Clinical Laboratory COVID-19 Response Weekly Call

May 18, 2020

Speaker Panel

Jasmine Chaitram, CDC Division of Laboratory Systems
Gary Procop, Chair, American Society for Clinical Pathology (ASCP) Commission on Science, Technology, Quality and Policy
Kerry O'Brien, Beth Israel Deaconess Medical Center
Kimberly Sanford, Virginia Commonwealth University
Bill Arndt, CDC Division of Laboratory Systems
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Sara Brenner, U.S. Food and Drug Administration (FDA)

JASMINE CHAITRAM: Hello, everyone. This is Jasmine Chaitram with CDC. I'm with the Division of Laboratory Systems. Thank you for joining the Clinical Laboratory COVID-19 Response Call. I am with the Division of Laboratory Systems. As I mentioned, I'm the Associate Director for Laboratory Preparedness.

And the Division of Laboratory Systems at CDC works to advance quality and safety, workforce and training, data and biorepository science and informatics for clinical and public health laboratories. We also work on emergency preparedness and response issues with the clinical and public health laboratories. And during this particular response, right now, we are serving as an interface between the CDC Emergency Operations Center and those laboratories that are responding to the pandemic.

What I'm showing here is the agenda for our call. We have a number of speakers. And I'm going to turn my camera off so you're not distracted. And I'm going to make a couple of announcements before we go into our agenda. Great.

OK, so we've covered a lot of topics. This is our ninth call. And I've listed some of the links from, information from previous calls as well as information that's available on the CDC website. These slides will be available after the call today, as well as the transcripts. And they will be posted on the CDC website, at cdc.gov/safelabss, under Tools and Resources.

As we've done for the last couple of weeks, we are taking a survey after the call to get your feedback to help us improve the usefulness of these calls. We've been having the calls since March 23 in collaboration with other federal partners, and we'd really like to get your feedback on the topics that we've presented so far, and, in general, having these calls on a weekly basis.

So if you would take a few minutes to complete the survey, it shouldn't take more than three to five minutes. And the survey this week is not open during the call, but we will send out an

announcement following the call by email to let you know when the link is live for you to submit that feedback to us. And the survey will close at 5:00 PM on Thursday, May 21.

Also, as we've done for the last couple of weeks, looking for your feedback on training and workforce development needs. So if you would email your ideas to this email address, labtrainingneeds@cdc.gov, we would appreciate your input. And as we've mentioned on previous calls, asking a question is always a good thing. And you can do that through the Q&A button in the Zoom webinar. Because of the number of participants on these calls we may not be able to answer your questions live, but we will do our best to address them either after the call or in a future topic, a future topic that's presented on a future call.

So please submit your questions. You can also submit ideas for future agenda items through this function. And just note that we will do our best to try to get those questions answered. And if you have media-related questions, please contact CDC Media Relations at media@cdc.gov.

And with that, I think we are ready to go to our first speaker, which will be Gary Procop, the Chair of the American Society for Clinical Pathology (ASCP) Commission on Science, Technology, Quality and Policy. And he will be talking about the urgent need for a coherent national testing strategy for COVID-19. Dr. Procop?

GARY PROCOP: Thanks so much. I appreciate the opportunity to speak to this group and all the laboratories that are listening. So I think you've heard this call from many different venues. It's almost impossible to not hear it from a nightly news. But I think all of our laboratory colleagues would also agree that they have great things to offer.

And when we have 50 governors maybe doing this 50 different ways, there is possibly a better way to go. So we really are making a call for a coherent national diagnostic test strategy. I hope to convince everyone on the call, and hopefully maybe lay some groundwork for a bit of a path forward. If you could advance to the next slide, please.

So the mission to serve patients and be a voice in our field, that is exactly why we're here. And what's happened already, there's been a call to action. And we've seen flexibility, we've seen laboratories bring up tests at, really, at an incredible pace. And really expand testing to continue to try to meet the needs of our patients.

We have responded to-- and this is the generic we, the entire pathology community, all of our societies, we have responded and worked with the government to get remote reads for pathology slides so pathologists could work distantly. We are working and continue to work on a national testing strategy. And this formation of a national task force to promote reliable testing is really why we're here today.

