

Clinical Laboratory COVID-19 Response Call

October 19, 2020

Agenda

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JASMINE CHAITRAM: Hey, everybody, thank you for your patience and thank you for joining the Clinical Laboratory COVID-19 Response Call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems here at CDC. And DLS has been hosting these calls since March. We have been serving as a liaison between the clinical and public health labs and the CDC Emergency Operations Center.

We've covered a number of topics in these calls that align with both our mission and vision. It's things that we've been doing before the COVID-19 pandemic and things that we will continue to do after. The topics that we cover on these calls include training and workforce development, quality and safety, informatics, biorepository and data science, and preparedness and response. And so we've been trying to formulate agendas to cover those topics as they relate to the COVID-19 pandemic.

Today, we have a very full agenda. I'm going to try to move quickly through the housekeeping slides so that we save time for our speakers. As you can see, I've got the agenda up right now.

And a couple of things, a reminder that we host these calls every other week. We were three weeks from the last call because of the holiday, but we will resume the two-week time period. And so on Monday, November 2nd at 3:00 PM, we will have our next call.

We continue to ask for your input on training and workforce development needs. Please send those needs to the LabTrainingNeeds@cdc.gov email. As I've mentioned in the past, we provide links to lots of resources on these slides. The slides are then posted on the CDC website for your access.

And this is the place where you can find the slides, the [CDC Preparedness Portal](#). This is a new DLS website-- new as of a few weeks ago, maybe a month ago-- and all of the information is available to you here, as well as our archived LOCS messages, as well as previous CLCR call transcripts.

We also have [new guidance](#) that's available on the CDC website. This is for point-of-care testing. It's general to point-of-care tests, and it's really intended for non-laboratorians, individuals that haven't routinely performed testing such as this. And it just provides general guidance for how to complete that testing safely, accurately, and how to report those results. So please visit that webpage if you're interested, or share it with facilities that you know are doing point-of-care testing.

Also, before I get to how to ask a question, I just want to mention again that these slides are posted on the DLS portal. And if you just go to that portal and search for the [Clinical Lab calls](#), you'll see the transcripts and the slides there, as well, for all of our previous calls, as well as all of our [previously sent LOCS messages](#). That's Laboratory Outreach Communication System.

And with that, I'm going to move quickly to how to ask a question. We've mentioned this before, as well. Please use the Q&A button in the Zoom webinar system. Type your question into the Q&A box and submit it.

Please do not submit your question to the chat button. We really want to keep a record of these questions so that, if we are not able to answer the question during the call today, we can follow up with you and answer those questions later by email, or we can have a speaker discuss them on a future call. We do use these questions to help us formulate our agenda topics, and so we encourage you to submit those questions.

If you want a response from CDC, please include your email so that we can provide a response. We will try to ask and answer these questions live during the call, but because of the number of questions that are submitted and because of the time allotted for these calls, it's sometimes not possible to get all of the questions answered. And so we apologize for that, and ask you to go ahead and submit them anyway, and we'll do our best. Finally, if you're with the media, please contact CDC Media Relations at media@cdc.gov, and if you're a patient, direct your questions to your healthcare provider.

So with that, we are going to move to our first agenda item. This is going to be an update on the National Healthcare Safety Network, NHSN, point-of-care reporting tool for COVID-19 in long-term care facilities. And Kathy Bridson from the CDC Division of Healthcare Quality Promotion

will give us that update. And there are no slides except for this one, so go ahead, Kathy. Take it away.

KATHY BRIDSON: Thank you, Jasmine. Hello, everyone. Thank you for the opportunity to give you a little bit of information about this new tool that we have released as a part of the [NHSN](#). I was actually asked to come and talk to you all because my understanding is that some of you are receiving questions from state health departments related to this new tool and needed a little bit more information.

And so I was given five minutes this morning, or this afternoon, to give you some information, so I will do that. And as always, if you have further questions after today that I'm not able to answer during the call, you can send any questions to NSHN@cdc.gov. And if you put in the subject line point-of-care testing, that will be triaged to the correct individual, namely me.

So I wanted to just tell you that this new tool that we have is an update that we have provided in response to enabling full recording of point-of-care tests that are required as part of the Coronavirus Aid Response and Economic Security Act, or CARES. That CMS subregulatory memo that was dated June 4th, and which we are actually expecting to be updated and published again, republished today, we are expecting that the language in that will actually identify that NHSN shall be the reporting mechanism for long-term care facilities to report any POC testing for SARS-CoV-2.

And that is obviously a change from how facilities have been reporting in the past, and we will continue to work with state and local health departments to make this happen, make sure that they're kept in the loop. And obviously, our plans, our hopes are for all of the agencies that need to get all the data to do so.

The reason that NHSN has been tapped for this is that it's currently in use by over 15,000 long-term care facilities already for reporting of mandatory COVID data. So it really makes sense for the system to be leveraged for the additional use. Once the data is reported to NHSN, the data will be packaged in an HL7 secure data file, and then sent to the AIMS platform for the Association for Public Health Labs, and from there to the state and local health departments and Department of Health and Human Services.

