Maine CDC Clinician Update: Monkeypox Diagnosis and Treatment

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Maine Center for Disease Control and Prevention

June 30, 2022

STATE OF MAINE
Department of
Health and Human Services

Monkeypox

- Rare, sometimes life-threatening zoonotic infection
- Endemic in west and central Africa
- Caused by *Monkeypox virus* (which is an orthopoxvirus)
- Specific animal reservoir unknown, but likely small mammals

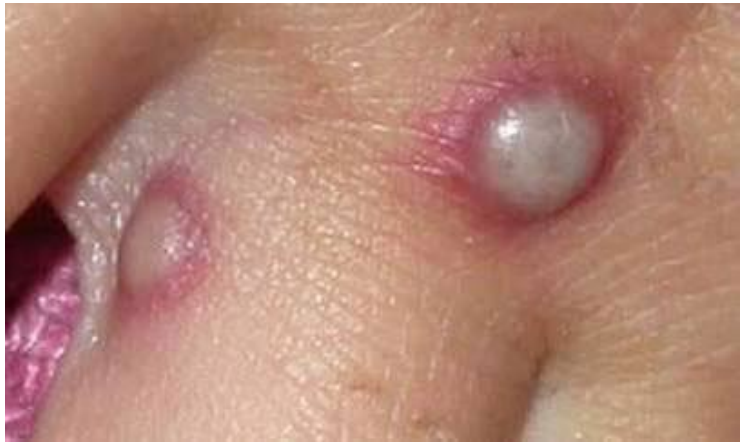
- Can spread from infected animals to humans and person-to-person
  - Respiratory secretions
  - Skin-to-skin contact with infected body fluids (e.g., fluid from vesicles and pustules)
  - Fomites (e.g., shared towels, contaminated bedding)

Pre-2022 U.S. cases

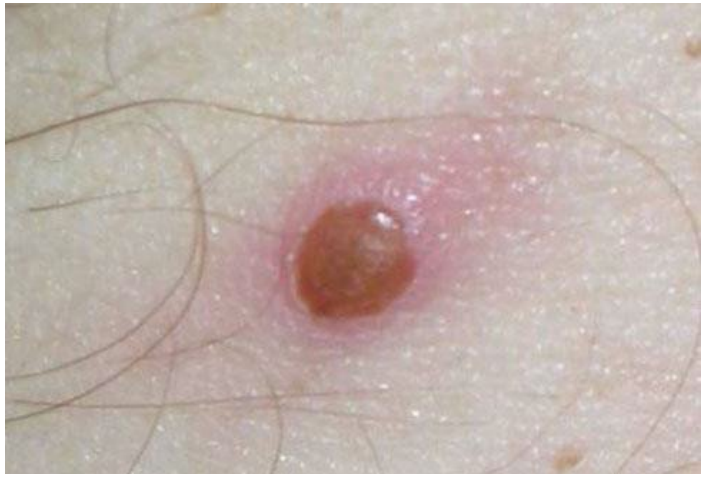
- 2003: Outbreak linked to small mammals imported from Ghana
  - Cases: 47, multistate involving upper Midwest United States
  - Cause was traced to spread of Monkeypox virus from: imported African rodents ➔ pet prairie dogs ➔ people who had contact with pet prairie dogs

- 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)

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

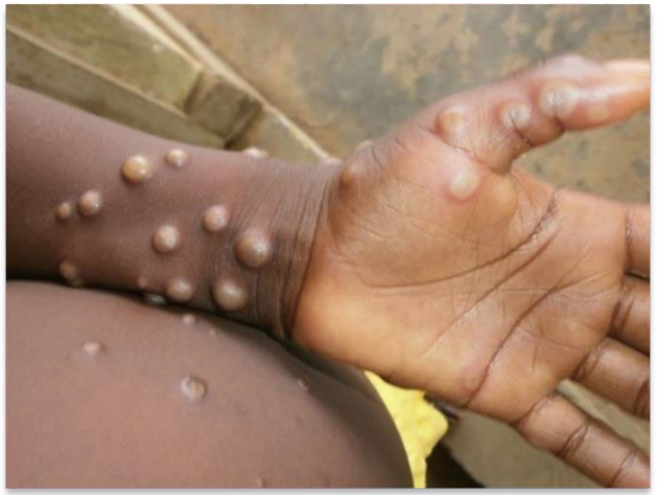


Lesions observed during 2003 U.S. monkeypox outbreak



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

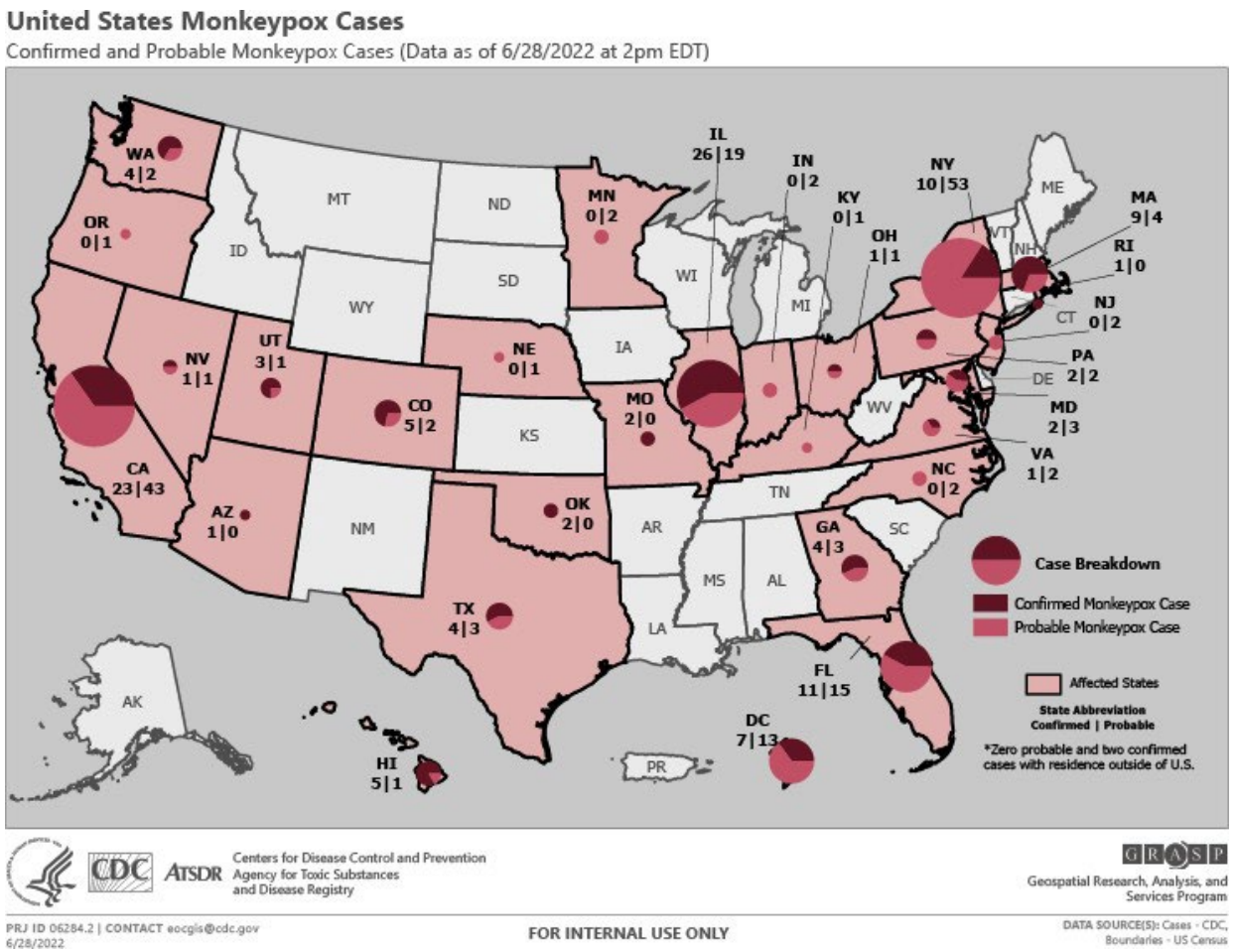


May 2022

- 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

Probable and confirmed cases* by U.S. state

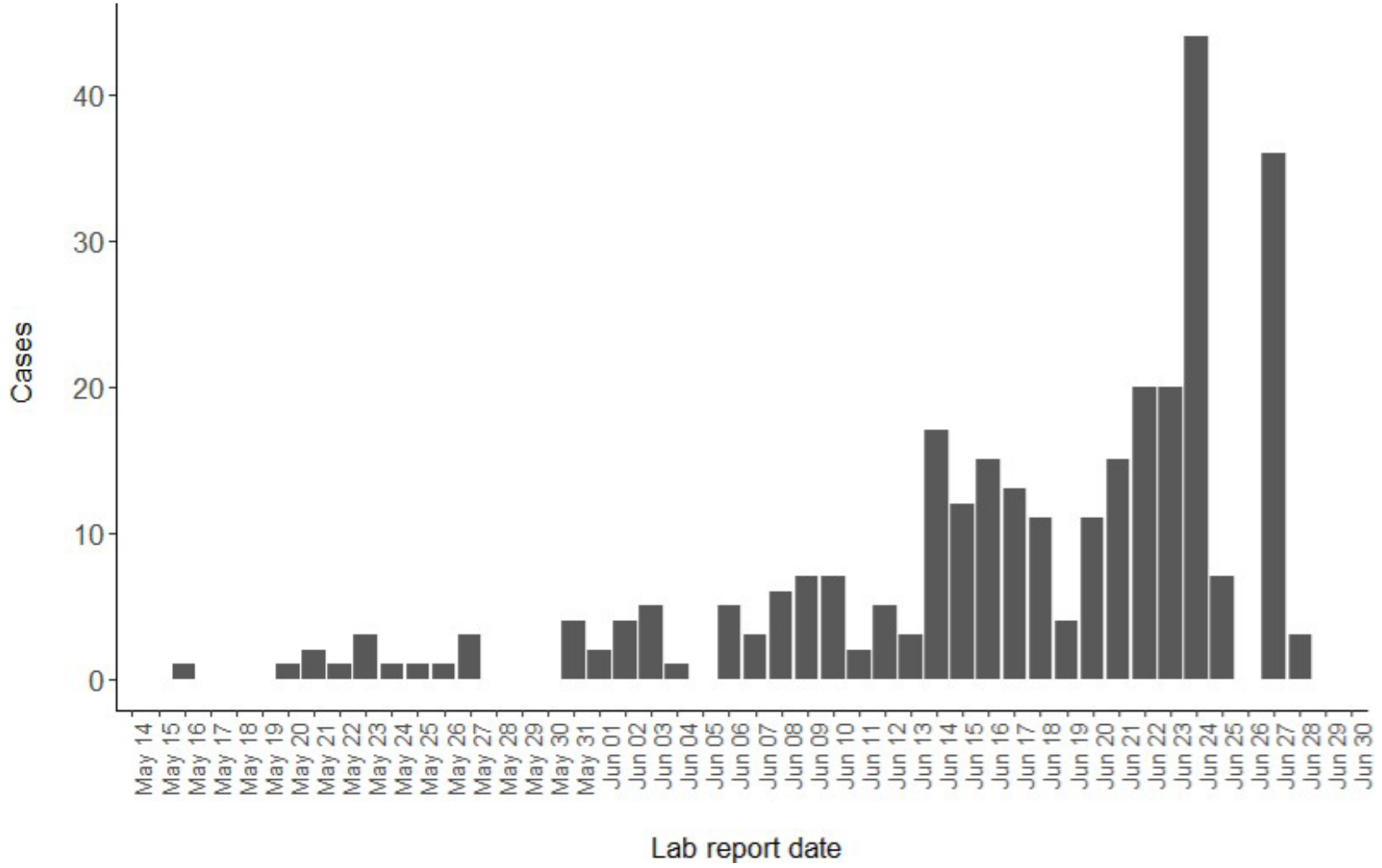


Total: As of 2pm ET on Tuesday 6/28, there are **305** cases diagnosed in the United States† among residents of **28** states and Washington, D.C.

*A probable case is presence of orthopoxvirus DNA by PCR of a clinical specimen OR orthopoxvirus using immunohistochemical or electron miscroscopy testing methods OR demonstration of detectable levels of anti-orthopoxvirus IgM antibody during the period of 4 to 56 days after rash onset in a person in whom there is no suspicion of other recent orthopoxvirus exposure (e.g., Vaccinia virus in ACAM2000 vaccination) Confirmed case is demonstration of Monkeypox virus DNA by polymerase chain reaction testing or Next-Generation sequencing of a clinical specimen OR isolation of Monkeypox virus in culture from a clinical specimen

†One patient is currently being monitored in Florida, but laboratory confirmation occurred in another country. This case is not included in some U.S. case counts including this one

Cases by date of lab report, N=305



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*

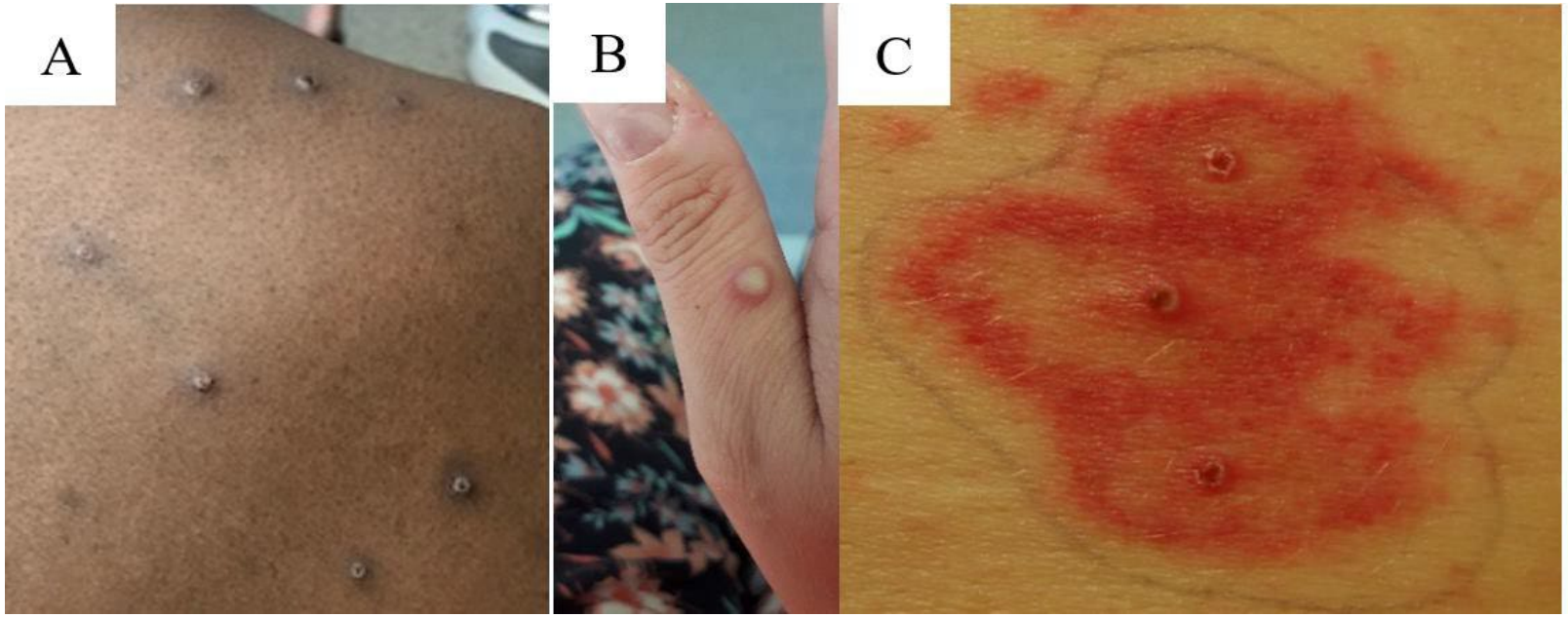
†male to male sexual contact

Clinical symptoms

- Skin rash or enanthem in all patients
- 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 region or lips/face)
- Presenting complaint sometimes anorectal pain or tenesmus; physical examination yields visible lesions and proctitis
- Prodromal symptoms mild or not occurring
- Fever, lymphadenopathy not occurring in all patients
- Some co-infections with sexually transmitted infections (STIs)

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

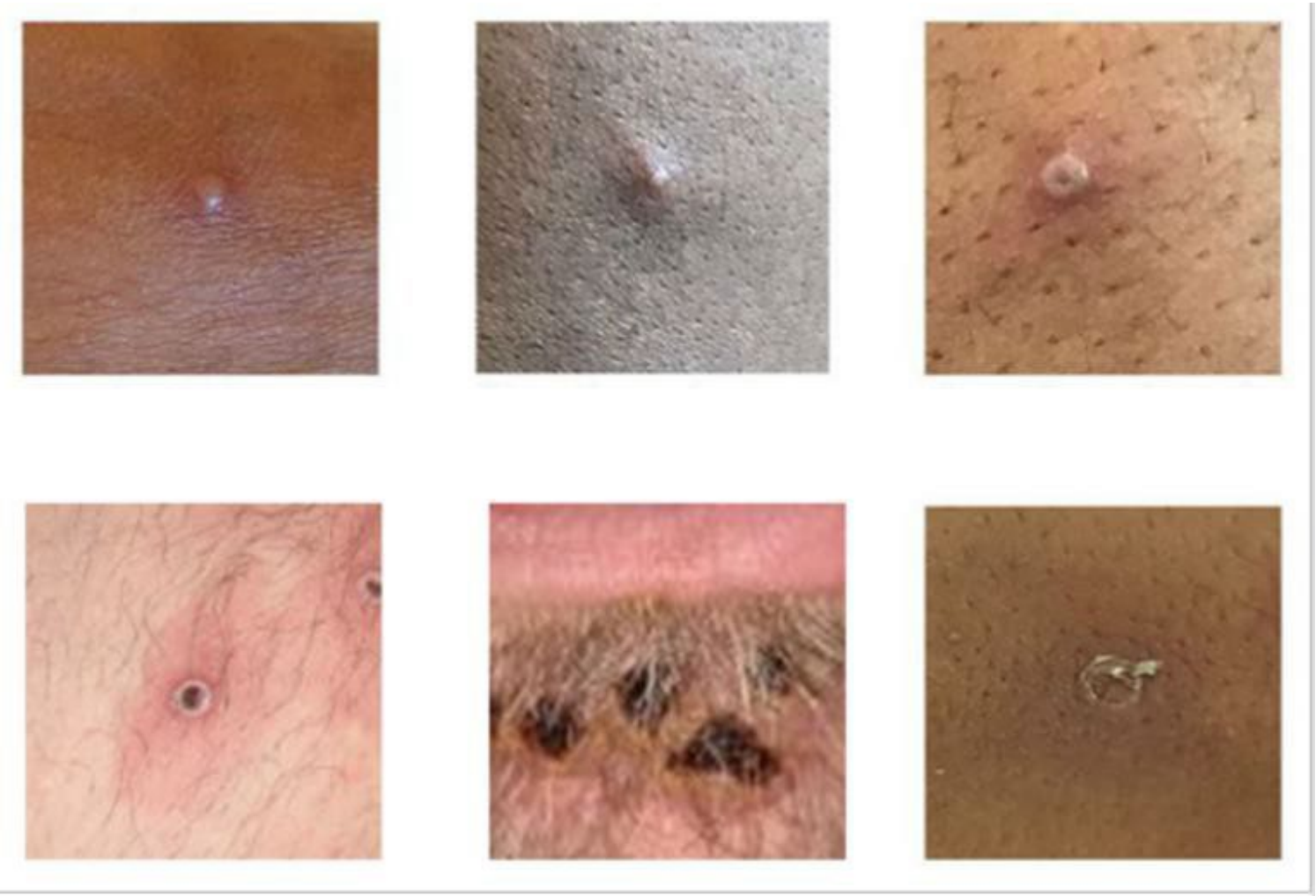


Photos A and B from NHS England High Consequence Infectious Diseases Network; photo C from Reed KD, Melski JW, Graham MB et al. The detection of monkeypox in humans in the Western Hemisphere. Page 346. Copyright © 2004. Massachusetts Medical Society. Reprinted with permission

