# Call Date 09/18/2023

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# Call Agenda

<u>Welcome</u> Sean Courtney CDC Division of Laboratory Systems

COVID-19, Influenza, and RSV Situation Report Manisha Patel CDC National Center for Immunization and Respiratory Diseases

SARS-CoV-2 Variants Update Lydia Atherton CDC Coronavirus and Other Respiratory Viruses Division

Monitoring Respiratory Viruses with Congregate Air Sampling: Spaces, Not Cases David O'Connor and Shelby O'Connor University of Wisconsin-Madison

<u>CDC's Logical Observation Identifier Names and Codes (LOINC) In Vitro Diagnostic (LIVD) Test Code</u> <u>Mapping Webpage Update</u> Muktha Natrajan CDC Division of Laboratory Systems

# **Call Transcript**

**Sean Courtney**: All right, we'll go ahead and get started. Thanks, everybody, for joining today. Good afternoon. My name is Sean Courtney. I am a Health Scientist in CDC's <u>Division of Lab Systems</u>. And on the screen is the agenda for today's call.

But before we get started, I want to cover a few announcements and some general housekeeping items. Can I get the slide to go? Here we go.

As you may have heard on previous calls, DLS is the CDC division that works closely with clinical and public health laboratories across the country to support laboratory emergency preparedness and response activities. And we've been hosting these calls since March of 2020. DLS supports this work across four goal areas-- quality, workforce and training, preparedness and response, and informatics.

As always, we'll be sharing the slides from today's call, along with audio and transcript. And we'll post them online, hopefully by the end of next week. You can find them on CDC's <u>Laboratory Outreach</u> <u>Communications page</u> shown at the link on this slide.

And so as always, we want to hear from you. Our Training and Workforce Development Branch is interested in hearing more about the education and training gaps you're currently experiencing. And we invite you to send feedback via email to labtrainingneeds@cdc.gov.

And so, CDC OneLab is an initiative developed to bridge, train, and sustain a capacity-building community among lab professionals and testers to collectively support rapid, large-scale responses to public health emergencies. Our OneLab partner toolkit is now available and includes email templates, social media text and images, a postcard, and a blog post.

We invite you to use customizable materials in this toolkit to tailor and share information about these resources within your networks. You can download and share materials through the <u>link</u> in the chat or through the QR code on the slide presented here.

And so, the 18th CDC International Symposium on Biosafety is going to be held on March 10th through the 14th in 2024 here in Atlanta, Georgia. The four-day, in-person conference will provide a series of engaging sessions about modernizing biosafety operations and practices.

There will be multiple opportunities to interact and share ideas with colleagues from the areas of clinical care, public health research, and animal care. Registration and details for the conference will be coming soon on the <u>website</u>, and please see the link in the chat.

And if you have a question today, we'd like to ask that you please use the Q&A function within Zoom so that we can address it during the call, and not the chat function. Also, please include your email so that we can follow up if we're not able to answer it during the call. And if you're from the media, we'd like to ask that you please contact CDC Media Relations at <u>media@cdc.gov</u>. And if you're a patient, please direct any questions to your healthcare provider.

And with that, I'd like to remind everyone that these slide decks may contain presentation materials from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect the CDC's official position on the topics covered.

And with that, I'd like to introduce our first speaker for today. We have Dr. Mo Patel from CDC's Center for Immunization and Respiratory Diseases, where she'll be providing us with a respiratory virus update. Mo?

**Manisha Patel**: Thank you so much, Sean. Really appreciate this opportunity to talk to your viewers and your partners here. And I'm looking at the participant list. It's almost 400 people have called in. So just again, appreciate the opportunity, and also to say thank you. This is such an important partnership to have with the clinical labs.

I'm Mo Patel. I'm the Chief Medical Officer for the National Center for Immunization and Respiratory Diseases. And what we're hoping to do today is just give you a snapshot of what our surveillance systems are telling us.

And like Sean said, these slides will be posted. But also, since I'm showing a couple of data slides, I did put the link for each of those data slides in the deck. And those data slides actually get updated every week. So hopefully I'll give you the story and that you can also continue to look at those sources at your own leisure. So next slide, please.

So I want to start with our top-line messages. And I will just let-- each of these points, I'm going to show you some supporting data slides about them to support those statements.

And then the other thing I just want to say is that I have sequenced the slides chronologically, and I hope to give you a little bit of a narrative as to why. Because again, one of the most important indicators that we get early is the work that you all do.

