

Good afternoon. I'm Nikki Grimsley and I'm representing the Clinician Outreach and Communication Activity, COCA, with the Emergency Rescue Communication Branch of the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA call, What Clinicians Need to Know About Monkeypox in the United States and Other Countries. All participants joining us today are in listen only mode.

Continuing education is not offered for this COCA call.

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

If you are a patient, please refer your questions to your healthcare provider.

If you are a member of the media, please contact CDC media relations at 404-639-3286 or send an email to media@cdc.gov.

I would now like to welcome our presenters for today's COCA call. We are pleased to have with us Dr. Agam Rao who is a medical officer in the Poxvirus and Rabies Branch in the National Center for Emerging and Zoonotic Infectious Diseases at CDC. Dr. Laura Hinkle Bachmann who is a Chief Medical Officer in the Division of STD Prevention in the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Control at CDC. And Dr. Brett Petersen who is the Deputy Chief of the Poxvirus and Rabies Branch in CDC's National Center for Emerging and Zoonotic Infectious Diseases.

I will now turn it over to Dr. Rao. Dr. Rao, please proceed.

Thank you, Nikki. Next slide.

So, this is a slide that's situational update. There are the non-endemic continents with cases are, at this time, Europe, North America, and Australia for Monkeypox. Most but not all of these cases are among men who identify as gay, bisexual, or men who have sex with men.

CDC's working with partners in U. S. states and several countries, and as of this morning, there are eight confirmed orthopox cases in the United States. And you can see from the footnote that this is a number that is as of this morning, and this number is changing rapidly. There's one of the eight cases that is orthopox positive is also monkeypox positive, and that is the case in Massachusetts has been reported. Next slide.

So, I just want to talk a little bit about the difference between a confirmed orthopox versus confirmed monkeypox case. Laboratory confirmation is a two-step process for testing specimens. So, first state labs that are part of a laboratory response network can perform OPX generic testing, and this confirms the presence of OPX DNA, orthopox DNA from the rash lesions. And that's what we call the positive, when that is positive, it's a confirmed orthopox case. Now, after that, specimens have to be sent to CDC for confirmatory testing, and that is performed by real

time PCR which is only available at CDC. So, a positive test at that step is then called a confirmed monkeypox case. Given the suspicion that we have for the situation going on worldwide, for this event, we're treating all confirmed orthopox cases as if they're monkeypox until proven otherwise. Next Slide.

Historically, the signs and symptoms have involved a characteristic rash preceded by prodromal symptoms. Those prodromal symptoms have been a fever, lymphadenopathy, and flulike symptoms, including malaise and headache. The current cases, though, have been atypical in that the rash is still that characteristic rash, a pimple-like firm rash, but it's often starting in the genital and perianal areas in most recent cases. And we actually have photographs of these rashes on our CDC website that you can look at, and we are planning on placing more photographs there as time goes on from worldwide cases. The rash is sometimes not disseminating to other parts of the body with these most recent cases worldwide, and they're being recognized for that reason at a lot of outpatient clinics, because they're easily confused. They're getting easily confused with sexually transmitted infections. Another atypical feature is that the prodromal symptoms are not occurring as often, and they're mild or they're not occurring at all. We don't know why these unusual presentations are happening, but we're certainly looking into that. The patient is considered infectious once symptoms begin, whether those are prodromal symptoms or the rash symptoms. As soon as symptoms begin, they're considered infectious until all the lesions scab and those scabs fall off. Next slide.

Monkeypox is endemic in several African countries, so this is not a new illness, and this is certainly occurs on a regular basis in some African countries. From 2018 to May 2022, there were nine imported cases of monkeypox to non-endemic countries, and that includes the first case that was recognized in the United Kingdom in this month. There's been two in the United States, five in the United Kingdom and, one in Israel, and one in Singapore. There's been no flight context who have developed infection in any of these cases which goes to show you that this infection is not very easily transmitted. One healthcare worker did develop monkeypox as a result of one of the cases in the United Kingdom, and there were two family members who were affected also by a case. Which is not unexpected given how it is spread. Next slide.

So, as far as transmission goes, it can spread through direct or indirect contact with body fluids or lesion materials. Also, contact with fomites and exposure to respiratory secretions. So, some examples of the high and intermediate risk exposures from these things are shared towels and bedding, for example, infectious bodily fluids if someone touches them, or scabs are present on bedding, and someone is touching those scabs on the bedding. There's also skin to skin contact with the patient who has monkeypox that can result in spread, and then being inside a patient's room or within six feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates. Like when someone's trying to shake bedding. Without wearing an N95 or equivalent respirator or hydrator and without wearing eye protection could be a risky exposure. And there's more information about these on our CDC website. And just to emphasize again that this is not something that is easily transmitted. Next slide.

