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MPox Virus Protocol

February 6, 2023

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What is MPox?

- MPox is a viral infection that can be transmitted from animals to humans and from person-to-person through respiratory secretions, contact with body fluids, and fomites.
- The disease is endemic to West and Central Africa. During the current multi-country outbreak, over 10,000 cases have been identified to date.
- It is usually a self-limited disease with symptoms lasting 2-4 weeks. Severe cases can occur and case fatality around the world is 3-6%, but much less in Europe and North America during the outbreak of 2022
- It typically presents clinically with fever, rash and swollen lymphnodes and may lead to range of Medical Complications
- Clinical presentation of MPox resembles, that of Smallpox, which is also caused by orthopox virus, but is less contagious then smallpox and causes less severe illness
- CDC is tracking multiple reported US MPox cases and monitoring cases is persons in countries without endemic MPox and with no known travel links to an endemic area

(Reference WHO/CDC)

MPox case numbers

As of January 11th, 2023 there were 84,716 confirmed cases globally in 107 plus locations. As of January 11th, 2023, USA had 29,980 confirmed cases and 21 deaths. As of January 16th, 2023, Florida had 2,866 (both confirmed plus probable) cases and out of which 1,732 were confirmed cases. Broward County had 708 (both confirmed plus probable) cases and out of which 533 were confirmed cases and Miami Dade had 896 (both confirmed plus probable) cases and out of which 611 were confirmed cases.

When should I suspect MPox?

Anyone can get MPox. However, based on the current outbreak, certain populations are being affected by MPox more than others, including men who have sex with men (MSM).

There are also some groups that may be at heightened risk for severe outcomes if they contract MPox. This includes people with weakened immune systems, elderly, young children under 8 years of age, and pregnant people.

What are the signs and symptoms of MPox?

Patients during the current MPox outbreak have presented with the following signs and symptoms:

- Skin rash or enanthem in all patients (see images in Appendix A)
- 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)
- Anorectal pain or tenesmus
- Rectal bleeding
- Physical examination with visible lesions and proctitis
- Please note that compared to classic MPox descriptions, during the current outbreak, prodromal symptoms may be mild or not occurring, and fever and lymphadenopathy are not occurring in all patients
- Some patients have had co-infections with sexually transmitted infections (STIs)

Examples of Monkeypox Rashes

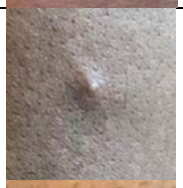
Photo credit: UK Health Security Agency

Key Characteristics of Monkeypox Rash

More Monkeypox Rash Photos

Photo Credit: NHS England High Consequence Infectious Diseases Network

Enanthem Through the Scab Stage

Stage	Duration	Characteristics	Images
Enanthem		• The first lesions to develop are on the tongue and in the mouth	
Macules	**1-2 days**	• Following the enanthem, a macular rash appears on the skin, starting on the face and spreading to the arms and legs and then to the hands and feet, including the palms and soles • The rash typically spreads to all parts of the body within 24 hours becoming most concentrated on the face, arms and legs (centrifugal distribution)	
Papules	**1-2 days**	• By the third day of rash, lesions have progressed from macular (flat) to papular (raised).	
Vesicles	**1-2 days**	• By the fourth to fifth day, lesions have become vesicular (raised and filled with clear fluid)	
Pustules	**5-7 days**	• By the sixth to seventh day, lesions have become pustular (filled with opaque fluid) – sharply raised, usually round, and firm to the touch (deep seated). • Lesions will develop a depression in the center (umbilication). • The Pustules will remain for approximately 5 to 7 days before beginning to crust.	 
Scabs	**7-14 days**	• By the end of the second week, pustules have crusted and scabbed over. • Scabs will remain for about a week before beginning to fall off.	

What do I do if I suspect a patient has MPox?

- Immediately ISOLATE the patient.
  - Place the patient in a private room, put a mask on them and close the door.
  - Place droplet and contact precaution sign on door
  - Call Infection Prevention at 786-266-0624
  - Complete Recent Travel History II PowerForm. If criteria is met for MPox, automatically isolation for Droplet and contact precaution will be ordered

"CDC link for case definition of MPox"
https://www.cdc.gov/poxvirus/MPox/clinicians/case-definition.html
Positive diagnostic results from testing of skin lesion material for *Orthopoxvirus* or *MPox virus* DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing.

If there are no identified epidemiologic risk criteria for MPox infection, other possible causes of rash in adults should be considered, including secondary syphilis, herpes, and varicella zoster. In children without identified epidemiologic risk criteria for MPox, varicella zoster and molluscum contagiosum (MC) should be considered in the differential diagnosis. MC is an infection caused by a poxvirus (molluscum contagiosum virus) that is diagnosed more often in children than in adults. MC infection is usually a benign, mild skin disease characterized by lesions that may appear anywhere on the body. CDC's FDA-cleared non-variola virus test used within the Laboratory Response Network laboratories and most commercial laboratories, does not cross-react with molluscum contagiosum virus. In children and adolescents, as in adults, other potential etiologies of illness should be tested for in parallel with or before *MPox virus* testing, based on clinical presentation and epidemiologic criteria.

JHS protocol for in-house lab testing for MPox virus

MPox PCR testing is now being performed in the Jackson Memorial Hospital Microbiology Laboratory. Testing will be performed daily, six days per week, Sunday – Friday. Samples received by 9AM will be reported the same day in the evening. Samples from all Jackson Health System facilities, including regional hospitals, urgent care centers, ambulatory care clinics, primary care clinics, long term care facilities, and corrections will be performed at the JMH laboratory.

The test can be performed on swabs from up to two separate skin lesions from patients with clinical and epidemiological features of MPox infection. For optimal recovery of virus DNA, vigorously swab the surface of the lesion or crust from a healing lesion. If two skin lesions are sampled, both swabs should be inserted in a single tube of viral transport media (VTM). There is no change to the current protocol or transport media used - swabs must be sent to the laboratory in a tube of Viral Transport Medium (VTM). This test is not indicated for screening in asymptomatic patients.

For questions, contact the JMH Microbiology Laboratory at 305-585-6508 or JMH Pathology administration at 305-585-6210.

MPOX

Tips for Adequate Collection of a Lesion Specimen from a Suspect Monkeypox Virus Case

Vigorous swabbing of lesion specimens maximizes the probability of achieving accurate diagnostic results. **Specimens that do not contain enough human DNA may lead to inconclusive PCR test results, with no positive or negative result.** Inconclusive results necessitate patients being sampled again which can delay diagnosis. Follow the instructions below to make sure your specimens are adequate for testing. While vigorous swabbing on the surface of a lesion should collect enough viral DNA, more viral DNA can be found in crusts when present. Recommended infection prevention and control practices, including the use of personal protective equipment (PPE), for caring for a patient with suspected or confirmed monkeypox infection should be used during specimen collection: What Healthcare Professionals Should Know. Unroofing or aspiration of lesions (or otherwise using sharp instruments for monkeypox testing) is **not necessary, nor recommended due to the risk for sharps injury.**

Swabbing of Lesion Surface:

1. Use sterile, synthetic swabs. Do not use cotton swabs.
2. More information on specimen collection can be found here: Preparation and Collection of Specimens.
3. Do not clean the lesion with ethanol or any other disinfectant prior to swabbing.
4. Hold the swab with a firm grasp. Avoid touching the swab shaft at least an inch before the tip if collecting a dry swab and the length of the swab shaft that will be submerged in liquid if using a swab to be stored in viral transport media.

5. Apply firm pressure (generally firm enough so that the swab shaft, if plastic, may bend slightly). This may result in discomfort or slight pain, but it is necessary to obtain adequate DNA.
    a. If lesion ruptures while swabbing, ensure that swab collects lesion fluid.
    b. If possible, avoid using swabs that bend too easily which may make applying firm pressure difficult.

6. Swipe the swab back and forth on the lesion surface at least 2-3 times then rotate and repeat on the other side of the swab at least 2-3 times.
    a. If material is visible on the swab surface (such as skin material or from lesion fluid that is leaking from the lesion), this is indicative of an adequate collection. Although please note that material may not always be visible on swabs.
7. Place swab within appropriate container.
    a. Ensure container, storage and shipping conditions are approved by laboratory that specimen is being sent to for testing.

Collection of crusts from healing lesions:

Crusts are not accepted by all laboratories as an approved specimen type. Ensure the laboratory that will be receiving the specimen for testing is able to test crusts before collecting or sending.