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



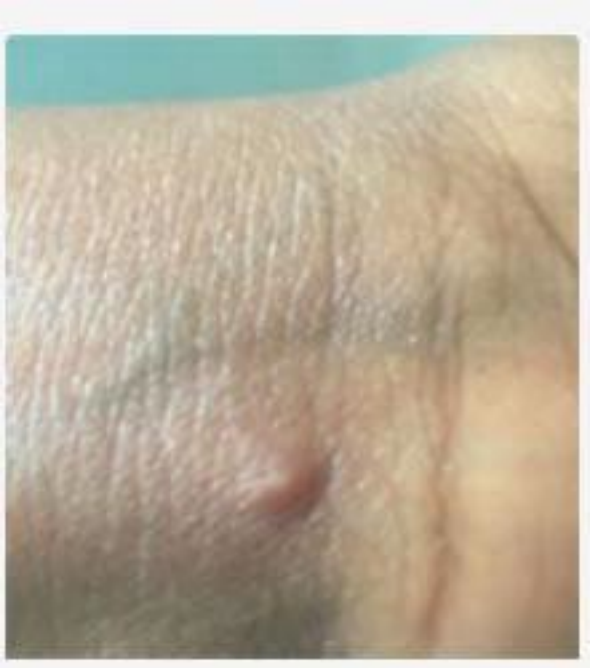
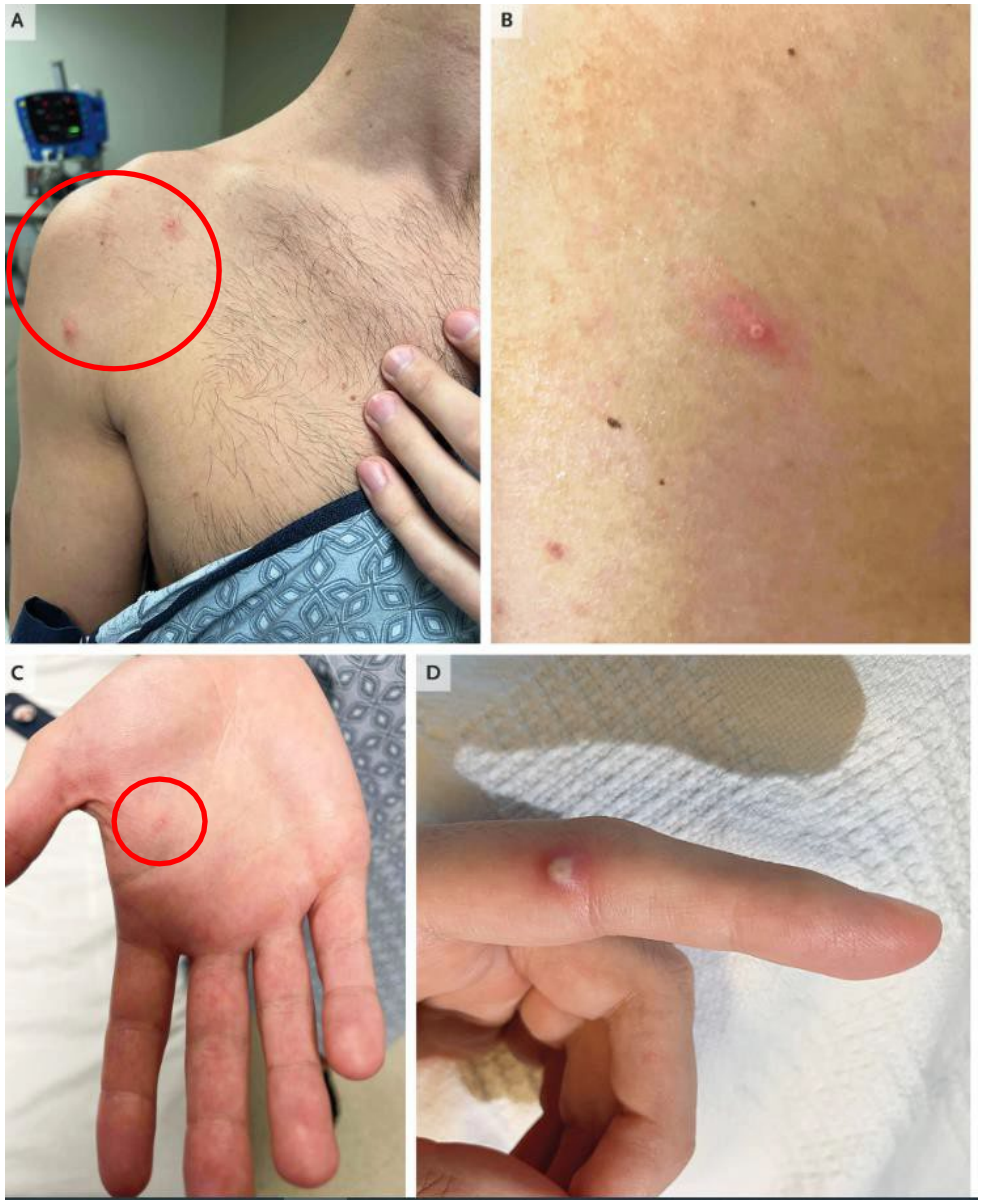


Photo Credit: NHS England High Consequence Infectious Disease Network

Monkeypox lesions, United States 2022



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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https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/monkeypox.shtml

Instructions for Collecting Suspected Monkeypox Samples

Providers who suspect monkeypox should:

1. Call Maine CDC at 1-800-821-5821 to report the suspected case and to request approval for testing at Maine's Health and Environmental Testing Laboratory (HETL)
   - Testing for diseases with
     the same time as monkey
     may instead go to a comr
2. Collect samples for HETL
   - HETL can accept the foll
     - Vesicle fluid, skin, cr
     - Swab of lesion
   - Collect two (2) swabs fro
     submitted to HETL

Health and Environment Testing Laboratory ORTHOPOX Specimen Submission Form

*This form **must be submitted** with Orthopox test requests. Specimens that are submitted for Orthopox testing without this form or with incomplete information may be delayed or not tested.* rev. 6/11/2022

Facility Information

Facility:	Ordering Provider Name:
Contact Person:	Telephone:
Address:	
Telephone:	
Secure Fax:	Contact Maine CDC at 1-800-821-5821 for consultation

Patient Information

Patient Name (Last, First, MI)

Patient Address

Travel History

☐ No

☐ Yes

If Yes: Where: _____

Ethnicity: ☐ Hispanic or Latinx

Detection of Monkeypox via Real-Time PCR

Laboratory Submission Information Sheet

Reporting of suspect case to Maine CDC	• Yes: Monkeypox is a Notifiable Condition. If you have not already done so, please report suspect or confirmed cases to the Maine CDC via the disease reporting line: 1-800-821-5821 (24hrs/day 7 days/week).
Required To Submit Laboratory Specimen	• Yes.
Required Information	• Information on requisition must include: suspected organism, patient name, DOB, date of collection, specimen source or type, Collection Location of Specimen (Body Site), submitter name and contact information. **Important: all specimens must be labeled with patient name and be accompanied by a unique Orthopox Specimen Submission form.**
Specimen Requirements	• Specimens from 5 separate lesions in duplicate, vesicles, or fluid • Preferably collect from lesions that are at different stages of development. • DRY SWABS ONLY
Collection Instructions	• Collect TWO DRY swabs from each lesion. • Place the two duplicate DRY swabs in an empty sterile specimen container. • Note: You will have 5 specimen containers each containing 2 swabs for a total of 10 swabs. • Note: You must have one submission form for each specimen container.
	• PCR Results should be expected within 24-48 hrs of specimen receipt.

Selected listing of current CDC priorities

- Understanding clusters and cases including risk factors to inform guidance
- Sequencing genomes of *Monkeypox virus* isolated from patients to monitor spread, variants, and track virus evolution
- Launching retrospective and prospective serosurveys to determine prevalence
- Refining case definitions based on data collected from clinics where cases are being detected
- Understanding natural history of current clinical presentation
- Expanding testing capacity at LRN laboratories and commercial laboratories
- Providing case-by-case consultations for clinicians considering treatment and post-exposure prophylaxis for patients

Interim information and tools for healthcare providers and public health authorities

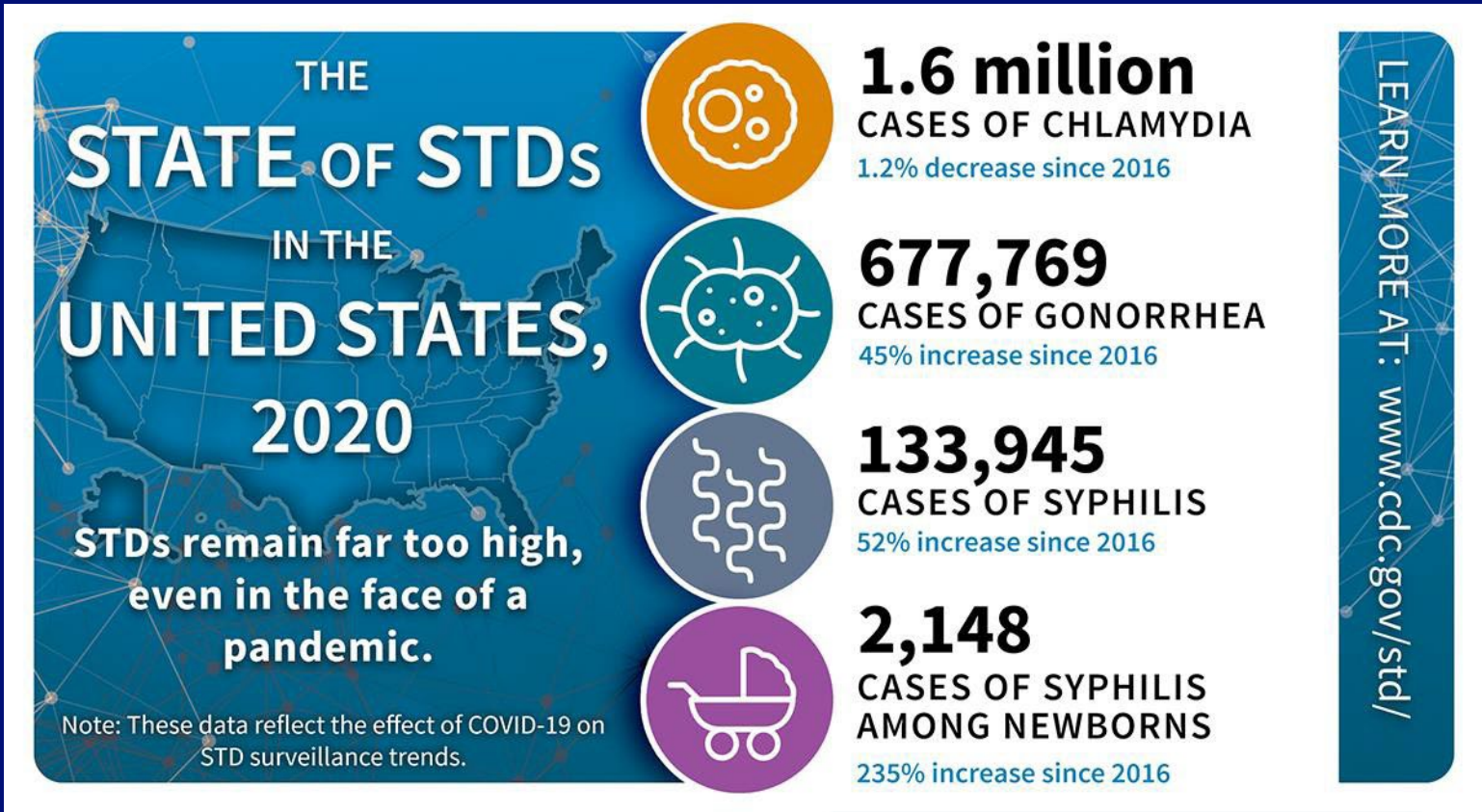
www.cdc.gov/monkeypox

- Case definitions
- Clinical recognition
- Prevention strategies
- Exposure risk assessment
- Guidance for monitoring exposed persons
- Infection control in home and healthcare settings
- Specimen collection
- Considerations for medical countermeasures

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
      - with similar appearing rash OR
      - 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.

2.4 million cases of chlamydia, gonorrhea, and syphilis were reported in the first year of the COVID-19 pandemic



Genital Ulcer Disease: Differential Diagnosis

Infectious

- Herpes simplex virus
- Syphilis
- Chancroid
- Lymphogranuloma venereum (LGV)
- Granuloma Inguinale

Non-infectious

- Recurrent aphthous stomatitis
- Behcet's Disease
- Trauma
- Squamous cell carcinoma
- Drug-induced
- Other

Other infections to consider

Diffuse Rash

- Syphilis
- Varicella/VZV
- Disseminated herpes
- Molluscum contagiosum
- Other pox viruses
- Disseminated fungal infections
- Disseminated gonococcal infection

Proctitis

- Gonorrhea
- Chlamydia (including LGV)
- HSV

Distinguishing monkeypox from other rash illnesses

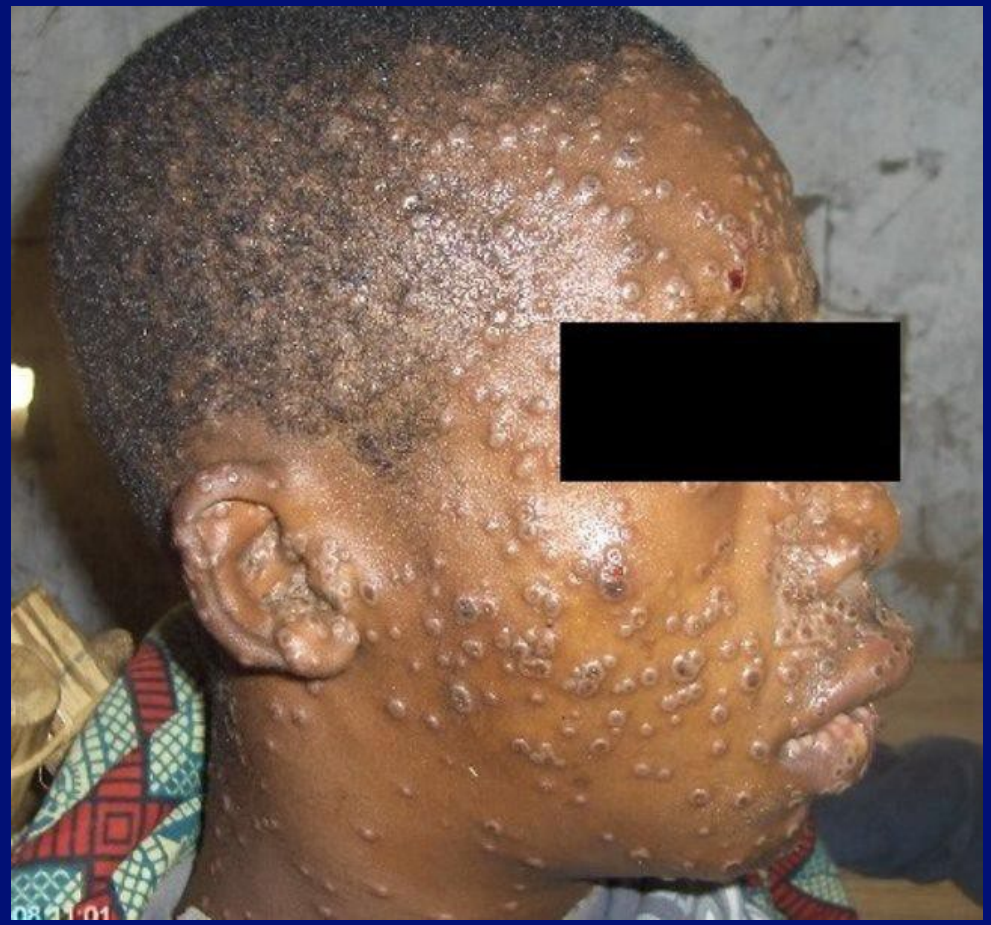
- **Comprehensive history**
  - **History of present illness** – typical sequence of clinical manifestations
    - Usually fever, malaise, headache, sore throat, cough, lymphadenopathy
    - Macules→papules→vesicles→pustules→scabs
    - Tongue/mouth→face→arms/legs→hands/feet (including palms/soles)
    - Pain and pruritis may be prominent
    - Clinical presentation in current outbreak may not be typical!

