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

Meeting Transcript

April 13-14, 2022

Atlanta, Georgia (Virtual)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

April 13, 2022

❖ Call to Order and Committee Member Introductions

CLIAC DFO: Good morning, everyone. My name is Ren Salerno and I am the designated federal official for the Clinical Laboratory Improvement Advisory Committee, and welcome to our Spring 2022 meeting. The Clinical Laboratory Improvement Advisory Committee, or CLIAC, is managed by the Centers for Disease Control and Prevention, and it provides scientific and technical advice, and guidance to the Department of Health and Human Services. The advice and guidance that CLIAC provides to HHS focuses on improving clinical laboratory quality, and the practice of laboratory medicine. In addition, the committee provides advice and guidance on specific questions related to possible revision of the CLIAC standards. Because this is a Federal Advisory committee meeting, it is public. The Zoom chat and Q&A functions have been disabled for audience members, but the Zoom chat and Q&A function functions have been disabled for audience members if you're experiencing Zoom difficulties, please contact cliac@cdc.gov.

So the first thing I'd like to do today is to recognize and express appreciation to Ms. Monique Spruill, who served as the CMS ex-officio to CLIAC during the April and November 2021 meetings, and for providing the CMS updates during those meetings. And I'd like to introduce to all of you Ms. Sarah Bennett, who will now serve as the CMS ex-officio. Ms. Bennett is the acting director of CMS' Division of Clinical laboratory. improvement and Quality, or DCLIQ. And prior to becoming the acting director, she was the acting policy branch manager and a technical director in DCLIQ. We welcome Ms. Bennett to CLIAC.

I want to specifically acknowledge that medical laboratory professionals week is April 24 to 30, 2022. It is an annual celebration of medical or laboratory professionals and pathologists who play critical roles in health care and patient advocacy. During the CDC update presentation, Dr. Fitzgerald will share how our division of Laboratory Systems is recognizing the clinical laboratory community during lab week and wait till you see the incredible graphics that our communications experts have developed for the lab week.

CLIAC CHAIR: During-- Good morning, everyone. During the period dedicated to committee discussion, participation is limited to CLIAC members only. We will have an extended public comment session tomorrow on the future of laboratory medicine in nontraditional testing sites. Public comment periods will be scheduled for five minutes tomorrow. 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-- like now-- to be added to the session. All written public comments received so far are available on the CLIAC meeting website. Committee members, please note that not all submitted comments were intended to be provided orally, but we will share a summary for each written comment that is not presented tomorrow. I want to call your attention to the public comments.

We have received 11 to date, of which four will be presented orally. They are coming from PC1, the American Clinical Laboratory Association, PC2, to the American Proficiency Institute, PC3. From Dr. Joseph Sirintrapun, director of pathology informatics at Memorial Sloan-Kettering. PC4, Alejandro Johns, CEO of Virtual Scientific Incorporated. PC5, Association for Pathology Informatics. PC6, Association of Public Health Laboratories. PC7, American Society for Clinical Pathology. PC8, Jeanette Williams Smith. PC9, American College of Medical Genetics and Genomics. PC10, College of American Pathologists. And PC11, Chris Balchunas, school nurse, Sebago Elementary School.

I want to remind the group of the quorum, to remind you of the importance of remaining in attendance on both days for the full meeting and returning promptly from breaks to ensure quorum until all matters before the committee are addressed and the meeting is adjourned. Members are expected to keep video on during committee discussions.
I want to just briefly remind all of 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, voted on by CLIAC, and obtain a majority vote. A reminder that all CLIAC discussions and deliberations must be available to the public. The chat box is not available to the public for viewing, so please, CLIAC members should not engage in topic discussions offline through the chat box. So you choose the chat box only to notify me of your desire to comment during the discussions, or ask a question of the speaker. You just need to type in me, and you're in the queue.

CLIAC DFO: It is my pleasure to welcome the new members of CLIAC. I'll wait for Heather's screen to share. We have five new members joining us, Mr. Michael Black, Dr. Kimberle Chapin, Dr. James Crawford, Dr. Ewa King, Dr. David Koch, Dr. Mark Tuthill. I would ask those new members to give a full introduction of themselves during the period of time, which will be shortly, when all the members are asked to provide an extremely brief introduction and to indicate their conflicts of interests. Valerie, I'll turn it back to you.

CLIAC CHAIR: Thank you, Valerie. So it is time to do our roster check, to call on members for very brief introductions and an indication of any conflicts of interest. So, Valerie, as our chair, I will start with you. Dr. Valerie Ng.

Dr. Valerie Ng: Good morning. I'm Valerie Ng. I'm chair of laboratory medicine and pathology at Alameda Health System. My conflicts of interest, I'm a consultant to Cardex, and I'm a director, on the board of directors, for East Bay Medical group. Thank you.

CLIAC DFO: Dr. Birthale Archie.

DR. BIRTHALE ARCHIE: Good morning. I'm Dr. Birthale Archie, assistant professor in the Department of Nursing here at Bowie State University, where I facilitate with leadership, and also research. I do-- I am the co-PI on a $10 million, or $9,900,000-- close to $10 million grant from HHS, and ONC. So I wanted to disclose that. It's public health informatic technology.

CLIAC DFO: Thank you. Mr. Michael Black.

MR. MICHAEL BLACK: Yeah, thank you. Good morning to everyone. Mike Black here at Avera Health System. I'm the ADP as well as the lab service line administrator. No conflicts of interest.

CLIAC DFO: Dr. Kimberly Chapin. OK. She's not here. Dr. James Crawford.

DR. JAMES CRAWFORD: Well, I'm Jim Crawford, the chair of pathology and laboratory medicine at Northwell Health, and my conflicts of interest are that I'm the chair of the board of directors for the nonprofit Project Santa Fe Foundation, and President of a joint venture relationship with Bioreference Laboratories for the delivery of genomic testing to Northwell.

CLIAC DFO: Thank you. Miss Heather Duncan.

MS. HEATHER DUNCAN: Hi, I'm Heather Duncan. I'm the microbiology manager for Vidant Medical Center. I have no conflicts to disclose today.

CLIAC DFO: Thank you. I believe Dr. Chapin is now on the line. If you are, could you introduce yourself-- and conflicts? OK, maybe she's not able to connect. So let's move forward. Dr. Mary Edgerton?

DR. MARY EDGERTON: Hi-- excuse me. We have bad pollen here in Houston. I am Mary Edgerton. I'm a breast pathologist at the University of Texas MD Anderson Cancer Center, and a pathology informatician. I received some grant money from the NIH to work on single cell genomics of breast cancer, and from Susan Komen Foundation to work on markers of aggressive breast cancer. And I also have some volunteer roles as chair of the PERT Committee for the College of American Pathologists. I think that's it.

CLIAC DFO: Dr. Lee Hilborne.

DR. LEE HILBORNE: Hi, good morning. I'm Lee Hilborne, and I'm a senior director in medical affairs for Quest Diagnostics, and that is my conflict, in that I am both an employee and shareholder-- also professor of pathology and laboratory medicine at UCLA.

CLIAC DFO: Doctor Ewa King?

DR. EWA KING: Good morning. I'm Dr. King. I'm the director of the State Health Laboratories in Rhode Island, and also a member of the Association of Public Health Laboratories.

CLIAC DFO: Thank you. I believe Dr. David Koch is not with us today. Am I correct? Give it one second to make sure he's not here. OK. Dr. Lavinia Middleton.

DR. LAVINIA MIDDLETON: Good morning.

CLIAC DFO: Sorry-- I'm sorry, Lavinia, I've just been told that I accidentally skipped Dr. Susan Gross. Apologies.
DR. SUSAN GROSS: That's quite all right. I'm Susan Gross, and OB/GYN physician, medical geneticist. I'm the CEO and president of the ObG Project, the digital Media. education company with the mission of promoting professional guidelines and best practices to our health care colleagues, including genetics and genomics. I have no lab ownership, nor do I have any lab-related positions involving fiduciary capacity nor honoraria over the past 12 months, nor financial interests involving specific lab tests under consideration at this meeting.

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

DR. LAVINIA MIDDLETON: Good morning. I'm Lavinia Middleton. I'm a professor of pathology at MD Anderson Cancer Center. I serve on the advisory board for the AAMC CMO group recognizing diagnostic excellence, and the advisory board for the Leapfrog Group regarding diagnostic accuracy. I have no conflicts of interest.

CLIAC DFO: Thank you. Miss Carole Moss?

MS. CAROLE MOSS: Hi. Good morning, everyone. I'm Carole Moss, founder of Niles Project, and patient safety leader. I have no conflicts of interest, and I'm proud to be a part of this committee who's been really focused on doing great work.

CLIAC DFO: Thank you. Dr. Nirali Patel.

DR. NIRALI PATEL: Hi, I'm Nirali Patel. I'm laboratory director at Tempus Labs in Durham, North Carolina, and I'm on the board of directors of the Association for Molecular Pathology.

CLIAC DFO: All right. Dr. Michael Pentella.

DR. MICHAEL PENTELLA: Good morning. I'm Mike Pentella, and I'm a clinical professor here at the University of Iowa, and I'm the director of Iowa State Public Health Laboratory, the state hygienic lab. And I'm also a board member of the Association of Public Health Laboratories. I have no other conflicts.

CLIAC DFO: Thank you. Ms. Jennifer Rhamy Is Jennifer not able—

MS. JENNIFER RHAMY: I'm sorry. I was on mute. Good morning. I'm a retired specialist in blood banking. My most recent position was as director of the Regional Blood Center here in Grand Junction, Colorado. My conflict of interest is that I received honoraria for a lecture on patient blood management last year from [INAUDIBLE] as well as service on their advisory panel on patient blood management.

CLIAC DFO: Thank you. Dr. Gregory Sossaman.

DR. GREGORY SOSSAMAN: Good morning, everyone, Greg Sossaman. I'm a clinical pathologist at Ochsner Health in New Orleans, and I serve as the system chair for clinical pathology. I serve as a volunteer with a couple of pathology organizations, as a board member of ASCP and the Compass Group, and I have no financial conflicts.

CLIAC DFO: Thank you. Dr. Mark Tuthill.

DR. MARK TUTHILL: Good morning, everybody, or good afternoon, as the case may be. My name is Mark Tuthill. I'm the division head of pathology informatics at Henry Ford Health. I do not have any laboratory ownership, or financial related positions in laboratory. I do play a volunteer role for the Association of Pathology Informatics, where I am their conference coordinator and their program committee chair. I do have an unpaid position with Sunquest Information Systems on their strategic advisory board. And I have received honoraria from the API to attend the USCAP meeting as their conference coordinator this past March.

CLIAC DFO: Thank you, Mark. Heather, unfortunately, I've just lost the screen, so-- Oh, it's back. OK, thank you. Maybe it's my fault. OK, so next is Dr. Chip Watkins

DR. CHIP WATKINS: Good morning. Hey, Chip Watkins. I am a family doc, and I'm an AAFP appointee to the COLA board of directors, which is kind of the circuitous way that I got here, I think. But I am also lab director at a small lab here in Asheville, and have-- and am lender to them. Otherwise, I don't think I have any other conflict of interests, but mostly my day job is being a regional medical director for a group called Community Care of North Carolina, and we are the vendor for Medicaid in North Carolina as well as some commercial and Medicare Advantage programs. Nice to be here.

CLIAC DFO: Thank you. Dr. Donna Wolk.
DR. DONNA WOLK: Good morning. I am the division director for molecular and microbial diagnostics and development at Geisinger Health in central Pennsylvania. I'm a professor at the Geisinger Commonwealth School of Medicine, and I am a volunteer for the AAMP-- American Association of Molecular Pathology board of directors, and the subdivision chair for infectious disease. In the last three years, I have grants and/or speaking, educational funding from the ABT in collaboration with the Center for Disease Control, a grant with-- a sub-grant with the University of Maryland and the Center for Disease Control, QIAGEN, SD Biosensor, Thermo Fisher, diasorin, Safeguard, Biosciences, and Cepheid.

CLIAC DFO: Thank you. Mr. Andy Quintenz.

MR. ANDY QUINTENZ: Good morning. I'm Andy Quintenz. I lead a scientific and professional affairs group for Bio-Rad Laboratories. I am on the board of directors for Clinical Laboratories and Standards Institute, CLSI. I'm also a member of the American Association for Clinical Chemistry's corporate advisory board, and also chair the US Technical Advisory group for ISO Technical Committee Two and Two, which is on clinical laboratories and in vitro diagnostics. Thank you.

CLIAC DFO: Thank you. Dr. Collette Fitzgerald.

DR. COLLETTE FITZGERALD: Good morning, everyone. My name's Collette Fitzgerald. I'm the deputy director for science in the division of laboratory systems at CDC, and I'm the CDC ex-officio for CLIAC, and I have no conflicts of interest.

CLIAC DFO: Thank you. Ms. Sarah Bennett.

MS. SARAH BENNETT: Good morning, everyone. As Ren said, I am the acting director for the Division of Clinical Laboratory Improvement and Quality, otherwise known as CLIA, and I have no conflicts.

CLIAC DFO: Dr. Tim Stenzel.

DR. TIM STENZEL: Good morning, everyone. I direct the Office of In Vitro Diagnostics and Radiological Health at the FDA. My spouse is a family doc with Johns Hopkins, and other than those employment situations, there is no conflict of interest.

CLIAC DFO: Ms. Nancy Anderson.

MS. NANCY ANDERSON: Good morning, everybody. I am the executive secretary for CLIAC, and a senior advisor for Clinical Laboratories in the division of laboratory systems at CDC. I have no conflicts for this meeting. Thanks.

CLIAC DFO: Great. Thank you. And for completeness-- completeness again, my name is Ren Salerno. I'm the Director of the division of laboratory systems at CDC, and the designated federal official of CLIAC, and I have no conflicts of interest.

CLIAC CHAIR: And I see Kim Chapin has jumped on. So—

DR. KIM CHAPIN: Sorry, Val. Yeah, I'm sorry Val and committee. For some reason, I can only join on my phone that's not letting me throw my laptop, which has never happened. So I apologize. I'm Kim Chapin. I am the CMO at Cepheid. and I don't believe I have any conflicts of interest. So sorry for the snafu. We'll try and get some help here.

CLIAC CHAIR: Thank you, everybody. A review of the schedule and the logistics for today's meeting. Copies of the PowerPoint presentations and other meeting materials are posted on the CLIAC website, 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 that will help clue you in.

This meeting is being webcast by a Zoom webinar. We welcome everyone to this virtual meeting of CLIAC. Links for accessing the webinar are provided on the CLIAC website. If you are experiencing any difficulty with accessing Zoom-- I think, Kim, this is for you-- please email cliac@cdc.gov. The meeting is also recorded to assist with preparing and accurate written summary of the proceedings.

There will be an hour break each day. CLIAC members need to arrive online promptly to ensure quorum so that we can begin the session. Before we go into our agency updates, just a quick comment to the members. You know how I am about wanting a picture from you guys. So right before we take the first break, I'm going to want that picture. So pay attention, and then get ready, blink, and we'll have the picture.

Our meeting agenda starts with the agency updates, and we will start with updates from the CDC, CMS, and FDA. These are the online presentations number one, two, and three. Following the agency update presentations, there will be a report on the CDC's board of scientific counselors, deputy director for infectious diseases, which is the online presentation number four. We will start with the CDC update from Dr. Collette Fitzgerald, presentation number one. Take it away, Collette.

❖ Agency Updates and Committee Discussion

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

DR. COLLETTE FITZGERALD: Thank you, [CLIAC CHAIR]. Good morning, everyone. Thank you for the opportunity to share updates this morning on our work in the Division of Laboratory Systems and the Center for Surveillance Epidemiology and Laboratory Services at CDC. I'll be referring to our division as DLS for the remainder of the presentation. Today I'm going to be focusing on sharing updates on activities in five areas-- laboratory preparedness and response, health equity, laboratory quality and safety, laboratory training, and lastly, partnership communication and outreach. Next slide, please.

So starting with laboratory preparedness and response. Next slide, please.

So CDC launched the Increasing Community Access to Testing for COVID-19, or ICATT website, on February 4, 2022, to help connect consumers in under-resourced communities with free COVID-19 laboratory testing. DLS was responsible for helping create the website in collaboration with the CDC COVID-19 Expansion for Screening and Diagnostics Task Force, and the CDC's Center for Surveillance, Epidemiology, and Laboratory Services. The four current ICATT partners include CVS, eTrueNorth, Rite Aid, and Walgreens. In total, more than 16,000 pharmacy sites across the country participate in ICAT. CDC's goal this year is to expand this number to 20,000 pharmacy sites across the nation. In the coming months, the ICAT website will feature an embedded single search function that will allow users to search for available test providers across all ICATT partners. In addition, the ICATT website will be the first of DLS' websites to be made available in Spanish. You can see more on the ICAT, or COVID-19 web page at the link at the bottom of this slide, and I look forward to sharing additional updates on this website at a future CLIAC meeting. Next slide, please.

CDC communication efforts aim to educate the public about COVID-19 and how to interpret results from those tests. DLS maintains and routinely updates the public facing testing for COVID-19, and self-testing at home or anywhere web pages and sub-pages, to make sure clinical and public health laboratory professionals, as well as those who perform their own tests, or perform tests at point of care, have the most up-to-date information and resources. These pages offer information on the different types of tests, when to test, who should test, and what to do if your self-test is positive, negative, or invalid, and the importance of following the manufacturer's instructions. Users can also find videos with manufacturer's instructions for doing the rapid COVID-19 tests on the self-test web page. You can find a link to the latest updates on the self-testing, at home, or anywhere web pages on the link shown on the top of this slide. Another great at home or anywhere testing resource is the Get Free At Home COVID-19 test website, where you can request free at home COVID-19 tests at covid.gov/tests. Each home in the US is eligible to order two sets of four free at home tests. If you've already ordered your first set, you could order a second set today. DLS has also developed three short, animated videos. Two went live in October 2021-- How to Use a Self-test, and How to Interpret Self-test Results. An additional third video was just released earlier this month, When to Use a Self-test. These videos are intended for consumers who have COVID-19 symptoms, may have been exposed to somebody with COVID-19, or may be gathering with others, particularly those at high risk of severe illness. The videos explain the basics of when and how to use COVID-19 self-tests, and what to do after a self-test. The videos can be found on the CDC self-testing page, shown in the links at the bottom of this slide. We've also developed in American Sign Language, or ASL version, of the How to Interpret Self-test Results video. This went live in February 2022 and is shown on the link on the bottom of this slide. Next slide, please.

Moving now to clinical laboratory community outreach, the CDC Laboratory Outreach Communication System, or LOCS, provides timely information to facilities that perform COVID-19 testing. Topics include point-of-care testing, specimen collection, antigen testing, biosafety, laboratory data reporting, and regulatory requirements, as well as training and other resources to support emergency preparedness and response. LOCS is one of CDC's top 10 most subscribed e-newsletters, with over 104,000 recipients. Now, if you haven't opted in yet, it's easy to sign up. You can send an email to locs@cdc.gov. You've heard me speak about the Clinical Laboratory COVID-19 Response, or CLCR calls, at previous CLIAC meetings. The CLCR 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. Over 3,700 organizations have participated cumulatively on these calls since they started in mid-March 2020. Notably, 60% of all attendees work in health care or the government. We have an important upcoming schedule change for the CLCR calls. Beginning Monday, April 18, the CLCR calls will move from a biweekly schedule to a monthly schedule. Future CLCR calls will take place on the third Monday of each month and will last for one hour. We hope you'll join us for our next call on Monday, April 18. It's a full agenda for the call. Our CDC director, Dr. Walensky, will share pre-recorded opening remarks honoring laboratory professionals, and there'll be CDC updates on Medical Laboratory Professionals Week activities, and updates on immunity after infection and vaccination, and updates on SARS-CoV-2 variants, as well as an FDA update. We're grateful for your support and participation over the past two years on the CLCR calls and look forward to future calls. Next slide, please.

So, moving next to health equity. Next slide, please.

At the last CLIAC meeting in November 2021, we presented to the committee CDC's plan to address the intersection between diagnostic excellence and laboratory testing to examine how laboratory professionals can engage with their clinical counterparts to reduce the incidence of diagnostic errors. As we know, laboratory testing informs the majority of diagnoses. Our main goal is to leverage clinical and public health laboratory capabilities to reduce the incidence of diagnostic errors associated with death or serious disability by 10% from baseline for conditions most likely to be misdiagnosed among ethnic, racial, or other disproportionately affected groups. One of our strategies is to identify health conditions at higher risk for misdiagnosis associated with death and serious disability within an ethnic, racial, disproportionately affected group, that is importantly amenable to a laboratory involved intervention. We are working with CDC's Division of Heart Disease and Stroke Prevention and the Million Hearts Program to design a study to add a laboratory outreach component to the Million Hearts quality improvement, Preventing Heart Attack and Strokes Project. There remains a significant number of patients in underserved medical communities who have severe hypercholesterolemia that do not receive guideline-recommended statin therapy. The Laboratory outreach component of this project aims to add a note to the test report with linkages to educational and decision support resources useful to the clinician and patient. The details of the project will be developed collaboratively with input also from external partners, including the National Association of Community Health Centers, health center-controlled networks, and participating health centers. Next slide, please.

Limited English proficient Hispanic patients are among the 25 million patients who do not access laboratory test results in patient portals. One of the primary reasons Hispanic patients do not access test results is because many patient portals are in English only. In addition, limited English proficient patients-- sorry, patients, are often not invited or trained to use the patient portals, and have not been educated on the health benefits or reviewing laboratory test results in patient portals. Clinical laboratory professionals have an important responsibility to alleviate the barriers, and to implement interventions that decrease these discrepancies. For example, laboratory professionals can support hospital and medical staff by measuring the use of patient portals for receiving and interpreting test results and comparing that data to health outcomes. This is an important role for laboratory engagement, since studies report that reviewing laboratory test results is the primary reason most patients access patient portals. So, we're developing a manuscript that identifies gaps and challenges associated with providing linguistically appropriate test results to non-English speaking populations. We are partnering with staff from Kaiser Permanente and the University of Washington to identify barriers that prevent, discourage, or hinder the use of patient portals by limited English proficient Hispanic patients, as well as potential interventions that could address these issues, such as encouraging the use of health literacy aids in laboratory portals for understanding laboratory test results. The manuscript has been commissioned by the Journal of Applied Laboratory Medicine, and we anticipate completing it by the end of this calendar year. Next slide, please.

So moving next to laboratories, quality, and safety. Next slide, please.

So I'm pleased to be able to share that the dates are set for CDC 17th International Biosafety Symposium. CDC co-sponsors the meeting, which is held every two years, with the Eagleson Institute, and the American Biological Safety Association, for ABSA international. DLS staff co-chairs the symposium, and serve on the planning and steering committees. The 2022 CDC symposium will be held on August 27th through the 31st, and the theme of the symposium is beyond the pandemic, building on the lessons learned. The meeting will provide a series of in-depth, engaging sessions to help laboratory staff develop plans for the future that build on lessons learned from the COVID-19 pandemic. There will be multiple opportunities to interact and share ideas with colleagues from the areas of clinical care, public health, research, and animal care. Approximately 10 pre-conference courses will also be offered, with topics that include the challenges of biosafety program management, and an interactive decontamination experience where attendees will practice hands on what they've learned. The keynote speaker will be Dr. Henry Walke, the director of the CDC Center for Preparedness and Response, and former incident manager of CDC's COVID-19 response. Sessions will examine how existing preparedness plans worked, and didn't work, lessons learned from virtual laboratory inspections, and the use of virtual reality for training-- for safety training activities. Next slide, please.

The next project I'm going to share updates on is the development of a National Quality Forum, or NQF, blood culture contamination rate measure. The goal is to establish a standard for evaluating and reporting blood culture contamination rates to reduce adverse patient events, and to encourage optimal antibiotic use, and reduce the number of single set blood cultures. The project is a collaboration between DLS and CDC's Division of Health Quality Promotion, or DHQP, and it's designed to foster collaboration between hospital antibiotic stewardship committees, and a clinical microbiology laboratory in order to reduce the number of blood cultures contaminated with skin and environmental contaminants in adults over 18. The project also seeks to reduce the number of single set blood cultures received by the laboratory to improve and meet blood culture volume requirements. So why are we submitting this National Quality measure? Currently, only the College of American Pathologists, or CAP accredited laboratories have quality measures in place for blood culture contamination and blood culture volume. This National Quality measure will bring all health care institutions up to the same recommended standards of quality and safety guidelines for blood culture collection. So where are we in the process? Well, the project team formally indicated their intent to submit an application to NQF in January 2022, and the complete measure package was successfully submitted to NQF on April 5, 2022. It will now be reviewed by NQF staff

with pre-evaluation commenting in May and June, then there will be standing committee review in July and August. The consensus standards approval committee meeting will be in November through December 2022, and we look forward to sharing additional updates on this project at future CLIAC meetings. Next slide, please.

