Clinical Laboratory COVID-19 Response Call

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Panelists

Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
Sara Brenner, U.S. Food and Drug Administration (FDA)
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Liron Pantanowitz, Director of Anatomic Pathology, The University of Michigan
Richard M. Scanlan, Chair, College of American Pathologists (CAP) Council on Accreditation
Sarah Shirey-Losso, Centers for Medicare and Medicaid Services (CMS)

JASMINE CHAITRAM: Hi, everyone. Thank you for joining the Clinical Laboratory COVID-19 Response Call. This is our 11th call hosted by the Division of Laboratory Systems. I'm Jasmine Chaitram, the host and Associate Director for Laboratory Preparedness in the Division of Laboratory Systems.

Our division is responsible for focusing on advancing laboratory quality and safety, data and biorepository science, informatics and workforce competency across the clinical laboratory community. We also work on preparedness and response issues with public health and clinical laboratories, and have been serving as an interface between those laboratories and the CDC Emergency Operations Center.

As I mentioned, this is our 11th call, and we do post the minutes and the transcripts for all of these calls on cdc.gov/~~,~~Safe Labs, under Resources and Tools. So if you missed something during the presentations, you can always go back and look there. Or if you are interested in copying over one of the links that we provide, you can find it on our website.

And with that, we're going to start off. I'm showing the agenda. And some other information I have for you-- as I mentioned, we provide important links to information such as the interim guidance for collecting, handling, and testing specimens. The LIVD tool that we recently posted can also be found on this page as well as a link to the CDC Laboratory Outreach Communication System, where all of our messages that we've sent by email through the system have been archived.

For the last four weeks, we've been asking for you to share your feedback, and we do appreciate all of the information that has been provided so far. It's been really good to understand your needs and to understand that these calls have been helpful to all of you. And so we are going to do the survey again this week. This may be the last time, though, to give us

your feedback, so please go to the link and fill out the survey. It should only take about five minutes.

We also want to hear from you on your training and workforce development needs. And you can do that by submitting an email to LabTrainingNeeds@cdc.gov. ~~the Lab Training Needs at cdc.gov.~~ That's shown on this slide.

And finally, to ask a question, please use the Q&A button in the Zoom webinar system. We get a number of questions during these calls. We do try our best to answer them. We try to take a few questions while on the call. And if we're not able to get to those, we will try to answer them in the week following the Zoom call. And sometimes, if we're not able to do either one of those, we try to address the question in a future agenda item.

So you can submit your questions through this mechanism. You can also submit your suggestions for topics for future calls through this mechanism. We do review all of the questions that we receive. And if your questions are associated with the media somehow, please submit those to Media@cdc.gov. ~~at cdc.gov.~~

And with that, I think we're ready for our very first speaker. It will be Jason Hall from the Division of Preparedness and Emerging Infections. And Jason has been working on the Data and Analytics Task Force in the CDC Emergency Operations Center, and has been working specifically on reporting data to state health departments and CDC. And so he's going to give us an update on reporting and the CARES Act. Jason?

JASON HALL: Thanks, Jasmine. Thanks for the opportunity to speak with everyone again today. So last Thursday, HHS announced new guidance that specifies what additional data must be reported to comply with the CARES Act, Section 18115. The CARES Act requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case on COVID-19 to report the results from each such test to the Secretary of HHS.

The guidance released last Thursday outlines the requirements for data submission under the law. Importantly, in an effort to receive these data in the most efficient and effective manner, the secretary is requiring that all data be reported through existing public health data reporting methods.

So as a guiding principle with this, that means that the data should be sent to the state, and, in some cases, large local health departments, using existing reporting channels for other reportable conditions in accordance with state laws, and policies, and regulations. This will ensure the rapid initiation of case investigations by those departments, because these data are sent to them for action-- and concurrent to laboratory results being shared with the ordering provider for the patients, of course, as appropriate.

The guidance specifies that all laboratories-- and once again, for the CARES Act, this updated guidance that came out last week also clarifies what is meant by laboratories. So it's basically all testing entities, such as laboratories. It could be pharmacies. It could be the drive-throughs. There are so many places that these tests are being executed now.

So, broadly, laboratories and testing entities should report data for all testing completed for each individual tested within 24 hours of their results being known or determined to the appropriate state or local public health departments, based on an individual's residence.