So the first point is that our early indicators, which are ED visits, test positivity, and wastewater for COVID-19 are actually declining. So this is sort of the first week or two that we're seeing since this uptick that we were seeing before.

Our later indicators, hospital admissions, they do continue to increase but at a lower rate than we were seeing in previous weeks. So that's good news. But again, none of us know for sure if that's going to be sustained. So we are continuing to closely monitor.

And then for RSV, we're starting to see that increase in the Southeast. I'll show you some data from Florida. But still, it's low nationally. And then the third point is influenza activity still remains low. Next slide?

So this is our <u>test positivity data</u>. What I'd like you to look at is just the orange line. I'll come back to the bars in a couple of slides. But this is data from our National Respiratory and Enteric Virus Surveillance System. And if you look at that end of the orange line, you can start to see that is starting to plateau or maybe even drop a little bit. Next slide?

So the next couple of slides are about our emergency departments. And this data comes from the National Syndromic Surveillance Program. And this is actually a new metric that we are putting out that's available on the <u>CDC website</u>. And it's a combined metric for COVID-19, flu, and RSV, and you'll see that in the black line.

But you can see that most of that black line is really being driven by COVID. And similar to the previous slide, it's starting to maybe plateau and maybe even downturn a little bit. Next slide?

So this is now looking at <u>ER visits</u>, again, parsed out by age group. Again, for COVID-19, we always worry about older adults and then the younger. Those are the ones who are at highest risk for COVID-19. And it looks like across the board, all of those age groups are also starting to take a downturn.

So we're not seeing necessarily larger age groups coming down and then our high-risk groups staying up. It actually looks like everyone is starting to show lower rates of emergency department visits. Next slide?

So this is a map. It's two weeks ago. In the middle is a week ago. And then on the right is the change that we saw this week. What you want to see is more green, and yellow is definitely heading in the right direction. So again, it's a little bit scattered, but we're seeing a decrease in the rate of ER visits actually across the United States, with some states even turning green. Next slide?

So this is <u>data</u> for our National Health Safety Network and looking at hospital admissions. It's the same slide I showed earlier, but this is just the bars. And here, you can see that hospital admissions are continuing to increase.

But remember, hospital admission data is actually a lag. We have to wait a couple of weeks to get that data in. So it doesn't necessarily show what's going on now.

And if you go to the next slide, this is <u>utilization data</u>, again, just demonstrating our inpatient beds and our ICU beds across the country. This is sort of normal. We're not seeing any indication that there is an overwhelming of healthcare capacity across the country. And next slide? Might be my last.

OK, so here are our <u>Nowcast estimates</u>. And just for folks to know, CDC manages looking at our strains of variants across the country for COVID-19. We're not really seeing any major changes. You can see there are a lot of colors in that bar towards the right. And that's because there are just a lot of variants that are circulating right now.

The majority seem to be that EG.5, FL.1.5.1, and HV.1 seem to be increasing, but at a low rate. And then many of you have heard about the BA.2.86 variant that has a number of mutations that are different than the currently circulating variants.

You may have also heard that we have some reassuring data from various labs across the country suggesting that the vaccine is still going to provide good immunogenicity against that variant. And then, certainly the updated vaccine is going to provide good protection. Well, we expect good protection to the currently circulating variants.

And I think the last thing I just want to say is that-- just one, if you can go back to the previous slide for a second. I just want to mention, I think it's kind of interesting that BA.2.86 is actually still grouped with BA.2. And that's because that particular highly divergent variant is still circulating at very low levels, less than 1%. And so we don't believe that that variant is actually what was driving the uptick in hospitalizations that we were seeing in the past couple of weeks. Next slide?

Here's some <u>RSV data</u>. Again, nationally, not too much activity. And if you look at the Southeast, if you squint, you can start to see a little bit of an uptick in our RSV activity. This is NREVSS data. And then Florida really pulls it out, to suggest that they are starting to see RSV activity. And this is a normal

geographic pattern. As many of you know, RSV starts in the South/Southeast and then spreads north and west. Next slide?

This is my last slide. So again, just a huge thanks to all of you who are contributing to the data for our <u>influenza surveillance</u>. It is so critical. I just heard a briefing from our flu experts the other day about how important this information is for strain selection for the vaccines.

And so again, a huge thanks. But really, the bottom line here is that we are pretty stable at low rates for influenza right now in the Northern Hemisphere and the U.S. I think that's my last slide. Yes, thank you.

