MPOX

Mpox 101: What Clinicians Need to Know



Source material for each slide is listed in the reference section at the end of this presentation by slide number. Unnumbered references refer to the whole slide.

Table of Contents

•	Background	4
•	Epidemiology	13
•	2022 Mpox Outbreak	18
•	Evaluation and Diagnosis for Current Outbreak	26
•	Differential Diagnosis	36
•	Mpox and Mpox Look-Alikes	40
•	Treatment	55
•	Mpox Vaccination	67
•	Vaccination Prior to Exposure	78
•	Post-Exposure Prophylaxis (PEP) and Monitoring	82
•	Infection Control, Isolation, and Monitoring	92
•	References	101

Background

Mpox Virus

Genus: Orthopoxvirus

• Family: *Poxviridae*

- Discovered in 1958 after two pox-like disease outbreaks in research monkey colonies
- Specific animal reservoir unknown, but likely small African mammals
- On November 28, 2022, the World Health Organization implemented a new preferred term "mpox" to reduce racist and stigmatizing language and <u>other issues associated</u> with the prior terminology

Other notable *Orthopoxviridae*

- Variola virus (smallpox agent)
- Vaccinia virus (used in the smallpox vaccine)
- Cowpox virus

Historical Clinical Manifestations (1/2)

- Incubation period: 3–17 days¹
- Illness duration: 2–4 weeks²
- Development of initial symptoms marks beginning of prodromal period
 - Fever
 - Malaise
 - Headache
 - Weakness
- Febrile prodrome lasts 1–4 days
- Lymphadenopathy: generalized or localized to several areas (e.g., neck and armpit)

Historical Clinical Manifestations (2/2)

- Rash appears shortly after prodrome
 - Lesions develop anywhere on the body but most commonly on the face and extremities, including palms and soles
 - Clusters of lesions in one area begin simultaneously and evolve together
 - Lesion evolution



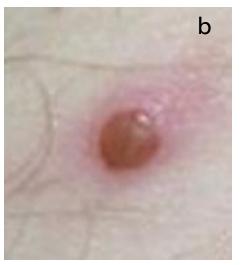
- Lesions are
 - Well circumscribed, deep seated, and often umbilicated
 - Often painful, then become pruritic during the healing phase

Classic Rash Presentation

Mpox lesions are typically **firm** because they arise from deep in the dermis







Lesions seen in the 2003 U.S. mpox outbreak





Lesions seen in endemic countries

Patients at Risk for Severe Mpox

- People with:
 - Underlying medical conditions
 - Inadequately treated HIV (CD4+ counts < 350 cells/mm3)
 - Moderate or severe primary immunodeficiency
 - Immunosuppression (e.g., organ transplant, therapy for autoimmune disorder, chemotherapy)
 - Lesions on certain surfaces (e.g., penile foreskin, urethral meatus, or vulva)
 - History of atopic dermatitis, eczema, or extensive breaks in the dermal barrier

Mpox Complications: Ocular

 Ocular mpox can cause conjunctivitis, blepharitis, keratitis, corneal ulcer, corneal scarring, and loss of vision







Photo Credits: Roddy Frankel, MD, PhD; Cynthia Pi, MD; Osasu Adah, MD; Rocio Bentivegna, MD; Ophthalmology Department, St. Louis University

Mpox Complications: Severe Lesions

- Mucosal lesions may appear as painful ulcers in the oral, genital, and/or perianal areas and result in
 - Inability/difficulty to eat, urinate, and/or defecate due to pain and/or development of strictures
 - Myonecrosis and/or secondary infection if ulcers penetrate deep tissue
- Skin lesions may
 - Become confluent or necrotic
 - Require specialized wound care/transfer to burn unit depending on body area or total body surface area





Photo credits: CDC

Mpox Complications: Other

- Neurologic complications may include encephalitis and/or myelitis
- Myopericarditis may present as chest pain/discomfort, shortness of breath, or palpitations
- Obstructions (most often in the lungs or gastrointestinal tract) secondary to
 - Ulcer-related strictures
 - Severe lymphadenopathy
 - Edema of surrounding tissue
- Sepsis/hemorrhagic disease

Epidemiology

Up-to-Date CDC Situation Summary

- US Map & Case Count¹
- US Case Trends²
- Global Map & Case Count³
- Case Demographics⁴
- Vaccine Administration and Effectiveness⁵
- Laboratory Testing⁶
- Multi-National Mpox Outbreak Technical Reports⁷

Transmission

- Mode: Direct or indirect contact with body fluids or lesion materials¹
- Risk of infection through contact with contaminated surfaces or objects is considered low²
- Transmission during brief interactions or between people in close proximity and for a long duration (such as passengers seated near a person with mpox on an airplane) is unlikely³
- How often mpox virus is spread via respiratory secretions is unknown³
- Patients may be infectious up to 4 days before symptom onset¹
- Patients remain infectious until lesions form scabs, scabs fall off, and a fresh layer of skin forms⁴

High Risk Exposure Examples for Health Care Providers (HCPs)

- Unprotected contact between an individual with broken skin or mucous membranes and an mpox patient's:
 - -Skin lesions —Bodily Fluids —Soiled Linens
- Injury from sharp object that has had contact with skin lesions or bodily fluids of an mpox patient
- Being within 6 feet of a mpox patient without appropriate personal protective equipment (PPE; NIOSH approved N95 respirator or higher-level) during procedures which may:
 - Generate aerosols, such as intubation or CPR
 - Resuspend dried contaminates, such as shaking/changing soiled linens

