Clinical Laboratory COVID-19 Response Call

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Speaker Panel

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JASMINE CHAITRAM: Hey, everyone. Thanks for joining the Clinical Laboratory COVID-19 Response Call. Sorry for the delay in getting started. We're having our usual technical challenges with hosting a call like this.

I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems at CDC. The Division of Laboratory Systems is responsible for working with the clinical laboratory community on issues such as workforce, competency and training, informatics, data and repository science, and quality and safety.

And today, we will be hosting this call. I'm showing the agenda. We've been working with the Emergency Operations Center at CDC to serve as an integration point for clinical and public health laboratories. We try to take the questions that you send us each week either by email or through the question and answers on the Zoom call and formulate the agenda based on topics we think that are relevant to you. I hope that these are the items that you are hoping to hear about when you tune into these calls.

I'm trying to control my slides. Give me one second. OK, so many of you know this is Lab Week. And today is actually the first day of Medical Laboratory Professionals Week.

And it's interesting that it's happening at this particular point in time. This week is about appreciating clinical and public health laboratory professionals who are on the front lines of the nation's health along with health care workers. And this year more than ever, it's clear that the risks that laboratory professionals are taking to serve patients during the pandemic-- and the measures that you're taking to mitigate the risk to your colleagues, as well as your communities. And we want to celebrate with you in laboratories all around the nation. And we want to also thank you for all that you're doing for this pandemic.

I also wanted to mention that we were successful in getting posted the questions and answers for testing and reporting. There's a lot of good information on these Q&As that are now on the CDC website. And I'm showing the link to the Q&As on this slide.

Please visit these questions, these Q&As. there's a lot of good information, both about testing, ordering supplies, and reporting results. And the questions have been separated into sections that apply to public health laboratories and clinical laboratories.

And again, we've used the information, the questions that you've submitted to us, the emails, to formulate the Q&As to address some of the things that we're seeing being asked by many laboratories pretty often. So we hope you find these helpful.

Reminder, when you want to ask a question, use the Q&A button on the Zoom webinar system. And you can type your question into the Q&A box and submit it there. Please go ahead and submit these questions. And as I mentioned, we will use them to help develop the agenda for future calls.

We are not answering every single question that is asked on these calls, but we do try to make sure that the questions are addressed in some way in the agenda topics that we present. And if there are some one-off questions that are not necessarily related to the agenda, just a need for information, we do try to answer those as quickly as possible. And if you are the media and you have any questions, please address them to media@cdc.gov. And if you're a patient, please address your questions to your health care provider.

And with that, we're going to move into the first agenda item. We took your feedback about moving biosafety up in the agenda. And so our first topic for this week is the laboratory biosafety update from Bill Arndt, who's also from the CDC Division of Laboratory Systems. And this week he's actually going to talk about a few things and, also, a focus on autopsy and anatomic pathology guidance for COVID-19. Bill?

BILL ARNDT: Thanks, Jasmine. So good afternoon, everyone. My name is Bill Arndt. And I am the biosafety program lead in the Division of Laboratory Systems at the CDC. I'm also currently serving as a lead laboratory biosafety SME on the CDC Laboratory Response Task Force.

Today, I will provide an overview of the biosafety risks associated with the practice of surgical pathology and some of the mitigation strategies that may be employed to address these risks. In surgical pathology, the risks begin in the operating room and procedural suite where blood and body fluids can contaminate paper requisitions and the outside surfaces of specimen containers. Pathologists and other clinical staff are accustomed to handling tissues and fluids, but maybe unaware of the presence of potentially infectious materials on the requisitions, as well as specimen containers, as contamination may not be visible. And it may subsequently be handled without Personal Protective Equipment, such as PPE.

Furthermore, non-clinical administrative support staff may be even less familiar with infectious risks and the safe handling practices. Additional risks associated with surgical pathology are correlated with manipulating large amounts of fresh or frozen tissues from patients who could have an unsuspected infectious disease. Potential risks increased substantially in the gross room, where manual specimen handling tissue dissection and the preparation of frozen sections of tissue using a cryostat may result in percutaneous droplet and aerosol exposures from punctures, cuts, splashes of blood, and other body fluids.