The data collection will involve the test results for both staff and residents in long-term care facilities for COVID-19, and will include both negative and positive results. It will include information about the device that's used, some personally identifiable information that is necessary in order for the states and local health departments to carry out their contact tracing or whatever other types of prevention and response activities that they need to do, the specimen source, the date of the testing, and who the ordering physician is, and his contact information.

Currently, the system only has three devices that-- for which results are able to be recorded. Those are the Quidel Sofia device, the Abbott BinaxNOW device, and the BD Veritor system. But

we recognize that although those were the devices that were sent out via DHHS, that some long term care facilities have purchased other devices and are using those. And so we will be doing an update to provide reporting for other devices as necessary.

And then finally, just wanted to tell you that if you're interested in more information, we're going to be doing two trainings this week, one on Thursday at 11:00 AM Eastern Time and one on Friday at 2:00 PM Eastern Time. And I can provide a link to that information the Q&A, the chat, or Jasmine, however you'd like me to do that, if that would be helpful. So I will stop here, and I don't know if you want to answer questions at the end or now, Jasmine.

JASMINE CHAITRAM: I'll ask you a couple right now if that's OK. The first one says, does this apply to just long-term care facilities? What about the daily testing of sports teams?

KATHY BRIDSON: Sports teams? Is that what you said? Sports?

JASMINE CHAITRAM: Yes.

KATHY BRIDSON: No, this is strictly for long-term care facilities.

JASMINE CHAITRAM: OK. And the next question is, will the NHSN data be available real time?

KATHY BRIDSON: Yeah. So as soon as it's entered into the system, the facility can see the data. The plan is that the data will be packaged every two hours and sent to the AIMS platform. But as soon as it's entered into the system, whoever has rights to view can view the data and do any analytics. Currently, the only analytics that we have available are line lists-- a line list for resident testing and a line list for staff testing.

JASMINE CHAITRAM: OK, great. And I've got one more question. I'm not sure if you're the right person to ask this question of, but hang on one second. Let me find it. Is the objective of the COVID-19 guidance for hospital reporting and FAQs published on October 6 to replace the daily totals currently provided with aggregations of data from CDC using data provided from state and local health agencies? If you're not the right person--

KATHY BRIDSON: Yeah, I'm not. That's not something that I could answer. Sorry.

JASMINE CHAITRAM: OK, no problem. Thank you so much for being on the call and for giving us that update on NHSN.

KATHY BRIDSON: Absolutely.

JASMINE CHAITRAM: We're going to move-- OK. We're going to move to our next item on the agenda, which is going to be influenza testing update and cover of the issues from Tim Uyeke from the CDC Influenza Division. Tim?

TIM UYEKI: Thanks. Thanks for the opportunity to speak. Next slide. So we really don't know what's going to happen with the coming influenza season this winter, this fall winter. What we've seen is that in the southern hemisphere, they have just gone through their winter. So if you look at temperate climate countries, they actually-- many saw very, very low influenza activity. And it's quite possible that the mitigation efforts done to control the spread of SARS-CoV-2 for the COVID-19 pandemic have actually resulted in really huge reduction in influenza virus transmission.

But we really don't know what's going to happen in the US. I will say that I've already heard of some hospitalized adults, including over this weekend, with influenza virus infection and SARS-CoV-2 coinfection. So we just don't know. It could be spotty, highly variable. Could be low overall. We don't know. But we've got to prepare for the potential for influenza and the potential for post-circulation of SARS-CoV-2 and influenza viruses.

And therefore, monitoring is really important. Surveillance is highly, highly critical for this. And it's both national public health surveillance but state and local. And the clinical laboratories are very important to this. It's not just the public health laboratories.

So clearly, there's a lot of surveillance under way for SARS-CoV-2, and we have all our surveillance for influenza that's been going on for decades. And so this will also be really important. And for the clinical community, they need to consult not only public health influenza surveillance and SARS-CoV-2 surveillance, but also be aware of clinical laboratory testing and hospital laboratory testing in their local communities. Next slide.

So because there's likely to be cocirculation of influenza viruses and SARS-CoV-2, although, again, we can't predict how much, there is the potential for coinfection. And there's also the potential when viruses are cocirculating have infection with either virus. So coinfections have been documented in case reports and small case series, but we really don't know how often it occurs. We don't know if it's a marker for more severe disease if you have both infections, and we don't risk factors. But we're going to learn a whole lot this coming season.

From the clinical perspective, there are overlapping signs and symptoms. There are some differences, but they're not differences that are going to allow you to make a clinical distinction. So the incubation period is shorter with influenza than with COVID-19. Viral shedding and the period of viral RNA detection in the respiratory tract, particularly upper respiratory tract, is generally shorter for influenza virus infection than SARS-CoV-2 infection.

The loss of smell and the loss of taste, which everyone has heard a lot about in outpatients with mild COVID-19-- it's actually not something that's completely unique to COVID-19. It does occur with influenza and other respiratory viral diseases. But it's more common with COVID-19 than others. So it's suggestive of COVID-19 if you have loss of smell, loss of taste.