DLS will be hosting a town hall on instrument safety and biosafety for instrument manufacturers and other stakeholders. The town hall will be held virtually on June 24, 2022. The town hall will include discussion on instrument design and safety to address biosafety gaps that were identified in a clinical laboratory biosafety gaps manuscript that was published in June 2021 in Clinical Microbiology Reviews. You may remember that I mentioned this publication at the last CLIAC meeting. DLS' is Dr. Nancy Cornish was the lead author on this publication. The town hall will include speakers who represent instrument manufacturers, clinical and public health laboratory professionals, and industrial hygienists. Topics that will be covered include FDA pre-market review for biosafety of instruments, biosafety design, and operator safety. The town hall will be open to the public, and a federal registry notice will be going out soon. Next slide, please.

The CDC and the Association for Public Health Laboratories, or APHL, and state and local public health laboratory partners, are collaborating to harmonize quality standards for next generation sequencing across public health, and to provide laboratories with confidence in reporting results. The NGS quality initiative is moving forward a coordinated and comprehensive plan to develop and implement an NGS-focused quality management system to ensure high quality, reliable data for nationwide disease surveillance systems, diagnostic or reference laboratory testing, and other public health actions that improve patient care and public health outcomes. The initiative helps laboratories that perform NGS to meet multiple requirements, including CLIA as a prerequisite for use of this transformative technology in NGS based diagnostic and surveillance activities. The NGS quality initiative is working to create the toolkit of resources that NGS testing sites can use as a starting point to prevent duplication of efforts, increase efficiencies, and save costs. Completed resources are all freely available and posted on the project website listed on the bottom of this slide. Next slide, please.
So the NGS Focused Quality Management System is based on the Clinical and Laboratory Standards Institute, or CLSI's framework of 12 quality system essentials, or QSEs. Since 2019, the initiative has published over 85 tools and resources to our web page, including resources for wet and dry bench personnel, and for leadership. With over 25 additional products in development, the NGS Focus QMS should be completed by the end of calendar year 2022. Once completed, this NGS QMS can act as a starting foundational quality system, which can be used to supplement and integrate into any laboratories existing quality system. As we have engaged and continue to engage with the public health laboratory NGS community regarding the benefits of a strong quality foundation, we want to understand the needs and remain cognizant of how the initiative's products are being used and implemented and can be of value also to the clinical laboratory community. Based on the successes of the initiative, the CDC's Office of Advanced Molecular Detection provided new funding for the next five years of this project. The new project is titled Expansion of the Next Generation Quality Initiative to increase NGS asset quality, and coordination of NGS activities across laboratory settings. Continued partnership within CDC, as well as with the Association of Public Health Laboratories, and state and local public health partners, as well as other quality-focused groups will continue to be important. This new project will support CDC, as well as state and local public health labs, to address quality related challenges for the continual development and maintenance of an NGS focused QMS that addresses persistent and emerging challenges, and to support implementation of the NGS Quality Initiative QMS with a focus on tools to assist with validation. At the conclusion of this new five-year project, the NGS Quality Initiative will generate an adaptive QMS that supports NGS workflows from onboarding, to validation, to accreditation, and is agnostic to sequencing platform, or pathogen. Next slide, please.

So moving next to laboratory training. Our OneLab Initiative to bridge, train, and sustain a capacity building community among US laboratory professionals continues to grow and expand. The OneLab Network brings together clinical and public health laboratory professionals for monthly live trainings and collaboration. As of March 31, we have over 2,300 members in the network. Since the last CLIAC meeting, we have started to develop new training resources tailored to testers at non-traditional and point-of-care sites. On March 31, 2022, we held a live training on the basics of waived point-of-care testing. A transcript and slides from that webinar as well as links to all OneLab training resources are available on the OneLab home page, shown here on the link in this slide. In the coming months, we will develop a training of trainers program for testers which will prepare personnel at wave point-of-care testing sites to train each other on the basics of safety, quality control, and risk assessment. Over the long term, we plan to create a community of practice, specifically for testers at nontraditional sites. Next slide, please.

So, what's up next for OneLab? Well, they have their inaugural one lab summit that will be held next week-- that's April 19 to the 21st, 2022. This will be a three-day virtual conference to connect live work to professionals to each other and to CDC. This year's theme is elevating connections, and building bridges in adversity. Speakers include Dr. Leslie Dauphin, Dr. Salerno from CDC, Dr. Hassan Aziz from the American Society for Clinical Laboratory Science, for ASCLS, Dr. Elsie Yu from the Geisinger Health System, Dr. Susan Harrington from the American Society for Clinical Pathology, or ASCP, Dr. Anthony Tran from the FDA San Francisco Laboratory, Dr. Linda Phifer from the University of Tennessee Health Science Center, Dr. Bryan Jackson from ARUP, Dr. James Crawford from Northwell Health, and many more.
So, in addition to speakers from across the laboratory community and sessions on training best practices that will be facilitated by Dallas health education specialists, this summit will also include a sneak peek of OneLab REACH. This is

CDC's new learning management system, which is customized to the needs of laboratory professionals and their organizations. REACH stands for Rapid Education and Capacity Building Hub. OneLab REACH will be a one-stop shop for all free CDC laboratory trainings. The target launch for one lab reach is early May 2022. Registration for the OneLab summit is free at the link shown here on this slide, and there's still time to sign up. On the same web page, you can find more information on how to join the OneLab network. In addition to updates on monthly live training events, network members will receive an email notification as soon as OneLab REACH Learning Management System officially launches online. Next slide, please.

So moving lastly to partnerships, communication, and outreach. Next slide, please. In March 2022, the Association of Public Health Laboratories published an APHL blog that features a Q&A style interview with our DLS director Dr. Ren Salerno. In the post, Dr. Salerno reflects on how public health laboratories adapted to meet the challenges they encountered in 2021, and shares how DLS accomplishments support the work of our clinical laboratory partners. Dr. Salerno also reflects on lessons learned throughout the pandemic, and elaborates on our DLS goals and plans for 2022. Next slide, please.

So as Dr. Salerno mentioned in his opening remarks, the week of April 24 through the 30th, 2022, marks the 47th annual Medical Laboratory Professionals Week, also known as lab week. In DLS, we observe lab week every year to honor the work of clinical laboratory professionals for their essential-- and too often overlooked-- contribution to public health and patient care. This year, DLS selects giving the gift of health as our lab week theme. We celebrate diversity among clinical laboratory professionals who give the gift of health by improving public health and patient care, driving innovation, and fostering health equity. We also recognize the generosity and service of clinical laboratory professionals, whose devotion and expertise strengthen public health laboratory-- public health and patient care by ensuring accurate, reliable, and timely results. Please join DLS in celebrating clinical laboratory professionals during lab week 2022 by using, adapting, and sharing resources we have created in the laboratory professionals digital toolkit, which you can access in the link on this slide. DLS is especially excited about our digital graphics that are found within the digital toolkit, and that you can see here on the left hand side on this slide, which showcases the creativity and authenticity of public art. Content in the toolkit can be used to increase public awareness of the amazing and important contributions of clinical laboratory professionals. We encourage you to show your support by sharing or adapting the sample social media messages and digital graphics across your network, using the lab week hashtags in your social media messages. You can download a Zoom or Teams background to showcase at a meeting, or share a newsletter bullet, or stakeholder email with your partners and community. Next slide, please.

And lastly, I'm just going to finish by taking the time to thank our partners, and all of the clinical laboratory community, for your hard work, collaboration, and support. I'd also like to acknowledge the expertise, dedication, and hard work of my many colleagues from DLS whose work I've highlighted here this morning-- work that advances our division center and agency's mission, so thank you.

CLIAC CHAIR: Thank you, Dr. Fitzgerald. That is just so amazing, all of these accomplishments. We have time for a few questions. I believe [CLIAC MEMBER] is first.

CLIAC MEMBER: Yes, thank you, and I echo your comments about what an amazing amount of work the CDC has done, what a great job. I had two questions. One is on the instrumentation, quality, and safety forum that you all are having. Will that include point-of-care testing as well as moderate and high complexity instrumentation? And then I'll go ahead and ask my second question, because it kind of rolls in. OneLab sounds like an amazing program, and I love the concept of a trainer-- a train the trainer at each site. I'm assuming that you've reached out to everyone with a certificate of waiver, so that you reach everybody. And then my question is, is there any way to make that more than a general encouragement?

DR. COLLETTE FITZGERALD: [CHUCKLING] Those are all terrific questions. For your first question, [CLIAC DFO], I'm not sure if you know the answer to the first one. I'm not sure if point-of-care is included, but I can certainly find out if that's the case. And for your second question, yes, absolutely, outreach to the end users is what will be critically important for the resources that are being developed. We absolutely can coordinate with our colleagues at CMS to think through how we can make sure we reach our waived partners that we know about.

CLIAC CHAIR: OK. [CLIAC MEMBER], and then [CLIAC MEMBER].

CLIAC MEMBER: Thank you, [CLIAC CHAIR]. Thank you for the excellent presentation, Dr. Fitzgerald. I really enjoyed it. I had two points I wanted to make, and to have you address. In the pharmacies who are now doing a lot of point-of-care testing for COVID-19, has there been anything done to address biosafety considerations? And then my second question is, will CMS inspectors be part of the NGS Quality Initiative, so that they know what to look for when they perform the inspections? Thank you.

DR. COLLETTE FITZGERALD: So maybe I'll take your second question first. So we are in discussions with our colleagues at CMS to share all of our resources for the NGS, and then to think about what coordination will look like partnering with them, or the surveyors. So I think there's more to come in that area, but certainly there's opportunity there for us to do that. Can you just mention your first question again? I'm sorry, [CLIAC MEMBER].

CLIAC MEMBER: Well, I was thinking about the pharmacies doing a lot of COVID-19 testing, and was wondering if anything's been done to address biosafety issues in those facilities, so they have a better understanding of what they need to have in place.

DR. COLLETTE FITZGERALD: Yeah. I might say if [CLIAC DFO] might take that one.

CLIAC DFO: Sure. For the pharmacies that are contracted with the ICATT program that Collette mentioned at the beginning of her presentation, we've done a tremendous amount of outreach with those pharmacies and those companies on all things testing, including biosafety. I think your general point, though, [CLIAC MEMBER], is spot on, and there's no doubt that we need to do more outreach, more engagement with our pharmacy partners, and frankly, in my opinion, with the waived testing community in general around biosafety, as well as testing quality. So it's a work in progress, but we definitely have that on our list of priorities, so thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, just following, I guess, up on [CLIAC MEMBER] comment, I hope that you all can include the point-of-care testing, because as a medical director of a network that's like 3,600 providers in the state of North Carolina, the vast majority of those folks are really looking at point-of-care testing. As a matter of fact, early on in the pandemic, I tried to keep up with all the point-of-care tests that were coming out, and trying to keep them apprised of what was going on, as well as quality of some of their standardization techniques that varied tremendously. But it's-- most primary care offices in particular are waived, and moderate complexity is fairly rare, certainly in more rural areas. So I would just encourage y'all to include the smaller practices there. Thanks.

CLIAC CHAIR: So you all are jumpstarting this next session, you know. So focus on the updates now, and then line those questions up. We have-- we're a little bit ahead of schedule, seven minutes. If there are no further questions for Dr. Fitzgerald, thank you again. And [CLIAC MEMBER], we're going to start with you. Our next update will be from CMS from Ms. Sarah Bennett. It is presentation number two on the website.

Centers for Medicare & Medicaid Services (CMS) Update
Sarah Bennett, MT(ASCP), CMS EX OFFICIO

SARAH BENNETT: Thank you, [CLIAC CHAIR]. As [CLIAC DFO] said earlier, I am Sarah Bennett, and I'm the acting director of the Division of Clinical Laboratory Improvement and Quality, which is really a mouthful for saying CLIA. People are actually more familiar with CLIA than DCLIQ, so those-- for us, those two terms are interchangeable. Next slide, please.

This is a disclaimer that we put on all of ours. I will certainly let you read this at your leisure, but basically what it says is that this presentation is for informational purposes only. Next slide, please.

So what I'm going to cover today in my presentation is we're going to talk a little bit about the CLIA division organization. There have been-- we get a lot of questions on what our organizational structure looks like now since we went through a major reorganization in 2019. I'm going to talk about some of our priorities, how we're using some statistics, which I think you will find very interesting, that we're going to let you know that we've compiled during the pandemic. I'm going to talk about some of the flexibilities and enforcement discussions that CLIA has afforded during the pandemic. There's some additional updates, and then we've put out some specific guidance and tools for consumers, and for the laboratory community, and the oversight bodies to help clarify information during the pandemic. Next slide, please.

So this is really what our organization looks like now. We used to be-- and I'm sure you guys are familiar with the term central office and regional offices. Back in 2019, we were-- those two entities were combined into one division, and this is what our division looks like. We have a director, we have two policy branches-- policy A and policy B. Those are located at CMS Baltimore, and that's what used to be known as central office. We have three operations branch-- Southern, Northeastern, and Midwestern, and Western, and Central. These are all of the CMS-- they're now called CMS locations, they used to be called regional offices-- are now consolidated into three branches, and we all fall under the same umbrella. So we are all one big happy family. Next slide, please.

So now I'll switch to talking a little bit about our priorities. Two of our biggest priorities right now are survey consistency and stakeholder engagement. It's very important for us, as well as for the laboratory community, the state agencies, and

the accreditation organizations that we are consistent in our messaging, consistent in our interpretation of regulations and policies. So we really are working on looking at-- since the reorganization-- we're really looking at where we might identify gaps in our consistency for surveying, so that we can identify those and try to increase consistency across the nation in our survey process, and our interpretation of regulations and policies. We have collaborated with various stakeholders, the state agencies, the accreditation organizations, and the exempt states, as well as our partners in the CLIA program, the CDC, and the FDA. The way that we're going to be kind of collaborating to help with survey consistency is included in the next major-- next priority that we have in stakeholder engagement. We are looking to increase our outreach activities with external stakeholders as well. One of the ways that we do that is CLIAC, and we are looking into other ways that we can actually reach out into the laboratory community. I will tell you we participated with the CDC on the CLCR calls that [CDC EX OFFICIO] was talking about. And we've done a fair amount of outreach with different groups that the CDC has been working with throughout the pandemic, presenting information about CLIA to them, because it's really important to us, in order to get engagement from the stakeholders, we really need the stakeholders to understand what CLIA does, and-- what CLIA does, what CLIA can't do, and make sure that they understand so that they can give us feedback. It's really helpful to us to move the program forward. Let's see. Oh, the other thing I wanted to say with regards to stakeholder engagement. We are also working with our data system to try to use data to help us inform policy decisions and regulations. We are really kind of focused on our data system and improving our data system as much as we can. So next slide, please.

This just summarizes the previous slide where all of the accreditation organization exempt states, the laboratory community, the state agencies, and all of our partners are all in continuous motion, and continuously involved with one another in order to help make the CLIA program move forward in a consistent manner. Next slide, please.

We're going to now segue a little bit into current statistics. The first slide here is a table of the actual numbers, and the next slide, when we get to it, it's more visual, and a pie chart. So currently, as of January 2022, we have 323,000 laboratories that are CLIA certified. As you can see, this is quite an increase from before the pandemic, which we'll talk about in a little bit later slide, and the majority of these laboratories are certificate of waiver laboratories. 240-- at least 246,000 of those, 323,000 are certificate of waiver laboratories, and that is the group of certificates that we see increasing the sharpest. The certificate of compliance accreditation and PPM, they hold pretty steady, kind of up and down across the years, but the certificate of waiver is really where the explosion of certificates has been. Next slide, please.

This is just the same information on the previous slide. It's just-- I'm a very visual person, so for me, something like this is much more of a wow factor to show exactly how many certificate of waiver laboratories we have. 79% of all the CLIA certified laboratories are certificate of waiver laboratories. And as you know, certificate of waiver laboratories are not routinely surveyed, nor do they have personnel requirements for either the director or the testing personnel. Next slide, please.

So now what I'd like to talk to you a little bit is our enrollment since March 2020. Since the beginning of the pandemic, the number of CLIA certificates that we have has gone up over 60,000 certificates from two years ago. And the majority of those, as you can see, are certificate of waiver laboratories. Over 57,000 of those 62,000 are certificate of waiver laboratories. And the most common of those new types of certificates are in physician office laboratories, pharmacies, assisted living facilities, long-term care, and home health care facility types. And a lot-- as you know, a lot of these facility types-- especially the pharmacies, the assisted living, the long-term care, and the home health-- were very much targeted during the pandemic to be able to increase the access to testing. So that's one of the reasons why you see a lot of these types in the numbers that have gone up so rapidly during the pandemic. Next slide, please.

I'm sure a lot of you are very familiar with the flexibilities that we have allowed during the public health emergency. All of them you can find at the link on the bottom of the page, the CMS emergencies page, but I just wanted to talk about a couple of them. Certainly, the top two are the ones we get the most questions about-- the remote review of clinical laboratory data results and pathology slides. We have allowed for enforcement discretion that the data, the results, and the slides can be reviewed at a remote site without needing to have a CLIA certification. And the reason why we had to do it enforcement discretion rather than just flexibility was because of the fact of the way that our statute and regulations are written about where cytology slides can be read. But the next one that I want to talk a little bit about is expedited review of CLIA applications. When we first allowed for this flexibility, what we were doing was any laboratory that was a certificate of waiver laboratory performing COVID testing, they applied to perform COVID testing, they would send in their application, we would generate the CLIA number, and let them know what the CLIA number was so that they could begin testing. And once it became very aware-- very clear that we needed to have even more access to testing rapidly, this was expanded to certificate of waiver laboratories that are applying to do COVID testing could simply submit their application and begin testing. They didn't necessarily have to have a CLIA number to start testing. Although they did have to have a CLIA number to bill, in order to start testing, they were allowed to do that. The pooled sample testing, what we've-- the FAQ that we released related to this-- it's tied to the surveillance testing as well-- is that as long as the laboratory was not in a pooled sample, whether it was negative or positive, as long as the laboratory-- or who was performing the testing-- did not give patient specific results to patients, then we would not require CLIA certification. So if you had a negative pool,

and everybody was negative in the pool, you couldn't tell all the patients in the pool that the test was negative. And that if the pooling result was inconclusive or positive, those individuals could not be told that they were at a positive or inconclusive pool, but had instead had to be referred to a CLIA certified laboratory for testing. With regard to expired reagents, while we currently have a regulatory, or a policy, that you can use expired reagents under certain conditions, we allowed more flexibility here that as long as there were certain criteria met, expired reagents could be used as long as when in date reagents were available that you no longer used expired reagents, and that all of the quality control was acceptable for the runs using those types of reagents. Next slide, please.

I'm not going to talk too much about this slide, because I think we're going to get an update later from the CDC, but currently we're involved with three CLIAC work groups-- the regulatory assessment work group, which is addressing the total testing process. There's a certificate of waiver PPM work group, and NGS work group. So next slide, please.

I did want to let you all know that we have published two notices in the Federal Register. The first we published in January of this year. As you all know, we published a proposed rule for proficiency testing back in 2019. Needless to say, moving-- movement on this was a bit stymied by the pandemic, but we wanted to be able to publish that final rule if we were able, and we were not going to be able to meet the deadline by which it had to be published, because all final rules have to be published within three years of the publication date of the proposed rules. So in order to be able to move forward, we published this extension so that would give us some time to be able to work that out. The other thing I'm really pleased to announce, that in March of 2020 we published a notice adding the specialty of pathology and COLA. This was a joint effort between COLA and CMS to get this moving forward, and we are very pleased that we were able to approve COLA for the specialty of pathology. Just for your information, if you want to know about what rules are coming up, you can go to the unified agenda, and the website is right here at the bottom. You can enter your words in for a search, and try to look for any rules. And when we say rules, we mean regulations. Whether they be proposed rules, or requests for information, or final rules, you can go to this website, and search, and see if something is coming up soon, or when it's coming up. Next slide, please.

All right. Now I'm going to shift just a little bit about this CLIA SARS-CoV-2 test result reporting requirement. I know this is very near and dear to everyone's heart. So I just wanted to provide a little bit of clarification for you on where we are here at CLIA. We are only assessing if a laboratory has reported or attempted to report test results. If there's a particular entity, or a facility that has something on their website that says you don't have to report certain test results, or that you have an email, laboratories do not have to continue to attempt results-- to attempt to report results they've been told that they don't need to report as long as they have that documentation, and when the surveyor gets there, they can show that documentation to them. In other words, if you run tests on Monday, and you attempt to report, and the health department says, don't report these, and you have an email or something like that, that's sufficient. And the next day, when you run tests, you don't have to attempt to report the negatives. You've already been notified by the where you're reporting that you don't have to. So as long as they have the documentation, they are good to go. Compliance with HHS secretary's guidance and the CDC guidance does not fall under CLIA oversight. So we have to-- in CLIA, we have to survey to and hold our laboratories to CLIA requirements, which is why we have put the reporting requirements in our regulations. I did want to let you know that this CLIA surveyor guidance is being updated to align with the effective date of the April 4 HHS secretary's guidance, but at this point it is in clearance, and we will let everyone know when it is issued. There will be an official memo that comes out with the updated guidance. Well, next slide, please.

OK, I wanted to talk a little bit about the COVID-19 inquiries that we release here in CMS. We have a team that triages and response to all the COVID-19 inquiries that we receive, and we received them from many different places. The CDC is very good at forwarding those emails that they get through their mailbox to us so that we can respond through our mailbox. Since January of 2020, we received over 4,900 inquiries. The top two areas that we hear, that we receive questions on, are CLIA applicability and applications. This is very broad, and can include many things, like do I need to have a CLIA certificate because I'm doing COVID testing. I need to make this modification to this test, so does that require me to get a different CLIA certificate? All the way down to, I want to perform, and here's my application. Or where do I turn-- where do I send my application so I can start? The second most common inquiries we get are about travel. I need to have a COVID test done within 24 to 48 hours of traveling. Where can I go? So we direct them. We have actually-- it's a very long email, if you've ever received this email, because we actually have done screenshots of how to work your way through the CLIA lab demographic work-- look up to try to find a lab in the state that you are located in. So it's really quite amazing, and I have actually been very surprised by the number of people who have been traveling for the last two years. I know I haven't, but it's really quite amazing how many people are traveling. And one of the interesting things that we've put in here when this first started was, people were inquiring they needed a copy of the certificate in order to prove that it was a CLIA certified lab. So what we've done in conjunction-- [CLEARING THROAT] excuse me-- in working with the State Department is we have language in our response that specifically says that anyone that you can find on this list is certified by the government to perform testing under CLIA. So-- because we just have no mechanism to provide a CLIA certificate, and where we don't have really a mechanism that we have to sign an attestation statement. So this statement that we have in this response helps to cover that, both of those issues. And this is a small but mighty team, and I will tell

you that our average turnaround time for all of these 4,900 inquiries is 24 to 48 hours. So I will tell you I think it's really quite impressive, the work that this team does. Next slide, please.

I wanted to talk a little bit about survey prioritization, because we do get this question a lot. We have just released, at end of March, a couple of weeks ago, a survey prioritization memo that talks about resuming full CLIA activity as states state requirements allow, and we have prioritized activities, such as complaint surveys, that might have immediate jeopardy in the allegation. We are resuming validation surveys as well. We are resuming all of our enforcement actions, and our proficiency tests testing desk review. That is done by the state agencies. Due to the pandemic, we do have a certain amount of backlog, and we're going to continue to evaluate the need to extend expiration date of certificates on a case-by-case basis. We look at that data each month, and try to determine who has to be extended in order to allow them to not panic about the expiration date of their CLIA certificate. Next slide, please.

