This content was published before guidance to change "monkeypox" to "mpox" was delivered to CDC programs in December 2022

Clinical Laboratory COVID-19 Response Call
Monday, June 27 2022, at 3:00 PM ET

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- **Monkeypox Biosafety Update**
  - Alicia Branch, Division of Laboratory Systems, CDC

SEAN COURTNEY: All right. Good afternoon, everybody, and thank you for joining us today. My name is Sean Courtney. And I'm a health scientist in CDC's Division of Laboratory Systems. On the screen is the agenda for today's call. And as you can see, towards the end, we have some discussion around the current monkeypox outbreak. However, before we get started, I just want to cover a few announcements, as well as some general housekeeping items.

So as you've heard on previous calls, DLS is the CDC division that works to advance laboratory quality and safety data and biorepository science and workforce competency. And we work closely with the clinical and public health laboratories across the country to support laboratory emergency preparedness and response activities and have been hosting these calls since March of 2020.

And so DLS supports this work-- oh, excuse me, this work across four goal areas. So quality and safety, workforce and training, preparedness and response, and informatics and data science. And so as always, we will be sharing slides from today's call, and we'll be posting them online by early next week, as well as the audio and transcripts from this call. And so you can find them on the link shown here on the slide.

And as a reminder, these calls are held on the third Monday of each month. And so our next call will be on Monday, July 18 from 3:00 to 4:00 PM. And so we want to hear from you. Our Training and Workforce Development Branch is interested in hearing about any of your education and training gaps that you may be experiencing. And so we invite you to contact us at labtrainingneeds@cdc.gov to share any of those needs.

And for today's call, if you have any questions, we ask that you please use the Q&A function within the Zoom menu and not the chat feature. This way we can capture your questions and be able to address them during the call. If we're unable to address them during the call, we also ask that you include your

email address when you submit your questions so that we can hopefully follow that up with the appropriate SME [subject-matter expert] after the call.

And then for the last part here, we just want to remind you that these slide decks may contain presentation material from panelists who are not affiliated with the CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topics covered. And with that, we will-- I do not think Natalie is on the call yet. So I'm actually going to move forward to Alicia Branch, who is going to be giving us an update on the pneumatic tube transport guidance from-- and she works within CDC's Division of Laboratory Systems as well. And so Alicia, I will hand it over to you.

ALICIA BRANCH: Thanks, Sean. We still receive questions about the pneumatic tube system guidance on the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19 [page]. So we would like to let you know that this guidance is just a recommendation, and there are no plans to make any updates to the guidance. So today, we really wanted to provide brief biosafety clarity for our recommendation considerations. Next slide.

Because all clinical specimens may contain potentially infectious material, health care and laboratory professionals should adhere to standard precautions and select the appropriate biosafety practices based on a site-specific and activity-specific risk assessment.

Therefore, to minimize the potential risk of exposure, CDC, again, we would like for you to definitely consider, regardless of whatever specimen that you are transporting through the pneumatic tube system, to perform a risk assessment. Next slide.

Now, the site-specific, activity-specific risk assessment should assess, but not be limited to the specimen type, any known hazards associated with that specimen. This may be the route of transmission. So for instance, you're transporting blood. It may contain bloodborne viruses, such as HIV, hepatitis B or C. Thinking about sputum, it may contain a bacteria that causes tuberculosis, which is possibly transmitted by inhalation of aerosols. Or, for instance, if there is a biopsy specimen, that may contain formalin, which could cause a possible exposure to harmful vapors.

You should also identify the hazards involved in a process, such as the specimen carrier or the specimen container. So the type of container and how it's packaged in the tube system is-- through the tube system carrier is very important. Is it in a transport bag? Is it made of glass? Or is it also in a secondary container type? This is important because the specimen carrier is not leak proof.

So you also want to know the competency level of the personnel that's using the pneumatic tube system and if they are competent and understand the specimen type that they're actually handling. Included in the training, you want to make sure that they understand the proper operating and control procedures, the personal protective equipment they should be using, safe handling practices. If there is ever a spill, that they understand the spill containment and decontamination procedures. You also want to adhere to any manufacturer's quality and maintenance recommendations, as well as the facility design.

