

TO: Vermont Health Care Providers and Health Care Facilities

FROM: Patsy Kelso PhD, State Epidemiologist

Update on Human Monkeypox Virus (hMPXV)

This health update provides recent information about hMPXV for health care providers and facilities and is based on information from the U.S. Centers for Disease Control and Prevention (CDC). See https://www.cdc.gov/poxvirus/monkeypox/index.html for additional information.

Approximately 18,500 cases of hMPXV have been reported in the U.S., disproportionately affecting gay, bisexual, and other men or trans people who have sex with men. Among cases reported to CDC through July 27, 99% were among men. Among men with available information, 94% reported male-to-male sexual or close intimate contact during the three weeks before symptom onset. To date, there have been three Vermont cases, as well as additional cases in Vermont among residents of other states.

Clinical Presentation, Modes of Transmission, and Contagious Period

Classically:

- 3 stages:
 - Incubation period (approximately 1-2 weeks)
 - Prodrome (fever and lymphadenopathy; also, headache, myalgia, malaise)
 - Onset of vesicular or pustular rash, often beginning centrally and spreading distally
 - Rash (including papules, vesicles, pustules, scabs that are deep-seated, firm or rubbery, and have well-defined round borders)
 - Vesicular or pustular stages are often umbilicated. They may be painful, painless, or itchy.
- Transmission through:
 - Direct contact with the infectious rash or body fluids
 - Respiratory secretions during prolonged face-to-face contact
 - Touching items (e.g., clothing) that previously were in contact with a patient's infectious rash or body fluids
- Contagious period:
 - Until scabs have crusted over and fallen off and
 - o A fresh layer of intact skin has formed underneath



Current outbreak:

- Clinical manifestations and transmission patterns may not follow the classical pattern.
- Any person can acquire hMPXV, but transmission is currently most common among gay, bisexual, and other men or trans people who have sex with men (transmission occurring primarily through intimate skin-to-skin contact).
- Prodrome does not always occur or precede the rash.
- Mucosal involvement (including genital, perianal, or oropharyngeal lesion) in approximately 40% of cases.
- Genital and perianal lesions associated with severe and painful balanitis, phimosis, urethritis, and proctitis.
- Oropharyngeal symptoms (including symptoms related to epiglottitis and tonsillitis) associated with pain or difficulty swallowing.

Diagnostic Testing for hMPXV

Testing should be performed on persons for whom hMPXV is suspected based on clinical presentation, especially if they might have had contact with someone in a social network experiencing hMPXV activity.

If patients report no close, personal contact with someone with hMPXV infection, other possible causes of rash should be considered, including:

- Adults: secondary syphilis, herpes simplex virus, varicella zoster.
- Children: varicella zoster, molluscum contagiosum.

Other potential etiologies of illness should be tested for in parallel with hMPXV testing, based on clinical presentation and epidemiologic criteria.

Laboratory Testing

Some commercial laboratories offer testing for hMPXV. Commercial labs typically have a turnaround time of several days and will bill private insurance, Medicaid, or Medicare. Those who are underinsured or uninsured will receive a bill for hMPXV testing. Refer to your organization's billing practices for identification of appropriate CPT codes. If you are using a commercial lab, please refer to their specimen collection instructions.

Testing at the Health Department Laboratory typically has a turnaround time of 1-2 days upon receipt and is provided at no charge. Please use the Health Department Laboratory preferentially, especially when you have a high clinical suspicion of hMPXV. Please consult with a Health Department epidemiologist 24/7 at 802-863-7240, option 2 when collecting specimens to arrange a courier for prompt receipt of specimens at the Health Department Laboratory.



Specimen Collection

There are Health Department Laboratory hMPXV specimen collection kits in most Vermont hospitals, Vermont Department of Health local health offices (available M-F 7:45 am – 4:30 pm), and in some outpatient clinics. Some hospitals have developed their own kits; please refer to those instructions where applicable. If you don't have access to a kit, you can assemble your own:

- Four dry Dacron, nylon or polyester swabs with plastic, wood or thin aluminum shafts
- Four sterile 15ml conical tubes (preferred) or containers
- Labels for tubes / containers
- Biosafety bag
- Clinical Laboratory Test Request form
- Cooler
- Frozen ice packs

Specimen Collection for Submission to the Health Department Laboratory

Read through the entire directions before proceeding. We recommend labeling your tubes before you begin specimen collection so that swabs can go directly into pre-labeled tubes.

