

Good afternoon, I'm Nikki Grimsley, and I'm representing the Clinician 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, Monkeypox Outbreak: Updates on the Epidemiology, Testing, Treatment, and Vaccination. 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&A session. You may submit your 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 receive many more questions than we can answer during our webinars.

If you are a patient, please refer your question 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. Jennifer McQuiston, who will give opening remarks. She is the Incident Manager for CDC's 2022 Multinational Monkeypox Response, Dr. Maria Negrón who is a Veterinary Medical Officer and the Epidemiology Task Force Lead. Dr. Christina Hutson who is the Laboratory and Testing Task Force Lead. Dr. Yon Yu, who is the Regulatory Affairs and Clinical Guidelines Team Lead for the Clinical Task Force, and Dr. Stephen Flores who is a behavioral scientist on the Clinical Task Force, and they are all part of CDC's 2022 Multinational Monkeypox Response.

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

Thank you. Welcome, and thank you everybody for joining us today. This is our third COCA Call on the Monkeypox Response, and we're happy to have you with us. First, an update, as of July 25, there have been 3,487 confirmed cases of monkeypox in 44 jurisdictions in the United States. This past weekend, the World Health Organization, or WHO, declared the global spread of monkeypox a public health emergency of international concern.

At CDC, we've been aggressively responding to the current multi-country monkeypox outbreak, with local, state, and territorial public health departments, clinicians, partners, and community members nationwide to educate and promote credible and accurate information to help people make the best informed decisions to protect their health and the health of their communities. Our response efforts have been focused on education, as well as equitably and efficiently making tests, vaccines, treatments, and more, available to clinicians, patients, and our public health colleagues.

Last month, we activated our Emergency Operations Center to respond to this outbreak, and today you're going to hear about several critical updates for healthcare providers. I want to highlight just a few of the items we'll be presenting. Dr. Maria Negrón will provide an update on the epidemiology of the current outbreak. Dr. Christy Hutson will outline our efforts to expand

the nation's monkeypox testing capacity, which we have increased from 6,000 specimens a week at the beginning of the response to 80,000 a week through a partnership with commercial laboratories that make orthopox tests available in their facilities. Dr. Stephen Flores is going to provide an update on our vaccination strategy.

As part of the National Vaccination Strategy that was announced in June, CDC and HHS have, so far, distributed more than 300,000 doses of Jynneos vaccine from the Strategic National Stockpile to states and jurisdictions nationwide. We're aiming to have an additional 786,000 doses allocated before the end of this month.

Dr. Yon Yu will provide an update on our work to make it easier for healthcare providers provide tecovirimat, or TPOXX, treatment to patients with monkeypox under the Expanded Access Investigational New Drug protocol, or EA-IND. This streamlined process that we've implemented in the last week reduces the number of required forms, patient samples, and photos and gives patients the option to see their doctor virtually.

So, we hope this will make it easier for clinicians to prescribe TPOXX to patients who need it. Throughout this outbreak, CDC has also worked closely and collaboratively with trusted messengers of the LGBTQ-plus community and partners, and I want to thank the many healthcare providers and members of this community who are working with us in amplifying correct information to gay, bisexual, and other men who have sex with men and the transgendered communities, all of whom are currently overrepresented [inaudible] outbreak.

While outbreaks of rare diseases are always of concern, especially in countries where they're not normally seen, we are taking the actions needed to control this outbreak. We must work together to educate and protect those at greatest risk, leading with education and not stigmatization, and we need you, our frontline healthcare providers and public health practitioners, who are so critical to helping get this outbreak under control. Thank you for your participation today, and thank you for your efforts to help us control this outbreak, and moderator, I'm now going to hand it back to you.

Thank you very much, Dr. McQuiston, for your comments and for joining us today. Dr. Negrón, please go ahead.

Good afternoon, my name is Maria Negrón, and I'm a Veterinary Medical Officer and the Lead of Epi Task Force in CDC's 2022 Monkeypox Response. Next slide. As of yesterday, July 25, at 2 p. m. , the total number of monkeypox cases reported to CDC was 3,487 cases. This includes 45 jurisdictions, including DC and Puerto Rico, and three cases in people residing outside of the US. The top reporting jurisdictions include New York, California, Illinois, Florida, Georgia, and Texas. Next slide.