So we really want stronger representation from the leaders in the pathology and laboratory medicine community at the state and federal level. And we really believe that we can be

additions to the great folks that already serve our country in the public health space. Next slide, please.

So as we've mentioned, many things, an incredible amount has been done in the past 18 weeks. And we've seen an incredible mobilization of the public health community, and just hats are off to public health laboratories, CDC, FDA, HHS. And then, also, hats off to the large reference laboratories, the hospital laboratories, the university laboratories who have answered the call and really ramped up testing.

And then, also, hats off to the White House, Congress, governors who have responded to do their best to provide resources that can support these, from Trump activating acts to have ventilators built, et cetera. So an unbelievable amount have been done in the past 18 weeks, and that deserves a check mark. Next slide, please.

So what are we really looking for here? Reliable testing, quality improvement, expedited research. And so, really, my last 10 years have been spent in optimizing test utilization. And that's what we're talking about here in a pandemic situation.

So we really want evidence-based best practices for reliable testing. And so we really want to optimize test use. So what's the optimal test in a particular setting? So if you were going to screen pre-surgical patients, what would you use? If you had a symptomatic person ambulatory setting, what's acceptable, not acceptable?

Many hospitals are moving to screen all admissions. And we know that this is really, essentially, off-label use of some of the EUAs that were really emergently put into practice for symptomatic detection. Which test should you use? What can you rely on? We're kind of feeling our way through the dark here.

When we do this, we'll have the ability to benchmark and compare. And from this will come new guidelines. And I think, also, you'll see a rapid dissemination of research. You've already seen that, really, in the literature. So next slide, please.

So I'm going to be a little bit unorthodox here, and I'm going to say that building a coalition, it's like baking a cake. And what do you need to bake a cake? Well, you know what you need to bake a cake. You need eggs, you need salt, you need flour, et cetera.

And I want to say that the experts from all of our individual wonderful national organizations are those ingredients. AMP has something to offer, ASCP has something to offer, ASM has something to offer. But if all you have is eggs, then you're eating eggs.

So what you really need is you need somebody to put this together in an appropriate way. And that's where the chef comes in. And who doesn't like Ina? So you pick a chef's that is really an honest broker and is going to pull these representatives from, again, our excellent

organizations. And then it doesn't all become about an organization. It doesn't become about ASCP waving a flag, or APHL waving a flag.

And I guarantee you, because I know so many of these individuals, they are selfless individuals. They would come at the call at the drop of a hat. And they are goal-oriented. Put a task in front of them and they'll get it done. And they have a team philosophy.

So when we get that honest broker, that's chef that will pull together all the right ingredients, I think we're going to have something that we all love. And in the analogy, it's cake. In the COVID world, it's evidence-based national guidance.

And so then, every governor from every 50 state-- each of the 50 states-- will have a document formed by the leaders, blessed by the honest broker, whether that be CDC, or FDA, whomever-- I think they're in perfect position to pull together a group like this-- they will know exactly how to handle these tests. And from this, you're going to get unbelievable innovations, and research, and development. Let's go on to the next slide.

So what do we have to deal with? And again, as I mentioned, this is about optimal test utilization. So on the left side of the slide, we've got issues to deal with, with respect to tests. What does it do? Well, we need to define it. And we do that scientifically.

And then, while we do that, we need to also think about, what can't it do? And when we do that, we're describing boundaries. And where we put those two things together, we really come up with how to use it.

And we can put guardrails around that test, because we want those tests to be used how they were meant to be used, on-label use. We can black box warning when there are off-label hazards. And we really put together best practices for the community.

So what do we have out there, now? We have direct molecular diagnostics that, of course, really came up first. And we're learning that some of these are highly sensitive and some are not so highly sensitive. Doesn't mean they're bad tests, it just means they probably need to go through this process to describe what it does, what it doesn't do, and how best to use it.

We have serology, that the market's been flooded with serologic tests. We need to answer these questions for serology. We have all qualitative tests all right now, but what about when we can determine titers? What about when we have tests that can determine neutralizing antibodies? Does it matter, doesn't it matter? Answering these questions will help.

