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Technical Bulletin

Date: **August 8, 2022**
Topic: **Monkeypox Virus Vaccine Guidance and Recommendations**
Contact: **Melissa Peek-Bullock, State Epidemiologist, Office of State Epidemiology**
To: **Health Care Providers, Hospitals, Laboratories and Local Health Authorities**

Background

According to the Centers for Disease Control and Prevention (CDC), since monkeypox virus is closely related to the virus that causes smallpox, the smallpox vaccine can protect people from getting monkeypox. Past data from Africa suggests that the smallpox vaccine is at least 85% effective in preventing monkeypox.

Smallpox vaccines such as JYNNEOS and ACAM2000 are effective at protecting people against monkeypox when given before exposure to monkeypox. But experts also believe that vaccination after a monkeypox exposure may help prevent the disease or make it less severe.

On June 28, 2022, the national vaccine strategy was released by the White House to help immediately address the spread of the virus by providing vaccines across the county to individuals at high risk.[1]

Currently, two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing monkeypox infection: JYNNEOS and ACAM2000. Both can be used before and after exposure to monkeypox, however ACAM2000 carries a higher potential for more serious side effects and adverse events than JYNNEOS and may not be an appropriate option for most patients. Because of the risks associated with ACAM2000, the Nevada Department of Health and Human Services (DHHS) has opted to order supplies of JYNNEOS through the Strategic National Stockpile (SNS). However, supplies of JYNNEOS are extremely limited. If ACAM2000 is clinically necessary for a specific person after consultation with CDC, the doses can be ordered at that time.

Below is a brief description of each of the two currently available vaccines.

JYNNEOS

- JYNNEOS contains a live virus that does not replicate efficiently in human cells.
- Administered as two subcutaneous injections 4 weeks apart.
- The immune response takes 2 weeks after the second dose for maximum development.
- Licensed by the FDA for use in the prevention of smallpox or monkeypox in people ages 18 years and older. Use in younger populations requires submission of a single patient Expanded Access Investigational New Drug (EA-IND) application.
- The effectiveness of JYNNEOS against monkeypox is supported by animal studies.
- Adverse reactions include injection site reactions such as pain, swelling and redness.
- People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.

[1] https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/28/fact-sheet-biden-harris-administrations-monkeypox-outbreak-response/

- Safe for administration to people with HIV and atopic dermatitis.
- While there are no data in people who are pregnant or breastfeeding, animal data do not show evidence of reproductive harm; pregnancy and breastfeeding are not contraindications.

ACAM2000

- ACAM2000 is a live vaccinia virus vaccine that is replication competent.
- Administered as one percutaneous dose via multiple puncture technique with a bifurcated needle.
- The immune response takes 4 weeks for maximum development.
- Following a successful inoculation, a lesion (known as a "take") will develop at the site of the vaccination; the lesion may take up to 6 weeks or more to heal.
- Licensed by the FDA for use against smallpox; allowed for use against monkeypox under an EA-IND, which requires informed consent along with submission of additional forms.
- The effectiveness of ACAM2000 is supported by human clinical trials and animal studies.
- Adverse reactions include injection site pain, swelling and redness; fever; rash; lymph node swelling; and complications from inadvertent inoculation.
- People with severe allergy to any component of the vaccine should not receive it. In addition, people with severely weakened immune systems should not receive this vaccine.
- ACAM2000 should not be given to people with the following conditions:
    - Cardiac disease
    - Eye disease treated with topical steroids
    - Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV (regardless of immune status)
    - Atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions
    - Infants less than 12 months of age
    - Pregnancy

Because ACAM2000 is a replicating vaccine, there is a risk for inadvertent inoculation from the vaccine site to other areas of the body (autoinoculation) and inoculation of others. The risk of side effects in household contacts is the same as those for the vaccine recipient. Living situations should be considered before prescribing this vaccine.

Pre-Exposure Prophylaxis/Vaccination[2]

Large scale vaccination is not recommended at this time. The Advisory Committee on Immunization Practices (ACIP) recommends that people whose jobs may expose them to *Orthopoxviruses*, such as monkeypox, get vaccinated with either ACAM2000 or JYNNEOS to protect them if they are exposed to an *Orthopoxvirus*. This is known as pre-exposure prophylaxis (PrEP). People who should get PrEP include:

- Clinical laboratory personnel who perform testing to diagnose *Orthopoxviruses*, including those who use polymerase chain reaction (PCR) assays for diagnosis of *Orthopoxviruses*, including monkeypox virus.
- Research laboratory workers who directly handle cultures or animals contaminated or infected with *Orthopoxviruses* that infect humans, including monkeypox virus, replication-competent Vaccinia virus or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains.
- Certain health care and public health response team members designated by public health authorities to be vaccinated for preparedness purposes.

People who can receive PrEP include health care personnel who administer ACAM2000 or anticipate caring for many patients with monkeypox.

[2] https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control.html

At this time, most clinicians in the United States and laboratorians not performing the *Orthopoxvirus* generic test to diagnose *Orthopoxviruses*, including monkeypox, are not advised to receive *Orthopoxvirus* PrEP. Laboratorians should consult with laboratory biosafety officers and supervisors to identify risks and precautions, depending on the type of work they are doing. Regardless of whether they get PrEP, clinicians and laboratorians should use recommended infection control practices, which are important to preventing any infection.

Post-Exposure Prophylaxis (PEP)[3]

Vaccination after exposure to a person infected with monkeypox virus may help prevent disease or reduce severity of symptoms. CDC believes that if the vaccine is given within 4 days from the date of exposure it may prevent onset of the disease. If given 4-14 days after the date of exposure, vaccination may reduce the symptoms of disease but may not prevent the disease.

PEP is currently recommended for individuals who have had a high degree of exposure, such as unprotected contact with skin, bodily fluids, bedding or clothing of a person infected with monkeypox, or being inside a 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.

PEP can be considered for individuals who have had an intermediate degree of exposure, such as 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.

Timely reporting of suspected cases of monkeypox to public health authorities helps ensure that contact tracing can occur within the window necessary to connect close contacts with PEP. To report suspected cases of monkeypox to public health authorities, see the reporting section below.

PEP is not currently recommended for people who have had low or uncertain degree of exposure. PEP may be considered for individuals who experienced other exposures, at the discretion of public health authorities.

Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP++)

People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. Nevada's current vaccine allocation is limited; highest priority for vaccine administration is PEP for those that have a known exposure to monkeypox.

[3] https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html

Reporting of Possible Cases

Patients who may have monkeypox or who might have been exposed to someone with monkeypox should be reported to public health authorities. Contact the appropriate health authority to report potential cases of monkeypox or for clinical consultation.

Health Department	County	Phone Number to Report
Southern Nevada Health District (SNHD)	Clark	(702) 759-1300 (24 hours)
Washoe County Health District (WCHD)	Washoe	(775) 328-2447 (24 hours)
Carson City Health and Human Services (CCHHS)	Carson City, Douglas and Lyon	(775) 887-2190 (24 hours)
Nevada Division of Public and Behavioral Health (DPBH)	All other counties	(775) 684-5911 (M-F 8 am to 5 pm) (775) 400-0333 (after hours)

Questions:

For updated guidance, review the DPBH technical bulletin web page regularly. Email stateepi@health.nv.gov for other questions regarding monkeypox.

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