Distinguishing monkeypox from other rash illnesses

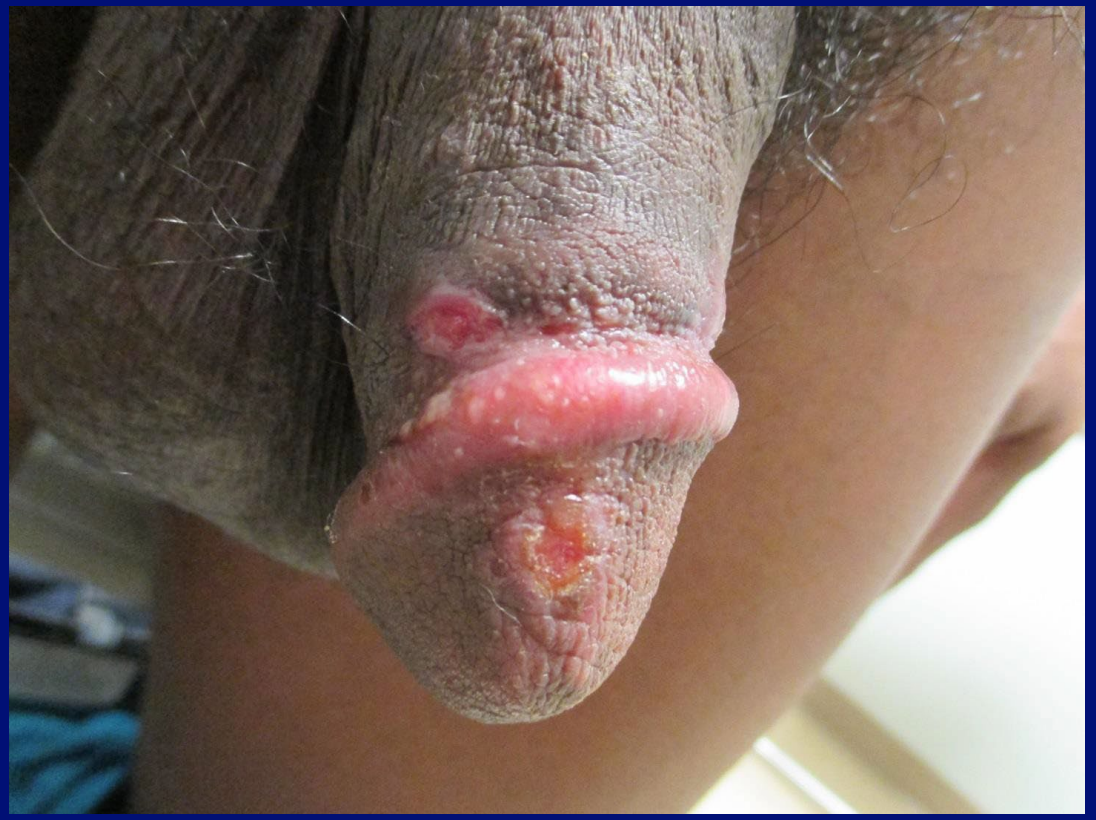
- **Social history**
  - Travel history – particularly to central and west African countries and other countries where non-endemic monkeypox has been reported
  - Contact with a person or people with confirmed or suspected monkeypox
  - Man who regularly has close or intimate in-person contact with other men, including those met through online website, digital application (“app”), or at a bar or party

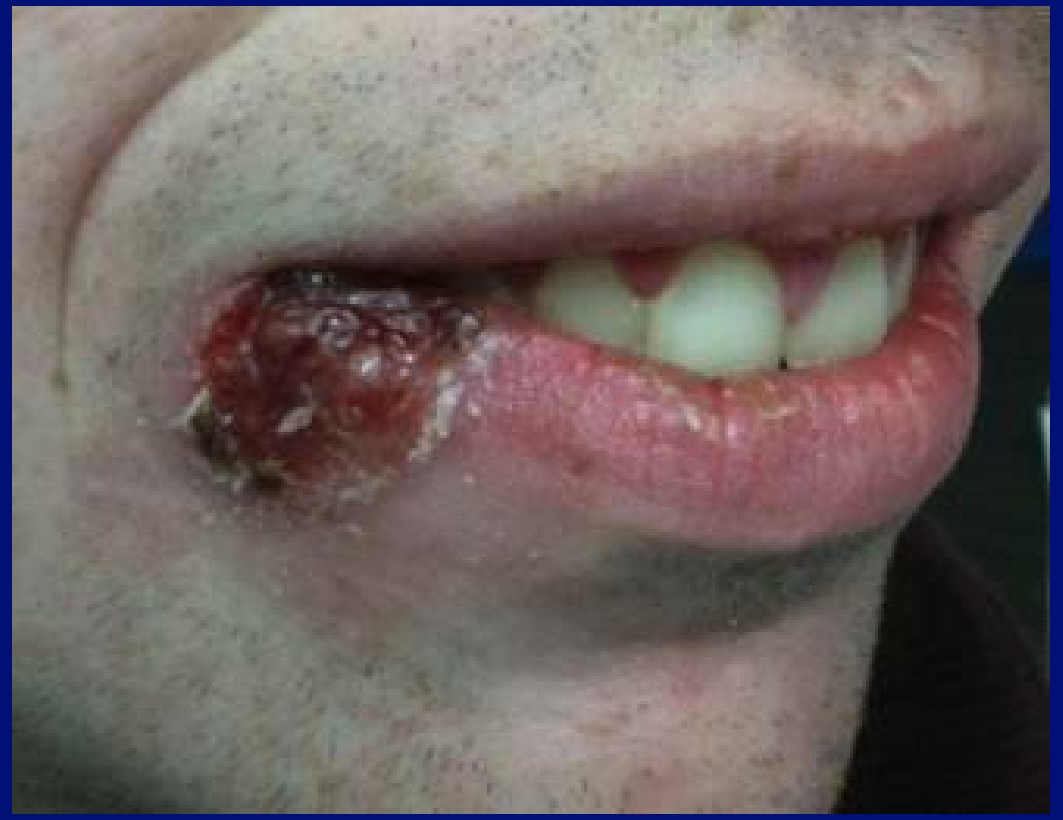
Physical examination

- **Perform thorough exam of all skin in room with good lighting**
  - Clues may be present in other areas of the body for persons presenting with genital/perianal complaints
- **Rash concentrates on face, arms, legs (centrifugal distribution)**
- **Lesions typically similar size and at same stage**
- **Lesions become umbilicated**

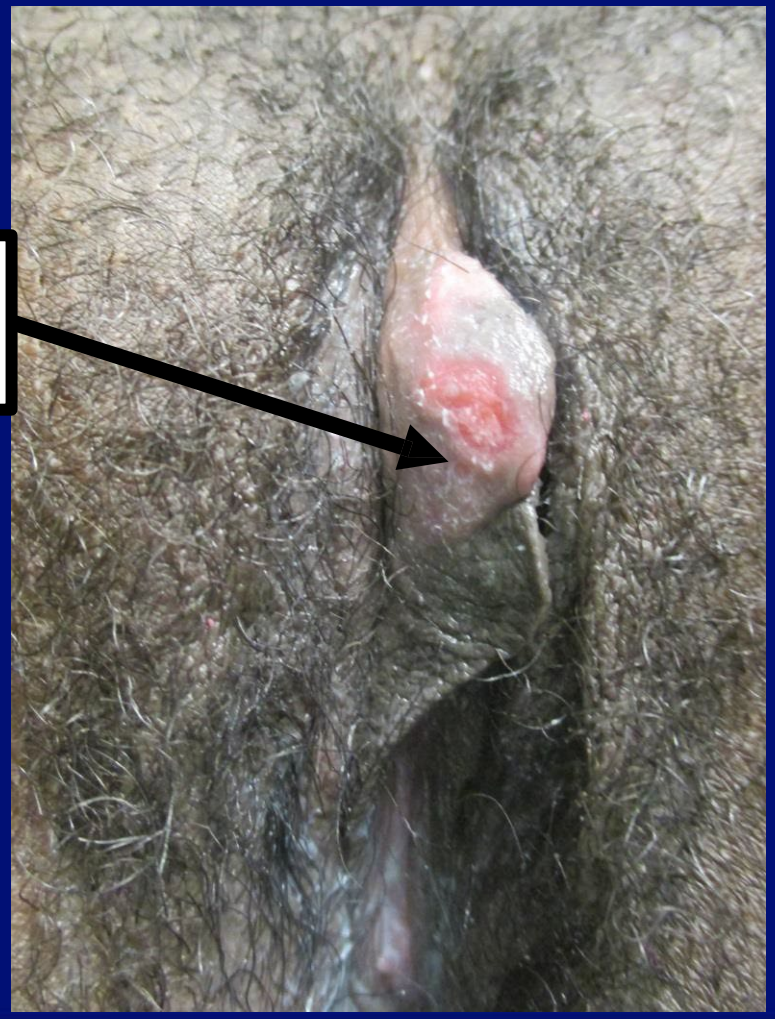


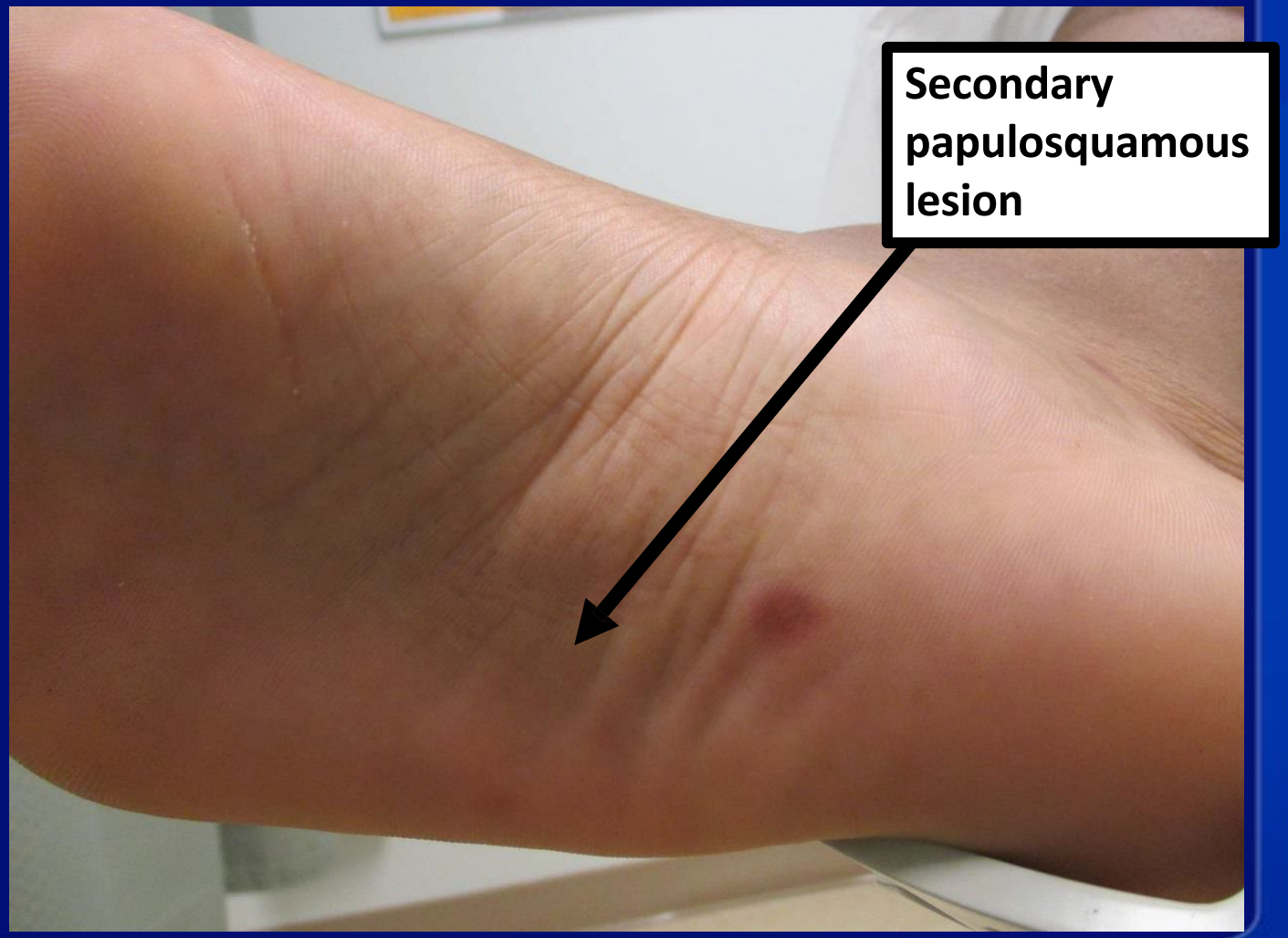
Primary syphilis



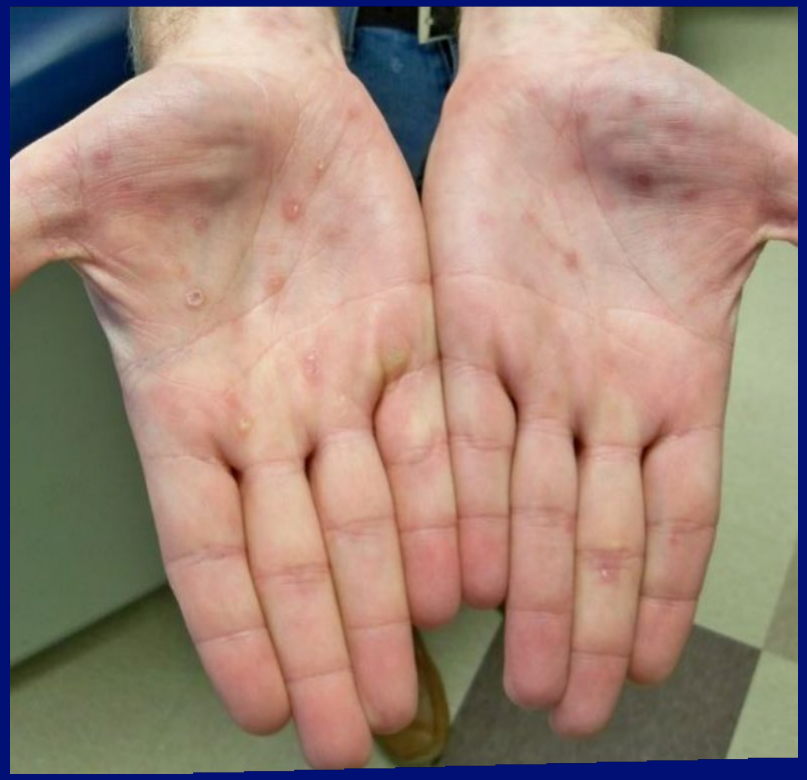


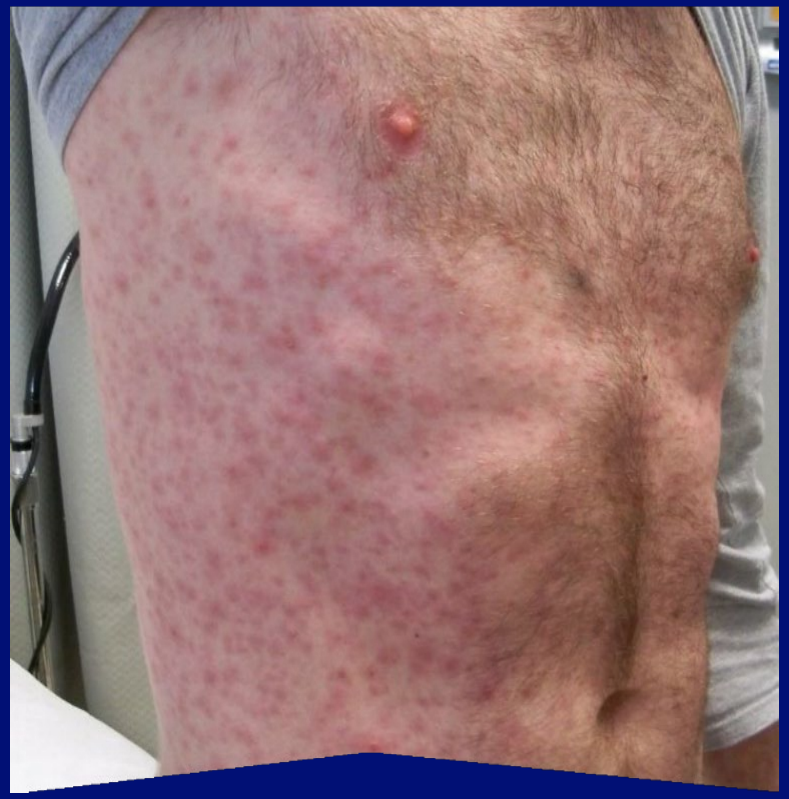
Primary and secondary syphilis – overlap