This is the epi curve for monkeypox cases reported to CDC as of July 25, 2022, at 2 p. m. The y axis is the number of monkeypox cases, and the x axis is the date of report to CDC. Also included in this epi curve is the 14-day moving average of cases reported to CDC. Next slide.

For those with available age data, the median age is 35 years, with a minimum of 18 years of age and a maximum of 76. I would like to highlight here that the pediatric cases are not reflected yet in our counts.

For those with available sex assigned-at-birth information, 99% of them were male, and the majority reported male-to-male sexual contact. Overall, amongst those with race and ethnicity available, 38% of cases were among non-Hispanic white, 32% among Hispanic or Latino persons, 26% among non-Hispanic black or African-American, and 4% among Asians. I want to highlight that this is a time snapshot. We will anticipate demographic shifts due to social determinants of health that can affect access to care and prevention services and can also be associated with differential stigma. We are prioritizing ongoing, timely reporting of race and ethnicity and other social determinants of health. Next slide.

The four most-common symptoms reported in CDC case report forms include rash, reported in 99% of case reports with available information, followed by malaise, with 70%, fever 64%, and lymphadenopathy reported in 63% of the case reports. Other common symptoms reported include chills, headache, and muscle pain. That's all for the epi side. Back to the moderator.

Thank you very much.

Dr. Hutson, please go ahead.

Thank you. Good afternoon everyone. I'm Christy Hutson. I'm the Lead of the Laboratory and Testing Task Force with the Monkeypox Response. Today, I'll be going over an overview of current monkeypox virus testing.

At the start of the monkeypox outbreak, the United States already had an FDA-approved test, the non-variola orthopox test, within the Laboratory Response Network. Next slide, please.

Which is the Laboratory Response Network, which is in our public health laboratories. In order to expand testing capacity and access throughout the nation, CDC has worked with five commercial laboratories to onboard the CDC/FDA-cleared tests. We have had significant success in expanding diagnostic testing for monkeypox to these commercial laboratories that have national reach and can perform tests ordered from anywhere in the country.

Lab Corps started testing on July 6th. Mayo Clinic Laboratories began testing on July 11th. Aegis Science began testing on July 14, and Sonic Healthcare started testing this week -- actually last week, on July 18th. These four commercial laboratories will each have capacity to perform 10,000 monkeypox tests per week, combined with the LRN capacity of 10,000 posts per week, national capacity of monkeypox virus testing with the CDC/FDA-cleared assay is now 50,000 tests per week.

In addition, Quest started testing on July 13 using a laboratory-developed test. Quest has indicated that they will be able to perform 30,000 tests per week by the end of July. So, our national capacity is now approximately 80,000 tests per week. Quest will also begin testing with the CDC assay in August, further expanding the nation's testing capacity. Next slide.

I'm going to give a little bit of an overview of specimen type now. For specimen collection, the recommended specimen type is lesion material, usually a swab of the lesion. A swab of a lesion from any part of the body is acceptable, as long as there is a visible lesion that can be swabbed. For some individuals, lesions may not be easily seen. Therefore, clinicians should utilize a thorough evaluation and other appropriate medical methods, as necessary, to visualize lesions for testing purposes. CDC is starting to evaluate other specimen types through our research protocol to help inform potential additions to acceptable specimen types in the future.

Specifics on the acceptable lesion specimen types, such as dry swabs or swabs in transport media, accepted within the LRN and the commercial laboratories may vary based on the lab's specific CLIA approval. Please contact the appropriate public health department or commercial laboratory to determine acceptable specimens. We wanted to remind clinicians that they should initiate diagnostic testing for any suspect monkeypox patient. This is based on clinical presentation and/or epi criteria. It is, however, important to point out that testing in persons who belong to populations for which incidents of monkeypox is expected to be low and decreases the positive predictive value of the test. Therefore, other differentials should also be considered if there are no known monkeypox epi links or risk factors. Next slide.

Some specifics for the commercial labs on ordering and billing. When requesting monkeypox testing at one of these commercial labs, as of last week, there was not a specific CPT ordering code. This code varies by commercial lab and can be found on each website.

These commercial laboratories will bill private insurance, Medicaid, or Medicare for all testing. Those who are underinsured or uninsured will receive a bill, but the Administration continues to work to identify funding that would cover the cost of monkeypox testing, and additionally, the testing at the public health laboratories is still an available option. Once orthopox virus tests are received from the labs, since there are no other circulating orthopox viruses within the United States, detection with a non-variola orthopox test is probable for monkeypox, and clinical care, such as isolation recommendations, should not wait on any additional viral characterization testing that may be done. Thank you. I will turn it back over to the moderator.

