

MPOX in the US

Jonathan Baker, PA-C, MPAS, DFAAPA (He/Him)

Anorectal & Sexual Health PA | Laser Surgery Care | NYC

Immediate Past President | NYSSPA

Past President | LBGTPA

Delegate | AAPA HOD

@RectalRockstar

JonathanBaker.PA@gmail.com

Financial Disclosures

Jonathan Baker has relevant relationships with ineligible companies to disclose within the past 24 months. (Note: Ineligible companies are defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.) Company name and type of financial relationship: Salary support from Franz Therapeutics, Inovio Pharmaceuticals, and Merck & Co.

*Off label content identified on slides

Learning Objectives

At the conclusion of this session, participants should be able to:

- Reference the epidemiologic trends of MPOX in the U.S. beginning in 2022
- Identify preventive measures including MPOX vaccination
- Recognize typical and atypical presentations of MPOX
- Recommend appropriate treatment modalities including antivirals and supportive treatment

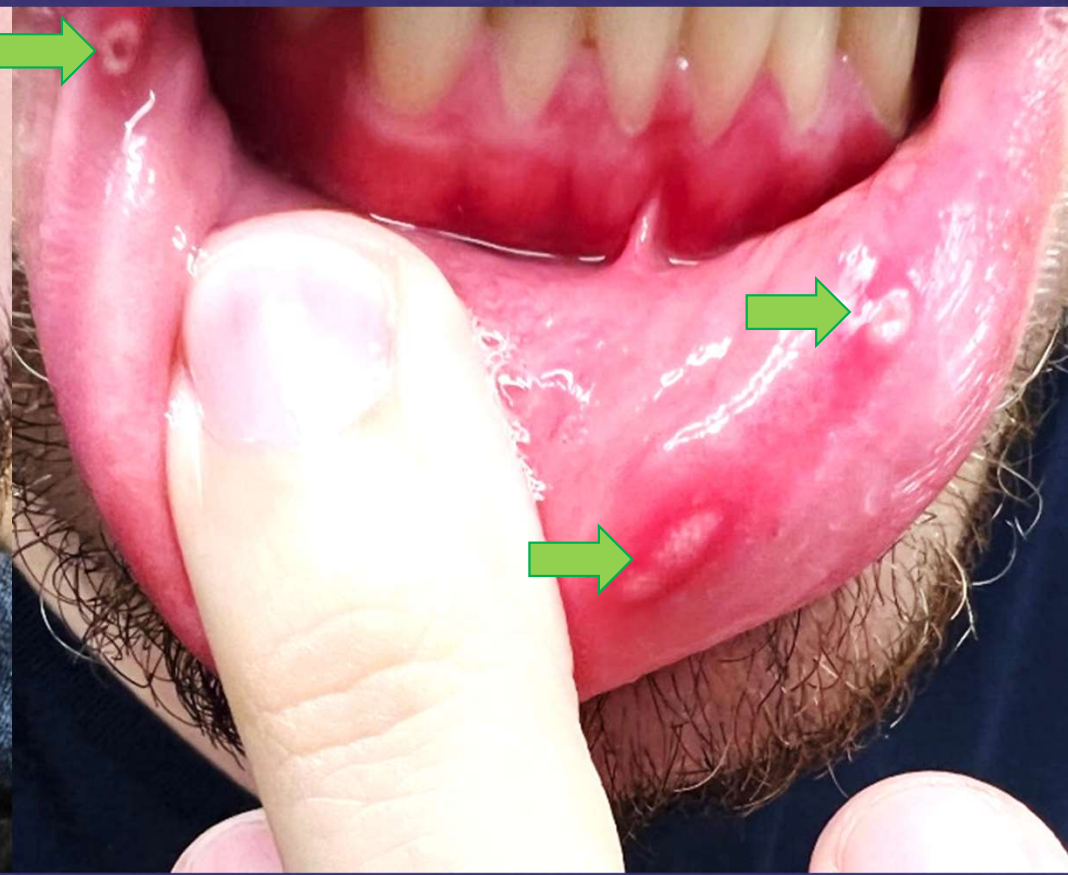
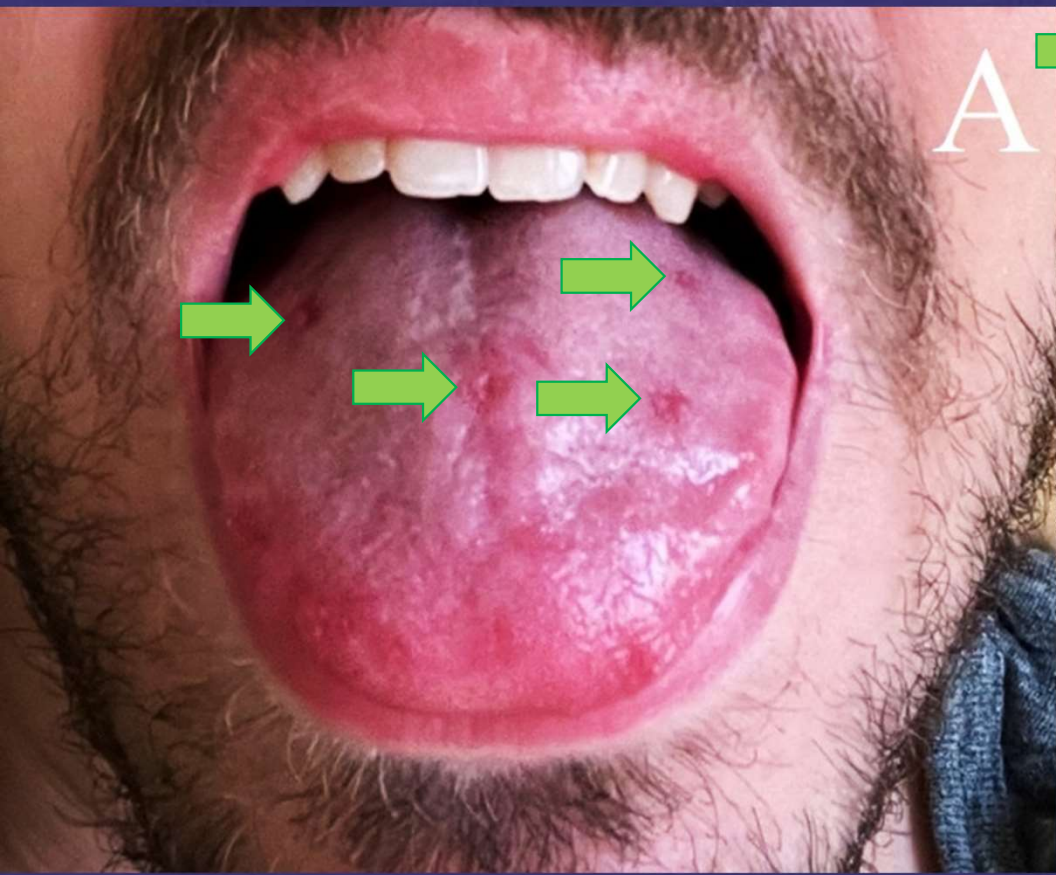
Case 1: June 2022

28 year old presents complaining of mouth sores x 1 week

“I think I have mouth herpes”

- No significant past medical history or medications
- Good dental hygiene and up to date on routine dental screenings
- Recent travel to Italy where the patient engaged in oral sex (patient’s mouth on partner’s genitals) 2 weeks prior; no other sexual activity in the last 6 months
- Had a subjective fever for 2 days overlapping onset of oral lesions

on physical examination:



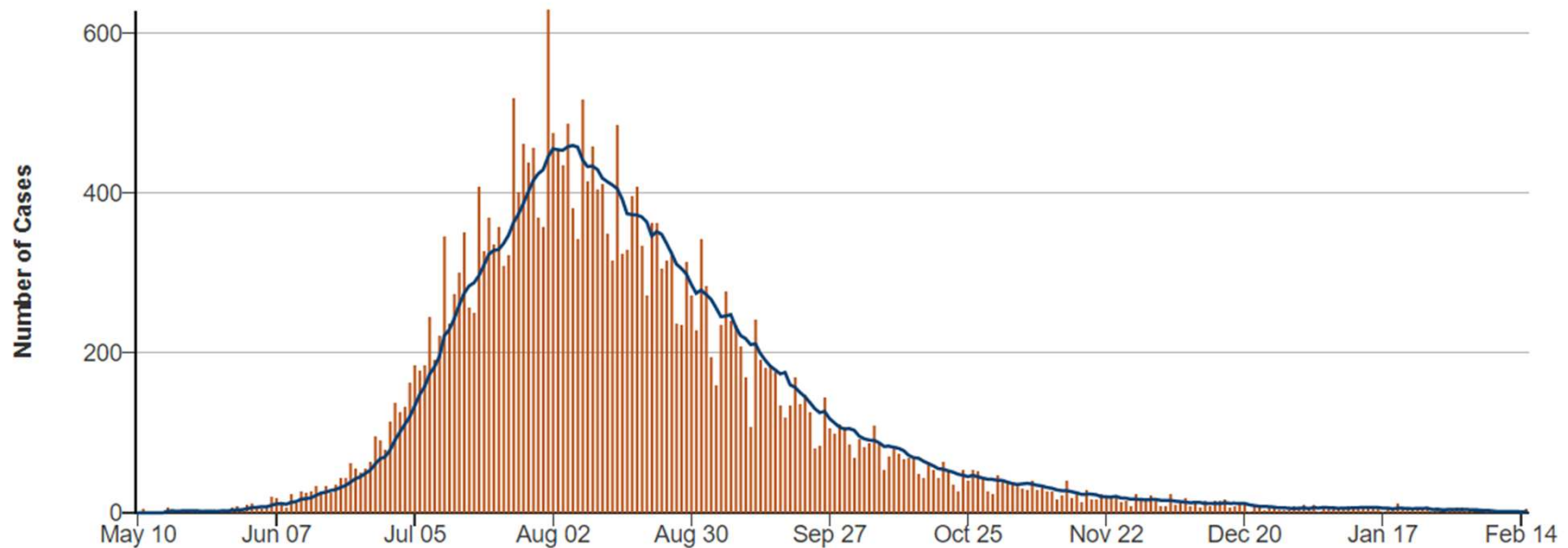
Case 1

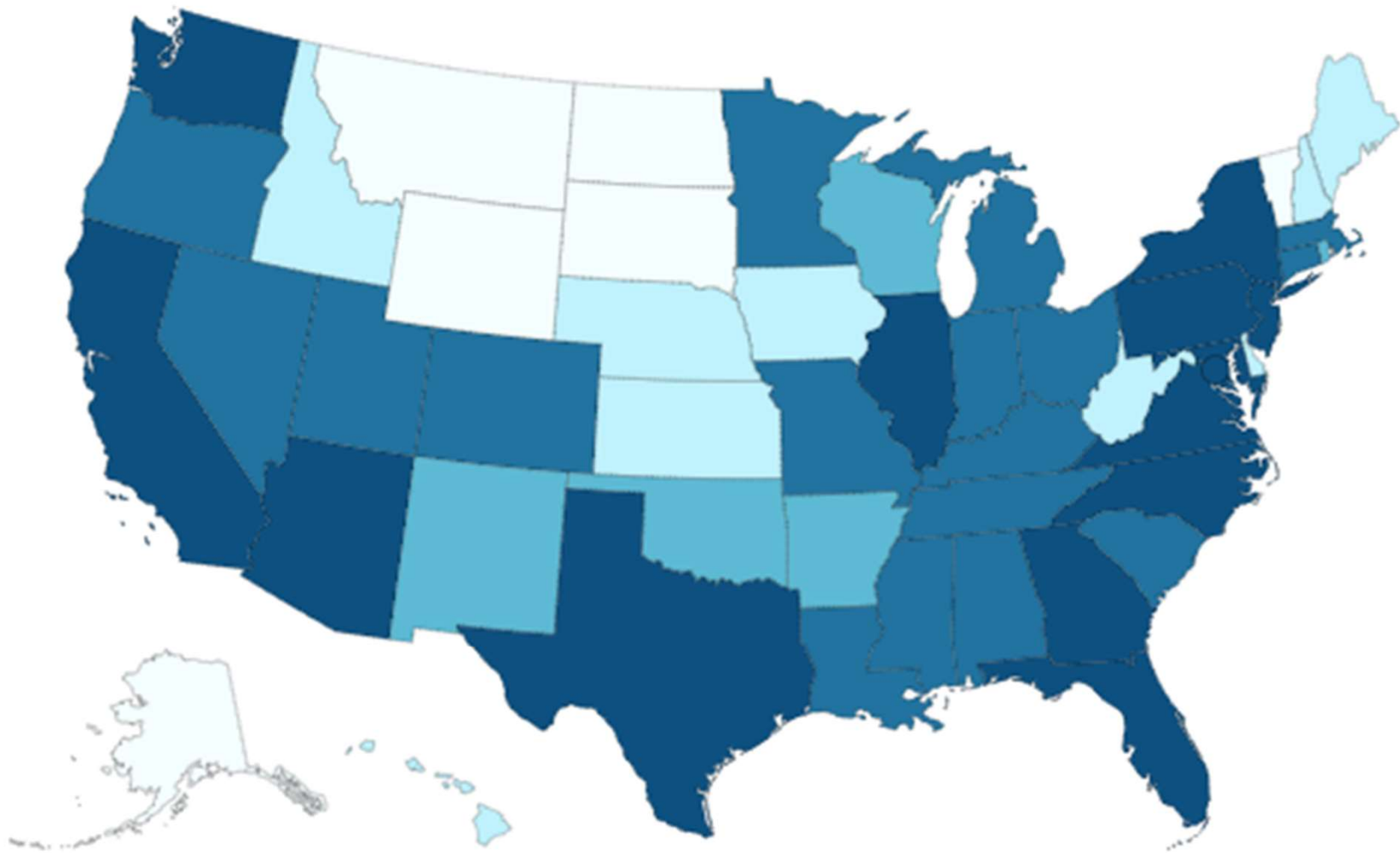
- Orthopox RT PCR+ (presumptive MPOX)
- Patient isolated until symptoms resolution
- No treatment needed

