Call Date

06/16/2025

Call Agenda

Welcome
Sean Courtney, CDC Division of Laboratory Systems

Mpox Updates
Whitni Davidson, CDC Division of High-Consequence Pathogens and Pathology

COVID Variants Update
Natalie Thornburg, CDC Coronavirus and Other Respiratory Viruses Division

Measles Response Update
Brian Wakeman, CDC Division of Viral Diseases

Brucella Updates: Delisting 2025 Case Definition, Exposure Monitoring and Sequencing
Rebekah Tiller and Zachary Weiner, CDC Division of High-Consequence Pathogens and Pathology

Call Transcript

Sean Courtney: Hey, good afternoon everybody. We're gonna start this call in about a minute.

All right. Good afternoon, everybody. Thank you for joining us today. It's good to be back on the calls with you guys. So my name is Sean Courtney and I'm in CDC's Division of Laboratory Systems. On the screen at the agenda for today's call. But before we get started, I just want to cover some housekeeping and some general announcements.

All right. So DLS is the CDC division that works to improve public health and patient outcomes by advancing laboratory systems. We work closely with clinical and public health laboratories across the country to support lab emergency preparedness and response activities, and we've been hosting this call since March of 2020.

So DLS supports this work across four goal areas, quality, workforce and training, preparedness and response and informatics.

And so, as always, we want to hear from you. So, our training workforce development branch is interested in hearing more about your education or training gaps that you're currently experiencing. And so we invite you to send any feedback to us at lab training needs at LabTrainingNeeds@cdc.gov.

And so we've updated our LOCS, webpages and as before we will be posting slides, audio and transcripts online at a later date, hopefully within the next couple weeks. Call material from prior calls can still be found on our LOCS webpage shown at the link here.

And so obviously as we hope you've noticed, we've had to move these calls over to Microsoft

Teams and we're no longer able to utilize the Zoom platform. Apologies if you hear the beeps that are going on as people join the call. Hopefully that's just on my end, so hopefully you guys don't hear that. But in our recent LOCS message that we sent out, we included links to download the Teams application to your various platforms, if you don't currently have it. And—but, unfortunately as of now, dial-in is not currently available. We do recommend that you consider creating a new meeting reminder with this login information so that these LOCS calls can be saved onto your calendar, and we'll be sending out LOCS messages should the meetings be cancelled in advance.

If you have a question today, we ask you—well, we want to let you know that the chat window is not operational, but as before, we want you to please use the question and answer, that Q&A function that's here in Teams, so that we can address it during the call. Also, please include your e-mail so that we can follow it up if we're not able to get to your question during the call. If you have non-laboratory testing questions, we ask you to please contact CDC info at the e-mail address shown on the slide. If you're with the media, we ask you to please contact CDC Media relations at media@cdc.gov. If you're a patient, please direct any questions to your healthcare provider.

And lastly, I'd like to remind everybody that the findings and conclusions in this slide deck are those of the authors and may not necessarily represent the CDC's official position. So please keep that in mind when you go back and look at some of the slides that are posted on our LOCS webpage.

And with that, I'd like to introduce our first speaker for today. We have Whitni Davidson from CDC's Division of High-Consequence Pathogens and Pathology, and she'll be providing an update on the Mpox response. Whitni?

Whitni Davidson: Thanks, Sean. As Sean mentioned, I'm Whitni Davidson. I work here in the Poxvirus and Rabies Branch, managing the diagnostic testing in the laboratory. Next slide, please.

So since November of last year, four cases of clade I mpox have been diagnosed in the United States. All cases have been associated with travel to countries experiencing clade I transmission. And all sought medical care for mpox symptoms after arriving in the United States.

The CDC continues to assess the risk of clade I monkeypox to the U.S. general population as low. However, given the widespread outbreaks in central and eastern Africa, additional travel associated cases may be reported in the US. Next slide, please.

CDC continues to recommend that laboratories using an orthopox- or monkeypox virus generic test without additional clade-specific testing send all orthopox- or monkeypox positive clinical specimens for clade-specific testing.

