Clinical **L**aboratory **I**mprovement **A**dvisory **C**ommittee

Meeting Transcript

October 28-29, 2020

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

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❖ Call to Order and Committee Member Introductions

CLIAC DFO: OK. Good morning. It's 11 o'clock on the East coast, 8 o'clock AM on the West Coast. Really appreciate everyone on the West Coast joining us so early.

CLIAC CHAIR: Oh, this is not a bad time at all.

CLIAC DFO: Welcome to the Clinical Laboratory Improvement Advisory Committee. We are really excited to have you. We really missed seeing you in the spring, and this is the first time that we've ever conducted this meeting completely remotely. So it'll be a bit of an experiment, but hopefully, we've done our due diligence and our homework, and we've thought of most of the problems that could happen. We're sort of reliant on all of your own internets to hold together as well as my own.

But we're really looking forward to this meeting with you. This is an incredibly important time for all of you and for all of us and for everyone that cares about clinical laboratory medicine. So thanks very much for your time and your commitment to this incredibly important event. And we do anticipate a large number of public participants. And so please, even though you will only see those of us who are on the panel, so to speak, through Zoom, keep in mind that there-- we anticipate a large number of public participants who will be listening and watching us throughout.

OK, so I have the honor of kicking off the meeting officially. I just want to let you know that I'm relying on my second screen for my script, and so if you see me looking this way, that's the reason. So the Clinical Laboratory Improvement Advisory Committee, or CLIAC, is managed by the Centers for Disease Control and Prevention and provides scientific and technical advice and guidance to the Department of Health and Human Services. The advice and guidance CLIAC provides to HHS pertains to general issues related to the improvement of clinical laboratory quality and laboratory medicine practice. In addition, the committee provides advice and guidance on specific questions related to possible revisions of the CLIA standards. As this is a federal advisory committee meeting, the Zoom chat and Q&A functions have been disabled for audience members. If you are experiencing Zoom difficulties, please contact cliac@cdc.gov.

CLIAC CHIAR: Good morning. My name is Valerie Ng. I have the honor of being the chair of this august committee. I would like to talk about public comments. During the period dedicated to committee discussion, participation is limited to CLIAC members only. CLIAC can only accept public comments that directly relate to the topics announced in the Federal Register notice of the CLIAC meeting and as related to the theme, "Laboratory Medicine in the Age of COVID-19."

Today, the committee will discuss and deliberate on the following topics-- preparedness and response, the partnership between clinical laboratories and public health, and laboratory data exchange during COVID-19. Public comment periods are scheduled at the end of each topic area for both meeting days. Today, public comments will be limited to a total time of five minutes per individual or group. If anyone in the audience wishes to address the committee, the public comment portion of the meeting is the proper forum to do so. Those who did not previously send a request for public comment and would like to participate, please email cliac@cdc.gov as soon as possible to be added to the session.

Now for the committee members, quorum, I want to gently remind you all of the importance of remaining in attendance on both days for the full meeting and returning promptly from breaks to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned. Members are expected to keep video

on at all times with the exception of breaks. This is so we can make sure you're engaged. I'm watching every one of you. OK, moving on, the process for official recommendations. Official recommendations are those related to an item on the meeting agenda that are put forward as a motion, seconded by another CLIAC member, and voted on by CLIAC and obtains a majority vote. OK, Ren, back to you.

CLIAC DFO: Thank you, Valerie. And thank you for reminding me that I should probably introduce myself as well. My name is Ren Salerno. I'm the Director of the Division of Laboratory Systems at CDC. I'm also the designated federal official for CLIAC.

We are-- we would now like to recognize those members whose last meeting would have been the Spring 2020 meeting. And so unfortunately, these five members are not with us today, but we do want to officially recognize their service to CLIAC. Dr. Keith Davis, Dr. Bradley Karon, Dr. Sharon Massingale, Miss Bonnie Rubin, and Miss Cynthia Wilkerson. Please visit the CLIAC meeting website to review a list of their contributions to CLIAC. We much appreciate their dedication to CLIAC and their service to the committee.

We next would like to recognize Dr. Peter Tobin for his service to the committee. Dr. Tobin was appointed to CLIAC as the FDA ex officio member in 2017. He provided the committee with five FDA update presentations. During his tenure as the FDA ex officio, there have been 44 CLIAC recommendations and three CLIAC workgroups. We thank Dr. Tobin for his service and commitment to CLIAC

We would also like to recognize Miss Karen Dyer. Miss Dyer retired from CMS on August 31st after 12 and 1/2 years of service. She joined the CLIA program in 2008 and later became the deputy director, and then the director of that program. Prior to joining CLIA at CMS, she worked at the Johns Hopkins Hospital medical laboratories as an affiliate laboratory supervisor and point of care testing coordinator. Miss Dyer was appointed to CLIAC as the CMS ex officio member in 2015. She provided the committee with nine CMS updates and additional presentations on laboratory information exchange and CLIA personnel regulations on behalf of CMS. During her tenure as the CMS ex officio, there have been 55 CLIAC recommendations and six CLIAC workgroups. We thank Miss Dyer for her outstanding service to CLIAC.

OK, now we move on to our introduction phase. I do want to point out that we have six new members. I will quickly list their names now, and then I will explain our introductory process. Our new members are Dr. Mary Edgerton, Dr. Nirali Patel, Dr. Michael Pentella, Dr. Chip Watkins, Dr. Tim Stenzel, and Miss Regina Van Brakle. OK, and we are extremely grateful to all of those new members. And so let me very quickly explain how we will introduce ourselves for this meeting. We will go around the table, so to speak, in the order that you see on the slide. For those of you who are not new members, we ask you to state your name, your affiliation, and any conflicts of interest you have. And please keep it at that. If you are a new member, we'd ask you to provide a very short introduction to yourself to help the rest of the committee members get to know you a little bit. But we ask you to keep it as short as possible. But new members are also responsible for indicating their affiliation as well as any conflicts of interest.

So as I've mentioned, my name is Ren Salerno, and I am the CLIAC designated federal official. I have no conflicts of interest. Valerie.

CLIAC CHAIR: My name is Valerie Ng. I work at Alameda Health System. I'm the laboratory director of the three clinical laboratories within the system. I am the chair of laboratory medicine and pathology for the system. I have no lab-related employment. I have no lab ownership. Lab-related positions involving a fiduciary capacity-- I'm a director on the board of directors for the East Bay Medical Group, which is a physician organization wholly owned by Alameda Health System. Relevant entities-- I was providing honoraria-- I receive honoraria from Cardax for being on their scientific advisory panel and being a consultant. I have no financial interests involving specific laboratory tests under consideration. I'm done. I'm going to pass it on.

CLIAC DFO: Thank you, I'll call on everybody just to make it clear. Dr. Birthale Archie, please.

BIRTHALE ARCHIE: Yes, good morning. I'm Dr. Birthale Archie, and I'm affiliated with Bowie State University, where I'm a professor, and I facilitate in clinical practice as well as theory facilitation. And I do not have any conflict of interest.

CLIAC DFO: Thank you. Dr. Marc Couturier. Marc, you may be on mute.

MARC ROGER COUTURIER: And I win the prize as the first one to do that, so we get that out of the way. So I'm Marc Couturier. I work for the University of Utah Department of Pathology in the microbiology division. I'm also a consultant for Area B Laboratories, which is a non for profit entity at the University of Utah, but does serve as a commercial national reference lab. Research reagents that I have as a conflict of interest include Apicor and Tech Site. I have clinical trials activities with Luminets, DiaSorin, and Genetic Signatures and I receive household income from BioPharma Diagnostics through my spouse, and I have stock ownership in bioMerieux.

CLIAC DFO: Thank you, Marc. Dr. Mary Edgerton.

MARY EDGERTON: Hi. I am Mary Edgerton. I work at the University of Texas M.D. Anderson Cancer Center as a breast pathologist and pathology informatician. I have no conflicts of interest, and I'm excited to be here. My passion is data standards. Thank you.

CLIAC DFO: Excellent. Thank you. There is always plenty of opportunity to talk about data and data standardization on CLIAC, so thank you for your participation. Dr. Susan Gross, please.

SUSAN GROSS: I'm Sue Gross. I'm an OB/GYN medical geneticist. I'm adjunct faculty at Icahn School of Medicine Mount Sinai, and I'm also chief medical officer at a company, employee company called Cradle Genomics that focuses on prenatal genetic testing, non-invasive.

CLIAC DFO: Any conflicts?

SUSAN GROSS: Yes so my conflicts are I am an employee of Cradle Genomics that is developing non-invasive prenatal testing.

CLIAC DFO: OK, great. Thank you. Dr. Lee Hilborne.

LEE HILBORNE: Good morning. I'm Lee Hilborne. I am a professor of pathology and laboratory medicine at UCLA and a medical director at UCLA Health. My one conflict of-- potential conflict of interest is I'm also an employee of Quest Diagnostics, and I do have shares in it. And other activities, I'm also adjunct member of the staff at Rand Corporation that, from time to time, does have funding from CDC. But there's nothing that I have right now, and I'm past president of ASCP and chair of the Effective Test Utilization Committee. Other than that, no other conflicts. Thanks. Looking forward to the meeting.

CLIAC DFO: Thank you, Lee. Dr. Steven Hinrichs.

STEVEN HINRICHS: Morning, everyone. I'm Steve Hinrichs, and I'm the chair of the Department of Pathology and Microbiology at the University of Nebraska Medical Center. As such, I have a large testing operation, and one of them is the Public Health Laboratory for the state of Nebraska. And we do have potential conflicts in that I have contracts through my department with the CDC and other federal agencies. In addition,

we run an outreach program that services a large number of hospitals and other private entities in our region. But those would be the limit of my conflicts. Thank you.

CLIAC DFO: Thanks, Steve. Dr. Jordan Laser.

JORDAN LASER: Hi. Good morning. How are you? Jordan Laser. I'm medical director of pathology and laboratory medicine at one of our tertiary hospitals based at Northwell Health in New York. I'm also an associate professor of the Zucker School of Medicine at Hofstra-- at Hofstra/Northwell. In terms of conflicts, for the Association for Molecular Pathology, I'm on the board of directors. I chair the Professional Relations Committee, and I'm a member of the Economic Affairs Committee. For College of American Pathologists, I vice chair the Personalized Health Care Committee, and I have a research grant funded by Natera. That's it.

CLIAC DFO: Thank you, Jordan. Dr. Thomas Lorey.

TOM LOREY: Yes, good morning. Tom Lorey-- I'm a pathologist by trade. I currently serve as director of strategy for National Integrated Services for the Permanente Medical Group, and that's with Kaiser Permanente in Northern California. I have no conflicts of interest financially or otherwise. I'm associate editor of the Journal of Applied Laboratory Medicine, but again, no conflicts. Thank you.

CLIAC DFO: Thank you, Tom. Dr. Lavinia Middleton.

LAVINIA MIDDLETON: Hi, good morning. I'm Lavinia Middleton. I'm a pathologist at University of Texas M.D. Anderson Cancer Center. And I have no conflicts of interest.

CLIAC DFO: Thank you, Lavinia. Miss Carole Moss.

CAROLE MOSS: I am the founder of Nile's Project. We are a patient safety organization focused on educating the public, working with the public on preventing preventable medical harm. And my passion is rapid diagnostics, and I'm really honored to be here on behalf of the public. And thank you all for joining me.

CLIAC DFO: And any conflicts, Carole?

CAROLE MOSS: No conflicts of interest.

CLIAC DFO: Great. Thank you. Dr. Nirali Patel.

NIRALI PATEL: Good morning. I'm Nirali Patel. I'm currently an associate medical director and senior pathologist at Tempus Labs. I come from both experience in academia as well as clinical trials testing, so I'm really looking forward to working with the committee.

CLIAC DFO: Thank you. Nirali, it's nice to have you here.

NIRALI PATEL: No conflicts to disclose. Sorry.

CLIAC DFO: Great. Thank you. Sorry. I forgot that, too. Dr. Michael Pentella.

MIKE PENTELLA: Good morning. I'm Mike Pentella, and I'm with the University of Iowa. I'm a clinical professor in the Department of Epidemiology, and I'm also the director of the State Public Health Laboratory.

I've worked in clinical microbiology since the 1970s in both the clinical lab and the public health lab, so I have experience in both areas. I have no conflicts of interest.

CLIAC DFO: Thank you, Mike. Dr. Katherine Perez.

KATHERINE PEREZ: Hi. Good morning. I am Katherine Perez. I'm an infectious diseases clinical pharmacist affiliated with the Houston Methodist Hospital, where I lead the Antimicrobial Stewardship Program. I have no conflicts of interest relevant to any laboratory entities. I am an investigator on several coronavirus therapeutics trials sponsored by the NIH and also Gilead Pharmaceuticals.

CLIAC DFO: Thank you, Katherine. I have Miss Jennifer Rhamy.

JENNIFER RHAMY: Yes thank you. I am affiliated with St. Mary's Regional Medical Center in Grand Junction, Colorado. I am the director of the Blood Donor Center there. And I have one conflict. I have received honorarium from Instrumentation Laboratories as a panelist on patient blood management.

CLIAC DFO: Thank you. Dr. Gregory Sossaman.

GREGORY SOSSAMAN: Good morning. This is Gregg Sossaman. I am the system chair for Clinical Pathology at Ochsner Health in New Orleans, and I also serve as the service line leader at Ochsner Health. I am a clinical pathologist. I'm also involved, as a board member, in the American Society for Clinical Pathology and also serve on several committees for ASCP. I'm also a board member of another laboratory group called the Compass Group, which is a system group of … a professional group of system laboratories. But I don't have any financial conflicts of interest.

CLIAC DFO: Thank you, Greg. Dr. Chip Watkins.

CHIP WATKINS: Good morning. I'm Chip Watkins coming to you from Asheville, North Carolina, where I am chief medical officer of Sanesco International and president and laboratory director of NeuroLab here, where I am an employee. Also, on COLA, the COLA board of directors as an AAFP, American Academy of Family Physicians appointee. And then I'm also a regional medical director for a company called Community Care of North Carolina, which is-- we're the vendor for Medicaid in North Carolina. Happy to be here.

CLIAC DFO: Thank you, Chip. Dr. Thomas Williams.

THOMAS WILLIAMS: Good morning. Can you hear me OK? All right. I'm Tom Williams, and most recently retired from the Division of Public Health, Nebraska State DHHS as chief medical officer and director in late 2018. And so I-- and I have been asked to come back and assist with the COVID response in April of this year, so I've been working in an ad hoc fashion with DHHS since then. I don't have any financial conflicts. I am a board member of the Public Health Association of Nebraska. And that's it. Thanks.

CLIAC DFO: Thank you. Just a reminder that if you're not speaking, please mute yourself. Dr. Donna Wolk.

DONNA WOLK: Good morning. I'm Donna Wolk. I'm an employee of Geisinger Health in Danville, Pennsylvania. I serve there as the division director for molecular microbial diagnostics and development. I have financial conflict of interest as a board member of Streck and as an editor at Elsevier. And my current grants are Cephied, DiaSorin, Sysmex, and Mediel. We're also a subcontractor for a company called ABT on a COVID grant that they have an affiliation with the CDC. We are a sample and data collection site, but we are not the principal investigators of that grant. Thank you.

CLIAC DFO: Thanks, Donna. Mr. Andy Quintenz.

ANDY QUINTENZ: Thank you, Ren. I'm Andy Quintenz, serving as scientific and professional affairs at Bio-Rad Laboratories and the AdvaMed Liaison. I also serve on the board of the Clinical and Laboratory Standards Institute, and I'm a member of the AACC Corporate Advisory Board and also chair the US Technical Advisory Group for Technical Committee 212. To ISO, that is all about IBD and medical devices.

CLIAC DFO: Thank you. Thank you, Andy. Dr. Collette Fitzgerald.

COLLETTE FITZGERALD: Thanks, Ren. Good morning, everyone. I'm Collette Fitzgerald. I'm deputy director for science in the Division of Laboratory Systems here at CDC. I'm the CDC ex officio for CLIAC, and I have no conflicts of interest.

CLIAC DFO: Thanks, Collette. Miss Regina Van Brakle.

REGINA VAN BRAKLE: Good morning. My name is Regina Van Brakle, and I'm CMS ex officio. I am currently the acting director for the Division of Clinical Laboratory Improvement and Quality. I have over 30 years of experience in laboratory medicine in the specialty of microbiology. And I have no conflicts of interest. Thank you.

CLIAC DFO: Thanks, Regina. Dr. Timothy Stenzel.

TIMOTHY STENZEL: Hello. I'm Tim Stenzel, and I direct the Office of In Vitro Diagnostics and Radiological Health at the FDA. I trained-- I did all my training at Duke MBA, PhD program through pathology residency, through fellowships in genetics and molecular pathology, and then opened the molecular lab at Duke, and then spent 15 years in industry at four different companies and gained significant FDA approval experience. And then I've been at the FDA for a little bit more than two years now. I also have significant experience, while I was at Duke, in developing LDTs. I am an employee of FDA. Otherwise, I have no conflicts.

CLIAC DFO: Thank you, Tim. And last but not least, Miss Nancy Anderson.

NANCY ANDERSON: Good morning, everybody. I am the senior advisor for Clinical Laboratories in the CDC Division of Laboratory Systems. With respect to CLIAC, I serve as the executive secretary and welcome everyone here today. Thank you.

CLIAC DFO: Thanks very much. We have completed our attendance and roster review. So I now turn things back to Valerie.

CLIAC CHAIR: Thank you, Ren. OK, it's my duty to talk to everybody about the schedule and the logistics housekeeping tools. For once, I don't have to tell you where the bathrooms are. But I will tell you now that copies of all PowerPoint presentations and other meeting materials are posted on the CLIAC website at cdc.gov/cliac. At the start of each presentation, I will announce the presentation number to assist you in locating the correct electronic file. It will be the blue number next to the presentation on the agenda. This meeting is being webcast via Zoom webinar. We welcome everyone to this first virtual meeting of CLIAC. Links for accessing the webinar are provided on the CLIAC website. If you are experiencing any difficulty with accessing Zoom, please email cliac@cdc.gov. This meeting is also recorded to assist in preparing an accurate written summary of the proceedings. There will be two 30-minute breaks prior to each main session, and CLIAC members need to arrive online promptly to ensure a quorum so that we can begin the session.

We are going to move directly into the meeting agenda with the agency updates. We will start today with updates from the CDC, CMS, and FDA. The online presentations are numbered 1, 2, and 3 in the agenda. We will start first with the CDC update from Dr. Fitzgerald.

❖ Agency Updates and Committee Discussion

Centers for Disease Control and Prevention (CDC) Update
Collette Fitzgerald, PhD, CDC EX OFFICIO

DR. COLLETTE FITZGERALD: So thank you, Valerie. Can you all see my screen? OK, great. So good morning, everyone. Thank you for the opportunity to share updates this morning on CDC's COVID-19 laboratory response work from our COVID-19 Laboratory and Testing Task Force on the work we have been doing in the Division of Laboratory Systems at CDC to support the Laboratory and Testing Task Force and the response.

Since launching an agency-wide response to the COVID-19 pandemic on January 20, 2020, CDC has been learning more about how the disease spreads and affects people and communities. From the beginning of the pandemic, CDC has been at the forefront of sharing what we've learned about COVID-19. From the laboratory perspective, CDC developed a real time reverse transcriptase, or are RTPCR test, to diagnose current COVID-19 infection and has helped equip state and local public health laboratories with the capacity to test people for the virus. CDC developed a laboratory serology or antibody test to help estimate how many people in the United States have been infected with SARS-CoV-2, the virus that causes COVID-19. CDC also developed a web page specifically for information for laboratories that includes laboratory testing, reporting, and safety guidance. CDC also developed the Influenza SARS-CoV-2, or multiplex assay. This is CDC's diagnostic multiplex assay for flu and COVID-19.

So the Laboratory and Testing Task Force plays an essential cross-cutting role in CDC's COVID-19 incident management system. This incident management structure is how CDC staff deploy internally within their agency to respond to outbreaks. We create task forces that are separate from our programmatic organization within the agency. The Division of Laboratory Systems, like all of the other organizational units or division, centers, and offices within CDC, deploy staff into the incident management structure to support the response. And many of our Division of Laboratory Systems staff deployed into the CDC COVID-19 Laboratory and Testing Task Force.

The mission of this task force is to increase scientific knowledge and laboratory testing capacity, and we really do this on a variety of ways. It's through work in CDC laboratories, support for clinical and public health laboratories, and engagement with other federal partners, commercial laboratories, and professional organizations. And then we have high level functions that are really tied into our mission. The way that we carry out our mission is by working in CDC laboratories to develop new laboratory tests and procedures and by evaluating laboratory reagents and instruments so that we can develop guidance and share that with laboratories, and then to provide technical support, technical consultation, and to perform laboratory testing.

The Laboratory and Testing Task Force's work focuses around three priority areas. The first bucket is around our laboratory studies, research, and development. So this is the area of the work that really goes on in CDC laboratories, either directly in the laboratory or through collaboration with external partners. One of our top priorities right now is to work with partners to assess rapid antigen test performance in the field, and then aligned with our mission to help increase laboratory testing capacity is to evaluate different sample types with our current molecular diagnostic tests and validate new reagents and platforms.

The second bucket is around the support that we provide through specimens that are submitted directly to CDC for testing or through the materials that we ship out from our supply, and then also to contribute to and assess performance of reference materials. Then the final priority area is a big bucket, where all of that laboratory work-- the research, the engagement, the collaboration-- really comes together so that we at the agency and our scientific subject matter experts are able to provide technical assistance. It's also to develop guidance, which comes in the form as guidance that's published on our website. It may be answering frequently asked questions. It may be responses to inquiries. There's a variety of mechanisms in which we can provide that technical expertise, and then there's field support. A big part of what we do-- and we do it quite often-- is to deploy laboratory scientists out into the field, who can really provide technical support for work that is ongoing outside CDC through investigations and transmission studies.

Some activities that are under way right now include the evaluation of alternative procedures and instruments, including automated extraction platforms as well as reagents that can be used with our currently FDA emergency use authorized singleplex or multiplex assays, as well as other diagnostic reagents. For collaboration and partnership, the task force is also looking at the current FDA emergency use authorized rapid antigen tests that are currently in use. The task force is really interested in looking at how these commercial products perform and in settings where they will be used, particularly with asymptomatic people.

Another area that is really supported by work in the Division of Laboratory Systems is guidance that is posted at our external website to support laboratory testing, to provide additional information about areas, such as bio safety and point of care testing. And then there are some ongoing activities. The task force will continually work to support testing when specimens are submitted to CDC and to provide technical support and deployments to the field. Right now, we have several studies that are either in the planning phase or about to begin when we do have to deploy staff to the field to provide support.

So in addition to supporting many task forces across the CDC response structure through deployment of staff, the Division of Laboratory Systems, given its responsibility to the clinical laboratory community, created a supplemental response team to specifically provide support to the Laboratory and Testing Task Force. So this Division of Laboratory Systems Response Team is really a function or an arm of the Laboratory and Testing Task Force. It has responsibilities in the following areas shown on this slide-- to lead the Tri-Agency Task Force for emergency diagnostics, to provide clinical laboratory technical support, to improve clinical laboratory coordination and communication, to provide training and education development support, to develop and support public private partnerships, to collect and report laboratory test data, to perform repository services by providing storage and sample management for samples collected, and lastly, providing policy support.

And I'll be spending the remainder of my presentation going into more details on these activities, starting with testing and reporting. The next few slides highlight some of the guidance we have developed. In July, we developed interim guidance for use of cooling procedures in SARS-CoV-2 diagnostic screening and surveillance testing. Its purpose is to provide guidance on the appropriate use of cooling procedures.

This next slide shows a graphical representation of the total number of views of the guidance page and the number of unique visitors over time. Since July 23, when the guidance was published on our website, until October 18, the guidance has been viewed a total of 56,000 times with 44,000 total unique visitors. The highest number of visits to the site peaked on July 26 with 9,229 visits. Web traffic has declined since then, and as of October 18, when the data was last pulled for analysis, the number of visits was close to 3,000 a day. And the total number of click-throughs or the number of link clicks for this interim cooling guidance web page was 6,000-plus since it was first published. The graph on this slide shows the click-through distribution by week, and you can see the highest peak occurred on August 2 at 1,150. The numbers have decreased since then, and as of October 18 it was 326 when this data was last pulled for analysis.

Interim guidelines for rapid antigen testing for SARS-CoV-2 were published on the CDC website on August 16th. This interim guidance is intended for clinicians who order antigen tests, receive antigen test results, and/or perform point of care testing, as well as laboratory-- as well as for laboratory professionals who perform antigen testing in a laboratory setting or at point of care and report these results. The purpose of this interim technical guidance is to support effective use of antigen tests for different testing situations.

This next slide shows a graphical representation of the total number of views for the interim rapid antigen testing guidance page and the number of unique visitors over time. Since August 16 when the guidance was published on our website, the guidance has been viewed a total of 587,000 times with 480,000 total unique visitors. The highest number of visits to the page occurred on September 13 with 71,699 visits. Traffic to the page now in October continues to be steady with over 55,000 visits and views a day.

There has been a total of 23,000 click-throughs of the interim guidelines for rapid antigen testing for SARS-CoV-2 since it was published. A graph on this slide shows a click-through distribution by week, and you can see the highest peak occurred at the end of August at 6,416. You'll be hearing specifics from Regina Van Brakle in the next presentation on the big increase in the number of CLIA certificate of waivers issued by CMS since the beginning of the pandemic. Guidance for SARS-CoV-2 point of care testing was published on the CDC website on October 14 and provides information on the regulatory requirements for SARS-CoV-2 point of care testing, including a link to the CMS website on how to obtain a CLIA certificate of waiver. It also has guidance on how to safely perform points of care specimen collection, handling, and testing for COVID-19 as well as how to comply with result reporting requirements. The link to the guidance can be found at the bottom left hand side of this slide.

To increase somatic interoperability for laboratory reporting for detection of SARS-CoV-2, LOINC in vitro diagnostic or LIVD test code mapping guide, the SARS-CoV-2 test was developed by a core group of SHIELD members. For those who may not be familiar, SHIELD is a multi-stakeholder public-private partnership and stands for the Systemic Harmonization and Interoperability Enhancement for Laboratory Data. The mapping is based on LOINC, SNOWMED, and HL7 standards. It was first posted to the Division of Laboratory Systems website on April 28 and is updated weekly. All tests that receive FDA, EUA authorization are automatically mapped and included in the tool. Several team members have also worked with HL7 to update the electronic laboratory reporting guidance document, which now consists of a format for reporting the test kit and device identifier. As of October 5, 365 tests have been mapped. You may note that that is more than the number of tests listed on the FDA EUA website. This is because some tests may receive authorization that include multiple IBD devices, and a separate line item is used to identify each device.

The number of downloads of the tool has steadily increased since the table was identified in the HHS reporting requirements. And the tool has over 13,000 downloads as of October 5, 2020. I'd like to thank the core SHIELD group for creating the rules to consistently apply the standards to map the data elements in the table, but also would like to thank HL7 for quickly convening a forum to update the electronic laboratory reporting guidance document. The reporting expectations and requirements for this pandemic are unprecedented, and reporting to state health departments and HHS is now required by federal law. The complexity of these large scale reporting requirements has been overwhelming for the laboratory testing community, and CDC has been part of supporting testing community's efforts to respond to these new requirements.

The Division of Laboratory Systems has provided continuous support and clarification to clinical laboratories on the CARES Act, HHS, and CMS requirements for reporting laboratory data through a variety of avenues, including our Laboratory Outreach Communication System or LOCS messages, through the clinical laboratory COVID-19 calls, through CDC's Laboratory Reporting web page, as well as FAQs, or frequently asked questions, and responses to numerous email inquiries. The Division of Laboratory Systems is also engaging with partners to address the challenges of how to appoint point of care tests for non-traditional testing sites.

Moving now to biosafety, the US supports development of laboratory biosafety guidance for the public health and clinical laboratories. This slide highlights the interim guidance for laboratory biosafety guidelines for handling and processing specimens associated with COVID-19. We also serve as laboratory biosafety SMEs for the public health and clinical laboratories by answering direct inquiries received from the laboratory partners. These inquiries are received for various mechanisms that include the duration of laboratory systems inquiries, the Laboratory Outreach Communication system, and CDC info. The primary laboratory biosafety topics covered includes general guidance, routine diagnostic testing, analytical pathology, anatomic pathology-- excuse me-- decentralized and point of care testing, procedures with a high likelihood of generating droplets or aerosols, environmental specimen testing, virus isolation, decontamination, laboratory waste management, and packaging and shipping.

The graph on this slide shows the web traffic for these interim laboratory biosafety guidelines over time, since it was published on March 13. There has been a total of 449,000 views and 324,000 total unique visitors with the largest number of views in March. The highest peak reviews occurred on March 15, with all visits at 57,715 and views at 50,558. As of October 18, there was 4,871 visits to the page and 4,560 views. And the total number of click-throughs for the interim laboratory biosafety guidance web page was 64,000.

This slide shows the distribution of the total click-throughs by month since the interim guidance was published on our website. And you can see it reached a high peak on March 29 at 8,011. And we continue to see traffic to the site with 761 click-throughs seen on October 13, when the data was last analyzed. The Division of Laboratory Systems has also supported the development of over 30 frequently asked questions or FAQs focused on laboratory biosafety issues relevant to public health and clinical laboratories. These FAQs are regularly reviewed and updated as new information becomes available. So the frequently asked questions, or FAQs, about laboratory biosafety and COVID-19 page was launched on February 20, 2020. On June 10, the redirect was created to a revised FAQ web page on the CDC COVID-19 response website. The metrics for both of those pages have been combined in the graph on this slide to show the web traffic for the laboratory biosafety FAQs. There has been a total of 381,000-plus views and 309,000-plus total unique visitors to these pages. The highest number of visits, which counts the number of sessions for visitors, occurred so far today on April 12, almost 47,440. And as of October 18, when the data was last pulled, all visits were still at 8,658, and the number of views was 4,135. So I'm going to move now to partnership, communication, and outreach.

So our partnerships with others are critically important. We chair weekly calls with the Tri-Agency Task Force for emergency diagnostics. We have calls with the American Clinical Laboratory Association, or ACLA, and large commercial laboratories every other week to provide updates on laboratory testing and answer questions from the clinical laboratory community. We participate in calls every two weeks with the Association of Public Health Laboratories, or APHL, and the CDC Laboratory and Testing Task Force and public health laboratories. We also have ongoing calls with our federal partners at FDA and CMS.

Related to clinical and public health laboratory issues, in 2017, the Division of Laboratory Systems created and now biannually convenes the Clinical Laboratory Partners Forum to strengthen relationships and facilitate communications. We've used this forum to encourage over 25 partners to share our LOCS messages and COVID-19 content. Many partners from the organizations listed on this slide have presented at our clinical laboratory COVID-19 response calls. The partnership between the Division of Laboratory Systems and the many professional organizations has had a positive impact on thousands of clinical and public health laboratories, point of care testing sites, and laboratory personnel nationwide since the pandemic began by providing critical and time sensitive information needed for COVID-19 testing.

Our Laboratory Outreach Communication System, or LOCS, allows clinical laboratories to access specific information and technical support from CDC. LOCS currently provides laboratories with a forum in which to ask questions and receive information. Email distribution has grown substantially this year. Currently, there are

over 500 LOCS subscribers compared to 52 one year ago. To date, DLS has distributed 82 COVID-19 or SARS-CoV-2-related LOCS messages during the response.

The LOCS website is the most visited DLS website today during the response. The clinical laboratory COVID-19 response calls provide a communication platform for CDC, other federal agencies, and partners to engage with and provide the most up to date COVID-19 information and guidance to the clinical laboratory community. We started these calls in mid-March as weekly calls, and then moved to a biweekly schedule in June. To date, there have been 21 calls with around 1,300 participants per week. And we have received 1,000-plus total questions from these calls. In addition, since February, we've received over 800 inquiries from clinical, academic, public health, and clinical laboratories. As you can see from the two bar charts on this slide, most inquiries, or 88%, come from clinical laboratories. And over half of the inquiries we've received since February, 2020, have been related to data and reporting and testing at 59%.

This slide shows the trends in the types of questions we received in the Division of Laboratory Systems over time, and the topic areas have changed over time. In the first couple of months of the response, we mostly received biosafety inquiries, as shown in this slide by the dark purple bar. But over time, data and reporting, which is a dark blue bar, and testing inquiries, which is the light brown bar, have become more common. So we recognize from all these inquiries that it would be helpful to the laboratory community to have information available in one place. Our answer was to create a one-stop shop resource, and so we developed and launched a preparedness portal on our Division of Laboratory Systems website. And you can find a link to the web page at the top of this slide.

On the portal, you can learn about LOCS and find recent messages. You can get participant information and more for our regular clinical laboratory COVID-19 response calls, including the slides, transcripts, and audio files from previous calls. You can find links to relevant training courses in the Tools and Resources section as well as easing links to get the latest information on the CDC's information for laboratories about coronavirus web pages and CDC's coronavirus website. So I encourage you to check out the web page and to share it with your partners.

So moving now to policy, the Laboratory and Testing Task Force policy function carries out legislative engagements in coordination with response policy as well as the other task forces in the response as appropriate. The Division of Laboratory Systems policy staff have been engaged in countless requests in support of the response. Dr. Redfield has testified in front of several congressional committees and will continue to do so. He requires materials that are updated, sometimes even on the day of the testimony, in order to answer a wide variety of questions.

Laboratory testing has been a focus of many of the hearings. Congressional members often send questions directly to CDC inquiring about topics, such as supplies and testing in their home districts, collection and access to demographic data, and national test capacity. Congress has passed several bills providing support for the response, and more bills are currently under consideration. CDC is often fortunate enough to receive drafts of these bills and can provide input, known as technical assistance, to make language more accurate and beneficial to the clinical laboratory community. Materials must be written, reviewed, and cleared, often with very little turnaround, sometimes within a matter of hours.

CDC and all federal agencies are held accountable through a variety of methods. Some of the most common mechanisms are records requests by the Freedom of Information Act, or FOIA inquiries, the Government Accountability Office, or GAO, and Office of Inspector General, OIG. FOIA requests come from a range of sources, such as city or county officials requesting test-related information, including supply allocation. They can come from news media outlets or academic researchers. The Division of Laboratory Systems policy office,

including policy staff, deployed to the Laboratory and Testing Task Force, have handled 25 FOIA requests since the pandemic began.

The CARES Act requires reports from CDC to GAO at specific time intervals when progress made on legislative mandates, such as supporting state testing plans and allocation of funds. OIG has conducted investigations of the test kit issues identified with the original CDC assay, as well as how CDC has and continues to engage the commercial laboratory community. Each of these types of requests requires coordination between the Laboratory and Testing Task Force and the regional laboratory systems policy offices given the overlap in staff and mission.

Leading now to laboratory training, the Division of Laboratory Systems has over 30 laboratory training e-learning courses listed on our newly redesigned website at cdc.gov/labtraining, where you can search by topic, keyword, or active filters. About 14 of these courses listed here on this slide are relevant to the current COVID-19 pandemic and that the knowledge presented is helpful when responding to a public health emergency. Since activating for the COVID-19 response on January 20, we've seen a large uptick in registrations by over 45% for these courses, as shown in the figure on the right hand side of the slide. This tells us that learners are taking training courses and are interested in courses that relate to the current COVID-19 pandemic.

To highlight just a few courses, this slide shows the top three e-learning laboratory training courses with the greatest number of registrations. It includes Fundamentals of Personal Protective Equipment, Packaging and Shipping Dangerous Goods: What the Laboratory Staff Must Know, and thirdly, the Fundamentals of Working Safely in a Biological Safety Cabinet. The Division of Laboratory Systems has numerous job aids inside our e-learning courses that are relevant to the COVID-19 response. In the past, learners were able to download job aids while taking our courses, but we realized that laboratory professionals who have not enrolled in the courses would also find them useful. Additionally, laboratories may want to brand the job aids with their own logos for distribution purposes. We have added PDF and Word versions of COVID-relevant job aids to our CDC Laboratory Training web page, and we just posted the first in a series of brief COVID-relevant videos on safely donning and doffing Personal Protective Equipment, or PPE.

I also want to let you know that we have released the first-ever CDC laboratory training course in Virtual Reality, or VR. This virtual reality course focuses on biosafety cabinet setup and safe use. The course is available on CDC TRAIN and STEAM, and with the appropriate VR equipment, it will allow learners to experience a safe and controlled simulated learning environment from the comfort and convenience of their own home. For those who may not be familiar with STEAM, it is a popular gaming platform with an estimated 1 billion users, and as of October, 2018, more than 19 million monthly active-- there was more than 19 million monthly active users. So you can think iTunes, but for games. This course is CDC's first listing on STEAM. As of October 23, there has been 286 registrations on CDC TRAIN, 2,491 STEAM downloads, and STEAM downloads by users in 30 countries. If you'd like more information on VR activities, please email vr@cdc.gov.

We have three additional VR training resources coming soon. By the end of the year, we are hoping to release two more courses, one which will expand the current biological safety cabinet course and go from setup to working in a biological safety cabinet and responding to emergency situations, and the second course will focus on donning and doffing PPE. They're also working on development of a multiplayer lab. This will be a virtual laboratory that will allow multiple players or learners to interact with each other in real time.

In partnership with CDC's COVID-19 Laboratory Testing Task Force, the Division of Laboratory Systems is taking a multi-tiered approach to rapidly identify and address COVID-19 training needs among the clinical laboratory workforce through a new project called ONE Lab, a unified response to training needs. Networks and communities of practice with clinical laboratory training and education staff, data-driven training and education programs, and targeted messaging through digital platforms will help drive behavior change and enhance the

readiness of the nation's laboratory systems' ability to respond to the current COVID-19 pandemic and future disease outbreaks.

This project is just beginning. You can be on the lookout for an invite to an organization to join the network coming soon, and we look forward to sharing updates on it at a future CLIAC meeting. I'd like to end by taking the time to first thank our partners and all of the laboratory community for your hard work, collaboration, and support this year as we work together to respond to this COVID-19 pandemic. We, too, love the lab and think laboratory professionals rock. I'd also like to acknowledge the expertise, dedication, and hard work of my many colleagues from the Division of Laboratory Systems and across the agency, who have worked tirelessly in the Laboratory and Testing Task Force, and the other task forces in our incident management structure to support our agency's response to the COVID-19 pandemic. Thank you.

CLIAC CHAIR: Thank you, Dr. Fitzgerald. Was very informative and a ton of information. Being the schedule keeper here-- and I'm looking at Ren-- we are at 11:57. So there are three minutes before Regina's talk. And are there questions from the committee for Dr. Fitzgerald? Seeing no acting out. Thank you, Dr. Fitzgerald. I think we need to digest it. And then we'll be back. Our next presentation will be a CMS update, and it's going to be provided by Miss Regina Van Brakle. Again, welcome to CLIAC. We're very happy to have you here.

Centers for Medicare & Medicaid Services (CMS) Update
Regina Van Brakle, MT(ASCP), CMS EX OFFICIO

MS. REGINA VAN BRAKLE: Thank you. Good afternoon, everybody. Again, my name is Regina Van Brakle, and I'm currently the acting director for the CMS Division of Clinical Laboratory Improvement and Quality, or the CLIA program. I'm excited to present the CMS CLIAC update, believe it or not. Next slide.

This is our disclaimer page. This presentation was prepared for informational purposes, and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages. And you can see the rest of it disclaimers here on this page. Next slide.

In November of 2019, CMS went through a realignment process. The Division of Clinical Laboratory Improvement and Quality now encompasses all of the previous CLIA regional offices under one umbrella. DCLIQ now consists of five branches to include two policy branches and two operate-- three operations branches. The regional offices are now called CMS locations and are divided among the three operations branches, which are listed here, along with the managers of each branches. Next slide.

Consistent with the theme of the meeting, I'd like to highlight what CMS has done and is currently doing to address issues and assist laboratories during the COVID-19 public health emergency. In order to assist new facilities with applying for a CLIA certificate, we have added a CLIA pay banner on the CLIA website, which leads the user to an online payment system for the CLIA certification fee. In addition, we have added a CLIA quick start guide banner to our website to assist laboratories with the application process and includes information on the expedited process that allows laboratories to start testing quickly. Next slide.

Here's a screenshot of the CLIA pay banner, and this site leads to pay.gov, which is an online payment system for certificate fees. It gives step by step instructions to assist the users to submit payment for a CLIA certificate. Next slide.

And here is a screenshot of the CLIA Quick Start Guide. This is a quick, user-friendly, step by step tool for those who are starting up a new laboratory, and it is extremely helpful for those facilities applying for a new CLIA certificate. This guide has received lots of positive reviews. Next slide. So let's delve into some statistics. As of October of this year, there are over 282,000 CLIA laboratories with the breakdown as follows. There are

over 207,000 that hold a CLIA certificate of waiver, over 30,000 that hold a certificate of provider performed microscopy, over 18,000 that hold a certificate of compliance, and close to 16,000 that hold a certificate of accreditation. Next slide.

During the COVID-19 public health emergency from March to October, we have added over 17,000 new laboratories, most of which are certificate of waiver laboratories. And you see the breakdown that we have here. Over 15,000 of those are certificate of waiver laboratories. Next slide.

As some of you are aware, there was a Health and Human Services initiative for nursing homes and pharmacies to begin performing SARS-CoV-2 testing. Of the new laboratories that have received CLIA certificates, most were physician's office laboratories followed by pharmacies. The rest were a mixture of laboratory types. There were over 2,800 new pharmacies were added, and 395 additional nursing homes have received certification. Next slide.

During this public health emergency, we had quite a few requests for CLIA waivers. The CLIA program is unable to approve Section 1135 waiver requests with respect to waivers of the CLIA program requirements, as the authority is only applicable to specified programs of which CLIA is not one of them. Sometimes people get confused and think that a certificate of waiver means that the facility is exempt or waived from CLIA requirements. That is incorrect. The certificate of waiver is a type of certificate for facilities that perform less complex testing. These facilities are still required to meet certain CLIA requirements. While we were unable to approve waiver requests, we have allowed certain flexibilities and have exercised some enforcement discretion. Next slide.

During the public health emergency, CMS released a memo providing guidance to surveyors regarding flexibilities and enforcement discretion. CMS has exercised enforcement discretion to allow pathologists to review pathology slides remotely at a temporary testing location as long as defined conditions are met. This helped to decrease exposure risk of personnel and allowed continued processing of workload. We have expedited review of CLIA applications. It was really important to us that we assured that facilities could begin testing as quickly as possible to support the national response to COVID-19, which is why we have the quick start guide and the pay banner. And it was very important to us that we got those up as quickly as possible. This flexibility allowed for testing to begin once the CLIA number had been assigned as opposed to when the CLIA certificate arrived by mail. So this expedited the processing. The laboratory can begin testing as long as applicable CLIA requirements have been met, such as establishing performance specifications for non-waived testing. We also allow flexibilities on multi-site exceptions. This allows laboratories to perform testing in parking lots or any other designated overflow locations in its facilities as long as the facility has the appropriate CLIA certificates and follow applicable CLIA regulations, state regulations, and guidelines. In addition, a temporary testing site may operate under another CLIA certificate as long as the temporary testing site provides testing consistent with the laboratory's CLIA certificate and under the direction of the laboratory director.

If the facility wants to or needs to become permanent, at that time, they have to apply for their own CLIA--separate CLIA certificate. We have offered flexibility with proficiency testing. If the laboratory is performing proficiency testing and providing patient results, PT is still required, according to the CLIA regulations. We have provided instructions to PT providers in the event that a PT provider would need to postpone, suspend, or cancel a proficiency testing event during the public health emergency. In the event where a laboratory temporarily suspends performing a specific test due to staffing shortage, stoppage, or reagent shortage, the laboratory must document the timeframe during which the test is not being performed and why. The laboratory must notify the inspecting agency and PT program within the time frame of submitting the PT results that it has ceased testing and why. And if the laboratory is still performing or resumes such testing and providing patient results, PT is still required and must be performed, as per CLIA regulations.

We've also allowed for alternate specimen collection devices to be used by laboratories as CLIA regulations are not prescriptive about the type of transport device, such as specimen collection swabs and viral transport media. The CLIA laboratory director can decide if subsequent validation studies are needed before tests are performed in instances where the FDA has indicated that certain alternate collection devices and specimen transport media could be used. Next slide.

CMS is also temporarily exercising enforcement discretion for the use of SARS-CoV-2 point of care antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA certificate of waiver when SARS-CoV-2 point of care antigen tests are performed on asymptomatic individuals. We are also temporarily exercising enforcement discretion for SARS-CoV-2 surveillance testing, where patient-specific results are reported-- for example, SARS-CoV-2 surveillance testing that does not use a pooling strategy. Specifically, neither CMS nor the state agencies that survey on its behalf will cite non-CLIA certified facilities, such as university laboratories that are performing such testing, provided that the facility does not actually report test results, but only refers the individual with the presumptive positive or inconclusive result to a CLIA-certified laboratory for further testing. Next slide.

During the public health emergency, CLIA surveys were placed on hold and then later reprioritized to focus on the following. We focused on complaints that represent situations in which immediate corrective action was necessary, because the laboratory's non-compliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm or death. And this is what we call an immediate jeopardy citation. We then are going to do any revisits to resolve current enforcement actions and any recertification actions for certificates that are about to expire. We extended the expiration date of certificates to December 31st so that we would not have any laboratories expire, because we were unable to perform surveys in a timely manner. And we're also going to be doing initial certification and other complaints. Next slide.

CMS will be issuing a remote survey guidance to provide important guidance to surveyors for optional implementation of a remote survey process during the SARS-CoV-2 public health emergency. During the reprioritization of surveys, we realized that many state agencies and CMS locations were unable to perform routine CLIA onsite surveys and may be experiencing a workload backlog. The remote survey process will be optional and effective only during the COVID health public health emergency. It will only apply to laboratories with good compliance history, and it is not applicable to initial surveys. Next slide.

To improve safety and quality around testing for COVID-19, CMS recently issued cease and desist letters to laboratories that did not have the appropriate CLIA certification. And the slide here is breaking down each location and the types of letter that we sent out. A cease and desist letter is issued when a laboratory or facility has not been CLIA certified to perform testing or when it performs testing outside of the scope of their certificate. Compliance is key, because incorrect information about COVID-19 status of individuals could negatively affect the spread of the virus and/or clinical treatments and hinder effectiveness in combating this pandemic. The letters ordered these laboratories to stop testing immediately to prevent potentially endangering individuals by providing inaccurate or unreliable results. Following receipt of the letter, the laboratories were required to stop testing or show or demonstrate that they had applied for the appropriate CLIA certificate. Next slide.

We have begun increasing our outreach to our external stakeholders and to the public via our communications listserv. The goal of the listserv is to disseminate important information to laboratories and lab professionals. The link to subscribe to our listserv is listed here, and we plan to keep the messages brief, so your email box won't get bombarded with messages, and we will get straight to the point. Next slide.

And here is an example of one of our listserv messages for the CLIA pay banner, so short and to the point. Next slide.

I'm sure by this point, everyone in the lab world is aware of the CARES Act. The CARES Act requires that every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19, to report the results from each test to the secretary of Health and Human Services. On June 4th, the secretary of HHS provided further guidance on required data elements. Next slide.

Reporting of results to state and local public health departments is not currently required under CLIA-- was not required under CLIA. In order to address reporting requirements of SARS-CoV-2, test results for CLIA certified laboratories as outlined in the CARES Act. It was necessary to amend or add several CLIA regulations through an interim final rule with comment or IFC-3-- IFC-3401. Laboratories performing SARS-CoV-2 testing will be required to follow this guidance or any updates to this guidance. CMA has made the following additions or modifications to the CLIA regulations. We have added a requirement for all certificate types to report SARS-CoV-2 test results as required by the secretary. We've added a requirement for accrediting organization and exempt states to report to CMS with any laboratories that have not reported test results. Next slide.

We've made a change to enforcement regulations to allow for imposition of civil money penalties on certificate of waiver laboratories, and we've also added the requirement to define the civil money penalty structure. Next slide. Who has to report? Again, the SARS-CoV-2 reporting requirements applies to any CLIA-certified laboratory, such as pharmacies, veterinary labs converted to CLIA labs, mobile testing units, et cetera that perform testing for SARS-CoV-2. This also includes any facility using point of care testing devices under a CLIA certificate of waiver. Next slide.

All CLIA-certified laboratories that report the results of-- test results that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 are required to report results regardless of the type of laboratory or the type of CLIA certificate performed in the testing. All SARS-CoV-2 results must be reported irrespective of the method used. Results for every SARS-CoV-2 test the laboratory performs, regardless of the number of times that an individual has to tested must be reported. Next slide.

Each laboratory must report SARS-CoV-2 test results in the manner and frequency by the HHS secretary. CLIA is not prescriptive about how a laboratory document's reporting of SARS-CoV-2 results, and the laboratory must maintain documentation of their reporting process. Next slide.

CLIA-certified laboratories will be assessed for compliance with the reporting requirement. Compliance will be determined through automated reporting methods or during routine random or complaint CMS surveys. Next slide. Again, CMS will be enforcing the results reporting requirement. Failures to report SARS-CoV-2 results may result in condition level noncompliance and imposition of civil money penalty of $1,000 for the first day of non-compliance, and then $500 for each additional day of non-compliance. Next Slide

If your laboratory is not performing any testing or if you're just collecting specimens that you are sending to a laboratory to perform testing, there is nothing that you need to do differently at this time. However, if your laboratory decides to start testing, we would need you to report that information and meet the reporting requirements. Next slide.

Here is a hypo-- hyperlink table of resources that we have provided during the public health emergency that we feel may be helpful with the IFC. There is a link to the interim final rule. One of our memos regarding the IFC and test reporting, the HSS COVID-19 reporting guidance, one of our memos to talk about laboratory guidance during the COVID-19 health emergency, and laboratory testing and COVID-19 testing infographic. Next slide.

You may contact us at labexcellence@cms.hhs.gov. If your inquiry is specific to the interim final rule, please add CMS-3401-IFC in the subject header. I'd like to take this opportunity to thank our CLIA partners, CDC and FDA, for all of their assistance and support during this public health emergency. And I'd like to take the opportunity to thank the CLIA team, all of the surveyors and the policy members, for working together and doing what we needed to do to make it through this public health emergency. Thank you all so much for the opportunity to present the CMS CLIAC updates. Thank you.