2022 US MPOX Outbreak

Trends of mpox cases reported to CDC during the 2022 outbreak by date*

Daily Mpox Cases and 7 Day Daily Average





- Legend**
- 1 to 10
 - 11 to 50
 - 51 to 100
 - 101 to 500
 - >500

Territories **PR**

Number of MPOX cases by state



MPOX Vaccination

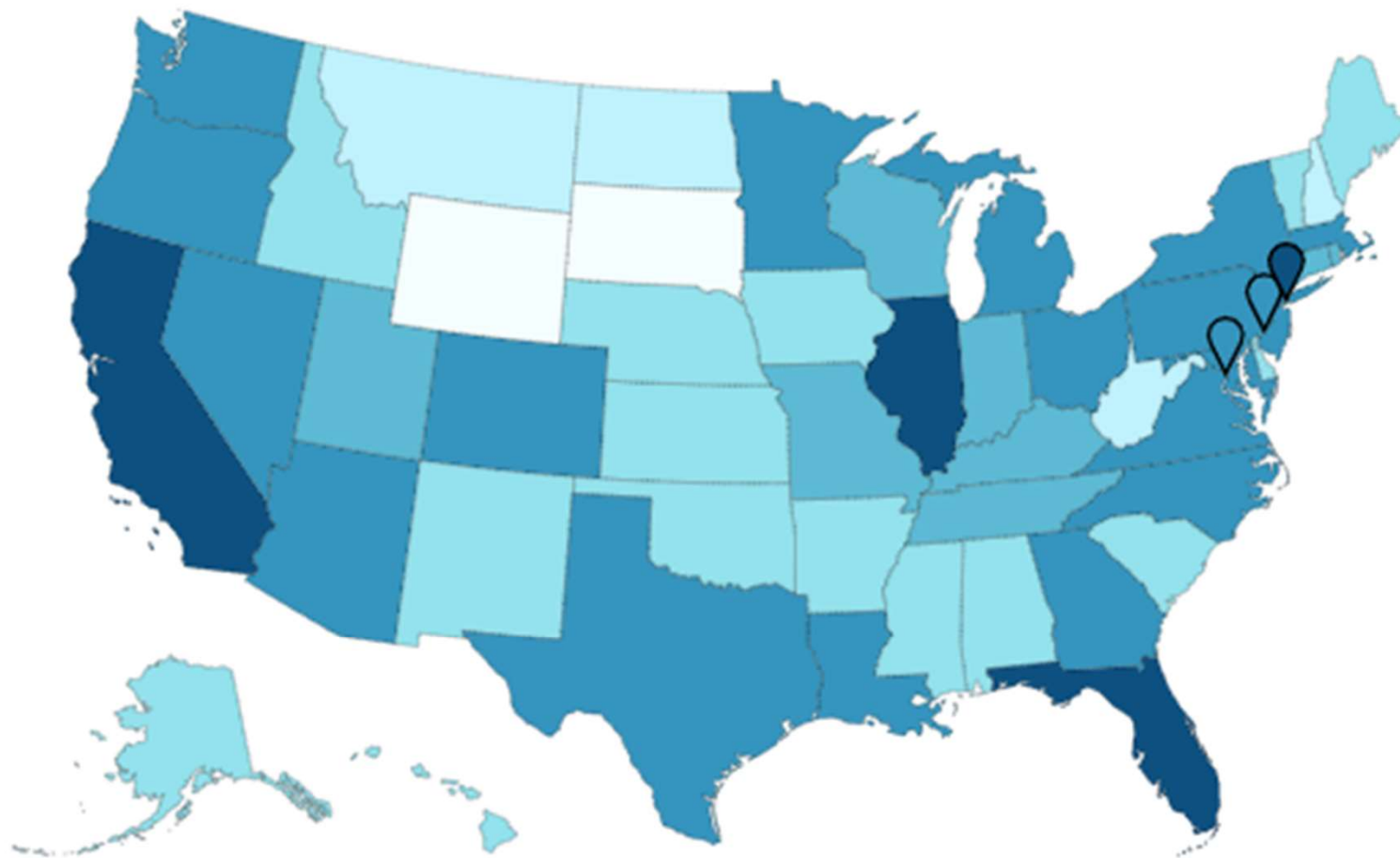
Vaccination available in the national stockpile at time of first cases in the US

CDC recommends vaccination against mpox if:

- Known or suspected exposure to someone with mpox
- Sex partner in the past 2 weeks who was diagnosed with mpox
- Sexual/gender diverse person* with >1 sexual partner OR bacterial STI in past 6 mos
- In the past 6 months:
 - Sex at a commercial sex venue (like a sex club or bathhouse)
 - Sex related to a large commercial event or in a high prevalence geographic area
- Have a sex partner with OR anticipate experiencing *any of the above scenarios*
- You have HIV or other causes of immune suppression and have had recent or anticipate future risk of mpox exposure from any of the above scenarios
- Occupational MPOX exposure (orthopoxvirus lab or HCW responding to mpox)

**gay, bisexual, or other man who has sex with men or a transgender, nonbinary, or gender-diverse person*

Total Vaccine Doses Administered and Reported to CDC



Legend

- 1 to 500
- 1,001 to 5,000
- 5,001 to 10,000
- 10,001 to 50,000
- >50,000

Territories

GU

PR

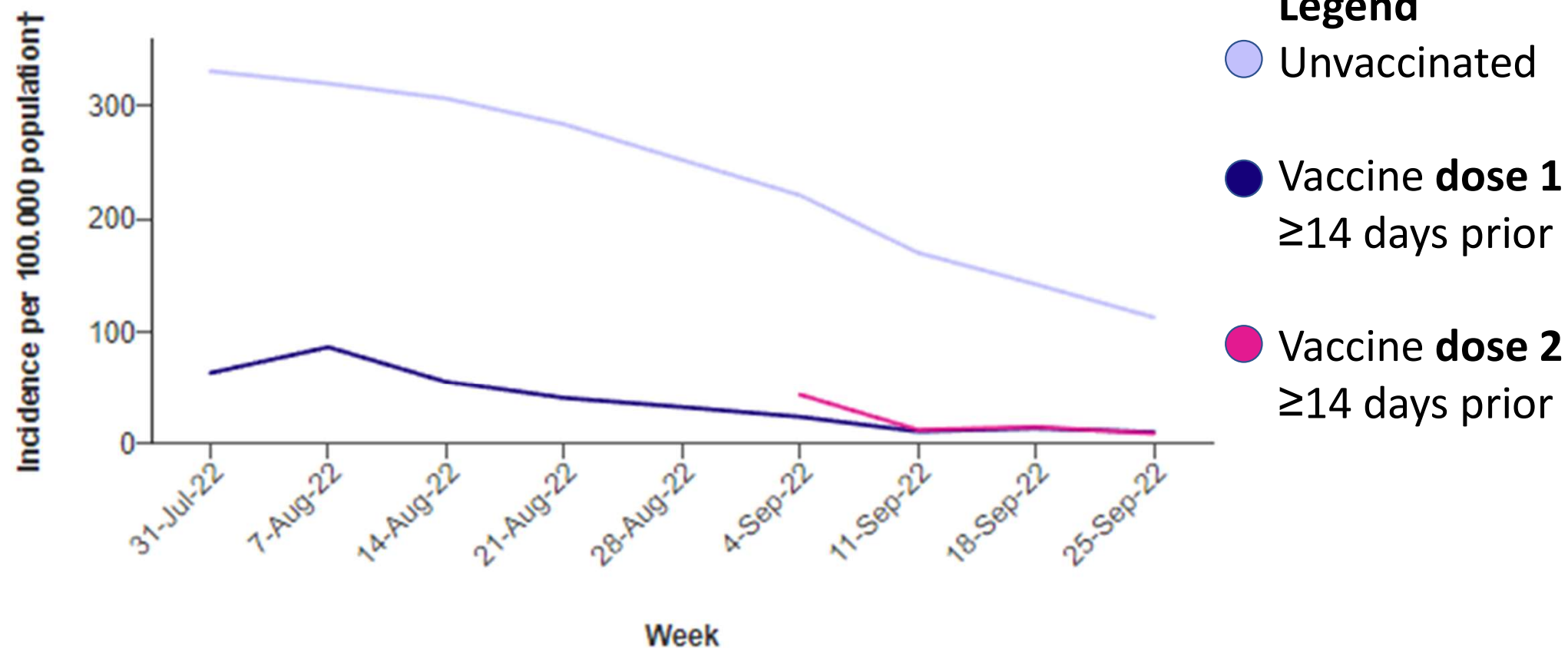
VI

MP



Rates of Mpox Cases by Vaccination Status*

July 31, 2022 – October 1, 2022 (43 U.S. jurisdictions)



Telltale sign he's gay



MPOX Vaccine Reactions



SubQ Upper Arm



Intradermal forearm



Intradermal forearm

Transmission

- Close personal contact; Skin to skin transmission
- Skin lesions highly contagious until all lesions have scabbed and fallen off (~21 days)
- Respiratory droplet transmission exceedingly rare
- Sexual & gender diverse (SGD)* people disproportionately impacted

**gay, bisexual, or other man who has sex with men or a transgender, nonbinary, or gender-diverse person*

MPOX Symptoms

- 1. Skin rash** with several stages, including scabs
 - Diffuse or local
 - Typically itchy, often pain, may affect mucosa
- 2. Prodromal Symptoms:** fever, chills, swollen lymph nodes, exhaustion, muscle aches, backache, headache, respiratory symptoms (e.g., sore throat, nasal congestion, or cough)
 - Onset before, concurrent, or after rash onset
 - May not occur

Exanthem through Scab Stage

Stage	Stage Duration	Characteristics
Enanthem		<ul style="list-style-type: none">• Sometimes, lesions first form on the tongue or mouth.
Macules	1–2 days	<ul style="list-style-type: none">• Macular lesions appear.
Papules	1–2 days	<ul style="list-style-type: none">• Lesions progress from macular (flat) to papular (raised).
Vesicles	1–2 days	<ul style="list-style-type: none">• Lesions then typically become vesicular.
Pustules	5–7 days	<ul style="list-style-type: none">• Lesions then typically become pustular– sharply raised, usually round, and deep seated.• Finally, lesions typically develop umbilication.• Pustules remain ~5-7 days before beginning to crust.
Scabs	7–14 days	<ul style="list-style-type: none">• By end of 2nd week, pustules crust and scab over.• Scabs remain for ~1 week before beginning to fall off.