It provides-- the guidance does three options for data submission-- directly to state or the large local public health departments using either HL7 messaging or a standardized flat file or CSV file-- second, as appropriate and where it's going to be made available, through a centralized platform, such as the Association of Public Health Laboratories AIMS cloud platform, where those data can then be routed, essentially, to all of the different states, but to each appropriate state. And then third, it can be delivered through existing state HIEs (Health Information Exchanges), that will then send the data to the appropriate state or large local health department.

But those are the three that were laid out in those-- once again, are three that are in use, to some extent, right now as the existing reporting channels. Through these mechanisms, the states would then be able to report these data, de-identified, to CDC to satisfy the requirement to report to HHS. So the guidance that lays out now prioritizes reporting to states. And from that point forward, they will report to CDC in order to fulfill the requirement of the law to give the data to HHS.

So we've heard questions about how to address the reporting of demographic information required as part of the CARES Act and in the guidance. We know that, in many cases, the information is not provided in the testing orders. So a lot of you all on the phone, we understand that you all aren't the ones interfacing with the patients, often. And so you're not the first point of data collection to gather those data.

We're going to be reaching out to make sure that everybody that's involved in the testing-- because the guidance lays out that, from order all the way through to reporting, these data need to be collected and then propagated along the chain. So we understand that you all aren't always in control of what's put on the orders.

But being able to receive those data now on the orders and being able to consume them, extending your interfaces with your orders or extending your database fields, and being able to store and propagate those data is what's going to be, I guess, chief among your responsibilities under the updated guidance.

So we're going to work to provide messaging to the health care providers who might order these tests and let them know that they're part of the responsibility of this to provide the

important demographic information however it is-- whatever mechanism they use to order the tests from you all.

So the guidance, once again, states that any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test should make every reasonable effort to collect complete demographic information, and should include such data when ordering that test to enable the entities performing the test to report them to state and local health departments. So the guidance is meant to cover every point in the chain-- not just the laboratories, but those that are ordering from them as well.

And additionally, the guidance states that, when information is not available, ordering health care providers or their designees' laboratories performing SARS-CoV-2 and associated tests, and the state public health departments, should try to leverage other resources, like the HIEs or some information networks, to get the missing data.

This is a lot of what states do right now. When they don't receive, they have to do follow-ups. That's why they need, like, the doctor's information so they can call up the offices and try to get the additional data. But this is just an admonition that, continue to try to obtain those data. And it's not meant to be a new burden. It's just acknowledging the existing one and trying to put out some ideas for helping to automate this to the extent possible.

So we'll continue to provide more information as we have it available, including some FAQs. And with that quick synopsis, I'm available for questions, Jasmine.

JASMINE CHAITRAM: Thank you, Jason. And we did have a number of questions come through. And I'm going to give them to you, but I'm going to ask you to try to be brief at the answers so that we can get through them.

JASON HALL: OK.

JASMINE CHAITRAM: All right. So does the testing-- the reporting requirements cover positives only or all test results?

JASON HALL: The guidance states all testing.

JASMINE CHAITRAM: Thank you. And another question. Is it the testing lab or the ordering lab that is responsible for reporting?

JASON HALL: So in all states, the performing lab, the testing lab, is expected to report. It's often that-- when a test is referenced out to another-- that, if it's a laboratory that referenced it out to another one, but the order was placed within, that they'll feel the need to report, too.

There are a number of states that have laws and regs that compel dual reporting, because this also goes back to the order as well, where they expect the doctor or the hospital-- the clinical

facility-- to report the findings that they receive back from the performing facility. So it's going to be based on the regs. But the testing facility definitely should be reporting, and it's going to be up to state regs as to whether other dual reporting is expected.

JASMINE CHAITRAM: OK. Can you comment-- does this mean that there is no longer a need to report to HHS directly?

JASON HALL: So for hospitals that are currently uploading their aggregates there, this reporting through the states, after they've finished their onboarding with the line-level data that includes your data-- it should preclude the need to upload those files. But until we're all-- have signed off on the fact that you've sent it-- they've sent it to CDC, and thus made available to HHS-- the secretary would still want people to upload those files until it's all been verified.

JASMINE CHAITRAM: Great. Thank you, Jason. I'm going to move to the next speaker so that we can have all of our speakers have time to talk. But thank you for joining us today.

JASON HALL: Sure.

JASMINE CHAITRAM: And the other questions, I'll share with you so we can keep them for the FAQs.

JASON HALL: Thanks.

JASMINE CHAITRAM: Thank you. And I forgot to mention that Jason didn't have any slides, so sorry about that. We're moving to our next speaker. This will be an update from the US Food and Drug Administration-- Tim Stenzel and Sara Brenner. And FDA also does not have a lot of slides. I have two slides with some links, so I'll be sharing those as they are speaking. Tim, do you want to go ahead?

TIM STENZEL: Sure, Jasmine. Can you hear me OK?

JASMINE CHAITRAM: Yeah, you sound good.

TIM STENZEL: All right. Great. And those slides with the links are helpful, because I'll be referring to them. So we're going through questions that have been received. And one-- is an EUA required for home collection if you are using an assay that has already received EUA approval? Yes, an EUA is required for home collection, and also for home testing.

Next question. Where can it be found about the stability studies for the Quantigen Biosciences for saline and dry swabs that have a right-to-reference opportunity? So Quantigen Biosciences has provided a right of reference to their data that can be leveraged by other EUA sponsors. And this has to do mainly with stability data with saline as a transport media with swabs or dry swabs. That entity owns the data, and the FDA cannot provide the specific data. Although, we

can use the data, using the right of reference, in authorizing additional sponsors that want to do home collection.

Can you please confirm if an EUA is required for saliva, is voluntary or not? So saliva can be added without an EUA by laboratories when it is a modification to an already-authorized EUA. The addition of saliva can be validated per recommendations in the guidance and in the template. Manufacturers are required to seek EUA authorization for saliva. So again, labs can validate and do not require an EUA. We're happy to look at it, though, for an EUA, if they wish.

EUAs are-- let's see. The next question is, what happens to the FDA's lab testing or authorizations-- EUAs-- when the emergency ends and expires? EUA are in effect until or unless they are revoked and the determination is terminated. And that's made by the Secretary. This is not likely to happen anytime soon. But when it does-- a long time, potentially, from now-- it would require FDA submissions in the order of either a de novo for the first one or 510(k)s for the follow-up. But this is unlikely to happen anytime soon. And only one previous emergency has ever been revoked, to our knowledge.

This person is confused by the statement that submitting an EUA from an individual lab is voluntary. If we plan to develop an LDT, is the submission of the data voluntary? I thought it was required. Yes, let me clarify. If a lab develops their own diagnostic LDT, they are required to submit an EUA. They can notify us and submit that within 15 business days of when they have certified that they have validated their assay, and then we'll review it.

If they modify an EUA-authorized diagnostic test-- so this is a modification to an EUA test-- and validate per our guidance and templates, they can offer that under the policy and the guidance without an EUA. This does not apply to new sample types, though-- only those that are mentioned. Serology LDTs may also be offered under the policy and the guidance without an EUA. So serology LDTs do not require an EUA, but they are encouraged.

Next, the May 20th FDA guidance document for at-home self-collection devices indicates the device should include and must have a specimen control, such as a testing of a gene. And this is a requirement because we want to make sure that, in the home collection, or away from a health care setting and not collected or under the direct observation of a health care professional, that the collection is adequate.

There was a question about one of the devices that we've authorized. Those devices have one or more different controls that ensure an adequate specimen collection in the unobserved situation. And there's flexibility in how that occurs. One of the best ways to do it is to have a control reaction. But there are other ways to ensure that a specimen is adequately collected.

Next question. Does self-collection at a work site under telehealth health care provider observation require EUA review? EUA-authorized assays, where self-collection is directly observed in-person by a health care provider, does not require an EUA to perform that. Telemedicine, however, in particular, has had some issues in our reviews, and we have seen

them in applications. And therefore, indirect or telehealth observation via technology does still require an EUA authorization before testing is started. So telehealth collection via telehealth does require EUA authorization.

Next question. Why are we contemplating saliva if fecal is even more reliable than nasopharyngeal? We are not aware of data that shows that fecal testing is more reliable than traditional upper respiratory sample types. Please submit data to us if there are studies. I don't believe we've authorized any other-- even prior to emergency situations-- any other respiratory virus to use a fecal sample.

However, if performance matches that of nasal cavity swabs, we would like to see the data. And of course, any new sample type would require an EUA authorization. So come discuss with us directly through our template's email address, if that's something that you want.

So then there's a couple of questions having to do with serology and low prevalence population in our calculator. So our calculator is on our serology EUA FDA performance page. Also on that page are the listed performances of a number of-- of all the serology assays we've authorized. That's another question. So we've listed sensitivity and specificity, as well as PPV and NPV for a 5% prevalence population.

And there's a question about, what is low prevalence? I think low prevalence is relative to the assay and the performance of the assay that you are looking at. And you can use the calculator to show what your PPV and NPV is. And this in particular a positive predictive value of what it means. We recommend that if your PPV is not high enough, that you use a secondary serology assay of a different type to confirm a positive result.

Next question has to do with pooling samples for molecular tests. So if you're using an EUA-authorized assay, the question is, can you pool? The FDA is preparing recommendations for validation. And labs certainly can validate as long as performance is good and labeling is updated with cautions. Look forward to our recommendations. They should be coming out relatively soon.

The caveat with pooling is that it's almost a certainty that if you pool samples, you will miss one or more-- if you have any sort of volume of this pooling-- one or more low positive samples that cannot be caught by pooling. And so labeling should reflect that.

The last set of questions have to do with serology tests again-- mainly, if the FDA has removed a serology test, what should labs do if they still have that test? Reach out to the template email address at the FDA for further discussion with our team. It's difficult and probably not wise to provide comprehensive recommendations on what to do in this situation. Our team has specific knowledge about, perhaps, all of the tests, and so we can provide some recommendations from that point of view.

And finally, if PCR wanes in sensitivity the further you go from symptoms, can we use IgM for the acute phase? Use of IgM or IgG serology for an aid in diagnosis is allowed. However, it should not be used as a sole measure for diagnosis. And if you want to supplement other information with serology, and you want to have reasonable certainty of a positive result, we do recommend a second high-performing serology test be performed.

And with that, Jasmine, that's the end of my prepared responses to the questions. And if there's time, or if there's other questions, I'm happy to try to address them.

JASMINE CHAITRAM: Thank you very much, Tim. I think you answered a lot of questions for us today. And with that, I'm going to move to the next speakers to allow for enough time for us to complete our agenda. We always seem to have that issue. But thank you so much for being on the call and for answering the questions.

Our next speaker is Liron Pantanowitz. He is the Director of Anatomic Pathology at the University of Michigan, and he's going to be talking about COVID-19 and cytology laboratories. Dr. Pantanowitz?

LIRON PANTANOWITZ: Hi, everyone. Yes, I know this slide says-- you can see that I am transitioning. This is my last week on service here. So I would like to inform participants on today's call about the impact of COVID on cytology labs. And if you can move to the next slide, the key issues that impact cytology services in labs are, number one, specimen volume.

During this time, the specimen volume has dropped precipitously, mostly the Pap tests and the fluids. F&A has dropped slightly, but not that much. These are our less-invasive procedures. And so when a patient requires a workup, this is preferable to taking them to the OR or more extensive surgery.

Number two-- cytology samples. Most cytology labs were practicing universal precautions, but there were concerns and questions that arose. What should be done in addition now for exposure to coronavirus, which I'll mention? Pathologists and cytology services are often asked to go on-site to evaluate specimens, and there was concern and anxiety at this time whether that service should be offered. And if so, how do you handle that? Trying to be conservative for using PPE.

During this time, it was recommended that pathologists that perform F&As should try and suspend that service, especially for elective F&As, unless it's urgent. With the suspension of care, it was recommended that staff could work from home. So for example, cytotechnologists could screen cases from home. Fortunately, the volume was low, so many labs did not do that. But it also meant that pathologists could work from home, for example, with telecytology.

And finally, there were staffing concerns in cytology labs around the country. Number one-- physical distancing. How do you apply that when cytotechs have to sit close together and screen slides? Number two, there were shortages too-- schools closing and so on-- to handle

those services, and there was a lot of anxiety. And fortunately, with the volume dropping, there was enough time to communicate with staff.

If you can go to the next slide, the American Society of Cytopathology, myself and some colleagues-- we sent a survey around the country-- and you can see we had responses from most of the states-- to basically tell us what they were doing, what their concerns were, and where they needed help.

And if you can go to the next slide, we'll see that one of the things that came up was that most of the labs in the US saw more than a 2/3 reduction in cytology samples. And this gave people a buffer to work on making modifications and also address issues, such as changing protocols and so forth.

And if you go to the next slide, one of the major concerns were, how do you handle cytology samples that come into your lab? There was very helpful guidance from documents by the CDC. So kudos to the CDC for putting those out early. And they were helpful for even cytology labs to extrapolate. CAP also provided helpful documentation. And there was very helpful email traffic on various listservs, such as the American Society of Cytopathology.

One of the recommendations was, check the COVID status of every patient, every time, in every sample. And that's very difficult. It's OK when you're on-site and you can look up in the EMR, but many of the orders coming to cytology labs through the electronic medical record do not include the COVID status. So it's very time-consuming for cytology labs to check that, although that is a recommendation.

The other recommendation was to make sure that any cyto preparation-- preparing slides, samples, et cetera-- that that now happened under a Class II biosafety cabinet. Do not do cytospins, for example, where you're centrifuging with the risk of aerosolizing samples. You can see the picture on the right. If you need to centrifuge, get a small centrifuge that easily fits under the hood-- is a recommendation.

A lot of labs use liquid-based cytology, and the vendors were contacted. What's their recommendation? Because there was concern that these instruments would aerosolize samples around the lab. These vendors did not have the virus to actually work with and test on their instruments.

And so the recommendation was, if you can avoid many labs using these liquid-based specimens, that would be ideal. Try and centralize so that you only have one single person-- one cytotechnologist-- working with that. And then you can limit your PPE and provide an N95 mask to that person. And so that's what many people did.

If you can go to the next slide, there was still a requirement for people to go on site and perform rapid on-site evaluations. And so for some cytology services, there was no way to opt

out of ROSE. And therefore, if cytotechnologists were going on site, it was certainly appropriate to make sure that they had adequate PPE.

And if you practiced in a center that had sufficient N95 masks, that would be ideal. Initially, at my center-- initially, we did not have N95 masks for everyone, but we included cytotechs, especially if they're going into a high-risk procedure, such as a bronchoscopy lab, where there's a specimen risk of aerosolization. Then it's appropriate for them to wear an N95 mask.

One of the other recommendations that quickly went out around the country was, try not to make air-dried slides with the risk of aerosolization of this material. Try and fix that immediately, at least in anything above 95% alcohol. Most labs did 95% ethanol, which is not standard practice for most labs, because it does alter the morphology. And I'll show you two examples.

You can go to the next slide. On the left is an FNA of a normal lung. And you can see that's the normal procedure where you air-dry the sample. And you can see these bronchial epithelial cells-- on the left, normally. On the right, when you practice, now, in the COVID era, and you fix immediately in ethanol, it makes the cells a little bit darker, harder to interpret.

If you go to the next slide-- and so the impact this has is, on the left is a lung cancer non-small cell carcinoma stained the traditional air-dried rate. You can see the blood is exposed or visible, and the specimen is not overly dark.

On the right-- now, in the COVID era, we don't air-dry anything. We fix it immediately in ethanol, and it's much darker. And what we have found is, those labs that practice telecytology from a distance, with the compounding of the monitor making things darker-- it's a little bit more challenging for cytopathologists to make these calls on site. But it's certainly safer for the people on site, so that's now the current standard of practice.

And then, finally, my last slide-- if you can show that-- is, there is a recommendation to use telecytology. That's if the technology is validated. We're not saying people must use smart phones or iPads if this technology is not being validated in a safe manner.

If you are able to have a cytotechnologist go on site, they can certainly then use a camera to stream the image to a pathologist. If you do not have a cytotechnologist or someone skilled to show the slide, then it's appropriate to have an instrument that can perform a robotic microscopy. And there are labs currently doing that now, both ways.

Fortunately, with the CLIA suspension, pathologists were permitted to work from home. And as you can see on the picture on the bottom right, one of my colleagues doing telecytology from home-- perfectly safe, well validated, and we're able to maintain continuity of care. Whole slide scanners today are not really designed for cytopathology to make primary diagnoses. They're not FDA cleared for that purpose, either.

However, there is a recommendation that, if you do need a second read or a quick opinion, or you need someone to do a QA review on a slide, you can certainly scan it. And there are not too many, but there are some labs out there that are using this option so that we don't have to bring too many people close together and maintain physical distancing.

And so that concludes my brief talk on impact of COVID on cytology labs. Thank you.

JASMINE CHAITRAM: Thank you. We did get a couple of questions. The first one, while you were speaking-- the first one regarding cytocentrifugation of specimens in the hood. Is this required for cytocentrifuges that have a secondary container that can be brought into the hood to be opened?

LIRON PANTANOWITZ: That's a good question. I don't know the detail for that. But certainly, it's better that, if you cannot move your centrifuge machine under the hood, that yes, take the secondary container and open that under the hood. But we do recommend that, if you're working outside the hood, obviously, to be aware that there is a risk of aerosolization. And appropriate PPE is then recommended.

JASMINE CHAITRAM: OK. And the other question-- is there a need to perform a verification when fixing smears in ethanol as opposed to air drying?

LIRON PANTANOWITZ: I would say yes. At my center, we did that. We did a brief-- I wouldn't say verification, but we did a brief validation study just to compare air-dried versus the fixed to make sure that your pathologist reading these slides remotely are able to do so and not compromise care. Plus, we documented that in the event of a future CAP inspection. So the answer to your question is, yes, it's recommended to validate prior to using that switch in protocol.

JASMINE CHAITRAM: Dr. Pantanowitz, thank you so much for joining us today and giving us this great presentation. Appreciate your time.

LIRON PANTANOWITZ: You're welcome.

JASMINE CHAITRAM: Our next speaker is from the College of American Pathologists, Dr. Mick Scanlan. He is the chair of the CAP Council on Accreditation, and he'll be talking about the CAP Laboratory Accreditation. He's giving an update. Dr.--

MICK SCANLAN: Thank you.

JASMINE CHAITRAM: --Scanlan?

MICK SCANLAN: Thank you, Jasmine. I've been an avid listener of these calls for the last 10 calls, and it's an honor to give an update to everyone on the CAP Laboratory Accreditation Program. Next slide.

We were going to discuss two topics today-- the status of CAP inspections and accreditation, and secondly to present the findings of a survey of CAP-accredited laboratories about COVID testing. First, the status of the CAP inspections and accreditation. We suspended all routine inspections in mid-March. We're resuming on-site inspections this month. We're piloting a few inspections and anticipate doing more in July.

Currently, we are rescheduling suspended inspections. We're organizing and reorganizing the inspections teams to minimize error and interstate travel to keep the infection risk down. We're also looking at a hybrid inspection model where we would combine virtual and on-site inspections to reduce team size. We are giving prior notification to the inspected laboratories.

So in this transition period, inspections will be announced for now. We do this so that we don't get into trouble with local institutional inhibitions about travel. We, of course, are communicating with CMS. The details of what we're going to do are still being ironed out, but this is our current working model. During this time, impacted laboratories remain accredited, so there is no concern about continuing accreditation. Next slide.

In late April, CAP surveyed accredited laboratories about COVID testing, and this slide provides the key takeaways from our data. The first takeaway is that there is no question that both pathologists and laboratory professionals are under substantial amounts of pressure. We surveyed CAP clinical laboratory directors, and 434 responded.

We were looking at things such as the rate of COVID-19 testing, barriers to expanding testing, and the impact of the COVID crisis on pathologists and laboratory professionals. The survey confirmed that the clinical laboratories were expanding testing at the time of the survey. Over 60% of laboratory directors reported difficulties in obtaining critical supplies needed to conduct COVID-19 testing. Next slide.

Drilling down a little bit on this data-- 59% of responding CAP laboratories were providing on-site COVID-19 testing of the time of survey, and another 9% reported that they expected to have testing up in the next two to four weeks. And this, again, was from late April.

Most laboratory directors reported that they have substantial excess capacity for providing COVID-19 testing. Many of them have two or three independent methods for COVID testing to ensure that they have a continuous supply of testing. Respondents at that time expected their COVID-19 testing to increase by about 40% over the next two weeks. And I think, from my personal experience, that's exactly what we saw. Next slide.

The impediments to testing reported by the laboratory directors included shortages of equipment and supplies, particularly test kits, swabs, and transport media-- 69% test kits, 66% swabs, and 62% shortage of transport media. All laboratories reported substantial losses in revenues and financial stress, but few had applied for federal assistance program. Laboratory work forces face substantial stresses, regardless of whether the laboratory has provided COVID-19 testing.

We'll start with the laboratory workforce issues first. The top issues reported by the laboratory directors among pathologists were reduced work hours, 72%, reductions in pay, 41%, increased burnout, 21%, and increased work hours in 20%. Next slide. Among the non-pathologists, laboratory professionals reported problems with reduced work hours, 69%, reduced staff capacity, 36%, and temporarily furloughed people in 34%. And burnout, again, was at 31%.

The financial stresses have been touched on by Dr. Pantanowitz, but were confirmed in this report, where we reported a median drop of 69% in AP testing and 46% in CP testing, regardless of whether the lab was doing COVID testing or not. Average and median laboratory revenue had decreased by about 50% among all respondents, regardless of whether they were doing COVID testing. This financial strain adds substantial stress to the laboratory pathologists and professional staff. While there are federal assistance programs that could help laboratories, only slightly more than half of laboratory directors were aware of these, and relatively few had sought assistance or received benefits. Next slide.

This last slide is the list of resources available on the CAP website. You don't have to be a CAP member. You'll land on the original cap.org site, and you can download survey findings that I just discussed or watch a town hall where this was presented. You can stay up to date with what's happening with CAP inspections. This is going to be a rapidly-moving target, and we'll keep the website updated so you can tell what's going on.

There's a Q&A on COVID-19. We have a CAP statement on current role of serologic testing. We have guidance to ensure the availability of reliable testing for rapid detection of COVID-19. We also discuss best practices for implementing SARS-CoV-2 tests in your laboratory if you're still on that part of the curve, best practices for using biological safety cabinets while testing for COVID. And we will also have material on there about the CAP proficiency testing for both detection of SARS-CoV-2 RNA and antibodies.

CAP has introduced two new proficiency test programs in response to the COVID-19. The first was the molecular method for detecting CoV-2, and the first mailing of that was last month. The second method that we've put out is for detection of SARS-CoV-2 antibodies, and this is scheduled to mail later this month. Program details can be found on the ‘For PT Customers” tab of COVID-19 information page on cap.org. Next slide. Thank you.

JASMINE CHAITRAM: Thank you, Dr. Scanlan. We did get a couple of questions, and I'm going to try to run through them quickly. I know we're running short on time now. But the first question was, you mentioned the CAP inspections will be announced. How many weeks or months out for sending the notification to the lab schedule to be inspected?

MICK SCANLAN: We're looking, at the moment, at about a two-week announcement, which would be consistent with CMS requirements.

JASMINE CHAITRAM: OK. If the state has a pause on any routine surveys, will CAP still conduct the survey?

MICK SCANLAN: Yes.

JASMINE CHAITRAM: OK. And I'm not sure if this question is for you, but it says, how do we find out what federal assistance programs are available to help with financial loss?

MICK SCANLAN: There are links on the CAP website, and also on other federal websites. So I think a good place to start would be the CAP landing page.

JASMINE CHAITRAM: OK, great. Thank you so much. Thank you for the presentation today, and thank you for joining our calls for the last few weeks. I do appreciate the support.

MICK SCANLAN: My pleasure. Thank you.

JASMINE CHAITRAM: Our last speaker for today-- we've gotten a lot of questions over the last couple of weeks about billing, and so we brought back Sarah Shirey-Losso from the Centers for Medicare and Medicaid Services to give us an update on billing, and hopefully answer some of the questions we've received over the last couple of weeks. Sarah?

SARAH SHIREY-LOSSO: Great. Hi. Thank you, everyone. Thank you for having me again. Today, I thought I would just highlight some recent Medicare fee-for-service work we've been doing pursuant to COVID-19. I'll start with talking about specimen collection. If you recall, in the first interim final rule with comment, we developed two codes for laboratories to use when they go collect a specimen from a patient who is homebound, or within a SNF, or in a home health stay. Those codes-- G2023 and G2024. And we set a payment for those.

