larger numbers of cases are reporting that high percentages of contacts cannot be identified
  - Desire to plan and implement expanded vaccination programs
  - Electing similar approaches to strategies being used in Montreal and the U.K.

- Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++
  - Vaccination of people with certain risk factors that might make them more linkely to have been recently exposed to monkeypox
  - Aims to reach these individuals for post-exposure prophylaxis vaccination even if they have not had confirmed exposure to monkeypox

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MONKEYPOX

Vaccine Strategy Considerations

- Currently limited supply of JYNNEOS although more expected in July, August and later in the year.
- Goal-focus allocation of currently available JYNNEOS doses in areas of highest transmission
- Distribute JYNNEOS to states for immediate use for expanded monkeypox vaccine post-exposure prophylaxis (PEP++)
- Allocation based on:
  - Areas of highest transmission based on current and projected population-adjusted incident cases
  - Weighted by population of MSM with HIV or eligible for HIV PrEP

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Treatment Considerations for Monkeypox

- Many individuals infected with monkeypox virus have a mild, self-limiting disease course in the absence of specific therapy
- The prognosis for monkeypox depends on multiple factors such as previous vaccination status, initial health status, and concurrent illnesses or comorbidities

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Treatment Considerations for Monkeypox

- Persons who should be considered for treatment following consultation with CDC might include:
  - Persons with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
  - Persons who may be at high risk of severe disease:
    - People with immunocompromising conditions (e.g., HIV/AIDS, leukemia, lymphoma, generalized malignancy, etc.)
    - Pediatric populations, particularly patients younger than 8 years of age
    - Pregnant or breastfeeding women
    - People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions
    - People with one or more complication
- Persons with monkeypox virus aberrant infections that include its accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

MONKEYPOX

Tecovirimat (TPoxx)

- Tecovirimat is an antiviral medication that is approved by the FDA for the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg
  - Also known as TPOXX or ST-246

- Oral capsule and IV formulations approved by FDA July 2018 and May 2022, respectively
- Indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg

  - CDC-held Emergency Access Investigational New Drug Protocol allows use of Tecovirimat for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)
    - Includes allowance for opening an oral capsule and mixing its content with liquid or soft food for pediatric patients weighing less than 13 kg

- Available from the Strategic National Stockpile as an oral capsule formulation or an intravenous vial

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

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

MONKEYPOX

Documentation for Tecovirimat

Tecovirimat use for monkeypox is under an EA-IND. Thus, certain documentation and return of information related to tecovirimat treatment are required. The IND protocol will be provided to healthcare providers at the time of clinical consult when tecovirimat therapy is indicated.

***Minimally required forms* to be completed and returned to CDC include:**

1. Informed consent obtained ***prior to treatment initiation.***
2. FDA Form 1572—To be completed by the responsible clinician/healthcare provider overseeing the patient's treatment. Patient intake form Adverse event form
3. Clinical outcomes form to report tecovirimat treatment duration and patient's clinical outcome upon completion of treatment.
4. Photos of lesions, to the extent possible: at least 1 prior to tecovirimat treatment and 1 during treatment (between days 7 and 14) with dates of the photo(s) indicated.
5. Additional forms as noted in the protocol

- ***Please note that given the evolving nature of the outbreak event and as additional data become available, the IND protocol may be modified as necessary.*

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

MONKEYPOX

Tecovirimat

Cost

- The drug is provided at no cost. There is no funding available to assist with laboratory testing. Testing plasma PK samples collected and sent by the hospital to the lab contracted to test PK samples and/or blood or specimens sent via the health department to CDC for serology or virologic testing would not have a cost to the patient.

How to Request

- To request tecovirimat for use in a patient with suspected, probable, or confirmed monkeypox, please contact your state/territorial health department or CDC through the CDC Emergency Operations Center (770-488-7100).