Examples of MPOX Rashes



(CDC 2023) Photos from CDC, Photo credit: UK Health Security Agency

MPOX Severe Complications

Oral

- dysphagia, odynophagia, anorexia

Rectal

- proctitis, perianal abscess, rectal perforation

Genital

- edema, paraphimosis, phimosis

Supportive Therapy

- Educate patient on disease course to manage expectations and encourage appropriate isolation
- Assist patient in isolation
 - Work excuse, meal delivery, referral to DOH for roommates/family
- Dermatologic care*
- Pain control*
- Control of complications*
- Antiviral therapy for moderate-severe cases*

Caring for the Skin

- Wash skin with mild soap and water
- Baths, warm, cool compresses
- calamine lotion, petroleum jelly, colloidal oatmeal
- Topical anesthesia (ie OTC lidocaine)
- Do not scratch
- Lesions are considered infectious until they have healed
- Keep affected sites and individual lesions covered
- Antibiotic ointment only for additional bacterial infection
- Scarring: apply SPF; consider silicone topicals

Pain Management

- OTC acetaminophen & NSAIDs
- Topical steroids, anesthetics, calamine lotion, petroleum jelly, colloidal oatmeal (gloved application)
- Oral histamines for itch
- Gabapentin (300mg+ 3x daily) for pain
- **Opioids** (*balance against the risk of side effects such as constipation and other risks such as potential for unintended long-term use of opioids, development of an opioid use disorder, and overdose*)

Anorectal Symptoms Management

- Gabapentin oral 300mg 3x/day
- 2.5% lidocaine/2.5% prilocaine (Rx) **OR** Recticare 5% (OTC)
- Mesalamine suppositories
- Colace/fiber supplementation (esp psyllium husk + hydration)
- Sitz baths (warm water 20-30 min)
- Oral analgesia (NSAIDS, opioid if uncontrollable)

Antiviral Treatments: Tecovirimat (TPOXX)

- CDC expanded access IND for Tecovirimat (TPOXX, ST-246)
- Oral or injection
- Indications for moderate to severe disease and specific populations
 - Severe disease: hemorrhagic, large confluent lesions, necrotic, necrotizing or obstructive lymphadenopathy, secondary bacterial infection
 - Involved organ systems: pulmonary involvement with nodular lesions; sepsis; encephalitis; myocarditis; ocular or periorbital infections
 - Severe pharynx, genital, anorectal disease at risk for complication
 - Immune suppression (incl. uncontrolled HIV)
 - Pediatric, esp <1 yo
 - Pregnant or chest/breastfeeding
 - Concurrent severe dermatitis (ie HSV, severe psoriasis)

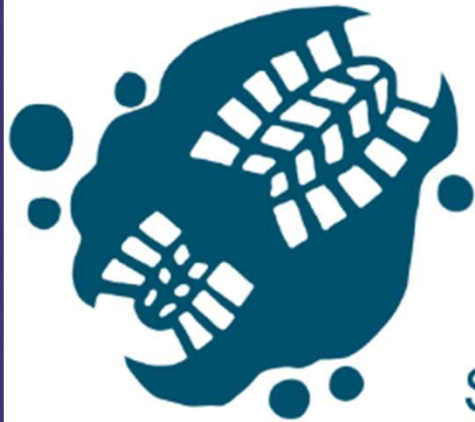
TPOXX Pearls

- Generally coordinated through local/state Department of Health
- Requires informed consent (investigational drug)
- Significant improvement often noted within 24 hours
- Must be taken with a fatty, high calorie meal
- When possible, coordinate with local Stomp Clinical Trial site***

Other Antiviral Treatment

- Brincidofovir (CMX001 or Tembexa)
 - Cidofovir prodrug, FDA-authorized single-patient emergency use IND (e-IND)
 - Severe disease/high risk for progression to severe disease, AND
 - Worsening or recrudescence disease while receiving tecovirimat OR otherwise unable to use oral/IV tecovirimat
- Vaccinia Immune Globin IV (VIGIV)
 - Expanded access IND protocol
 - To request VIGIV, clinicians can contact the CDC Clinical Consultation Team by email (eocevent482@cdc.gov) during business hours, or for urgent clinical situations, contact the CDC Emergency Operations Center (770-488-7100)
- Cidofovir (Vistide)
 - Serious renal toxicity; brincidofovir has a better safety profile

Call Center: 1-855-876-9997 (U.S. only)



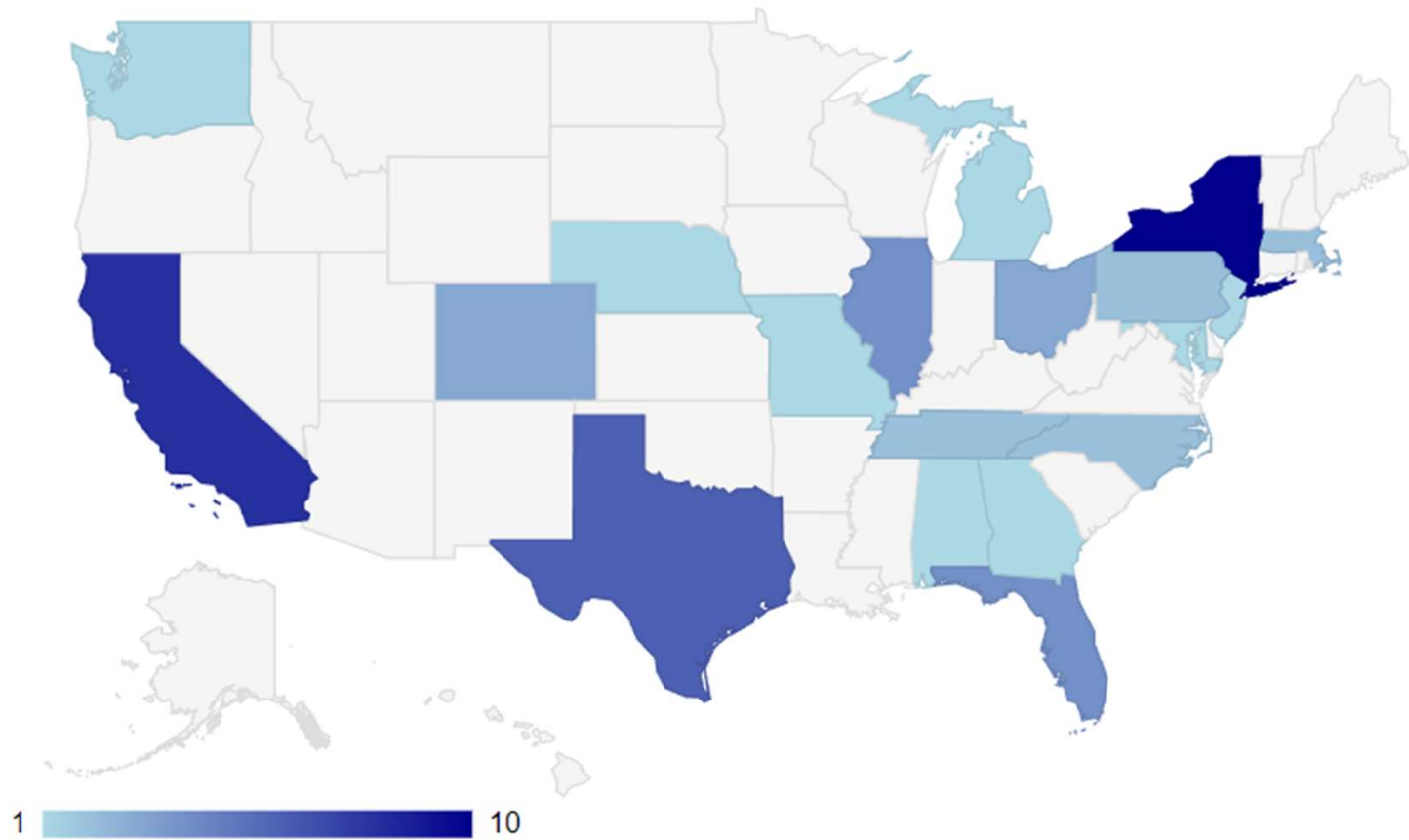
STOMP

Study of Tecovirimat for Human Monkeypox Virus

STOMP About the Study

Participating Research Sites

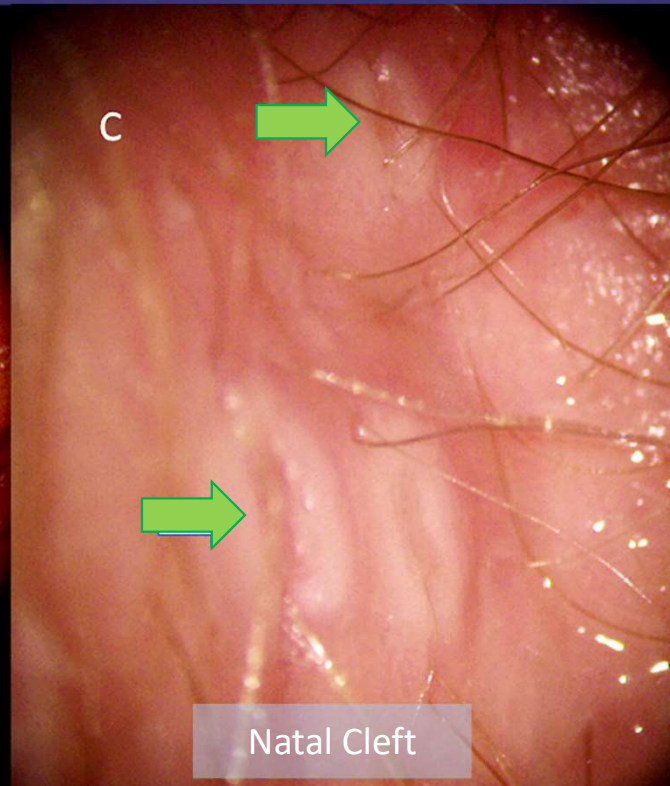
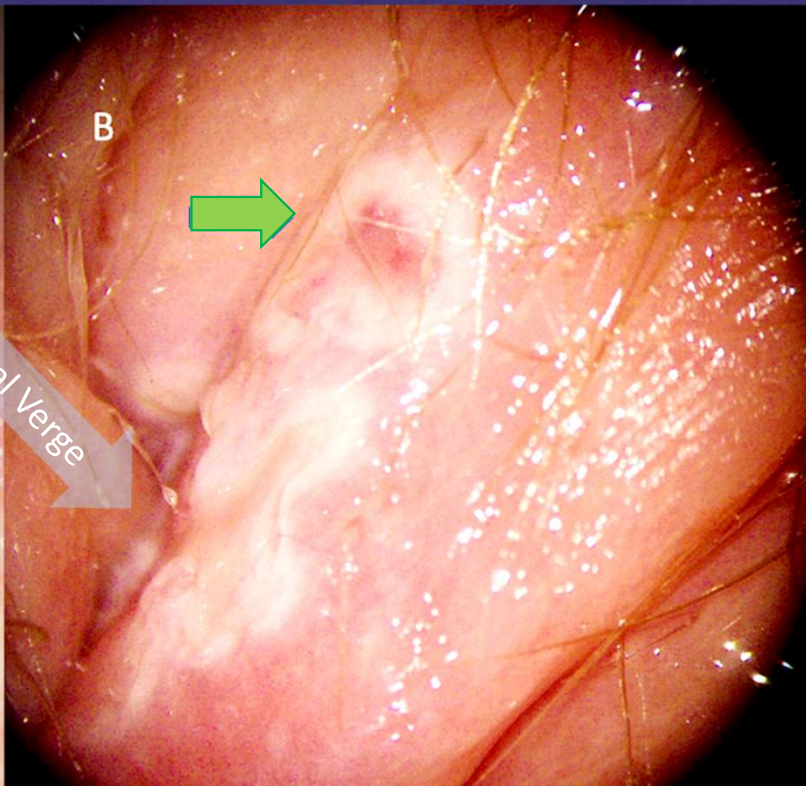
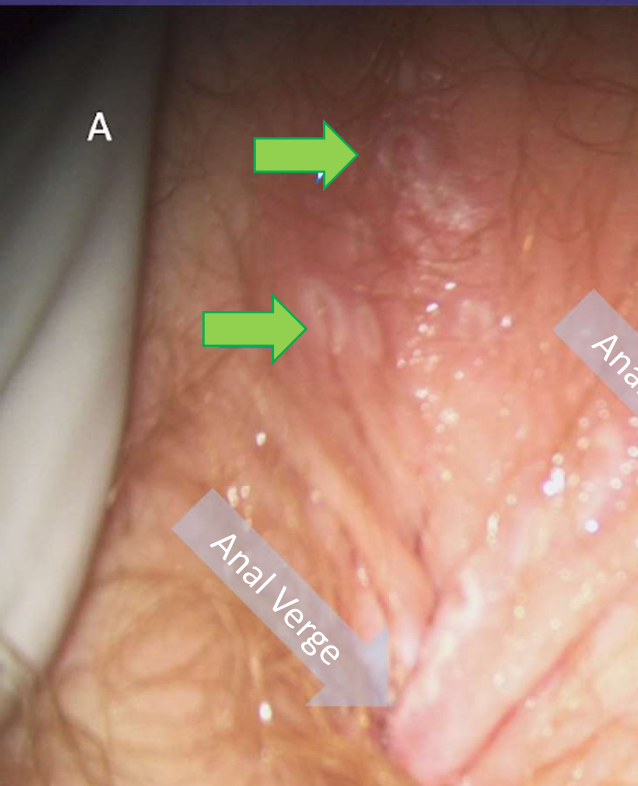
Clinical Research Sites are located in the following states:



Cases

“Painful Hemorrhoid”

- 54 yo MSM LWH (CD4 WNL; UVL)
- No prior smallpox/MPXV vaccination
- 1 week of anal pain that was preceded by subjective fevers, fatigue, and mild gastrointestinal distress
 - Anal itch → sharp, intense pain + mucoid discharge, BRB with BM
- He denied recent travel but had an anonymous sexual partner just prior to symptom onset