1. Use a forceps or other blunt-tipped sterile instrument to remove all or a piece of the crust at least 4mm x 4mm – about the size of this dot: ●

2. Separate each crust into a dry, sterile container.
    a. Ensure container, storage, and shipping conditions are approved for laboratory that specimen is being sent to for testing.

3. Cover lesion with band aid.

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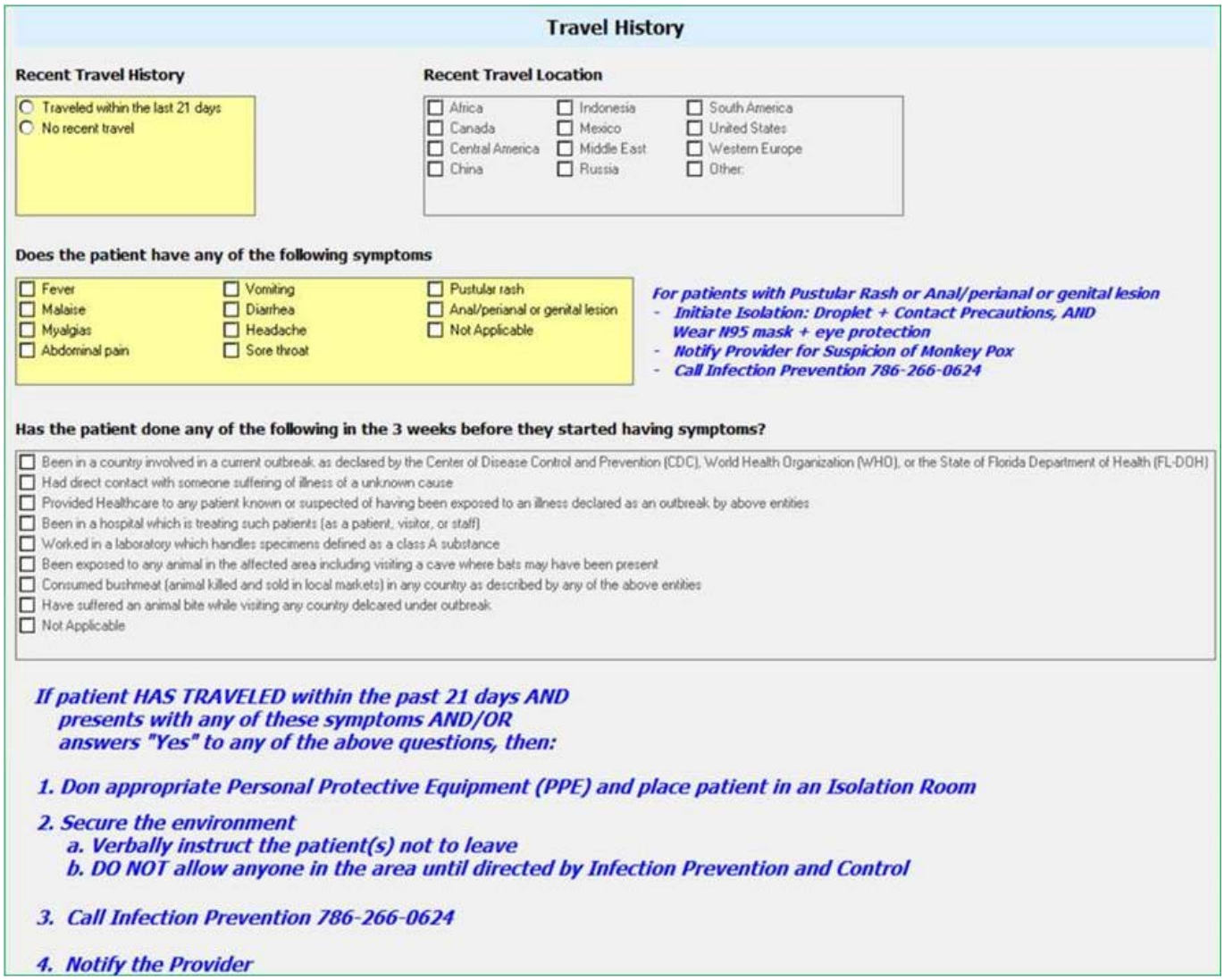


Travel History

Recent Travel History

- ○ Traveled within the last 21 days
- ○ No recent travel

Recent Travel Location

- ☐ Africa
- ☐ Canada
- ☐ Central America
- ☐ China
- ☐ Indonesia
- ☐ Mexico
- ☐ Middle East
- ☐ Russia
- ☐ South America
- ☐ United States
- ☐ Western Europe
- ☐ Other:

Does the patient have any of the following symptoms

- ☐ Fever
- ☐ Malaise
- ☐ Myalgias
- ☐ Abdominal pain
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Headache
- ☐ Sore throat
- ☐ Pustular rash
- ☐ Anal/perianal or genital lesion
- ☐ Not Applicable

For patients with Pustular Rash or Anal/perianal or genital lesion
- ***Initiate Isolation: Droplet + Contact Precautions, AND Wear N95 mask + eye protection***
- ***Notify Provider for Suspicion of Monkey Pox***
- ***Call Infection Prevention 786-266-0624***

Has the patient done any of the following in the 3 weeks before they started having symptoms?

- ☐ Been in a country involved in a current outbreak as declared by the Center of Disease Control and Prevention (CDC), World Health Organization (WHO), or the State of Florida Department of Health (FL-DOH)
- ☐ Had direct contact with someone suffering of illness of a unknown cause
- ☐ Provided Healthcare to any patient known or suspected of having been exposed to an illness declared as an outbreak by above entities
- ☐ Been in a hospital which is treating such patients (as a patient, visitor, or staff)
- ☐ Worked in a laboratory which handles specimens defined as a class A substance
- ☐ Been exposed to any animal in the affected area including visiting a cave where bats may have been present
- ☐ Consumed bushmeat (animal killed and sold in local markets) in any country as described by any of the above entities
- ☐ Have suffered an animal bite while visiting any country delcared under outbreak
- ☐ Not Applicable

If patient HAS TRAVELED within the past 21 days AND presents with any of these symptoms AND/OR answers "Yes" to any of the above questions, then:

1. Don appropriate Personal Protective Equipment (PPE) and place patient in an Isolation Room

2. Secure the environment
a. Verbally instruct the patient(s) not to leave
b. DO NOT allow anyone in the area until directed by Infection Prevention and Control

3. Call Infection Prevention 786-266-0624

4. Notify the Provider

- Staff entering the patient's room must wear N95 respirator, eye protection, gown and gloves
- Enter order for "MPox Virus DNA, Qual RT PCR *Ref*" and collect a specimen. See appendix A for instructions on specimen collection.
- **For Emergency Departments and Inpatient units—walk the specimens to your central laboratory**
- **For patients in the ambulatory care center, primary care center and urgent care centers all specimens will be sent to JMH lab unless insurance dictates otherwise (e.g. Quest).**
- Once a patient is either discharged or admitted and the room they used is vacated, the room must be terminally cleaned and disinfected immediately. Do not place any patients until the room is terminally cleaned.

What treatments are available for patients with MPox?
See Appendix B for Pharmaceutical Treatment for MPox.

What do I do if I think I was exposed to a patient with MPox?
According to the CDC, transmission of MPox requires prolonged close contact 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 post-exposure prophylaxis.

The Florida Department of Health is currently offering vaccination to groups at high-risk of infection. To schedule an appointment for MPox vaccine follow the attached link on Google Chrome, Microsoft Edge or mobile devices: https://book.appointment-plus.com/d6b7yl3g.

Miami-Dade County is giving MPox vaccines, to high-risk population, at 2 sites only by appointments. One at Tropical Park and other one in Miami Beach. Please visit Miamidade.gov/MPox or call 1 833 875 0900.

Isolation at Home

CDC recommends that people with MPox remain isolated at home or at another location for the duration of illness, but that might not be possible in all situations. Prioritizing isolation and source control strategies helps prevent transmission while balancing the impact of this infection on the daily lives of people diagnosed with MPox. These considerations may change as we learn more from the 2022 global outbreak of MPox.