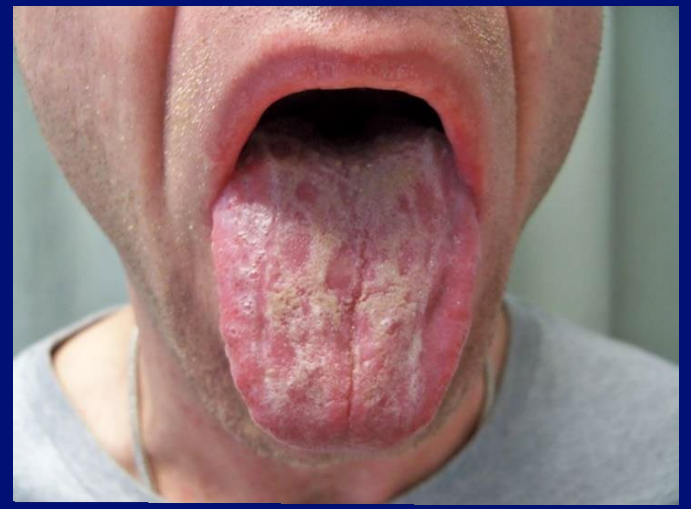


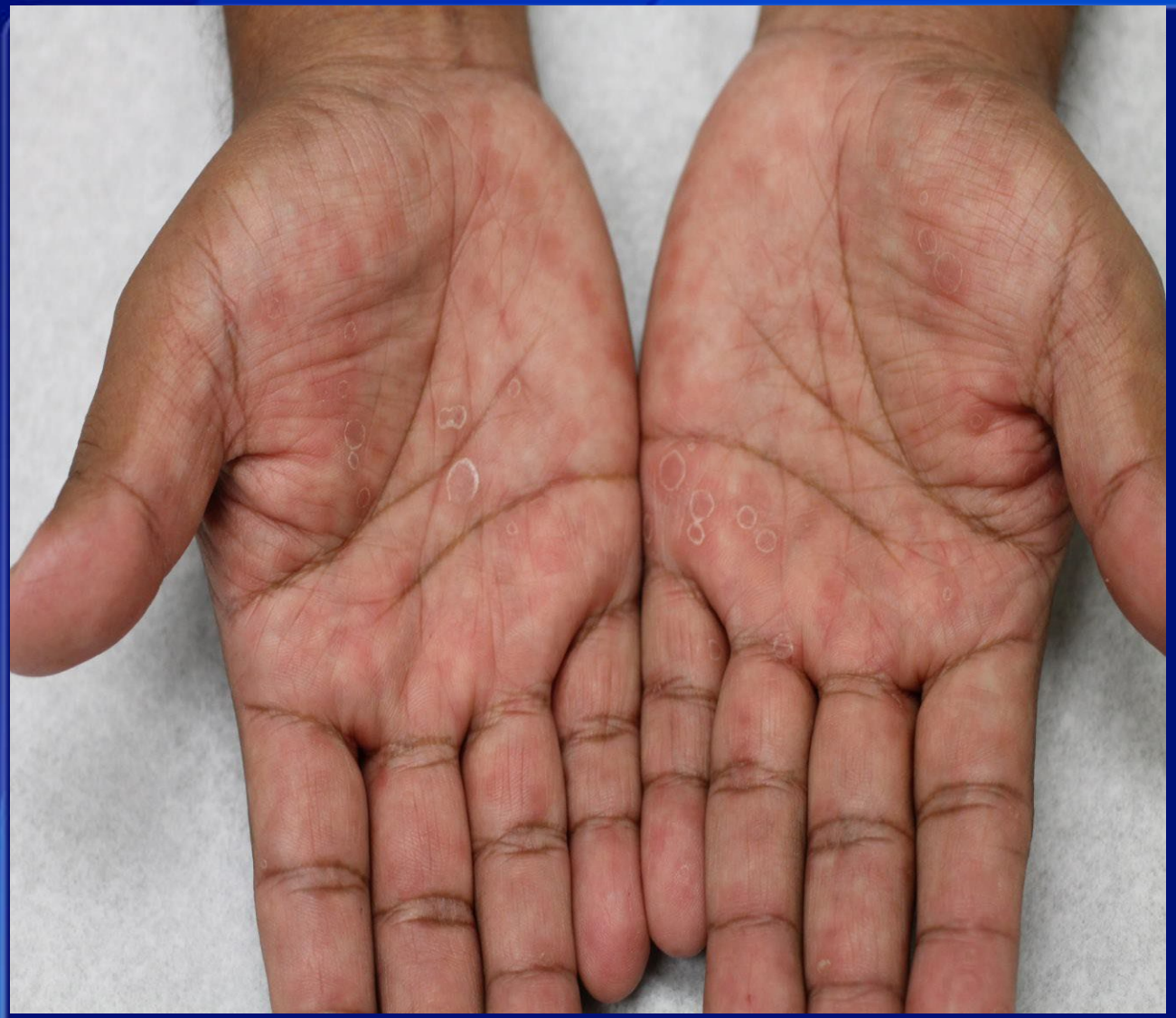


Secondary syphilis





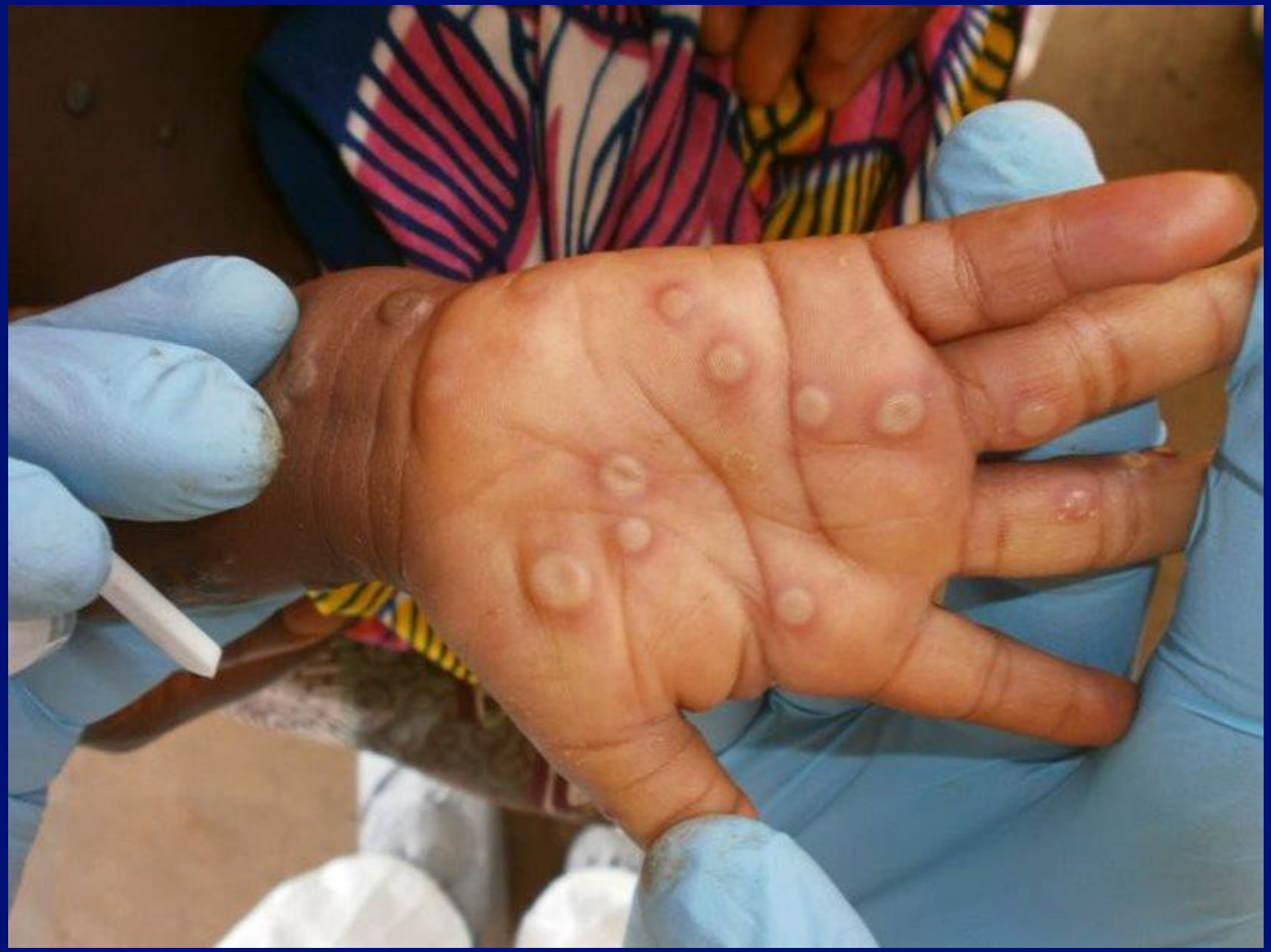




Secondary syphilis*

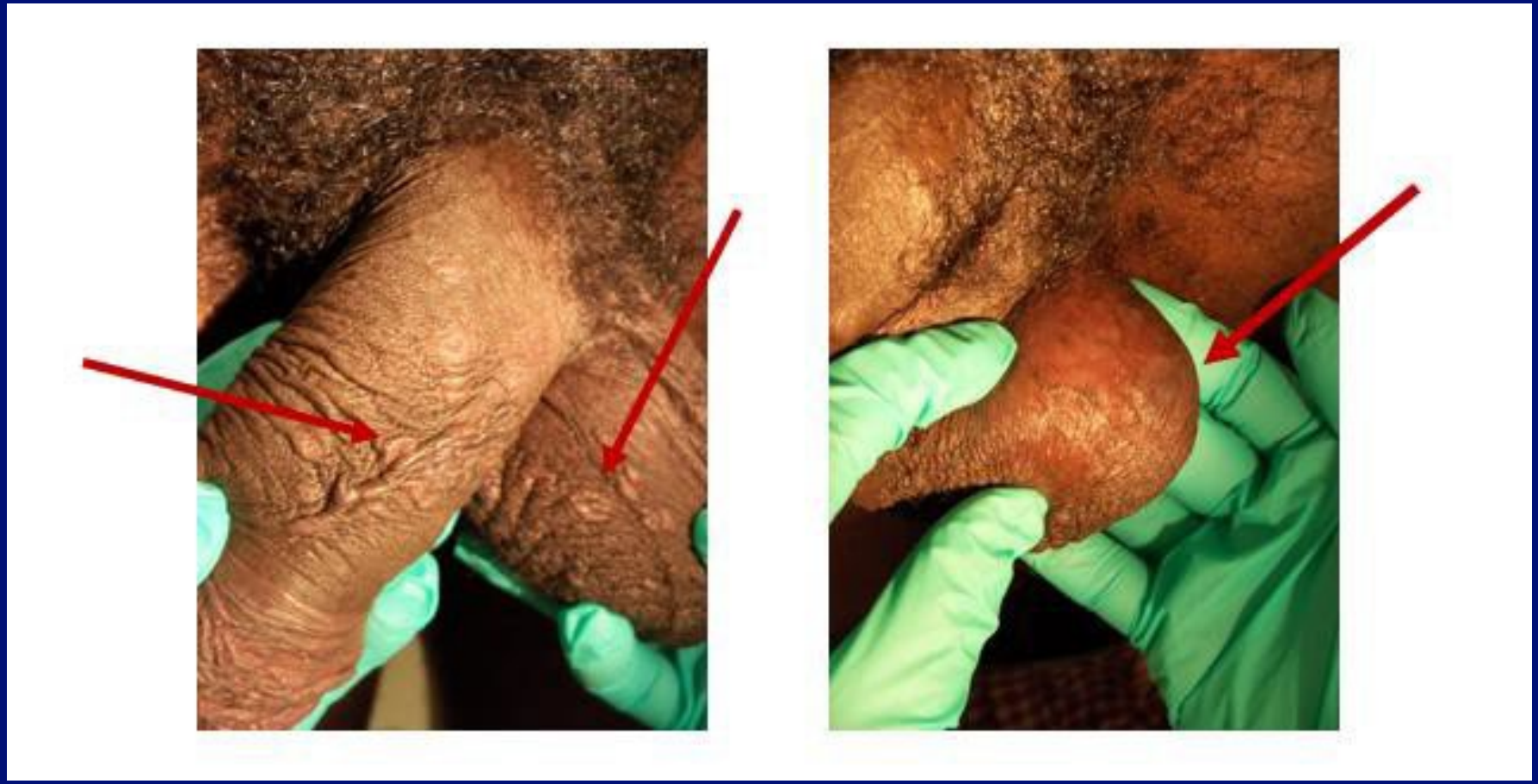
Monkeypox

*Slide attribution: Orange County Health Care Agency



Monkeypox

Secondary syphilis



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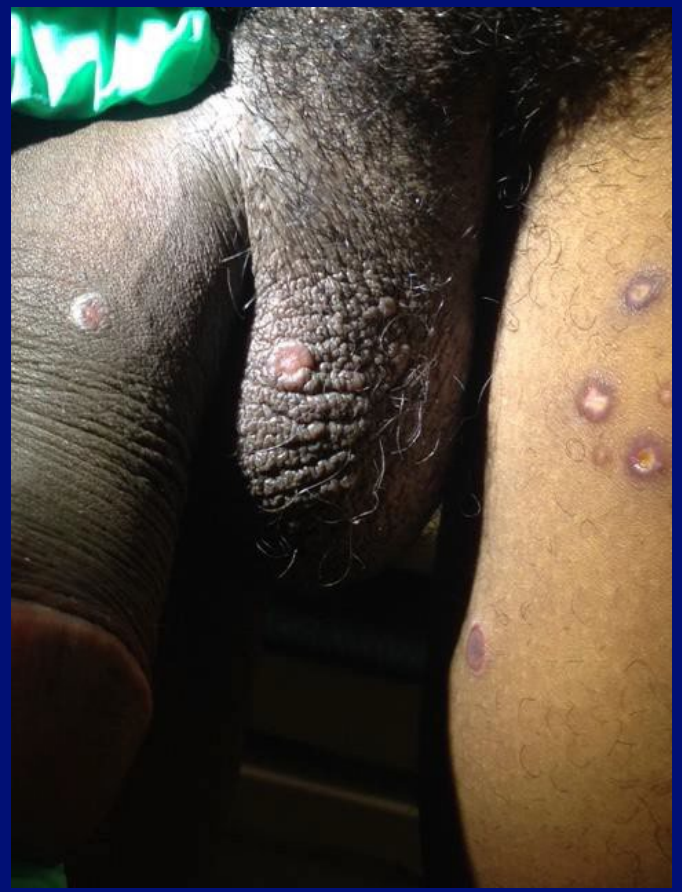

