

-- Outreach and Communication Activity, COCA, with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA Call, Update on Monkeypox in Children, Adolescents, and People Who are Pregnant or Breastfeeding.

All participants joining us today are in listen-only mode.

Continuing education is not offered for this COCA Call.

After the presentations, there will be a Q&A session. You may submit questions at any time during today's presentation. To ask a question using Zoom, click the Q&A button at the bottom of your screen. Then type your question in the Q&A box. Please note that we often receive many more questions than we can answer during our webinars.

If you're a patient, please refer your questions to your healthcare provider. If you're a member of the media, please contact CDC Media Relations at 404-639-3286 or send an email to [media@cdc.gov](mailto:media@cdc.gov).

I would now like to welcome our presenters for today's COCA Call. We're pleased to have with us Dr. Romeo Galang, Dr. Jeremy Gold, and Dr. Anne Kimball, who are all part of CDC's Monkeypox Response.

Please note that there are no content slides for today's presentation. Slides will not advance during the presentation. However, the resources you see on your screen, including CDC clinical consultation information and CDC monkeypox guidance documents can be found on this COCA Call's webpage at [emergency.cdc.gov/coca](https://emergency.cdc.gov/coca). I'll now turn it over to Dr. Galang. Dr. Galang, please proceed.

Thank you, and good afternoon. In this section in today's call, we will briefly review what we know about monkeypox in pregnant people, considerations for diagnosis and treatment, and considerations for infection prevention and control, especially as it relates to vaccination, mother/infant contact and to breastfeeding.

So what do we know about monkeypox during pregnancy? The monkeypox virus is an orthopoxvirus which can spread from infected animals to humans and also from person to person through skin-to-skin contact with skin lesions or body fluids from patients with monkeypox. It can also be spread through fomites for example, through shared towels or contaminated bedding, and through respiratory secretions. We do know that monkeypox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth.

Data regarding monkeypox virus infection during pregnancy are limited. Adverse pregnancy outcomes, including spontaneous pregnancy loss and stillbirth, have been reported among the five cases of monkeypox infection reported in the literature. Preterm delivery and neonatal infection have also been reported. It is unknown if pregnant people are more susceptible to monkeypox virus or if infection is more severe in pregnancy, and it is not known if vaginal birth and the presence of genital lesions can cause congenital monkeypox. The risk factors for and

frequency of adverse pregnancy outcomes from monkeypox infection during pregnancy are not known.

In the United States, as of October 21, 2022, 17 pregnant or recently pregnant people and two breastfeeding people have been reported to CDC with probable or confirmed monkeypox. Case counts for these populations are updated in the Monkeypox Technical Report published approximately every four weeks, available on the CDC website.

Today is the first presentation outlining some details about these cases which can inform clinical management. Given the limited understanding of monkeypox during pregnancy, we encourage that all cases during pregnancy or the postpartum period are reported to state and local health departments and ultimately to CDC. Among these cases, pregnant people acquired infection through close contact with an individual with confirmed infection, whether via sexual contact or close contact within households. Infections in all trimesters of pregnancy have been reported.

The signs and symptoms of infection in pregnant people appear similar to those in nonpregnant people with monkeypox. And this includes prodromal symptoms such as fever, headache, lymphadenopathy, malaise, sore throat and cough, and, of course, rash. Illness has generally been mild to moderate, with no cases resulting in critical illness or maternal deaths.

As reported in yesterday's *MMWR*, three people who are pregnant have been hospitalized for monkeypox, two who were hospitalized for pain control, and one for superimposed cellulitis. All patients were discharged home still pregnant, with reassuring maternal and fetal status. Among those who have received Tecovirimat treatment, this medication has been generally well-tolerated with no report of complications. And Tecovirimat has been provided to pregnant people in all trimesters of pregnancy.

CDC has initiated enhanced pregnancy surveillance to collect additional information to improve our understanding of monkeypox in these populations. This is specifically illness severity, information on treatment, and on maternal pregnancy and infant outcomes.

Additionally, to aid in the understanding of the manifestations of the infection and the impact on the pregnancy, testing of pregnancy related specimens, such as placenta, umbilical cord tissue, umbilical cord blood, and breast milk have been made available and can be facilitated through CDC.

Clinical diagnosis is key to timely treatment and implementation of infection prevention and control measures. Rash is the most common presenting sign with monkeypox. In a pregnant person with monkeypox exposure, any rash needs to be differentiated from other dermatoses of pregnancy, including polymorphic eruption of pregnancy, also known as pruritic urticarial papules and plaques of pregnancy or PUPPPs. Monkeypox lesions can mimic those seen in other infections, and patients with rashes initially considered characteristic of more common infections, such as Varicella Zoster or sexually transmitted infections, should be carefully evaluated for a characteristic monkeypox rash; and diagnostic testing should be considered, especially if that person has epidemiologic risk factors for monkeypox virus infection.

During pregnancy, the cause of fever may be difficult to differentiate from other infections, such as intraamniotic infection or chorioamnionitis, until the rash appears. Coinfections of monkeypox virus and sexually transmitted infections and HIV have been reported. And the presence of an STI does not rule out monkeypox, so a broad approach to testing is encouraged. STIs should also be considered if anogenital lesions are present. A full exam of the anogenital region and the vagina is important when evaluating a pregnant person or any female with suspected monkeypox.