So, what clinicians need to know about diagnosis. So, at CDC, we issued a health advisory on May 20th, and the advice within that was for clinicians to be vigilant to the possibility of

monkeypox if they see a patient with the characteristic rash present. Footnote here at the bottom of the screen actually takes you to some photographs of lesions that are monkeypox lesions. I mentioned earlier that we'll be adding to those as well. We are hoping that clinicians will know that the illness is presenting atypically. So, even though the descriptions out there aren't a typical presentation, to keep an open mind and suspect monkeypox. And then, clinicians working in outpatient clinics should perhaps be on the greatest lookout because a patient may present to them first. And many of those patients are having mild symptoms, and the illness can be confused with a sexually transmitted infection or varicella zoster virus. If you could obtain a sexual and travel history, that would certainly help with trying to figure out what we're dealing with, and if you can also determine if any contacts have or had a similar rash. That might also lead to an increased suspicion. Specimens should then be obtained by clinicians, and there's some information at the website with the link below about specimen collection and yeah, how to obtain specimens. And then, the health department should be notified, and the health departments can give you advice about contact tracing and monitoring of healthcare personnel who've been in your hospital. And again, the link here at the bottom of the screen explains that in more detail, explains the different risk categorizations and what type of monitoring needs to be done for how long. It can also facilitate the laboratory testing that can happen at state health laboratories to determine whether or not the specimen is OPX generic positive or negative. Next slide.

Now, for treatment and prevention, what we'd like clinicians to know is that all specimens reported from patients so far outside of endemic countries where this occurs, have all been the west African clade of monkeypox. So, that is the clade. There's two clades of monkeypox. That is the clade that's associated with milder illness.

Supportive care has typically been enough. Of course, we're dealing an unknown situation right now, so we are prepared for severe cases if they are to occur, and we have antivirals available through consultation with CDC. And Dr. Petersen will be speaking more to the information on this slide, including antivirals. For contacts, monitoring the healthcare personnel should be reported to health departments. That monitoring is for 21 days. Post exposure prophylaxis can be given, depending upon the level of risk that healthcare workers and others experience, and that could be with one of two licensed vaccines in the United States, depending upon the risk level. And then, preexposure prophylaxis has always been recommended in the United States for people who were at occupational risk for orthopox virus exposures and the two vaccines that are available in the United States, Dr. Petersen will be talking about a little bit more. Next slide.

So, finally, just miscellaneous issues that clinicians might want to know. We have all of these topics available on our website. There's information if you got to the website that is listed at the bottom of the screen. So, infection control, hospital and home, duration of isolation, decontamination of contaminated surfaces. These are all covered on our website, and we also have experts from CDC's division of healthcare, quality, and promotion on this call to answer any questions that might come up during the Q and A today. So, just want to emphasize that monkeypox does not have the potential to be a pandemic. The number of worldwide cases are still low, and if you consider the number of people that are in the world. And to keep an open mind because, although the large number of the cases that are being reported worldwide have been among certain communities, that does not mean that there are not cases occurring in other communities. It's possible that these cases, it's the detection bias, and that we're just identifying

cases within certain communities because that's where it's being, you know, that's where it's being identified really. So, there could very well be cases in other communities, and we'd like the clinicians and public to keep an open mind. Next slide.

I'll turn it over to Dr. Bachmann now for the second part of this presentation.

Thank you. First, I do want to warn the audience that some of the slides in the following presentation are graphic, and the slides are being shown for educational purposes. There is currently a high level of concern related to the recent cases of monkeypox described internationally and in the U. S. as just detailed by Dr. Rao.

However, it's important to keep this in perspective. Our latest surveillance report shows that STDs continue to increase with 2.4 million cases of chlamydia, gonorrhea, and syphilis reported in the first year of the COVID-19 pandemic. Common things are common, and so it's very important to be alert to the possibility of monkeypox, but it's also important that we continue to evaluate patients comprehensively for STIs. Next slide.

