

Clinical Laboratory COVID-19 Response Call

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Speaker Panel

Jasmine Chaitram, CDC Division of Laboratory Systems

Marc Couturier, ARUP Laboratories

Kirsten St. George, New York State Public Health Laboratory at Wadsworth

Michele Owen, CDC Laboratory Task Force

Stuart Streck, U.S. Department of Transportation (DOT)

Tim Stenzel, U.S. Food and Drug Administration (FDA)

Sara Brenner, U.S. Food and Drug Administration (FDA)

Janet Hamilton, Council for State and Territorial Epidemiologists (CSTE)

JASMINE CHAITRAM: Hi, everyone. Thanks for joining the fourth clinical lab COVID-19 response call. I am Jasmine Chaitram. I am the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems at CDC. Our division works to advance laboratory quality and safety, informatics, data science as well as biorepository science and workforce competency and training.

We are closely aligned with the clinical and public health laboratories across the country to support emergency preparedness and response activities throughout the COVID-19 response. We have been supporting the CDC's emergency operation center by serving as an interface between the CDC and the clinical lab community. Some of the tasks that we've been focused on include biosafety, the regulatory requirements on under the Clinical Laboratory Improvement amendments known as CLIA, additional laboratory quality issues, and the challenges associated with implementing tests.

And I'm going to just show you the agenda, hang on. All right. So for today, as you can see, this is our agenda. And we are trying very hard to focus on topics based on the questions that you submit each week. I know that some folks do submit questions when we send out our LOCS messages. And we are working to provide responses to those questions in addition to make them topics for the agenda. But usually they're going to be on the agenda for the following week.

So if you submitted questions this weekend, we will either try to give you an answer, or we will be posting-- or we will be hosting agenda items that will respond to those questions on the next call, which will be one week from today. So in addition to having this agenda and these topics, we also want this to be an opportunity for the clinical laboratories and other government agencies to provide valuable information to each other.

We anticipate a large number of participants on this call and many questions. We may not be able to directly and immediately address every issue. However, we will note your questions, as I mentioned, and we'll get that feedback and tailor the future calls accordingly. We will be sharing the slides from this week's call along with the transcript of the call. And those will be posted on the [DLS website under Safe Labs](#). And I will provide some more information about that towards the end.

I also wanted to mention that we've been working on some frequently asked questions about testing and reporting. And those will be going up on the CDC COVID-19 website under the laboratory section, hopefully in the next couple of days. We will send out a LOCS message once those FAQs are posted. And I think that they will provide a lot of information and help answer some of the questions that we continue to receive from different laboratories.

So regarding questions, here's some information about how to ask a question on these calls. This is an overview of some of the Zoom functions that you might find useful, especially for asking the Q&A. For added security now, participants have been asked to use a password when we join the calls. The password is with the Zoom information online and in the LOCS message we send out and should also be posted to listserv.

So I hope that the having the password has not created any challenges for anybody to join the call. So with that, I'm going to move to our first presenter. Marc Couturier from ARUP laboratories is going to talk about the reference laboratory experience. And Marc, are you ready?

MARC COUTURIER: Yeah, I'm good to go.

JASMINE CHAITRAM: OK. Go ahead.

MARC COUTURIER: All right. Jump to the first topic slide. So actually, what I wanted to talk about today are a lot of different aspects rather than just drilling down on one feature. And I think a lot of it is just, we've learned a lot of different little lessons in the course of this entire challenge.

So the first one that I think was evident really early, was the specimens we were getting from reference work for COVID testing and for non-COVID testing. So we were getting a lot of leaking tubes, specimens that weren't packaged correctly. And some of the ones we saw that were really bad offenders were whether the swab fit in the tip or not, just jamming it and then quickly scoring the cap down.

That essentially made a spring. So when people are opening those, those swabs we're bouncing out or they were compromising the integrity of the tube. Another thing we saw, and we've seen this in previous years with other transporting of specimens using airlines is people thinking that if you parafilm the top of a screw top shut, that's going to make it more secure.