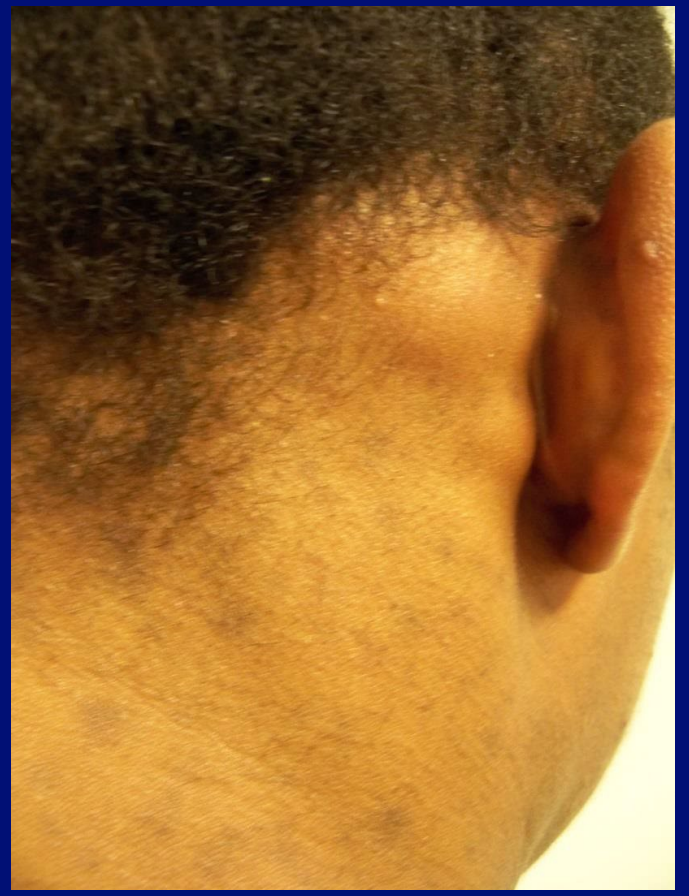

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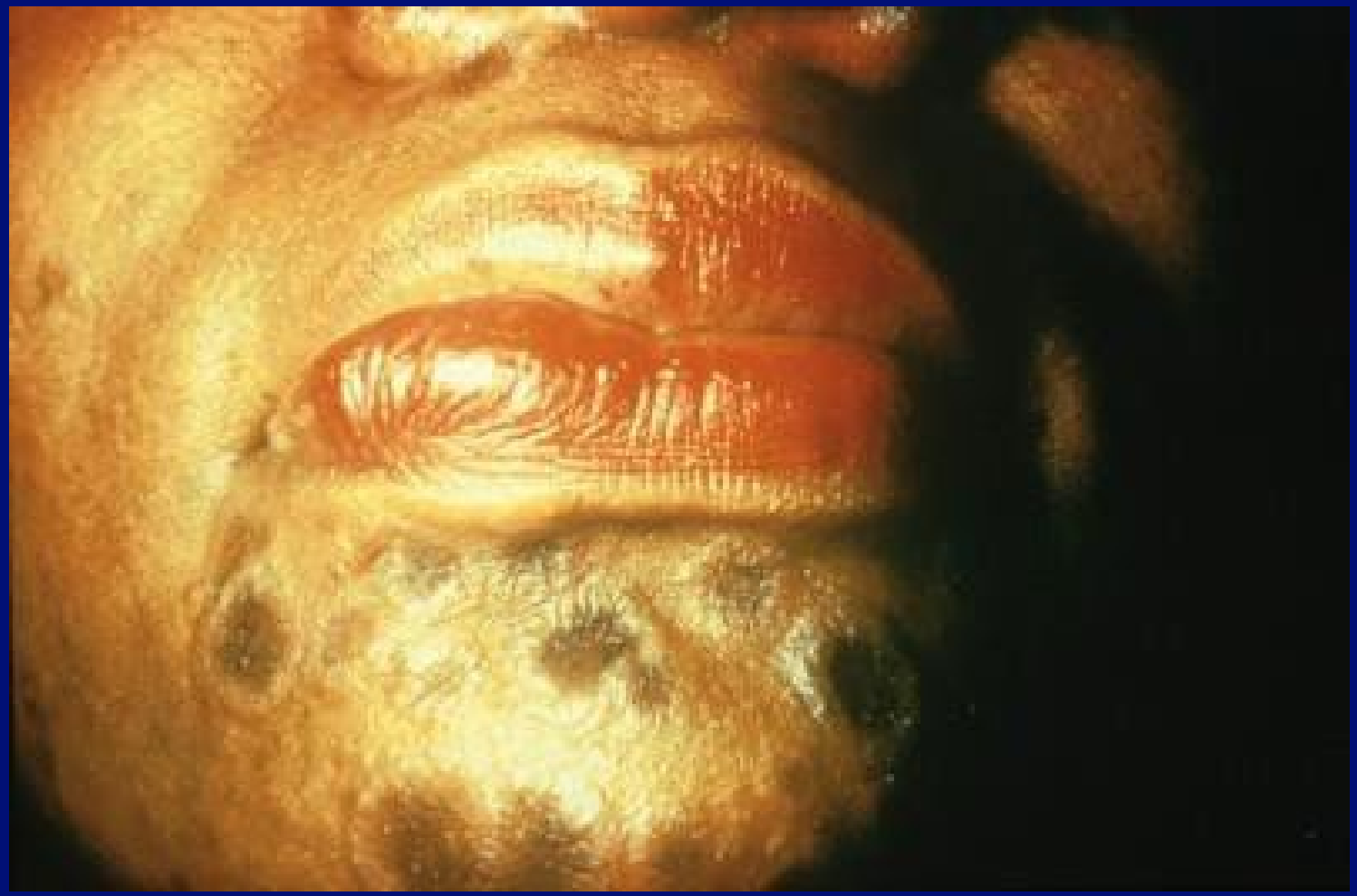
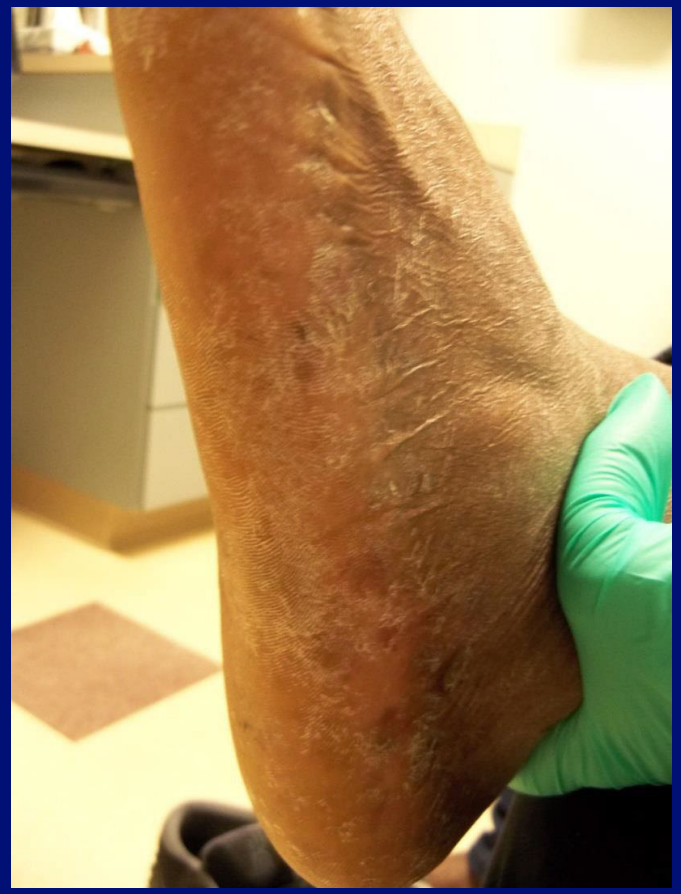
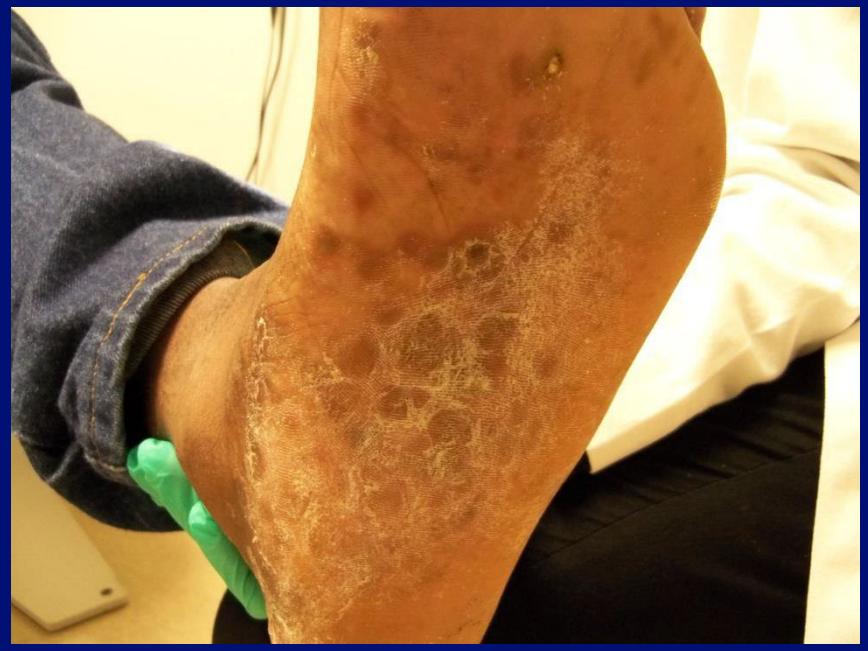


www.cdc.gov

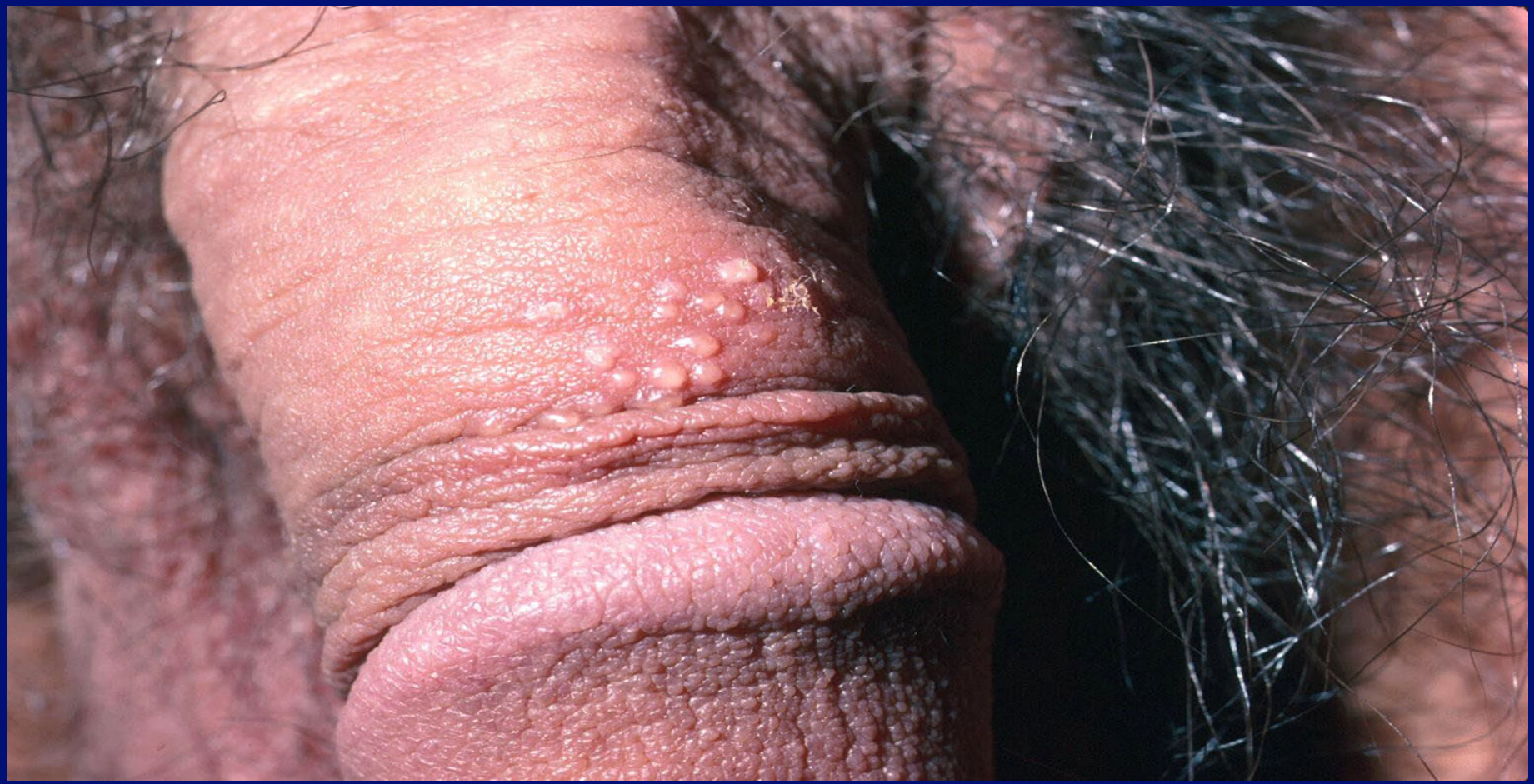
Secondary syphilis





Secondary syphilis – condyloma lata

Genital herpes



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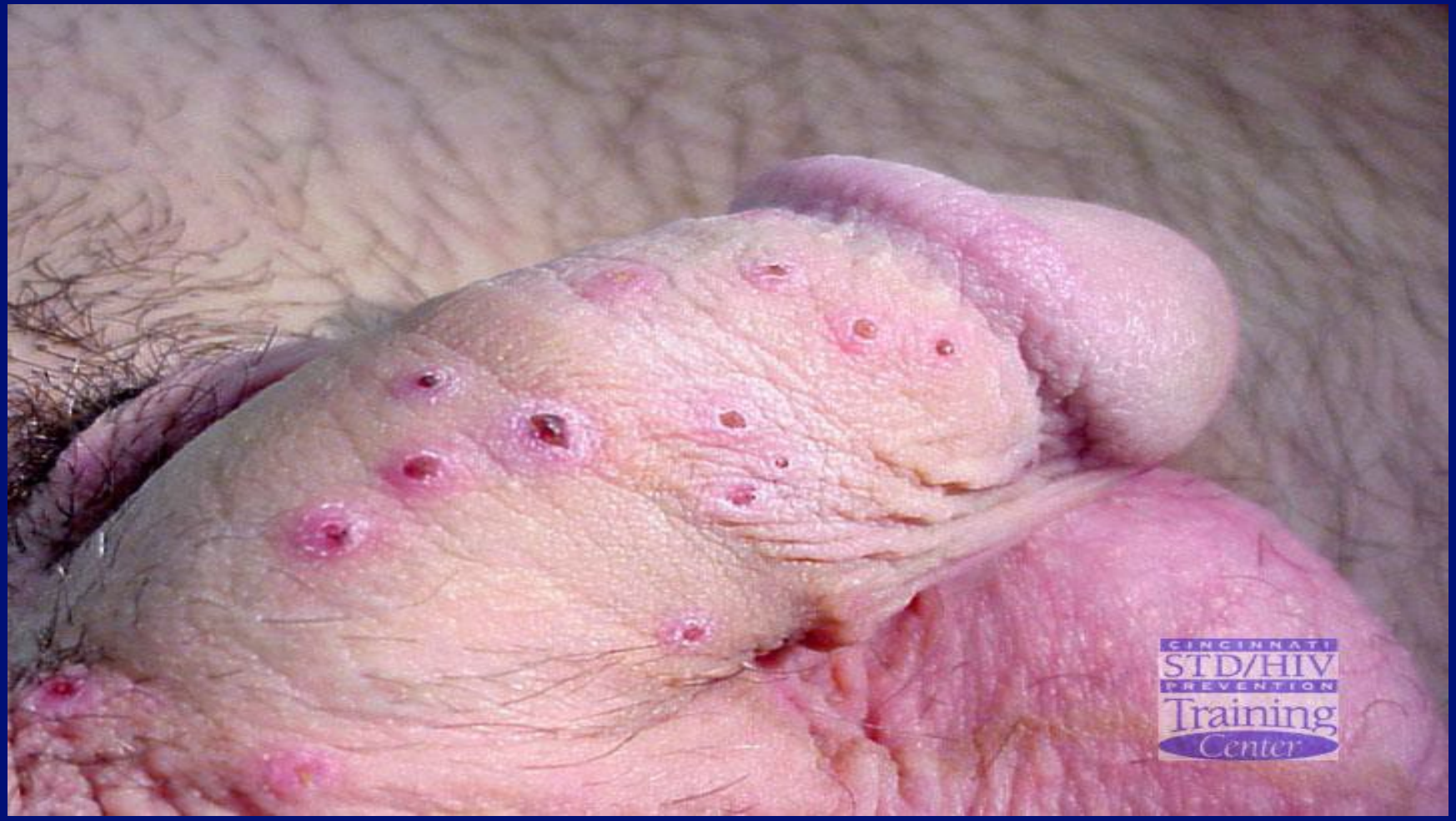
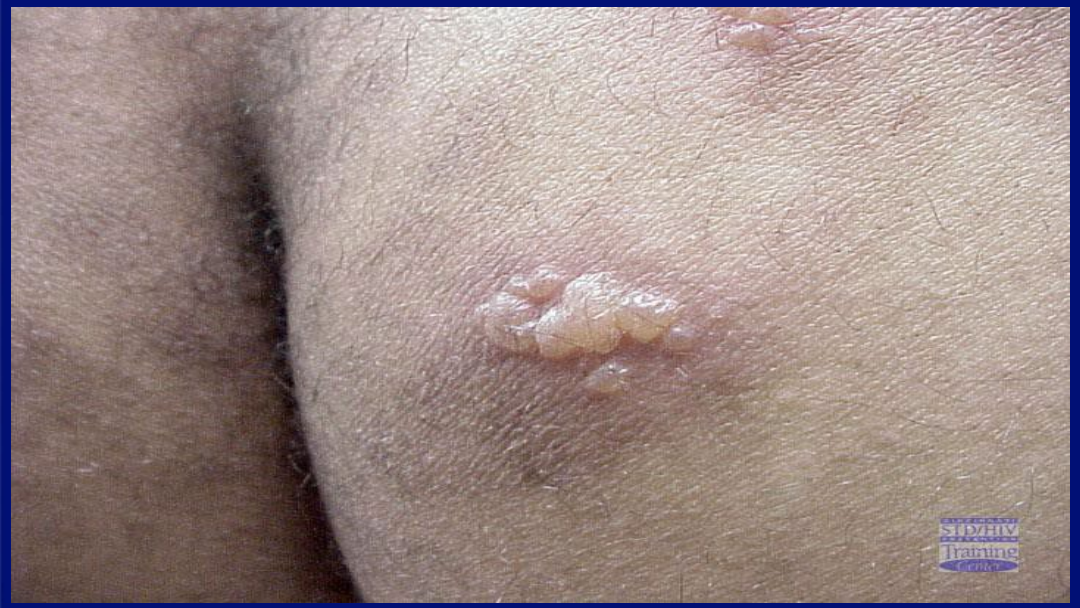
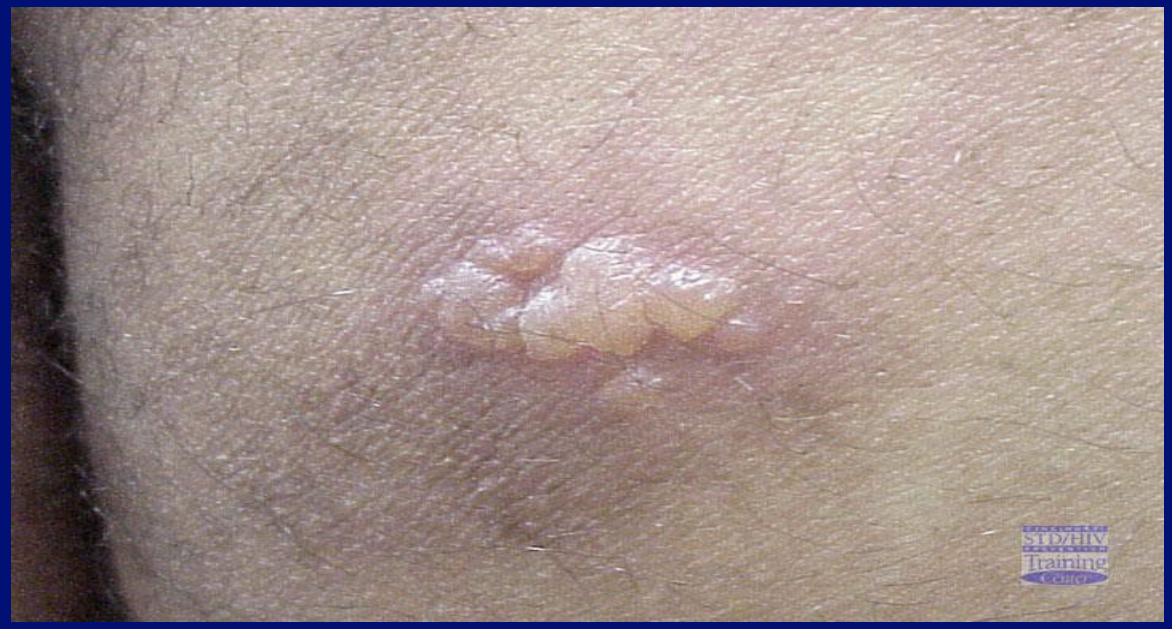