So you may be asking, who should really be involved in the risk assessment process? Well, basically everyone who uses the pneumatic tube system. You want to also include the facility and laboratory biosafety personnel, any laboratory management, industrial hygienists, occupational health professionals. Your quality management, you want to make sure that they're involved as well, and any clinical or health care laboratory personnel. Some other people you also want to include me included in the risk assessment process is your pneumatic tube system manufacturer and also your facility management. Next slide, please.

This is just some helpful resources that you may want to use when you're performing your risk assessment, as well as just some guidelines just for safe practices. Back to you, Sean.

SEAN COURTNEY: All right, thank you, Alicia, for that update. I currently do not see any questions relevant to your discussion right now. Wait just one second. So, no, sorry, I don't see any current questions that are relevant to this discussion, Alicia. But if you could please stay on. I know we have you later on the call as well, but if any questions pop up regarding the pneumatic tube system guidance, if you could please answer them, that would be super helpful.

And so I believe Natalie Thornburg is on the call now. And Natalie, I'm going to-- I think I hear you. I'm going to stop sharing my screen so that I can give it over to you, OK?

NATALIE THORNBURG: Hey, Sean, I am on my phone. I'm having some network problems. So is there any way you could pull up the COVID data tracker and show the genomic surveillance website from the genomic data tracker?

SEAN COURTNEY: Yes, but give me one minute, please.

NATALIE THORNBURG: OK, great, thanks. Well, while you're pulling that up, I'll just go ahead and give an introduction. It's been probably a month or so or more since I've presented to this group. My name is Natalie Thornburg. And I am one of the leads for the immunology and virology lab in DVD [Division of Viral Diseases] of CDC. So since I last presented to you there have been some minor changes in the genomics data tracker.

There have been two new variants that have been added to the COVID data tracker, BA.4 and BA.5. But lots of things have not changed. It's still all Omicron lineages circulating in the United States. Throughout the spring, BA.2 and sublineage BA.2.12 had been increasing in the late spring. And those have now begun to decrease, although they're still, or at least as of last week, they were still greater than 50% of circulating lineages.

BA.4 and BA.5, which were first identified by the very robust sequencing capabilities of South Africa, started-- I'm sorry, let me look to see if where you can find that-- variant proportions. Thank you, Sean. So BA.4 and BA.5, which are shown in teal, light teal and dark teal, could first be detected in early May and

have been increasing in proportion. And it seems as if BA.5 is slightly outpacing BA.4, although both of them are increasing in proportion.

BA.4 and BA.5, notably, they evolved independently. However, they have the same spike sequence in comparison to each other. So as far as immune breakthrough of vaccination, they should have very similar profiles and laboratory tests thus far have demonstrated they are quite similar to each other. Can you scroll down to show country? Thank you.

And so you can see both lineages are detected in all HHS regions and are actually showing pretty similar proportionality across the United States. And those are really the only updates I have for this week. And I'll take some questions if there are any. Thank you.

SEAN COURTNEY: OK, great, thank you for that, Natalie. And apologies for getting the page up.

NATALIE THORNBURG: No, apologies I couldn't share my screen.

SEAN COURTNEY: That's no problem. We made it, so it's OK. I'm not seeing any additional questions at this time either. I'm not sure, I guess since you're on your phone, you probably don't have access to them if any pop up later during the presentation.

NATALIE THORNBURG: I can see them. I can see the chat; I just can't share screen.

SEAN COURTNEY: OK, great. And either way, if not-- if any questions come up, we can also respond later via email to answer those. But as of right now, I do not see any questions that have come up on the screen. So thank you for that.

All right, and so moving to our next one, to keep us on our toes we're going to shift again a little bit here and hand it over to Wendi Kuhnert, who's going to provide an update on the Monkeypox outbreak.

WENDI KUHNERT: Hey, Sean. And thanks, especially for having me on the call today. I'm Wendi Kuhnert and I'm the Senior Advisor for Laboratory Science to the Deputy Director for Infectious Diseases at CDC. I don't have any slides today, but happy to follow up in the chat with additional questions based on the information I will be providing today.

I'm going to be providing a brief testing update on monkeypox. Just looking at the total number of cases across the US, as of today there is a total of 236 cases across 26 jurisdictions, with one additional case being diagnosed by the UK in Florida.

