

# Clinical Laboratory COVID-19 Response Call

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## Panelists

**Jasmine Chaitram**, CDC Division of Laboratory Systems

**Lyle Petersen**, CDC Emergency Response Task Force

**Sara Brenner**, U.S. Food and Drug Administration

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

**Jody Hooper**, Johns Hopkins University

**Reynolds (Ren) Salerno**, CDC Division of Laboratory Systems

**JASMINE CHAITRAM:** Hi, everyone. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. And we're going to start today's Clinical Laboratory COVID-19 Response Call. I think this is the 14th call that we've posted. We've now moved to having calls every other week. So thank you, again, for joining us.

I'm showing the agenda for today. Before we start off with our first speaker, I do want to give you a couple of reminders, like I usually do. First, a little bit about the Division of Laboratory Systems. We are focused on work that advances laboratory quality and safety, data repository science, informatics, and training and workforce competency across the US clinical and public health laboratories. We also work closely with these laboratories for preparedness and emergency response.

Since the beginning of the COVID-19 response, the Division of Laboratory Systems has been serving as an interface between the Emergency Operations Center here at CDC and with the clinical and public health laboratory community.

And a couple of other things that I wanted to talk about-- let me move my slides forward. OK, so as I mentioned already, we're moving to every other week. And so our next call will be on Monday, July 20. And also, note that the calls are now an hour long, instead of 45 minutes.

Also, we have links in the slide sets that we show, and this is information that's either in reference previously or new information that might be helpful to all of you. And as a reminder, we post the slides, the transcript, and the audio for all of our calls under [cdc.gov/SafeLabs](https://www.cdc.gov/SafeLabs), and Tools and Resources. So you can go there if you wanted to find any of these links, as well as any of the other information in the slides.

And we also, in the past, have done surveys. And I think we skipped the last two calls doing a survey, and so we're going to probably move to doing surveys once a month. And we do appreciate the feedback that you give us.

So please take some time to [complete the survey](#). It's very short. And we use the information to help us with forming the agenda for future calls.

We also are interested in hearing any information you have about training and workforce development needs. And we have a separate email box for that. So this is the email address where you can send your suggestions and needs—[LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov).

Then, finally, I always review how to ask a question. On the Zoom features there, there's a Q&A button. And if you type your question into the Q&A box and then submit it, we can see that live. We do try our best to answer all of the questions. We have taken a few questions live, and we answer those. We also can have our speakers or any of our panelists respond to questions that are being submitted.

If your question is not answered during the call, we do go back and review them, and try to provide a response. Or we use the question to help guide future agenda items. So please keep on submitting those questions. They are very helpful to us as far as understanding what your needs are and what your concerns are.

And then also for media questions, please remember to contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov). And if you're a patient, please direct your questions to your health care provider.

And with all of that, I think that-- oh, I guess, one more thing. One other way to submit information to us-- questions or inquiries that you might have, suggestions for these calls, is at [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov).

All right, now we are ready to go to our first speaker today. It's going to be Dr. Lyle Petersen. He is serving on the CDC Emergency Response Task Force. And he's going to be giving us an update on CDC's serology guidance. Dr. Petersen?

**LYLE PETERSEN:** Yes. So good afternoon. So as you recall, we posted our serology guidance on May 23, and in that guidance, there was a quote that said, "definitive data are lacking, and it remains uncertain whether individuals with antibodies, neutralizing or total, are protected against reinfection with SARS-CoV-2. And if so, what concentration of antibodies is needed to confer protection?"

So that guidance basically assumed that we could not make any statement or any guidelines based on some assumption about immunity. And as such, we made recommendations that there should be no change in clinical practice based on a positive antibody test. They shouldn't be used to make decisions about grouping persons residing or being admitted to congregate settings. And serologic test results should not be used to make decisions about returning persons to the workplace.

However, since then, more epi lab animal data are available that suggests that at least, there is some degree of short-term immunity. The existing guidance-- also, another point-- the existing guidance also gave some examples of the predictive value positive assuming a 95% specificity, which surprised me. But maybe I shouldn't have been surprised that there was some press following this. The press honed in on the fact that well, if you're testing a population with 5% prevalence, your predictive value positive is only going to be 50%.

But obviously, since then, there's been a lot more data on the FDA with an increasing number of EUA tests-- EUA authorized tests with specificities of 99.5% or greater. There are no slides on this.

So suggesting that some of these tests are reporting 100% specificities so our current change for changing the guidelines is the easy thing to do-- and which we will do shortly-- is that we'll give an example of a predictive value positive of an assay with a higher specificity, let's say, 99.5% or greater. So that's an easy fix to the guidance.