CLIAC CHAIR: Thank you, Miss Van Brakle. That was very informative, and we very much appreciate CMS's flexibility and nimbleness during this pandemic. We have a few questions lined up. We'll start with [CLIAC MEMBER].

CLIAC MEMBER: Yeah, I mean, this is a complicated question that maybe can't be addressed, but it's been the one that's come up a few times, and I'd be interested to know if there's any answer that could even be given at this point. But what is considered a temporary CLIA testing location? Is that going to be predicated on when the virus is a seasonal illness? Is it going to be when surge capacity is no longer required? Is there any definition? And I ask, because it seems like one of those things kind of like EUAs, where we still have EUAs for Zika out there, even though Zika is almost not even circulating in most parts of the Western hemisphere and a lot of countries. But these EUAs sometimes just sit there anyway, despite the fact that the need isn't really there. So is there any kind of guidance on when someone will be told that, like, your temporary status has now run its course? It's not necessary. Or is it just kind of open to the discretion of the user.

MS. REGINA VAN BRAKLE: Right now, we have it defined that it will be during the public health emergency. But we will reevaluate in the future, because you're right. Sometimes the EUAs go on forever ad nauseum, and so we will be evaluating at a later point to determine if these temporary sites now must become permanent.

CLIAC MEMBER: So that will be federally defined as opposed to state to state.

MS. REGINA VAN BRAKLE: Yes.

CLIAC CHAIR: OK, thank you.

CLIAC MEMBER: OK, thank you. Thank you for a really great presentation, and welcome to the team. Look forward to working with you and certainly thank all of the partners for their commitment to science during this challenging time. The question I had was really whether CMS or DLS is collecting data on performance for some of the allowed flexibilities. And I ask that, because some of the issues were longer term recommendations from the personnel task force, like remote slide evaluation, and having those data from this, what turns out to be a natural experiment, could be very useful in expediting future recommendations. Again, thanks.

MS. REGINA VAN BRAKLE: Hi, and thank you. At this time, we have not collected any data. I don't know if DLS has. But we are looking at the flexibilities that we've extended during this temporary emergency to see if there are any that would make sense to become permanent.

CLIAC CHAIR: Thank you.

DR. COLLETTE FITZGERALD LEAUMONT: [CLIAC CHAIR], I was just going to answer that maybe before [CLIAC MEMBER] goes, just to say that we, too, aren't aware of any specific data but certainly would welcome any specific

CLIAC MEMBER: OK. Hi. Thank you again for a good presentation. I had a question about nontraditional laboratories that are now doing COVID testing. These can be agricultural laboratories or environmental labs. They often seem to be hired-- a laboratory often seems to be hired as a contract with a large company or perhaps a school system that wants to be doing testing. And it would seem like a special challenge for CMS oversight currently, and I'm curious about, in the future, if CMS has contemplated how they will manage those as oversight. Thank you.

MS. REGINA VAN BRAKLE: Well, we will manage them currently as we do now. And I know with all of the additional, I guess, facilities that are inquiring for a CLIA certificate, it is becoming a lot. But we will still maintain our current guidance and requirements for certifying laboratories and surveying laboratories. And I think I answered your question.

CLIAC MEMBER: Thank you.

CLIAC MEMBER: Am I on mute? OK, yes. I echo all of the thanks. I wonder how-- what percentage of CLIA certified laboratories with any kind of certificate that are performing COVID tests are actually submitting full reports of all the required data to HHS.

MS. REGINA VAN BRAKLE: Well, right now, we don't have that information, because we had a three-week grace period when the rule went into play. So we are in the process of collecting that data.

CLIAC MEMBER: OK, thank you.

CLIAC MEMBER: Thank you. I have a question similar to [CLIAC MEMBER] in relationship to the saliva direct test promoted by the Yale University Department of Epidemiology. They seem to be the people who are vetting other clinical laboratories and other laboratories and academic institutions to be allowed to perform the saliva direct test-- been through that process, just to see what it's like. My question is how is Yale, a non-clinical laboratory, being the agency for which the other clinical laboratories with lots more experience are being vetted? That seems backwards to me, and I understand it's a surveillance test, but it is also a test on which people base their behavior, which lends to the seriousness of the result of that test. So is this a CMS issue, is this an FDA issue, or both?

MS. REGINA VAN BRAKLE: I'm not sure I can answer that. Right now, CMS does not seem as-- CLIA does not cover surveillance testing. So if they are performing surveillance testing, that does not apply to CLIA at this point. DLS, did you have anything you'd like to add? Thank you.

CLIAC DFO: I'm going to jump in here. Probably we'll end up talking about this a fair amount, but I think the definition of surveillance testing has evolved during COVID. And I think it's causing a lot of complications for how we traditionally have thought of CLIA and clinical laboratory quality. But CDC does maintain a definition of surveillance testing that we believe is consistent with FDA's posted definition of surveillance testing. And I'll just leave it at that for now.

CLIAC MEMBER: OK. That's good enough for now. Thank you. We'll look forward to further discussion.

CLIAC CHAIR: And the final question will be from [CLIAC MEMBER].

CLIAC MEMBER: Hey. Yeah, I'm just curious if CMS has any plans, I guess, to make state testing and reporting consistent. I mean I know in North Carolina, we don't have to report antibody testing to the state. I mean, clearly, here, you guys are requiring everything to be reported. But I didn't know if there was any plans to have consistency across the US and what is being reported.

MS. REGINA VAN BRAKLE: I think that may be an HHS issue, because CLIA, we're not prescriptive as to how things get reported. Right now, we're only requiring that results are reported. As long as the laboratory has a process for reporting and can show that they have done so, we're not prescriptive as to being-- we are not prescriptive about determining how a laboratory does it and the exact items that are required.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: Thank you.

CLIAC DFO: Hey Valerie, maybe I'll just jump in on that one, too. Another really good question. You know, I think on laboratory data result reporting, we-- there-- HHS, as you all know, I'm sure, put out guidance on June 4th that indicated what data elements need to be reported with each and every test result related to COVID-19. However, as [CMS EX OFFICIO] just explained, CMS is only enforcing the sort of reporting of positives and negatives. And I think there is a wide recognition within the government that the reporting has always-- reporting of reportable diseases has always been a function of state government health departments. And so the states really have jurisdiction over the details of what is reported and how it's reported. And so [CLIAC MEMBER], I do think we are going to continue to see a fair amount of differences in application of expectations for COVID reporting because of states' rights issues. So I recognize it's a challenge. It's a huge challenge, especially for those laboratories who are reporting across more than one-- across state lines. But to some degree, it's a function of our federal system. Over.

CLIAC CHAIR: Thank you, all. Thank you, Miss Van Brakle. What I learned from this is that when you finish your talk early, that gives us the opportunity to jump in. And with that, we'll-- So Tim, what we learned from Miss Van Brakle's talk is if you finish early, we're going to ask a lot of questions. So I'll let you pace your talk. Floor is yours. Thank you.

Food and Drug Administration (FDA) Update
Timothy Stenzel, MD, PhD, FDA EX OFFICIO

DR. TIMOTHY STENZEL: I'm sure I'll get a lot of questions no matter what. Anyways, pleasure to join all of you today and have the ability to discuss the FDA's response to the COVID emergency. Next slide.

You know, we are granted emergency use authorization authority during a pandemic, so I'll go into a little bit of that. Overall, high-- at the high level. This allows the FDA to lower the bar for authorization on tests, relative to what we normally require for tests. And this is obviously to, as quickly as possible, address the emergency situation. So this is in the Food, Drug, and Cosmetic Act, and it does give the commissioner and, therefore, the FDA the ability to allow unapproved devices and uses of approved devices in the emergency situation. And we'll go into-- in the guidance on the next slide, what are some of the factors here, because we do make a determination with each application that comes in whether this falls under the EUA authority or not. And it does require, in order for this to get picked off, this termination and declaration from the HHS secretary that there exists a public health emergency or a significant potential public health emergency. And then next, that declaration that authorizes the FDA to issue EUAs. Next slide, please.

And we've issued a general guidance for EUAs, and these are important. It must cover serious or life-threatening disease or condition caused by the agent in the emergency declaration. The product is determined it may be effective, rather than safe and effective, to diagnose, prevent, or treat the condition. There is, as I

described in the previous slide, a lower level of evidence and effectiveness for [INAUDIBLE] standard. The known potential benefits outweigh the known potential risks. A little more tightness to that criteria for non-pandemic authorizations. And finally, that there's no adequate approved or available alternative. And unavailable includes insufficient supplies of an approved alternative. So we began this process well before this pandemic, because this is in the 2017 guidance of preparing. And we've worked with our federal partners to prepare. However, this pandemic is truly an unprecedented event in our lifetimes. And I'll talk later in my talk about lessons learned.

And then I'd also say that very early on, in January, we made available recommendations for validation and engaged all types of developers in this. So we got engaged specifically-- you know, that's one by one, more than 20 developers. And that included all types of developers, including [INAUDIBLE] developers, kit developers, reference labs, et cetera, academic labs. And then more than 100 developers by the end of February. This authority allows us to authorize in days or weeks what would typically take months or longer because of this significantly less evidence required, the greatly reduced data that we review, the submissions are much, much smaller orders of magnitude less on tens of pages instead of thousands of pages and pages sometimes. However, there's a tradeoff. So we don't have as much data. In the beginning, there weren't actual samples. We allowed contrived samples.

And so as the pandemic progressed, we found out that there were some issues with some tests that I'll go into it a little bit later that did not perform as well as expected. Next slide, please. of course, a part of the preparation was experience. So there are six previous public health emergencies or potential public health emergencies that we at the FDA have experienced with-- starting out in 2009 with H1N1, which is one of the few, I think, that has been retired. Most of them, as has been stated before, do stay open. I'll go into that a little bit more. So in each of these cases, there are often times EUAs that are issued, and they remain open, and the ones that remain open are listed on the FDA website. So you can go in and investigate these and see all of the assays that are still enforced. One of the reasons why we keep these EUAs, enforced, first of all, as long as the emergency declaration remains open, that is a requirement that we maintain that. And there's a good reason to keep that open. And that is if we ever see a resurgence of any of these.

There's already authorized tests that can be brought to bear. If the emergency declaration were to be-- were to to expire, then it would be required that these tests that are currently allowed to be marketed would be removed from the market. So you can imagine that some of these, like Ebola, enterovirus, are important to keep around. And Zika is brought up, you know, and again we have a long history of keeping these open for a long time, and for good reason, as I stated. We have seen authorizations for many, if not most of these emergency declarations for Ebola. Let's see. How many? I don't have the exact number here that we're authorized, but one of them has been converted to a regular de novo submission and authorization. It was a rapid test that has usefulness worldwide for investigating potential Ebola outbreaks, and so a great tool to have. And many nations outside the US really look to the US authorizations here by the FDA as evidence that they can be used and a certain level of assurance that they will perform. For E7N3, there were three authorizations. I mean sometimes, of course, LDTs have been authorized. MERS-- there were two. Zika-- there was a long list, and then four have been converted. First one was a Genovo and subsequent ones were 510Ks. Next slide, please.

So to date our various pathways to market, allowed to market situation, including guidances that provided flexibility through a notification pathway. There are approximately 600 tests that currently have been allowed to be on the market. As far as actual authorizations, just under 300, so just over 220 molecular tests. These are all as of October 22. 56 antibody-based serology tests, six antigen tests-- as well as over 200 EUA supplements. So these are changes, modifications to assays that expand perhaps sample types, equipment, home testing-- home collection, rather. Pooling, asymptomatic claims-- all those sorts of things. So we've also denied-- I don't have it on the slide here-- about 100 EUA submissions. These were usually due to performance related matters and

issues, but some of them were due to potentially fraudulent activities and/or data submission to the FDA. Next slide, please.

So we have maintained a very public face through this pandemic and established a number of outreaches that included those developers we reached out to in January and in February and beyond. So one of those is the virtual town hall that we've been hosting, primarily by me, on a weekly basis since March. And we had a couple of webinars before that, but the Wednesday town halls-- last week was our 31st, today is out 32nd. Because of this meeting, I don't get to participate in that town hall. Those who have called in know that it is highly interactive between developers and the FDA. And it's our desire to help all developers, and to give them technical questions as direct as possible-- as clear as possible-- on the development and validation of test for SARS-CoV-2. We've had, as it says here, over 30,000 participants on those calls.

We have provided an FAQ page. I'll go into that in a little bit more detail. Some of that is just to provide great clarity about what our thinking is. It's a tremendous resource. This is now scores of pages in length, if you were to print it all out. And so we have heard great and positive things about that. We've stayed in communication with the lab testing and healthcare worker community through safety communication, and addressed a number of issues through press releases as well, the first of which is probably for the Abbott ID NOW, which had reported a number of false negative results, which we investigated and made public. We like to do that when we have established an issue, and that is something that we do outside of a pandemic, but during the pandemic we really work hard to make this clearly transparent. And we work with the companies, and sometimes we will go ahead on our own to do this sort of thing.

So we've issued to healthcare provider letters, such in this case, and in some cases, such as the false positives seen with the BD SARS-CoV-2Reagents on the BD MAX system. In another letter to healthcare providers, the FDA alerted labs and healthcare providers about inaccuracies in the Thermo Fisher TaqPath COVID-19 combo kit. And then also we did address some issues related to serology testing, which I will talk in a little bit more detail in subsequent slides. I think one of our greatest outreach efforts has been through our email inbox. Those who have sent an email know who Yvonne is, and have found her here almost uniformly to be highly interactive, quick, direct-- helpful. I get so many positive feedbacks about Yvonne, and she is doing a great job.

We have received and responded to thousands of inquiries, including EUA and pre-EUA submissions, serology PTR test notifications, as well as VTM notifications. Questions related to import, products, exports, distributors, compliance, self-collection, home testing, and a host of other inquiries. Based on the latest data available in September, we've received more than 172,000 emails, and we closed most of those. And most of those get closed within a day or two, if not immediately. Next slide, please.

So as we were heading into February and through February, we were engaged with scores of developers, but we did have a paucity of tests that actually had come in for EUA authorization, in which we could authorize at that time. We talked about some of the limitations of that. Some of them had to do with actual access to samples or any material that could be used to validate, but on February 29, we did issue new testing guidelines. This was in order to address and expand more quickly on testing availability in the US. This allowed validated newly-developed tests to be used prior-- that were validated to be used for clinical use prior to even submission to the FDA, and prior to our review. And this was directed towards LDTs.

And those developers could notify the FDA and get validated. We asked that they confirm their first five positives and negatives with the newly-authorized test. In the beginning, that was largely the public health labs and the CDC. They were to indicate on their test report forms that this test had not yet been independently reviewed by the FDA, and we asked that they submit their data within 15 business days of initiating the testing. There were steps that we asked them to take if there were any failures in the confirmatory testing-- those first five positive and five negatives. We did have some of those, and we did address those for public health, safety

procedures. This did put the labs on an honor system, so we had never before seen the volume of LDTs as were submitted in this and in any prior public health emergency, and this flexibility was great.

We did do an internal study on the first 125 LDTs that we received. Out of those 125, we did identify issues in 82 of those. They had to do with either the design or validation. Some actually had no validation data submitted in their EUA. We actually saw really no significant differences between commercial kit manufacturer submissions and the LDTs with regard to these types of issues. And also, there were no distinct differences between the different types of LDTs, whether it's an academic, commercial, or a large reference lab. In all cases, not just with LDTs, but also with commercial kit manufacturers, we worked with them to try to solve their issues, rather than just deny them. Because of the notification pathways, they could stay on the market during that. Next slide, please.

On March 16th, because of the success of that program and the greatly expanding need for testing, we did roll this out to commercial test developers-- this type of thing. And also introduced a new policy that allowed states to oversee tests developed by labs-- by LDT labs in their jurisdiction. And also introduced a policy that obviously became a little bit problematic for us-- serology tests without an EUA-- where those tests were validated, where there was a notification to the FDA, and where they stated and adhered to certain limitations in their promotions, including labeling. For example, the serology tests could not be used to diagnose or exclude active infections, et cetera. Also that those tests were not EUA authorized.

At that stage in the pandemic in March when we issued this, at least relative to serology tests, it's different than we are in now. So at that stage, antibody tests generally were not thought to-- and in prior pandemics were not thought to-- play a huge role. It limited utility, and in this pandemic we thought it was important to make them available for a number of reasons-- for research to determine the prevalence in the population, determine issues and scientific issues like immunity. When people get it, how long do they keep antibodies? We thought there could be uses for therapeutics, and subsequently convalescent plasma. And then potentially measuring responses to vaccine. The only way to answer some of these questions really was to make these tests available. And so we did require them to be validated, to notify us. They were limited to high complexity labs who were in a position to look at the evidence and closely monitor the testing of this type of test. So next slide, please.

Now obviously we began to see issues, and we addressed this when we discovered it, through a number of different types of communication. One was a letter to healthcare providers, and one was a recommendation and statements relative to serological test validation and education efforts. So we saw that these serology tests were being touted for opening up the economy, which led to some false advertising and creating a marketplace that really should not have existed, such as self-testing at home, immunity claims, point-of-care testing. So this really flooded the market with these tests in a manner that was not really allowed by that prior guidance.

We received numbers of reports. We investigated them, of course. And we established, in fact, as you know testing at NCI. This was a collaborative effort across many agencies is in the US government, notably BARDA, CDC, NIH of course, NCI, and the FDA. Which was somewhat unique, in that we utilized that US government testing to inform our decisions going forward. I'll go into a little bit more of that later. But obviously, these issues that we saw in the marketplace led us to change our guidance, and we'll discuss that next slide. So in fact to date, I've signed well over a dozen warning letters, mostly having to do with inaccurate marketing-- shall we say-- of serology tests, many of them in the home situation. We haven't yet authorized a home test for COVID-19, but I will talk a little bit about that later. So we did update the guidance on May 4th, and we said that now that commercial developers of serology tests should submit an EUA to the FDA within 10 business days of their notification or the publication of the guidance, whichever is later. So those that had already notified us, they had 10 business days to get their data into us for beginning their review process. And then we maintain the previous policy for serology tests as developed by LDTs or labs for LDTs, and we maintained our prior policy for diagnostics tests, which did require EUA submission. Next slide, please.

Further guidance on the 11th started the process of providing templates to developers we now have a long list of templates that we have been given a lot of positive feedback about. Obviously we also get some negative feedback, which we listen to carefully, and as a result have adapted. So most of these have been revised. In fact, the antigen template was just revised Monday this week and made available publicly. So these undergo constant review and revision, and then once we get cleared to release them, we do that. But obviously for molecular templates for labs, for commercial providers, antigen templates for manufacturers, Rally templates for manufacturers and labs. Home specimen collection-- and with the home collection template, we did see a flurry of activity and authorizations around home collections that we're pleased to do. And then the most recent one, and I'll talk a little bit about this later, and I already alluded to it-- the non-lab or what we call home test situation. We have a template for molecular antigen, and we are working on serology. Next slide, please.

So to sum much of this work up, there have been quite a few firsts, not just for this pandemic, but first time for the FDA to do some things here. So of course we've authorized molecular tests. The CDC has, too-- lots of LDTs, commercial kits, point-of-care test panels. But that is a growing area-- is this point-of-care test. Home collection, including swabs and saliva. We placed home swab collection by-- the first one was LabCorp. And that was not without some controversy, but I think it's been shown to be very useful tool. Saliva is a very difficult sample type-- not a traditional respiratory virus sample type-- and we're pleased to authorize Rutgers, and then their home test as well-- home collection, rather. And then one of the most unique things about this pandemic and showing our flexibility and adaptability to address certain needs is the FDA test protocol for distribution authorization we made for saliva direct. And we've given them the authority to designate labs who can perform the test in a way that the test protocol has been authorized. And that has seen a huge amount of interest and positive feedback to both. Yale of course, but also to the FDA.

So I seem to have lost video, but hopefully you can still hear me. So I will continue my presentation. We've authorized pooling-- swab pooling, asymptomatic testing, number of serology tests. I did want to mention again that the NCI testing effort is the first for providing a US government regulatory input on test performance. And then antigens have also shown a huge increase in testing volumes. Hundreds of millions of the antigen tests can be produced annually, and this is a fast-growing area. I also wanted to mention our work with RADx. This the NIH effort to establish tests that can address hopefully our needs yet this year. We are very active with RADx. We have multiple meetings a week and a senior level, and we also provide through our front-line reviewers direct feedback to both RADx and for those sponsors, developers that authorize that, and to the sponsors and developers themselves. Next slide, please.

We have, during this pandemic, I think provided an unprecedented amount of transparency in post-authorized tests-- all our FAQs, all our weekly town hall meetings, all our communications, press releases, safety communications. But in addition, we began work in February on a reference panel. We had begun planning for it in January, actually, but began work in February, which we then launched and began sending out the EUA authorization holders. And now we've made public the results of that reference panel testing, which gives the public-- this is a public facing website-- relative analytical sensitivities. We've also been very transparent about serology test performance and sharing the NCI data publicly once we've made decisions on that. Next slide, please. Going to lessons learned-- so I just published an article in The New England Journal of Medicine-- a perspective piece-- last month. The key lessons learned were that getting samples and specimens early on is very important. And we think there should be a coordinated effort worldwide to make this available to any country that is potentially going to experience the pandemic. In our case, the pandemic didn't start on our shores, and samples obviously didn't hit our shores until January, and not very many in number.

Second was in order to provide the kind of reagent volumes and supplies that are needed to address a very large-scale testing need, we see an effort to focus on a smaller number of well-designed and well validated tests that they can operate on high throughput platforms-- to really focus our energies and efforts, both financial and other resources-- the US government. And then followed by point-of-care testing. Now of course this can apply to

LDTs. There's no reason why we couldn't work with LDT developers who then make their formula available to commercial manufacturers and scale up production. A perfect example of this is once the CDC primers were published, IDT and other developers started producing them for research-use application, and then in February we made efforts to allow those to be sold under the CDC's authorization. And within a week, millions of test reactions were available, and by the first week of April, those-- IDT, Biosearch and other developers of kit and test reagents-- made available 40 million-- 4-0 million-- test reactions by the first week in April. So that ramp up of available test reagents is key.

We think that reimbursement upfront for the development will remove obstacles to this. We heard from companies that said we don't know early on-- we don't know if we even want to get into this, because we don't know if it will turn out to be a big deal. And it's costs millions of dollars to develop a test and market it, and get it to the FDA, even-- for them, even in a pandemic situation. And so that's a huge spend, but more importantly, sometimes to them it's an lost opportunity cost if they're developing something that doesn't become a pandemic, isn't needed, and they've delayed development of other important tests in their menu. We do think that all tests should be accurate and reliable. And so we see a common approach to validating test design and validation, and establishing performance is important to continue to support common legislative framework. And rather than taking, at this point, administrative action, that this pandemic really highlighted the critical need to have legislation to ensure tests all tests are accurate and reliable.

The final lesson learned was there could be an expansion of education. We see that in many spheres that education of actual how to understand test performance, how to apply it-- could be utilized in the test community among healthcare workers. I am probably running short on time. I didn't think I was going to take this long, so I will say just briefly that we did begin to address shortages in March when we started hearing about them. Now we are not responsible for the production, distribution, and availability of test supplies. However, we took multiple efforts to address that through regulatory flexibility, working with manufacturers, working with the DOD to airlift in swabs from outside the country, for example. And we continue those efforts until today. And then next slide.

I did want to briefly mention that we are strongly supportive of additional authorizations and working for additional authorizations, and we've done a lot already, as I elaborated. But home tests-- performed in the home, and potentially more easily in other non-traditional testing sites even though they may require CLIAC EUA of certificate-- is we believe an important unmet need. We provided templates for recommended validations months ago, and I think we're going to have some authorized home tests in the not too distant future. And I want to thank everyone, especially our federal partners CDC, CMS, BARDA, NIH, DOD, HHS, et cetera-- clinicians, labs, patients. Thank you so much.

CLIAC CHAIR: Thank you, Dr. Stenzel. That was very informative, and we have five questions lined up for you. So I'm going to start with [CLIAC MEMBER]. You're on mute.

CLIAC MEMBER: Yes, thank you. And thank you, Dr. Stenzel, for that excellent information. I know quite a while ago, convalescent plasma received the FDA emergency authorization use. And so I just wanted to do a follow up question and ask-- I'm sure clinical trials are continuing. Are there any findings that would suggest it's available-- going to be available very soon for wide-spread use in treating COVID-19? Could you give me a little bit of an update on the status of convalescent plasma in the emergency use authorization?

DR. TIMOTHY STENZEL: Yeah. So I'm not sure if you're talking about tests that might identify potential donors, or the actual convalescent plasma authorization?

CLIAC MEMBER: The actual convalescent plasma authorization for use in treatment.

DR. TIMOTHY STENZEL: Yes. Yeah, so convalescent plasma with EUA has been authorized-- is available. And that is and that is a Center for Biologics responsibility. So I would refer you to them for having more details on that. But we obviously work very closely with them, for their related testing needs.

CLIAC MEMBER: Hi. Yeah, very nice to meet you over video today. I've been participating in all the LOCS calls, and you've been very informative. I'm really urgently concerned about the CDC numbers on the fact that over 50% of these cases of COVID are being transferred by asymptomatic people. And until now, and this continues-- the public has been pretty much left out of the solution. And the solution is, as you know more than anybody-- it is to identify those people who are carriers. And we're finding out that many people don't have symptoms for five days while they're carrying it. And I know that you've mentioned you don't have an EUA or over-the-counter daily fast tests at home for self-tests. You've mentioned that several times. At what point does our government finally say, for public health, we'll build this ourselves. We will come up with a rapid at home test. At what point do we say that we don't want this to be a money grab-- we need to do this urgently? I'm just curious.

DR. TIMOTHY STENZEL: Yeah, that's a great question, and we definitely see a need. Just in my piece in The Hill explained my willingness to be really flexible to make this happen. I'll tell you that we are working with a number of developers in this area now, and I can no longer claim that we haven't received a home test submission.

CLIAC MEMBER: OK! All right, good to hear. Good to hear.

DR. TIMOTHY STENZEL: I would say that I personally have reached out to a number of developers to encourage them to do this, hopefully the ones that can do it in volume. They know, because I've reached out to them. And then the RADx program is really laser focused on some of this. And that's, of course, up to $1 billion I think $500 million at least on this category of test overall. They're primarily focused on point-of-care testing and/or home testing, and nontraditional setting testing, like workplaces and schools. And lots of exciting new technologies that we've obviously already authorized-- some RADx program tests, and there is a lot more to come.

CLIAC MEMBER: So just as one piece of really critical information, and we know that these tests will require-- when you get a positive antigen test, it's really-- I've heard you say you would recommend getting another test. If there was a way to use-- since today we can't typically get a PCR test unless we have symptoms. If we could use this antigen test as like the golden ticket when you're calling in to get a PCR test. And if they ask do you have symptoms, no, but I have this golden ticket, then we would be able to free up and really make progress on preventing the spread. That would be so wonderful.

DR. TIMOTHY STENZEL: Yeah. So I think our labeling and the intended use will address this specific issue. So antigen tests are great. The ones we've authorized to date I think are performing pretty well. I look at a lot of data in all the MDRs that are-- we investigate all, and we look at all, and investigate those that really need investigation. But no test is perfect, and you have the false positives. And you do the math, and there can be a lot of false positives. So we'll address that upfront in the intended use statements as applied to the technology. And we're hoping that the test developers will think ahead how they're going to handle this. We've obviously already authorized a number of home collection situations. So could they be overnight-ed-- a home collection swab and then send it back.

CLIAC MEMBER: We need it daily. We need it daily.

DR. TIMOTHY STENZEL: It would be better, but you could also go-- yes, it would be better to do that. I agree.

CLIAC MEMBER: There's a lot of nurses-- a lot of nurses, a lot of moms-- they would really be thankful. You'd be their hero.

DR. TIMOTHY STENZEL: Well, it's not actually the FDA's sole responsibility here, but I am making a note of it. I think that is a great idea.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [CLIAC MEMBER], I think we will definitely come back to this in some of the other talks, so hold that thought and make sure you bring it up. Three more folks in this order—[CLIAC MEMBERS]

CLIAC MEMBER: Thank you. A two part question really-- really do thank the NCI for validation of the antibodies was really smart and appropriate. Wondering whether you considered it for the point of care tests as well, because of their performance that's sensitivity isn't nearly what was advertised, and would have benefited, I think, from that validation. A second question is could you say a little bit about the FDA's thinking in terms of not requiring the EUAs anymore for LDTs? And this only saliva, or it's all LDTs? Thank you.

DR. TIMOTHY STENZEL: Can you clarify your question about not requiring permissions for LDTs? You want to know what was behind that?

CLIAC MEMBER: Thank you. So I'm told-- it may be incorrect-- that an LDT for COVID no longer requires an EUA submission.

DR. TIMOTHY STENZEL: OK. Yeah, I can address both of those. So back to your first question-- thank you about the NCI. Think it's a brilliant program. We're so grateful to our federal partners who helped stand that up. We have been working together behind the scenes on antigens-- the rapid test. It's a little bit more of a challenge, technically, to do that. I explained that on the town hall call, I think last week, where the panel-- the reference panel, for example, that reproduced an inactivated virus may not be great for antigen tests.

We're doing some of that testing, so when we can make that public, we'll let you know. Not necessarily us, the FDA, but US government. And we would love to have that sort of program stood up, but we've got to find the right way to do it accurately. And then it may fall just to analytical accuracy and sensitivity, which is not quite what we're dealing with serology. Serology, we have actual patient samples. We're actually measuring serum plasma performance, so that's ideal for any sort of test.

The change in the LDT situation was brought about by a statement posted on the HHS website that said that the FDA could not require EUA submission for LDTs. And due to the overwhelming number of tests applications before the FDA, and in wanting to preserve our resources for those that-- and get through them as quickly as possible, we made the decision that focusing on those EUAs that required an FDA authorization was the right thing to do for public health. So hopefully that addresses that question.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: OK. Thank you, and again, thanks for the presentation. And my question really is revolving around the reference panel that you created. I think it's an incredible resource moving forward. And you don't necessarily have to answer this here if it's too complicated, but at least maybe on the website-- we've heard from some members of the diagnostic community that-- if you could provide some clarity in terms of the units of your LOD assessments on the reference panel. We see that you're using an NDU per mL. And how does that relate to, I guess, the more classic LOD units that we use, such as copies per mL, et cetera.

DR. TIMOTHY STENZEL: Yeah, it is certainly not an LOD unit home. It may be related to an on LOD unit. It's related to nucleic acid amplification technique, where we look at diluted detection for a number of different targets within the viral genome-- RNA. And we sort of came up with a harmonized number across those targets, because they were not all equivalent, for whatever reasons. And so we created this NDU unit. And it has been done before for other things, but you can think of it-- I call it now a relative analytical sensitivity. You think of it as a relative LOD.

So we attempted to provide information across all the EUA authorized tests, just what their relative sensitivities were. Now that's analytical, and has nothing to do with clinical sensitivity-- their ability to detect people with clinically important amounts of virus. I think there's been some other studies that have shown there can be a wide variety of relative LODs, and so there can be a reasonably good performance across a large dynamic or a large range of relative LODs. So we have been emphasizing not to over interpret those results. We are beginning to dabble in using them to identify potentially high sensitivity tests, which we can use as benchmark for truth. So hopefully that's helpful.

CLIAC MEMBER: Yep. Thank you.

CLIAC CHAIR: Thank you all again to all our three presenters. That was most informative this morning. We are cued up now for a 30-minute break, but I do note that our next session is starting at 1:30, which is only 13 minutes away. So I know there are folks who are attending remotely, and are expecting us to be on schedule. Sorry guys. How about we come back at 1:35-- I'm looking at [CLIAC DFO] for OK. And that'll give you an 18 minute break. So the break is starting. Please put yourself on mute so we don't hear your conversations. There won't be a countdown clock, and please be back on time. Thank you very much.

❖ Presentations and Committee Discussion

Clinical Laboratory Medicine in the Age of COVID-19

Overview of Meeting Topics
Valerie Ng, MD, PhD, CLIAC CHAIR

DR. VALERIE NG: OK, good. So I am delighted to welcome you to our next session, which is titled as part of the meeting agenda of Clinical Laboratory Medicine in the age of COVID-19. Our topic of this session will be clinical laboratory medicine in the age of COVID 19. Thank you all for attending.

I want to give an overarching statement in that this particular CLIAC session is unusual in that it is entirely devoted to COVID-19. The COVID 19 pandemic shown a bright light on all aspects of laboratory medicine, identifying what worked well, as well as exacerbating known gaps or identified new and unexpected ones in the total testing process. Through this series of presentations and committee discussion, I am hopeful the collective wisdom of this expert group will have ideas as to how we manage the next wave of this pandemic, or the next pandemic. The talks in this session will encompass the totality of laboratory medicine, from rapid test development and scale up, to the critical pre-analytical and post-analytical components embodied in information systems and reporting to both patients and public health agencies. And finally, the health inequities and disparities uncovered and prominently laid bare through the lens of COVID-19.

The first session is titled Preparedness and Response-- The Partnership Between Clinical Laboratories and Public Health. During this session, we will have three presenters who will focus on challenges and successes related to COVID-19 testing. The first presentation will be from Dr. James Crawford, the Senior Vice President of Laboratory Services at Northwell Health in New York. Dr. Crawford will present from the perspective of a

clinical laboratory heavily engaged in COVID-19 testing and rapid scale up, as New York experienced the rapid spread of infection and consequent impact on clinical care. The second presentation will be from Dr. Alex Greninger, the Assistant Director of the University of Washington Clinical Virology lab. Dr. Greninger will be presenting from the perspective of an academic clinical laboratory with an existing substantial outreach business. His laboratory was one of the first to recognize and develop testing to address COVID-19 spread in the Northwest, including new experiences of going through the FDA EUA process and navigating supply chain issues. The last presentation on this topic will be from Dr. Elizabeth Palavecino, the Medical Director of Clinical Microbiology at Wake Forest Baptist Medical Center. Dr. Palavecino's responsibilities span both a clinical and the public health laboratory. Early in the COVID-19 response, precious commercial reagents and instruments seemed to be preferentially allocated to public health and not available to the clinical laboratory community. She will present from both of these perspectives, and the value of partnership between these two sectors. Next slide, please.

We will-- at the end of these presentations, I asked the committee members to ponder these questions. And it would be lovely if you could speak to them. In particular, what challenges and successes have been identified as clinical and public health laboratories have played a critical role in responding to the COVID-19 pandemic? And secondly, what additional guidance or resources should CDC, CMS, and FDA provide for laboratories to facilitate the needed SARS-CoV-2 testing? Next slide, please.

Our second session will be on laboratory data exchange during COVID-19. During this session, we will have three presentations focusing on data reporting challenges and successes. And while we will focus on data reporting, or the outbound, we must remain mindful of the inbound input and total pre-analytical and post-analytical processes that are gathering data upfront to route clinical specimens to their correct destinations for testing. Electronic transmission of orders out and results in and to the correct person tested, and appending demographic information gathered at data input to results reporting. Additional challenges exists with point-of-care testing, since these often do not have the standard laboratory testing accessioning and reporting infrastructure.

Our first presentation will be from Dr. Tony Tran, the Director of the District of Columbia Public Health Laboratory. He will present on the development and utilization of electronic test orders and results, or ETOR, in the Public Health Laboratory during the COVID-19 response. The second presentation will be from Dr. Rajesh Dash, a pathologist and Medical Director of Laboratory Information Systems at Duke University Health System. Dr. Dash will provide the clinical laboratory perspective on data exchange during the COVID-19 pandemic. And the final presentation on this topic will be from Dr. Stanley Huff, the Chief Medical Informatics Officer at Intermountain Healthcare. Dr. Huff will provide the point-of-care testing perspective on the topic. Next slide, please.

Questions we would like the committee to consider and discuss after these presentations will be what are the challenges and barriers for laboratories and reporting SARS-CoV-2 test results and related data to public health agencies? How can HHS promote consistent use of standards for reporting laboratory test results? And how can HHS plan for automated standard space data collection processes that meet current practices for reporting to Public Health, and are easily adapted for future public health emergencies? Next slide, please.

The final session, which will occur tomorrow morning, will be the clinical laboratory's role in identifying health inequities. This will be the first time that CLIAC will discuss the topic of health disparities, inequities, and social determinants of health. Previously we've discussed an expanded role of commonly used laboratory tests for health assessment-- for example hemoglobin A1C, or serum creatinine-- as surrogates for diabetes or renal disease, for assessing population health, and as a tool to assist with identifying health inequities and disparities. The COVID-19 pandemic has, however, dramatically exposed related health inequities and disparities in its initial eight months of existence in the United States. Presentations will focus on experiences with or

observations of health inequities and disparities during this pandemic. They will provide a springboard off which the committee discussion can be launched regarding the role or roles the clinical laboratory may have for population health, affected by COVID-19 pandemic or other clinical conditions.

The first presentation will be from Dr. Marissa White, who is an Assistant Professor of Pathology at the Johns Hopkins Hospital and a consultant on the Breast Pathology Consultation Service. Dr. White's education research focuses on using novel teaching methods to train the next generation of pathologists and improving diversity, equity, and inclusion in pathology. The second presentation will be from Dr. Nicole Lurie, who served as the Assistant Secretary for Preparedness and Response at the US Department of Health and Human Services during the Obama administration. She is currently a consultant to the World Bank and the Coalition for Epidemic Preparedness Initiatives. She has led multiple successful community-wide initiatives to improve the health of under-served populations. Next slide, please.

And during these presentations, we ask the committee members to consider how laboratory data has been used to identify health disparities during the COVID-19 pandemic, and how can clinical or public health lab data contribute to the identification of other health disparities and improvement of health equity. I believe that's my final slide? Yes.

And so with that, I have a few more housekeeping tools. This current session will have three speakers-- Dr. James Crawford, Alex Greninger, and Elizabeth Palavecino. These are presentations five, six, and seven in the agenda. If you wish to provide a five-minute public comment, please email CLIAC@cdc.gov. We currently have two public comments lined up-- one for Mr. Daniel Edson, President of the American Proficiency Institute, and one from Dr. Jonathan Myles, representing the College of American Pathologists. The public comment will follow the presentations. With that said, we will start with Dr. James Crawford and Lessons Learned From the COVID-19 Response. Thank you.

Preparedness and Response: The Partnership between Clinical Laboratories and Public Health

Lessons Learned from the COVID-19 Response
James M. Crawford, MD, PhD

DR. JAMES CRAWFORD: Thank you very much. It is a real honor to present to this committee. I was asked to speak to lessons learned from our experience in the New York area. I will spend the first portion of this talk setting the scene, in terms of what we were going through at the height of the pandemic. And then I'll walk you through my thoughts on the lessons learned.

Shown here is the April 224th New York Times national map-- hopefully I can minimize this-- which certainly felt like it-- that New York was the epicenter of what was going on. And for my part, I was posting weekly messages to the Association of Pathology Chairs Listserv, trying to pass along these lessons learned and experience in anticipation of what might be happening elsewhere in the country. If we back up a few weeks to April 8th, which was really the height of the curve that we experienced in the New York area, this was the epidemiological information available to us at the state level and the institutional level. On the left is a linear plot showing in green the relentless rise in case incidents, documented by PCR testing at New York State Department of Health and other laboratories. The next line down on the left in red is the testing out of Northwell Health Laboratories. And the two lines at the bottom, which look small on a linear plot, are the death rate-- both for New York and black and then in Northwell.

But what is much more revealing is to plot this on the right on a log-10 plot, and to show the rise in case incidents at the state and the Northwell Health level. And then the two lower curves in dark gray and in maroon-- the death rate. This was when we didn't know how this was going to turn out, and I don't think any of us will forget what it felt like to be in the midst of a world pandemic and truly not know what was going to happen to these curves.

Fortunately, they were flattening by April 8th, but on a log-10 curve with a slope of 14, that means whatever you are looking at, and at the time it was deaths-- if it's still linear at log-10, that means in 14 days you're going to have 10 times more deaths. And Northwell was out of the gate very quickly in getting testing up and going. On March 18th, our positive tests represented 35% of all resulting cases in the state. I suspect there was a reporting lag, because very quickly this corrected down to around 25%. And by the 10th of April, which was really the study period that I'm going to be reporting on, our positives represented about 14% of all cases in the state. Looking at how we've done since-- for the duration-- and this is through October 10th. The top left chart is in blue-- the total number of PCR tests that we've been doing on laboratory-based platforms for the duration of the pandemic. The curve in red of positives has come down now to around 60 to 100 positive PCR tests per day. On the upper right, it is our positivity rate. And at the height of the pandemic, for patients presenting to the emergency departments of our hospital and getting admitted, the positivity rate was 70%. And you can see in blue and green the positivity rates for our urgent care centers and for other ambulatory sites.

We started up antibody testing on April 26th, and the very first thing we did at about 8,000 tests per day-- 7,000 to 8,000- tests per day-- was to do a serosurvey on a voluntary basis of Northwell Health employees. Ultimately 48,000 of Northwell's 72,000 employees were tested by the end of May. And you can see that although we still have a capacity on the order of 7,000 to 8,000 tests per day, the use of antibody testing stays down and in the 2,000 per day.

But you can see on the bottom right that our positivity rate all in runs around 16 to 19% on any given day. And so we're resulting between 350 and 450 sero positive patients per day at Northwell. The statistics as of the end of September are for Northwell-- we are one of the major health systems in the country for having admitted over 16,000 patients. On September 30, it was 16,056 patients had been admitted. Our maximum daily sent census was over 3,000 inpatients in our health system, which was the first two weeks of April. When I submitted these slides, our daily census was at 135.

Inpatient deaths are also something we're never going to forget. If you just do the simple arithmetic, this represents the height of the pandemic. And the tale of the pandemic-- 21% mortality. Clearly it's lower now, and that's a great relief. The maximum daily COVID deaths on April 14 of 92 is more than four times the daily seasonal that we have experienced in prior years. And I'm sure you saw the news stories of the stress that that imposed on our mortuary operations. As of September 30, more than 800,000 PCR tests and more than 400,000 serology tests. We published the March 3rd to April 10th accrued data-- 46,000 plus patients tested in the New York area. You can easily find this paper by typing in the seven digits at the lower right into Google.

And I'm going to show you just a very few slides. This first slide is a geographic zip code distribution in which the color of the dot is when the first positive case in that zip code appeared-- color coded by date as shown on the right. And you can see that very quickly COVID blossomed in our area, once Northwell had testing available, supporting the premise that COVID was already widely distributed by the first week in March. The size of the dot is the normalized incidence of SARS-CoV-2 positive patients by zip code as of April 10th, and you can see the concentration in Queens, especially. There are also hot spots elsewhere on the island and in our region.

A full follow through of these 46,000 plus patients as regard where they were tested, were they hospitalized on the left side, or were they emergency department treat and release in the middle, or ambulatory-based tests in

the community-- is shown on this plot. The basic message is that of patients who tested positive, 45% of them had presented to a hospital site-- our EDs primarily. And of those, 60% admitted on the spot, and 40% were released. On the other part, 55% of positive patients were positive in the community.

The key point from this slide is that of the community-based testing or the ED treat and release, 4.5% of those patients were admitted to hospital, and the average time from test sample procurement to admission was 4.8 days. So that being an ambulatory tested patient still carried risk of admission to hospital in a very short number of days. Foreshadowing the discussion on health disparities, something that was quite important to us as we were looking at our data was, was there disparate access of persons to testing by Northwell Health. And the left chart shows on a log-log basis. The percent of persons in any given zip code tested by Northwell Health Laboratories as a function of average household income in that zip code. And across a very broad range of zip codes for service areas that we had at least 10% of all tests performed in that zip code, there was, in essence, a flat curve, supporting the premise that persons in those zip codes across the whole range of income had access to Northwell Health Laboratory's testing.

On the right, though, is a log-log of the percent positive test rates by the same x-axis, which was average household income. And between the range of $25,000 to $125,000 average annual household income per zip code, there was an inverse relationship between test positivity, percent positivity, and the zip code income. Which raises discussion of whether the disease had-- infection rates had penetrated more deeply into those zip codes-- those lower income zip codes-- by the time patients presented for testing.

And it was very interesting that on June 4th, in the midst of a rapidly-evolving discussion on COVID feeling health disparities, these charts, which are an x-axis of, in this case, median household income by zip code, and then various chronic conditions-- this is for all metropolitan-- all major metropolitan areas in the United States-- the curves are very similar. And so in our follow up to this particular study, we are pursuing information about vulnerable populations as reflected by these healthcare disparities.

Lastly for that serosurvey of Northwell Health employees, 48,000 employees tested for antibodies to SARS-CoV-2 in the midst of standing up community based testing. And on the very bottom is shown the positivity rates for Northwell Healthcare workers, which is all employees for this purpose. First responders, when compared to patients that we were taking care of, and community positivity rates. And by zip code and by community, healthcare workers were consistently below the positivity rates in their communities. And in terms of just getting information out, this was enormous endorsement of the premise that front-line workers were being protected by personal protective equipment.

So that is the backdrop for the comments that I'm going to be making about lessons learned. And in preparing for this talk, Dr. Ng invited me to compare our experience with COVID with that of the 2009 novel H1N1 virus, because we were the sentinel laboratory in Queens-- that's where the high school students coming back from Mexico first turned positive. We were the first ones to get to 1,000 positive patients-- one of those few times that a submitted paper is accepted within a matter of hours, which is the paper at the top. The paper at the bottom, which was reporting on what it means to be a sentinel laboratory and respond to a pandemic, took me four journals to finally get an acceptance in emerging infectious diseases. And every time there's a new virus, this paper gets traffic, including now.

Looking at the second paper, these are the lessons that I would present to you from the 2009 pandemic. And the first is decisive and immediate response on the part of the laboratory with regards to staffing supplies, LIS, things that you are familiar with-- immediate strategies for providing coverage in the laboratory for the surge response. Coordination across a broad swath of your operations. Reporting is what I'd like to focus on, because this to me is the pivot point for the current discussion. We were getting what was at that particular moment in time viral culture samples, and we were in touch with the CDC immediately, and with local civic and state

officials. The CDC sent us primers within the week. Within 10 days, we had the PCR-based assay up, and it was really a breathtaking moment of communication and collaboration between the civic authorities, the CDC, and our laboratory.

Client services public relations-- a very, very important role for the laboratory to play. And I wrote the sentence which you see at the bottom, which is we believe that there will be future infectious outbreaks that will strain the standing capacity of clinical laboratories, requiring effective implementation of surge capacity responses, independent of Public Health Laboratory support. The concept of the sentinel laboratory to me is critical for response to an emerging pandemic. The bottom line from every single outbreak we've had, whether it's Ebola or H1N1 or COVID-19, is that when you see the crisis coming, you commit to the response-- there is no other option. So what about lessons learned this time around? And I'm going to break it up into strategic and tactical.

Strategic-- top of the list. Working with civic authorities is absolutely critical in-- [AUDIO OUT] --absolutely critical, including clear delineation of duties and redundancy, which translates into resiliency. We did have people get sick, and when an officer is out for three weeks, you have to have resiliency in your incident command. To me, the most important word on this slide is workforce safety. It's protecting your workforce, first from what is still an unknown contagion, but also the stresses of responding to the surge of testing that's coming in. And cross coverage, not just of technical, but also non-technical support is very important. Supply chain-- big discussion point, which can be subsequent.

Laboratory science-- a new microorganism, a new virus, which means it's a whole new game as far as test performance and quality control. That has to be done in your CLIAC approved lab, to make sure that you yourself can attest to the validity of your test results. And the journey of discovery, medical science. I put down patient outcomes, which includes, in this case, learning about false negatives and positives. Notice that I did not include test utility. How does this impact patient care? That is still a journey. And then discovery-- where this has been a breathtaking time of discovery.

Tactical-- there is a long list of tactical objectives that I can't speak to in the time available. But what I would point out, that at the very top, support from the health system, which must be unwavering in your laboratory's response. Staff redeployment-- this is a 24/7 activity. And then extensive attention to other tactical objectives. What I do want to concentrate on is the next two slides-- the worst of it. As we were going through this, what were our largest stress points? The time to respond for laboratory testing was one of the most excruciating times in my career. I can tell you exactly where I was on February 29th when the FDA EUA came through, authorizing us to work with the New York State Department of Health to stand up our testing.

The politicization of the pandemic as we were bringing testing up-- it felt like we were in a political environment, which I have not experienced before. Particularly for us, the supply chain issues-- it was very difficult to navigate in the midst of an unclear national strategy for the supply chain and other aspects. And then reporting-- the ability to report to the state, to national authorities-- was also a journey.

Something that I actually feel very deeply about is the fact that the near patient laboratories-- the in-system laboratories, the small laboratories, the hospital-based laboratories-- always seem to be bringing up the rear in supply chain. And our most excruciating times were when we could not provide testing for patients coming to our hospitals. That was especially in May and June, as the health systems were waking up. The unreliability of the supply chain it was hard enough as it was, but when the rest of the USA became affected, our supply chain in New York worsened. | was a relentless mental toll. It continues, but particularly when we did not know how this was going to turn out, the stress was considerable. And the sense that lessons from New York were not heeded at the national level.

The best of it I think outshines the worst of it-- the workforce, the absolute commitment to the tasks at hand, the teamwork in the health system, in our region, with civic authorities, with the National Laboratory community. Public relations strategies did work-- our aggressive commitments. And standing up a consortium of laboratory leadership across the state to help learn from one another and inform the state, and then the discovery that has come with it. Hopefully the inherent value of the clinical laboratory was amply demonstrated.

Regulations where their own journey, as I've already mentioned, the drama of Saturday, February 29th. It was a historical date for us in the laboratory community. And New York state had its share of regulations that guided our life. What I would ask for here is there have been relaxed regulations. To me, it's worth being thoughtful as these regulations-- pre-existing regulations-- are reinstituted. What has been gained? Generational visibility, education of the public, working with policy leaders at the state level. Especially, to me, tremendous strengthening of the National Laboratory community. The opportunity of a clinical lab to lift up a health system and region. An incredible investigative opportunity at all levels.