Diarrhea occurs with influenza in young children more typically. COVID-19, you can see that in any age. The timing of the onset of complications, a progression of more severe disease is

typically earlier with influenza within the first week, whereas with COVID-19, progression to severe disease is really in the second week after illness onset.

The high-risk groups for complications are very similar with two exceptions. One, for influenza, young children. The younger you are, particularly less than five and less than two years old, you're at high risk for hospitalization. Very, very, very young infants at high risk for death. Pregnant women we know are at high risk for influenza complications leading to hospitalization. We haven't seen young children or pregnant women to really be-- to jump out as a signal for them to be high risk groups for COVID-19. However, there clearly has been severe critical illness within these groups. Next slide.

So the implication of the potential for coinfection, if there is cocirculation in the issues I outlined clinically that you can't really distinguish in clinical signs and symptoms, history complications alone, is that you need to test to really distinguish them. And so you need to test in hospitalized patients setting, a patient being admitted with acute respiratory illness. Overall nucleic acid detection assays are preferred, either by singleplex assays testing, separate respiratory specimens for SARS-CoV-2 and then for influenza viruses, or by multiplex assay. One respiratory specimen you can test for both SARS-CoV-2 and influenza A and B viruses.

The outpatient setting, you can also test for both viruses. Clearly, we do want from the public health perspective people to be tested for SARS-CoV-2. From the influenza virus perspective, we typically say you should test if it's going to change your management of the patient. And the reason is that you can make a clinical diagnosis of influenza and prescribe antiviral treatment, and particularly in the outpatient setting for high-risk groups and for those with more severe disease who are not being admitted to the hospital. So the multiplex assays in the outpatient setting can also be used if they're available. Next slide.

So from the influenza perspective, before the pandemic and still now, there are a wide range of diagnostic tests that are available to detect influenza viruses and respiratory specimens. They differ by the time that results are produced, the information provided, the approved respiratory specimens, approved clinical settings, and accuracy. And clearly, there are a lot of FDA-cleared singleplex antigen detection assays.

There's also some multiplex assays that detect-- in the past, have detected influenza A, B, and RSV. There is one-- and this is all a moving target, so there may be more to come-- but currently, there is one multiplex antigen detection assay that detects SARS-CoV-2 and influenza A and B viruses that has received FDA emergency use authorization.

From the influenza perspective there's quite a few nucleic acid detection tests that are FDA cleared both singleplex and multiplex. And by my count, there are nine multiplex assays that can detect SARS-CoV-2 and influenza viruses that have received FDA EUA to date. This is a moving target, and there may be more to come.

So all of these influenza assays, you know about this better than me. They're point-of-care, CLIA-waved, they're moderately complex, or they're highly complex. Next slide. I put this together this morning. This is showing the nine multiplex assays. These are the nucleic acid detection assays that have received FDA EUA. And again, this is a snapshot of today. There could be more in the weeks and months to come.

But the top four assays detect other respiratory viruses, not just influenza A, B, and SARS-CoV-2. And the 5 below are really influenza A, B, SARS-CoV-2 assays. So all the of top eight are clinically or commercially available in clinical settings. The bottom one is the CDC real-time assay. This is for public health laboratories and highly complex clinical laboratories and public health laboratories. So there's a wide range of time to results as short as 20 minutes up to eight hours. And again, in the far right, many different settings that are approved. Next slide, please.

Just a couple points I want to highlight about the source of the respiratory specimen to detect influenza viruses. So in the upper respiratory tract, a couple things. One, influenza viruses typically are detectable for about three to four days by antigen detection and longer by nucleic acid detection. We know that there are certain groups such as young infants and immunosuppressed patients with influenza virus infection that can have longer detection of virus in the upper respiratory tract. But in general, nasopharyngeal swabs specimens are the highest-- had the highest yield for influenza viruses. And again, it's best the closer to illness onset you can collect the specimen.

The other acceptable specimens, of course, you want to look at the assay and see what's FDA cleared for that assay. But in general, nasal swabs, nasopharyngeal aspirates, nasal aspirate, and combined nasal and throat swabs are all going to be better than a throat swab alone. Jumping to the lower respiratory tract, we know that in patients who are critically ill with respiratory failure on mechanical ventilation, if you test the upper respiratory tract, they might be negative. The diagnosis of influenza can be made by testing lower respiratory tract specimens such as an endotracheal aspirate or bronchioalveolar lavage specimen by a molecular assay. And we saw this about 10% to 20% of the time in critically ill patients during the 2009 H1N1 pandemic. Next slide, please.

So what tests are recommended? If we look at the Infectious Diseases Society of America-- and generally CDC, we utilize their guidelines. And for full disclosure, I led the IDSA guidelines. So in outpatients, we do recommend rapid influenza nucleic acid detection of molecular assays over the antigen detection test.

Of course, it's easy to say this. We know that in the outpatient setting, most influenza assays that are available are, in fact, the rapid influenza antigen detection tests, which have lower sensitivity and can actually lead to some false negative results. In the hospitalized setting, we do recommend nucleic acid detection assays, including the singleplex or multiplex assays that were FDA cleared before this pandemic, as well as some of the multiplex assays that I mentioned that have received FDA, EUA authorization that also detect SARS-CoV-2.