Now I want to switch a little bit to some of the tools that we've put out there for the public to use. I'm going to talk first about our policy memo, The Guidance for Temporary Testing Sites Under the Multiple Site Exception. One of the reasons why we did this memo is because, as you know, we have many, many pop up sites that are performing COVID testing. While pop up is not a CLIA term for CLIA with their temporary testing sites, but certainly pop up is an easier concept to understand that temporary testing site. So this memo does several things. It clarifies the notification requirements by laboratories for temporary testing sites. They must notify CMS-- any laboratory must notify CMS of all of the temporary testing sites that are being operated under that main CLIA number. Our surveyors can ask the laboratory to provide that list at any time, and it needs to be provided. The other thing that it clarifies is that, when surveyors go out to do complaint surveys on these temporary testing sites, that temporary testing site needs to be able to provide to the surveyor the number of-- the CLIA number under which they're operating. Many of these sites do not know the CLIA number that they're operating under, so that is something that this memo is trying to help mitigate and make laboratories understand that they have to be able to provide that information for us. The other thing-- the last thing that this memo does is it clarifies the difference between the enforcement discretion for remote review of slides, and data, and those types of things versus the regulatory exceptions for temporary testing sites. The temporary testing sites fall under a regulatory provision that we already have allowing for that. We cannot-- our regulations do not specify how many temporary testing sites a laboratory can have, so we cannot mandate a number that they can have. That versus the-- and I talked a little bit about it earlier-- the enforcement discretion related to the remote review. One we had to give enforcement discretion for, the other we already have the regulatory provisions for, and they are separate and distinct. The consumer complaints FAQ and the temporary COVID-19 testing site infographic, I'm going to talk about in just a little bit more detail in the next couple of slides. These two publications were developed specifically with consumers in mind to address complaints and the pop up sites. So if you could go to the next slide, please.

We'll talk about the consumer complaint. OK. So the consumer complaint FAQ includes all of these questions for the consumers. First of all, what is CLIA? They need to understand what CLIA is. What do-- what would be a complaint under CLIA? What does that look like? How do I file it, and where do I file it? And then, how much information do I need to give when I file a complaint, and can I remain anonymous if I want to remain anonymous? And then, to close the loop with the complainants, because one of our requirements is we have to close the loop with complainants and let them know the resolution of the complaint-- what happens after they file a complaint, what will they hear from CMS? And then where can they find additional information about CLIA? The next slide is just-- next slide, please.

This is just actually what it looks like. It's very-- it's written in very plain language, easy for the consumer to understand. The link for both of the next two is in the previous slide. There were just-- I would have had too many linked slides at the end if I had to include all of the links that I have in the presentation here, so I, like [CDC Ex Officio], included them throughout the presentation. And I promise, I did check that they were live and would work, so hopefully that is true. So this is not the entire document. It's just kind of the top, to give you an idea of what it actually looks like. Next slide, please.

The temporary COVID-19 testing site infographic. This is really-- it's a one-pager that provides consumer information about laboratory quality and safety, and how to ensure that. It talks about what consumers should look for when they're out getting testing at a COVID testing site. I'm sure, as you all have driven around, you've seen all kinds of interesting looking COVID sites, you've heard about a lot of interesting COVID sites, and things going on. There have been a lot of them in the news. So this was another document that we issued to kind of help the public understand. They should be very careful about giving personal, medical, or financial information to laboratories, and to contact tracers. There's been a lot of preported contact tracers who are getting this information, and then using it for fraudulent purposes, because they're not really contact tracers. What should the personnel look like when they're collecting and running their tests? So do they have gloves, on do they have a mask on? We give them information about how to file a complaint. And then some information related to fraud-- a contact information. If they think something looks kind of funny and they're concerned about it, they can report that to the contact information that is put in here. And this document is actually a result of a collaboration of several areas in CMS that included CLIA. So it's not just a CLIA document, it's a document that includes multiple types of information. Next slide, please.

And again, this is-- back one. There you go. And again, this is just a screenshot. It's not the whole thing. But you can see, it's really set up in a bulleted format, so it's easy to read it in plain language. So if you guys get a chance, go and look at some of these products. They really, I think, are very well done. Next slide, please.

We also, as many of you know, of the-- the two biggest areas that we've had an increase in the number of CLIA certificates are in schools, and kind of non-traditional laboratory facilities that might not-- like workplace, workplace testing. So we have created quick start guides to help these specific facility types to fill out their CLIA application. I've only got the quick start guide here for schools, but we also have a workplace one that we've put out. And basically, the yellow highlighted sections are the required fields that must be filled in to generate a CLIA number. And so, when we get these types of applications, as long as they have all of the yellow highlighted information filled in, we're able to generate that number and get it to the facility. Next slide, please.

We also have-- and we have the same thing for a workplace, how to get certification for school testing, and also workplace place testing. And this is just a screenshot. It's a one-pager that's supposed to be very helpful. Next slide, please.

I know we've talked about this before, but I wanted to put it back up in this slide deck so you all continue to be aware that we do have a Listserv where we do send out messages to anyone that is enrolled. We can't respond in the Listserv, but we do push out notifications and announcements via the Listserv. Next slide, please.

Contact information. This is our telephone number in CMS Baltimore. We do have a mailbox where individuals can email questions to anything related to CLIA, and it's the Lab Excellence mailbox. I also wanted to let you know this is my email address, if you happen to need to contact me. And then next slide, please.

And this is just some additional resource information. It's the CLIA website. I had the Emergencies page on an earlier slide, but this is basically where all of our FAQs-- you can find all of our FAQs during the pandemic that we have. And you want to go to the laboratory section. We have some frequently asked questions during the pandemic. And then, this is a link to the secretary's guidance that was updated on March the 8th and was effective April the 4th. And like I said, we are getting our guidance through clearance, and we hope to have that out soon. So that-- in all of our memos that we publish in CLIA our publicly available. They are public facing. I can get those two links and send them to you, Heather, if you want, but you can search through that website and find any memos that we've put out as well. I thought of that after I'd turned in our slide deck, so-- and I think that's it for me. Thanks, everyone, for listening, and I would like to say the same thank you to all of our partners who, especially during this pandemic, we've really-- while we worked very closely before, I think the pandemic has really brought home the fact that we work well, and we work closely with all of our partners, and we're talking to state agencies, our AOs, our ESs-- hopefully I won't leave anybody out-- the CDC, and the FDA, and the laboratory community. We couldn't do it without everybody helping us, so we really appreciate that. So thank you.

CLIAC CHAIR: Thank you, Sarah. We're all lined up in the door trying to get to ask you questions, and we only have four minutes. So [CLIAC MEMBER], you're first out of the gate.

CLIAC MEMBER: OK, thanks. Sorry, I'm last to join, but first to ask a question. [CHUCKLING] So Sarah, that was great. I can't believe, 60,000 waiver labs added. Amazing. So kudos to your team, and everyone else who helped with that. That's great. So I have a question. How long does it typically take to get a waiver-- or certificate of waiver? That's one. And then all those 60,000 sites, do you think they will continue as laboratory sites, or were there really just special circumstances for doing COVID testing? I'm just wondering where that might move, or if they may actually, especially, say, in schools, try and do some of this other stuff they might need to do. So just your thoughts on that. Thanks.

MS. SARAH BENNETT: Sure. So in order to get a CLIA certificate, it's dependent upon how complete the application is when it's received by the state. Currently under the pandemic, they can begin testing without waiting for it, but the state still has to review all of the applications to make sure that they're complete, so it all depends. If there's anything missing, then the ball is in the court of the laboratory to provide that information. So typically, I would say 30 days. But again, it's all dependent on the completion. With regard to the 60,000 laboratories, that's a great question. We don't know the answer to that question. We suspect that those that were just doing COVID testing, when that need is no longer there, they may not. But then they may discover that they want to continue testing. We don't know. Also, with regards to schools, there were many schools who were performing all types of testing, like glucose, strep tests, those types of things prior to the pandemic. The need for schools with regard to the pandemic was for all of the COVID testing, then who was-- that was being performed in the-- especially those schools that weren't doing any types of testing before, because those schools that already had a certificate of waiver, they simply could add the code and testing to their test menu.

CLIAC MEMBER: Thanks so much. Think that some of the places at sites that really needed some of the stuff in place is great. So thank you.

CLIAC CHAIR: I will ask only one of my three questions. I'll ask you the others separately. Sarah, I'm curious about the CMS memo about using expired supplies and reagents. We continue to have supply chain issues. That memo, as I read it, was specific for SARS-CoV-2 testing. Others have interpreted that memo to apply to other laboratory tests that are not SARS-CoV-2. So my question to you was, did this memo cover only SARS-CoV-2 testing?

MS. SARAH BENNETT: I think the original intent was for SARS-CoV-2 testing, because at the point that it was written, it was a supply chain issue for that-- swabs, and transport media. I think for us, that we need to be reasonable and flexible. I know there's been like a blue top issue for coag testing. So I think, depending on what the actual situation is, we look at that on a case by case basis. But I think, especially during the pandemic, we need to be flexible.

CLIAC CHAIR: Thank you. And then [CLIAC MEMBER], one last question.

CLIAC MEMBER: Thank you. And thank you for an excellent presentation. I really learned a lot from it, Sarah, and also I'm really convinced that CLIA-- all that CLIA has done has been very helpful during this pandemic, and we really appreciate it. My question is, has CLIA considered an online self-evaluation for these sites who are not likely to ever see an inspection? I think it would be worthwhile for them to make sure themselves and verify that everything is in place. I used your complaint process on three different occasions, because I learned of pop-up sites, and I have to admit it worked very well, and you had very good response and in each instance. But I'm still worried that sites aren't following all of the standards, and that will have a negative impact on quality. So have you considered the self-evaluation?

MS. SARAH BENNETT: I don't think that's something that we have looked at this point. I think it's a good suggestion. I will say that the CDC has a wonderful product-- Ready? Set? Test! And they have a lot of training, and we do send these laboratories to the CDC website to look at those trainings and utilize those booklets that the CDC has on their website. We worked with the CDC on that Ready? Set? Test! book, but it's a great resource for these laboratories, and we do point them to that at any opportunity. I'm sure [CLIAC EXECUTIVE SECRETARY] and Heather can attest to probably the number of inquiries they've gotten over the pandemic about the Ready? Set? Test! and the other tools that are available on the CDC website.

CLIAC CHAIR: I see [CLIAC MEMBER] and [CLIAC MEMBER] have their hands up. I know we are past the start time for Tim. So Tim, if you can indulge us for three more minutes, and we will have [CLIAC EXECUTIVE SECRETARY] and-- OK, so [CLIAC EXECUTIVE SECRETARY] –

DR. TIM STENZEL: Absolutely.

CLIAC CHAIR: Thank you.

CLIAC EXECUTIVE SECRETARY: Yeah, mine will only take 30 seconds. I do want to say that on our online resources, we have that self-assessment that [CLIAC MEMBER] is asking about. So you can go to the waived testing resources, and find it immediately.

MS. SARAH BENNETT: See, problem solved. Excellent.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I'm wondering if the problem is solved. So a follow up to both of these comments. There is a lot of training available, and the self-assessment apparently as well. The question is, it mandatory, or is it required for these sites to really complete any of this before they start operation? And I think that would actually solve the problem, perhaps.

MS. SARAH BENNETT: Yeah. And so when I said, problem solved, I meant that there was a self-assessment available, not the other problem that was referenced. There is no mandatory requirement that these assessments be done. The requirements for certificate of waiver laboratories is that they must apply for and pay for their certificate, and they must follow manufacturer's instructions. That is a statutory requirement for certificate of waiver laboratories, and it's reflected in the regulations as well. Like I said earlier, we do not have the ability to require a certificate of waiver laboratories to have any type of personnel requirements, or perform proficiency testing, or anything like that. So—

CLIAC CHAIR: Thank you all. Thank you, Sarah, for being on the hot seat for extra time. Our next presentation is an FDA update from Tim Stenzel. Tim, floor is yours.

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

DR. TIM STENZEL: Oh, thank you. Next slide, please.

So I wanted to update on MDUFA, and MDUFA-- [CLEARS THROAT] Let me clear this throat. MDUFA is the Medical Device User Fee Amendments that are enacted in law every five-year cycle. We're in the process of completing MDUFA IV, and MDUFA V has been under negotiation for a long time. The commitment letter has gone to Congress, and they've begun having hearings, and then we hope to see this MDUFA five enacted by the end of July. That's the current goal right now. So this is a joint effort between the medical device industry and FDA to come up with a program that best meets the needs. So this user fee program provides extra monies for the FDA to hire extra staff so that we can perform our reviews on a negotiated timeline. There's nothing related to the standard of those reviews. It all has to do with how long it takes to do those reviews. So those timelines are set forth in the legislation, and that is tracked closely, and publicly. We post our review timelines every quarter publicly, and then annually as well. So, this is tracked by many, including Congress, to make sure that the FDA is using this program to try to accelerate access to new tests. Next slide, please.

So our regular MDUFA work is what we call-- call it-- doesn't have anything to do with pandemic work. We do not charge any fees for the pandemic submissions, the EUAs, and we've received now more than 5,000 EUAs and pre-EUAs just for tests since the beginning of the pandemic. So, this is a rather large volume on top of the existing volume of MDUFA related work-- these are just standard, non-pandemic related submissions, diabetes, chemistries, non-pandemic viruses, bacteria. All this is done routinely. Our office that I lead is staffed to take care of that routine work. Our office is not staffed for both routine work and pandemic work. It would take a large amount of effort to staff for something as challenging as this pandemic has been. So as a result of needing to prioritize pandemic tests somewhat over non-pandemic tests, there were delays in the review of MDUFA applications. We are now back to reviewing for IVDs for tests, all of the usual full marketing submissions, De Novo, and PMAs. However, there are extended timelines that are being used for the FDA to review these because of the overwhelming workload. There's another category of submissions. They're called pre-submission, or Q-subs. This is something that there no fee basis in the legislation, so the FDA doesn't charge for this. And we have seen these pre-submissions are simply-- a developer of a test can send a package of the plan they use they would like to make to develop and validated a test, and the FDA gives feedback. And again, there's no fee for this, and maybe because there's no fee, we've seen volume in this grow really, really quickly. Our office typically gets about 1,000 of these a year under guidance, and we typically try to review these within 60 days, which can include a meeting with the test developer, either face-to-face, or in person. So, there is quite a lot of work that goes into this. We did set aside-- [CLEARS THROAT] excuse me. We did set aside quite a number of these during the pandemic, but we continued to review those that were of public health importance, COVID-related, companion diagnostics-- and those that require legislative requirements, such as the breakthrough designation program. Excuse me. So, we have begun and resumed all pre-sub, Q-sub reviews except for 510(k)s. That's a situation where there are predicate devices-- devices, tests that have been authorized before. That developer can look at what the FDA asks of those developers and can pretty much mimic those. So, we hope that category of test development doesn't require as much interaction as, say, a pre-market approval PMA, or a totally novel device that comes through the De Novo pathway. However, we do expect a transition towards normal MDUFA timelines through the course of this calendar year. Next slide, please.

Moving to another topic that the FDA has continued to work on through the pandemic, and that is the Collaborative Community Program. A collaborative community is a continuing forum in which private and public sector members, which can include the FDA, work together on medical device challenges-- or in the case of IVDs, tests and challenges to achieve common objectives and outcomes. And if a collaborative community is formed and the FDA is invited to join, we will look at that community, and see if it meets our guidance on-- our participation by the FDA and make a decision. Next slide, please.

And this has been a very successful program so far. So, this is the listing of the current collaborative communities that the FDA has decided to participate in. Four of these are largely related to testing. The STRIPE one, Standardized Laboratory Practices and Pharmacogenomics Initiative is a collaborative community. So, this is a cooperative community of multiple stakeholders, all looking at how we can advance testing for pharmacogenomics. The second one is the International Liquid Biopsy Standardization Alliance, or ILBSA, and there's a lot of interest, particularly for, obviously, early diagnosis of cancer in the liquid biopsy space. And the next one is the Pathology Innovation Collaborative Community or PICC, and this has to do with image analysis using AI or machine learning to make-- potentially make pathological diagnoses on a standard pathology tissue slides. And then finally, the Rescue Program, Reducing Suicide Rates Among Individuals with Diabetes collaborative community, and it's our office that reviews diabetes devices. And there is a significant risk among diabetics who use these devices with regard to suicide risk. So, we would like to see those risks reduced. My next slide, please.

Back to EUAs. We'll spend a good amount of time on pandemic response here by the FDA. So, this is the list of-- this is a chart showing the reauthorizations through the pandemic pretty much to date. You can see that the FDA has authorized well over 400 tests. In blue diagnostics, those are molecular and antigen, rapid antigen tests, and then serology tests. Next slide, please.

This is a listing with a little bit more detail of the tests that the FDA has authorized. Quite a variety of different tests. I want to-- there's a great focus right now, and for good reason, on home tests. So, we have authorized four molecular home tests-- one prescription, the rest-- the other three are over the counter, so they can be sold in stores, or ordered online by consumers, and used in their home. We also have authorized, as you can see, 74 home collection devices, and this has been a significant part of our review process. These home collection devices are sent to the home, and when patients need them, they can collect an anterior nasal swab, or a saliva sample for COVID, and then there's packaging to send that back to the lab, and then they get a result. This has been a really successful program to help manage COVID. Moving to the rapid antigen test, we've authorized 40 point-of-care tests, and two prescription home tests, and 17 over-the-counter home tests. One of those-- or two of those are basically the same test, the Abbott BinaxNOW. They just come in two different forms. And we know that now tens of millions of home users are testing themselves at home with over-the-counter antigen tests to help manage this pandemic. And to give them more control, more control over management of their lives, and we hope and assume that this has been very helpful to them. It was interesting in the PMS talk that they now oversee well over 300,000 labs. The majority of those are CLIA waived labs. Well now, really, with the pandemic, we now have, in essence, tens of millions of home labs that are doing testing, and this and home testing has gone then therefore way beyond and complexity and importance to some of the other over-the-counter tests that are available. You know, the commonly used ones are important, obviously, but-- you know, like diabetes test strips and devices, test instruments, and home pregnancy tests. But now we're managing pandemics in this way, and it will never go back. I mean, all future pandemics, we'll be looking to do this. I mean, we were very interested from the very beginning in the Spring of 2020. We stated on the town hall that home tests were a priority. We provided recommendations for developers in the summer of 2020. We wrote several times in opinion pieces that you would really like to see these tests submitted. And then thankfully, with the RADx program, and now with the ITAP program, which I'll go into a little more detail-- and also with government funding of this effort. Oh, in the late summer of 2021, we saw a tremendous upswing in the availability of these tests. So, a lot of those elements are important to make over-the-counter tests really a good option for people. We saw that vaccines had been subsidized very early on in the pandemic, but tests were not subsidized in the same way for the development and manufacture of those tests. And then serology tests, you know, I think it's largely an open question of just how much value the average serology test is to manage patients. There are people who are immunocompromised, and that is probably the focus, the most important focus in the use of serology tests, to manage the disease for them. Next slide, please.

So, our most recent policy statement on managing the pandemic from the FDA perspective happened on November 15, 2021. We updated our priorities of those tests that we were going to prioritize review for with the focus being on, you know, how can we greatly expand-- further expand testing opportunities for those of us in the US, and that included both central lab options, point of care, and home. On that same day, the Secretary did withdraw a previous HHS policy on laboratory developed tests. The Secretary stated on November 15 that, effective that day, HHS no longer has a policy on LDTs that is separate from FDA's long-standing approach in this area. With that policy change at HHS took, the FDA then, on November 15, began reviewing LDTs again, and we've received many submissions, and we're going through those right now. Next slide, please.

The priorities laid out in this updated guidance on November 15, 2021, are stated here. First and foremost, we wanted to greatly expand at home and point-of-care diagnostic tests, either with or without prescription, and that are manufactured in high volumes. So, the volumes typically only ask for high volumes for any sort of COVID test. We would like to see manufacturing capability for at least 500,000 tests per week, or that's 2 million tests per month. So, with so many tests already authorized by November 15, we really wanted to focus at the efforts on how we could greatly expand testing. And if those volumes were not high enough, it wasn't going to meet that objective. This volume included a laboratory based molecular test, and in expanding capability and accessibility in other ways, such as home collection, pooling. And also, a test that could test multiple respiratory viruses, when we're now-- especially now, we are seeing other viruses pop up when patients have symptoms. Certain high volume antibody tests that are typically central lab, but can be point of care, fully quantitative antibody tests, as well as neutralizing antibodies, we see these two different options for serology test development to be the areas that we're most focused on in determining how we treat patients based on results. So we would like to see more of those. And then finally, any government stakeholder that funds the project, we automatically make those a priority review. Next slide, please.

I want to talk to you a little bit about a unique program called ITAP, Independent Test Assessment Program. This is a collaboration between FDA and NIH to independently validate tests that are produced by private companies. And the focus here is to try to get the maximum production volume from this effort. And so, ITAP has a-- NIH has a funnel, that they look at a lot of different companies. They weed out most, and then they get down to just the companies that they think that can deliver on the quality, on the quality of the production and tests, and on the volume for the US market. And so we have now authorized five through this program. Because ITAP and NIH uses a standardized validation program and standardized data entry, FDA reviewers know exactly where to look for all the data. There's obviously a high level of trust when the NIH is overseeing all of the validation work, rather than entities that the FDA is unaware of their prior work in this area. So they have not come to the FDA before. And today, those tests that have been authorized through the ITAP program starting in late 2021 are capable of producing for the US market about 200 million tests per month. And there is a

pipeline-- a robust pipeline of additional rapid OTC tests that ITAP is looking at, and the FDA is working hand-in-hand with the NIH on. Next slide, please.

This is the list of the over-the-counter tests. There are 20 authorizations-- actually, 19 unique tests. Three of them, as I said, were molecular. The rest of them are antigen. And we're really happy with the ITAP program now, because it really assures high volume, high manufacturing quality, and high test quality, and it aligns with our November 15, 2021 review priorities. That is, point of care, at home test-- so 500,000 per week or more, and obviously, anything sponsored by the US government. Next slide, please.

Unfortunately, we've had numerous safety issues with COVID tests, and many of them unfortunately have been with rapid tests. These tests have-- on this list were distributed without FDA authorization. Some of them have performance concerns. In addition, they've agreed to recall, but we maintain vigilance in tests that are making it into the US market to make sure that they are high quality, that they do give accurate results. And so, we have unfortunately had to take some action. Next slide, please.

And one thing that is perhaps not so well known is that the FDA is very involved with viral mutation surveillance, and examining the potential impact that it has on diagnostic tests-- also serology tests, although we fortunately-- and probably we wouldn't have expected it, but not seeing any impact of the variants for the use of serology tests. The use of serology tests, especially in the face of variants and waning immunity from either a natural infection or vaccine, is a key focus of many researchers now, and see if something can be gleaned from that. What I'm talking about here is when the virus mutates, and when we have new variants, is there any impact on tests? And so, because the FDA has confidential details about all the tests that have been submitted, including sequences of primers and probes, the sequences of antigens that are used to create the antigen test, and the antibodies used in the antigen tests, and even, for many of them now, the epitope mapping of where those antibodies bind the virus. And we are able to, through our database, input any mutation or variant that is found in the US, or maybe found outside the US, prior to getting to the US. And we've done this for most of the more recent variants, including Delta and Omicron, where we haven't yet detected a case in the US, but we know it's likely to be coming. We have our bioinformaticians look at the sequences of the virus. We compare it to the known tests that we've reviewed, and then we have a program of working with NIH RADx. They have a variant task force who is able to do in laboratory testing for the FDA upon our request, it's been an invaluable program to guarantee that the rapid tests, and molecular tests, in some cases, continue to be able to detect the various mutations and variants. Occasionally, the FDA does find something, and puts out information. We did put on information last year that we felt like, based on the data we were receiving, that rapid antigen tests are not individually, but across the board, seem to show a lower sensitivity to Omicron. And for Omicron, we also found three molecular assays that were not able to detect Omicron. We posted that information on the FDA website, and we worked with those developers to move those tests from the market. One of the developers updated their tests to prove to us that they could detect Omicron, and they are back on the market. Next slide, please.

