Communicable Disease Epidemiology and Immunization Section

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Health Advisory: Updated Monkeypox Guidance for Testing, Reporting, Treatment and Vaccination in King County – 3 August 2022

Action Requested

- Be aware of the global outbreak of monkeypox with local transmission in King County
- Consider monkeypox in all individuals with compatible clinical presentation or epidemiologic link to known cases
 - Symptoms of monkeypox may include prodromal symptoms (e.g. fever, headache, lymphadenopathy, fatigue, chills, sore throat) and a characteristic rash. Most cases of monkeypox will have a rash which can be located in the mouth or the body including the anorectal mucosa. <u>Rashes</u> typically evolve over time beginning as a maculopapular lesion which then progresses to become vesicles and/or pustules (some with umbilication), before scabbing over and falling off.
 - o Individuals remain infectious from onset of first symptoms (including prodromal symptoms) until the scabs have fallen off and an intact layer of fresh skin is present for all lesions; typically 2-4 weeks.
 - Patients should be counseled by their provider to isolate from time of suspicion of monkeypox until negative test or complete resolution of symptoms.
- Report all cases of monkeypox <u>immediately</u> to Public Health at the time of suspicion and/or testing (206-296-4774)
- Provide <u>appropriate recommendations</u> for isolation to patients with a suspect case of monkeypox while results are pending and if they test positive.

Testing

- Be aware that testing for monkeypox can now be initiated through several commercial laboratories
 - Commercial testing is available for providers to use through the following partners and does <u>not</u> require Public Health approval of testing: <u>University of Washington</u>, <u>Labcorp</u>, <u>Quest Diagnostics</u>, <u>Aegis Science Corporation</u>, and <u>Sonic Reference</u> <u>Laboratory</u>
 - Washington State Public Health Laboratory (WA PHL) may still be used as an alternative to commercial testing <u>with prior approval</u> from Public Health; without prior approval, specimens may not be tested and results may be delayed.

Vaccination and Post-Exposure Prophylaxis Guidance

- Consider post-exposure prophylaxis (PEP) for people with sexual or close intimate contact with an individual with confirmed monkeypox virus infection
 - To date, King County has been allocated 9,120 doses of JYNNEOS vaccine for use, an amount much smaller than demand and need.

- Public Health is prioritizing giving the first dose of vaccine to as many people at high risk of recent exposure as possible with the expectation that we will deliver the second dose as close to the 28 day mark as possible.
- Vaccination as PEP is being prioritized for high-risk exposures to a person with diagnosed monkeypox virus infection.
- Vaccination is also prioritized for people who meet both of the following criteria as part of a strategy known as PEP++ (PEP plus plus):
 - Gay, bisexual, or other men or transgender people who have sex with men AND
 - At least one of the following:
 - More than 10 sex partners in the prior 3 months
 - History of early syphilis or gonorrhea in the prior year
 - Methamphetamine use in the prior month
 - Attendance at a bathhouse, other public sex venue, or group sex (sex including at least 3 people at the same time) in the prior 3 months
 - Experiencing homelessness/unstable housing AND currently living in a congregate setting AND had any sexual activity in the prior 3 months.
- o If your practice does not have JYNNEOS vaccine available:
 - Instruct patients to call our Public Information Call Center at (206) 477-3977 and speak with a public health nurse. Eligible individuals will be referred to Harborview's Sexual Health Clinic or other local vaccine provider.
- O In the coming weeks, we anticipate additional shipments of vaccine doses to King County. Assuming we receive a sufficient number of doses, we aim to expand our network of providers who can vaccinate eligible individuals at highest risk and who serve a wide range of geographies and communities across King County. In addition, we are working to identify providers who can vaccinate unestablished and/or uninsured patients at no cost.
- If you would like to be updated on provider practices accepting referrals for monkeypox vaccination, send an email to <u>vaccineinfo@kingcounty.gov</u>. We will alert you when we have additional providers able to accommodate referrals.

Treatment

- Consider treatment for confirmed, probable, and high suspicion monkeypox cases with the antiviral tecovirimat (TPOXX) if patients are experiencing severe disease, or are at high-risk of severe disease
 - Tecovirimat, an FDA-approved antiviral treatment for human smallpox disease caused by *Variola virus* in adults and children, may be considered for treatment in people with monkeypox virus infection. Its use for monkeypox virus infections is not approved by the FDA but is available for use under a non-research expanded access Investigational New Drug (EA-IND) protocol.
 - Request tecovirimat and enroll providers in the Investigational New Drug (IND)
 protocol using the secure TPOXX IND Enrollment and Treatment Request Form
 - Severe disease includes those experiencing severe pain, widespread infection, or infection of the eyes.