Additionally, laboratories using CDC's non-variola orthopoxvirus test that are not performing their own monkeypox clade specific testing, should continue submitting the duplicate specimens from patients with positive non-variola orthopoxvirus test results to CDC. Specimens can be submitted to CDC under surveillance or for clinical—or under CLIA. And I

just want to mention that there are now two different test codes for poxvirus molecular detection. The one for CLIA remains the same. And then there's an additional test code for non-CLIA specimens. Next slide, please.

If clade-specific testing is not available in a jurisdiction, specimen submission to a capable public health laboratory or the CDC is encouraged. Your state or local health department can help coordinate specimen submission to CDC. Expedited clade testing should be performed for monkeypox cases that have known international travel to countries with clade I mpox cases. If you guys have any questions, feel free to reach out to us at poxviruslab@cdc.gov. Thank you, and that's it.

Sean Courtney: All right. Thank you for that update, Whitni. I am looking at the Q&A now. I don't see any questions that are currently in there, so I just say thank you for joining today's call. If you can hang out, if there are questions that come later while other speakers are presenting, if you're still on the call, you can, if you could, you can actually respond to them directly within the Q&A feature. So that would be great. But thank you for joining today's call.

Whitni Davidson: Thank you.

Sean Courtney: All right, all right. Well then moving to our next speaker, I'd like to please welcome Natalie Thornburg from CDC's Coronavirus and Other Respiratory Viruses Division. And she's going to provide us with a COVID variants update. And Natalie, I will stop—Oh, I see that I already stopped sharing. Take it over.

Natalie Thornburg: Thank you, Sean. Okay, so I'm going to share just a little bit about COVID epidemiology right now and then touch on the variants that are circulating at the moment.

So for the week ending June 7th, which is the most recent reporting period, our percent positivity was right at 3%. It has been sitting quite low for the past couple of months. Our winter wave, if you look here in the COVID data tracker, was smaller than other, more recent winter waves. We had a peak of test positivity at about 6.7% January 4th, and it's sort of been declining since then.

If patterns of transmission and seasonality reflect what we've seen in recent years, we could expect a summer/fall wave last year. If you look at the COVID data tracker, we started seeing an increase in positivity right at the very end of June/ July. I'm sorry. That's right there. Very end of, well, kind of started in May, June and we saw a peak of at up to almost 20% peak in August. In the previous year, late June/July and we saw a peak kind of in late August as well. So we may in the coming weeks start to see an increase in COVID activity if it is like more recent years.

So if you look at the genomics webpage on the COVID data tracker, the first thing you'll notice is this banner that pops up. And it's just stating that due to low number of sequences being reported to CDC, the precision of our Nowcast modeling is—and our weighted estimates are low. We are going to be pivoting to longer reporting periods just so we have a little bit more data

to use in our model. And so in this next reporting period, we are going to be binning data in four week reporting in four week data bins instead of two weeks data bins. If you'll think way back when we originally developed Nowcast, we had one week reporting periods, data bins and when we kind of saw a reduction in sequences about 2-3 years ago, we expanded our data bins to two weeks and we now, expanding our data bins to four weeks and then we'll plan on doing updates every four weeks thereafter.

So we are seeing a change in lineage proportion right now. We are predicting that NB.1.8.1 has been increasing or is currently increasing in proportion. We've seen LP.8.1 the most prevalent lineage throughout the—the late spring during low transmission, but we are seeing this other lineage sort of increase in proportion right now and that's shown in purple.

And our confidence intervals because of the low number of sequences that we have to use in our Nowcast modeling, our confidence intervals are very, very wide. But we expect that NB.1.8.1 represents somewhere between about 10-13% of viruses all the way up to 70% of viruses. So again, it is a very wide, predictive interval range.

What is NB.1.8.1? Well, it is circulating internationally for a couple of months. It was prevalent in other parts of the world earlier this spring and it does now seem to be increasing in proportionality in the United States. If you look at our dendrogram on the COVID data tracker, it kind of sits in an odd place. It sits here, so it is a sub lineage of something called XDV.1. It looks like it's quite different than everything else that's been circulating since winter of '23/'24 has been JN.1, but it's actually very similar to these viruses. This is not accurately this location in the DENDROGRAM is not accurate—does not accurately represent how different it is.
It is XDV.1 is a recombination event between JN.1 and an XBB virus, which is why it's sort of rooted upstream of JN.1. But it is very, very similar to XEC which is the lineage that was most prevalent sort of during that large peak in the fall of 2024. Notably, it has two substitutions in the spike protein that are a little different. It's got one at residue 435. We're seeing that substitution pop up in several lineages, so that's indicating that it's got some sort of selective advantage. And then there's a substitution at 478 in the spike protein, which is a little bit unique to this NB.1.8.1.