Thank you, Dr. Hutson. Dr. Yu, please go ahead.

Dr. Yu, are you still with us?

Yes, can you hear me?

Yes, we can. Thank you very much. Please go ahead.

My apologies. Hello, my name is Yon Yu from Regulatory Affairs with the Clinical Task Force for CDC's Monkeypox Response. I will be providing a brief overview of the recent updates to the CDC's expanded access investigational new drug protocol for tecovirimat, which was posted on the CDC website on July 22nd. Next slide please.

A quick recap of tecovirimat, also known by its name, TPOXX or ST-246 [inaudible] antiviral that was developed for smallpox preparedness and is available from the Strategic National Stockpile.

Tecovirimat comes in two formulations, as oral capsule and injection for IV infusion. The oral capsules are the predominant supply available in the SNS. Both formulations are FDA approved for treatment of human smallpox in adults and children. However, tecovirimat is not approved for any other indication, including monkeypox, and its approval for smallpox indication was based on animal efficacy data from nonhuman primates inoculated with monkeypox virus, in rabbits inoculated with rabbit poxvirus, with supportive safety data from approximately 360 healthy adult subjects. While the animal rule provides a regulatory path to approval when human efficacy studies are unethical or not feasible, there are inherent [inaudible] to drug approval based on efficacy data. While efficacy studies of tecovirimat for monkeypox during the current outbreak are underway, it currently lacks human efficacy data in patients with orthopox virus disease. Next slide please.

For these reasons, tecovirimat use -- thank you. Tecovirimat use for monkeypox during the current outbreak is required to proceed under a regulatory mechanism, such as an expanded-access IND or -- I'm sorry. I think you went one slide further. Back one slide, please. Thank you.

Mechanisms such as an expanded-access IND, or EA-IND. For this reason, CDC holds our EA-IND application that is reviewed and authorized by FDA to allow legal access to, and use of, tecovirimat for non-variola infections, such as monkeypox, as mentioned, because it is not approved for that indication. CDC's EA-IND protocol provides an umbrella regulatory coverage with the IND requirements, which includes [inaudible] of the protocol buy-in institutional review boards [inaudible] has reviewed and approved tecovirimat IND protocol.

All of this is to help the clinician and healthcare facilities, so that they do not need [inaudible] and maintain their own INDs. CDC IRB, serving as the central IRB, will also provide a reliance agreement for facilities that elect to rely on CDC IRB review. Of note, we recognize and acknowledge that, initially, it was noted in the Dear Healthcare Provider letter that accompanied the protocol that reliance agreement wasn't being provided. However, since late June, CDC IRB has been providing reliance agreements to facilities that have requested it. So, please be informed of this availability.

Lastly, tecovirimat use under the EA-IND also ensures the liability protection available under Public Readiness and Emergency Preparedness Act, also known as PREP Act, that applies for liability protection for healthcare providers prescribing, administering, or dispensing the drug. As well, the use under EA-IND preserves the ability for patients to seek compensation if they're seriously injured by the medication through the [inaudible] Countermeasures Injury Compensation Program. Next slide, please. Now [inaudible] of the recently revised tecovirimat EA-IND Protocol. Now the current version that's in [inaudible] use.

CDC [inaudible] with FDA has made a first to revise the protocol to streamline and substantially reduce the number of patient visits, monitoring parameters, and reporting burdens. What this means is all patient visits and assessments can be conducted via telemedicine. It has the option of

doing so by [inaudible] or inpatient in those circumstances, per the clinician's judgment, that requires in-person assessment due to the patient's underlying condition or severity of disease. All of the laboratory testing are optional. The required safety reporting is specifically and only focuses on reporting serious, adverse events.

There is no pre-registration or prior approval that's required for clinicians and healthcare providers to obtain from CDC to begin providing tecovirimat treatment. Forms that are required to be completed and returned under EA-IND, per IND regulations, can all be returned to CDC after treatment begins. Next slide, please. This slide outlines what was just mentioned. The only requirement that must take place prior to initiating a patient on a tecovirimat treatment is obtaining informed consent, and in the revised protocol, we have clearly also mentioned for one [inaudible] document to be returned to CDC.