We've got one antigen test on the market. How are we going to use it? I don't know. Now, this group could define that. And we have question marks, because we know we have brilliant people putting new tests out there, seemingly every day. Next slide, please.

And so I think, with a coherent national test strategy, we will be promoting reliable tests and we'll be defining when it should be used and in what patient population, we'll be disseminating accurate scientific information about testing that's open to everyone. People don't have to guess how to use a test. We'll develop best practice, provide logistic support for public health and patient care outcomes for patients with COVID disease.

And then, just a final summary slide. Next slide, please. And so I want to say, for all of my brothers and sisters out there in every organization, pathology and laboratory medicine professionals are ready to lead and reduce unnecessary doubts. And I guarantee you if asked, we will come together collegiality and help build a coalition that can put forward best practices. And I will yield back my last 10 seconds to the next speaker.

JASMINE CHAITRAM: Thank you very much. We did get one question. And I'm going to read it for you. Most laboratories have validated and are operating three or four systems to ensure appropriate supply chain of reagents to test. What can we do to rationalize timely availability of testing across the nation, where and when it is needed?

GARY PROCOP: Well, I think the first thing-- and I'm not a supply chain expert-- but the first thing you would want to do in a supply chain situation is understand the need. And so once you understand the need-- and I know federal government is trying to do this because they are redirecting some supplies from manufacturers, which I completely get-- I think what you'd want to do is understand the use so that you can understand the production need and then try to link those two.

Not quite sure that that would be exactly within the scope of the national testing strategy group. But I definitely think your point deserves attention. It is something that, every day, we all wrestle with. So I hear you and agree 100%.

JASMINE CHAITRAM: OK, well, thank you very much. We don't have any other questions. And I just want to comment that we are working to have an update on the next call, which will be on June 1, because of the holiday next week, and we're working to have an update on supply chain. So hopefully some of these questions, there'll be an updated response for that on June 1.

So our next speaker is Kerry O'Brien. And she is from Beth Israel Deaconess Medical Center, and she'll be talking about COVID-19 convalescent plasma and the transfusion service.

KERRY O'BRIEN: Hi! I'm just waiting for my first slide.

JASMINE CHAITRAM: Got it, thank you.

KERRY O'BRIEN: Thank you. Thank you. As Jasmine said, I'm the Medical Director of the blood bank at Beth Israel Deaconess Medical Center in Boston, Massachusetts. And I'm just going to be speaking to you about convalescent plasma and the transfusion service that does not have

their own donor center. So we are a transfusion service that has a main supplier of blood products, and we issue and modify those products, but we do not have our own donor center.

Next slide, please. So how can clinicians obtain CCP for their patients with COVID-19, currently? So there are three options available in the United States today. The emergency investigational new drug application for one patient at a time. Next.

The expanded access program, which is a program that is sponsored by the government and the Mayo Clinic. Next slide. As well as clinical trials. And our institution has been involved with transfusing plasma using two of these three options, currently, and we are potentially getting involved in the third option. Next slide, please.

So the EIND, or the single patient emergency investigational new drug application to the FDA, next, is for a single patient and requires FDA approval prior to receipt of the plasma. But no protocol is required. Next.

The request can be submitted to the FDA by email or phone from the clinician, and it takes a couple of hours, but it's relatively quickly obtained. And it is the individual physician-- so the treating physician who is actually applying for the IND in this case. Next.

And plasma is sourced from an FDA-licensed blood establishment. So our institution, our first patient that we treated with COVID convalescent plasma was via the EIND. And it was at a point in time where our primary blood supplier was still relying on the hospitals to identify donors.

So we actually had a patient whose relatives were seeking to donate plasma for this patient. So our EIND patient actually received a directed donation from a blood relative. And this was in mid-April that this happened.

And basically it fell in line with our multidisciplinary group. So we actually formed a multidisciplinary group at our hospital at the end of March, and started meeting at the beginning of April. And this group included infectious disease specialists, intensive care unit specialists, and then representatives from the laboratory as well as the blood bank.