At this point, as mentioned, some reported cases of monkeypox were men who report sexual contact with other men. We do not currently have evidence that monkeypox is sexually transmitted in the typical sense. But it can be transmitted, as already detailed, during sexual and intimate contact as well as with personal contact in shared bedding and clothing. So, anyone can spread monkeypox through contact with body fluids, monkeypox sores, or respiratory droplets when they're close to someone who has the infection. Some of the more recent cases, as detailed, started in the genital or in the perianal area. There have also been some anecdotal reports of proctitis. We have a lot to learn about the clinical presentations of individuals with monkeypox in this current outbreak. In the meantime, given this clinical presentation, it is possible that affected individuals will present to outpatient clinics, specifically sexual health clinics, for care. Therefore, I wanted to cover today a few points related to the differential diagnosis that providers should consider, particularly when patients present for STI evaluation. Next slide.

Given the reports of monkeypox presenting as perianal ulcers or genital lesions, it's important to review the differential diagnosis of genital ulcer disease. The differential includes infectious etiologies from the most common cause of genital ulcer disease in the world, herpes simplex virus, to rare infections like granuloma inguinale. The noninfectious disease list is similarly long and includes ulcers caused by a variety of different mechanisms from autoimmune diseases to cancer to even a reaction to medications. Next slide.

Similarly, it's important to keep in mind the differential for diffuse rash and also the syndrome of proctitis. So, this is, what you see on this slide, there's not comprehensive lists that specify some of the more common etiologies to consider when evaluating patients with rash or with symptoms of proctitis. Next slide.

To assess a patient's risk for monkeypox, it is key that clinicians take a comprehensive patient history. I know you do not need to be reminded of all the components of a good history, so I will just, I'm just going to hit on some highlights in the history of present illness and in the social history. Really to reiterate some of what Dr. Rao has already presented. The sequence of the

illness can be helpful in sorting through the varied etiologies that clinicians must consider. The typical sequence of monkeypox manifestations include a prodromal of fever, malaise, headache, sore throat, cough, and/or lymphadenopathy. When the rash develops, it usually starts as macules that then move to papules, vesicles, pustules, and then scabs. There's also a typical sequence for the rash that starts in the tongue or mouth as an enanthem and progresses to the face, to the arms and legs, to the hands and feet, including the palms and soles. Pain and pruritis are can be prominent with pruritis primarily as the lesions are healing. But again, with this is all said with the caveat that the clinical presentations may not be typical in this particular situation. Next slide.

The social history should include a travel history and based on the current epidemiology of the cases we're seeing domestically and internationally; the travel history should focus on travel to central and west African countries as well as to other countries where non-endemic monkeypox has been reported. And as mentioned earlier, that list does continue to evolve. It's important to ask patients if they've had a contact with a person or people with confirmed or suspected monkeypox, and as mentioned, some of the individuals with monkeypox are men who regularly have close or intimate in-person contact with another man, including those who met partners through online websites, digital applications, or apps or at a bar or party. Again, since monkeypox can be transmitted in any humans with close, intimate contact with an infected person, it is important to keep an open mind when evaluating any patient with a concerning rash. Next slide.

Moving on to the physical examination, I wanted to stress the importance of performing a thorough exam of all skin in a room with good lighting. Clues may be present in other areas of the body in person presenting with genital or perianal complaints. So, it's important to examine all skin. In typical monkeypox, the rash concentrates on the face, arms, and legs in the centrifugal distribution. Lesions are typically similar in size and at the same stage, unlike for other viral rashes. And lesions become umbilicated, which is quite a distinctive feature. While the more recent cases of monkeypox have presented in an atypical manner, the lesions may still appear classic. And again, they may have more typical appearance on keratinized skin versus the mucosa. So, now, I'm going to run through some common STIs in the next several slides to help you familiarize yourself with various presentations of syphilis, herpes, and STIs as well as some other slides with monkeypox lesions and other non-STI viral rash illnesses. Again, the slides are graphic. Next slide.

The rash of monkeypox is quite distinctive, as mentioned earlier. It often occurs on the palms and soles which can be confused with secondary syphilis. However, while syphilis is the great imitator and the syphilis rash can look very different from one individual to the next, syphilis does not typically produce a widespread, umbilicated, pustular, or vesicular rash. Now, the individuals in these photos actually have primary syphilis. So, the first state, with the individual on the left having multiple primary lesions, and the individual on the right has an oral shanker. Remember, these lesions occur at the site of inoculation of the organism. The lesions demonstrated are ulcerated, but on palpation, they're usually indurated a bit. Next slide.