Although studies often lack the granularity to identify risks exclusive to pathology, it has been proposed that laboratory staff and pathologists are likely among the higher risk groups of health care professionals. Developing mitigation strategies starts with performing a site specific and activity specific risk assessment to identify and mitigate the risks prior to starting work. Laboratory personnel should follow standard precautions when handling tissue and fluid specimens, all of which may contain unknown or known potentially infectious materials.

Standard precautions include hand hygiene and the use of PPE, such as lab coats, gowns, gloves, and eye protection. Manual processing of fresh, unfixed specimens, including frozen sections, should be conducted in a manner that provides a barrier between the specimen and personnel during specimen manipulation. Examples of these barriers include working in a certified biological safety cabinet, if possible, or using other physical barriers, such as a splash shield and additional PPE, such as mesh cut resistant gloves, plastic aprons, shoe covers, bonnets, surgical masks, N95, respirators, or sleeve or lower leg covers if the risk assessment dictates the need for that.

Use PPE to protect the mucous membranes of the eyes, nose, and mouth during procedures that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions. Select masks, goggles, face shields, and combinations of each according to the risk assessment conducted for each task performed in the possible infectious agents anticipated. When performing droplet and aerosol general procedures, examples of PPE that can be used include a face shield that fully covers the front and sides of the face, a mask with attached eye shield or a mask and goggles in addition to double gloves and gown, surgical scrubs, shoe covers, plastic apron and hair coverings, N95 respirator or face shield, for example, when cutting lung tissue or lymph nodes from a patient who could have tuberculosis or COVID-19.

Additional mitigation strategy may include wearing gloves when handling surgical pathology requisitions, storing requisitions in plastic sleeves until discarded, placing specimen containers in clearly labeled plastic tubes for waste pickup, purchasing a BSC when working with fresh tissue and fluids. And that's kind of all I had for that this week. Jasmine, would you like to address a few of the questions that came in on the previous calls?

JASMINE CHAITRAM: Yes, we do have a few. So the first one is, can blood or urine samples be sent through the pneumatic tube system from a COVID-19 patient?

BILL ARNDT: So due to the risk of exposure to infectious aerosols or droplets, it is not recommended to transport respiratory specimens from patients with suspected or confirmed COVID-19. But at this time, other types of specimens, such as blood and urine are still OK to transport through the pneumatic tube system. It's important to note that facility should ensure that all personnel who transport specimens via the pneumatic tubes are trained in safe handling practices, specimen management, and spill decomp procedures. Next one?

JASMINE CHAITRAM: Thanks, Bill. I got another one for you. Do the same biosafety PPE and isolation testing requirements apply to point of care rapid tests?

BILL ARNDT: Yeah, the same safety practices apply when conducting diagnostic testing of specimens outside of a traditional BSL-2 laboratory, such as the rapid point of care tests. Staff should still treat all specimens as they are potentially infectious and follow standard precautions to provide a barrier between the specimen and personnel during specimen manipulation. However, it's important to note that the final determination of the safety practices selected should be based on the site and activity specific risk assessment to determine if additional biosafety precautions are warranted based on the situational needs. If it's determined that there is a high likelihood to generate aerosols and droplets, additional proportions provide a barrier between specimen and personnel can be used, such as PPE or other physical barriers, like splash shields. Next question?

JASMINE CHAITRAM: OK, thanks. Thank you. Here's another one. Are there any updated recommendations for laboratory staff to protect themselves while performing regular testing, such as CBC chemistries? Should bench techs be wearing masks and eye protection?

BILL ARNDT: Thanks. So currently, all clinical specimens should be handled as potentially infectious, and laboratory personnel should adhere to standard precautions to reduce the risk of personal exposure. Standard precautions, again, include hand hygiene and the use of personal protective equipment, such as lab coats or gowns, gloves, and eye protection. Determining the appropriate type of PPE to wear should be based on a site specific and activity specific risk assessment. And as I said before, if that risk assessment determines there is a high likelihood that aerosols or droplets will be generated, then additional precautions may be needed to provide a barrier between specimen and the personnel. And examples of these additional precautions include BSC, other types of PPE, such as a surgical mask or face shield or other physical barriers like a splash shield.

JASMINE CHAITRAM: OK. And are there special requirements for doing other types of testing on pleural and BAL specimens, like cell counts, that need to be performed in a biosafety level 2 cabinet?