Now there's no—there is a little bit of data, some laboratory data looking at sort of like cross neutralization of current—current lineages. And there's no data that indicates that this virus is antigenically, much—very different than anything else that is currently circulating. So everything else that's circulating and has been circulating for about a year, year and a half are all descended from JN.1, which is the current vaccine strain JN.1. So this is—it does seem to have a little bit of a selective advantage, but it doesn't seem to be dramatically different than anything else that has circulated in the past year and a half. And that is all from me. Thank you.

Sean Courtney: All right. Thank you for that update, Natalie, appreciate you joining the call. While you were presenting there are a couple questions that came up. The first one was approximately how many sequences go into the biweekly and in the future monthly SARS-CoV-2 reports that you cited?

Natalie Thornburg: Yeah, so we like to have about 3000 to accurately detect new emerging lineages and to use for Nowcast modeling, we like to have about 3000 in the most. I think the past two times we've done this analysis, we've only had about 500. So we are still not going to have the number that we like to have, but 1000 is much better than 500.

Now, notably, we only use sequences that CDC generates or that are tagged as baseline in a public repository. There are a lot of sequences that are in there that aren't tagged baseline, so we don't know if they could be from outbreaks or something specific. So we don't use those in our analysis because we don't know that they are representative of everything that is circulating in the community.

Sean Courtney: Excellent. Thank you. Next question that we had was—it was actually around this new SARS-CoV-2 strain that you were discussing showing up in the U.S. and it being more infectious. Would you—would it be classified as more infectious or what are your thoughts on that?

Natalie Thornburg: You know, there's a little bit of data I think, and I would have to look at the preprint, that said, maybe like the affinity for, it's a very, you know, sort of artificial lab data that says the affinity for ACE2 might be a little different. I think anytime you see anything that is increasing in proportion, that's sort of proof in the pudding-pudding that the virus has a selected advantage in the—in whatever population you're looking at. So I think that the fact that it's increasing in proportion right now is sort of indicative that it has a selective advantage.

Sean Courtney: Great, thank you. The next question came up was, are sequences from wastewater being considered for the forecasting or is it just from clinical specimens?

Natalie Thornburg: It is just for clinical specimens because wastewater is an inherently mixed specimen, you-you can't tell like this is the number-this—you can't estimate this number of infections is being caused by this virus because they are mixed– they are mixed. But our wastewater colleagues do-do detection and they also do estimated proportions. The-the analysis is a little harder because of those– those issues around it being a mixed proportion and there is a dashboard I'll have to dig it up. It's I think it's-it's moved to a different URL in the past couple of weeks so I can look for that and-and share that.

Sean Courtney: Great, thank you. Next question was, are there any differences noticed in the symptomology with the new variant?

Natalie Thornburg: We don't have any data to indicate the symptoms are any different than any other lineage that has circulated previously.

Sean Courtney: Great, thank you. All right, let's see. Let me refresh this. One question around test kits and detection of the new variant, do you have any data supporting detection?

Natalie Thornburg: We have no reason to believe that that approved diagnostics would not detect this lineage, but our FDA colleagues are really-really—work with manufacturers to-to-to watch those. So you would really need to watch the FDA space for any indication about that.

Sean Courtney: Perfect. All right. All right, I'm not sure if you can answer this, I'll ask you, but if– if you need to defer or they need to send it in, just let us know. But it's around—Do you—are you aware of immunity after recent infection protecting you against other variants?

Natalie Thornburg: I mean, these are very similar viruses that have been circulating recently. Infection with a similar virus should provide you some level of protection if-if one is immunocompetent some level of protection for some time and vaccination with a similar lineage should do the same. So, yes.

Sean Courtney: Excellent, thank you. Well, I appreciate you joining the call today. If you're able to join– to stay on the call a little bit longer if additional questions pop up in the Q&A that you're able to take care of, we'd appreciate that.