Current data suggest people can spread MPox from the time symptoms start until all symptoms have resolved, including full healing of the rash with formation of a fresh layer of skin. Ideally, people with MPox would remain in isolation for the duration of illness, which typically lasts two to four weeks. However, if a person with MPox is unable to remain fully isolated throughout the illness, they should do the following:

- While symptomatic with a fever or any respiratory symptoms, including sore throat, nasal congestion, or cough, remain isolated in the home and away from others unless it is necessary to see a healthcare provider or for an emergency.
    - This includes avoiding close or physical contact with other people and animals.
    - Cover the lesions, wear a well-fitting mask (more information below), and avoid public transportation when leaving the home as required for medical care or an emergency.
- While a rash persists but in the absence of a fever or respiratory symptoms
    - Cover all parts of the rash with clothing, gloves, and/or bandages.
    - Wear a well-fitting mask to prevent the wearer from spreading oral and respiratory secretions when interacting with others until the rash and all other symptoms have resolved.
    - Masks should fit closely on the face without any gaps along the edges or around the nose and be comfortable when worn properly over the nose and mouth.
- Until all signs and symptoms of MPox illness have fully resolved
    - Do not share items that have been worn or handled with other people or animals. Launder or disinfect items that have been worn or handled and surfaces that have been touched by a lesion.
    - Avoid close physical contact, including sexual and/or close intimate contact, with other people.
    - Avoid sharing utensils or cups. Items should be cleaned and disinfected before use by others.
    - Avoid crowds and congregate settings.
    - Wash hands often with soap and water or use an alcohol-based hand sanitizer, especially after direct contact with the rash.

Isolation and Prevention Practices for People with MPox
https://www.cdc.gov/poxvirus/MPox/clinicians/isolation-procedures.html#:~:text=Congregate%20care%20settings%2C%20such%20as,be%20possible%20in%20all%20situations

Some additional information on Infection Prevention and Control of MPox in Healthcare Settings

Human-to-human transmission of MPox virus occurs by direct contact with lesion material or from exposure to respiratory secretions. Reports of human-to-human transmission describe close contact with an infectious person. Transmission in healthcare settings has been rarely described.

Activities that could resuspend dried material from lesions, e.g., use of portable fans, dry dusting, sweeping, or vacuuming should be avoided.

Transport and movement of the patient outside of the room should be limited to medically essential purposes. If the patient is transported outside of their room, they should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.

Intubation and extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.

Waste Management

Waste management (i.e., handling, storage, treatment, and disposal of soiled PPE, patient dressings, etc.) should be performed in accordance with U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR; 49 CFR parts171-180.)

Required waste management practices and classification (i.e., assignment to a category under the HMR) currently differ depending on the MPox virus clade (strain). The DOT indicates that waste contaminated with the West African clade of MPox virus should be managed as UN3291 Regulated Medical Waste (RMW) in the same manner as other potentially infectious medical waste (e.g. soiled dressings, contaminated sharps). The Congo Basin clade is classified as Category A under the HMR and should be managed accordingly. See the DOT website for more information (https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Cat%20A%20Waste%20Planning%20Guidance_Final_2022_06.pdf). Facilities should also comply with state and local regulations for handling, storage, treatment, and disposal of waste, including RMW.

Pursuant to 49 CFR 173.134(a)(1)(i), classification of waste as a Category A substance for transportation must be based on the known medical history or symptoms of the patient, endemic local conditions, or professional judgment concerning the individual circumstances of patient.

During the ongoing 2022 multi-national outbreak of West African clade MPox, if a clinician or their public health authority determine that a patient does not have known epidemiological risk for the Congo Basin clade of MPox virus(e.g. history of travel to the Democratic Republic of the Congo, the Republic of Congo, the Central African Republic, Cameroon,or Gabon in the prior 21 days) it is appropriate to manage the patient's waste as Regulated Medical Waste. However, if epidemiological risk factors indicate a risk for Congo Basin clade MPox virus, waste should be managed as a Category A infectious substance pending clade confirmation, and while local and state public health authorities are consulted.

Environmental Infection Control

Standard cleaning and disinfection procedures should be performed using an EPA-registered hospital-grade disinfectant with an emerging viral pathogen claim. Products with Emerging Viral Pathogens claims may be found on EPA's List Q.
https://www.epa.gov/pesticide-registration/disinfectants-emerging-viral-pathogens-evps-list-q
Follow the manufacturer's directions for concentration, contact time, and care and handling. Terminal cleaning and disinfection of the room is required once the patient vacates the room or discharged.

Soiled laundry (e.g., bedding, towels, personal clothing) should be handled in accordance with recommended standard practices, avoiding contact with lesion material that may be present on the laundry. Soiled laundry should be gently and promptly contained in an appropriate laundry bag and never be shaken or handled in manner that may disperse infectious material.

Activities such as dry dusting, sweeping, or vacuuming should be avoided. Wet cleaning methods are preferred.

Management of food service items should also be performed in accordance with routine procedures.

Duration of Precautions

If a patient requires inpatient medical care and is isolated for MPox, decisions regarding discontinuation of isolation precautions in a healthcare facility should be made in consultation with the infection prevention department. Isolation Precautions should be maintained until all lesions have crusted, those crusts have separated, and a fresh layer of healthy skin has formed underneath.

Visitation

Visitors to patients with MPox should generally be limited to those essential for the patient's care and wellbeing. Special situations should be discussed with the leaders on the unit. Decisions about who might visit, including whether the visitor stays or sleeps in the room with the patient, typically take into consideration the patient's age, the patient's ability to advocate for themselves, ability of the visitor to adhere to IPC recommendations, whether the visitor already had higher risk exposure to the patient, and other aspects.

JHS would follow the CDC Guidance and provide PPE for Droplet and Contact precautions including N95 to the visitors (1 at a time).

CDC Isolation and Infection Control: Home
https://www.cdc.gov/poxvirus/MPox/clinicians/infection-control-home.html

CDC Guidance on Autopsy and Handling of Human Remains
https://www.cdc.gov/poxvirus/MPox/clinicians/autopsy.html

Appendix A

Monkeypox

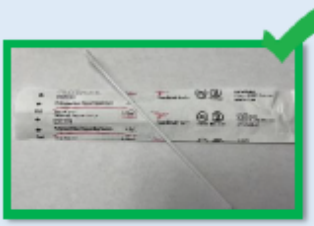
Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder, and monkeypox is rarely fatal. Monkeypox is not related to chickenpox.

Specimen Collection: Equipment and Supplies

1. *Universal Viral Transport tube
2. Sterile dry swabs

(Must be Sterile-Plastic Stem swab, do not use flexible NP swab)

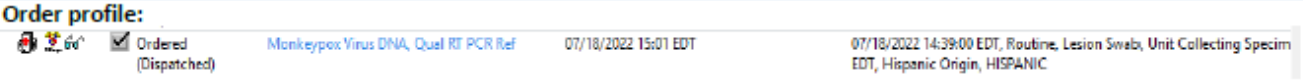
3. Personal Protective Equipment
   a. Gown
   b. Gloves
   c. N95
   d. Eye protection (i.e., goggles or a face shield that covers the front and sides of the face)
   (*required for aerosol generating procedures)



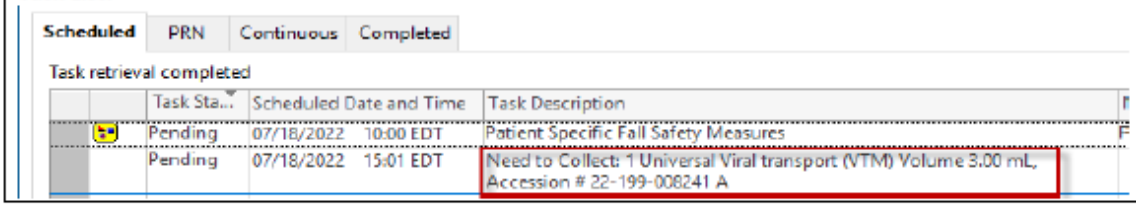
Visual Examples of Monkeypox Rash:

Once order is placed you will see

Order profile:



Task List:



Please note that results will be provided to the patient by the Physician

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CDC Guidance on Preparation and Collection of Specimens
https://www.cdc.gov/poxvirus/MPox/clinicians/prep-collection-specimens.html

Appendix B
Pharmaceutical Treatment for MPox
v. 8.30.2022

This section includes information on the following

I. Treatment of active disease
   a) Criteria
   b) Pharmacotherapy (Agent, Dose, Duration) & Monitoring
   c) How to apply for Tecovirimat with Step by Step Instructions for use under EA-IND

II. Prevention of disease for exposed and high-risk individuals
   a) MPox vaccine information
   b) Who qualifies for vaccine
   c) How to schedule an appointment for vaccine with the Department of Health (DOH)
   d) Interim guidance for use of JYNNEOS

I. Treatment of Active Disease

Ia. Criteria for Pharmacotherapy

Patients who are microbiologically diagnosed with MPox **do not ALL require treatment**. Mild and self-limiting cases in immunocompetent patients do not require active therapy and should follow the isolation guidelines as described. Additionally, if lesions have already started crusting over and patient is improving without therapy (afebrile, no leukocytosis, etc.), therapy may not be warranted. Any questions should be discussed with an ID Specialist.