**Sean Courtney**: Thank you for that update, Mo. Really appreciate you joining today's call. Just had one question come in, so let's read it really quick. It says, "For COVID, is this data skewed from the lack of readily available free testing in many parts of the country, as well as the home rapid test data that's not being captured?"

**Manisha Patel**: Yeah. It's an interesting question about skewing because I do think that you're right, that we don't fully know the burden of COVID-19 in the U.S. because not everyone has access to tests. And there's certainly a lot of changes that are happening behaviorally. People aren't necessarily always testing when they have COVID-like symptoms, like maybe they used to do in the beginning of the pandemic.

So there's a number of reasons that could be shifting. But I do think for this year in the past couple of months, it's pretty consistent. Because our data is coming for-- the lab testing data is coming from NREVSS, which are clinical laboratories that are submitting. So that data is not picking up home point-of-care tests and never actually did.

So appreciate the question. It's an important one. But I think we have enough information that the trends are interpretable and have been regularly interpretable in terms of the way the data is being submitted to CDC.

**Sean Courtney**: Great. Thank you for that response. I do not see any other questions at this time, and I know you need to drop off a little early for this call. So again, I just want to thank you for joining and providing this respiratory virus update to our listeners today. Really appreciate that.

One more just came in, sorry, while I still have you.

# Manisha Patel: OK.

**Sean Courtney**: It says, "Do you have any data for the efficiency of the current rapid kits towards recent COVID variants?" And I could probably answer that. That's not really-- that would probably be more directed towards FDA. And I don't think they've seen anything or reported anything just yet about decreased efficiency with those tests on detection. So I'm not sure if you have more to add to that.

**Manisha Patel**: No, that's it. I don't think we're seeing any signals that are worrisome about the currently available tests for BA.2.86, as well as the other circulating variants.

**Sean Courtney**: Great. OK, great, thank you. Well, again, appreciate you joining our call today. If we get any additional questions, we'll try to get their information and get it over to you guys to answer those at a later time. But really appreciate you joining our call today, so thank you, Mo.

**Manisha Patel**: Thank you. And again, thanks so much for everything, the callers-- almost 500 now-- do for evaluating and monitoring COVID-19, RSV, and flu in the U.S. Thank you.

**Sean Courtney**: Thanks. So we'll move on to our next speaker for today. So we'd like to please welcome Dr. Lydia Atherton from CDC's Coronavirus and Other Respiratory Viruses Division, CORVD.

And she'll be providing us with an additional update on SARS-CoV-2 variants. And Lydia, I think I need to turn the screen over to you. So just one second for me to stop sharing, and then I think you'll be good to go.

**Lydia Atherton**: Perfect. Thanks, Sean. Thank you for the opportunity to present. I'm a Senior Scientist in the Laboratory Division of CORVD, and I'm going to give you a brief overview of what the SARS-CoV-2 variant landscape looks like currently. So I'm going to share my screen here. All right, great. Please let me know if you cannot see that.

Sean Courtney: It looks good here. Thank you.

**Lydia Atherton**: OK. So I think Dr. Patel touched on this a little bit. So some of this may be repetitive, but just to start from the beginning. If we look over time, we've got on blue our weekly COVID-19 new hospitalization admissions. And then in the orange line, this is going to be our weekly percentage test positivity.

And if we all remember back into that December 2020, that was when the origination of SARS-CoV-2 occurred. And we saw the first real variant wave that peaked here right around August, September time of 2021. And this was mainly due to the Delta variant that emerged.

And then this very large spike we see here, this is from Omicron variant, which I'm sure we're all very familiar with now. And that occurred around December, January 2022. And then if we look out here to last September of 2022, that was when we started to see the emergence of BA.4 and .5, which was the last bivalent booster that was approved before the current one.

And then the next peak we're going to see, right around here of December and January of 2022, that was when we started to see the XBB variants of Omicron starting to peak. And then where we are currently out in September of 2023 looks very similar in time to the magnitude we saw in September of 2022 in terms of cases and test positivity.

However, we believe this wave can be attributed more so to the 456L mutation lineages, which I will talk about here in a second. So I'm just going to do a new share with our Nowcast data screen. See if I can pull that up. Sorry, bear with me.

So if we look at our variant proportion data here. Please let me know if you cannot see my screen. Is that showing for everybody, Sean? OK, great.

Sean Courtney: Yeah, you're good.