We don't recommend antigen detection in hospitalized patients unless nucleic acid detection assays are not available. We also always recommend to clinicians, don't order viral culture for the initial or primary diagnosis of influenza. It's not going to yield timely results to inform clinical management. It's important for public health purposes, but not for clinical management.

And don't order serology. Sadly, there are commercial laboratories that offer influenza serology, and clinicians do order it. It's a single serum specimen. It's uninterpretable. You need paired acute and convalescence sera collected two weeks apart and tested at a specialized public health laboratory. Next slide.

So just wanted to end by showing some examples of information we have about influenza testing on our web pages. This is a screen shot from this morning. We put this up Friday night, late Friday night. This box there that says testing and treatment of influenza when SARS-CoV-2 and influenza viruses are co-circulating.

We have three clinical algorithms there. It's about testing and treatment, testing for both SARS-CoV-2 and influenza viruses, and then treatment from the, really, from the influenza perspective. Those are for clinicians. This is our general web page on influenza virus testing for clinicians on our CDC web pages. And then on the right side, there are those three tables, two, three, and four, about FDA-cleared rapid antigen test, and nucleic acid detection test, and then the multiplex assays. Next slide, please.

So this is a snapshot. Give you an idea of one of the algorithms we put out. This is going to be for both patients being admitted and patients not being admitted. Next slide. And this is what it actually looks like. I couldn't get the other one all on one page, but this is what it looks like. And again, it's to assist clinicians. This is for ambulatory care practices as well as emergency department clinicians. Patients who may or may not be admitted to hospital. Next slide.

So then in terms of the outpatient setting for patients not being admitted to hospital-- next slide-- we have a similar one available. Just guidance on SARS-CoV-2 and influenza testing, and then treatment from the influenza antiviral perspective. Next slide.

And then finally, the same kind of algorithm for patients requiring hospital admission this winter when there is cocirculation of these viruses. Next slide. And this is what the algorithm kind of looks like. Again, it's information. This is for patients being admitted to the hospital. And there's different nuances for each of these different settings. I think that's my last slide. Yeah. So thanks for that opportunity.

JASMINE CHAITRAM: Thank you so much, Tim. And I'm glad we didn't have any technical challenges. I do have a couple of questions for you. First one-- can influenza be asymptomatic as frequently as SARS-CoV-2?

TIM UYEKI: Yeah, it's a great question. So first of all, I'll just say, we don't typically recommend testing someone for influenza virus infection. People who are asymptomatic. From the SARS-CoV-2 perspective, it's really important for public health to know who's actually infected because we know that asymptotically infected, and particularly, presymptomatic persons can transmit SARS-CoV-2.

Now, from the influenza perspective, I'll answer it in a couple of ways. One, we know that a lot of people, in fact, can have asymptomatic influenza virus infection. The question is, do those people with asymptomatic influenza virus infection transmit to others? And the answer is, we don't really know, but we don't think it's to the extent of SARS-CoV-2.

We believe that most people with influenza virus infection who actually spread to others are people who are symptomatic. And so typically, we never test people who are asymptomatic for influenza virus infection, except for epidemiological studies. Household transmission studies, and so forth.

So we don't know as much about asymptomatic infection and transmission or presymptomatic transmission. Theoretically, it can occur. Theoretically, you can sample someone. You can detect influenza viruses in people who are asymptomatic. Typically, it's a lower level of virus in the upper respiratory tract and of shorter duration than in someone who has symptomatic influenza virus infection.

JASMINE CHAITRAM: Thank you, Tim. OK, one more. Do you feel it's important to test for RSV at the same time that one tests for SARS-CoV-2 and flu A and B?

TIM UYEKI: That's an excellent question. So from the pediatric patient perspective, definitely, yes. Again, local, state, national respiratory virus surveillance information is going to help that, and, like, local children's hospitals' laboratory testing. That information is going to be helpful. Are RSV viruses circulating in that patient population?

But as we all know, it's not just young children to worry about for RSV virus infection. It's older kids and adults, and particularly elderly and especially immunocompromised patients. We know that elderly, as well as immunocompromised, can get RSV pneumonia and be extremely ill. So I think the answer is yes, but hopefully-- and in the inpatient setting, a patient being hospitalized with, say, pneumonia, it may be much more important than in the outpatient setting.

And so I'm not really an RSV expert, and so I won't fully answer that other than to say that yes, it should be considered depending upon cocirculation of other respiratory viruses such as RSV and the patient being potentially tested. Thanks.

JASMINE CHAITRAM: Thanks, Tim. We do have a lot of other questions, but in the interest of time, I'm going to have to move to our next speaker. I will probably contact you later to get some of these other questions answered because I think they're all good questions. Thank you again for being on the call today. I appreciate your time.

Our next speaker today is Dan Diekema from the University of Iowa. He's going to be talking about a survey that was done by the Infectious Diseases Society of America. Dan?

