Local Health Department Call: Monkeypox

May 24, 2022

North Carolina Communicable Disease Branch

Overview of Situation

Overview of Situation	**Zack Moore, MD, MPH** State Epidemiologist and Epidemiology Section Chief
Risk assessment and testing	**Victoria Mobley, MD, MPH** Medical Director HIV/STD and FSU
LHD control measures and monitoring	**Erica Wilson, MD, MPH** Interim MCU Medical Director and Medical Director for Respiratory/VPD Program
SLPH Update and Overview of Handling and Shipping of MPX Specimens	**Scott M. Shone, PhD, HCLD(ABB)** Laboratory Director, NC SLPH
Vaccine Issues and Updates	**Tim Davis, PharmD, BCNP, PMP** Medical Countermeasures Coordinator
Question & Answer Session	**Open for Questions — Please use the Zoom Q&A function**

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Risk assessment and testing

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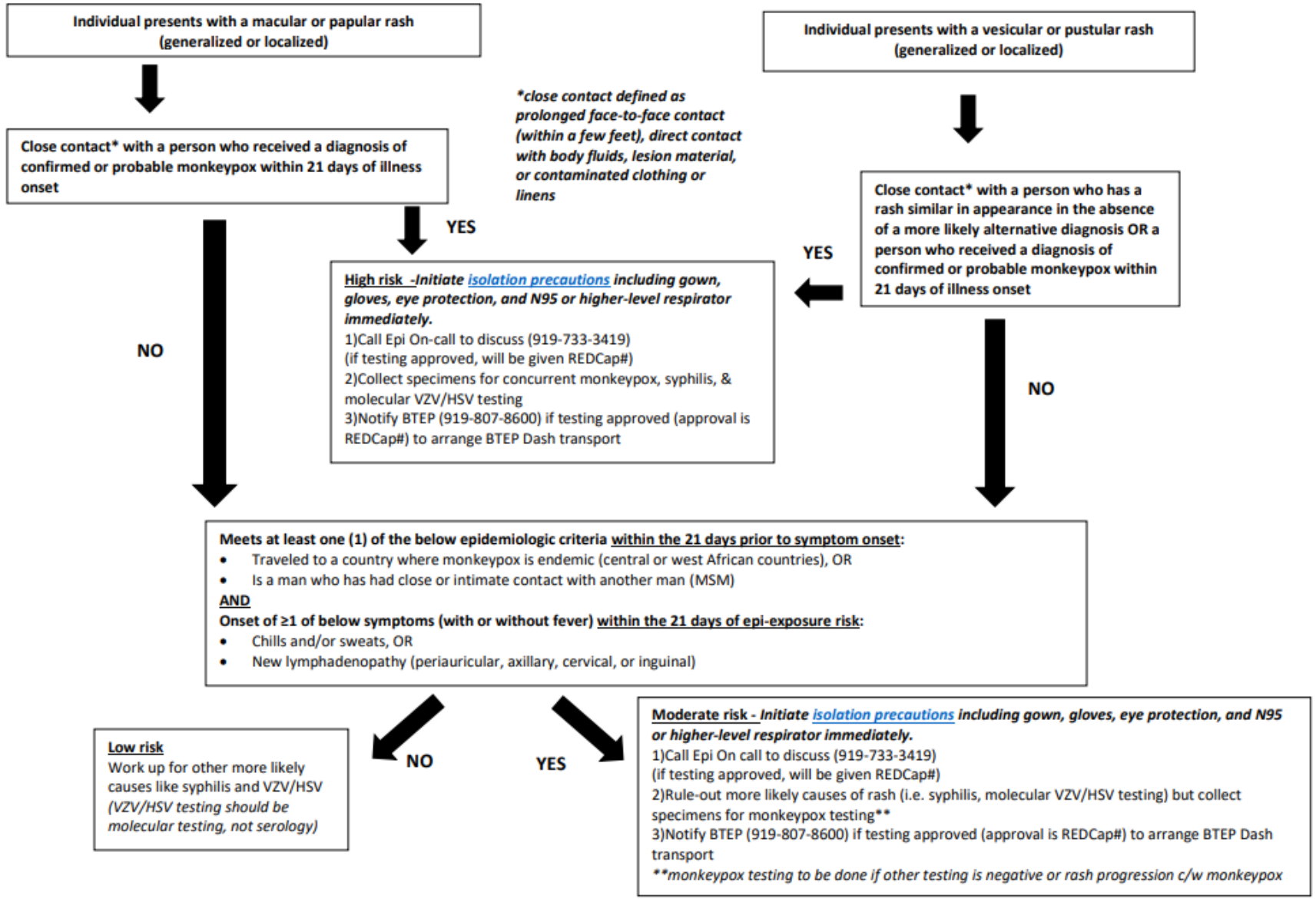
Evaluating Patients for Monkeypox (5/24/2022)