**Lydia Atherton**: So Dr. Patel also touched on this a little bit, but just to go a little bit more in-depth. On the left-hand side here, we have our weighted estimates. So those are going to be variant proportions based on reported genomic sequencing results.

And on our right-hand side, we have our model-based projected estimates for Nowcast of these variants. And that is a two-week-out prediction based on real genomics data.

And what you can see here in general is the observed SARS-CoV-2 sequences, the frequency has increased over the last several weeks, along with increases in cases. So for 8/19/23, for example, we've got about 5,000 sequences for that week.

The changes in these proportions that are used to calculate growth rates continue to see that the same lineages that we contribute to growth in the weighted estimates continue with the model-based estimates here on the right. So most of these-- EG.5, FL.1.5.1, and the XBBs, those are all part of the F456L mutation grouping.

So predictions for the next two weeks would be that there are going to be very few changes numerically from the last report. XBB.1.5 is projected to decrease in proportion nationally about by 2% of cases. Many viruses still contain the identical or closely related spike protein sequence for that variant.

And then for those lineages that encompass F456L, those together are comprising almost over 64% of viruses nationally. Within that group of variants, EG.5, which you can see here in yellow, that is the major component at around 25%. And then HV.1, which you can see here in green, that's the fastest growing variant nationally and is predicted to comprise about 8% of cases.

And then in terms of where we're looking geographically in the Nowcast, XBB.1.5 has dropped below 3% of cases in all regions. And as I mentioned, HV.1 currently has the highest growth rate in each region, with doubling times from 18 to 22 days. Just to give you a range, proportions in each region are predicted between 3% and then up to 11% in the different regions.

And I think that is all I have for an update for variant lineages. I am happy to take questions. I will stop sharing my screen. But thank you for the opportunity to present. and I look forward to answering any of the questions that I can.

**Sean Courtney**: Thank you so much for that, Lydia. We really appreciate that update today. I do not see any questions in the Q&A right now. I'm trying to keep an eye out. But again, really appreciate you joining the call. If you can hang out a little longer, if there are any questions that do appear in the Q&A section, you can kind of just respond right in that window and respond to those questions that pop up.

And if they don't or they come later, we can try to get their information and get you that information over there so that you can respond at a later time. But again, thank you for joining today's call. And I really appreciate the update, as always, from you guys over there, so appreciate it.

Lydia Atherton: Thank you, Sean. I'll keep an eye on the chat.

**Sean Courtney**: Awesome, thank you. We'll move to our next one. And we have Drs. Dave O'Connor and Shelby O'Connor from University of Wisconsin-Madison. And so they're going to be discussing monitoring respiratory viruses with congregate air sampling. So I will turn it over to you guys, and I think you guys are going to share your screen as well.

David O'Connor: Yes. Can you see my screen OK?

Sean Courtney: Yes, we can. Thank you.

**David O'Connor**: Well, thank you, everyone, for giving us the opportunity to talk about some of our work today. Shelby and I are both professors at the University of Wisconsin-Madison, and we've been doing this work for the last couple of years in the Upper Midwest.

And so we're going to talk today about indoor air sampling for respiratory viruses. And this has several advantages, some of which are obvious, and others less so. It's very cost-effective to sample an indoor space, such as a school cafeteria, an unhoused shelter, an emergency room, for respiratory viruses in the air. It's also anonymous to the individuals who are contributing viruses that are detected in the air. And of course, as was alluded to earlier, it's resilient to individual testing behavior.

The type of air sampling we're talking about today uses a Thermo Fisher AerosolSense air detection instrument. This is a versatile and portable instrument that can be deployed immediately to new settings and has very simple ease of operation, such that in some of our schools, we have fifth and sixth graders who are responsible for changing the air cartridges a couple of times a week.

So we have explored a variety of different types of use cases for indoor air sampling for viruses. We got started using it as a way of monitoring virus transmission within and between communities. One example

of this is doing K through 12 school monitoring for pathogens, including SARS-CoV-2, influenza, and RSV, as a way of understanding community risk.

We can also use the same technology as an early warning system for looking at settings that are at high risk for consequential outbreaks. So for example, we have a couple of air samplers running in a complex care long-term care facility. And finally, it can be used to identify novel virus threats. An example of this would be using this technology in international airports to look at the introduction of viruses of concern. So we began in the middle of 2021 with support from the Rockefeller Foundation to ask the question how well this technology works in real-world congregate settings. And so over the course of about a year, we looked at a variety of settings across four locations in the Upper Midwest.