In reality, what that actually, we've shown to do, is under pressure and temperature changes, can actually make the parafilm act almost as a wrench. And as it wraps off, will actually take the tube threading open. And so it actually creates the specimens to leak more.

Next slide, please. So the second major issue that came up with us as a major viral reference culture lab, was reference specimens coming in for respiratory cultures were basically coming to us from all over the United States. We didn't know what the prevalence of COVID in those regions were. Oftentimes, we were completely blind as to what was being sent to us.

So it's being submitted for a non-respiratory culture specimen. But then there was ambiguous labeling on it that said rule out COVID, or patient positive for COVID, but this was actually a lesion for some reason. And we just got to the point where we really couldn't trust what was coming to us for respiratory and non-respiratory.

Also, in areas like New York where SARS-COV-2 was really predominant, we didn't know if we were unlikely to inadvertently grow a virus we weren't intending to. So essentially, set up a culture and the [INAUDIBLE] of COVID-2 is so prevalent, that's what grows in the culture. So after the recommendations to stop using the Rmix, and also some concerns for rhesus monkey kidney cells from the previous SARS virus, we've followed some of the guidance from Wadsworth and others and just basically shut down our respiratory viral cultures.

Next slide, please. So then you want to clarify, ARUP right now is not operating as a national reference lab functionally for NAAT testing. And I'll explain why that is. So when we first brought NAAT testing online, we offered it to all of our current clients on March 12th. With a bolus of specimens we got in the first couple days, completely overwhelmed our instruments and supply chain.

So on the 16th we had to actually turn off the ordering capability for our national lab customers. So right now what we're doing is we're serving more as a Utah and neighboring regional reference setting. And by doing this, we're able to ensure that our capacity is reasonably maintained and our turnaround times are clinically meaningful.

Next slide, please. So if you work in a true reference lab setting, often you don't really have any control of what you're getting. Because we are also the University of Utah Hospital lab, we have a pretty tight control on what they are using for swabs, type of specimens they're collecting. Some of our other regional partners though, it's not necessarily quite as tight.

So we sometimes are getting questions about, is this source the same as this source? The labeling we're getting isn't always clear. Some might say NP/OP, NP, OP, PP, which I clarified once meant posterior pharynx, which wasn't even a specimen type we had indicated. And we also ran into trouble when specimen recommendations were fluidly changing. It took our lab IT system longer to update that so that we were actually getting specimens that were within the indicated acceptability.

Next slide, please. And then we had the other complication of, as this fluid process has been evolving, we see more specimen collection media, different transport types, being listed on the FDA website.

And we just, with all the testing we're doing, have limited bandwidth to generate the type of data to give information on what collection devices and transport media are best for our test, what's comparable. So even in our reference lab, our R&D staff are just not able to keep up with all this. As well, we have to keep in mind reagent burn.

So if you want to take 30 specimens and test them on three different methods, you're talking 90 potential patients you're not going to test because you're looking at the in-depth of a transport medium you don't have a ton of data on. We've also seen inconsistency on patients who are suspected to be clinically false negative sometimes not getting a follow up test, or sometimes getting follow up test after follow up test after follow up test. And you just see that as another potential waste of reagents, counting a patient six times tested when they really did need to be.

Next slide, please. And then we have multiple tests in-house. I know a lot of other institutions do as well. So we're using three methods right now. And we're using some for different purposes. We have a rapid nearer to point of care molecular test. And then we have large workhorse platforms. And then within the state of Utah, the other large health systems are using different platforms and test than us.

And so that's a question that we really don't have a comprehensive data set for is, how well does a state and us compare to each other as far as that data? So we're trying to work on getting a local proficiency testing exchange going, and then hopefully also waiting for organizations like CAP to hopefully have something available soon.

Next slide. So if this has been a hot topic for us for questions as serology. There's a lot of rapid tests on the market, really vendors that a lot of us don't recognize. We're getting questions like, is this a good test, is this a good kit? And you try to look at the performance characteristics on the package inserts, and they're either unclear or not believable. And these kits aren't really amenable to a large reference lab, because the idea is for them to be done more like the lateral flow-type format.

At this point, we don't have any data generated in-house to support IgG or IgM at this time. So we've not been able to really address that. And we're really not clear how physicians are planning to use serology results. So we're having to work really closely to communicate this. Just like molecular, supply chain. It's becoming an issue for the serology already.

So even though we want to use this theoretically as an epi tool, we have to make sure we have enough reagents to do this. And we've collaborated with other reference labs early on to communicate lessons learned, kits that have worked well, kits that were more problematic, and that's been really important.

One more slide. And I want to spell this out just in closing. This has been, in my mind, one of the greatest successes of this pandemic. In the state of Utah we've had a fantastic group of individuals come together to work openly, collaboratively, and transparently. So this includes local and state health officials, public health lab directors, state epidemiologists, lab directors from all the major hospital systems in Utah. They're-- traditionally would be more competitive, working really collaborative.

So we have three times a week nightly phone calls. We get together and we report on how are people doing, what are supplies like, what are challenges. We've worked together to be consistent with collection criteria and testing criteria. And that's really helped us be efficient. And in some cases, finding out that a lab is running low or out of a reagent, we've stepped up and offered workspace, offer reagents, kind of did a lend-lease type approach.

So I've talked to other colleagues in other states who have said they've really struggled with this aspect. So I think Utah's done a really good job of creating this type of collaboration. And I would just offer that up to other states. If you could get all the key players involved, this is hugely effective. And in that I'll close, thanks.

JASMINE: Marc, thanks so much for sharing that experience and these important tips and lessons learned already. We are very grateful for everything that you're doing. And I'm also very grateful that you were able to participate today and share this with us. We're going to move to our next speaker.

Also on the front lines, this is Kirsten St. George from the New York State public health laboratory. Kirsten, are you on?

KIRSTEN ST. GEORGE: Jasmine, hi. Can you hear me?

JASMINE CHAITRAM: Yes, I can hear you now.

KIRSTEN ST. GEORGE: Great. Thank you very much. And thank you for the opportunity to speak to people this afternoon. So much has changed just in the matter of really a fairly few short weeks since the end of February for us and I'm sure for everybody on the call today. It's really a very different world that we're all operating in now. And our experiences are numerous and variable as I'm sure they are for everybody.

It started, for us, back in January when we first started watching this virus, and then in February when we started to implement the CDC test, and then made the decision to submit our own EUA to the FDA, which was granted very, very quickly. And that decision was based on a desire to be able to purchase as much reagent as we felt we were going to need and not be limited by the amount that was going to be potentially limited in distribution to the public health labs. But also because we wanted to be able to cross validate the assay onto numerous other extraction and amplification platforms.

And so there were a number of-- excuse me, one second-- there were a number of subsequent amendments that were submitted. And I just would really like to say that the FDA-- our interactions with the FDA were all extremely positive. And the turnaround times for us were extremely rapid. But since then, we've implemented numerous tests and instruments and methods and so on as I know many other labs have.

And this has been a challenge, because we've experienced, as has everyone, this tremendous issue with shortage of reagents. And so being able to switch from assay to assay, platform to platform, while it has been a challenge to do that and constantly training and retraining not only our own staff, but a lot of surge staff that came in to assist, that presents its own challenges.

If we had not had the reagents and instruments to be able to do that, it would have been extremely difficult to maintain the level of testing that we were required to maintain. So our testing load increased very rapidly from 30 to 50 a day at the very beginning. It increased exponentially to almost 2,000 a day. And it stayed at that level for a while.

It has subsided a little. We're down around maybe 1,000, 1,200 a day. Some days a little under 1,000. When the testing was then picked up by the hospital labs and other clinical labs around the state and we assisted many of those in bringing the tests up and issued a lot of guidance on validation and verification. There was a lot of confusion over what would be required for that and the process for that.

And just recently published with the ASM team, a document hoping to clarify some of those issues and what the expectations would be for validation and verification. There have also been, obviously, difficulties with availability of transport media and recipes for that, for guidance for people attempting to either have it made or make it themselves. And we've had to cross validate all sorts of different types of transport media.

I'd just like to comment, notably, that the molecular transport media, which has been very successful for many or most of the analyzers and extraction devices into instruments, it is not usable on some analyzers. So you do have to be very careful, the MTM is not universally usable on all molecular devices. So just a caution there. We've also looked extensively at different sample types.

There's been a huge challenge with shortage of swabs, as we all know. And so we've also had some studies running to look at the different sensitivities of different types of swabs and also saliva and have a paper in preparation on that. That was an interesting exercise as well to work through. We've got tremendous cooperation with all of the clinical labs, as Mark said also. Here in New York, we had a wonderful working relationship with our hospitals and other clinical testing sites. And that has been really, a very successful exercise.

And in addition to the just straight diagnostic testing at our own site and in collaboration with those other labs, we've developed a tremendous number of collaborative projects on studies

on viral evolution and growth characteristics and response to drug therapy. The development now of serological assays and a huge growth area there in trying to understand the actual serological response and immunological response in general, which is looking more unusual the more we look at it.

It's not a standard immunological response at all that we're seeing at this point. And working in collaboration with some of the big hospitals, and that started a large initiative towards using convalescent serum as a treatment for acutely ill patients, and working on not just measuring IGG and IGM, but also neutralizing antibody titers. And the data was not coming up anywhere like expected. And hoping to get that out in not just the peer-reviewed literature, but much faster than that, onto rapid posting sites fairly quickly.

We've also looked at point of care instruments and assessed a number of those. We do use those in the lab ourselves, particularly for the late night, middle of the night, rapid urgent testing situations, but also to help deploy them out to some of the point of care test sites around New York. And that is an ongoing process still. And we've also evaluated quite a number of the control materials for other labs to be able to use to validate tests and to use as control material in the ongoing testing in their labs.

We do perform culture here on a very specialized basis for use in our R&D programs. And I think, perhaps, I will leave it there. To address all of this, we obviously brought in many, many dozens of surge staff, not just in the labs but also in our clerical areas and IT and logistics and maintenance and operations. That's been an enormous collaborative effort.

And just eternally grateful to the support and assistance that we've had from all of those people, but also from our colleagues at the CDC and APHL and elsewhere around the country have also enjoyed working enormously with many, many commercial companies. We have nondisclosure agreements with more than 12 of them now, and working with them to continue to help now more with serological assays, previously with molecular assays, in developing and validating those to help put them through the FDA as well. Thank you very much, Jasmine.

JASMINE CHAITRAM: Thank you, Kirsten. It sounds like you guys have had to overcome a lot of challenges and do a lot of things to be as effective as possible during this response. And thank you for all of your hard work. And thank you for taking the time out today to join us on this call. I know you're super busy.

We're going to go ahead and move to our next speaker. This will be the CDC laboratory response task force. And Michele Owen, she joined us last week. And she was going to give an update again on serology testing. Michele?

MICHELE OWEN: Yeah. Good afternoon. This is Michele. So I want to two parts to the update today. First, I want to give a quick update on what I talked about last weekend as far as the multi-agency task force that's been set up related to evaluation of commercial tests that are out there that haven't yet officially been reviewed by FDA. As I mentioned, that is going

forward with all hope. The testing will actually begin on Wednesday. And the idea is to have the results from this initial screen of commercial assays within the next three weeks. And hopefully the data will be disseminated very quickly after that.

The other thing that I would like to give an update about is actually the CDC serologic assays that have been developed, just so people are aware. CDC does have an ELISA that was developed. And it's based on the spike protein, the same antigen that's actually used in the VRC vaccine trials. So far, this assay seems to be performing quite well.

It has been, up until this point, the data have been compared with in vitro neutralization assays. And so far we've had very good correlation between the two assays with the hope that in the future, the neutralization assays will not be needed, except to answer some very specific scientific questions. At the moment, the assay is being used at various CDC studies.

We've started some seroprevalent studies on basically, convenient samples from LabCorp and Quest. And we were grateful to them to have that collaboration. The other types of studies that the CDC assay has been used for is some field studies, such as household studies. Once again, to look at natural history of virus in households, transmission, serology, etc.

So those are the main types of assays that the CDC assay is being used for. Currently, we are not planning to have a EUA for this assay, as it is being developed primarily for surveillance in the natural history type studies. So hopefully, I know we are getting considerable amount of request for doing work with the CDC assay from various partners around the country. I think we can be contacted and we can discuss if we can be beneficial. But, as I said, we're not planning to roll it out as an EUA. That's it for me. Thanks.

JASMINE CHAITRAM: Thanks, Michele. Can you, just real quick because got one of the questions in the chat box, can you share how many assays CDC is evaluating per serology testing?

MICHELE OWEN: So it's not just CDC. Like I said, it's a huge consortium of BARDA, CDC, FDA, NIH, DOD. And the plan was to evaluate up to 20. I know that, so far, five have come in to the testing lab at NCI that's going to be doing this with more on the way. But I think the idea is around 20 at the moment. And they are being prioritized by FDA.

JASMINE: Great. Thank you so much. Thanks for joining. I know, like everyone else, the lab task force is also very busy. So we appreciate your time to be with us on the call. The next speaker is from the Food and Drug Administration. It's actually two speakers, Tim Stenzel and Sara Brenner. And the topics we asked them to talk about based on the questions we received, were home specimen collection kits, home testing, point of care, and serology testing. So, Tim?

TIM STENZEL: Yeah. I'll start off and then Sara will pick up. Thanks. And the first thing is, I do want to just say that we have not authorized a home collection or home testing EUA yet. And

those should come into us for a prior authorization. The things that we're concerned about in the home environment are, first of all, consumer safety.

We've seen some of the potential collection devices have had potentially poisonous compounds and have concerns about that. Also, we want to make sure that in the home environment, the lay user can accurately collect and/or test. And then of course, when there's a shipping situation, the shipping the sample back say to a lab, that the sample stays intact and there are no increase in false negatives.

We have seen some potential plans where something might be dropped in a drop box on Friday afternoon, but not make it to the lab until Monday. And that's quite a long period of time for something to be in ambient temperature, which might be rather high or rather low. And then the other thing is, we're seeing increased interest in saliva as a specimen type.

Today, we've authorized one EUA for saliva. However, we have seen a great amount of variability in performance. And some of them have not really been sufficient in performance compared to an NP or OP swab in order for us to feel comfortable with its performance. Obviously, there's a lot of advantages to using saliva.

So we continue to ask that those interested in validating saliva, that they seek input from us and that they also achieve EUA authorization for their particular test. This would be all developers as well as for the home collection and home testing. For saliva, it may well be that certain tests work well, certain collection devices work well, and not others. So far, we've not really been able to pin down on why results appear to be so variable. So with that, I'll turn it over to Sara. Thank you.

SARA BRENNER: Great. Thanks, Tim. Can folks hear me?

JASMINE CHAITRAM: Yeah, we can hear you.

SARA BRENNER: Great, thank you. So serology, the topic was covered nicely by CDC. But I'll just note a couple of things from FDA's perspective. We have had many, many questions regarding serology testing coming at us as I know all agencies have. So as was previously mentioned on these calls, the FDA is not reviewing validation data unless the developer or manufacturer submits an EUA. But as was mentioned by a colleague earlier, we're pursuing joint inter-agency efforts to investigate the quality of serological assays that are being marketed here in order to determine if their performance is accurately described, advertised, and labeled by the manufacturers.

So with NIH and CDC, we're working on that as was previously described. Meanwhile, FDA does not intend to object to the development and distribution by commercial manufacturers or development in use by laboratories for serology tests to identify SARS-COVID-2, where the test has been validated by them. And notification has been provided to us at the FDA with certain information described.

And that information, which is needed, is in our March 16th guidance. There were a couple of other questions that came in between last week and today that I just wanted to comment on as well. There was a question on sharing updates regarding specific tests. So in the-- I'm sorry, the distribution of specific types of tests that have been approved, and unfortunately we don't have information on a developer or company by company basis with regards to allocating or distributing tests.

There was a question that came in on nasal swabs. Labs are beginning to make their own flocked swabs. And the question was about an EUA. So this is an interesting question. We've had other folks reaching out with nasal swabs that have been manufactured in non-conventional ways, such as 3D printing. So we have a team assembled at FDA that's looking at nasal swabs and how we're going to handle those if they're not made by their typical-- through their typical manufacturing process.

So I'd encourage you to reach out to us, send us an email if you're considering making your own swabs and we'll engage with you about that process. And the last question was about stakeholder contribution. So laboratories and academic institutions and medical centers have been reaching out to us to see what they can do and how they can work with the federal government, with the FDA specifically, to combat a number of things. Everything from shortages to expertise.

So you know, we're looking at ways that we can engage with all of these different types of stakeholders so that they can contribute maximally and efficiently to the needs arising from the pandemic. So different types of national organizations such as the AAMC at AU and APLU, for example, with universities and medical centers are speaking with us. So hopefully we can work together.

There was also a question about labs, research labs wanting to perform assays in their own laboratories and asking if that was an EUA type of situation. That's actually a question more for CMS. That type of approach doesn't require an EUA. But it would require flexibility from CMS with regards to allowing testing outside of a CLIA lab, or relaxing personnel requirements to get a CLIA certificate. So we alone, FDA alone, cannot answer that specific question. And that's all I had, thank you.

JASMINE CHAITRAM: Thank you very much, Tim and Sara. We did have one question that popped up on my screen while you were talking. And I think it's pretty easy to answer. And I do think you covered it last week. But it's always good to repeat since we have new individuals calling in week after week. And so the question is, is there a list of approved serological tests?

TIM STENZEL: So, yes. On the [FDA EUA authorizations page](#), we list all of the EUA authorized tests, including serology and molecular.

JASMINE CHAITRAM: Thank you. OK. We're going to move to our next speaker. Thank you again, Tim and Sara, for your time. Our next speaker is from the Council of State and territorial

epidemiologists, Janet Hamilton. She's been on several of these calls as well. And Janet is going to be talking about some of the challenges with providing demographic data and what CSTE is trying to do to address that.

JANET HAMILTON: Thank you. Thank you, Jasmine. And good afternoon, everyone. This is Janet Hamilton with CSTE. And I wanted to first take the opportunity to just remind people that as you are bringing up tests, that all test results, positive, negative, and indeterminate, should be reported to your state health department with identifiable information. And there are electronic file formats in which to do that.

So as you are coming online with your tests, our recommendation is to please contact your state health department as soon as possible in the process so that you can have access to that file format information. And of course, it's at the state and local health department level where the case investigations are occurring, and thus ensuring that your data is able to be sent to them as quickly and as in real time as possible. It is critical to this response.

We're also very much aware, as are all of you, about the interest in demographic information. And because laboratory test results, at this point in time, really are the primary source of case identification. When the demographic information is missing, a missing patient address, zip code, phone number, as well as race and ethnicity information, it limits the data and the national picture that can be given based on those data.

And while state and local health departments are actively working to follow back up with the providers to be able to get that information, we are very much interested in working with all of you at the laboratory to also follow up to get that missing information. It is critical for the response. And we do recognize that on the lab side, it does take resources to reach back to your submitters to gather that information when it's missing.

But we very much appreciate your partnership and your willingness to do that. In addition, to help educate your submitters at the time of submission, how critical that information is. We recognize that information is not needed to actually perform the test. But it is needed to be able to respond effectively and to curb the spread of this virus as well as to be able to make good evidence-based recommendations, particularly about certain types of populations that may have impacts at a different level than others.

So thank you all so much for working with your providers. We are also interested in working with all of you to help with this. So we are working towards writing a letter that could help and be distributed to providers, as well as some of the big provider associations to help with the education piece. So that when those orders are submitted to you all, hopefully they will be more complete.