The signed informed consent should be provided to a copy [inaudible] and to keep a copy at the treatment facility. That it does not need to be returned to CDC. For those clinics and institutions where keeping [inaudible] is not feasible, then there is an option it to return to CDC. As mentioned, the number of visits have been substantially reduced to three in total. That corresponds to at baseline, prior to treatment, once during therapy, once after completion of treatment, and those visits correspond to completing just two forms, a total of seven pages, and these forms [inaudible] consolidated so that they could be used for patients whether they're being treated as outpatients or inpatients.

As mentioned, all other options have been listed under the bullets of optional are not required. Just of note, to highlight one of the items under optional would be regarding lesion samples. [inaudible] feasible, if new lesions, especially persistent, new lesions developed during or even after completion of treatment [inaudible] requesting for clinicians to consider to the extent feasible to swab and send those to CDC for testing and keeping vigilance on potential [inaudible] of antiviral resistance. Again, patient diary to keep track for the patient to be their own advocates reporting. However, that is also optional. Next slide, please.

On this slide, just going to highlight a few of the additional changes, as well as [inaudible] protocol [inaudible] IND is still retained for primary use of tecovirimat for treatment of laboratory-confirmed orthopox virus or probable monkeypox, as well as [inaudible] therapy for presumed positive, based on known exposure and compatible clinical disease manifestations with monkeypox. The IND protocol for tecovirimat, it's intended to be used in concert with [inaudible] and clinical guidance, for the treatment of monkeypox posted on CDC's website. Refer to that website for the most up-to-date information on specific indications and criteria for considering treatment of patients with monkeypox. In the spirit of keeping the IND protocol evergreen, the intended use may be a little bit broad stroked, and thus, the reason for referring to the website on the up-to-date information regarding treatment considerations.

As well, in that spirit of expecting likely evolving situations and potential need for PEP consideration have included postexposure prophylaxis in the revised protocol to be considered on an individual, case-by-case situation for certain individuals for whom might clinically necessitate an alternative to PEP vaccination, and that is to be determined in clinical consultation with CDC. Last item to note in the revised protocol would be that for pediatric use of tecovirimats for the

approved labeled indication has a lower weight cap. Those are removed, so that it could provide treatment options for the youngest children, including neonates, if they were to be infected. There have been questions from pharmacists and from the care facilities regarding IV formulation, especially specific to use of syringe pumps. We have included an explanation for the reasons the syringe pumps, as well as the longer duration of infusion time, that should be applied to the extent possible, to be following those instructions. Next slide, please.

The revised protocol that has reduced the number of visits and reduced data collection, as well as reporting requirements, will help facilitate treatment access and lessen the paperwork burden to providers and institutions. Based on some early feedback from providers in academic centers, we feel optimistic that the revised protocol will help to lessen the burden and facilitate easier access to tecovirimat treatment for monkeypox. We recognize that even the revised protocol may still pose challenges for certain practice sites, geographical locations, and providers with varying degrees of resources and infrastructure. While a one-size-fits-all protocol isn't quite possible, CDC's committed to help improve the overall treatment access, while together with frontline providers [inaudible] and health departments, to also ensure safe and appropriate clinical use of this antiviral.

To request tecovirimat, currently, would be to contact your health department. As well, there is an option for clinical consultation for any cases that clinicians or health departments would consult with CDC at the number of Emergency Operations Center, would bring on the CDC on-call clinical staff for consultations. As well, we are dependent on the information being returned back by the treating physicians and treatment [inaudible]. So, to that extent, we would like to thank you for all of the forms that have been returned. As well, going forward, we continue to rely on the clinicians to provide us visibility by returning the required forms on patient assessment and outcomes.

On that note, in the next few slides, I will share a preliminary summary of baseline information on patients who receive tecovirimat treatment. Next slide, please.

A few caveats that since the information is based on completed patient intake forms received as of past Friday, this certainly does not represent total number or estimate on the total number of tecovirimat-treated patients. We definitely do note more than 233 patients have been, you know, treated to date. With that said, I wanted to still go ahead and provide a snapshot of the information, basic demographic information, that we have on this slide that of the cutoff date of 07/22, based on the [inaudible] that we have received on the intake forms based on [inaudible], there were 233 adults patients who received tecovirimat. They were predominantly male with a median age of 37, and the race and ethnicity are broken down shown on the slide. Next slide, please.