Again, I'll reiterate that if-if people have questions and they like to ask them if we can't get to them, please include your e-mail address so that we can follow up at a later time. Or you can send them into that CDC Info mailbox that I mentioned earlier in the call. But thank you for joining the call again, Natalie, and yeah, thank you.

All right. And let me go back to sharing the presentation. Right. And we will be moving to our next speaker. All right. And now we have—I'd like to please welcome Brian Wakeman from CDC's Division of Viral Diseases. And he's going to provide an update on the measles response. Brian, I will hand it over to you.

Brian Wakeman: Thank you. Yeah, so I'm currently serving as the deputy lead of the Measels Laboratory Task Force at the CDC. So I'll be providing a brief update on the current 2025 measles response. Next slide.

So first I'll provide a situational update. This is updated weekly on the link below. Next slide.

So as of the end of last week, there are 1,197 confirmed measles cases in 35 different jurisdictions, with the largest outbreak centered in Texas, specifically west Texas. Additional cases have been seeded from the outbreak in Texas, as well as related outbreaks in Mexico and Canada. Additionally, measles importation from international travel continues, especially as the busy summer travel season ramps up. Next slide.

Of the approximate 1,200 cases, 29% are under the age of 5 and 66% are under the age of 19. Currently, 95% of all cases are from unvaccinated or vaccination status unknown individuals, while 2% have one dose of MMR and 3% have two doses of MMR. The current hospitalization rate is approximately 1 in 8. And there's been 3 deaths, two children in Texas and one adult in New Mexico. Next slide, please.

As you can see, the number of confirmed measles cases is significantly higher than 2023 and 2024, and we're currently on pace to eclipse the 1,274 cases of measles that we saw in 2019, which—with a large outbreak concentrated in New York. And we're also on pace to be the greatest number of measles cases since the early 90's. Next slide.

So now a little bit about some epidemiology in the United States.

So the number of measles cases in the United States was in the hundreds of thousands until the introduction of the measles vaccine in 1963, which resulted in a quick decline in the number of cases. A second dose was recommended in 1989, which resulted in the elimination of measles from the United States in 2000. Elimination is actually defined as the absence of endemic measles transmission in a region for 12 months. Which means that while we have measles cases in the United States since 2000, including the large number of cases in 2019 and the large number of cases right now, if the cases cannot all be linked for 12 consecutive months, elimination status remains. Next slide, please.

Since elimination status in 2000, there's been sporadic outbreaks across the United States. These outbreaks are often represented in populations with low MMR coverage. With high transmissibility of measles, a required vaccination rate of 95% in a community is required to prevent outbreaks. This map illustrates some of the larger outbreaks and the MMR coverage at that time. So as you can see, MMR percentage was often significantly lower than the required 95% coverage. Next slide.

Since 2020 and COVID, there's been a slight but steady decline of two dose MMR vaccination coverage among children from just above the necessary outbreak prevention coverage of 95% down to 92.7% in 2023 and 2024. Additionally, as indicated by the shading, the drop in coverage is not evenly distributed among states, with some states maintaining 95% coverage, while others have dropped below 90%. Next slide, please.

While drilling down even further to county levels, coverage with states MMR coverage is often not evenly distributed within some counties with coverage rates below 80%. So it's possible that certain areas are more prone to potential measles outbreaks, given the coverage rate by county, and it varies county to county from high to low in some states. Next slide, please.

So this is slightly outdated as the tribal health notice has been removed and the recommendation is for all international travelers to be up-to-date with two doses of MMR. And while large outbreaks in the United States are still rare, travelers-associated measles is still a common occurrence most years. And not reflected on this map is large outbreaks in both Mexico and Canada, with Mexico exceeding 2,000 cases currently, and five deaths in Canada, exceeding 1,500 cases. Next slide.

Overall, the risk for widespread measles in the United States remains low due to robust U.S. immunization and surveillance programs and the outward outbreak capacity support. And MMR remains the most important tool for preventing measles. Next slide, please.

For reporting measles cases—so measles is a nationally notifiable disease. State and local health departments have the lead while investigating measles cases and outbreaks, and below is the recommendation that—to report measles immediately and preferably within 24 hours directly to the CDC and through the national Notifiable Diseases surveillance system. Next slide, please.

So now I'll talk a little bit measles testing.

So these days, most US measles cases are detected by PCR, typically performed on NP and OP swabs, but can also be detected in urine. PCR is most commonly done in public health laboratories, but can also be done in commercial laboratories.