DAN DIEKEMA: All right. Can you hear me?

JASMINE CHAITRAM: Yes.

DAN DIEKEMA: Yeah. Oh, OK. Good. Well, thank you very much for having me here to sort of briefly describe the results of this EIN survey on the effects of increased SARS-CoV-2 testing on laboratory services. I think for this group, I'm basically going to be telling you sort of what you're currently living. So I'm not sure a lot of this will be surprising. Next slide.

So as you all know, the emergence of COVID-19 has resulted in a massive demand for diagnostic testing for SARS-CoV-2, which has placed a major stress on clinical labs, has led to-- and public health labs-- has led to laboratory supply shortages, not just for SARS-CoV-2 testing, but also for non-SARS-CoV-2 testing as well. So this survey was done a little over a month ago to help better understand the scope of this problem, to bring this information to policymakers and other stakeholders. Next slide.

So just to give you a little background on Emerging Infections Network, it's a clinician-based sentinel network funded by CDC and IDSA say with over 2,800 participants, mostly in North America, designed really to detect new or unusual clinical events, clusters, outbreaks, clinical aspects of emerging infections, and to connect members to public health as well. Next slide.

So this particular survey was sent out three times to EIN members between August 25 and September 10 and then was separately sent to clinical microbiology laboratory directors via the ClinMicroNet, the listserv of lab directors, and ASM, American Society of Microbiology, division C listserv. The EIN response rate was 34%, and between the ClinMicroNet and division C, 85 lab directors responded. Next slide.

So virtually all of the respondents had SARS-CoV-2 testing performed on-site. 60% to 65%, depending on the respondents, it was on-site only, and about a third of labs were sending some testing offsite as well to deal with demand. Next slide. So it would not surprise you, when asked whether they were aware of delays in results or unavailable tests, non-SARS-CoV-2 tests, due to the demand for SARS-CoV-2 testing, 86% of lab directors said yes.

Interestingly only, about a third of ID physicians said yes. And I mean, maybe that's not interesting. Obviously, if you want to know the impact on labs, you need to ask lab directors first. I think the impact really is felt somewhat later by ID clinicians. Next slide.

So in most cases, the ID physicians and lab directors described delayed test results as being the major problem. But I think importantly, a non-trivial percent of the time, 17%, there was described just unavailability of certain tests due to supply shortages and demand for SARS-CoV-2 testing. Next slide.

And so we asked as well what tasks were most often impacted. The graph is on your right. In red are the Clinical Microlab-- director responses. In blue are the ID physician responses. And as you can see, the most commonly affected tests were molecular tests, in many cases due to reagent or supply shortages. And the most commonly impacted tests were for sexually transmitted infections both-- so HIV, viral load PCR and chlamydia, and gonorrhea NAAT testing. Next slide.

And just a few specifics in the comment sections about what sort of shortages labs were dealing with, including various types of media, Mueller-Hinton, Blood agar, CNA, Mikacel, Thayer-Martin. Many reagents, and during periods of time, reagents for nucleic acid extractions steps were a big problem. Other consumables including swabs and other supplies like pipette tips.

Cartridges for the major molecular platforms that were-- became in short supply as they converted their manufacturing to SARS-CoV-2 testing. And then importantly, personnel issues related to having to reassign personnel to do-- to keep up with the demand for SARS-CoV-2 testing, and then also potentially losing personnel to either isolation or quarantine when a community within which the lab was situated was being hard hit by COVID-19. Next slide.

And this is just sort of a numerical description of some of the shortages that were the biggest problem, including reagents by 85% of lab directors and other supplies by 66%. But as I mentioned regarding personnel, almost 40% of lab directors said that there were significant personnel issues, shortages that arose because of this. Next slide.

And then we asked what things sort of, quote, unquote, deteriorated in your lab as a result of SARS-CoV-2 testing demand, and most often reported 70% of lab directors said it was turnaround times followed by overall availability. But about a third also mentioned communication issues, not just within the laboratory, but communication with clinicians and others. External communications as well. I know that, for example, in our lab, you know, we had to develop a whole new phone tree because the phones were just jammed with questions, concerns, demands for SARS-CoV-2 testing. Next slide.

I just included a couple of quotes because I think they sort of describe it, what many of you have, I'm certain, sure gone through. This one, we've had to redesign our lab to adjust to the new workflow from high test volumes, new instrumentation, and new personnel. We've had to send some elector tests to reference labs to free up thermal cyclers for testing. We've had to send other molecular tests to reference labs that we generally do in-house due to reagent shortage. We've run low on several different agar plates, having to source them from other vendors. Just non-stop juggling and troubleshooting. Next slide.

And then a few other quotes. SARS-CoV-2's left us scrambling in ways that were previously unimaginable for a clinical lab in the US. And then a couple of quotes, and there were more of these types of quotes really getting at the issue of diagnostic stewardship and whether it's possible or we ought to be doing better with SARS-CoV-2 testing.

