Guidelines for JYNNEOS Vaccine Use

Updated December 23, 2022

The current monkeypox epidemic is rapidly evolving and these guidelines will be updated as we learn more about populations at risk for monkeypox virus infection and as vaccine supply changes.

These guidelines are designed to ensure that Washington state's supply of JYNNEOS vaccine goes to people who have been exposed to monkeypox virus (MPV or Mpox) or are at high risk for MPV/Mpox and that, within those groups, the provision of vaccine is equitable. Because the current MPV/Mpox epidemic is concentrated in gay, bisexual, and other men who have sex with men (GBMSM), the Department of Health (DOH) is prioritizing GBMSM and transgender persons who have sex with men to receive the state's limited supply of vaccine. The guidelines further prioritize groups of people who may be at higher risk of MPV/Mpox, including historically marginalized or excluded populations that have been disproportionately affected in other epidemics.

JYNNEOS is licensed for a 2-dose series given at an interval of 28 days. In the setting of sufficient vaccine supply, DOH recommends prioritizing complete vaccination series. Currently, DOH has sufficient supply of JYNNEOS vaccine and encourages two-dose series completion for individuals receiving vaccination. It is important to ensure a complete vaccination series for full effectiveness for those who began the series and to continue to reduce the risk of ongoing outbreak. In the setting of limited vaccine supply, DOH recommends prioritizing the administration of first vaccine doses rather than retaining inventory for second doses. This means that some people may have their second dose of vaccine delayed beyond 28 days until vaccine supply increases. Exceptions include people with moderate to severe immunosuppression, for whom the second dose should be administered as close to 28 days after the first dose as possible.

There is no recommendation for routine vaccination of the public. CDC recommends that vaccination with JYNNEOS be considered for persons determined to be at high risk for infection to prevent mpox.

Food and Drug Administration Authorization

On August 9, 2022, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) allowing for a smaller intradermal dose of 0.1 mL for adults in lieu of the 0.5 mL subcutaneous injection. Intradermal vaccination should produce a noticeable pale elevation of the skin (wheal). More information about vaccine administration including intradermal vaccination when a wheal is not obtained after administration can be found: Vaccine Administration Errors and Deviations | Monkeypox | Poxvirus | CDC. Please review the EUA Guidance for more information about individuals who intradermal route would not be advisable. There is flexibility regarding the route of administration for adult recipients to offer the intradermal or subcutaneous. If an individual is unwilling to obtain the intradermal route and has self-identified as high risk, the health care provider may administer via the subcutaneous injection at the full 0.5 mL volume.

The EUA only authorizes the administration of a 0.5 mL subcutaneous dose for children and adolescents under 18. For individuals under the age of 18 meeting the identified criteria, obtain consent in accordance with Washington state law.

To vaccinate more individuals with the current vaccine supply, DOH strongly encourages providers to use the smaller dosing intradermal route for vaccinations of adults when possible.

Post-Exposure Prophylaxis (PEP)

Vaccination guidance post exposure:
CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease.

If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of MPV/Mpox. Link for additional information: Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC.

Medical Providers
Offer vaccine to the following persons based on current post exposure criteria:

1. Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
    a. Persons who report high-risk exposure to a person with diagnosed MPV/Mpox. infection. This will include people who had sexual contact with a person with MPV/Mpox or significant skin-to-skin or mucous membrane contact with a person with MPV/Mpox*.
    b. Persons who report exposure to a person identified as exposed to diagnosed MPV/Mpox infection (second level contact).
2. Presumed contacts who may meet the following criteria:
    a. Know that a sex partner in the past 14 days was diagnosed with MPV/Mpox.
    b. Had multiple sex partners in the past 14 days in a jurisdiction with known MPV/Mpox.
    c. Persons who know that a sex partner or close social contact was exposed to a person diagnosed with MPV/Mpox.
3. Medical providers are not required to verify that patients had contact with a person with known MPV/Mpox infection.

Outbreak Response Pre-Exposure Vaccination

To more accurately reflect MPV/Mpox vaccination strategy, we transitioned from utilizing the term expanded PEP or as previously identified PEP++ to instead identify those who remain at high risk of exposure. The goal remains to reach additional persons with risk factors that might have recently exposed them to MPV/Mpox even if they have not had a documented exposure to someone with a confirmed diagnosis and to reach people with risk factors for infection before they are exposed. This allows the addition of criteria that expand the population of people eligible for vaccination, while still focusing on those at high risk of MPV/Mpox exposure. Outreach to and vaccination of individuals who meet the categories below should be prioritized with vaccine supply limitations.

1. The following populations should be offered vaccination:
    a. Gay and bisexual men and transgender individuals who have had multiple or anonymous gay, male bisexual, or transgender sex partners in the last 6 months
    b. People who have used methamphetamine in the last 6 months
    c. People who have exchanged sex for money, drugs, or other purposes in the past 6 months
    d. People who have been sexually assaulted, regardless of gender or sexual orientation
    e. People who have had sexual contact or prolonged skin-to-skin exposure with people who were exposed to MPV/Mpox
    f. A new diagnosis in the last 12 months of one or more nationally reportable sexually transmitted diseases (i.e., acute HIV, chancroid, chlamydia, gonorrhea, or syphilis)

2. The following populations (among those who meet the above criteria) should be prioritized for outreach and for vaccination:
    a. Black, Hispanic/Latinx, Native Hawaiian and Other Pacific Islanders, Asian, Indigenous, or American Indian/Alaska Native who are GBMSM.
    b. Individuals who have attended a bathhouse or public sex venue, or participated in group sex (sex including ≥3 people at the same time) in the last 6 months.
    c. Individuals who have experienced homelessness/unstable housing (including living in a shelter, car, or congregate setting; living with friends or relatives; couch surfing; agricultural workers and seafood workers) in the last 6 months.
    d. Individuals who are currently or in the past 6 months have been incarcerated.
    e. Individuals who are currently taking PrEP to prevent HIV infection.