One of the most important things the FDA has done during the pandemic is our outreach. So starting in the first Monday in March of 2020, I and other FDA experts have hosted virtual town meetings and webinars to assist test developers and labs with any questions they have. These are live call in question town halls. They started out weekly, more recently we've gone to every other week. We've more recently have gone-- you can pre submit questions, and we can prepare them in advance, and speak to them on the calls. We also use these calls to highlight any modifications, changes, updates to FDA recommendations on test validation. The call in-- live question call ins span the gamut from specifics about validation recommendations, to safety issues, to supply issues. And so, you know, we have found that has been a very good way to keep the community informed, to rapidly address questions that come up in a global way that is open to all developers, large and small, labs, non labs. And so, we are continuing that effort through today. And the other thing is that myself and others at the FDA and our office have routinely attended CDC lab calls as subject matter experts to address questions on those calls, as well as the Association for Public Health lab calls as well. So those additional outreaches aren't listed here, but we have an FAQ page that we constantly update having to do with SARS. A lot of important laboratory information here, especially early on, when there were severe supply chain issues, and it was designed to help labs and developers address those issues, and give them alternatives if they were not able to get a particular part of their test, like a swab, or BTM, or something like that. We've constantly been communicating through safety communications. We have resources for patients, health care providers, and developers on the website. We've created numerous templates that are listed on-- that are present on the FDA website that, in detail, give developers guidance and recommendations on validation, and what the FDA expects to see in a submission. We maintained email boxes, and so we'll continue to do that. Next slide, please.

So there's a new FAQ up. There's been a lot of questions around should the emergency no longer be declared, the public health emergency no longer be active, and the separate declaration for use of EUA authorities no longer be in existence, what would happen to test availability, and what would happen to developers, whether it be labs, or kit manufacturers, should this happen. So just to go into a little bit of the detail of the laws, there is first a public health emergency determination. That is the Public Health Emergency Declaration. There's a separate declaration that enables the FDA to

use EUA authorities. For the EUA, we greatly decrease the bar for what we normally expect for test validation. So as where we usually expect a lot more positive than negative, a lot more work by developers for a fully authorized test, for EUA tests, we typically only ask for 30 positives and 30 negatives. And in fact, in the beginning, people couldn't get-- labs couldn't get a hold, and developers couldn't get a hold of samples, so we allowed surrogate samples. So these were samples that were created in the lab, either with transcribed RNA that was then diluted into negative patient matrix, or the nasal swabs, et cetera, or inactivated virus, or extracted whole virus. And then that continued for many weeks, until samples were more and more available, unfortunately, and then we did transition for example to asking developers to use actual patient samples-- many times banked, and that is still the case. So these EUA authorities allow the FDA to lower our usual bar in order to speed the access to these tests. The FDA has published draft guidance on transition for these EUA IVDs. As long as the comment period is open, we encourage people to comment on this. The idea here is that should either the public health emergency no longer be in existence, or the Declaration of EUA Authorities be removed, there would be-- it's unlikely that both of those things would happen any time soon, but in the case that it would, we would have a transition period, at least 180 days, for developers who can come in with a full application. As long as they come in with that full application before the deadline, whatever that deadline is in the final guidance, they could stay on the market all the time the FDA is reviewing that. So we want to guarantee access to tests even during the transition period, and we would love to see as many full authorization submissions as soon as possible, so that we can be certain the country has enough of these tests available. Next slide, please.

There has been several tests that have already come through. The first one for the category is De Novo, then the subsequent are 510(k). Essentially, the same amount of information is being asked of the developer, so you can look at what's now being asked for molecular tests for full authorization. Next slide, please.

And that was my last slide. I thought I was close to getting out of time. So I'm happy to take some questions.

CLIAC CHAIR: Yeah, Tim. Thank you. Very informative. [CLIAC MEMBER], your hand is up.

CLIAC MEMBER: Thank you so much for everything you did, and you've been doing to empower the public at home, to be able to self isolate with these at home tests. I mean, this is a game changer for everyone. And I want to thank everyone that has been involved with this ability to have these tests at home, all the organizations that fought to bring science to light. And I think it's very important that we understand, from the FDA, what we're going to do next time there's another type of a pandemic. What will we do? How-- I'm asking my question. It's how do we get this done quicker to prevent the number of deaths that happened? We really need to know, how do we make this happen again?

DR. TIM STENZEL: Yeah, well I'm on record in several publications about how to do this. The FDA is not in control of the next pandemic response, but obviously, we would like to be closely involved. Bottom line, we would like to imitate a little bit more what the South Koreans did. So I've got a publication out there on what the South Koreans did. They, based on their MERS outbreak years ago, decided that they needed to have a very well designed public health response. And so their equivalent of the CDC and the FDA worked with their government to put into law a plan that they then acted upon during this pandemic. Part of that plan was that they funded manufacturers ahead of any pandemic to be ready-- sort of warm based manufacturing, design, and development. They planned how these manufactured tests would be rolled out, to which labs to be used, and those labs were certified for the pandemic, to be able to test for that. The government and people of South Korea had assurance that the right labs were doing the testing, and they were getting the right results. So we think that funding in advance of the next pandemic, warm based manufacturing, as they say, a select group of manufacturers that know how to make high volume molecular tests that can be used on common platforms, that know how to develop quickly the rapid tests that we would like to have, are on board are ready before the next pandemic. And that there are funding mechanisms to give developers assurances that even if the pandemic is handled well, or doesn't go to the extreme that this one did, as we've seen with other prior pandemics, where it wasn't quite as severe, many of the developers out there who were engaged in those efforts before never saw full return on their investment. They were happy to be involved, but many were hesitant. And this around in January and February to jump in and do development, because there was no guarantee to funding reimbursement for their efforts, and they would have to put aside other projects. So I personally reached out-- and it's also been reported in the press-- to developers, and others at the FDA, and others within the government to please, please develop tests. You know, because we heard that they had looked at the opportunity, and decided not to. And that was certainly not in the best interest of the country. So hopefully, that gives you a little bit of a flavor where we would like to go in preparation for the next time that this occurs.

CLIAC MEMBER: Thank you very much. The one thing I would like to just make-- kind of put it out there for this committee is to discuss the possibilities of finding a way to improve the availability, which we'll be talking about a little bit later. But along this line, obviously, we need to come up with some other ways to provide these tests from our government that is a public health solution that may not need to go through the FDA. So I think that these are some things we need to bring up throughout our organization, throughout this committee to see-- so we don't have to wait for the vendors to decide that this is going to be profitable. What can we do for our government, through our government, as a public health solution? But again, thank you so much for all your work. I know that you work very hard on this, and so did so many other

people. And we really do learn from these things that we have had challenges with, but what a great outcome to help people now testing themselves at home, and isolating themselves. So thank you very much.

CLIAC CHAIR: I'm going to take-- thank you, [CLIAC MEMBER]. Thank you, too. Let me take the chair's prerogative and no more questions. So sorry, [CLIAC MEMBER]. Sorry, [CLIAC MEMBER]. Save your questions for the session, perhaps, this afternoon if it fits in. I'd like to move to our next speaker-- oh, and then for [CLIAC MEMBER], I was just saying the next one on the horizon is the fentanyl epidemic.

CLIAC MEMBER: Yes.

CLIAC CHAIR: I can just share experiences how this is mirroring with the developers [INAUDIBLE]. Our next and final speaker of the session is Dr. Donna Wolk. She will be reporting on behalf of the CDC Board of Scientific Counselors, the Deputy Director for Infectious Diseases. This is presentation number four on the website. Donna, take it away.

Report: CDC Board of Scientific Counselors, Deputy Director for Infectious Diseases Donna Wolk, PhD, D(ABMM)

DR. DONNA WOLK: Thank you very much. So, it's my honor to present the information that was given last January at the Board of Scientific Counselors, and this is two days condensed into 30 minutes. So this is going to go a little fast.

The CLIAC involvement is a non-voting member. So, I sit and listen and take notes at the Board of Scientific Counselors, which actually did not meet during a certain point of the COVID pandemic, but it was resurrected, and John Auerbach reported on a new special advisory committee to the Director Rochelle Walensky. And this new unit is going to advise the director and the HHS Secretary. It's not confined to a specific topic, and it is intended to prioritize CDC's activities, and also to address disparities which we know did crop up during the pandemic.

This will be an ongoing scheduled meeting, and it is being reestablished, and here is the timeline. And so, I think, look forward to those online live webcasts that you can sit-in on, and look forward to a lot of exciting things coming from this group.

This is the listing of the president's budget, and the topics that have been assigned with this committee. Public health infrastructure and capacity you can kind of read for yourself-- infectious diseases, climate and health, it's a very broad view, and it covers many pandemic and non pandemic pressing issues.

Next reported by Barbara Mahon about the COVID-19 response from the CDC.

She reported on the case surveillance summary, the Omicron prevalence dashboards, and the seven-day average risks. Also, their dashboards for COVID vaccination uptake domestically, and a multitude of other web information there. There's a website there that you can refer to, and you will be taken to somewhere where you can access-- many of us in the laboratory community use some of these dashboards on a daily basis. They're very helpful.
Looking ahead, that group was talking about updating surveillance strategies, evaluating vaccine effectiveness, and some of the international issues that arise for vaccine delivery and administration, and transitioning the emergency response activities to standardize infrastructure and some of the home programs. So a lot of work done by that group.

CLIAC CHAIR: Donna, can is there any way we can have you do this in presentation mode so the slide looks bigger? We only see one at a time.

DR. DONNA WOLK: Yes. I thought it was. My apologies. Anybody want to help me out here? I'm a Teams—

CLIAC MEMBER: Yes. So the display setting, box at the top, Donna, just click that, and change it to my own monitor. There you go.

DR. DONNA WOLK: To which?

CLIAC MEMBER: Swap.

DR. DONNA WOLK: Swap. OK, better?

CLIAC CHAIR: Oh, those informatics, jeez. Yes, Donna, it's great. Thank you.

DR. DONNA WOLK: OK, do you all-- I have-- I see the people in there. Are you seeing that, everyone, or just me? Do you want to see that? Like it's sort of occluding the view, I think, but—

CLIAC MEMBER: You can slide it to the next panel.

CLIAC CHAIR: Oh, Caitlin Rivers. Yeah. Now it's good.

DR. DONNA WOLK: So Caitlin Rivers reported about the data analysis for the pandemic, and talked about how disease outbreaks are becoming more frequent, more disruptive, and how at a national level we lack data analytical infrastructure to respond quickly and effectively. So their goal is to improve these systems and develop new capabilities, new forecasting, new modeling, predictive modeling, and analytics with a special focus to underserved communities and health equity.

She laid out a very big outline about how these new outbreak analytics would encompass the environment, the ecosystem, both food, wild animals, the human case and clusters, to the pandemic and recovery modes. Their goals are to predict inform and innovate, and these are some of the outbreak analytics that they are planning. And you can see that ranges from risk assessment all the way to burn and impact, and vaccine, and therapy effectiveness, phylogenetics, and disease forecasting. So a huge effort by this team.

Then Michael Johanson talked a little bit more about the modeling and forecasting that is going on at the CDC in the Real Time Epidemic Preparedness, where they are looking to assess the risk and move towards more infection prevention and control, rather than more of a passive surveillance. They are looking to speed the data communication, and link with a more diverse group of data suppliers so that the models can help contextualize data coming from all sources of different types and diversity in the United States, and indeed abroad, and then working on the communication of these results.

So they have developed a public health and analytics modeling fellowship, and the link can be seen there, but this is really a two-year commitment, learning through service where people that have the appropriate educational background can apply to have CDC mentors in the community of practice, modeling community. And they already have 12 fellows in their inaugural class, and looking to recruit more biostatistician predictive modelers, AI and machine learning to this new fellowship.

Greg Armstrong-- Greg Armstrong then reported on the Advanced Molecular Detection program and the response to infectious disease outbreaks, and this is their Twitter logo.

He gave a brief history of the AMD program. It was actually going on before the pandemic, and was funded to bring pathogen genomics to the US Public Health system at the CDC and state level. Their innovations then were focused on wet and dry laboratory pipeline sectors, workforce development, and computing capacity.

Also before 2020, there was sequencing going on it nearly all the infectious disease areas with a focus on tuberculosis, flu, and foodborne illness. They had 60 bioinformaticians managed by different groups within the government sector, but they still had insufficient access and capacity in terms of workforce and education, so they collaborated through what's called a broad agency agreement with academic collaborators. At the state and local level, all laboratories had sequencing capacities, and they launched this out of the previous Pulsed-field Gel Electrophoresis PulseNet, which was at each of the states to look at foodborne illness. And that was being-- that was upgraded to include NGS, next generation sequencing, to that. And there were seven regional or state bioinformaticians who helped with the states on a regional level, but there was still some workforce development. They began designing curriculums, and quality practices were in the process of being standardized, but they did not have access to high performance computing.

So forward to the pandemic, and during the pandemic, these initiatives grew quite quickly. CDC launched the SPHERES Initiative, which many of us are familiar, with in April of 2020. They had coordination calls with over 200 sequencing type of organizations and bioinformatic organizations. They had BAAs with 29 organizations, and they launched the NS3 program, which was the National SARS Strain Surveillance Program, as well as their COVID-19 epidemiology toolkit from these sites. Now at the state level, there were SPHERES activity in some states. There was a six-year plan, and there was a massive amount of funding received even for construction, as well as infrastructure. And they did report that the biggest problem for them is that there's capital money, there's infrastructure construction money in some cases, and reagent money, but trying to get the appropriate bioinformatic people hired at the government rate was problematic, because industry can pay so much more. So, there are initiatives and brainstorming on how to increase the national bioinformatic infrastructure. And we hear that also, in collaboration with our public health colleagues, that that's the key. You still need to hire people at the technical bench level and in the bioinformatic pipeline area.

And Greg Armstrong reported on the American Rescue Plan money, as specific to the epidemiology, and this really was still under the sequencing-- the sequencing report, but it is a subsection of the sequencing efforts that are tied to the ARP. So the government funding is available for sequencing to expand capacity, build genomics and bioinformatics, and to innovate in those areas-- all those areas.

They then launched full-out sequencing through nine contract laboratories that sequence right now about over 3,500 a week, I'm sure, by now. The NS3 project, that links back to those. That is a separate outside the BAA process, and they sequence about 1,500 every two weeks, but they also provide live virus to state, and local, and national laboratories where live virus work needs to be going on. And some of the BAAs here, they talked about 50% are still contract laboratories while the state, and local, and other infrastructure is being advanced.

Tim Jones then talked about the CDC modernization of enteric surveillance, and he talked about culture-independent diagnostic tests, which many of us in the clinical laboratories are aware of. We work with our public health colleagues and partners to make sure that even though we're detecting them by molecular methods, the enteric pathogens that we do subculture and try to identify if we can, the actual isolate that then is sent to the state laboratory. We do this routinely in our laboratory, but evidently, not all laboratories take the time or the expense to do that. So he talked about the public health areas of risk due to culture-independent diagnostic technology, and he focused on case-based surveillance, outbreak investigation, antibiotic resistance monitoring, and screening processes for return to child care, or food services, et cetera, and gave some information, which should not surprise any of the clinical laboratory people on the call, about the increasing number of CIDTs in mainstream diagnostic laboratories across the US. The enteric branch action plan short term is to maintain organism viability sources, and expedited organism recovery processes, and work with clinical laboratories on reflex testing, and reimbursement strategies, because right now, our productivity metrics in our clinical laboratories are not reimbursed anything for extra work we do on behalf of the public and national-- public health response, the state and national. And we are all under the thumb of productivity metrics, which rely on billable tests, or reimbursable tests. So there's some discussion going on there to encourage other laboratories to bring back the processes that they feel they need. And then they are also looking to improve extraction protocols, highly multiplexed amplicon sequencing that might be used for antibiotic resistance. And they're working with platforms called the Fluidigm Juno and the Illumina MiSeq and they are building out bioinformatic pipelines and wet laboratory pipelines to the public health laboratories at the state, or in some cases, the Metropolitan city level. Future topics they're addressing, he talked a lot about their new wastewater response plan, and the fact that they are doing wastewater sampling. I know in New York, there the state laboratory is beginning to enter into some of those processes, as are many states that are listed there.

There are future topics that are going to impact the entire branch, where climate change, health equity, bridging the gap between environmental, zoonotic, and humans, new impacts of virulence and biomarkers, and looking at strains that are recurring, emerging, or persisting. And he had hoped to take some of what we've learned through the SARS-CoV-2 pandemic and apply it to other pathogens in terms of modernization of data, and integration, into compatibility of data, and working with clinical partners, and integrating with the electronic health records in hospital systems.

Dan Jernigan talked about the data modernization initiative at the CDC, and their urgent and very successful needs-- or plans to modernize the data infrastructure. And he focused on the problems they're trying to solve, which we all, in some way, shape, or form experienced during the pandemic-- that there are siloed information, sometimes outdated skills, either in the clinical or public health arena, heavy burdens for providers and health departments, as well as, to be honest, clinical laboratories, who had to stop what we were doing during the pandemic-- building new tests-- and make sure we were reporting appropriately through the infrastructure to the public health. There were no pre-mapped expectations, but many of that was built from scratch.

Sometimes we were linking with older technology, and the fact that the public health departments are not part of the health care data ecosystem, except in certain states that have electronic reporting for certain pathogens, but we were not allowed to use that during the SARS pandemic. There was a massive amount of data that had to be uploaded to the government websites daily, and he talked about making those connections ahead of time before the next pandemic.

So their goals are to build the right foundation, accelerate the data actionability for the next pandemic, improve the workforce to a state-of-the-art extend partnerships. And they already have a lot of partnerships that you can see there going on in the bottom right.

In terms of the right foundation, he called out automatic real time data collection and cloud based services. They talk about their North Star infrastructure and reducing the silos.

And then, in terms of the accelerated data into action, the focus was on the rapid outbreak response, and funneling that into the predictive modeling groups and outbreak analytics that are going on already in the CDC and other areas. And moving away from the data silos to the combined our data approach, connecting public health and health care data.

So the DMI initiative is a foundation for data sharing across all kinds of levels. It should be scalable and coordinated with shared capabilities, and expanding the prepared data science workforce, decreasing the burden on data reporters, public health staff, and hopefully clinical laboratory staff as well.

Katie Fullerton added on with the Data Modernization Initiative, and she talked about the external consortium of partners. And I confess, I-- besides APHL, I'm not privy to-- and HIMSS. Those are the only two abbreviations I recognize, but they're there for your-- for you to view. She also talked about taking what they had from COVID, and moving it beyond for streamlined reporting, vaccination data, and genomic data flow.

Next, Robbie Goldstein presented on the CORE Initiative, the transforming commitment to health equity. Here the CORE stands for cultivating comprehensive health equity, optimizing interventions, reinforcing and expanding partnerships, and enhancing capacity and workforce engagement. This is another initiative that's incredibly important. At the meeting was diversity, health equity, and the impact of inclusion.

Which led to Emily Mosites, talking about special population, and the CDC's focus on homeless and incarcerated populations with critical information related to high risk infectious disease, and cross-cutting across different types of organizations such as prisons, and homeless shelters. And this is a very small team with a very big job.

And so they are working with partners, and have made some success in certain regions of the country. They have health and homeless centers of excellence that they've launched during the pandemic in San Francisco, Seattle, and Minnesota, working with coalition building, on their strategies, on infectious disease prioritization, and best practices. And so they plan to continue to expand that work.

They also have collaboration with correctional facilities. And they are challenged by the lack of a data linking system with correctional facilities and public health. So they have a whole outreach program going on to jails, ICE detention, and federal and state prisons.

Patty Simone-- talks about the future of the public health workforce. And this is near and dear to everyone's heart on the CLIAC committee, I believe. The thing that hit everybody is that the US needs to hire a minimum of 80,000 more full time equivalents in state and local government, public health departments-- an increase of 80% to provide adequate infrastructure to the public health system in our country. And that, I will say, is also mirrored in the clinical laboratory system, where our needs for medical laboratory scientists outweigh the capacity at which we're training them. So the workforce development projects are-- initiatives are to bridge to the next COVID-19 phase and then beyond. They are looking at specialized specialty workforce titles, such as disease intervention specialist. They are launching a public health AmeriCorps, which is kind of a call to service for America's youth in science, epidemiology, biostatistics, bioinformatics. And they are offering internships and fellowships, some of which I mentioned, so that they can sustain the COVID-19 progress and events in the future in all the things that all of us who hire people recruitment, retrenchment, hiring and on-boarding, fellowships, training, and including diversity, equity, and inclusion, and the bioinformatic needs of our public and clinic and health care health-based initiatives. So thank you very much I couldn't include everything, but I believe that the meeting is also taped and available to everybody.

And if there are any questions, I will try to answer them. I am not the expert. I'm just madly taking notes about everything they're doing, and they're doing so much. It was amazing to see the group back together. My heart was happy that they're back together and meeting again because I think it's an important critical need to move forward. In addition to CLIAC, this focus and communication to public and clinical laboratories and public health systems is critically important. So thank you, everyone.

CLIAC CHAIR: Thank you, Donna. That was an incredible tour de force report. Much appreciated. Are there questions from the committee? I must say, I was really heartened there is overlap with the prior conversations around shoring up the public health infrastructure. I think [FDA EX OFFICIO] was most compelling about the South Korean model. And if we can train and hire those 80,000 people, maybe we might be ready for the next pandemic. [CLIAC MEMBER], you have your hand up. Go for it.

CLIAC MEMBER: Yeah. I loved that talk. I loved the plans. How will it be funded? And is it possible to put it into the infrastructure bill?

DR. DONNA WOLK: Well, I think in terms of the sequencing and the bioinformatics initiatives, back to the first slide, there is an immense amount of funding going in through the American Recovery Act and had been initiated from the government to CDC and state public health laboratories. As I understand it, the money passes through the state epidemiology divisions. When the money is awarded, it goes to CDC. And maybe some of our colleagues can help here, but if it is assigned to the state, I'm told that it goes to the state epidemiology department. And then they decide how it's distributed within the state either to other local epidemiology state-based epidemiology services, or state-based public health laboratories. So, when you see laboratory money going through the pipeline, it doesn't necessarily automatically go to your partners in the state public health laboratories. And I think that the laboratorians on this call are most familiar with working with them. I mean, our calls are probably 10 to 1 to conversing with the laboratories. How can we help? What do you need from us versus the epidemiology, which in our state, goes electronically for most of that. And we're only really

contacted if there's an outbreak that they need samples from us or something like that. So that was something that I had learned. And there is funding for three years. And one of those is an extension for another six years. So on one of the slides, there was an issue about funding for six years. And I think all of us need to be active with our state and local-- state, and federal representatives and senators because part of why we weren't ready is because public health did a great job at keeping outbreaks off the mainland, that they had people across the globe, and they still do, but public health funding was decreasing throughout the years. And so the challenge, I think, for everyone is to keep it in the awareness zone because when something's going well, the human tendency is to ignore that and under fund it. And so there was so much good that public health did, and then they just kept-- like clinical labs-- not unlike clinical labs being asked to do more with less, more with less. And so some of this new infusion is based on the pandemic. But I think that the mode of the meeting was like, let's not let this just be another cycle. Let's really continue efforts to keep the funding mechanisms. And once we build that to where we need it, it has to be maintained. And that's the tough part, I think.

CLIAC CHAIR: Yeah. [CLIAC DFO].

CLIAC DFO: Yeah. Thanks, Donna. It's a great answer. What I would add is not all of those programs, but many of those programs that Donna was just talking about have benefited from large infusions of what we call sort of temporary funding, the CARES Act, the American Rescue Plan, which, as I'm sure you all know have invested large amounts of multi-year, but limited year funding into public health. So, the majority of Cares money is five-year money, which is now less than four years of money. And so many, many new substantive programs at CDC and across public health are in good shape, but very, very temporarily. And as I say, within three years or so, most of that new money, if funding doesn't change at the Congressional level, will go away. And we'll be back to pre-pandemic funding levels over.

DR. DONNA WOLK: Thanks, [CLIAC DFO] for filling that in.

CLIAC CHAIR: I see no more questions. And I would like to keep this meeting on time. The break was scheduled for 1:30. It is now 1.41. So, I would like to adjourn this morning’s session. We will reconvene at 2:30. And members, I want that picture. So, if you can just indulge me. I need you to get closer.

CLIAC CHAIR: Wait, wait. Hold it! OK, got you guys. Got you. OK, now go to lunch. Come back, turn your camera off. We don't like to watch people eat. Thank you.

❖ Presentations and Committee Discussion

The Future of Laboratory Medicine in Non-Traditional Testing Sites

CLIAC CHAIR: My atomic clock just clicked to 11:30, 2:30 Eastern time. And I think we're all here. I'm missing [CLIAC MEMBER]. But regardless, welcome back. I would like to open the afternoon session. The agenda is titled Clinical Laboratory Medicine in the Age of COVID-19. And the theme of this session is the future of laboratory medicine in nontraditional testing sites. We will kick off the session with an introduction to the topic and speakers by Dr. Fitzgerald. After these presentations, we will have a short committee discussion before the next two presentations. The four presentations-- 1, 2, 3-- the 5 presentations, we will hear now are listed as numbers 5, 6, 7, 8, and 9 in the agenda. Dr. Fitzgerald, the floor is yours.