Case identification and reporting of a patient with suspected monkeypox is the same for pregnant and nonpregnant people. And it is encouraged that all cases are reported to increase our understanding of the impact of infection on people who are pregnant and their neonates. Recommendations for clinicians on case finding and answers to frequently asked questions can be found on the CDC website. Clinicians should first consult their state health department as soon as monkeypox exposure or illness is suspected. And a risk assessment will need to be conducted to determine if postexposure prophylaxis or treatment is recommended.

When gathering specimens for diagnostic testing, all infection prevention and control measures should be carefully followed to prevent any risk to healthcare personnel collecting samples. Unroofing or aspiration of lesions or otherwise using anything sharp for monkeypox testing is not necessary and is not recommended due to the risk for sharps injury. There are known cases of transmission to persons who have acquired infection through testing, and precautions are available on the CDC website.

Next, let's assume that your pregnant patient has been exposed to someone with confirmed monkeypox but has not yet manifested any symptoms of monkeypox. Postexposure prophylaxis with vaccine should be offered when indicated to people who are pregnant or breastfeeding.

The risks and benefits of postexposure prophylaxis should be discussed with the patient. When postexposure prophylaxis by vaccination is chosen, JYNNEOS vaccine can be used for people who are pregnant or breastfeeding. The ACAM2000 vaccine should not be used. JYNNEOS is a live nonreplicating viral vaccine approved by the Food and Drug Administration for the prevention of both smallpox and monkeypox disease. It is for use in individuals who are determined to be at higher risk for smallpox or monkeypox infection.

Available human data on JYNNEOS administered to people who are pregnant are really 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, and it is not known whether JYNNEOS is excreted in human milk.

The data are not available to assess the impact of JYNNEOS on milk production or on the safety of breast milk for children for persons who are vaccinated with JYNNEOS. However, we know that JYNNEOS vaccine is replication deficient and, therefore, should not present a risk of transmission to breastfed infants.

And, again, JYNNEOS can be offered to people who are pregnant or breastfeeding or otherwise eligible. Any adverse reactions should be reported to the vaccine adverse event reporting system, also known as VAERS. Reports can be filed by healthcare providers or by vaccine recipients. And to file an adverse reaction report, please visit [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call 1-800-882-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

For U. S. healthcare providers and health department staff with a complex monkeypox vaccine safety question about a specific patient here in the U. S. or a vaccine safety issue, they can contact the Clinical Immunization Safety Assessment Project, also known as CISA, at [cisaeval@cdc.gov](mailto: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 CDC's Emergency Operations Center Watch Desk at 770-488-7100.

Next, let's talk about treatment considerations for monkeypox during pregnancy. While most nonpregnant adults with a monkeypox virus infection experienced mild illness and recover spontaneously, pregnant, recently pregnant, and breastfeeding people should be prioritized for medical treatment if needed. This is because of the possible increased risk of severe disease during pregnancy, risk of transmission to the fetus or to a newborn by close contact during an afterbirth, and possible risk of severe infection in newborns. Treatment for monkeypox virus should be offered when indicated to people who are pregnant, recently pregnant, or breastfeeding; and the risks and benefits should be discussed with the patient. Close monitoring for severe disease and pregnancy complications is important, and the decision to treat or monitor a pregnant patient as an outpatient or in the inpatient setting should be individualized.

But all patients should have follow-up to ensure that monkeypox has resolved. If treatment is indicated, Tecovirimat, also known as TPOXX, should be considered the first line antiviral for people who are pregnant, recently pregnant, or breastfeeding.

Tecovirimat 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 orthopox infections, including monkeypox, is not yet approved by the FDA. Therefore, CDC holds a nonresearch expanded access investigational new drug protocol that allows for the use of Tecovirimat for primary or early empiric treatment of non-variola orthopox infections, including monkeypox 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 when 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 monkeypox. There are no human data on the effect of Tecovirimat on milk production and the presence of drug in human milk or the effects of breastfed children.

Information is limited to animal studies. Tecovirimat was present in breast milk in animal studies in which subjected 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 breast milk are sufficient for treatment of a breastfeeding child who has monkeypox. As such,

if indicated, children with monkeypox who are breastfeeding should be treated independently. Tecovirimat use allowed under the EA IND protocol is intended to be used in concert with CDC guidance for treatment of monkeypox. Tecovirimat is available from the Strategic National Stockpile and is provided at no cost.

Regarding other treatments, although cidofovir and brincidofovir have been considered as alternative antiviral therapies to treat monkeypox infection, animal studies showed evidence of teratogenicity. And, as such, these medications should not be used to treat monkeypox 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. Animal reproduction studies have not been conducted with vaccinia immune globulin intravenous, also known as VIGIV. Therefore, it is not known whether VIGIV can cause fetal harm when administered during pregnancy or whether it can affect future fertility.

However, immunoglobulins have been used widely 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. And because many drugs are excreted in human milk, caution should be exercised when VIGIV is administered to a person who is breastfeeding. For details on these therapeutic recommendations, please see the CDC website.