The following populations **meet criteria for active therapy**

Severe Disease	• Hemorrhagic disease • Confluent lesions • Sepsis • Encephalitis • Other sequela from MPox requiring hospitalization
Immunocompromised	• AIDS or HIV with CD4 count < 200 • Leukemia, lymphoma, or malignancy with ANC < 500 or undergoing active treatment • Solid Organ Transplant, Stem Cell Transplant, or CART-T recipient o < 24 months post-transplant o ≥ 24 months post-transplant & GVHD, treatment for rejection or receiving immunomodulating therapy as described below • Primary Immunodeficiency
Active Immunomodulating Therapy	• Alkylating agents, antimetabolites, radiation, TNF inhibitors • Prednisone ≥ 20 mg daily for ≥ 14 days or other corticosteroid equivalent • B-cell depleting therapies within the last 6 months • BTK inhibitors (i.e. ibrutinib, acalabrutinib)
Pediatric	• Special consideration given to children < 8 years of age • No clinical studies have been performed to date in this population
Pregnant or Breastfeeding	• Discuss risk vs. benefit with patient • For patients with smallpox, transmission to fetus is possible • Adverse effects have not been observed in pregnant animal studies; pregnant patients were not included in original studies; it is not known if TPOXX crosses into breastmilk
History of Atopic Dermatitis or Other *Active* Skin Condition	• Eczema, impetigo, psoriasis, burns • Concurrent VZV, HSV • Severe diaper dermatitis with denuded skin • Darier disease (keratosis follicularis)

Presenting with ≥ 1 of the Following Complications	• Secondary bacterial infection • Gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration • Bronchopneumonia
Accidental Contamination to High Risk Sites	• Eyes or mouth • Genitals, anus

Ib. Pharmacotherapy

** Please note that treatment recommendations are based off of *in vitro* data, case reports. The exact effects of therapy remain vastly unknown at this time. Recommendations are based off of current available literature and CDC guidance **

Tecovirimat (TPOXX): Oral capsule or Intravenous (IV) formulations available
TPOXX was granted Emergency Access (EUA) Investigational New Drug (IND) for use against MPox. TPOXX is an antiviral medication that prevents intracellular envelope virus formation and subsequent viral dissemination. This agent was originally developed to treat smallpox and is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing **at least 3 kg**.

***Oral 200mg capsules**: Pediatric and Adult Patients*

Weight	Dose & Duration
3 kg to 5 kg	50 mg (0.25 capsule) PO q12h x 14 days
6 kg to 12 kg	100 mg (0.5 capsule) PO q12h x 14 days
13 kg to 24 kg	200 mg PO q12h x 14 days
25 kg to 39 kg	400 mg PO q12h x 14 days
40 kg to < 120 kg	600 mg PO q12h x 14 days
≥ 120 kg	600 mg PO q8h x 14 days

Administration:

- Administer within 30 minutes after a full meal containing moderate or high fat (about 25 g of fat)
- TPOXX Capsules can be administered by carefully opening the number of capsules noted below and mixing and administering the entire contents in 30 mL of liquid or soft food
    - 50 mg or 0.25 capsule- combine one capsule (200mg) in 30mL of water, measure out 7.5mL of mixture and administer within 30 minutes
    - 100 mg or 0.5 capsule- combine one capsule (200mg) in 30mL of water, measure out 15mL of mixture and administer within 30 minutes
    - 200 mg (1 cap), 400 mg (2 caps), or 600 mg (3 caps)- combine 1 to 3 capsules as noted by dose in 30mL of food or liquid; administer all of the drug-food mixture
    - For more information, please review the CDC instructions for mixing TPOXX capsules with food

Missed doses:

- Administer missed oral dose as soon as possible if up to 8 hours prior to next scheduled dose
- If <8 hours until the next scheduled oral dose, skip the missed dose and resume dosing at regular scheduled time

***IV 200mg/20mL vial**: Pediatric and Adult Patients, Crcl >30mL/min*

Weight	Dose & Duration
3 to 34 kg	6 mg/kg IV q12h x 14 days
≥ 35 kg to 119 kg	200 mg IV q12h x 14 days
≥ 120 kg	300 mg IV q12h x 14 days

Administration:

- Infuse doses over 6 hours; DO NOT give as an IV push

Monitoring:

- Renal function; if CrCl < 30 mL/min, discontinue IV formulation; may continue oral capsules if CrCL < 30 ml/min
- Adverse Effects (not all inclusive)
    - >10 %: Local pain and injection site swelling/erythema with IV, headache
    - 2-10 %: Abdominal pain, diarrhea, nausea, and vomiting
- Drug Interactions; several interactions may be unknown at this time
    - Repaglinide (hypoglycemia), midazolam (decreased efficacy of midazolam)

Ic. How to Obtain and Start Tecovirimat (additional information can be obtained at the CDC website)

TPOXX oral capsules **must** be requested patient-specific from the local health department. A separate process is required for IV formulation, please contact ASP for assistance.

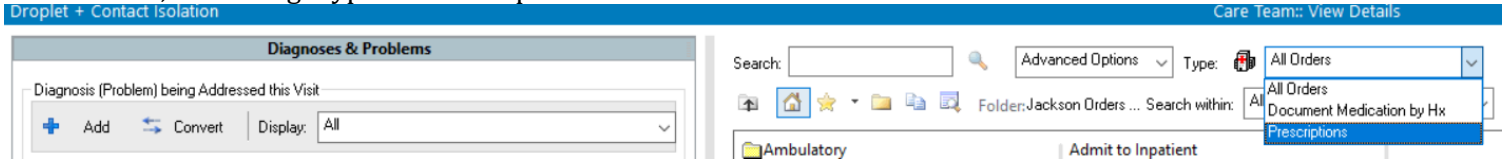
- The **Florida DOH Miami-Dade** should be contacted at the end of this process to ensure all documentation was received
    - Florida DOH Disease Control Epidemiology Line at 305-470-5660 (Alternative line: 305-470-6820)
    - In no response from above: CDC Emergency Operations Center: 770-488-7100 or email poxvirus@cdc.gov
- **Step 1**: Complete and email patient consent form to **miamiMPox@flhealth.gov** (Form 1 below, link provided) or can also fax to Miami-Dade DOH: 786-732-8714
- **Step 2**: Complete and email patient intake form (Form 2 below, link provided) along with patient consent form to (regaffairs@cdc.gov) within 3 working days
- **Step 3**: Send TPOXX prescription electronically to the FDOH Pharmacy in Flagler
    - **We highly** recommend calling DOH to ensure they received the prescription
    - The prescription process is currently undergoing improvements at JHS
        - Tickets have been submitted to IT to add to Cerner (please see last page for step by step instructions on how to order until this is complete)
- **Step 4:** Order TPOXX inpatient as a non-formulary medication (Pharmacy to assist)
- **Step 5 (Optional)**: Complete Clinical Outcome form (Form 3 below, link provided) and email to the CDC (regaffairs@cdc.gov) within 3 working days of last patient follow-up
    - At any point during treatment if patient experiences a serious adverse event, complete a MedWatch Form (Form 5 below, link provided) and email to the CDC (regaffairs@cdc.gov)

Required Forms (with links; also available on ASP app: https://jhsmiami.org/stewardship/)

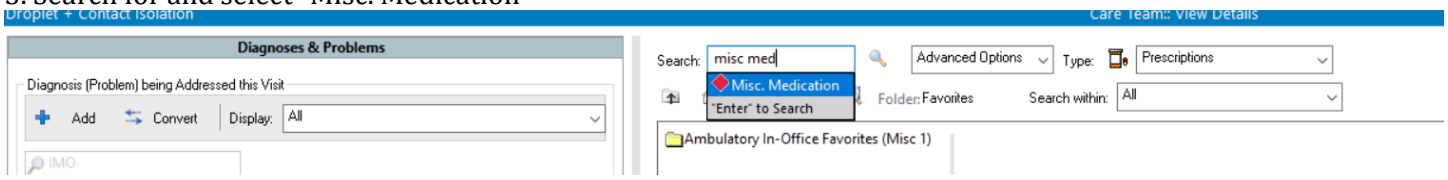
- Form 1: Informed Consent: Obtain prior to consent (return to CDC within 3 working days)
- Form 2: Patient Intake Form: Baseline assessment (return to CDC within 3 working days)
- Form 3 (Optional): Clinical Outcome Form: Progress information during and post treatment (return to CDC within 3 working days of last patient follow up)
- Form 4: FDA Form 1572: One signed per facility suffices for all TPOXX treatments under the EA-IND at the same facility; please check with your facility's ASP team to see if form already completed
    - ***This has already been completed for JMH, JNMC, JS***
- Form 5: MedWatch Form: Complete to report life-threatening or serious adverse events associated with TPOXX; return to CDC via email (regaffairs@cdc.gov)