Introduction to the Topic
Collette Fitzgerald, PhD, CDC EX OFFICIO

DR. COLLETTE FITZGERALD: Great, thank you, [CLIAC CHAIR]. Afternoon, everyone. It's a real pleasure to provide a brief introduction to the future of laboratory medicine in the nontraditional testing sites session this afternoon. Next slide, please.

So CLIAC focused three meetings, back in 2006 and 2007, considering the future of laboratory medicine or health laboratory practice, as it was referred to at that time. At these meetings, the committee discussed challenges for public health laboratories clinical laboratories that perform non-waived testing in traditional laboratory facilities, and clear waived testing performed in diverse sites. Examples of the presentations at the meetings from 16 years ago included topics such as enhancing connectivity between public health and clinical laboratories, outbreaks and public health responses, laboratory and industry perspectives on regulations, standards, and guidelines for emerging technologies such as microarrays and high throughput mass spectrometry, test reporting standardization, impacts of rapid and molecular tests for infectious disease agents on public health, clear weaved rapid HIV testing, and good laboratory practice for waived testing. So many things have changed with respect to clinical and public health laboratory testing in 16 years, especially in light of the COVID-19 pandemic. But some of the topics discussed back in 2006 and 2007 are still at the forefront for the

laboratory community today. Technology has evolved and automation has increased, which has resulted in the availability of simpler tests that can more easily be performed in a variety of testing sites, both traditional laboratories as well as nontraditional testing sites. The number of non-traditional testing sites, as we've heard, has increased in recent years, especially as a result of the COVID-19 pandemic. We expect this expansion to continue as simple accurate tests continue to be developed for emerging infectious agents as well as other analytes. Next slide, please.

So the next three slides summarize for the committee the three workgroups that have just begun or are being planned and their current status. We thought this would be helpful for your discussions following the presentations in this session. So as mentioned during previous CLIAC meetings, CDC, in collaboration with FDA and CMS, have convened three workgroups who reported to CLIAC back at the April 2019 meeting. Those workgroups were a personnel regulations work group, a non-traditional workflow models work group, and a next generation sequencing work group. The work group report outs at the 2019 CLIAC meeting resulted in 23 recommendations from the committee. Two of those recommendations focused on the CLIA regulations and what needs to be updated in the regulations to address new technology and changes in laboratory practice that has occurred since the regulations were written. So a new clear regulatory assessment workgroup was formed to provide input to CLIAC so that CLIAC could make recommendations to HHS about how CLIA might specifically need to be updated, especially thinking about the recommendations and advice given by those prior workgroups. The CLIA regulatory assessment workgroup has been formed and is co-chaired by CLIAC committee members Dr. Kim Chapin and Dr. Greg Sossamon. The work group, they had a meeting on April 1, 2022, and they will continue to meet monthly. An initial workgroup report will be provided to CLIAC during tomorrow's session. Next slide, please. Yeah. Next slide, please. Thank you.

So while refining the work group topic areas for the CLIA regulatory assessment work group, it was determined that an additional second work group would be better suited to address the CLIA certificate of waiver and certificate for a provider performed microscopy or PPM procedures, especially with the expansion of nontraditional testing sites during the pandemic. The CLIA certificate of waiver and PPM procedures workgroup will be chaired by CLIAC committee member Miss Heather Duncan. This workgroup is charged for providing advice to CLIAC for consideration and making recommendations to HHS on the potential need for expanding regulatory oversight of CLIA certificate of waiver sites. The workgroup will also provided by [INAUDIBLE] on the potential need for expanded regulatory oversight of certificate for provider performed microscopy or PPM procedure sites. CDC, CMS, and FDA are refining the workgroup topic areas for discussion. Recruitment for workgroup members will begin later this month. If you would like to nominate a candidate to be considered for this workgroup, please send in candidate nominations to CLIAC@CDC.gov. Next slide, please.

So during the November 2021 CLIAC meeting, CLIAC heard presentations and deliberated on next generation sequencing in clinical and public health laboratories. CLIAC recommended CDC, CMS, and FDA convene a third workgroup to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatics, data analysis, and interpretation to produce test results that inform clinical decision making. As a result of this recommendation, a new NGS workgroup is being formed. Workgroup discussions will focus on the education, training, experience, and competencies that should be required by CLIA to qualify personnel performing next generation sequencing, bioinformatic, data analysis, and interpretation. CDC, CMS, and FDA are refining the workgroup topic areas for discussion. Recruitment for workgroup chair and workgroup members will begin late spring. If you'd like to nominate a candidate to be considered for the workgroup, please send in candidate nominations again, to CLIAC@CDC.gov. Next slide, please.

So in this afternoon's session, with six presentations in total this afternoon, I have Dr. Michael Palm and Dr. Norman Moore from Abbott will share an industry perspective on current and future applications of point-of-care testing. Dr. Palm is the director of commercial innovation strategy at Abbott, and Dr. Moore is the director of scientific affairs at Abbott. The second presentation on current and future applications of point-of-care testing will be provided by Dr. Sheldon Campbell. Dr. Campbell is a professor of laboratory medicine at Yale School of Medicine. Our third presentation on digital pathology, the past, present and future will be presented by Dr. Keith Kaplan, the chief medical officer for Corista. This is the publisher of tissuepathology.com, the industry's leading pathology blog. Dr. Heather Carlton, chief of the enteric diseases laboratory branch at CDC, will then share an update on culture-independent diagnostic testing impacts on enteric disease surveillance for the fourth presentation. Following committee discussions, then we'll move to the fifth presentation on personnel challenges in nontraditional testing sites by Mr. Matthew Kossman, the senior vice president of operations at Worldstar Urgent Care in Atlanta, Georgia. Our final presentation in the session is on the American Association of Clinical Chemistry, or AACC, points of care testing certification program, and will be presented by Dr. Scott Isbell. Dr. Isbell is an associate professor of pathology and pediatrics at St. Louis University School of Medicine. Next slide, please.

So, we've put together some questions for the committee's consideration to be thinking about as you listen to the presentations in this afternoon session and in your discussions that follow after them. The three questions are what will laboratory practice in nontraditional testing sites look like in the future? What are the implications for public health as a result of the expansion of testing performed in nontraditional testing sites? And importantly, how can CDC, CMS, and FDA assist in filling needs in nontraditional testing, including testing quality and safety, workforce development and training,

and personnel needs? I think that's it for me. If you go to the next slide. I think I'm going to hand it over now to Dr. Palm and Dr. Moore to start us off with the first presentation.

Current and Future Applications of Point-of-Care Testing – The Industry Perspective
Michael Palm, PhD

DR. MICHAEL PALM: OK. And I'm going to send the regrets from Dr. Moore. You're going to have to have me for the full session today. So it's nice to meet everyone and see some old colleagues and partners here. And I appreciate the opportunity to give you a little bit of the Abbott perspective as to point of care. And while we're bringing up the presentation, I'll give you a very quick introduction of maybe my background. I've been with Abbott for quite some time, over 25 years. In that time, I have spent a lot of it in centralized testing, in molecular. And more recently, about 2 and 1/2 years ago, I moved over to our point-of-care and rapid diagnostics division, leading strategy and innovation. So you can imagine starting about six weeks before COVID really hit was a little baptism by fire in the care space. But ultimately, I was very involved in our decentralization of lateral flow through home test partnership with telehealth as well as then over the counter testing. So at this point, I have I guess a point-of-care background that has been brought on by trial by fire. So in that, the first aspect-- and if we moved to the first slide-- I wanted just baseline. This is one thing that as we have people joining our rapid team, we have a conversation that looks a lot like this slide. There's a definition of clinical diagnostics which I do not need to read here. Everyone knows that. But the reality is that location is not part of that definition. And when we think of clinical diagnostics from an Abbott perspective, we're really looking at what is the right access point for the information required clinically at that moment? And so we obviously have a very large presence in centralize diagnostics, where things are high throughput complex, critical care testing, consolidation are our drivers. But we've really established over the last years our decentralization or near-patient testing with through point of care, enabling those access points. And when we do that, we have truly unique scenarios as we talk through these disease states and what's trying to be accomplished at that access point by the health care system. And our biggest takeaway through all of this is really, both are required to achieve the best health care outcomes. And you'll see a little bit later, when we're thinking through this, we're not thinking of it as a single event, but rather a continuum of care. And that patient who's accessing health care accesses it in different ways. And that is the fundamental premise of how we're approaching our clinical diagnostics. So if we go to the next slide

When I was asked to cover this topic, I thought, wow. Where do I start? And I said, maybe I'll do what the first speaker did is go back to where were before COVID? Because there's been this functional foundational shift in what health care is and how it's accessed. And I went and pulled up some of our reports and some of the bullets. And when we were prior to the pandemic, we were really looking at a lot of pressures in the health care system to reduce cost, improve quality. And we knew things needed to change. Change was acknowledged and medicine was actually transitioning from activity paid decisions to quality-based decisions. I think COVID has helped us get there a little bit faster and maybe exacerbated some of these shortcomings that we had in that system. And we saw, even before COVID, this consumerism, the payment infrastructure changes, and increase in care settings all changing through the ability to network and through digital platforms. So a lot of what we saw really accelerate was already in the mix. It may have been the minor activities in health care that have become so present in COVID. And the question for us is going to be how to really go forward? And when we think about where does the US health care system stack up, I pulled a couple of references here. So this isn't my opinion. This is summaries out of there. So in those references, we've got a health care system that's underperforming in access, quality, and cost, compared to other countries. And you know, in rural US, you can see that really exacerbated by too few providers to really meet the population's needs. And one of the things I've heard recently, which I agree with, is if you line up the attributes of health care and access that you have in South Dakota and you line those up in sub-Saharan Africa, they're more similar than they are different. And I think that's one of the realities of our health care system is it doesn't even have to be South Dakota. We can experience those kind of health care challenged areas or under-resourced centers even in very urbanized centers. And healthy people's progressive goals-- in this kind of sets the vision for 2030-- is really to reduce and eliminate health care disparities and doing that through health equity. And this is an area that Abbott is very interested in. It's also an area that's very nebulous. And so as we look at some of our key strategic elements, which are access, affordability, and equity, we are really trying to pay attention in not just providing a test, but looking at the infrastructure that's required to execute and provide health care in that scenario. So our next slide.

I'd like to cover a little bit of what are the lessons learned from our pandemic response. And if we go back to the beginning-- and I know there are people on this call who know way better than I do-- so I just would like to summarize really, it became overwhelming for our laboratories. It was overwhelming for our health care system. And there was a long waits, prioritization of testing, and we were looking at results in days and not minutes. And often, it was a lagging indicator of where we were, and not a leading indicator. What we saw in a response to that was-- and it was already mentioned-- pretty significant increase in CLIA wave sites that were enabled by the new legislation. But what we also saw was a growth of telehealth that has rebounded. And now we believe it's about 30% of health care engagement is telehealth. That number at its highest point was in the upper 40s. So you can imagine almost half of our health care engagement at one point in the last two years was going through telehealth. And what ultimately and where we ultimately got was a multilayered health care engagement where we had health care sites, hospitals, infrastructures, ERs, urgent care, alternative sites, you know, pharmacies, parking lots. We were trying to figure out how to have our products work in sites

where literally the data could blow away if we printed it. So we had not experienced that challenge here in the US prior. And I think we all learned from it. But I think the biggest piece was when we got to the balance of the access points for a continuum, that multi-tiered health care engagement really allowed us to manage more effectively where we were at. Also, I think I don't have to be too provocative here, but diagnostics was a critical component of data. And that data not only was used to treat patients, but also was used for situational awareness, understanding policy setting. And if we apply that to other kind of public health challenges, whether it be opioids or even cancer, you can see the benefit of diagnostics and having that data to set policy is a critical element for the success of a public health entity. And then the last piece is three years ago, if I were to walk around my neighborhood and told people what I did, and that was PCR, they would not even understand what that meant. I'd have to go through a long explanation and we'd be done walking the dog. Now people are telling me they've got tested by PCR or they've been tested by rapid lateral flow. So it's a unique scenario where patients have become more and more educated, and they've taken the burden upon themselves to really be proactive and empowered in their health care. So if I have respiratory illness symptoms, I'm going to self-isolate. If I can test at home, I'm going to do that so I can help manage and do my part. And patients and caregivers are hesitant to expose those who are in their care. So they want to test. And we've seen this infrastructure really just grow from not necessarily being pushed by the health care, but the empowerment of the patients and the caregivers. So what is this-- if we go to the next slide—

What does this all mean for us? And the summary that I've hit on it, is patients are accessing health care more and more frequently along a continuum of care. One point they may be at a pharmacy. The next point they may be in their physician office. They might be in an urgent care or an ER. But that's all the same patient who's coming in, and they have some clinical lead. They have some intervention that they're seeking. And we have to ask ourselves, what's the right information to provide at that moment? We too often-- and this is an Abbott piece-- think of things as an individual event. That model, we need to shift that and say OK, there's a patient. How do we make sure they have the right access to that care across that continuum? Because we don't know if they're driving home from work and going to the health care or if they're sitting at home, we need to make sure that access point is available to them. And in order to do this, diagnostic testing, centralized versus decentralized, is not or, it's an and. And in one particular scenario, it may be correct to access centralized testing, and then the next one it's going to be decentralized. We tend to like to group things and put them in a very simple structure, but not all things are created equal. Not all diagnostic questions or technologies truly lend themselves to decentralize access points. And that's where I think there's a opportunity for us all to align on what are the right clinical attributes? And what are the right clinical situations for decentralized access points? Obviously, COVID blazed up front, but I have a couple of things in here we can talk about. And I didn't put a lot of detail because I think it's a dialogue that we need to start. But understanding how we use multilayered diagnostic infrastructure truly will be important as we go forward. And for us at Rapid, one of the mantras that we are building into our future products and our current products, really, is trusted. And trust means a lot of things, but it's a trusted point-of-care diagnostics. So it is not just about a test any longer. It's not just about creating a lateral flow device that can get a accurate result. That's important. But we need to take approaches that are-- we like to call it Fisher-Price simple. And that gives you the connotation of kids' toys. But if you look at the environments where people are being tested, they're chaotic. There are a lot of things to do. The aha moment for me was standing at the pharmacy and watching that pharmacy tech take on about 10 things in five minutes, and thinking OK, now they've got to go read a lateral flow. How do we make it simple for them? And utilizing technology to support those novice users in our usability testing for Binax, the learning curve was so incredibly steep. And we knew we were pointed in the right direction when we had first-time users getting through it and saying, I felt confident that I had executed this properly and I was able to get the result. So it's not just-- of course, decreasing failure rates is very, very important, but you're really supporting those extended health care users as well as novice users is got to be intrinsic to the product and the product design. And then connectivity-- There's so many manners in which you can connect or utilize technology to support, that we've got to determine what information is needed where and when. And that's again, a dialogue as well. So on the next slide

I have the three tenets and premise of everything else we'll discuss. And the first is access. And I've talked a lot about that. Affordability, we know that the majority of health care decisions utilize diagnostics. Diagnostics are a critical element and need to be affordable and appropriate within that health care system. And there has to be clinical impact. If we don't have clinical impact, then we're running-- respectfully, say a life science or a translational medicine medical instance that someday will have access and affordability. And we've got to balance these three measures. So if we go to the next slide—

And I just put some summaries in some examples in here. I'm not going to read through each one of these because I think everybody on this phone has their own experiences. But I've already stated while it was not perfect, our experience with COVID can be used as a learning environment of how diagnostic infrastructure can have an advantage of a multi-tiered approach. And so that is one of Abbott's central premises, as we're moving forward strategically, is looking at how do we build in that infrastructure for all access points? If we go to the next slide

We can actually look at-- I thought of an example of OK, prior to COVID, what was the most decentralized testing we had? And I would argue, at least for infectious disease, HIV could be considered one of those. And access here is really a

public health outreach. It has been a public health outreach where we had vans and over the counter. There's been a ton of work not only in HIV, but STIs generally, in trying to get to these populations that maybe don't want to necessarily be found or want to remain anonymous. And as we do this, the infrastructure and how we build that can be utilized for health and wellness markers. The learnings can be utilized there. So as we're looking at access and then affordability for HIV, globally, we can take that model and try to apply it to these other access points where we're trying to layer in multi-tier diagnostics. And of course, with HIV, clinical impact of identification and subsequent treatment and therapy monitoring is essential for public health awareness. So if we go to the next slide—

And I put two on here. And I'm going to apologize. I realized about 10 minutes before I got on here, they have the same titles. They're not quite the same. On the left-hand side, we have ILI really, where we have somebody who's at home-- has been trained over the last two years, stay at home if you experience these symptoms. Now, the question is, hey, is it flu? Is it SARS? Is it allergies? How do I do this? What is the right thing for me to do? And when we answer that, our answer needs to be in the multi-tiered access and understanding what is the clinical need for each of those access points? And the cost benefit of that, it would be part of the future that I see collaborating with this team. And then if we go to the other side, which is really meant to have a discussion of sore throats and strep throat with children, we've done a lot of work here. And there's a balance. This is a tough one because you've got children who very often have sore throats-- are very, very common. You have parents who are under duress that their kid is not feeling well. They've got to go to work. A good portion is a strep infection, but we have to also balance this out with our antimicrobial stewardship. And I don't have the answers here. I wish I did because I would love to be able to come in and give the answers. But I think this is a collaboration is where is that balance? What are we trying to accomplish? And what is the endgame for this because it's consuming health care resources at a large level, especially in particular to pediatrics? And more and more what we hear from parents are they're less inclined to go into the doctor because they're afraid their child's going to come out sick. And so that's again, two challenges as we go forward. How do we work together and understand that clinical benefit and the access points for diagnostics? If we go to the next slide.
It's actually I believe, my final slide. And so a couple of components that I really want to reinforce. And that's trusted. And trusted is a word that I think it needs to be trusted by the health care provider. It needs to be trusted by the infrastructure, guidelines, reimbursements, the individuals on this call, that what is a trusted diagnostic? And defining that is up to us. Clinically impactful at the access point is really a key element. In fact, if we think about oncology markers, not necessarily-- I'm definitely not going to promote over-the-counter oncology markers because I think that's too complex a clinical discussion for any lay user to understand, but there are components where over the counter may be valuable-- cholesterol, health and wellness markers. And being able to increase that access, it cannot be underestimated going forward in our health care journey. So utilizing both centralized and point-of-care diagnostics. And we need to, as a community really, work on those point-of-care tests and defining the appropriate performance at the point of access. Overall, affordability and impact to patient health care-- it's got to be top of mind. For me, it's not good enough for us to just build the most sensitive and most specific tasks. We need to look at how that fits into the health care infrastructure. And we are motivated to build point-of-care testing, which will enable test and treat algorithms for specific clinical scenarios. And that's a lofty goal in today's world, and to keep expanding that as we improve our technologies and our capabilities. Central diagnostics will always play a critical role for complex and less time constraint diagnosis. And I think I've said it probably too many times, but we cannot say it enough. It is all about clinical impact at the point of access. And medical provider is an essential component when accessing health care, I believe. We have seen individuals and heard from consumers in our research that the health care provider-- I'm empowered. I'm now my own health care provider. And that is a nice mentality to have to be more empowered, but I think there also is a complexity that comes with that. So finding that right balance of that empowered patient with the health care provider is really what we're looking for. And really, as I put it to my team here in our organization is we have to ask ourselves why is this patient accessing health care here? Why are they standing in front of us? And what do they need from us to make good health care decisions? So with that, I believe that is my last slide. I can turn it over to Dr. Campbell or turn it back over to the moderator.

CLIAC CHAIR: Thank you very much, Dr. Palm. I'm going to hold all questions so that we can get presentations in on time. So [CLIAC MEMBER] and [CLIAC MEMBER] here on the lineup already. And you all who wanted to comment, just throw it in the chat box so everyone can see. Our next speaker will be Dr. Sheldon Campbell. And he will be speaking on current and future applications of point-of-care testing, the laboratory perspective. Sheldon? And of course, Sheldon, we're going to ask you to put it in presentation mode.

Current and Future Applications of Point-of-Care Testing – The Laboratory Perspective Sheldon Campbell, MD, PhD

DR. SHELDON CAMPBELL: That's good, OK. Thank you for the invitation. I'm going to talk about point-of-care testing, a little bit of the past and more future.

I always write learning objectives for my talks. And I hope that you'll recognize the evolution of modern practices in point-of-care testing from some very old data I'm going to show. And then talk about how this might change-- point-of-care

testing might change health care and laboratory practice. Why would you ask an old guy though, to talk about the future? And I am an old guy. For example, Kim Chapin and I have known each other for longer than either of us cares to admit. But maybe that's because the past informs the future.

And point-of-care testing has been around a lot longer than people think. If you look at the urine, the practice of uroscopy is incredibly ancient. A Sumerian dictionary lists body parts and changes in the color and constitution of the urine observed by physicians. So clear urine, dark urine, clouds of urine, and explains in many cases, what conclusions one might draw from that. I was not personally around for this though.

And the analysis of the urine by uroscopy advanced over time. Theophilus employed heat to further the analysis of urine. Arguably, the first analytic technique in medicine in 600 to 641 AD. Alsahavarius about 1,000 AD noted the effect of certain foods on the color of the urine, and cautioned physicians against being fooled by intentional ingestion, a pre-analytical concern in uroscopy. Actuarius moved the practice of uroscopy along by recommending a special glass, a special container to look at urine. And as it sedimented out, you could look at various parts of the urine and draw conclusions from them.

In the early 12th century, Gilles de Corbeil created a comprehensive quality assessment program for uroscopy. He wrote the whole thing as a poem in dactylic hexameter. I'm still going to try and write something in dactylic hexameter to see if the Journal of Clinical Microbiology will publish it. But he went through both pre-analytical, analytical, and post-analytical aspects of uroscopy in this poem, the Liber de Urinis.

Perhaps the first historical attempt to comply with CLIA was a urine glass disk that was a colorimetric standard dating from 1400 or before in urine diagnosis. And this showed different colors of urine and how to interpret them in a very systematic way, allowing people to make their practice more consistent.

So like us, the ancient uroscopists paid attention to both pre-analytical, analytical, and post-analytical components. They tried to standardize their procedures. They tried to train and assess and assure competency, and to improve the practice of their craft. So we're not that different from everybody else. This will come as little surprise to most of you.

The modern era of point-of-care testing may have started, at least from the somewhat parochial view of a microbiologist in 1984 with the first rapid group A strep test. And this publication came out of the University of Connecticut, right up the road from me. It was a major advance over existing methods because you could get an answer in minutes instead of overnight. It required an extraction followed by latex agglutination on a glass slide. This would not be CLIA waivable today. But why did they start with group A strep? And I would argue that it's the clinical setting that drove the first point-of-care test to be the group A strep. A single test allows for treatment. The differential diagnosis for pharyngitis is very limited. It's group A strep versus a bunch of viruses that you can't treat versus some rare things that are quite unusual. And there's no need for imaging or other tests to complete the clinical encounter. And all of those things drive and have driven the wide utilization of rapid group A strep test.

Come the COVID world, point-of-care became controversial, like essentially everything else in COVID. Molecular testing is highly sensitive, maybe too sensitive for some applications. It was extremely expensive when lots of tests were needed. On the other hand, labs are connected to laboratory information systems, and report their results to public health. Antigen tests are insensitive. All of us in microbiology world started off COVID by saying antigen tests suck. Why would we do antigen tests? And then well, maybe not because we're the-- it depends on what you're trying to test, right? Depends on whether you're trying to make a diagnosis or assess infectiousness. Antigen tests are cheap, except not really. They're still about $15 a pop, no matter who's paying for them. But home-based testing has become pretty widely and rapidly available. I include here a picture of my daughter's positive COVID test. She wanted to be acknowledged in this talk because she sent it to me when I needed it the other day. It did not get reported to public health. It did, however, get loaded to Instagram, which points out one of the issues in point-of-care testing. Exactly where does the data go and why? And how?