Another aspect of this outbreak that I think that is important to mention is that the monkeypox virus infection was recently added to the Nationally Notifiable Conditions list. This list is maintained by CSTE, or the Council of State and Territorial Epidemiologists. And annually, they develop and update position statements that help to standardize surveillance case definitions. And they recently updated the case

definition for monkeypox. And as I said, have added it to the Notifiable Disease list as of Thursday, June 23.

And as you know, the cases in the US are on the rise, but the cases worldwide are also on the rise. And in response to this, the WHO director general met last week and decided that they concurred with the advice offered by the International Health Regulations Emergency Committee regarding the multi-country monkeypox outbreak. This group has determined that at present the event does not yet constitute a Public Health Emergency of International Concern or what you might know as a PHEIC, P-H-E-I-C.

So now that we've talked a little bit about the cases that we've been seeing, I wanted to touch a little bit on the existing capacity within the US. The initial capacity that was stood up is within the public health laboratories. And this has been focused within the Laboratory Response Network, or the LRN laboratories. And in addition to that testing, we are also in the process of expanding to additional commercial laboratories.

And while the capacity within the public health labs is really only being tapped at about 2%, we have received reports of some specific jurisdictions that feel that they need additional capacity and communities that want additional access to testing. And so in response to this, CDC has been working with five large commercial reference laboratories to provide this additional testing capacity. Unfortunately, we do not have a specific timeline on when these tests will be available within these large laboratories, but we are working with them as quickly as possible to stand up this testing in a high-quality way.

So one other question that we thought might come up is, is there a need for additional testing beyond the public health lab network as well as the commercial labs? And we are aware that some laboratories are standing up their own testing. If a laboratory decides to stand up a Laboratory Developed Test, or an LDT, we would ask that you please remember to contact your local public health department to report any positive results before you send that data electronically.

At this time, laboratories do have the option to create these Laboratory Developed Tests, however there is limited material for validation. And additional sites that start to test could actually start to create a strain on the supply of positive controls, as well as other reagents. What we want to stress is that it's most important for laboratories that are testing to always contact your local health department as soon as possible for any positive results.

The only other thing that I wanted to touch upon is that for any facility that is sending in samples for testing, at this time there is a fair amount of flexibility for the swab type and the collection container, but please review the guidance provided on the CDC website. It's important to note that most any swab, except a cotton swab, will be fine for submission and to always remember to use a leak-proof container. And I think there's going to be some biosafety guidance that is also shared in this later in this call, so I wasn't going to address that. But with that, I'm happy to answer any questions that come up.

SEAN COURTNEY: OK, great. Thank you so much for that, Wendi, for that update. Give us a second here. I'm just going to go through the questions. We did have a few that came through while you were talking. A lot of them are around LDT. So just one second.

So the first one we have is, if we bring a test as an LDT, do you provide a sample for correlation?

WENDI KUHNERT: At this time, the CDC is not able to provide a sample for correlation. We really don't have that many samples that have been coming into CDC. But I believe we're trying to post on our website some recommendations for where positive controls can be located. And in addition, I know that we've posted protocols for both the generic non-variola orthopox assay as well as the monkeypox specific assay on our website.

SEAN COURTNEY: OK, great, thank you. Next question here is, of the 236 cases in the US, are they primarily in adults or have there been any pediatric cases noted?

WENDI KUHNERT: Thus far, there have not been any pediatric cases noted. The majority are adults. And I'm trying to remember the age range from a slide I saw earlier today. Our age range does tend to be wider than some of that in the other countries, but nothing in the pediatric population yet.

SEAN COURTNEY: OK, thank you. Next question was, are all states now accepting swabs in VTM for monkeypox?

WENDI KUHNERT: Each laboratory, unfortunately, needs to have its own validation from a CLIA perspective before they are able to accept specimen types. And so while the CDC laboratory is able to collect-- or to test samples in viral transport media, and it is also permissible within the 510(k), each laboratory would need to perform their own validation. So I'm not able to speak to what the acceptance criteria would be for an individual jurisdiction. I'm sorry.

SEAN COURTNEY: OK, thank you for that clarification. The next question would be, how can commercial laboratory staff who are testing for monkeypox be provided access to the smallpox vaccination?