The underlying symptoms, as shown here, not surprisingly, predominantly HIV, and the time of exposure to symptom onset, the median time was 6, averaging from zero to 21. The median time from symptom onset to tecovirimat treatment, first dose given, was 8, ranging from 36 days. Next slide, please.

Formulation that has been used for tecovirimat treatment, to date, has been predominantly oral. We are aware that there have been additional IV doses given, and in many situations, switching from IV to oral after the first few doses, and this is reflecting based on information that's been returned, information that's been completed and returned by clinicians. The number of lesions at the start of tecovirimat, again, predominantly between [inaudible] to 100 lesions at the time of tecovirimat treatment, and the signs and symptoms during [inaudible] illness is reflected, as shown on that slide.

That concludes my presentation, and I want to extend my sincere thanks to the frontline clinicians, healthcare facilities, providers, and health departments in providing tecovirimat treatments, as well as patients with the revised process and the revised protocol. We much appreciate, again, your compliance with returning patient and treatment information, and together, we are committed to providing and ensuring continued access and availability of tecovirimat.

Thank you, and I'll turn it over to the moderator.

Thank you, Dr. Yu. Dr. Flores, please go ahead.

Thank you and good afternoon. My name is Steve Flores. I'm the Vaccine Team Co-Lead on Clinical Task Force here at CDC Interim Monkeypox Response. Today I'll be providing an update on the National Monkeypox Vaccine Strategy. Next slide.

Currently, the National Vaccine Strategy is operating under a limited amount of supply of vaccine. As such, the strategy focuses on postexposure prophylaxis. For the current outbreak, this approach can be considered standard PEP for monkeypox. People can be vaccinated following exposure to monkeypox to help prevent illness from the virus. If there is a high degree of exposure, then PEP is recommended.

In cases with intermediate-degree of exposure, informed clinical decision-making is recommended on an individual basis to determine if the benefits of PEP outweigh the risks. Brief interactions and those conducted using appropriate PPE, in accordance with standard precautions, are not high risk and generally do not work postexposure prophylaxis. Next slide. Some considerations for PEP. CDC recommends that the vaccine series be initiated within four days from the date of exposure for the best chance to prevent onset of the disease.

If the vaccine series is initiated between four and 14 days after the exposure, then vaccination may not prevent disease but may reduce the symptoms of the disease. Also note that vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks in preventing further transmission of monkeypox. Next slide.

Another key component of the current national vaccine strategy is expanded PEP or PEP++. This expanded approach can be considered as an individual-directed PEP for monkeypox, often referred to as expanded PEP or PEP++. This approach aims to reach people who are more likely

to have been recently exposed to monkeypox, even if they have not had documented exposure to someone with confirmed monkeypox. Lastly is PrEP, or Preexposure Prophylaxis. This approach refers to administering vaccine to someone at high risk for monkeypox in advance of exposure. For example, laboratory workers who perform diagnostic testing to diagnose monkeypox. Next slide.

Some considerations for monkeypox vaccination. No data are available yet on the effectiveness of these vaccines in the current outbreak. People who get vaccinated should continue to take steps to protect themselves from infection by avoiding close skin to skin contact, including intimate contact with someone who has monkeypox. This is really important to underscore.

Although vaccination is a key tool, it alone will not be enough in this outbreak response. It is most effective when used in conjunction with behavioral prevention strategies. Lastly, to better understand risks and benefits of these vaccines and the current outbreak, CDC is working with partners to collect data on vaccine safety and vaccine effectiveness. Next slide.

Let me say a little bit about Jynneos allocation. As you're likely well aware, given the current limited supply of vaccine is being allocated to jurisdictions in a phased approach for use with the following individuals. Known contacts who are identified by public health via case investigation and contact tracing, as well as risk exposure assessments, and presumed contacts that are defined by meeting the following criteria: That know that a sex partner in the past 14 days was diagnosed with monkeypox or had multiple sex partners in the past 14 days in a jurisdiction with known cases of monkeypox.

Okay. Jynneos doses should be prioritized for people who are at risk for severe adverse events with ACAM2000, the other vaccine available, or severe disease for monkeypox, such as people with HIV or other immunocompromised conditions. Next slide. So, as just mentioned, we are using a phased approach to allocations, which adjusts as vaccines become available. We're currently at a point where we have completed phase one, which made approximately 56,000 doses available at the end of June.