And at this point in time, we were searching any and all ways to obtain this plasma for our patients. So our ICU doctors, especially, were very eager to use this product at the end of March, beginning of April. Next slide, please.

The EAP or expanded access program is the second option for obtaining convalescent plasma and using it in your patients. So the Mayo Clinic put this out at the beginning of April, and this was seen as wonderful. Our clinicians were extremely excited because this EAP actually, you can see on the slide here, we have a nice web address, and their website is very user friendly.

So it's an open-label expanded access program that is targeting patients with severe or life-threatening COVID-19, or those patients with a high risk of developing severe or life threatening

COVID-19. However, there is no real exclusion criteria. And the primary objective of this large study is the availability of the COVID convalescent plasma, as well as a secondary objective, which would be the occurrence of serious adverse events. So while our first patient was treated under the EIND, the next 10 patients we had at our hospital were all treated under the EAP program.

One issue that has come up from our provider's perspective is because there is no exclusions in this protocol, the clinicians are finding somewhat a sense of a lack of clarity regarding the appropriate patient to offer this product. Because in Massachusetts we have, obviously, a lot of COVID patients, and we have a lot of patients in our ICUs that could qualify for this program with severe life-threatening COVID-19. But which of those patients would be best served by being treated with this plasma? It's hard to tell.

And at the beginning, especially the beginning of April, mid-April, we didn't have the plasma. So we just didn't have it available. So initially, our while our providers were extremely interested in this product, because we had such troubles, initially, in getting this plasma, our clinicians became very discouraged, and now they're not as eager to use the product. So I would say about mid to late April we started having increased availability of this product.

So a wonderful event that happened was donor centers throughout the country were found to be very eager to assist the hospitals in getting plasma, irrespective of customer contracts. So this is something that was a wonderful occurrence that happened. And actually, the vast majority of our plasma, or our convalescent plasma did not come from our primary blood supplier, it came from a blood supplier that we use as a secondary supplier, usually.

And now the availability is not an issue, whatsoever. So when I get requests currently, I can issue the plasma right away. So initially, we were having delays of up to a week at a time. And that's what actually caused a lot of discouragement of our clinicians.

And then, next slide, please. So as I said before, this is a collaboration between the government and the Mayo Clinic. And the plasma is issued free-- or not free-- it's sponsored by the government, but the plasma is not charged to the patient or the hospital. And it is overseen by a central IRB which basically is very good.

So there are very minimum data reporting requirements. And those include the adverse events at four hours, outcomes at seven days, 30 days, or hospital discharge. And the central IRB is very vigilant in obtaining these reporting requirements.

So our providers are contacted via email, so they are basically tracked down if they forget to submit any of the paperwork. They are tracked down and they do so. So it is a very well-run program. And the rate-limiting step has been having access of convalescent plasma to all the patients within this program.

And as I said, we currently do not have a problem today. We did initially have a big problem getting plasma. And the study PI, Dr. Joyner, was very responsive to these concerns. And the website has been updated very quickly with-- it is a very great-- it's a very good website. So it's a very well-run study, and I think it's going to provide some useful data.

And early pre-published data that was available on the internet as of May 12, looked at 5,000 patients that had been treated so far. And early indicators suggested that it is safe. So the convalescent plasma is at least safe to provide to these patients. So further studies and further patients are going to have to be looked at to see, who is going to benefit the most? Next slide.

So as of Saturday, I looked under the clinical trials website, and I looked at basically all of the interventional trials involving COVID convalescent plasma in the United States. And there were 12 trials that were actively recruiting along with tens more trials that are either observational, or interventional but are not yet recruiting.

So this is going to be a wonderful opportunity to study which patients are going to benefit. Because we don't know. Is it going to be the patients before they hit the ICU that are actually going to benefit? Or is it still going to be the patients that are severely ill in the ICU that are going to benefit? So nobody really knows.

And that's what's so difficult for our physicians, the front line clinicians. They just really don't know at this point. Which patients should we target? Should we target patients before they hit the ICU? Or is it a last resort? Once they're in the ICU, they're severely ill, they've already been on other trials, is this when we try the convalescent plasma? So nobody really knows. And we really need that data to help the clinicians best.