BILL ARNDT: OK. Yeah, so typically the CDC does not have specimen specific handling guidance at this time. However, what I can say is that all clinical specimens should be handled as potentially infectious. And laboratory personnel should adhere to standard precautions to reduce the risk of personal exposure. And again, the standard precautions are the use of PPE,

such as lab coats, gowns, gloves, and eye protection. But, again, final determination should be based on a site specific and activity specific risk assessment. Thank you. I think that's it.

JASMINE CHAITRAM: Thanks. That's it for the questions for you. I do want to say thanks to those folks that are submitting questions to the Q&A function in Zoom right now. We are seeing your questions coming through, but because there are so many and we have limited time we're probably not going to be able to address these questions. But we will incorporate them in our next call in the talking points for biosafety. So thank you for those questions.

We're going to move to our next speaker, who is also going to be talking about anatomic pathology, but more about emergency preparedness and recovery planning. And it's going to be Vinita Parkash from Yale University School of Medicine. Dr. Parkash, are you on?

VINITA PARKASH: I am ready. So happy Lab Week everyone. I know everybody's working really hard. My slides are a little busy. I put a lot of information there, so that you guys could see it. But I'm not going to read the whole thing out.

So as you know, in 2001 after the anthrax and 9/11 events, the government put into effect the Public Health Emergency Preparedness and Response Capabilities Program, which has elements at the federal, state, and local level. And all hospitals are part of the local level response.

And The Joint Commission (TJC) actually requires us all to have mass casualty incident plans. These are at the hospital level. A line item in there is mortuary readiness for mass fatality incidents.

And mortuaries often fall, at least at academic centers, under the pathology domain. But COVID-19 is a never before event. We have not seen this before. The US has never had 50 states, all 50 states, declare an emergency at the same time.

So I'm going to review our readiness plans. And actually we are in the response phase, so I will go over some of that also. Next slide, please.

JASMINE CHAITRAM: OK. And Dr. Parkash, before you move forward, I'm just going to ask you to speak a little bit louder or come a little bit closer to the microphone.

VINITA PARKASH: OK, I'm going to do that. OK, so this is an animated slide basically showing you an emergency management cycle. And for most part, we rest in the preparedness component, which is the two green-- hi, can you hear me?

JASMINE CHAITRAM: Yup, we can hear you.

VINITA PARKASH: But once an emergency is declared-- and I don't know if you hit the return slide, whether the circle will turn, could we try it? No. OK, so basically this is a cycle. And the cycle moves, and so mortuary and autopsy lead the response for anatomic pathology. And once

that is stabilized, then surgical pathology and psychology roll into the picture. Next slide, please.

So our hospital has three mortuaries and three hospitals. We have a capacity of 12 decedent bodies each in two of the hospitals and 27 in a third hospital, which is the flagship hospital. Once we saw what was happening in New York, our director of autopsy and mortuary services who is also a forensic pathologist pulled together a task force to prepare for it. And the goal of our plan was to manage the mass fatalities from COVID while protecting health care workers and supporting our research and education program. Next slide, please.

So this is just an overview of all the things that we did. So first, we assessed our needs, and this was done in light of our values and missions. We did a literature review. Experts were consulted, and front line staff were consulted to put together a plan.

The plan was a scaled stepwise plan. And we determined what we would need for facilities and equipment, what we needed to do for worker safety, who we needed to communicate with, and what processes and procedures to put forward. We also had a monitoring and data management plan.

And right now, we've already implemented the plan. And we have to evaluate and modify it. We're monitoring outcomes and processes. Next slide, please.

So this is just the highlight of some of those things. So facilities and equipment, we realized that we were very quickly going to exceed our capacity.

So we arranged for portable mortuary units, which are refrigerated trucks. We cleared out a parking lot. Security came in and set up cameras so that the PM use could be monitored.

We also conducted drills. The drills were really important, because we realized that the ramps that we had were inadequate for our purposes. So facilities and management helped to create new ramps.

We also communicated upstream and downstream. So there were state and local officials, in particular, the Office of the Chief Medical Examiner DPH who advised us. And downstream, the Funeral Directors Association was particularly helpful, because they were giving us feedback on what their challenges were. And so that kept everything moving. We also reached out to our floor safety managers, who made sure that the decedent bodies were sent to us with all their tubes removed and things like that. So that would reduce risk for our mortuary staff. Next slide, please.