Source: Cincinnati STD/HIV Prevention Training Center

Genital herpes





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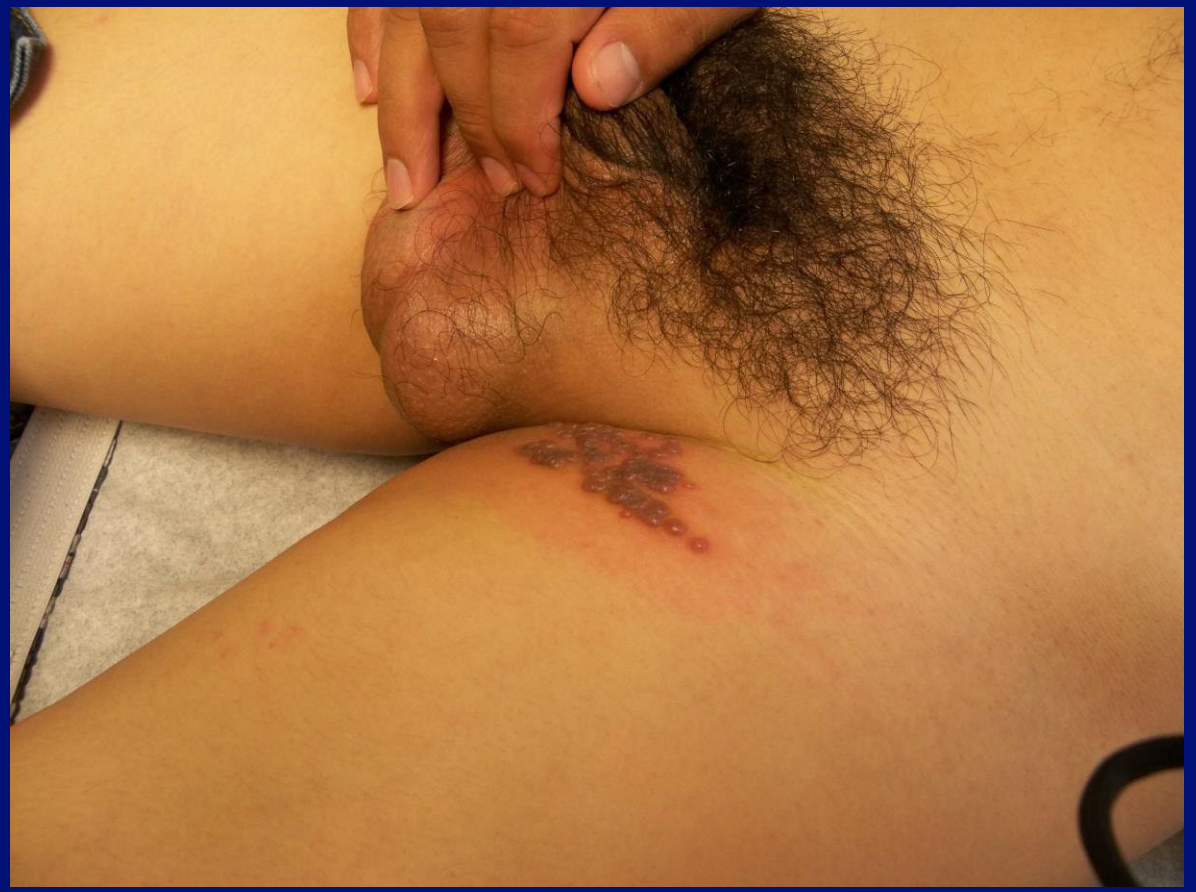
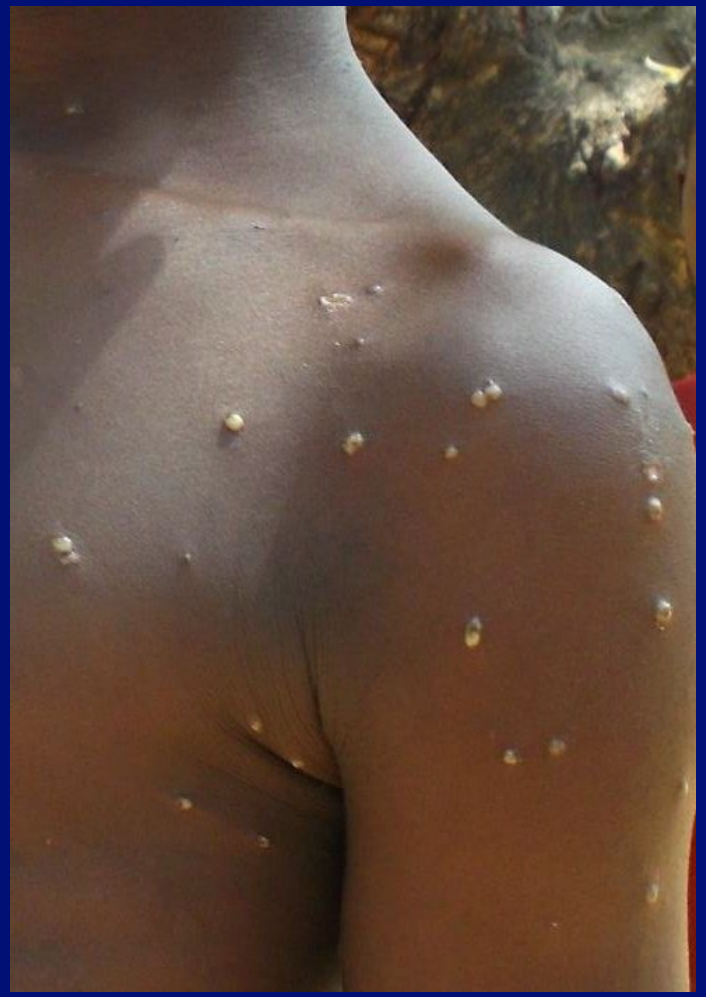
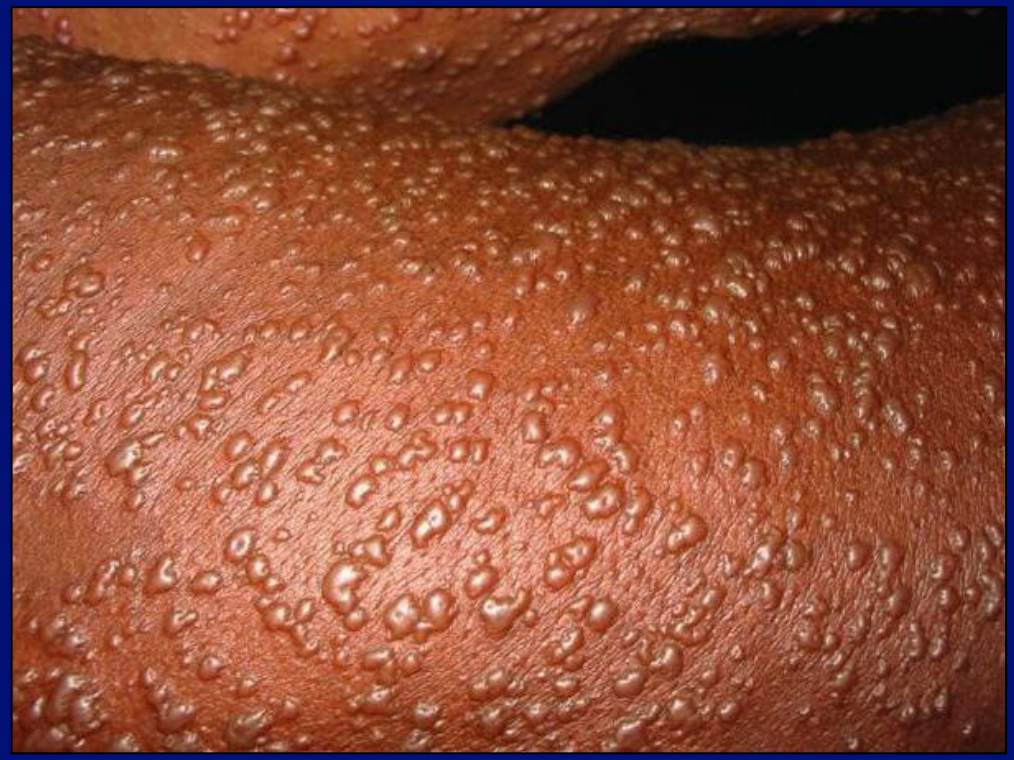
Herpes Zoster



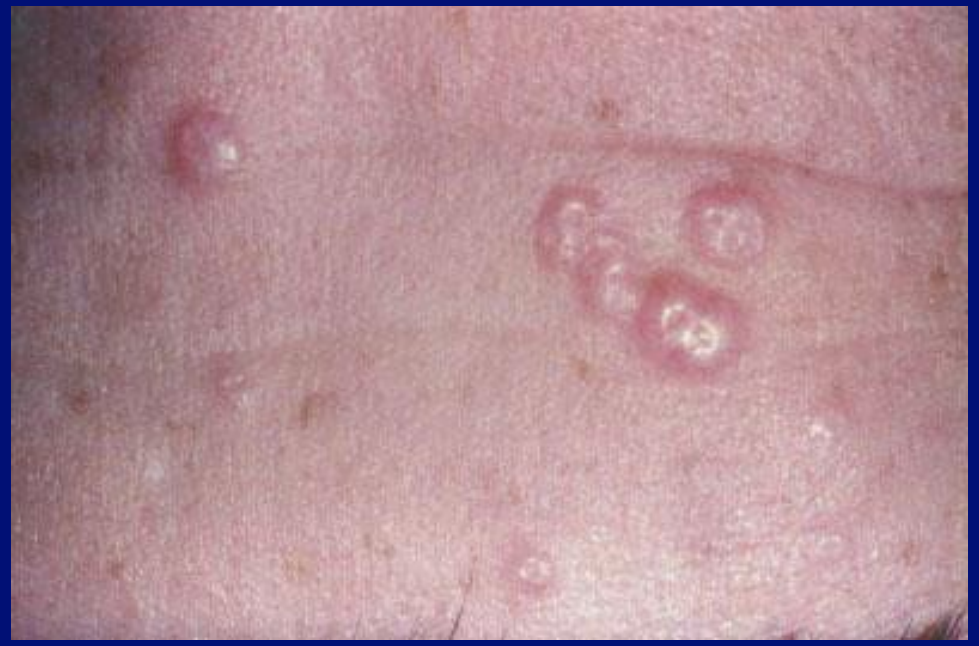
Varicella Zoster Virus



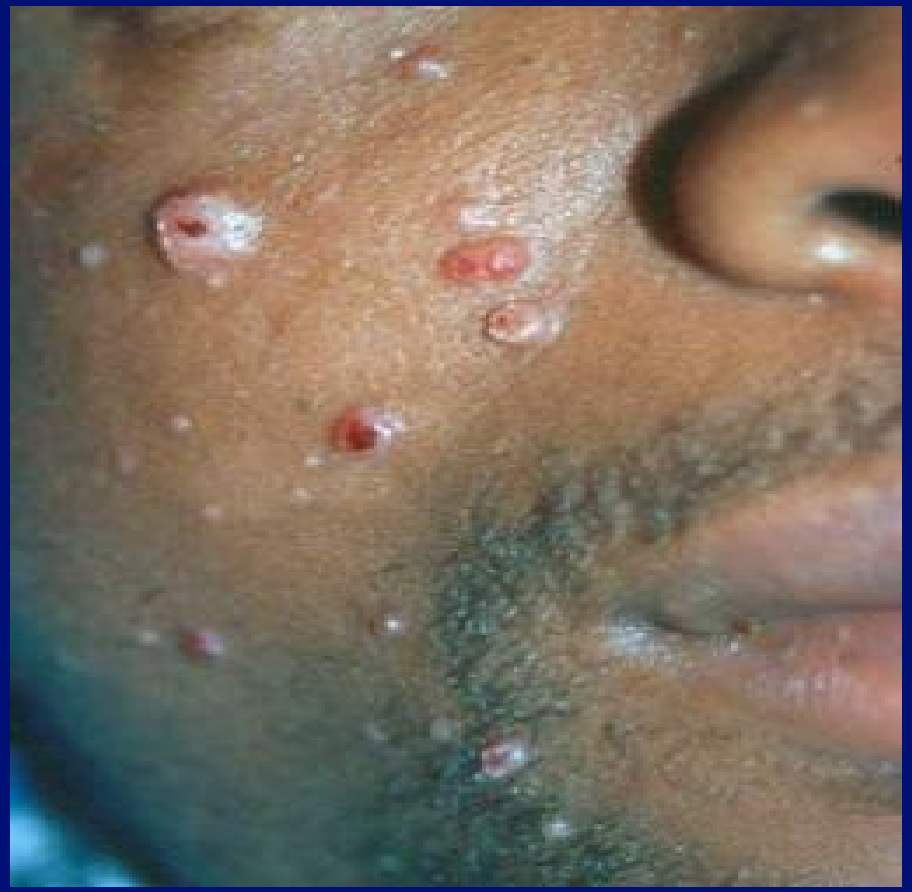


Monkeypox

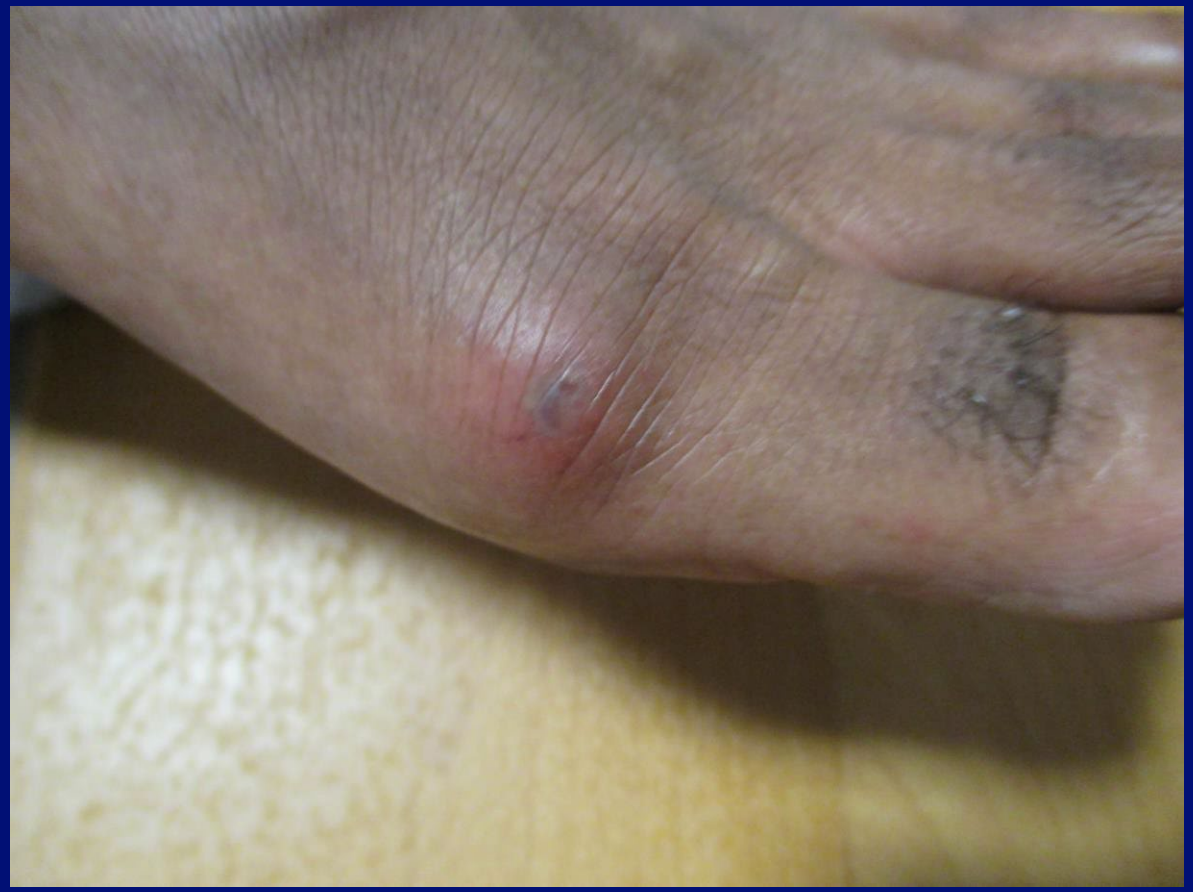
Molluscom contagiosum

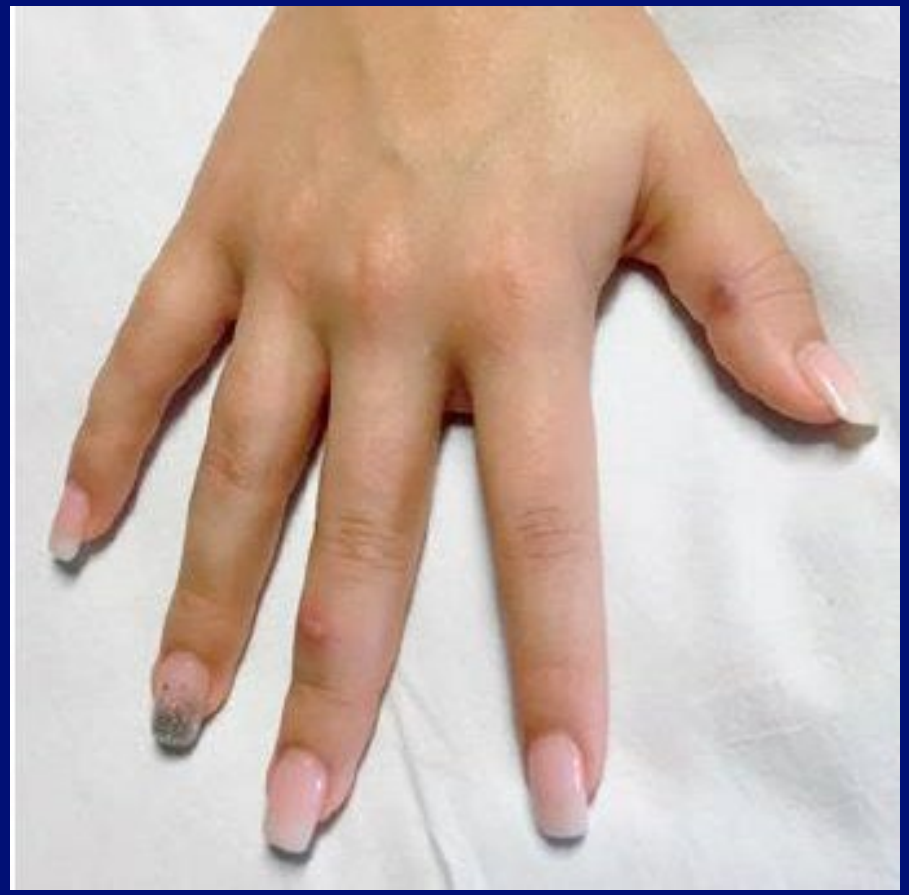


Disseminated cryptococcal infection



Disseminated gonococcal infection





https://www.nejm.org/doi/full/10.1056/NEJMicm1811120

Diagnostic considerations for STIs

- **Genital ulcer disease diagnostic evaluation**
  - Syphilis serology tests
  - Darkfield examination from lesion exudate or tissue (or nucleic acid amplification test (NAAT) if available)
  - NAAT* or culture for genital herpes type 1 and 2
  - Serologic testing for type-specific HSV antibody
  - NAAT or culture for *Haemophilus ducreyi* in settings where chancroid prevalent
- **For unexplained rash, consider syphilis serology tests**

*Preferred

Workowski KA, Bachmann LH, Chan PA, et al. *MMWR Recomm Rep* 2021;70(4): 27-56

STI Treatment Guidelines

2021 RECOMMENDATIONS NOW AVAILABLE

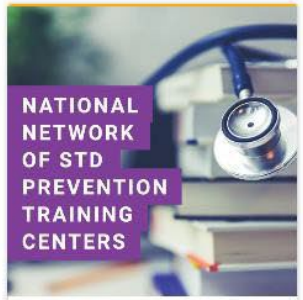
STI Treatment Guidelines Update

CDC's Sexually Transmitted Infections (STI) Treatment Guidelines, 2021 provides current evidence-based prevention, diagnostic and treatment recommendations that replace the 2015 guidance. The recommendations are intended to be a source for clinical guidance. Healthcare providers should always assess patients based on their clinical circumstances and local burden.