How to order TPOXX as a miscellaneous medication in Cerner and send to DOH pharmacy

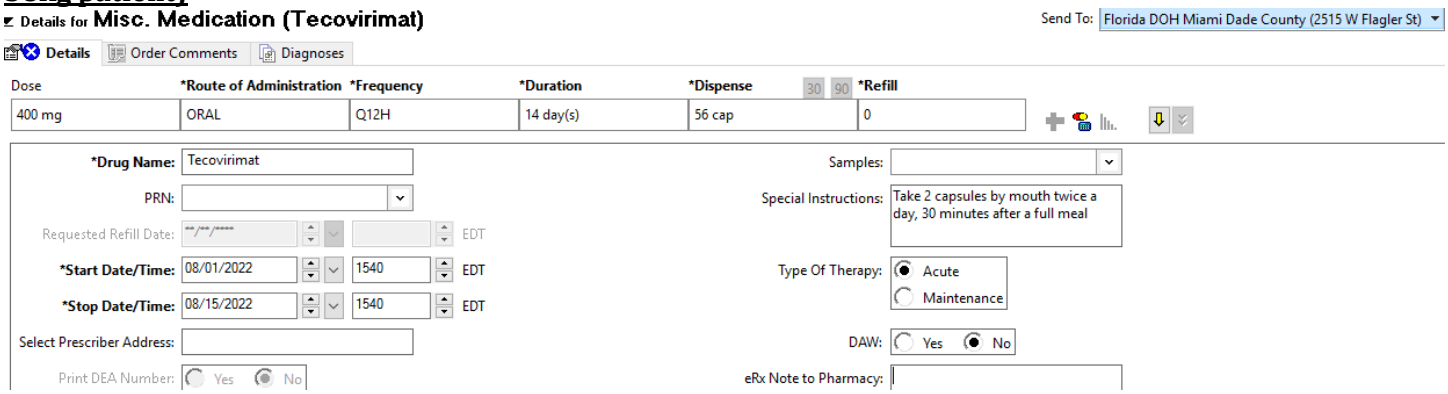
1. Orders
2. Add order, and change type to "Prescription"



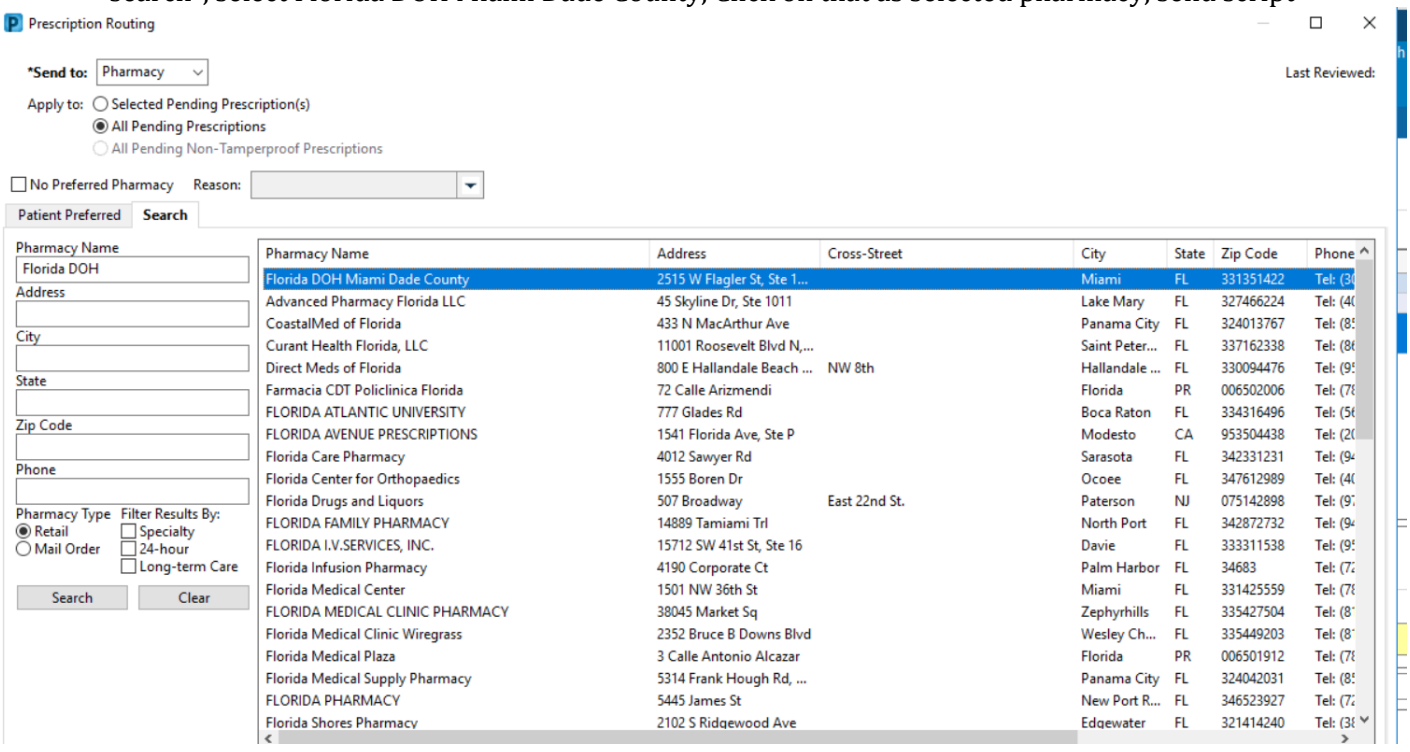
3. Search for and select “Misc. Medication”



4. Enter drug name “Tecovirimat”
5. Select dose, frequency, duration, and capsule number pending on patient weight **(example below for a 38kg patient)**



6. In upper right corner, change “Send to”
    a. Click on “other”, send to “Pharmacy”, select “search”, enter Pharmacy Name “Florida DOH”, click “search”, select Florida DOH Miami Dade County, Click on that as selected pharmacy, send script



II. Prevention of Disease

IIa. MPox Vaccines

ACAM200 and JYNNEOS™ are currently licensed in the United States for the prevention of smallpox and are currently recommended by the CDC in conjunction with ACIP for the prevention of MPox in certain populations

Vaccine	Virus type	Administration	Fully Vaccinated	Precautions
ACAM2000	Replicating live *Vaccinia virus*	Skin prick	4 weeks from vaccination	• Lesions from vaccine are contagious and may spread; recipients should take proper precautions • Avoid use in certain populations[1,2]
JYNNEOS™[,2]	Non-replicating live virus	Two **0.1mL Intraderm** injections, 4 weeks apart OR Two **0.5mL** Subcut injections, 4 weeks apart	2 weeks after the 2nd dose	• No risk of spread to other parts of the body or people • Do not administer if allergy to egg protein, gentamicin, or ciprofloxacin[2] • Do not administer vaccine intradermally in patients with history of developing keloid scars or patients <18 years of age

1. Cardiac disease, eye disease treated with topical steroids, congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV (regardless of immune status), atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions, in patients with history of developing keloid scars, infants less than 12 months of age, and pregnancy
2. For patients who are unable to receive the vaccine, TPOXX may be considered for post-exposure prophylaxis (PEP) on a case by case basis. Any PEP use must be in clinical consultation with CDC

Vaccine Storage

- All vaccine from the manufacturer is originally frozen
- If stored <u>frozen</u> (-25 to -15°C), product should be used within the printed expiration date on the carton
    - If carton is not available, please refer to expiration date by lot number found at https://aspr.hhs.gov/SNS/Pages/MPox.aspx
- If stored <u>refrigerated</u> (2 to 8°C), product may now be stored for <u>up to 8 weeks from thawing</u>, do NOT refreeze
    - This differs from the 12 hour beyond use date guidance in the package insert based on updated stability data from the manufacturer
    - Vials require approximately 10 minutes to thaw from frozen temperature (-20°C)
    - Once a vial is punctured, if it is not used in its entirety it should be stored +2 to +8 C and discarded within 8 hour of first puncture

IIb. Qualification for Vaccine per Florida Department of Health, Pre-and Post-Exposure

Currently, the Department of Health is only providing the JYNNEOS™ vaccine to certain populations that are at high-risk for infection. These groups include:

- Laboratory personnel and select health care personnel at high risk for MPox
- Close contacts of MPox cases
- Immunocompromised MSM (men who have sex with men) with HIV/AIDS (<200 CD4 white blood cells per ml[3])
- Other MSM with a recent history of a sexually transmissible diseases (STD)

Post-Exposure Prophylaxis (PEP) Timing:

- Administer within 4 days from exposure in order to prevent onset of disease

- May be given up to 14 days post exposure; if given between 4-14 days post exposure, vaccination may reduce the symptoms of disease but may not prevent disease
- If a person has previously received the small pox vaccine, but it has been >3 years ago, they qualify for vaccination
- Vaccination after onset of signs or symptoms of MPox is not expected to provide benefit

IIc. Scheduling your Appointment for Vaccination

To schedule an appointment with the Florida Department of Health for MPox follow the attached link on Google Chrome, Microsoft Edge or mobile devices https://book.appointment-plus.com/d6b7yl3g

IId. Interim Guidance for Use of JYNNEOS – Enhanced Vaccination Strategy

Globally, supply of JYNNEOS is currently limited. Although more is expected in coming weeks and months.