3. If there is a surplus of vaccine, the following populations should be included:
    a. All individuals who have had multiple or anonymous sex partners in the last 6 months.
    b. Healthcare and public health workers who provide direct care to individuals with syphilis or other STIs.

**Examples include (but not limited to) sexual intercourse, intimate skin-to-skin contact (such as club dancing, cuddling, hugging, etc.)*
***Incubation period is up to 21 days; use of 6 months is to expand identification of individuals at risk*

For individuals under the age of 18 meeting the identified criteria, obtain consent in accordance with Washington state law.

While some people at risk for MPV/Mpox will seek out vaccine, low-barrier access, outreach, and education will be needed to reach all populations at risk and to reduce disparities in vaccine uptake (and therefore disease incidence). Utilizing a checklist to validate eligibility may cause stigmatization and should not be used. This is especially important to make vaccine more accessible to individuals who have not chosen to disclose their sexual orientation to others.

Local health jurisdictions and community partners may adapt criteria based on local epidemiology with DOH consultation. Every attempt should be made to maximize vaccine usage in open vials by planning clinical events while ensuring to follow requirements to discard unused portions in open vials 8 hours after opening and ensuring second doses are administered to prevent wastage. This could include expanding recipients of vaccine to those outside the identified prioritized group to include other GBMSM and transgender persons who have sex with men.

The Advisory Committee on Immunization Practices (ACIP) recommends that people whose jobs may expose them to orthopoxviruses such as MPV/Mpox, which could include clinical laboratory personnel who perform testing to diagnose orthopoxviruses, get vaccinated. At the present, most clinicians and laboratorians not performing orthopoxvirus generic test to diagnose orthopoxviruses, including MPV/Mpox are not advised to receive pre-exposure prophylaxis. At this point in time, there is no recommendation for routine vaccination of health care workers due to effective protection provided with appropriate personal protective equipment (PPE). A recent study in Colorado *"illustrated that the risk for HCP acquiring monkeypox after exposure to patients with monkeypox was very low despite incomplete adherence to recommended PPE, especially among primary and urgent care settings, and receipt of PEP by fewer than one half of eligible exposed HCP. Despite these gaps, no HCP in Colorado developed monkeypox during their 21-day monitoring period."* Health Care Personnel Exposures to

Subsequently Laboratory-Confirmed Monkeypox Patients — Colorado, 2022 | MMWR (cdc.gov). Healthcare employers should review and follow Isolation Precautions | Guidelines Library | Infection Control | CDC for more information.

Outreach Strategies

For local health, use PHIMS-STD to support MPV/MPOX investigations and vaccinations:

1. Be sure to search PHIMS-STD for STI/HIV history on any patient diagnosed with MPV/Mpox or named as exposed to MPV/Mpox.
2. If the person was recently diagnosed and interviewed, this may already give you possible contacts and locations for outreach and offer of vaccination. You can also identify if the patient was concurrently diagnosed with an STI and avoid having multiple public health workers contacting the patient concurrently, which could be confusing or stigmatizing.
3. Consider using HIV/STI data to support invitations for vaccination – recent MSM cases of syphilis, HIV, gonorrhea, and possibly chlamydia and their named contacts could be directly contacted and invited to be vaccinated. DOH staff can provide a line list of cases and exposed partners to support your jurisdiction.

Intersectional implementation of pre-exposure vaccination strategies through clinics and organizations that serve Black, Indigenous, Latinx, Native Hawaiian/Pacific Islander, and Asian people, people experiencing homelessness, people experiencing incarceration, people living with HIV, people who use methamphetamine, and refugee and immigrant communities (e.g., the temporary agricultural workers) may make vaccine distribution more equitable and more effective at the population level.

Apply pro-equity vaccination strategies when approaching outreach for vaccinations.

1. Engage communities to inform vaccine prioritization and planning.
2. Integrate a pro-equity approach into vaccine allocation and distribution.
3. Prioritize allocation and support to providers who effectively serve disproportionately impacted communities.
4. Invest in trusted community leaders, messengers, and organizations.
5. Ensure all communications, education and outreach efforts are culturally and linguistically appropriate and accessible.
6. Strengthen the public health system's ability to center communities in vaccine outreach and access
7. Foster opportunities for collaboration.
8. Support a trauma-informed approach to vaccine conversations.
9. Strategies used for equitable vaccination during COVID-19 vaccination response can be applied to JYNNEOS vaccination. For additional information on equity and engagement, visit COVID-19 Vaccine - Equity and Engagement | Washington State Department of Health.

References

Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC

Tordoff DM, Barbee LA, Khosropour CM, Hughes JP, Golden MR. Deviation and Validation of an HIV Risk Prediction Score Among Gay, Bisexual, and Other Men Who Have Sex With Men to Inform PrEP Initiation in an STD Clinic Setting. J Acquire Immune Defic Syndr 2020;85:263071.

UK Health Security Agency. Investigation into monkeypox outbreak in England: technical briefing 3. July 8, 2022.

NYC Health Monkeypox Vaccine Plan: https://www1.nyc.gov/site/doh/health/health-topics/monkeypox-vaccination.page

San Francisco, CA Monkeypox Vaccine Plan: Monkeypox Vaccine | San Francisco (sf.gov)

Jynneos Health Care Provider Fact Sheet 08092022 (fda.gov)

Jynneos EUA FactSheet Recipients Caregivers 08092022 (fda.gov)

Health Care Personnel Exposures to Subsequently Laboratory-Confirmed Monkeypox Patients — Colorado, 2022 | MMWR (cdc.gov).