Regarding contact, 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 monkeypox with close contact and potential for severe disease in newborns, direct contact between a patient in isolation from monkeypox and their newborn is not advised. Separation, meaning separate rooms of a patient with monkeypox from their newborn, is the best way to prevent transmission to the newborn. Full-time rooming in with a newborn is not recommended during the 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 a 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. Fresh gloves and gowns 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, and the patient should wear a well-fitting source control, that is, a medical mask, during the visit. These precautions should be continued until criteria for discontinuing that isolation have been met. This means that 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, the ability to strictly adhere to these isolation precautions, and availability of alternative caregivers.

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

Breast milk is the best source of nutrition for most newborns, and it provides protections against many illnesses. However, given that monkeypox is spread by close contact and neonatal monkeypox infection may be severe, breastfeeding should be delayed until criteria for discontinuing isolation has been met. Some people who are breastfeeding may need additional support from a lactation provider to initiate and maintain their milk production and to avoid a breast infection while monkeypox and lesions are healing. It is unknown if monkeypox virus is present in 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 monkeypox virus, a healthy caregiver can feed pasteurized donor milk or infant formula.

And 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. Regarding visitors, visitors to pregnant or postpartum patients with monkeypox should be limited to those who are essential for that patient's care and well-being. The use of alternative mechanisms for patient and visitor interactions such as video-call applications should be encouraged for any additional support. Visitors should also be informed about appropriate use of personal protective equipment, or 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 practices for the care of patients who are pregnant with monkeypox infection are really the same for those patients who are not pregnant with monkeypox, and this includes appropriate isolation of patients with monkeypox; training for healthcare personnel on the maternity and newborn care units on the correct adherence to infection control practices and on PPE use in handling; and ensuring that there's sufficient and appropriate PPE supplies are at all points of care.

If a patient who is pregnant is diagnosed with monkeypox, the pediatric team should be made aware of the diagnosis to inform the evaluation of the newborn. And newborns born to people with monkeypox should be placed in isolation, and healthcare personnel caring for those newborns should also follow recommendations as specified in CDC's Infection and Prevention Control of Monkeypox in Healthcare Settings recommendations. This concludes my section, and now I'll pass on discussion to Dr. Jeremy Gold.

All right. Thanks, Dr. Galang. So my name is Jeremy Gold, and I'll be speaking about some recent data collected by CDC and jurisdictional partners about monkeypox virus infections in children and adolescents under 18 years old. I'll discuss some of the main findings today, which will be part of an upcoming publication and *MMWR* in more detail in early November.

So our webpage currently states that children under the age of eight years old may be at increased risk for severe disease, and this is based on limited data from Clade I monkeypox virus. Information on monkeypox virus in children at -- information on monkeypox in children and adolescents from the current outbreak is limited. To learn more, CDC and partners have collaborated to describe the epidemiologic and clinical features of monkeypox virus infections in children and adolescents.

For our investigation, we included children and adolescents under 18 years old across the country, with reported cases between May 17 to September 24. The children and adolescents all had symptoms compatible with monkeypox, and a PCR test result for orthopoxvirus or monkeypox virus. And in cases for which PCR tests cycle threshold results were available, persons whose specimens had non variola orthopoxvirus, orthopoxvirus, or monkeypox virus PCR Ct values greater than or equal to 34, which could potentially indicate a false positive result, were excluded if they also had atypical features or no known epidemiologic risk factors were known.

Data are collected through national surveillance, CDC clinical consults, and outreach to jurisdictions. In our analysis, we describe demographics, exposures, symptoms, treatments, and outcomes. We analyzed the data by age group, grouping the children and adolescents from age 0 to 4, 5 to 12, and 13 to 17. Overall, we describe 83 children and adolescents who had monkeypox during the study period, and this represents 0.3% of all cases reported nationally during that time.

There were 16 children aged 0 to 4, 12 children aged 5 to 12, and 55 adolescents aged 13 to 17 years old. Overall, 80% were male with the highest male proportion among adolescents; 47% were Black, 35% were Hispanic or Latino; and 10% were White. Among children aged 0 to 12 years with known exposure information, household exposures were most common, which usually involved skin-to-skin contact with an adult caregiver.

In two instances, caregivers contracted monkeypox after caring for children with monkeypox in household settings. The expected exposure routes were skin-to-skin contact during diapering and other routine childcare activities. One child was thought to have acquired their infection through shared fomites such as through towels and linens with a person known to have monkeypox. Among adolescents aged 13 to 17 years, sexual contact was the most commonly suspected exposure route with most reporting male to male sexual contact.

We know about 10 instances with a -- with attendance at school or daycare while a person with monkeypox is symptomatic -- while a child with monkeypox was symptomatic. PEP was offered or postexposure prophylaxis was offered in four of these cases, and no secondary transmission was identified in any of these settings.

Overall, all children and adolescents had rash, 35% had fever, 29% had lymphadenopathy, and 36% had malaise. Among children 12 and under, the most common lesion locations were the trunk, head, and face. And no children under 12 had anogenital lesions. Among adolescents, the most common locations were anogenital and trunk for the lesion. Twenty-two -- overall, 22% were treated with Tecovirimat or TPOXX.

And within each age group, 50% of children aged 0 to 4 years, 17% of children aged 5 to 12 years, and 15% of adolescents received TPOXX. One infant was treated with VIGIV, and this infant's case report was described in a previously published *MMWR* report. Nine children and adolescents were hospitalized, which accounts for 11% of all cases. Two children aged 0 to 4 years were hospitalized. Both of these were infants under the age of 6 months, and both had diffuse rash and eyelid involvement and were treated with Tecovirimat and prophylactic Trifluridine eyedrops.