We changed our processes and procedures. And actually the first one, direct to morgue discharge, that was a no-brainer. I have no idea why we needed an emergency to put that into effect, but we do now have that.

So there can be a direct to morgue discharge. This allows us to anticipate what is going to happen and who is coming. The body bags, whence they came in, we do an identification. So the body bags where misted with alcohol or wiped down.

An identification was done, and we created a new label which was glued to the outside of the bag which we didn't use to do previously. And this was to protect our funeral directors, so that they would not have to open the body bags a second time to do identification. The bags are labeled with COVID.

We are hoping that DPH will soon be able to provide us yellow body bags, which will distinguish between the two. And of course, we conducted quite a bit of education and drills both upstream and downstream.

With respect to worker infection control and well-being, the first thing was to eliminate everything that was not needed-- so no students, no trainees, nothing in the autopsy and mortuary area. We got rid of conferences that we had regularly. Then we instituted administrative controls, which is moved seating around. We created schedules, so that we had non-overlapping teams to cover the shifts.

And that all seems to be working very well. We're obviously following all the social distancing recommendations. We actually made all of our staff review PPE requirements.

Because as we all know, even though we've been through that training, unfortunately, there's a lot of decay there. And so we don't always follow through. So everybody had to re-go through PPE training and ensure that hand hygiene was instituted as part of it. Next slide, please.

So with respect to autopsies, we wanted to maintain doing at least some autopsies, because we are an academic institution. But we have had to suspend them, because of the PPE pressures that we face. We are also having a little bit more of a discussion about all of this, because there's been a recent report of a death of a forensic pathologist in Taiwan. And it looks like there was probably postmortem transmission. So that is a concern.

Last night, I was watching 60 Minutes, and there was another mention of a mortuary transporter who has passed away in New York. So it's not definitive evidence, obviously. But we are concerned about it.

So we are moving to a situation where we're going to do a nasal swab potentially on all patients when we resume autopsy services. We are also developing a specific protocol for COVID-19 patients. Again, that's primarily because we're an academic institution and we have a large research community that is interested in exploring and understanding and finding a cure for this situation.

But specifically things that we are not allowing is there is no use of isolating saw and no running of the bowel. Because those are two aerosol generating activities. So that at least is not going to happen.

And we will be releasing our modified protocol. We'll post it on our web page, if necessary. Next slide, please

We can skip this one. Next one, please. We can skip this, too. So now, we're moving into surgical pathology and cytopathology preparedness and response.

So we need to estimate risk for our workers, which is a combination of figuring out what the opportunity for exposure is and what the dose might be, which is related to the volume, the time of exposure, the concentration, and the infectivity. It's important to note here that only 18% of lab associated infections can we find out what the incident exposure was. So all of these precautions have to be taken at all times.

And just historically speaking, it's important to remember that there were three small outbreaks after the SARS outbreak was controlled. And these were lab outbreaks from lab accidents. So we are a high risk population.

So we are in the process of doing a job hazard and safety analysis. We are eliminating, we hope, a significant amount of our exposure, because the hospital is moving to a system where all our patients will undergo a rapid COVID testing before any elective surgeries are done.

That said, the data is that up to 30% of COVID results are false negatives. And it's not clear. So we still need to take precautions.

All small specimens will definitely be coming in formalin. So that sort of obviates some risk. Next slide, please.

This is a slide that I actually put together just yesterday just to display and sort of make people think about our real risk. So at Yale, we have more than 65 ORs. We have three surgical pathology grossing areas, a frozen section area, a very large gross room, and a third room where small specimens are grossed.

Unlike ORs, where there's one surgery going on at one time, one team, and there's room containment with doors closed, we've got 10 stations going at the same time in a very large room. So that's a risk. We do have aerosol generating activities. We cut bones using bone saws. GI specimens are often cleansed using running water.

We clean our scalpels and forceps by swishing them around in water. And frozen section is obviously very high-risk, because that's fresh tissue. It's frozen. And we are facing it often. So there is aerosolization that occurs at that time, also.

I don't know about other people's lab, but at least in our lab there's quite a bit of traffic. And we do not insist on wearing scrubs. So people will come in and out with street clothes. So these are all things that we're looking to change.

Obviously, there's an issue of balancing risk. When is it overkill where we are putting in so many precautions that work can't be done? So we're in the process of analyzing this.

But we have come to the conclusion-- next slide, please-- that there are two very high-risk situations, which is the frozen section and the rapid on site evaluations, that we do for cytology. So with respect to both of these, but primarily for frozen sections, we are moving towards or we're discussing-- we haven't implemented any of this yet-- eliminating all non-necessarily frozen sections. As an academic institution, there's some overuse of frozen sections in our institution.

So we determine that we need to know why the frozen section is being done. There needs to be a very specific question that is being asked. And we evaluate whether the frozen section can actually answer that question to a reasonable certainty, so that action can be taken during surgery.

One can substitute for certain things where possible. We will be encouraging our clinicians to do rapid processing where we can turn around using formalin fixation specimens in a two-hour time period. We are going to be reducing the number of blocks that we freeze and also reducing the number of sections that we take, because this obviously reduces the amount of opportunity for exposure.

We need to modify our work practices. And the cleaning stations, traditionally we have not used sterile disinfecting wipes every time. But we're planning to use them.

And PPE, at least for frozen section, we think that N95 respirators are necessary for the sectioning technicians, because they are at higher risk. And obviously, we're going to be using administrative controls and controlling who is walking in and out of those spaces. And next slide, please.

So I'm going to end with this slide. This is the donning, doffing, and disposal of PPE in surgical pathology. And our concern is that actually the disposal is a specific risk in surgical pathology, because we often have open containers, a lot of soiled swabs. And paper towels are exposed and thrown into containers that stand by our grossing stations. And those probably pose some risk. So we need to think about that.

And the other thing that we're focusing on is at the time of doffing PE, because people tend to think that you've taken off your PPE, throw it in that disposal unit. So we've introduced that first step, which is in pink, which is that the trash can needs to be tamped down before you take off your PPE, so that all the PPE falls into the receptacle as opposed to sticking out and

falling over. Because our PPE, especially the gloves and gowns, are pretty messy coming out. So this is the process that we're using.

We will be sharing all of our publications-- when this is all finalized. My email is fairly easy. It's vinita.parkash@yale.edu. Please feel free to send me an email. And thank you very much.

JASMINE CHAITRAM: Thank you so much. That was a great presentation. We've gotten a lot of questions about anatomic pathology. So I think that was really helpful information. So thank you for taking the time to put that together.

We are going to move to the next speaker. Valerie Ng from the Alameda Health System is going to talk about her experience. And hopefully, we will not have any technical issues. Dr. Ng, are you there?

VALERIE NG: Hello, can you hear me?

JASMINE CHAITRAM: Yes, success.

VALERIE NG: Fabulous. For all on this call, we just spent 40 minutes just so that I could be heard. OK, next slide, please.

I just wanted to lay the groundwork for where I'm speaking from. On the left is a map of the San Francisco Bay Area. The arrows point to three of the hospitals in our health system.

We are in an area where there are 17 other hospitals. So we're a relatively small footprint. However, we are the public health hospital for this county.

The slide on the right shows you, as of April 13th, the number of COVID-19 detected cases. You can see Alameda County is there on the right with 843. The hot zone below us is Santa Clara and San Mateo off to the left. And you can see the distribution of cases in our local area Next slide, please.

OK. To run through the timeline-- and it's a busy graph, but we're going to start. The y-axis is the total number of specimens. And the dates go across on the x-axis.

We'll start on the left. On March 6th, we began testing. And we really restricted it to testing for admitted patients only. The green bars represent not detected, red detected, and blue pending at the time this slide was taken.

On March 13th, the CDC expanded the list of who should be tested. You can see that big jump in the number of specimens. And then the following day, we expanded our testing to include health care workers.

At the time we did that, we ran smack into the national shortage of both swabs and viral transport media. You can see that greatly affected the number of specimens we could collect. We sort of recovered, now, in early April, where we decided we had hit a period of stability. And we expanded our testing to include symptomatic emergency department patients.

On April 12th, we expanded to include the skilled nursing facilities and the unhoused. You can see the next day, on April 13th, we had a whopper number of specimens submitted. At the same time, we ran smack into the national shortage of nasopharyngeal swabs. And you can see the decrease in specimen collections after that was directly related to the short in specimen collection kits. Next slide, please.