Intermediate Risk Exposure Examples for HCPs

- Being within 6 feet of an unmasked patient with mpox for ≥ 3 hours without wearing appropriate PPE
- Having unprotected contact between an individual with intact skin and mucous membranes and an mpox patient's:
 - -Skin lesions

- -Soiled Linens
- -Bodily Fluids
- Performing activities that result in contact with an mpox patient's body fluids or soiled material without appropriate PPE
 - - Turning Bathing
- Assisting with a transfer

2022 Mpox Outbreak

2022 Mpox Outbreak Signs and Symptoms

- During this outbreak, mpox may present atypically
 - Characteristic rash present but often starts in mucosal areas
 - Genital
 - Perianal
 - o Oral
 - Skin lesions are scattered or localized to a specific body site but not disseminated



Rash Presentations (1/2)



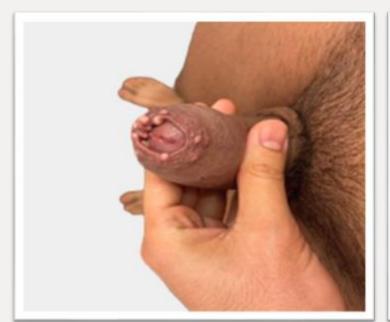
Photo Credits: a-c) Basgoz et al.1; d-f) CDC; g) Miller MJ et al.2

Rash Presentations (2/2)



Photo Credits: a-f) UK Health Security Agency, g) CDC

Genital Lesions (1/2)



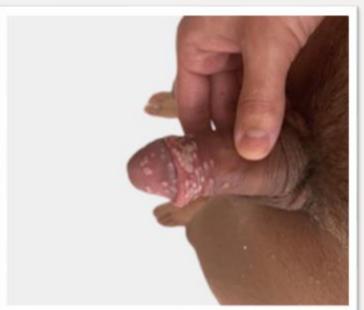


Photo Credits: DC Health and Wellness Center

Genital Lesions (2/2)





Photo Credits: a) Photo appears in Basgoz et al., b) DC Health and Wellness Center

Perianal Lesions



Photo Credit: DC Health and Wellness Center

Current U.S. Outbreak Response

- Surveillance
 - Case identification
 - Most cases have been identified in immunocompetent men who are gay, bisexual, and other men who have sex with men
 - Laboratory testing
- Containment
 - Isolation of cases
 - Contact tracing
- Mpox vaccine prior to exposure or as postexposure prophylaxis



Evaluation and Diagnosis for Current Outbreak

Clinical Recognition

- Clinicians seeing outpatients may be first to encounter patients with mpox
- Comprehensive patient social and sexual histories (including attendance at social gatherings) and physical examination are essential
 - Patients may have mild symptoms
 - Mpox may present similarly to sexually transmitted infections (STIs) or varicella zoster
 - Patients being evaluated for mpox should be tested for HIV and other STIs
- Notify the health department of suspected, probable, and confirmed mpox cases for
 - Case reporting
 - Help with laboratory testing

History of Present Illness

- Mild or absent prodromal symptoms
- Presenting symptoms may be consistent with proctitis and include
 - Anorectal pain
 - Tenesmus
 - Pruritis
- Presenting signs
 - Perianal vesicular, pustular, or ulcerative skin lesions
 - Rectal bleeding

Social History

- Sexual history
 - Gender and number of sex partners
 - History of HIV and other STIs
 - Engagement in sex work or sex trades
 - Sex associated with commercial sex venues, sex parties, group sex, etc.
- Living situation: congregate setting or homelessness
- Within 21 days of illness onset
 - Travel to a country with mpox (endemic or recently reported non-endemic)
 - Contact with an African-endemic wild animal or exotic pet (dead or live) or derivative products

Physical Examination

- Should be complete and include a thorough skin and mucosal (e.g., oral, genital, anal) examination in a well-lit room
 - Persons presenting with genital/perianal complaints may have clues in other bodily areas
- 2022 outbreak lesion characteristics:
 - Often scattered or localized, rather than diffuse
 - Often do not involve face or extremities
 - Typically of similar size and stage
 - May be painful, but painless lesions have been described

Case Definition

Suspect Case

- New characteristic rash OR
- Meets one of the epidemiologic criteria and has a high clinical suspicion for mpox

Probable Case

- Absence of recent orthopoxvirus exposure (e.g., vaccinia virus from ACAM2000 or JYNNEOS vaccination)
- Demonstrated presence of
 - Orthopoxvirus DNA by polymerase chain reaction testing of a clinical specimen OR
 - Orthopoxvirus using immunohistochemical or electron microscopy testing methods OR
 - Detectable levels of anti-orthopoxvirus IgM antibody during the period of 4 to 56 days after rash onset

Confirmed Case

- Demonstrated
 presence of mpox
 virus DNA by
 polymerase chain
 reaction testing or
 Next-Generation
 sequencing of a clinical
 specimen OR
- Isolation of mpox
 virus in culture from a clinical specimen

Epidemiologic Criteria

Had contact with a person(s) with a similar-appearing rash or who were diagnosed with confirmed or probable mpox **OR**

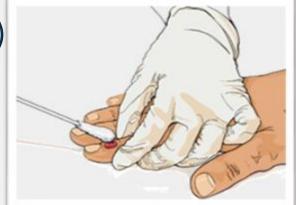
Had close or intimate in-person contact with individuals in a social network experiencing mpox activity; this includes men who have sex with men (MSM) who meet partners through online websites, digital applications ("apps"), or social events (e.g., a bar or party) **OR**