And we've also really seen during this response that we've seen a big change in the orders that are getting submitted to labs with a much higher proportion of that basic information missing at the time that the orders are submitted. So again, thank you all for working with us. I also just

want to highlight-- we recognize that it's not at all uncommon that specimens are forwarded from one lab to the next sometimes, for testing. And when that happens, the patient's information is also often not forwarded with the individual.

And again, I just want to bring to your attention that to please, ensure that when you all are forwarding specimens to other labs for testing, that you all are providing as much of the information about that individual that you have as well. So again, when the results are reported to state and local health departments, they are immediately actionable as opposed to taking days and weeks sometimes to gather that missing information. And thank you all for your tireless work. Jasmine?

JASMINE CHAITRAM: Thank you, Janet. In the interest of time, we going to keep moving. We have another speaker, Stuart Streck, from the Department of Transportation, is going to talk to us about category B and materials of trade, specimen packaging and shipping. And this is because there's been a lot of discussion in various forums about packaging and shipping of COVID-19 specimens. And DOT was gracious enough to participate in the call this week, to help us understand what they believe is the most appropriate. Stuart?

STUART STRCK: Good afternoon. A lot of what we're going to discuss today is based on inquiries posed to CDC throughout the clinical laboratory folks who've just-- there's a lot of confusion going around about how to ship this stuff nationwide. And I want to try and help inform and maybe debunk a couple of things that would help ease the transportation as we're dealing with this COVID-19. Next slide.

So one of the first things that we need to do is define what is the materials of trade, or MOTs as we'll discuss-- as we'll call it the rest of the day today. So the definition for the materials of trade is actually a three part definition. For the purpose to protect health and safety of the motor vehicle and/or passenger. So in that sense, it's safety equipment, fire extinguishers for example, which are a 2.2 gas.

But if transported for the safety of the vehicle, we don't require people to have hazardous materials declarations for that. We give them the materials of trade exception. For the purposes of supporting the operation and/or maintenance of the motor vehicle or its auxiliary equipment, so maybe a couple extra fuel cans for the lawnmowers if you've got a lawn service, extra you know, a can of WD-40, that sort of thing we give an exception to.

And then the last one is, and I've got it highlighted, by our private motor carrier, including vehicles operated by a rail carrier, in direct support of a principal business that is other than transportation by motor vehicle. So materials of trade excludes your common carriers. So we're not sending hazardous materials and using a MOTs exception if we're using some of the common carriers throughout the United States.

Most often, this is applied to labs at a university transporting materials from one building to another. A lot of places have a central collection point at major facilities for regulated medical

waste. And so being able to transport that on a company vehicle to get the hazardous materials where they need to be, but it's not for transportation, it's for the continuance of that business or that service that's being provided. Next slide.

So one of the biggest questions that I got that we've been discussing back and forth, is we want to use MOTs vs. category B because of training. Now, what I have on the screen are the exact sentences when it comes to training for both MOTs and category B. And as you can see, they're almost identical. With most state laboratories, a lot of times not only are they handling category B, but they're also handling category A.

In that sense, because you're handling category A, that's where you get the four-prong training – the general awareness, the function-specific, the safety, the security awareness. That's where that long DOT class that everybody just absolutely loves, that's where that comes into play. So if you're also shipping category B, you get lumped into that training.

However, for the 49 strictly with category B, it's each person who offers and transports Category B infectious substances under the provision, must know the requirements of this section. Now, full disclosure, in this section, you do need to know how to ship category B if it's a liquid, the packaging requirements if it's a liquid. If it's a solid, the packaging requirements for solids.

If you're going to be-- if you have any sort of preservative that is going to be with your samples, you need to know about the provisions for preservatives. But also shipping with dry ice, there's also packaging requirements and as far as following the manufacturer's closure instructions. So the training may not be as healthy as a category A training. However, there are still requirements to make sure that that hazardous material is being transported safely in commerce.