So each row here represents a single deployment site. And in aggregate, what you should take away from this slide is that we ran about 500 samples across all these different sites. And about 100 of these were positive for SARS-CoV-2 RNA, about 20% positivity. And the results from this initial study were published in Nature Communications last year.

One of the things that we were able to do in this study was use a 40-plex, multiple pathogen detection panel. And what we saw was different signatures of pathogens in the air from different settings. So what you see on the right here is a grid with a variety of pathogens along the y-axis, and dates through the winter of 2021-2022 on the x-axis.

And what you can see is that we captured an influenza A virus outbreak that was occurring on the UW-Madison campus. And you can see where the gray boxes are that it was interrupted by winter break, when the coffee shop where we were running this air sampler was closed for the winter holiday.

In contrast, if we make the exact same sort of map using data from a preschool at the same time, there they did not have any influenza virus spread. But you saw a bunch of viruses that are associated with young children, including adenovirus, bocavirus, and seasonal coronaviruses, with some regularity.

The next question that we wanted to ask was how this compares to other measures of respiratory virus activity. So for this, we partnered with the CDC-funded ORCHARDS Program and the Oregon Wisconsin School District. This is a program where Dr. Jon Temte and his colleagues have been doing a full-court press on respiratory virus surveillance predating the COVID pandemic and going back about almost 10 years now.

And so what they've been doing is looking at a variety of measures of respiratory virus consequences within a school district. And so what we were able to do is overlay air sampling data on top of other types of data outputs that they were already generating.

So on the top, what you see is the number of households who reported having sick students. And on the left, you have influenza data, and on the right, you have SARS-CoV-2 data. Below that, you see school

absence reporting, again, for influenza and SARS-CoV-2; in-school rapid antigen tests for flu and SARS-CoV-2; and on the bottom, air sampling data from the cafeterias of the schools in the same school district.

What I hope you can see from this is that there was a narrow period of influenza transmission that was reflected in all of the data types that ORCHARDS collects. And we saw the exact same superimposition of this date range in terms of when we saw influenza RNA in the air samplers from the school cafeterias. In contrast, SARS-CoV-2 was a year-round virus, as measured by all of the ORCHARDS indicators. And indeed, we saw the exact same thing in air surveillance, where SARS-CoV-2 RNA was seen throughout the entire school year.

So we're now reasonably confident that we can detect viral RNA by PCR and using other molecular tools to assess what is in these air samples from indoor congregate settings. So the next question we wanted to ask is, can we actually use these same samples for sequence-based viral detection to look for a wider variety of pathogens, both ones that we are expecting and those that we might not be expecting to see?

So to do this, we have a couple of different metagenomics methods that we're using. The specifics of the methods aren't that important, but I'm going to talk mainly today about data that was obtained with the SISPA method. This was the method that we've been using for a couple of years in the lab. And we're beginning to replace it with an alternate method called SMART-9N that has reduced hands-on time and gives much longer individual sequence reads, which aids in classification of viral sequences.

So what you can see here is that when we were looking at air samples from a household outbreak of SARS-CoV-2, we were able to capture sequence reads, tiling most of the viral genome, as shown here on the x-axis, with the number of reads shown on the y-axis.

And using just the sequences that we obtained from the air, we were able to accurately classify this as an XBB.1.16.2 variant. This matched the sequencing genotypes that were obtained from the individuals who were in this household outbreak.

Interestingly, one of the people who was involved in this household outbreak reported feeling ill prior to the onset of SARS-CoV-2. And in fact, we also detected in the same air samples from early following SARS-CoV-2 a diagnosis RSV sequencing reads from the same air sample, again, with coverage of much of the viral genome.

We've extended this now to a variety of other samples. This data is in a MetaArchive preprint. We found human viruses in 86% of the air samples that we've looked at so far. This includes a variety of respiratory viruses-- influenza A, influenza C, SARS-CoV-2, RSV A, RSV B, rhinovirus, seasonal coronaviruses. And then we also picked up some enteric viruses that were likely on the hands of people who were in the vicinity of the air samplers-- rotavirus, astrovirus, *Mamastrovirus*. Again, on the right, you can see that the sequence coverage of these was strong enough that we could reliably classify the presence of the viruses. But we still have a bit of work to do to get full genome sequence coverage consistently from all of these viruses.

The one virus that I'd like to call your attention to, I think, is important because it makes a broader point. And that is that within a preschool where we were running this air sampler, we consistently detected sequencing reads from influenza C over a period of about a month. And in one of these samples, we were able to reconstruct nearly a full genome from all of the virus segments.