Traveled to a country with endemic mpox or reported non-endemic mpox OR

Had contact with an African-endemic wild animal or exotic pet (dead or live) or derivative products (e.g., game meat, creams, lotions, powders)

CDC-Issued Specimen Collection Guidelines

- Wear recommended personal protective equipment (PPE)¹
- Depending on the phase of the rash, use different procedures and materials to collect specimens²
- Do not unroof or aspirate lesions (or use sharp instruments for mpox testing) due to the risk for sharps injury³
- In severe cases, the CDC Infection
 Diseases Pathology Branch can assist
 when a biopsy is performed⁴



Testing for Mpox

- Skin lesion material is the recommended mpox virus specimen for initial laboratory testing¹ at either:
 - Commercial laboratories
 - At a facility within the <u>Laboratory Response Network</u>²
- Contact the appropriate <u>public health department</u>³ or commercial laboratory to determine criteria for acceptable specimens, as this may vary
- There is a specific protocol for <u>submitting specimens to the CDC</u>,⁴ which may differ from that of local health departments
- High clinical suspicion is sufficient to initiate treatment

Additional Diagnostic Considerations¹

- Patients with rashes characteristic of more common infections (e.g., varicella zoster or STIs) should be evaluated for mpox
 - Diagnosis of an STI does not exclude mpox, as mpox infection may be concurrent
- Consider submitting lesion specimens, especially if epidemiologic risk factors for mpox are present
- Evaluate any individual presenting with genital, anal, or perianal ulcers; proctitis syndrome; or diffuse rash for STIs per the <u>2021 CDC STI Treatment</u> <u>Guidelines</u>²

Differential Diagnosis

Other Genital Ulcer Diseases

Infectious

- Herpes simplex virus (genital herpes)
- Primary or secondary syphilis
- Chancroid
- Lymphogranuloma venereum (LGV)
- Granuloma inguinale
- Molluscum contagiosum

Noninfectious

- Recurrent aphthous stomatitis
- Behçet's disease
- Trauma
- Squamous cell carcinoma
- Drug-induced
- Other

Clinicians should be aware that patients may have concurrent infections.

Genital Ulcer Disease Diagnostic Evaluation

- Syphilis serology tests
- Darkfield examination (or nucleic acid amplification test [NAAT], if available)
 from lesion exudate or tissue
- NAAT* or culture for genital herpes type 1 and 2
- Serologic testing for type-specific HSV antibody

Other Infections Causing Rash or Proctitis

Diffuse Rash

- Syphilis
- Herpes zoster
- Disseminated varicella zoster
- Disseminated herpes
- Molluscum contagiosum/other poxviruses

- Disseminated fungal infections
- Disseminated gonococcal infection
- Scabies
- Hand, foot, and mouth disease

Proctitis

Gonorrhea

Chlamydia (including LGV)

HSV

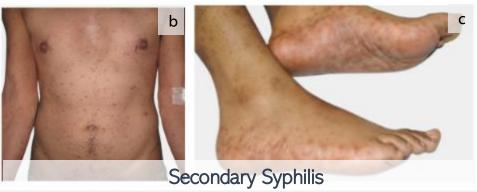
Mpox and Mpox Look-Alikes

Macular/Papular Rashes: Mpox

- Early stage mpox can be macular
- Lesions are regional (anogenital, thighs, buttocks) or localized to a specific site but not disseminated
- 2022 outbreak rash often excludes palms and soles (unlike endemic mpox)







Macular/Papular Rashes: Secondary Syphilis

- Maculopapular rash is typically diffuse, symmetric, an involving trunk and extremities; includes palms and soles
- Localized, possibly scaly lesions may also occur
- May be pruritic



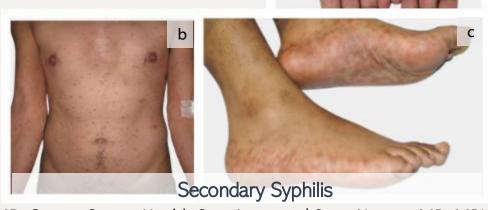
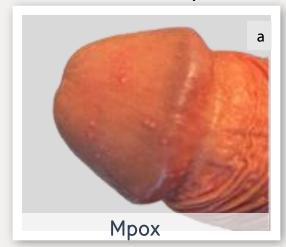


Photo Credits: a) CDC; b) Christopher Ried, MD, Orange County Health Care Agency; c) Scott Norton, MD, MPH; d) Public Health Image Library #3508

Vesicular Rash: Mpox

- Solitary vesicles are regionally distributed
- May or may not be painful
- Initially, vesicles are small with no central umbilication
- Often the first presenting symptom in the 2022 outbreak



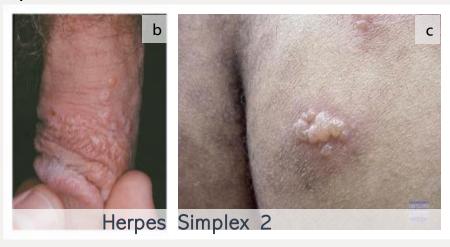


Photo credits: a) DC Health and Wellness Center; b) Scott Norton, MD, MPH; c) Cincinnati STD/HIV Prevention Training Center

Vesicular Rash: Genital Herpes

- Grouped vesicles on an erythematous base of penile glans/shaft or vulva
- Associated with local pain and pruritis
- No early papule or late umbilical phase like mpox vesicles