Just lab directors primarily really questioning whether all of the testing that's being done is really justified or should be done in a clinical lab, the sense being that a lot of the screening testing, whether it be pre-op or other, may be either beyond the scope or less important than focusing on the diagnostic testing that is generally the primary mission of the clinical lab. And then finally, the situation is unacceptable for the most wealthy country in the world. Next slide.

So in summary, SARS-CoV-2 testing has been a major stressor for US clinical labs. Supply chain and personnel issues have led to delays and unavailability of tests, with the greatest impact being on sexually transmitted infections, in particular chlamydia and gonorrhea testing. And so obviously, this brings up concerns for an ongoing adverse impact on patient care in public health. Next slide.

And I know, obviously, CDC is aware of this. And this is just a screenshot of the DR colleagues letter sent last month with some guidance about how to prioritize limited availability of chlamydia and GC testing. Next slide.

So this just acknowledges some of the folks who are involved in this survey, including Susan Beekmann and Phil Polgreen here in Iowa and the EIN. Tom File, Cliff McDonald, and John Brooks. I also want to mention and many of you probably know that ASM has a major effort ongoing to provide more granular data about these shortages and issues related to the impact of SARS-CoV-2 testing on clinical labs.

And they have a website that is being updated weekly with information that's provided longitudinally by lab directors. I sent that link to Jasmine. Many of you probably already have access to it, but I think she could probably send it out on the chat, which provides more detailed information about these issues. So with that, I'll finish, and thank you very much for the time.

JASMINE CHAITRAM: Dan, thank you so much for presenting these survey results. You know, we are hearing from all different sources about challenges that the laboratories are facing. It's nice to see some data associated with it. Here's a question we received. Have these shortages, are these-- I guess, it's are these shortages improving, worsening, or about the same in your opinion?

DAN DIEKEMA: My view-- and my view is fairly narrow. It's from our hospital clinical lab perspective. It's been a moving target. In other words, it'll be one shortage one week or one for a couple of weeks, and then that will ease, and then something else will pop up. So it might be extracting reagents one week, and then suddenly, there's an issue with swab availability, or then it will be another.

We'll find out that we're not going to get any more [C. Diff](#) testing cartridges for the next x number of weeks. So I think the reason I think that ASM is doing this longitudinal look is just to see how things are shifting over time because our experience is really that it's been varying quite a lot.

JASMINE CHAITRAM: Great, thanks. And then final question-- what is the specific reason for impact to STI testing? Is it equipment availability or another reason?

DAN DIEKEMA: I think there's someone at CDC who probably can best answer this.

JASMINE CHAITRAM: OK. Well, we can follow up with you.

DAN DIEKEMA: Well, I actually saw something in there that said they would like to answer this question.

JASMINE CHAITRAM: Oh. I didn't see that, but they are welcome to type it live for everybody to see it. And I just want to thank you again for being on the call today and presenting this data to us. We're going to move to our next speaker. That's Tim Stenzel from the US Food and Drug Administration giving an update and answering questions from previous calls. Tim?

TIM STENZEL: I'm great. Thanks, Jasmine. And two things is answering some questions that were submitted and-- or trying to, and then also addressing some of the testing that's going on in nursing homes and other locations with direct antigen tests.

So the first thing is, there are questions about our new policy around LDTs and whether or not such things like pulling of samples, saliva testing, and home collection were covered. So I want to briefly review some of the language around LDTs. And that is, typically, they're designed, manufactured, and used within a single, high-complexity, CLIA-certified lab. And this wouldn't include things like test components, or collection devices, or instruments, and reagents for sale.

And also, typically, it doesn't include home collection tests. At-home tests, direct-to-consumer tests, over-the-counter tests, and tests that are distributed or used beyond that individual lab. And so with regard to some of the questions-- so on pooling of samples. So if there's an LDT and they deciding they want to pool samples and validate that, they're welcome to use our recommendations for how to validate pooling that are posted on the FDA website. But we would decline to review an LDT addition of existing EUA or a new EUA for the pooling, solely for the purpose of pooling samples in the lab.

And then the second one was on saliva. And so we would decline to review any updated sample type for saliva. And again, if you want to look at our recommendations for validation of saliva testing, please do so. And then finally, it has to do with home collections. So as stated earlier about what our typical views are on home collection, home tests, DTC tests and OTC tests, those are things that we would encourage you to submit for EUA reauthorization for that particular application. So hopefully that cleared that up a little bit.

And then a second thing I wanted to briefly talk about was there has been some reports of false positives in the field, particularly in nursing homes around the country. And I know there's been discussion on that general topic earlier on the call.

But I'd like to reiterate that in a low-prevalence population, a population that doesn't have much as far as detectable biomolecular or antigen tests, that even if you have a highly specific test such as one that's 99% specific-- so out of 100 people who are not infected, only 99 will be negative, and one will be a false positive. So there are a number of reasons why that false positive might occur, but that's a pretty high-performing test. When you roll that out into a larger population screening-- and I'll apply it to nursing homes and I'll also apply it to home testing-- suddenly, you get into the situation where you're going to have a lot of potential false positives.

