

Мрох Ноте

Clinical Considerations for Mpox in People Who are Pregnant or Breastfeeding

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Mpox and Pregnancy

Data regarding mpox virus infection in pregnancy are limited. It is unknown if pregnant people are more susceptible to mpox virus or if infection is more severe in pregnancy. Mpox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth. Adverse pregnancy outcomes, including spontaneous pregnancy loss and stillbirth, have been reported in cases of confirmed mpox infection during pregnancy. Preterm delivery and neonatal mpox infection have also been reported. The frequency and risk factors for severity and adverse pregnancy outcomes are not known.

By comparison, smallpox, a disease caused by a similar orthopoxvirus (variola virus) that was eradicated in 1980, has more severe manifestations than mpox and is associated with more severe illness during pregnancy and risk for adverse pregnancy outcomes.

Signs and Symptoms

The signs and symptoms of mpox virus infection in people who are pregnant appear similar to those in non-pregnant people with mpox virus infection, including prodromal symptoms (e.g., fever, headache, lymphadenopathy, malaise, sore throat and cough) and rash.

During pregnancy, the cause of fever may be difficult to differentiate from other infections, such as intra-amniotic infection (chorioamnionitis), until the rash appears. Rash in a person who is pregnant with risk factors for mpox virus infection needs to be differentiated from dermatoses of pregnancy, including polymorphic eruption of pregnancy (also known as pruritic urticarial papules and plaques of pregnancy). In addition, mpox lesions can mimic those in other infections. Patients with rashes initially considered characteristic of more common infections (e.g., varicella zoster or sexually transmitted infections) should be carefully evaluated for a characteristic mpox rash (see images), and diagnostic testing should be considered, especially if the person has epidemiologic risk factors for mpox virus infection. Co-infections of mpox virus and sexually transmitted infections (STIs) and HIV have been reported and the presence of an STI does not rule out mpox, so a broad approach to testing is encouraged.

The case-finding approach to a patient with suspected mpox virus infection is the same for pregnant and non-pregnant people.

For additional recommendations for clinicians, please visit: Updated Case-finding Guidance: Mpox Outbreak—United States, 2022.

For clinician FAQs, please visit: Questions and Answers About Mpox for Healthcare Professionals.

Treatment

While most non-pregnant adults with an mpox virus infection experience mild illness and recover spontaneously, pregnant, recently pregnant, and breastfeeding people should be prioritized for medical treatment if needed. This is because of the probable increased risk of severe disease during pregnancy, risk of transmission to the fetus during pregnancy or to the newborn by close contact during and after birth, and risk of severe infection in newborns. Treatment for mpox virus should be offered, when indicated, to people who are pregnant, recently pregnant, or breastfeeding. The risks and benefits of treatment should be discussed with the patient using shared decision-making.

Close monitoring for severe disease and pregnancy complications is important. The decision to treat and monitor a pregnant person as an outpatient or in the inpatient setting should be individualized.

For information about skin and wound care for individuals with mpox lesions, please visit: Mpox: Caring for the Skin 📕 [165 KB, 2 pages] 🖸 and Mpox: Treating Severe Lesions 🗹 .

Tecovirimat (also known as TPOXX or ST-246)

Following consultation with CDC, if treatment is indicated, tecovirimat should be considered the first-line antiviral for people who are pregnant, recently pregnant, or breastfeeding. Tecovirimat 📙 [527 KB, 24 pages] 🗹 is an antiviral medication that is FDA-approved for the treatment of human smallpox disease caused by variola virus in adults and children. However, its use for other orthopoxvirus infections, including mpox, is not approved by the FDA. Therefore, CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol (sometimes called "compassionate use") that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including mpox, in adults and children of all ages.

Information about the impact of tecovirimat on reproductive development is limited to animal studies. No specific fetal effects were observed in these studies in which subject animals were administered oral tecovirimat at levels approximately 23 times higher than the recommended human dosage. It is not known if treatment with tecovirimat during pregnancy prevents congenital mpox.

There are no human data on the effect of tecovirimat on milk production, the presence of the drug in human milk, or the effects on breastfed children; information is limited to animal studies. Tecovirimat was present in breast milk in animal studies in which subject animals were administered oral tecovirimat at levels approximately 23 times higher than the recommended human dosage. It is not known if levels of tecovirimat expressed in breastmilk are sufficient for treatment of a breastfeeding child with mpox. As such, if indicated, children with mpox who are breastfeeding should be treated independently.