But I think our field has done a really nice job in getting this product available as soon as they could. I think there was no doubt that all of the blood suppliers were working as hard as they could to try to get this product collected, which was very difficult because it involved getting patients recovered from COVID, and then proving they were no longer infectious. So it was a huge undertaking.

And the donor centers really stepped up and helped hospitals that were not normally their customers, they really stepped up and helped us out. So I think it was a little success in that sense, that we were able to get a plasma so quickly. But it's still, the lack of having it when the clinicians initially wanted it kind of soured them a little bit on it. So that's just our experience.

So again, we do not have our own donor center. So we are dependent on the blood centers in the United States to get this product. And that's my last slide.

JASMINE CHAITRAM: Thank you very much. We did have a couple of questions I'm hoping you can answer.

KERRY O'BRIEN: OK.

JASMINE CHAITRAM: And I'm not sure why we're having an echo right now, but-- so the first question is, have you given pooled convalescent plasma, or only one-to-one donations?

KERRY O'BRIEN: We've only given one donation. So we've only-- when the patients get enrolled in the EAP program, they get an EAP number. The physician will give me the EAP number, and then we will issue one unit of ABO-compatible plasma, and that's it.

JASMINE CHAITRAM: OK. Hang on one second, let me see if we've got another question Is there a titer cutoff for a convalescent plasma? Is more serology needed for that?

KERRY O'BRIEN: Yeah, that is a great question. So that's one of the other aspects that I did not mention. So we do not know the titer of any of the plasma we are giving. So we are getting the convalescent plasma from these blood centers, and we do not know the titer.

So that's another aspect that is making the clinicians uneasy about using the product because they're wondering, is this just a waste of time? We don't know. So that, I think, is more of a donor center question, and they'll, kind of, the studies will show, hopefully, what titer is best, or what titer is actually clinically effective.

JASMINE CHAITRAM: Great. Thank you so much for all the information you've presented. It's great. I have to move on because of the interest of time. So the next speaker is going to be Kimberly Sanford from the Virginia Commonwealth University. And she'll be talking about the unexpected impact of COVID-19 on the blood supply. Dr. Sanford?

KIMBERLY SANFORD: Yeah, and I just want to say what an honor it is to be able to join this conversation today, I also, like Gary, have an Association with the ASCP. I'm currently the President-elect for the ASCP.

So I'd like to talk to you about the unexpected impact of COVID on our blood supply. So if you can advance to the next slide, please. So it's important to understand, first of all, where does the US blood supply come from? So about 80% of the US blood supply is actually collected by mobile blood drives.

So that means blood collectors go out into the community, set up blood drives in different organizations, and then bring it back to the collection center in order to process that blood. What we saw, or what I first saw on March 5, was that we got a notification that the New York blood-- that New York City had placed a stay at home order, which ended up closing large businesses, university, and schools. And we knew that this would have a ripple effect on our blood supply, not just here in Richmond, Virginia, but also nationally.

And what we saw is that the American Red Cross, which is the largest blood supplier for the nation, reported that more than 4,600 blood drives had been canceled, which resulted in the loss of 143,600 units of blood. On March 15, Dr. Pampee Young, the Chief Medical Officer, Biomedical Services at American Red Cross, issued a statement to all of the medical directors

and blood banks. And she requested that we immediately reduce our transfusions by more than 25%.

Following up with that, elective surgeries and procedures were recommended to be nationwide canceled or postponed by the US Surgeon General, Dr. Jerome Adams. And thankfully, in the state of Virginia, our governor, who is also a physician, heeded that call and helped to reduce some of the tension and pressure that we felt on our blood supply.

Recognizing the blood supply having these significant shortages, the FDA did look back at some of their recommendations for blood eligibility guidances. And they did revises recommendations for several guidances is for blood donor eligibility in the first week of April. Next slide.

So in my time at VCU and in the blood bank world, we had prepared for emergency preparedness. Mostly, we had focused on planning for mass casualty incidents. And even though in our own personal experience here at VCU, we looked at pandemic preparations, but my focus and that of my leadership was actually looking at staffing issues. And we were not focusing on some of these long-term blood shortages that we're currently experiencing.