What has been lost? I think reputationally and operationally, this has been a tough time. We do have a direct relationship with the public, and educating the public, and the foibles of trying to do laboratory testing I think has been amply demonstrated. Final slide, next steps. These, to me, are general principles. They have not been changed by COVID. Strong working relationships at labs and public agencies, the incredible contribution that lab can make to population health, which is something that we've articulated before. Optimizing healthcare in spite of COVID-19-- we're well on our way to recovery and strengthening of healthcare delivery. And always is there a better way to deliver health care. I firmly believe that we have to measure what we do in quantitative fashion, and be champions of the role of pathology and laboratory medicine in healthcare education and discovery. I want to acknowledge our entire workforce of 2,200 laboratory professionals, but especially our laboratory incident command team, our community outreach team, and the informatics team that has made it possible to bring this information to you. Thank you very much.

CLIAC CHAIR: Thank you very much, Dr. Crawford. That is just so breathtaking-- the totality of what had to go into that response. Thank you. Next speaker is Alex Greninger, who will speak on SARS-CoV testing in the real world. Alex, floor is yours.

SARS-COV-2 Testing: The University of Washington Experience
Alex Greninger, MD, PhD, MS, MPhil

DR. ALEX GRENINGER: Thank you, Dr. Crawford, again for that excellent talk. That was fantastic to hear and just really important. I think every lesson there we shared as well here in Washington state. Thank you Dr. Ng and the committee members for the invitation to speak here about our experience and SARS-CoV-2 testing. Instead of focusing-- I'm not going to talk a lot about what happened here in Seattle from the pandemic standpoint-- we've actually been doing pretty well. I just wanted to focus on things-- Dr. Ng told me to talk about things we could focus on we could do better and things that worked during this time period.

So I think the first point that I'd just like to start out with is it comes up again and again, and maybe I even have a sore point to it, but just the degree to which clinical labs are part of the public health system. That was eminently apparent on Dr. Crawford's talk and what he said about independent public health lab support, but here I just put up the scale of testing during the first few months for the public health labs where they're reporting that on the CDC web page versus then across the country.

And you can see very quickly within-- as soon as the clinical labs are able to test, they can scale and be up 90%. They're probably like 95% of total tests run today in the country as it stands. The problem is that we're not often seen as part of that public health response. So here, I'm putting up an email from January 31 from trying to get clinical SARS-CoV-2 positive samples from other labs. They were another analytes this wouldn't necessarily be

a big problem, but here all of the excess samples have gone to the CDC. There's no way that you can get that analyte.

And this was continually-- I'm really going to focus a lot of the talk on the difficulty in obtaining positive control specimens to be able to start testing. You couldn't get-- in February-- the tests from the CDC. So once the CDC had an authorized test on February 4th, we're not considered part of a CDC qualified lap, even though we actually do do the CDC flu protocol. So the state public health labs, military labs are going to get those.

And obviously there were issues with the CDC kit, but just from the outside, I actually had one of our scientists bang his head into a wall several times. Not literally, but actually asking repeatedly from IRR from the CDC to ask, hey, can we get the one authorized test in the United States? Because I basically wanted it on the record that we couldn't get it.

Now I think Matt Binnicker has a great editorial in Clin Chem from earlier, basically that would be really nice-- we expect these samples to go to the CDC early on. We expect the first test potentially to come from the CDC. But being part-- having academic labs, certain public, large academic clinical labs be part of that response, we will say what we see. We will evaluate the test, and we will publicize that information. I think having that sunlight on the process could be potentially helpful in the future. So I really wanted to highlight that op ed from Matt Binnicker.

So in terms of-- that was our experience with the CDC in February, in terms of the FDA. So we engaged on February 4th initially, because that was what we had to do. And it was a very-- and I also would say-- I'd say one of the reasons, although we'd been told by others that this was going to be a lot of work, and that it might not be what we need, what we should do-- I was really curious, actually, just to understand what it was like. I mean, I've been sort of taught from an LDT perspective. I'm a young assistant director. What do I know?

I've been told that the FDA is going to regulate laboratory developed testing potentially someday, and that will be the end of laboratory developed testing. We sometimes treat the FDA like the boogie man when it comes to these things. And so I wanted to be like, all right, what's behind door number two. And so let's go through this process and see what happens. This is one opportunity to see that.

And I think we rapidly figured out that the type of positive control material that we needed to validate or assay on was just not available. There was a lot of discussion about that. And I would even say that the first time we submitted our pre-EUA documentation was because I couldn't get a straight answer to the question of how long of a piece of RNA do I need to use to authorize-- to use a positive control material? Because the CDC had used the N gene-- in vitro transcript derived RNA-- and coronavirus viruses are unique. They're the largest RNA viruses among mammals, right? And so I can't actually synthesize the whole genome. One of the transcripts is 20,000 bases long-- nucleotides long. I can't synthesize that. Can I synthesize the E gene What is it that would be OK?

And I think I learned a lot in terms of just how consultative and back-and-forth this process was. Initially you think of this like this is the rules, and this is what you need to do. And there's a lot of negotiation there, and talk about back and forth. And so next time, I'll be able to appreciate that.

But I would say that most clinical labs don't have someone to deal with the FDA. This took a great deal of time. I was happy to do that, and learned a lot, especially given the dynamic nature of the process. I think that also meant that there was a lot to do back and forth. And we learned a lot, but I do agree-- when we talked to some of the major test manufacturers that you would normally buy tests from in min-May, they were saying to us that we would basically would not expect an EUA until late April or early May. And so it again continued to bulwark our desire to offer laboratory developed testing throughout February as we sort of tried to figure out

how we could get access to materials that allow us to validate the test. The original template was quite long, and used the word recommend 43 times, which I found actually-- and now I understand what that means. But at the time, I had no-- it was really hard to know when the FDA recommends, what does that mean? How does that actually have the full force of law, or can we talk about it? How much can we negotiate?

And I would also say that some of the-- when it's shortened to the 6 1/2 pages, all the change here is so positive and good, but I think this caused a lot of laboratories to look at that initial process, to look at the best Zika processes, and be like, you know, we're not going to do it. And you just can't get ready overnight. It was because we went through this process and learned a lot that we were able to stand up testing within two days after that February 29 guidance came through that Dr. Crawford mentioned. And of course I also just say how is a risk-based framework deal with the risk of not testing? I think that's a fundamental issue that came through here in February. So in terms of difficulties in obtaining positive samples-- so at the time, there were thought to be only 14 positive cases across the entire US in much of February, right? And so there's was a direct relationship between the epidemiological criteria and the testing supply.

One of the other things I'd like to just talk about-- that one curve on the public health testing. The CDC was offering basically five to seven day turnaround time within a couple of weeks after that first case that was detected. I mean, it's really remarkable the degree to which-- many of these reference-- these labs-- are not set up to offer the fast turnaround time. Meanwhile, we just got rules that basically said we're going to go to reimbursement cut if we don't get it done in 48 hours, right?

So I would also say that, like I said, I showed you before the email some difficulties in obtaining specimens directly from clinical labs. I even wrote to a friend at the federal national quarantine center, because they got the first patients, and I was wondering. There were ethics rules about getting samples from people under federal quarantine, which I totally understand, but I do think it is a potential solution going forward. This is where we actually have seen people being repatriated to in the past for Ebola, as well as SARS-CoV-2.

I think the CDC to BDI process has really improved. The fundamental flaw here is a cultured virus was available on February 12, 2020, but there was really not a ton of consideration for what BSL-2 and what clinical labs could work with. So for instance, we had the RNA. RNA became available sometime around the first week of March, maybe the very tail end of February. It was touch and go on when that was going to be. But even that extracted RNA doesn't really recapitulate the virus. And when you try to spike that in, you actually really have to adulterate your practices before the RNase is coming in to chew that up and affect your test sensitivity.

And even at the local-- so if we had gotten that virus, or we wanted to get that virus from BDI, it would only work with the BSL-3 level. Our committee here at UW would only meet like 2 1/2 weeks later, where they'd look at the paperwork. And then you'd have to get the sample, grow it up locally, and then inactivate it. So when we explored that time-frame, we were looking at a six to eight week time-frame for being able to get that material.

And ultimately the virus beat every single process that we had, including the NIH material. We found a lab in Galveston that could send us RNA, and the virus beat it by about 12 hours, or maybe 14 hours, in terms of getting here. So it was only in testing for all of the samples that were coming through the lab for SARS-CoV-2, we were able to identify a positive sort of like on a research level.

So what we can do here-- I would really like to have more-- I think there's opportunity to talk about standards for in vitro synthesized positive control material. I think that has a lot of genes, so this gets better and better. We don't really have an understanding of how we can use that. Clearly the CDC was able to use that-- they didn't have a positive from China before they were able to do their first diagnostic testing. It'd be helpful for clinical labs to understand what we could do in that process.

I do think we need to release early materials. I know the FDA is on board with this, to large test manufacturers early, and that will help them get on board faster. We need to make those BSL 2 inactivated reagents available. There are some new international networks that we're actually part of here. NIH has just funded 11 centers, basically to wrap around the country and have relationships and bilateral relationships and be in almost every country to be able to obtain bio specimens, should this come up. It actually was sort of happening at the same time.

I think that national quarantine unit samples-- our military bases-- there's an opportunity there. I think people will actually be happy to have a couple more nasal swabs that would help get samples out into circulation and to our test manufacturers and our clinical labs, if we expect the viruses to merge abroad first. And then we're going to have to-- well, likely, one of the sources will be repatriation, in case we don't have access to those samples from those countries. And we know from Zika with Brazil, and we know from SARS-CoV-2 with China that was a-- that just was very, very difficult to get those samples.

And I'd also say-- I'd like to give a shout out to our own MTA office. I mean, because of this issue of going through this and all of February and not be able to get samples, we shared 79-- and we processed 79 MTAs over a 50-day period. So we had a full-time person just dealing with shipping for those MTAs to get samples out to other labs so they would have to deal with this. Because even if you get a Hologic or a Roche, you still need those positive samples to verify the test performance. A lot of these test manufacturers aren't providing those reagents at the exact same time.

Supply chain-- Dr. Crawford talked about this as well, but this has just been an entire University and department affair. Every single thing has been an issue. We specifically zagged a lot, honestly, when it-- I say that when we've adopted testing platforms we wouldn't really want to use, but they at least then have reagents that would be available in a crunch. And I really want to echo what he said about-- for us it was June and July. When Florida, California, Texas, and Arizona had a lot of cases, a lot of our allocations went away, and I'm going to talk a little bit about that a little bit more.

It helped us that Seattle had early cases, so we were early. We were able to place our big orders in the first week of March, as opposed to the second or third week of March. And so I do think that's actually something that helped us. I wouldn't say that's a generalizable lesson or anything like that, but we were actually insulated from a lot of this process, because kind of went through it first. And we were aware in these lessons.

The LDT and the diversification-- Dr. Crawford talked about this. I couldn't agree-- we have nine testing platforms. I would never want to do this, but we have to do it, because we don't know who's going to come in, or who's going to have a QC failure in San Diego or Germany, and we've got to have other testing platforms to be able to offer it.

It's also interesting that respiratory testing does not have standardized collection tubes, like blood processing for blood chemistry. I think we're going to actually change some of these processes. That's been a big part of us-- our testing here-- is being able to offer more standardized testing to increase throughput when you're offering 8,000 to 9,000 tests a day.

It is incredible number of times that China, Germany, and Korea have come up as we've gone through and looked for where we're going to get materials from. A lot of these things are just not made in the US, and we haven't really prioritized making them in the US. And that's affected us locally here. But thankfully there hasn't been much bad behavior from manufacturers-- just a lack of supplies. You don't see any price gouging, at least in what we're seeing.

And maintaining a healthy reimbursement has been one of the few dogs that has not barked in this whole operation, and continues to-- I'll be honest-- it does continue to drive the whole organization to be able to perform testing at a high level. It's having that higher-- that hundred dollar reimbursement.

I'd also give a shout out to our Washington state regulators, who took over testing authority on March 16. All of our emergency use authorizations have been from Washington state. I don't think it's a coincidence that it's both Dr. Crawford and I are both talking from states that went through would have that deemed CLIAC authority or CLIAC exemptions. And we were also able to take over some of the testing regulation. It's been fantastic. Honora Estes in the Department of Health has been incredible. I wanted to put that on the slide so it's on the record.

And then it has been really helpful to have one person to talk to in the same time zone that I can basically get in contact within one to two or three hours-- talk about validations, talk about what she's seeing-- those sort of things. She can even bounce things off me that she's getting information from other test providers or whatnot. That's been very helpful, and that's been able to offer us much faster testing, and be able to handle the diversification that was required. We had to go-- we had to change assays many times because of this, and it's allowed us to get authorization for each time of those.

And I'll also say-- echo on the need for LDTs. I mean, so I know that the FDA would like, prefer, be easier, more streamlined, if we were able to have a few well-designed panels that are testing platforms that we could authorize and run those and be more efficient. The problem is that just hasn't been-- it doesn't fill in the February gap. So skip ahead here. In those first Dr. Crawford showed his stats will show ours from the first two weeks I mean, sometimes we were 20% to 50% of testing in the country. So it's fundamentally a market failure from the end of February to the first two weeks of March when you start getting authorizations here so Roche and Thermo-- most labs have a test up if they're not going to do an LDT until you can buy these tests. And even then, when they get the authorization, it takes them a week for them to ship it and for you to get verified and be able to run. And so to be able to offer testing those first two weeks of March, it was entirely the LDT.

The other thing-- I actually spent a lot of time on this graph. I want to show this. This is all of our testing by LDT or not LDT. So I say EUA if it's like a sample to answer instrument or something that has an FDA EUA on it. So clearly at the very beginning, everything was LDT, because there were no commercial EUAs to offer. Then we got our Hologics and our Roches installed, and they were fantastic. And if we could, we would only run those all the time. As you can see here, during April and May and early June, we ran them-- 95% of our testing went through those instruments. We do not want to run a laboratory developed test if we do not have to, but then when the supply chains went away, we had relied ever, ever, and ever more on our LDT to perform testing. And that's also been bulwarked by other things. So we were able to get authorization for pooling on June 29th in Washington state. And pooling is a godsend for being able to offer testing when you have these positivity rates below 10%, and we think that maybe a CT39-- it would be OK to miss that versus a CT40.

And so that's fourfold pooling-- works great. It ensures its reagents. Once you get the informatics and the workflow set up, it's been great. We've been able to offer that and our LDT now for two or three months, and we're just now getting it set up, because the authorization just came through in the last few weeks. And that takes time for the informatics, and they're also not open access instruments, so it actually takes even more work to get the informatics set up for that. So as I said here, you would have been able to-- because of that Washington state and local regulation, and because of our own LDTs, we've been able to offer sample pooling, which allows us to offer a high level of testing when we don't have the reagents coming in from our commercial platforms.

So with that, I'll close with a few closing thoughts. So just really want to highlight again-- I think this comes up again and again. Clinical labs are part of the nation's public health system. And I don't think anyone disagrees,

but you do see from public health sometimes-- we work very closely with public health. They were fantastic, and state public health. But there's all these data requests, and we're going to talk about that more in the next session-- there's all these data requests, specimen requests-- other things. Really being part of the team is important, and when we were not part of the team in February, that was very frustrating.

We need better ways of getting BSL-2 compatible clinical positive material. If public health is going to be data-science oriented, they need to fix the pipes. They cannot accept the data that they want right now, and that is just-- that's what the next session will be about, so I'm not going to harp on it. But it just over and over has come up. We have broken-- it seems like every single reporting scheme has been broken in every state, and we don't even really understand how the states and the CDC-- and there's new data requests. People think they know how it works, but they don't know how it works.

Our LDTs have been great to insure against supply chain risk. I think it's going to be hard for the FDA to regulate LDTs, given the staffing it would require and given this crush. You've seen how much interest there is. This is only one analyte-- not the other analytes as well. And then, just as another-- while I'm here, I want to be able to say on the record-- we should make CLSI open access some way. If you want to increase regulatory science and regulatory standards, it needs to be out behind a paywall, and we need to find a way to make that financially possible. Because it makes it harder and harder to discuss these things, and it just seems silly to put standards behind a paywall.

And then finally, if you want to talk about data requirements, we need a universal patient identifier, or else you're going to come to the labs every single time, and you're going to ask us to fix what is-- because you can get data from us, but it's going to be unfunded mandate after unfunded mandate. And without that universal patient ID, then we can tell you to go get that data somewhere else. And that's what I'd like to see.

And with that, sorry. Dr. Ng, I said I'd be somewhat opinionated, but not entirely. Be positive-- I was positive. I'd like to thank Keith and Jeff and Patrick here-- have been a great team, as well as Greg, our laboratory manager-- just made it everything possible. Huge team here, just as Dr. Crawford said. And with that, I'm happy to talk about it more later. Thank you.

CLIAC CHAIR: Thank you very much, Alex. Both you and Jim have made my stomach sink to the ground reliving all of that experience. So thank you for describing it so succinctly and to the point. So our next speaker will be Elizabeth Palavecino, and I would love to hear her perspective, because she spans both the clinical laboratory, which went through great pain, as you heard, and to also provide the perspective of the Public Health Laboratory and the partnership. Elizabeth, the floor is yours.

Clinical Laboratory and Public Health Partnership
Elizabeth Palavecino, MD, FACP

DR. ELIZABETH PALAVECINO: Well, thank you for inviting me. It is a pleasure for me to return to CLIAC. Next slide.

During this talk, I will discuss my experience as a laboratory director of a clinical laboratory, as well as the director of a county laboratory of public health during the pandemic. I will also describe the challenges that we have encountered along the way. And finally, I will describe some of the possible recommendations to be better prepared for future events. Next.

So before discussing my experiences, I wanted to show you a little bit of information about the facilities where I work. The Wake Forest Baptist Medical Center that is the main hospital in our health system. And this health system also includes four other hospitals that are across three other counties in the Western part of North

Carolina. The Forsyth County Health Department on the other hand, is also located in Winston-Salem, and provides the services for the people of Forsyth County, in particular for providing investigation and surveillance for the county. The Forsyth County, as you could see in this map here, is in the middle range for the number of cases of COVID, compared to other counties in North Carolina. And the mission of the clinical laboratory, of course, in relation to COVID, is to provide clinical diagnosis for diagnosis of the infection, as well as patient management and treatment. On the other hand, the mission of the laboratory is to tests individuals or groups in organization throughout the county to decrease the spread of COVID in this case. So even though the public health laboratory and the clinical laboratory have differed missions, I would say that these experiences and the issues that we have had with COVID testing have been very, very similar. And just to show you here, in Forsyth County, we had had, as of October 20th, a little bit more of 1,000 cases and about 114 dead. So it is not like the previous speaker, that they have a lot of cases, but still-- we still have to do the testing for our population. Next slide.

So as you can see in this graph, at the clinical laboratory we started off doing COVID testing in mid-March, as I sent out tests to our North Carolina Health Department. And that testing was very restricted, and it needed approval by the epidemiology team at North Carolina Health Department. So it was not really very available. So on April 7th, we started offering testing in-house, using a commercial PCR test. The fact that we started performing tested in-house really was game changing, because it really improved drastically the management of the patient, as well as the isolation practices in our facility. So it was very, very well received.

However, to meet the demand of COVID testing, and because of the limited location of reagent that we were receiving, we expanded our testing capacity by adding multiple tests, as other speakers have said. My experience is not unique, as most laboratories have been forced to implement two, three, four, and even five or more tests-- molecular tests-- on different platforms. So this, of course, creates multiple challenges-- for verification, for validation, for training of the staff, for competency testing, and for proficiency testings, as we know that proficiency testing, when we receive a sample it has to be tested only on one test or one instrument. And for now, we have multiple instruments and multiple platforms, which complicates things for proficiency testing.

In the middle of this two of our manufacturers, from which we were receiving some allotment of reagent, stopped the production of the single COVID test to the standard production of a multiplex PCR test that include the detection of SARS-CoV-2. But this change, of course, required additional verification by the laboratory. So in the last six months, I have verified or validated about seven different tests. And in addition to that, each test has been validated for the different transport media and diffident swab, because we couldn't find this swab and the transport media that we originally used for the verification at the beginning. So this has been a very stressful situation for all of us, really. Although, and still, we have not been able to fulfill all our needs, so we are still sending some samples-- especially from pre-op screening-- to commercial laboratories. Our positivity rates have been between 5% and 7%, and it's been increasing in the last two weeks. Next.

So COVID testing at the Forsyth County Public Health Laboratory has been challenging as well. We did not start it often in the tests, until Hologic, the manufacturer for which is the only instrument that we have in the County Public Health Laboratory. So we have to wait until June to start receiving kits from them. The good thing is the verification and training of additional personnel was completed very quickly, because I have a lot of experience in the clinical lab. So I could provide the identified positive and negative sample very quickly to the Public Health Laboratory. So after we received the first shipment of reagent from the manufacturer, we were up and running in a couple of days. So this was very well received by the community, of course.

So testing at the Public Health Laboratory-- in my case, at the County Public Health Laboratory-- is really mainly done for contact tracing and surveillance testing in congregate settings. And we have a very specific group within Forsyth County that were affected the most. So we have tested in those cases. But I would say we

didn't receive a lot of support to implement that testing from our North Carolina State Health Department. But rather, the testing was based on our own effort and a long-standing relationship with the vendors. So shortage off of kits really has limited testing for COVID in the Public Health Laboratory in the County Health Laboratory.

So right now, because of that, and because of our other limitation-- is the reporting requirement. We were very prepared to report positive, but we have not prepared to report negative and positive, and we have not collected that element needed. So that's been a huge problem for us in the Public Health Laboratory. We don't have the IS support that I have in the hospital. In the hospital, immediately I was able to have a team of people that are expert and are yes to help me with the reporting. I don't have that in the Public Health Laboratory. So believe it or not, because of that, we can't continue-- we are way, way below our capacity of testing, because we have a problem with reagent limitation, but mainly because of the reporting requirement. Next.

So the state support for clinical and public health laboratory varies by the state, and North Carolina-- some of their public health laboratories located in areas where the highest number of cases received instrument and/or reagent to perform rapid molecular testing, and those reagents we were provided by the US HHS. And those public health laboratories continue receiving weekly allocation of our ID NOW testing. However, even though we didn't receive specific instrumentation of kit, we really received a lot of local guidance from our North Carolina Health Department. At the beginning, we have a specimen sharing for verification in the clinical laboratory for our development of our laboratory developed tests. And, of course, they have communicated some changes with supply chain to HHS.

In our public health laboratory, again we did not receive reagent from the Health Department, but they provided a lot of support to do testing at the state lab, and also provided financial support so we could send some of the samples to local commercial laboratories to improve turnaround time. Most clinical laboratories around the country have not received a lot of reagent or supply from their state health department. However, some of my colleagues around the country have told me that their laboratory had received some weekly allocation of rapid PCR tests. And those clinical laboratories are usually located in areas with high prevalence of COVID infection. Next.

So the allocation of reagent by commercial manufacturers-- this has to be a big challenge for clinical laboratory as well as the public health laboratory. So the next slide, I'm going to tell you about these challenges. As you know, each manufacturer has an allocation strategy, and this allocation strategy has been the target of frustration due to the lack of transparency. Early in the pandemic, most reagent were allocated to California and New York, and that was understandable, because they have a lot of cases there. But even though COVID started spreading to all areas of the country, the allocation, for us at least, continues to be the same. It remains the same. So at the end, and this is my personal opinion, the reason that most laboratories had been successful in obtaining reagent from the manufacturer and have been able to implement in-house testing using the commercial test is because they had the instrument needed, and because they have a longstanding relationship with the manufacturer. I don't think it has to do with prevalence, at least in my opinion, and this is my personal opinion. Right now, I'm receiving limited allotment for five different tests, and we are still not able to keep up with the demand. Next.

So another challenge that we have is to decide the extent of the verification of this EUA tests. Manufacturers are telling us, oh, you need to do a very limited validation. But as a laboratory director, I really question that. Is that going to be enough to assess the performance of that test? What is CLIAC going to require? What is the implication for CAP accredited lab. It's a lot of questions that we have in the clinical as well as the public health laboratory that need to be answered. And ASM likely has published a recommendation for their ratification, and this has been very well received by our laboratory community. For full disclosure I participated in the writing of the guidance for verification of antibody testing. The other thing that we need clarification is about this waived

test. Is that the same as the FDA CLIA waived test? Meaning no verification is needed? And when we are using for a group that are not included in the package insert, does this still continue to be a waived test, or have they made it a moderate or high complexity test. So we have a lot of questions still on that. Next.

So another challenge that we have is sometimes the CLIA guidance for a lot of those things. Laboratories have been dealing with guidance and may differ from different organizations-- CDC, FDA, or even the state guidance. So for example, I have two examples here. Antigen tests-- these tests have received EUA for clinical diagnosis of symptomatic patients. However, CDC as well as, in my case, North Carolina Health Department as well as other the states, have recommended the use of antigen testing in certain asymptomatic groups. So is verification for asymptomatic patients required in these cases?

Again, if I test an asymptomatic patient, is that now a moderate or high complexity test? The CLIA statement that I have here really helps to clarify those questions, but still, it may need a little bit more clarification. And sometimes it's hard to fight all of this documentation. I know the speaker in the morning, they were showing us all that information, and I was aware of most of them, but I wasn't aware of some of the information they presented. It's because we are overwhelmed with the amount of information we have received, and it's hard sometimes to find the information that we need. Another discussion among that laboratory's directors is the precision of the guidance from pre-market review of laboratory developed tests. What does this change really mean? I mean, everybody has a different interpretation of these changes. So I think, in my opinion, we still need a lot of guidance regarding this specific change. Next.

So another important-- very important-- challenge that we have is that our technologist are exhausted. We have exhausted. Our volume in the microbiology lab did not decrease as it did for other areas of the clinical lab due to the stay at home period. And the molecular technologists particularly are working long shifts and come in addition weekends and trying to train new people. And volume continues to increase. Recruiting newer staff is challenging, because the pool of qualified candidates is low.

Another thing is adjustment of the work flow and the schedules has been very challenging-- especially challenging for the public health laboratory, because we only got one laboratory there. We cannot pull people from other laboratories, because it's only one laboratory in the County Public Health system. So that's been particularly challenging for us. Other laboratory staff in the clinical setting have been relocated to help us in the microbiology lab, because again, volume continues to increase, and we really need more people. But that creates additional concern regarding training of those people and competency testing. Next.

So just the end-- you probably have heard several speakers talking about this-- shortage of reagent. Wow, this has been a very, very, very important challenge for us. There's been a significant back-order on basic microbiology test supplies. ASM in association with the supply chain management developed an online tool to collect this information from clinical laboratories. And as you can see in this table, and this is courtesy of ASM-- at one point, 73% of the laboratories in this country had problems getting commercial reagent for performing COVID testing. And not only that, 65% of the laboratory were having problems getting the basic supply for performing bacterial culture. At one point in my laboratory, I had seven blood culture positives, and I didn't know if I was going to get the shipment for blood. I got plate to do the sub cultures. My lab administration was following-- checking the FedEx truck to be able to be outside waiting for it, so we could use that. So it's that critical. Next.

I mean, sometimes COVID testing really competed with other testing that we were performing in the clinical laboratory. For example, it couldn't be that technology is working mainly in the COVID testing, and they cannot perform other tests. But mainly it's because we are performing COVID testing in this same instrument that we use to perform other testing. And that is the case, for example, for testing sexually transmitted diseases. In the county lab, we perform that test in the same instrument that we are using to perform COVID testing. And so

now we don't have enough reagents to do that. So we have to prioritize which patient are we going to be testing. Luckily, the CDC published a very good guidance regarding prioritization for *Neisseria gonorrhea* testing. And we had to use that-- we starting using it a couple weeks ago, because we don't have reagents. And this really worries me, because we have seen an increase in disseminated cases of *Neisseria gonorrhea* in our area.

In the clinical laboratory, we are experiencing this same type of shortage. We have a high throughput instrument-- somebody already mentioned it-- from Roche, but we can't get the pipettes that we need to run the test. So we have a good instrument, they have a high throughput, and we get reagent for COVID, but we cannot use it, because we don't have the pipette needed to run the test. And we use that instrument to run other tests, like GC, and chlamydia, and HIV viral load, and hepatitis viral load.

So as director of our laboratory, we are every day making decisions-- which days are we going to continue perform, and which days I'm going to have to discontinue, or send out, if that possibility exists. So we are really, really under a lot of stress with all these shortages of reagents, not only for COVID, but for the others tests as well. Next.

So here we go to the last part, where I wanted to have some suggestions for improving the process. Redundancy-- I would like to have redundancy. I would like to have more equipment, and especially in the Public Health Laboratory. Like we don't have any other left in the health department, so we really need to have more of that. We need to have more supplies and laboratory personnel and clear guidelines so they are credentialed in this time of crisis. We have to have clear guidance for the extent of verification of the EUA tests, and who can do what testing, because sometimes we have volunteers, but we are not sure if we can use them. Transparency about allocation of instrument and reagent by vendors. I don't know if that can be done, but I'm putting it in here. Prevent I think is a strong word, but at least highly recommend the manufacturer from discontinuing their single test for detection of SARS-CoV-2 in this case and replacing them with multiplex PCRs-- they may be more expensive, more cumbersome to badly validate, and potentially not covered by payers.

And I can't emphasize this enough-- we really need a good reporting system on this day in national level. In collaboration rather than competition for testing in the community, I think is the key for success. I'm very proud to say that my collaboration between the clinical lab and the public lab has helped me tremendously, and has been very rewarding as well working with other clinical laboratories from other large healthcare systems in the community. We help each other during this time, and I hope that we continue to do the same. Thank you very much for inviting me.

CLIAC CHAIR: Thank you, Elizabeth. I think a number of items were made crystal clear about improvements for the future. I loved your talk about the partnership as a lab director straddling both entities, how you partnered with yourself. I hear from Alex that more could be done on that, and I hear from Dr. Crawford that there might be opportunities in New York in your situation. We will come back to discussion.

Public Comments

CLIAC CHAIR: We do have two public comments that are ready to be delivered. We'll start with Mr. Daniel Edson, representing the President of the American Proficiency Institute. Mr. Edson, the floor is yours

MR. DANIEL EDSON: Thank you. Can you hear me? Yes, OK. Thanks. Madam Chairwoman and members of the committee, my name is Daniel Edson, and I'm President of the American Proficiency Institute. Thank you for the opportunity to speak with you today as you examine the response and preparedness for clinical laboratories during the COVID-19 pandemic.

Established in 1991, the American Proficiency Institute is one of the nation's largest accredited proficiency testing providers, serving over 20,000 hospital and physician office laboratories. API is particularly proud of innovations. First PT provider to offer liquid chemistry samples, complete blood count with automated differential, blood cell photographs, and practitioner performed microscopy. Almost a decade ago, we revolutionized the PT field by creating a paperless transmission of proficiency results directly from laboratories' information system, and now offer a one-stop panel of analytic options so laboratories do monitor their performance. This year, API developed one of the world's first proficiency testing programs for SARS-CoV-2, which brings me to your focus today.

The urgent and massive demand for testing, especially at the onset of this pandemic led to the swift development of assays to detect the coronavirus. At API, our objective was to assess the accuracy of these newly developed tests. We feel it's our duty to share the aggregate results of SARS-CoV-2 accuracy by laboratories participating in the API proficiency testing program. Results from the first 2020 event were published on July 20, 2020 the American Journal of Clinical Pathology. To recap those results, 302 laboratories or 97.4% correctly reported positive results. Eight laboratories, or 2.6%, incorrectly reported negative results. For the next sample, 306 laboratories or 98.3% correctly reported negative results. Of the nine laboratories that reported the testing problem, all were using the same SARS-CoV-2 reagent on the same equipment.

In this first challenge. There were over 30 test methods reported by more than 300 respondents from 46 states and four countries. Please refer to the AJCP article for a breakdown of performance by test method. Overall, performance in the first SARS-CoV-2 RNA detection challenge was excellent, which should provide confidence in these molecular test results. We will soon publish results from the second SARS-CoV-2 molecular challenge.

Today I will provide a glimpse into these raw data. Of 1,003 laboratories reporting, 995 laboratories, or 99.2%, correctly reported a negative result on the negative result. For the positive result, 992 laboratories out of 1,005 returning results, or 98.7%, correctly reported a positive result, with 1.3% of the laboratories incorrectly reporting a negative result. From these results, we also assessed how the more popular test methods faired. For those test methods with 10 or more laboratories responding, 99.3% correctly reported a negative result, and 0.7% incorrectly detected a positive result on the first sample. Of this subset of laboratories in the second sample, 99.2% correctly reported a positive result-- 0.8% incorrectly reported negative.

Monitoring and analyzing proficiency test results from clinical laboratories helps assess the accuracy of test methods applied in a variety of settings and individual performance. These benchmarks have added meaning when a test is new and widely practiced. SARS-CoV-2 RNA amplification results are used for patient management, infection control in healthcare settings, contact tracing, and epidemiological survey surveillance data. The API detection challenges shared with you today show excellent accuracy by test participants, when evaluated by test method and type of laboratory. This should provide confidence in clinical laboratory test results for patient management and public health decisions. Thank you for your attention. I would be pleased to answer your questions.

CLIAC CHAIR: Thank you very much, Mr. Edson. Our next speaker will be Dr. Jonathan Myles, representing the College of American Pathologists. Dr. Myles, the floor is yours.

DR. JONATHAN MYLES: Thank you for this opportunity to speak today. Good afternoon. My name is Jonathan Myles and I'm here today on behalf of the College of American Pathologists. As physicians providing services during this unprecedented public health crisis, we've contributed firsthand to helping manage this crisis. The pressures faced by pathologists and the laboratory workforce are increasing. Laboratories are imposing hiring freezes, reducing benefits, furloughing employees, and cutting pay. As documented by the media, problems with supplies delayed a ramp up and testing, impacting our most vulnerable communities.

A comprehensive study of our COVID-19 response should occur before any changes are made to federal policies, guidance, or regulations. As the COVID-19 pandemic has progressed, collaboration among stakeholders is greatly improved, but a strong public private partnership is key to ensuring adequate laboratory preparedness and a successful response to future pandemics. Generally, an overarching national government is responsible for broader governance, while the states and cities govern the issues of local concern. For a pandemic, coordination between the federal and state governments as required with clearly defined roles and responsibilities. Included in these roles and responsibilities should be who has primary responsibility for interfacing with clinical laboratories on resources, such as supplies. For your consideration, we will focus on three specific comments-- one, consistent uniform action, two, regulatory guidance, and three, coordination among the federal systems.

Consistent uniform action-- during the COVID-19 crisis, clinical laboratories have had difficulties managing the differing policy guidance that were released by the various federal agencies. While it may be difficult, given time and resource constraints, various federal agencies should collaborate on guidance to ensure consistency among their respective guidance given.

Clinical laboratories work quickly to ramp up diagnostic testing. To do this successfully, consistent regulatory guidance is needed to support these efforts. While the FDA and CMS have made recent improvements in this area, initial delays and shortcomings continue to affect the prevalence of testing. In the future, to increase testing capacity during large-scale public health emergencies, a broader base stakeholder group of laboratories should be included in discussions to advance quality testing to build surge capacity.

Two-- regulatory relief. Once a public health emergency is declared, certain regulatory requirements are waived or reduced. A similar process should be enacted for CLIAC to allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic. During the COVID-19 crisis the CAP specifically requested a temporary waiver of CLIAC requirements, so pathologists and other licensed health care professionals could utilize remote review and sign up. Further, the CAP requested that agencies postpone inspections of accredited laboratories, which would allow personnel to devote the necessary time to fully verify and validate new coronavirus testing assays. We're pleased that both of these issues were addressed, but are concerned that they may not have been without CAP advocacy and congressional appeal.

And finally, coordination of federal assistance. Clarity is needed on the role of federal versus state governments in the pandemic response. The administration released a testing plan calling for states to lead many of the testing activities, and various entities were competing for testing supplies. Many laboratories report excess testing capacity, but are being constrained by other factors. Generally, an overarching national government is responsible for broader governance of larger territorial areas, while the states and cities govern the issues of local concern. The severity of the next pandemic may drive ultimately who is on the flagpole, but at a minimum, officials from the CDC, the FDA, and CMS' CLIAC program should be part of the federal response team. Thank you for providing us the opportunity to speak today, and the CAP looks forward to working with CLIAC federal officials and the entire laboratory community to develop solutions for COVID-19 and any future pandemic. Thank you.

CLIAC CHAIR: Thank you, Dr. Myles.

Committee Discussion

CLIAC CHAIR: I see no other public comment, so now it's time for a committee discussion. If we could bring up the slide with the questions as a framing for the discussion. And again, go into the chat box when you want to say something. I ask you to reflect on what we heard. I ask you to think about what are our recommendations for ameliorating the impact of the next surge on some of the items that I heard. How do we strengthen that

relationship between public health and clinical laboratories? How do we manage a supply chain? I want to call out-- Alex didn't specifically talk about it, but how he was able to get pipette tips going to the food industry. Do we need to think outside of our clinical lab box? What kind of recommendations, if any, do we want to consider giving, for example, the FDA in terms of assay verification?

Do we want more information and requirements around what the controls look like? If we're using synthetic nucleic acid controls, do we want some guidelines around the length and the type of transcript and the type of matrix that it is embedded in before we do the verification study? And then do we want to make any comments or recommendations around how surgeons in pandemics affect other laboratory testing using the same technology? Such that in today's discussion, are we fostering a wave of sexually transmitted infections, because we cannot do that testing, because those manufacturers have redirected their manufacturing lines for COVID testing?

CLIAC MEMBER: [CLIAC CHAIR], could I start off by asking, because it's been so long since I've been involved in one of the meetings. I kind of want to know how you as the chair want to proceed. So would you like to have a recommendation put up first for discussion, or would you entertain some comments and discussion about a potential recommendation and then the drafting of a recommendation?

CLIAC CHAIR: Yeah, thank you, [CLIAC MEMBER]. My sense from committee meetings is when we start drafting a recommendation, we get hung up in word-smithing. So I would prefer we start with a rather philosophical discussion about what we think is important. And if we can coalesce around that issue, then we can do the editorializing around the recommendation. Does that sound reasonable?

CLIAC MEMBER: That would be just fine. So for example, I'd like to follow up on all of the previous presentations which were quite good, but also share an experience I had by having and searching out a resource inside of BARDA early on in the discussions, as well as within the aspect of HHS. We also had a desperate need for access to reagents, and we could not obtain them from our commercial sources, even though we had one of the first EUAs in operation. We just still needed additional help.

So through the governor's office, we approached both of those organizations and got a hearing, and then went to a conversation about allocation of reagents. And I totally agree with the previous speakers, that it was not clear how commercial companies were making decisions about allocating resources, whether it was first to the table, prevalence, et cetera, et cetera. And so I would like the committee to consider our recommendation and have some discussion about whether or not it would be appropriate for us to recommend that the appropriate federal agency engage in allocation-- in an emergency response situation only, the allocation of commercial reagents across the United States.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Look, I am repeating some of the things that came up, as lessons. But as I said, I a proponent of data standards, and I'm a big proponent of standards. And standards and sample collection materials, as mentioned before-- maintaining a stockpile, federal oversight of supply chains based on disease prevalence. And then one that came up over and over and has come up at CAP before-- I'm also a member of CAP-- is definitely engaging high complexity laboratories in developing LDTs early on.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So my comment originally was sort of different, but actually it's much on what [CLIAC MEMBER] said as well. So I think one of the biggest areas that was exposed in some of our private-public partnership work that I did with DLS previously was nimbleness, and how important being nimble and not

being stuck in cemented processes that are inflexible. We did a tabletop exercise, and we identified that if you're not nimble, you're not going to respond.

And I think we saw in the first two to three months of this pandemic the lack of nimble processes, and reaction-driven, more close to real time response was so crippling in so many ways. And there's been a lot of culpas on the federal side about that. Which I think comes to my next side point of federal oversight of stock piles and allegations. I'm not sure that the track record has been shown from the nimbleness of the response that anyone would trust that. I think you've probably created a Civil War era state first, no federal oversight-- for lot of states, especially some of the more conservative self-walled-off states. That would say no way-- we'll do our own thing. We don't trust the federal oversight.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Oh, I'm sorry. Troubling hearing there. Yes, so I thank all the presenters. It was very informative, and I think especially those in New York and some of the early states, just to say that our thoughts and hearts are with you. It looks like an absolute phenomenal job. When we look at the pandemic, one thing we certainly have learned is how it has impacted those communities that are marginalized, both social, certainly ethnic groups. And the importance of our public health lab systems, public health in general, both nationally, the World Health Organization, et cetera I think have been tremendous. And so I guess I think just the plea to acknowledge the fact that we desperately need to increase the funding for these services, both during pandemics-- obviously are not the time to withdraw our support, but during the interim, so that they have the resources, bandwidth, and capacity to respond in a timely fashion. Thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you. I just wanted to expand upon with [CLIAC MEMBER] already mentioned about the laboratory system. And I think that by looking at both the clinical labs and public health labs, but also thinking about the veterinary diagnostic lab and potentially commercial labs in your area for resources. So I know that I turned to our veterinary diagnostic lab, and I had huge support with equipment suppliers even people. So if I hadn't turned to them I would've made it through those dire months of supply chain shortages so it's very important to expand that and as said the flexibility, which we need.

CLIAC MEMBER: Yes. First, I just wanted to kind of reflect back to everyone really how remarkable it is that we've had these experiences shared with us today from across the nation-- yet they were all extremely similar. Everyone really had the same experience no matter where we were. And as we look at-- and I think we're really beginning to discuss and appreciate-- that a pandemic response requires both public health and clinical laboratories.

We are two sides of the same coin-- to really manage pandemics effectively. I think it's important for us to look at the general infrastructure of our public health and clinical laboratories, and appreciate how fragmented it is. It's actually quite similar to our electrical power grid before we developed and invested in the infrastructure to make it a national grid. Right now we're able to take advantage of excess power to feed demands of power throughout the nation, but I think we need to look at the laboratory services across the nation in a very similar way-- to kind of break down that fragmentation.

I think some of the obvious benefits of doing that enables us to share resources-- identify areas that have excess capacity to be able to divert testing towards those areas. I think from an infrastructural perspective of just information sharing, sharing simple things as results across laboratories, which could also then result in standardization of reporting to public health agencies as well. So I don't know if you want-- you want us to write recommendations in the chat, or shall I say it here?

No, say it. So I mean obviously, we'll have to wordsmith it, and forgive me if the agency that I'm kind of going to make this recommendation to is not the correct one, but I would make a recommendation that the CDC do a study to see what would be the financial requirements, risks, and rewards of creating a national grid-like system for public health and clinical laboratories-- standardizing communication, resources, et cetera.

CLIAC CHAIR: Thank you. Don't lose that thought. I would like to hear from other committee members before we get into the crafting of recommendation. Next is [CLIAC MEMBER].

CLIAC MEMBER: Yes, this is she. And as I reflect on what we've heard today and the information that has come before us regarding the deficiency in test kits, even test kits to run STD lab studies, as well as select reagents, we realized that we're going into the winter, and we know-- we hypothesize based on data that we have already that we're going to need a tremendous more number of COVID-19 test kits, or SARS-CoV-2-- to assess for SARS-CoV-2.

And so with that, I would like to entertain the fact that we need a comprehensive list of all of the shortages. And then if we could look at just a running list, because I've heard several different departments and organizations talk about their deficiencies. If we had that list, then we could look at prioritizing are there such serious shortages that we need to ask the president or the federal body to commandeer-- to use that special act-- to be able to have certain other industries produce these products for us. Very similar to what we had when we needed more PPE and other kinds of things. Because we cannot really be caught short this fall and say that we're not able to have sufficient kits to test for COVID-19 at PLC, as well as in the laboratories. OK? So that's what I would-- I would really like to see a comprehensive list of the shortages, and then prioritize how we're going to tackle that.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you very much. So I particularly like [CLIAC MEMBER] comments, and I think I would agree substantially with his idea of the communication and coordination piece of this-- would be hugely impactful to understand where resources are needed, where things would need to be diverted.

I also agree with [CLIAC MEMBER]-- I don't believe that the federal government is best positioned to allocate these resources. We have a market-driven economy, and I believe that those forces are going to put resources where they're most needed when the government doesn't interfere. I would use the antigen test as an example. I was quite excited to hear that antigen-based tests were available, and then the next day heard that the government had bought 750 million of them.

So I would contend that it's the coordination and communication and transparency piece that would most benefit us around the allocation of these resources. And that the partnership with the public health labs-- with the health system laboratories, our laboratories-- to serve in the surge capacity would be most needed. But we need to be prepared for that beforehand, right? And that some study, and like [CLIAC MEMBER] idea about some kind of look into this. How can we best partner? I would advocate and in that direction. Thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you. I'd like to comment about perhaps co-deploying the Laboratory Response Network, which has already registered practically every laboratory in America that's a clinical laboratory of history. Has a tiered system that responds-- could respond in a regional laboratory way. Because these outbreaks were geographical-- they're regional. They're not necessarily-- they don't necessarily fit. Walking, well, let's send our samples to the for-profit venture-capital-funded laboratories.

And my observation was that at the beginning, I mean, with all due respect to those for-profit, venture-capital-funded laboratories, the interdisciplinary hospital networks-- the not-for-profit reference laboratories that many, many people depend on and were taking care of the hospitalized could not get supplies, while at the same time, the large mega-laboratories were testing asymptomatic patients, using up reagents when symptomatic patients couldn't even be covered at the local level.

So while the hospitals and the public health labs were strictly screening-- I mean, we had a Geisinger screened every person for the CDC symptomology before we quote "used" a test on one of these people. And yet, there were people walking around sending samples out on people that were just worried. And it seems like the hospital labs should be included in that. There's a time and a place for each of the emergency responses-- the localized hospitalized I think should have been given deference to while in parallel with the for-profit venture-capital-funded laboratories, who are far away, and at the beginning were only delivering test results up to over 14 days, while the hospitals needed results to conserve their PPE and ventilators and beds and all of those things. And it just seems like the whole response was backwards.

There's a very important role for people who don't do sick care, that can do mass production testing at a low price, and were able to easily prop up tests, but I think you can see by our presenters today and other hospital systems, that we're just as capable of propping up LDTs or EUAs. But getting the reagents when they were all-- and supplies-- when they were all going elsewhere, not only to the public health who needed them, but also to this walking well population.

Now granted, it was probably a small percentage. They did ask you if you were sending a symptomatic patient or an asymptomatic patient when you submitted to them, I understand. But the asymptomatic patients were not rejected. And I think that the early days when New York needed supplies, that was a big disservice to Washington and to New York. And that's just my personal opinion-- if we could pull the hospitals in earlier, if we could leverage the LRN-- that the level B and C laboratories that are more capable in regions of the country could also help our community-based partners and develop what they did in New York, what we did in Pennsylvania, where we were sharing resources with people in nursing homes and things that weren't our clients. But we were able to regionally help in a reasonable amount of time, and I suggest something similar like that to be considered.

CLIAC CHAIR: Thank you. You know, while we have a number of more comments to be heard, but I'm going to ask my two peripheral brains -- because you seem to have split brains where you can listen and create recommendations. That perhaps the two of you could start drafting something for us to consider based on what we've heard. I've heard about transparency and allocation, stockpiling, prioritization by prevalence of infection, and then [CLIAC MEMBER] spoke very convincingly around lab stewardship. So if you tie those together, plus other things you're thinking of, we'd appreciate that.

CLIAC MEMBER: There we go. And I promise I'm not being political, but just to add to what [CLIAC MEMBER] was saying, I think, too, particularly N95 masks were actually sold and sent to other places around the world, which is one reason we were kind of caught I think with our-- in a bad position. But I just wanted to make a point, too, about making sure that we-- and I'm not-- because I don't know the rules. But you know, to make sure that we recommend to somebody that we keep these worldwide surveillance stations, if you will, that our lab folks can work with nationals in those areas when another pandemic hits. That we are able to keep those resources where they are, to really have eyes and feet on the ground where we need it and when we need it.

CLIAC CHAIR: Thank you,

FDA EX OFFICIO: Yeah, and I'll provide some information briefly there was a comment on FDA staffing, and I just wanted to relate where we were in January, regarding those people who were trained up to be able to

review virology submissions. In our office of IVD we started January with only 25 people who were reviewing virology applications, and that's all virology applications.

So we had specialists for respiratory, and then obviously non-respiratory. And through September, we had received over 2,400 pre-EUA submissions. So it is a huge, huge, huge volume. And we were honestly not staffed for that. We're staffed for regular annual submissions. Wish that staff of 25 people, as far as test applications goes-- there's other kinds of submissions. They saw on average for a complete test about 100 per year. So they saw in the first half of the year 25 times the normal annualized volume. So that was a big swing for us. Thanks.

CLIAC CHAIR: [FDA EX OFFICIO}, I'm just curious. Is there any role for partnering with academic institutions who share many of the same concerns and validation and statistical infrastructure to assist the FDA during surges?

FDA EX OFFICIO: Now I think that's a great idea, but how to deal with surges. One of the ways we did it was hand some control over to those states who wanted it, as Alex has spoken about. And New York has also benefited from that. So I think as we sit back and, as CAP said, let's get together, and let's figure out how to do this better the next time. We'll want to look at that as one of the issues here.

CLIAC MEMBER: Well, in listening to these presentations and really participating in many of the other discussions that are happening at the CDC with regards to the types of cases that are falling through the cracks, and talking with people that I know that have not been able to get the help that they need, more than ever it's clear that labs need help from the public. Labs need the public to be more educated, and they also need to off load some of the work. I don't think there's a better time to begin a recommendation to discuss the possibilities of a new category of self-serve screening.

Many of us test ourselves at home to find out what our blood pressure is. We walk-- we find out what our pulse is. We also could fill the gap with the issues as it relates to the sexual transmission areas, and all the other areas that weren't able to get tests, if we were able to put them on a program that's not just during surges, but to develop a new program for self-serve care and monitoring of our own health. If we feel like we have an infection of some kind, we should have a full category of antigen tests that can help us understand which direction can we move in. You guys should not be screening patients.

There should be a way for us public people to start screening ourselves, because there's just not going to be enough resources. So if we could talk about a self-category that is sponsored and led by the government to educate the people, we could also use this type of testing in antibiotic resistance-- the problem there. If we could determine if we have a virus, or if we have a bacteria, and do we need to go further. So this is a topic I'd like to discuss as a way to off-load the huge demand on the labs.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you. Great presentations-- very, very informative and interesting. First of all, I think we've been concerned in this discussion, and the presenters have as well, about the availability of reagents. But I think we should tip our hats to the diagnostic products industry, who really, over a very short period of time, turned out an enormous number of new assays for a new infectious agent we didn't even know about before. When I was back at state earlier this year, I cataloged platforms across Nebraska, though. There were probably 30 or 40 or more labs that were capable of doing COVID testing, and for several weeks, none of them had reagents, except labs in Omaha. And that illustrates, I think, some of the issues discussed. A quick comment on the grid model that [CLIAC MEMBERS] have discussed-- I think that relates primarily to communication's interoperability, given the diversity of platforms. I think if we need to stay ahead on reagents, the S & S model

probably applies, although it's a new agent. Stockpiling reagents is probably something that we need to try to get ahead of, that we can distribute them. So thank you.

CLIAC CHAIR: All right, lost in the chat box.

CLIAC MEMBER: Thank you very much. I wanted to just remind the group that there are reasons why some of those asymptomatic individuals are being tested. This may be unique to Colorado, but all patients coming into the hospital for an invasive procedure, whether it be cardiac cath, surgery, whatever, have to be tested prior to their procedure. And so you do have a lot of asymptomatic individuals, at least asymptomatic for COVID-- they have these other co-morbidities that are going on.

For our area, which did not have a large number of cases until very recently, that was the primary reason for testing-- was to ensure the safety of the healthcare workers caring for these patients coming in for other purposes. And some of the delays, because of the rationing of tests, and who gets the rapid test. The ED patients get the rapid test, because you want to make sure before they get treated, and you don't have the option of saying come back later when you're in the ED. A lot of the allocation, and there were a lot of disruptions of other types of care, due to the lack of resources-- due to the need to send these out. But it also did end up adding quite a bit of volume for these asymptomatic individuals.

The other thing I wanted to point out, living in a fairly large geographic area with a lot of rural laboratories, is many of these folks-- critical access hospital laboratories that we see, and I work with closely it's their blood supplier-- also brought in two different platforms for PCR and an antigen test. And so as we think about the resource constraints on laboratories, I think it's important that we remember that the rural labs were getting these same types of issues and having to manage some of these same challenges with the regulatory and validation and supply chain impacts with laboratories that might only have 5 or 10 personnel in the entire lab. But yet they needed to supply a fairly large number of patients. So thank you for allowing my comments.

CLIAC CHAIR: Thank you. A number of you are putting in what I'm viewing as sort of editorial comments, and I'm going to skip over those, but please pop up if you want to say something. My judgment can be faulty. [CLIAC MEMBER], you're next.

CLIAC MEMBER: So two comments. One is I just want to thank Dr. Crawford. I don't see him on the screen, but I'm hoping he is still on, as well as [CLIAC MEMBER]. So I'm speaking as a someone who's been a lab director, but from a clinical point of view. Because of the testing program that Northwell did, we had some really wonderful clinical data that was used to manage care. So I think it's also worth everybody remembering everything starts in the lab when you have this situation.

And if we don't have good data-- and there was a lot of great screening data. I'm an obstetrician. I'm not practicing now, but just following the literature, and my colleagues were so grateful, because a lot of those women were asymptomatic when they came onto the labor floor. And they were able to get picked up. But without-- so this is just a plea for everyone to understand how incredibly important that lab data is-- it drives quality care. People are alive today because of the excellence of the lab team. So I just want to thank you all.

The second comment I want to make is I'm enjoying reading the chat, because I think what [CLIAC MEMBER] is getting at and [CLIAC MEMBER] has said so well-- we don't want to well we do want to get into the weeds to a certain extent, but I think what [CLIAC MEMBER] was after is a root cause analysis of what happened here. When you hear that labs have to go to veterinary labs for equipment-- OK, what is that saying? So clearly this is our opportunity to try to do better. And so this idea of bringing back a pandemic response, it's very broad. Obviously, there's so many pieces, but to do this properly for the lab, that's what I'm looking at really in

recommendation one, and actually recommendation two as well. That's the supply chain. We need a coordinated system.

So again, I'm seeing such great stuff that I can now shorten my comments, because everything is there, but all the issues, we're hearing. And also just again, there is a wonderful point here I think also, [CLIAC MEMBER], about the stakeholders. So yes-- it's amazing that companies are able to get tests up so quickly. You have the public health labs. You have the hospital labs. You have the public-- the reality is there's so many stakeholders. And again, the clinicians can help very much drive what needs to be done. So I'm going to stop now, because again, I'm seeing this amazing stuff in the chat. But again, just really thank you to all, speaking from the clinical community as well.

CLIAC EXECUTIVE SECRETARY: Can I just interject quickly that I have copied all the recommendations-- there's three of them that I saw in chat. I have meant a Word document when the time comes, so if you want me to share the screen to work on them further, I'm glad to do that. And also I'll also make the point that the information-- the really good comments that are being made in the chat-- will not be captured as part of the meeting records. So you might want to save some time by not typing quite as much in there. And if it is something that you want part of the meeting record, you'll need to verbalize that as part of the discussion.

CLIAC CHAIR: Thank you. [CLIAC MEMBER] has already stolen the screen. So [CLIAC MEMBERS] have been furiously collaborating behind the scenes, and two recommendations are there. I heard [CLIAC EXECUTIVE SECRETARY] comment around number three, and [CLIAC MEMBER], who had to step out-- I wanted to make sure we understood her recommendation that control material or other reagents that can be manipulated in a BSL-2 facility needs to be a high priority. So [CLIAC MEMBERS] which one of you wants to use present recommendation number one? [CLIAC MEMBER], I'm going to call on you.

CLIAC MEMBER: OK. Yeah, I didn't draft that one. So if whoever drafted it wants to put it, otherwise I'm happy to read it.

CLIAC MEMBER: Sorry, I was sharing my screen and I couldn't find-- on mute. So [CLIAC MEMBER] was number two, and then I made number one based on some comments from multiple people and I can consolidate. So this came from [CLIAC MEMBER] concern, which I thought was very, very valid, and I added to. And someone else touched on it. So CLIAC recommends the CDC should identify larger academic and community laboratories-- identify larger academic and community laboratories in distinct diverse geographic regions to join the public private partnership task-force, in addition to the commercial laboratories, to ensure the pandemic responses are more ubiquitous and equitable in regards to response.

CLIAC CHAIR: I think I heard [CLIAC MEMBER] say that in addition to academic in communities, she specifically called out clinical laboratories. And if we could somehow also include acuity of illness, since clinical laboratories are managing the most acutely ill, which we would think, maybe not correctly, that testing would take precedence over asymptomatic, pre-procedure, or even asymptomatic worried well. So larger academic, clinical-- oh yeah--

CLIAC MEMBER: Sorry. Sorry.

CLIAC MEMBER: Yes, now you go sorry. We're touching at the same time.

CLIAC MEMBER: I don't have control.

CLIAC MEMBER: You don't have control?

CLIAC MEMBER: I think we're both fighting for control?

CLIAC MEMBER: OK, one of you do it. One of you.

CLIAC CHAIR: OK, and everybody come off mute and just jump in. I can't manage the chat box at this speed. So raise your hand, I can see you.

CLIAC MEMBER: Here. Marc, I gave it back to you.

CLIAC MEMBER: OK.

CLIAC MEMBER: For some reason, mine's not working.

CLIAC MEMBER: So I can identify larger academic and community-based clinical--

CLIAC CHAIR: Laboratories.

CLIAC MEMBER: Yeah, regional clinical laboratories that like New York, like ARUP, like Geisinger, the people in the region that could respond that had the infrastructure. I think community-based or regional clinical laboratories, something like that. My point was that, you still need a hefty infrastructure to be able to do this. I mean, it's not likely to be done at a community laboratory at the beginning. But in each region, laboratories could be designated to partner with public health to take care of the communities that they serve. For instance, in Pennsylvania, we have a Regional Response Network for nursing homes. And each of the big hospitals applied to be that steward or that helper. And they're assigned by region and have a list of the hospitals and nursing homes in that area, so that communication can occur.

CLIAC MEMBER: I think that's a good point. And I can say for in Utah, we kind of created that organically between ARUP Intermountain Healthcare and some of the state labs and some of the smaller hospitals. We came together. We just did it ourselves. But I think having a roadmap for other states would be valuable, because we were able to get ahead of it pretty quickly and say, OK, we're worrying about Utah right now. We're going to make sure everyone's getting testing. Our turnaround times are better than this. And it was a Herculean effort, but it was-- we made a lot of mistakes. I think other people could at least avoid those if there was a template, if that's an option.

CLIAC MEMBER: Yeah. I mean, I think that to have that pre-designed, I mean, I don't want to keep going back to LRN. But our laboratories are all connected already. So can we leverage that to prop up these regional resources, so that when the next one hits, we already know, there's listings somewhere of what nursing homes, what community hospitals, who needs help. And sometimes, those things are governed by legal service footprints. And in each state, that might be different. But the state laboratory would have a grip on that as they collaborate regionally, and then push that up to the larger federal level or communicate with each other in that way.

CLIAC CHAIR: I'd like to do a little bit of word smithing.

CLIAC MEMBER: Yeah, for sure.

CLIAC CHAIR: So the third sentence regions to join the Public Private Partnership Task Force along with, strike in addition to, the, along with the commercial laboratories to diversify the pandemic response.

CLIAC MEMBER: Oh my gosh, you guys have the wrong person typing.

CLIAC CHAIR: Diversify the pandemic--

CLIAC MEMBER: Diversify and prioritize maybe, because of, you said about the prevalence and you know, that.

CLIAC CHAIR: To meet the fluctuating needs of the community. And you could have local community, I don't know how you all feel about that.

CLIAC MEMBER: Yeah. I think what [CLIAC MEMBER] is saying about the LRN, we have a Public Private Partnership Task Force Pandemic Response already in place with that DLS staff and then others have been involved with several of us. So I just wonder if this is the opportunity maybe to say, OK. Now we had a real event and we saw that commercial labs wasn't actually the solution. It was a piece. But maybe now, that partnership task force has to involve more. So that recommendation could cover that. Because rather than saying, we have to create something new, we make the LRN with this in mind. There is already a system in place. It just wasn't nimble for this. It was really predicated on the Zika response, which was different because not everyone wanted to run Zika testing. But respiratory virus is a different deck.

CLIAC MEMBER: And the LRN had already looked at an influenza pandemic. But somehow, during the last several years, the LRN has deteriorated and states haven't kept up. State public health labs, for example, who should be leading the LRN in their jurisdictions haven't kept up with the needs of the LRN and haven't kept engaged with their clinical labs. And I think that's created part of the problem with this, is that the state public health labs were not leading the efforts. And that actually fell on the clinical labs, who should've been dependent more on the state public health lab very early on, until your supplies from manufacturers became available and you could get them.

CLIAC CHAIR: So do we want to--

CLIAC MEMBER: May I share my screen for the recommendation that I suggested?

CLIAC CHAIR: Sure.

CLIAC MEMBER: I was going to say, that would be easier than--

CLIAC MEMBER: OK, let's see.

CLIAC MEMBER: Does this save automatically, before we do that. Because I--

CLIAC MEMBER: Oh, it did. OK. Could someone else, I don't know, stop for a moment? Because it's not allowing me.

CLIAC MEMBER: I'm just going to save just one second.

CLIAC MEMBER: OK.

CLIAC MEMBER: I don't want to lose what we've written, because I don't know how this Whiteboard works.

CLIAC DFO: Yeah. I think you actually dropped another recommendation, as well.

CLIAC CHAIR: And while we're doing this, [CLIAC DFO] has his hand raised.

CLIAC MEMBER: OK. It looks like mine is still not going to do-- I get that problem the other day. I will send it to someone, OK?

CLIAC CHAIR: Yes. And [CLIAC DFO], jump in right now.

CLIAC DFO: All right. Thank you. I just wanted to-- I have a couple comments. One was to sort of tag onto what [CLIAC MEMBER] was just saying first, a little bit of additional clarity. So [CLIAC MEMBER} is absolutely right. In 2018, in response to Zika, we at CDC and in particular, our division, because of our role supporting the clinical laboratory community, took responsibility for creating and arranging for a memorandum of understanding between CDC, the Association of Public Health Laboratories, the Council for State and Territorial Epidemiologists, the CSTE, and the American Clinical Laboratory Association, which is essentially the professional organization for the very large commercial laboratories.

And what we recognized back in 2018 was that we needed to really improve meeting CDC's relationship with the commercial laboratory sector so that we could address surge laboratory testing requirements that the commercial laboratories might be able to support. And for that reason, I think we-- and also, because there was so much desire to increase testing so rapidly early in the pandemic at a national level. Your observations are absolutely right, and it's very fair criticism that we initially put a lot of our eggs in the baskets of these large commercial laboratories.

But I do think, and I completely agree, that MOU, that partnership that we created with ACLA and the large commercial laboratories was really beneficial for CDC and for laboratory preparedness and response. But it's not enough. And somehow, and I think this is what I heard [CLIAC MEMBER] saying, we need to build on that and expand that concept that we started with the large commercial laboratories a couple of years ago, and really make it more comprehensive. And I'm not exactly sure how to do that. But I think if you could help us with a recommendation that was sort of explicitly suggesting, building on that particular MOU with the large commercial laboratories, that could help us.

The second comment I wanted to make very quickly is around this idea of shortages in supplies. And I guess I did want to just ensure that you all knew that, ASPR, which is the HHS office of the Assistant Secretary for Preparedness and Response, really does have responsibility for supplying distribution, supplies and distribution. And actually, I'm going to I read from their ASPRs goal four, which is to improve distribution, to ensure medical countermeasures can be dispensed and distributed rapidly to reach the people who need them. Medical countermeasures include tests and the supplies associated with tests.

And so I think if you want to go down that route, I think we need to build ASPR into that recommendation somehow. Because that's really the role that they've played. And a lot of the decisions about allocations of tests and resources for laboratories have been made at that level, and really have not been made by any of our three agencies, nor do I think that we really have the ability to change large scale laboratory supply district and distribution issues over.

CLIAC CHAIR: Thank you, [CLIAC DFO]. Just a time check. We were supposed to end the session in two minutes. We have two recommendations that I would like to complete or fully discuss in the next 10 minutes. [CLIAC MEMBER] recommendation is up on the screen, and it's related a shortage of supplies. And I think it ties in nicely with what [CLIAC DFO] had just commented on. And so [CLIAC MEMBER}, if I could ask that we understand your intent and that we go back to the recommendations that [CLIAC MEMBER] was working on and try to incorporate ASPR as well stockpile. And then try to figure out how to incorporate other reagents that are affected, while manufacturers are diverted to producing testing for companies.

CLIAC MEMBER: That will work.

CLIAC CHAIR: OK. So I don't know who can pull back up. And I don't know who's going to--

CLIAC MEMBER: Yes, do you still have it on your whiteboard that you can share?

CLIAC MEMBER: Let me stop sharing.

CLIAC MEMBER: I honestly don't know what happens to the whiteboard. But I can try and see what happens.

CLIAC CHAIR: Or you can put up your Word document.

CLIAC MEMBER: There it is. It's there.

CLIAC CHAIR: Yeah, OK.

CLIAC MEMBER: If I put in my Word document, though, it's just showing that document and I'm the only one that can--

CLIAC MEMBER: Correct. The Whiteboard is the one we could all take. So actually, can I grab control?

CLIAC MEMBER: Yeah. I got to approve you. One second.

CLIAC MEMBER: Looks like I have control now. So I'm going to add another recommendation. Come on.

CLIAC MEMBER: It is a little clunky, I got to admit.

CLIAC MEMBER: Yeah. The lag is hard to work through. So I'm adding another recommendation. It's very similar to the first one. So I think we can smush them together. And we may need some guidance from [CLIAC DFO] and everyone from the agencies. But from previous CLIAC meetings, I suspect we can actually-- we don't have the authority to charge any of the agencies to actually do anything. But we could ask them to look into things or make recommendations to look into things.

So kind of putting that whole National Grid idea together, which basically, it sounds like we have a pre-existing partial National Grid that we want to then subsequently expand with more clinical laboratories in order to meet that need. My understanding is, what we can do is ask the agencies-- and correct me if I'm wrong. I think the responsibility or the authority falls under the CDC at this point, to perform a study to see, what would it take in order to engage more clinical laboratories. What additional infrastructure would need to be made, standards of interoperability to be agreed upon. Because then, that sets the platform for, assuming this will need funding at either the federal or state level, that study is the foundational information for the agencies to then speak to whomever can provide their funding and resources for that. I'm looking at [CLIAC MEMBER], who is not moving. OK. So again, I'm trying to copy and paste out of the chat and into this thing, and it's not working.

CLIAC MEMBER: You have to double click, yeah. So enter.

CLIAC CHAIR: And an option would be--

CLIAC MEMBER: It's not letting me do it.

CLIAC CHAIR: Would we like [CLIAC EXECUTIVE SECRETARY] to help us with the scribing while we think? And if correct, could you just grab control while we talk?

CLIAC MEMBER: Yeah. I can't seem to control it at all.

CLIAC CHAIR: OK.

CLIAC MEMBER: If you double click inside the box.

CLIAC MEMBER: I'm not doing that.

CLIAC MEMBER: The cursor is right under Recommendation. So if you just take control again and don't do anything but type, you should be fine.

CLIAC MEMBER: Yeah. I'm typing. It won't let me do it. Oops, there it goes. Now I'm frozen again.

CLIAC MEMBER: So I think what we have, we have an understanding as to what we want this particular recommendation to state. I don't know, maybe if it's worthwhile. I don't know if we need to come up with a final wordsmithing of it now. Or is that something we can work on during a break or even between today and tomorrow, from a procedural perspective? But I do also hear that there's that second recommendation as well, which again, I think we may be overstating what we can recommend.

CLIAC MEMBER: Well, can I speak to that?

CLIAC MEMBER: Sure.

CLIAC MEMBER: We absolutely can recommend. And so I would just-- if I could propose some slight changes to number two, it would be something like CLIAC recommend that ASPR coordinate, that ASPR, yeah I think-- yeah, there you go. Coordinate, because those other agencies are all part HHS. So that ASPR coordinate a national process. And then everything else reads the same. CLIAC recommend that ASPR coordinate a national process.

CLIAC CHAIR: Or allocation.

CLIAC MEMBER: Formal process for allocation, yeah.

CLIAC CHAIR: OK.

CLIAC MEMBER: Take FDA, CMS, and CDC out.

CLIAC CHAIR: Take the rest of that line out.

CLIAC MEMBER: There you go.

CLIAC CHAIR: Yeah. You can take formal out.

CLIAC MEMBER: Take formal out, and then you're there. And so again, the spirit of this is, I don't think this will solve all supply chain challenges, right? I mean, certainly not. As you can imagine, at the beginning of a

pandemic when we really know so little about whatever the virus may be, you can't expect manufacturers to turn on right away.

But at least creating this process provides that transparent situation where everyone understands the decision making process. There are defined ways of providing information and feeding that decision making process, and making all of that public. Obviously, very few people get up in the morning and say that they want to hurt people. So I'm sure whoever was making these decisions were doing the very best that they could with the information that they had. I think that what this reflects is the frustration from the diagnostic community, is not being able to feed or guide that process and not being able to understand why resources are being shifted away from us to someone else. It very well may have been a very good reason.

CLIAC MEMBER: Well, I would say that it appeared to me that BARDA and ASPR were not exercising the authority they had. And we're calling them out in this regard to say, that's critical to the nation during a national emergency. As a follow up, it may be that we invite ASPR or a representative to come to a follow up meeting to address this particular recommendation.

CLIAC DFO: I just want to jump in. I'm wondering if the recommendation too, you should make it specific to clinical laboratory and testing.

CLIAC MEMBER: Oh, sorry. Yes.

CLIAC DFO: Because I think ASPR would argue that they do that first sentence already. I think the problem that we saw was, if you look at the strategic national stockpile, for instance, there really weren't any laboratory testing-related resources in the strategic national stockpile. And the powers that be that we're thinking about, large scale resources, initially in the pandemic were thinking about rest respirators maybe, PPEs, but they weren't thinking about reagents and swabs and tips and all that kind of stuff, because laboratory wasn't foremost in their mind. And I think that's the big lesson for me is that, we need to leverage the importance that everyone's now putting on testing, that nobody really thought about before outside of our community, to say, hey, we and our resources, our basic resources like reagents, need to be explicitly identified as critical resources.

CLIAC MEMBER: For pandemic planning. Yeah, can I then add or modify after critical, insert the word testing? Or whether or not anybody wants to use the word reagents or whatever. But at least that's the--

CLIAC MEMBER: How about diagnostic?

CLIAC MEMBER: Diagnostic testing resources, sure.

CLIAC MEMBER: And then I have some word smithing suggestions for the first one.

CLIAC CHAIR: But I'd like to get out in front. It seems to me recommendation number two is all encompassing, and it includes one. And so I am proposing we remove one, we remove three, and we focus on two, which will become the sole recommendation.

CLIAC MEMBER: Valerie, what I heard is that maybe there's really not the public-private partnership in two and that we are advocating for more of that in one.

CLIAC CHAIR: OK.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: I actually view one as, yeah, different as well, distinct as well. And, again, to use the terminology we were using before, I think one is really calling for the National Grid version of laboratories. But I do think what we can recommend-- I don't think we can ask CDC to-- well, I guess maybe we could. But I think it's much larger than just asking to identify labs that could join the public-private partnership task force. I think it really does require a study to assess what is needed to build a national virtual laboratory network because there will be some IT infrastructure involved, again, standards of interoperability. So I would suggest-- and I'll defer to the groupthink as to whether this is appropriate or not-- but that CLIAC recommends CDC carry out a study to explore the resources needed--

CLIAC MEMBER: One second. Because I'm not sure everyone's going to agree on this, I'm going to duplicate this.

CLIAC MEMBER: Oh, yeah. I mean, if you have the ability of copying and pasting out of the chat, that'd be awesome.

CLIAC MEMBER: No, I'm just-- your comment you're reading right now, I just duplicated it. So go ahead and say again what you're going to say so we have both versions up.

CLIAC MEMBER: So CLIAC recommends CDC carry out a study to explore the resources needed to develop a national laboratory virtual network. And then high level goals could include standardization of interoperability, capacity reporting, reporting to public health agencies.

CLIAC MEMBER: Thus to breaking information. I mean, right now, we have to go to multiple websites to find out the updates from all the agencies. It seems like in a pandemic, there should be one site that all the agencies dump into, and I would also argue that maybe we need to recommend that people talk to Canada and other places where they have distributed laboratory testing. And they've mastered a lot of this through their public health systems in a regional way, and maybe not call Canada out per se. But I do think there's folks that have this tiered system already in place in Europe and other places and that there would be information out there that could be leveraged for our own country.

FDA EX OFFICIO: One thing Canada does is they harmonize how they do testing, and they discuss that. I'm not necessarily saying that should be done, say, with an extreme. But one thing in the existing public health lab network, for example, is they're set up to be able to handle something that can be distributed quickly and set up and run. For example, they all have the same real-time thermocycler and the same extraction equipment. And so when you're talking about interoperability, I think you've been talking about informatics and reporting. But interoperability could also be applied to standardize equipment in this grid system so that large scale production can supply them all with reagents that can be used across the board. And you don't have to wait for a commercial manufacturer on their proprietary instrument to get that to those labs that have that.

CLIAC MEMBER: So, I totally missed like 75% of what you said. So I'm trying to piece it together from my aging memory, and I failed.

CLIAC MEMBER: So CLIAC recommends that CDC carry out a study to explore the resources needed to develop a national laboratory network, including attributes such as standards for interoperability at the information and technical level or technological level or--

CLIAC MEMBER: That'd be-- address standards for the sample collection also, which would make it easier to share it.

CLIAC MEMBER: Yeah, and I do have a worry about-- I mean, we saw that the common platforms like chaotropic salt extraction reagents were impossible to get at the beginning. So I do agree there should be maybe some harmonization. But over-harmonizing the technology-- I think it's more important to harmonize the data and make sure that those things feed in appropriately then. We could be creating our own shortage if we're focusing on doing too much harmonization on the technology side. But that's just a sidebar.

CLIAC MEMBER: But I do agree with you. Originally, when I drafted this, it was about harmonizing the data because-- just thinking about the New York region and where areas of excess capacity were for testing. And one of the major limitations of being able to use that capacity was let's say I had extra capacity, and someone sent me specimens to tests. I had no reliable interconnected way of getting that information and those results back to whoever sent it to me.

CLIAC CHAIR: So, [CLIAC MEMBER], that might refer to information transfer, which is sort of our next session. I want to jump in because I am sensitive-- our next session is scheduled to start in 15 minutes. We're still in the full swing of this. Is there a subgroup of you who would like to break out during the next 15 minutes to refine these recommendations that we can bring back at the next session for approval? I don't know if we have a breakout room. I don't know if we're allowed to do this in a breakout room as a public meeting.

CLIAC MEMBER: Just make [INAUDIBLE] those of us on the West Coast who have not been able to eat anything.

CLIAC CHAIR: Yeah. So you're between me and my lunch, which is why I raised this issue.

CLIAC MEMBER: Yeah, that's a problem. If I go to a breakout room, I'm not eating today. That's not going to work.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Yeah, I need at least 15 minutes to go grab some food.

CLIAC MEMBER: Plus, I think it's important for everybody to weigh in at the same time, to be honest.

CLIAC MEMBER: Yeah, and I don't know if we should wait until after those information talks because I know Raj Dash, and I've been on several calls with him just about this exact issue. So there may be-- that we may be wordsmithing recommendation number 2A or number two a little bit more.

CLIAC CHAIR: So then let's work on one and three, right? Do we have either of them near final?

CLIAC MEMBER: I mean, I think one for what we're asking to be done is there, that it's just a charge to CDC, really specifically DLS, if [CLIAC EX OFFICIO] agrees-- is basically recommending that DLS within the CDC expands the existing system that's there in light of what we've seen with this pandemic to make it more flexible and reaction capable. And I think the system is in place. It worked. It wasn't as quick as we hoped, but it did work. But it exposed more opportunity for improvements. And I think if we make a formal recommendation that that should be improved, then it's on DLS's plate to have to at least look into. So that's kind of why I was thinking this one is really important to be succinct and given kind of a discreet charge of a recommendation.

CLIAC CHAIR: So these are still unformed, and I'm thinking we still need a lot more discussion than 15 minutes will allow us. So I am proposing we take our 12-minute break and that we continue working on this later today, if not even tonight. And I wanted to call your attention to—[FDA EX OFFICIO] has a specific comment in there that let's think about, do we-- and if we do-- can we incorporate that? So with that said, keep

thinking. Go on your break, 12 minutes. I will see you back at 1:20 my time or 4:20 East Coast. And you're somewhere in between.

CLIAC MEMBER: OK. Thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Are people wanting to leave that screen shared up?

CLIAC CHAIR: Oops. Yeah, yeah. I would like it.

CLIAC MEMBER: OK. I'll leave it up. If you try to take command, though, and I'm not at my computer, you won't be able to take command of it. You can read it and make some notes on your side. And then when we come back, if you want to dictate to me, I can write it.

Laboratory Data Exchange during COVID-19

Utilization of Electronic Test Orders and Results (ETOR) in Public Health Laboratories during the COVID-19 Response
Anthony Tran, DrPH, MPH, D(ABMM)

CLIAC CHAIR: Thank you. We are back. It is 1:22. Please turn on your video feeds so I can determine if we have a quorum. OK, I do believe we have a quorum. So thank you for being on time. We are going to come back to the discussion of these recommendations either later today or tomorrow morning. So keep them in your brain. And we're going to move on with our next session, which is laboratory data exchange during COVID-19. Our presenters will include Dr. Tony Tran, Raj Dash, and Stan Huff. The online presentations are numbers 8, 9, and 10. If you wish to provide a five-minute public comment, please email cliac@cdc.gov. We have one public comment lined up from Dr. Alexis Carter, representing the College of American Pathologists. That is PC3, and we will take that after the presentations. So with that, let us start. And our first speaker will be Dr. Tony Tran, who will be talking to us about utilization of electronic test orders and results, ETOR, in public health laboratories during the COVID-19 response. Tony, floor is yours.

DR. ANTHONY TRAN: Good morn-- no, actually, it's afternoon for everybody. Good afternoon to all. Thank you so much for the opportunity to speak with you today. I'm going to share my screen. And hopefully you all can see that. Can you all see the slides? Valerie's saying yes. Thank you so much. All right, so I have 15 minutes. I'm going to go through this relatively quickly. I am the director of the DC Public Health Laboratory. Again, thanks for the opportunity to speak. I will have a little caveat here. Some of you on the panel already know me. I came from New York City. I can speak very quickly. I have a lot of slides, but I'm going to go through this at New York City breakneck speed, OK? So here we go. All right, so I want to give you a little bit of an intro about us when I got here. I've been here for about four years. And when I got here-- this is the politically incorrect term. We don't use the term Dark Ages, but I'm going to use it anyways because that's what it was when I got here at the DC Public Health Laboratory. We were the only public health laboratory that was not at all using an electronic test order or reporting mechanism with external partners, i.e. our hospitals, our clinics.

We had a paper-based system that our stakeholders, our clients, our customers had to fill out. They would have to send that with the sample back to us. We would test it here, manually enter the data into a system, I'll just say, an electronic system. It was not really a LIMS at that point in time. And then we would have to manually fax results out, right? So that's kind of where we were four years ago. That was 2016. I just wanted to remind

you of that. So this was, as defined by Britannica, a period of intellectual darkness and barbarity. Moving forward, it was a dark and stormy day, right? I don't know what the weather is where you are. The storm is coming for me in the-- it's Hurricane Zeta, I believe, or Tropical Storm Zeta is coming. So it's going to be very dark and stormy for us soon here. And this is where it was.

Now a little bit before I got here, May of 2016, the public health lab received a complaint from our health department. A little bit unique here, the public health lab is actually not part of the health department in the District. We're sister agencies. So this was in and around the Zika outbreak in 2016. And there were about 50 reports that had not yet been reported to our epidemiologists, and they were kind of wondering where they were. We actually formulated-- the lab formulated a working group that was kind of set to figure out, well, what happened to all of them. And all of them actually were stuck in a backlog that nobody even knew about. Nobody even knew about it. So that's not good, right? So that was like, wow, really? Seriously? Yeah, that's how bad it was.

So when I got here, this is what we were using. Because who needs a LIMS when we have an Excel spreadsheet, right? We were using Excel, ladies and gentlemen. I see some of you are laughing. It was not very fun for me dropping in. And I was like, we got to be kidding me. We have a LIMS, but we're not using it. What is happening here? So this is how the accessioning group was logging in samples coming in from you can see our hospitals in the District. Patient information, it had an outbreak number. It had our lab accession number. And this is how things were being tested. Then not only was there one spreadsheet, folks, not one-- because if one wasn't enough, let's have two because the reporting actually went on copy and pasted with the result onto another spreadsheet. So it was really-- we had two log books that I found when I first got here. And there was, again, one for accessioning and one for reporting. That wasn't really going to work out very well, right? So one of the things-- and I'll just show you real quick here. This is our sample template for reporting. This, folks, again, was a Word document. Can you imagine that? So this had to be manually generated each and every time a result went out. Everybody take a pause. Shake your head yes. This is where we work, right?

But then, oh, wait a minute, the Renaissance, right? So here it comes, defined as primarily a time of revival, classic learning, wisdom after a long period of culture decline and stagnation. So one of the biggest things for me coming in was this culture change because this is really where-- I mean, this is an extreme example of public health laboratories. I know I have public health laboratory colleagues on the line here, and you're probably laughing at us, too, right? But this is really an extreme, I think. But it is a culture change. We are in public health laboratories very much a reference lab, much like Marc's lab at ARUP, much like LabCorp, Inquest, and Mayo. However, with all of the different jurisdictional regulations, rules, we also have to follow data issues, reporting issues. They're all a little bit different. But there's also obviously a lot more that's involved with regards to not just dollars and cents, right? Although a lot of it is dollars and cents.

But first for here was basically changing the culture of the laboratory to say, hey, look, everybody, we have a LIMS. We may not like it. Not everybody likes it. The LIMS is never perfect, right? The LAS, the LIMS, is never perfect. But we have a system. We got to use it. So moving forward, it was really the reimplementation of that laboratory information management system. And it all kind of stemmed around a product update moving to-- we were at version 11. We moved to version 12.5. So it took a lot of effort. We didn't have a lot of staff at that point in time either and really nobody dedicated to LIMS specifically, specifically our LIMS within the public health laboratory.

So it was a lot of working with the vendor, the vendor really working with us. It was a lot of contracting that we had to do. We had to clear all of these backlogs. We had to kind of retrain all the staff. And this is kind of what it was, right? I mean, this was like, oh my gosh, what are we talking about? Where's our Excel spreadsheet? No, no, no, no. Not anymore, right? So all of these things had to happen, and it was systematic. It had to be a lot of buy-in. And I will be honest with you. It was a slow process. This is all, again, like I said, back in the end of

2016 moving into 2017. We slowly chugged along. We definitely were using LIMS for quite some time. However, we still had a lot of issues with the electronic test ordering and reporting, right? We were now at least entering results in the LIMS. The LIMS is basically generating the results. But we still had to-- instead of a Word document, at least it was printing out the template for our reports. But we still had to fax them.

So in comes along this little thing called SARS-CoV-2 or COVID-19, right? It seems like so long ago, doesn't it? But it's really only been about eight months, right? Can you believe it? Eight months going on nine months. It seems like it's been forever, I know. And sometimes it just really takes a pandemic. It's really interesting. My agency director and I were actually talking about this. It's like, hey, you know what we really need? We really just need a good outbreak to come hit us in the District. And the lab will be able to get some funding for it. We'll be able to work on this LIMS project with regard to something that I've been wanting to do ever since I got here, which is more or less kind of the integration of our laboratory information management system directly into hospital EMRs, so much like what you all do at the commercial labs and much like what you all have at your own hospitals with your own labs.

So this was really a collaboration between Department of Forensic Sciences where the public health laboratory sits with DC Health as our first primary partner because we wanted to use electronic laboratory reporting for our results to go from our LIMS directly into their NEDSS base system or NBS. That's our electronic medical record system. And the office of the chief technology officer, or OCTO, really was the broker of all this. So we actually got them involved. And it really went all the way to the mayor's office, right? Because we were in the middle of this or the beginning of this pandemic, I should say. And the mayor wanted to set up these publicly funded walk-up, drive-through testing sites where we would see a large number of samples come through. And so we knew there was no way we'd be able to hand-enter the samples in as they were being ordered and then manually reporting them out. It was just not possible. So we really needed an electronic solution. And one was actually created for us and in conjunction with Microsoft. So we actually-- and it's a very apropos name. It's the Microsoft app is what we still call it to this day, right? So they still get the publicity for it. And that's what we started off with. It was a minimally-- it was a CLIA-based approved and HIPAA compliant system that would provide minimal amount of data where at the sites, they could basically electronically order through an app, like an iPad/iPhone type app created by Microsoft, and that information would go through to us electronically via the cloud and then download directly to us once we scanned-- it was a QR code, not a barcode, but a QR code.

So we worked through those issues. We actually were able to get it up and running within a couple of weeks, which is actually pretty amazing time. I mean, our folks as well as DC Health, the epidemiologists, as well as OCTO, I mean, they were burning-- and Microsoft-- were burning the midnight oil. But we got it all done. So that was working out fantastically well. But it really wasn't what we wanted, right? It was this third party application that really didn't provide us any sort of demographic information at all. It was basically just pretty much almost anonymous to us, right? It had patient date of birth, and it had kind of a medical record number. And that was pretty much it. So we at the lab had no sort of information, and that really wasn't working out very well.

So one of the things that we started working with our LIMS vendor, which is Horizon, was their own LabOnline, which is a web-based portal. For folks out in the community, to be able to order a test electronically, they would get credentials. They would get their own password and username. It's a portal, though. It's portal based. So it's cloud based. Health care providers could then log in, and then they would be able to order a SARS-CoV-2 test. We had set this up at that point in time purely for molecular-based testing. We eventually now set it up also for serological testing as well. And here's kind of a screenshot of what it looks like. And it's pretty simple, right? You log in. Once you're in, you can actually look at all the samples that you have, all the patients that you have, and all the reports that are ready to go. If you start moving on through here, you can order a test. It pops down. You can see you start filling out the information. It's a SARS-CoV-2 test. You fill out the date of collection and the time of collection, obviously very important for quality assurance purposes. And

then you start moving through. And then once that loads, it loads into the system. We have something called a chain of custody, and it's really an artifact of us being part of Department of Forensic Sciences. We deal with a lot of law enforcement. And so for us, a chain of custody is more or less a specimen kind of manifest, if you will. We want to be sure that everything that we receive is everything that was actually sent, right? So it kind of generates that. It has a little chain label that's unique to that chain of custody up to 10 per chain. And then once that's scanned, all of those accessions will actually come into our LIMS. So it actually works pretty well.

Here's a test request form when it prints out. It actually prints out just a regular 8 and 1/2 by 11 sheet of paper. You can see up at the upper right-hand corner here that's a little chain number there that's a unique identifier. We scan that in. And it automatically generates within our LIMS. Here it has all of the appropriate demographic information as well. We've actually added some epidemiological information with regards to symptomatic status and what kind of signs and symptoms. So that all can be captured on there. And then on the reporting side, what's really nice as well is that once they log in, they can kind of see either-- download a line listing, again, what you kind of see down in the lower left-hand side, or you can actually download and print out like an actual PDF at that point, electronic, that can then load into the electronic medical record, right? So our Epi's actually like the line list. They don't need the actual report itself. Whereas facilities obviously want the report so they can have a physical hard copy, provide that and print that out to the patient and then load that into their EMR.

But what are we looking at for the future? So the future really here is interfacing. That's really what we want to do. And part of the interfacing here is we're actually going to use a cloud-based message broker. Really, at this point, we're looking at Horizon still, which is our LIMS manufacturer, as I had indicated. And it's all through HL7 messaging, right? So the orders will come through from the hospital. It'll go through the message broker. It comes to us. And then once the results come in, goes back to the cloud. The cloud then bounces back to the hospital system. So it's bilateral, right? It communicates both ways, which is probably pretty similar to a lot of the commercial labs and what they do, which is fantastic, the difference here being government-based organizations. We don't have a ton of money.

However, with the federal funds that we have received through COVID, this is kind of the future. And this is where we want to put a lot of our eggs, if you will, to kind of really build this up in the next, I would say, year or so, minimally a year, max of about two years, so that we can ensure that, at least with us and the District-- and it's a small jurisdiction. We have less than a couple of handfuls of hospitals. We want to start off with that and then potentially move into the clinics, if not-- because there's so much more of those-- or doctors offices, potentially keep that portal as an option for them, too.

One other thing that I will mention is that we are also trying to replace, as I talked about, the Microsoft app. So not only do we have two kind of ETOR systems. We actually implemented a third during this pandemic. So again, that's really kudos to the staff here to not only implement one and get into the modern age, but not only one, not only two, but actually three. This is something that through the Association of Public Health Laboratories and the AIMS platform, which really helped us to work with the LIMS vendor, which is iConnect here-- right now, it's just called Lab Web Portals. Again, nothing fancy yet. No real marketable name that's kind of snazzy. But here, it's still a web portal. And what's a little bit different here is that it actually allows for batch uploads. And that's one of the things that the Microsoft app allows as well. So one of the main major constituents that we're testing for now every week are long-term care facilities. So we're testing all health care workers every week, once a week and all the health care facilities or long-term care facilities in the District. Excuse me. So we're getting quite a few samples from them. So if the same employee is getting tested week after week every Monday, every Tuesday, every Wednesday, they don't want to have to sit there-- the nurses don't have to sit there and order again Joe Smith every Monday, Joe Smith every Monday, right? They just kind of can take basically an Excel type spreadsheet and really just kind of upload it, and all of that information will-- demographic information everything else, will actually load directly into the portal.

That's something that LabOnline, which is directly from our LIMS manufacturer, can't quite do yet. We're working with them to see if they can actually do that. But that can't be done as of yet. So there are some pros and cons. So the Lab Web Portal we actually use again for these mass testing events. Whereas the LabOnline portal, which we actually prefer, we have a bit more control over it. We use for the doctor's offices, the clinics, the hospitals that want to send to us. And here are some screenshots of what the Lab Web Portal looks like. It's pretty much similar to LabOnline. It's just a slightly different user interface. But what's nice here is that it's kind of like your Amazon. It's kind of like when you want to track your Amazon package after you purchase it. So this has that little feature in there where it actually tells you when it was collected, when it was submitted, when we've received it, if testing is in progress. And then, hey, now you have a published report. So you can kind of track the status of that, which is pretty nice again for us to be able to do. Here's the requisition form. This one has a slightly longer barcode and what we call a chain label. This has an order ID label here. Again, it has all of that type of information you can see that we need demographically. It also has a little bit of a Q&A for the Epis. So that's kind of nice. And that's all customizable and for us to be able to create. So kind of want to go over a little bit as I close here where we are and what are next steps. So we're going to continue to use Horizon lab-- the LabOnline portal for ETOR. It has full customizability for us. It works directly with the LIMS manufacturer, which is great. So they have complete control over that, and we have a great relationship with them. So that's really helpful.

Expansion phase one, the implementation of Lab Web Portal, that's already been done, again, for these nursing homes, long-term care facilities to test the vulnerable populations. So phase one is complete. And we're using that mainly as our mass testing ETOR system. And then phase two is-- using Lab Web Portal, that's what we're looking at right now, moving forward into next year kind of that complete integration with hospital EMRs and their LASes as well. And then potentially, we did get, like I said, a windfall of funds through the federal response for COVID-19. So if there is an opportunity within the next couple of years-- and the decision will need to be made soon-- but if the current LIMS manufacturer is not meeting our needs, then we could always also look for a different LIMS to bring on board. So with that, I will stop and show you a beautiful photo of our gorgeous new laboratory that was built just-- actually, it's eight years old now almost. It's not that new anymore. And happy to take any questions from the panel.

CLIAC CHAIR: Thank you, Tony. Very informative to go from the Dark Ages to 2020 in four years. We're going to hold questions until the end of the session. So don't go away.

DR. ANTHONY TRAN: No worries. Thank you.

COVID-19 Laboratory Reporting Challenges and Opportunities
Rajesh C. Dash, MD

CLIAC CHAIR: And next, we will be hearing from Dr. Raj Dash about the COVID-19 lab reporting challenges and opportunities. So Dr. Dash, the floor is yours.

DR. RAJ DASH: Thank you. And let me start here. Slide show. All right, are you able to see my screen? Yes? Excellent. So I'm here. I'd appreciate the opportunity to speak to you about the laboratory reporting challenges and opportunities representing Duke University Health System. I do want to say there's a large team of folks, and these are just the leaders of multiple teams, that have been working towards responding to the pandemic as well as in large part specifically the laboratory reporting challenges. And in part, that's because there's a lot of components that build up to public health reporting. And, indeed, the entire specimen lifecycle for diagnostic testing leads up to ultimately what ends up in the chart and, from the chart, what ends up in public health reporting. And so I'm going to touch on a few of the elements that might seem unrelated to reporting, but I think are key elements to understand how the data is pulled together at the back end when it's sent over an electronic

interface. I will say that I'm thankful that we're not in as dark an age as the prior presenter indicated at his public health laboratory.

I, in fact, was a little bit surprised when we started to hear about potentially faxing in data and sending spreadsheets, which is kind of how we started. It was a quick and rapid way to start communicating information. But I was very pleased that we were able to transition to an electronic interface. So here's a quick outline. I'm going to go through some of the steps preliminary to generating the result and in the context of what else was going on in terms of managing the pandemic and some of the historical elements that perhaps provide some lessons learned relative to the communications, the types of data elements, the reporting requirements, the challenges we face, and some opportunities for the future.

So the key elements that have kind of been distilled here for a COVID-19 order that we decided early on-- we have three hospitals and 400 clinics-- was to come up with a standard naming convention that would help us understand what's happening with the pandemic in our local community and provide some guidance, inherent guidance to providers as they are trying to take care of patients. So we created order names and a naming scheme as new requests for orders came in as various hospital leaders, administration wanted to create all sorts of different order names in order to be able to classify and guide exactly the type of diagnostic test. I should clarify that we only perform nucleic acid testing. We are not performing in a clinical setting any antibody testing or antigen testing. So this is strictly on nucleic acid testing.

And so we want to be able convey exactly what's being tested for, which is, of course, SARS-CoV-2 and COVID-19 as a disease. We're doing all PCR testing. But we wanted to make sure that that was conveyed. We wanted to be able to track inpatient versus outpatient settings. We want to be able to convey the expected turnaround time, whether something was rapid or routine. Sometimes this doesn't always hold true. But I'll get into some of the details of an inpatient rapid test versus an outpatient ambulatory point-of-care test. We wanted to convey the performing lab so a provider knew and the patient knew whether there would be a delay based on sending their test to a reference lab versus performing it in-house. And then certain orders are designed to trip various flags and statuses. And so order guidance was definitely needed as a number of orders started to grow. And here's an example panel for inpatient that provides guidance at the time that the order is being placed. And so it breaks it down first by whether the patient's symptomatic and then the setting in which the test is being ordered. So our surgeons wanted to have pre-op screens before they go in for procedures. Similarly, our pulmonologists, our gastroenterologists, they wanted to have a recognition of the COVID-19 status for patients going for some of these procedures where they might be exposed to an aerosol.

And so there's some guidance here to help them and some recognition of what some of the turnaround times are going to be as they click through some of these decision support guidance. And similarly for ambulatory, it's broken down into symptomatic, asymptomatic. And so they know if a sample's going to be tested in-house, or it may potentially be diverted if the demand exceeds our ability to provide in-house testing. So we put in warnings like, for example, for point-of-care where we have very limited capacity at certain drive-through tents. And it's only supposed to be ordered in-- obviously, if you don't have a point-of-care testing device, you don't have the reagents. It doesn't matter what you order. You're not going to get that test. And so we had our chief medical officers at the different facilities kind of guiding the supply chain issues out to the point where the order was being placed and that the nasopharyngeal and swaps were being collected for patients. So these orders and results potentially lead to downstream actions. So here are the different things that can happen. And I'm not going to go into the full algorithm, except that the algorithm had to be decided upon, and it took a significant amount of effort to do that. And I feel like all of our organizations reinvented the wheel here in terms of understanding what is the key algorithm. What should happen within our EHR based on a particular order or a result?

So what can happen, we can set an infection status with an informative banner on the EHR. We can text page key individuals or administrative roles or group pagers to start doing certain things based on results for an order being placed. And then we could have additional orders that are linked to the COVID-19 diagnostic testing order such as an order for patient isolation. And then we instituted best practice advisory alerts, BPA alerts if a doctor or provider forgot to order something or didn't sign an order, and it didn't activate. These BPAs would pop up to make sure that there was guardrails up that the algorithm was being followed. And potentially, we changed the algorithm, tweaked the algorithm as we noticed some things were falling through the cracks or we needed additional guardrails put up.

So here's the full spectrum of orders that we finally arrived at over time. Not all orders are, should I say, active at any given time. So you see the ones in red at the top are all different reference lab tests. We only had one available at a time. And it was really based on turnaround times for the various reference labs. So we started out with BAR Corp, which was a very expensive test for our Duke patients. But the cost gradually came down. Turnaround times varied for these different groups based on availability of reagents and their own supply chain issues and our inability to perform to meet demand in-house. At a period of time over the summer, as we were able to bring more instrumentation online, we eventually turned all these off. And we were able to-- we have a peak capacity of around 2,000 tests per day, which is able to keep up with demand currently with in-house testing. We do have separate orders for employee screens, separate orders for pre-op screens, as I mentioned before. We have certain administrative orders that can only be used by certain groups in the hospital, for example, when a patient needs to move off isolation or into isolation and they need to ensure that the COVID status is now negative, these kinds of things. We have point-of-care testing, and that's what our rapid tests kind of imply at our various hospitals. And then we have an outpatient test.

So one of the key things to understand that I'm sure many of you are aware, but our inability to source collection kits meant we had to make many things on our own. So we would put together our own collection kits with nasopharyngeal swabs. And we would test directly would be our preference. Viral transport media has the issue of longer-- while you have to be able obtain it, it also decreases sensitivity but obviously provides longer viability if you need to keep it and transport it for a longer period of time. Reagents are very limited for particular platforms. Instrument bandwidth is an issue as well. And here some of the challenges is that each of these different platforms operate in a different way. So you might think, hey, why don't we all just do rapid tests and devote all our resources to one particular platform? So the problem with the point-of-care test that we used, the idea now is that you put one on at a time. You have to wait till that sample comes off before you can use the next one. There is different times whether it's positive or negative. But still, it's one at a time serial. Others are batches. And so then the question becomes, do you wait to run a full batch or do partial batches? There are others that are much more flexible that you can just load a sample on, and it starts processing. And you can do multiple, but you don't have to wait for the batch. So that's fantastic. Of course, it depends on how many instruments of those that you have and how many reagents that you have. And there's a lot of manual aliquoting and human intervention that's required to get the sample into the machine, which I didn't actually realize until I was putting these slides together, despite having been involved on daily hour long calls with these folks. They were just absorbing this effort without complaint. But it is a significant physical limitation in that a human is changing gloves between processing samples or loading into the machines. And even if the machine can do many in a batch, there's still that physical limitation and limits, particularly in smaller laboratories. And we were throwing a lot of people at this.

So we were lucky to have the resources and such a large team. Not all laboratories have that resource. So PCR tests, despite the technology, are not just load and go. And they can fail during a run, and that needs to be monitored. So there's also the transport, receive, and triage process. We need to know when a patient needs their result. And that helps us plan which is the best platform that we have available to us that has reagents that we can then leverage. If someone needs something immediately, again, if they need something in 15 minutes, we can try to use a point-of-care platform. But obviously, that only works for a very limited number given the

bandwidth of those platforms. There's times when our load would dip, and we try to transfer our peak periods over to those low periods if possible if there's not an urgent patient need to have that result. And so getting this type of information, for example, the time that their procedure is scheduled onto the order turned out to be very challenging because there's all different types of procedures that occur. An endoscopy is completely different than a bronchoscopy is completely different than an interventional radiology procedure, which is different than an OR procedure. And the data elements are in all different places. So this speaks to the complexity of EHR systems and the downstream effort that's required to get some of these data elements into public health reporting.