This individual has primary and secondary syphilis overwrap. So, you can see on the left, the shanker that is resolving on the clitoral hood and the initial macula papular secondary lesion on

the sole in the picture to the right. This picture also illustrates, again, the importance of a thorough skin exam in individuals presenting with genital lesions. Next slide.

Here are some additional pictures of secondary syphilis. So, we see the palmar rash. We see a diffuse truncal rash, and then also oral mucus patches. So, this rash is macula papular in nature. It is not firm or nodular. And the mucus patches actually can be helpful to clue the clinician into what's going on as well, even though they can be more subtle. Next slide.

Here, we have a comparison between the rash of secondary syphilis. In this case, they're mostly papular, macular with some mild papular component. And also, notice there's a bit of peeling which is not uncommon in secondary syphilis. On the right-hand slide, you see the classic monkeypox rash which they are composed of firm nodules. You can see that one of them is starting to umbilicate, and there's a pustular component as well. Next slide.

Another picture of monkeypox with more prominent umbilication in this picture. Again, firm lesions with some pustular component at this stage. Next slide.

Getting back to some other pictures of syphilis, and this patient has a slightly different type of syphilitic rash in terms of the configuration of the lesions. In the first photo, they're a rather discrete papular lesions on the penile shaft and scrotum. In the second picture, you see targetoid, and that's what the arrow's pointing to. They're subtle. Targetoid flat lesions in that same individual. Again, very different from monkeypox rash. Next slide.

This individual has an annular syphilis, and you can also see postauricular lymphadenopathy that is prominent in this patient. Next slide.

And then, another picture of annular syphilis. Next slide.

The plantar rash of secondary syphilis. Again, different than the monkeypox rash, but confusing because it's one of the few rashes that involves palms and soles. Next slide.

This individual has condylomata lata from secondary syphilis. So, if you see a concerning rash on the arms and legs and find these lesions on a genital exam, it would bring syphilis much higher up on your differential diagnosis list. Like next slide.

I'm going to move on quickly to the most common genital ulcer disease in the world, genital herpes. Now, these are classic lesions of genital herpes. Clinically, we don't often see the classic lesions. But these are described as genital rose petal. Next slide.

This individual had a primary episode of genital herpes that is now healing. Next slide.

I also want to remind you that genital herpes can present on the buttock, and it's often confused with shingles or zoster when it presents in that area. Next slide.

Herpes zoster, which can be confused with herpes simplex virus infection, could also in turn be confused with monkeypox because this rash can also umbilicate. Next slide.

Varicella zoster virus in its disseminated form may be one of the more common entities that can be confused with monkeypox. Some of the difference between the two diseases is that VZV has more superficial lesions, while monkeypox is deep seated. The monkeypox lesion is deep seated, round, and firm. VZV will have the same stage of rash throughout the body, while monkeypox will be in the same stage at the same site of the body. And VZV has a centripetal distribution. It occurs initially on the extremities and spreads to the back, torso, and face. While monkeypox demonstrates centrifugal spread as noted earlier. Next slide.

Molluscum contagiosum is a very common infection that can be sexually transmitted also caused by a pox virus. Molluscum can be found anywhere on the body, and it is umbilicated. However, these lesions are generally pearly in characteristic. And you can see on the, you can compare them to the pictures on the left which are typical lesions of monkeypox. Next slide.

I wanted to point out that another cause of diffuse umbilicated lesions can be disseminated fungal infection. In this case, disseminating cryptococcal infection in an individual with HIV coinfection. So, another etiology to have on your differential. Next slide.

Disseminating gonococcal infection, which is estimated to account for a small proportion of gonococcal infections, commonly presents with petechial and/or pustular skin lesions. They can be vesicular pustular. They can be hemorrhagic. And you can see papules, bulla, and rarely nodules. Usually, the skin lesions are found on the distal extremities. Very rarely on the face. Next slide.

In addition to a comprehensive patient history to assess whether the patient may be at risk for monkeypox and a thorough physical examination to look for distinctive features of monkeypox, use of point of care diagnostic tests and other tests may be helpful in supporting an alternative, more likely diagnosis. I wanted to remind the clinicians today of what a comprehensive evaluation for genital ulcer disease would entail. The evaluation should include testing for syphilis with serologic tests and also direct testing with darkfield examination from the lesion or a nucleic acid amplification test if available. A NAAT or nucleic amplification test should be sent for genital HSV. And serologic testing must be performed for genital HSV as well as in addition to support a diagnosis of genital herpes. Though, that would not tell you for sure that that was what was causing the lesion. And while increasingly uncommon in the U. S. , if shanker is suspected, NAAT or culture should be performed. For more diffuse rash illnesses, consider syphilis serology test. Please keep in mind that STI diagnostics cannot rule out monkeypox but could strongly support an alternative, more likely diagnosis. In monkeypox, if monkeypox is suspected by a clinician, they should consult their state health department. And if the health department cannot be reached, CDC should be consulted through the CDC emergency operations center at 770-488-7100. Okay. And next slide.