Within the context of the COVID pandemic, people started thinking more deeply and more broadly about the role of testing and the role of testing, particularly in this outbreak situation. And this is a widely quoted and widely discussed and passionately discussed modeling study looking at the predicted impact of COVID-19 testing related to test sensitivity and test availability and turnaround time. And at least this article purported to show that the sensitivity was not nearly as important as how often you tested and how rapidly you got the results, in terms of overall impact on the pandemic, that if you could screen everybody a lot with, even an insensitive test, whose results were immediately available, that you could potentially get a whole grip on the pandemic. It's unclear how much impact more widely available testing modalities have had on the pandemic. I doubt we'll ever know definitively, but the studies to really set that question up have not yet been published.

So where are we going? I've got sort of four things I want-- points I want to make-- parsing of the question I'd like to put out there. What are the drivers? Actually, after I put this talk together and send in, I realized that what I'm going to say is not the drivers, but the constraints on point-of-care testing. Give you sort of my SWOT analysis-- strengths, weaknesses, opportunities, threats-- analysis of point-of-care testing going forward. Talk about both point-of-care and the environment of care and point-of-care and the information environment.

So the constraints on point-of-care testing, I call Campbell's laws. And Jim Kirby, you can blame him. He let this get into a publication. So they're actually semi-official. And Campbell's laws of point-of-care testing are one, almost nobody goes into medicine or nursing because they want to do diagnostic testing. And Campbell's second law is, no point-of-care test, however, simple is easier than filling in one more box on a laboratory test order. And these things can strain point-of-care testing because people don't do tests at point-of-care for fun. And people don't do tests at point-of-care unless it's if you need other lab tests. People don't do tests at point-of-care if you need other lab tests to make the clinical decision because otherwise, the second law comes into place. You might as well just fill in one more box and wait for everything to come back. So that the inpatient corollaries are that an inpatient point-of-care test is useful only if the time for transport to the laboratory. For that single analyte, it significantly and it negatively impacts care. Or if the test is performed on an easily obtained sample, like fingerstick blood more frequently than routine blood draws or obtained. The outpatient corollary is that an outpatient point-of-care test is useful only if the test result is available during the patient visit and a decision can be made or action taken on the basis of it without waiting for other laboratory results, or-- and this is always the corollary of almost anything-- if you can make money doing it. I can't speak too much to that second corollary practicing predominantly in the VA system my whole career.
With that background, I'd like to sort of try and parse out the strengths, weaknesses, opportunities, and threats in the point-of-care realm. Strengths-- everything everyone loves about point of care-- we get the answer immediately. Patients get their answer immediately. Patients maybe have some control over it if it's home-based testing. Point-of-care testing isn't novel anymore. In these inpatients are accustomed to all sorts of things, including the COVID tests. Some of the point-of-care test, not rapid antigens, but CLIA waived and other simple PCR-based tests and some of the point-of-care chemistry tests, have improved performance over the test comparable to laboratory-based methods. And many clinically relevant specimens are readily available. Weaknesses-- it almost always costs more to do a test at point-of-care than in a central lab. For the same reason that it costs less to make furniture in a factory than by a hand by a single craftsman. The instrumentation costs are divided up amongst a much larger number of specimens. The cartridges don't have to be manufactured in the same way. You can manufacture reagents instead of single cartridges. Specimen type restrictions may be an issue, depending on what kind of swabs you're trying to get and how many tests you're trying to get out of them. Serum and plasma currently are beyond the scope of most point-of-care because there has to be centrifuged. There are a very limited number of infectious disease conditions where antimicrobial susceptibility testing is not relevant. Some, but not all. In most infectious disease conditions, you need antimicrobial susceptibility testing. And certainly, for the next five years, and probably for the next 10 years, we won't be able to do that in any kind of comprehensive way at the point of care. We always worry about how well the tests are performed by non-laboratory staff. I don't have time to go into the rather limited data on this, but there are concerns with that. Limited menus, therefore limited clinical impact. And even if you have a lot of analytes available at point-of-care in theory, if you start piling up a whole bunch of instruments to cover that range of analytes, the complexity of the operation starts to approach that of having a small physician's office laboratory. And then you're back into a central laboratory type of model. Opportunities-- as Michael pointed out, there's continuing advances-- lots of technological advances coming in the point-of-care testing world. Antimicrobial stewardship is more and more important. And any way of limiting antimicrobial use and focusing appropriate antimicrobial use is important. Development of biomarkers for antimicrobial stewardship to not only detect pathogens, but also to detect host responses has got a lot of potential. Potentially, if we can treat more conditions, then more conditions will be amenable to point-of-care testing. Now we can treat COVID, so we need to test for it. Before you could treat things, the drive to test for them is not as strong. I've been telling the point-of-care molecular people for the last decade SDI, SDI. It's such an important potential application for point-of-care testing. And being able to bring specific offsite tests into specific settings to address specific-- particularly difficult and marginal-- difficult to find in marginalized populations is really important.
Maybe we can also use point-of-care testing as it evolves to facilitate new models of care. Maybe as the tests evolve, so will how we take care of patients. And I'll talk about that in a bit. Also, microbiology laboratories are getting consolidated. People are taking those functions and putting them into central labs. And that may also be a driver of doing things locally. Threats-- reimbursement-- reimbursement drives a lot of stuff. Physicians' offices may not want to bring in half a dozen instruments. Theranos has already been a problem in the investment world. Is there going to be regulatory and investment problems with novel point-of-care things? And who does it? And who gets reimbursed for it? So all of these different places in the health care system will be competing for this turf.

CLIAC CHAIR: Sheldon, I'm going to give you a 3-minute time check.

DR. SHELDON CAMPBELL: Oh, really?

CLIAC CHAIR: Yes.

DR. SHELDON CAMPBELL: You're right. I'm sorry. I-- forgive me. OK. So you can imagine point-of-care happening in any of these environments, inpatient, emergency, urgent care, ambulatory, telemedicine, outreach, and home-based testing sites. And thinking about what turnaround time is needed in each of these sites is different.

Want to mention the information technology is critical to the future point-of-care. Being able to reach out to underserved populations, the widely available devices, being able to run complex analytics remotely, and being able to react rapidly to emerging infections. But how do we get this data into the public health system, particularly if every manufacturer builds their own data universe. That's going to be a really complicated and difficult thing to manage. And security, security, and also security are issues.

Point-of-care testing and how and where we deliver care are going to interact. How different this next step in point-of-care testing from a current physician's office laboratory models? Maybe not that different. But when we start extending it to pharmacies and to telemedicine, may be very different. There are different models that we may use here. I think that decentralized testing may drive decentralization of care. Highly complex analyzes are going to be laboratory performed, but also new models of laboratory practice are likely to evolve with the decentralization of testing. How do you manage QC for analyzers in 50 decentralized sites or in 10,000 homes? I think we still need to keep in mind that point-of-care testing will need to close the clinical encounter to have impact. But that may be the clinical encounter will change too. Lots of interest in doing this study.
I'm showing a slide that I've shown for several years on the longitude prize. It started in May 2014. It still continues for point-of-care testing for bacterial infections

I need to acknowledge the discussion tables from paper that David Peaper and Tom Durant, and I wrote a few years ago. Melissa Grafe gave me all the wonderful historical information on uroscopy. And I'll leave you with a remarkable breakthrough in testing technology here from an 1826 watercolor.

CLIAC CHAIR: Thank you very much, Sheldon. Very illuminating, as usual. All of you have your hands up. We are holding questions until 4 o'clock.

And [CLIAC MEMBER], you are now sixth in line. We are moving on to the next talk, which is Culture Independent Diagnostic Testing Impact on Enteric Disease Surveillance, Dr. Heather Carleton. These are presentations 8 and 8A on the website. Dr. Carlton.

Culture Independent Diagnostic Testing Impact on Enteric Disease Surveillance
Heather Carleton, PhD, MPH

DR. HEATHER CARLETON: Thank you. For those who may not know me, my name's Heather Carleton. I'm the branch chief of the enteric disease laboratory branch in the Division of Foodborne, Waterborne, and Environmental Diseases at the CDC. I'll be talking to you today about an update on culture-independent diagnostic testing for foodborne pathogens. Next slide, please.

So, I won't go over this much. Culture-independent diagnostic tests also include point of care tests, and are used to identify the type of bacteria, virus, or parasite causing illness without having a culture or grow the microorganism in the laboratory. And generally, they're used as a syndromic panel in they are widely used in clinical labs. Next slide, please.

When we think about culture-independent testing and the testing workflow that's needed for public health, specifically for gastrointestinal illness surveillance, in the past, when someone would get ill, eat contaminated food, develop illness, a stool sample is collected. That identification or culture would occur in the clinical lab. And then that isolate or culture would be forwarded to public health. And public health relies on these isolates for molecular surveillance and outbreaks of testing or outbreak detection as well as antimicrobial resistance monitoring. Next slide, please.

Now in the culture-independent diagnostic test era, that burden of culturing or generating isolates shifts to public health. Some clinical labs do continue to do culture, but many of them, once they received their culture-independent diagnostic test result for that sample or specimen to public health, and then that burden of isolation falls on the public health lab. Next slide, please.

And there are several benefits for CIDTs, as you all are familiar. You have faster results to targeted treatment. So you learn much more rapidly that it's a Shiga toxin producing E coli that may be causing an illness. And you may have waited several days for culture in the past. You can use a single test that can detect or rule out multiple pathogens, including

viruses, parasites, and bacteria, and including some pathogens that weren't previously tested for. There is no practical test for. It's a unified workflow in a public health lab. Likely, it can be more sensitive than culture and has high potential in some resource limited settings. Next slide, please.

But there's some challenges too to CIDTs. Uncertain meaning of some targets, multiple positive analytes in a single specimen. What does that mean? What's the pathogen causing someone illness? CIDTs do not distinguish between viable and non-viable cells. There's no susceptibility information that is necessary for really doing targeted treatment. Specimens may be rendered incompatible with culture-based tests. So you don't have the opportunity down the line to isolate the pathogen and then do testing like antimicrobial susceptibility testing. And as I said, they do not result in a culture. Next slide, please.

And there is also some performance considerations for CIDTs. So some pathogens and platforms yield sub-optimal test performance. So an example we're providing here is we need a methodological way for ongoing assessing test performance and identifying CIDT issues. And how should public health respond if there is poor performance? And one example here is Vibrio false positive issues. And we provide an example of a publication about that below. Next slide, please.

An additional consideration for performance is really the time it takes from the time of collection to when that sample ends up in a public health lab for that reflex culture or isolation of pathogen. And multiple public health labs have been cited in the past couple of years for using specimens that are too old, so greater than four days after collection. In the package insert for Kerry Blair media, the transparent media that's commonly used, is a bit unclear, but appears to recommend less than four days from collection date for further testing. And now some public health labs are having to reject specimens that are greater than four days old. After the collection date, this can adversely affect foodborne disease surveillance. Next slide, please.

Back in 2018, we had a forum on culture independent diagnostic tests, charting a path forward for public health. And this was a collaboration between [INAUDIBLE] CSTE, Ohio State University, CDC. And we had many experts from the field come and join us to talk about the main issues for CIDTs and public health. And some of the ones that we discussed include estimation of burden of disease, monitoring antibiotic resistance, public health guidance, and molecular surveillance and outbreak detection. Next slide, please.

So for estimation of disease burden trends and attribution analysis, disease burden trends data is used to understand progress in reducing foodborne illnesses. And changes in detection methods can affect overall trend data. Next slide, please. And we really need to understand how CIDTs differ from culture. And they differ in a few different ways. So the how and why the tests are ordered by health care providers who use characteristics, the sensitivity and accuracy of the ordered tests performance characteristics, as well as how individual illnesses and outbreaks are not reported to public health once they are identified and how they are counted. Next slide, please.

Additionally, antimicrobial monitoring, antimicrobial susceptibility is performed through isolates. And we perform that through genotypic or phenotypic methods. We have robust surveillance systems for antimicrobial resistance information, including NARMS, the National Antimicrobial Resistance Monitoring System, that's a collaboration between CDC, FDA, and FSIS. And that surveillance data can lead to treatment guidelines for some of our enteric illnesses. And we need cultures for all of this. Next slide, please.

Additionally, people use CIDTs for screening and outbreak settings, like daycare or food service. And traditionally, individuals that are positive for certain pathogens like STECH or salmonella, are not allowed to attend until at least two negative cultures. But CIDTs are increasingly used for screening and outbreak settings. And what's unclear is in the case of colonization in asymptomatic carriage, what this looks like on a CIDT test and what really is pathogen clearance when you're doing this testing by CIDTs. This is an off-label use of CIDTs. And it's unclear how well they work because CIDTs detect nucleic acid as opposed to viable organisms. So what does that mean in these settings? Next slide, please.

And lastly, CIDTs impact our national network for molecular surveillance of bacterial enteric infections or PulseNets. PulseNet relies on isolates for whole genome sequencing and uses that information to identify close genetic matches in a defined time period and identify potential foodborne outbreaks. PulseNet is a system that exists in over 80 public health labs and state and local. And regulatory labs are FDA and USDA regulatory partners. And we also link with PulseNet Canada and other public health agencies around the world through PulseNet International. And through our work in PulseNet, we can connect the dots to detect foodborne outbreaks and prevent over 270,000 illnesses. And through this work, we also save the US economy at least half a billion dollars per year. And all this work relies on isolates. Next slide, please.

So given all these considerations for CDITs, our division came up with a plan to address CIDT-related issues in collaboration with APHL last year. So our focuses were to preserve PulseNet, address case space and outbreak

surveillance, address antibiotic resistance monitoring, and establish recommendations for use of CIDTs in sensitive settings. Next slide, please.

So first focusing on preserving PulseNet, we've looked at the current short term and long term needs to be able to preserve our ability to do molecular surveillance and outbreak detection. And currently, we're still encouraging our public health lab partners and clinical labs when possible to use reflex culture to obtain isolates for whole genome sequencing. In the short term, we'll be relying on whole genome sequencing. And currently, we're still relying on whole genome sequencing. And those reflex culture are short term. We're working on developing expedited isolate recovery protocols that can be used in the public health lab, and also developing reflux culture testing and reimbursement strategies. And in the long term, we're looking towards specimen-based subtyping. So developing a direct from specimen sequence-based pathogen characterization method. And part of that is also improving IT infrastructure at state and local public health labs for the transmission of that expanded data from sequence data from basically metagenomic samples. Next slide, please.

So for maintaining isolate availability, we're developing expedited isolate recovery protocols and creating streamlined methods for reflex culture with public health labs in APHL. Then for developing reflex culture testing and reimbursement strategies, currently, there's no standard approach to who should perform and pay for reflex culture. So we've been working with external partners to explore testing and payment options for reflex culture. Next slide, please.

Additionally, for maintaining isolate availability, one approach we're taking is creating model reporting rules for the states. So states have disease reporting rules and requirements or suggestions for submission of clinical materials, be it isolates or specimens, from cases of reportable diseases, including the pathogens we study as part of PulseNet. Reporting ruling, which varies considerably from state to state, and how the rules are written impacts whether laboratory regulatory agencies can enforce compliance, which in turn may impact reimbursement. So we're continuing to work with APHL and the CDC Public Health Law Project to develop approaches to help states in their review and revision process. Next slide, please.

Also for PulseNet, in that long term approach, we're looking at specimen-based subtyping. So part of the challenge here is that we're really trying to pull the signal of the bacterial pathogen in the stool out from the background signal of human DNA and commensal bacterial DNA that will also be found in the stool. And to do this, we're looking at targeted approaches to address these signal to noise challenges. Next slide, please.

So one approach we're looking at is an approach we're calling highly multiplexed amplicon sequencing. And this is specimen-based subtyping where we extract the nucleic acid from a stool sample and then do thousands of PCR reactions on that stool sample, targeting informative regions of our pathogen that we know will be in that stool sample because there was a CIDT-positive test. Generating those libraries, we go on to sequence those libraries. And then we can generate a similar analysis workflow to what we currently do for isolate. So we focus on what we need. So thousands of pieces of the genome of the pathogen in this case, rather than the whole genome that we do with isolates currently. And we do have some improvements to the system. Since we skipped isolation step, we have a quicker from specimen to answer timeline. And we can also process more samples together. And we're in the process of piloting this approach with a couple of public health labs currently. Next slide, please.

So transitioning to addressing key space and outbreak surveillance. We propose monitoring CIDT usage trends among reporting clinical labs, and better understanding how CIDTs affect our ability to monitor cases and trends. We're looking to characterize the CIDT test denominator data, really, the volume of tests, and show how CIDT use patterns are changing. And this is done in collaboration with our partners and Food Net and enteric disease epi branch. So one of the projects they're doing is lab volume project that contains that denominator data for Food Net sites. And the current plan is to conduct this type of survey every five years. And we'll continue to collect electronic laboratory records, including test volume data from two major commercial laboratories. And plans are underway to expand data collection to other ordering practices such as diagnosis and reason for tests. We plan to expand data collection by HL7 messaging through an NDSS to include test type and diagnosis data for salmonella typhi, paratyphi, vibrio species, and listeria monocytogenes from commercial labs, with the long term goal to expand electronic data collection to all states and all reportable enteric pathogens. Next slide.

We'll continue to address case-based and outbreak surveillance by adjusting surveillance data to account for increased use of CIDTs for better understanding of trends, as well as work with different organizations to improve our case and outbreak definitions so they integrate in the use of CIDTs and some of those pathogens that we can detect with CIDTs that we haven't detected by more traditional mechanisms. Next slide, please.

Additionally, to continue addressing antibiotic resistance, we plan to maintain collection of some isolates to identify novel antimicrobial resistance mechanisms and integrating AR targets into our specimen-based surveillance so that highly multiplexed amplicon sequencing panel that I mentioned, as well as developing practices to interpret the AR gene detection from specimens. Next slide, please.

And additionally, we're working on establishing recommendations for the use of CIDTs in sensitive settings as I mentioned before, in daycares and food service settings that require serial negative culture. And we're working with Food Net to conduct a study in state sites where outbreak cases in the above settings are tested by both methods, so culture and CIDTs. Next slide, please.

So lastly, I'd just like to say CIDTs presented a lot of opportunities as well as challenges for public health surveillance and outbreak detection, particularly of foodborne illnesses. Our division has developed a multi-step action plan to address the effect of CIDTs on our foodborne disease surveillance. And clinical labs continue to rapidly transition to CIDTs, which present challenges to implementing the action plan, and of course encourage us to implement even sooner. The next slide, please. Thank you. And look forward to your questions at the end of the session.

CLIAC CHAIR: --you very much, Dr. Carleton. Our next speaker will be Dr. Keith Kaplan speaking on Digital Pathology the Past, Present and Future. Dr. Carleton, I mean, I'm sorry. Dr. Kaplan.

Digital Pathology: The Past, Present, and Future
Keith J. Kaplan, MD

DR. KEITH KAPLAN: Well, thank you to Heather and thank you to the committee for the opportunity to speak today. I was asked to speak about Digital Pathology Past, Present and Future. So I have some personal slides, quite frankly, kind of looking back on the past 20 plus years, and what I think may happen in the future. Although as Yogi Berra once said, "it's difficult to make predictions, particularly about the future." But I will try.

So I'm a practicing pathologist in Chicago. I'm also a chief medical officer for a software company called Corista. This is not a technology specific talk. And I also publish the digital pathology blog.

And these opinions are solely my own, and not those of any employer, partners, associates, or affiliates.

So this is another Yogi Berra quote. So I thought I would kind of look back over the past 20 years, try to assess where we are today, and hopefully, where we'll be in just a few years the way things have been progressing.

As I was preparing for this talk actually, I realized something else, but this was my son's first grade science class in 2010. And so we had 125-- actually five classes, 125 kids, and from the five first grade classes. And the science teacher asked me to show them some slides. So I brought in the microscope. There, you can see my son at the microscope in the lower right. We hooked up a camera to it and we were able to project it here in the classroom and show kids the slides. And I showed him acute appendicitis and those sorts of things. And hopefully, your questions won't be as complicated. But first graders ask very complicated questions. It was probably one of the most intimidating audiences I've ever had to deal with. They ask you what causes cancer? Where does cancer come from? If bone is white, how come it's pink under the microscope? Very thoughtful questions. But the science teacher asked me to-- asked me what was digital pathology, as I was setting up the microscope? And so we had that discussion. And I was actually able to look at some images on my iPad in the classroom off the school Wi-Fi and show the kids some whole slide images. And one of the children in the front row said, does this mean that doctors all over the world can look at the same slide at the same time? And I said this is exactly what it means. So I think the new generation hopefully gets it. And I expect good things to come from this group as they head off to college here in a few months.

Long before that, while I was at Walter Reed, this was the beginnings of what was to become the army telepathology program in conjunction with the Armed Forces Institute of Pathology. And this was perhaps maybe technology even ahead of its time, but we used robotic microscopes with robotic stages that could be navigated over the web using simple TCP/IP. We started to advance away from cathode ray tube monitors. We had flatter panel monitors, albeit smaller than what most of us are accustomed to. We still had smart card readers, of course. Most of the applications, programs, updates were still necessary to run off of CDs. Looks like I put in a 3 and 1/2 inch drive here as well, actually but this was the state of the art. This is our cooling system down here for all this stuff. You can see Windows XP manual here on the shelf. So this grew a little bit. We moved our robotic microscope over. We added a photo station. This was something called a Nikon Cool Scope that could create whole slide images on the tabletop. We had a 35 millimeter Kodachrome scanner because up to this point, we were still largely probably actually printing our slides and showing them in a carousel on a 35 millimeter slide projector, which pathology residents today have absolutely no knowledge of. And then we had also a color printer here, which I'm sure on the GSA schedule was several thousand dollars. But we were able to install that as well. We had an APC backup unit here. I brought a 2 by 4 from home because occasionally the equipment here in histology lab would leak. And this was our water deterrence system. I'm not sure what the milk crates were for, but they're present as well.

So we did a study looking at actually the efficacy of telepathology for-- the efficacy of telepathology for frozen sections. And I intentionally start with the frozen sections thinking that if you do it with frozens, if you could actually move an image rapidly enough for a frozen section, it would meet the community standards of accuracy for formalin-fixed paraffin embedded tissue. And so we did this a couple of different ways. We did this across the parking lot between Walter Reed and AFIP. For validation, we actually also did it between a hospital in Germany-- an army hospital in Germany and Walter Reed, and showed that.

And as I said, this was the beginnings of the army telemedicine program for pathology. And initially, the idea was really to have a hub and spoke, so smaller regional largely kind of community sized hospitals would refer cases to the regional medacs or medical centers for expert consultation, or if they needed hem path or derm path, and perhaps that wasn't available in some of these one in two man spots, they could rely on regional experts, but ultimately most of the material was sent to AFIP for expert consultation, as well as people knew each other or trained with each other, could send cases, to their colleagues that they knew and wanted to share information with.

And so this grew to 20 some odd hospitals overtime where we deployed these robotic pathology units.
And here's our hematopathologist in the day with his hem path following a couple of our residents, looking at a bone marrow here from Landstuhl, Germany about 2003.

So the most popular show on television in 2007 was House. And even House was showing images on a computer screen in some form, although there's really no camera that I can tell attached to this microscope. But the oncologist-- if you were friends of the show-- Wilson here is saying it's definitely not cancer. You checked the biopsy twice, and it's not cancer.

So I mentioned this largely for historical purposes because this actually was ancient history. It's ancient history now and really, it was ancient history then because people had shown this as a proof of concept that this could be done 20 years prior. And we were moving computer images from El Paso to DC for example, in 1986 where pathologists could say you can have a piece of tissue under a microscope in Texas and an image so clear that you can see the diagnosis-- you can see the tissue clear enough to make a diagnosis by satellite.

And even in 1986, this was somewhat ancient history because there were discussions at AFIP using television technology going back to 1955. And Toby Cornish at the University of Colorado has thoroughly researched this from the AFIP archives from the day, and came up with some really, really neat images and stories about this. But this article here from 1955 says, as the patient identified only as a quote unquote "lovely 46-year-old woman lay anesthetized on an operating table in Philadelphia, a pathologist there microscopically examined a piece of tissue removed from her right breast. And the doctors in Philadelphia, Washington, and Baltimore watched."

And there were ideas and schematics and plans to have studios and television communications between operating rooms and auditoriums and between the autopsy and auditoriums and so forth with control rooms.

In any event, we were able to deploy the technology into the field in Iraq. And these two pictures just illustrate at the time we had a single slide system and the technology had evolved to, I think we could hold 60 slides at a time. I don't recall for certain, but you could view multiple slides at a time. We were initially limited. And then this grew following Moore's law in terms of the rapidity of technology.