Now, how did we do testing? At the very beginning and on the left bottom corner, we started with our local public health lab, the Alameda County Public Health Laboratory. Shortly after that, Quest came live, and we flipped over Quest.

But after three days when Quest became fully inundated and unable to turn results around, we moved back to our partners at the Alameda County Public Health Lab. Specimens were coming in left and right. We looked like Lucy in the Chocolate Factory.

There was a short period there between March 29th and March 30th when the public health lab assay went out of control. So it was me jumping in my car, driving samples from our hospitals up to the state lab. The little map there shows the location of the Public Health Lab. And above that north is the Viral Rickettsial Disease Laboratory up in Richmond.

So I was the courier to drive specimens up and down for those few days followed by the Public Health Lab recovered. So we're back to a short period of stability until we hit March 13th when our specimen numbers vastly exceeded the capacity of our Public Health Lab. And we activated UCSF as backup testing. Next slide, please.

What are the barriers we encountered in this? We recognized early on that our public health colleagues did not have adequate staffing. And we volunteered two pathologists and our lab administrative director as labor, free labor for our Public Health Lab.

But we ran into this barrier that the California regulations state only a public health microbiologist is allowed to work in the Public Health Laboratory. This was overturned on March 30th by our governor, who put out an executive order that waived any of the professional licensing requirements for those parts of the business law that affect laboratories. So while we could have been allowed to work in there, thankfully our public health colleagues found a different way to accommodate the workload. Next slide.

What were the opportunities? Well, I think we and every other lab in this country learned that the just-in-time inventory we all worked on through lean processes over the last two decades is completely incompatible with pandemics. The swabs and the VTM, UTM shortage continue today.

We learn connectivity remains a problem. When we move any test outside of our health system, there's no connectivity. So results come back by fax and have to be manually entered And we learned the usual problems with faxes, folks forgetting to put paper in, toner running out, et cetera.

For our public health colleagues, we convinced them-- it took a little bit of convincing-- but we convinced them that we needed to have testing seven days a week. And they were able to accommodate that a week or two ago and we had to rearrange all of our courier schedules to coordinate everything across the system to get them to the public health laboratory on the day, so that they could start their run. Next slide, please.

What are the other opportunities? Well, the advent of the in-house rapid testing for admitted patients is something we were critically in need of. This was needed to manage PPE, isolation, staffing, ventilators, et cetera. And we needed to have a technology that was feasible for a non-molecular laboratory that does not have a BSL 3 facility.

None of these were immediately available commercially. But as you can see in this little snapshot on the bottom right, the FDA did have EUAs for two technologies that we could have implemented, one being Cepheid, which was EUAed on March 20th, and one by the Abbott Rapid Tests EUAed on March 27th.

But we, as well as pretty much every other lab like mine in the country, tried to order these kits, only to find out ordering is not possible by any of us and that distribution is through the national allocation strategy. And that allocation changes day by day. And we are still learning.

The only way we can request things is through our Public Health Laboratory. And the public health laboratories must put in the requisitions for us. Next slide, please.

What are the distractions? Let me just say serological testing. There has been such an aggressive marketing to the emergency departments. And probably I spend an hour or two a day just saying no. Next slide, please.

What are our heroes and our beacons of truth and the national assistance brought to bear on this problem? These four entities get our top marks, ASM, ASM. ClinMicroNet-- the most up-to-date Listserv, anything you ever want to know that everybody is suffering through, and you can share your pain.

The Public Affairs Group-- in particular calling out Peggy McNult and Melissa Miller, making the needs of our community heard and brought up to the National Task Force. Kudos to the FDA, lightning fast EUAs. And I cannot tell you how appreciative I am for posting the instructions for use on their website.

The CDC-- for real time guidance and updates on everything related to COVID, clinical guidance, everything, and, of course, this weekly call. And then finally CMS, participating in these weekly

calls with the regulatory updates, it was the first time I learned that the near patient test was equivalent to waived categorization during this EUA period only. Next slide, please.

And of course, our local heroes of our state and our county Public Health Lab, our Public Health Department, and our public health laboratories plural who provided testing for us when there was no alternative. I really appreciated the seamless vertical integration between our local public health and our state lab. I really appreciated how much they were able to adapt to rapid cycle change. Thank you.