Then July, we saw phase 2a and 2b occur, during which approximately 24,000 doses were made available. We are on the cusp of announcing the next phase, or phase 3, during which we expect approximately 750,000 doses or more to be available to jurisdictions. HHS anticipates making a total of 1.9 million doses available during 2022, with an additional 2.2 million doses being available during the first half of 2023. I'll also note that for ACAM2000, there are currently over 100 million doses available. Next slide.

At this time, two doses of Jynneos are required. This is the FDA approved dosing regimen. A second dose should be administered 28 days after the first dose. Jynneos has been evaluated in clinical studies involving people with HIV infection and atopic dermatitis and shown to be safe and effective in eliciting an immune response in these populations. People who do receive Jynneos are considered to reach maximal immunity 14 days after their second dose. We do not know if Jynneos will fully protect against monkeypox virus infections in the context of this current outbreak. So, it is important that individuals take additional prevention measures and self-isolate, as soon as they develop symptoms, such as rash. Infections, despite vaccination, may

still occur, which is also important to note, and there are currently no data on effectiveness of Jynneos in the context of this current outbreak. Next slide.

I want to briefly mention a few upcoming guidance related products that are relevant for Jynneos. There are some interim clinical considerations that we expect to be posted soon that cover the following topics: Exceptions to the two-dose vaccine series for people who have been diagnosed with monkeypox; vaccine dosing interval clarifications that are specifically about the seven-day grace period on the second-dose timing; guidance about co-administration with other vaccines, and guidance for contraindications and precautions. Additionally, we will be posting storage and handling guidance, as well as developing some templates for providers to use for standing orders. So, look for those. They should be posted soon. Next slide.

Lastly, I just want to make a quick note about some of the messages that we're sharing broadly with health departments, as well as with providers. There are many considerations, but I'm just going to highlight one particular aspect, which is the focus on equitable distribution. So, there's a lot more to say, but for the purpose of time, I'll just focus on these real quick, so you can hear these messages, as well.

We're encouraging jurisdictions to engage with diverse partners that are already working with the populations affected by the outbreak and working in those communities to use non-stigmatizing language wherever possible, or as much as possible, rather, and also to reiterate the privacy of information and how data will be used and to communicate about that as transparently as possible. To bring vaccines to where people are through pop-up events and mobile outreach, as appropriate and as feasible, and to engage with people from these affected communities while doing this planning and to use peer education models, as well. That is the end of my presentation. I think the next slide has some resources on it, if we can go to that real quick, and that is my last slide. So, I'll turn it back to the moderator.

Presenters, thank you for providing our audience with this timely information. We will now go into our Q&A session. Joining us for the Q&A section are Dr. Agam Rao who is working on the clinical team, and Laura Quilter and Ali Coor, who are both on the Community Outreach and Partnership Engagement team. These are all part of CDC's 2022 Multinational Monkeypox Response.

Please remember that to ask a question using Zoom, click the Q&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 webinars.

For our first question, "Can you please review when ACAM should be used?".

This is Steve Flores. I don't know if you're on, Dr. Rao. That seems like a question for you to answer.

I can speak to things about ACAM. Is that the question, like the benefits of the risks and that sort of thing? If so, I guess I can speak to that. This is Agam Rao from the Poxvirus and Rabies

Branch. ACAM2000 is a vaccine that's been licensed for some time now. Its precursor, Dryvax, was actually used to eliminate -- to eradicate smallpox.

So, unlike Jynneos, there is more data about ACAM2000. However, ACAM2000 does have a lot of contraindications associated with it, unlike Jynneos, particularly people who are pregnant, people who have eczema or any other skin conditions that are similar to that, also people who are immunocompromised. There are several contraindications to ACAM2000. So, that needs to be kept in mind, particularly for this outbreak response where people who fall into each of those groups might be impacted, and then additionally, ACAM2000 is associated with more adverse events than what we know about Jynneos. We're still studying Jynneos.

It is a new vaccine, but just based on the fact that Jynneos is a nonreplicating virus vaccine and ACAM2000 is a replicating virus vaccine, we do believe that there are more adverse events associated with ACAM2000 than Jynneos. So, weighing all those considerations, clinicians can decide whether or not ACAM2000 is appropriate.

Thank you. Our next question asked, "What are the recommendations for surveillance screening for healthcare systems and facilities? For example, should we be screening for rash, travel, or something else?".