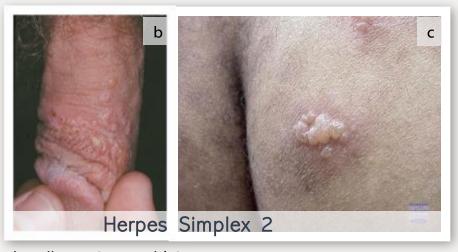


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Pustular Rash: Mpox

- Well-circumscribed, deep-seated, umbilicated
- Develop and evolve simultaneously
- Any part of body (e.g., anogenital, palms, soles)
- Painful







Molluscum Contagiosum

Photo Credits: a) CDC; b) CDC; c) CDC Smallpox poster; d) Public Health Image Library #16693; e) Scott Norton, MD, MPH

Pustular Rash: Varicella

- Crops of pruritic vesicles on erythematous bases occur varying stages over several days
- Lesions can progress to pustules before crusting
- Febrile prodrome typically presents with the rash





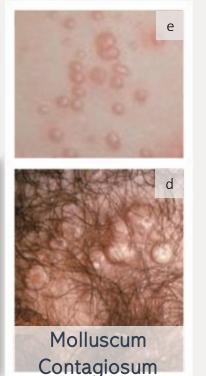


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Pustular Rash: Molluscum Contagiosum

- Chronic, painless localized infection
- Firm, dome-shaped, umbilicated papules with shiny surfaces
- Appears anywhere except palms and soles







Molluscum Contagiosum

Photo Credits: a) CDC; b) CDC; c) CDC Smallpox poster; d) Public Health Image Library #16693; e) Scott Norton, MD, MPH

Genital (Oral) Ulcer Disease: Mpox

- Genital, perianal, or facial lesions can coalesce into a large ulceration with crust and edema
- Can become secondarily infected

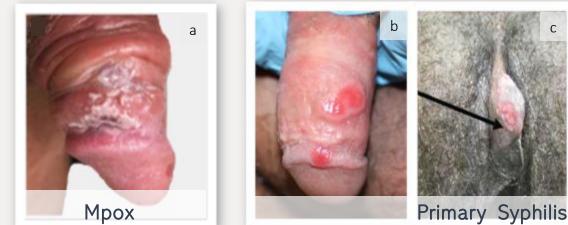




Photo Credit: a) Photo appears in Patrocinio-Jesus and Peruzzu¹; b) Christopher Ried, MD, Orange County Health Care Agency; c) CDC; d) Public Health Image Library #12623

Genital (Oral) Ulcer Disease: Primary Syphilis

- Classically, a single painless ulcer or chancre
- Can present with multiple, atypical, or painful lesions 1-2 cm in diameter with raised, indurated margins and non-exudative bases
- Usually on genitalia, but chancres can occur at any inoculation site









Photo Credit: a) Photo appears in Patrocinio-Jesus and Peruzzu¹; b) Christopher Ried, MD, Orange County Health Care Agency; c) CDC; d) Public Health Image Library #12623

Oral Mucosal Lesions: Mpox

- Thin-roofed white pustule on erythematous base
- Painful

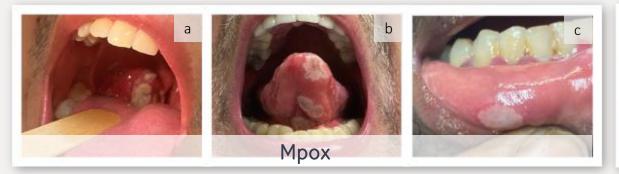




Photo Credits: a-c) CDC; d) CDC mucositis slide deck1

Oral Mucosal Lesions: Aphthous Ulcer

- Unroofed mucous patches and whitish erosions on oral mucosa or tongue
- Painful

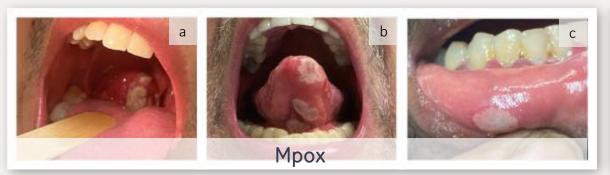




Photo Credits: a-c) CDC; d) CDC mucositis slide deck1

Crusted Skin Lesions/Scabs: Mpox

- 7-14 days after the rash begins, mpox lesions crust over and scab before desquamation
- Can become pruritic at this stage



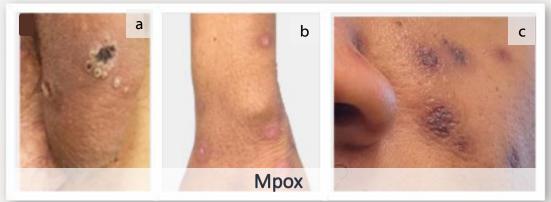




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Crusted Skin Lesions/Scabs: Genital Herpes

 Genital herpes primary infections resolve after a mean of 19 days; recurrent infections resolve after 10 days



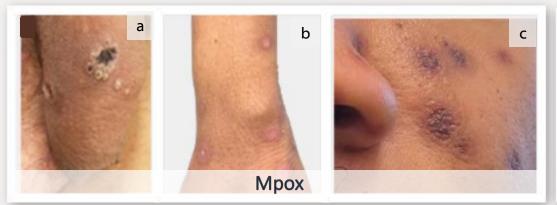




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Crusted Skin Lesions/Scabs: Herpes Zoster

- Begin as erythematous papules in a single dermatome
- Progress to grouped vesicles or bullae
- Most common presenting symptom is pain
- Associated with immunocompromise or advanced age











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Treatment

Mpox Prognostic Indicators (1/2)