WENDI KUHNERT: So, we have been working closely with the commercial laboratories that we are partnering with for this initial round of testing. However, it's important to note that there should be a risk assessment performed on which staff should get tested. And I think there's a lot of-- there's a number of factors involved in that decision. And so I don't have the specific answer on who to contact if you need vaccination, however I do think that a full risk assessment should be performed and each of the employees would need to be-- they would need to accept the vaccination as well.

SEAN COURTNEY: OK, great, thank you. The next question we have here, and there are quite a few questions in the chat, I'm just not sure if they could be answered on the call today. But the next question we have is it acceptable to use the Puritan foam tipped applicator if a polyester swab is not acceptable?

WENDY KUNERT: Yeah, I'm going to defer that one. And I'm happy to take that one offline, Sean. I would want to make sure I touched base with the SMEs before answering that specific question.

SEAN COURTNEY: Yeah, thank you. I think there were a couple of questions, actually, in the Q&A function that look probably more relevant to the lab SME. So I'm going to do a quick glance right through, real quick, to see if any one additional ones have popped up. I think they're pretty specific to probably the lab team. So I appreciate you joining our call today, Wendi. And if any additional questions pop up that are relevant, that you can take care of, we'd appreciate you take care of them in the chat. Otherwise, we'll try to address them via email after the call.

WENDY KUNERT: Great, thanks, Sean. And thanks for having me on the call.

SEAN COURTNEY: Absolutely, thank you. OK, and moving along, we will continue. And go back to Alicia Branch, who's going to provide a monkeypox biosafety update. Alicia?

ALICIA BRANCH: Next slide, please. As we know, all current US monkeypox cases are associated with the West African clade, and this clade is not a select agent. We will discuss the proper shipping name and classification during the packing and shipping section of this presentation.

Again, because all clinical specimens collected may contain potentially infectious material, health care personnel and laboratory personnel should follow the standard, contact, and droplet precautions when handling these clinical specimens. And as always, you should always perform a site-specific and activity-specific risk assessment.

If, and when possible, you would also want to limit the number of laboratory personnel working doing the manipulation of monkeypox specimens. Next slide, please.

When we look at vaccination, it's recommended that those are testing the monkeypox lesion specimens, that they actually have a recent vaccination. However, vaccination is not an absolute requirement for handling specimens. Vaccination is not recommended for personnel that is handling and processing routine clinical specimens, such as blood for CBC or urine for urinalysis.

When unvaccinated personnel are unavailable, a combination of personal protective equipment and additional precautions should be used to reduce the risk of exposure. And we will discuss some of those additional precautions later in this presentation. Next slide, please.

Because lesions are known to have the highest level of orthopoxvirus, thus the manipulation of the monkeypox specimen should be performed in a BSL-2 [biosafety level 2] facility, using BSL-3 [biosafety level 3] practices. Some of those BSL-3 practices include but may not be limited to what is listed here, such as an N95 respirator, a solid front gown with cuff sleeves, double gloves. And you also would want to tape the gloves around your sleeves. Eye protection, safety glasses, a snug fit goggles, face protection, such as face shield, and use a class II biosafety cabinet. Next slide, please.

If procedures cannot be formed in a BSC [biosafety cabinet] you should use, again, like we said, a combination of PPE [personal protective equipment] and additional precautions. Now these precautions could be an aseptic containment isolator centrifuge safety cup, seal rotors. But you also want to make sure that you do all the work behind a bench top splash shield. And this will actually provide some additional barrier between the specimen and the laboratory professional. Next slide, please.

Again, if you're just performing routine diagnostic testing, as we said earlier, for blood for CBC, and the specimen actually did still come from a monkeypox patient, you would perform those in a BSL-2 laboratory and you would use just BSL-2 practices. Clinical and diagnostic laboratories should not be performing monkeypox virus culture-based testing as a routine diagnostic procedure. Laboratories that do consider culture-based testing should have a BSL-3 facility, a validated virus culture protocol, and vaccinated staff. Next slide, please.