Although a prodromal illness (i.e. flu-like illness) commonly presents 1-3 days before rash onset with monkeypox, there have been reports of several cases presenting with perianal or genital lesions in the absence of subjective fever. Providers are encouraged to contact the epidemiologist on call to discuss any concerns or complicated situations not covered by this algorithm.

LHD control measures and monitoring

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SLPH Update and Overview of Handling and Shipping of MPX Specimens

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Orthopox Testing

- **Criteria**
  - All specimen submissions must be approved by the NC DPH Communicable Disease Branch **before** laboratory testing.

- **Testing Performed**
  - NCSLPH Bioterrorism and Emerging Pathogens (BTEP) Unit has validated the CDC Orthopox, Non-variola Orthopox, and Variola real-time PCR (RT-PCR) assays.
  - Turn around time is 6 to 48 hours depending on time of receipt and volume of specimens.
  - Presumptive positive specimens are forwarded to the CDC for confirmation.

Orthopox Testing

- **Specimen Collection**
  - Contact the BTEP unit (919-807-8600) as soon as approved for orthopox testing.
  - Use standard, contact, and droplet precautions when collecting specimens for monkeypox testing.

PREFERRED SPECIMENS for suspected monkeypox RT-PCR testing are swabs of lesions/lesion fluid	
More than one lesion should be sampled, preferably from different locations on the body and/or from lesions with differing appearances. To allow for confirmatory analysis at CDC, two dry swabs should be used simultaneously to vigorously scrub each lesion. Place swabs in screw-capped container. DO NOT ADD TRANSPORT MEDIA.	
Disease Stage	**Acceptable Specimen Types**
Macules / Papules	Lesion biopsy
Vesicles / Pustules	Swab of lesion fluid (preferred), roof, or biopsy
Scabs	Lesion scab

Orthopox Testing

- **Specimen Storage and Transport**
  - Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection.
  - Contact the BTEP Unit (919-807-8600) prior to any shipment for orthopox testing. BTEP will arrange for transport of specimens to SLPH.
  - Specimens shipped to SLPH must be packaged Category B
  - All specimen submissions must have an accurately completed BTEP Specimen Submission Form

HSV, VZV and Syphilis Testing

- **Contact routine testing laboratory for HSV and VZV Molecular Testing and Syphilis serology specimen requirements**

- **Submitters to NCSLPH**
  - Refer to SCOPE Appendix A for NCSLPH-specific specimen storage and transport requirements.
  - Submitters must complete a NCSLPH Syphilis Serology Test Requisition form if syphilis testing is to be done via NCSLPH.
  - Submitters must complete a NCSLPH Virology Test Requisition form if VZV/HSV testing is to be done via NCSLPH.