So let's just say that a particular provider rolls out and sells 10 million tests. If they have a false positive rate of just 1%, there will be on the order of a lot of false positives. If you do the math, that's 100,000 false positives for a very specific test. So it's very important to confirm those false positives, of those positives, because we know that some of the positives will be real.

If the population is, say, a 0.2%, 0.2%, you will have 20,000 true positives, and you'll have 100,000 false positives. In order to catch, basically, the 20% that have true positives, it's important to follow up and test all those with an alternate method. It's important in the first case to detect those. I think in certain populations like nursing homes, I think there's great value in finding those 20% carriers.

And are detectable by a direct antigen tests are probably folks who could spread a disease within the nursing home. So it's just important to understand the math there. If you were to apply the same thing for a home test-- that is, the same specificity-- then you're going to have the same math. For every 10 million tested at home, you're going to have a lot of false positives relative to the true positives. And so just be cautious in utilizing that. And you know, I just wanted the folks to know that, should we authorize a home test, that this issue will come up.

We're absolutely thinking about it. And in our authorization, we're going to mitigate that risk of misinterpretation of potentially false positive results. So we're going to be carefully looking at that, and in all likelihood, recommending if not requiring a follow-up test, depending on the population, to confirm a positive. So hopefully, that addresses, Jasmine, the questions you wanted. And if there's any time, I'm happy to address any other questions.

JASMINE CHAITRAM: Tim, thank you so much. I'm going to, because we've got one more presentation planned for today, I'm going to push forward and have our next speaker present their slides. And then if there is time at the end, we will come back, and there are questions for you, Tim, as usual. But if not, we'll just follow up after the call. Our next speaker is-- well, we've got two folks, but I believe it's going to be Ed Lockhart giving the presentation. He's from the Division of Laboratory Systems, and then Jason Hall, who you heard from before from the Division of Preparedness in Emerging Infections. They're going to talk about how the data that you all have been sending to the state health departments, which then comes to CDC, how we've been using that data. So Ed?

ED LOCKHART: Yes, thanks. Thanks for the introduction, Jasmine. Should we just go ahead and jump right in? Next slide. So the agenda for today includes a discussion on COVID-19 electronic lab reporting. Next, I will give a brief overview of how the lab data is transitioned throughout CDC, or through CDC, I should say. Following that, I would also speak on how CDC uses laboratory test data to inform the public. And then we'll conclude with some follow-up questions that we've gotten back previously from some of these calls. Next slide.

So as we all are familiar here, lab data are reported to state and jurisdictional health departments in accordance with applicable state or local law and in accordance with the Coronavirus Aid Relief and Economic Security Act, also known as the CARES Act, section 1.8.115. The data for each state are sourced from either data submitted directly by the state health department, via COVID-19 Electronic Laboratory Reporting (CELR), or from a combination of commercial, public health labs-- I should say commercial labs, public health labs, and in-house hospital laboratories. Next slide.

For the sake of time, I won't go into everything on this slide, but the take-home message here is that state health departments, through AIMS, submit data to CELR, which is then submitted to HHS Protect. Something that I want to point out, though, is that the data that the states and other jurisdictions send are coming to us, and we're making a hard effort to make sure that the data is not only clean, but any data submitted through HL7 is also extracted to meet specific required data elements to feed it to HHS Protect. And also, very, very importantly, all PII is strict. Next slide.

So one of the more visible ways CDC informs the public using lab testing data is through our CDC COVID data tracker website. The lab test data that CDC receives are used to populate this dashboard. And so the data used to create the map on the right represents the viral COVID-19 lab test or reverse transcription polymerase PCR reaction results from laboratories in the US, including commercial and reference laboratories.

I want to be clear here for the image that you guys are seeing today, though, that the data represents only lab test totals and not individual people. And this excludes antibody as well as antigen tests. So these are only RT-PCR test results that you're seeing. The totals you're seeing for tests reported are as of last week. Slide needed to be cleared, so these were the totals last Wednesday, I believe.

I believe the new totals today are 131 million. Over 131 million US tests reported, followed by just under 10 million positive tests with still a 7% positivity. On the website, there is seroprevalent survey data that's present there. I won't go into a lot of detail about that. But I will say that CDC is working with commercial laboratories to conduct geographic seroprevalence surveys to estimate the percentage of people who were previously infected with SARS-CoV-2.

And so as you can imagine, this strategy involves working with not only the state but also local and territorial partners to better understand COVID-19 in the US. And one positive note that I'd

like to end with on this slide and then we can move on is the fact that dating back to May of this year, we've had over-- excuse me-- 77 million views and counting. So I'd like to believe that the public is finding this very useful. Next slide.

So some of the more internal uses of the data that we sort of carry out on a daily basis is to assist with the creation of guidance documents and recommendations. One example that comes to mind is I know there were communications back and forth with CMS and CDC in coming up with the guidance for nursing home testing. Another use is, of course, HHS and White House briefings that are done. Often, we'll get requests from leaders that are interested in specific states, whether it be testing or looking at testing volumes over time.

And then that's also followed by our sort of morbidity and mortality weekly report publications that we send out every week. And so the graph that you see to the right points out percent positivity for age stratification in counties with, I guess, increases in COVID-19 transmission rates. Next slide.