The not so easy fix to the guidance is, how do we change the guidance based on some assumption of immunity? And right now, of course, we have incomplete knowledge. The only real complete knowledge that's going to come is the follow-up of cohorts of people over long periods of time showing that they don't transmit to others or they don't get re-infected. Obviously, we want to make some kind of recommendation before that time. But given what we know, or don't know, can we identify some low risk situations where we would feel comfortable with making recommendations with limited knowledge about the durability of antibody?

So I've drafted some possible scenarios that have low risk situations where an antibody testing might be useful if we make some assumption about short-term immunity. And an example of this could be somebody who's seropositive, who is exposed to somebody with COVID infection. And do you need to quarantine that person for the recommended quarantine period? And this is a fairly common scenario that happens out in the states, which is a pretty low risk situation, I would think.

So I had an initial meeting with APHL and CSTE regarding some of these options for changing the guidance based on some assumptions about short-term immunity. They came back and said, well, we want to review what CDC knows now before any further consideration of changing guidance. So that initial meeting with CSTE and APHL is tomorrow. And after that discussion, we will revisit the issue of changing the guidance.

So that's where we're at right now. And I think I can take any questions that you may have.

**JASMINE CHAITRAM:** Thank you very much, Dr. Petersen. Right now, I'm not seeing any questions. Here's one. It just says when will CDC guidelines be updated in writing to reflect the information that you're sharing verbally?

**LYLE PETERSEN:** Well, I--

**JASMINE CHAITRAM:** You have any idea on when?

**LYLE PETERSEN:** Well, the guidance on adding the example for change for the predictive value of the assay, I think, can probably happen in the next week or two, possibly sooner. The guidance change on the assumption of immunity is going to be a longer-term process. I think, a lot will depend on the discussion I have with APHL and CSTE tomorrow. But if there are some-- so I think that process is going to take a number of weeks to play itself out.

**JASMINE CHAITRAM:** Right OK, the next question is if there is a change in the guidance, how will CDC publicize it? And I'll just go ahead and answer that for the clinical labs on this call. When there's a update to the guidance, we usually send out a Laboratory Outreach Communication Systems—that's LOCS-- email message to all of our professional lab organization partners and those that are on our distribution list to receive emails directly. So you should receive the communication through one of those channels.

And if you are not signed up or you're not receiving those LOCS messages, please send an email to [LOCS@cdc.gov](mailto:LOCS@cdc.gov).

OK, the next question, Dr. Petersen, it's a question about the letter that was sent-- ACLA letter that was sent to the CDC director, Dr. Redfield, regarding serology guidance. And just the general question about it being reviewed. And a comment that there are several specific clinical scenarios that should be considered.

And so, I can also just comment that CDC has received that letter, and we've reviewed it, and we are considering that as we develop and update the guidance. I don't know if you want to add more.

**LYLE PETERSEN:** Yeah, so I did read the letter. And when I was drafting some possible changes to the guidance to be presented to APHL and CSTE for their input, I did take into consideration those scenarios that were presented in the letter. Over.

**JASMINE CHAITRAM:** Thank you. And another question is, what will be defined as a short-term immunity?

**LYLE PETERSEN:** Well, I think-- that's a question that we still need to figure out. And it's actually, a more complicated question than you might imagine. Or maybe you are imagining it.

Certainly, we have pretty good data up to about 90 days. Obviously, the epidemic has not been here longer than 90 days or not much longer-- maybe longer-- but there's just not a lot of data after 90 days, even coming out of places like China. So that period is yet to be determined-- how the short-term immunity is defined. It's one of the questions that I'm posing to APHL and CSTE after they review the data we present to them. So that's a good question.

The other more complicating factor of this is, what do you do with people who are antibody positive? You don't know when they were infected. Asymptomatically infected people who now have an antibody response-- that's a little bit more complicated situation.

But very pertinent to a question like, do you require quarantine of somebody who's antibody positive who's been exposed to somebody with COVID? So it's an important question and one that should be further addressed. Over.

**JASMINE CHAITRAM:** OK, thank you. And then another question is just a clarification, you mentioned a meeting tomorrow. And I think they're asking, you mentioned to APHL and CSTE. So APHL stands for the Association of Public Health Laboratories and CSTE stands for the Council of State and Territorial Epidemiologists.

And I believe that is it for questions for you Dr. Petersen. Thank you so much for joining us today and providing that update.

**LYLE PETERSEN:** OK, thanks.

**JASMINE CHAITRAM:** OK, next up on our agenda is Drs Sara Brenner and Tim Stenzel from the US Food and Drug Administration. They've, pretty much, I think, been a regular on every single call we've had so far. So they will give us our FDA update. Thank you.

**TIM STENZEL:** Thank you, Jasmine. I have four relatively brief updates. One for diagnostic tests-- the differences between surveillance screening and diagnostic testing. That's a frequently asked question update. That was last week.

Also, an update to the molecular templates, having to do with pooling. I summarize those updates. Also, a little blurb about multi-analyte testing as we head into the normal respiratory season in the fall. And finally, a letter to clinical lab staff and health care providers about the BD assay on the BD MAX that just was posted just a few minutes ago.

So first on surveillance. So there's been a lot of questions about what surveillance is so we've updated our frequently asked questions page with this. And surveillance, at a high level, includes ongoing systematic activities including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice. It is generally used to monitor for an occurrence, such as an outbreak or to characterize a disease once detected.

To cut to the chase, though, whereas population-based testing can be done and FDA does not generally regulate this surveillance testing, anytime that a patient-specific result is to be reported by a facility, it must first obtain a CLIA certificate and meet all requirements to perform testing for the emergency, which would include EUA authorization.

So surveillance testing is fine at the population and pooled level, but not at the individual level, unless you have a CLIA certificate and an EUA authorized assay.

Screening is basically, looking at the individual level, whether pooled or not, even if there's no individual reason to suspect infection. And you do want-- if you find positive and negative and for the negatives, that you report the results back in. And again, that should be done in a CLIA lab within an EUA authorized test.

And then, finally, diagnostic tests is pretty straightforward. Patients suspected of having COVID-- and that's a fairly broad category including individuals who have a recent exposure, individuals at a high risk group such as health care providers with no exposure, or testing to determine resolution of an infection. And then, of course, in the clearly diagnostic category and that, again, should be performed at a CLIA lab, with a CLIA certificate, and meeting all the requirements on testing, including EUA authorization.

Moving onto pooling, we provide some recommendations on pooling validation. And it does require an EUA or EUA amendment. Once a developer, whether a lab or a kit manufacturer, has validated pooling with their test, they can simply notify the FDA, and then begin testing after they've validated. And then they can continue to test. And have 15 business days to submit the data for FDA review. And all the while the FDA is reviewing the data, the lab and/or the developer can promote the pooling.

Of course, if we have any concerns upon our initial review, we would reach out and talk to the developer to address those concerns. But we offer the same quick access to the market with this validation.

There are, of course, multiple details in the templates about our recommendations for how to validate. But at a high level, if you have an existing EUA test, we're asking that 20 unique positive patient samples be used in the validation of the pool. And that you consider the normal distribution of positivity in your lab or with your test and validate to that. So you don't just put very strong positives into the pools. But you also show the appropriate number of weak positives.

And that you have an overall acceptable performance that if you are developing a new assay, you can use the same 30 positives that you had used for your clinical validation in the pooling validation, as well. So that makes it more straightforward when you're developing a new test. We're expecting to come out with more details and performance expectations, but since pooling is relatively new and we haven't reviewed a lot of data, we're awaiting some of that data review to inform what our expectations are going to be.

Next topic is on multi-analyte testing. So this is testing where you don't just test for SARS, but you develop a test that also tests for other respiratory viruses, such as flu A and flu B. We welcome those tests as we approach the respiratory season so that there is efficiency in testing. Now, obviously, many, if not most, of the patients will have overlapping symptoms or concerns

for not only SARS, but other respiratory viruses. And so instead of setting those patients up with multiple different assays, using precious time and resources and personnel to do that testing, it's more efficient to do that testing all at once. So we do encourage multi-analyte testing.

If you're interested in developing such a test, approach us via the EUA templates email address. And we will have more details forthcoming in a template update in the near future.

And finally, I wanted to alert you to a letter that was just distributed to labs and health care providers, having to do with the BD test on the BD MAX system. There are two tests that are authorized for the BD MAX, and I'm only talking about the BD test.

It has been observed that approximately 3%-- that's just 3% of the results were false positive results. So the FDA is recommending that you consider any positive result presumptively positive for tests using this assay. And consider confirming with an alternate authorized test.

Also, we ask that you report any issues using this test to the FDA. And you can go to our FAQ website for different ways of reporting that information. You can also report that to the company. We are working closely with a company to resolve this issue. We expect that we will be able to resolve this issue. And as soon as that resolution is available and validated, you can expect further communication.

And with that, I don't believe Sarah has anything today, Jasmine. And turn it back to you.

**JASMINE CHAITRAM:** OK, I'll just make a comment that there were several folks in the chat box that had difficulty hearing you, Tim. And so, to all of those folks that had trouble-- as I mentioned at the beginning the call, we will post the transcript. The transcript is usually up by Thursday or Friday of the same week of the call. So you can always go back and reference the transcript if you need clarification or want to hear or read, rather, what Tim said.

So we did get a couple of questions.

**TIM STENZEL:** Yeah, go ahead.

**JASMINE CHAITRAM:** Go ahead.

**TIM STENZEL:** Did you have trouble hearing me, Jasmine?

**JASMINE CHAITRAM:** It was OK on my end. But a few folks just messaged us, and said they had some trouble.

**TIM STENZEL:** All right. Go ahead.

**JASMINE CHAITRAM:** OK, so the first question is, what is the difference between a CLIA-certified high-complexity lab using the CDC primers and probes and developing their own method, this

would require submission to FDA for EUA and the same lab using the CDC primers and modifying the test to run on different equipment or with different reagents, and does not require a EUA submission? So I think they're just looking for clarification on when an EUA submission is required.

**TIM STENZEL:** Right. So if you copy the CDC assay and you buy your own primers and probes, that does require an EUA submission versus if you buy one from one of the vendors that sells an authorized version of the CDC assay that's covered under their EUA authorization, an EUA is not required. It's only if you develop your own version of the CDC assay.

If you make a modification to an existing EUA assay, whether it be the CDCs or another, for the allowed modifications that are mentioned in our guidance and on the FDA website, the EUA amendment is not required. Obviously, it's required for home collection or home testing. It is now also required for pooling and claims about asymptomatic testing.

So those are the exceptions. We will always welcome an EUA amendment for any modifications if you want to get an EUA authorization for that change. So hopefully that clarifies those two situations.

**JASMINE CHAITRAM:** Thank you. The next question is, which FDA EUA methods are approved for screening asymptomatic individuals without known COVID-19 contact in a university or school setting?

**TIM STENZEL:** So to date, we have not authorized a test that specifically can claim that they can test and detect asymptomatic individuals. However, all EUA authorized tests are prescription only. And if there is a prescription for a test, if that individual happens to be asymptomatic, our FAQ website information asks that the labs perform testing on that physician-ordered or clinician-ordered test, and report out the results. That is absolutely OK to do. And we are, obviously, working with a number of developers who want to make the established claim that they can detect asymptomatic individuals.

**JASMINE CHAITRAM:** Thank you very much, Tim. Because of time, I'm going to move to the next speaker. But thank you for being on the call every week, and for answering questions.

**TIM STENZEL:** You're welcome.

**JASMINE CHAITRAM:** Our next speaker is Dr. Jody Hooper from the Johns Hopkins University. And she's going to be talking about biosafety for autopsies. And I think she's also going to be touching on pathophysiology. Dr. Hooper.

**JODY HOOPER:** Muted here. There we go. So very briefly today, thank you for having me on the call. Can you hear me?

**JASMINE CHAITRAM:** Yes, I can.

**JODY HOOPER:** Very good. So I'm the director of autopsy at Johns Hopkins and run the research autopsy program. On my first slide here on the right figure that you see, this is from one COVID autopsy that we did. This is skeletal muscle from the shoulder. And in A and B, you can actually see some degeneration of the fibers. And we were, indeed, able to demonstrate viral particles on electron microscopy, which you can see in D and E. We've done 25 COVID autopsies, and have done EM on a good many of those.

Next slide, please.

So just to touch briefly on the public recommendations, I don't actually have the initial OSHA recommendations because they've been modified. But they were, shall we say, unfortunate. What you do see there is a paraphrase of something that was put out at a major university basically using the OSHA recommendations as a reason not to do COVID autopsies. And this happened in a lot of places.

In a lot of places, the autopsy services were closed down altogether because of the COVID situation. This was really unfortunate, and a loss of an opportunity for learning.

I just put some of the CDC recommendations about performing COVID autopsies down there for your reference. Of course, doing this under airborne precautions in a negative pressure room. Limiting the number of personnel working there. Possibly using a biosafety cabinet for small specimens. And then trying to avoid the use of an oscillating saw, including for brain and spinal cord removal. And you'll see in a few moments, how we've addressed that at Hopkins.

Next slide, please.

So my good colleague, Alex Williamson, at Northwell created an autopsy listserv that has been very illuminating. And did a survey on that listserv to see who was performing autopsies and how many. And so out of 62 respondents, as you can see, just over half of the institutions were doing COVID autopsies. Most under some kind of restricted protocol. And they had various reasons for doing that.

And then he and Greg Davis subsequently published a paper in Archives, looking at transmission at autopsies. So they had looked at 225 autopsies across 14 US states. 102 of those actually did have brain removal under various conditions. And only one person developed COVID.

This was very early in the epidemic. And it was felt to be a community exposure, rather than something from the case. And the other 12 people who worked on that autopsy service did not develop COVID.

There are really no well-documented reports of transmission. There was one report out of Thailand, but that had a lot of needed facts missing, I think.

Next slide, please.

So I think trying to do COVID autopsy practice really rests on four pillars-- and I lost my animation there. That's too bad. One, of course, is the clinical needs. And I think we, as physicians, have those, perhaps, at the top of our minds even more than our staff do. What does the case need, what do our patients need to get a good diagnosis and to help with research?

Published guidelines is another one of those pillars, of course, as well as personal safety.

I've taken a very collaborative approach to physician and staff comfort with COVID cases because it's such an extraordinary situation. So rather than trying to dictate, we're just going to do this on the service, now we've done a lot of discussion. And we've done some modification. Not all of which is based on pure logic and reason, in order to bring people along in their comfort levels.

This does mean that, in some cases, we might have done less than, perhaps I, as a physician and a researcher, wanted to do. But it does mean that now I have staff, in particular, who are happy, and collaborative, and not burned out. And who have advanced what they're doing over time as they became more comfortable.

Next slide. So, and again, my animation was going to reveal this gradually. So I apologize for the fullness of this slide.

But there were initially PPE concerns at Hopkins, as there were in many places. There was a question of whether the hospital was going to take all of our PAPR respirators away-- for example-- and they did take some of them. Whether we were going to get to keep our N95s. But we were able to get through that happily, thanks to the support of our Chair, among other things.

We are still conserving. So we're reusing, pretty much, all PPE that is not soiled to try to conserve. Still have some issues with ordering.

At Hopkins, we used to accept a certain number of private autopsies, but we're not currently accepting outside of system cases. Again, to conserve the PPE and the strain on the workflow.

We triage all patients by their history and by their nasopharyngeal swab results. And thanks to our microbiology department here, we are able to test if we have a patient, for example, who arrived in the ED and did not have testing. And they've put us on the stat list so we can get results in a couple of hours.

Currently, all autopsies, negative and positive, are done in our negative pressure room. Although, I am hoping to advance that so that our patients who screen negative by testing and history can be done in our main room, but we're not doing that, yet.

Institutions have all different ways that they've been doing the autopsies. I think our method actually cuts a middle road between a full autopsy, which some places do, especially in these offices, and just in situ biopsy sampling. So we remove all of the chest organs, as we would in a normal autopsy. And we do in situ sampling of the rest of the organs.

And when I say in situ, if an entire organ is easy to get like the spleen or the right kidney, then I'm taking that entire organ. But I'm using in situ techniques. For bowel, for example, we're tying off sections, and taking them out. And this, again, is a middle ground between diagnostic means to the case and the risk to staff and physicians.

We have not been doing brains until recently because we're not using the oscillating saw at all. So we're using a rib lopper on the ribs. We're not taking spinal cord, even in negative cases, unless it's clinically warranted.

But recently, we've begun working with Dr. Matt Stewart, an HENT surgeon, who was initially just taking mastoid samples from the temporal region, and then, actually, used a method using hand tools to get the entire calvarium off. So the last few cases that we've done, we've actually gotten the entire brain without using the saw.

Some places are using a stream of water over the saw. Some places are using just a plastic bag over the saw, similar to a CJD case. I, myself, was not really comfortable with those methods. We have a vacuum shroud on order, but it's been many months, and it hasn't arrived, yet.

We have always inflated the lungs with formalin, typically. And the literature says 24 hours or so would be sufficient to inactivate the virus. We're letting the tissues fix for 48 hours, just to be cautious about it. We were initially sectioning all organs in our negative pressure room. Now we're still sectioning the lungs there because they're not entirely fixed, but the other small pieces that we're taking in situ can be sectioned under a hood with PPE.

I think a key part of this also is that even though it's unsettling to everybody, change and adaptation is unavoidable in this kind of situation. We've had shifts in what we thought was going to happen with PPE, with what our personnel was comfortable with. And so we've actually gone from having only two pathology attendings do COVID positive cases to just recently, we had our first resident be in. And our staff are in these cases now. So it's important to realize that it's going to be a changing situation, and adapt to it.

Next slide, please.

So that was really what I had on the biosafety. And I don't know how time is getting on, did you want to take questions on that part? Or shall I just whip through some of the findings?

**JASMINE CHAITRAM:** We actually are not showing any questions right now. So you can go ahead and keep going.

**JODY HOOPER:** OK, great. So this is really just a bare touch on some of the findings we've had. What you're seeing here are some fixed lung slices. The one on the left is from a patient with a shorter duration of disease, and the one on the right, a longer duration. But they're very typical.

The lungs have been weighing about three to four times normal, often. And we see these tan firm areas of consolidation, such as you see in the upper lobes of both of this lung slides that you see.

And then we have a trachea in the middle that's been opened up posteriorly, we often see erythema and some erosions in the trachea. Not always necessarily associated with intubation. I think there's a certain amount of inflammation associated with the disease itself.

Next slide.

Just some quick microscopy on one of our patients here. So I can't point it out, but we're looking at the alveolar spaces in the lung. And many of these have fibrous tissue inside of them. There's one down towards the center right that you can see the pink of the collagen in the nuclei of the fibroblasts and hyaline membranes.

And the literature shows that the typical changes are those-- in pathology, we would say diffuse alveolar damage and clinically, we would say ARDS. But this is accompanied by acute pneumonia only some of the time. It's not a very neutrophilic disorder.

And on the right, you can see, again, electron microscopy, where we were able to demonstrate that viral particles and endothelial and epithelium.

Next slide.

Just interesting findings-- I know there's a lot of talk about thrombosis in their literature. We've seen gross thrombosis in only two cases out of the 25 that we've done. We have seen microthrombi in eight cases out of 19. We've got some histology still pending. But only in the lungs. We have not seen them elsewhere. We have not seen them in the heart.

We've seen myocarditis in just a single patient, and that was a pediatric patient, age 15, who did appear to have an inflammatory syndrome and had vasculitis.

We have not found any pathologic findings that correlate to the abdominal pain. I know there's a lot of interest in this, and a lot of interest in whether there is virus in the GI tract. Of course, we're battling the degeneration of the mucosa at autopsy, but we have not seen inflammation changes. And we've done electron microscopy on bowel, and have not demonstrated viral particles there.

The picture there is one woman that we had who did have abdominal symptoms, but she turned out to have an umbilical hernia-- a transverse colon trapped in the hernia. So that may have had more to do with her abdominal symptoms than her COVID.

Next slide, please.

Along this line, I think distinctions that are important to make are patients who die of their COVID and patients who die with their COVID. And I think there's been a tendency, especially in the state statistics, to lump everybody together. If they had COVID, then we put that on the death certificate, and that's what they died of.

But what we've seen and what we know is that there is death from COVID itself and most often, acute lung injury or acute kidney injury and failure. There's death from exacerbation of existing disease, and, pretty well, all of the patients that we've seen have some other major comorbid illness, with obesity being very frequent.

Two cases that we had-- the first case that we did, I think, was a clear death from an acute MI, but likely the exacerbation from COVID helped cause that. And a case that we saw of unsuspected sickle cell disease. And that's probably why the person died, as opposed to their literal COVID infection.

And then we certainly have patients that we've seen with COVID infection who've died of other diseases altogether, and who'd not show the characteristic lung findings. I think it's important not to forget those folks as we think about national statistics.

And I think the next one is my last slide.

We are working with many research groups at Hopkins. Each case that we do, we're sampling from multiple different groups who are working on everything from endothelial damage to inflammatory cells. This is an important moment to remember that autopsy, post-mortem examination can play a tremendous role in the elucidation of disease. And I hope that you will all take this home and encourage the practice of autopsy in your places. If you're clinicians, ask the families of deceased patients if they want an autopsy if it's offered at your hospital because it really can contribute a tremendous amount.

And I thank you so much. I think that was the last slide. And I'd be happy to take any other questions.

**JASMINE CHAITRAM:** Thank you so much for that great presentation. There was one question that came through, asking about if the presentation of COVID is similar to Dressler's syndrome. And if the pleura and pericardium are affected.

**JODY HOOPER:** We have not seen pericardial inflammation, except in that one case that I cited. And, again, the inflammatory, there isn't that much inflammation in the lungs, either. There's

damage, but we don't even see particularly lymphoplasmacytic inflammation in most of the patients. A few of them do show an acute pneumonia with neutrophils, and some of our researchers are wondering if that is super infection-- which I would have assumed as an autopsist-- or if that represents another stage of the endothelial damage. I don't think we know the answer to that, yet.

**JASMINE CHAITRAM:** Great. And sorry, I've got one more question for you. Hang on, I'm just looking for it. OK, how would you treat the transportation of formalin fixed tissue samples, including the lungs-- for example-- for inter-institutional collaboration?

**JODY HOOPER:** Yeah, so we've had a lot of talks with our biosafety about that. And they are not putting restrictions on the transportation and use of formalin fixed tissue. Again, I make sure it's thoroughly formalin fixed. So, for example, transferring across labs, we're free to do that. So I have not yet transported specimens outside of the institution, but I'm assuming that the rules would be the same. The virus is inactivated by that formalin, and it would be safe to transport.

**JASMINE CHAITRAM:** Great. And have you found evidence of direct viral infections in the kidney?

**JODY HOOPER:** Yes, we have. In multiple cases, we've been able to demonstrate it there.

**JASMINE CHAITRAM:** Next question is on the electron microscopic slides, are you able to see the virus?

**JODY HOOPER:** Yes. And actually, if you go-- we had two examples of it in the presentation, where we can see the particles and the spikes. We've demonstrated it in kidney, lymph nodes, skeletal muscle, lung. I think those are the main places we've been able to demonstrate it.

**JASMINE CHAITRAM:** OK, for known COVID positive specimens, should large resection specimen samples be grossed, then fixed, or fixed, then grossed?

**JODY HOOPER:** So are we talking more about autopsy or surgicals?

**JASMINE CHAITRAM:** I'm not sure. That's how the question came through.

**JODY HOOPER:** We are fixing-- we inflate and fix the lungs before sectioning, which was always the practice. I think is doubly important with COVID. When it comes to the heart, I also typically section and fix that because that's my normal practice. But we're certainly manipulating and cutting fresh organs in the suite. And I think we're relying on good practice and our proper PPE, as we always do, for infectious cases.

So I wouldn't-- so I guess, for us, we haven't really changed what we're fixing for manipulation because that's what we always did. But I would certainly say, I want to limit that manipulation to what is really necessary for diagnosis.

**JASMINE CHAITRAM:** OK, and would you expand on the identification of virus in skeletal muscle, and if or how it might relate to pathophysiology.

**JODY HOOPER:** It is interesting, and we've actually written a case study for that one-- which we haven't got accepted yet, but we're still working on it. Because it's provocative in the sense that patients have those mialgias and you wonder about that. This particular case did have a few microthrombi in the muscle and had a little inflammation, but not very much.

It's interesting because it almost parallels what we see in the lungs, in that we have damage and virus, but not so much inflammation. I find myself wondering, is that because of a very direct effect that the virus itself has on the endothelium? Or is it something else? I might need even better scientists than I to answer that question, but it's interesting.

**JASMINE CHAITRAM:** OK, and last question, are you finding an abundance of eosinophils in any of the tissues?

**JODY HOOPER:** No, we are not. Again, we haven't found an abundance of inflammation anywhere. And in the one myocarditis case, there were some eosinophils, but there were also lymphocytes and plasma cells.

**JASMINE CHAITRAM:** OK. Well, thank you so much for joining us today and taking the time to develop this presentation and answer all those questions.

**JODY HOOPER:** Thank you.

**JASMINE CHAITRAM:** Our last speaker for today will be Dr. Ren Salerno from the CDC Division of Laboratory Systems. And he's going to be talking about COVID-19 safety in the laboratory environment.

And apologies for not mentioning this earlier, that Dr. Petersen from CDC did not have any slides. Dr. Ren Salerno also does not have any slides. I maybe show a slide or two with some biosafety links that we've shown previously. But other than that, there are no slides. Dr. Salerno.

**REN SALERNO:** Jasmine, can you hear me?

**JASMINE CHAITRAM:** Yes. Sounds good.

**REN SALERNO:** OK, great. Thanks so much. Good afternoon, everybody.

Yes, apologies for no slides, but I'm talking today about guidance that was cleared through our system just earlier today. And so we didn't have the opportunity to prepare any clear slides. And I'm going to talk about [guidance](#) that should go up on our CDC COVID laboratory website within the next 24 hours.

And we've received a large number of questions on this call, as well as through other venues to address general laboratory safety practices in addition to what we've tried to focus on during the pandemic, which has been biosafety. So we've tried to provide a lot of biosafety guidance, specifically for clinical laboratory testing for COVID-19. And what I'd like to talk about today is more general guidance that will sound fairly similar to probably, lots of guidance that public health officials have been promoting.

There are four sections to this guidance that will appear on our website in the next 24 hours. The first section is a general section, which talks about the importance of risk assessments. Again, now risk assessments for the general facility. So considering such specific issues as how many people are in that laboratory space and in the office spaces associated with a laboratory on a regular basis. And how do those numbers compare with the ability to maintain safe social distancing?

Assessing the flow of personnel traffic throughout the general laboratory facility. And wherever possible, design one-way pass for staff to walk through the laboratory space, as well as the accompanying offices and administrative spaces.

A specific assessment of procedures for cleaning and sanitizing commonly shared equipment in areas. So not just focusing on the instrumentation that would be used for testing, but also the frequency of use of certain counters, bench tops, and desks to determine whether or not they deserve additional cleaning attention.

And also, really a focus on what do emergency communication and operational plans look like? And, in particular, is there documentation for the facility on protecting staff at higher risk for severe illness from COVID-19?

So the other thing our guidance says in the general section is a recommendation that every institution should have a COVID-19 health and safety plan. And we describe a number of pieces that we think would be important to be in such a health and safety plan.

How do you handle if an employee feels sick? Have you instructed employees to stay home and not return to work? If they are sick, at what point may they return to work after having been sick? Do you have flexible sick leave and supportive policies and practices? Do you need to implement emergency sick leave policies? Has someone been designated to responding to employee's COVID-19 concerns, specifically? And does training need to be reinforced for proper handwashing and routine infection control precautions?

So that's really the general section. Then the social distancing section focuses on recommendations for facilities to consider adjusting staff schedules, adding additional shifts, or implementing non-overlapping teams to minimize personnel contact. Also consideration of identifying laboratory tasks and activities that can be performed with reduced or no face-to-face interactions. And using video and phone conferencing services and tools as often as possible, even for work that might occur within the same location or building.

The other thing that's mentioned in this section is a recommendation to consider to the extent possible, reconfiguring workspaces and locations where there's shared equipment to specific reduce crowding. Again, creating one directional pass in workflows, decluttering workspaces, and disposing of all unnecessary items to help with that reconfiguration.

And if reconfiguration is not possible and the space is either cluttered or crowded, consideration for placing barriers such as plexiglass partition or plastic between computer workstations, desks, or equipment to help ensure that staff are rarely ever within 6 feet of each other, if that can be achieved.

We also recommend to do everything possible to reduce personnel traffic by limiting visits from vendors and other external partners, as well as engaging those partners remotely or virtually whenever possible.

The face coverings section is a recommendation to wear cloth face coverings in settings where social distancing measures are challenging, such as office spaces, computer workstations, and break rooms. But a recognition that those sorts of face coverings are not disposable face masks or respirators. And they're not appropriate substitutes when risk assessments or work procedures recommend or require an employee to wear respiratory personal protective equipment.

But we do include in this guidance, a recommendation that laboratory employees should wear a face covering in laboratory spaces that do not have requirements for respiratory PPE and where other social distancing measures are difficult to maintain. So we've heard many reports of facilities where there isn't a strong guidance or policy for face coverings outside of the limited laboratory spaces that require respiratory PPE. And we'd like to try to encourage organizations to develop such a policy for the use of face coverings whenever and wherever there are not requirements for respiratory PPE and where social distancing measures are hard to maintain.

We recognize that we also want to recommend that any facial protection that's worn in a laboratory area where personnel work with potentially infectious material should not be worn outside of that laboratory area. And so there need to be procedures in place to ensure that whatever kind of facial protection that you're using within a laboratory area that's working with potentially infectious material, you have a way of doffing that material inside-- that mask or that face covering inside the laboratory before leaving the laboratory and leaving the facility. And we reinforce that risk assessments are going to be important parts of an organization determining what their facial covering policy should be.

And then, quickly, the last section of the guidance is around personal hygiene and disinfection. And we hope this is just a reinforcement of what is already happening in all clinical laboratories. But recognizing that extra measures may be needed to ensure a clean and appropriate environment. And so we want to encourage all laboratory leadership to review protocols for cleaning, use of personal protective equipment, and handwashing. And focus on those high

touch locations and equipment that have a high frequency of handling and contact because those areas would present a higher probability of potential contamination. And therefore should be disinfected, perhaps, more frequently than prior to COVID-19.

We want to encourage laboratories to increase the number of available cleaning supplies, and distribute them throughout the laboratory and general work environment to encourage more frequent cleaning of surfaces and equipment. We encourage, in this guidance, the use of more visual reminders and posters in common areas, restrooms, as well as throughout the facility to emphasize the importance of hand hygiene and encourage frequent handwashing. And then we give some more specifics around handwashing or the use of alcohol-based hand sanitizers.

So that's a very quick summary of our general safety guidance for laboratories and their facilities. Again, we hope to publish that guidance on our CDC website within the next 24 hours. That's it for me, Jasmine.

**JASMINE CHAITRAM:** Thanks, Ren. The only question that we got was about whether or not the guidance would be published, and where it would be. So you already answered that. So thank you for that. And thank you for providing that guidance and those recommendations.

I think we've only got a couple of minutes left. So I think I'm going to go ahead and wrap up today's call. I wanted to remind everybody that we are having calls now every two weeks. So the next call, as I mentioned before, will be on Monday, July 20.

And if you haven't already signed up for messages from the Division of Laboratory Systems through LOCS, please send an email to [LOCS@cdc.gov](mailto:LOCS@cdc.gov). Inquiries and questions can be submitted to [DLSInquiries@cdc.gov](mailto:DLSInquiries@cdc.gov). You can send it to any one of these emails. We'll get it, and we'll do our best to respond to it.

Thank you, again, to everybody, for joining us this afternoon. Thank you to our presenters for taking time to provide those updates and presentations. And the information will be posted by the end of the week at [cdc.gov/safelabs](https://cdc.gov/safelabs) under Tools and Resources. Thanks, again, for all that you're doing. Stay safe.