Now, influenza C is not something that we would have been testing for. And so this sort of unbiased sequencing led us to identify the presence of a virus in the air that we weren't even looking for. And I think this gives it a lot of promise as a tool for identifying outbreaks of things that we are not necessarily looking for.

So where are we with this right now? Well, we're working with an intermediate care facility for individuals with intellectual disability to see about extending the therapeutic window for early intervention. So there, we're looking to do daily air sampling with rapid turnaround to see if we can more quickly identify and mitigate when there is the introduction of viruses into a facility.

We're working with Ginkgo Concentric to incorporate air sampling into the CDC's Traveler Genomic Surveillance program. I'm sure some of you on the call are familiar with this and might be aware of this as something that's coming soon.

We're working to increase the sensitivity, cost, and throughput of viral metagenomics so that we can make this a more reliable first readout of what's present in an air sample. We're looking to make the detection itself faster by introducing point-of-source testing, as well as improving high throughput multiplex detection to be lower cost and faster.

We're also working with a different type of air sampler to recover live virus so that we can also study infectivity, as well as the presence of viral RNA. And actually just today, we put air sampler inside of an animal facility where they're doing Mpox studies so that we can see if we can recover infectious MPXV from the air.

And then we're working with a variety of partners in the Upper Midwest to extend this in collaboration with local public health departments. So here in Dane County, which is where Madison is located, we're working with Public Health Madison and Dane County to take the data that we have from the schools that have the air samplers and put it onto their publicly available data dashboard.

So we have about 20 samplers deployed here in Dane County. We have four deployed in partnership with our colleagues in the Milwaukee Health Department. Those were largely in unhoused shelters. We're deploying six more samplers in collaboration with Minneapolis Health Department and Hennepin County Health Department in Minneapolis. We're working on the deployment sites for this year at those sites. Our colleagues at the Chicago Department of Public Health are doing the largest deployment that we know of. They're deploying about 50 of these air samplers to various high-risk sites. And then we're also

working with Marathon County, which is where the Marshfield Clinic is located, to prototype the use of this technology in more rural settings.

So with that, I'd like to acknowledge everyone who has been involved in this work and then really thank our support, which includes an NIH R01 grant, initial funding from the Rockefeller Foundation, Thermo Fisher, who provided some in-kind support for air samplers, and then the Gates Foundation, who has supported a comparative study of clinical samples, wastewater samples, and air samples from those same ORCHARDS schools that I talked about earlier. So thank you very much, and we'll be happy to take any questions.

**Sean Courtney**: Thank you, guys, for that update, Dave and Shelby. Really appreciate you joining the call. There's a couple questions that have come in. I know that Shelby has also answered a couple of them within the Q&A as well.

And you actually mentioned this on one of your last slides. And the question came up around putting this into airports. And I know you mentioned the traveler program. I was wondering if you could maybe just expand on that a little bit, just for those on the call that may not be as well aware of that program.

**David O'Connor**: Sure. So going back a couple of years ago, my understanding is that the Q branch has worked with Ginkgo Concentric and what was formerly known as XpresSpa to do pooled PCR testing of arriving international travelers at a variety of international airports. So that's been ongoing for a while.

So when people arrive, they can opt in to contribute a nasal swab at a kiosk. That then gets pooled and brought back into the lab for PCR testing and sequencing. We're looking to put the air samplers at those same kiosk locations so that while people are registering for participation in pooled PCR testing, we'll also be sampling the air at the same time to see if we're able to detect SARS-CoV-2 in the air and determine what genotypes of SARS-CoV-2 are in those samples.

**Sean Courtney**: Great, thank you. A couple more questions here popped up. So one of them is, for congregate settings with positive air detections of S-C-2, flu, et cetera, do you know what actions would be taken to mitigate transmission in those settings? Or is that kind of further down the road from you guys?

**Shelby O'Connor**: So I was going to respond to that one, but I thought since it was just up there, I'd try to address that one. Although now, it just disappeared. Oh, there it is.

So basically I think it depends on where. It's kind of up to the user how they want to use it to mitigate transmission. I agree that putting one of these air samplers in a school setting, where you can get very important information about which variants are circulating in the community, that may not be as immediately actionable.

However, in a setting like the one where Dave talked about, where we are hoping to place them in congregate care facilities like the intermediate care facility for individuals with intellectual disability, what we are hoping to do there is use these instruments to detect virus in the airspace before there is an outbreak so that staff in those facilities could either isolate individuals or increase testing to try to minimize the likelihood for an outbreak in those facilities.