2021 Mobile App in Development
Learn how to use the interim, mobile-friendly solution.

View the full STI Treatment Guidelines.

Access print-friendly versions of the wall chart, pocket guide, and guidelines.



Explore STD trainings, technical assistance, clinical consultation services, and more.

Learn about recommendations and tools to help healthcare settings improve STD care services.

National Network of STD Clinical Prevention Training Centers

STD Treatment Resources: www.nnptc.org

Clinical Consultations: www.STDCCN.org

Medical Countermeasures Currently Stockpiled for Orthopoxviruses

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

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

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

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 Vaccine Pre-Exposure Prophylaxis

- **On November 3, 2021, the Advisory Committee and Immunization Practices (ACIP) voted to recommend vaccination for select persons at risk for occupational exposure to orthopoxviruses**
- **Policy note published June 3, 2022**
  - Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022

https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm

Monkeypox Vaccine Pre-Exposure Prophylaxis

- 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

https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html

Monkeypox Vaccine Pre-Exposure Prophylaxis

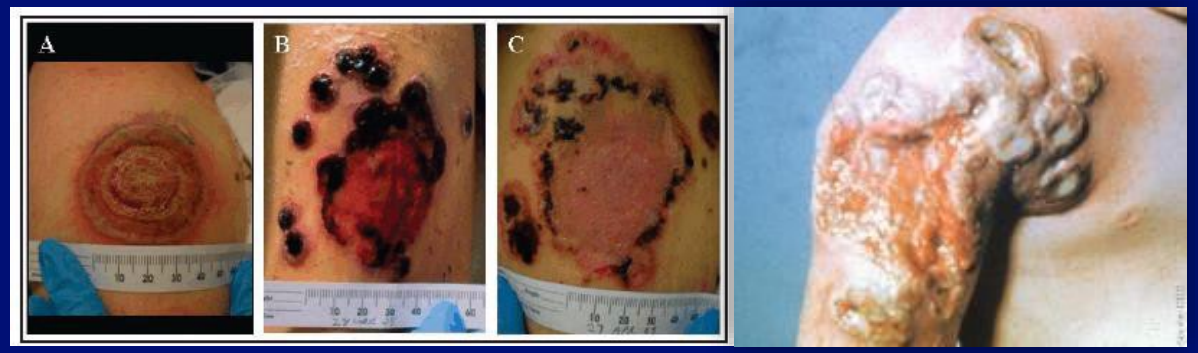
- At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP
  - Laboratorians should consult with laboratory biosafety officers and supervisors to identify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

https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html

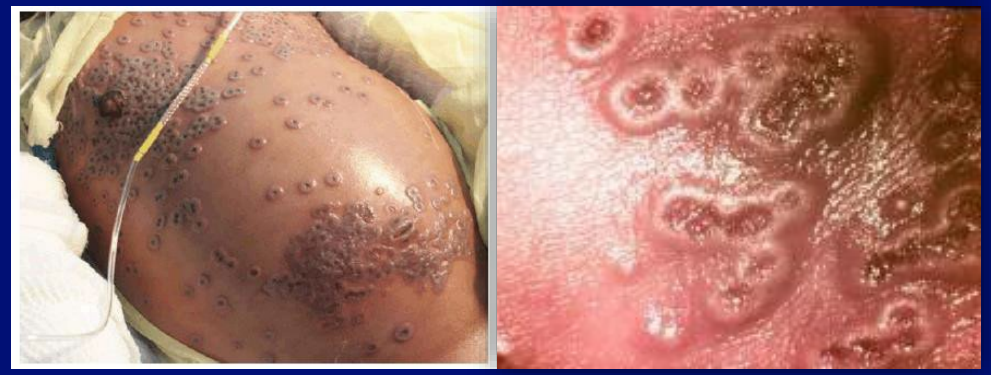
ACIP Contraindications for ACAM2000 and JYNNEOS for PrEP for Persons at Risk for Occupational Exposure to Orthopoxviruses

Contraindication	ACAM2000 Primary Vaccinees	ACAM2000 Revaccinees	ACAM2000 Household Contacts[1]	JYNNEOS
History or presence of atopic dermatitis	X	X	X	
Other active exfoliative skin conditions	X	X	X	
Conditions associated with immunosuppression	X	X	X	
Pregnancy	X	X	X	
Aged <1 year	X	X	X	
Breastfeeding	X	X		
Serious vaccine component allergy	X	X		X
Known underlying heart disease (e.g., coronary artery disease or cardiomyopathy)	X	X		
Three or more known major cardiac risk factors	X			

Severe Vaccinia Virus Complications
Uncontrolled Viral Replication



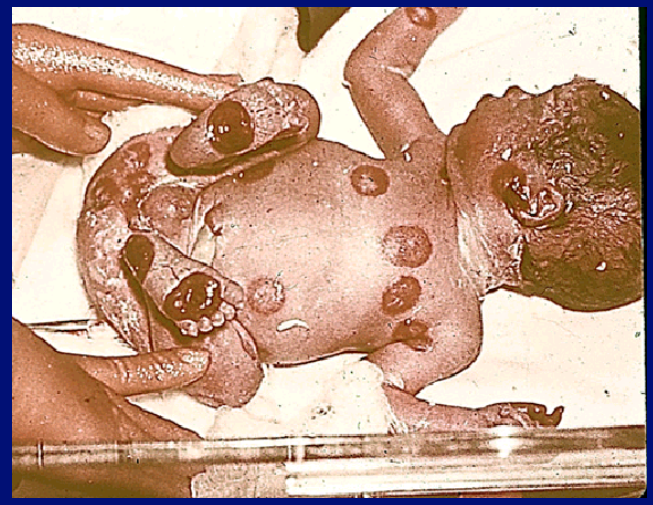
Progressive vaccinia



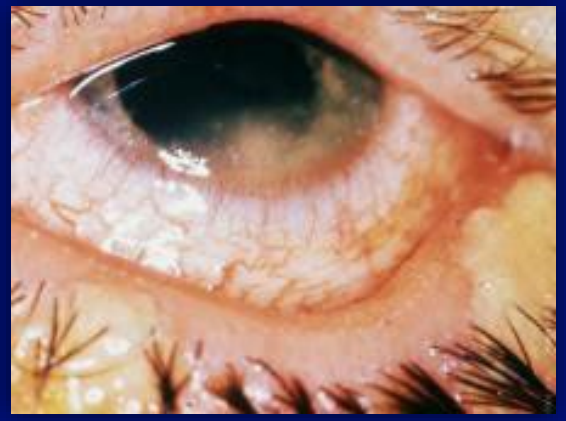
Eczema vaccinatum

Severe Vaccinia Virus Complications
Inadvertent Transmission

- **Fetal vaccinia**
- **Autoinoculation / inadvertent inoculation**
  - Ocular infections



Fetal vaccinia



Ocular vaccinia

Severe Vaccinia Virus Complications
Uncertain Etiology

- Postvaccinial encephalitis
- Myopericarditis

Post-Exposure Prophylaxis

- Transmission of monkeypox requires prolonged close interaction with a symptomatic individual
- 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

Post-Exposure Prophylaxis

Degree of exposure	Recommendations		Exposure characteristics
	Monitoring§	PEP¶	
High	Monitoring	Recommended	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 -OR-
			Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances)

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure

Post-Exposure Prophylaxis

Degree of exposure	Recommendations		Exposure characteristics
	Monitoring§	PEP¶	
Intermediate	Monitoring	Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks ¶¶	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 -OR-
			Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate)

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure

Post-Exposure Prophylaxis

Degree of exposure	Recommendations		Exposure characteristics
	Monitoring§	PEP¶	
Low / Uncertain	Monitoring	None	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 -OR-
			Exposure that, at the discretion of public health authorities, was recategorized to this risk level based on unique circumstances (e.g., uncertainty about whether Monkeypox virus was present on a surface and/or whether a person touched that surface)
No Risk	None	None	Exposure that public health authorities deemed did not meet criteria for other risk categories

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure

Current Outbreak Response in the US

- Surveillance (case identification, laboratory testing)
- Containment (isolation of cases, contact tracing)
- Monkeypox Vaccine Post-Exposure Prophylaxis (PEP) - Vaccination of close contacts 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

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure

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 likely 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

Vaccine Strategy Considerations

- Currently limited supply of JYNNEOS although more expected in July and later this 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

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

https://www.cdc.gov/poxvirus/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)**

https://www.cdc.gov/poxvirus/monkeypox/

Tecovirimat

- **Tecovirimat is an antiviral medication developed to treat smallpox**
  - Also known as TPOXX or ST-246
- **Oral capsule and IV formulations approved by FDA in July 2018 and May 2022, respectively**
- **Indication**
  - Tecovirimat is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg
  - CDC-held Expanded Access Investigational New Drug Protocol allows use of Tecovirimat for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)
- **Available from the Strategic National Stockpile as an oral capsule formulation or an intravenous vial**

Other Treatment Options

- VIGIV is licensed by FDA for the treatment of complications due to vaccinia vaccination
- 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 Expanded Access Investigational New Drug Protocol allows use of VIGIV and Cidofovir for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)

https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/vaccinia-immune-globulin-intravenous-human
https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/020638s003lbl.pdf

Other Treatment Options

- Brincidofovir (also known as CMX001 or Tembexa) is an antiviral medication that was approved by the FDA for the treatment of human smallpox disease in adult and pediatric patients, including neonates
- Brincidofovir is not currently available from the SNS
  - CDC is currently developing an Expanded Access Investigational New Drug Protocol to help facilitate use of Brincidofovir as a treatment for monkeypox

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214460s000,214461s000lbl.pdf

Other Treatment Options

- Trifluridine (also known as Viroptic) is an antiviral medication licensed for the treatment of herpes keratoconjunctivitis/keratitis
- In vitro evidence of activity against orthopoxviruses
- Case reports of use for ocular orthopoxvirus infections

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=abc1d07f-91ee-4421-bc9b-457d0ed41f4c

Medical Countermeasure Requests

- CDC is available for consultations to assist with medical countermeasure utilization including appropriate vaccine and antiviral use
- Clinicians should work with State or Territorial Health Authorities to requests vaccines, Tecovirimat, VIGIV, or cidofovir
- Health departments can reach CDC consultants through the CDC Emergency Operations Center
  - CDC's Emergency Operations Center: (770) 488-7100
  - poxvirus@cdc.gov

Monkeypox case study

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

Penile Lesions – Day 1

Of note: these lesions appeared after his morning telehealth visit

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 NYC 05/29/2022
  - He did not know whether any of these partners had recent travel
  - No international travel
  - No fever, swollen glands, or fatigue

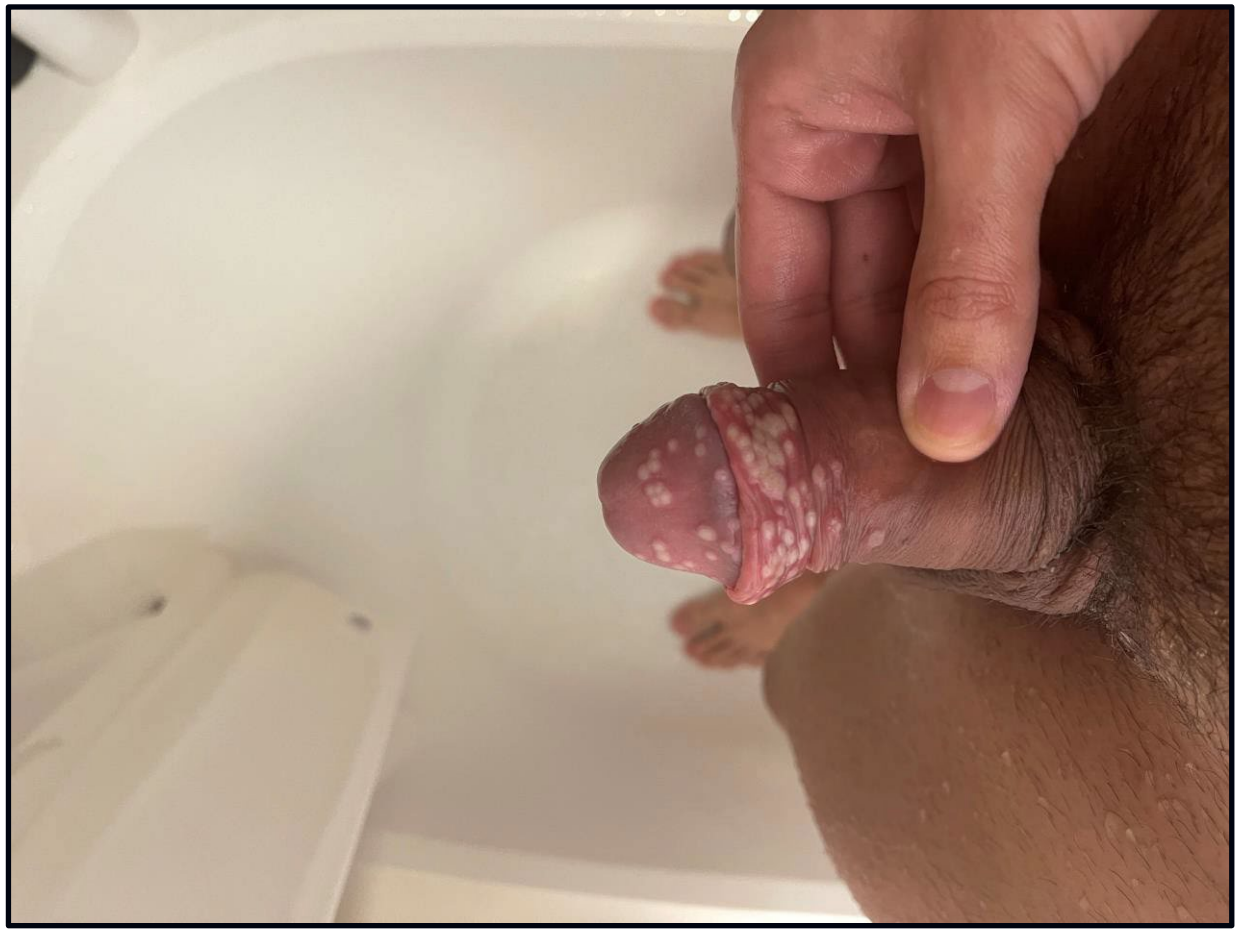
Friday, June 3 – Day 2 – Patient Exam Findings

- **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

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

- Routine Pre-exposure HIV Prophylaxis (PrEP) Clinic human immunodeficiency virus (HIV)/Sexually Transmitted Infections (STI) testing was done – including a rapid plasma reagin (RPR) test
  - A herpes simplex virus (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

Penile Lesions – Sunday, June 5 – Day 4



Monday, June 6 – Day 5

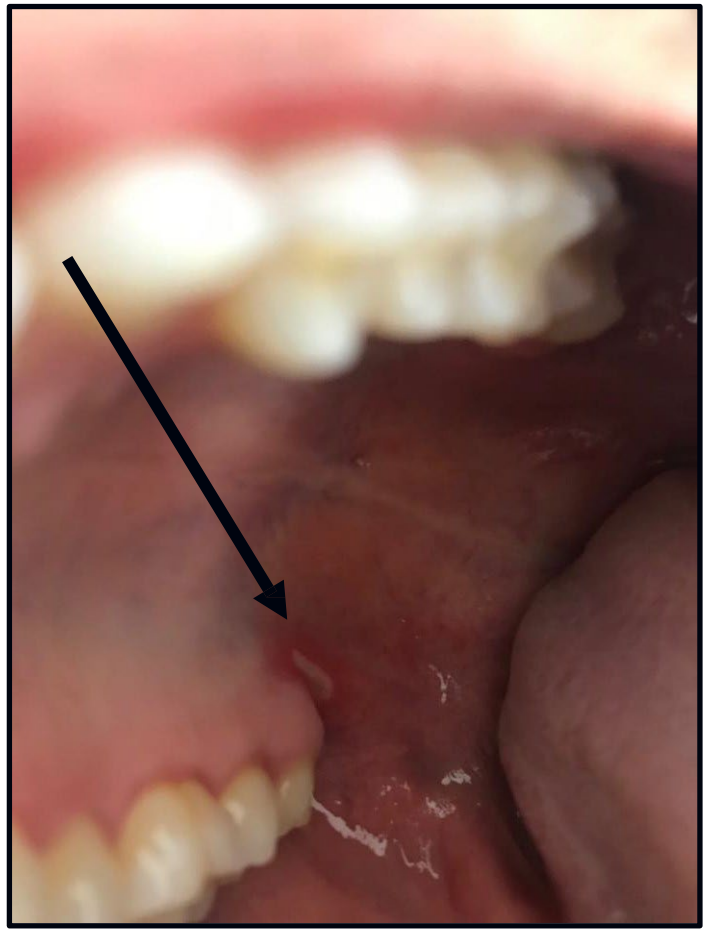
- **Patient called the clinic to discuss lab results and provide update on symptoms**
- **Lab results**
  - RPR non-reactive, HSV culture negative
  - Pharyngeal and rectal NAAT were negative for both chlamydia and gonorrhea
  - Urine NAAT was positive for chlamydia (and negative for gonorrhea)
- **Symptom 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 had received a monkeypox diagnosis**