Vaccine Issues and Updates

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Monkeypox 2022: Medical Countermeasures Overview

VACCINES

Both options ~85% effective at preventing smallpox; thought to be similarly effective for monkeypox

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
Jynneos	FDA Approved for prevention of smallpox & monkeypox in **Adults 18+**	2 doses (0.5 mL each) administered 4 weeks apart. **Subcutaneous injection** in deltoid.	SNS request; **Limited supply (~1,000 doses in SNS)**	**Keep frozen** at -25°C to -15°C (-13°F to +5°F). Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 12 hours	Live attenuated virus vaccine; **Non-replicating** modified vaccinia Ankara-Bavarian Nordic (MVA-BN) May ship refrigerated for immediate use **Single dose vials;** SNS does not provide ancillary supplies
ACAM2000	FDA Approved for Smallpox prevention **Expanded access IND for monkeypox**	1 drop of vaccine suspension via scarification using bifurcated needle. CDC Training Videos for ACAM2000 administration	SNS Request; **> 100 Million doses in SNS**	Prior to reconstitution, **store frozen** at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months. Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F).	Live vaccinia virus Myocarditis risk Contraindications for severe immunocompromise Only administered by trained individuals Counseling on covering wound and handling bandages **100 doses per vial; comes with diluent and 100 bifurcated needles; transfer syringes not included.**

VACCINATION AS POST EXPOSURE PROPHYLAXIS (PEP)

Timing of PEP
- Vaccine should be administered within 4 days of exposure[1]
- Vaccine administered between 4 to 14 days after exposure may reduce symptoms but not prevent disease

Determining who should receive PEP
- Transmission of monkeypox requires prolonged, close interaction with a symptomatic individual
- Brief interactions and those conducted using appropriate PPE in accordance with Standard Precautions are not high risk and generally do not warrant PEP.

Current PEP Recommendations Based on Degree of Exposure[2]
- High
  - PEP recommended
- Intermediate
  - Individual risk/benefit analysis performed to inform clinical decision if PEP should be provided
- Low/Uncertain
  - PEP not recommended
- No Risk
  - PEP not recommended

[1] https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html
[2] https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html

CURRENT PUBLIC HEALTH RECOMMENDATIONS FOR EXPOSED INDIVIDUALS

Degree of Exposure: HIGH

Recommendations:

- Monitoring - Yes
- **PEP – Recommended**

Exposure Characteristics:

- Unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids from a patient (e.g., any sexual contact, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) -OR-
- Being inside the patient's room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances)

Source: https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html last updated 5/21/22

CURRENT PUBLIC HEALTH RECOMMENDATIONS FOR EXPOSED INDIVIDUALS CONT'D

Degree of Exposure: INTERMEDIATE

Recommendations:

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

Exposure Characteristics:

- Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask -OR-
- Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate)

Source: https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html last updated 5/21/22

CURRENT PUBLIC HEALTH RECOMMENDATIONS FOR EXPOSED INDIVIDUALS CONT'D

Degree of Exposure: LOW/UNCERTAIN

Recommendations:

- Monitoring - Yes
- **PEP – None**

Exposure Characteristics:

- Entered the patient room without wearing eye protection on one or more occasions, regardless of duration of exposure -OR-
- During all entries in the patient care area or room (except for during any procedures listed above in the high-risk category), wore gown, gloves, eye protection, and at minimum, a surgical mask -OR-
- Being within 6 feet of an unmasked patient for less than 3 hours without wearing at minimum, a surgical mask -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level based on unique circumstances (e.g., uncertainty about whether Monkeypox virus was present on a surface and/or whether a person touched that surface)

Source: https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html last updated 5/21/22

CURRENT PUBLIC HEALTH RECOMMENDATIONS FOR EXPOSED INDIVIDUALS CONT'D

Degree of Exposure: NO RISK

Recommendations:
- Monitoring - None
- **PEP – None**

Exposure Characteristics:
- Exposure that public health authorities deemed did not meet criteria for other risk categories

Source: https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html last updated 5/21/22

TREATMENT OPTIONS

Currently there are no proven, safe and effective treatments for Monkeypox virus. However, there is animal data to suggest that smallpox treatments could be used, given proper regulatory authority.