I wanted to share a few additional resources that may be helpful. And this is where this STI treatment guidelines are available. The and you can see there's a variety of different resources associated with the STI treatment, the CDC STI treatment guidelines. Next slide.

Providers interested in learning more about STIs, the National Network of STD Clinical Prevention Training Centers, or NNPTC is an important resource. The NNPTC offers didactic

and experiential training in addition to a warm line at stdccn.org where providers can submit consults. And we also have a national curriculum available. Alright. And so, I'm going to now turn it over, back over to Dr. Petersen.

Thank you very much. I'll start by also providing a warning that my presentation does contain graphic images as well. For educational purposes. Next slide, please.

We are fortunate that we have multiple medical counter measures stockpiled for orthopox viruses such as monkeypox. With respect to vaccines, we have two vaccines available called JYNNEOS and ACAM2000. And for treatment, we have an antiviral called tecovirimat, and we also have vaccinia immune globulin intravenous product. I'll describe each of these separate medical countermeasures on the next slides. Next slide, please.

JYNNEOS is a live virus vaccine produced from the strain modified vaccinia Ankara-Bavarian Nordic and is an attenuated, nonreplicating orthopox virus. It is also known as IMVAMUNE, IMVANEX, or MVA. JYNNEOS was licensed by FDA in September of 2009 and is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox virus infection. Next slide.

ACAM2000 is a live virus vaccinia virus vaccine. It was licensed by FDA in August 2000 and replaced the previous orthopox vaccine, dryvax whose license was withdrawn, and the manufacturer destroyed the remaining vaccine doses of dryvax. ACAM2000 is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The CDC holds an emergency access investigational new drug protocol which allows the use of ACAM2000 for non-variola orthopox virus infections, for example, monkeypox, during an outbreak. Next slide.

There are several notable differences between ACAM2000 and JYNNEOS. With respect to the vaccine virus, ACAM2000 is a replication competent vaccine antivirus. Whereas JYNNEOS is a replication deficient modified vaccinia Ankara virus. As such, ACAM2000 does produce a take or major cutaneous reaction which is a vaccine site lesion occurring at the site of inoculation. By contrast, JYNNEOS does not produce any take after vaccination. Consequently, there is a risk of inadvertent inoculation and autoinoculation with ACAM2000 from the vaccine site lesion. No such risk of inadvertent inoculation or autoinoculation exists with JYNNEOS. With respect to serious adverse events, ACAM2000 does have a number of adverse events which I will discuss in the next slides Whereas, JYNNEOS has fewer expected serious adverse events. Cardiac adverse events have been reported with ACAM2000 and myopericarditis is expected to occur in up to 5.7 per 1000 primary vaccines. Myopericarditis has not been observed as associated with JYNNEOS and as such, the risk is believed to be lower than that for ACAM2000. With respect to effectiveness, FDA assessed the effectiveness of ACAM2000 by comparing immunologic responses and take rates of ACAM2000 to dryvax. Similarly, FDA assessed the effectiveness of JYNNEOS by comparing the immunologic response from JYNNEOS from ACAM2000 and also incorporated supportive animal studies. With respect to administration, ACAM2000 is administered percutaneously by multiple puncture technique in a single dose using a bifurcated needle. JYNNEOS is administered subcutaneously in two doses 28 days apart. Next slide.

With respect to preexposure prophylaxis, on November 3, 2021, the Advisory Committee on Immunization Practices voted to recommend vaccination for select persons at risk for occupational exposure to orthopox viruses. Research laboratory personnel, clinical laboratory personnel performing diagnostic testing for orthopox viruses and designated response team members at risk for occupational exposure to orthopox viruses are recommended to be vaccinated. In addition, healthcare personnel who administer ACAM2000 or care for patients infected with orthopox viruses, can be offered vaccination based on shared clinical decision making. Next slide, please.