One of these infants, as I mentioned, was treated with VIGIV, and that was previously described in another report. And one child in the A -- in the 5- to 12-year age group was hospitalized with periorbital cellulitis and viral conjunctivitis and received TPOXX and Trifluridine eyedrops. Six of the adolescents were hospitalized. For five of them, the reasons for hospitalization included pain management and treatment of secondary bacterial infections; and three were known to be treated with TPOXX. One adolescent was hospitalized for isolation purposes rather than for pain control or other reasons.

All hospitalized patients were discharged and recovered, and no patients became critically ill. And no -- there were no deaths. So, to summarize the findings, we found that monkeypox is rare and generally nonsevere in children and adolescents during the current outbreak.

We also found that Black and Hispanic children and adolescents have been disproportionately affected. The younger children, those aged 0 to 12, were most often exposed in the household setting by adult caregivers during routine caregiving activities, and adolescents aged 13 to 17 usually had a sexual exposure.

Some limitations to these data include missing data, especially around exposure characteristics; and potential biases related to social desirability and case ascertainment. Overall, the findings highlight the need to improve equitable access to prevention, testing, and treatment and to strengthen prevention measures for children and adolescents, including isolation guidance for adult caregivers of children and health education and vaccination for sexually active adolescents. Thank you so much, and I'll now pass it on to Dr. Anne Kimball.

Good afternoon. Thank you, Dr. Gold, for that excellent overview of monkeypox infections in children and adolescents in the current outbreak in the United States. Be on the lookout for that report and *MMWR* next week. I am a practicing pediatrician and a medical epidemiologist, and I've been on the Clinical Consultations Team of CDC's Monkeypox Response since early August.

For my portion of this talk, I will provide an overview of clinical considerations for prevention and management of monkeypox infections in children and adolescents. So, first, let's review a little bit about what we know about monkeypox in children and adolescents and some of the considerations for clinical recognition and for monkeypox testing.

As Dr. Gold stated, there is some prior evidence from patients infected with Clade I of monkeypox virus, which was previously called the Congo Basin Clade, that the disease may be more severe in children under the age of 8 years. This current outbreak is caused by Clade IIb virus, which was previously called the West African Clade, and it typically causes less severe disease than Clade I.

As Dr. Gold stated, our experience of monkeypox infections in children in this current outbreak in the US has been limited. But, so far, it is reassuring, with infections occurring rarely and with most children having mild and self-limiting disease. A recent case series of 16 children and adolescents with monkeypox in Spain was published in *The Lancet Child and Adolescent Health*,



which was similarly reassuring, as none of the children and adolescents in that report were treated with antivirals, none were hospitalized, and no deaths were reported.

Now, in addition to what Dr. Galang shared, here are a few more specifics about cases of perinatal and congenital disease that we know of. A letter to the editor was recently published in the New England Journal of Medicine describing a neonate in the United Kingdom with perinatally acquired monkeypox infection.

The baby developed a rash at nine days of life and also had an adenovirus coinfection. The infant did have severe disease and required intensive care and mechanical ventilation, and the infant was treated with enteral Tecovirimat and IV cidofovir and did recover. The author stated that the clinical illness cannot be attributed to either monkeypox or adenovirus infection but that monkeypox virus should be considered as part of the differential diagnosis of a neonatal vesicular rash.

Now, in terms of congenital infection case series that Dr. Galang mentioned of pregnant people with monkeypox infection in the Democratic Republic of Congo was published in 2017 in the Journal of Infectious Diseases, and one of the cases included in this series did result in fetal death and had evidence of congenital disease with diffuse maculopapular skin lesions, hepatomegaly, and hydrops fatalis.

Now moving on to the signs and symptoms of monkeypox in general, so similar to infection in adults, the most common sign of monkeypox in children and in adolescents is a rash. It typically progresses from maculopapular lesions to vesicles and then to pustules and then to scabs, and then the rash heals. Systemic symptoms such as fever, lymphadenopathy, fatigue, and headache can occur either as a prodrome to the rash or along with the skin lesions.

And other symptoms can occur, depending on the location of the lesions, such as with oral pharyngeal lesions, with ocular involvement, and with anogenital lesions. It's also important to note that the rash of monkeypox can be confused with other rash illnesses that may be more commonly considered in children, such as varicella; hand, foot and mouth disease; molluscum contagiosum; syphilis, including congenital syphilis; HSV; and even allergic skin reactions.

So, when indicated based on the clinical presentation of the child, evaluation for other etiologies should be done at the same time as testing for monkeypox, especially when there are no epidemiologic links to a person with monkeypox. It's also important to remember that coinfections with monkeypox are possible. And clinicians who are caring for sexually active adolescents who present with lesions that are consistent with monkeypox should test for monkeypox, as well as for HIV and for other STIs and then offer management accordingly.