Most recently, in the second interim final rule with comment, we also created a code to be used in the hospital outpatient setting. This is C9803, and this is to bill for a clinic visit dedicated to specimen collection. We also, in terms of physician offices, said that physicians and offices could also bill with using code 99211 when an office clinical staff furnished an assessment of symptoms and specimen collection incident to the billing professional services.

So those were three recent things that we did in terms of specimen collection. I also wanted to highlight that, last week-- or perhaps it was the week before now-- we posted, on our website, an updated list of pricing by the Medicare administrative contractors. We posted that, actually, on May the 19th. It includes a table of the relevant tests.

And I'll just remind folks that, for Medicare pricing under Medicare fee-for-service, in order to develop national rates, we typically go through an annual laboratory meeting process where any new or revised HCPCS or CPT code comes to the meeting, and recommendations are submitted from the public for crosswalking or gap-fill. And that's the procedure we go through to set a national rate.

When codes are created before the annual meeting, they are priced at the contractor, and that's the Medicare administrative contractor. So currently, the prices available now for U001,

U002, 87635, 86769, and 86328 are all priced at the contractor by the Medicare contractors. And those prices now are available on our website, and I can share the link to that momentarily.

Additionally, as part of our second interim rule with comment, we revised the ordering requirements. We removed the requirement that certain clinical diagnostic lab tests must be ordered by a treating physician or non-physician practitioner. So this will allow any health care professional authorized to do so under state law to order a COVID-19 diagnostic laboratory test. And this actually also includes the serological and the antibody tests.

We have posted a list of codes on our website that do not require an order, at least for Medicare purposes, on our website as well. And I can share that link with you. We also-- I may have spoken about this last time, but we had a CMS ruling for tests performed using high throughput technologies. Medicare set a rate for those tests at $100, and that is through the ruling.

All of the test codes that I mentioned are all going to Medicare's annual laboratory meeting for discussion, which occurs on June 22 this year. This is a fairly iterative process in that, first, tests go to the annual lab meeting. Then later, in July, we have an advisory panel, that we have another-- it'll be a two-day public meeting. And then later on, CMS will post preliminary determinations. In November, we publish final determinations. And then there is a reconsideration process.

I wanted to highlight, as well, we have a number of FAQs, a lot of them billing-related, on our website. This is in the COVID-19 Frequently Asked Questions. These have been updated. They're typically updated weekly. I think we'll be expecting some more updates later this week. But some of the topics highlighted there are billing and coding, specimen collection, the high throughput technologies, and basic Medicare payment policy or lab testing.

So I will stop there. I will have all these links sent out through the CDC. And that's all I have for today. So thank you.

- **Medicare Fee-for-Service (FFS) FAQs** https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
- **Medicare Administrative Contractor (MAC) Pricing** https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf
- **Tests which do not require an order for Medicare** https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf

JASMINE CHAITRAM: Thank you, Sarah. We'd be happy to send out those links. Two quick questions for you. Do you have a code for the antigen testing yet, and would that code be listed on the CMS website?

SARAH SHIREY-LOSSO: So to our knowledge, there is not a CPT code for an antigen test related to COVID-19. Our guidance has been, in the absence of a more specific code, that U0002 is available for billing.

JASMINE CHAITRAM: Great. And the next question is, for emergency room visits due to COVID, if the specimen will be collected, can C9803 collection fee be used?

SARAH SHIREY-LOSSO: Yes. It's for an outpatient. It is available for hospitals under the Outpatient Prospective Payment System, so yes. In some cases, the code would be packaged. The payment is packaged. But the code is available.

JASMINE CHAITRAM: OK. Well, thank you very much for joining us and providing that update. And we are going to close out today's call. Thank you, again, for joining us. Our next call will be on June 15 at 3:00 PM, just like this one. If you are not getting our messages about these calls or the other important information that we've been sharing, please sign up for communications through LOCS. That's the Laboratory Outreach ~~and~~ Communication System. You can send an email to locs@cdc.gov, and we will add you to our distribution list.

Thank you for joining us today and thank you for all that you're doing. And that concludes today's call.