So this is the point where we'll pivot, and these are recent follow-up questions on reporting that was submitted by Jasmine to us. And this is where Jason Hall will come in to answer some of the questions that we received in the past pertaining to lab reporting.

JASON HALL: Can you hear me?

ED LOCKHART: Yes.

JASMINE CHAITRAM: Yes, we can.

JASON HALL: I'm going to go ahead and take a few from the Q&A while we're at it, just quickly. So there was a few questions that were put in here about what about the RT-PCR testing report to the state of Texas with the Abbott-ID Now? If the state of Texas is receiving those, unless there is something, some way that they are receiving them that would cause them not to fit into their normal process, they're going to be including those findings to what they report to CDC.

Another question is it seems like CDC might be getting duplicate data from the large labs, the six that is and state-- the department's failed. If they report to the DOH as well, is there a safety mechanism? So first of all, the labs that report directly to the CDC, it's a separate string. And we don't use those with what the state reports. So when states cut over their line-level data, we use only what the state reports.

Anything that goes to a public health lab is going to be going to the health department for use. The lab doesn't actually use the data. So they make sure that they forward those on to the health department if they're reportable, and the epi side of the health department uses them. So we've minimized the risk of getting a lot of duplicate data from the different data streams that CDC has.

Let's see. And then there was another one that asks, is the objective of COVID-19 guidance for hospital reporting and FAQs published on 10/6 to replace the daily totals currently provided with aggregations of data from CDC with those from the state agencies? So to be clear, for a while now, states that have been reporting line-level data to CDC, labs in those states did not have to continue submitting aggregate files to HHS.

HHS is wanting to make even more clear for those that still may be doing it, there's a map. There's a way to know if your state is already cut over the line-level data. You don't have to do that anymore. When we start using the state's line-level data, we do not look at those aggregates from the hospitals that are submitted to HHS anymore. So not only are you doing something you don't have to do, we're not using it, either. So make sure you know if your state history is using-- is sending line-level data to CDC in production.

Let me address some of these on the recent follow-up questions here quickly. So on this slide that's being shown, should test results we reported to the local state health department where the lab is located or where the patient lives? There's some other questions down below that will be caveats. But as the rule, it's where the patient resides. That's the state health department that it needs to be reported to, not where the lab is located.

And then the next question. If a reference lab-- if the reference lab is sending samples to another state, are they required to send results? So if a reference lab-- so in this instance, I think what the question is is if a lab-- if the sample's being sent out to another lab, being referred out to another lab in another state, do they need to send the results?

Typically, the performing lab reports, but there are definitely situations where labs are referring samples, sending samples out to other labs. If those data are flowing in basically an automated way, it's fine for the performing lab to go ahead when the result is out to send those data on with their normal reporting channels, particularly if the lab that they reference it out to doesn't have a reporting connection established already with that state health department.

So it's a little complicated. But as a rule, it's a performing state-- I'm sorry, the performing lab that does it. But there are some instances when a sample is referred out that it could be that the lab that referred it is the one that ends up reporting it.

Next question is about SAMHSA. So for patients that are seeking drug and alcohol treatment, are they exempt from reporting? Long story short, the drug and alcohol testing, you don't report those. Those diseases have public health concerns that are required by state law to be reported, and you report those. So you report COVID. You don't report the drug test.

If a patient were a student on a college campus, would they need to report locally or to their home address? This is one it would be nice to get straight. Where they're being tested and where they are located is going to be on the college campus. It would be nice to get the local address for the patient for the college, while they're attending college, because that's the health department that's going to end up addressing the situation.

We know that there's a mix up there where students come in and they use their home address, parents' address. Could be in another state. Could be in another county. It consistently would be nice if all students were giving their local college address. That's the best way to get the cases handled in an expeditious way for public health purposes.

And then last question on this slide, if your lab serves patients from all 50 states, is it required to set up interfaces with all 50 states? I hate to say that last part, but you need to report to all the states that you have patients. And there are ways to try to help that. The NHANES hub is one potential option.

There are other options being worked on. You heard at the start of this that NHSN is a way for certain facilities to send their results to one place, and they could have patients that end up being in multiple states. But you need to report to the patients' state health department based on their residence. So if you test patients from all over the country, you need to report all over the country.

And now, we're happy to try to help with that where we can. We've got a mailbox, eocevent405@cdc.gov, you can send questions to. And Jasmine, do you want me-- I know we're a little over. Do you want me to try to address these last three questions or not?

JASMINE CHAITRAM: Jason, thank you so much for your time. I think that we're going to end it here because we're over time, and I know we're losing some folks on the phone. And I do appreciate you and Ed and all of our panelists today for participating. I warned everybody that it was a full agenda. It really was.

We got lots of good questions online. We will do our best to answer them or have somebody speak about them on the next call. I want to remind everybody to sign up for LOCS Messages. LOCS@cdc.gov. And then our next call will be on Monday, November 2nd. Apologies for going over. Thank you all for participating, and stay safe.