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

MONKEYPOX

Vaccinia Immune Globulin Intravenous (VIGIV)

- VIGIV is licensed by FDA for the treatment of complications due to vaccinia vaccination, including:
  - Eczema vaccinatum
  - Progressive vaccinia
  - Severe generalized vaccinia
  - Vaccinia infections in individuals who have skin conditions
  - Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis)

CDC-held Emergency Access Investigational New Drug Protocol allows use of VIGIV for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/vaccinia-immune-globulin-intravenous-human

MONKEYPOX

Cidofovir

- Cidofovir (also known as Vistide) is an antiviral medication that is approved by the FDA for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS)

- CDC-held Emergency Access Investigational New Drug Protocol allows the use of Cidofovir for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)

https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/020638s003lbl.pdf

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Current Outbreak Response in the US

- Surveillance (case identification, laboratory confirmation)
- Containment (isolation of cases, contact tracing)
- Vaccination of close contacts (PEP) based on risk exposure assessment*
  - 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

Webinar June 29, 2022 - Monkeypox: Updates about Clinical Diagnosis and Treatment (cdc.gov)

MONKEYPOX

Infection Control: Patient Placement

- A patient with suspected or confirmed monkeypox infection should be:
  - Placed in a single-person room; special air handling is not required.
  - The door should be kept closed (if safe to do so).
  - The patient should have a dedicated bathroom.
  - Transport and movement of the patient outside of the room should be limited to medically essential purposes.
  - If the patient is transported outside of their room, they should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown

Infection Control: Healthcare Settings | Monkeypox | Poxvirus | CDC

MONKEYPOX

Exposure risk assessment and public health recommendations for individuals exposed to a patient with monkeypox

HIGH RISK EXPOSURE RECOMMENDATIONS

- Monitoring * AND PEP (vaccine) – Recommended

Exposure Characteristics

- Unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids from a patient (e.g., any sexual contact, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) -OR-
- Being inside the patient's room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection

- Monitoring People Who Have Been Exposed | Monkeypox | Poxvirus | CDC
- *Monitoring includes ascertainment of selected signs and symptoms of monkeypox: fever (≥100.4°F [≥38°C]), chills, new lymphadenopathy (periauricular, axillary, cervical, inguinal), and new skin rash through 21 days after the exposure to the patient or the patient's materials.

MONKEYPOX

Exposure risk assessment and public health recommendations for individuals exposed to a patient with monkeypox

INTERMEDIATE RISK EXPOSURE RECOMMENDATIONS

- Monitoring* AND PEP (vaccine) – Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks

Exposure Characteristics

- Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask -OR-
- Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown

- Monitoring People Who Have Been Exposed | Monkeypox | Poxvirus | CDC
- *Monitoring includes ascertainment of selected signs and symptoms of monkeypox: fever (≥100.4°F [≥38°C]), chills, new lymphadenopathy (periauricular, axillary, cervical, inguinal), and new skin rash through 21 days after the exposure to the patient or the patient's materials.

MONKEYPOX

Exposure risk assessment and public health recommendations for individuals exposed to a patient with monkeypox

- **LOW/UNCERTAIN RISK RECOMMENDATIONS**
- Monitoring*, NO PEP

Exposure Characteristics

- Entered the patient room without wearing eye protection on one or more occasions, regardless of duration of exposure -OR-
- During all entries in the patient care area or room (except for during any procedures listed above in the high-risk category), wore gown, gloves, eye protection, and at minimum, a surgical mask -OR-
- Being within 6 feet of an unmasked patient for less than 3 hours without wearing at minimum, a surgical mask

- Monitoring People Who Have Been Exposed | Monkeypox | Poxvirus | CDC
- *Monitoring includes ascertainment of selected signs and symptoms of monkeypox: fever (≥100.4°F [≥38°C]), chills, new lymphadenopathy (periauricular, axillary, cervical, inguinal), and new skin rash through 21 days after the exposure to the patient or the patient's materials.

MONKEYPOX

Monitoring Exposed Healthcare Professionals

- Any healthcare worker who has cared for a monkeypox patient should be alert to the development of symptoms that could suggest monkeypox infection, especially within the 21-day period after the last date of care,
- Healthcare workers who have unprotected exposures (i.e., not wearing PPE) to patients with monkeypox do not need to be excluded from work duty, but should undergo active surveillance for symptoms, which includes measurement of temperature at least twice daily for 21 days following the exposure.
- Healthcare workers who have cared for or otherwise been in direct or indirect contact with monkeypox patients while adhering to recommended infection control precautions may undergo self-monitoring or active monitoring as determined by the health department.
    - https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html

MONKEYPOX

Websites

- What's New & Updated | Monkeypox | Poxvirus |CDC
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html
- https://www.cdc.gov/poxvirus/monkeypox/specific-settings/index.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html
- https://www.cdc.gov/poxvirus/monkeypox/faq.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html
- https://www.cdc.gov/poxvirus/monkeypox/symptoms.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/pregnancy.html
- https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

For more information, contact CDC

1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov