Agenda
Clinical Laboratory COVID-19 Response Call
Monday, May 16 2022 at 3:00 PM ET

- **Welcome**
  - Sean Courtney, Division of Laboratory Systems, CDC
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, Laboratory and Testing Task Force, CDC
- **CLIA SARS-CoV-2 Test Result Reporting Update**
  - Sarah Bennett, Centers for Medicare and Medicaid Services (CMS)
- **Scent Discriminating Canines as a Tool for COVID-19 Management**
  - Julian Mendel, Florida International University
- **Supply Chain Challenges and Solutions**
  - Gregory Sossaman, Ochsner Health

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 the CDC Division of Laboratory Systems. On the screen right now is our agenda for today's call. But before we get started, I just want to cover a few announcements and some general housekeeping items. The screen goes forward. All right, so as you've heard on previous calls, DLS is the division in CDC that works to advance laboratory quality and safety data and biorepository science and workforce competency across the US clinical lab community.

We work closely with labs across the country to support emergency preparedness and response activities and have been hosting these calls since March of 2020. So DLS works to support these activities through quality workforce and training, preparedness and response, and informatics and data science. So as always, the information that's going to be presented today will be available on the CDC Preparedness Portal that's shown on the link on this slide. That page will contain information pertaining to the calls, transcripts, and audio recordings, on that page.

So as always, our calls now are held on the third Monday of each month. However, our next call is going to be moved to Monday, June 27th, in observance of the Juneteenth holiday, and that will be from 3:00 PM to 4:00 PM Eastern time. And so we want to hear from you. Our Training and Workforce Development Branch is interested in finding out more about your education and training needs. So if you have any suggestions, we ask you to email them directly to labtrainingneeds@cdc.gov. And also, during the call today, if you have any questions, we ask that you use the Q&A button within the Zoom features and not the chat button.

That way, we can capture your questions. And also, please include your email in those as well, so that if we're not able to address them during the call, that we can email you after the fact, when we are able to answer those questions. And then lastly, I want to do a reminder that these slide decks may contain presentation material from panelists who are not affiliated with the CDC, and so presentation content from these external panelists may not necessarily reflect the CDC's official position on the topics covered.

And so with that, we'll go ahead and get started with Natalie's presentation on SARS-CoV-2 variants. And Natalie, I'm going to stop sharing my screen and hand it over to you.

NATALIE THORNBURG: Great, thank you. All right, confirming you can see my screen and hear me?

SEAN COURTNEY: Yes, go ahead.

NATALIE THORNBURG: OK, great. All right, so this is the weekly Nowcast and we did a weighted estimates for the viral genomic tracker. And the weighted estimates are shown for the week ending April 23rd with the Nowcast estimates ending May 7th. This will update tomorrow morning, but there won't be-- I can already tell you there won't be any dramatic changes from what you're seeing right now. I believe it's been a few weeks since I have been here to present this to you.

And I believe since we last presented this data, the BA.2 sublineage has been subdivided into-- another sublineage has been subdivided from the BA.2 parental lineage. So Omicrons are still the only circulating viruses in the United States, but some of the versions of Omicron that were really predominant in the winter, in the early spring, have contracted. So the BA.1.1 had been predominant and started contracting in late February, and that is less than 1% of circulating viruses right now.

B.1.1.529 is aggregated several different versions of Omicron, and that is also less than 1% of circulating viruses right now. The predominant lineage of Omicron is BA.2 nationally. It's about 56% of circulating viruses with the predictive confidence interval, 95% confidence interval of about 50% to 63% of circulating viruses, and that's shown in pink. But the BA.2.12.1 has been increasing in proportion. Now the BA.2.12.1 is a sublineage of BA.2, and it has two amino acid changes in the spike protein as compared to BA.2.

There's a change at residue of 704, which is not within the receptor binding domain and therefore should not affect neutralization of the virus. But there is a change in the 452 residue of the virus, which has been seen in other variants of concern. It was seen in delta. And a change at that residue is also seen in BA.4 and BA.5 which has been circulating and increasing in prevalence internationally, but the change is different. The change in BA.4 and BA.5 is two in R, and B.2.12.1 is, I believe, it's two. It's either an L to a Q or a Q to an L, so that's the picture nationally.

The picture regionally is a bit different. So the region with the greatest predominance of B.2.12.1 is region two, and that is at-- that's reached predominance and it has taken over. BA.2 is predominant. It's about 66% of circulating viruses. The region with the lowest predominance of BA.2.12.1 is region 10, so the Northwest of the United States. It only has about 14% of circulating viruses at the BA.2.12.1. So lastly, you'll see from our national Nowcast, we do not have BA,4 and BA.5 listed on here.

Those are the lineages of Omicron that have been increasing in some countries internationally. We do have BA.4 and BA.5 detected in the United States, but those numbers are still very small and they've still been less than 1%. So as with other variants in other sublineages, we add them to the tracker once they

reach about 1% of circulating viruses. So if either of them reaches 1%, they will be added to the tracker. And that's all. Thank you.

SEAN COURTNEY: OK, great. Thank you for that update, Natalie. I do not see any questions right now in the chat, and I know you have to drop off for actually another call, so if any pop up, we'll forward them to. There's one that just came up, and it actually says, for the genetic surveillance, is it only lab testing?

NATALIE THORNBURG: Yes, that is only lab testing. Anything that's at home, rapid antigen tests, they cannot collect any genomic information, and so, yes, only tests that are going for PCR are fed into the genomic sequencing pipeline.

SEAN COURTNEY: OK, great. Thank you for that. Yeah. Right now, there's no more questions, so if any come in during the rest of the call today, we'll be sure to forward them over to you so that you can respond to them at that time, so I appreciate your call today. All right. Well, moving on to our next speaker, it's now Sarah Bennett, and she's with the Centers for Medicare and Medicaid Services. And I'm going to share the screen again.

SARAH BENNETT: I said thank you, Sean.

SEAN COURTNEY: Oh, yes. Here we go. Apologies, here you are? Go ahead, Sarah.

SARAH BENNETT: All right. Thank you, Sean. So, hi, everyone. I'm Sarah Bennett. I'm a Technical Director with the Division of Clinical Laboratory Improvement and Quality. That's just a long way to say the CMS CLIA program. And the CDC asked me to come and speak with you today about our updated CLIA reporting requirements for SARS-CoV-2, so next slide, please.

This is just a disclaimer that we put on all our presentations. It basically says, for information purposes only, and I will let you read this at your leisure. There's a lot of legal in here but it just basically, as I said, says this is for informational purposes only. Next slide, please.

What I'm going to cover today is I'm going to talk about the updated CLIA SARS-COV-2 test reporting requirements, and I'm also going to give you all some additional information about CLIA reporting requirements. Next slide, please.

So on April the 15th, we issued our updated guidance related to SARS-CoV-2 test reporting in them, in a memorandum. It's QSO-21-10-CLIA REVISED on this. This is a hyperlink here, so you can go right to the memo. Basically, before April the 15th, all SARS-CoV-2 test results had to be reported. That's both positive and negative, for all methodologies. As of the 15th of April, we have updated our guidance to allow for some optional reporting. We have divided it up and this table is actually in our guidance. We divided it up by the certificate type. We thought it might be easier to digest by the laboratories, by certificate type, so you can see for COW, Certificate of Waiver.

And Certificate for Provider-performed Microscopy, that if an EUA is authorized for waived settings, then for antigen and molecular test, reporting is required for positives, but it's optional for negatives, and all serology testing is optional. Reporting of serology testing results are optional. Once you move into a certificate of compliance or a Certificate of Accreditation or a Certificate of Registration, it's dependent on how the test is authorized by the FDA, what is the authorized setting.

So if it's authorized-- an antigen test, if it's authorized for waived, tests that perform waived testing, moderate or high complexity, you're still required to report positives, but reporting of negatives is optional. Once you get to the molecular tests, both positive and negative are required to be reported as are when you-- but however, if you have a molecular test that is authorized for a waived setting, only the positive is required to be reported under CLIA and the negative is optional. And again any serology or antibody test is optional to report positives and negatives under CLIA. Next slide, please.

I wanted to give you some additional information related to the SARS-CoV-2 CLIA reporting requirements, because we get these questions a lot through our mailboxes. So I just wanted to make clear that when CLIA is surveying for test reporting requirements, we are surveying against the CLIA requirements for SARS-CoV-2 test result reporting, which is the table that was on the previous slide. We are only assessing if labs have reported or attempted to report test results, and the laboratory must have documentation that has reported or attempted to report those test results.

It is OK if you have documentation, like a printout of a website, like the health department website, that says that you don't have to report certain results or if you have an email or something like that, an official something that says that you don't have to report negative results for any reason, then you don't have to continue to attempt to report those results every time and get the printout or the screenshot. So as long as you have some documentation that their tests that are required to be reported have been reported or you have attempted to report those results, then we would consider you to be in compliance.

I did also want to make clear that the data elements and the timelines for reporting that are in the HHS Secretary's guidance are outside the scope of CLIA, so we are not determining under CLIA whether all of the data elements have been reported and if the timelines for reporting have been met. Next slide, please.

This is just a slide with some resource information. That's our general CLIA website. There's a lot of information on here that you can go and find out about CLIA, which I'm sure a lot of you-- most of you, already know a lot about CLIA and, certainly during the pandemic, have learned a lot more about CLIA than you ever thought you would need to know. All of our FAQs, our frequently asked questions, that we have published during the public health emergencies are on the CMS Emergencies page. And I wanted to put the link in here again for the memo, where we revised our SARS-CoV-2 test reporting requirements The table, in the I believe it was slide three, is included in this memo, so you don't have to try to memorize it. It's all there for you, and this is a direct link to that.

And I think that was my last slide other than a question slide, so thank you.

SEAN COURTNEY: Yes, thank you, Sarah. There is one question that came in, and I'll go ahead and read it to you. It says, have any high complexity labs been exempted from reporting requirements or have institutions deemed reporting unnecessary? In particular, they're referring to VA reporting requirements.

SARAH BENNETT: OK, so the VA does not fall under CLIA. They are a separate-- they have a separate authority from CLIA. But with regard to the question, nobody has been exempted. If there is a reporting required, then reporting is required.

SEAN COURTNEY: OK, great. Thank you. I do not currently see any other questions relevant to your discussion. Oops, one just popped in. It says, upon inspections, how far back will the reporting review go?

SARAH BENNETT: The surveyors can review back as far as two years, but we are currently writing citations based on the current guidance. So the guidance that went into effect the 15th, regardless of when the data is looked at, we are using that as our guidance for citations.

SEAN COURTNEY: OK, thank you. Another question just came in. Let's see. And I think we can answer that on the side, so I think that's it for now. And if any more come in, if you're on the call, you can kind of answer them yourself as well. If not, we can send them to you to address at a later time.

SARAH BENNETT: Sounds good. Thanks, Sean.

SEAN COURTNEY: Thanks so much, Sarah. All right, so next speaker is Dr. Julian Mendel from Florida International University, and he's going to be discussing scent-discriminating canines as a tool for COVID-19 management. Dr. Mendel?

JULIAN MENDEL: Thank you, Sean. Thanks for having me. I'm happy to share with you all some of the applied research that's happening at Florida International University with regard in this topic, so you can go ahead and go into the next slide for me. So canine olfaction, just a bit of introduction for you, is not new. Since the domestication of canines, humans have used them for their highly evolved sense of smell. In terms of law enforcement, they've been utilized for any number of things, such as drugs, explosives, tracking human beings. More recently, wildlife trafficking and trafficking tracking wildlife, but also for non-law enforcement purposes as well, if you'd go to the next slide.

So outside of law enforcement, canines have been used to detect fungi and mold in buildings and homes, as well as in the hotel industry for pests such as bedbugs and termites, and more relevant to this discussion today, canines have been utilized and demonstrated to be efficient and effective at detecting various diseases, such as cancer, diabetes, and of course, most recently, COVID-19. Next slide.

So canines we know are able to do this work because they are up to 100,000 times more sensitive in their olfaction than human beings are. They have greater than 100 times the number of olfactory cells, receptor cells, in their olfactory system or nasal canal. And in addition to that, they're just highly evolved. When

you talk about anatomy of the canine nose, their abilities enable them to actually pull different streams of air through each nostril, separate those streams of air for respiration purposes only, as well as separate some for the olfactory recess to do detection. So through that, they're actually able to garner, with concentration gradients, which direction is the way to go right or left up or down depending on that airflow. Next slide, please.

So this is a little bit off topic, but I thought it was relevant because it is the first documented success we've had in dealing with disease diagnostics or this disease detection with canines. This speaks to a particular disease in avocado trees caused by a fungal pathogen that we were able to apply traditional canine training techniques to detect symptoms early and treat these trees. I won't spend too much time on this. Next slide.

Essentially, this disease has killed over 500 million Laurel trees in the wild and spread to our avocado industry in South Florida leading to about one third of the industry being wiped out. We were able to take the approach and successfully train our canines and show across four canines an average of about 98% accuracy of detection of this particular disease. Next slide.

And those papers have been published and are out there, in case you're interested. But I'll move and this brings us into our talk on COVID-19. To the next slide, please.

So we actually have, based on our history, and over a decade of experience and training in canine olfaction, for forensic purposes primarily, we knew that once the pandemic hit and we began to see shutdowns and closures, especially of our university, that we could apply these techniques and utilize them to detect COVID-19 or rather the metabolic changes in the volatiles expressed in exhaled breath of infected patients.

So through our partnership with Baptist Hospital, we were able to obtain, for this study, positive personal protective equipment, namely face masks that were worn from patients that both tested positive for COVID-19 with PCR testing, as well as those who demonstrated flu like or cold symptoms, but did not test positive for COVID-19. We also utilized healthy patient masks as well as masks that were unworn for the design of this study. One of the things that we're interested in at FIU and some of the research we do is not just to train the canines to do the work, but we're also interested in what that chemical profile is.

So we do a lot of GC mass spec chemical profiling of those samples to determine what exactly are the changes in the volatilum of individuals that are infected versus healthy and those that are also demonstrating symptoms, but not infected with COVID-19. Our study also involved the development and of training aids that were safe and useful for COVID-19 training that I'll discuss in a bit. And here, Redland Ahead as just I mentioned there, a company that maintains the care of our canines for all of our research studies at FIU, and we have currently five canines that are capable of detecting COVID-19. Next slide, please.

So in order to be successful in this study, we actually utilized a couple of patented items that came out of research through FIU's labs. The one on the left, I won't talk about much. That's essentially a stainless-steel canister that just enables us to store material safely when training, so the canine won't bite or destroy them when they detect them. But the ones in the middle and right, we utilize heavily in this study.

The controlled odor mimic permeation system, or a COMP, is essentially a polymer packaging that enables us to vary the pore size of that packaging, so that the odors trapped inside can then dissipate the external environment at a constant rate making for a good and reliable training aid. On the right, you see UDC, which is the universal detection calibrant and other patented technology out of our labs here at FIU. I promise you, being in the forensic world, that it is not cocaine despite what it looks like. It is actually cellulose powder, which is spiked with a chemical compound that is not found in nature.

So what that means is that we are able to train green dogs or inexperienced dogs very quickly utilizing that scent, and then it becomes a more simple matter of imprinting the canine on the intended target odor, which takes a matter of weeks to do. So go ahead to the next slide, please.

So one of our initial concerns when embarking upon this study was whether or not we would be able to safely handle the materials we obtained from the hospitals when we're training our canines. The concern was, of course, for the handlers and the trainers, but also, initially, we were unsure of how transmissible it was from humans to canines.

So we actually developed a study to test with UVC radiation. We did 10 minutes on each side. Masked material was spiked with a cocktail of human scent compounds. And we did a pre and post evaluation and determined that we were able to successfully sterilize the surface of those masks, while not affecting the odor composition or concentrations on the mask as well, so that was good news, and it meant that we could reliably and safely prepare training aids from the biological materials we received from the hospital for use in this study. Next slide, please.

So regarding to training canines, I won't spend too much time on this. There are standard procedures out there. Every trainer is a bit different, but it typically always relies on positive reinforcement, so the association of your intended odor with some kind of reward for the canine. Some trainers utilize food or treats as a reward. In our case, we utilized a toy that the canine would only play with during training, so they associate alerting to the correct odor with receiving that toy and being allowed to play.

Our initial studies actually concentrated on training to detect on surfaces, to help reopen the universities and office buildings on campus. So we were actually training to detect the presence of COVID-19 scent or in exhaled breath or expectorants in classroom spaces, as well as on surfaces. Next slide, please.

So the results of the study after doing 217 training runs prior to then doing 40 double blind trials. A double-blind trial consists of the case where the positive target aid is not known in terms of location to either the canine or the handler at the time of the deployment.

We were able to demonstrate an accuracy that ranged across four canines between 96% and 99%. And I'd like to point out the positive predictive value or PPV that is also listed in that column is actually a measure that takes into consideration how many times their false positive alerts. So I like to use that value, because it gives you an indication of how sure you can be when the canine actually does alert during a deployment, that that is in fact a true positive COVID-19 alert. You can see that when taken into consideration, the false positive, that number, drops between about 87% to 97% in terms of positive predictive value, still very good numbers. Next slide, please.

I've also mentioned that we're focusing on doing a chemical analysis study to look at the volatiles that are changing in exhaled breath during the COVID-19 infection in humans. This is a very early indication that we've utilized, albeit a small sample size, that we do show that even in individuals that have tested positive for COVID-19, compared to those that are showing symptoms that are sick, but do not have COVID-19 tested negative, we do see a distinct separation between those groups with our cluster analysis here. We hope to have more data on that published soon, where we'll have run the samples and we're currently compiling that data set. Next slide, please.

This moves me to talk about the deployment, so the actual putting into practice. We've not just done the training of the canines and published that study, but we've also had several deployments, where we've actually determined how to actually implement this and how well it works. Most notably, we've had deployments at the Florida State Emergency Operations Center where we had our K-9 search and employees and surfaces in office spaces there.

We also help to reopen the South Beach Wine and Food Festival here in Miami through pivoting to now having the canines search individuals or patrons entering the events at the gates. And we've just completed a final report on our Miami International Airport deployment, where we actually partnered with American Airlines to be able to determine how efficiently we could search employees coming into the terminal in high traffic areas at peak times during the day and we have additional data and reports compiled on that, should anybody have any request on that.

We do have a couple of additional deployments pending with Port of Miami and the Stephen P. Clark Government Center that we hope to get more information and data on the usage of the canines in those settings. But with that, I'd like to thank you for your time, and I'll take any questions you have on training or on the study itself.

SEAN COURTNEY: OK, great. Thank you, Dr. Mendel. It was a really interesting discussion. We do have a few questions that came in while you were talking. A couple of them, actually, I think you kind of addressed it during your talk. It was actually around susceptibility of canines to SARS-CoV-2, if you could just kind of readdress that as well?

JULIAN MENDEL: Yeah, so that's one of our initial concerns upon starting. We definitely did not want to have our canines actually contracting or getting COVID-19 from the efforts of the study. So while we did not actually do PCR testing of our canines, at no point during the study did our canines get sick. And the

way that we manufactured those training aids through the process of doing UVC radiation and then actually sealing the training in that COMP packaging that we told you, really reduced the risk to almost negligible of actually having the canines get infected.

SEAN COURTNEY: OK, great. Thank you. So the next question was, were any of these study animals infected with COVID and asked to confirm findings of the study. They're curious as to whether if the animal is infected, if it would skew the ability to find a correct scent?

JULIAN MENDEL: That is something that I can't speak to. We don't have any information on that particular topic at this time.

SEAN COURTNEY: Right. OK, thank you. What about transmission of the virus to humans?

JULIAN MENDEL: From canine to human?

SEAN COURTNEY: Yes, sir.

JULIAN MENDEL: So we have not done any studies on that. That, I would imagine, someone in the CDC would actually have a better answer to that question, as whether or not it can go from canine to human. But we have not seen through our literature searches any indication of that as to date.

SEAN COURTNEY: OK, great. Thank you. Next question was-- there's kind of a few questions in here, but it's, what is the approximate total cost to train a canine to be proficient in detecting SARS-CoV-2, and how long, once trained, are the trained canines competent to detect it? And also, do they equally detect variants?

JULIAN MENDEL: So we actually-- it takes about $25,000 to $30,000 to obtain a canine that is bred for detection and get them trained to the point where they can be deployed. I would say that it takes six to eight months to have a dog that you can be confident and be proficient in. If a dog is experienced in detection work, you can actually imprint any number of odors on that canine. So you can actually have that time cut down to a couple of weeks to have a dog on a new scent, if you have a dog that is already experienced in training.

The cost, for example, for the Miami International Airport study, our cost analysis showed that in COMP, it was about $17 per person screening with all the costs considered to do the screening of employees at the terminal there at American Airlines. So the overall cost to get a dog ready for detection, I would say is about $25,000 to $30,000. In terms of proficiency after training and or practices, we actually keep our dogs trained. Even if they're not actively deploying, they are trained two to three times a week.
So if you do that, as long as the dog remains healthy, the dog will remain proficient in whatever order it is they're trying to detect.

SEAN COURTNEY: OK, thank you. That actually leads into the next question, which is, are these dogs trained for more than one analyte or are they just specific to one or the other?

JULIAN MENDEL: Right. So our dogs used in this study, two of them had previously been used in the Laurel wilt disease study, so they were also trained previously to do that fungal pathogen. These dogs were also trained to do tegu lizard detection, for example. So the research has demonstrated that there isn't really a limit on the amount of odors that you can train a canine on. So two of our canines for the study were COVID specific, two of them had been experienced dogs that were utilized in previous studies. But you really would-- the consideration here is whether or not you would-- what environment that dog would be working in.

You wouldn't necessarily want a dog that is trained on many odors that they would then encounter in the target environment. So that's the only thing that would be-- you'd consider. But typically, dogs are trained on a specific odor, and that is what they do, but there is no limit to the amount of odors you can actually imprint on a canine.

SEAN COURTNEY: Wow. OK, great. Thank you. So I'll ask you one more. I know there's a few more questions in there, but just in, due to time constraints here, I'll ask another question, which is, was there any correlation done with the time course of infection CT value like so comparing it to like RT-PCR CT values with the canine detection?

JULIAN MENDEL: Yeah, so there's a lot of questions that we would have liked to address in the study. One of the things that we are really interested in, I know someone mentioned variants as well, is how different the volatile makeup is there? But we were unable, with the way the study was designed, to obtain any personal information about individuals. The only information we obtained was whether there was a positive PCR test or not and where. So we did not actually get any information about variants, any information about when the PCR test was done.

But we do know that the protocols that we had in place at the hospital was that once a PCR test was positive, that mask would be collected from that patient and would be packaged and sent to us, so we would be able to process it. But there were no additional considerations there with respect to CT values and PCR to compare it to real time PCR.

SEAN COURTNEY: OK, thank you. I really appreciate your discussion today, Dr. Mendel, and I'm sure there's more questions. If you have time, you can jump into the Q&A and respond to a few if you're able to. If not, we can share them with you at a later time. But we'll move on to our last speaker, Dr. Gregory Sossamon, from Ochsner Health, and I will give the slide over now. Dr. Sossamon?

GREGORY SOSSAMAN: Thank you, Sean. Hi, I'm Greg Sossaman and I'm joined by my colleague Elise Occhipinti. We're both clinical pathologist at Ochsner Health in New Orleans. And we're here today to briefly share some of the information that was gathered by ASCP on a survey about supply chain

challenges, and then some of these solutions that we've implemented at Ochsner to address some of these challenges. Next slide, please.

So we've all witnessed the impact the COVID-19 pandemic has had on our laboratories, particularly early on, when we struggle to get access to testing or to perform testing due to lack of reagents or staffing. But as time has passed, we've entered a new phase, where supply chain challenges have extended to other shortages, things like specimen tubes and other very common lab consumables. And so, as this issue has bubbled up worldwide, we've discussed this at ASCP, and several actions came out of these discussions.

And we would like to highlight some of these in response to this ongoing and deepening crisis. One action was that ASCP decided to use its media platforms as well as its established academic venues to send this message out to a wider audience. Next slide, please.