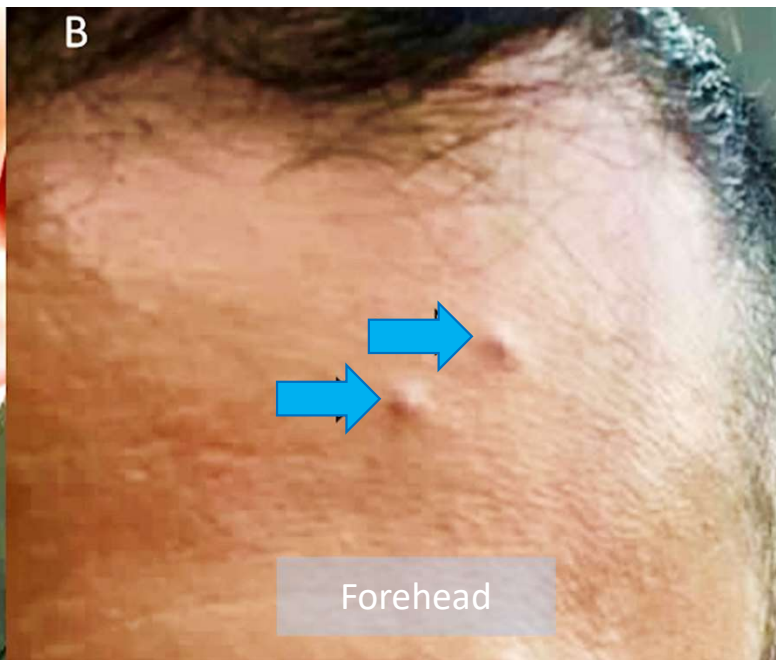
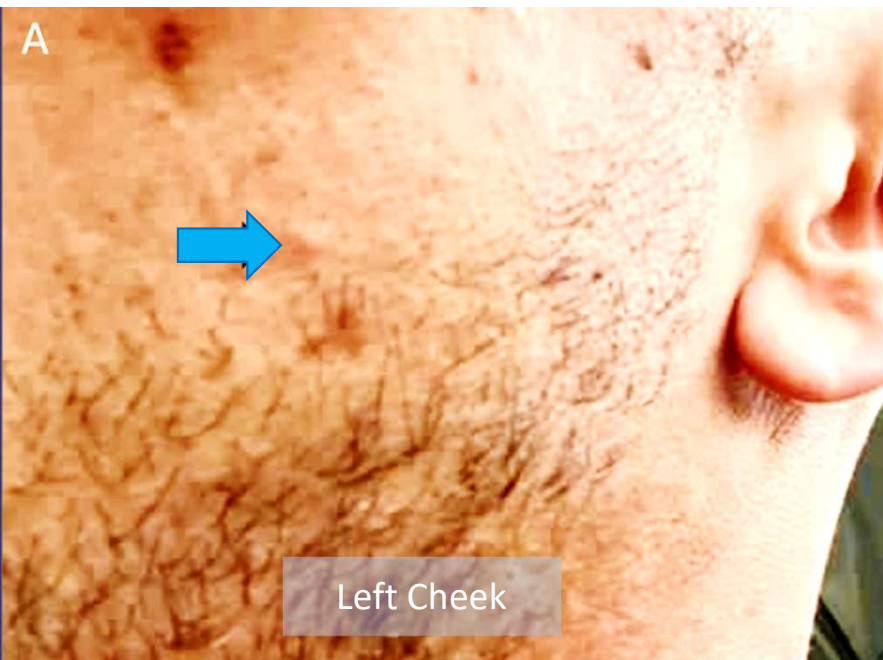
Case Disposition

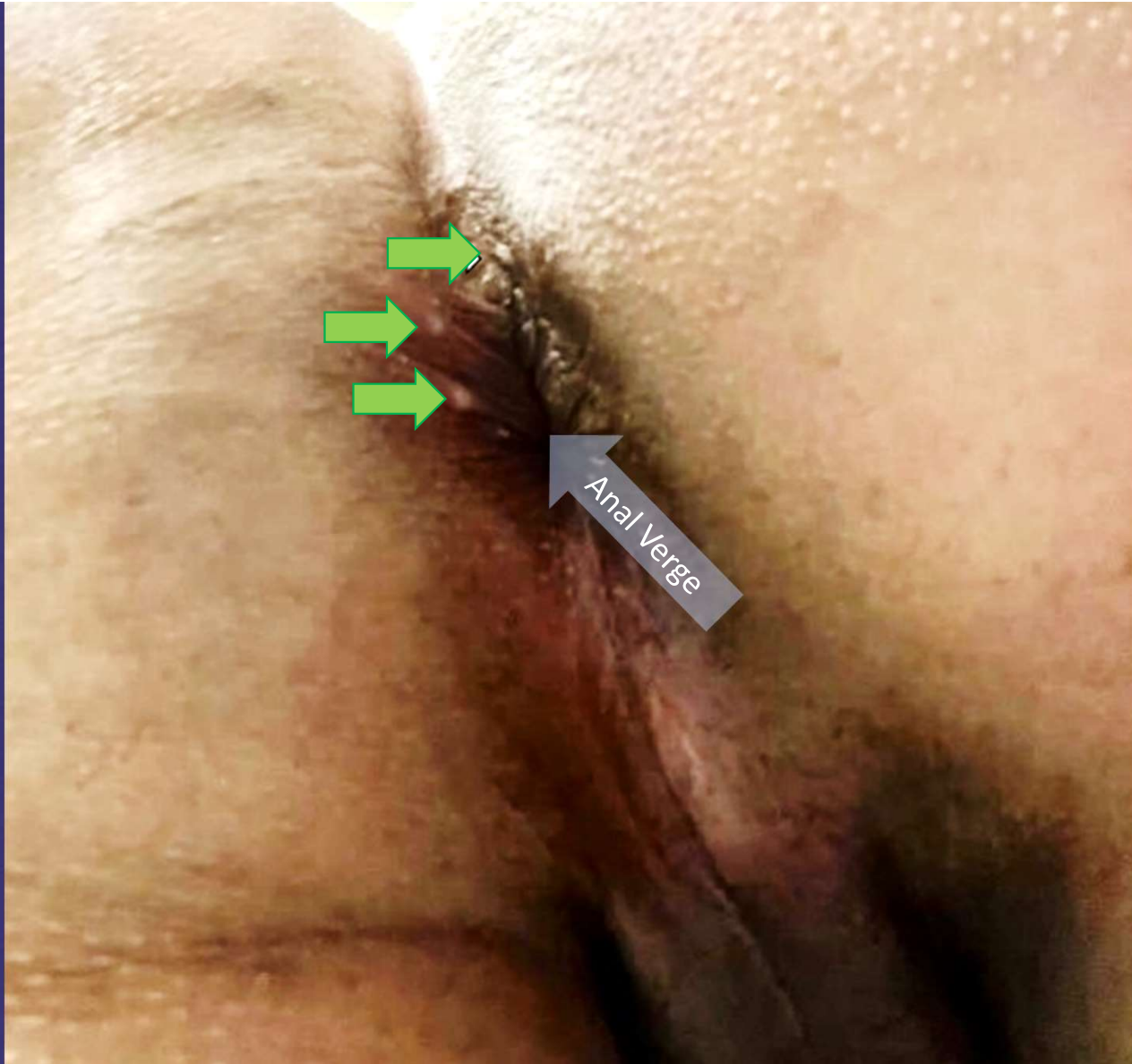
- **Non-variola orthopox RT PCR reactive**
 - Nonreactive gc/Ct, syphilis serology, HSV1/2 DNA PCR
- Treatment plan: TPOXX, sitzbaths, gabapentin, ibuprofen, oxycodone/acetaminophen, and isolation
- External hemorrhoidal tags and hyperpigmentation at the site of the healed lesions at 1 month follow up

“Red Pimples Everywhere”

- 44 yo on daily F/TAF PrEP
- Smallpox vaccination in childhood
- Recent travel to Berlin & new sexual partners
- Reports “breaking out all over my body” with “red pimples everywhere”
- Papular rash on his face → back, torso → perianal anal area (painful)
- 2 days after the rash: stiff neck, severe headaches, dizziness and fatigue x 4d