Hi, this is Marie Negron speaking. Definitely, the considerations you that may take when you have a patient presenting will be any atypical rashes and also history will be key.

Thank you. Our next question, "What positive control material is available for monkeypox or orthopox virus lab-developed tests?".

Hello, this is Christy Hutson again. So, we are aware of a couple of different commercially available sources of positive control material. NIST is one that has developed a positive control material. It's synthetic and should work in numerous different orthopox virus or monkeypox virus lab-developed tests. So that's N-I-S-T, NIST, and then Twist Biosciences also has positive control material, and ATCC does, as well.

Thank you. Our next question, "Is TPOXX useful for prevention in close contacts, especially with children?".

This is Yon Yu, I'll take and also defer to our poxvirus SMEs, Agam and Brett. The primary PEP option is with vaccination. As mentioned, there is no efficacy data, even with treatment. The potential option that we have added for into the revised protocol is in certain individuals where some [inaudible] and circumstances that it would allow for use of PEP on an individual, case-by-case consideration. There is no recommendation currently for tecovirimat to be used for PEP generally. Its primary use is for treatment of monkeypox.

Thanks, Yon, and this is Agam Rao. I agree with you that tecovirimat should be considered primarily for treatment, and the vaccine should be primarily considered for post-exposure prophylaxis.

Thank you.

Thank you. "Is there a situation in which a patient should receive both vaccines?"

This is Agam Rao. I can take that one. So, both vaccines meaning Jynneos and ACAM2000 is, I assume, what is being asked. No. I mean, they're both the ACIP deliberations have determined that the two-dose Jynneos series is comparable to the one dose of ACAM2000.

So, anyone receives who one or the other would be considered appropriately vaccinated. The only time there's potentially mixing is when individuals were previously vaccinated with a product. For example, years ago, if they received ACAM2000 or its precursor and are now due for a booster dose, which is only applicable to people who are at occupational risk for orthopox viruses, example, laboratorians. You know, this is longstanding ACIP recommendations unrelated to this response, but that's the only reason that someone might receive both vaccines. It is if they are due for their vaccine, per the ACIP recommendations and end up getting a different vaccine, but as part of this response, there's no reason that anyone would get both vaccines.

Thank you. Our next question. "If the lesion is not open and cannot be dehooded, should samples still be collected?"

Hi, this is Christy Hutson again. Yes. So, for this PCR test, you do not need to derroof the lesion or lance the lesion. Just a vigorous swabbing of the lesion surface is sufficient for us to get enough viral DNA, if it's monkeypox virus. If it's in the crusted phase, which I saw there were a couple questions about that, sometimes the swabbing doesn't always give us high enough DNA values, compared to when it's more in a pustular stage, but if it's in the crusted phase, we at CDC are actually able to test the crust from the lesions, and some of the LRN labs are, as well.

So, you should definitely reach out your public health labs if you want to get a crust tested, to make sure they're able to receive that specimen type. I believe commercial labs have not yet added that. Then I did want to mention also why we suggest that different lesions are swabbed while we were talking about lesion swabbing. So, occasionally, we see a co-infection where, and this is somewhat from our survey studies that we've previously done, where one lesion might actually be positive for monkeypox and other lesions on other parts of the body be positive for other viruses. We do suggest that you swab the lesion with just one swab.

Don't move around to other lesion types, and generally, one swab is sufficient for testing, but we suggest two to three, just because, occasionally, the lesion isn't swabbed vigorously enough. So, we don't get high enough DNA values. So, then there's a second swab lesion to go back to. Hopefully, I covered some of the different lesion swabs, but again, I know this is a common question. You do not need to lance the lesion or derroof it. Just a vigorous swabbing of the lesion surface is sufficient.

Thank you very much. Yes, there were a number of questions on that topic. "Can CDC standardize what swabs can be used for sample collection?"

This is Christy Hutson again. So, unfortunately, the way that the labs are run is the different specimen types are dictated by their CLIA approvals. So, although all of the public health LRN labs, the commercial labs, and CDC lab, the standard specimen type that's being tested is a swab of the lesion, the specifics, for instance, if it's a dry swab, if it's a swab in VTM, viral transport media, or universal transport media, is going to differ slightly by each lab. So, we do encourage clinicians to confirm with whichever lab they are sending those specimens to on which specific lesion swab specimen type they can accept.

Thank you. Our next question. "Can you clarify when phase 3 vaccines will be allocated in the United States?"