As stated earlier, the West African clade monkeypox strain is currently circulating in the US. And CDC worked with DOT [US Department of Transportation] to clarify the US circulating strain is not a select agent. And this can be detailed in the updated DOT planning guidance for handling category A solid waste. This strain is classified, and packaged, and shipped as a UN33-- 3373 biological substance category B. And this is for the current edition of the DOT Transporting Infectious Substances Safely or the IATA [International Air Transport Association] Dangerous Good Regulations.

And the IATA dangerous goods is mentioned because if specimens are shipped via air, FedEx, most commercial carriers are members of IATA. And it has actually the most stringent packing and shipping instructions. And therefore, if you're following the IATA guidelines to pack and ship, you're complying with the DOT regulations and air.

Personnel should be trained based on their role-specific packing and shipping responsibilities. And this is very important. Before anyone starts to actually start packing and shipping, you should actually have had training. And your facility should have certified you to actually pack and ship. Next slide, please

Decontamination should be performed on the laboratory surfaces and equipment using a US Environmental Protection Agency registered hospital disinfectant or any product on the List Q with an emerging viral pathogens label claim. And these are some of the examples that you may find on there. And as always, you should follow the manufacturer's recommendations for the use. This means that you shouldn't be using something for a particular surface or the equipment. You should also think about the contact time as well as safe handling.

Waste should be packaged as UN3291, regulated medical waste, monkeypox waste. And as always, you should always treat and dispose of such waste by following your applicable state, local, tribal, and territorial laws and regulations for regulating medical waste. Next slide, please.

And again, this is just some resources that you can use if you have any questions about anything that was presented on today.

SEAN COURTNEY: OK, great, thank you so much for that, Alicia. Really appreciate that discussion. There are a few questions in the chat that I'm going to ask you. Just one second. The first one is, what about for clinical labs doing lesion testing for other routine viruses, such as HSV [herpes simplex virus] or VZV [varicella-zoster virus], is the CDC recommending the same enhanced practices?

ALICIA BRANCH: I'm not sure about that. We might have to ask-- I'm going to ask one of the SMEs about that. Because I know that there has been some questions surrounding even just doing some routine things and they actually ended up growing some of the monkeypox virus, so they needed to change their practices. So I'll have to defer that to one of the SMEs.

SEAN COURTNEY: OK, great. Thank you. One second. So the next question would be, what if there is a spill in the lab of other specimen types, such as urine, blood, or other bodily fluids, what precautions are necessary?

ALICIA BRANCH: OK, so for that one, you would still need to have had a risk assessment. Because if that's something that you handle on a regular basis, that blood-- because most of the time in the clinical lab, you already don't know what additional infectious agents are involved in that sample. So that's why it's very important that you would actually perform your risk assessment to account for any of those hazards and have your spill SOPs [standard operating procedures] already readily available in the case that you do have a spill, regardless of if it's a monkeypox specimen from a patient.

SEAN COURTNEY: OK, great. Thank you. Next question we have is, are there specific disinfecting procedures on instrumentation for chemistry or hematology on specimens suspicious for monkeypox?

ALICIA BRANCH: Again, that's one of the discussions you would probably want to most likely have with your-- as I talked about earlier, in your risk assessment process, you may want to include the actual manufacturer of your instrument. So you may want to definitely contact them to make sure. Because you don't want to use something that you shouldn't be using as a disinfectant in that particular instrument.

SEAN COURTNEY: Great, thank you. Next question is, is the waste still considered category A?

ALICIA BRANCH: No, the waste from this clade, the US clade, the West African clade is considered UN3291 regulatory medical waste, not as a category A.

SEAN COURTNEY: OK, thank you for that. Let's see, I think there's at least one more question here, and if you can answer, that'd be awesome. It is, are BSL-3 conditions no longer necessary for diagnostic testing of monkeypox virus?

ALICIA BRANCH: That is correct. It is no longer necessary for diagnostic testing.

SEAN COURTNEY: OK, thank you. And I do not see any other questions right now. Doing one last go through. All right, I think that covers it. Really appreciate you joining our call today to discuss these biosafety updates regarding monkeypox testing and just orthopoxvirus testing in general.

And I just want to say thank you to all of our speakers today. And as mentioned before, we will post the slides, transcript, and audio to our website by early next week. And I just really want to thank you all for joining us today. And we continue to be grateful for your work and we will talk to you again on Monday, July 18. Thank you. Have a great one.