Severe vaccinia virus complications can occur with replication competent vaccines like ACAM2000. The adverse events here seen are progressive vaccinia and eczema vaccinatum which can occur due to uncontrolled viral replication in certain individuals. For progressive vaccinia, this was generally seen with individuals with immunocompromised. Whereas eczema vaccinatum can occur in individuals with atopic dermatitis or eczema. Next slide, please.

As mentioned, inadvertent transmission can also occur with replication competent vaccines like ACAM2000, including vertical transmission resulting in fetal vaccinia which was commonly fatal to a fetus or newborn as well as autoinoculation or inadvertent inoculation which can present a special hazard when infections occur in special anatomical locations such as the eye. Next slide, please.

Lastly, a replication competent vaccines like ACAM2000 can also produce adverse events of uncertain etiology. For example, post vaccinia encephalitis and viral pericarditis. Next slide, please.

Due to these risks of adverse events, the ACIP has compiled a list of contraindications for ACAM2000 and JYNNEOS for preexposure prophylaxis. Notable here is that ACIP has recommended contraindication for administration of JYNNEOS for persons only with a serious vaccine component allergy. Next slide, please.

With respect to post exposure prophylaxis, I will start by noting that transmission of monkeypox virus requires prolonged, close interaction with a symptomatic individual. Brief interactions and those conducted using appropriate PEP in accordance with standard precautions are not generally high risk and generally do not warrant PEP. Next slide.

CDC has created interim guidance to assess the risk of exposures and make informed decision making with regards to post exposure prophylaxis. Exposures with a high degree of exposure are recommended to be monitored as well as received post exposure prophylaxis vaccination. The example of exposure characteristics with a high degree of exposure would include unprotected contact between a person's skin or mucus membranes and the skin lesions or body fluids from a patient. For example, any sexual content, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with a patient, or contaminated materials. For example, linens or clothing. Additionally, being inside a patient's room or within six feet of a patient during a procedure may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates such as shaking of soiled linens without wearing an N95 or equivalent respirator

or higher and eye protection. Public health authorities can recategorize the risk levels based on unique circumstances. Next slide.

An intermediate degree of exposure would carry a recommendation for monitoring as well as informed clinical decision making recommended for an individual based on individual basis to determine whether benefits of PEP outweigh risks. Exposure characteristics for intermediate exposures include being within six feet for three 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 dressing. For example, turning, bathing, or assisting with transfer while wearing gloves but not wearing a gown. Next slide.

Lastly, low or uncertain exposures would have a recommendation for monitoring but no recommendation for post exposure prophylaxis. Exposure characteristics of low or uncertain exposures include entering a patient room without wearing eye protection on one or more occasions, regardless of duration of exposure or during all entries in the patient care area or room except for during any procedure listed above and high-risk category wore gown, gloves, eye protection, and at a minimum, a surgical mask. Or being within six feet of an unmasked patient for less than three hours without wearing at minimum a surgical mask or exposures at the discretion of public health authorities was recategorized to this risk level. Clearly, exposures with no risk do not require any monitoring or vaccination recommendation. Next slide.

Moving on to treatment. Tecovirimat is an antiviral medication that is approved by the FDA for the treatment of human smallpox disease in adults and pediatric patients weighing at least three kilograms. Tecovirimat is also known as TPOXX or ST-246. Oral capsule and IV formulations were approved by FDA in July 2018 and May 2022 respectively. Tecovirimat is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least three kilograms. A CDC help emergency access investigational new drug protocol allows the use of tecovirimat for non-variola orthopox virus infections such as monkeypox. This protocol also includes allowance for opening an oral capsule and mixing its contents with liquid or soft food for pediatric patients weighing less than 13 kilograms. IV formulation of tecovirimat can be administered in individuals weighing at least three kilograms. Tecovirimat is available from the strategic national stockpile and is both in oral capsule formulation and an intravenous vial. Next slide.

CDC is developing interim guidance for the treatment of monkeypox. Many individuals infected with monkeypox virus have a mild, self-limiting disease course, even in the absence of specific therapy. But the prognosis for monkeypox may depend on multiple factors such as previous vaccination status, initial health status, and concurrent illnesses or comorbidities. Next slide.

Persons who should be considered for treatment following consultation with CDC might include persons with severe disease, for example, hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization or persons who may be at high risk of severe diseases. For example, persons with immunocompromised pediatric populations, particularly patients younger than eight years of age, pregnant or breastfeeding women, and persons with one or more complications. For example, secondary bacterial skin infections,

gastroenteritis with severe nausea vomiting, diarrhea, or dehydration, bronchopneumonia, or concurrent disease or other comorbidities. Lastly, persons with monkeypox virus aberrant infections that includes its accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard. For example, the genitals or anus. Should be considered for treatment. Next slide.