I'm sorry. That sounds like a vaccine question. Would you mind repeating that?

Yes, absolutely. "Can you clarify when phase 3 vaccines will be allocated in the United States?"

Yeah, the timing of that is not set just yet, but I think it's going to be set, and there will likely be an announcement on that timing, I'll say very soon, but if you want a date, I would say we're all hoping that it's going to be in days as opposed to weeks from now. So, very soon.

Great, thank you. Our next question. "What are CDC's recommendations for pregnant healthcare workers and seeing monkeypox patients under investigation or patients with monkeypox?"

I can give a partial answer, which is that routine for healthcare workers, routine standard precautions and PPE should be enough, and they shouldn't need exposure prophylaxis via vaccine after that, but for a more detailed answer, I'd defer to someone on the clinical team.

This is Agam Rao. I can add some information to that. So as part of the ACIP recommendations that preceded this outbreak, the guidance, the recommendations were that people who are pregnant or immunocompromised, they might not have as -- first of all, someone's who immunocompromised might not have as robust a response to any vaccine, not just these vaccines, and immunocompromised people and pregnant people, if they were to have an exposure, whether it was despite vaccination or because they were not vaccinated, their illness could be more severe. So whenever possible, it would be good to, in addition to ensuring that proper personal protective equipment is used, that, perhaps, if there is a way of avoiding exposure to people who might have monkeypox, that that be requested. I don't know if anyone else has anything to add about that, but I do know that we are developing some guidance specific to pregnant persons, and we can think about this issue, as well, and guidance for it.

Thank you. "Can you comment on whether the vaccine will eventually be made available to healthcare workers, especially those who see patients in high-risk groups?"

This is Steve. I can give an answer, maybe not the definitive answer, but I would just link that to the availability of vaccine. So, you know, recall with COVID vaccination and vaccine availability, as that increased, more and more groups were able to get access to it. I think we're in a very parallel situation for reaching into larger, you know, number of people that are interested

in and want to and need to get vaccinated and getting into preexposure prophylaxis. We're just not quite there yet.

So, I don't have the timing for that, but I think the answer, qualitatively, is when vaccine supply allows that. We do expect to have a lot more vaccine available in the coming -- you know, I think the numbers that I shared by the end of this year and into next year, that there should be enough for people who are at high risk to be able to get more vaccinations done.

And this Agam Rao. I'll just add that we're not aware of healthcare workers being impacted significantly during this outbreak worldwide. So that, hopefully, is some reassuring news. That personal protective equipment has been preventing illnesses and exposures.

Thank you. Our next question, "How long does immunity last after the first infection?".

This is Agam Rao. I'll just say, you know, we really don't know this information yet. We are actively trying to investigate this. We do say that somebody who -- I think we will soon be saying more information on the CDC website about whether vaccinations are even indicated for people who have recovered from monkeypox, and also if they've developed monkeypox in between, you know, after they got their first dose, what the subsequent vaccine guidance will be. So, more to come on that.

There will be some guidance on the CDC website about those two scenarios, but about the actual question about how long the immunity lasts, that's under investigation, but certainly, in the short term, they would most definitely be protected. I'm talking about decades from now. We don't know.

Thank you, our next question -- oh, excuse me, are you finished, Dr. Rao?

I'm sorry. I was just going to say that that's what we expect, but we are studying it further. I'm sorry, Nikki.

No, no problem. Thank you. Our next question, "Can you please discuss the 1572 Form and who needs to complete it, and how is the term facility defined? Is that the individual clinician or the healthcare facility, or you know, the state or local health department?" [Inaudible speech] I think we have lost Dr. Yu. So, we have time for one last question.

"Do clinicians need to wait on a monkeypox test result to initiate training after a positive orthopox virus test is received?"

No, this is Christy, from just a testing standpoint because the non-variola orthopox test does not detect any -- so, basically, within the United States, sorry, there are no endemic orthopox viruses that are detected with our non-variola orthopox tests. So, that positive test result is indicative of monkeypox virus, and treatment can begin. Isolation can begin, as needed, based on clinical picture, etc. So, you do not need to wait on any specific monkeypox characterization testing that may be performed after that initial orthopox virus result is received.

Thank you. Thank you, presenters and to our subject matter experts for participating in the Q&A session and for sharing your expertise with us today.

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Again, thank you for joining us for today's Call. Have a great day.