Quick turnaround time for testing is crucial. Specimens are ideally collected within three days of rash onset for optimal sensitivity, but PCR can be positive up to 10 days after rash onset. It's best to collect specimens for RT-PCR as soon as possible after rash onset to optimize detection.

Proper specimen collection, storage and processing is important to maintain the stability. RT-PCR has a much higher sensitivity and specificity than serology, as most people know, but false positives can occur, but it's much less common.

The CDC assays are run on the ABI 7500 in Quant Studio 5 DX. But can be validated on any other instrument. We're also aware some groups have bringing on measles testing using the Fusion Panther systems. And additionally, we've been getting some questions about primer mismatch with some measles variants in the past have shown a 3 U-C mutation. That mismatch is fixed by adding a reverse primer containing the mismatch at a 50:50 ratio. Next slide, please.

Measles can also be—measles can be diagnosed by detection specific of IgM, though, CDC does not recommend performing serology. It can—It is recommended to be collected along with RT-PCR. IgMs produce starting 1-3 days after rash onset and can be detected for 6-8 weeks after rash onset. And so it's important collection tool when that window for PCR is being extended out and you may have a false negative with PCR. Next slide.

Use of IgM alone is not recommended, especially in settings with low measles incidence like the United States. First, cross-reactivity with other causes of febrile rash illness has been documented. This is especially true for HHV-6 and parvovirus, which can mimic measles febrile rash and illness, and turn up false positive on IgM testing. Second, false positive results are more common when the likelihood of measles is low. So for example, when there isn't local active transmission and patients have not traveled and when patients without known exposure have been fully vaccinated, a positive IgM is not necessarily confirmatory. Next slide, please.

One implication of vaccinating during an outbreak is the possibility of vaccine reactions appear very similar to measles infections. The measles vaccine contains a live attenuated measles

virus and approximately 1-5% of persons vaccinated may develop fever and rash that's clinically indistinguishable from measles infection. While individuals with vaccine reactions have not been shown to transmit measles, when vaccinating occurs during an outbreak, in order to take appropriate public health action, it's imperative to know when a person has a vaccine reaction or measles reaction. Next slide.

The Measles Vaccine Assay, or MeVA assay, is a PCR test that distinguishes the detection of measles vaccine virus genotype A from wild-type measles virus. CDC and the Vaccine Preventable Reference Centers located in California, Minnesota, Wisconsin and New York run this assay and additionally some commercial assays have been bringing this test online. Next slide, please.

Measles—MeVA testing should be performed when there is an epidemiological risk of measles infection in a recent vaccine recipient. Testing a person with mild fever and rash after recent vaccination is not necessary if there's no actual risk of measles. If there is an epidemiological risks, meaning international travel, local outbreak, or a known exposure, MeVA should be performed after standard RT-PCR confirms measles. Next slide.

So to summarize, first, collect NP/OP and urine specimens for measles RT-PCR testing. Serology IgM should not be used alone, but can be used with RT-PCR. Third, measles IgG antibodies show immunity to measles either from prior infection or vaccination.

And then two final points I'd like to touch briefly on is the need for measles genotyping. Measles genotyping is done at the CDC and the reference centers mentioned earlier. Genotyping's conducted for surveillance purposes, linking cases and importation, and is crucial for maintaining elimination status. Since this is so crucial and the uptick in testing occurring at commercial laboratories, there's been a greater need for specimens being forwarded from commercial laboratories. So to help facilitate this, we are in the process of onboarding commercial laboratories to CSTOR, which is the CDC's electronic test ordering system. This will make it easier for states to request samples be forwarded to CDC for sequencing and streamline the process for commercial laboratories. So we've been reaching out to commercial partners, but you may also reach out to us at the contact address at the end of this presentation. Next slide.

And one last final point—is for laboratory and healthcare workers—is to ensure that everyone has presumptive evidence of immunity to measles if working with measles or measles patients. So this is either a documentation of vaccination with two doses of live measles virus containing vaccine, laboratory evidence of immunity, so IgG Testing, laboratory confirmation of disease in the past, or those born before 1957. Next slide.

And so as mentioned earlier, just please reach out to the inbox if you have any laboratory-related questions about measles, be it assay design, general questions or onboarding to CSTOR. And with that, I will stop.