JASMINE CHAITRAM: Thank you. And you are all heroes. Thank you for everything you're doing on the front lines. I'm going to move to the next speaker. I know we're running a little late today. Our next speaker is from the Centers for Medicare and Medicaid Services. Sarah Shirey-Losso is going to be talking about coding and reimbursement. Sarah?

SARAH SHIREY-LOSSO: Great. Good afternoon, everyone. Can you hear me?

JASMINE CHAITRAM: Yes, we can hear you.

SARAH SHIREY-LOSSO: Great. So thank you for having us. To our colleagues at CDC, we had heard that, in the last few calls that you've had, questions have come up regarding Medicare reimbursement encoding. So we wanted to give everyone an update on the COVID-19 coding and payment under the Medicare fee for service.

Test developed and guidelines, as we all know, are moving quickly. And CMS and the AMA CPT have been trying to create codes to keep up with this sort of ever-evolving situation. And just as a reminder, Medicare fee for service pays for laboratory test under the general regulations surrounding the clinical laboratory fee schedule. And we price tests on an annual pricing cycle.

Generally, until new HCPCS codes or CPT codes describing new tests are presented through our annual public meeting process, new testing codes are priced locally by our Medicare Administrative Contractors. Those are typically where the lab would send their bill, to their local contractor. To recap, there are currently seven HCPCS and CPT codes that describe COVID-19 testing.

And I'll walk through those now at a high level. First, CMS created U, as in you, 0001. And this is a code to describe the CDC's test, so that sort of first test that we were aware of.

Coming right after that, we created U002. And that was because it was kind of early on, and we weren't really sure what types of tests and methodologies were going to be coming down the line. We wanted a code that could sort of capture any techniques, any targets, things that wouldn't be represented in the non-CDC tests.

Subsequent to that, AMA CPT created a code 87635, level one CPT code. And that describes the infectious agent detection by nucleic acid DNA or RNA for COVID 2 and amplified probe technique.

Most recently, last week was a pretty busy week. CPT developed two new codes, and those were our more to capture the serological and antibody tests. They created one for multi-step and single step methods. And those are 86328 and 86769.

And I know I'm throwing a lot of codes out here. But at the end, I can certainly share with our colleagues at CPT-- I mean, at CDC, a list of the codes, and et cetera, and descriptors. And we also have a lot of FAQs on our website.

Most recently last week, there was a CMS ruling that wanted to look at codes or types of equipment or machines that could process high throughput. So we were looking at 200 or more specimens per day could be processed. And so with that, we created two additional codes, U002 and U004.

And basically-- sorry, U003 and U004. U003 is basically the same is the CPT code 87635, but for a high throughput version. And U004 is, again, more general, but for high throughput. And this would be to capture maybe tests that aren't covered or aren't described by any of the other codes.

Back to here, I know that CDC received a few questions on the last call. And if it's OK, they did share those with me. And I thought I could just walk through those quickly. And then I'll turn it back over and provide you our inquiries mailbox.

One of the questions CDC provided was that CMS had posted a Federal Register notice that mentioned coverage for specimen collection. Is there going to be a CPT code? So yes, part of an interim final rule with comment, we had created two codes describing specimen collection.

That was use for Medicare policy when labs travel to a homebound patient or a patient in a SNF stay, a Skilled Nursing Facility stay, or is a home health patient to collect specimens. And we have statutory authority to pay an additional amount for specimen collection in addition to travel allowance. So we did create two codes for that. And those are in the G code series, G2023 and G2025 that describe the specimen collection.

At this time, we're not aware of CPT creating a code for specimen collection. And I know we've also gotten questions as to whether other settings can bill for those specimen collection codes. And we're still looking into that.

Let's see, another one we had received from CDC I believe came up on the call last week was can the Abbott tests be billed under the U0002 code. I wanted to clarify that U002 was created and exists to make sure that any test that isn't described by one of the other COVID-19 codes could be billed to Medicare. To our knowledge, the tests that are currently available can be

billed using a more specific code, such as 87635 or 86769, U004. So in the case where there tests then which another descriptor doesn't describe what that test is doing, U002 is always an option.

Another question and the last one we had received was, do clinical labs now use 87635 instead of U0002? And I think-- and we have an FAQ on this as well on our website. But if your laboratory uses the method described in 87635, the appropriate code to use would be that one. If your laboratory has a test that uses methods not described, this is similar to the response before by any of the current codes. It would be appropriate to use U0002.