So a little bit more specifics on testing, the recommendations for testing for monkeypox are similar for children and for adults. Tests should be performed when monkeypox is suspected based on both the clinical presentation and epidemiologic factors, which include having contact with a person who has a similar rash or who has been diagnosed with monkeypox, or having close or intimate in-person contact with individuals who were in a social network experiencing monkeypox. So, if testing is indicated, the lesions should be vigorously swabbed and sent for

PCR testing. A positive PCR test for either orthopoxvirus or monkeypox virus in a person who does not have a known exposure or who has an atypical presentation should be verified. PCR tests are very specific and very sensitive. But when these epi criteria are absent or unknown, and especially when the cycle threshold or Ct value is high, such as 34 or higher, CDC does recommend reextracting and retesting of the specimen.

The CDC can be consulted for complex cases, including those that appear atypical or questionable, and CDC's lab can perform additional viral-specific and Clade-specific PCR testing, as well as serologic testing.

So, for more information on this topic specifically, we do recommend that you review a report that was published in *MMWR* back in September on orthopoxvirus testing challenges. And this report included one case that I wanted to highlight that was actually in a school-aged child who had no known exposures, had no risk factors and did have a rash but that was not really consistent with monkeypox. The child had PCR testing, which was initially positive for orthopoxvirus. But then, when they went back and reextracted and repeated testing on the specimen, it tested negative. And the child was ultimately diagnosed with hand, foot, and mouth disease, with positive tests for enterovirus. Medical countermeasures were used in this situation while they were waiting on the repeat test results which were later deemed to be unnecessary. Speaking of medical countermeasures, we're going to move into a discussion about postexposure prophylaxis or PEP. So, similar to adults, monkeypox infections in children and adolescents can occur when there is prolonged close contact to a person with monkeypox.

Based on the data that Dr. Gold just shared with us of cases where CDC was able to obtain exposure information, transmission in young children has typically occurred due to close contact in a household setting with an adult caregiver, and transmission among adolescents has typically involved male-to-male sexual contact.

Now, data on postexposure prophylaxis to prevent monkeypox in children are extremely limited. The only vaccine that is authorized and recommended for use in children and adolescents as PEP is the JYNNEOS vaccine, and decisions about whether to offer PEP should take into account the level of risk of the exposure as well as the individual's risk of severe disease. PEP options in general include vaccination, vaccinia immune globulin, and antiviral medication.

But, for most people, vaccination is the best option when PEP is indicated. Immune globulin or antivirals could be considered for very young infants under the age of 6 months, given their immature immune systems and the possible decreased response to vaccination. So the JYNNEOS vaccine specifically contains a nonreplicating vaccinia virus. And wild JYNNEOS has not been studied specifically among children or adolescents, the same nonreplicating vaccinia virus, the modified vaccinia Ankara, is in the JYNNEOS vaccine. And it's been in a few other vaccines against diseases against tuberculosis, measles, and Ebola. And the studies for these vaccines did not include any serious safety concerns and involved children as young as five months.

So, as of October 25, in the U. S., there have been 242 children aged 0 to 4 years, 335 children aged 5 to 11 years, and 445 adolescents aged 12 to 17 years who received a dose of the

JYNNEOS vaccine during this current outbreak, and these data are publicly available on CDC's website. We are aware of infants as young as 4 months of age who have received the JYNNEOS vaccine after a monkeypox exposure during this outbreak.

And based on the limited data that we have, vaccination with JYNNEOS in children has been well-tolerated. Vaccination with JYNNEOS is available for use in those under the age of 18 years who are determined to be at high risk for monkeypox infection under the emergency use authorization that was issued by the FDA in August. And vaccination for children and adolescents should be administered via subcutaneous injection with two doses of 0.5 ml each given [inaudible] part. Ideally, for PEP, the first dose should be given within four days of exposure.

And prior to administration in infants under the age of 6 months, we do recommend that clinicians contact their jurisdictional health department. So, in terms of other options, the vaccinia immune globulin, which is approved for treatment of smallpox vaccine complications, is a potential option for prevention of monkeypox, but its effectiveness is unknown. It's available through the expanded access investigational new drug or IND program. And in order to obtain vaccinia immune globulin, consultation with CDC is needed because we can facilitate release of the product from the Strategic National Stockpile. We at CDC have facilitated the use of vaccinia immune globulin as PEP for a few newborns who had significant concerns for peripartum transmission in this outbreak, and the newborns tolerated the therapy well.

It's important to remember that this is an IV infusion, so it's generally considered only for very high-risk exposures. And then, finally, Tecovirimat could be considered for monkeypox postexposure prophylaxis in unusual circumstances, but the effectiveness is unknown. So, in addition to going over these postexposure prophylaxis options, I wanted to briefly highlight some of the isolation and infection control, infection prevention measures. So, if an adult household member has monkeypox, extra care should be taken to try to avoid close contact with other members of the household and especially for children as much as possible. We know that monkeypox has been spread through routine caregiving and through household contact to children in this outbreak.

Additionally, sexual health education is another really important component of monkeypox prevention, especially for adolescents, as well as covering prevention of HIV and other STIs. And while condom use is a very important part of sexual health, monkeypox transmission could occur through skin-to-skin contact if lesions are elsewhere on the body.

Now, finally, let's move into a discussion of the clinical management and some of the treatment considerations. As with adults, children and adolescents with monkeypox should be closely monitored throughout their illness and likely will benefit from supportive care and from pain control. And depending on the location of the lesions and the extent of the lesions, comanagement with pediatric subspecialists may be important.