Sean Courtney: All right. Thank you for that update on the measles response that's going on.

Quick question for you, one that popped up was, are those the maps, the measles maps of the outbreaks—are those any—are those available online anywhere?

Brian Wakeman: The outbreak of the international? If yeah, if yeah, I assume so, yeah.

Sean Courtney: I think the current one well, I guess both.

Brian Wakeman: So the state map is updated on the CDC website weekly on Fridays. And the international map that comes from—like I said, it used to be the travel health notice, which has now been taken down for just a recommendation of all travelers to have two doses of MMR when traveling internationally, however, the outbreak in the cases can be found on the CDC website as well. It's updated not as frequently. It's updated, usually through WHO and is dependent on the country itself. For Mexico and Canada, they're updating more frequently due to their current ongoing outbreak and so theirs is updated as frequently as the CDC.

Sean Courtney: All right, thank you. Some questions came in again, not sure if you'll be able to answer, but I'll ask you if-if you can't, you know we can defer, follow up and get them an answer. But can you speak about measles titers and how effective they are on determining immunity?

Brian Wakeman: Yeah, so the-the recommendation is that that people with two doses of MMR are considered presumptive immunity and it's recommended that they do not need to be tested for IgG. I mean there's always the possibility that you have protection, but an IgG titer too low for measles IgG assay to detect, yet you're still protected. So the recommendations at the end of the of the presentation—I guess a history, a documentation of two doses, or laboratory confirmed in the past diagnosis of measles, or pre-1957 before introduction of vaccine and most likely exposure to measles is-is the recommendations and further IgG testing is-is not necessarily recommended.

Sean Courtney: Okay, great. There is another question in there, it's kind of around sharing the reverse primer sequences that you kind of mentioned earlier in your talk, I'm going to recommend them to actually e-mail you guys at CDCmeasleslab@cdc.gov that you have up on the slide. For more information, Brian.

Brian Wakeman: Yeah. And so, yeah, just. Yeah, I was gonna say in the in the follow up with that if if people are concerned. So there's only been 14 of those variants detected in the U.S. since 2023, and none have been detected in 2025. There was a paper put out by the CDC, and you can e-mail us at CDCmeasleslab@cdc.gov. But the paper is Beck, et al. 2024, Eurosurveillance paper.

Sean Courtney: Great, thank you, and actually was one of my follow up questions I was gonna have so thanks for answering that already. I think you kind of touched on this, one last question though, it's kind of around the use of IgM and PCR together or in a certain algorithm.

Brian Wakeman: In the United States, due to the low prevalence, it's recommended that all measles testing is-is confirmatory with a PCR test. Like I said, the IgM adds a piece to it

because it is possible that you miss that window of rash onset and then a nasal or OP swab. However, in the United States, given the fact that we have such a low incident rate, the positive predictive value of an IgM test alone is-is fairly poor and would not be recommended.

Sean Courtney: Okay, great. All right, Brian, well, thank you. I really appreciate you joining our call today. If you're able to hang around, there might be a couple more that have popped up in the Q&A window, if you're able to answer some of those, we'd appreciate you just typing them right in there, but thank you for joining the call, really appreciate this update on measles.

Brian Wakeman: Thank you.

Sean Courtney: All right and we will move to our last talk for the day. We have Rebekah Tiller and Zach Weiner from CDC's Division of High-Consequence Pathogens and Pathology, and they're going to be providing a few important updates on *Brucella*. So I will hand it over to them.

Zachary Weiner: Awesome. Thank you very much for the introduction. As mentioned, I'm Zach Weiner. I am the lead of the Zoonoses and Select Agent Laboratory here in Bacterial Special Pathogens Branch and with me is Rebekah Tiller, our brucellosis experts. Next slide, please.

All right, so as many of you, hopefully all of you have seen already, that *Brucella* has been removed from the select agent registry and we just kind of wanted to hit on a couple things on where that changes things for you, what that means for how samples are shipped, how they should be handled in your laboratory, et cetera.