And so I think this is probably the first example of a real-time worldwide teleconsultation network where you could send a request in for consult. The request could be picked up and a report generated in about three hours. And if you had to send cases via AFIP at that time, you certainly weren't going to get that kind of turnaround time with analog cases. And then you had the ability, although it didn't always happen, but you had the ability to look at the same slide at the same time with the consultant. Pretty staggering if you're in Germany or Korea and you have the ability to do that.

So, all of this taught me that there were some basic value propositions for digital pathology that I think have remained true. The first one obviously, telepathology or remote reads, consults, reviews, quality assurance. Any time that the slide and the reader at some distance for information to flow. And then I also think that we didn't know what the technology was. We probably weren't using artificial intelligence or AI as loosely as we do now. But we appreciated the fact that once you had these content-rich data sets that you could share and store and analyze, this idea of image analysis was very intriguing in terms of maybe we were just scratching the surface scanning an HNE or an immunohistochemical slide and there was more to be learned. And that brought up other ideas about content-based image retrieval, searching images with images, et cetera. But ultimately, I think one of the main value propositions for digital pathology is machine learning, deep learning AI, and probably I think going forward, at least in the near term, what I would say is computer-assisted diagnosis, not necessarily replacing, but helping, assisting with diagnosis.

So these initial ideas about perhaps quantifying percent of tumor or grade of tumor, grading of immunohistochemical stains, rare event detections, for example in AFB smears or cytology smears. And we've seen this obviously with liquid-

based cytology already. Grading of fibrosis and liver biopsies, of personal interest to me, FISH analysis, CISH, crystal identification, et cetera.

And so probably by about 2007, I think we started to think about the ideas about having someone reviewing a slide, having a secondary pathologist reviewing that slide as well, models for virtual immunohistochemistry started to come online about that time, and then perhaps even the first notions of glass lists sign out, primary diagnosis using whole slide images, virtual microscopy, consultation, et cetera.

And so any time we think about histology, we always use the term workflow. And maybe it's an overused term, but how do you get from getting this in the frozen room or the gross room, getting the tissue to a reasonable size to be fixed and processed and embedded, and onto a glass slide. And then where does digital pathology embedded, and cut and stained, and on a glass slide, labeled, et cetera, where does this fit into the overall workflow?

And so we're all familiar with this in histology where there's order collection, transport, receiving, grossing. And then there's one little step here, really. In the grand scheme of things, there's a lot of details here, but it's just one circle in this workflow diagram in terms of what needs to be done. And then once the slide is scanned, who does it go to, how do they get it, and reviewed and signed out, et cetera? And how does all of this fit into the workflow? And so then we started to have discussions about LIS integration, which I think is paramount for adoption for digital pathology, to be able to have the right person review the right slide at the right time, and complete this loop to get a result out from that initial order.

And so really, what I think we're talking about are differentiated service models. We have this collective intelligence, shared expertise, coverage, collaboration, improved consultation and turnaround time, elimination of slide shipping issues, and perhaps even better connectivity to patients, colleagues, clients, and hospitals in a more distributed health care system and larger health care systems, where you're more distributed from your colleagues and perhaps, the point of care. As I mentioned before, image analysis applications and searchable image databases.

So let me say a few words about-- this is also a Yogi Berra quote-- let me say a few words about the future.

So I think for pathologists, we've always viewed ourselves-- and I was told in medical school that we were the doctor's doctor-- and largely, as a surgical pathologist, you provide anatomic consultations to other physicians. And over the years, growth of commercial labs, subspecialty labs, consolidated health care systems with core labs, pod labs, office labs, et cetera, in many ways has distributed where the care is delivered, where the care is delivered relative, as I mentioned, to the point of care. So we're seeing increased distance between pathologists and patient, and perhaps by some measures, loss of status, stature, and recognition as about valued member of the health care team, if you're not under the same roof or you're some distance from your other colleagues within larger health care networks.

I would suggest that we think of ourselves as the patient's doctor, being uniquely positioned as gatekeepers and diagnosticians and agents of the tissue, in terms of image guided fine needle aspirations for tissue conservation, molecular diagnostics, triage, and correlation with synoptic reporting.

And as I said, I think currently, it's fragmented. I think we all experience communication and IT issues, even within quote unquote, "integrated health care delivery systems." There's local versus regional versus national referral centers based on relationships. We've seen declining reimbursements, uncertainty and fear in the marketplace, perhaps with some challenge to innovate or make workflow modifications. And as I mentioned, little direct patient contact, particularly if you're in a core laboratory, again, some distance from point of care.

So hopefully, we can restore the importance of pathology, and have that importance valued by patients and their families, reestablish our status in medicine, and use these technologies to facilitate information transfer with direct correlation for pathology with patient questions.

So had I given this talk-- and I've given variations of this talk, maybe going back to about 2017, I would have said predicted pathologist shortage. But the pathologist shortage is real. There were a couple of articles published in the Archives of Pathology and Laboratory Medicine going back to 2013 that looked at pathologists staffing models. And those papers predicted that we would start to see some shortages by 2015. And there would be really kind of, I guess, a peak shortage or the full effect seen by 2021. And it would take years to reverse that. And again, this is going back to 2013, so this predates March 2020. But I think they got it right on the head. If you look at staffing situations, there's a tremendous shortage of pathologists right now. There's one website that I think everybody is familiar with in terms of job opportunities. There's a record number of jobs posted. And most pathologists get multiple emails, texts, phone calls from folks looking for either part-time coverage, locum coverage, or even full-time employment. And so this is a real issue. I think that digital pathology is being offered, proposed as perhaps, a way to augment this, but I think the funnel is only so big that you'll still have fewer people doing more. And I'm not sure that this would enhance the situation any or try to correct the situation any. And I think on top of that—

CLIAC CHAIR: Dr. Kaplan, you have a 2-minute time check, please.

DR. KEITH KAPLAN: Very good, thank you. And on top of that, I think we have to do more with less, in terms of the tissue that we get, and adopt to being information specialists in terms of triaging the tissue for all of the necessary ancillary studies now for patient care beyond morphology.

So let me just say a few words about AI. I think that's what everybody's hearts and minds are thinking about right now. We think about digital pathology. We've kind of moved past primary diagnosis and we're thinking about AI. Familiar with hype cycles, kind of a conventional hype cycle curve here.

If you go back to 2017, here's deep learning and machine learning, just for reference autonomous vehicles are here. And if you look at 2021 now, we're a little bit further along. We're down the slope of disillusionment and to this trough here and during the peak of the plateau here, so to speak. And so we'll see where this goes. I think there's a lot of unanswered questions. There's certainly a lot of investment in this area towards trying to use computers, machine learning for diagnostics.

Ultimately, I think the goal for one of the suggestions I would have, if I may, is without CPT codes, without ways to measure this and help offset the investments that are required, certainly, a lot of money has gone into it. And those companies would like to return on their investment, I'm sure, for hospitals and groups to institute this. I think that there needs to be some reimbursement for the technical services in terms of scanning, storage, and analyzing.

So I've probably shown the slide nearly every digital pathology talk I've ever given. And I've touched on most of these already. I would just suggest perhaps, at this juncture, we think about putting the patient in the center of this, rather than the image, and think about ways to become the patient's doctor, as I mentioned. Thank you for your time. I've enjoyed my time on the committee. I think my term was up in 2016, but I appreciate the work you do, and I hope you found this talk beneficial. Thank you.

Committee Discussion

CLIAC CHAIR: Thank you very much, Dr. Kaplan. Very illuminating. We have 50 minutes for questions and discussion. The lineup is [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER] and [CLIAC MEMBER]. If you want to speak after them, get in line now. We'll start with [CLIAC MEMBER].

CLIAC MEMBER: So I just want to thank everybody. Those were actually just-- they were awesome. Thank you. So my question is for Dr. Palm. So obviously, the benefit during the pandemic of using these rapid tests-- there is no discussion, right? It's been a remarkable thing to see, especially if used appropriately. But you touched on it, but there's a real disconnect with the health care system. And it's a bias being a physician. But this idea of having this physician-patient relationship is still a value, I believe, and I think is data to support it. I mean, the care needs to be coordinated on a personal level, but even from a public health level, the case metrics we now have don't actually include these at-home tests. It's not connected into the system. You mentioned the issues. But are there solutions that are currently being considered that we may want to hear about today? And a follow up question, is there a risk for widening disparities regarding who has access to these tests? You know, I've had to take the myself, of course. Just reading the instructions, the level of health literacy. And if you're using an app, that gets into a whole other issue as well. So those are my two questions to you. And again, thank you to everyone who spoke during this session.

DR. MICHAEL PALM: Now thank you, [CLIAC MEMBER]. I am definitely off mute? Yes. OK. So first thing, for a solution again. And again, in today's world, we reacted very, very quickly. We did build a companion application with the noted challenges. And you can connect in and report there through that app and through a website. Not perfect. We acknowledge that not being perfect. And given lateral flow is currently visually read. We have implemented the solution, not here in the US, but in India, that is a photograph interpretation that digitizes the result. And maybe as we look forward, as we decentralize, we're looking to digitize. And so what that means in reality is that the results of the test are not in that test. They can be liberated through digitization. So we need to look at things such as biosensors, AI was a great. Dr. Kaplan's talk on AI was fantastic. Where is that? Can we help through machine learning? And how do we make that reporting function just part and parcel to the diagnostic? To your equity question, that is a great question. And we are struggling with that as to one of the parameters? What are the metrics aligned to that? Infrastructure-wise, we also can look at that because I can digitize a result on our next generation lateral flow. But if there's nothing to put that through, there's nothing to hang that on, it's just going to sit there in the same way it does today. So I think there are a lot of challenges. I think the answer lies in working together to understand how can the test digitize that result and then connected into the patient and the health care provider in the most appropriate fashion? Telehealth steps in there. We saw some of the infrastructure coding languages. That's another piece that's really critical for us to nail down. And I think

there's a lot to unwrap on that second part of equity. So hopefully, that addresses your question. I know it acknowledges the problem more than it answers the question.

CLIAC CHAIR: Thank you very much. Dr. Palm. Has to leave at 4:15, so we're jumping the line for those who have questions specific for him. [CLIAC MEMBER], you are next.

CLIAC MEMBER: Yes, thank you. And thank you to all the speakers for excellent presentations. And I'm going to piggyback, I think, on [CLIAC MEMBER] comments that in some ways I'm more concerned with the comprehension of what to do with those results then how the tests actually being performed. And I'll give you a case example. I was talking last night to a young lady whose son was sent home from school sick two days ago. The school nurse said it's not COVID. He was negative on the rapid test. Kids still symptomatic two days later. No discussion of if he continues to be symptomatic, consider getting a PCR test or repeating the rapid test. So clearly, the folks at that site of the waiver didn't quite understand or didn't have the opportunity perhaps to talk directly with the parent about what to do with a negative test result and how to handle that in the face of ongoing symptoms. I've got another example, a personal example of I know somebody who tested positive on a trip and didn't understand that they really shouldn't get on a plane. They understood that they should wear a mask. They didn't quite-- So I think there's a lot-- I think we're, in some ways, who are missing that provider patient relationship of, OK, you tested negative, here's the next steps, particularly if you continue to be ill. Or you tested positive. Here's the next steps. And telemedicine might be one way of bridging that, but it concerns me that whether people know what to do with their test results and what to do in the particularly, reflex testing in the face of a negative result?

DR. MICHAEL PALM: And [CLIAC MEMBER], I think it's a really good concern. I think it's legitimate. I will tell you, actually I have a mug on my desk that says not that kind of doctor. And it [INAUDIBLE] because I was playing a different type of doctor because there are so many questions from so many people. I think the infrastructure, as this test moves out-- you hit on it a little bit-- telehealth and how do I access the right information? There's a responsibility when that test is acquired and taken to actually follow up and have that health care service be there. You saw in the adoption chart some of the chat bots and some of the AI, ML, VR, virtual reality. I think those are real opportunities for us to put that support a little closer to that patient so that they're not off-- I call it doom searching in Google-- and figuring out what's the latest thing on Instagram and you're getting my health care advice from there. So when we look at it, our responsibility is that holistic piece. It's not just to put the test out there. It's to bring the infrastructure to that access point and assure that as they go forward, that-- and I really believe telehealth is one of the big foundational premises of getting access at that point-- the pathology example was a phenomenal example of how limited resources are now expanding and you're able to get that specialty down range. I think we have to think about how to re-replicate that for rapid infectious disease diagnostics.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: All right. Next question, I want to insert a commentary. What we ran into was how do the person who claims they were tested was actually tested? And then we went down a rabbit hole on who's allowed to proctor, who's allowed to watch, all that stuff. OK, the next question for Dr. Palm is from [CLIAC MEMBER].

CLIAC MEMBER: [CLIAC CHAIR], you mentioned just part of the whole problem of informatics, you know. How do you how do you connect the results of that patient? And then for you, Dr. Palm, I loved your talk, but with all this distributed care, how do we aggregate that data? And you just mentioned again, freeing the data by digitizing it. But I think it becomes more free for consumption by also standardizing it. So how do we bring the vendors together and say, we're going to have a standard way of communicating this digitized data so that it can be easily consumed?

DR. MICHAEL PALM: I love the question. And the question sits in-- when we're looking at it, we have ASTM, we have HL7, we have Fire, we have POC 1A. That's the standardization that we're doing today, it's actually getting a little bit bigger as we try to improve it. So I think we're in that curve that Dr. Kaplan said, we're not quite over the hump. I think actually, we may be over the hump and crashing into despair because as I look at it, we don't have a standard. Now we've done a lot of work through COVID with APHL to try to make sure that the data we do collect drives through and into the CDC reporting. But that showed us that there needs to be an easier way. We can't rely upon the person, whether that be the patient, that be the test individual, to load that data. It has to be automated. So that's where getting to a standardized structure of how will that load into-- and FIRE might be a really good methodology. I'm not an IT person. But my teams are saying FIRE is a solid language, but there's not universal agreement. And I think your point is how do we get to a universal agreement on when the data is presented, it's not an-- I'll call it Abbott-ise-- or it's universally accepted and can be digested? And I think that is, as I look to it, the holders of the data, the owners of the data, whether it be HHS or CDC, can really help drive that standardization. And that is out of our wheelhouse from a company standpoint. And we are trying to align to as many of those as possible.

CLIAC MEMBER: So I will just add one thing. Working in that area, I find that vendors often want to walk away from a standard and say it's OK, I got this. I've got to do it my way. And so I would urge you to get your vendor colleagues to align themselves with your line of thinking of adopting a standard. OK.

DR. MICHAEL PALM: Perfect. Thank you.

CLIAC CHAIR: I see no more questions directed at Dr. Palm. Thank you very much, Dr. Palm.

DR. MICHAEL PALM: I apologize for having to run, but thank you. I was honored to be part of this and to present too. Thank you all, and look forward to following up with all of you.

CLIAC CHAIR: Thank you. And moving back to the list, first to [CLIAC MEMBER], who has been very patiently and graciously waiting. [CLIAC MEMBER], your turn. And you're on mute.
CLIAC MEMBER: Thank you so much to all of the speakers today. I really learned a lot. And it did generate some questions here. I wanted to specifically talk to Dr. Campbell. Your presentation is incredible. As we shine a light on the checking of the box on your application, this is a personal challenge that I ran into with my son, that died from a preventable hospital acquired infection, after contributing-- after getting MRSA. And we were unable to test him. The doctor would not test him. All that he was tested for was strep. And so he just guessed, guess on what it was that. He had he didn't go further to test further. And so my son died. It will now be 16 years ago Sunday, on Easter because doctors did not test, and they took too long to diagnose, and he ended up dying from MRSA as it turned into sepsis. So my question to you is this. More than anything, antimicrobial resistance is being expanded upon. It's getting worse because of what we're seeing today with COVID. The most important thing that patients and families need are answers quickly, when many times physicians refuse to test. I cannot begin to tell you the number of times people come to me as a patient safety advocate when they've asked to be tested for MRSA because they've been working in a nursing home, and now they're going to go to a daycare and a physician refuses. So what is critical and key is to use what we've learned with COVID in adopting a single test that incorporates what you discussed and highlighted. And that's respiratory infections. And I wanted to add to your areas of conversation, when you discussed could this respiratory infection be the, flu could it be COVID, could it be strep, or please add could it be MRSA because the CDC has now shown because of the COVID outbreak and epidemic, there has been a 30% rise in methicillin-resistant staphylococcus aureus infections in hospitals and spreading into the communities. So I'd very much like to be a part of the committee, the working group that works on the outside and outpatient facility point of care solutions to adopt something very quickly with what we've learned so far on at-home and rapid test for facilities at outpatient clinics like doctor's offices because many doctors offices don't have these kinds of tests available. And the most important thing is that we need to make sure that we keep this affordable and available for all, and simple so that as we now see with COVID, there is a test and then we can also treat because of an oral medication that's approved. We need this same type of adoption for doctors' offices, and to make this more available and to use what we've learned so far. So I'd love to hear your thoughts on incorporating a single test for those respiratory infections.

DR. SHELDON CAMPBELL: That's an extraordinary story. I'm a little bit moved and have a little bit of a struggle to respond. There are broad range tests for respiratory pathogens. Right now, they're pretty expensive. We struggle with particularly, those broad range tests right now. We struggle with which patients benefit from them. And we worry about over testing for things like MRSA, in particular because we're concerned that we'll generate more antibiotic resistance for treating a test rather than treating a patient. So you've asked some profound and deep and broad questions that I don't have time to go into, nor am I particularly the right person to go into them. But I think it's important for us to keep that perspective in mind. I'm afraid that's a somewhat unsatisfactory answer, but you asked some questions that are so big that they're hard to address in this kind of setting.

CLIAC MEMBER: OK. Well, I will just add to that of course, it wouldn't be just your normal respiratory. I would say something that is urgent, like with a fever, coughing up phlegm. Those types of symptoms. You know, of course, these are the people that are on the edge that really need to know quickly what is this? Do I have sepsis? that's really where I'm going with this question.

DR. SHELDON CAMPBELL: Very good. Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you very much. And thanks to the lead representatives today. And thanks to those who organized the session. It's very thought-provoking. I wanted to make more of a comment than a question. And maybe Sheldon would comment too on his thoughts. I've been part of a number of outbreaks and epidemics. I'm a veteran of many of these, and now a pandemic. And I am thinking that we're basing our future thoughts on this experience. And I'd like to note that in past epidemics we didn't need this kind of testing available. Not everybody needed to be tested.

So this is unlike any of our past experiences. And I'm not quite sure how our next experiences will be, of course, because I can't predict the future. But I'm wondering if we're putting too much emphasis on this. And I'm worrying a lot about the emphasis on point of care testing using the EUA technology for point of care tests. This is 40-year-old technology. It's been proven through the years not to be as good as we would like. And we know it's not as good as PCR. But we know now particularly from this pandemic experience, that PCR is not a panacea either. And I think we should be focused more on what can be in our future testing arsenal so that we have the tools to meet that next pandemic. And we need something that has the capability to ramp up so we can do larger capacity and get results out quickly. And I certainly think that public health, as was emphasized in the PulseNet presentation, needs to have the data and samples to do the sequencing so the prevention efforts can be targeted and done quickly. So that's my thoughts on this. And I make them in the hopes that other may express some thoughts as well.

DR. SHELDON CAMPBELL: Since you called me out on that one, my hobby-- one of my hobbies is history. And we're all in history we're always preparing to fight the last war. And that happened in COVID, where our response in many ways, was informed by what we'd done with Ebola just a few years ago. I think that one of the lessons we need to learn moving forward is flexibility and building systems that adapt to a new-- the next damn thing as rapidly as possible, rather than being sort of in the mindset of the last damn thing. And that flexibility and early data gathering and early informed guesswork that we don't lock ourselves into. But nonetheless, early informed guesswork is how we plan to fight the next war, not using the strategies from the last one.

CLIAC CHAIR: Thank you, Sheldon. Thank you, [CLIAC MEMBER]. Next is [CLIAC MEMBER]. [CLIAC MEMBER], you're on mute.

CLIAC MEMBER: --on? Mute. On mute, [CLIAC CHAIR], So, OK. I just want to respond back to [CLIAC MEMBER] quickly. I feel for your story. And I know antimicrobial resistance is also a big, huge health care problem, and where CDC and others want to focus. And I would tell you that if you go into a provider's office now, they are so busy, they have very limited time with patients, and they often treat empirically. It's easier to treat empirically than do a test and treat the right way. And the only way we're going to get teeth in that is really, by sort of figuring out how we can solve that circle. So that's one thing. And there are rapid tests for MRSA. So hopefully, we'll get what you need. OK. My question really, for Sheldon is that you sort of mentioned oh, as the menu gets bigger in point of care-- and it made me think, as we're moving towards looking at new regulations in point of care or figuring out how we do we make more appropriate guidance, should we really be thinking about the number of analytes potentially a site is doing, the size of where they are performing them, is it adequate or not? Maybe that's based on the type of patient, patient base. And then [CLIAC MEMBER] had brought up earlier about biosafety. And is any of that? So I'm wondering, are we moving a waived site potentially just because we're looking at one test? What happens when we look at it as a conglomerate of what they're actually doing? So just your thoughts on that?

DR. SHELDON CAMPBELL: I think that's a great question. I mean, when you've got a whole set of waive platforms, does that become more complicated? I mean, I wonder if the simplicity of the waive moderate highly complex model is starting to become outdated? And whether some kind of gradations within the waive world, some kind of oversight of waived testing laboratories that's less onerous than that for moderate and high complexity testing settings is time to go on the table? I don't know what that looks like. I think a whole bunch of us would have to sit down and bang our heads together for a while.

CLIAC MEMBER: And to be honest, Sheldon, it comes back because like you said, except for crazy people like you and me who went into medicine wanting to do diagnostic tests, most people in a point of care setting, they are running around doing all these other things. And doing the test is not their primary objective. It's just not what they really want to do. And if there is an available central lab, it's much easier to send it to that. So it is a really--

DR. SHELDON CAMPBELL: My personal definition of point of care testing is testing that's done by people whose main job is doing something else.

CLIAC MEMBER: Yeah. [LAUGHTER] So anyway, that's just my comment, I think, for we need to think about that going forward because if you look at where the market is going for point of care testing, it's only getting bigger and bigger and bigger. And you have 60,000 CLIA waive labs. So something's got to happen. OK, thank you.

DR. SHELDON CAMPBELL: Thanks.

CLIAC CHAIR: [CLIAC MEMBER] wanted to respond to you, [CLIAC MEMBER]. So I'm going to let her insert. [CLIAC MEMBER], you're up next. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you so much for your thoughts, [CLIAC MEMBER]. My point I'd like to make real quickly is my son died in 2006. And at the time, yes, I know. There was a rapid test for Cepheid available. It was $200. But this hospital

and these physicians decided that they don't want to carry that test or offer that test for screening patients. So that's the problem. Here in lies the problem is that the public needs to have the ability to be empowered. And if there was the capability to have this test at home, like we are doing today with screening ourselves at home, if I would have had a test that could-- and I've talked with experts in labs. There is a way to incorporate multiple diseases in a single test. If I had that at home, I could take that test to my doctor and say please test further. My son is very ill. But that's the problem is the tests are available, but doctors aren't using them. Neither are hospitals. And that's the problem. The patients need to be empowered. And no one was more clear than to describe the importance of relationships and serving the patients, not the doctors. Serving the patients.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]. And I'm going to move on to [CLIAC MEMBER]. And [CLIAC MEMBER], you have two hands up. So if you're done--

CLIAC MEMBER: First of all, I want to thank all of the presenters for excellent, excellent scientific, very good, usable information. And many of my questions have been answered. So I'll be brief. And it's a good follow up to you, [CLIAC MEMBER] because my question has to do with the point of care testing, particularly the rapid test, the home test. And we know that there is a major push to have a test in every home, in every office, and so forth. And so the question I have, I don't know if this for Dr. Palm or Dr. Campbell or Dr. Fitzgerald. But is there more research or work being done to ensure the reliability and validity of the findings of these tests. Because it's from my understanding that the rapid tests and the home tests and all of those tests, except for the PCR, are still has a very high rate of error. And so even though one may be really sick and really utilize this test, may not be able to get that second layer of treatment within that narrow time frame. And so if you could speak to that in reference to is there more research and work being done? And do we need to take any action in reference to or encouraging or is it our role to do that? Because if those tests are going to be used, we really need to be able to count on what the findings are. And I think for Dr. Campbell, maybe to just clarify this. You talked about test sensitivity is secondary to the frequency of the turnaround time in COVID testing. OK? So that kind of relates to what I've said. So could you explain more in terms of that? Because I still see the importance of when a test is carried out, we should be able to rely on the findings and be able to use that for care and treatment. Thank you.