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
Vistide (Cidofovir)	FDA approved for treatment of CMV retinitis in AIDS patients **EUA or IND required for monkeypox**	5mg/kg IV once weekly x 2 weeks Must be administered with fluids and probenecid	**Commercially available**	75 mg/mL in clear glass, single use vial Store at controlled room temperature 20-25°C	Causes severe nephrotoxicity Renal function monitored within 48 hours prior to administration
Tembexa (Brincidofovir)	FDA Approved for treatment of smallpox **EUA or IND required for monkeypox**	**Adults and Peds ≥ 48 kg**: 200 mg (tablet or oral suspension) once weekly x 2 doses **Adults and Peds 10kg – 48 kg**: 4 mg/kg oral suspension once weekly x 2 doses **Peds < 10 kg:** 6 mg/kg oral suspension once weekly x 2 doses.	**SNS Request**	100 mg tablets in blister card in child resistant "wallet". Each wallet contains 4 tablets. Store at room temp. Lemon-lime flavored oral suspension; 65 mL bottle; 10mg/ml Store at room temp	May cause significant diarrhea or increase LFTs Avoid concomitant use with clarithromycin, rifampin, cyclosporine, gemfibrozil and HIV/HEP-C protease inhibitors, Take on empty stomach **Do NOT split or break tablets or come into direct contact with suspension**. Wash thoroughly with soap and water

TREATMENT OPTIONS CONT'D

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
TPOXX (Tecovirimat)	FDA approved for treatment of Smallpox in adults and pediatric patients weighing at least 13kg. **Expanded access IND for monkeypox**	Oral or IV formulations **Adults up to 120 kg:** 600 mg of TPOXX twice daily for 14 days **Adults > 120 kg:** 600 mg of TPOXX three times daily for 14 days **Peds 13 to less than 25 kg:** 200 mg of TPOXX twice daily for 14 days **Peds 25 kg to less than 40 kg:** 400 mg of TPOXX twice daily for 14 days **Peds 40kg or more:** 600 mg of TPOXX twice daily for 14 days	**SNS Request**	200 mg capsules, each bottles contains 42 capsules. Stored at controlled room temperature IV – requires refrigerated shipping and storage	TPOXX should be taken within 30 minutes after a full meal of moderate or high fat

TREATMENT OPTIONS CONT'D

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
Vaccinia Immune Globulin (VIG)	Indicated for the treatment of complications associated with vaccinia vaccination **NOT FDA approved for PrEP, PEP or treatment of Monkeypox**	**6,000 U/kg IV x 1 dose** Higher doses can be given if patient does not respond	**SNS Request**	Product may be stored frozen at or below 5°F (≤ -15°C) or refrigerated at 36 to 46°F (2 to 8°C); If product is received frozen, use within 60 days of thawing at 2 – 8°C. Intravenous infusion should begin within 4 hours after entering the vial. Do not reuse or save VIGIV for future use. This product contains no preservative; therefore, partially used vials should be discarded.	Withdraw entire contents of vial to calculate dose Administer via dedicated IV line Infuse at ≤0.04 mL/kg/minute and ≤2 mL/minute. Monitor for infusion reactions and adjust infusion decrease rate as needed.

ACCESS TO MONKEYPOX MCMS

- State health officials may request these MCMs on behalf of those needing pre- or post-exposure prophylaxis or treatment for monkeypox. (ASPR memo specifically mentions Jynneos, ACAM200, & TPOXX as being available)

- States with confirmed cases and/or exposed contacts linked through epidemiological investigation will be prioritized for MCMs.

- Once a request is made, a consultation will ensue with CDC subject matter experts, which will ultimately allow the state health department to determine the appropriate product and quantity as well as whether the MCMs needed are for PrEP, PEP or treatment.

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