Vaccinia immune globulin is an intravenous product licensed by FDA for the treatment of complications due to vaccinia vaccination, including eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, vaccinia infections in individuals who have skin conditions, and aberrant infections induced by vaccinia virus except in cases of isolated keratitis, for example, for ocular infections. CDC does hold an emergency access investigational new drug protocol which allows the use of the VIGIV for non-variola orthopox virus infections such as monkeypox. Next slide.

Medical countermeasure requests for monkeypox can be made to the CDC Emergency Operations Center at 770-488-7100. Requests for vaccines for post exposure prophylaxis, tecovirimat, or VIGIV should come from state or territorial health authorities. These products will be supplied by the United States Strategic National Stockpile. Vaccines for preexposure prophylaxis will be supplied by the CDC drug service. CDC is available for consultations to assist with medical countermeasure utilization, including appropriate vaccine and antiviral use. Next slide.

At this time, we will begin the question-and-answer session.

Presenter, thank you for providing our audience with this timely information. We will now go into our Q and A session. Joining us for the Q and A session are Dr. Alex Kallen and Dr. Aaron Kaufman from CDC's National Center for Emerging and Zoonotic Infectious Diseases.

Please remember that to ask a question using Zoom, click the Q and A button at the bottom of your screen. Then, type your question. Please note that we receive many more questions than we can answer during our webinar. And one thing that I wanted to mention before we do begin our Q and A session. We noticed in the Q and A box were quite a number of questions requesting CDC's emergency operations telephone number again. That number is 770-488-7100. Again, the number for CDC's emergency operations center is 770-488-7100.

Our first question. How long until we receive test results from CDC?

I can take that one. This is Agam Rao.

So, specimens that are tested at the LRN laboratories that usually is a, that test result, I guess is dependent on the state health department's ability to perform the test. But once specimens are sent to CDC for confirmation of monkeypox, it is usually the same day as the specimens arrive at CDC. So, this testing actually doesn't take very long. It's typically about two days from when the patient is first reported to public health that we know whether or not we're dealing with monkeypox, assuming this happens on a weekday. But, like I mentioned earlier, that first test is

enough to really, at this time, assume that we're dealing with a monkeypox case if the OPX generic is positive.

Okay. Thank you. Our next question.

Do those administering the vaccine need to be vaccinated first?

Hi. This is Brett Petersen, and I can answer this question.

So, as discussed for preexposure prophylaxis, persons administering ACAM2000 vaccine can be offered vaccination under shared clinical decision making due to the low risk that they may be exposed during the vaccine administration procedure. With regard to JYNNEOS, there's essentially no risk to persons administering vaccine due to its characteristics as a nonreplicating vaccine. Thank you.

Thank you. Our next question. Can monkeypox be confused at all with COVID-19?

Let me take that one. This is Agam Rao again.

So, monkeypox, you know, the rash is a really characteristic part of the diagnosis, and the rash, as Dr. Bachmann and I have already mentioned, is a really characteristic one. I mean, it certainly can be confused with other illnesses, but it's, you're going to have a rash. And that rash, just to remind everyone, it is a firm, deep seated rash. It kind of looks like a, you know, a pimple type rash sometimes. And the distribution, I think we may have put up some consistency information. I just want to clarify. It is historically and typically more common in the face and the extremities and can occur on the palms and soles. It's less distributed on the torso, which is kind of the opposite of chicken pox. But you know, because these cases are presenting atypically in that the distribution is different, we'd like people to keep an open mind. But the actual appearance of the rash is the same, it's very similar, I guess, to what we've always known the monkeypox rash to be. It might be going through the stages of the rash a little bit differently, but it still has those characteristic features. I think the question was can it be confused with COVID. You know, because that rash has to exist, you know, that doesn't really happen, you know, commonly with COVID. And so, the rash really is the distinctive feature. If someone does develop the prodromal symptoms like the fever and the malaise and all of that, it's usually just a couple days before they develop the rash. And you know, at any person who develops a fever, particularly because we're in the middle of a pandemic, really should be self-isolating at home until that illness sort of clears itself. But there's nothing really to worry about in terms of it being monkeypox unless that rash appears. They could be infectious, though, as soon as those prodromal symptoms develop.