So I think that it really just depends on the site where you're using them to determine whether or not there could be an action applied. I hope that answers that question.

**Sean Courtney**: Yeah, I think so. I appreciate it. Thank you. Thank you for touching on that. The next question I see-- I'll try to clean it up a little bit- is, "If I understand the data you presented today on air sampling positivity correctly, the timing of respiratory virus positivity matched the clinical cases. What would the advantage, then, of respiratory specimens using air specimens versus clinical respiratory specimens for closed environments, such as a school or home?"

**David O'Connor**: Sure. So if we are able to see-- that is, to generalize-- the advantage is largely cost. You can do respiratory virus surveillance on air for-- an air sampler that costs a couple thousand dollars and about \$40 to \$80 a week in consumables to have an understanding of when the levels in a school or other closed setting are going up or going down, even if you don't have the kind of comprehensive testing program that's available in the ORCHARDS study.

So if we can show that it is an accurate indicator of respiratory virus activity within a school, you could get the same kind of data that we get with expensive comprehensive testing at a tiny fraction of the cost and effort.

**Sean Courtney**: Great, thank you. And next question. I see, again, Shelby's answering her right now, but I'll ask it. That way, you can just talk about this. Have you evaluated the impact of masking on capacity to detect these respiratory viruses?

**Shelby O'Connor**: So the answer I was just typing is we didn't do a careful comparison of this, but we did detect SARS-CoV-2 and other viruses in the air when there were mask mandates and then after mask mandates ended. So we detected viruses in both cases.

But there's going to be definite variability in the types of masks people are wearing and the adherence of them being used. So we didn't do a careful comparison, but we detected viruses in both cases.

**Sean Courtney**: Awesome, thank you. The next question is, "How long is the recommended runtime to collect an accurate sampling for each environment?" So what's the turnaround time for testing?

**Shelby O'Connor**: So instead of me typing out an answer to this, I'll just answer this one as well. This also comes back to what you're trying to get out of the situation at hand. So if you're just trying to do surveillance-- not just-- but if you're trying to do surveillance in a school setting, we like to run ours for

about three to four days so we can really capture a long period of time. We get a lot more bang for our buck with respect to what we're detecting off of the air cartridge.

However, if you're trying to respond more quickly in a care facility, you want to be detecting or sampling every single day and then getting that data back as quickly as you can so that you can provide an actionable response.

So one thing we want to move into is what Dave mentioned as the point of care or point of source testing, where you could have a rapid PCR detection that you could run immediately after you pull the cartridge from the machine. Say you do that on a Monday, you detect there's virus present Monday night. And then on a Tuesday, you could actually do something in that facility to try to mitigate an outbreak. So it depends on the goal.

**David O'Connor**: I'll also add that in that household study that I alluded to, we wanted to estimate how long it would take for someone to be in proximity of the air sample for it to register positive. And so we had the people in the household stand at a meter distance from the instrument for varying periods of time while talking.

And it took less than five minutes for the air sampler to turn positive with SARS-CoV-2 RNA, as well as control RNA, host RNA. So you really only need to give the machine somewhere on the order of like 15 breaths in order for there to be enough genetic material there for the virus to be picked up.

However, as Shelby said, we often use sampling intervals that are a couple of days in schools, though it really is dependent on the use case.

**Sean Courtney**: Well, that's really interesting. Thank you. So I'll ask you guys one last question so we save some time for our last presenter. But the last one is regarding monitoring Mpox virus in the air and whether that's indicative of prevalence and if there's any reports of this virus by inhalational-- inhalation-- oh, sorry-- inhalational exposure.

**David O'Connor**: I think this gets at the point that was right underneath it, with detection not equaling infectivity. We completely agree with that. A number of groups in Europe have used the same AerosolSense air sampler, either in clinic waiting rooms or in discos and have detected MPXV RNA in air.

What we're trying to do in this other study that I alluded to was use a second type of air sampler that is more gentle and tries to settle the virus onto a gelatinous filter to recover infectious virus. But that's something we're just getting started with. Right now, we're thinking 95% of our activity is focused on detection and sequencing.

**Sean Courtney**: Great, thank you. Really appreciate those answers, and really appreciate you both for joining today's call and kind of discussing this really interesting work. So thank you, and also thank you for

answering the questions or any additional ones that pop up as we continue today. So really appreciate you guys joining today's call.