As of August 9th, 2022, the CDC has released interim guidance regarding an alternative vaccine administration regimen under an Emergency Use Authorization (EUA) to increase the number of available JYNNEOS vaccine doses, based on a clinical study demonstrating that the reduced intradermal dose was immunologically non-inferior to standard subcutaneous dosing[5]. This alternative administration produces more local redness/itching but less localized pain compared to subcutaneous administration.

As part of the EUA, JYNNEOS may now be administered:

- **Intradermally** (ID) with an injection volume of **0.1 mL** to patients **age ≥ 18 years** who do NOT have a history of developing keloid scars
- To patients **< 18 years** of age via standard **subcutaneous** route

Vaccination schedule remains unchanged. Two doses of JYNNEOS are recommended, administered 28 days apart, regardless of administration route.

EUA Fact Sheets:

- Healthcare Providers (www.fda.gov/media/160774/download)
- Patients and Caregivers (www.fda.gov/media/160773/download)

REFERENCES:

1. https://www.cdc.gov/poxvirus/MPox/
2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214518s000lbl.pdf
3. MPox and Smallpox Vaccine Guidance | MPox | Poxvirus | CDC
4. Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. MPox Outbreak. Updated: August 9, 2022.
5. Frey SE, et al. Comparison of lyophilized versus liquid modified Ankara (MCA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-naïve subjects. *Vaccine*, 2015; 33(39): 5225-5234.

Appendix C

Monkey Pox Virus Protocol: Labor & Delivery
August 8, 2022

According to the CDC, *MPox virus* can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth.

The signs and symptoms of MPox virus infection in people who are pregnant include prodromal symptoms (e.g., fever, headache, lymphadenopathy, malaise, sore throat and cough) and rash.

A characteristic MPox rash in a person who is pregnant with risk factors for MPox virus infection should be carefully evaluated and diagnostic testing considered. Close monitoring for severe disease and pregnancy complications is important.

Infection Control

Infection control practices for the care of patients who are pregnant with MPox infection include Special Droplet Precautions to include eye protection, N95, gown and gloves. EVS terminal cleaning using bleach products is required with appropriate disposal of linen (Reference JHS MPox Protocol located in Badge Buddy). Negative pressure room is not required. All healthcare personnel on maternity and newborn care units should receive training on correct adherence to infection control practices, hand hygiene and PPE use and handling; and ensuring sufficient and appropriate PPE supplies are positioned at all points of care.

Medical Consideration

If a patient who is pregnant is suspected or diagnosed with MPox, the adult and pediatric infectious diseases teams must be consulted, made aware of the suspicion/ diagnosis to inform evaluation of the newborn.

Isolation Guidelines

The benefits of skin-to-skin contact and rooming-in on breastfeeding and infant physiology are well-known. However, given the risk of neonatal transmission of *MPox virus* with close contact and potential for severe disease in newborns, direct contact between a patient in isolation for MPox and their newborn is not advised.

Separation (e.g., separate rooms) of a patient with MPox from their newborn is the best way to prevent transmission to the newborn. Full-time rooming in with a newborn is not recommended during a patient's infectious period. Newborns born to people with MPox should be placed in isolation.

The patient should be counseled about the risk of transmission and the potential for severe disease in newborns. If the patient chooses to have contact with the newborn during the infectious period, strict precautions should be taken, including the following:

- There should be no direct skin-to-skin contact.
- During contact the newborn should be fully clothed or swaddled and after contact occurs the clothing or blanket should be removed and replaced.
- Gloves and a fresh gown should be worn by the patient at all times, with all visible skin below the neck covered.
- Soiled linens should be removed from the area.
- The patient should wear a well-fitting source control (e.g. medical mask) during visit.

These precautions should be continued until criteria for discontinuing isolation have been met (i.e., all Breast milk is the best source of nutrition for most newborns, and it provides protection against many illnesses. However, given that *MPox virus* is spread by close contact and neonatal MPox infection may be severe, breastfeeding should be delayed until criteria for discontinuing isolation have been met (i.e., all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed).

Breastfeeding

It is unknown if *MPox virus* is present in breast milk. Breast milk expressed from a patient who is symptomatic or isolated should be discarded while breastfeeding is delayed. To avoid inadvertently

exposing an infant to the *MPox virus*, a healthy caregiver can feed pasteurized donor human milk or infant formula.

Visitation

Visitors to pregnant or postpartum patients with MPox should be limited to those essential for the patient's care and wellbeing. Visitors should have no direct contact with the patient. Visitors should be informed about appropriate use of personal protective equipment (PPE) according to facility visitor policy. Visitors should be instructed to only visit the patient room and should not go to other locations within the facility, including the newborn nursery.

Transfer/ Transport of PUI MPox Infants

When a neonate born to a MPox positive or MPox rule out mom is ready for transport the team members inside the delivery room/ OR will push the isolette/ transporter out of the room. The receiving team wearing PPE aligned with contact precautions and droplet precautions will monitor the patient until the team inside the room has removed the PPE worn inside and donned new PPE outside the room if indicated. Neonate will be transported to designated unit in an air-mode incubator. Upon arrival to designated unit, linens, medical equipment will be wiped down before terminal cleaning. All disposable products will be discarded.

Discharge

All infants born to MPox positive mothers can be discharged when medically necessary. Social work should be consulted for all discharges of PUI infants.
https://www.cdc.gov/poxvirus/MPox/clinicians/pregnancy.html