OK, so here's a summary of everything that we have running at Duke Health with the different platforms and run times and our theoretical capacity, which basically, if you add everything up, is around peak at 2,000 per day. And I'm not going to spend too much time on it so we can look at other areas. I'm also not going to spend too much time on the communications. It's not to give you a full historical perspective of every communication that came, only to recognize that there are two different types of communications, one directed at hospitals, one directed at laboratories. A number of data elements continue to grow. There was some overlap because some of the hospital reporting required some of the laboratory data in terms of cumulative specimens tested, new tests, and aggregated data for positives and negatives. So that number also didn't necessarily jive with the laboratory testing numbers, which we had to reconcile and validate because of the way in which the data is flagged for hospital reporting in that once a patient is negative for COVID-19, they're no longer counted as a COVID-19 positive patient. And so their population changes, which is very different than our specimen-centric counting where we want every test result, whether it's positive or negative, to be counted. And the concept of having it aggregated around the patient was less relevant for laboratory-based reporting.

So there was multiple different ways to submit, starting from the more simple technology. And gradually, I think it continued to evolve to allow for web portals and interfaces and eventually the ELR spec was published in July. There was a good deal of confusion with some of the terminology around whether something is required, requested, optional, if it's available. And that was a problem and stress point I think for many laboratories that try to adhere to every element of the request coming from both HHS and CDC, as well as local health departments. So the other element was that there was often requests that would come on one day with a request to start reporting the next day. And this is very stressful, even if there's no penalties, monetary or otherwise. And we're told to just do the best we can. It is stressful for folks that are used to being able to be successful to be put in a position where there's no way they can succeed. And that's, I think, the position that we found ourselves in.

And even with a team of several dozen people on the IT side working on this, I think we've done as well as any lab and IT can. I won't say that we were able to hit every single deadline. We certainly tried. And we put it in our ask-at-order entry questions. But we were put into situations where, for example, we had a lab core reference interface that we hadn't activated or hadn't turned back on. But then the ask-at-order entry questions came out. And it was unclear if we needed to go to the trouble to build the ask-at-order order entry questions into every reference lab interface that we had already validated. And in asking some of these reference labs, some reference labs were able to and were working towards accommodating the ask-at-order entry questions, and others were not. And that left us in a precarious position of, well, what do we do? We're ready to send it. How do we comply with the regulatory side of the request if the receiver is not accepting the information? And, in fact, our North Carolina HHS was unable to accept our ELR data on August 1 as was required. So here are some of the reporting challenges. So there's the laboratory reporting versus the hospital reporting.

There's incongruent data. There's two different teams we had to coordinate. Reporting to all 50 state health departments based on patient address, as stipulated in the CDC guidance in the June 4 document, is very inefficient and impractical, particularly for smaller organizations. We were very lucky. Our North Carolina HHS agreed to forward on to other states and relieved us of the obligation to do so. But not all states do that.

In the early days of reporting, we had to send information to multiple different areas. We created a box with spreadsheets and gave access to public health officials. Now we have this electronic lab reporting interface, which is a vast improvement in efficiency but required a significant build effort, significant validation effort, significant collaboration, again, within NCHHS, for which we're very grateful. Not all the reference labs I mentioned accepts the ask-at-order questions. And bottom line is we didn't understand the value. The value proposition was never explained to us. And we were being asked to make changes so frequently we really didn't have the time to think about, is there a better way we can do this?

Luckily, we had a EMR system that had a lot of others in the same boat. And so we were working together on trying to at least come up with a reasonable approach. The extent to which data on it could be transmitted, I indicated, was very unclear. We were worried about burnout on our ordering providers having to answer all of these questions. We tried to do what we could to fill in default answers. That was our approach because it was very prescriptive about how to put the data in and how to obtain the data as part of the order as opposed to retrieving it from the EHR. Large HIT vendors are more capable. And so if you have a small community lab with a small HIT vendor, I just don't see how this would be possible.

There is issues and confusions around the device identifier, about use of LOINC and SNOMED CT. Again, many folks are not terminology experts, ontology experts. They may pick the wrong code. We worried about data integrity. We went to a lot of validation effort. And we have some LOINC and SNOMED expertise on staff. But this is, I think, a real issue that needs to be dealt with if we really want solid data that's actionable coming into our national agencies. So what are the-- two slides on optimizations and opportunities, and I will conclude with that. So my recommendations would be that communication should be sent to one central agency after full coordination with other agencies.

And then at the federal, state, and local levels, the reporting requirements for laboratory should be clearly defined with real world examples, and laboratories can help with this. The purpose for collecting any specific data element should be documented so that the laboratory really understands the specification for the data element but also if there's a better way to get to the data that achieves the objective in a more efficient way. Then it becomes a little bit more clear and less burdensome. The burden on small hospital and labs need to be addressed. I just don't think it's feasible to hold them accountable for not reporting given the effort required. I am worried about data integrity, duplicate reporting given the multiple different requirements coming from different agencies.

And then finally, I would conclude by saying that the College of American Pathologists is really a rich resource of leaders that volunteer and are passionate about providing input. And I think that they can be a real resource if they're involved proactively as opposed to responding reactively to regulations that are published. And I will stop there. Thank you.

CLIAC CHAIR: Thank you very much, Dr. Dash, especially for pulling back all the layers of the onion that has collapsed into a single word of reporting. Thank you very much. Our next speaker will be Dr. Stanley Huff, and he will speak and share his experience on the Intermountain Healthcare point-of-care perspective. Dr. Huff, the floor is yours.

Intermountain Healthcare Point-of-Care Perspective
Stanley M. Huff, MD

DR. STANLEY HUFF: OK. Yeah. Let me share my screen, and we'll jump in. A lot of-- yeah. Some common experiences, sympathetic sort of discussion here. So I'll just jump in. The first thing is there may be details I don't know. I'm representing a large group of people. And if we need more details, I know how to get a hold of those people. So given that, I'll just go ahead and explain what I know anyway.

So this was already mentioned in a roundabout way, and it has pertinence. This is actually probably a simplification. Depending on how you count, we had 13 or more mandated or necessary communications that had to go on around COVID. And this is a summary of that. Two of those are lab reporting. The others are case reporting, resource reporting, other things. And the purpose in saying-- it reinforces the need to consolidate the reporting activities to a common authoritative tree or communication line. Because what happens when we have to communicate with nine different agencies, the resources that can solve a problem that we're having are spread across these different requirements. And so it creates a backlog of software or testing or software testing, things like that, that we need to do. And so there's a real need for greater coordination between the state, the federal, and the different branches of the government that are interested in this kind of testing.

Like a lot of you have already said, the thing that we're working on and trying to do is electronic lab reporting and individual case reporting kinds of things. But we have a bunch of things where what people are doing are actually typing data into an online app, or we've got spreadsheets, or we've got people phoning stuff down. We've got fax stuff. And that creates a lot of, again, bottlenecks and confusion based on all of the different modalities that people use and have to use to get their work done. So one thing that-- and this comes back in, I think, some things that Raj said or others have said-- when things got really busy at the testing stations, they had to streamline the registration process because of the volume of things. I mean, they needed to get through everybody who was in line, and people were waiting after dark.

And so unfortunately, the streamlining at that level caused then inaccuracies in how we reported to the state. And so we've had to make changes to both the front end and the back end of data exchange services to support those streamlined processes and make sure all of the required data got reported correctly to the state. And that's kind of closely related to another thing that was mentioned earlier, which is ordering challenges. The lack of interoperability of order entry upstream caused problems at the collection center and then the laboratory in terms of the testing. So just to set the context of that, Intermountain is essentially on one electronic health record system. We've got one electronic lab system. So within Intermountain Healthcare and all of the hospitals that we serve and our laboratories, we have good communications and good electronic interfaces.

However, in this pandemic situation, we have unexpected situations where physicians who are not aligned with Intermountain and don't have any other alliance that would allow them-- any other affiliation that would allow them to get COVID testing send their patients to us. And essentially, we don't the physician. They're not affiliated. They're not registered to practice with Intermountain, et cetera. And the patients aren't known to us. And so they may have an office EHR system or something else that we can't-- there isn't actually a specification sufficient. The orders across systems don't match exactly. And ultimately, then, a lot of orders had to be placed manually essentially at the testing site or in other unusual situations.

And it causes-- we don't know exactly what tests they want. We don't know the circumstances. This is hearkening back to what Raj was saying. We don't know whether this-- the context of how fast we need to have a result, how to triage the result. We don't know how to trigger other downstream decision making based on the report, et cetera. So that was a challenge.

I'm going to do this in two slides. This slide is a high level summary. In the next slide, I'm going to tell you the details. So the electronic individual case report standard is not yet adopted among all of the providers and the health care health information exchanges. And in the data store services for outside testing are immature. So this results in delays in seeing outside lab data that's coming into us. So now we're in a different situation. And I talked about the orders coming in and us not knowing people. Now we've got Intermountain patients who are tested somewhere else. And now we want to be able to know the results of those testing in order to take care of patients in our facilities when they show up in the emergency room or show up to admission with the signs and symptoms.

So to say just a bit more about that, what happens is that-- whoops, I went back. I went too far forward. The Utah Health Information Network maintains patient to provider attributions for push notification. So they have a list that says, oh, we know John Doe is a patient at Intermountain. If we get results for that patient, we know to push a notification to Intermountain about the new data that's available. And so UHIN was getting notifications from external lab results. And they knew that they were Intermountain patients.

But the eICR templates built for the national reporting weren't working. And so we did a workaround basically to modify an existing UHIN interface, just an ADT interface, in order to get the results to the hub. And then that got them in. But our ability to automate then the process of inclusion of that data into the electronic health record so that appropriate logic could run at the time of patient admission and help us classify the patients according to whether they needed isolation, not isolation, all common themes with things that Raj was saying. And again, the challenge was that product prioritization was for scarce resources. So we've got nine people-- nine organizations that are wanting other information. And the IT resources, the information systems resources that can test those interfaces or implement new interfaces or other kinds of things are stretched thin.

The people that do know about LOINC codes and SNOMED codes and HL7, those same resources get stretched across different things besides just laboratory data reporting. And so that's a challenge. And that's one of the-- the fact that there are so many groups that we need to report to and, in some cases, they're redundant. And in fact, in most cases, they're redundant. The people that we're also reporting to just aggravates the resource situation for trying to resolve the things.

Another thing-- and this just sort of embarrassing in a sense-- to describe at a high level what happens is we have testing that's done in the laboratory. And I'm putting that in one box for now. And the results come out. They go to our EHR. That's it. That's a well-tested and well-known interface. And so it goes to our EHR. When it has to do with external reporting, then those results go to an interface engine that's configured specifically to be able to send data to public health or to other interested parties. So the lab is sending out the results using version 2.5 of HL7. The interface engine is-- and I was amazed-- is working at HL7 version 2.2. And some of you may be aghast at that, and you should be. Because 2.2 was a version of HL7 that was first implemented 25 years ago. I didn't even know anybody implemented 2.2. because the earliest implementers I knew implemented version 2.3. So it's like this is the most archaic sort of interface.

And then the interface engine, though, when it sends out, I mean, that's what's curious. It's taking in version 2.2. But it sends out the data in version 2.5.1 of HL7. And what happens is that there's some small but important incongruities and differences between those different versions of HL7. And so it took a long time to process the results. And sometimes those batches would fail. Basically, the software was so old that it doesn't have the same throughput, same performance characteristics that the more modern software has. And so things happened like we couldn't distinguish, couldn't figure out how to tell the difference between collection date and time from the time it was resulted. And, of course, that's an important distinction when you're reporting and trying to understand and get on top of the challenges of surges and other kinds of activities that are going on. So that was a challenge.

And I'm going to get done here pretty much on time. So this is my summary. Why doesn't the leaky roof ever get fixed? So when it's raining, it's slick and dangerous to get on the roof. And so you don't fix it while it's raining. And when it's not raining, it's not leaking. So it doesn't get any resources. Nobody pays attention to it. And if you put that into the context of what we're talking about, you could say, why aren't all the things that we're reporting now-- why weren't they solved back with the Zika virus? Why weren't they solved with HIV? Why weren't they solved? And the answer is it's this leaky roof problem.

Right now, it's really difficult to implement new interfaces and do it in a consistent and thoughtful manner and have them be robust and tested and effective. And as soon as this is over, people are going to start thinking

about where the money should go to do other things. And so my conclusion is that we need to make a substantial and sustained investment in creating, and not only creating but mandating, standards for sharing the public health data. And that includes enhancing the computer systems and the networks and other infrastructure for public health.

And the idea is that we don't create those for use in pandemics. We create those for the average everyday routine reporting that we're doing now. And when a pandemic comes along, all we have to do is use the thing that we're already using. And we might have to add some new LOINC codes or some new SNOMED codes. But it's already in place. We don't have to recreate it. In fact, we're getting value out of it every day for our routine work, if you will. But it is adequate and tested. And we know it works because we're using it every day for the routine data. And then when a pandemic or other kind of emergency comes along, those pipelines are already running. And if anything, we just need to make some new codes and maybe tweak some of the information.

But those are things that we can do while it's raining. Putting the infrastructure in place and other things have to be done when we're not in line at a testing center. So that's all I had. This is the list of folks that know the real details. And so I can go back and ask these folks if you have questions that I can't answer. Thank you.

CLIAC CHAIR: Thank you very much, Dr. Huff. Your comment about having a stable templated infrastructure we use every day that can meet a surge demand is an excellent idea. And it sort of parallels some of the conversations around, believe it or not, FDA approval of standardized kit formats that we can just switch and swap out primers, et cetera, to target different things. So the commonalities are there. Thank you very much, all three speakers.

Public Comments

CLIAC CHAIR: We now have a public comment from Dr. Alexis Carter. And while she's coming on, I want to remind all the panelists please use the chat function only to get in line to speak. We should not be sharing comments with each other and not in the purview of the public. Dr. Carter.

DR. ALEXIS CARTER: Good evening. My name's Dr. Alexis Carter. I am a practicing physician specializing in clinical informatics and molecular pathology. And I am here today on behalf of the College of American Pathologists to speak to the Clinical Laboratory Improvements Advisory Committee, or CLIAC, on the topic of laboratory data exchanged during COVID-19. Thank you for this opportunity to speak this evening.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The College of American Pathologists supports clinical laboratory reporting of SARS-CoV-2 results as codified in the CARES Act, which requires every laboratory performing SARS-CoV-2 to report positive and negative results to the secretary.

However, we oppose reporting in the manner specified by the secretary in the guidance released on June 4, 2020. And we remain concerned about this very much unfunded mandate. The CMS interim final rule imposes new requirements on clinical laboratories for reporting SARS-CoV-2, COVID-19 test results to agencies for public health purposes. On June 4 2020, HHS issued special requirements that, in addition to positive and negative test results, expanded the clinical data elements that laboratories are expected to report for SARS-CoV-2 tests.

CMS has also indicated that it will impose civil monetary penalties as condition level penalties of $1,000 for the first day of noncompliance with the new reporting requirements and then an additional $500 per each

subsequent day of noncompliance up to a maximum penalty of $10,000 per day of noncompliance. While supportive of the need for improved public health reporting regarding SARS-CoV-2 and COVID-19, the College of American Pathologists believes that the new rules and penalties place unworkable requirements and undue burden on laboratories during a time in which laboratories resources must focus on performing vital SARS-CoV-2, COVID-19 testing.

Accordingly, the CAP recommends that CMS and HHS rescind the June 4 guidance regarding SARS-CoV-2 and COVID-19 reporting requirements and reconsider the threatened civil monetary penalties for the following reasons. Number one, following release of the Health and Human Services SARS-CoV-2, COVID-19 data reporting requirements on June 4, HHS, CDC, and state public health officials have issued multiple complicated guidance documents that, at times, have also contained conflicting information. Consequently, clinical laboratories have encountered great confusion and expended significant energy in attempting to understanding and comply with the new requirements and mandates.

Number two, certain technical aspects of the requirements pose challenges and barriers to laboratory compliance. The requirements added numerous clinical data elements beyond the actual test results to the data that laboratories must report. The data elements are often not available to the laboratory nor within its information systems or in its scope of operations. A related example is that the guidance specifies that clinical laboratories report to the Department of Public Health of the state or locale in which the patient resides, regardless of where the laboratory is located. For many clinical laboratories, meeting these requirements has necessitated working with public agencies and frequently health information technology vendors to establish multiple systems interfaces. These processes are costly, laborious, and time consuming.

Number three, clinical laboratories have expended great time and energy to meet SARS-CoV-2, COVID-19 testing needs amid shortages of swabs, reagents, and testing platforms and have done so during this period of significant financial pressures. While the CAP understands the intent of imposing mandatory penalties is to encourage compliance, imposing new requirements and systems such as penalties for noncompliance further strains clinical laboratories resources.

The College of American Pathologists request that the civil monetary penalties be removed, delayed, or reduced in amount, particularly in light of the complexity of the requirements and conflicting messages from agency and other public health officials. We continue to offer Health and Human Services, the CDC, state and clinical laboratories our assistance in mitigating the regulatory burden by discussing ways of developing tools and guidance to help automate the process. Thank you again for the opportunity to speak and to provide these comments.

CLIAC CHAIR: Thank you, Dr. Carter. There are no other public comments.

Committee Discussion

CLIAC CHAIR: There are no other public comments. And for the panelists, are there any questions for Drs. Tran, Huff, or Dash?

CLIAC MEMBER: Could I start by just saying thank you and thanks to you, [CLIAC CHAIR], for assembling an all-star panel of IT specialists?

CLIAC CHAIR: I didn't do it. They came out of the woodwork. They wanted to be heard. I'm just thankful.

CLIAC MEMBER: That's very impressive. We heard from the best in the country. That's great to know. I don't know how to really synthesize them into one recommendation. That's going to be a difficult challenge. Maybe tomorrow we can come up with a recommendation based on what they're suggesting.

CLIAC CHAIR: Well, [CLIAC MEMBER]-- thank you. We still have an hour left.

[LAUGHTER]

And if we could throw up the framing question. Because the things I heard would be a single way to report, a single place to report, a single place where that data can be shared in real time, and perhaps even the pipelining and templating of how that report goes, both inbound data and outbound data. But I look to my usual [CLIAC MEMBER] duo to help refine all of those thoughts.

CLIAC MEMBER: But can I also add, though-- so how do we get coordination then between the Office of the National Coordinator and the other components of the system? That seems to be where we may have some disconnect.

CLIAC CHAIR: Yeah, I would agree with you with getting different mandates from different organizations, which overlap but were not identical. Is that something we want to suggest, recommend? I think [CLIAC MEMBER] and I think perhaps [CLIAC MEMBER] spoke or were raising these very issues in our other session earlier today, If Either one of you wants to repeat your comments.

CLIAC MEMBER: I'd be happy to. I think it'd be very important-- and I believe [CLIAC MEMBER] said the same thing-- to establish a central repository. There are methodologies and data structures that were actually developed by ONC or developed with funding to respond to ONC's call for interoperability. One of these is the structured data capture that's used. And then you can package that in an HL7 wrapper and send it. So the California Cancer Registry is actually developing a project to receive data from the cancer protocols and actually in almost real time create a patient case instead of the two-year backlog that they typically have going through paper.

So there is a lot of technology in terms of data structures. And I think that having a central repository would enhance and facilitate the use of structured disparitized data with a controlled vocabulary, so the use of all these standards. Instead of sending it to the 50 states and have their format and then they reformat it and send it to the central registry, you send to the central registry. And the individual states can then-- and localities can download this to understand what's needed in their own vicinity.

So I think it depends upon how deep we want to go in terms of dictating standards. But I definitely think that this is like the trains. So until the 1860s, there had been trains in North America for nearly 200 years. But there was no standard track. And as you went from state to state, because of states' rights, people had their own gauge for the track. And as you went from state to state, you would actually have to pick up your train cars and put them on another rolling platform in order to accommodate the new gauge. And finally, it was decided that a single gauge would be used. So there are many different examples of this. And I think that it's time for us to put the trains on a single gauge. Thank you.

CLIAC CHAIR: Thank you. I thought HL7 was the gauge.

[INTERPOSING VOICES]

CLIAC MEMBER: If I may make a comment.

CLIAC CHAIR: Yeah, but you're not on yet. I'm going to hold you to the end because a bunch have lined up. So, [ADVAMED LIAISON], you're next.

ADVAMED LIAISON: Thanks. I appreciate what you started off with, [CLIAC CHAIR], as some ideas of what should be added. I don't want to forget Dr. Huff's comment about having to send data that was being received by a 25-year-old interface. I think-- I'm not sure. I may have missed who that interface resides with. I'm assuming it is one of the agencies. And given all the interoperability discussions we've had over numerous CLIACs, I think that that should be one of our recommendations, that the receiving interface, preferably one for all, the receiving interface is brought up to current standards.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you. Wanted to support what [CLIAC MEMBER] was saying about trains. When I typed in, it was right before your comment, [CLIAC MEMBER]. But HL7 is supposed to be that standardization. But from what I understand-- and I'm not an expert in this area-- from my IT people is that there's many dialects of HL7. So it's very time consuming and expensive to make all these connectivities with all these different facilities. And in the pandemic, as the speakers described, we've had to connect with over 750 different facilities. And there's no way you can do that. You have to just take the highest submitters. And we need a standard method and a cheap method to do it.

CLIAC CHAIR: Thank you. I'm hearing some coalescence around standardization and cheap and easy.

CLIAC MEMBER: OK, I'll go. Thanks. And thanks to the presenters. I think this does fit into what we said where we were going before about really having a national plan and that this be part of it. And the National Coordinator could clearly be part of that effort. And it may be that there's-- well, not everybody's going to update at the same time. But if there were a central repository where everybody reported in and the data were distributed out. And I think that's what we're speaking to.

It may be backwardly compatible for a couple of versions. And that could all be handled centrally rather than the way it's handled now where all of our laboratories are asked to figure this out for everybody. So I would just suggest that as we go back and we revisit the ones we were still working on from the last time, that I think we should be able to integrate this into it, which is probably why you asked us to wait.

CLIAC CHAIR: [LAUGHS] I didn't ask you to wait because of that. I asked you because we ran out of time. I wanted lunch. But it is a great idea. Thank you.

CLIAC MEMBER: Thank you. I totally agree with all the prior comments, that we need to have a simpler way, less burdensome way for labs to report data as centrally as possible, standardized as simple as possible. But I also wonder about, as we've seen the push for more serial screening using antigen tests, that there could be a loss of reporting from those, as those are done in congregate settings or schools or things like that. It seems like we also need to remember it's not just the lab submitting data, but it could be these waived mobile sites also, that we want to make sure we're not losing any of that data. And I'm not sure if that would require a separate interface or a separate process. But I think it would argue for a simplest process as possible.

So virtually anybody could do this either in a highly automated interface or in a more manual way where somebody's reporting or a provider's reporting interface-- I mean, it's something like an antigen test either from their office or a mobile testing site or something like that. As now as we begin to see a push towards more of the antigen or kit-based testing, I worry about losing some of that data if it's too complicated.

CLIAC CHAIR: Thank you. I've certainly seen prototypes of things like rapid flu or rapid diseases where there's wireless connectivity built into the device. And if it signals positive or negative, it anonymously goes over to some collection agency. I guess to do that in public testing would be a great area to distribute that to. Would we and could we collect personal demographics if contact tracing were needed? Now [CLIAC MEMBER], your turn.

CLIAC MEMBER: Thank you, Madam Chair. [LAUGHS] OK. I just wanted to speak in favor of what I've heard [CLIAC MEMBER] and several others have talked about the value that we think would bring to the problem that has been presented to us if we had an automated central repository. And I guess the question that I have with that is that, do we have existent systems that could be built upon? I know we don't have to do it personally. But I'm just saying the powers to be, will this be a system that you think would need to be built out with specific specification to address the problem or problems that have been brought before us? But, yes, I'm in agreement. I'm speaking to the information that's been put on the floor.

CLIAC CHAIR: Thank you. Next is—[CLIAC MEMBER], I don't know if you want to give this comment about HL7. And you're on mute.

CLIAC MEMBER: There we go. I think it was [CLIAC MEMBER] I believe who said-- mentioned that the problem with HL7 is that there are many different versions of HL7. And HL7, yes, was meant to be that universal pipeline or that single gauge. But it has not persisted as such. However, not to go and try and reinvent the wheel altogether, HL7 can be used as a wrapper around other discrete data models. And that's how it's being used in California. So you can still use the train, but you have a little bit of control on the disparitization of the data values within. Say, for example, as an anatomic pathologist, the anatomic pathology reports are consumed as the whole thing without disparitizing necessarily the diagnosis of the patient. Whereas you really need to break this down into discrete elements.

CLIAC CHAIR: OK, thank you.

CLIAC MEMBER: Yeah, hi. Thanks to all presenters for really good presentations. I actually have a non-technical comment, more dealing with process. I think it would be useful for federal agencies, before dispensing regulations that can be unduly burdensome, to field test them. I don't know how much that's done. But there are things that are necessary and practical and perhaps not necessary and impractical. And I think it would be useful to dialogue. There is an article in the Archives of Pathology this month by Dr. Kost. And there are more than one article that deal with point-of-care and, in fact, inequities. But the article includes this comment about the Tri-Agency Task Force for Emergency Diagnostics that was mentioned earlier in this meeting. The quote is as follows. "Except for one medical technologist, laboratory medicine professionals, public health education institutions, and industries developing new EUA technologies appeared not to be represented." I think that's something that.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Hello. Yes, sorry. I had to unmute. Yes, I'd just like to point out-- and I think Dr. Carter mentioned this well and on a less technical note-- there are some data collection elements which labs are legislatively required to do. And this allows us to individually identify our patients and their samples. I understand the ease of adding requirements, say, the demographic house of address type collection requirements. But I think it sort of behooves us in this situation to acknowledge the limitations of what a lab is best handled to do and what may be another group such as a public health contact tracing group may be better set up to do, which is, where does a person live? Where have they come in contact with?

And so I think that data sharing requirements should not only be looked at in terms of what the most comprehensive data set that can be used to assist in a response is, but also as to who is most accountable for some of those data elements and where ownership of those data elements most definitively lies, rather than the ease of saying, OK, you have the specimen, and you are now responsible for everything. I think there does need to be some acknowledgment of the nuances as to who this data should be collected by.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: I'm sorry, I was having trouble getting myself off mute. I just want to-- again, I don't want to rehash because I think everybody's agreed about standardization and centralization to a certain extent. But, again, just want to make the point that one of the benefits of doing that is bringing in multiple stakeholders here. And those reports go out to clinicians. So one of the really great things is if we do go down that path is getting feedback from the clinicians will actually be interpreting the tests. And again, not the purpose of the meeting necessarily today, but we've spoken about in other meetings and I've enjoyed the discussion so much about educating those that are going to use the tests.

Clinicians are just flying-- some are flying by the seat of their pants and actually, in a good way, learning what positive predictive value means. That's something that's really been so important. So there is a lot of good things that can come out of it as well. Just remember to partner with the people who are going to have to be interpreting the test.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: A couple comments. And I very much like the train analogy. And from my experience, the train and the train track has been built in the United States. You heard from New York saying that the ETOR methodology worked. It does work. It not only has the train tracks but the roundhouse, the translator, the power supply. Everything's there. And I just wanted to then let everybody hear maybe one too many times where the obstacles are. Because we actually have made great progress in 20 years, and we're no longer using the pink sheet to submit to CDC, for example. But the issues are that the governors want control of data in the states. And they want to be the first person to find out about an epidemic. They don't want to hear about it from a national repository. We need participation by the chief medical officers. And [CLIAC MEMBER], having been one, could speak to that. The leadership has to come from the individuals who actually own the public health data. And that not only is the governors but the chief medical officers and the epidemiologists.

So laboratory people are great at putting it together. We even can standardize it. We can get that part done. But up to this point, we have not had a national leader or the leadership to say this is a priority for the country. And then there is still yet one more obstacle. And we've advocated for this at a number of ways. And that would be a national health identification number. They don't even want us to use Social Security. But if we're going to put data and aggregate it together, we got to make sure it's not redundant. It's not the same person that's getting reported five times. And there has to be a way to deal with either an EMPI or a equivalent to a Social Security number. So just wanted to make those points. Thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Yeah. So there's so many great ideas. It just sounds like-- it sounds like we need to have a working group on it because the consideration of NHSN and all of the stakeholders that would be involved, I just think that it would be great to pull something together like that that would address this.

CLIAC CHAIR: Thank you.

CLIAC CHAIR: Well, let me reflect on what I think I heard today. And then I'm going to throw out to the committee, what should we do? So I heard [CLIAC MEMBER] say we should propose a workgroup to outline what is needed to make this reporting system work. I'm hearing folks saying the standardization, the single place to report and get data back with or without state control and with or without HL7 version control.

There's the option to have that as a separate recommendation that really relates just to reporting or data exchange. Or there have been a couple of you who said, can we roll that up into the one of the three recommendations we were discussing with today's session earlier? So I'd like to hear your comments on whether or not we should have a workgroup, whether or not we should develop a separate recommendation, or whether or not we should roll this up into one of the three we're working through.

CLIAC MEMBER: So I've been quiet in this post-presentation discussion because I've been trying to consume all the comments and put out a recommendations. So I have one if I can share my screen.

CLIAC CHAIR: I would have expected nothing less.

CLIAC MEMBER: Well, we'll see if you like it first.

[LAUGHTER]

CLIAC CHAIR: Not just me. There are a lot of others here.

CLIAC MEMBER: But also, while I actually have the mic, do you want to forward me either through chat or by email the other one, that we could put it all in this Word document? And hopefully Word will move a little bit faster than the whiteboard.

CLIAC MEMBER: [CLIAC EXECUTIVE SECRETARY] just emailed me, and she's got it all--

CLIAC EXECUTIVE SECRETARY: I have everything on a Word document. I'm ready to share as well.

CLIAC MEMBER: So what do you want me to do? You want me to share? You want me to send it to you?

CLIAC EXECUTIVE SECRETARY: If you want to send it to me, yeah. For right now, I'll put up what I've got.

CLIAC MEMBER: OK, and then I'll send you both these recommendations.

CLIAC EXECUTIVE SECRETARY: OK, yes.

CLIAC CHAIR: So let's have [CLIAC EXECUTIVE SECRETARY] coordinate the technology. That will free others to talk and share your thoughts.

CLIAC EXECUTIVE SECRETARY: I hope I picked the right one here.

CLIAC CHAIR: Don't embarrass us.

CLIAC EXECUTIVE SECRETARY: Yep. Yes, this is the one. So here are the three recommendations from this morning. And then at the bottom of the page is what [CLIAC MEMBER] just sent. And you tell me where you want to go and what you want to change, and I'll do it.

CLIAC MEMBER: And so you want me to send it via chat directly to you?

CLIAC EXECUTIVE SECRETARY: Sure, sure.

CLIAC MEMBER: OK, that'll be faster.

CLIAC EXECUTIVE SECRETARY: Yep. Let me get back to chat.

CLIAC MEMBER: OK, just sent it.

CLIAC EXECUTIVE SECRETARY: All right. Now that I'm sharing my screen, the meeting went away-- or the chat went away. So how do I show chat again? All right, my chat went away when I shared my screen. So now--

CLIAC MEMBER: I think if you unshare, if you want stop sharing your screen, then your chat will come back. You can copy.

CLIAC CHAIR: Or, [CLIAC MEMBER], can you email her?

HEATHER STANG: [CLIAC EXECUTIVE SECRETARY], it's also at the top of your Zoom panel if you select your-- it'll be the More option, and you should be able to see the chat then. You click Chat.

CLIAC EXECUTIVE SECRETARY: More, More, More. There is no More.

[LAUGHTER]

CLIAC CHAIR: Yeah, I don't have a More either. Technology.

CLIAC EXECUTIVE SECRETARY: Yeah, every computer's different.

CLIAC CHAIR: [CLIAC MEMBER], email it to her. Email it to her.

CLIAC EXECUTIVE SECRETARY: Yeah, can you email it to me? I think that should be fast.

CLIAC MEMBER: You got it. Coming.

CLIAC CHAIR: And, [CLIAC MEMBER], I'll just give you my reaction. It's just a reaction to your proposed recommendation. It's very broad based, very, very big. And the question is, do we want to recommend such a very overarching thing? Or is there any desire to limit it perhaps to COVID-19, perhaps to something else other than every infectious disease? I'm just throwing it out there.

CLIAC MEMBER: Yeah. I mean, whatever will go through. So if we just limit it to COVID-19, let's do that, if that will help.

CLIAC CHAIR: And perhaps another way to frame it is to highlight pandemics or beyond COVID-19.

CLIAC MEMBER: OK, good idea.

CLIAC CHAIR: And to link it to surge capacity.

CLIAC MEMBER: Or public health emergency.

CLIAC CHAIR: Yes, yes. And then I would say, do one of our original one, two, and threes-- do they kind of get at what [CLIAC MEMBER] asking or recommending? Now here, recommendation number four is the one that's focused on the session we just completed. Thoughts? Discussion?

ADVAMED LIAISON: The recommendation as I read it sounds like it would be something additional and is not written to replace or remove the individualized reporting to other states.

CLIAC MEMBER: Say that again.

ADVAMED LIAISON: The recommendation four talks about convening a working group to upgrade existing information. Blah, blah, blah, blah, blah. But it sounds like it's talking-- there's nothing here specific about looking to replace what the existing infrastructure is or to-- I think the other comments were about to potentially eliminate the need to report to all the different states, to have more of a central clearinghouse approach, and to replace what's already existing. And I think the replacing would be an important component to add into there.

CLIAC MEMBER: OK. So you're thinking about replace, not upgrade.

CLIAC MEMBER: Replace. Yeah, that's what it. [INAUDIBLE].

CLIAC CHAIR: [INAUDIBLE] have a single system to maintain. It would be much cheaper. So if--

CLIAC MEMBER: May I ask whether or not people are aware of how many or how many states represented on the panel have interacted or connected to the AIMS platform, which is a collaboration between APHL and CDC? And I bring that up because that's what this does. I mean, that's what it is. So it is a national information infrastructure that allows exchange route-not-read or read, whichever way you want to do it, and then can be connected to all the partners that are connected. I'm pretty sure that the two main big laboratories, Quest and LabCorp, are members of it. You may know that. But anyway, I just wanted to say that there is a model out there, and it's working.

CLIAC MEMBER: So I think part of the workgroup could be just that, right? First, just understand what the landscape is and what's out there and what's working and what's not. Because, yeah, if something works and it just needs expansion, that's great.

CLIAC CHAIR: Yeah. So I'm not aware of it. So maybe the first thing is education. [CLIAC MEMBER] trying to break in. So [CLIAC MEMBER] you're on mute. You're on mute.

CLIAC MEMBER: Wanted to speak to recommendation number four, specifically the part where it says information exchange for pandemic-related data. My question is, do we want to have it that general so everything and all information comes here related to pandemic, related to COVID-19? Do we want to detail that so that we don't get everything? OK? We were talking about data related to lab reports and other things related to pathology. But do we want to-- I'm recommending that we probably look at this area and try and have it be more specific. What are your thoughts?

CLIAC MEMBER: Right. Like, we don't need to wait for a pandemic. It can be an epidemic.

CLIAC MEMBER: That's right.

CLIAC MEMBER: Or it can be ongoing so that we just use this every day.

CLIAC MEMBER: Right.

CLIAC CHAIR: That was Dr. Huff's recommendation, to have a standard platform in place that can meet a surge.

CLIAC MEMBER: But what I'm also asking is, what kind of data do we want to receive in this repository so that just everybody and whatever can send data here? I think that needs to be specified.

CLIAC CHAIR: Well, so the workgroup, the idea of a workgroup is to flesh out what are the data elements of interest that the collecting agencies want versus what do we as senders want to know what's happening around us.

CLIAC MEMBER: Sounds good. OK.

CLIAC CHAIR: OK.

CLIAC MEMBER: I would say I think it could start as communicable diseases. And we have a template there and something that's working. You could eventually work towards non-communicable diseases also. But once you have the basic data model, then you just add on, replicate the model and adjust it as needed for non-communicable diseases.

CLIAC CHAIR: So we're already reporting cancers, right? How big do we want to make this tent as a standalone platform that we can layer on different entities?

CLIAC MEMBER: That would be for all public health reporting.

CLIAC MEMBER: The problem is that states determine what's reportable. So we might want to have the committee look at more of a standard process.

CLIAC CHAIR: So on the sentence, the third sentence, information exchange for how about "public health reporting," period?

CLIAC MEMBER: Yeah. Public health reporting is all encompassing.

CLIAC CHAIR: So if you-- yeah, public health reporting and strike the rest of the sentence.

CLIAC MEMBER: Agreed.

CLIAC CHAIR: And then do we even need to break out key attributes? Because would that be the work of the workgroup?

CLIAC MEMBER: Sure.

CLIAC CHAIR: Go ahead.

CLIAC MEMBER: It is still pretty general because it's standardization of reporting requirements of public health chemical labs or other diagnosis services. So that's not really very detailed. That just speaks to the fact

that its standards have to be incorporated. And, again, I would say I have little familiarity with the AIMS APHL. I think one of the things is they receive messages from all over, and then they have to map them from one to the other to aggregate them, safely report and on. And I think what would be easier-- one of the things that happens with structured data capture is you actually create a form. And you can download the form and fill it out or have it automatically filled out and send it so that everybody has one standard form as opposed to sending it in different orders or something, and it has to be sorted and mapped and so on. So it could build upon the AIMS APHL infrastructure but take it to another level.

CLIAC MEMBER: I'll also say this may be an opportunity as an attribute of such a system to have universal patient identifiers as well.

CLIAC MEMBER: So it's interesting. The HIPAA legislation actually originally legislated against national patient identifiers, but that has since been removed. So the opportunity is there. But not so two decades ago. There was pretty strong feeling that it shouldn't there.

CLIAC MEMBER: So we've actually explored this quite a bit, and we use the cell phone numbers. And actually, a cell phone number stays with a person now longer than their address or any other feature of the individual.

CLIAC MEMBER: True. That's true.

CLIAC CHAIR: OK.

CLIAC MEMBER: What role does this have with respect to the state mandated reporting? And is there currently a place where we can identify which states require which reporting and sort of a catalog to kind of see what already exists and maybe can identify a good starting place?

CLIAC CHAIR: I would look to the workgroup to do all of that catalogue.

CLIAC MEMBER: Right, right.

CLIAC CHAIR: We don't know.

CLIAC MEMBER: OK, so nothing exists currently.

CLIAC MEMBER: Again, sorry for interrupting. But, yes, the epidemiologists have done that and done a really good job, actually, and have harmonized across most of the platforms and most of the states. So there now are very few outliers in most states in terms of reportable conditions and the components required to be mapped.

CLIAC MEMBER: And there are federal reportable conditions that are required by all states. So this wouldn't be the only time to collect that data on this kind of reporting.

CLIAC CHAIR: So it seems many of us appear to be in agreement with this recommendation. And if I just wanted to parse it and wordsmith it a little bit for conciseness, the last sentence-- "Key attributes of the study should include, but not be limited to, standardization of reporting requirements and/or other diagnostic services, technical specifications of such systems, and advantages and weaknesses of investing in a centralized reporting infrastructure."

CLIAC MEMBER: Do we need to use the word interoperable somewhere in there?

CLIAC CHAIR: I think so. [LAUGHS]

CLIAC EXECUTIVE SECRETARY: Can I ask a question for clarification? Because are you asking-- the first sentence doesn't mention anything about a study. And earlier, one of the other recommendations that Jordan made this morning was asking CDC to conduct a study. So it's not really clear to me what you're asking a workgroup to do versus what you're asking CDC to do by both of these statements. And generally, workgroups that we have are rather short term. And they're experts that are brought together that include only a couple CLIAC members as well as other SMEs to gather information. But they don't generally conduct studies, which are usually quite long term or longer term than what we convene a workgroup to do. So I'm just wondering, is this what you would like CDC to do? Or I'm not quite sure how a workgroup would do this.

CLIAC MEMBER: Can I ask a question? Is there anybody else in line? OK. What is the process to start a working group within CLIAC? Do we need to get approval? Or is that something that [CLIAC CHAIR] can approve?

CLIAC CHAIR: No, I'm going to make you go back through orientation.

CLIAC MEMBER: No. No, but that's what I'm saying. It sounds like we need to get approval from the CDC to form a working group. So that's probably what this paragraph should be about.

CLIAC CHAIR: So let me take you--

CLIAC MEMBER: I think crux of the question--

CLIAC CHAIR: Do we need workgroup? Do we need a workgroup? Or are we going to CDC to study? Go ahead, [CLIAC MEMBER]. Is that where you were coming to?

CLIAC MEMBER: Yeah. I was just going to say the crux of the question is-- if we're agreeing on the content, the question is, what's the method? So is the ideal method a workgroup? Or is the ideal method to the CDC? Thinking through, some basic fundamental background that needs to be acquired is, what systems are out there? How do they perform? What do all the state public health labs and governors want in terms of data? I would suspect that the CDC has the clout to pull all of that where a working group may not.

CLIAC EXECUTIVE SECRETARY: And the other thing is a working group cannot provide information directly to the government. Working groups are charged with gathering information and to then report to CLIAC, and in CLIAC must deliberate on it. So there may be something that it would be helpful to recommend a workgroup to do. But I'm not sure that conducting a study in and of itself would be the right thing. And if you do want to recommend that CDC conduct the study or assess the feasibility, then CDC could determine which is the best way to go about doing it.

CLIAC MEMBER: Well, also, CDC might have already started something like this, understanding the challenges that everyone has been hit with over the last five months. So it would be good to ask anybody on the phone here from CDC if anybody knows if this kind of an evaluation has already begun.

CLIAC MEMBER: Can I ask a question real quick? I haven't been involved for several years since I retired. But I was involved with some CAP committees and also the ONC lab tiger team. And ONC was expending enormous amounts of effort on interoperability with major systems, for certifying systems. I don't know what happened to that, If anybody on here knows. But I know they made a lot of technical advancements in all of these basic items. So maybe someone on this call knows.

CLIAC MEMBER: So ONC did fund the development of SDC, which is one of the data modeling protocols that I've been talking about. They left the topic for a little while, but they've come back and emphasized interoperability and requirements for interoperability. There was a large pushback from vendors, and one very large EHR vendor threatened to go to court over it.

[LAUGHTER]

CLIAC MEMBER: I think that's a really important point because one of the barriers, I believe, in interoperability is a lot of the vendors don't want it.

CLIAC MEMBER: Yeah. Yeah, exactly.

CLIAC MEMBER: So this makes even more good reason. For those people that are having to actually serve the public, this would be the perfect group to say, we need this. Who will help us do this? Can we bring in the experts? And CDC, will you lead the way? And can a couple of us be on your team and be involved in the investigation?

CLIAC MEMBER: Yeah. So I think the step that we're at now is it sounds like we're coalescing around making the recommendation for the CDC to perform the study. Obviously, giving CDC, who has done this before-- they have a whole bunch of tools in their toolbox. They may decide, create a working group. They may decide-- and even if it is started, that may come out later. But I don't think it prevents us from making this recommendation whether it's already been started. It's also nice to get it in the public record as well.

CLIAC MEMBER: Well, and I think if we build it all on the debacle of what happened and use a little bit stronger language to address the urgency of we need to start this now, maybe that will help.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: And can we throw in the assessment of whether or not the AIMS platform might be the tool? And that would further a partnership between clinical and public health laboratories. I'm completely ignorant about AIMS. Maybe our solution is there.

CLIAC MEMBER: Well, I think we could just add to the specificity of key attributes to review existing reporting systems and understand the range of data that's collected from state by state.

CLIAC MEMBER: …receives and distributes. So they receive from all the laboratories but in different formats. It could well be the place to start before when you're talking about standards. We also want to say, I want you to collect the data in this standard and then transmit it to me using this standard. And that goes a little further than saying, OK, transmit it to me using whatever messaging device you have, and then I will have some middleware that will reformulate it into a standard. Now this is saying, hey, all of you laboratories, this is the standard that--

CLIAC MEMBER: Standard. That's right.

CLIAC MEMBER Yeah, I think we need one standard. And if AIMS is built, let's see if it will work for everybody.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: And I think that focusing on the public health reporting makes it less threatening to the big laboratory vendors. I mean, we're really only talking about emergency response right here, right? What the CDC talks about public health, the PHEs. So it's not like all of their systems have to be completely interoperable. That's not what we're talking about to take away their market. We're talking about them having a functionality that ought to be basic to every vendor in the globe. I mean, it's one thing in the United States. But theoretically, people travel so much that-- the point I also wanted to make is that someone brought up before we have individual states have their own reporting mechanisms. But having worked in a couple of states, they're 99% the same. And what's wrong with having a state have a separate line item and everybody else just automatically says not applicable?

I mean, I do think that one common list that could be updated-- the other thing I guess I would say is that I'm not sure that individuality is such a big deal right now. Those rules were made when people traveled by horse and buggy and cars that went 10 miles an hour. So if it's an outbreak in one state, we all should be looking for it, not necessarily, oh, well, that's Pennsylvania or that's Arizona. Because it's not that way anymore. So I do think maybe that'll take some of their autonomy away. But I think that we should be looking at this differently in terms of global or at least national travel.

CLIAC MEMBER: And that would help the commercial labs because think of it. You have to go with 50 different rules. It's very difficult, I think, for commercial labs--

CLIAC MEMBER: Yeah. Also the regional-- yeah, the regional public health collaborations might cross states-- New Jersey, New York, Pennsylvania, Maryland. I mean, even if it's not a commercial laboratory, those things would be helpful for public health emergencies.

CLIAC MEMBER: Yeah, if you're a lab on the border, you have a really hard time knowing where your patient came from to start with. Where am I supposed to report this? And it will take longer to get the information of public health because of the different means.

CLIAC MEMBER: One of the major burdens that Alexis Carter spoke to of HHS, reporting requirements was that you have to report also to the local public health, to that patient's local public health authority. And since everyone has a slightly different format, you're filling out different state's forms all the time. And that's a huge burden. So this reduces the burden on the pathologist.

And then if you extend the forms-- and I think Dr. [INAUDIBLE] talked about how the pathologist doesn't have the-- I mean, I don't know if this patient has a fever. And I just know what their specimen looks like. And so if you actually extend forms and, in fact, if you had a universal patient identifier, then the clinics who are seeing the patient can answer those questions or the person who's collecting the swab can answer those questions.

And you've built out this architecture where you can aggregate the information, and you get it from the source. So I, Mary, the pathologist, don't have to go to Jane, the family practitioner, and ask her and then take it and then type it again into my report. You actually get the truth from--

CLIAC MEMBER: That's just awful.

CLIAC MEMBER: Yeah.

CLIAC MEMBER So antiquated.

CLIAC MEMBER: So antiquated, yes.

CLIAC MEMBER: So within regards to this recommendation, where are you, [CLIAC CHAIR]? Are you here? I don't see you up on my screen.

CLIAC CHAIR: I am here. And we've almost approached the seven seconds of silence, which means we're almost in agreement, which means we're almost ready to vote on this. So I'm waiting for the last few comments.

CLIAC MEMBER: Can we put interoperable somewhere in there?

CLIAC CHAIR: Yeah, you were supposed to tell us where to put it.

CLIAC MEMBER: Oh, OK, OK. Attributes of this study should include, but not limited to, interoperability.

CLIAC MEMBER: Yeah. [LAUGHS]

[LAUGHTER]

CLIAC MEMBER: That was perfect.

CLIAC MEMBER: There it is.

CLIAC CHAIR: That's number one.

CLIAC MEMBER: That was great.

CLIAC DFO: If I could jump in on this, I'd like to.

CLIAC CHAIR: Yes. Please, go.

CLIAC DFO: OK. So a number of us from CDC are chatting on the side. This meeting is much more difficult to do over Zoom. But I do want to bring you up to speed on some of what's going on at CDC that touches on this. And this is not secret. I mean, in the CARES Act, I think $550 million was dedicated to what's called DMI, the Data Modernization Initiative.

But it's big picture data around health care in the broadest sense. But it came into CDC and is being distributed now and in the near future to all the states. And so all the states will receive DMI funding. And, well, I have to be careful about what I say publicly. But I think, like so much in health care and even in public health, the laboratory isn't necessarily what the first thing that everybody thinks about.

And so a lot of this funding, for instance, is going toward electronic case reporting, which I know somebody-- it was mentioned earlier on, which is great, and I think deserves funding and attention. And it's the idea of automatically reporting public health information from the electronic case report to health departments. And I'm the squeaky wheel in the room who's saying, well, what about lab data? And they're like, well, yeah, we'll get there. We'll get there. If lab can just integrate-- the LIMS system can integrate with the health record in the hospital, it'll all work out fine. But I think what I would find helpful in this recommendation would be to, again, really make it clear here that-- maybe even reference the public health Data Modernization Initiative or something and encourage CDC and the US government to ensure that some of that funding and work is going towards addressing these fundamental clinical laboratory reporting issues.

And part of the reason that we wanted to talk about ETOR today was that we see that as fundamental as well. Like, if we can really connect in theory all the hospital labs around the country with all their respective public health labs around the country electronically in a system that's analogous or similar to what Tony Tran talked about today, that would be a huge leg up. And then we can also work on this sort of centralized data platform thing. And, yeah, the AIMS platform is great. But we're having trouble scaling it. We don't have enough money and resources dedicated to centralized laboratory reporting to make that happen.

So in the public health sphere when it comes to data modernization, as always, laboratory is competing with the other big players, who tend to get more attention and therefore more funding. So I guess I would-- I'm really supportive of this recommendation. But I think if there's a way that you can really emphasize the clinical laboratory reporting aspect of it as something that needs attention. So, over.

CLIAC MEMBER: Well, I was kind of getting at that, about partnering with the big players, which are the clinical teams. Like, if we can work in here some place-- and I think the clinical world would be extremely receptive to that. But that's the idea I was trying to mention about not letting us get siloed as the lab. Nothing moves. Nothing works. There's no research without the lab, right? There's no medication without the lab. There's no treatment-- you can't develop a treatment if you don't know who actually is infected. So if we can work in, again, those other stakeholders because we're so vital-- aside from, again, just general education for whoever's going to be using any of the reporting. I'm not sure the right way to say.

CLIAC MEMBER: I maybe heard this slightly differently. I think what's missing from our recommendation is the word laboratory.

CLIAC CHAIR: OK, that's--

CLIAC MEMBER: [INAUDIBLE] standardization of reporting requirements of public health/clinical laboratories and--

CLIAC MEMBER: Laboratories and diagnostic services.

CLIAC MEMBER: Yeah. Because actually, this speaks to the bigger issue. It doesn't specifically address laboratory, and that's the part we need to bring in is the laboratory data.

ADVAMED LIAISON: So maybe laboratory needs get moved up closer to the beginning of it for the emphasis. And then also, do you really just want to assess the feasibility? Or are you recommending that CDC drive to replace and upgrade?

CLIAC MEMBER: And to [CLIAC DFO] point about the difficulty scaling the AIMS platform, that's because of the fact that it's taking in-- I know I keep saying this over and over again. But it's taking in the data in different formats and different orders and having to operate on it before it can put it into a central house. So by templating labs reporting-- so by giving you the pipe and say, here, put it in this pipe. It's this big. Put it in this pipe. Use this train gauge. Then you get that on, and then I think this can act as a template so that other areas of the clinical care of a patient with a patient-facing physician may also be able to put in that kind of data. And then it can be aggregated. So I think one of the things that Dr. Fauci has said is the protean manifestations of this disease, anywhere from asymptomatic to death, terrible death, indicate that we do need to understand when we're looking at these test results how many people are carriers, how many people are asymptomatic. These are important things to know. But we laboratorians don't know this.

CLIAC MEMBER: But, again, I think the other point is that actually, the laboratories, the public health laboratories and the laboratory system and AIMS is not getting a priority funding. The functionality is there. It is scalable, except you have to add more money to it. And the money is not coming to this particular issue.

CLIAC MEMBER: And I agree. I think it's long past feasibility. I think everyone knows it's hard. I just would recommend a strategic plan for program development or something more tangible.

CLIAC MEMBER: Yeah. Now you see right-- "assess the feasibility." How about "CLIAC recommends CDC developing a strategy to fund, replace, upgrade existing laboratory information infrastructure?"

CLIAC MEMBER: I like that.

CLIAC MEMBER: A strategy to fund. Not assess feasibility. A strategy to fund.

CLIAC MEMBER: And then that will make people think of the additional money in the CARES Act.

CLIAC MEMBER: And maybe we need to reference that, as [CLIAC DFO] suggested, that we reference the data modernization funding.

CLIAC MEMBER: And could I ask if you would be willing to put the word laboratory after existing?

CLIAC MEMBER: It would probably just need to also say diagnostic testing.

CLIAC MEMBER: Sure.

CLIAC MEMBER: To be as blunt and clear, for clarity.

CLIAC MEMBER: Well, if you wanted to be really specific, you could say "develops a strategy for use of modernization of information funds to replace/upgrade." Although that might be saying, here, you got the money, but we're going to tell you what to do with it.

CLIAC MEMBER: Yeah, I like that we get the funding.

CLIAC MEMBER: Also, not to be-- oh, I don't know how to say this. But the laboratory thinks we own the word diagnostic, and we are perfectly happy owning that. However, after talking to all the leaders in the diagnostic accuracy sphere and funding spheres, the talk about diagnostic accuracy and providers, providers actually think diagnostic is their word, not the laboratories.

So we'll have to be specific to laboratory diagnostic I think because a lot of people want to own diagnostics. Radiology wants to own diagnostics. Internal medicine wants to own diagnostics. And all of that is important, of course. But the truth of the matter is, if the laboratory had a strategy at the beginning of-- had this at the beginning, everything else could evolve. I mean, [CLIAC DFO], what you're saying, they're telling you sort of backwards. Oh, we're going to start with the EHR and work backwards. But what we really needed to know is how many cases we had and the simple lab demographics that might have been age, gender, something simple that could have given people real time information while we bring in fever and symptoms. And I mean, the clinical piece is just so big.

But at the beginning of an emergency, we just need to know where the cases are, like zip code, something pretty simple to start spewing information so that decision makers can say, New York needs reagents right now. Look

at all this bundle per capita. And so I don't know that that would fly. But that's just-- it seems backwards to me when-- even if it is mapped from an electronic medical record, it still has to be the laboratory functionality and the laboratory data and the reporting to public health is more important from a test result perspective in these pandemics than all of the other things at first. And then, you know.

CLIAC MEMBER: But if you want the money, you tie it into clinical. It's like just being realistic. Big projects get big money. And it's just a reality. And clinical-- because that's even-- and it makes sense, right? and I made the statement in my first comment, OK? Everything is the lab. There is no clinical without a lab. But from the perspective of people who fund things, what they see is patients, right? They will never understand that without a functional lab system, you could shut the whole thing down that you won't see. So to me, use this is an opportunity to make that pipeline flow and connect it into the clinical pieces. And honestly, if they got this fixed for the lab, public and private, and put together this grid, I don't care who calls it diagnostic. Like, you want to be the diagnosticians? Congratulations. Just get this fixed so it doesn't happen again.

CLIAC MEMBER: And I would really emphasize how important this upfront period is because you take so much time to get all the data into your system when it's coming from another facility that already has it. sometimes? We're wasting time putting data in when the results are already available. So it's slowing the turnaround time in this important time of a pandemic.

ADVAMED LIAISON: I'd like to make a recommendation. The "develop a strategy for funding," my experience is that's fairly-- sounds kind of wishy-washy. It could be we're just asking them to develop the strategy. Again, as I said before, I think you really want them to do this. And it might be better to say something along the lines that CLIAC recommends that CDC utilize funding through the CARES Act, the $500 million, blah, blah, blah, and drive the replacement or upgrade of existing laboratory information and keep the rest. I think the "develop a strategy for funding," fits nice with HHS as a-- something that you can think about, but you don't ever have to actually do.

CLIAC MEMBER: Yeah. I think that's good.

CLIAC MEMBER: And I would agree.

CLIAC MEMBER: Even better. Yep.

CLIAC EXECUTIVE SECRETARY: Can you repeat that please, [ADVAMED LIAISON]? I missed after.

ADVAMED LIAISON: How about that CDC should utilize funding from the CARES Act, specifically data surveillance and analytical infrastructure funding to there and just leave it at that. And then get rid-- specifically--

CLIAC MEMBER: I think we need to add in something about improve patient outcomes.

CLIAC EXECUTIVE SECRETARY: OK, can I just get-- can I get this phrase from [ADVAMED LIAISON] first?

ADVAMED LIAISON: Sure. The CARES Act, specifically the half billion or $500 million for data surveillance and analytical infrastructure. Million for data surveillance and analytical infrastructure. And analytical infrastructure. And delete "to develop a strategy for funding."

CLIAC MEMBER: Do we want to talk about, we want to improve turnaround times? Improve turnaround times on test results.

CLIAC CHAIR: Too big, [CLIAC MEMBER]. Too big. Well, this is just getting data in and data out and like fixing that part. And then we can talk about patient outcomes, patient safety.

CLIAC MEMBER: And I think we should remove the word include after address.

CLIAC EXECUTIVE SECRETARY: Oh, yes.

CLIAC MEMBER: It's redundant.

CLIAC MEMBER: And then we've got kind of a mix of commas and semicolons you might want to take a look at.

CLIAC EXECUTIVE SECRETARY: Oh, OK. All right.

CLIAC MEMBER: The sentence needs a little reworking because its "key attributes the strategy should address." But we're not calling a strategy anymore. So its "key attributes that should be addressed are" or that "should be addressed include, but are not limited to."

CLIAC EXECUTIVE SECRETARY: Now we put the word include back in. [LAUGHS]

CLIAC MEMBER: And I don't know if there is a place to say it. But there are studies that show that 70% of-- at least 70% of medical decisions are made based on laboratory data.

CLIAC MEMBER: Oh, that would be a good statement.

CLIAC MEMBER: Except there's no way to back that up.

CLIAC MEMBER: I have actually seen that referenced.

CLIAC MEMBER: I have, too. I have the original reference, and it was just an opinion. And all lab community grabbed onto it and ran with it. And so it's become gospel.

CLIAC MEMBER: So can we say for a pandemic-- but for a pandemic, I can't treat somebody if I don't know when they have. I mean, it's not doable. You can't develop a treatment. You can't develop a drug. You can't do research. You can't do anything. And you actually can't run a hospital. And that's why we had to get everybody tested when they came on to labor for because they're young women. So they were asymptomatic. So it literally touches every single thing.

CLIAC MEMBER: OK, now that we're talking about commas and semicolons, I think we're 98% of the way there. And I'm looking to a couple of people who would just want to finish the wordsmithing and then bring it back tomorrow morning for our approval. Do we have any volunteers? Who are the grammar people?

CLIAC MEMBER: I'll help with grammar.

CLIAC CHAIR: OK, And then it is 6:33, three minutes beyond our allotted time. And I would like to adjourn today's meeting unless there's any opposition. And I'll see you all at the happy hour shortly. Thank you so much. Bye.

October 28, 2020

Call to Order/Roll Call/Meeting Announcements

CLIAC DFO: OK. Good morning, everybody.

CLIAC CHAIR: Good morning.

CLIAC DFO: OK. Just one second, please. Let me introduce the meeting for the day. My name is Ren Salerno. I'm director of the Division of Laboratory Systems. I'm also the designated federal official of the Clinical Laboratory Improvement Advisory Committee, or CLIAC. Welcome to day two of our CLIAC meeting.

CLIAC is managed by the Centers for Disease Control and Prevention and provides scientific and technical advice and guidance to the Department of Health and Human Services. The advice and guidance CLIAC provides to HHS pertains to general issues related to improvement in clinical laboratory quality and laboratory medicine practice. In addition, the committee provides advice and guidance on specific questions related to possible revision of the CLIA standards. As this is a federal advisory committee meeting, the Zoom chat and Q&A functions have been disabled for audience members.

And an added addition to our CLIAC members is that because of that fact that the Zoom chat and Q&A functions are disabled for the public, we ask that you, members, do not use the chat function to have substantive technical conversations with each other. You may use the chat function to alert our chair that you would like to make a comment during the discussion. If any of you are experiencing Zoom difficulties, please contact CLIAC@cdc.gov.

Members are reminded of the importance of remaining in attendance on both days, actually, we're on the second day, for the full meeting to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned. We ask that members remain on camera while the meeting is in process so that we know you are in attendance. We do have a note today that Dr. Mary Edgerton may be on the phone only for the first hour, but I thought I saw her already on Zoom.

OK. So I now need to perform the roll call. And this morning, we do not need to provide our affiliations or our conflicts of interest. So I just ask that each member, when I call their name, just answer that they are here or present or indicate that they are part of the meeting today.

I will start with our chair, Dr. Valerie Ng.

VALERIE NG: Here.

CLIAC DFO: Dr. Birthale Archie. Yes. I would like to announce that along with three other colleagues, I have a research grant from the Maryland Department of Health. Thank you.

BIRTHALE ARCHIE: Here.

CLIAC DFO: Dr. Marc Couturier.

MARC COUTURIER: Here.

CLIAC DFO: Dr. Mary Edgerton.

MARY EDGERTON: Here.

CLIAC DFO: Dr. Susan Gross.

SUSAN GROSS: I'd like to add to my conflict. I didn't mention yesterday that I'm also the president and CEO of the ObG Project, which is a site that promotes best practices and guidelines to health care professionals. And I am here.

REN SALERNO: Great. Thank you, Susan. Dr. Lee Hillborne.

LEE HILLBORNE: Here.

REN SALERNO: Dr. Steve Hinrichs. Steve, are you with us today?

HEATHER STANG: He's joining later, Ren. He--

CLIAC DFO: OK. Sorry, I missed that. Dr. Jordan Laser.

JORDAN LASER: I'm here.

CLIAC DFO: Dr. Thomas Lorey.

THOMAS LOREY: Yes, here.

CLIAC DFO: Dr. Lavinia Middleton.

LAVINIA MIDDLETON: Present.

CLIAC DFO: Miss Carol Moss.

CAROL MOSS: Here.

CLIAC DFO: Dr. Nirali Patel

NIRALI PATEL: Here.

CLIAC DFO: Dr. Michael Pentella.

MICHAEL PENTELLA: Here.

CLIAC DFO: Dr. Katherine Perez. Is Katherine with us this morning?

KATHERINE PEREZ: Yes, I'm here.

CLIAC DFO: Miss Jennifer Rhamy.

JENNIFER RHAMY: Here.

CLIAC DFO: Dr. Gregory Sossaman. Greg, are you here today?

MARC COUTURIER: He may have been hit by the hurricane.

CLIAC DFO: Was he hit? I was, I can tell you that.

HEATHER STANG: He may be a little late. He's trying to find a Wi-Fi signal.

CLIAC DFO: Got it. OK. Dr. Chip Watkins.

CHIP WATKINS: Here. I was just asked to be on Merck, I guess, Merck and Company US Outpatient COVID-19 19 Expert Input Forum. Not exactly sure what that means, but needed to announce it.

CLIAC DFO: Dr. Thomas Williams.

THOMAS WILLIAMS: Here.

CLIAC DFO: Dr. Donna Wolk.

DONNA WOLK: Here.

CLIAC DFO: Mr. Andy Quintenz.

ANDY QUINTENZ: Present.

CLIAC DFO: Dr. Collette Fitzgerald.

COLLETTE FITZGERALD: Here.

CLIAC DFO: Miss Regina Van Brakle.

REGINA VAN BRAKLE: Here.

CLIAC DFO: Dr. Timothy Stenzel.

TIMOTHY STENZEL: Present.

CLIAC DFO: And Miss Nancy Anderson.

NANCY ANDERSON: Here.

CLIAC DFO: OK, great. Now I've got to go back to my notes. I don't have two monitors today, unfortunately, so I'm going to be jumping back and forth between my notes and the Zoom. OK. During the period dedicated to committee discussion, participation is limited to CLIAC members only. CLIAC can only accept public comments that directly relate to the topics announced in the Federal Register notice of the CLIAC meeting, and as related to the theme, laboratory medicine in the age of COVID-19.

Today, the committee will discuss and deliberate on the following topic, the clinical laboratory's role in identifying health inequities during the COVID-19 response. Today, public comments will be limited to a total time of five minutes per individual group, but Heather, correct me if I'm wrong, I believe we have no public comments today. Is that correct?

HEATHER STANG: That is correct.

CLIAC DFO: OK. If anyone in the audience wishes to address the committee, the public comment portion of the meeting is the proper forum to do so. Please send a request for public comment to CLIAC as soon as possible. Valerie, turn it over to you.

CLIAC CHAIR: Thank you. Few comments around housekeeping and schedule and logistics. Copies of all PowerPoint presentations and other meeting materials are posted on the CLIAC website, at cdc.gov/CLIAC. At the start of each presentation, I will announce the presentation number to assist you in locating the correct electronic file. It is the blue number next to the presentation on the agenda.

This meeting is being webcast by a Zoom webinar. Links for accessing the webinar are provided on the CLIAC website. If you are experiencing any difficulty with accessing Zoom, please email CLIAC@cdc.gov. This meeting is also recorded to assist in preparing an accurate written summary of the proceedings.

Today's meeting agenda is focused on the clinical laboratory's role in identifying health inequities during the COVID-19 response. This will be the first time that CLIAC will discuss the topic of health disparities, inequities, and social determinants of health. This session will serve as an introduction to the topic to start committee discussion on the laboratory's role in identifying or generating data to assist in the identification of health disparities and improvement of health equity.

Presentations will focus on experiences with or observations of health inequities during COVID-19 pandemic and the potential roles that the clinical laboratory may have in this area. I will ask the committee for suggestions on how the government can help in this area. The first presentation will be from Dr. Marissa White, who will present on the role of clinical laboratory in mitigating health disparities. The second presentation will be from Dr. Nicole Lurie, who will present on health inequities as it relates to COVID-19.

If you wish to provide a five minute public comment, please email CLIAC@cdc.gov.

The Clinical Laboratory's Role in Identifying Health Inequities during the COVID-19 Response

Mitigating Health Disparities: The Role of the Clinical Laboratory
Marissa White, MD

CLIAC CHAIR: OK, thank you. If you do want to make a public comment, please email CLIAC@cdc.gov. With that introduction, we will start with our talks this morning. The first is Mitigating Health Disparities, the Role of the Clinical Laboratory, provided by Dr. Marissa White. It is presentation number 11 on the agenda. Dr. White, you have the floor.

DR. MARISSA WHITE: Thank you very much. Let me get set up here. And thank you very much for the introduction and the invitation to be here this morning.

So this morning, we'll be discussing mitigating health disparities. the role of the clinical laboratory. I'm on faculty here as a surgical pathologist at Johns Hopkins University School of Medicine, however, I am intimately associated with health disparities in terms of diversification of the workforce. So I do have some perspectives on what we can do from a pathology perspective to mitigate health disparities.

I have no disclosures, but at the end of our conversation today, which will be brief, hopefully you'll be able to list the five domains of the social determinants of health as defined by the US Department of Health and Human Services, identify an example of how SDOH exacerbated health risk disparities during the COVID-19 pandemic, list some resources to further understanding of health disparities, and as a laboratory professional, design and implement an initiative to mitigate a health disparity.

So as a reminder, social determinants of health, or SDOH, are conditions in the environments where people are born, work, live, do anything. So what does this mean? These social determinants of health are intimately tied to your health, where if you are working in a setting that has environmental exposures, you're an increased risk for developing lung cancer. Again, poor health and poor health access and outcomes are directly attributed to inequities in education, socioeconomic stability, community construct, support, living conditions.

If you are living in an urban setting where there's increased gun violence, you're an increased risk for develop for trauma from secondary violence. So why is this relevant for us in pathology? Because increased awareness of how social determinants of health impact health disparities can help us improve our research concepts, our research design, the patients who we enroll in our clinical trials, improve how we as pathologists provide care, obviously we are dealing with our patients that are suffering from health disparities, and how we can improve how we train the next generation of pathologists, being mindful that we have to start early in the conversation about social determinants of health and how that impacts health outcomes.

With that said, ultimately, increasing workforce diversity is a critical element of increasing our awareness of social determinants of health. So let's take a step back and look at some of the federal initiatives that have been designed to identify, measure, and address US health disparities. Again, we're thinking about what we as laboratory professionals can do. There are plenty of federal resources that are available. Sorry, I'm getting a phone call. Sorry about that. I'm in the office.

So here's a brief timeline of some of the federal initiatives starting back in 1985 with the Port of the Secretary's Task Force on Black minority health, progressing all the way up until 2018 with the National Health Care Quality and Disparities reports. And I'd like to highlight these National Health Care Quality and Disparities

reports because these serve as a really nice overview of disparities in terms of their existence and then how have they progressed. So you can look at a comparison of white patients versus Black versus Asian versus Hispanic to kind of really get a nice, granular look at how disparities have been progressing over time. So I would strongly encourage you to reference these federal resources as a springboard for your future initiatives.

So let's briefly take a look at the impact of social determinants of health during the COVID-19 pandemic. So what we started to see in the early stages of the pandemic were alarming trends where individuals like our frontline employees or essential service employees were at increased risk of exposure without adequate PPE or without adequate, I guess, protections. Individuals, after they got ill, were not making it to the emergency room in time. And when they were hospitalized, we had some that had a rapid precipitous almost fatal clinical course.

Individuals that were able to be safely discharged sometimes lived in settings where they were living with other individuals who were at risk or they were having difficulties obtaining access to follow-up care. This is very real for my family, where I had an aunt that is a nurse anesthetist, so again, very savvy with navigating the health care system. So with that said, even her, someone who has the ability to navigate the health care system, had difficulties obtaining adequate pulmonology and cardiology follow-up. So this is for someone that's health care savvy and intimately associated with the system. For an individual that has limited access and limited abilities to navigate the health care system, imagine how difficult it is for those individuals.

So the underlying theme are social determinants of health here, where for those that were developing, that were at increased risk for exposure, were those, again, in essential settings, those that were in transportation, those that were in group home living situations or incarcerated where, again, there's close contact, that's a social determinant, their occupation. Looking at our social determinants, we're talking about those that arrived in the ED, were their potential biases? And who was triaged more quickly as opposed to who was asked to wait in the ED for a little bit longer and not seen immediately? So care delays and possible bias.

And then in terms of after discharge, what's going on there? Where the individuals that were discharged, did they have to go back to work immediately because they didn't have disability insurance so they weren't able to take time off to really recover? Do they have additional comorbidities? Do they have issues accessing, again, follow-up care? So these are all the social determinants of health that exacerbated what we have been seeing in the COVID-19 pandemic.

And to take a closer look, let's look at our Native American communities where, unfortunately, there's a higher baseline risk or prevalence of chronic diseases, similar to other underrepresented minority groups. Higher rates of poverty, a vulnerable elderly population, in some settings, larger households, in some settings, linguistically and culturally inappropriate public health communications where, for example, in Navajo communities, information was not disseminated in the proper language. And again, remote and isolated communities, where we're looking at individuals that may have access to one hospital that may have a few intensive care beds.

The National Congress of American Indians, the largest American advocacy group, identified that the Indian Health Services had only 1,257 hospital beds, of which contain 36 intensive care units. And many patients were hours away from those facilities.

And more issues with the remote and isolated communities, again, limited health care infrastructure and access, limited access to potable water and safe wastewater disposal, some subsistence lifestyles where individuals are not able to-- if you're asking them to quarantine at home for two weeks, do you have the adequate food resources to quarantine at home for two weeks? Limited internet and mobile phone service. So if you're talking about if a patient tests positive and you're calling them back, are you going to be able to get them back in a timely fashion because of the internet and mobile phone service connectivity issues.

Again, very real issues. But this should not come to a surprise to us because this has been published in the data well before COVID-19. This is a nice paper published, American Journal of Public Health … that establish systemic health inequities and disparities. And COVID-19 only exacerbated what we had been seeing for quite some time.

So how can laboratory professionals identify opportunities to mitigate health disparities? So going back to this nice outline, again, published by Thakur et al. Let's look at the opportunities for action. For us as pathologists, there are many opportunities. We can work with our frontline employees, so our phlebotomists, our lab technicians that are actually seeing our patients in the clinics, and advocate for PPE and hazard pay.

We can advocate for expansion of government subsidies for testing. In terms of office hours, again, thinking about we don't see many patients, but we can think about our laboratory office hours. If we're working with our colleagues to set up satellite COVID-19 community test sites, do those test sites have flexible hours? That was something that came up for us here at Hopkins when we were working on building a field site for COVID-19 testing. We had to make sure that our hours were late because a lot of the individuals that were going to get tested at that location would be working a full 10-hour workday and need to be available to get testing over in the evening. Or if, for example, they're taking care of children and they have remote school in the daytime, you're not able to step away and go get tested.

In terms of opportunities for action in the care setting, for us as laboratory professionals, we can make sure that the information that's disseminated from a laboratory perspective is equitable and is mindful of cultural and linguistic competencies. In terms of post follow-up care, again, flexible office hours for our laboratories and advocating for expansion of government subsidies for laboratory testing, anything that's relevant for us from a laboratory perspective. Medication cost is in there, but for us, I would advocate for laboratory costs. So again, there are many opportunities. Even though we are not seeing our patients directly in clinics, interfacing with directly, there are multiple opportunities for us to engage with our patients in different ways.

So to look at some of our federal resources as something that can help guide our implementation of initiatives to mitigate health disparities, I'd like to first bring your attention to the National Standards for Culturally and Linguistically Appropriate in Health Care standards. So these were developed by the Office of Minority Health and launched in 2004. And the goal is to provide effective, equitable, and understandable and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred language, health literacy, and other communication needs.

So what this ends up looking like are 15 action steps to advocate for health equity and to improve quality and to help eliminate health disparities by providing a blueprint for health organizations to implement, again, culturally and linguistically appropriate health services. So what this looks like, the 15 standards are further broken down into subcategories with a unifying principle standard, and then the rest of standards are lumped into governance, leadership, and workforce, where we're looking at diversity with our providers and our leadership.

Communication and language assistance. Again, making sure that the information that we share with our patients is culturally and linguistically appropriate. So looking at our Navajo patient communities where English may be a second language in many households. Making sure that the laboratory information is an appropriate language for us here at Hopkins, we had to make sure that all our information was also shared in Spanish.

Engagement, continuous improvement, and accountability. Other standards are focusing, again, on making sure that we're doing continuous improvement and continuously doing needs assessment to find out where our gaps are and where our opportunities for improvement are. And for community partnerships, this also falls under

engagement. And that means looking out to our communities and saying, how can we improve laboratory services in our communities? What do you need?

Another wonderful resource that's available through, again, the federal agency is Healthy People 2030. So Healthy People is another nationwide federal initiative established by US Department of Health and Human Services first in 1979, when there was a clear need to increase an emphasis on health, disease, and prevention. However, we're now under the 2030 iteration where Healthy People 2030 provides 10-year measurable public health objectives and tools to track progress. And again, objective.

So what this looks like is you are able to identify the needs in part of your populations based off of the measurable objectives. And then you, as a laboratory professional, can set your own targets based off of the objectives outlined by Healthy People 2030. And then you can find inspiration and practical tools using their website and then monitor your progress compared to the national benchmarks and national data.

So again, a nice outline for using existing federal data to create and implement your own health disparities initiative. Again, if you are to access this website, there are over 355 data-driven objectives to improve health, well-being with an emphasis on high priority public health issues. You may note that there are core developmental and research objectives. The core objectives have clear defined data, whereas the development and research may not have defined it at this point but are still regarded as high priority public health issues.

Again, all tied back to the common theme of the social determinants of health. So if you're looking for a good place to start, this is another helpful resource. So let's look at what some of these objectives look like, relevant for us in pathology.

One objective under research and development is increasing the proportion of state public health laboratories that provide comprehensive laboratory services to support emerging public health issues. Another is increasing the proportion of state-held public health laboratories that have implemented emerging technology provide enhanced laboratory services. So for us in COVID-19 pandemic, this is becoming very more important where the role of a clinical laboratory is becoming even more important than ever.

And along the same lines, another objective is enhancing the use and capabilities of informatics, using data sharing, data exchange, and application to practice and use in decision-making. Again, not specifically highlighting COVID-19, but this is, again, becoming more critical as we're thinking about how we can track health disparities data. Having a strong data sharing network is critical for understanding our long-term trends.

And here are some core objectives. So again, the core objectives are those that have defined data. So I would like to highlight a few that are relevant to us in pathology, more so on the clinical pathology side. Increased serum creatinine lipids and urine albumin test for Medicare beneficiaries. So again, this is where you can partner with your local clinics.

Increase the portion of adults with diagnosed diabetes who receive an annual urine albumin test, reduce the female breast cancer death rate. So for us in surgical pathology, this is really important for us. So I'm going to be looking at triple negative breast cancers, for example, or ER positive breast cancers that even though they are lower grade breast cancers, African-American patients still have a worse prognosis.

Increase the proportions of persons who know their sexually transmitted infections status. Again, this is where we as laboratory professionals can partner with our public health colleagues to see how we can increase access and dissemination of information. And finally, here's another example, reducing the rate of new cases end-stage kidney disease. And I just want look at this a little bit more carefully to see how this would look for us in pathology if we're trying to focus on one health disparities initiative.

So reducing the rate of end-stage kidney disease, hemoglobin A1C point of care testing in under-resourced settings. So as we all know, glycemic control drives diabetes outcomes. And long-term glycemic control is measured through hemoglobin A1C testing. However, there are well-established racial, ethnic, socioeconomic, and geographic disparities in prediabetes and diabetes prevalence and outcomes.

So we're thinking about how we can improve care. We want to make sure that our patients are able to have an accurate, timely hemoglobin A1C result that a clinician can act on immediately while the patient is seen in the clinic, as opposed to calling the patient a week later on to follow up and say, oh, well your hemoglobin A1C came back elevated. We need to alter your dose. In this setting, where you're calling a patient after the fact, you may have issues with contacting them because of loss of follow-up, so in some settings, patients may never even receive the results.

So hemoglobin A1C point of care has the potential to reduce diabetes disparities by allowing for immediate clinical decision making. However, as laboratory professionals, we are all aware of the significant limitations of hemoglobin A1C point of care instrument performances. So for us, when we're thinking about how we can work on reducing health care disparities, we can focus, perhaps, on hemoglobin A1C point of care as a mechanism to improve health disparities for diabetes, focusing more attention to how we can improve technology for these instruments and these assays. So that's just one example of many. So again, you can go to the Healthy People 2030 to search for some objectives that might be relevant to your clinical practice.

So what happens when we laboratory professionals do not do our part? We have an inadvertent exacerbation of health disparities where we provide culturally inappropriate and non-patient-centered care, especially for phlebotomist and our front-facing staff. A patient may come in the door, feel uncomfortable, and walk right out the door and not get their laboratory test.

Diagnostic, therapeutic, and risk stratification algorithms. The clinical relevance for our laboratory reference ranges and electronic medical record systems. I'd like to highlight that many of these are inadvertent, however, historically, this is not always true. The US, unfortunately, has a long history of systematic exclusion, racism, and unethical medical practices and research towards African-Americans, Hispanics, other underrepresented minority groups, marginalized communities, including the LGBTQIA community. So despite significant improvements in overt bias, there's still implicit bias that can inadvertently exacerbate health disparities. And there's still profound distrust in some communities. We have to be very mindful of this.

So to take a quick look at what this looks, like I'd like to highlight risk stratification algorithms with an emphasis on the estimated glomerular filtration rate. As we all know, GFR, or glomerular filtration rate, is difficult to definitively assess in the laboratory. So using estimated EGFR, which is adjusted based on the patients serum creatinine level, age, race, sex, body size.

So this is a nice paper that published analysis of many of these race-adjusted algorithms, including EGFR, where it inadvertently encourages race-based medicine, where we now recognize that race, in many settings, is a social construct. So for myself, I identify as African-American, but I'm also Danish, my great grandma was Danish. I'm also Puerto Rican. So race does not always correlate with a specific biology.

And so what ends up happening is when you adjust for race inappropriately and not in a standardized way, you may have inadvertent exacerbation of health disparities and diversion of resources and/or medical attention away from racial and ethnic minorities. So again, for EGFR, the thought is that for African-American patients, there are higher baseline serum creatinine levels, and it's postulated this may be secondary to higher muscle density in these patients.

Clearly, that probably is not validated rigorously. So for us as pathologists and laboratory professionals, there are opportunities for us to collaborate with our clinical colleagues to reconsider and rigorously validate these algorithms.

For transgender patients and non-binary patients, there are numerous barriers to health care access, so I'd like to be mindful that for us, when we implement our laboratory information systems or when we're working with our clinical colleagues and streamlining our EMR, we have to be mindful of using preferred names, preferred pronouns, and gender identities in our EMR, as another opportunity to make the patient experience more inclusive. So for us here at Hopkins, this is what documentation of SOGI, or sexual orientation and gender identity in the EMR looks like.

And so the last piece of the puzzle is workforce diversity. Again, awareness of health disparities comes with increased workforce. However, increased workforce diversity also provides higher quality care, helps us diversify our clinical trials, increases innovation, has higher financial performance. So while we have limited abilities as laboratory professionals to improve patient care with provider-patient concordance or provide culturally appropriate care, there are numerous opportunities for increased workforce diversity to improve our care.

And so just to look at what we currently see for our pathologists in practice, we are not seeing a significant trend in terms of increased representation of our underrepresented minorities. So this is an opportunity for us to be mindful of how we can increase our workforce diversity. This is on the pathologist side of things. This is certainly not on the laboratory professionals, but future studies would need to be performed on that side, as well.

So in summary, social determinants of health directly impacts health equity. As gatekeepers of diagnostic tests and data, laboratory professionals are uniquely positioned to mitigate our disparities. Failure to emphasize diversity and inclusion equity in pathology may inadvertently exacerbate health disparities. There are numerous federal initiatives and resources that can assist with your development and implementation of a pathology-specific health equity initiative and [INAUDIBLE] towards diversity is critical. With that, I will end, and thank you for your time.

CLIAC CHAIR: Thank you very much, Dr. White. That was wonderful. More food for thought than we can digest right now. We will come back and we will discuss this after Dr. Lurie's talk.

How the Laboratory Community Can Contribute to Addressing Health Disparities
Nichole Lurie, MD, MSPH

CLIAC CHAIR: Our next speaker will be Dr. Nicole Lurie, talking about health inequities in COVID-19. It is presentation number 12. Dr. Lurie, you have the floor.

DR. NICOLE LURIE: Thank you. And thank you so much. I mean, Dr. White's presentation really covered so much ground and is really terrific. And I think I was also asked to speak about inequalities and disparities more generally, and I will try to apply a lot of these comments now to COVID-19. So just give me a moment if I can to share my screen and we'll go from there. And I'm going to try hard not to cover more of the ground or go over the ground that she just covered because it was terrific, but maybe really try to amplify on some of these general comments with some real-world examples.

We don't really need to go through this. I think we appreciate all of the different ways that our society impacts on health. But what I really wanted to think about, and then we'll do some of this through the lens of COVID,

are all of the opportunities for the lab community to contribute. And I've just sort of put them in a number of different categories, or sort of six As.

Obviously, Dr. White talked a lot about access. And we see access coming in lots and lots of different forms. Service location and hours for our patients, even to get not only laboratory tests done in a lab, but places where they might get sampling done, where they might get blood drawn, those other sorts of things are super important. Clearly, laboratory access and access to testing has been such a gigantic issue in COVID, particularly early on, but even now, with lots and lots of testing sites and sampling sites being in locations that are difficult for many low-income patients, in particular, to access.

Similarly, while lots of tests are covered by insurance, we also know that there's copays and out-of-pocket costs. And particularly for the folks in our population that remain uninsured or have substantial out-of-pocket costs, they still are inhibited from seeking testing, including COVID testing. And I think it's important to understand that they're so conditioned to having to pay out-of-pocket for tests that they don't understand, necessarily, even when testing is free, and they continue to think that they are going to be stuck with a bill, so they just don't want to come. And obviously, worse than that, if they test COVID positive, they can't work, or shouldn't work, and so that is yet an additional inhibitor.

Language access, something Dr. White talked about a lot, but again, it's an important part of access. And again, we're finding that a lot of even the basic constructs in COVID, whether it's testing in the hospital or interpretation of what happens to you in the hospital with regard to laboratory tests, don't necessarily translate. And obviously, class standards are part of all of our care. But the resources, we're finding, particularly during COVID, are really stripped out.

And then finally, another part of access that I really want to harp on, and something I think we have seen very much during this time of COVID, has been the inequitable distribution of internet access. And that's played itself out around the country in both our major cities and rural areas, when it comes to work and when it comes to education, particularly education of school kids. But it also really plays itself out, obviously, in telemedicine, as well, but in people A, being able to identify and access testing facilities, and as importantly, being able to electronically receive lab results and particularly lab results related to COVID. If you don't have access to get those things electronically, the delays in reporting are really, really substantial.

Obviously, we've talked a lot now about algorithms and reference ranges. And Dr. White, again, talked about that. There is so much discussion now about age-based differences, about ACE2 receptors, all of that. I think we have to continue to be aware of the way algorithms, including future algorithms, are going to play themselves out.

Third A that we need to talk about, obviously, is awareness. And one of the things I am really struck with in terms of lab professionals is that while the pathologist or the person who is in a lab running a test doesn't usually encounter the patient, again, the front end of that, the phlebotomist, the person who's doing the sampling, those other things, which are all part of a laboratory system, are places where people actually touch the patient or see the patient. And there's a huge opportunity there, I think, for education. We are not seeing at all very much in terms of explanation other than I'm going to shove this thing up your nose.

This is what a COVID test is this, is what a COVID test does. This is, when you get the result, how it is that you might interpret it. And so that's just for COVID. But the same thing goes for testing somebody's hemoglobin A1C, for testing somebody for Hep C, for doing all of these things. The opportunities for education by the lab community, I think, are really under-recognized and really untapped. And we have lots and lots of opportunity to do that.

And that could be, in part, and we'll talk about this in a minute, because most people in this community think about the highly educated tier of people who make up the lab community, and don't necessarily remember as clearly that there is a huge workforce that supports them in being able to do that work. And it's that workforce that is at the patient interface so much. Another opportunity, I think, that the lab community has to contribute to addressing inequalities is to remind the clinician who the patient is and what they might do.

So I'm sort of struck, for example, if I order a pap smear on a patient or do some other things and it comes back with a long explanation of all the caveats, but never do I get an explanation that says, gosh, this patient's creatinine is 1.6. And by the way, their residential address puts them in an area that scores high on a social vulnerability index for a moment. And so the implications of that are X, Y, Z. So I think that there's some opportunities for the lab community to think about here, not necessarily intervention, but doing their part to enhance the awareness of the ordering clinician about some other aspects of the patient's situation.

I would not for a moment assume that the ordering clinician knows it or that the electronic health record is going to take care of that. And even if it doesn't, it's a little redundant. Hey, we get redundancy all the time. But again, I think that there's opportunities here that are sort of untapped for the lab community.

Along with that, again, at this sort of point end where the patient interfaces with the laboratory system, there are additional opportunities to identify gaps in care or needs that the patient have. A number of care systems have developed all kinds of checklists and other tools to identify what other resources a patient might need to manage their care or to deal with their social situation. As you know, they range from transportation, housing, food access, all of those things.

It has made me wonder a lot, again, at that point end of care, whether and where there are opportunities for lab professionals also to collect that information and simply to report it back to the provider or to the health system. It's probably as important as running the agency itself. Dr. White also talked about the importance of workforce diversity. And I totally agree and endorse there everything she had to say. But maybe want to take that a step further.

Again, the laboratory community and the institutions you work with and the large laboratories are, themselves, pretty substantial employers of lots of people. So they have the opportunity not only to work on diversity, but to think about career ladders and workforce development, particularly for underrepresented minorities in their communities. And doing so also enables you, I think, to think about those parts of the workforce both as an educator and an ambassador in the community.

Whether you're in a university-based system, to think about particularly, again, those patient interface places where there is a health care worker, maybe it's a phlebotomist, maybe it's somebody else, but a health care worker who works in your institution. They go home, they interface with their community. They are incredibly poised to start to say, let me explain to you what a COVID test is.

Maybe now, you're a health care worker, are you going to get a COVID vaccine? Can I be educated enough as a laboratory worker or a laboratory professional to go back home and explain to my family, my faith community, my neighborhood, whatever, what is a vaccine. What is a COVID vaccine? How was it tested? How will I know it's safe? Am I getting vaccinated?

And so now, particularly, as we are confronting our next challenge of COVID beyond testing, and what am I going to do with the result, it's how on Earth are we going to get our nation vaccinated. Here's a place where I think there are just tremendous opportunities, not only, frankly, in the lab community, but for health care workers of all kinds to serve as educators and ambassadors in their community. In general, being employed in

the health care workforce, regardless of what it is that you do, is a set of trusted professions. And those people are really super trusted in the community. And so I really just wanted, again, to highlight that, as well.

And then finally, none of us do this alone. I think we all know that. There are areas in which the laboratory community has advocated quite well. They have incredible advocacy arm when it comes to reimbursement. They've done some really nice things when it comes to coverage and insurance. But I think that there are lots of aspects of achieving health equity and addressing the social determinants of health that are squarely in your sights and in your vision. And making alliances with some of those other organizations, really important.

Maybe as I close this, for those of you who work in large institutions or those in others, there are just tremendous opportunities to think and push your institutions to be more creative than they are. Some institutions now-- and this isn't necessarily about the laboratory itself, but it's about your role in your institution. Some institutions now have taken some steps forward to, for example, map all their workers as well as to map all of the patients who come from their community. To look at those areas that are especially impacted by social vulnerabilities, the social vulnerability index, particularly when it comes to their workers.

To use their workers, again, as ambassadors, to develop some of those workers as community health workers and ambassadors for their institutions. And again, particularly when it comes to COVID, whether it's about testing, whether it's about getting people the support they need to stay home and isolate once they are positive, or whether it comes to understanding how and where to get care if you're sick or to get vaccinated, there are super important roles that I think all can play here.

So let me end there. I'm going to apologize in advance for my really inelegant slides, but COVID has been all-consuming for me, which has largely meant that I can't make slides. Thank you.

CLIAC CHAIR: Thank you very much, Dr. Lurie. Again, most informative. And you and Dr. White have given us so much to consider. Are there questions from the committee members for Doctors White or Lurie?

Committee Discussion

CLIAC MEMBER: Thank you. Those were just fantastic. Thank you so much for bringing up the New England Journal paper. It was actually mentioned twice. It was excellent. And any clinicians who are really paying attention, I think it hit hard. But any suggestions today what to do?

The problem is that these are associative studies, so race is a proxy for-- we heard, for example, muscle mass. We don't actually know what we're picking up in many of these algorithms. And you did a great synopsis in one or two sentences of such an important concept. You both mentioned it, but Dr. White you actually addressed it directly.

Any advice that could be implemented immediately because it's pervasive? You brought one example of so many, and I'd be very interested to hear your thoughts. Thank you, again, to both of you.

DR. MARISSA WHITE: Thank you for your question. I think this is where we need research because you're right, a lot of these algorithms are developed based on associative experiences and perhaps not data. I would argue that the concept of muscle density, that goes back to slave times. So it's clearly a racially biased and problematic and probably not scientific ground truth.

So I think this is an opportunity for us as laboratory professionals to start actually producing the data. So there are some more studies that have been published moving forward. And I think, for those of us that are larger

institutions, reaching out and saying, hey, let's do our own study. And as there more data that come out, we can even advocate as laboratory professionals for look, here are x, y, z studies that demonstrate this. We should probably shift away from using EGFR with adjustment for race and transition to this other validated model.

CLIAC MEMBER: Do you advocate? Because in some centers, they've done it. They're saying just pull it out immediately. Do you think that will alter the predictive value of the algorithms? Do you advise that we do that and just, starting today, pull it out? Or keep it in until we have more data?

DR. MARISSA WHITE: Yeah, that's part of the problem. A lot of the algorithms are not just tied to estimation of kidney function, but also posting for transplant. So for an African-American patient, they might be delayed for posting for transplants. So I think the whole system would need to be rethought. I think that needs to be intentional and cross-disciplinary and make sure that everyone is on the same page that OK, we as a lab do not support this, but we need to make sure that everything else is in place so that patients aren't falling through the cracks or we're ensuring that the patients are being followed and managed appropriately. But yes, several large institutions have gotten rid of the EGFR. And personally, I want to make sure that I'm posted for a transplant in a timely fashion.

DR. NICHOLE LURIE: So I might come back to one of the suggestions that I made and then make a couple of additional comments. I understand, as well, the American Society of Nephrology and others are convening, really, a task force to grapple with this and grapple with a lot of what this means, also in the context of our national dialogue about race.

And so I think it would be-- I don't know the degree to which the lab community is as formally represented on this. It's hard for me to believe that they're not. But that would be sort of an immediate place. And the whole community is going to try to come up with a set of recommendations about how to handle this to really engage in impact. And in the meantime, as we talked about, I think there's a lot you can do in interpretive mode. Even if you report adjusted EGFR for now, it can certainly come with a caveat that this adjustment is open to a lot of question and debate. And to look at this just through different sets of eyes, it can come with information about social vulnerabilities. It could come even with sort of a warning about this interpretation alone should not be used to list somebody for transplant or whatever it is. But I think you could all develop a series of pretty immediate action steps that could tide one over until the whole community sort of figures out where to go there. I think not taking action really sort of compromises so many people. Over.

CLIAC CHAIR: A quick break to acknowledge Steve Hinrichs has joined. Second, [CLIAC MEMBER] has a comment in the chat, a reminder to all please do not put these comments in chat. Just chat exists for you to tell me you want to talk. The comment is interesting idea about test reporting including zip code evaluation of risk. That would be a simple AI project. [CLIAC MEMBER] also has a comment about laboratories looking outside traditional roles, validated surveys as a diagnostic tool, linking to reporting social risks, question mark.

My question is for doctors White and Lurie. Do you have suggestions for the CDC, CMS, and/or FDA as to how the clinical laboratories and laboratory medicine should work to improve health equities?

DR. NICOLE LURIE: Want to go ahead first, Dr. White?

DR. MARISSA WHITE: Sure. So this is just thinking off the top of my head. I personally would like to see national guidelines. I think that every laboratory should be charged with making sure that they're being mindful of the communities that they serve because that's what happens in other specialties. When we're thinking about our primary care colleagues, our family medicine colleagues, everyone is focusing on health disparities in their own unique way. And so I think for us as laboratory professionals, we have the responsibility to be involved with that, as well.

So I would personally advocate for some sort of-- as we all are forced to do quality improvement projects, I think that that would be an important thing to consider. Perhaps laboratories over a certain size or serving a specific community demographic should be encouraged, at least one point or a couple of times, to do some sort of improvement process to make sure that they're properly treating the patients that they serve in an equitable way.

DR. NICOLE LURIE: So I guess I would say for CDC, whether it's either promoting the use of the Social Vulnerability Index or the COVID Vulnerability Index, if we're talking about COVID specific stuff, in laboratory testing, reporting, and patient education would be, I think, really, really critical. I think, from the FDA perspective, they could move to advise or even require something like that with regard to test reporting and reporting of results just as another way to continue to alert clinicians.

And then whether it's FDA or CMS or CDC or just whole of government acting together, nailing down the critical questions on a short validated survey, as [CLIAC MEMBER] pointed out, that just gets asked all patients about what the other vulnerabilities, needs, whatever else, are so that we cannot lose sight of the patient's needs anywhere in the system would be great. I don't know, quite honestly, what the reimbursement issues are with regard to that, whether you get a bump in reimbursement for doing that or not and whether it matters, but I would not be averse to looking to some pilots to that, given that we understand that it's financial incentives that make our health care system work, whether we like it or not.

CLIAC CHAIR: Thank you both.

CLIAC MEMBER: Yes, thank you. Presentations were excellent. And I think picking up on your comments, I'd love to know your thoughts on this one. When we have the pandemic, we immediately focus on the acute clinical care setting and obviously develop diagnostic tests for that specific purpose. But when we think about these ethnic and racially marginalized groups, certainly those in extended care, long-term nursing homes, to develop pathways within the FDA to allow development of these inexpensive, point of care testing that we can rapidly deploy to survey these communities, find out where the prevalence is and how do we stop the disease transmission. If we can make those, picking up on your coverage and access point, if we are able to make that type of testing available earlier and have multiple channels of development, perhaps we could stop the spread in these communities that are clearly so vulnerable. So is that something that you have considered or would consider for development?

DR. NICOLE LURIE: I'm personally not in a position to consider those things for development, but one thing I would want to say about that is most of these tests, and especially these rapid point of care tests and ultimately, the point-of-patient tests, are sort of being developed a little bit in a vacuum and a little bit in a lab and not necessarily with real-world testing. Low literacy instruction, simple to follow things so that when we get to a point-of-patient test or things that are able to be widely used in the community, that we understand that there's been some acceptability testing for the user, whether it's in a nursing home, whether it's in a community, or whether it's in the home. And there's that part of the EUA, the Emergency Use Authorization, and/or the licensure ought to have to consider whether different kinds of communities could use it. Over.

CLIAC MEMBER: Excellent point. Yeah, I agree.

CLIAC CHAIR: Yeah. I would comment that some of the waived tests, which got conflated with point of care during the COVID pandemic, definitely has a human factor study baked in so that we can understand how the non-lab person out there, the facility with which we can use these devices. OK. Moving down. [CLIAC MEMBER].

CLIAC MEMBER: Morning and thank you both. A topic that maybe was alluded to but wasn't fully that it was the microbiome for gender reassignment surgery. I think that's something that could be easily coordinated by CDC groups or outreach to people. I mean, we've been trying to look at this and assess the vaginal microbiome across those sectors, but our numbers are too small. And so to really understand that, I think you would need a national effort to combine numbers from those communities. So that was just a comment that maybe could be something pretty easily done. We have the cultures, but we really don't always know what to do with them and how they might be different.

And the second thing I wanted to just comment upon is that there is a group that our organization belongs to called Project Santa Fe or Clinical Laboratory 2.0, and they are actively engaged in risk stratification for a variety of things, alerting simple pregnancy test and alerting that there's no prenatal follow-up in underserved communities. And there's a variety of projects, opiate use, anemia, and even sepsis and relate it to poor dental care in underserved communities.

So every one of the projects that they're doing has some type of social determinants of health baked in. And to your point, [CLIAC MEMBER], you sometimes, even though it should be done for the right reasons-- for instance, with the pregnancy project, they're finding that the health insurers really want to know this information and it's financially beneficial to them to do so. And so it's sort of a strategy that you don't want to muddy the purity of the intent.

But sometimes, linking that to HEDIS measures or appropriate financial incentives, the end result is better care. And I think that that also has to be considered. And there are several projects on that website that I think would fit well with some of the things that you're talking about today and inclusion of multidisciplinary sites in rural communities and metropolitan communities, which is encompassed by this group. So I definitely will take this back to the group, but I wanted to make you aware that there are some laboratories across the US that are combined to look at these types of things.

CLIAC CHAIR: Fabulous. Thank you.

CLIAC MEMBER: OK, off mute. So just again, I wanted to thank you both for coming and presenting today. And forgive me if this is already done and I'm just not simply aware of it, but I have two back-to-back questions that are related. One is has there been a systematic review of the pathology and laboratory medicine landscape to find opportunities to improve health care disparities? And the follow-up question is, would you think that undergoing such a systematic review is a useful strategy or do you think the community should tackle opportunities as they get identified, such as EGFR, et cetera?

DR. MARISSA WHITE: So I'm not aware of a systematic review of disparities in pathology. I know that there have been some papers published by, I'm blanking on his name now, but he's focused on the LGBTQIA community for reporting in LAS, but not on issue-specific-- I think he's got a little bit of that reference ranges, but hasn't done a systematic review, to my understanding.

--Or a diverse inclusion equity initiative. Having a needs assessment should serve as a ground truth. So I would advocate for that and I think that's a really great idea. In terms of workforce, I published a systematic review of the workforce diversity for trainee and pathologists, but we need more data on what the rest of our pathology workforce looks like. But I would advocate for a review on if there have been studies looking at how laboratory professionals have focused on health disparities in the past. That's a great idea.