Tecovirimat use allowed under the EA-IND protocol **I** [1 MB, 22 pages] is intended to be used in concert with CDC guidance for treatment of mpox. Tecovirimat is available from the Strategic National Stockpile 🗹 and is provided at no cost 🗹 .

Learn about how to obtain tecovirimat and the requirements under the EA-IND protocol.

Learn about the National Institutes of Health (NIH)-funded clinical trial of tecovirimat 🗹 .

For management considerations of mpox in children please visit: Clinical Considerations for Mpox in Children and Adolescents.

Cidofovir and Brincidofovir

Although cidofovir 📙 [828 KB, 6 pages] 🗹 and brincidofovir 📙 [670 KB, 21 pages] 🗹 have been considered as alternative antiviral therapies to treat mpox infection, animal studies showed evidence of teratogenicity. As such, these medications should not be used to treat mpox virus infection in people who are in the first trimester of pregnancy. It is not known if cidofovir and brincidofovir are present in breast milk, so they should not be used in people who are breastfeeding due to the potential for serious adverse reactions in the breastfeeding infant.

Vaccinia Immune Globulin Intravenous (VIGIV)

Animal reproduction studies have not been conducted with vaccinia immune globulin intravenous (VIGIV) \square ; therefore, it is not known whether VIGIV can cause fetal harm when administered during pregnancy or whether it can affect future fertility. However, immune globulins have been widely used during pregnancy for many years without any apparent negative reproductive effects. The risks and benefits of VIGIV administration should be assessed for each individual patient. It is not known whether VIGIV is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VIGIV is administered to a person who is breastfeeding.

For details regarding therapeutic recommendations, visit: Treatment.

Vaccines

Type of vaccines

JYNNEOS

JYNNEOS is a live, non-replicating viral vaccine approved by the Food and Drug Administration (FDA) for the prevention of both smallpox and mpox disease. It is for use in individuals who are determined to be at high risk for smallpox or mpox infection and is intended to be administered by subcutaneous injection into the upper arm. FDA also issued an emergency use authorization (EUA) to allow healthcare providers to administer the vaccine intradermally (between the layers of the skin) for individuals 18 years of age and older who are determined to be at high risk for mpox infection.

Available human data on JYNNEOS administered to people who are pregnant are insufficient to determine if there are any vaccine-associated risks in pregnancy. Studies of JYNNEOS vaccine in animals have shown no evidence of harm to a developing fetus.

The safety and efficacy of JYNNEOS has not been evaluated in people who are breastfeeding or in young children. It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the impact of JYNNEOS on milk production or the safety of breast milk for children from persons vaccinated with JYNNEOS. However, JYNNEOS vaccine is replication-deficient and therefore should not present a risk of transmission to breastfed infants.

JYNNEOS can be offered to people who are pregnant or breastfeeding who are otherwise eligible. The risks and benefits of JYNNEOS should be discussed with the patient using shared decision-making.

For more information, please see 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 and The Food and Drug Administration's JYNNEOS Package Insert.

ACAM2000

ACAM2000 is a replicating viral vaccine licensed for prevention of smallpox. Vaccination with ACAM2000 is contraindicated in people who are pregnant or breastfeeding, due to risk of pregnancy loss, congenital defects, and vaccinia virus infection in fetuses and newborns and the availability of a non-replicating viral vaccine. Vaccinia virus infections following vaccination with replication-competent smallpox vaccines have been reported in fetuses and newborns of people who are pregnant or

breastfeeding. When vaccination is indicated for a person who is pregnant, breastfeeding, or trying to become pregnant, JYNNEOS is the vaccine of choice because it is non-replication competent.

If an individual is vaccinated with ACAM2000, they should be counseled to avoid becoming pregnant (or getting their partner pregnant) for 4 weeks after vaccination, and until the vaccination site has healed, the scab has fallen off, and a fresh layer of intact skin has formed. For information on contraceptive guidance, visit CDC Contraceptive Guidance for Health Care Providers.

Vaccination with ACAM2000 is contraindicated if the recipient cannot sufficiently isolate from household contacts with contraindications to vaccination; household contacts include anyone who might have direct contact with the vaccination site or with potentially contaminated materials (e.g., clothing or vaccination site dressings).

Persons vaccinated with ACAM2000 should isolate from household contacts with contraindications to vaccination for 4 weeks after vaccination and until the vaccination site has healed, the scab has fallen off, and a fresh layer of intact skin has formed. Precautions is should be used to avoid transmitting live vaccinia virus to other household contacts.

For more information, please visit: Mpox Vaccine Considerations.