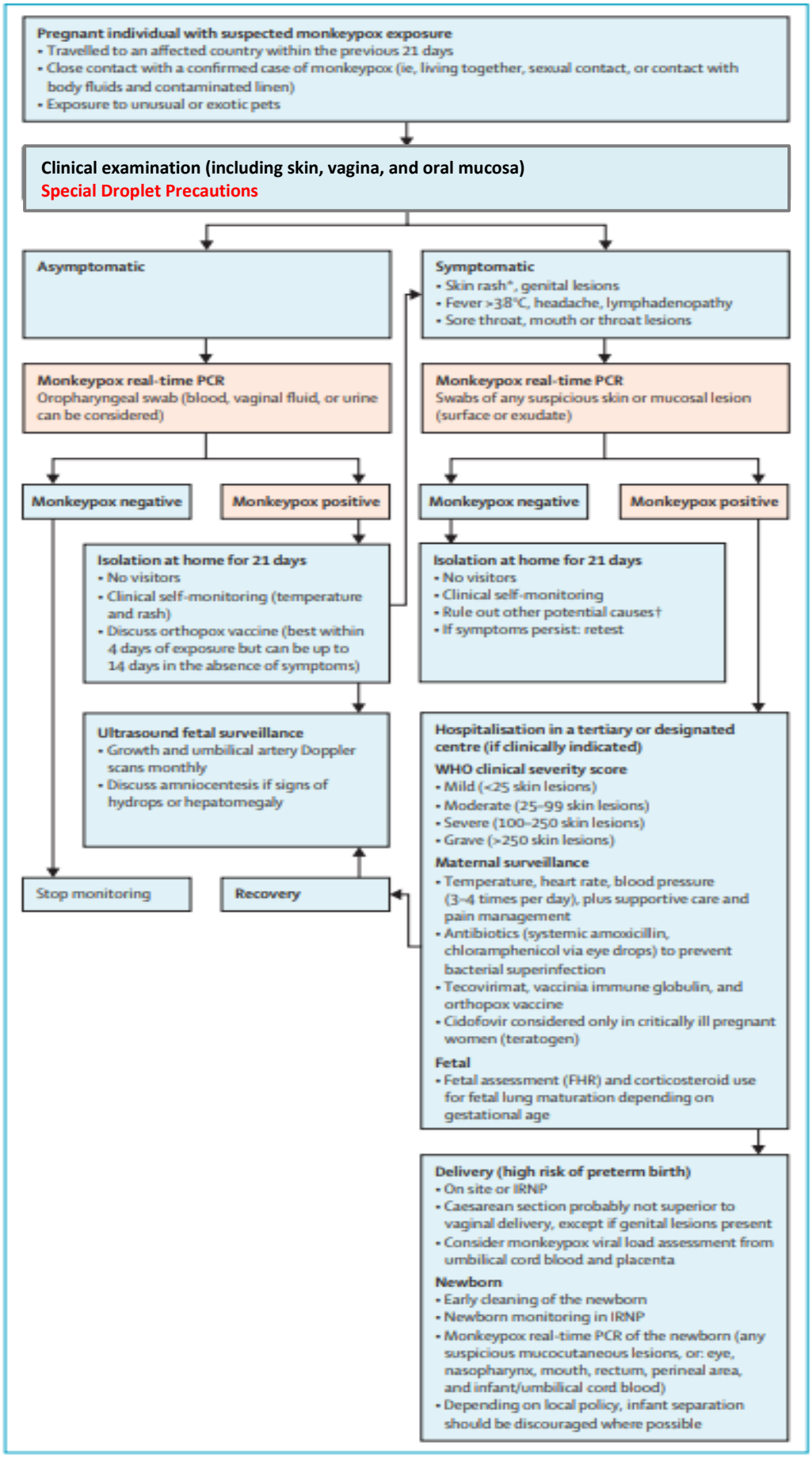
Patient Placement for MPox Rule Out

NICU/ PICU Placement
* Pre Term and/ or low birth weight and/or systematically ill placed in PICU private isolation room with Special Droplet Precautions activated OR in NICU when there is a separate area designated for Monkeypox isolation.

ET Placement
Full term baby in private isolation area with Special Droplet Precautions activated

ET3A Placement
Mother in private isolation Room with Special Droplet Precautions activated.

**Note: Any newborn PUI or confirmed MPox admitted to PICU must be managed by NICU physicians and nurses*


Pregnant individual with suspected monkeypox exposure
• Travelled to an affected country within the previous 21 days
• Close contact with a confirmed case of monkeypox (ie, living together, sexual contact, or contact with body fluids and contaminated linen)
• Exposure to unusual or exotic pets
Clinical examination (including skin, vagina, and oral mucosa)
Special Droplet Precautions
Asymptomatic
Symptomatic
• Skin rash*, genital lesions
• Fever >38°C, headache, lymphadenopathy
• Sore throat, mouth or throat lesions
Monkeypox real-time PCR
Oropharyngeal swab (blood, vaginal fluid, or urine can be considered)
Monkeypox real-time PCR
Swabs of any suspicious skin or mucosal lesion (surface or exudate)
Monkeypox negative
Monkeypox positive
Monkeypox negative
Monkeypox positive
Isolation at home for 21 days
• No visitors
• Clinical self-monitoring (temperature and rash)
• Discuss orthopox vaccine (best within 4 days of exposure but can be up to 14 days in the absence of symptoms)
Isolation at home for 21 days
• No visitors
• Clinical self-monitoring
• Rule out other potential causes†
• If symptoms persist: retest
Ultrasound fetal surveillance
• Growth and umbilical artery Doppler scans monthly
• Discuss amniocentesis if signs of hydrops or hepatomegaly
Hospitalisation in a tertiary or designated centre (if clinically indicated)
WHO clinical severity score
• Mild (<25 skin lesions)
• Moderate (25–99 skin lesions)
• Severe (100–250 skin lesions)
• Grave (>250 skin lesions)
Maternal surveillance
• Temperature, heart rate, blood pressure (3–4 times per day), plus supportive care and pain management
• Antibiotics (systemic amoxicillin, chloramphenicol via eye drops) to prevent bacterial superinfection
• Tecovirimat, vaccinia immune globulin, and orthopox vaccine
• Cidofovir considered only in critically ill pregnant women (teratogen)
Fetal
• Fetal assessment (FHR) and corticosteroid use for fetal lung maturation depending on gestational age
Stop monitoring
Recovery
Delivery (high risk of preterm birth)
• On site or IRNP
• Caesarean section probably not superior to vaginal delivery, except if genital lesions present
• Consider monkeypox viral load assessment from umbilical cord blood and placenta
Newborn
• Early cleaning of the newborn
• Newborn monitoring in IRNP
• Monkeypox real-time PCR of the newborn (any suspicious mucocutaneous lesions, or: eye, nasopharynx, mouth, rectum, perineal area, and infant/umbilical cord blood)
• Depending on local policy, infant separation should be discouraged where possible

APPENDIX D

July 14, 2022

DOH-Miami-Dade is offering appointments to high-risk populations for Jynneos Vaccine for the prevention of MPox

The Florida Department of Health in Miami-Dade County (DOH-Miami-Dade) is offering appointments for **Jynneos Vaccine** for the prevention of **MPox.** To become fully immunized you must be vaccinated with 2 doses, the second dose 28 days after receiving the first.

Currently, we are only providing the vaccine to certain populations that are at high-risk for infection, these groups include:

- Laboratory personnel and select health care personnel at high risk for MPox
- Close contacts of MPox cases
- Immunocompromised MSM (men who have sex with men) with HIV (<200 CD4 white blood cells per ml^3)
- Other MSM with a recent history of a sexually transmissible diseases (STD)

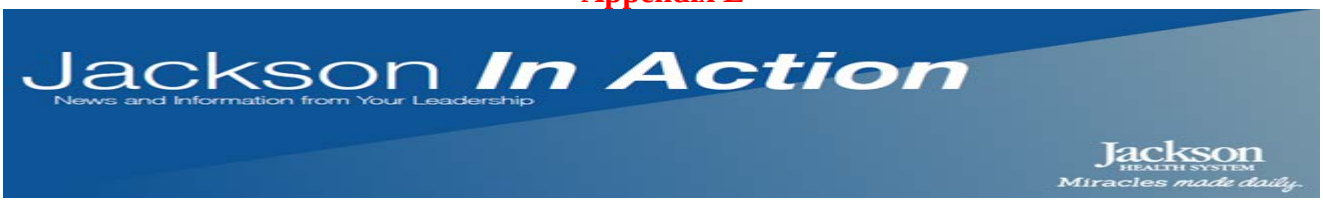
DOH-Miami-Dade is providing vaccines to individuals that are at high-risk for infection. If you are currently experiencing symptoms of MPox, we encourage you to get tested first to ensure you are not already infected. Symptoms of MPox include:

- Fever
- Headache
- Muscle aches and backache
- Swollen lymph nodes
- Chills
- Rash that can look like pimples or blisters that appears on the face, inside the mouth and on other parts of the body like the hands, feet, chest, genital, and anal area.

Please only schedule your appointment for your first dose if you are in one of the high-risk categories. Also, be aware that you should only make one appointment. Once you receive the first dose our clinic staff will provide you with a follow-up appointment for the second dose.

To schedule an appointment for MPox or other vaccines such as the COVID-19 vaccine for ages 5 and older, vaccine booster follow the attached link on **Google Chrome, Microsoft Edge or mobile devices:** https://book.appointment-plus.com/d6b7yl3g

Appendix E



Dear Jackson Team,
Over the last month, the United States has seen an increase in the number of people infected with MPox, a viral infection that can be transmitted person-to-person through respiratory secretions, direct contact with body fluids, and close skin-to-skin interaction. Throughout our Jackson hospitals and urgent care centers, we have tested 180 people suspected of having the virus, and 82 – or 45.5 percent – have tested positive.

While the majority of reported infections have occurred among men who have sex with men with multiple partners, the virus can easily be spread to others. **The Centers for Disease Control and Prevention (CDC)** recommends vaccination for people who are at high risk of contracting the virus, including:

- People who have had contact with someone confirmed to have the virus
- People who have multiple sexual partners in areas with known MPox outbreaks
- Immunocompromised men who have sex with men with HIV or a recent history of sexually transmitted diseases
- People whose jobs may expose them to the virus, including laboratory workers who perform testing, and select frontline healthcare workers in emergency departments and urgent care centers who may encounter a person with the virus

Beginning next Monday, August 15, Jackson will offer MPox vaccines to any employee or credentialed medical staff provider who wants to receive it. Vaccines will be administered on a walk-in basis from 8 a.m. to 2 p.m., Monday through Friday, at Employee Health Services at the Jackson Medical Towers, suite 1103, on the Jackson Memorial Medical Center campus. No appointments are necessary. The two-dose vaccine is administered four weeks apart, and full immunity is achieved six weeks after the first dose. At this time, we will only be administering vaccines to employees who show their Jackson badge.