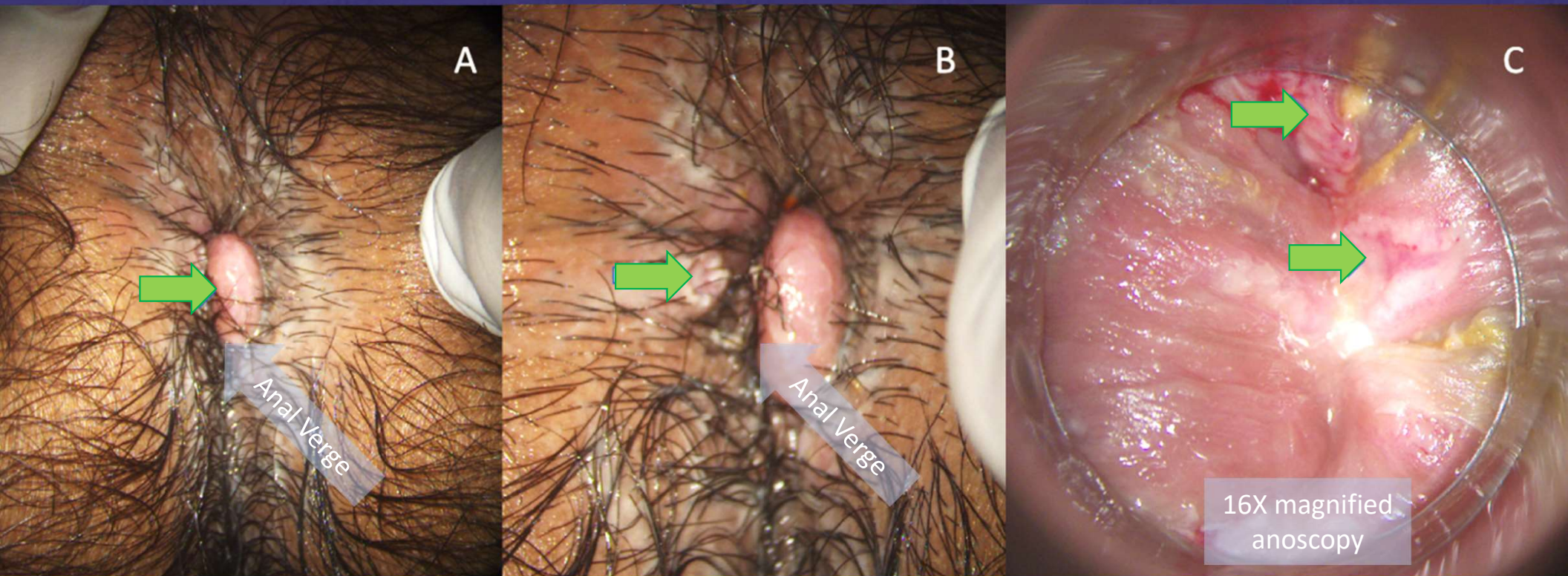


Case Disposition

- Supportive therapy
- The patient required no antiviral treatment and isolated until symptoms resolution
- Full recovery and has no scarring from the skin lesions

“Like there is Broken Glass in the Rectum”

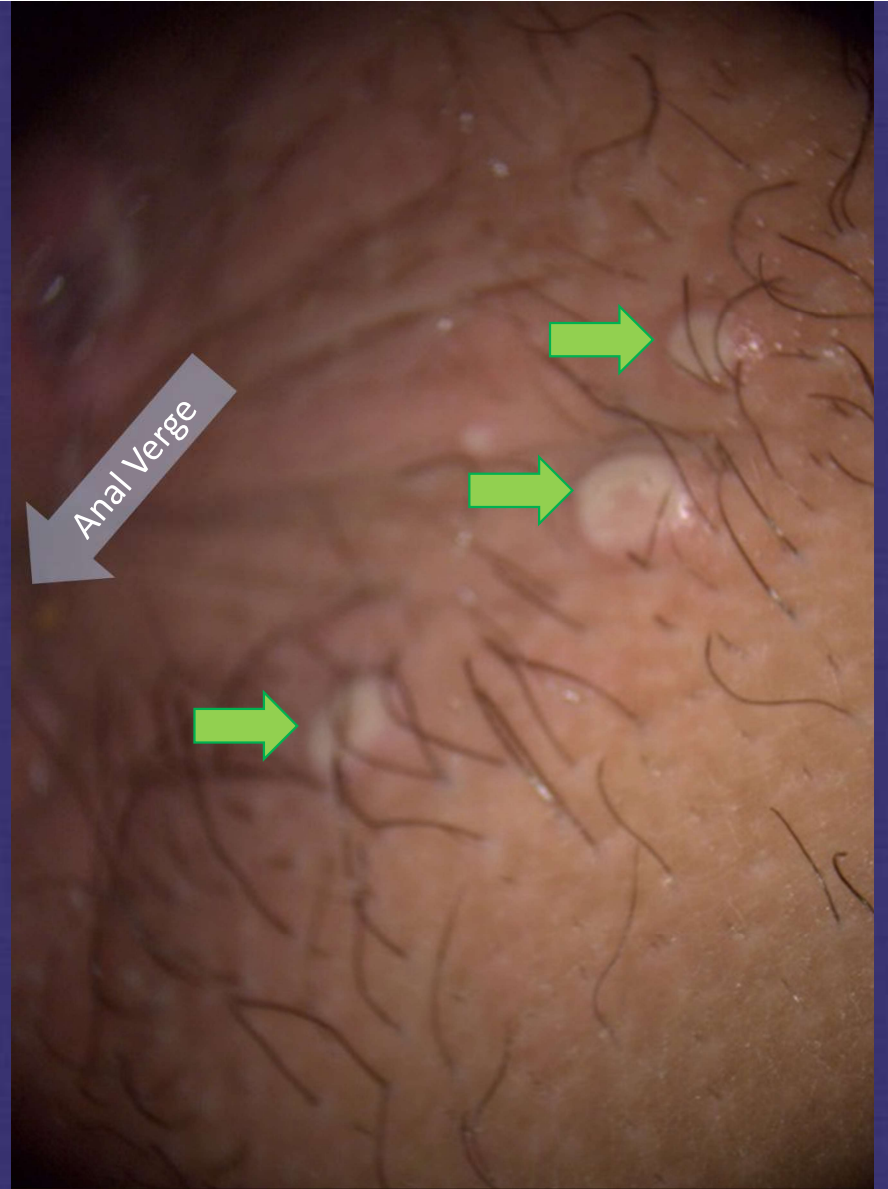
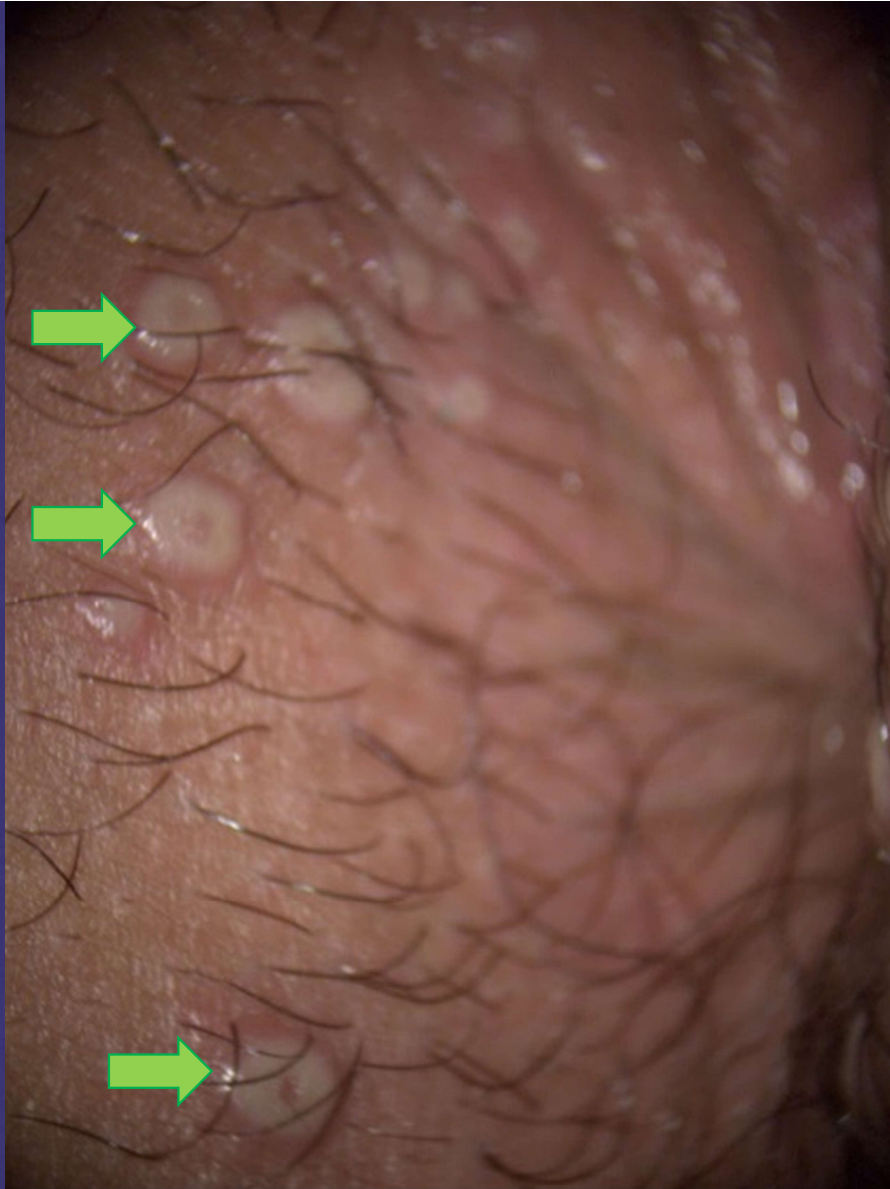
- 34 on daily F/TDF PrEP
- Smallpox vaccination in childhood; JYNNEOS 2 weeks prior to presentation
- 4 days of excruciating, burning anal pain
 - Subjective fever and chills 2 days after anal pain onset
 - No relief with oxycodone (from UC)



- A & B. Inflamed skin tag with superficial ulceration at the anal verge. The perianal skin is covered in a thick, whitish exudate.
- C. Scattered ulcerations on the internal anal mucosa.