So what has been the response at VCU, and also with other colleagues within our discipline? First of all, of us have been very keen to let the hospital administrators know what we're dealing with, as well as to alert the surgical and the trauma areas. One thing that we did was that we pulled all of the blood units that were set up in some of our remote locations and consolidated them all back to the blood bank, so that we could monitor the usage of this blood product within our institution.

We also enforced strict adherence to our transfusion guidelines within our institution. And we also put out the call to our hospital leadership that we needed to do something to increase the blood drives. The hospital is an area, we have 1,000-bed hospital, we have multiple thousands of employees that come here despite the teleworking that many of our employees have done, that could then serve as donors in our community.

So our leadership actually closed off the second floor of our cafeteria and we held multiple blood drives. I just received back from the American Red Cross, we held 10 blood drives since the beginning of March. And we've collected, here at my institution, 470 units of blood since March, which is truly an all-time record for our institution.

We also set up a blood conservation task force of all the particular stakeholders that perform transfusions within our hospital, so that we can put together methods to try to conserve the units of blood that we had, and also for me to keep them informed of where we were with our blood supply. We also did not have an emergency management of our blood supply policy. And we literally put together stages of where our blood supply inventory was and line items to take action on for each one of these. Thankfully, I have submitted that to our medical executive board so that they can approve this and put this out into our environment.

The other thing that we had issues with is that our medical staff had actually been handling blood products with contaminated PPE. And we had to create a bagging policy in order to minimize contamination in the event that the unit was not transfused to that patient. Next slide.

So some of the impact that we saw. We did have conference calls with a number of our stakeholders so that we could review individual patients and try to reduce blood usage immediately. We also reduced all of the components that were in our massive transfusion protocol.

So for each of our trauma patients that came into the emergency department, we reduced how many products and components were being dispensed at any given time. We also implemented the Jehovah's Witness protocols that we had used-- we have a large Jehovah's Witness population-- in order to reduce blood usage. We then also reviewed all of our patients with sickle cell anemia in an effort to prolong intervals between red blood cell exchange procedures, and even switch some of these to simple transfusions.

We also deferred cellular therapies for our patients and suggested self-isolation and testing for anyone who couldn't be deferred. And then we increased our intervals for patients who undergo apheresis procedures for chronic medical conditions or alternative therapies. Next slide.

So what has been the impact to the transfusion services? We've had an ongoing reduction in blood donors. We continue to see that we have nationwide shortages. Importantly, our minority donors, which are the donors that we use predominantly to transfuse our sickle cell patients.

And this is related to the ongoing shelter-in-place orders that exist for many states throughout our country. And there's also fear going out and donating. And additionally, blood centers are also, or blood collection centers are stating that they are having a hard time finding facilities large enough to actually collect blood. In the past, they've gone to large schools with auditoriums, gymnasiums that they could do this, but now schools are closed and they're not allowing blood collection centers to actually come in.

We're also daily managing local, regional, and national blood shortages. And now that elective surgeries have opened back up, we are continuing to see 75% to 85% of cases that were similar to pre-COVID, now taxing this recovering blood supply. And then Dr. O'Brien already touched on a number of issues with this new product that we're providing, convalescent plasma, and the limited resource. We are use using a secondary blood supplier in order to get convalescent plasma because of the prolonged delays in getting convalescent plasma. And then there's a lack of consistent antibody testing. Some blood suppliers are not performing any qualitative antibody testing, much less titration and quantitative. Next slide.

So what are some suggestions for action? Number one, increase the national awareness of the blood shortage that persists. Because this is going to go on for an indeterminate amount of time. Also, to make a call for donations, in particular, for our minority donors, with the assurance that there is safety in donation.

We want to continue to provide support to strengthen the AABB interorganizational task force on domestic disasters and terrorism. We also want to provide national support for the implementation of the FDA guidelines for donor reentry of these deferred donors. This guidance was delivered in April. Many places, it has still not been enacted until after June 1.