- Mpox prognosis depends on multiple factors:
 - Previous mpox vaccination
 - Immune status (e.g., CD4+ count/viral load)
 - Concurrent illnesses and comorbidities
- Mpox infection is often mild and self-limiting without specific antiviral therapy¹
- Pain management,² skin care,³ and wound care are often vital components of mpox treatment plans

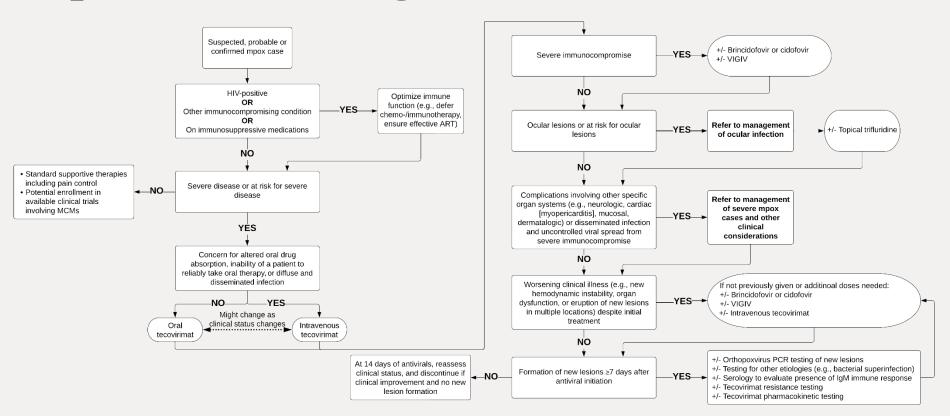


Photo Credits: Photo appears in Miller MJ et al.

Mpox Prognostic Indicators (2/2)

- Patients with underlying immunocompromise are at risk for severe, systemic, protracted illness and death and likely need combination therapy
- CDC is available for clinical consultation, as needed (CDC Emergency Operations Center Phone: 770 488-7100; Email: poxvirus@cdc.gov)
- Prompt consultation with CDC is recommended for immunocompromised patients and patients at risk for severe mpox

Mpox Treatment Algorithm*



Optimize Immune Function

- For immunocompromised patients:
 - Facilitate competent native immunity (e.g., ensure persons with HIV are receiving effective antiretroviral therapy)
 - Limit the use of immunocompromising therapies (e.g., chemotherapy, corticosteroids)
- Doing this may:
 - Decrease duration of mpox therapies
 - Minimize morbidity and mortality

Tecovirimat

- Antiviral approved by the FDA for treatment of human smallpox
 - Also known as TPOXX or ST-246
 - Approved for adults and children weighing at least 3 kg
 - May be used for non-variola orthopoxvirus infection (e.g., mpox) under a
 CDC-held <u>Expanded Access Investigational New Drug Protocol</u>
- Mpox treatment efficacy
 - Animal studies suggest mortality benefit
 - Human case reports suggest reduced illness duration and viral shedding
- Mpox postexposure prophylaxis (PEP) efficacy is unstudied

Tecovirimat Should be Considered for Patients with:

Severe Disease

- Hemorrhagic disease
- Confluent lesions
- Sepsis

- Encephalitis
- Other conditions requiring hospitalization

Involvement of anatomic areas which might result in serious sequelae

- Eves*
- Genitals

Anus

High Risk for Severe Disease

- Severely
- Pregnant
- Breastfeeding

- Children <1 year
- immunocompromised Has a condition affecting skin integrity

One or more complications

- Secondary bacterial skin infection
- Gastroenteritis with severe nausea/ vomiting, diarrhea, or dehydration
- Bronchopneumonia;
- Concurrent disease or other comorbidities

Tecovirimat: Availability

- Oral capsules
 - Must be taken with a full, fatty meal for adequate absorption¹
 - May be opened and mixed with soft food for pediatric patients <13kg
 - Available through

 - Some health departments (limited supplies)
- Oral and intravenous (IV) formulations available through the Strategic National Stockpile (SNS) via consultation/email with state/local health authorities or CDC as needed



Tecovirimat: Safety and Side Effects

- IV formulation contraindicated for creatinine clearance <30 mL/min
- Minor side effects in healthy subjects
 - Headache
 - Nausea
 - Abdominal pain
- Likely safe in pregnancy and breastfeeding without affecting fertility¹
- Not studied in pediatric patients



Cidofovir and Brincidofovir

Cidofovir

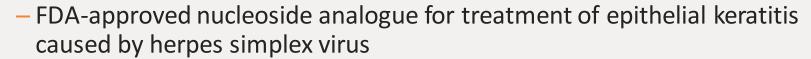
- FDA approved for cytomegalovirus retinitis
- Demonstrated in vivo efficacy against orthopoxviruses
- Commercially available
- Limitations
 - Uncertain efficacy for treatment of mpox
 - Renal toxicity

Brincidofovir

- FDA approved for treatment of smallpox in children of all ages and adults
- In vitro and in vivo data suggest efficacy against orthopoxviruses
- Available through SNS following FDA authorization for single patient use
- Limitations
 - Uncertain efficacy for treatment of mpox
 - Hepatic toxicity

Ocular Mpox Treatment

- Ophthalmology referral strongly encouraged
- Tecovirimat dose needed to achieve therapeutic ocular concentration is unknown
- Avoid topical steroids to prevent viral persistence and corneal damage
- Trifluridine



- Preferred treatment for ocular orthopoxvirus infection (e.g., keratitis and conjunctivitis)
- Use beyond recommended duration may cause corneal toxicity