DR. NICOLE LURIE: I also think it's a really good idea, but I would make two additional comments. One is it's going to be of most use if you think about the system broadly rather than narrowly, particularly in terms of the parts of the workforce that you talk about and provide the different kinds of opportunities across the whole

spectrum of workforce in particular, as well as different kinds of laboratory tests and settings to be able to do it. And second, I wouldn't wait for it to be done to take action on things that you know need to be taken, but maybe view the taking action, as somebody else suggested already, I think [CLIAC MEMBER], in quality improvement mode so that you actually start to develop the system and the muscle memory from making all the changes that you're going to need to make.

CLIAC MEMBER: Good point. So basically, do them both, concurrently. Fair enough.

CLIAC MEMBER: Yeah, hi. Good morning or good afternoon. Thank you so much to both doctors, White and Lurie for excellent presentation. And I'm sitting here reflecting on the fact that we deliver primarily health care, which addresses maybe 10% of the social determinants. And yet what we're talking about here today is how to address 50% of the social determinants and it's time that we get more engaged as a laboratory community in doing that.

And as we have our discussion, and Dr. Lurie, you sort of agreed to it or commented on it, and implied by Dr. White, as well is that there are validated surveys to identify social determinants, for example, and social vulnerability. And I wonder whether we need, as a laboratory community, to start thinking that we're really providing a diagnostic service and not just a laboratory test. And we've talked about integrating laboratory diagnostics with other social data that we already have.

But maybe we ought to think, and I've been thinking about this a lot, about really having social determinants or social vulnerability assessments, validated surveys, actually be an orderable test just like everything else. And most of our laboratories have patient interfaces where surveys could be done. And that information would then go back and reported on a laboratory report with, perhaps, information about how to close those gaps.

Anyhow, I lay that out because I think one of the challenges that I'm feeling, particularly from the presentations we heard this morning, is I think we need to get out of our box and figure out how we can play a bigger role. And I'm just sort of asking, both from the group and the presenters, whether that's something that we should really think more wholly about.

CLIAC CHAIR: Go ahead, Doctor Lurie.

DR. NICOLE LURIE: I think it's a really, really interesting idea. And I think what you're highlighting is we're all in this together and each of us play a part. And even in COVID, we're sort of talking about these layered interventions. It's not any one of them works alone. If we're going to deal with the social vulnerabilities and disparities, there have to be layered interventions and layered approaches just to be sure that no one and nothing falls through the cracks.

The one thing I would say, if you're going to take that on, and I think that's really great, is if you're going to do a diagnostic test, you need to do something with the results. And so I think it's going to be-- and it's a great opportunity for this community to push the rest of the health care community or the rest of our society or whatever to do something with the result, but I just don't want you to think that after you do the diagnostic test, you're done.

CLIAC MEMBER: So first, thank you very much, Dr. White and Dr. Lurie. I learned a lot and they're both excellent presentations. I really think that as pathologists or laboratorians, we have spent a lot of time making sure that our clinicians understand the diagnoses that we render. And as [CLIAC MEMBER] just said, we need to go outside of our box and make sure that our patients who are now our end users understand our diagnoses.

So coupling informatics and test results with information about social determinants of health, like the EGFR example, examples of how these tests should be evaluated based on certain parameters, we already do that. My field is also breast cancer. And so when we render a diagnosis and we know that there is perhaps a confounding variable that may affect the result, we put that in the report or we put a link to that result.

So I think that there's an opportunity to link test resulting, informatics, and information about social determinants of health. And I think we as laboratorians have done this for our community and the hospital in ambulatory care, and it's probably our responsibility to consider doing it for our patients, as well.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Thank you, and thanks for the presentation. I have just a few comments. And I thank Dr. Lurie's comments, as well, as a previous presenter about things we could do. I think opportunities in the lab are that lab personnel pathologists and doctoral scientists have a couple of unique attributes. One is they have an intrinsic understanding of systems. And what we're talking about a systematic change in health care.

And two, they have a built-in relationship with multitudes of doctors, caregivers, systems, and institutions. And most other specialties don't have that. One thing, since I've been involved in public health for the last several years more intensely, believe we need to partner with public health. And I think that that can be at the data level. A lot of things that are talked about now, public health, at least in Nebraska, and I'm sure most state public health departments, have an enormous trove of data by zip code of education and regional diseases and prevalence and poverty and so on.

And that stuff is there. I just don't know that it's being used effectively. So I think that's a way that we could partner with them. And also, I think it's important to get caregivers involved in public health. When I was CMO at Nebraska, we had great meetings. Community caregivers and health disparities. And there would be 150 nurses and public health people and me and one other doctor, even with CME. So given current practice models, I think it's hard to address the upstream issues. And these are upstream issues. And I think there needs to be probably a change in practice models to do it. So getting people that are involved in traditional medicine involved has been one of the things I've tried to pursue.

And lastly, I'd like to recommend that you all look up the Archives of Pathology in August of this year. There are two articles on point of care. I mentioned this yesterday. The second article title is Point of Care Testing and Equity. And they both produce strong arguments and in the positioning of point of care, which obviously incorporates us, and how that can advance bringing testing to communities that need it. Thank you.

CLIAC CHAIR: Thank you. I want to just interject quickly. A lot of this makes me reflect on yesterday's session around reporting interfaces interoperability. And to touch on [CLIAC MEMBER], trying to gather at the SODH data up front, can we leverage off the COVID pandemic and the rush to build the order entry AOEs? Can we leverage off that to pull that forward to the reporting on the back end to then interweave with the public health information systems to arrive at the final SoVI score? I'm not sure how you pronounce the Social Vulnerability Index score. So I just want to throw that out there for us to think about when we talk about recommendations.

CLIAC MEMBER: So thank you both, Doctors. This is such an important topic right now. And as I listen to Dr. Lurie, specifically, as she related to the interaction and touch with people in these labs, I would say right now, the urgent need of information to people, we're missing an opportunity right there every single day because these rooms, even though we're distancing apart, there are so many people there that need information. So I would ask, and target this comment towards CMS and the CDC, so as the FDA approves newer and more

consumer-simplified home testing for COVID, these labs and these waiting rooms would be an excellent place to start educating each and every person there.

And just by setting a brochure in the room because everyone is waiting, a poster on the wall, just like the CDC has done so well with many campaigns for sepsis and antibiotic resistance. This is a wonderful opportunity to educate every person. And even where the person at the registration could point them to, if we could give specific instructions to, you might want to take a look at this brochure sitting on a table regarding these COVID tests that are available, and they're available to the public, when they are available. I think this is a wonderful place to interact and improve the education for everyone, but especially for the underserved.

DR. NICOLE LURIE: Just a comment on the last comment for just a minute because I think you're going to find, coming out of COVID, some really great precedent. So right now, for example, CMS, as well as DOD, have been building models to look at how to prioritize people for vaccines based on CMS claims and their diagnoses, but also based on the Social Vulnerability Index. And so it's the first time I really know that the Social Vulnerability Index is being incorporated into a mainstream system that is going to drive action. And that's really because of the National Academy of Medicine report about doing that. So I think you're all poised to follow on the heels of that really well with some great innovation. Having spent many years managing public health emergencies for the US government, I would always say never let a good crisis go to waste. This is your opportunity.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: I have one final question for Doctors White and Lurie. Dr. White, you raised the issue of some of the basic infrastructure barriers. Lack of a mobile phone, lack of internet access, distrust of the medical community, not willing to set up internet connectivity for fear of sharing personal information. Do either of you know or have recommendations for how to bridge or knock down those barriers?

DR. NICOLE LURIE: So a couple of thoughts. And this is, again, where partnerships come into play. So for example, I served on the DC re-opening council. And one of the things that they grappled with is how you reopen with equity. And so they actually went, for example, to the broadband providers and the cell phone companies and got them to provide lower cost Wi-Fi to people. The FCC has a lot of money right now to expand broadband, particularly in rural areas.

And I think looking at both current and potentially future infrastructure investments and putting your muscle in your advocacy, that other A, behind that and helping people really understand why it is so critical to health. And it goes well beyond just telemedicine or well beyond remote monitoring at home. But for all the issues we've talked about and all the issues you deal with, I think the more of the medical community, health care community, they hear about why it's important to do this, the better off we're all going to be.

CLIAC CHAIR: Thank you. And I certainly love both of your suggestions to use our own lab staff, the front facing, as the ambassadors. Dr. White, did I cut you off? I'm sorry.

DR. MARISSA WHITE: No, I was just going to say I mean, we can't even get it right for our children at this point. So I honestly don't have a great answer because our children are still doing school virtually at the age of five.

DR. NICOLE LURIE: If they have virtual access. And if they don't--

DR. MARISSA WHITE: If they have virtual access.

DR. NICOLE LURIE: Right. If they don't, they're toast, right?

DR. MARISSA WHITE: So we can't get right for our babies, so I don't--

DR. NICOLE LURIE: That's right. But that's going to-- so, again, you're at Hopkins. Is Hopkins really leaning on the city of Baltimore and the state of Maryland to expand broadband access for communities that need it in Baltimore? I sure hope so. Yeah.

DR. MARISSA WHITE: Yeah, but that's a good question. I've seen a lot of press releases and communications. That's something I haven't seen. So that's a really good-- you're right.

DR. NICOLE LURIE: But when we talk about advocacy, each of you is in an institution that is poised to do this around the country. Sorry to be so activist about this.

DR. MARISSA WHITE: No, you're right. You're right.

DR. NICOLE LURIE: But that's what you've asked me to do.

CLIAC CHAIR: Yes. Thank you. I see no one else queued up for questions, so with that, I will thank Doctors White and Lurie again. Thank you very much.

FDA EX OFFICIO: This is Tim. This is Tim with the FDA. I had suggested I wanted to comment.

CLIAC CHAIR: OK. Go ahead, Tim. I'm sorry. I didn't see that.

FDA EX OFFICIO: OK, yeah. So there were questions about antigen tests. We have authorized six point of care antigen tests. And I would like to know, and both talks were great, I would like to know what additional needs there are. We certainly are working with a lot of other developers for more rapid point of care tests.

We also have a home testing template out. It's been out there for months. Jeff Shuren and I published an opinion piece in The Hill trying to get more developers for home tests to come into the FDA. Up until recently, we haven't even had a single submission for a home test, but now we have that. And so we hope to see an authorized home test in the very near future.

As far as studies go for point of care, we do support CLIA waived settings. We do require user studies, but it's limited. Obviously, the bar each EUAs is much lower than for regular FDA authorizations. And then for a home testing, we do require a diverse population representative of the target population and do recommend testing on both those who speak English and those who speak Spanish, for example.

So I think the FDA is doing a lot already. Also at the time of authorization, especially during an emergency situation, we don't want to layer on too many requirements or recommendations. When a test appears to be accurate, we want to authorize that as soon as possible. We can require things to happen postmarked after the authorization. So we can make additional recommendations or requirements as appropriate.

So I would like to hear from folks what additional things the FDA should consider. Because we're doing a lot already, but I just want to make sure I understand. Thanks.

CLIAC CHAIR: And this certainly would be a topic for the committee. Don't know if Doctors White and Lurie, if you have any comments on this. I see closed mouths. And then that spurred [CLIAC MEMBER] to ask a question.

CLIAC MEMBER: Hi. I just wonder if there is not the possibility somehow of CDC, even FDA, partnering with the FQHCs across the country, the federally qualified health centers or community health centers. Seems that that might be a way to automatically get your diversity numbers up. My gosh, FQHCs fight for Medicaid patients because so many folks are either underinsured or uninsured. So that might be a good place. And then even piloting things like broadband. Having your rural health center or FQHC being the hotspot for the community might be a way to also pilot some ideas regarding broadband access for rural communities and communities with lower socioeconomic status.

CLIAC CHAIR: I'm going to take that as a comment. So [CLIAC MEMBER], and then I would like to wrap up and have the committee discuss.

CLIAC MEMBER: A quick question to [FDA EX OFFICIO]. What does a product insert information look like for the potential home tests that are coming through the pike? And is there an opportunity, perhaps, if there's a QR code, to make sure that the person who's taking the home test, once they log on to the website, assuming that they have access, is there an opportunity to link that with, perhaps, some targeted specific instructions or recommendations for marginalized communities?

FDA EX OFFICIO: I think there is the opportunity to work with developers for that. It's a long discussion about some of the feedback the FDA has had about our expectations for what's required or recommended for authorization. And obviously, some of us thought that we expect too much and some have thought that we expect too little. And we're trying to find the right balance. So all those additional recommendations or requirements that we make on developers will slow the process down.

There's a demand to get things authorized as soon as possible. So that's the balance that we're looking for. We're certainly open to working with any of the communities and stakeholders to make this better for all. And I think the developers are, too. So finding the right mechanism to do this is important. And the FDA is all ears for how we can help.

CLIAC CHAIR: Thank you all, especially Doctors White and Lurie. It sounds like the tenor of our questions are now morphing into the committee discussion. So we will now open the floor for further discussion.

CLIAC MEMBER: Hi. Thank you both for those very informative talks. One comment I had was on translational or interpreter services and whether that's something that could have some sort of either private or maybe just some government funding attached to it. The COVID trials, the research trials, have gotten a lot of scrutiny based on the health disparities and the demographics not really matching what the general population look like. And one big obstacle that we faced, even here within our own center, was having quick access to, essentially, global services. And this doesn't really just span to English and Spanish, but it really spans across a lot of different languages. And I think that when we think about lab test results, it's like trying to explain what a medication does. It's very difficult. It can be very complex. And it can easily get lost in translation. And so I wonder if there are any efforts to create sort of a sponsored group of translational services that are available at a moment's notice to help patients understand what their laboratory results mean.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I'll just speak from my personal perspective. And for [CLIAC MEMBER], we are FQHC. That's all we are. And we have a very vigorous video interpretive service that can acknowledge the 35 languages that are spoken at our organization. We have encountered technical difficulties in our COVID drive-throughs, the connectivity, getting the Wi-Fi to work, finding the right

interpreter. But for me, that certainly is a requirement of our health system, that laboratories don't take that on our own.

For result release, we have a telephone bank that can tap into the interpreter service to speak directly with the folks we've tested. And aside from oversharing, because I hog the podium, I would also like to hear from [CLIAC MEMBERS].

CLIAC MEMBER: So my comment and discussion is around specifically what [FDA EX OFFICIO] just talked about, and that is the rapid diagnostics, at-home, over the counter testing, if we could have a discussion on that within our organization here today. So the need to identify people quickly, and so that carriers of COVID can be identified with daily fast tests, has never been more important. And the ability to create this kind of a solution that we can purchase over-the-counter.

Let's say when we used to buy a pack of gum and there are sticks, paper tests, that are in there that are the tool that will get us all back to work, get us back to school, get people back to visiting their loved ones in nursing homes. And so to really focus on this diverse group of people who don't have access to physicians and to doctors. So this would be without symptoms because we know now that 40% of the people that are contracting COVID, it's coming from people without symptoms.

So as we address the diverse group here, the focus on this issue and the importance of at-home, over-the-counter testing that is approved by the government, that is educated by the government, and that there's a standardized test that everyone can use. So there's the ability to have a quick test. You're taking it daily. And I think this is something we really need to focus on to offset and offload much of the work that the labs are doing today. And then as we, again, talk about the way that we can access the public, I can now really envision some of these labs and local doctor's offices as ways to educate the public about what's available for them today.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: First of all, appreciate everything and all the information that our speakers gave this morning. This is a great topic. And I wonder if there is now a way we could move towards a recommendation in this area. And one of the questions I would have, maybe, first goes back to [CLIAC MEMBER] because I did not read that article you mentioned.

Are there other areas already known in our laboratory reporting where inherent bias is clear or could be uncovered? And could we work towards a recommendation, perhaps, asking CDC to conduct such a survey, a review, of laboratory reports and/or processes that reflect inherent bias so that we can make that public to everyone?

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [FDA EX OFFICIO] would like to respond about home testing, but while he's doing that, if we can multitask,[CLIAC MEMBER] drafted a possible recommendation. If we could pull that up and show it so while [FDA EX OFFICIO] is talking, we can also consider that in light of [CLIAC MEMBER] recommendations.

FDA EX OFFICIO: Yeah. Just some information about home testing. So we do have recommendations for testing diverse populations, but not necessarily all the languages that may be helpful currently. There are also test issues in the population. There is a couple of issues.

One is actually supply. I mean, to test everyone in the country on one day for once, it requires 330 odd million tests. And I don't know that all the rapid developers together have produced even quite that. I think there are

well over 100 million or on the way to that and probably will be on the way to 300 million, but 330 million every day or every week or every month is a lot of tests to produce, all of high quality.

And the thing is if you consider that even high quality tests are not 100% specific, the PPV, in low-incident populations, is very low. For example, I did the math before, so I can go back to that, even though the numbers may not be exactly right. So if you just establish that a home test would be 98% specific, so the patient doesn't have COVID 98% of the time, it's going to be negative. 2% of the time, it's going to be positive.

And if the prevalence of active disease that's detectable by that antigen test is 0.2%, and this changes based on prevalence, but I'm just giving this example because, for example, in our nursing home population, the prevalence, fortunately, right now is pretty low because of all the things that we're doing. Anyways, whether it's 0.2 or 0.5, it's something in that range depending on where you are, except in hotspot isolated facilities.

But anyways, if you were to test everybody in the country, that specificity is the same. So if it's 98%, 2% of the population of 330 million is a 6.6 million false positives. So every time you cycle through and you test everybody in the country one time for the test that's 98% specific, if you do it all in one day, there will be 6.6 million false positive results. And that's to be expected.

So how do we deal that overall, and especially in a population that has a difficulty in getting access or understanding all of this? So that's just a couple of important considerations here.

CLIAC MEMBER: [FDA EX OFFICIO], could you do the same calculation or analysis with sensitivity? Because we're more concerned about the sensitivity with the rapid assays than we are specificity.

FDA EX OFFICIO: That's actually not true. We're equally concerned with both sensitivity and specificity. In Nevada--

CLIAC MEMBER: I guess I meant about the performance. So we've done quite a bit of work with the performance. And the performance is less than what we would desire on the sensitivity, but we can live certainly with the specificity.

FDA EX OFFICIO: So can we live with 6.6 million false positive results a day in the US if we tested everybody? I think that adds an additional burden. CDC now recommends that you, within 48 hours, do a molecular test. Imagine adding, every 48 hours, an additional 6.6 million molecular tests. On average, we test about a million a day now in the country by all the testing formats. So there is real considerations here.

As far as sensitivity goes, we, early on, set the bar for rapid tests at 80%. In the Hill piece, Jeff and I said you could go lower than that if you have certain mitigations. One of those mitigations might be serial testing. If you test more than once, can you get the overall performance up to 80%, say? The challenge, though, is while the sensitivity is additive, you also have an increased risk of more false positives.

If you require combined two tests, you've got to take all the positives, then, and it could impact specificity significantly, too. So this isn't anything wrong with these rapid tests. This isn't anything wrong with testing, in particular. This is just math. This is reality of tests. Because molecular tests, if we had the volume for them in a home situation, it would be the same thing. It may be slightly different specificity, but you'd still have significant false positives. Hopefully that's helpful as for information. I don't know of a solution, but that's the information.

CLIAC CHAIR: I'd like to pull us back out of talking about the test. I want to come back to social determinants of health and our overarching discussion. [CLIAC MEMBER] has a comment.

CLIAC MEMBER: Yeah. I just wanted to pick up on [FDA EX OFFICIO] comments. And I think they're very appropriate. And I certainly think the home testing, like a home pregnancy test, is not something that's going to happen quickly. But as part of the pandemic playbook, developing alternative assays that can be utilized by our public health department to do surveillance on a far more rapid turnaround time, they're inexpensive. But they can utilize it within the context of surveillance and identifying positives. And certainly, they can have a lower sensitivity because we're looking for infectious individuals, not necessarily folks who've been exposed. Thank you.

FDA EX OFFICIO: Yeah, I would agree. And just so it's clear, the FDA, for this pandemic, is not exerting any authority over surveillance testing. Anybody wants to do pure surveillance testing and follow the FDIQs lined up by CMS, CDC, and the FDA on surveillance testing, they can use whatever tests they want. However, there might be limitations. They might want to make sure that it has certain performance characteristics before they use it for surveillance.

CLIAC CHAIR: [CLIAC MEMBER], then [CLIAC MEMBER], then we're going to look at this recommendation.

CLIAC MEMBER: Yeah. Just commenting, obviously, [FDA EX OFFICIO], the math is obviously correct, and those numbers are certainly staggering. I think that one of the challenges we're having in the nation is being able-- I think the appropriate comparator is what does it mean if we don't test? The alternative of not testing, is the 6.6 million false positives, is it worse than not testing? I don't have the answer there. I'm not sure anyone has the answer there. But yeah, just as a comment.

FDA EX OFFICIO: Well, I'll tell you some of the feedback we get from the public. So we have, obviously, various ways for people to complain about testing. And we get very strong letters saying, I had a false positive result and I was made to stay at home from work for two weeks. And I couldn't afford to stay home for two weeks. So and ideally, if you have a positive home test or with any tests that might have low positive predictive value, you can get a second test quick. But that's the key, I think. So just some more flavor on this.

CLIAC MEMBER: Thank you. I just wanted to comment that, I think, as we look at social inequities and health inequities, it's a little bit broader than just looking to see who's got the virus. I would encourage us to keep our eye on the ball as far as the comorbidities and the access for identifying what things might make some populations more vulnerable or might need to accelerate their access to care. And I think those have to be equally considered, as well, as the incidence of the virus itself.

And I think [CLIAC MEMBER] made an important point a little while ago about, do we really understand what that poor testing profile looks like that we need to understand and make sure that there's universal access to obtain that testing so that we rapidly identify those who need, perhaps, a different level of care or a different level of surveillance for their comorbidities. Thank you.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: We have a draft proposal from [CLIAC MEMBER] who is very passionate about this topic and [CLIAC MEMBER] would like to address it.

CLIAC MEMBER: Thank you. I think this is a great start. I just want to throw up one more bullet item related to our presentations this morning, related to the analysis of current test reporting to detect inherent bias or inherent problems that are connected with perceptions about race.

CLIAC CHAIR: For those of you who would like a larger font, at the top of your Zoom screen, the right black button that says View Options, it allows you to personally zoom to whatever ratio you would want to view this to be easy on your eyes.

CLIAC EXECUTIVE SECRETARY: Could I ask [CLIAC MEMBER] to repeat his phrase? Because I only got part of it.

CLIAC MEMBER: Yes. Analysis of current reporting-- excuse me. Analysis of embedded inherent bias, embedded inherent bias, involving current test reporting. And maybe someone else can help me here. The current test development or process and reporting. Current test process and reporting. Process and reporting. And if someone then also wants to add related to race, that'd be fine, too. Or not, depending. I think inherent bias gets really-- it's cross-cutting, but maybe we need to be more specific. I don't know.

CLIAC MEMBER: I think it also needs to include access to testing because this is where the problem lies right now.

CLIAC MEMBER: I thought the other bullets addressed access. This particular one, this bullet, is addressing the issue that was brought up in the New England Journal article, meaning that we may have, for a period of time, a long time, accepted current perceptions and actually incorporate that in the test itself. And we've got to get rid of that. But the point of it, we need to find out how many of those are out there. And maybe, as [CLIAC MEMBER] mentioned, maybe they're already fully identified. But I'd like to make sure that's the case.

CLIAC CHAIR: [CLIAC DFO] has put into the chat box a link to the CDC COVID-19 Response Health Equity Strategy. I've not looked at it. Accelerating Progress Towards Reducing COVID-19 Disparities in Achieving Health Equity. It could be, [CLIAC MEMBER], some of the comments you're making about access, race, ethnicity, et cetera, might be umbrella'd in that document. And we might, perhaps, reference that in the opening statement.

CLIAC MEMBER: OK. I'll take a look.

CLIAC MEMBER: So yeah, two comments. One is as we're looking at the recommendation, thinking to who should participate in it, I just want to make sure that obviously we include laboratorians, a good representation of laboratorians, but patients and patient advocacy groups, as well, I think would be critical stakeholders that participate in this.

And the other thing is more of a question for [CLIAC DFO], because I know he did share that link. I did open it up. There seems to be quite a bit of overlap between the charge and vision of that existing strategy. Yes, it's focused on COVID-19. It seems like this recommendation is a little bit more broad. But the question to [CLIAC DFO] is were you showing this to kind of tell us this is under way, or do you think there are avenues for both groups?

CLIAC DFO: Yeah. I think it would be helpful for CLIAC to recognize that CDC has this overarching strategy. But expect CDC to do something specifically within that strategy around clinical laboratory medicine, its role. My own concern with that big CDC strategy, much like I talked about yesterday, is that the big public health doesn't always think laboratory first. And I think the key thing here from a CLIAC perspective is what should CDC be doing in the laboratory medicine field to augment and contribute to that much bigger strategy. Is that helpful?

CLIAC MEMBER: Yeah. So in essence, you're supporting this recommendation in the sense that it's laboratory-focused and specific to laboratories.

CLIAC DFO: Yes.

CLIAC MEMBER: As opposed to-- I guess I suffer from the opposite issue. I heard COVID-19 and think only lab. But you're right. It's obviously much larger. So yeah, thank you.

CLIAC CHAIR: [CLIAC MEMBER] has sent in a recommendation that we can look at. I want to remind the committee members my email is locked down now from external emails. So if you could either email [CLIAC EXECUTIVE SECRETARY] or Heather or put in the chat box so we can copy it into this. But I cannot see your external emails. And [CLIAC MEMBER], I would ask you to think about, is [CLIAC MEMBER] recommendation congruent with yours, or is it different? And should we have separate recommendations?

CLIAC MEMBER: I think it's congruent. It may be more-- I'm reading it now, but it may add some color or specificity. And I think it's along the same lines. Clearly, I wrote my recommendation before we heard the presentations. So the fact that there's more detail now after having had the discussion is a good thing.

CLIAC CHAIR: [CLIAC MEMBER], perhaps you might want to add some commentary? You're on mute. You're on mute.

CLIAC MEMBER: So this is a straw man that I wrote while listening to the presentations. I welcome the committee's expertise in wordsmithing it. I just think that we should also consider a recommendation that is outward facing, with the end user in mind. And especially with the comments that [FDA EX OFFICIO] just made regarding sensitivity and specificity, which are extremely important and need to be communicated to the end user in a way that they can understand it.

CLIAC CHAIR: [CLIAC MEMBER], since there is overlap, is there a place to wordsmith your recommendation to include Lavinia's explicit points?

CLIAC MEMBER: I think so. I lost my-- it's gotten smaller. Now I need to-- you told me how to make it bigger. Oh, View Options.

CLIAC CHAIR: Yeah. Well, thank you.

CLIAC MEMBER: OK.

CLIAC EXECUTIVE SECRETARY: I can only show one at a time if I increase the font, so let me know which one you want to look at.

CLIAC MEMBER: Well, I think that first statement is really a more in-depth description of part of what was in the preamble to my specific bullets. And then the second piece are really, I think, some of the bullets. So I think it kind of follows the same construct. But I would let Lavinia comment because it's her recommendation, if she agrees.

CLIAC MEMBER: Again, as you, [CLIAC MEMBER], wrote this before listening to the presentations, I took notes while listening to the presentations expressed by Dr. White, which was very comprehensive and Dr. Lurie's, which complemented it. I would need your help in placing it in the appropriate-- I think expansion of traditional laboratory activities is an area where we could really develop based on what we heard. So we could say, i.e., and then add to that and just cut and paste.

CLIAC MEMBER: OK, sorry. Yeah, both good comments. I have somewhat of a preference for a less specific and more general goal for this approach, which I think likely would and could include the more specific attributes that Lavinia suggested. I think specificity has issues. You can leave things out. For example, and I'm not seeing her recommendation on my page at this time, but specifically specifying races to be involved. My kids are South Korean and they're not included, for example. And there are many other ethnic groups. So I think less specific maybe is a little better. Thanks.

CLIAC MEMBER: Yeah. My comment was along those lines. I think the second recommendation could very much end up being an outcome of the first recommendation, being the work group. I think my own personal tendency is to let the expertise of the work group figure out what specific steps that maybe we should take after doing kind of a survey of the landscape. So yeah, I basically share the same perspective.

CLIAC CHAIR: I just want to comment. Structurally, [CLIAC MEMBER] recommendation is to establish a work group, and [CLIAC MEMBER] was a recommendation to the three agencies. Is there agreement amongst the panel members that it should be a work group? Can we discuss it?

CLIAC MEMBER: So again, that kind of was pairing with my original question. It was is there the presence of a systematic review of the landscape? I think that's always a good place to start. And I personally think a work group is the right place to start that.

CLIAC CHAIR: I want to just counter with that our interoperability discussion yesterday. We started with a work group, but then we asked the CDC to study or to provide to us an update on the landscape. So curious to hear what others think. [CLIAC MEMBER] says a work group would be best to start.

CLIAC MEMBER: I think that a work group would be best because I think this is more the frontline than an agency response because I think the frontline knows better what's happening.

CLIAC MEMBER: In looking at the link that [CLIAC DFO] sent out, it sounds like the part of the strategy that the CDC's put together includes some of the development of the baseline. Is it possible to recommend adding a laboratory-centric work group to the existing group? Or does it need to be completely separate? Because it seems like there is significant overlap with the broader scope, it's just that what we're recommending is specifically in laboratory medicine.

CLIAC MEMBER: Yeah. So that's possible. I think the alternative to what [CLIAC MEMBER] just said would be for the-- first of all, I thought it should be a work group because I figured with our two presentations this morning, we would be more fired up but we wouldn't have all the answers. And I think that's probably and that's why I sort of bulleted what I thought probably would come out of it. And so I think that the role of the work group would really be to put more meat on the bones. And then I think that the work group should probably start with the framework that [CLIAC DFO] shared, that CDC is taking as a whole. And then hopefully, based on the recommendations and the guidance and the specifics, would then get plugged in and make laboratory or diagnostic medicine a prominent component within the bigger picture.

CLIAC MEMBER: Yeah, I think a work group is appropriate here also because I think we need more diverse representation geographically, ethnically, socioeconomically than just what this committee can represent in this discussion.

CLIAC CHAIR: I'm hearing loud and clear the group seems to be favoring a work group. Is there any further wordsmithing? We have not yet incorporated the CDC information [CLIAC DFO] has sent.

CLIAC MEMBER: [CLIAC DFO] has his hands up.

CLIAC CHAIR: Oh, sorry.

CLIAC DFO: Thank you. So I agree with all the comments that are advocating for a work group because I do think that we at CDC don't have enough information and the right people. And we're not, as so many of you said, especially [CLIAC MEMBER], we're not in the frontlines in the pathology labs on a daily basis. So the one hitch that we have about a work group is that work groups fall under CLIAC and they end up getting all the bureaucracy associated with CLIAC. And what that means is that we have limited capacity to run multiple work groups simultaneously. As many of you know, we already have an NGS work group that's under way, and there's a couple others that are in the queue. [CLIAC EXECUTIVE SECRETARY], you can jump in and help me remember exactly which ones are in the queue.

But it may take some time just to get this work group off the ground and staffed. And so I just want to alert you to that just because you say we want to work group doesn't mean it's going to happen overnight. And you may want to-- I mean, one consideration would be to add a little bit of language that tells CDC to do something on this clinical lab medicine issue at the same time while we try to get a work group established in case it takes six months or a year before the work group is able to meet. Maybe we can do something from CDC that could contribute to the initial meetings of that work group once it does happen. Over.

CLIAC EXECUTIVE SECRETARY: Yeah. So can I just jump in, too? Yeah, just to remind everyone that we do, as [CLIAC DFO] mentioned, we have an NGS forum that we're currently planning under CLIAC and as a result of a previous recommendation, as well as the very major recommendation to form a work group to look, overall, at where CLIA needs to be updated. And so we're hoping to get both of those activities going in the next few months.

And not to say that this is not a very valid recommendation, but again, there may be other things that CDC could do. I think we intended this session to be an initial introduction to the topic and planned that at the next meeting, we would continue on. And so those are the other points just to think about in your recommendation. And certainly recommending a work group, there's not a problem with that, but just as Ren said, it may not be something that we can immediately take significant action on.

CLIAC MEMBER: Yes. I was looking at what is here and I was wondering whether or not it would improve what we have here if in that last paragraph, we added opportunities for pathologists to educate, engage, collaborate with clinical colleagues and other interprofessional groups to reconsider and rigorously evaluate. I wasn't sure that it was broad enough to include other interprofessional groups. It seems like it was clinical labs throughout. So I ask your clarity on that.

The only other area that I saw might be interprofessional would be the establishment of a public-private partnership between federal, state, and local governments. But I'm looking at making sure that social workers and others could be considered, as well as the nursing profession. So my recommendation would be for your consideration maybe to add interprofessional collaboration.

CLIAC MEMBER: I'm sorry. I'm a bit confused. Please clarify. I thought we actually had two unrelated proposals on the table. Is this now combined into one proposal? Thanks.

CLIAC CHAIR: So, guys, keep me honest. But my understanding is the top part that ends with the last bullet is the original proposal, and then [CLIAC MEMBER] recommended the second one. There's overlap between the two and we were trying to decide can we or should we consolidate into one. And then finally, we are discussing the logistics of the recommendation of a work group, which will not be as timely as I think some of us would like.

And so can we distill down anything in these into an action request for any of the agencies? [CLIAC MEMBER] my comment to you, and it may be wrong in my thinking, but I see [CLIAC MEMBER] second paragraph about the opportunities for the pathologists. That's a call to arms for us, internal to our profession, and that we should just take this on, period. We don't need any kind of recommendation to external authorities. We should just do this. So really, what this committee should work on is, do we have a recommendation? A work group will take a long time. Is there some action item we want to hear about April 14, 2021?

CLIAC MEMBER: Is it appropriate or has it been done before where CDC or any of the agencies have actually placed a call to professional societies to take something on, just to your point? So could the action item be, out of CLIAC and the agencies, that public call to do this?

CLIAC CHAIR: I'm not familiar with such, but I live in a very cloistered environment. I certainly know there are hotspots throughout all the professional societies that are moving on this, maybe not in a coordinated fashion.

CLIAC DFO: So the committee could definitely charge CDC with doing a study that would require engaging professional organizations. You could tell CDC, hey, we want you to do this. We want you to engage these organizations. So that's a possibility. [CLIAC EXECUTIVE SECRETARY], did you want to say something? You're on mute.

CLIAC EXECUTIVE SECRETARY: I was just going to add, too, that the NGS forum that is being planned right now is a way that CDC will be working with professional organizations that develop NGS guidelines. We will be bringing them together and giving them an opportunity to talk about what guidelines are already out there and where there may be gaps or needs for additional guidelines. So there could be a way to kind of tweak this recommendation that says we would encourage professional organizations to explore these things if that's something that you are interested in.

CLIAC CHAIR: [CLIAC MEMBER], you have a comment? And we are coming up to our break time.

CLIAC MEMBER: OK. So just really quickly, I wondered if it can be-- I mean, we don't want to delay it, but the action is imperative. So could we simply ask CDC to prop up a web page with information that was discussed today and a resource for laboratories so that-- and announce this in a way that people who want to learn about this more could have a resource of important publications and the things that the speakers talked about today.

Because most people-- you can do a PubMed search and you may have 10,000 articles on this topic, but if there are known things about the laboratory that are already published that CDC knows about or the speakers, could we just do the CDC LOCS or something like that that would have a topic or an educational piece that people could refer to and could be disseminated among laboratories and professional organization? Is that a first place to start?

CLIAC MEMBER: Oh, OK. I think so. I'm reminded of what Dr. White talked about with-- I think she kind of implied that sometimes algorithm, even though they're in plain sight, can have some biases. Do you recall that?

CLIAC CHAIR: Yes.

CLIAC MEMBER: And I'm saying that it really takes it interprofessional team, other than clinical experts, clinical pathologies. It takes a broader picture to look at that because it's-- from what I was hearing her say, is that there is a body of people who don't see it. So you need to have some other eyes who look at it, OK? So that is the perspective from which I was saying that maybe we need a broader perspective because I read through

what is here, and it seemed to be, as appropriate, very clinically focused in terms of labs, et cetera. So I was recommending that maybe we could do that, interprofessional organizations to take a look at it. Maybe when the recommendations are ready to go to CDC is then just to have it reviewed by others.

CLIAC CHAIR: So thank you, [CLIAC MEMBER]. [CLIAC DFO] has reminded us that the CDC writes guidelines, period. That's kind of their job. So there's a proposal in [CLIAC MEMBER] recommendation. We could just simply reword it to say the CLIAC recommends that CDC provide guidelines for America's laboratories. Oh, and I'm sorry. And whether or not we include all the bullets, does that lock us in or recommends that CDC provide guidelines? And then you snap in for America's laboratories and everything below. And then perhaps a final bullet will be opportunities for pathologists and to snap in [CLIAC MEMBER] final comment.

CLIAC MEMBER: Guidelines are a great idea. I'm sorry if I cut somebody off. Guidelines are a good idea. And I think at colleges of public health, you'll find expertise of individuals who study these issues that could help us dig into laboratory bias that may be present and better recognize it than those of us who've been working with it for years.

CLIAC MEMBER: OK. Yeah, thanks. What was I going to say? I actually forgot, can you believe that? As I'm watching this be modified, I think we should wordsmith the last bullet a little bit. Perhaps marginalized persons or impact diverse marginalized groups, something like that. I'm somewhat opposed to just stating ethnic groups specifically. You'll never get them all. In Omaha, there's probably 20 or 30 ethnic groups, for example. And a lot of them are marginalized.

Oh, I know what I was going to say. Guidelines. I believe, up there, said who's the CDC going to consult? I think that having government-issued guidelines, no offense, I mean, I just worked in public health, but I think their needs, they need to be field tested with input from other individuals, as has been previously mentioned, which could include people in the laboratory community, specialists, community health workers, and non-laboratory types, so.

CLIAC CHAIR: So, [CLIAC EXECUTIVE SECRETARY] in that last bullet, if you could replace pathologists with laboratory and pathology professionals. It is 10:11. We were scheduled for a break at 10:05. And we are to come back at 10:20, which is different on your time, I understand. 1:20. So I am going to recommend we take a break. Those of you who would like to wordsmith this further, feel free to do so at the break for us to review. You were the most vocal. But until then, we are on a break until 10:20. Thank you.

CLIAC EXECUTIVE SECRETARY: I can keep this posted and work on it, for anyone that wants to do that. I'll be here as your scribe.

CLIAC MEMBER: Yeah, I think to the point that [CLIAC DFO] made to my comment is exactly the point, which I think if we just leave this open, we don't know who's going to be assigned to help with the guidelines. And I think we might need to be more prescriptive about who is engaged in these guidelines.

CLIAC MEMBER: My sense, you know, and I certainly share that. I think that it's OK as guidelines right now. I'd like to put it on the back burner for work group because it may be that more information is needed. And then ultimately, I kind of saw this as really having this discussion would be the focus of what used to be those CDC institutes. Because this is bigger than all the health care issues that we address because it's a bigger component than anything else. So I just want to make sure that we keep this one going. I think it's more than just issuing guidelines. It really needs to engage the laboratory community in a big way.

CLIAC DFO: Yeah. Just jumping in real quick. I totally agree with you. What was I going to say? It's harder now than it used to be for CDC to engage limited number of professional groups like those institutes used to do because now we get hung up on FACA issues, Federal Advisory Committee issues. So I do think it's important that you consider pushing this as a CLIAC work group because I think that's how we efficiently get the wide inclusion of everybody in this issue.

And I think you're absolutely right. This is a long term project for us and for everybody. I don't think, and [CLIAC EXECUTIVE SECRETARY], correct me if I'm wrong, but I don't think it's easy for us to create these institutes in the way that we used to because the FACA rules have become more rigid in terms of how CDC engages with certain groups and not the public when it comes to guidelines.

CLIAC MEMBER: So it may be that what comes out of that, if there's a work group and that we get the right representation and it includes multiple professions and the specialty societies, that they may form a consortia to really do this and provide that piece, which is-- I understand the limitations from the federal government's side, but I think if CDC can really help drive that to happen, that's as good as owning it.

CLIAC MEMBER: Yeah. My concern with this is it seems like it could be potentially very contentious and political. And I fear that any work that we do and guidelines that are made could die in the clearance process with CDC because there's going to be so much contention and so many varying opinions. I've seen straightforward documents die.

CLIAC DFO: That's a good point. It's a good point.

CLIAC MEMBER: I'd rather it go through other organizations and maybe having a joint memorandum externally with CDC in collaboration, maybe.

CLIAC MEMBER: Yeah. That's a great point.

CLIAC EXECUTIVE SECRETARY: I was just going to suggest, because this is long-term and is large and may, at some point, end up in being a work group, what I would ask is you think about steps that CDC could take between now and the next meeting that would be helpful as you have more discussions then and maybe can focus in a little bit more, if there's certain information that you would like CDC to gather to bring back to CLIAC. So try to focus in on the next six months what you would like that would make your next discussions on this topic helpful.

CLIAC MEMBER: So, I agree with the comments about calling out diverse marginalized groups, and so I would like to state-- instead of taking diverse marginalized persons of color, we add diverse marginalized groups. And to answer your question about what we could do in the next six months, I think the comments about non-binary and LGBT community with different lab results and how to manage those and communicate, again, communicating information to marginalized groups, that might be a good presentation to have, as well. This is what [CLIAC MEMBER] spoke of earlier.

CLIAC EXECUTIVE SECRETARY: Yeah. So I think what we need to be careful of here is that we are just making tweaks to the recommendation and not having additional discussion about things that need to be discussed in the larger group and with the public having access. So if you're suggesting something that I can wordsmith here, then I'm glad to do it, but if this is something that you're throwing out for [CLIAC MEMBER] to think about, then this would not be-- we need to do that with the entire committee there.

CLIAC MEMBER: OK. So I would-- just marginalized groups.

CLIAC EXECUTIVE SECRETARY: OK.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: And then your question about what we can look at in the next six months, I was just throwing that out as a recommendation, just really reinforcing what [CLIAC MEMBER] had said.

CLIAC MEMBER: Some of it seems to me it's going to ultimately end up in how because I do think that, for example, to look at embedded bias is a health services research study. And that may go on the research agenda of CDC to sponsor interdisciplinary health services study to really do that. I think this group or with input can study it. But it probably, to do it in a rigorous way, is something that probably needs to be done from a lab. We don't have that level of detail as much.

CLIAC DFO: You could also ask us to do a study.

CLIAC MEMBER: So maybe that second to last bullet should be to conduct a study to identify embedded inherent bias involving current test processes and reporting. Is that what I was hearing?

CLIAC CHAIR: It is--

CLIAC MEMBER: Process should be processes.

CLIAC CHAIR: It is 10:20. Are we all back? OK. So it sounds like, [CLIAC MEMBER], you were doing some wordsmithing during the break. Would you like to identify those?

CLIAC MEMBER: I can briefly touch on it. Maybe the other people that were talking-- the main activities happened, really-- well, there were several. At the beginning, that the CLIAC recommends that CDC provides guidelines for America's laboratories and sort of focuses on what [CLIAC DFO] reminded us, that really, the laboratories at CDC, that's the business they're in is to produce the guidelines and so on. We think ultimately that a work group and a broader discussion and really charging the laboratory community as a whole and those who use the laboratory with figuring this out in a much better or broader spectrum would be important.

We tweaked the second to last bullet that you see there to actually say that CDC should consider conducting a study to identify embedded inherent bias involving reports because we think that while there is broad discussion of this, and we heard that from the presentations this morning, that really, this is a much broader health policy, health services piece of work that really needs to be done. And then on the last bullet, we changed persons of color to marginalized groups. And the main reason being is that we recognize that while clearly it's important for persons of color, that there are other groups that are equally important, such as people in terms of LGBT and transgender and other kinds of individuals that may be marginalized that go beyond just being people of color.

So I think that was general. And we added, also, laboratory professionals to pathologists. I would say-- yeah, that's fine the way it is. And we often use the term pathologists and other laboratory professionals. But I don't care about that. I'd let other people who were discussing this indicate any of the other items that we entranced.

CLIAC CHAIR: I just want to comment that last sentence, to include mathematically appropriate discussion, that maybe we should broaden that to the on-test test performance, comma, including specificity and sensitivity because we have other issues around test performance that will influence. We don't want to lock ourselves in.

CLIAC MEMBER: So I wonder is low math and literacy instruction the appropriate word to use? It implies that marginalized groups have low math and literacy instruction. Would we say inappropriate vernacular for broad consumption across multiple education levels?

CLIAC CHAIR: So [CLIAC MEMBER], number one, could you speak up a little? And number two, could you identify the exact place you would like to revise?

CLIAC MEMBER: Yes. This will be in the last sentence, the [INAUDIBLE], instead of the culturally appropriate and then the parenthetical expression, say for reporting tests. And I would actually say reporting results because it's not so much the test, but the result. Reporting results in appropriate vernacular-- I actually put it in the chat if anybody wants to look there. In appropriate vernacular for broad consumption across multiple education levels.

CLIAC CHAIR: Is there some preferred term? I mean, I like what you proposed. Is there some commonly used term to get at? Dr. White sort of had some comments. I didn't capture the exact verbiage.

CLIAC MEMBER: Well, I know the New York Times talks about its reading level. And I was looking up synonyms of vernacular and that would be-- I mean, you could just say in language. In language for broad consumption over multiple education levels.

CLIAC CHAIR: It's already a compound sentence. But it would be something like for reporting results in a culturally appropriate manner comma acknowledging variability in literacy and-- in just literacy? Do we need to include math?

CLIAC MEMBER: Absolutely. So I actually have a lot of experience in this because of the non-invasive prenatal screening issue. It all came down to the fact that the companies were out there. And at one point, I helped develop the test. The companies were out there pushing 99.2 sensitivity, 99.7 specificity. This is for those non-invasive prenatal test, except the PPDs are 50% on a lot of them.

So this is the same story again. And just from now a decade of experience with this test, the doctors are the ones who end up having to communicate this to patients. That is just how this tends to go. So if we can just-- obviously, I like the language. And it does cover the communities, in general, that we serve. But if there isn't-- and I mentioned this yesterday. I don't know if you feel otherwise, but a lot of the doctors who are frontline don't know the difference between a sensitivity and a specificity and all the things we heard today.

And the CDC, thank you, because that page that you've been updating has actually been quite good trying to help. And BMJ had a fantastic article on antibodies that had an interactive. Has anybody seen it? An interactive page where you can play around with the antibodies, specificities, and PPDs, MPDs. And we have the educate there. I love it.

And clinical colleagues, I just can't overemphasize. I don't know if there's a way to really highlight that physicians are the first and the providers are the first line. Or if people feel this is enough, I'm fine with that. But I just want to make the case having lived it. It doesn't matter if the providers who are receiving a test don't get it.

FDA EX OFFICIO: Yeah. So that's why in our New England Journal article one of the lessons learned is education. And it's not just specificity and sensitivity. I've talked to people and say, well, the specificity is 99%, so why am I getting false positives in the nursing home population? And so they've got to understand specificity and sensitivity. They also have to understand it PPV and NPV. And if they don't understand specificity and sensitivity, there's no way they're going to understand PPV and NPV. And those are so critical. This is a large educational opportunity. Those are my comments. Thanks.

CLIAC CHAIR: And I'll comment. Marissa White gave us the language in the chat box. So I'm going to recommend in this big bullet that starts with the opportunity that we take the sentence beginning with recommend and make that a separate bullet.

CLIAC MEMBER: That'd be great.

CLIAC CHAIR: And I'm going to recommend the wordsmithing. Recommend developing guidelines-- oh, [CLIAC EX OFFICIO] putting that together-- for reporting test results in a culturally and linguistically appropriate manner. And then up for discussion is whether or not we talk about test performance and whether or not we talk about broad consumption. I think across multiple educational levels should be umbrella'd, correct me if I'm wrong, under the cultural and linguistic appropriateness.

CLIAC EX OFFICIO: I didn't know if you wanted to keep that last phrase about sensitivity and specificity or not.

CLIAC CHAIR: So that's up for discussion. And [CLIAC MEMBER] is in line. Go ahead.

CLIAC MEMBER: I think it's too hard. Thanks.

CLIAC CHAIR: So would you strike it?

CLIAC MEMBER: Mm-hmm.

CLIAC CHAIR: Would you end after manner or do you want to include the clause for broad consumption across multiple education levels?

CLIAC MEMBER: Well, I would suggest striking the bullet. I think [CLIAC MEMBER] made a few comments. This is hard stuff. Doctors do not understand this stuff. And it depends on the assay. I mean, we talked about EGFR. Any EGFR that you calculate is plus or minus 30% of the number. I think it's complicated. And I don't know how you can incorporate something this challenging into a test result however it's stated. Thanks.

CLIAC CHAIR: Is there anyone who feels strongly we should include this bullet that's highlighted? There's some head nods and there are no mouths moving. So we do want to keep the recommend. We don't want to keep the that they serve to include mathematically appropriate description. OK. And then--

CLIAC CHAIR: Although, the Nobel Prize should go to somebody who can figure out how to teach Bayes' theorem to the general community.

CLIAC CHAIR: I would propose [FDA EX OFFICIO]. But do we want to include the clause for broad consumption across multiple education levels? Do we feel we need to call that out over and above culturally and linguistically appropriate?

CLIAC MEMBER: I think it's redundant. I think it's clear without it.

CLIAC CHAIR: Anyone disagree? Seven seconds of silence wins. Are we--

CLIAC MEMBER: You could put culturally comma-- you could put educationally, culturally, and linguistically to make sure that education is in there.

CLIAC MEMBER: Yes, thanks. I'm not seeing the first bullet on my screen at this moment. But I don't understand it as I remember it. It had to do about expansion of laboratory tests parentheses insights from common tests. I'm sorry. I just actually don't understand what that bullet means. Thanks.

CLIAC MEMBER: I guess since I wrote it, I have to explain it.

CLIAC CHAIR: You do.

CLIAC MEMBER: That was really-- in light of the discussion that followed, what it was meant was the insights that we get from, for example, that the creatinine has been going up in a patient that may not be recognized. How do we use the lipids and the A1C and the traditional laboratory tests insights that specifically link to identifying potential gaps in care as opposed to non-traditional roles? Which, to me, when I was writing this, had to do with the expansion of maybe including doing surveys as part of our patient facing LIS as a non-traditional activity. So that's what I meant by these without trying to be too specific because I figured we'd discuss that more.

CLIAC CHAIR: Would you like to modify the wording, [CLIAC MEMBER], based on the comment?

CLIAC MEMBER: Well, if I'm the only one that's confused, then it's probably OK.

CLIAC CHAIR: There is seven seconds of silence have passed. No one seems-- oh, [CLIAC MEMBER] has popped up. [CLIAC MEMBER], please discuss your comment.

CLIAC MEMBER: Want me to say-- OK. So maybe the only primary care doc in the group. I'm going to push back a little bit on what frontline docs know and don't know. I think, on the whole, although certainly you could find some that don't know sensitivity and specificity, but I think, on the whole, they do understand these concepts. In our company community care of North Carolina, we're actually teaching not only those concepts but also probability based on community prevalence and clinical picture and using some of the calculators that are found online to help docs understand really what the probability [INAUDIBLE] sitting in front of them has if they have a negative or a positive test. And so is more education good? Abso-freaking-lutely. But I think I just wanted to push back a little bit, respectfully, that I think in general, most primary care docs understand sensitivity and specificity.

CLIAC MEMBER: Well, [CLIAC MEMBER], if you're teaching it, why are you teaching it? You're teaching it because you're supporting a knowledge gap, OK? You don't have to teach them. Well, maybe you do. Maybe you have educational programs around how to identify a primary hypothyroidism, let's say, right?

But for primary care-- I'm OBG/YN, so also frontline. If you ask primary care screening for colorectal cancer to discuss where online you can find calculators to help you, and actually ask straight up the difference between sensitivity and PPE, which are the two that are always confused, whatever you're doing, actually, could be something that we could use.

You've got this program. It could be something that could be extremely valuable to share. A knowledge, a way to share the knowledge, is kind of what I'm after.

CLIAC MEMBER: I'm happy to--

CLIAC MEMBER: So what you're doing should be-- if we could bottle it and put it in a jar you get it to everybody, that'd be amazing.

CLIAC MEMBER: No, I'm absolutely happy to share that. I think in terms of permissions and whatnot, I think I can't. But happy to. And it came out of the COVID testing because we're looking at some of these tests. And specificity of 100% and sensitivity of 98.5%. And you look at how they did it and it's taking-- their negatives were 30 patients. And 30 prior to COVID and that's their negatives. And so wow, 30 out of 30 were negative. So 100% specificity, right?

And then they spiked those 30 negatives with COVID-19 and their sensitivity is 99%. So it's just helping docs kind of understand. That sort of thing is why we started that kind of training, just so they can actually look at a package insert and go, well, that's BS or it's not. Which is another point, if possible, I don't know if there's a way that we encourage laboratories or-- and you guys know certainly better than I what's going on in the community, that as we get these tests with, I think, really poor validation upfront, that we as laboratories continue the work of validation on these tests.

And I'm not quite sure how to put that into words or who that would go to, but boy, that's just something that-- again, you talk about docs on the frontline that information, they really need to know how good these tests are or how not good they are. So I would encourage that, too.

CLIAC CHAIR: Thank you both. [CLIAC MEMBER] has a comment. Before she speaks, [CLIAC MEMBER] and [CLIAC MEMBER] have agreed that the first two bullets appear to be duplicative. So [CLIAC EXECUTIVE SECRETARY], if I could just have you highlight that second bullet, my suggestion would be we delete it. But let's just think about that while [CLIAC MEMBER] talking.

CLIAC MEMBER: [CLIAC MEMBER] comments made me think about the fact that we do that training for our primary care. The lab is doing what he's doing, trying to make sense of this mayhem. And not all systems have that, obviously. And I think it's great that he's doing it. But that is really a pre- and post-analytic laboratory responsibility to interpret that for our providers.

And we do with webinars and pamphlets and all kinds of engagement. But maybe that has an overlap with racial disparity. I mean, really, if you look at it, it's part of our post-analytic interpretive responsibility as a laboratory to interpret whether it's COVID in easy ways, whether it's-- I mean, we do this for genetic mutations, for a hypercoagulability. We make those interpretations.

We already do this in some obvious ways, but it needs to be expanded. And I think that we really need to marry it with not necessarily the pre-analytical but certainly the post-analytical interpretation of the laboratory tests that we're putting out. That's on us. So I would like to see something about-- I think we're covering it, but it's also linked to clinical medicine and all this stuff, which it needs to be.

But I also think that laboratories just need to be-- I could've had a V8. This is part of post-analytical interpretive responsibilities of laboratory medicine to combine with our clinical colleagues to work through this. And I say we do this, but we don't do it in a vacuum. We have ID with us. We have internal medicine with us. We're constantly creating that post-analytical environment for our organization. And I think we need to say that it is our responsibility and that laboratories in general need to own that when it comes to inequities of any kind and interpretive comments of any kind.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER] has put in the chat box why bullet two does not duplicate bullet one. [CLIAC MEMBER] has suggested bullet one be restated to identify diagnostic tests helpful in guiding care for at-risk patients. I personally think we are at the point where we are really down into the details and I would like to pull this back and say, do we have enough? Without wordsmithing this more, do we have enough to approve this recommendation? And I put that in the context. We have three remaining recommendations we brought forward after yesterday's first session that I would like to get back to.

CLIAC MEMBER: Would you go up a bullet point there? You just passed it. Keep going. Here. Bullet three. Establish key metrics to demonstrate laboratories are contributing to addressing health disparities as part of their post-analytical responsibilities. Can we throw something in there about post-analytical?

CLIAC MEMBER: I think that's too restrictive because some of it may be pre-analytical.

CLIAC MEMBER: OK.

CLIAC MEMBER: Right? That you understand why you needed the test in the first place.

CLIAC MEMBER: Then it is, as part of-- I mean, do we list them all out? Or do we just say the analytical spectrum in each aspect is part of each analytical spectrum?

CLIAC MEMBER: Well, then the time would be across the total testing process.

CLIAC MEMBER: There you go.

CLIAC CHAIR: Because you got to get intake, right? Across the total test process.

CLIAC MEMBER: Right. Because in the example of the microbiome, that's an analytical piece, and you're rightly-- there's pre-, there's analytical, and there's post-. So it's the entire spectrum, as you said.

CLIAC CHAIR: So I'm going to move, put the motion on, that we accept this recommendation on the screen that ends with the final bullet and to ignore the comments below. Is there a second?

CLIAC MEMBER: Second.

CLIAC CHAIR: Is there further discussion?

CLIAC EXECUTIVE SECRETARY: Can I just ask a question for clarification? This phrase recommendations should consider.

ADVAMED LIAISON: Yes.

CLIAC MEMBER: What do you mean by that? Do you mean the guidelines should consider?

ADVAMED LIAISON: So I was going to comment on that. I think in that third line, that should be rephrased to get rid of recommendations because the first line says you're recommending CDC-provided guidelines. I think that should be rephrased to CDC should consider. And then in the-- oops, wrong place.

CLIAC MEMBER: Yeah, that's fine. Because that was a carryover from the old wording.

ADVAMED LIAISON: Right. And then the same in the last bullet. It says recommend developing guidelines, which doesn't tie with that. I think it should just say, because the CDC should consider--

CLIAC MEMBER: Just start with reporting.

ADVAMED LIAISON: Just start with guidelines. Guidelines for reporting.

CLIAC MEMBER: Just reporting. I agree.

CLIAC MEMBER: Yeah. You don't need guidelines because that's the parent.

ADVAMED LIAISON: And then [CLIAC EX OFFICIO] , in the fourth bullet, your cursor went wild and started typing in CDC.

CLIAC MEMBER: We know CDC's everywhere.

CLIAC CHAIR: Yeah. The word is across. There's an extra space.

CLIAC EXECUTIVE SECRETARY: Oh. All right. And I have one other question, actually, for clarification of this phrase right here, rigorously validate algorithms of test results. To me, that doesn't read quite right. Algorithms for performing testing?

CLIAC CHAIR: No. It's more like validating algorithms for test result interpretation.

CLIAC EXECUTIVE SECRETARY: OK.

CLIAC MEMBER: I mean, is reconsider the right word? Isn't it reassess and revalidate?

CLIAC MEMBER: And from a grammar perspective, some of these bullet points are starting with a noun and some of them are starting with a verb when there's already a verb. CDC should consider, there's already a verb. CDC should consider, identify potential roles, so we need to go back and make sure these connect.

CLIAC MEMBER: And don't we want to reconsider and rigorously validate algorithm for test reporting for clinical importance? I guess, to me, it doesn't make much sense to have algorithms that are group specific if they don't really impact the outcome and the care that's going to be provided for those individuals.

CLIAC MEMBER: I think that can be dangerous. Because think about MSM communities with higher identified level of syphilis. And that's documented and they're tracking those patients for new infections. If you apply the quote on quote "reverse sequence algorithm", that's a disservice to that population because it's unnecessary testing that can be falsely indicating a false negative on the … specific. Then someone misinterprets that they don't have syphilis anymore. I think that is important to-- one algorithm doesn't fit every population.

CLIAC CHAIR: Do we have enough to vote and to allow the grammatical corrections to be performed by staff? To move the nouns to verbs? Are we in agreement on that? Is the intent clear?

CLIAC MEMBER: Well, the only other thing, there were several things in the chat that bullet point number one and bullet point number two was the same.

CLIAC CHAIR: [CLIAC MEMBER], we put the note below. Bullet one was to leverage it. And that would be a note to staff. That was [CLIAC MEMBER] explanation of the difference. So we have a live motion.

CLIAC MEMBER: As amended.

VALERIE NG: As amended, there being any further discussion. Can we vote on the amendment first? [CLIAC MEMBER], what was the amendment? These word changes?

LEE HILLBORN: Yeah, the word changes.

CLIAC CHAIR: Do we agree? Is all opposed to the word changes? Any abstentions? The word changes are approved. Now we vote on the motion. Any opposed? No opposed. Any abstentions? No abstentions. The motion passes. Oh, I'm sorry. Were you abstaining in chat or your hand? I can't see. OK. One abstention.

CLIAC MEMBER: I'm abstaining.

CLIAC CHAIR: So the motion passes. And we would ask staff to help us with the grammar and fix it. Thank you. Thank you all. Now if we can move back up to the other three that came out of yesterday's discussion.

Oh, and you're going to have to show it, maybe. So we did some wordsmithing last night and it's really ugly. So we're going to show you the wordsmithing piece, but we can show you the clean copy without the track changes. And I would prefer we do that so you're not distracted by all the changes.

So we have recommendation number four. Let's go back up to three, two, and one. Three, two, and one. And then I would suggest we take them in reverse order because number four got the closest to an action item and because it includes money. So I am opening. I am moving approval of recommendation number four. Is there a second? Open for discussion. You all are remarkably quiet given yesterday. Well, no one's in the chat. No one's waving their hand. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I'd like to comment that maybe we do not want to tie the hands of CDC as to where these dollars might come from. I recall hearing from another meeting that there were new dollars in the budget for IT purposes to make enhancement in IT. So maybe we just say leave out where the funding should come from.

CLIAC MEMBER: We could also--

CLIAC MEMBER: We say CARES Act or others?

CLIAC CHAIR: We could say e.g. We could say e.g., right? CLIAC recommends that CDC use funding, e.g., CARES Act.

CLIAC MEMBER: Yeah. No, exactly. No, you're right. I just don't want to-- I think [CLIAC DFO] brought that up yesterday, that that's happening and he's advocating to have the laboratory included there and they're not. So I think either saying CARES Act or other related funding or an example of the CARES Act would be appropriate.

CLIAC MEMBER: Whatever is most helpful to the CDC. I just thought maybe it might be too tight of a statement.

CLIAC CHAIR: Good idea.

CLIAC MEMBER: Well, we do that as an example. Should we take out specifically the CARES Act, for example, the 500 million.

CLIAC MEMBER: Take out the word specifically?

CLIAC CHAIR: How about enclosing the e.g. through infrastructure in a parentheses?

CLIAC MEMBER: That works.

CLIAC MEMBER: Should the existing laboratory information system infrastructures also include an example?

CLIAC CHAIR: Such as?

CLIAC MEMBER: AIMS? Could we put AIMS in there?

CLIAC MEMBER: Well, we don't want to replace AIMS, but we could be saying upgrade AIMS.

CLIAC MEMBER: It is there as replace or upgrade.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: So after infrastructures, parentheses e.g. AIMS in parentheses? Is that what you're getting at, [CLIAC MEMBER]?

CLIAC MEMBER: Yes. Or instead of replace or upgrade, how about improve?

CLIAC CHAIR: Well, you could say to improve comma replace or upgrade.

CLIAC MEMBER: Yeah. Whatever is fine. I just thought AIMS may be the thing to put in there.

CLIAC MEMBER: And what about NEDS?

CLIAC CHAIR: I don't even know what these things are. I don't even know what these things are. So AIMS comma NEDS.

CLIAC MEMBER: I don't know if NEDS is a good example. I'm just asking the question for the public health folks on the call.

CLIAC MEMBER: I don't think it is a good example.

CLIAC MEMBER: OK.

CLIAC MEMBER: Another example might be the influenza reporting system. I'm blanking on its name right now.

CLIAC DFO: NRRVS. NRRVS.

CLIAC MEMBER: NRRVS?

CLIAC DFO: Isn't that what it is? NRV-- NRRVS or something like that? I can look it up.

CLIAC MEMBER: In my own opinion, I think AIMS does the job.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: Is there further discussion? Your 7 seconds have passed. Hearing no discussion, I'm going to call the vote. Is there any opposition? Hearing no opposition, are there any abstentions? Hearing no abstentions, this motion passes. Let's go back and look at three. Can't even remember what ASPIR is.

CLIAC DFO: Assistant secretary For preparedness and response.

CLIAC CHAIR: That's right. I'm going to open the motion. I'm going to move approval of recommendation number three. Is there a second?

CLIAC MEMBER: Second.

CLIAC CHAIR: Discussion. Floor's open. That was 12 seconds.

CLIAC MEMBER: Oh, I'm not sure. I tried commenting, sorry. I'm not great at grammar but I'm pretty sure that there is run-on sentences and a partial sentence at the end. But we could leave it to staff to clean that up, but it just doesn't sound right to me. I get all the component pieces, but I'm pretty sure it's not grammatically correct.

CLIAC MEMBER: Yeah, I agree with Nirali.

CLIAC MEMBER: Yeah, that's right.

CLIAC CHAIR: Do we want to wordsmith it now? My preference is no. Do we want to ask staff who may be grammatically better than us? I would propose we do that considering--

CLIAC MEMBER: That last sentence might be as simple as saying will be made public.

CLIAC MEMBER: Add a verb.

CLIAC MEMBER: Again, I don't agree with having staff edit that last sentence because it's missing an intention. There's a subject, predicate, deficit there.

CLIAC CHAIR: So [CLIAC MEMBER], I can't even remember what predicates and subjects are, so will you please reword it?

[INTERPOSING VOICES]

CLIAC CHAIR: Oh, we are missing a verb. Sorry. Please--

CLIAC MEMBER: Decisions as well as data provided by public health lab elected officials will be made public.

CLIAC CHAIR: And you're OK with that?

CLIAC MEMBER: OK. Now

CLIAC MEMBER: Can we spell out laboratory? I know that's weird, but we need all the public credibility we can get and lab is colloquial.

CLIAC DFO: [CLIAC EXECUTIVE SECRETARY], I have a process question. Since ASPIR is not part of this federal advisory committee, do we need to actually-- does CLIAC have to ask HHS to recommend that ASPIR do this?

CLIAC EXECUTIVE SECRETARY: Yeah. So basically what will become of this recommendation from our perspective is that we will send a letter to HHS. So it's fine to make the recommendation, but just know that is what the outcome will be.

ADVAMED LIAISON: And then, Nancy, what is a typical response? HHS secretary sends a thank you letter? And we'll take it under advisement?

CLIAC EXECUTIVE SECRETARY: Yeah.

ADVAMED LIAISON: So does one of the agencies have a recommendation for, or have any insights, as to how this could be bolstered up? Is there some somewhere within the tri-agency that could be doing this as well or pressuring for this?

CLIAC MEMBER: I think it's going to work because after all, we are appointed by the secretary. And so I think if CDC forwards it or from the director, it will get the attention it needs.

CLIAC EXECUTIVE SECRETARY: So it will be coming from CLIAC. It does not come from the CDC director. It comes from Dr. Ng as chair of CLIAC.

ADVAMED LIAISON: And there have been past recommendations that have been thanked, taken under advisement, and not acted upon.

CLIAC CHAIR: So [ADVAMED LIAISON], I think we can do what we can do and then we would work through our professional societies as we're already doing to try to raise this issue. Is there further discussion?

CLIAC MEMBER: [INAUDIBLE] are referring to because it's ambiguous now because there's multiple subjects in the first sentence that isn't clear. There was a key features of the process include?

CLIAC CHAIR: Yeah.

CLIAC MEMBER: I think we need to be clear on that.

CLIAC CHAIR: Is there further discussion?

CLIAC MEMBER: I think, grammatically, you need an and before clearly defined because then you go on to put another list in there. So there's features include transparency, yeah.

CLIAC CHAIR: Further discussion?

CLIAC MEMBER: Do we need to put clinical in front of decisions?

CLIAC MEMBER: Maybe patient care.

CLIAC MEMBER: This was more about resources, meaning about how to decide how to allocate resources as opposed to patient care or that type of clinical decision.

CLIAC MEMBER: OK. Since decisions is kind of bad, should we put resource decisions?

CLIAC MEMBER: Oh, maybe that's too long of a sentence. The last phrase, about elected public health officials need to provide information to guide resource decisions. And that becomes a separate short and sweet sentence.

CLIAC MEMBER: Yeah, I think maybe a second sentence is necessary because we already have resource allocation in the first clause right after key features.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Then that first sentence also has to be public health laboratories and clinical laboratories.

CLIAC MEMBER: Huh. I don't like it.

CLIAC MEMBER: Rather than a comma.

CLIAC MEMBER: Where is that?

CLIAC CHAIR: Right above the third line.

CLIAC MEMBER: [INAUDIBLE] for public health laboratories and clinic laboratories, yeah. [INAUDIBLE] It might help you say both public health and clinical laboratories, or both. And then you're not saying laboratories twice.

CLIAC MEMBER: Just take "laboratories" out for public health and clinical laboratories.

CLIAC MEMBER: Take that laboratories out so that you only say it once. Now I think if you say both, it kind of prefaces and prepares you for another and. And you're not wondering, how does this and fit with the other and if you say for both public health and clinical laboratories.

CLIAC MEMBER: So now public health officials are not elected, right?

CLIAC MEMBER: You're right. I think they're not.

CLIAC MEMBER: Only our bosses are.

CLIAC MEMBER: You can take elected out.

CLIAC MEMBER: And it should be the public health officials and not the elected officials.

CLIAC MEMBER: Well, we started with elected officials being involved. Now I don't think they're in there anymore.

CLIAC MEMBER: They're at the end.

CLIAC MEMBER: Are they at the end? OK, you're correct.

CLIAC CHAIR: Is there further discussion? [CLIAC MEMBER], your lips are moving, but I don't hear you.

CLIAC MEMBER: So was it just public health officials that need to provide information? It wouldn't be the entire clinical and public health community or leadership or-- do we--

CLIAC MEMBER: I agree with that.

CLIAC MEMBER: I like the word leadership.

CLIAC MEMBER: Doesn't that just create kind of guidance coming from everywhere?

CLIAC MEMBER: It does. I just don't know if we want to get-- I mean, we're proposing that the clinical laboratory be involved in this MUA and other things. And then yet, we're going back to-- public health officials, as great as they are, can't really speak for the clinical laboratory needs in any way, shape, or form. And maybe if they've been involved, they can speak a little, but if they're not currently entrenched in hospitals and health care, then I think we need to either add it or--

CLIAC MEMBER: Yeah, I'm good with that. So public health officials and clinical laboratory representative?

CLIAC MEMBER: Does it need to be specified that they need to collaborate?

CLIAC MEMBER: It's supposed to happen, but maybe we don't want to say it because it may not always happen.

CLIAC MEMBER: We need to collaborate to provide information.

CLIAC CHAIR: [CLIAC MEMBER] trying to make a comment. [CLIAC MEMBER] You're on mute. we cannot hear you. We can't hear you.

CLIAC MEMBER: I think it's much better.

CLIAC CHAIR: And [CLIAC MEMBER], we still cannot hear you.

CLIAC EXECUTIVE SECRETARY: And I have a question now after adding that verb will to the last sentence. That's more of a statement. So do you mean to say should be made public?

CLIAC MEMBER Sure. That's great. Should.

CLIAC CHAIR: [CLIAC MEMBER], can you type your comments into the chat box? I see you trying to talk. And are the rest of you satisfied because you're all quiet right now?

CLIAC MEMBER: Well, we need a unique-- separate out those ands. As well as data provided by the public health and clinical laboratories comma and by public health officials to be made public.

CLIAC MEMBER: Or did we just delete elected officials?

CLIAC MEMBER: We did.

CLIAC CHAIR: We did.

CLIAC MEMBER: Want to do that?

CLIAC MEMBER: That requires an election.

CLIAC EXECUTIVE SECRETARY: I took it out here because it had been removed from the previous sentence, which I thought this needed to coordinate with.

CLIAC MEMBER: Well, they have a say, you know. A serious say.

CLIAC CHAIR: [CLIAC MEMBER], where would you put that back in?

CLIAC MEMBER: Would it be public health and elected officials should be made [INAUDIBLE]

CLIAC MEMBER: I think that's fine.

CLIAC MEMBER: Or practical.

CLIAC CHAIR: OK. And then [CLIAC MEMBER] wants to include obtain and allocate.

CLIAC MEMBER: Where?

CLIAC CHAIR: [VALERIE NG], you didn't say.

CLIAC MEMBER: I would-- probably the first.

CLIAC CHAIR: Yeah, the first sentence. Ask for coordinate a national process to obtain and allocate. [CLIAC MEMBER] nod your head yes if we got it in the place you want. Is there further discussion?

CLIAC MEMBER: If I'm inclined to leave it, I was trying to-- public health and elected officials is really responsible authorities because it may not-- there's other than public health officials and elected officials. And so I wondered whether it just said responsible authorities parentheses e.g. public health.

CLIAC CHAIR: Yeah, I like that.

CLIAC MEMBER: Good.

CLIAC CHAIR: OK. Hearing no further comments, so I'm going to call the vote. Are there any opposed? Hearing no opposition, are there any abstentions? Hearing no abstentions, this recommendation passes. Let's go up to number two. OK. So number one and two are relatively encapsulated. I would want to start with recommendation number one first. It's a little broader based. So I am moving approval of recommendation number one. Is there a second?

CLIAC MEMBER: Second.

CLIAC CHAIR: Thank you. Floor is open for discussion.

CLIAC MEMBER: Looks good.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. That was 10 seconds. I gave you three more.

CLIAC MEMBER: I'm just wondering if there is any way or whether we should include the second recommendation into one in some way if we're talking about a laboratory network and how would that be different from the public-private partnership task force?

CLIAC CHAIR: I saw the task force as being broader and saying how does the laboratory get our voice heard in this public-private partnership, whereas I saw number two as really talking about interoperability and reporting.

CLIAC MEMBER: And then the point about-- again, sorry that I jumped to two, but I think it's still relevant because we do have a Laboratory Response Network, the LRN. So I wanted to make sure that was addressed or distinguished from what we're actually talking about in our recommendation.

CLIAC CHAIR: So perhaps we could park recommendation number two and specify that related to the NLRN. Put that in our parking lot, unless others feel we should umbrella it with recommendation number one.

CLIAC MEMBER: I don't see how we can parking lot it, respectfully, because it is something that really needs to happen. I think, [CLIAC MEMBER] if I understand you correctly, you're just saying that we need to clarify that we don't mean the LRN, but we mean an IT-driven network. Is that what you're saying? I want to make sure I understood what you're saying.

CLIAC MEMBER: Yeah, correct. We have an LRN. But we are talking about the information component. So if we modify network, maybe, or add words to that piece of it, it may be appropriate and then would not be part of recommendation number one.

CLIAC MEMBER: So if we said laboratory collaboration instead of network, then nobody would mistake it for the LRN? Something along that nature? Is that what you're saying?

CLIAC MEMBER: So let me back up and say I don't hear any drive to merge it with number one. So let's finish number one then we can come on to number two. So I'm sorry that I merged them, but I'm now withdrawing that.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. OK, we have [CLIAC MEMBERS]

CLIAC MEMBER: Thank you. So I have to confess I'm getting a little confused as to the differences between one and three now. And I confess it that I don't probably understand the scope of the federal network that's already been organized around the preparedness network, the interface between HHS, CDC, all the other linkages here. I think what I felt and tried to express earlier was that I just felt like whatever the LRN encompasses, whatever HHS activities are happening, there is no transparency to the larger health system labs.

Maybe the larger commercial labs understand how all this is put together, but I don't think a lot of the larger health system labs or community-based labs understand how all this comes together. And it may all meet at the top very well, but I think what I understood from recommendation one was that we were going to try to do something in coordination with what's already out there as we have in recommendation three.

So I'm a little fuzzy as to actually how these recommendations are going to be different or similar at this point. And again, I just want to emphasize I think that whatever is currently out there that we just need to figure out how to involve all of our community and larger health system laboratories to be involved and have that level of transparency. So I'm not sure if there's anybody on the staff at CDC or any of our other members who can help pull this together. I just want to make sure we're going in the right direction for what we're asking.

CLIAC CHIAR: So [CLIAC MEMBER] is going to jump the line because he thinks he can answer your question.

CLIAC MEMBER: Yeah. So I've sat on this committee since its inception. And so, [CLIAC MEMBER] the idea that came up with this was that right now, this committee only involves the large commercial laboratories. And that was designed as a response to Zika. But now that we've seen it in play with an infection that is better tested, probably, near the point of patient care, near hotspots like [CLIAC MEMBER] was mentioning yesterday, that this recommendation would be too broad in the incorporation to not just commercial labs, but instead, to bring in key stakeholders in different geographic regions to represent academic and regional laboratories that could play a analogous and maybe even more appropriate role than just the commercial labs.

But the reason why a lot of people don't know about it is because they weren't on a commercial lab interested. So asserting that we're going to bring in more people, more people would learn about this and what it's doing. I guess that was the idea.

CLIAC MEMBER: OK. Thank you very much, [CLIAC MEMBER]. And [CLIAC CHAIR], don't want to have a conversation with [CLIAC MEMBER], but that is very helpful to me. And it sounds like to respond to that, though, it sounds like maybe what we're talking about is an expansion of what already exists with the Laboratory Response Network. And then do we name it something like-- do we put that in there as to include, as [CLIAC MEMBER] was saying, do we include those in that Laboratory Response Network? I'm not sure if that's the right direction or not, but that's kind of what I was hearing from what [CLIAC MEMBER] was saying.

CLIAC MEMBER: Well, kind of along the same lines, I guess, I'm struggling with the difference between recommendation two and recommendation four. I realize that recommendation four has some specifics about funding. So really, aren't we doing-- two says explore resources and four says find a funding source. I don't know. I see a lot of overlap between two and four.

CLIAC MEMBER: Well, I initially had a question about recommendation one, but [CLIAC MEMBER] answered it. But I would second [CLIAC MEMBER]. I had the same thought about two and four.

CLIAC MEMBER: I was just going to follow up on the LRN, which was created shortly after the anthrax attack because there was a recognition that there was no communication between clinical laboratories and the Public Health Laboratory. And I was going to put [CLIAC MEMBER] on the spot to say is that still a funded element of the CDC funding to public health laboratories, that they are supposed to connect with the regional and the private laboratories in their state? I don't know that anymore.

CLIAC MEMBER: It is still a funded element. It's still a requirement. And I think the problem with it is the metrics of how to measure that because each state has done that so differently. Having experience in two state public health labs, Massachusetts and Iowa, I see two different versions of it really up close. And parts of both are good, but other parts of failing. And those of you in other states can recognize that.

So when we got to number two, I was going to suggest that we want to explore modernizing the Laboratory Response Network so that we can have a better response system in place. The connection between clinical laboratories on that frontline and the public health lab is so critical because we cannot function without each other. And we need a good advocacy relationship that we work together.

CLIAC MEMBER: Yeah, I just wanted to make a comment in terms of the question that was posed between the relation between two and four. And I guess it may be worthwhile summarizing one, two, and four. So one, again, specifically seems to be a call out to increase those that participate in this partnership. Four, to me, is a specific recommendation to find funding to standardize and centralize public health reporting. I view two as a

recommendation for a more robust laboratory network in a operational sense so that this could be able to leverage moments in areas that have excess capacity, really more of the clinical operation laboratory network as opposed to public health reporting, which I think is the critical distinction between recommendation four.

CLIAC DFO: Yeah. I think that's a really good point that [CLIAC MEMBER] just made. And I would encourage you to try to include that language in recommendation two because I don't see it there at the moment. And honestly, I think [CLIAC MEMBERS] would agree with me. I'm not sure that the Laboratory Response Network, as it's currently constructed, does that either. And so that's a really good point. But I think it needs to be articulated a little bit more comprehensively in number two. Over.

CLIAC CHAIR: The open motion is for number one. [CLIAC MEMBER] wants to wordsmith.

CLIAC MEMBER: Yeah. I think we were saying the public private partnership task force already includes commercial laboratories. I just want to make sure we're clarifying this enough. Perhaps saying pandemic response to meet changing, what did I say, regional and community health care needs or hospital needs or something that-- because the commercial laboratories will say, well, we're in all regions. We have lab draws everywhere. But that's not really what we're talking about.

We're talking about the hospitals where people are coming to be seen. I'm OK with expanding to expand the public-private task force. I don't know that we need to say along with commercial laboratories. That's already included. But diversify and include hospital-based health care systems to prioritize pandemic response to meet changing regional and community health care needs. Something more specific like that.

CLIAC CHAIR: Thank you. So [CLIAC EXECUTIVE SECRETARY], the wordsmithing is after task force, strike along with commercial laboratories. And then to diversify and prioritize pandemic response to meet--

CLIAC MEMBER: To include. Health-- no, no. After task force. To diversify the task force to include-- I forget what I said. Health care organizations and collectively prioritize the pandemic response to meet the changing regional and community health care needs or pandemic needs or whatever we want to say there. I don't know that I have the right words. But I think we need to include-- OK. Selectively. And I don't know if selectively needs to be in there, but prioritize the pandemic response means changing regional and community health care needs.

CLIAC CHAIR: We need health care before needs.

CLIAC MEMBER: Yeah. And regional and community. We don't just want a bunch of-- I think the point here was to have a regional response network that would partner with public health, with commercial laboratories, and not necessarily a community hospital-based-- it has to be the bigger, regional health systems that incorporate and spread the umbrella to help the health care need somehow and not just saying, well, we have draw sites and couriers and pickup places, so that meets the community and regional needs. It does. Not we need on-site testing in the early days of these pandemics, for sure.

CLIAC MEMBER: And I think we need to drop pandemic because that's actually not the goal of the public-private partnership task force. It's not just pandemics. It's for any emerging critical health response.

CLIAC MEMBER: Public health emergency.

CLIAC MEMBER: Public health emergency, yeah. I think that's a better wording because it could just be localized to the eastern United States. And we still want to have that partnership respond.

CLIAC MEMBER: So you may want to be careful with the term public health emergency because that is a formal declaration.

CLIAC MEMBER: Oh, good point.

CLIAC MEMBER: Right. So maybe just emerging pathogens. Keep it more broadly so it doesn't require a declaration.

CLIAC MEMBER: Part of it, though, [CLIAC DFO] might be able to confirm that. [CLIAC DFO], didn't we put that together? It's for when there's an actual emergency declared or? I can't remember if we limited it that much.

CLIAC DFO: Yeah. I'm not sure that we limited it that much. But yeah, it'd be nice if we came up a little bit broader terminology here. Maybe just take off the word public. Would that work?

CLIAC MEMBER: How about adding coordination? To prioritize a coordination of a--

CLIAC MEMBER: So I'm going to go back and suggest something else because there's too many "toos."

CLIAC CHAIR: Right. Those are important.

CLIAC MEMBER: Yeah. So if you went back up to geographic regions, instead of to join the public-private partnership, why don't we say, to diversify the public-private partnership, and then take out to do to diversify the task force.

CLIAC MEMBER: So that the task force includes health care organizations to prioritize and coordinate the health emergency response.

CLIAC MEMBER: Would it be to diversify the public-private partnership task force by including health care organizations?

CLIAC MEMBER: Yes.

CLIAC MEMBER: And using them to-- or including health care organizations in the coordination of the blah, blah response.

CLIAC MEMBER: Health care organizations as stakeholders. I don't want them to just include us and have them tell us what we should be doing. I think we need a stake at the table.

CLIAC CHAIR: As stakeholders in prioritizing and coordinating the health emergency response to meet changing regional community health care needs.

CLIAC MEMBER: I mean, I think that's also expanding what that task force does right now because commercial laboratories don't really have a role in prioritizing or coordinating. They are just engaged and then asked to do specific roles. That creates a different focus of that group if you're asking for that. Because that is still a driven process by the CDC is the way that task force works.

CLIAC MEMBER: So I don't I don't think we have a chance of changing that then. If that's what you're saying, [CLIAC MEMBER], how would you say it? Do we say stakeholders, in helping CDC prioritize and coordinate--

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Or advising CDC. If they're the leaders, then all we're saying is commercial labs are already at the table. Health care laboratories need to be there, as well. That's really what we're saying.

CLIAC MEMBER: So the existing structure is a OK, CDC and the public health labs are starting to look like they might be overwhelmed. The next step in the process is typically to reach out to commercial labs to say, if we provide you with the reagents, can you augment our testing and help us? So they think the change there would be that conversation would now include more regional, academic, health system-type stakeholders. But it's very-- that process is really-- that's a step where they can reach out and say, can you help test? Can you deploy this assay? So that's--

CLIAC MEMBER: And we probably need testing in there somewhere to be included in the testing--

CLIAC MEMBER: Testing coordination

CLIAC MEMBER: yeah.

CLIAC MEMBER: Yeah. So I think that's really the idea, is that instead of it just going to the commercial labs now, considering it being a broader group that gets engaged earlier. Because I think from the perspective of what we saw with SARS, the engagement even in the commercial labs was a bit delayed. And that delayed everything else. So if it had been a more diverse, encompassing group, that could have been one less step of delay.

CLIAC EXECUTIVE SECRETARY: So I have a question. If you're not talking about changing the function or purpose of the task force, could that whole phrase about what the task force does be removed? You're just saying you need to include health care organizations in order to meet the regional and community health care needs. Or are you talking about expanding the role of the task force?

CLIAC MEMBER: What I heard, from some of the docs, was just getting representation and getting people on the same team because right now, it's not very--

CLIAC MEMBER: Yeah. I don't think we're in the place to tell them how to change the role of that task force, necessarily. If they're reaching out to help, then they are prioritizing and coordinating their response. The key is that they do it with commercial laboratories as well as non-commercial health care-based laboratories kind of thing.

CLIAC MEMBER: Was some of this is driven by the fact that it took so long for the laboratories to be engaged to produce LDTs and then for them to be approved and used? So if that's the case, we need to make sure that we're speaking to that point.

CLIAC MEMBER: I do think that's a whole separate issue that was clarified with the summertime announcement of CMS being in charge of LDTs. But this is related to not being in the conversation at the beginning when health care needed to be. Not having a voice to say this is going to require two to four-- if we want to preserve PPEs and ventilators, this requires a two hour response, which none of the commercial laboratories can have. So I think your point is well taken and the hospital labs do now have the authority to just

prop up an LDT and always have, I guess, but I think that yellow part could come out. We just want to be added. I think that's the point we're trying to say, right?

CLIAC MEMBER: And there is a recommendation on the table about-- it doesn't directly address LDTs and you can't see it on the screen, but it does pertain to that. So I'm sure we'll get to it later.

CLIAC MEMBER: Yeah. So I think, [CLIAC MEMBER], if this makes sense, adding more broad membership to this group would allow a first right of refusal to engage. So for instance, a highly infectious respiratory virus would localize transmission like this, those laboratories, if they had a seat at the table, probably would have said we need to test. We need to get these reagents. We need to work with you. So if Ross River virus becomes endemic in the US, it may not be some type of ELISA testing for antibodies at every hospital lab is even prepared wants to do. And they may say, you know what? It's not our gig this time. But at least they have the right to refuse. Does that make sense?

CLIAC CHAIR: So I'm going to propose a wordsmith. So I'm going to read. Does CLIAC recommend CDC-identified academic and community-based regional clinical laboratories in distinct geographic regions to diversify the public-private partnership task force comma including health care organizations as stakeholders comma to meet changing regional and community health care needs? Discussion around that?

CLIAC MEMBER: I think that gets to the point that we were trying to make.

CLIAC MEMBER: But no comma after stakeholders. I don't think you need a comma there, grammatically.

CLIAC CHAIR: OK. I'm not the grammar person, but thank you.

CLIAC MEMBER: Actually, I think you do. Well, depends on how you want to emphasize it.

CLIAC MEMBER: We should say by including, maybe.

CLIAC CHAIR: We had by there, but I thought the by was extreme.

CLIAC MEMBER: Oh, OK. Yeah. It could be parenthetical.

CLIAC MEMBER: You need a comma after stakeholders because it's a clause.

CLIAC CHAIR: OK, thank you. You're a blood banker, I can tell. Is there further discussion on this? I'm going to call the vote. Any opposed? Hearing no opposition, any abstentions? Seeing no abstentions, this motion is passed. Now I move approval recommendation two that you all want to work on. Is there a second?

CLIAC MEMBER: Yes.

CLIAC CHAIR: [CLIAC MEMBER] seconds. The floor is yours.

CLIAC MEMBER: OK. We've had so many conversations, it may have changed everything around. So one of the questions was, did some of two fit into four? And then is the real effort now on two to actually improve the current LRN? And I heard the phrase that maybe resources are needed to modernize LRN. Go ahead and call it LRN, put in parentheses that it's supposed to include I forget exactly, Lee, what you said. I'll let you say that in a minute. And then make it all focused on the LRN.

Anyway, so I will stop and just say I think now it could be just focused on modernizing the LRN, defining what it is, and that the original issue that it had in it has now been addressed in one and four. Over.

CLIAC CHAIR: Thank you. [CLIAC MEMBER], you had some more recommendations.

CLIAC MEMBER: All right. Unmuted. No, I just put in the chat recommended updates, which I don't think is inconsistent with what was just mentioned. But to kind of [INAUDIBLE] request to make it a little bit more clear, I guess, after laboratory-- so to develop a robust laboratory network that balances moments and areas of access testing capacity to meet clinical needs during a public health emergency.

CLIAC DFO: [CLIAC EXECUTIVE SECRETARY], grab [CLIAC MEMBER] text in the chat to just copy and paste it.

CLIAC CHAIR: All right. And then do we strike key attributes and everything beyond?

CLIAC MEMBER: I think so because that concentrates so much on the electronics. And if I look at this recommendation now, we're really looking at balancing capacity.

CLIAC MEMBER: And it also starts to get in to what should be done in order to achieve it, where I think the recommendation is what we want to make is a network that we can flex in a public health emergency. I think the path of how to get there is part of this study. Let the study figure out the path and the components.

CLIAC CHAIR: So can we jump even further? The original recommendation was to explore. Your update is to initiate a study. Can we take the original recommendation and say recommend CDC identify resources needed to develop a robust national laboratory blah, blah, blah.

CLIAC MEMBER: Yeah. I would defer to our government colleagues of what's the best word. I don't know if study implies a group and it's finite or exploration is more casual. What does the terminology mean at that level?

CLIAC DFO: Yeah. So if I can jump in. I'm trying to-- so the Laboratory Response Network is very specific. And it has a very specific budget and mission. And although I really like the idea of focusing on it, I'm a little bit concerned that what I'm hearing being asked for is quite well beyond the current capacity of the LRN to do. The LRN, from my point of view, and please correct me if I'm wrong, [CLIAC MEMBERS], is primarily a government-based response network.

It integrates all the public health labs as well as DOD laboratories and some USDA laboratories. And it and it standardizes their methods, platforms, so that assays can be distributed quickly and used by everybody in the exact same way. It standardizes proficiency testing. Now in addition, the LRN does have an expectation of each of the government labs to communicate and work with their clinical labs in their jurisdictions to essentially be the sentinel laboratories of the LRN. But I do think what the discussion was yesterday and what I hear [CLIAC MEMBER] asking for is almost more of this strategic level understanding of the dynamic nature of a really broad laboratory network that wasn't left limited to, primarily, the government labs, but really understood does Missouri need a whole bunch of reagents in their clinical labs right now and how do we get those reagents to them. So I guess I'll stop there.

CLIAC MEMBER: Well, I think from being in a reference lab, a portion of that pyramid, I've always thought of as the State Public Health Laboratory communicating with the sentinel labs in finding the resources for the sentinel labs to do what they needed to do. So in this pandemic, we supply all of them with the transport tubes and collection devices that they need to collect samples. And we supply the means to get them to us. So we're

communicating constantly with them and figuring out what they have in place, what are their needs, and how we can help them.

And I see it as a system for the LRN and not just the government labs, which true, very important, the standardization of equipment and testing. Very important part of it. But when you get to the frontline of the sentinel labs, they have to be in strong communication with the labs. It's up to one lab, the State Public Health Lab, in our case, communicating with all of them and making sure that all the needs are met.

CLIAC MEMBER: Can I add to this?

CLIAC MEMBER: Yeah.

CLIAC MEMBER: So that's a great conversation for everybody on the committee to hear about. And maybe back to the point. So there's a lot of things that have changed over time. But when it was created, the LRN was supposed to have had and established a communication with every clinical laboratory in the state. Everyone. And they were all supposed to know the name of the person coordinating the LRN. And if it was still working appropriately, every laboratory in the state would have received bulletins and upgrades and even reagents from the CDC stockpile through their Public Health Laboratory into those local hospital laboratories.

That's my point. And I think that's what we've now done is talked about it. It's probably out of date. It needs to be upgraded. And I think that current statement now addresses a lot of that, whereas the other issues we were talking about, I think now are addressed in four and one. I'm really glad that the issue the LRN has come up. It's probably something we should have been talking about and advocating for previously.

CLIAC CHAIR: Just want to do a quick time check. It is 11:45. We have 15 minutes left. We have not finished this motion. We have two additional motions submitted , one by [CLIAC MEMBER] from yesterday, one by [CLIAC MEMBER] today, that I don't think we're going to get to. And finally, we were supposed to be discussing future topics for CLIAC. And I'm just going to recommend please email your suggestions for future topics to CLIAC@cdc. We will not discuss them.

I would like to try to come to a resolution on recommendation number two. I think that's probably all we're going to be able to complete today. So if folks are still unhappy with it, will someone just grab that bull by the horns and suggest the wording?

CLIAC MEMBER: Yes, could I just jump in?

CLIAC CHAIR: Yes

CLIAC MEMBER: And I guess maybe I'll start by saying would the committee accept that this one be focused on the LRN, modernizing it, and distinguishing it from the other two topics? Could I get, maybe, some feeling about that? And then Mike and I could probably fix recommendation number two. If it's supposed to be related to everything else, like IT, et cetera, then that's a different direction.

CLIAC MEMBER: Yeah. My opinion is I think it is supposed to be related to everything else. And I think the second recommendation, too, is broad enough where the LRN can be in scope and part of the discussion, but it's not focused on the LRN. It allows the discussion and part of that study to be broader.

CLIAC MEMBER: And then that's fine.

CLIAC MEMBER: But then it should be mentioned--

CLIAC MEMBER: I was just going to say back to future meetings, I think would really be beneficial for this committee to hear what the LRN's job is and what it does.

CLIAC MEMBER: And I think if you go with the second recommendation that LRNs should be used as an example, because our colleagues have properly stated it is the only way that has communication channels, whether they're verbal or email or IT communications. That could be encompassed in there pretty readily. They keep the master list of all the laboratories and what they're doing.

And it includes the USDA and DOD which could be helpers. And DOD sort of was pulling reagents from hospitals for a while. To have this as part of an expanded scope of the LRN or something like that, maybe the LRN evolves to be named something different, but I think that would have been much smoother in terms of communication, specifically because CDC puts out guidelines. We've been checking three, four different websites, sitting on three or four different webinars a week.

What I said yesterday is if all of those government agencies could channel through some common network, maybe it's not the LRN but something like that, where everybody gets the blast, everybody knows what's going on from one common source, I think it would go much smoother than us checking three, four different major websites all the time looking for updates that if you register for LOCS, you get it. But everybody has to register for LRN. It's not a choice. They're already in it. And LOCS is a choice.

So maybe you make LOCS the-- maybe you make that the mandatory piece. But right now, it's not mandatory, and I think that's where the communication breaks down sometimes. Even though it's great communication, it's not mandatory, so it doesn't get to everyone who isn't living and breathing this every day like the higher subspecialty laboratories. It reaches the community members.

VALERIE NG: I'm going to jump in here. We have [CLIAC MEMBERS] lined up. But given the discussion around this, I'm hearing we might have an opportunity to ask, as a future topic, to revisit the NLRN. And from that, we could consider making recommendations surrounding the conversation. So I'm going to move to [CLIAC MEMBERS].

CLIAC MEMBER: Yeah, I'm here.

CLIAC CHAIR: OK, go.

CLIAC MEMBER: OK. I just had one minor wordsmith to change the word robust to maybe an extensive national laboratory network or a comprehensive. Robust is not necessarily the perfect word, the best word.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Number two. Recommendation number two. Develop an extensive national laboratory network or a comprehensive. Which one is your pleasure?

CLIAC CHAIR: We'll put them both in, slash extensive. And then we'll decide if we're going to vote on this.

CLIAC MEMBER: OK.

CLIAC MEMBER: I think she's talking about the second recommendation two, aren't you, [CLIAC MEMBER]?

CLIAC MEMBER: Right. Yes. Where it says explore resources needed to develop a robust, put comprehensive/extensive and take out robust.

CLIAC CHAIR: OK.

CLIAC MEMBER: Thank you. I'd like to speak in favor of recommendation number two.

CLIAC MEMBER: May I follow up?

CLIAC CHAIR: Oh, I'm sorry.

CLIAC MEMBER: OK. Can you remove the word robust? Thank you.

CLIAC CHAIR: And [CLIAC MEMBER], back to you.

CLIAC MEMBER: Thank you. Again, just like to speak in favor of recommendation number two, the updated one, the second paragraph there, the CDC initiative study. As [CLIAC MEMBER] mentioned, frankly, I'll admit in a recorded public forum that I was very woefully uninformed about the LRN. I'm in a health system and manage the chair of a large health system lab that has done a tremendous amount of testing, and I know not much at all about our public health lab in our state and didn't have much communication with them, unfortunately.

So I know they don't know much about me. And I understand, just from the website, I've learned more in the last five minutes about the LRN than I've known previously. So glad to know that. But I think that exemplifies what didn't happen during this time. And so that's why I think that the LRN could be a perfect opportunity for us to modernize, but it may not be nearly enough.

And as we know, clinical laboratories, health systems labs do 60% of the testing in this country. And we need to have a much more-- I like the word comprehensive, extensive network that's going to include everybody on this. So if modernizing the LRN is part of that, that's great. But I do think we could benefit from a study to really explore everything that's needed, not just modernizing that LRN. That's my recommendation. Thank you.

CLIAC CHAIR: So [CLIAC EXECUTIVE SECRETARY], can we remove the original recommendation two? It sounds like recommendation two update is what folks like. So that will become the recommendation two. And then I'm thinking [CLIAC MEMBER] wanted the word robust removed. Is there any opposition to that?

And then I'm thinking do we want to include the word national in front of laboratory network because that might be confused with the NLRN? Do we want to make it broad, laboratory network?

And do we want national? Because I don't want to go international, but this pandemic did not respect borders.

CLIAC DFO: Yeah. I do think that recommendation would either need a parenthetical e.g., the LRN, or it would need to explain that if you're looking for something that's different than the LRN that would exist side by side with the LRN.

CLIAC MEMBER: I kind of feel like that would just be duplicating efforts. I like adding a parent parentheses and say example, the LRN, National Laboratory Network. So before then. Extensive. Oh, yeah. Extensive laboratory network, example, the LRN, and get the national out in front of laboratory network.

CLIAC CHAIR: And next to the e.g., do we want to insert enhancing the existing national laboratory network?

CLIAC DFO: I think that would be a good addition.

CLIAC CHAIR: So enhancing the National Laboratory Response Network. Further discussion on this? That was 10 seconds I'm going to call the vote. Are there any opposed? Hearing no opposition, are there any abstentions? Hearing no abstentions, this is passed. We have five minutes left in this meeting. [CLIAC EXECUTIVE SECRETARY], if you could please scroll down to what [CLIAC MEMBER] has thrown out, and then [CLIAC MEMBER] had another recommendation around.

CLIAC MEMBER: So I think there are three more, right? There's recommendation five up top here and then two more.

CLIAC CHAIR: Oh, right. Right, right. So we are not going to get to these today. And I would suggest submitting to CLIAC@cdc.gov as topics for future meetings.

CLIAC MEMBER: OK.

CLIAC CHAIR: And [CLIAC MEMBER], I'm really sensitive to yours about the frontline categorization of laboratorians because the moment is now to try to seize that opportunity.

CLIAC MEMBER: So I don't know how procedurally this should go, but I liked what you were doing in terms of stating the recommendation, say is this something we want to wordsmith? Is it worthwhile or are we even allowed to make that determination in these remaining three recommendations, that there's something that should even be on the table or off the table? And if on the table, are we subsequently allowed to wordsmith outside of this meeting?

CLIAC CHAIR: So no, you're not allowed to wordsmith outside of the meeting. And I think in three minutes, we are not able to do these justice. So please submit as a future topic.

CLIAC MEMBER: And back on the previous conversation, should you be interested, I think it would be beneficial to have a presentation by the LRN as it stands now.

CLIAC CHAIR: So if all 24 of us write in we want a future presentation, maybe April 14, on the NLRN, maybe we'll have one.

CLIAC MEMBER: I think if you just ask [INAUDIBLE] have one.

CLIAC CHAIR: Well, I'm going to ask, but it helps to have support. OK. It is 11:57. There's no room for new business and it's at the time. Unless somebody pulls me back, it's time to adjourn. Is there a motion to adjourn? Is there a second?

CLIAC MEMBER: Second.

CLIAC CHAIR: Thank you. The meeting is adjourned. Thank you all. Very much appreciate everyone's input.