It is particularly important to try to keep a child's skin lesions covered and to prevent the child from scratching their lesions or touching the lesions and then touching their eyes because this could lead to, first, a secondary bacterial skin infection; and, secondly, to potential

autoinoculation and ocular monkeypox. If there are lesions near the eye or in the eye, an ophthalmologist should be consulted; and a careful ocular exam should be performed. And then, additionally, in terms of supportive care, optimal fluid intake should be encouraged, particularly if there's extensive skin involvement, as this could lead to additional fluid losses because of the disruption of skin integrity. Now, when considering treatment for a child or an adolescent with monkeypox, clinicians can consult the jurisdictional health department, and health departments can facilitate consultation with us at CDC for additional guidance or for access to therapeutics as needed. While most cases of monkeypox do resolve without treatment, treatment should be considered for people who have the following clinical manifestations in line with CDC's guidance.

So, number one, people with severe disease, which may include disseminated rash, a large number of lesions, confluent lesions, hemorrhagic or necrotic lesions; for people who have severe lymphadenopathy, as this could cause airway obstruction; and then for people with involvement of the eyes with ocular disease; with cardiac involvement, with myocarditis; with neurologic or pulmonary involvement; and then also with sepsis or with, really, any situation requiring hospitalization; and then, secondly, people who have involvement of anatomic areas that may result in serious sequelae, including scarring, strictures. So this has been seen specifically with anogenital lesions with monkeypox.

So these are the two groups where we think treatment should be considered just based on the clinical manifestations of the disease alone. Treatment should also be considered for children and adolescents who may be at high risk for severe disease. And, at this time, we consider the following groups at potentially high risk: one, very young children; two, children with severe immunodeficiency or who are immunocompromised; three, children with a condition that affects their skin integrity, such as severe eczema; and then, fourth, children or adolescents who are pregnant themselves.

The limited available -- the limited evidence regarding pediatric disease outbreak suggests that the clinical presentation in children may not be more severe than that of adults. And, additionally, there are limited data for neonates and for young infants. But given the concern for more severe disease in younger infants, clinicians may consider treatment based on young age alone. Now, a few more specifics on the treatment. Tecovirimat, or TPOXX, is our first-line treatment for monkeypox for children and for adolescents.

Many hospital systems and health departments do have Tecovirimat available through prepositioning. And to access Tecovirimat for your patient if you do not already have access through your health system, you should reach out to your local or state health department. The IND protocol has information on weight-based dosing of Tecovirimat, as well as instructions for opening the capsules and mixing with food or with liquid for infants or for young children who need less than the single capsule dose, which is a 200 milligram dose. And we have links to these instructions on our clinical considerations page. Data on the effectiveness of Tecovirimat to treat people with monkeypox are not available, but studies in animals have shown that Tecovirimat can effectively treat disease caused by orthopoxviruses.

And per the data presented by Dr. Gold, we know of at least 18 children and adolescents who have received Tecovirimat as treatment for monkeypox, including one adolescent who initially received IV Tecovirimat, which was later transitioned to oral. Close monitoring of renal function is recommended for children aged less than 2 years who are treated with IV Tecovirimat. Now, other treatments might be considered in addition to Tecovirimat or as an alternative to it in the unusual circumstance of very severe disease, disease progression despite Tecovirimat treatment, or if Tecovirimat were to be contraindicated or unavailable. And use of these additional treatments should really be done in consultation with infectious disease specialists, with pharmacists, with state and local health department, and with us at CDC.

Vaccinia immune globulin or VIGIV, as we mentioned before, can be obtained through consultation with CDC. And this has been used in the current outbreak to treat very young infants with concern for severe disease, and it was well tolerated. The use of the antiviral medications cidofovir and, when it is available, brincidofovir may also be considered. And then, finally, topical trifluridine could be considered if there is ocular involvement or for prevention of ocular disease, and this should be done in consultation and with close oversight of an ophthalmologist due to the potential risk of corneal toxicity with long-term use. For more information on severe monkeypox disease, we suggest that you review a COCA Call from earlier in the month, from October 6, as well as a report that was published in *MMWR* yesterday and CDC's web pages.

Now can we please advance to the next slide? Thank you. So if you are interested in consulting with CDC to discuss management or to obtain access to vaccinia immune globulin, for example, CDC does offer a clinical consultation service that's for both healthcare providers and for health departments. And we have the information here. You can consult our clinical consultations team specifically by emailing [eocevent482@cdc.gov](mailto:eocevent482@cdc.gov).

Or you could get in touch with the clinician on call for our team through calling the CDC Emergency Operations Center or the EOC at the number that is provided here, which is 770-488-7100. Next slide, please.

So here's some of the resources. These are all CDC web pages from which we have pulled most of the information that we've shared today. And these are also all available on the COCA Call web page under the Additional Resources tab.

And now I will turn it back over to our moderator for the question and answer portion. Thank you.

Thank you so much, presenters. Thank you for providing this timely information to our audience. As Dr. Kimball mentioned, the resources you saw can be accessed at COCA Call's web page under Additional Resources. Please direct your browser to [emergency.cdc.gov/coca](http://emergency.cdc.gov/coca) where you will see this COCA Call's additional resources as well as the earlier October 6 COCA Call that Dr. Kimball was referring to. We will now go into our Q&A session.