Vaccinia Immune Globulin Intravenous (VIGIV)

- FDA-approved for the treatment of vaccinia vaccination (e.g., ACAM2000) complications such as
 - Eczema vaccinatum
 - Progressive vaccinia
 - Severe generalized vaccinia
- May be used for prevention and treatment of orthopoxvirus infection complications under a CDCheld <u>Expanded Access Investigational New Drug</u> Protocol
- Efficacy as pre-exposure prophylaxis (PrEP), PEP, or mpox treatment is unknown



Mpox Vaccination

JYNNEOS Vaccine

- Live virus vaccine
- Produced from the replication-deficient vaccinia virus strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN; also known as IMVAMUNE, IMVANEX, MVA)
- FDA licensed in 2019 to prevent smallpox and mpox in adults ≥18 years old¹
- May be administered intradermally or subcutaneously for persons ≥18 and subcutaneously for persons <18 under Emergency Use Authorization
- Administration in 2 doses at least 4 weeks apart
 - Standard regimen: subcutaneous² injections
 - Use only subcutaneous route for people with keloid history
 - Preferred alternate regimen: intradermal³ injections
- Can be used either prior to or after exposure (i.e., postexposure prophylaxis [PEP])

JYNNEOS Vaccine: Efficacy

- Vaccine effectiveness supported by:
 - Animal data
 - Immunogenicity studies
 - PEP efficacy data are limited
 - Used in mpox outbreaks outside the US in recent years
- Vaccine performance¹
 - Mpox incidence in unvaccinated persons was 7.4 times that of 1-dose recipients and 9.6 times that of 2-dose recipients¹
 - No differences in protection between intradermal and subcutaneous routes¹





JYNNEOS Vaccine: Safety

- Safe for use in those who are immunocompromised or have atopic dermatitis
- Demonstrated to be safe in current outbreak
- Safety not established in:
 - Pregnant persons
 - Breastfeeding persons
 - Children
- Animal models using high doses showed no harm to a developing fetus
- Contraindicated in patients with prior severe allergic reaction to JYNNEOS
- Use with caution in those with allergy to eggs, gentamicin, or ciprofloxacin
 - Produced using chicken embryo fibroblast cells
 - Contains small amounts of gentamicin and ciprofloxacin

ACAM2000 Vaccine

- Live, replicating vaccine
- Administered as a single percutaneous dose using a <u>multiple puncture</u> <u>"scarification" technique</u>
- Licensed by FDA in 2007 for active smallpox immunization in ≥18-year-olds
 - Has not been used in the current outbreak
- May be used for prevention of non-smallpox orthopoxviruses during an outbreak under a CDC-held Emergency Access Investigational New Drug Protocol

ACAM2000 Vaccine: Efficacy^{1,2}

 Vaccine effectiveness likely similar to that reported for other live smallpox vaccines in endemic countries (>85%)³

PEP efficacy is not well studied in mpox

ACAM2000 Vaccine: Safety and Side Effects

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Contraindications

Myo/pericarditis (1 in 175)¹

Pregnancy

Progressive vaccinia

Young children

Eczema vaccinatum

Immunocompromised

Postvaccinial encephalitis

Exfoliative skin condition

Fetal vaccinia

Known underlying heart disease (e.g., coronary artery disease or cardiomyopathy

Inadvertent inoculation or autoinoculation

Capable of person-to-person spread through close contact²

Eczema Vaccinatum from ACAM2000 Vaccine



Photo Credit: CDC, 2007 MMWR¹

- Photo showing 2-year-old household contact of ACAM2000 recipient
- The child had eczema
 - Increased risk of complications from vaccinia virus inoculation

Severe Vaccinia Virus Complications from Inadvertent Transmission

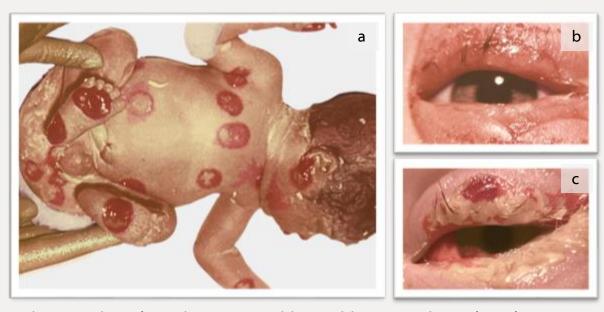


Photo credits: a) Fetal vaccinia, Public Health Image Library (PHIL) #14269; b) Ocular vaccinia from autoinoculation, PHIL #3248; c) PHIL #3247

Contraindications: ACAM2000 and JYNNEOS

Contraindications for ACAM200 and JYNNEOS Table

Clinical characteristic	ACAM2000 Primary vaccination	ACAM2000 Revaccination	ACAM2000 Household Contacts with condition*	Contraindication to receipt of JYNNEOS
History or presence of atopic dermatitis	X	X	X	
Other active exfoliative skin conditions [†]	X	X	X	
Immunosuppression§	X	X	X	
Pregnancy [¶]	X	X	X	
Age <1 year**	X	X	X	
Breastfeeding ^{††}	X	X		
Serious vaccine component allergy	X	X		X
Known underlying heart disease (e.g.,	X	X		
coronary artery disease or cardiomyopathy)				
Three or more known major cardiac risk factors §§	X			

Footnotes may be found in the notes section of this slide

Summary: ACAM2000 and JYNNEOS Vaccines

JYNNEOS is preferred over ACAM2000 because it has far fewer side effects

	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	Myo/pericarditis 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 or intradermally in 2 doses, 28 days apart