So first of all, it's still a Risk Group 3 pathogen so mostly how it's handled in your lab shouldn't change. Still should be handled in a BSL-3 laboratory space. Any isolates presumptive isolates or confirmed isolates should still be shipped category A, but really most of the changes are revolving around updating your protocols to reflect the regulatory changes. So it changes how you do your inventory, no longer requiring Form 2 shipments, no longer requiring Form 4s for reporting to the Select Agent Program. But yes, you still should maintain your inactivation protocols and validations for moving DNA or other derivatives out of your BSL-3 'cause it is still quite infectious. Next slide, please.

So we have been getting a decent amount of questions related to this delisting and how it relates to occupational and lab exposures. We still think it is important to recognize potential exposures in the laboratory so the next steps can be taken. Laboratory should continue to conduct risk assessments after a potential exposure. We do have a convenient Brucellosis Reference Guide that is publicly available online, although I will point out we are still in the process of modifying this ourself. It still has select agent all over and we are in the process of-of fixing that and reflecting the recent changes.

So depending on the exposure scenario, symptom watch and serological monitoring or PPE may be recommended. If serological monitoring is performed, we do recommend agglutination testing is-is done over ELISA because it's easier to compare results over time. And that is a service that we still do offer diagnostically here in ZSAL. If you are doing serological monitoring,

sera is drawn at 0 at 6-, 12-, 18- and 24-weeks post-exposure.

We still do not have serological testing available for *B. canis* or RB51. Although I would like to mention we have an IRB protocol in place, so if you are aware of any patients with exposure-suspected cases of brucellosis caused by *B. canis* or RB51, we are looking to enroll them and collect samples so we can develop serological methods to detect these 2 species—or strains.

And then at any time, CDC's BSPB is available for consults. I believe our epi, Dawn Blackburn, is on the call and she will be the one to happily answer any inquiries you have should you reach out about exposure—any exposures that you may have. Next slide, please.

Rebekah Tiller: All right. Thank you, Zach. So we're tag teaming.

Another update that we have is that we recently in the past year, have updated the brucellosis case definition. We worked very hard with a group from the Council of State and Territorial Epidemiologists to update the brucellosis case definition, which hadn't been updated since 2010.

The main updates were to better define and differentiate the brucellosis causing *Brucella* species and the non-brucellosis is causing *Brucella* species. Which was due to a reclassification taxonomically of the genus where a group of bacterial species, previously known as ochrobactrums, were recategorized into the *Brucella* genus. So we've updated the case definition to reflect how to, you know, distinguish those by-by terms, so we have BBS and nBBS to distinguish these two.

We also removed direct detection by PCR as a-as a diagnostic tool and—as a lab—in the laboratory criteria. And then we added the detection of IgG antibody by ELISA as supportive laboratory evidence.

There's a lot of other updates, and, you know, the clinical criteria, one was that we removed the-the criteria to have fever as a mandatory clinical symptom because we have encountered over some, you know, data analysis, some brucellosis patients that actually did not present with fever. So we did not want to make that a mandatory criteria to meet the clinical case-case criteria. Okay, next slide, please.

So we also have been working with ASM and APHL to do—to update the sentinel-level clinical laboratory guidelines that clinical laboratories use when they're identifying or ruling out potential select agents. So *Brucella*, as Zach mentioned, has been delisted from the Select Agent Program, so we kind of had to go through these guidelines and walk back on some of the regulatory terminology to—as far as handling and reporting and things like that in the clinical lab setting.

We also have updated the testing algorithm workflow that most clinical labs would-would use to rule out a *Brucella* or rule in a *Brucella*. And this also takes into consideration that you would encounter the previous *Ochrobactrum* species that are now going to be called *Brucella* species

on most of your Rapid ID systems. So we removed language and guidance applicable to the select agents and so I think that though is probably in clearance now. I know we've completed it and it's gone through all the pre-approvals so I can, not give you a hard deadline when it would be published, but it's-it's nearly finished and should be available to be released in the near future. Next slide.