- Populations at high-risk for severe disease include people with weakened immune systems, children especially those under 8 years of age, people with a history of eczema, and people who are pregnant or breastfeeding.
- The CDC has provided <u>guidance and clinical indications</u> which providers may consider using for determining which patient requires treatment
- Pre-emptively register with the CDC's Expanded Access Investigational New Drug application (EA-IND 116039) proactively to allow access to and use of stockpiled tecovirimat (TPOXX) for non-variola orthopoxvirus infections
 - King County hospitals and health systems should proactively consider how they may manage tecovirimat treatment for their patients if needed as the IND protocol includes multiple steps before, during, and after treatment is complete.
 - CDC has shortened and simplified the EA-IND requirements recently and is considering further simplifications to minimize the administratrive burden on clinicians.
 - King County clinicians interested in starting this process, can fill out the secure <u>TPOXX</u>
 IND Enrollment and Treatment Request Form. Procedures are outlined as follows:
 - Prescribing clinician must initiate/complete paperwork prior to first tecovirimat prescription.
 - Upon receipt of an enrollment request, Public Health will provide instructions from CDC Regulatory Affairs along with the IND protocol and FDA Form 1572.
 - Clinicians must obtain informed consent from the patient prior to treatment initiation.
 - Clinicians must complete the FDA Form 1572 within 3 days of prescribing treatment and submit this along with the principal investigator's CV to CDC (this form only needs to be completed once by the clinician); a courtesy copy of the FDA Form 1572 should also be submitted to Public Health.
 - The listed principal investigator must be a clinician with a physician license and is not restricted to infectious disease subspecialists
 - Sub-investigators can include other advanced practice providers.
 - Prescribing clinician is responsible for paperwork outlined in the IND protocol for tecovirimat and should submit as directed.
 - o IND protocol updates may occur and can be found on the <u>CDC's TPOXX webpage</u>.
 - The procedure for prescribing and obtaining authorization of release of tecovirimat from Public Health stockpile is as follows:
 - To be dispensed, an authorization form is submitted by Public Health to the Harborview Medical Center (HMC) pharmacy where our doses are stored for regional use.
 - All suspect, probable or confirmed cases of monkeypox in residents of King County must be reported to Public Health Communicable Disease Epidemiology (24/7 line: 206.296.4774).
 - At the time of tecovirimat treatment, providers should fill out the secure <u>TPOXX IND Enrollment and Treatment Request Form</u>; once completed, Public Health will reach out to the provider to facilitate the prescription processing and dispensing.

- Tecovirimat IND patient consent form (included in the IND protocol document) must be completed and signed prior to authorization to release of tecovirimat.
- Medication can be picked up by the patient at Harborview outpatient pharmacy curbside pick-up during their normal pick-up hours or arrange for courier transport from Harborview pharmacy to a receiving pharmacy within the provider's healthcare facility; courier transport is available through the Washington State Department of Health and should be arranged through Public Health.
- For clinics that are unable to fulfill the steps required under the tecovirimat IND protocol, we encourage proactive discussions within existing referral networks to develop a plan to obtain treatment.

Infection Prevention and Control

- Ensure <u>infection control measures</u> are in place when evaluating patients for <u>monkeypox</u> in your facilities
 - Notify infection prevention immediately when a patient seeking assessment for monkeypox is identified.
 - Patients with suspected monkeypox should be placed in single-person room and no special air-handling is required; intubation and extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.
 - All personnel entering the patient room are recommended to wear gown, gloves, eye protection, and a NIOSH-approved respirator with N95 or higher filter
 - Standard cleaning and disinfection procedures should be carried out using EPAregistered hospital-grade disinfectant with an emerging viral pathogen claim. Laundry should be <u>handled with standard practices</u>, and promptly contained in a bag and never shaken, avoiding dispersal of infectious lesion materials
 - Complete infection prevention guidance may be found at the <u>CDC Infection</u>
 Prevention page

Background

Monkeypox virus is a DNA virus in the *Orthopox* genus and is acquired through close contact with an infected person or animal. In the 2022 global outbreak of monkeypox, contact with infected animals has not been established as a means of transmission. After infection, there can be an incubation period of roughly 1-2 weeks. The virus may be transmitted through direct contact or close contact with an infected person, through contact with objects contaminated with the monkeypox virus, and may be transmitted by a pregnant person to their fetus transplacentally. Although in this current outbreak men who have sex with men are overrepresented, anyone who is in close contact with an infected person or objects contaminated with monkeypox is at risk of developing monkeypox. Most infections in this outbreak resolve within 2-4 weeks of onset, even without treatment but severe outcomes are possible. Immunocompromised persons, persons who are pregnant or breastfeeding, and children and adolescents may be at higher risk of severe disease.

Local Case Counts

- As of August 2, 2022, a total of 128 cases of monkeypox has been identified in King County; current case counts are updated Monday – Friday and can be found on the King County monkeypox webpage.
- Local transmission in King County has been ongoing since July, with the majority of recent cases reporting no travel during their exposure period.
- o To date, all cases are among men and most cases are among men who have sex with men.
- Most cases reported sexual contact during their exposure period.

National and Global Case Counts

- On July 23, 2022, the World Health Organization (WHO) declared monkeypox a global health emergency.
- Between May 14, 2022 and August 1, 2022, over 23,600 cases have been identified globally in 80 countries including 7 deaths that have been reported to the WHO.
- As of August 2, 2022, there are 6,326 cases of monkeypox in the US across 48 states,
 Washington, DC and Puerto Rico; no deaths have been reported in the US to date.

Resources

Case Definitions for Use in the 2022 Monkeypox Response

Monkeypox: Information for Healthcare Professionals

Clinical Recognition of Monkeypox

Clinical Considerations for Monkeypox in Children and Adolescents

Clinical Considerations for Monkeypox in People who are Pregnant or Breastfeeding

CDC Exposure Criteria

CDC Health Alert Network (HAN)

U.S. Monkeypox Outbreak 2022: Situation Summary

WA DOH Monkeypox Guidance