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

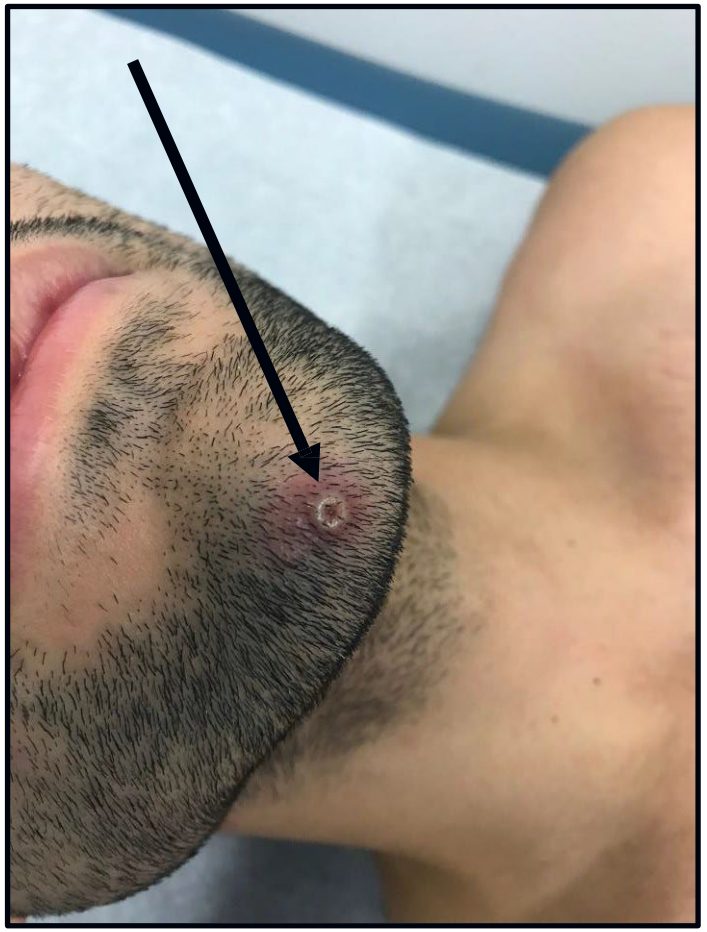
Tuesday, June 7 – Day 6 – Patient Exam Findings

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



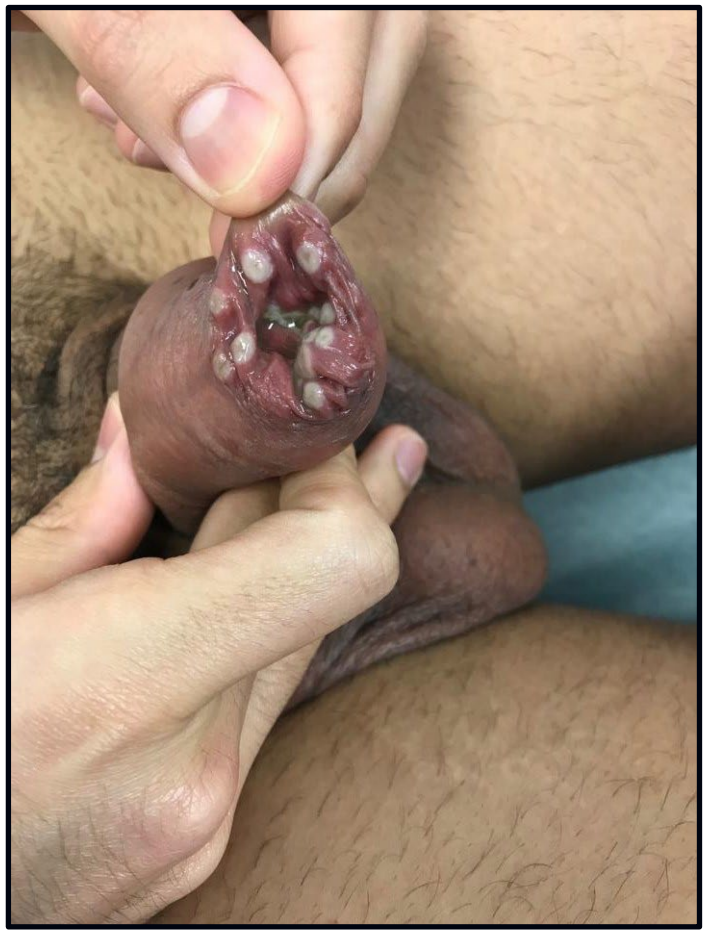
Tuesday, June 7 – Day 6 – Patient Exam Findings

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



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



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

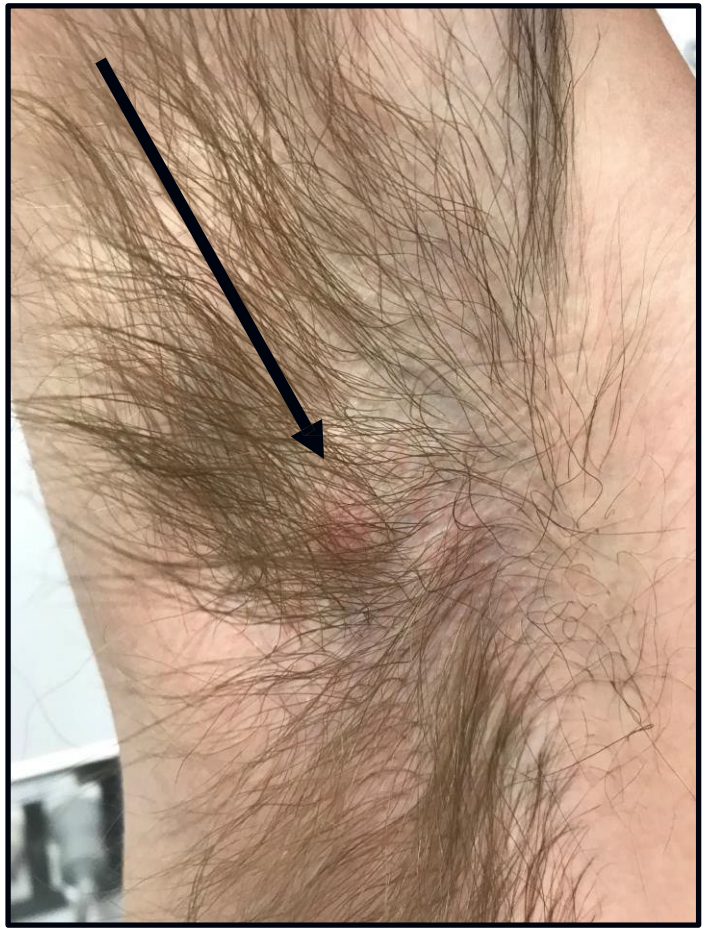
Tuesday, June 7 – Day 6 – Partner History

- 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

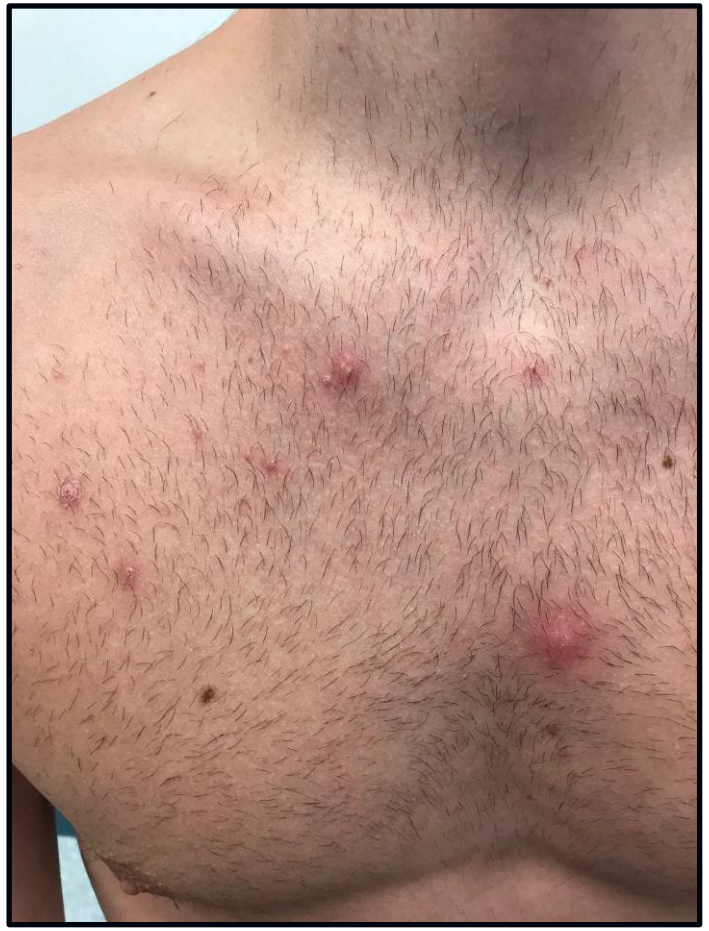
Tuesday, June 7 – Day 6 – Partner Exam Findings

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



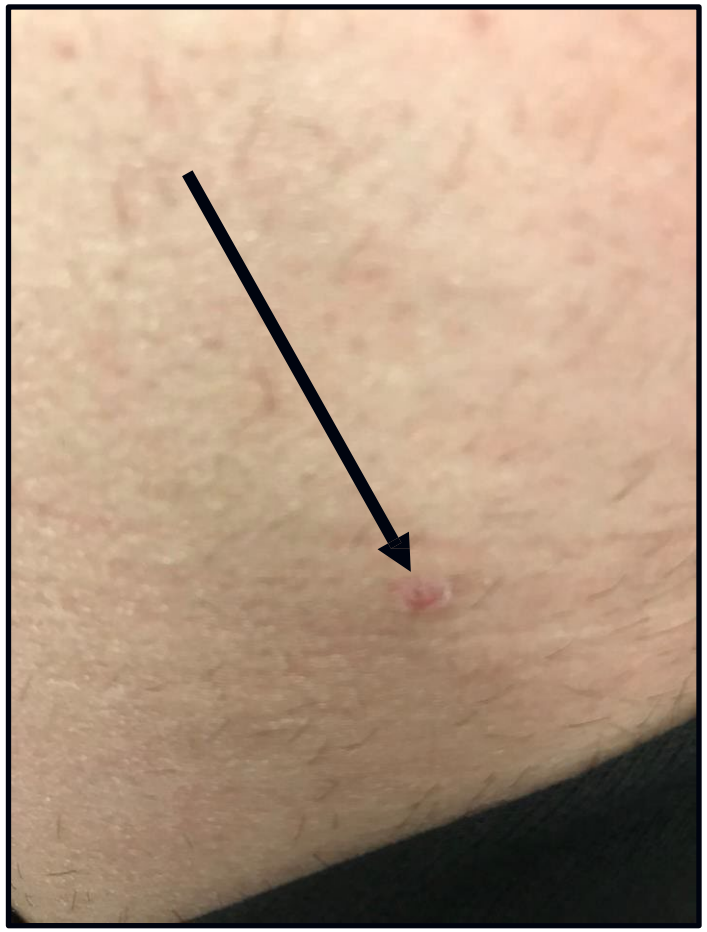
Tuesday, June 7 – Day 6 – Partner Exam Findings

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



Tuesday, June 7 – Day 6 – Partner Exam Findings

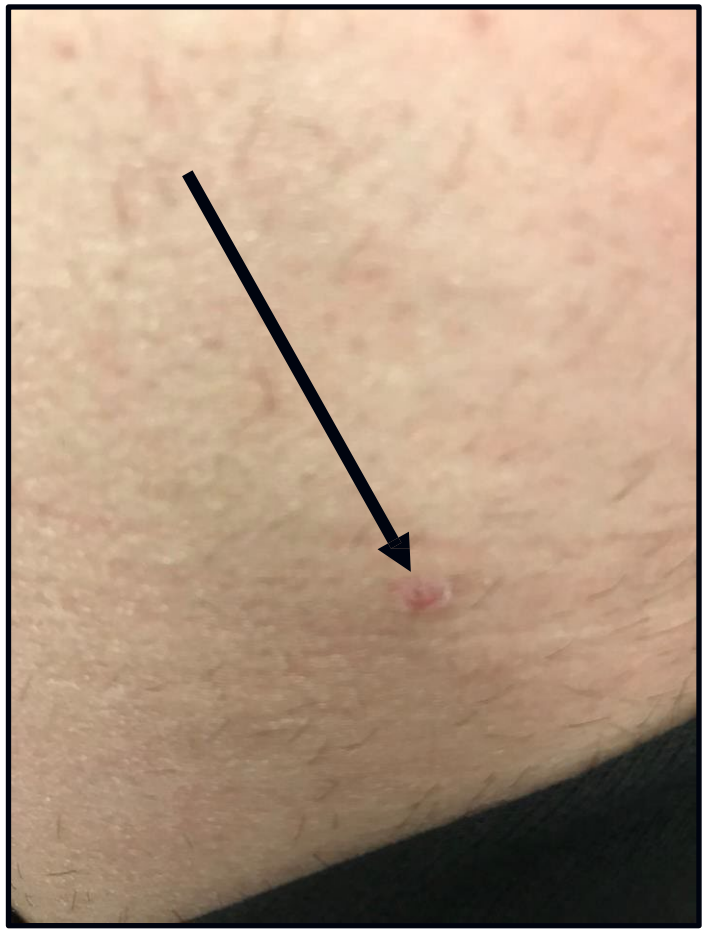
- **Buttocks**
  - One very small papule on skin of left lower buttock



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



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

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.**

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

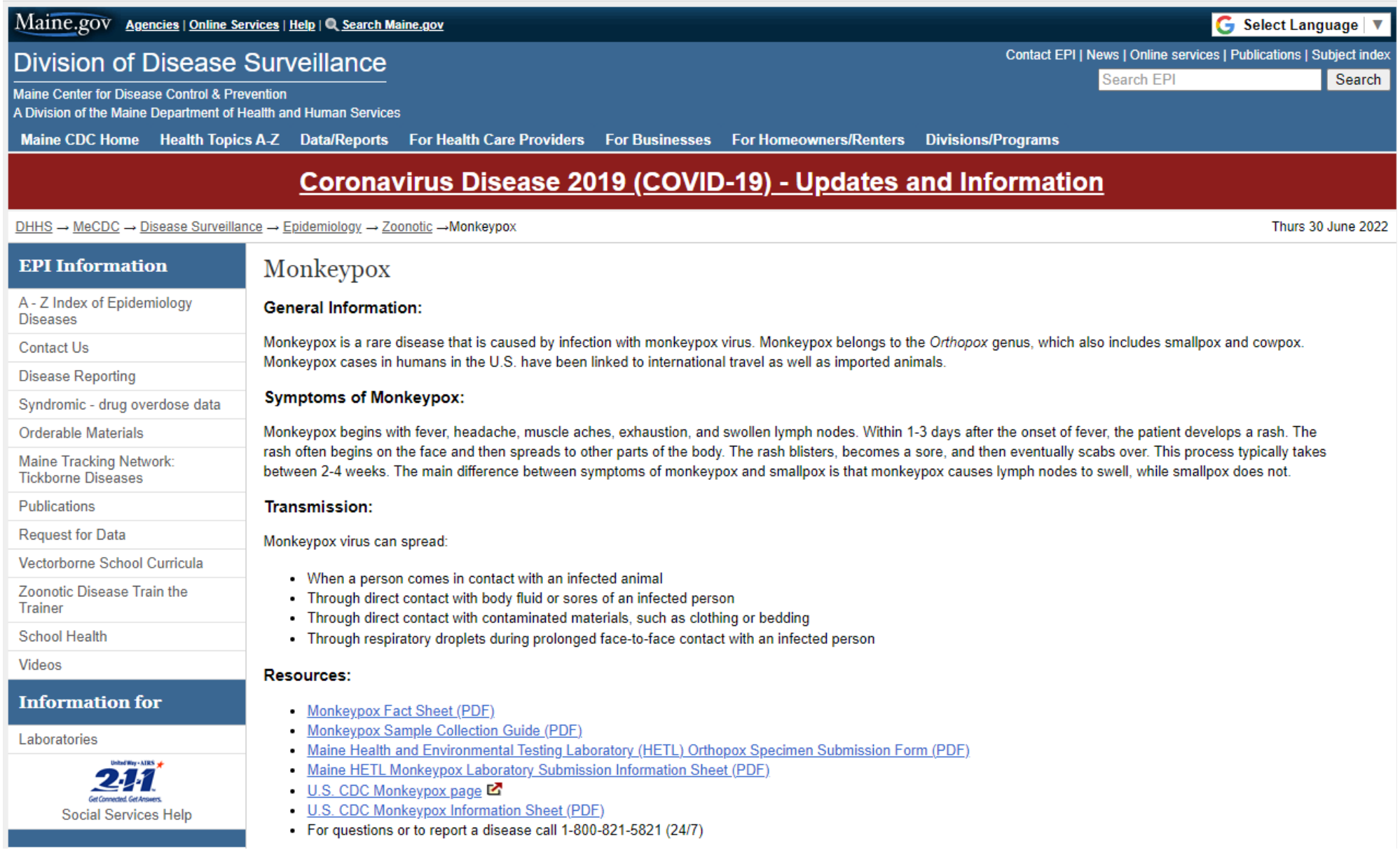
Thursday, June 10 – Day 9

- 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

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**

For more information, go to: https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/monkeypox.shtml



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Maine Center for Disease Control & Prevention
A Division of the Maine Department of Health and Human Services

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Monkeypox

General Information:

Monkeypox is a rare disease that is caused by infection with monkeypox virus. Monkeypox belongs to the *Orthopox* genus, which also includes smallpox and cowpox. Monkeypox cases in humans in the U.S. have been linked to international travel as well as imported animals.

Symptoms of Monkeypox:

Monkeypox begins with fever, headache, muscle aches, exhaustion, and swollen lymph nodes. Within 1-3 days after the onset of fever, the patient develops a rash. The rash often begins on the face and then spreads to other parts of the body. The rash blisters, becomes a sore, and then eventually scabs over. This process typically takes between 2-4 weeks. The main difference between symptoms of monkeypox and smallpox is that monkeypox causes lymph nodes to swell, while smallpox does not.

Transmission:

Monkeypox virus can spread:

- When a person comes in contact with an infected animal
- Through direct contact with body fluid or sores of an infected person
- Through direct contact with contaminated materials, such as clothing or bedding
- Through respiratory droplets during prolonged face-to-face contact with an infected person

Resources:

- Monkeypox Fact Sheet (PDF)
- Monkeypox Sample Collection Guide (PDF)
- Maine Health and Environmental Testing Laboratory (HETL) Orthopox Specimen Submission Form (PDF)
- Maine HETL Monkeypox Laboratory Submission Information Sheet (PDF)
- U.S. CDC Monkeypox page
- U.S. CDC Monkeypox Information Sheet (PDF)
- For questions or to report a disease call 1-800-821-5821 (24/7)