- 1. If possible, select two lesions, preferably in different stages and/or locations (e.g., vesicle, pustule). Vigorously swab or brush **each lesion** with two separate sterile dry polyester, nylon, or Dacron swabs. This will result in two pairs of swabs, one pair for the Health Department Laboratory and one pair for CDC. If two lesions are swabbed, there should be a total of four swabs. **For example:** if you chose an elbow lesion and a knee lesion, there should be two elbow swabs and two knee swabs.
- 2. Insert each swab into a sterile screw-capped tube, such as a 15mL conical tube, or a 1.5-or 2-mL screw-capped tube with O-ring. A sterile container can be used if tubes are not available. Do NOT add or store in viral or universal transport media. Label each tube to indicate which lesion the swab was taken from (e.g., elbow, knee). For example: if you chose an elbow and a knee lesion, there should be four tubes total, two marked as elbow and two marked as knee. Each tube would contain one swab.
- 3. Refrigerate $(2-8^{\circ}C)$ specimens within an hour after collection and maintain at this temperature during shipping.
- Complete a <u>Clinical Laboratory Test Request Form</u> for each site. Include the site of the lesion on the request form. Select "Other" under Molecular Virology and write in "NVO".
- 5. Specimens should be packaged and transported as Category B specimens as outlined in Transporting Infectious Substances Safely.
- 6. Segregate tubes by site of lesion. In each biohazard bag, include the request form in the outer pocket, not in the bag with the specimens. **For example:** if you chose an elbow and a knee lesion, you should have two bags, one with the two tubes labeled "elbow" and one with the two tubes labeled "knee."



7. Place the bags with specimens and request forms in a cooler with a frozen ice pack. Seal the cooler and label to: VDHL, 359 South Park Dr, Colchester, VT 05446. Please add a UN 3373 Biological Substance, Category B label to comply with DOT/IATA shipping regulations. Mark "NVO" on the outside of the package.

The Health Department will provide guidance on shipping specimens to the Health Department Laboratory in Colchester through a courier service to ensure prompt receipt. For more information visit healthvermont.gov/hMPXV.

Pre- and Post-Exposure Prophylaxis with Vaccine

ACAM2000 and JYNNEOSTM (also known as Imvamune or Imvanex) are the two currently licensed vaccines in the United States to prevent smallpox. JYNNEOS is the primary vaccine being used in the current U.S. outbreak. JYNNEOS is administered as a 2-dose series 28 days apart. The vaccine contains live virus that is non-replicating; there is no risk of spread to other parts of the body or to other people. Those who receive the JYNNEOS vaccine are not considered vaccinated until two weeks after receipt of the second dose.

JYNNEOS can be administered subcutaneously with an injection volume of 0.5mL or intradermally with an injection volume of 0.1mL. Vermont has been allocated a limited amount of JYNNEOS vaccine to date. Therefore, we strongly encourage use of the intradermal route to reach more Vermonters.

Current JYNNEOS eligibility is as follows:

- Gay, bisexual, and other men or trans people who have sex with men, who had or expect to have more than one sexual partner.
- People who have had recent exposures to individuals with confirmed or possible hMPXV infections. Administration of vaccine within 4 days of exposure may prevent hMPXV, while administration 5-14 days after exposure may decrease the severity if infection occurred.
- Certain health care and laboratory personnel whose jobs regularly put them at high risk of
 exposure to the virus, such as performing testing or caring for multiple people infected with
 hMPXV. Routine immunization of health care workers against hMPXV is NOT recommended.

The Health Department is working with health care providers and partners that already care for people at highest risk for hMPXV to vaccinate their patients. Planned Parenthood locations, some Community Health Centers of Burlington locations, and the University of Vermont Infectious Disease/Comprehensive Care Clinic sites have limited supplies of vaccine. Health Department's local health offices are also offering small clinics to meet pre- and post-exposure vaccination needs. For more information visit healthvermont.gov/hMPXV.



Treatment

There are no U.S. Food and Drug Administration (FDA)-approved treatments for hMPXV. Tecovirimat (also known as TPOXX or ST-246) is approved by the FDA for treatment of human smallpox disease and CDC has an <u>expanded access Investigational New Drug application</u> (EA-IND) to allow access to and use of TPOXX to treat hMPXV in adults and children of all ages. This drug is available in oral and intravenous formulations.

How to Obtain Tecovirimat (TPOXX)

TPOXX is available through the Strategic National Stockpile and has been pre-positioned in Vermont. To inquire about obtaining TPOXX from the Health Department call (802) 863-7240, option 2.

Health care providers should perform the following:

- Obtain <u>informed consent</u> prior to treatment. Treatment may be started upon obtaining informed consent. All other forms can be completed and submitted after treatment initiation to facilitate timely care of the patient.
- Provide patient dosing instructions which can be found on page 4 of the <u>TPOXX</u> Protocol.
- Conduct a baseline assessment and complete the <u>Patient Intake Form</u>.
- Sign the <u>FDA Form 1572</u>. One signed 1572 form per facility suffices for all (including future) TPOXX treatments administered under the EA-IND at the same facility.
- Complete the <u>Reliance Request</u> form to rely on the CDC's IRB. This only needs to be done once per facility.
- Report life-threatening or serious adverse events associated with TPOXX by completing a <u>PDF MedWatch Form [226KB, 3 pages]</u> and returning it to CDC via email (<u>regaffairs@cdc.gov</u>) or uploading to <u>ShareFile</u> within 72 hours of awareness or sooner, if possible.
- Comply with FDA requirements described here: <u>Information for Healthcare Providers on</u> Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox.

REQUESTED ACTIONS:

- 1. Be familiar with the:
 - a. Clinical presentation, modes of transmission, and contagious period for hMPXV.
 - b. Procedures for specimen collection and diagnostic testing.
 - c. Use of vaccine for pre- and post-exposure prophylaxis.
 - d. Treatment for hMPXV.





HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention. Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.