Jackson will be offering the vaccine for a limited time through September to cover first and second doses. **Miami-Dade County** and **the Florida Department of Health** are also offering the vaccine at no cost, by appointment at multiple locations. For those high-risk populations, vaccination is a highly effective tool in preventing the spread of MPox.

As we continue to monitor the evolution of this virus, it's important you know what to look out for. MPox symptoms are similar to those of smallpox, and, fortunately, it is rarely fatal. Most people with the virus may first start with a fever, and then they develop lesions or rashes that are reported to be quite painful. Typically, people with a confirmed MPox diagnosis do not require hospitalization; however, they are advised to self-isolate at home for two to four weeks until the rash has fully resolved.

While the number of confirmed MPox cases continues to exponentially grow, it is not an airborne virus like COVID-19. Therefore, it is not as easy to contract. For most people, the risk is still low – but it is important that we all be educated and cautious.

We know the threat of another virus can be anxiety-inducing for many frontline caregivers. But MPox is not a new virus, and we are armed with the information and tools to prevent it.

Thank you for the continued compassion you show our patients, and the excellent medical care you provide daily.

Sincerely,

Lilian Abbo, MD, FIDSA
Associate Chief Medical Officer for Infectious Diseases
Jackson Health System
Professor of Infectious Diseases
University of Miami Miller School of Medicine

Appendix F

COCA Now

CDC Clinician Outreach and Communication Activity

September 19, 2022

Recommendations to Prevent Occupationally-acquired MPox Infection in Healthcare Personnel

Currently, there are more than 61,000 reported cases of MPox infection worldwide. Reports of occupationally-acquired MPox infection in healthcare personnel (HCP) remain rare in this outbreak, with most reports involving HCP sustaining a sharps injury during specimen collection or not using recommended personal protective equipment (PPE).

The Centers for Disease Control and Prevention (CDC) recommends HCP adhere to all recommended infection prevention and control measures including recommended PPE to reduce the risk of MPox virus transmission in healthcare settings.

Infection Prevention and Control

- Establish a process to screen patients for signs and symptoms of MPox at or before arrival so that they can be identified promptly in healthcare facilities (e.g., urgent care clinics, emergency departments, clinics providing evaluation for sexually transmitted infections) that are most likely to provide initial evaluation of patients with MPox.
- Dedicate adequate resources to support infection prevention practices, including access to all recommended PPE, particularly in outpatient settings, where MPox patients are frequently initially evaluated.
- Review infection prevention and control practices including carefully putting on and taking off PPE to ensure HCP are properly trained and provided the opportunity to ask questions and practice their technique.

Cleaning and Disinfection

- Review cleaning and disinfection practices to ensure they are being completed effectively. Cleaning and disinfecting rooms and equipment between patients is important to prevent transmission to others.

Safe Specimen Collection

- Use methods to safely collect MPox specimens. Unroofing or aspiration of lesions during specimen collection or using sharp instruments for MPox

lesion testing is not necessary or recommended due to the risk for sharps injury.

Healthcare Provider Exposures

- Know the signs and symptoms of MPox.
- Do not report to work if any signs or symptoms develop, even in the absence of recognized exposure.
- Leave work if signs or symptoms develop while at work, and notify supervisor or other appropriate group (e.g., occupational health services) for further evaluation.
- Healthcare facilities should provide flexible, non-punitive sick leave policies to allow HCP to take leave when indicated.

Additional Resources

- Infection Control: Healthcare Settings | MPox | Poxvirus | CDC
- Health Care Personnel Exposures to Subsequently Laboratory-Confirmed MPox Patients — Colorado, 2022 | MMWR (cdc.gov)

The Emergency Risk Communication Branch in the Division of Emergency Operations, Center for Preparedness and Response is responsible for the management of all COCA Products.

For information about this update or other clinical issues, or to send your feedback, please contact us at coca@cdc.gov
CDC Clinician Outreach and Communication Activity Facebook page—connect with COCA on Facebook
Clinician Outreach and Communication Activity—resources for healthcare providers
COCA RSS Feed—subscribe to be notified of conference calls, updates, and CDC guidance for health providers
Crisis & Emergency Risk Communication Training—training program that draws from lessons learned during public health emergencies, and incorporates best practices from the fields of risk and crisis communication
Health Alert Network—CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories

Centers for Disease Control and Prevention

1600 Clifton Rd Atlanta, GA 30329 1-800-CDC-INFO (800-232-4636) TTY: 888-232-6348

Appendix G

COCA Now

CDC Clinician Outreach and Communication Activity

September 21, 2022

Interim Tecovirimat (TPOXX) Guidance and Clinical Considerations for Pain Management of MPox

The Centers for Disease Control and Prevention (CDC) has updated its Guidance for Tecovirimat (TPOXX) Use Under Expanded Access Investigational New Drug Protocol, based on data from the published literature and recently released data from the Food and Drug Administration, which suggest that broad use of the antiviral drug TPOXX could promote resistance and render the drug ineffective for some patients.

All patients with MPox benefit from supportive care and pain control that is started early in the illness. For most patients with healthy immune systems, supportive care and pain control may be enough. However, there are some instances where TPOXX could be beneficial, and CDC has updated guidance to reflect this.

Specifically, TPOXX should be considered for use in people who have—

- Severe disease—meaning someone has a condition such as hemorrhagic disease, confluent lesions (i.e., individual sores have joined into one larger sore), sepsis, encephalitis, eye infections, or other infections that require hospitalization
- Involvement of anatomic areas which might result in serious disease including scarring

TPOXX should also be considered for use in people who are at high risk for severe disease, including—

- People with immunocompromising conditions
- Children, particularly patients younger than 8 years of age
- People who are pregnant or breastfeeding
- People with certain skin infections

However, for those patients for whom TPOXX is recommended, early administration is best. Patients can begin treatment as soon they have provided informed consent to their healthcare provider and the provider is enrolled in the Expanded Access Investigational New Drug protocol.

Additional Resources (updated September 15, 2022)

- Treatment Information for Healthcare Professionals
- Patient's Guide to MPox Treatment with TPOXX
- Study of Tecovirimat for Human MPox Virus (STOMP) Clinical Trial

The Emergency Risk Communication Branch in the Division of Emergency Operations, Center for Preparedness and Response is responsible for the management of all COCA Products.

For information about this update or other clinical issues, or to send your feedback, please contact us at coca@cdc.gov
CDC Clinician Outreach and Communication Activity Facebook page—connect with COCA on Facebook
Clinician Outreach and Communication Activity—resources for healthcare providers
COCA RSS Feed—subscribe to be notified of conference calls, updates, and CDC guidance for health providers
Crisis & Emergency Risk Communication Training—training program that draws from lessons learned during public health emergencies, and incorporates best practices from the fields of risk and crisis communication
Health Alert Network—CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories

Centers for Disease Control and Prevention

1600 Clifton Rd Atlanta, GA 30329 1-800-CDC-INFO (800-232-4636) TTY: 888-232-6348

Please see previous Reference list at this link (02). New References below

1. Mpox (formerly named monkeypox) situation update, as of 3 January 2023 https://www.ecdc.europa.eu/en/news-events/monkeypox-situation-update#:~:text=Global%20update,45%25%20against%20the%20preceding%20week.
2. Reduced Risk for MPox After Receipt of 1 or 2 Doses of JYNNEOS Vaccine Compared with Risk Among Unvaccinated Persons — 43 U.S. Jurisdictions, July 31–October 1, 2022 https://www.cdc.gov/mmwr/volumes/71/wr/mm7149a5.htm?s_cid=mm7149a5_x
3. Safety Monitoring of JYNNEOS Vaccine During the 2022 MPox Outbreak — United States, May 22–October 21, 2022 https://www.cdc.gov/mmwr/volumes/71/wr/mm7149a4.htm?s_cid=mm7149a4_x
4. Preliminary JYNNEOS Vaccine Effectiveness Estimates Against Medically Attended MPox Disease in the U.S., August 15, 2022 – October 29, 2022 https://www.cdc.gov/poxvirus/MPox/cases-data/mpx-JYENNOS-vaccine-effectiveness.html
5. CDC provides updated MPox vaccine safety data https://www.contemporarypediatrics.com/view/cdc-provides-updated-MPox-vaccine-safety-data
6. Human MPox: a comparison of the characteristics of the new epidemic to the endemic disease https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07900-7