And so lastly, we'd like to please welcome Dr. Muktha Natrajan from CDC's Division of Lab Systems. She'll be providing an update on CDC's LOINC and LIVD Test Code Mapping web pages. So Muktha, we're ready for you.

**Muktha Natrajan**: Thanks, Sean. Good afternoon, everyone. I'm Muktha Natrajan, and I'll be presenting an update on CDC's LOINC IVD Mapping web page, as Sean mentioned. I'll also start by discussing the use of the LOINC coding system to communicate test results and how LIVD tools were initially developed. I'll then go over the most recent changes to CDC's <u>LIVD web page</u>. Next slide, please.

So when communicating results from a device to a laboratory information system, certain concepts have to be mapped, including the device's vendor analyte code to the laboratory information systems test result code. At present, there's no requirements for IVD test codes or laboratory information result codes to be based on a standard vocabulary.

So to enable proper data analytics and clinical decision support across health infrastructure, harmonization to a common vocabulary is critical for moving forward to an interoperable system. Using Logical Observation Identifier Names and Codes, or LOINC, to identify and report lab results and electronic reporting systems can facilitate timely reporting of high-quality data and ensure that state and federal public health agencies receive interoperable data.

The LOINC database provides a set of universal names and codes for identifying laboratory and clinical test results in the context of existing observation report message structures and can help with moving this system forward. Next slide, please.

For now, most IVD devices cannot provide the appropriate LOINC code with the test result as soon as it comes out. And so to address that issue, LIVD mapping tools were created to help assist with populating information into a laboratory's existing IT infrastructure to improve interoperability between laboratories and healthcare systems.

LIVD tools contain a lot of detailed information to identify which tests were ordered and results components associated with those tests, as shown here. So you can see the manufacturer can provide information, such as the manufacturer and model of the instrument, test kit details, like identifiers or name and type of test kit, vendor specimen, and results descriptions to associate certain specimens with these tests and test-ordered LOINC information and long names.

This guidance could help reduce the scope of potential LOINC codes to consider for the laboratory, improving efficiency and quality of the mapping process and also arriving at the same LOINC code for the same test between different groups. Next slide, please.

So to help promote this, CDC has collaborated with several partners, including FDA, APHL, and developers for public health laboratory order and results reporting to help create and collate standardized codes for diagnostic tests into LIVD files. This group worked to initially create and maintain a SARS-CoV-2 LIVD file early in the pandemic and to assist with reporting requirements during the public health emergency. The group also created the same during the Mpox emergency as well.

They have assisted with the creation of additional disease-specific LIVD files that are not associated with public health emergencies, including one for HIV diagnostic tests and Lyme disease diagnostic tests. CDC's LIVD web page, shown here on the right, helps host these files and provides additional information on the purpose, use, and additional resources related to the LIVD standard.

The web page was recently updated to reflect a change in focus from the public health emergency responses to the use of the LIVD standard in general, highlighting a new section seen here at the start of the web page, listing disease-specific LIVD mapping tools, as well as publicly available LIVD files from IVD manufacturers.

Other vendors, of course, can also provide details of their tests in the LIVD format directly to those who purchase their kits. But those are not necessarily publicly available to be put onto our web page. This collaborative effort hopes to continue to update and publish LIVD files on our web page to improve awareness and availability of these valuable resources. Next slide, please.

Thank you for your attention. I'm happy to take any questions related to our LIVD updates. Thank you.

**Sean Courtney**: Thank you so much for that update, Muktha. Really appreciate it. I do not see any questions at this time. So again, I'll just say thank you, and thank you for joining today's call. And really appreciate that, so thank you.

And with that, I just want to thank all of our speakers today. As a reminder, we hold these calls on the third Monday of each month. And our next call is scheduled for Monday, October 16, from 3:00 to 4:00 Eastern time.

And also, please let us know if you have any suggestions for topics for future calls, as we look forward to continuing to discuss any hot topics and to answer your laboratory and testing community needs. And as we mentioned at the beginning of the call, we will post the audio transcript and slides from today's call on the website, hopefully by the end of next week or within the next two weeks.

And as always, you can find CDC on Facebook, Instagram, LinkedIn, and Twitter. And please follow any of these to stay up to date with the latest news and recommendations. And again, just thank you all for joining us today. We continue to be grateful for your work. And we will talk to you again on Monday, October 16. So have a great afternoon. Thanks, everybody. Bye.