And this message was around turning crisis to opportunity as you can see from the title and an editorial in American Journal of Clinical Pathology. And by that, we mean can we use this opportunity of scarcity to bring attention back to its scarce resources.

As we've said many times in the Choosing Wisely, it's the right test at the right time with the right patient. So and this is, we thought, a good time to look and turn this. Again, turn this crisis to an opportunity knowing that this can be an uncomfortable conversation and a difficult time to bring up these issues and these times of unprecedented stress with physician and provider burnout and delayed care. Next slide, please.

So as I mentioned, ASCP took several actions. One of which was this survey, which was performed in December of last year and January of this year, which was a survey of the Choosing Wisely Advisory Board and ASCP membership, and asked the questions of the participants of, please tell us about your supply chain issues impacting your lab? What initiatives have you undertaken to address these supply chain issues, and what suggestions do you have to reduce unnecessary supply consumption? Next slide, please.

So around the impact of supply chain issues in the lab, a big majority, almost 64%, saw an impact in the shortage in their laboratory. And most of these were around the common supplies of tubes, reagents, needles, pipette tips, as we've seen for COVID tube testing, media, and personal protective equipment.

Several labs and, I think, the second and third themes around critical time for diagnosing cases and using alternative methods are actually linked in that participants indicated that when they were trying to use alternative supplies or methods, they would have to scramble to do validations or change procedures and do training on the fly, which led to delays in reporting. And then because the staff were divided between validating these alternative supplies and performing and testing, which, of course, led to disruption of workflow, the aforementioned delay in diagnosis, and then, of course, additional stress and burnout in the

laboratory. There's a smaller percentage that referred to or that utilized reference laboratories and borrowing other supplies from hospitals. Next slide, please.

Some of the initiatives that participants noted, or respondents noted, in trying to address this issue were-- or a common strategy was around using alternative test supplies, for instance, switching SST or SS tube to lithium heparin tube were available, utilizing different collection tubes, different sized tubes. And some participants also mentioned switching vendors when possible and/or loaning loans from other laboratories within or outside their own hospital systems.

And again, some mentioned reporting or sending to reference laboratories. The second most commonly used initiative was test conservation strategies. For example, decreasing extra tube drawers, stopping the practice so-called rainbow draws in the emergency room, and identifying other ways to conserve reagents. Participants also noted trying to change ordering practices, for example, stopping the ability of physicians to order morning daily labs for multiple days or timed orders for different days, and then just an overall encouraging effective test utilization.

Surprising, at least surprising to me and my colleagues were around communication with hospital administration. If you see them on the table, around two, a little over 2%, which was actually one of the strategies that we used early on at Ochsner to kind of get the mention out or get the message out. Next slide, please.

And so, suggestions around reducing unnecessary supplies were not surprisingly lumped under a couple of categories. One of which is the test utilization strategies, which participants mentioned things like Choosing Wisely best practices, limiting unnecessary and frequent testing, eliminating non-specific tests, and the like.

The second category was around education and awareness. For instance, educating physicians and test importance are working with physicians to reduce testing and prioritize testing, and then discussion with other providers on efficiency and ordering. There were some other suggestions, which was actually a large percentage, 27%, in the other category, which included things like understanding where alternative supplies are available and developing process to utilize those alternatives, and possibly other things like working with manufacturers on ways to extend reagent life while remaining within valid parameters.
So next, I'm going to hand this over to my colleague Dr. Occhipinti, who's going to take us through some of the specific interventions that we utilized at Ochsner.

ELISE OCCHIPINTI: So good afternoon, everyone. My name's Elise Occhipinti and I'm a pathologist at Ochsner Medical Center, a colleague of Dr. Sossaman. So here, from the data that Greg showed, it was obvious that laboratories across the country were well aware of the problem and they were handling it in a variety of different ways, probably depending on the severity of shortages at their institution or what types of products were under shortage. I'm going to discuss a little bit about what we did at Ochsner Health.

So it was probably around early to mid-December, which was our reflection point, where we realized we really needed to do something urgently. At this point, we had only four days of tubes on hand for a variety of different types of testing. It wasn't just one kind of blood collection tubes. It was pretty much every tube. And this was bad enough on its own to know that we only had four days of tubes on hand, but we were also staring down and approaching Omicron wave, and we were reaching the end of the year, which our hospital is usually very full during this time, so we had to take some drastic action.

And when you have a component of scarcity, there's usually two things that you can do. You can either increase your inventory or decrease your utilization. So we tried to do both of these things at the same time with our initial focus being on increasing inventory. So the first thing that we did was really double down on our communication with both our vendors and our supply chain teams. We were having daily multiple meetings per day with both of those groups. We were escalating it to as high as we could in leadership but realizing that they weren't really able to do much for us, because there wasn't any inventory and it just wasn't anywhere in the US.