Pre- and post-exposure prophylaxis

Pre- or post-exposure prophylaxis should be offered when indicated to people who are pregnant or breastfeeding. The risks and benefits of pre- or post-exposure prophylaxis should be discussed with the patient using shared decision-making.

When pre- or post-exposure prophylaxis by vaccination is chosen, JYNNEOS can be used for people who are pregnant or breastfeeding. ACAM2000 should not be used.

For more information, please visit: CDC's Mpox Vaccination page and The Food and Drug Administration's JYNNEOS Package Insert.

Vaccine adverse events

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be filed by healthcare providers or by vaccine recipients. To file an adverse reaction report, please visit www.vaers.hhs.gov $rac{1}{2}$ or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

U.S. healthcare providers and health department staff with a complex mpox vaccine safety question about a specific patient residing in the U.S. or a vaccine safety issue can contact the Clinical Immunization Safety Assessment (CISA) Project at CISAeval@cdc.gov to request a case consultation. In case of an emergent clinical vaccine safety inquiry, healthcare providers and health department staff can call the CDC Emergency Operations Center (EOC) Watch Desk at (770)-488-7100.

Contact and Breastfeeding

The benefits of skin-to-skin contact and rooming-in on breastfeeding and infant physiology are well-known. However, given the risk of neonatal transmission of mpox virus with close contact and potential for severe disease in newborns, direct contact between a patient in isolation for mpox and their newborn is not advised.

Separation (e.g., separate rooms) of a patient with mpox from their newborn is the best way to prevent transmission to the newborn. Full-time rooming in with a newborn is not recommended during a patient's infectious period.

The patient should be counseled about the risk of transmission and the potential for severe disease in newborns. If the patient chooses to have contact with the newborn during the infectious period, strict precautions should be taken, including the following:

- There should be no direct skin-to-skin contact.
- During contact the newborn should be fully clothed or swaddled and after contact occurs the clothing or blanket should

be removed and replaced.

- Gloves and a fresh gown should be worn by the patient at all times, with all visible skin below the neck covered.
- Soiled linens should be removed from the area.
- The patient should wear a well-fitting source control (e.g., medical mask) during visit.

These precautions should be continued until criteria for discontinuing isolation have been met (i.e., all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed).

Discharge planning should take into account the duration of isolation, ability to strictly adhere to recommended isolation precautions, and availability of alternative caregivers.

Patients in isolation for mpox may experience increased stress because of separation from their newborns, and postpartum depression symptoms may be worsened. Providers are encouraged to share resources with patients about coping with stress during this time.

Breastfeeding

Breast milk is the best source of nutrition for most newborns, and it provides protection against many illnesses. However, given that mpox virus is spread by close contact and neonatal mpox infection may be severe, breastfeeding should be delayed until criteria for discontinuing isolation have been met (i.e., all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed).

Some people who are breastfeeding may need additional support from a lactation provider to initiate and maintain their milk production and avoid a breast infection while mpox lesions are healing.

It is unknown if mpox virus is present in breast milk. Breast milk expressed from a patient who is symptomatic or isolated should be discarded while breastfeeding is delayed. To avoid inadvertently exposing an infant to the mpox virus, a healthy caregiver can feed pasteurized donor human milk or infant formula. People who are breastfeeding should talk with their healthcare provider to determine if their lesions have healed and they can resume direct breastfeeding or feed expressed breast milk.

Restricting visitors

Visitors to pregnant or postpartum patients with mpox should be limited to those essential for the patient's care and wellbeing. Use of alternative mechanisms for patient and visitor interactions, such as video-call applications, should be encouraged for any additional support.

Visitors should have no direct contact with the patient. Visitors should be informed about appropriate use of personal protective equipment (PPE) according to facility visitor policy. Visitors should be instructed to only visit the patient room and should not go to other locations within the facility, including the newborn nursery.

Infection Control

Infection control practices for the care of patients who are pregnant with mpox infection are the same as those for patients who are not pregnant with mpox infection – including appropriate isolation of patients with mpox; training for healthcare personnel on maternity and newborn care units on correct adherence to infection control practices and PPE use and handling; and ensuring sufficient and appropriate PPE supplies are positioned at all points of care.

If a patient who is pregnant is diagnosed with mpox, the pediatric team should be made aware of the diagnosis to inform evaluation of the newborn.

Newborns born to people with mpox should be placed in isolation, and healthcare personnel caring for newborns born to people with mpox should also follow recommendations as specified in CDC's Infection Prevention and Control of Mpox in Healthcare Settings.

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