Payment right now-- well, I'd say that payment until their codes are nationally priced on the clinical lab fee schedule, as I stated, are by the Medicare Administrative Contractors. For the CDC test, it's $36. For the earlier CPT code 87635 and CMS's U0002, there's a reimbursing about $51.

The new codes created for high throughput are reimbursing at $100. And the two new CPT codes that describe the antibody testing, those prices have not yet been determined by the MAC. So we are working on that as we speak.

So again, I'll share the website. We have a lot of FAQs already out there. I'll share that with Jasmine, and perhaps she can get that out to everyone.

And for general inquiries on Medicare payment and lab and the clinical lab fee schedule, we have a resource box, which is CLFS_Inquiries@cms.hhs.gov. So thank you.

JASMINE CHAITRAM: Thank you very much. I know a lot of folks were asking about slides as Sarah was talking. We didn't have any slides for CMS.

And we don't have any for FDA. We will be posting the transcript as well as the slides from the other speakers on the CDC website. And I'll give you that information in just a minute.

We're up to our last topic, which is from FDA. And Sara and Tim, we are getting very close to 4 o'clock. We're 10 minutes over, so just asking you to be aware of that as you cover the last agenda item, maybe just sticking to the really important topics.

TIM STENZEL: Yes. And Jasmine, I have the questions. So I can just speak and then try to do this rapidly, OK?

JASMINE CHAITRAM: That would be great, thank you.

TIM STENZEL: OK. Just some key updates, one is it was starting to go out last week that the Abbott ID NOW was having some issues with the VTM sample type. As far as we know, and we are in communication with multiple parties, we believe that the direct swabs are still working. I know that some centers are doing some additional work around the direct swabs.

But for now and going forward until further notice, with the Abbott ID NOW the VTM sample type should not be used. Also, if there are any additional performance issues for any authorized test, you can go to our MedWatch link on the FDA website and submit that information. You can also submit any concerns to our CDRH-EAU-templates email, and we will log those.

We've made substantial changes in the last week to our Frequently Asked Questions page. One of the key updates was those serology tests that were manufactured and notified us through the pathway D. We have now listed whether or not those tests are authorized. Some of them have been authorized.

And we've also designated the deemed CLIA status, whether it's high, moderate complexity, or if it is deemed waived. So that is now available on our website to make it easy to see. And then I'll run into some other questions.

We now have authorized four serology tests. Two of them are rapids. Yes, we do post names once we have verified a few things with the manufacturer. But as soon as the manufacturer notifies us and gets confirmation of that notification, they can sell their tests.

Moving on to our CLIA status and point of care testing, pathway D is designated high complexity until such time as those rapids and serology tests are deemed to either be moderately complex or point of care even if they were designed to be point of care. And then whichever the lab setting, the testing sites will need the appropriate CLIA certificate in order to do that testing. Some have asked why can't these automatically be point of care. And that is because we cannot deem the CLIA status without an authorization. And then, also, those that intended to be allowed in the point of care setting, there are some studies that are required for that authorization, including lay user studies.

We received a question about a number of tests that have come from South Korea. Any IVD manufacturer can follow pathway C-- that's for molecular tests, as well-- by notifying us and telling us that they have validated. And they're going to submit their EUA, and then they can launch those molecular tests in the US.

There are questions about lack of sensitivity and specificity information for LDTs and commercial test platforms. Please see our EUA Authorizations page, as all those performance characteristics are listed. And for those that are in pathway D and have not yet been authorized, we do have an inter-agency effort to demonstrate performance at least at some level. Stay tuned for information on that.

There were tests about whether specific tests have been FDA authorized. Please check our website. And then that pretty much ran through the questions at a high level. So I did that pretty quickly. Thank you.

JASMINE CHAITRAM: Thank you, appreciate it. Apologies, again, to everyone for going over on time. Thank you to all of our speakers. It was a lot of good information. And so I think it's OK that we went a little bit long today.

Reminder that the transcript and the slides are posted on cdc.gov/safe labs. Look under Tools and Resources. Also, sign up for LOCS if you want to receive information from CDC. A lot of this information that we present on these calls is also provided in emails.

And the next call will next Monday, April 27th. You guys are the heroes. Thank you for all that you're doing out there. Happy Lab Week.