Now materials of trade, it's very similar. The operator, typically it's the operator of the vehicle is going to be the one who has to bear the most training, because they need to know what they have. They also need to know how to restrain it in the vehicle, how it needs to be placed in the vehicle. There's marking requirements. There are packaging requirements.

So again, it's not so much different than category B shipping. So saying that MOTs is a lot different than category B training, not necessarily so. Next slide, please. So packaging requirements for category B, of course, this is not for Category A. But it is a combination packaging. Now, you'll see in the next slide, but don't change the slide just yet, it is a combination package. MOTs also require a combination package.

However, for category B, it's a triple packaging consisting of a primary receptacle, which is going to be your vial or whatever is containing the sputum or the nasal swab. A secondary package, and inside that secondary package you'll have cushioning and you will have absorbent material to absorb whatever contents may leak out of the primary receptacle. And then the outer package, there is a requirement for a rigid package.

So we're looking for a box of some sort or some packaging that has rigid sides. Now, the absorbent and cushioning material, again, we want to absorb the materials that may leak out of the primary receptacle and I believe the language we use is, must be able to absorb the entire contents. The cushioning material is twofold. We want to make sure that it protects the receptacle, the primary receptacle. But we also want to make sure that the outer package doesn't become compromised by the packaging on the inside.

The marking on the outside of the package is very similar. Except for category B, we require the marking of the UN ID number, which is going to be UN 3373 in a square on point. Plus, the proper shipping name, which is biological substance, category B. Similar to MOTs, there is that communication requirement on the outside of the package.

When we start getting into air crash shipments, because again we could go by many modes, it does have packaging requirements for a 95 KPA for aircraft shipments. And that can either be the primary receptacle, or it could be the secondary receptacle that actually has that 95 KPA capacity to ensure that it's not going to leak when pressure changes due to altitude. Next slide.

Packaging requirements for MOTs. Again, this is not a category A. It is a combination package with an inner and an outer. The liquids require a leak-proof inner with enough absorbent material to absorb the entire contents. So that has not changed from category B. And then the packaging's must be leak-tight for liquids and gases and sift through for solids to securely close, secured against shifting, and protect against damage.

So we want to, again, ensure that the hazardous material remains inside the package, does not compromise the package in any way by leaking and affecting the structural integrity of the fiberboard box if that's what we're using as a rigid outer. So ultimately, the goal is to keep the hazardous material in the packaging. And then, for a non-bulk packaging other than a cylinder, it must be marked with a common name or proper shipping name to identify the material on the inside.

Essentially, we want to prepare for the inevitable. If for some reason the shipment becomes compromised in any way due to an accident of nobody's fault, but first responders need to be able to respond and be able to readily identify packages that may be of concern to the transportation system. So they need to be able to identify easily what they may potentially be encountering. Next slide.

Now, we do have a Hazardous Materials Information Center. Granted, that this presentation was pretty well tailored to just very specific questions that have been asked, but the 49 CFR covers a lot. And we don't have enough time to cover everything. If for some reason that there is a question, you can continue to contact your CDC counterparts.

But I do invite you to contact your Hazardous Materials Information Center. 1-800-467-4922. Or you can email your question to Info Center, that's infocenter@dot.gov. Now, their operation hours are from 9:00 to 5:00 Eastern Standard Time. And they're able to answer your hazardous

materials questions. One of the things that they typically don't do is tell you how to ship your package. But they will try to give you enough information for you to make an informed decision on how to best prepare your packaging for transportation and do it safely. So at that, I will turn it over.

JASMINE CHAITRAM: Thank you so much, Stuart. In the interest of time, because we are over, I am going to skip the biosafety update, our intent really was to make this the biosafety update packaging and shipping, I do have a couple of questions for Bill. But we do answer those questions as they come in, and we will be updating our biosafety FAQs on the CDC website. So the information will be available there.

Just really quickly, reminders to everyone before we end the call, that the transcript and the slides for today's call can be found at cdc.gov/safelabs. If you go to Tools and Resources, you can find it there. Also, the next call will be on Monday, April 20th at same time. So we will see you then. And that concludes today's call. Thank you.