So and finally, since we've now have *Brucella* delisted from the select agent registry, it makes sharing strains a lot easier, which then gives us a lot of opportunity to improve strain surveillance for *Brucella*, that's causing human disease in the United States. And we've-we've-we've been inviting labs when they have identified a *Brucella* species to submit them to us for sequencing so that we can at least have data if there is a need to have some information on any kind of case, investigations that may occur. Brucellosis clusters happen very slowly over a long period of time. We may have a case in November and then another one will pop up in, you know, the beginning of December and then another one. So going ahead and having sequenced sequence data can really, you know, close-close the loop on some investigations a little bit quicker. So we are reaching out to labs to send them under a test order called *Brucella* species Study. And because these are not CLIA samples, they can be submitted de-identified.
And certain labs, we have suggested, because we have a lot of labs that do get a number of *Brucella* isolates in a few months or a few week time period that they can batch send samples quarterly or you know every few months. And so we do use these sequencing results in lots of situations. We've worked with many states on case investigations and it's been really helpful. And then also it helps with pathogen discovery. So that's all I have for *Brucella* updates and we'll take any questions if there are any.

Sean Courtney: Oh. All right.

Rebekah Tiller: Okay, here's-here's our contact information. There's BSPB, which is mostly our our epidemiology team, and then the Zoonoses, the ZSAL e-mail is is-the lab side. And then there's myself and Elke, who are the point of contacts for specifically for *Brucella* testing, and then Zach.

Sean Courtney: Well, perfect. Thank you, guys, and appreciate the update on today's call. Yeah, there's a couple questions that went in there. The first one was, if you guys could provide any additional detail about what went into the decision to delist *Brucella*?

Zachary Weiner: Oh man, I think this process took almost a decade. But there-there is a process with the Federal Select Agent Program with the two advisory boards, both for the agricultural side and the HHS side, to go through and reevaluate every agent on the list. Looking at new data that may come across, consulting SMEs in the field, and they use a rubric which kind of grades different aspects of each pathogen and the disease they cause. And when this came up for *Brucella,* following the-the rubrics, which I believe is published. And-and you can review, I can maybe find that link and send it to go out after this call.

It was determined that it did not meet the thresholds to be a select agent in light of new data and better repackaging and understanding of those data. And then it was a lot of back and forth

with a lot of different government agencies. And yeah, and it was finally delisted, which I think we agree with that decision, it was a big plus.

Rebekah Tiller: Yeah, it was. I think the USDA really put forth a very strong argument for delisting just due to the-the-the need to be able to do more research on animal-animal vaccines and animal studies to be able to maintain our brucellosis free status here in the United States.

And the select agent, you know, regulations were just very, very impeding to doing any kind of advance-advancement in any kind of research on the animal side. And there were, I think that there were some—the requests for comments may have justifications that were put out. And we could probably also dig up those-those links as well.

Zachary Weiner: Yeah, but it wasn't fast, so.

Rebekah Tiller: It took a very long time.

Sean Courtney: Thank you for that. I do want to point out that ASM actually commented while you guys were presenting that they are in the PDF proofing stage and that they are hoping to publish soon, so that's good news.

Rebekah Tiller: Thank you, Paige.

Sean Courtney: Yes. Next question was, are you all interested in any *B. canis* from domestic pets?

Rebekah Tiller: Yes, that's that's predominantly where our exposures are from. So I think from animal isolates, those give us as much of they-they-they deepen our picture of you know what could be circulating here in the U.S., so yes.

Zachary Weiner: Yeah. And to kind of add on that, it's not unusual that we'll get, you know, aquatic brucellosis species or from frogs. So basically anything that pops up has *Brucella* on any of your instruments or algorithms, we are more than happy to take and investigate further. We're not super picky over here.

Sean Courtney: Awesome. All right, guys. Well, thank you. I don't see any more questions at this time, so I just want to thank you again, Zach and Rebekah for joining our call and providing this update for everybody.

All right. Well, let's move on. And again, I just want to thank really all of our speakers today. It's been fantastic updates that we've had and want to remind everybody that our next call is scheduled for Monday, July 21st from 3:00 to 4:00 PM.

As a reminder, these calls typically take place on the third Monday of each month. And also please let us know if you have any suggestions for topics for future calls. We look forward to

continuing to discuss these hot topics and to answer any laboratory and testing needs that you guys have.

As I mentioned at the beginning of this call, we're going to post the audio transcript and slides from these calls, from today's call once they're all clear on our website within the next few weeks. As I've mentioned previously, you can find CDC on various social media platforms such as Facebook, X, Instagram, LinkedIn.

And again, I just want to thank you all for joining us today and we continue to be grateful for all the work and wish you all a really happy Monday. So thank you all for joining and we will see you guys next month. Thank you.