Thank you. Can you please elaborate on PPE for healthcare personnel, specifically airborne and droplet precautions?

Sure. My name's Aaron Kaufman, and I'd be happy to take that question.

So, I'd just like to clarify that our guidance for protection of healthcare workers is being actively updated in the context of the current outbreak as part of a review of which changes are

warranted. And these changes will be posted quite shortly to the relevant sections of our website. But so, to clarify that question, patients may be, first of all, just in terms of the room management. So, patients may be managed in single person rooms. Special air handling is not required. With respect to that question about, you know, the airborne. So, if a patient has procedures performed that may spread oral secretions such as intubation or extubation, we recommend that those specific procedures are performed in an AIIR room or an airborne infection isolation room. For healthcare personnel that are entering the room, the personal protective equipment which our updated guidance recommends is a gown, gloves, eye protection, so such as goggles or a face shield that covers the front and sides of the face. And then, a NIOSH approved N95 filtering face piece or equivalent or otherwise a higher-level respirator. The recommendation for the N95 stems from a concern of potential spread to the air by lesions that have contaminated sheets as well as concerns about the possibility of short-range aerosol transmission from respiratory secretions. And I would just emphasize that these aspects of transmission of monkeypox in healthcare settings are based upon fairly limited data to date. And so, you know, you may see that these recommendations evolve over time as we learn more. Thank you.

Thank you. Next question. Can you also address the biosafety of specimens sent from suspect monkeypox cases for a workup? Specifically, the handling of blood and urine specimens and a level of protection needed for lab members.

Dr. Petersen, do you want to take that one?

Thank you. In terms of personal protective equipment, I would refer to the previous statements from Dr. Kaufman with respect to personal protective equipment that should be worn when collecting specimens for diagnostic testing. Thank you.

Next question. Is it known whether or not there is any protection from monkeypox from those who have received the smallpox vaccine?

This is Brett Petersen. I can take that question.

So, yes. We do expect individuals who have received the smallpox vaccine to have some protection from monkeypox. We do not know exactly what the duration of immunity is following vaccination, and we don't know exactly how long that protection lasts. It likely depends on multiple factors, including what vaccine was received and the health status of the individual. And there is some evidence that protection can wane with time and may not be lifelong. For example, in the monkeypox outbreak in the United States in 2003, there were individuals who had been vaccinated against smallpox as a child who did become infected with monkeypox virus. But in general, because of the fact that viruses within the orthopox genome induce cross protective antibodies across the genus, we do expect smallpox vaccine to protect against monkeypox. Thank you.

Thank you. Our next question. Can we discuss whether or not there is any difference in disease presentation in children, or will it always be similar to that of adults?

Yeah. This is Agam Rao. I can take that.

It should be similar to what is, what occurs with adults. We have seen cases in endemic countries that appear similarly, but I'll see if any of the other speakers want to add anything to that.

This is Brett Petersen.

I'll just add that epidemiologic studies from endemic areas in Africa have suggested that there may be an increased risk of severe disease in pediatric patients, particularly in children and infants less than eight years of age. So, there is potentially an increased risk of severe disease in pediatric patients.

Thank you. We have time for one more question. Are there any recommendations for screening questions related to monkeypox for patients who are entering a healthcare facility?

This is Agam Rao.

I guess I can start and then see if our other speakers want to weigh in. What could be considered is asking about whether or not somebody has an unusual rash on their body, whether or not they know somebody else who has an unusual rash. If they both, you know, if the person says that they have a rash, then asking further if they know someone else who has the rash that is characteristic of monkeypox. It would be helpful to know, you know, a travel history, but I don't know that that would necessarily be screening information. Just knowing whether or not they traveled anywhere where we know that the countries where we know that there are cases being reported would be helpful. And just before I turn it over to my colleagues to see if they have anything to add to that, I also just want to say that health departments should be contacted when clinicians suspect monkeypox or if they have any, you know, questions about that. And then, the health departments, after, you know, evaluating further, will reach out to CDC. So, although we provided the CDC emergency operations center phone number, I'd advise people to first go through their state health departments, and only after not reaching their health department, reach out to CDC. Including for antivirals and post exposure prophylaxis.

But does anyone else want to add to what I said? Dr. Petersen or Dr. Bachmann?

No. Nothing to add. Thank you.

Thank you, again, to all of our presenters and to those who participated in the Q and A session. We appreciate your time and expertise.

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Again, thank you for joining us on today's call.

Have a great day.