

Guidelines for JYNNEOS Vaccine Use

Updated May 20, 2024

Background

In May 2022, a global outbreak of mpox (formerly known as monkeypox) was reported in countries where the disease was not regularly occurring. This outbreak, unlike previous outbreaks in the past, was primarily driven by transmission through close sexual and intimate contact, which disproportionately, but not exclusively affected gay, bisexual, and other men who have sex with men (GBMSM). Individuals who test positive for mpox continue to be reported across the United States and in Washington state. When combined with other prevention measures, vaccination prior to exposure or if exposed within 4-14 days after may help control outbreaks by reducing transmission of mpox virus, preventing disease, or reducing disease severity. There is sufficient supply of JYNNEOS vaccine to provide vaccinations for individuals at high risk for disease. These guidelines are designed to ensure equitable access to Washington state's supply of JYNNEOS vaccine for people who have been exposed to monkeypox virus (MPXV) or for those who are at high risk for acquiring mpox.

Because cases continue to be concentrated in GBMSM, the Department of Health (DOH) is prioritizing GBMSM and transgender persons who have sex with men to receive the state's supply of JYNNEOS. The guidelines further prioritize groups of people who may be at higher risk of mpox, including historically marginalized or excluded populations that have been disproportionately affected in other epidemics.

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.

JYNNEOS Vaccine Interval and Administration

JYNNEOS is licensed for a 2-dose series given 28 days (4 weeks) apart. 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 optimal effectiveness for those who began the series and to continue to reduce the risk of ongoing outbreak. If vaccine supply is not sufficient, DOH will update guidance to support public health needs.

The standard route of administration approved by the Food and Drug Administration (FDA) is subcutaneous with 0.5mL of JYNNEOS. On August 9, 2022, the FDA issued an Emergency Use Authorization (EUA) allowing for a smaller <u>intradermal administration of 0.1 mL</u> for adults to make more doses available at a time when vaccine supply was limited. There is currently adequate supply of JYNNEOS vaccine, so providers can administer the vaccine using either the standard subcutaneous or the alternative intradermal route.

Please review the <u>EUA Guidance</u> for more information about individuals whom intradermal route would not be advisable. When administering an intradermal dose, consult with the patient on their location preference.

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. In situations where there is a limited supply of vaccine, recommendations may be updated.

Post-Exposure Prophylaxis (PEP)

CDC recommends that JYNNEOS vaccine be given ideally 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 and may still provide some protection against mpox. 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 mpox. Link for additional information: Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC.

A patient's verbal attestation of exposure is sufficient. Medical providers are not required to verify that patients had contact with a person with known mpox infection.

Persons Recommended to Receive Vaccine

Outreach to and vaccination of individuals who meet the categories below should be prioritized. Reduce barriers to vaccination by allowing individuals to self-attest to meeting criteria to receive mpox vaccine, and provide mpox vaccination without requiring individuals to specify which criterion they meet.

- 1. The following populations should be offered vaccination:
 - a. People who had known or suspected exposure to someone with mpox.
 - b. People who had a sex partner in the last 2 weeks who was diagnosed with mpox.
 - c. Gay and bisexual men and transgender, nonbinary, or gender diverse individuals who in the past six months have had the following:
 - A new diagnosis of one or more sexually transmitted infections (STIs; e.g., chlamydia, gonorrhea, or syphilis).
 - More than one sexual partner.
 - d. People who have had any of the following in the past 6 months:
 - Sex at a commercial sex venue (like a sex club or a bathhouse); or,
 - Sex in association with a larger public event in a geographic area where mpox transmission is occurring.
 - Sex in exchange for money, drugs, other purposes...
 - e. People who are sexual partners of people with any of the above risks.
 - f. People who anticipate experiencing any of the above scenarios.
 - g. People with HIV infection or other cause of immunosuppression who have had recent or anticipate potential mpox exposure.
 - h. People who work in settings where they may be exposed to mpox (e.g., people who work with orthopoxviruses in a laboratory).
- 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.
 - f. Individuals who have used methamphetamines in the past 6 months.

- g. People who have been sexually assaulted regardless of gender or sexual orientation
- h. People who have had sexual contact or prolonged skin-to-skin exposure (secondary contacts) with people who were exposed to mpox.
- i. All individuals who have had multiple or anonymous sex partners in the last 6 months.

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 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.

Preexposure vaccine should be given to people whose jobs may expose them to orthopoxviruses such as the monkeypox virus (MPXV):

- Research lab personnel working with orthopoxviruses.
- Clinical lab personnel who perform testing to diagnose orthopoxviruses.
- Health care worker response teams designated by public health and antiterror authorities.

Other people whose jobs may expose them to orthopoxviruses and should be offered vaccine:

- People who administer ACAM2000 (Smallpox [Vaccinia] Vaccine, Live)
- People who care for patients infected with orthopoxviruses

There are currently no recommendations 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.

^{*}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

Outreach Strategies

For local health, use the Public Health Issue Management System for Sexually Transmitted Diseases (PHIMS-STD) to support mpox investigations and vaccinations:

- 1. Be sure to search PHIMS-STD for STI/HIV history on any patient diagnosed with mpox or named as exposed to 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.
- 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

Dalton AF, Diallo AO, Chard AN, et al.; CDC Multijurisdictional Mpox Case Control Study Group. Estimating effectiveness of JYNNEOS vaccine in preventing mpox: a multijurisdictional case-control study—United States, August 19, 2022–March 31, 2023. MMWR Morb Mortal Wkly Rep 2023;72:553–8. https://doi.org/10.15585/mmwr.mm7220a3 PMID:37200229

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

National Coalition for Sexual Health: <u>For Healthcare Providers | NCSH</u> (national coalition for Sexual Health.org)

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

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.

Jynneos EUA FactSheet Recipients Caregivers 08092022 (fda.gov)

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