“I Didn’t Take the Valtrex”

- 27 yo on F/TDF daily oral PrEP
- Condomless RAI **4 weeks** prior to onset of symptoms
- No smallpox/MPXV vaccination history
- Concurrent nights sweats, anal pain, and anal bumps x 5 days
- Attended ED 3 days prior; diagnosed with HSV

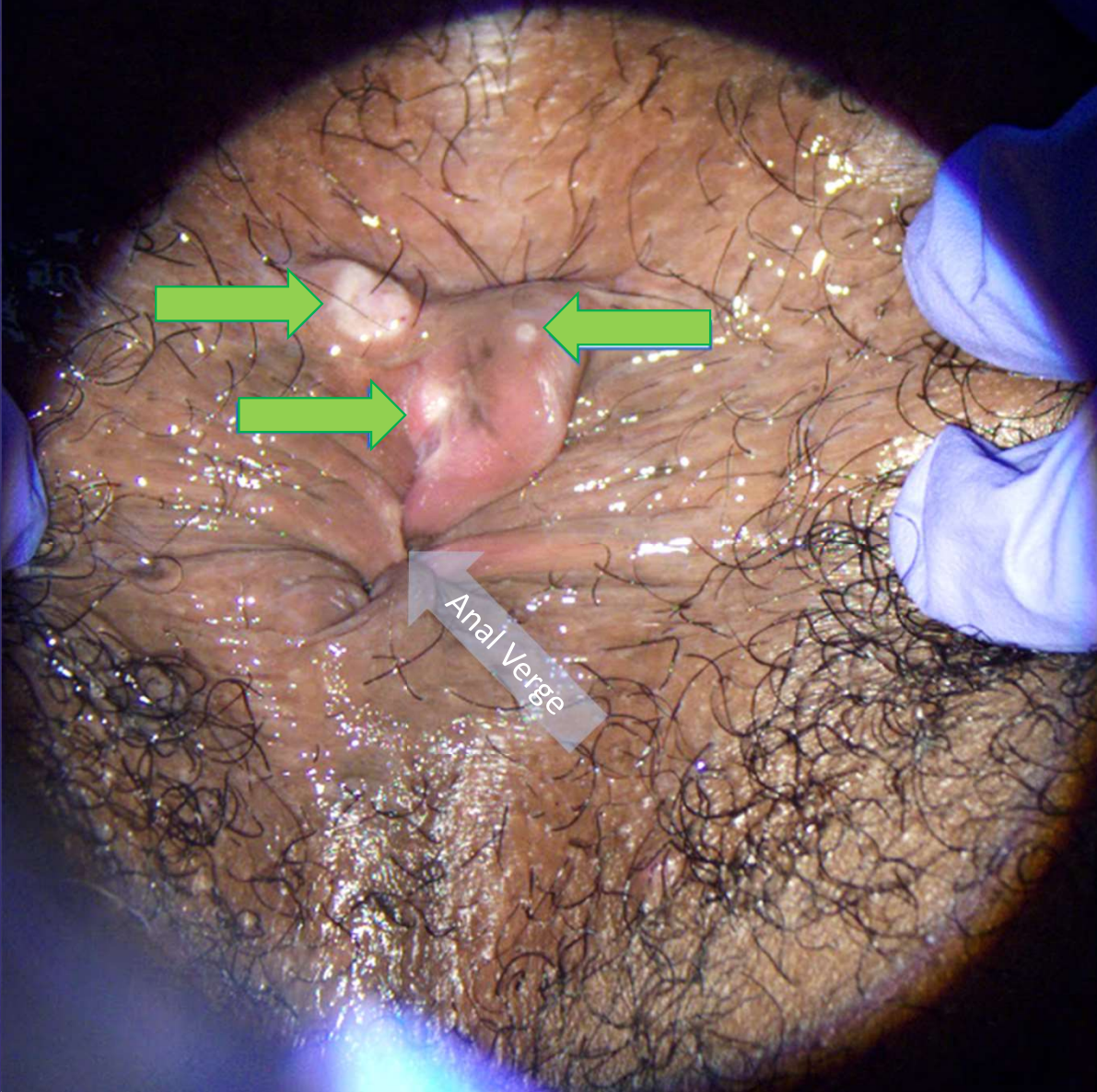


Case Disposition

- **Non-variola orthopox RT PCR reactive**
 - Nonreactive HSV1/2 DNA PCR, gc/Ct, syphilis serology
- Treatment plan: TPOXX, sitzbaths, gabapentin, ibuprofen, topical lidocaine, and isolation
- Full resolution with no lesions noted on follow up

“What is Happening to Me?”

- 30 yo, no PMHx presents severely anxious
- JYNNEOS 2 doses several months prior to presentation
- Painful anal nodules, intense anal itch, tenesmus, and bright red blood with BM x 4 days
- Subjective fevers, chills the day lesions appeared
- No travel Hx; condomless receptive anal intercourse 2 weeks prior



Anal Verge

Case Disposition

- Started on valacyclovir 1g 2x/day x 1 days and supportive therapy
- HSV PCR NR the following day
- **Non-variola orthopox RT PCR reactive**
- Seen same day at local STOMP site

What Do These Cases Have in Common?

- ~~HIV status/PrEP~~
- ~~Severity of disease~~
- ~~Type of sexual exposure~~
- ~~Time since sexual exposure~~
- ~~Travel history~~
- ~~STI history, concomitant STI~~
- ~~Prodromal Sx before, after, at all?~~
- ~~Local vs diffuse skin lesions~~
- ~~Race/ethnicity~~
- ~~Smallpox/MPXV vaccination status~~

MPOX Pearls From the Front Line

- Examine the patient, including anogenital
- Expect ulcerations in areas of increased friction
- Assume internal lesions if symptomatic especially if visible lesions are present
- Have a high index of suspicion
- Don't let patients talk you out of it
- Don't rely on prior diagnosis- evolving disease
- TPOXX is indicated in *many* anorectal cases
- Post inflammatory conditions common (ie fissure, tags)

Future of MPOX

- Uncommon infection often transmitted through sexual contact
- Pediatric/school transmission of high concern
- Ongoing recommendation for vaccination for at-risk populations
- Likely clusters in unvaccinated geographies/social circles

5/20 10:30	Preventive or Primary Care for Transgender or Gender-diverse Patients	Room TBD
5/20 2:15	Gender-Affirming Hormone Therapy for Adults: Initiation, Monitoring, and Management	Room TBD
5/22 8:00	Healthcare of Gay Men, Men Who Have Sex with Men, and People Who Engage in Anal Sex	Room TBD
5/22 9:15	Gender-affirming Surgery: Culturally Competent Care for the Transgender Patient in the Primary Care Setting	Room TBD
5/22 10:30	Update on Sexual Transmitted Infections (STIs): Advanced and Interesting Cases	Room TBD
5/22 1:00	Prescribing HIV Prevention: Preexposure Prophylaxis (PrEP)	Room TBD
5/23 9:15	Gender-affirming Surgeries: Procedure, Complications, and Long Term Care	Room TBD
5/23 10:30	Sexual Health: How to Ask, How to Help	Room TBD
5/23 1:00	HPV: When It's Silent and When It's Seen	Room TBD
5/23 3:30	Monkeypox in the US	Room TBD

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