In addition to our presenters, I would like to welcome to the Q&A session Dr.

Agam Rao, who is part of CDC's Monkeypox Response.

Audience, please remember to ask a question using Zoom, click the Q&A button at the bottom of your screen. Then type your question. And please note that we often receive many more questions than we can answer during our webinars.

So our first question to our presenters is regarding breastfeeding. And the question asks, can you share any guidance for mothers to use nipple shields when breastfeeding to minimize contact with the skin or, in addition, cover surrounding skin? And if the lesions are not present on the breasts, is it okay for a monkeypox positive person to breastfeed?

Hi. This is Dr. Galang. I'm happy to start and happy to hand over the rest of the answer to our other colleagues in the call. Regarding breastfeeding, I know that, with other types of infectious diseases, you know, such as with HSV, you know, we often recommend covering of lesions but that the patient is still able to breastfeed or breast pump at that time.

This particular virus is a little bit different. And when somebody is still within their infectious period and still has lesions still scabbed over, we still believe that that patient is viremic and still has some degree of viral load. You know, we did highlight, of course, that transmission occurs through contact with lesions and fluid. Close contact in and of itself, skin-to-skin contact, contact with any potential contaminated items and even respiratory secretions are still also modes of transmission. And it is -- while there may be different measures we recommend to reduce exposure if visitation and contact with the infant is necessary, you know, the guidance at this time is still to avoid breastfeeding if possible.

We are still trying to gather more information clearly about the presence of transmissible virus in breast milk. And, again, if there are any patients that our clinicians on the call are taking care of who are able to offer samples of breast milk for testing, that testing can be facilitated again through CDC and labs that are in cooperation with us. That being said, as much as we recommend against breastfeeding, we know that there are -- that there's going to be contact or desire for contact between mom and baby. And, for that reason, we do add those listed recommendations on CDC's website if contact needs to be taken.

And, again, it's you know, no direct skin-to-skin contact. Making sure that that infant is fully clothed and swaddled. And that, after that contact, those covers should be removed or replaced. For the patient themselves who has monkeypox, gloves, a fresh gown should be worn by that patient at all times. And any of that visible skin below the neck really needs to be covered. And, of course, that patient needs to be wearing a well-fitting mask or source control while providing that care, care of the infant.

But you know, at this -- again, to reiterate, at this time that this is based on what we know or don't know yet about, about breastfeeding and breast milk with patients with monkeypox. And this is probably the most -- most precautionous that we're being here. We did consider options for -- in -- with the guidance and thinking about whether or not to be a little bit more permissive with the language or looser with the language. But just knowing how easily monkeypox is transmitted from lesions, from fluids, through close contact and other routes, this became a bit more apparent

that we needed to be a little bit more stronger with the language. I'm happy to chime in or tag with any of our other clinicians on the call if they would like to comment.

Thank you very much for that response. Along the same lines, you mentioned collection of samples and analysis samples. Does CDC have any special recommendations for neonatal testing postdelivery for patients who have tested positive during pregnancy?

This is Dr. Galang. I'll hop in again. Just thinking about examples from this particular outbreak and from what we know, first off, the testing of specimens in an asymptomatic -- an asymptomatic newborn, no lesions, no signs or symptoms of monkeypox, there really isn't any information we have to guide on the timing of when to test, how frequently to test after they're born, or what specifically to test if there isn't a lesion present. You know, we are hoping that patients who have monkeypox, once they are delivered, that we can facilitate testing of those pregnancy specimens to look for a little bit more evidence of whether or not there is any evidence of a virus or infection or antigen in any of these tissues.

Again, we tried to facilitate this through CDC. There is -- there are partner labs that are out there that are also testing specimens of umbilical cord blood and breast milk. But, typically, we would try to start off with a phone call between clinician, the health department, and CDC to help iron out some of the details there. But regarding the testing of the neonate immediately after birth, we don't have specific recommendations for asymptomatic neonates.

This is very helpful. Thank you. Our next question asks if there's any data about transmission in schools and if there are any recommendations or guidance for educational institutions at this time?

I can -- hi. This is Jeremy Gold. I can take a stab at a little bit of what we can say about that so far. Like I mentioned, there were -- we know about at least 10 instances where a child or adolescent who -- who had monkeypox attended school, and we're not aware of any instances in which secondary transmission occurred. And I don't have -- and, in some of those instances, we know that PEP was offered and in some cases taken by people who were in close contact with the child or adolescent who attended school. But kind of the information we have is a bit limited in that regard.

One thing I would say is -- and I don't have the link on hand but something we could certainly put in the chat is we sort of have a frequently asked questions about -- about this very issue of, like, considerations for what to do if a child with monkeypox attends school, that sort of thing. So I'll find that link and post it to the correct place.

Thank you very much. Our next question asks, what are your recommendations for pregnant people if someone they're living with has monkeypox?

This is Dr. Galang. So, you know, for that type of a scenario, you -- there certainly needs to be risk assessment, you know, with that particular pregnant patient and other household members for the kind of exposure that they might have to their household member. This is done, of course,

in partnership with the health department, so please contact your health department. And sometimes they contact us here at CDC.