We also encourage to provide national financial relief for blood collection centers who have experienced an increased amount of expenses due to increased PPE, as well as a reduction in the number of products that they can offer, which also affects their profit centers. Also, national recommendations for antibody testing on convalescent plasma. Should it be qualitative? Should it be quantitative? Should it be looking for neutralizing antibodies, or just the absence or presence of antibodies? This needs to be defined.

Some other things that we can do since we have a limited blood supply is consider genotyping donors to build a genotype library, which could assist with finding compatible blood for some of our patients with multiple antibodies, or some of our complex sickle cell anemia patients who require rare donor units. And last, to consider national alloantibody registry of patients who could help improve transfusion safety.

Different hospitals do not share electronic medical record information, and therefore, if an antibody is discovered in one hospital, it is not shared with another hospital. And some, as we know, antibodies can wax and wane. And so this important information is not shared between hospitals that could ensure safety of our patients. And with that, I will take any questions and answers. Any questions, thank you.

JASMINE CHAITRAM: Thank you so much, Dr. Sanford. Unfortunately, are running short on time today, so we're going to move to our next speaker. But I do appreciate your time and participation in today's call. The next speaker is going to be Bill Arndt from the CDC Division of Laboratory Systems, giving the laboratory biosafety update. Bill?

BILL ARNDT: Thanks, Jasmine. So good afternoon, everyone. As Jasmine said, my name is Bill Arndt, and I am the biosafety program lead in the Division of Laboratory Systems at CDC. I also serve as the lead laboratory biosafety SME in the CDC response task force, laboratory response task force.

So over the last couple of weeks we have received a number of questions related to the use of pneumatic tubes for transporting COVID-19 patient specimens. As such, I figure it would be a good idea to review the current interim guidance provided by the CDC on this topic. So currently, the CDC is recommending that respiratory specimens from patients that are suspected or confirmed for COVID-19 should not be transported through the pneumatic tube

system. This recommendation only applies to a suspect or confirmed COVID-19 respiratory patient specimens.

The types of respiratory specimens this recommendation applies to includes NP/OP swabs, nasal mid-turbinate swabs, anterior nares swabs, nasopharyngeal wash aspirants, nasal aspirants, pleural fluids, tracheal and lower respiratory tract aspirants, as well as BAL specimens and sputum. Other types of cases and specimens from suspected or confirmed COVID-19 patients such as blood, urine, and feces, are still acceptable to transport through the pneumatic tube system. So again, this only applies to the respiratory specimens, as I stated previously.

However, the final decision to use a pneumatic tube system or not is entirely a facility-specific decision, that should be based on a risk assessment. Facilities that do choose to use a pneumatic tube should ensure that all personnel who transport specimens via the pneumatic tubes are trained in safe-handling practices, specimen management, and spill decontamination procedures.

Due to the limited amount of data on this virus, the CDC believes this is the best course of action to ensure the safety of the staff at this time. This pneumatic tube recommendation will soon be posted to the CDC's laboratory biosafety FAQ page, and a LOCS message will be send out, letting everyone know that this information is now available on the website.

Lastly, I'd also like to let everybody know that the CDC's interim laboratory biosafety guidelines page was recently updated with some new information related to POC testing, or point-of-care testing. And additional updates are planned over the next couple weeks as well, for both the guidance and the FAQ page. So please continue to regularly check the website for the CDC's most current recommendations and guidance. Well, that's my update for today. So now, I'll turn it back over to Jasmine.

JASMINE CHAITRAM: Thanks, Bill. Our last update for today is going to be from the U.S. Food and Drug Administration. Tim Stenzel and Sara Brenner. I think they're going to just give a general update in response to a few questions we've had over the last few weeks.

TIM STENZEL: OK, thank you. Go ahead.

JASMINE CHAITRAM: You go.

TIM STENZEL: All right.

JASMINE CHAITRAM: We're good.

TIM STENZEL: All right. Yeah, there isn't much time left, and we had quite a long list of questions. So I'll probably work with one topic, here. And then anything else we'll carry over into, most likely our weekly virtual town hall for CDRH on Wednesday.

