INFORMATION PAPER

DHA-IHD
31 May 2024

SUBJECT: Mpox Disease and Mpox Vaccine

1. Purpose. To describe mpox disease and mpox vaccine (JYNNEOS)

2. Facts.

   a. Microbiology. Mpox virus is a poxvirus of the genus Orthopoxvirus. Orthopoxviruses are large, complex, brick- shaped, double-stranded DNA viruses that cause infections characterized by a rash. Poxviruses have highly specialized modes of replication and pathogenesis allowing them to replicate in the cytoplasm of infected cells.

   b. Disease.

      After exposure to mpox, incubation period is 3-17 days. Infected persons are asymptomatic during incubation and not infectious to others.

      After incubation, mpox symptoms begin with a febrile prodrome (characterized by fever, malaise, headache, or back pain) followed by widespread, vesiculopustular rash (classically described as rubbery, well circumscribed, deep-seated lesions that can become umbilicated) that sometimes involves the palms and soles. Lymphadenopathy is common in classic presentations of mpox. Some cases have begun atypically, with lesions in the genital and perianal region and without subjective fever or other prodromal symptoms.

      A person is considered infectious from the onset of symptoms until all lesions have crusted over, those crusts have separated, and a fresh layer of healthy skin has formed under the crust. Illness typically lasts 2-4 weeks.

      There are two types of mpox viruses: clade I and clade II. Clade I mpox may cause severe illness and death in up to 10% of infected patients. Clade II mpox is generally less severe. The clade IIb variant of mpox was primarily responsible for the global outbreak that began in 2022.

   c. Epidemiology. Mpox is a zoonotic disease for which the animal reservoirs are not fully defined. Mpox is endemic in several countries in central and west Africa.

Both clade I and II mpox viruses can be spread via:

1) Direct contact with infected animals.
2) Close contact with a person infected with mpox. Close contact means direct skin-to-skin contact with mpox rash, or contact with saliva, upper respiratory sections, or body fluids. Exposure may occur during intimate contact, including hugging, massage, kissing, or oral, anal, or vaginal sex.
3) Contact with contaminated materials (e.g., touching objects, fabrics, and surfaces that have not been disinfected after use by someone with mpox).

d. Vaccine. JYNNEOS was approved for preventing mpox disease by the FDA in 2019. JYNNEOS is a live, attenuated vaccine that contains non-replicating Modified Vaccinia Ankara virus. When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.

e. Vaccine Handling. The JYNNEOS manufacturer has provided guidance on expanded duration of storage at refrigerated temperatures that is different than indicated in the package insert. This updated guidance can be found at aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf

The vaccine is available in single dose vials and stored frozen at -50°C to -15°C (-58°F to +5°F).

1) Once thawed, the vaccine may be kept refrigerated at +2°C to +8°C (+36°F to +46°F) for up to 8 weeks.
2) Count 8 weeks from the date when the vial was first thawed and mark this “beyond use date” (BUD) on the vial label. If the product expiration date on the carton is earlier, write that date on the vial instead.

f. Contraindications and Precautions.

1) JYNNEOS vaccine should not be administered to people who have had a severe allergic reaction to a previous dose of JYNNEOS vaccine or a vaccine component.
2) JYNNEOS contains minute amounts of gentamicin. Persons allergic to gentamicin may be at increased risk for severe allergic reactions after JYNNEOS.
3) Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.

4) Pregnancy. While animal studies assessing fetal risk associated with JYNNEOS were reassuring, human data on JYNNEOS administered to pregnant patients are insufficient to assess vaccine-associated risks in pregnancy. If JYNNEOS is administered to a pregnant patient, this should be reported to the DoD Smallpox Vaccine in Pregnancy Registry. [See DHA IHD Information Paper on this topic.]
5) Breastfeeding. It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the effects of JYNNEOS in the breastfed infant or on milk production. Because JYNNEOS contains no replicating virus, it should not create risk of transmission to a breastfed infant. CDC considers breastfeeding a precaution, but not a contraindication, to JYNNEOS receipt.

g. Immunization. CDC defines the current indications for mpox risk-based use of JYNNEOS. These can be found at Interim Clinical Considerations for Use of JYNNEOS Vaccine for Mpox. DHA-IHD Standing Orders will reflect the CDC indications for use of JYNNEOS for mpox protection. DHA-IHD Standing Orders will be regularly updated and can be found at IHD Mpox Page.

When JYNNEOS is indicated, administer 0.5 mL subcutaneously in the upper outer arm. A complete primary series of JYNNEOS is 2 doses, spaced at least 4 weeks apart.

JYNNEOS may to be administered as a booster for individuals with occupational risk factors ONLY, so long as exposure risk continues. Currently, there is no recommendation for boosters for non-occupational exposure to mpox. If considered necessary, a single 0.5 mL booster dose should be administered subcutaneously as follows:

1) Every 2 years for individuals with occupational exposure that is considered high risk (persons working with more virulent orthopoxviruses, e.g., variola virus or mpox virus).
2) Every 10 years for individuals with occupational exposure that is not considered high risk (persons working with less virulent orthopoxviruses, e.g., vaccinia virus or cowpox virus).

h. Adverse Events. Many people experience mild reactions after JYNNEOS vaccination that include injection site pain, redness, swelling, and/or itching; symptoms of myalgia, headache, and fatigue may also occur.

Syncope has been reported following vaccination with JYNNEOS. Procedures should be in place to avoid injury from fainting.

Adverse events following immunization with JYNNEOS, or any errors in administration of JYNNEOS, must be reported to the Vaccine Adverse Event Reporting System (VAERS). https://vaers.hhs.gov/reportevent.html

i. Special Considerations. JYNNEOS may be given at the same time as other vaccines. However, out of an abundance of caution, CDC suggests that people at increased risk of myocarditis, including adolescent or young adult males, may consider waiting 4 weeks between administration of JYNNEOS vaccine and any COVID-19 vaccine.

j. DOD Policy. Administer JYNNEOS for mpox protection to DOD beneficiaries as per current CDC/ACIP recommendations, local public health guidance for outbreak prevention, or IAW service specific guidelines.

3. Special note on mpox and smallpox.

This Information Paper addresses the use of JYNNEOS vaccine for mpox prevention. Please refer to separate Information Paper and related resources for the use of JYNNEOS vaccine for pre-event protection from smallpox.

4. References.

a. Centers for Disease Control and Prevention. Mpox Outbreak - Nine States, May 2022. MMWR 2022;71;1-6
b. Centers for Disease Control and Prevention. Use of JYNNEOS (Smallpox and Mpox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices - United States, 2022. MMWR 202271(22);734-42
c. JYNNEOS Package Insert dated 9/2019. Bavarian Nordic A/S, Denmark
d. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the Immunization Healthcare Division.
e. Centers for Disease Control and Prevention Yellow Book: https://wwwnc.cdc.gov/travel/page/yellowbook-home

Pacific Region Vaccine Safety Hub
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