We also considered, as Greg mentioned, validating alternate tube types. Well, that was really onerous on our laboratory staff. We were already short staffed. We were inundated with testing and we just-- in order to do the types of validations that would really be necessary to pass inspection, we just did not have the time or manpower to do it on such a large scale, because we were going to have to validate test, alternate tube types on multiple tests. We also tried to explore alternate vendors, which as everyone knows, every vendor in the country and even internationally is having the same problem.

So we learned early on, probably in the first day or two of the crisis, that increasing inventory wasn't going to be an option for us. We really needed to focus on decreasing utilization. And some of those things that we considered emergently immediately was eliminating a rainbow draw, eliminating extra tubes that were collected in phlebotomy, or by nursing as part of the morning labs. We also consider decreasing daily labs in the inpatient setting, decreasing repeat orders, so we reviewed a lot of our labs that were traditionally known for being ordered too frequently, And we also consider ceasing non-essential orders which would be routine wellness and things like that. So, next slide.

So whatever we were going to decide to do, we needed to have a framework of governance structure to enact the changes that we wanted to do system wide. So our hospital system is multiple hospitals, probably 20 to 30 hospitals throughout Southeast Louisiana and Mississippi that we have influence over. And so we really needed some kind of framework or governance structure to enact changes.

Luckily, we already had a stewardship framework in place, which is called Tier Variation committee. This is a multidisciplinary committee. It's over 25 members of all of our hospital locations and every major specialty is represented. We have been meeting monthly since 2017. We had taken a few hiatuses during COVID, but at the time of this shortage, we were meeting regularly. And we had already done a lot of great work regarding laboratory testing, so reducing variation and lab testing via either sent out labs or in-house labs, we were focusing on appropriate utilization, both over and underutilization.

And we also vetted new test requests from physicians and vendors. Most of our decisions were based on Choosing Wisely and best practices throughout the country. And we definitely relied on our inter-departmental experts to help get our message across. We did not have any of our decisions made or owned solely by laboratories. So I think that is one of the most important parts of this committee, was that it was multidisciplinary and spoke with one voice.

So when we decided to enact a rule or change on the EMR, which honestly-- EMR changes were probably one of our most effective interventions and we did use a lot of those, so our medical staff was used to that these decisions were voted upon by the entire committee and owned by the committee, not by laboratory. So when people had a question about why we did what we did, we always had a committee backing to help us get our message across and to communicate. So the next slide.

So in our committee, we kind of reviewed the effectiveness of the three most common interventions that we had done in the past. So as you can see here, these interventions, in increasing order of effectiveness, are education, even more effective is audits or physician report cards and personal feedback, and then the most effective is the EMR restrictions. And we usually chose different interventions based on the seriousness of the problem.

So if it was just something that was minor or didn't really have a huge impact on patient care, we would try to start with education and feedback first, but because these two interventions are slow and they're minimally effective and they're far to reach people. EMR restrictions, this is something that, as everyone knows, it is fast. It can be standardized, and it could be quickly rolled out across the entire system. The problem with this is that although they're highly effective, they're poorly received.

So when you do an EMR restriction, there's usually a lot of blowback from the medical staff, and a lot of concern from the administrative team about physician burnout, making the EMR more difficult for physicians, so that's definitely not a big gun that we want to use all the time. But in this case, we realized that we had to do that. So next slide.

So once we decided in the committee that EMR interventions were going to be what we focused on, the next thing to do was lay out a roadmap of how we were going to do this. So, it's composed of these four buckets, I would say.

So the first thing we did was collect data. I'm going to go into this in a little more detail in other slides, but we focused on two dues per day across the whole system. How much were we wasting per day? How much was each hospitalist group ordering per day in daily labs? What was our outpatient chest volume, and what kind of repeat orders were we getting on tests that could definitely serve to not be repeated at the frequency in which they were being ordered? Once we had data, the next thing we did was consult best practices. As said before, Choosing Wisely and societal guidelines are always our first go to.

If we see something on Choosing Wisely that we think will be applicable to our teams, then we vet it even further with societal guidelines and experts within our own system. So for example, if we want to eliminate

daily CBC in the hospitalized patients, we'll also consult ABIM recommendations or American Society of Hospital Medicine, and we'll vet that with the chairs of those different departments. Lastly, we did start to rely on the NHS retesting interval guidance. This isn't something that we've ever used before.

But in this situation, it was helpful to show our teams that this was a worldwide problem not just something that was localized even to our region or to the USA, in general. So it helped us show what they were doing throughout the world, and I think that did help our physicians understand the seriousness of the problem. And then, we also had to communicate and educate. This was something, as I mentioned before, we did predominantly through our governance, our care variation committee, but we also had to kind of do boots on the ground. So Dr. Sossaman and I we were very transparent.

We shared our data with anyone who asked. We share the effectiveness of our data and where we got the ideas for our interventions. We also had to have frequent meetings with multidisciplinary groups, so we had to meet with-- we met multiple times with surgery, internal medicine, hospital medicine, infectious disease. We tried to be very visible and responsive to whatever questions were happening during this time, because we recognize that our need to make a change that would benefit a large majority of patients was directly conflicting with a physician's challenge to treat the patient that was in front of them.