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

Vaccination Prior to Exposure

Orthopoxvirus Vaccine Recommendations for Healthcare Providers and Laboratorians

- As of June 3rd, 2022, Advisory Committee on Immunization Practices (ACIP) recommends mpox vaccination only for:
 - Research laboratory personnel working with orthopoxviruses
 - Clinical laboratory personnel performing diagnostic testing for orthopoxviruses
 - Orthopoxvirus and health care worker response teams designated by appropriate public health and antiterror authorities
- Persons who administer ACAM2000 or care for patients with infection with replication-competent viruses should be offered the vaccine

Mpox Vaccination Indications: Sexual History Risk Factors (1/2)

 Mpox vaccination should be offered to adults and adolescents, who over the last 6 months:

were diagnosed with a sexually transmitted infection

OR

had a new sex partner

AND

are gay, bisexual, or are other men who have sex with men

OR

are transgender or nonbinary

Mpox Vaccination Indications: Sexual History Risk Factors (2/2)

- Mpox vaccination should be offered to:
 - Anyone who has had sex during the last 6 months:
 - At a commercial sex venue or other social gathering
 - In association with a large public event in an area with ongoing mpox transmission
 - With a partner with the above risks
 - People with HIV infection or other causes of immunosuppression who have had recent or anticipate possible future risk of mpox exposure

Postexposure Prophylaxis (PEP) and Monitoring

Vaccine Strategy Considerations

- Health departments have received allocations of JYNNEOS vaccine based on jurisdictional numbers of¹:
 - HIV+ men who have sex with men (MSM)
 - HIV PrEP*-eligible MSM
- JYNNEOS is being distributed to jurisdictions and provided to patients at no cost



Mpox Vaccine Postexposure Prophylaxis¹

- Risk exposure assessment determines need for vaccination of close contacts²
- Initiate postexposure prophylaxis (PEP)*:
 - Within 4 days of suspected exposure to minimize disease incidence
 - From 4–14 days after suspected exposure to reduce illness severity

^{*}Based on data from live, replicating vaccinia virus vaccines for smallpox

PEP and Monitoring for Healthcare Setting Exposures (1/3)

Risk level of exposure	Exposure characteristics	Recommend Monitoring	Recommend PEP [¶]
	Unprotected contact between an exposed individual's broken skin or mucous membranes and the skin lesions or bodily fluids from a patient with mpox (e.g., inadvertent splashes of patient saliva to the eyes or mouth of a person), or soiled materials (e.g., linens, clothing) OR Being inside the patient's room or within 6 feet of a patient with mpox during any medical procedures that may create aerosols from oral secretions (e.g., cardiopulmonary resuscitation, intubation) or activities that may resuspend dried exudates (e.g., shaking of soiled linens) without wearing a NIOSH-approved particulate respirator with N95 filters or higher and eye protection	Yes	Recommended

PEP and Monitoring for Healthcare Setting Exposures (2/3)

Risk level of exposure	Exposure characteristics	Recommend Monitoring	Recommend PEP [¶]
Intermediate	Being within 6 feet for a total of 3 hours or more (cumulative) of an unmasked patient with mpox without wearing a facemask or respirator OR Unprotected contact between an exposed individual's intact skin and the skin lesions or bodily fluids from a patient with mpox, or soiled materials (e.g., linens, clothing) OR Activities resulting in contact between an exposed individual's	Yes	Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks of transmission or
	clothing and the patient with mpox's skin lesions or bodily fluids, or their soiled materials (e.g., during turning, bathing, or assisting with transfer) while not wearing a gown		severe disease 11

PEP and Monitoring for Healthcare Setting Exposures (3/3)

F	Risk level of exposure	Exposure characteristics	Recommend Monitoring	Recommend PEP [¶]
		Entry into the contaminated room or patient care area of a patient with mpox without wearing all recommended PPE and in the absence of any exposures above	Yes	None
		No contact with the patient with mpox, their contaminated materials, nor entry into the contaminated patient room or care area	No	None

Footnotes may be found in the PowerPoint notes section

PEP and Monitoring for Community Exposures (1/3)

Degree of exposure	Exposure characteristics	Recommend Monitoring	Recommend PEP [¶]
	Contact between an exposed individual's broken skin or mucous membranes with the skin lesions or bodily fluids from a person with mpox OR Any sexual or intimate contact involving mucous membranes (e.g., kissing, oralgenital, oral-anal, vaginal, or anal sex (insertive or receptive)) with a person with mpox OR	Yes	Recommended
	Contact between an exposed individual's broken skin or mucous membranes with materials (e.g., linens, clothing, objects, sex toys) that have contacted the skin lesions or bodily fluids of a person with mpox (e.g., sharing food, handling or sharing of linens used by a person with mpox without having been disinfected [†] or laundered)		

Footnotes may be found in the PowerPoint notes section

PEP and Monitoring for Community Exposures (2/3)

Degree of	Exposure characteristics	Recommend	Recommend
exposure		Monitoring	PEP¶
Intermediate	Being within 6 feet for a total of 3 hours or more (cumulative) of an unmasked person with mpox without wearing a surgical mask or respirator OR Contact between an exposed individual's intact skin with the skin lesions or bodily fluids from a person with mpox OR Contact between an exposed individual's intact skin with materials (e.g., linens, clothing, sex toys) that have contacted the skin lesions or bodily fluids from a person with mpox without having been disinfected or laundered OR Contact between an exposed individual's clothing with the person with mpox's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., during turning, bathing, or assisting with transfer)	Yes	Informed clinical decision making recommended on an individual basis to determine if the benefits of PEP outweigh the risks