So I was asked to provide an update on the Abbott ID NOW. Overall, we've authorized about 60, 6-0, molecular diagnostic kits to date. And overall, the performance, as we monitor them on market, has been good. We really have not seen any significant challenges, except that we have seen a number of reports that-- preliminary reports that have suggested that the Abbott ID NOW might have a lower sensitivity relative to other molecular diagnostics kits.

And working with Abbott, and they've been very collaborative in this, and out of abundance of caution, we're going to make an update to the intended use. And going forward, negatives with Abbott ID NOW will be treated as presumptive negatives until at least post-market studies have been completed that can verify the performance against other molecular tests.

So we do recommend that if the clinical situation warrants, that you consider reflexing negatives from the Abbott ID NOW to another molecular diagnostic test. We do say that, use the right tool for the right purpose here in the pandemic. Our floor for diagnostic, that is viral detection technology, is about 80% sensitivity.

We've authorized one direct antigen test, and that was the floor for that. So we expect that any subsequent direct detection assay, whether that's molecular or protein-based, that it'll at least achieve that 80% sensitivity relative to a high sensitivity molecular diagnostic test. We think if you at least achieve that sensitivity, there is a role for such a test in this pandemic, in managing patients.

That might be that if you have a relatively high-prevalence population, and you want to quickly screen for positives, and these tests presumably have, and they've demonstrated so far, high specificity, that you can quickly, in a point-of-care setting such as an ER, or other such relative setting, establish that a patient is positive and properly triage that patient.

So again, we've seen good overall performance as far as when we are monitoring the situation for the vast majority of Dx molecular diagnostic kits. And out of abundance caution, we are updating the IU for the Abbott ID NOW. And with that, I think I probably have to turn it back over to Jasmine. Thank you.

JASMINE CHAITRAM: OK, thanks. I know we're almost out of time here, but we have had some questions come through, Tim. And I think it would be helpful if you can just provide some information about what's available on the FDA website. There's questions about performance of tests, there's questions about instructions for use. If you could just make a general statement about where this information can be found, I think that would be helpful.

TIM STENZEL: Yeah. So we do have three different web pages that address the pandemic as far as diagnostics goes. One is the EUA authorizations web page. Simply you can Google EUA FDA authorizations and that should come up.

We also have a serology performance page, and we have frequently asked EUA COVID page. The EUA authorization page lists all the actual authorizations that we've made, along with their

CLIA waiver status, CLIA complexity status, along with things-- there's the letter of authorization, the instructions for use, and also information for both ordering clinicians as well as patients.

On the serology performance page, we list all of the authorized serology tests, along with their CLIA complexity. We also where we are making public so far, the NCI testing data. So far, that has only been for the EUROIMMUN IgG. Please check the transcript from the last call. I may have mumbled the information, and I apologize.

The EUROIMMUN IgG is still an authorized assay and is still listed on our website. And the only update is that we did use NCI data when we made that authorization, and we've provided that data on the web page. Subsequently, when we make decisions about serology tests, and we've utilized NCI testing data, we will also make that information public. And finally, the frequently asked question page has a long, long, long list of helpful information for all developers. Thank you.

JASMINE CHAITRAM: OK, thank you so much. So I was showing some links as you were talking, and those links to those pages you are mentioning are in the slides that are posted on CDC.gov/safelabs. And we are showing the same links that we've shown in previous slide sets, so you don't have to wait for this week's slides to be posted to get that information. You can go to a previous slide set and you should be able to get those links.

I want to thank all of the speakers today. I'm sorry that we went over, but it was really good information, great presentations. So thanks everybody for taking the time to participate in this call. Don't forget to sign up for LOCS, that's the Laboratory Outreach Communication System. That's where we send emails with a lot of information relevant to the response, and similar to the information that we cover in these calls, answering some of your questions in those messages. So if you don't get them, please sign up for them.

Our next call will be on June 1. Next Monday is Memorial Day. We are going to skip the call on May 25, and the next call will be on June 1. And thank you, again, for your time. And please remember to complete the survey when we send out the announcement with the link. And that concludes today's call.