Based upon that type of exposure, you know, low, intermediate, high risk, there are recommendations for whether or not to use any sort of postexposure prophylaxis for that -- for that household member, for those household members that do not have monkeypox. And in this case, that postexposure prophylaxis is done with the JYNNEOS vaccine, just about in all cases that we've had so far. Other considerations, you know, for people who are living in the household, we do have guidance on the CDC website for isolation recommendations within households, you know, with information such as how to isolate, you know, reducing the number of rooms that are shared by people; trying to avoid use of shared tools, instruments, supplies; separate bathrooms, if possible; instructions regarding -- regarding hand hygiene and cleaning in the area; as well as for things like the use of masking and other things like that if they do need to be around any of the other household members. It's a -- it's quite a page but easy -- easy to walk through. But that is also available on CDC's web page.

And that is explicitly a separate guidance on recommendations for isolation, people with monkeypox in the home setting. Over.

Thank you very much for that. Our audience can also direct to the chat box right now where they'll find that FAQ link that Dr. Gold had mentioned in the previous question. Our next question asks, are there any prenatal screening, imaging, or testing recommendations considering fetus can contract monkeypox through the placenta?

Thank you. At this at this time, we don't have data that necessarily guides which type of ultrasound screening or antenatal surveillance that might be done for a pregnant patient with monkeypox or even how frequently to do it, for that matter. Again, the number of cases published in the literature before this outbreak was five. Most resulted either in a early pregnancy loss. There was one healthy newborn and then at least one stillborn infant that was found, and it's hard to know [inaudible] would have prevented that particular case.

In that case, that stillborn did have extensive evidence of monkeypox both as far as physical findings as well as PCR positivity in placenta and pregnancy tissues. So, at this time, we don't have specific recommendations. But, certainly, some of the things that folks have done for antenatal surveillance have included, you know, ultrasound testing, the usual type of surveillance that we do for growth for infants and the like. But there's no specific standard that we have for this at this time.

Thank you very much. Our next question asks, are there any contraindications or adverse interactions to be aware of for pregnant and/or breastfeeding people receiving treatment for monkeypox?

So far in this outbreak, I think we've had about nine or so pregnant patients or postpartum patients who received Tecovirimat or TPOXX. And this is the PO or the form taken orally, and then at least one was switched over to IV. As far as we know, they tolerated the medication quite well. We were able to do with the recommended full course. We did not receive a report of any



adverse reactions. And these patients or lesions ultimately resolved, and they were able to be discharged home without any complication.

Thank you very much. Our next question asks, are you aware of any changes or updates to the regulatory mechanisms to allow younger people to be vaccinated?

Hi. This is Agam Rao. I think I can take this one. So if there's a question about who should be vaccinated, the guidance on the CDC website at this time, even though it's referring to men, actually does apply to children as well. So there is recommendations about preexposure prophylaxis, people in certain risk groups. And that applies to children, as well, adolescents as well. So in terms of a regulatory mechanism for vaccination beyond that, there is -- there are discussions going on. There -- there are also going to be ACIP considerations. The ACIP workgroup has formed to discuss vaccinations of people at risk for monkeypox, including children. And so I guess more to come on that issue.

Thank you for that. And we have time for just one last question. The question asks, has CDC's data shown that severe monkeypox is more prevalent or more common in younger children and infants? And, if so, what are the ages?

So I can start and then if Dr. Gold wants to jump in as well. So, as we mentioned, our compilation of data thus far on children and adolescents with monkeypox will be published next week in the *MMWR*. And based on what we know so far, it does not appear that younger children necessarily have higher risk for severe disease.

When we look at, you know, the proportion of children who were hospitalized, for example, by age group, among the 83 children who were included in this report, when we looked at the 0 to 4 age group, there were 13% of children hospitalized. Among the 5 to 12 age group, there were 8% of children hospitalized. And then, among the 13 to 17 age group, there were 11% of children hospitalized. So a slightly higher proportion were hospitalized as well as a slightly higher proportion were treated with Tecovirimat among the age group. But it does not appear from the data that we have that that was necessarily because of more severe disease. And it may have been related to increased caution around the younger age groups.

We are continuing to collect data and, you know, trying to better understand the risk for severe disease. As I mentioned in my portion, we have just such limited data around infection in the neonatal age group so less than 28 days that it's just really hard to say, you know, whether -- whether our data shows more severe risk or not. We will be updating our information as we receive it. But, at this time, we are considering just because of a heightened concern for other infections in young children and then extrapolating data from Africa that there is the potential higher risk for severe disease among the very young children, somewhere like the infant age group. But it's an active area of trying to investigate right now.

Thank you very much. I want to thank everyone for joining us today with a special thanks to our presenters. Today's COCA Call will be available to view on demand a few hours after the live COCA Call at [emergency.cdc.gov/coca](https://emergency.cdc.gov/coca).

A transcript and closed caption video will be available on demand on the COCA Call's web page next week. Continue to visit [emergency.cdc.gov/coca](https://emergency.cdc.gov/coca) to get more details about upcoming COCA Calls and additional resources shared today. We invite you to subscribe to receive announcements for future COCA Calls by visiting [emergency.cdc.gov/coca/subscribe.asp](https://emergency.cdc.gov/coca/subscribe.asp).

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Again, thank you for joining us for today's COCA Call, and have a great day.