So we had this definite kind of culture change, that we had to communicate to our medical staff, to think about the good of the whole rather than the individual patients that we're finding. So I think the only way to get that done was via lot of communication. And we also had to make our communications diverse. So as I mentioned here, we had to communicate with the C-suite differently than we communicated with nursing and phlebotomy, differently than we communicated with providers, differently than we communicated with our lab operations team.

So it was very challenging, the communication and education, but I think it was rewarding in the end. And then lastly, we decided to make most of our interventions through the EMR, which I'm very grateful that we have a strong, strong relationship with our EMR team and our physician builders, and they were extremely responsive and helpful. We decided to do this via hard stops by eliminating some esoteric testing, by eliminating some routine testing, and eliminating daily labs in the hospital setting.

We also pulled every order set and worked with our EPIC analysts and our experts in the field to review them and curate them, try to figure out what labs we could remove from the order sets or what frequencies we could change. And then once start to inventory started stabilizing, we opened up some more testing, but we did that via special tube restriction. So we allowed only certain specialists to order testing as tubes became more available. So next slide.

So we'll talk a little bit more detail, and we're almost out of time, with how we did our data collection. So the first thing we did was figure out how many tubes we were getting per day. This was about 50,000 throughout the system, and we realized that our top utilizers were emergency medicine, internal medicine, that's the hospitalist teams and family med, so we targeted those departments upfront. We also figured out where our pure waste is coming from, and these are extra tubes rejected tubes and rainbow

drawers. One thing I want to mention about this is it was good and bad. It was good because a lot of this was completely under our control. We could target our phlebotomist, but also the data was incomplete.

So the only way that we could capture, whether or not a tube was actually extra or rejected, was if someone documented that in the LIS. A lot of times, they didn't, so we knew that this data wasn't complete. Similarly, with the daily lab orders for hospitalists, we were able to capture that, but we were not able to calibrate the patient volume and complexity. And so the reason why I'm mentioning this is because I just want to share that one of our lessons was you know that your data is not going to be perfect, but don't let that stop you from making a change or from using it to lead you to a story or to lead you to where to intervene.

It's not going to be perfect, but if you spend a lot of time waiting to make it perfect, it might be too late, so that's something that we had to do. And then lastly, we monitored the order sets, as I mentioned before, so we were able to kind of curate them to eliminate as much redundant testing as possible. Next slide.

So reduction of daily orders, I'm just going to go through this really quickly. We got the idea to do this via Choosing Wisely, and then we vetted it through our chairs of hospital medicine and internal medicine. Next slide.

And you could see that it really helped. So beginning on this is, this is December 9th. This was when we started collecting data. The red lines are when we did interventions. So the first red line on December 9th was just a soft intervention, mostly regarding education. And then the one on January 7th was when we put in an elimination of daily labs in the EMR, which was kind of a hard stop. And you could see, at that time, we saw a drastic decrease in the amount of orders that we were having every day, which has been sustained with no detrimental impact on patient care. Next slide.

And then lastly, I'm just going to show you. This is an example of some of the educational interventions that we did. These were targeted towards nursing and phlebotomy. We had similar printouts like this all over the hospital. We had posters. We distributed this via email. We just had links in our EMR. So we tried to get this out as much as possible, knowing that it's a soft intervention of education, but I think people really appreciate in knowing why and how we were doing this. So basically, in a nutshell, that's some of the things that we did at Ochsner Health to stabilize our tube shortage.

It was successful. We're not perfect, but now, we are able to-- we're not in a danger zone anymore. So I know we're running out of time, so I'm going to give Greg the last slide to kind of close this out.

GREGORY SOSSAMAN: Yeah, thank you. Just to reemphasize a couple of things, that these disruptions require decisive change and strong intervention. When we say that we were able to implement these things by committee, these things didn't take place over months. We actually made these changes very quickly over weeks because we had that infrastructure in place. So we had the data, we had some of the standard processes and interventions, and we focused on the communication piece and the inter-departmental collaboration. The other thing I wanted to say is that this needs to be a sustained change.

Some of the things we did were really hard, and we don't think there's any going back on this. And so we look at this as an opportunity to continue on these changes that have been catalyzed. We need to continue on and sustain them. And just emphasize Dr. Occhipinti's one point, education alone is insufficient. It needs to be long term change. It needs to be coupled with process change. So thank you. I'm happy to answer any questions if we have any time.

SEAN COURTNEY: OK, great. Thank you both for that great discussion today. In the interest of time though, since we're already at 4:00 PM, we're going to go ahead and call that a day. But I just really want to thank all of our presenters today for these really great presentations. I want to remind everyone that these slides should be available by next week, and that our next meeting is on Monday, June 27th at 3:00 PM. So thank you everybody and we will see you guys next time.