PEP and Monitoring for Community Exposures (3/3)

Degree of exposure	Exposure characteristics	Recommend Monitoring	Recommend PEP [¶]
Lower	Entry into the living space of a person with mpox (regardless of whether the person with mpox is present), and in the absence of any exposures above	Yes	None
No Risk	No contact with the person with mpox, their potentially infectious contaminated materials, nor entry into their living space	No	None

Footnotes may be found in the PowerPoint notes section

CDC and Other Mpox Consultation Services

- CDC provides consultation on mpox vaccine indications and a variety of treatment modalities, including antivirals
- For patient care consults or to obtain intravenous tecovirimat or VIGIV, contact CDC
 - Phone: (770) 488-7100
 - Email: poxvirus@cdc.gov
- To obtain brincidofovir, contact FDA
 - Phone (business hours): 301-796-3400 or 1-855-543-378
 - Phone (after hours): 301-796-8240 or 1-866-300-4374
 - Email: DDI.EIND@fda.hhs.gov

Infection Control, Isolation, and Monitoring

At Home: Infection Control

- People with mpox who do not require hospitalization should follow <u>CDC's</u>
 <u>Isolation and Prevention Practices for People with Mpox¹</u>
- CDC recommends that patients isolate at home for 21 days following potential exposure OR until symptoms have fully resolved

Factors influencing at-home isolation

Presence of other people or pets

Presence of children aged under 1 year, pregnant or immunocompromised people, and individuals with eczema or atopic dermatitis

Ability of the person with mpox to follow recommended precautions

At Home: Isolation and Monitoring

During the 21-day monitoring period, if:

Rash occurs

Follow isolation and prevention practices until:

- 1. The rash is evaluated by a healthcare provider
- 2. Testing is performed, if recommended by a healthcare provider
- 3. Results of testing are available and negative

Other signs/symptoms occur, but no rash

Follow isolation and prevention practices for 5 days, extending beyond the original 21-day monitoring period if needed

- If no new signs or symptoms develop, stop isolation and prevention practices. Monitor for the remainder of the 21-day period
- If additional signs or symptoms develop, a new 5-day isolation period starts, even if it will end after day 21

Healthcare Settings: Patient Monitoring

- Monitor asymptomatic patients in healthcare facilities who were exposed to mpox virus for 21 days after their last exposure
 - In general, isolation is not required
- During the monitoring period, assess the patient for <u>signs and symptoms</u> of mpox and conduct a thorough skin exam at least once daily
- Adapt postexposure risk assessment and management from <u>community</u> <u>guidance</u> or <u>healthcare guidance</u> according to the nature and location of a patient's exposure

Healthcare Settings: Patient Isolation

Isolation precautions

- Notify infection prevention and control personnel immediately if a patient has suspected mpox infection
- Place a patient with suspected or confirmed mpox infection in a single-person room
- Special air handling is not required

Isolation duration

- Suspected mpox: 21 days until infection is ruled out
- Confirmed mpox: 5 days after any new symptom develops, extending beyond the original 21-day monitoring period if needed
 - Maintain until:
 - All lesions have crusted
 - Crusts have separated
 - A fresh layer of healthy skin has formed underneath
- Confer with local or state health department on decision to discontinue isolation

Healthcare Settings: Housekeeping

 For any staff cleaning mpox patient areas (e.g., housekeeping and janitorial staff, certified nursing assistant)

- Provide appropriate personal protective equipment (PPE) and train on proper use
- Instruct on <u>recommended standard practices</u> for infection control
- Perform waste management in accordance with <u>U.S.</u>
 <u>Department of Transportation Hazardous Materials</u>

 <u>Regulations</u>

Healthcare Settings: Healthcare Providers (HCPs)

- HCPs who enter a contaminated patient room or care area while wearing recommended PPE should be aware of the signs and symptoms of mpox
- HCPs who develop any signs or symptoms of mpox should:
 - Notify occupational health services for further evaluation
 - Leave work and begin home isolation if signs or symptoms develop while at work
 - Stay home and isolate if symptoms begin at home

Additional Information on Disinfectants for Mpox

- EPA-Registered Disinfectants for Mpox
- <u>Disinfecting Home and Other Non-Healthcare Settings</u>



For clinical consultation, please contact

CDC Emergency Operations Center Phone: (770) 488-7100

Email: poxvirus@cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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2022 Mpox Outbreak

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Pre-Exposure Prophylaxis

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Infection Control, Isolation, and Monitoring

Slides 88-90: PEP and Monitoring for Community Exposures

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Slide 93: At Home: Infection Control

1. CDC [2022]. Isolation and Infection Control At Home https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html

Slide 94: At Home: Isolation and Monitoring

 CDC [2022]. Monitoring and Risk Assessment for Persons Exposed in the Community https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure

Slide 95: Healthcare Settings: Patient Monitoring

• CDC [2022]. Infection Prevention and Control of Mpox in Healthcare Settings https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Infection Control, Isolation, and Monitoring

Slide 96: Healthcare Settings: Patient Isolation

CDC [2022]. Infection Prevention and Control of Mpox in Healthcare Settings
 https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Slide 97: Healthcare Settings: Housekeeping

CDC [2022]. Infection Prevention and Control of Mpox in Healthcare Settings
 https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Slide 98: Healthcare Settings: Healthcare Providers (HCPs)

CDC [2022]. Infection Prevention and Control of Mpox in Healthcare Settings
 https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html