SHELDON CAMPBELL: So there's a simple and a more complicated answer to the first question about how reliable the tests are and is there research. In the very focused world of infectious disease, virus testing, antigen versus PCR, it's clear that antigen tests are insensitive relative to PCR. We've known that for 20 years in flu. And it's basically exactly the same in COVID as in flu. More broadly, in terms of point of care tests, it really depends on the test. Some of the point of care tests are very accurate, indeed. Some of them are less so. I think a lot of us in the laboratory world are concerned that some tests may not be as well performed by people whose main job is not doing laboratory tests. They're all complicated machines with lots of moving parts and have to be done properly to give you good results. In terms of the specific question on COVID, the information that I was referring to was a modeling study that looked at the public health impact of testing models that were either highly sensitive tests that were done at long intervals and took a couple of days to come back, like COVID PCR tests did at that time in the pandemic versus tests that were given very frequently, not that sensitive, came back immediately and were really inexpensive, like they thought maybe antigen tests could be, though I'm not convinced about that. And so this modeling study said that testing real frequently, even though the test is less sensitive, had bigger public health impact than testing less frequently with a more sensitive test. Didn't say anything about how good a diagnostic tool it was, just as a tool for pandemic response and public health response, that people would not be diagnosing themselves that way, but would be isolating themselves using this test. And that's a whole different thing than professional providers using tests for diagnosis. And I agree with [CLIAC MEMBER] and a lot of other people that I'm very dubious about the future of antigen tests as diagnostic tools. Does that answer your question?

CLIAC MEMBER: Yes, it does. Thank you.

DR. SHELDON CAMPBELL: Sure.

CLIAC CHAIR: [CLIAC MEMBER] had a comment in the chat box. I don't know if, [CLIAC MEMBER], if you wanted to share that?

CLIAC MEMBER: Absolutely. I think just to Sheldon's point, I was first on CLIAC 20 years ago when rapid antigen tests first came out. And people were like oh! 40% is good enough. And lab people were shocked at that. But I think it gave that comfort to a provider that well, I know if I can use this new antiviral drug or not. But then, subsequently, we decided no, molecular is definitely better to diagnose flu. With COVID, we were so overwhelmed and the prevalence was so high, that rapid antigen tests in a symptomatic person really did quite well. I think we don't have enough data to see with all the different variants and the ups and downs and the prevalence, how it really would perform. But I would question as we move into the fall where the prevalence still is quite low, and we have influenza and we have RSV and we have the typical rhinovirus that we haven't seen in two years, are people going to keep testing over and over and over because they think they're positive for COVID, but they really aren't? Or are we missing it because prevalence is so low? So to answer your question, [CLIAC MEMBER], it's a little bit more complicated than just sensitivity and specificity. It also has to do with prevalence of disease. And that we've known for years with influenza as well.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER] is nodding, so I'm assuming she's satisfied. I'm in line, then [CLIAC MEMBER], then [CLIAC MEMBER]. And my question is shift gears is for Dr. Carleton. It relates to the culture independent diagnostic tests. And what I've been observing, is oftentimes the transport medium or the culture medium that is used to grow the organism is contaminated with dead organisms that will amplify, but will not grow. We've had periodic things with brain, heart infusion having gram negative things coming out of the seaweed. And most recently, had a positive blood culture pseudo epidemic because of dead vibrio in the blood culture media. So I'm curious how that would impact the plans for the CIDT going forward for public health?

DR. HEATHER CARLETON: Yeah, great question. And that was captured in part of those additional considerations. You're not the only one who's noted those issues because you're looking at nucleic acid and not viable organisms. Sometimes things that were used to make the transport media will be detected in that by that CIDT test. And that causes challenges when you get into case definitions for surveillance. So if you accept CIDT positive as your case definition, do not require further culture, you're going to increase the number of, for example, maybe vibrio cases because you're just looking at that CIDT positive. So part of our planning going forward has to be a way to capture those considerations too and communicate with the manufacturer because ultimately, this gets back into a challenge with their test performance as well that we're picking up these things that aren't really causing illness in patient. So it's definitely something that we're keeping an eye on and trying to figure out how best to communicate about that and address it in our surveillance systems.

CLIAC CHAIR: Thank you. And I would respectfully ask as this gets rolled out for those labs doing CIDT to perhaps consider collecting a natural specimen in addition to the swab or whatever else so they got a backup like we do with group A strep.

DR. HEATHER CARLETON: Yep. Completely agree.

CLIAC CHAIR: Next is [CLIAC MEMBER].

CLIAC MEMBER: All right. Thanks, [CLIAC CHAIR]. You know, I think it's sort of in line. First of all, as you were talking or as others were talking, I reflected on the first CLIAC meeting that I attended as a speaker, not as a member. And I did present our study with CDC and with California that showed that people who know what they're doing do a better job than people who don't basically that comparing lab testing. And this really sort of reflects-- I was going to comment during Dr. Palm's discussion section, but since I know that I know they had to go-- that I think that as we talk about designing test systems and working to improve those-- some are good, some are not-- that it seemed to me that this needs to be something like either a cell phone or frankly, an automobile. Right? I don't need to know how the engine works or the tail light works. I know it works. But I can effectively and hopefully safely drive this instrument if you will, without knowing all the details. And I think that as we work, as FDA works, as others work that we need to design it, design systems in a way that will facilitate that. The other piece of that, as we've had these discussions and you know, whether it's CIDT or some of the other things that Dr. Campbell, that you talked about, that as the designs are being done to look more like a car than a high tech device, that we probably need to design these-- as the tests are being looked at an designed, they need to be designed, I think, for clinical utility. And so although we technically look at analytical and clinical validity, that really that the value of a test is going to depend on when it's used, how it's used, who's using it, and on what patients it's being used. And so it seems to me if there's a group looking at point of care testing-- and I'd love to participate-- that it's really going to be important to look at that spectrum. So that was my comment, just reflecting on some of all the presentations.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: Thank you. And I think in some ways I just want to reiterate my comment that I think everyone on this panel understands these tests are imperfect. And we don't want the perfect to be the enemy of the good. And we understand those limitations. And Dr. Campbell’s example of we don't have to understand how the car was made in order to drive it. But I do think we need more interaction for those people that do know how the car was made to be interpreting and explaining to [CLIAC MEMBER] comment what to do next with those results. And I think that's to me, as I mentioned earlier, that's the missing piece is understanding hey, great test. These are the limits and this is what you need to do next. And yes, in a low prevalence situation, that may shift even more. We understand that, but I'm not sure that the certificate of waiver providers nor the over the counter really gets at that. And [CLIAC MEMBER], to me that kind of gets to your question--

CLIAC MEMBER: Yes.

CLIAC MEMBER: --that I think a big part of what we're missing is how to counsel people with both negative tests and positive tests.

CLIAC MEMBER: Thank you. You're right.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I would say using these example, what we really need is an autonomous car, and that when you're done, when you step out, it tells you what to do. OK, next is [CLIAC MEMBER].

CLIAC MEMBER: you're muted.

CLIAC MEMBER: Just to follow up on [CLIAC MEMBER] example. You have to build more things in. It's got to automatically transmit to public health. It's got to be able to give you a clear result, negative, positive. And then my question is as a provider, maybe a telehealth provider, they're going to rely on how that test performed. And I think that's the other big piece. My COVID test comes up negative, but I have symptoms. Is that person going to treat you for a sinus infection? Are they going to say, oh, maybe you have flu. I'll give you Tamiflu. So I think it's just one of those things where all those loops have to be closed, but clinical utility is absolutely the key part for point of care. So anyway--

CLIAC CHAIR: I see no one else in line, so I'd like to add a commentary. As I understand, a lot of these point of care devices are manufactured in the million, billion fold quantities. And as a defect is found, and when recalls happen, that becomes a significant challenge on the user end. There was a huge recall of a particular cartridge type in early March 2020. And that triggered about a year of whatever was around could not be used, whatever was released was not yet FDA approved, therefore became high complexity, and then is now categorized as moderate, but the actual original categorization was waived. And with that through a number of labs through was rapid. How do I make this an LDT? When it became moderate, how can IQCP it? And where is the data to support it through all of these recalls? So my plea is on the supply chain front end, as these are manufactured in massive quantities, how do we get our arms around when some of those are recalled to protect the public from not being tested with those things? And I don't know if anyone wants to respond to that. [CLIAC MEMBER] still had her hand up, but she took it down.

DR. SHELDON CAMPBELL: I'll throw something out. I mean, if it's been easy to criticize FDA and CDC and anybody you'd want to count for not responding rapidly enough to COVID and whatnot. But there are a bunch of tests that were thrown out there that turned out to be terrible. It's always a trade off, and especially in a fast moving, emerging environment. The trade off is between getting the working tools to people and keeping the non-working ones out. And it's a sensitivity, specificity trade off for complicated engineering processes and human craziness. And the ROC curve for complicated engineering trade-offs and human craziness is never very good.

ADVAMED LIASION: OK, Sheldon. [ADVAMED LIASION], you have your hand up?

CLIAC MEMBER: Yes, I thank you. So I've been attending CLIAC for a number of years as an observer, before as a member. And I think it's very interesting that we're at a point-- I think we have to think if there is a silver lining in pandemic, thank the pandemic that it's taught us that there really is some value in point of care. Point of care oftentimes, in certain circles was looked upon to be a bad thing as it is taken away from core lab. But I think if we look back at some of the questions that Colette started us up with today, for these nontraditional sites-- and I'm thinking point of care-- certainly certificate of waiver sites are a different beast, and unfortunately, they are regulated by statute. And there's little that can easily be done to try to increase some compliance or increase quality there. But when I think about point of care testing and we think that the FDA is doing a good job in reviewing, clearing point of care tests, then the question really comes to what else can we do? What can we recommend in terms of changes to CLIA regulations that would help the laboratories or help the site to improve their own testing processes, to improve the training of their individuals, and to look at some of the things that [CLIAC MEMBER] and others brought up about where the test is being done? How many tests are actually being performed in a very limited setting? And I'm wondering if some of the other members have some suggestions or ideas, just based upon their own experience of the types of things that they would love to see be thought about in the CLIA reg?

CLIAC CHAIR: So [CLIAC MEMBER], that is a long conversation. And I'm sure everyone in this group wants to speak three times. So with—

DR. SHELDON CAMPBELL: You have two minutes.

CLIAC CHAIR: Yeah, with respect, can we have that conversation tomorrow? Can you ask that question again?

CLIAC MEMBER: Absolutely. Absolutely.

CLIAC CHAIR: OK, thank you. And then [CLIAC MEMBER] will have the final commentary.

CLIAC MEMBER: Which is only that. And I've been waiting for that one or two minute sliver of time to do this. Given this whole discussion, and particularly the societal transformation that we've gone through over the last two years, I think framing this as non-traditional is creating a very peculiar optics because to the extent that delivery of a valid analyte for

use both for clinical and public health reasons is where our society is, I would submit that we use a different framing of traditional versus nontraditional. I think we're sort of anchoring ourselves in the past. And we should be embracing the future and select our terminology accordingly.

CLIAC CHAIR: You know what they say? You raised the issue. We're looking to you tomorrow to bring us the terminology. With that being said, we are almost on schedule.
So we close out the day with a presentation from Mr. Matthew Kossman on personnel challenges in nontraditional testing sites. So Andy, this may get at what you're asking. And Dr. Scott Isbell on the AACC point of care testing certification program. After these presentations, we will have a short committee discussion. So as a reminder to committee members, there will be additional committee discussion time tomorrow. So if you can't get your question in today, we will talk about this tomorrow. And we, today, will now focus on presentations 10 and 11. So first, we will have Mr. Kossman speaking on personnel challenges in nontraditional testing sites. Mr. Kossman, floor is yours.

Personnel Challenges in Non-traditional Testing Sites
Matt Kossman

MR. MATTHEW KOSSMAN: Well, thank you very much. It's certainly a privilege to spend a few minutes with this group today. Just in the way of introduction, my name is Matt Kossman, and I am a senior vice president of operations for WellStreet Urgent Care. Heather, if you would please flip over to the next slide.

In WellStreet Urgent Care, we operate over 70 urgent care centers. The majority of those are in Georgia. And then we also have 28 urgent care centers that are located in Southeast Michigan. Our business model is that we partnered with health systems. And for those of you that are based out of Atlanta, you will recognize this as Piedmont Urgent Care, which is well known throughout the Atlanta metro area. We're a provider-based model. Every patient that comes into one of our centers is seen by either an MD, NP, or PA as part of their care delivery of care. We believe in that quite a bit in terms of how we administer care to patients. As I will share with you, over the past two years, as a result of COVID, our business has grown quite a bit. In fact, in 2021, we saw over a million and a half patients in our urgent care centers. Part of our mission is to be there to support the communities that we serve. Our centers are open 365 days a year. We are open every single day. And most of our locations are open from 8:00 AM to 8:00 PM again, designed to serve the communities that we are in. And just in terms of taking care of people, our facilities accept all major insurance plans, Medicare. And the vast majority of our centers also are happy to see Medicaid patients. So again, it's all centered around being there to take care of patients in our locations. In addition to urgent care, we offer X-ray services. We do a significant amount of lab testing, a lot of that related to COVID. We administer the COVID vaccine in a good number of our locations. And then lastly, we have a virtual platform where we can see patients virtually as well. So if you could please flip to that side.

In terms of talking about the personnel challenges that we've faced, I wanted to begin by sharing with you the way our patient volumes have expanded over this period of time. And you can see that we experience a 33% increase in patient volumes in 2020, and then a 37% increase in 2021. And very intentionally in thinking about this, I wanted to share with this group what we had planned on seeing versus what we actually saw. And you can see that in the green area.
And to a lot of people thinking about things from a business model, to exceed your plan is a wonderful thing. But it has brought significant challenges to us because we've seen many, many more patients that we anticipated seeing. And the challenges from the staffing standpoint have been significant to truly manage that. If you would please flip to the next slide.

This provides an overview of what our staffing levels-- the increase in staffing and new hires that we have been faced with over this period of time. And what I refer to on here is a clinical support staff under a CSR, which is labeled in the legend at the bottom. That's the equivalent of an MA. That's just our term that we use as a CSR. But you can see that we've hired several hundred new team members every year over the past three years to keep up with the demand of patients that our industry has experienced. And it has been taxing on a lot of different levels. Can we please look to the next slide?

What we really see is that our model has changed. And to begin with, we see fewer people that are interested in health care jobs than we saw pre-pandemic. And I think we've all seen on the news, staff and challenges that hospitals and health care providers have faced, but I think there's something particularly unique about urgent care and the fact that we are testing so many patients for COVID. Some people would be fine working in health care, just not in urgent care. Along the same lines, we've also been faced with team members that have been with us for years and years. And once we came back into full swing with the pandemic, they evaluated what we were doing and they just simply said this is not for us anymore and we're moved on to other forms of employment inside of health care as well as outside of health care. Another big challenge we faced is the fluctuations in our patient volumes. And we have some periods of time when we're sort of in a normalized state. And then-- As closely, if not more closely than we do, we see COVID cases start to go up. And our volumes overnight, they go up 25%. And then a week later, they're up 50%. And the challenge that goes along with trying to right size our staff has been significant for us. Another significant challenge is the amount of testing that we do outdoors. We have drive-throughs and some centers. At different points in time, our team members will come outside

to see a patient. Exposure to the elements, especially when our team members are wearing full PPE, as you all know, in Georgia it gets very hot and humid during the summer months. And for people that are outside all day wearing full PPE, it's not a great job to have. In our locations in Southeast Michigan, we're faced with some pretty harsh winters, and the same thing applies in the complexity of PPE with winter coats and hats on top of it. It creates for an unpleasant work environment. From a financial standpoint, we've also been in a scenario where our average wage for our frontline workers has gone up, stressing our business model. And we've seen on average an increase of 15% in our hourly rate to remain competitive. A story that sticks in my mind in one of our locations in Southeast Michigan, the Burger King across the street was offering the same starting wage that we were with a sign-on bonus, and that's the level that we're competing with. And it's stressed our model, and it's caused us to go in and evaluate and increase our pay rates across the board. And then lastly, the great resignation, as we have all read about and heard about. This is real, and we experienced this quite a bit over the past two years where we simply have struggled to find workers. And in many instances, it's impacted our operations. And I can share with you for a fact that if we had had more workers, we would have been able to take care of more patients. And that's a very-- it's a hard thing to walk into every single day when you know that patients are lined up out in front of your building, and you simply have a cutoff point where you can't see any more because you do not have the staff to take care of people. Next slide, please.

Training has also created a lot of challenges for us. And it's one of the things that we pride ourselves in, training our team members to provide the best care. And it's happened in a point in time where the number of new team members that we're training has in some instances doubled on a weekly basis. It's created stress for our training teams. And sometimes it's simple things, simply just having the space to do it. We upload a lot of our training rooms and have had to break things up in different segments. And in many instances, rented outside spaces that were larger to train new team members. In the beginning of the pandemic, we were doing a lot of our training virtually. And just simply put, it wasn't as effective as it had previously been. And we've since gone back, and everybody is in person, which we're very thankful for. But it just-- it wasn't as effective and the same as we were used to doing previously. And then also, we've created new roles as a result of the pandemic and the type of testing that we're doing. A large percentage of our volume is point-of-care COVID testing. We've created new roles in terms of lab techs that we've never had before. It's added a lot of complexity from a management standpoint around the clarity and responsibility, clarity of scope of those roles, and designating the difference between that and our traditional medical system. And then lastly, our process has since changed. I was listening to the earlier conversation. Things are happening quickly, and new tests are entering the market. There are new guidelines and new standards in terms of how to complete those tests. And for our existing team of almost 1,000 medical assistants, things change very quickly. And at the bottom, I've kind of laid out just what the past two years have been like for us from a testing standpoint. And we've gone from having no COVID testing to PCR to a reference lab. And then we started doing a lot of antigen testing onsite, and we shifted our model to accelerate the turnaround time on PCR tests the same day. And then as of recently, we've been fortunate and we're able to do RT-PCR testing onsite, which is a tremendous benefit for our patients and the communities that we serve. However, as you can imagine, with 70 locations the workflows and the training and ensuring that before we launch any of this that we have the systems down from a quality and flow standpoint, it's created a lot of work and a lot of just being-- our teams demonstrating a tremendous amount of agility to ensure that we're doing everything in the best possible, safest possible manner. If you could flip on to the next slide, please. One more slide, please. Perfect.

The final area that I wanted to touch on during this short time is a challenge that frankly I haven't seen in nearly 20 years of working in health care operations, and it's abuse to health care workers. And occasionally, we see an article about this or something pops up. But I'm here today to tell you that this is a very real thing. And there's a lot of frustration amongst patients that are-- and I understand it. I get it, that people are confused. They're concerned. They think that they might be sick. They're concerned about exposure to their loved ones and coworkers. And we have had periods of time where we were very busy. The picture that's on there, this is very real. We've had teams that will come to work at 7:30 in the morning and see 50 people lined up around the side of the building, and really start the day off knowing that we're not going to be able to take care of everybody that's there. We're going to have to cut it off after an hour or two of being open for the day. We've had patients that have reacted not well to this. And we've had team workers that have been abused verbally. We've had some folks that have been abused physically by patients that either were not happy with the care that they had received, the wait that they were faced with, or the fact that there were primarily asymptomatic patients that we simply were not able to see them. And unfortunately, I had to tell them to come back on a different day to receive care. And one of the unique things-- and I get asked this a lot-- is around, what can we do for security? Our urgent care centers are for small in size on a day like today. We have some urgent care centers that have five staff members. We are in strip shopping centers and stores and buildings like that. And there are some instances where we do have security or the building or the shopping center will provide security for us. But given our size, it's just not possible in a lot of instances to have security that's there to monitor situations, which put our team members at a risk. Pre-pandemic and even today in the midst of this as we design a new center, we're very focused on being there for the patient. And a lot of our registration desks are at a desk level where the registrar is seated, and there's no glass. And in some instances, you can actually walk behind the desk. It's creating environments where patients have become upset and frustrated with things. We've had patients that will go behind the desk and become verbally abusive or threatening physical abuse to our registrars, which is just-- it's a very unfortunate, very sad thing to see that happen, the impact that has on team members. So it's an important

thing. And I put the picture on there. And I say to everybody, thank your health care workers, because our members are doing amazing work. In conclusion, the staffing at the urgent care continues to provide a needed service in communities we serve.

CLIAC CHAIR: Matt, we are having trouble hearing you.

MR. MATTHEW KOSSMAN: Oh, I'm so sorry. Can you hear any better now?

CLIAC CHAIR: We heard you better before. [LAUGHS]

MR. MATTHEW KOSSMAN: OK, weird. I don't-- nothing changed.

CLIAC CHAIR: Oh, that's good. That's good.

MR. MATTHEW KOSSMAN: OK, I won't move. We continue to be challenged in staffing. With the fluctuations in our volumes, it seems like some days we're overstaffed and some days that we are understaffed. And it creates challenges on all fronts. In closing, our role-- we consider our role to be there in the communities that we serve. We're really thankful to be there and thankful and proud of the services we provide to our communities.

CLIAC CHAIR: OK. Thank you very much. [CLIAC MEMBER] stuck her hand right up. So [CLIAC MEMBER], you have four minutes.

CLIAC MEMBER: Oh, I don't need four minutes, but thank you for the opportunity. We man 23 urgent cares ourselves and have worked with a variety of people in our point-of-care system, from nurses to pharmacists to lab scientists. And what always intrigues me is the personnel requirements for waived tests ignore phlebotomists and technical laboratory assistants. So we have launched our own job descriptions for these folks, because we find that phlebotomists and technical lab assistants that are part of the laboratory follow quality control guidelines and cleaning guidelines and everything a heck of a lot better than providers. We have pretty good luck with pharmacists and physician assistants. However, we're paying two or three times more per hour for those people, and nurses even more than that, when our laboratory staff could oversee and do perhaps a better job in some cases. So I wonder if that's something that-- I mean, if a new classification that didn't exist in the beginning of how we classify folks might be something to think about in terms of shortages and luring-- not luring, but recruiting folks to think about a laboratory career if they don't want to have a degree. There may be opportunities for them. And that's what we're doing here that has helped quite a bit. But it's probably something that is not covered in CLIA necessarily. And certainly if it was, it wasn't intended to be at the broad scope that we're now talking about. But we have very good luck with that type of staffing. And while we still have to recruit them, and phlebotomists are not easy to find either, we're doing our own online training and in-person training for these folks, and people with bachelor's degrees who are in the med tech pipeline that were hired as laboratory assistants, because they didn't know about medical lab scientists, and now they want to get a categorical degree. So we've been able to recruit from colleges, from two-year associate programs, from high schools, and really kind of keep them under the laboratory umbrella. And that's been pretty useful. Thank you for the insight, Mr. Kossman, or Dr. Kossman. It is a challenge, for sure. And it was a great presentation.

MR. MATTHEW KOSSMAN: Thank you very much. I appreciate the thoughts on that. I'd love to talk offline at some point. We've kind of explored some of that, but probably some additional work to be done.

CLIAC CHAIR: Thank you both. And it sounds like [CLIAC MEMBER] just teed it up for Dr. Isbell to speak to us around the AACC Point-of-Care Testing Certification Program. Dr. Isbell.

AACC Point-of-Care Testing (POCT) Certification Program
T. Scott Isbell, PhD, DABDD, FAAC

DR. SCOTT ISBELL: Right. Can you hear me OK? All right. Got the thumbs up. Let me see if I can project this better for you. One second. How's that look? OK, great. Great. All right. Well, thank you, Dr. Ng, and thank you to the rest of the committee for the opportunity to be here. I really appreciate having this time to tell you about the Professional Certification Program in Point-of-Care Testing that was developed by the AACC. So just as way of background, I'm a clinical chemist by training. I'm here at Saint Louis University where I spend most of my time in the university hospital, overseeing the clinical laboratory operations, specifically the sections of chemistry and point-of-care testing. So I spend a lot of my day actually practicing what I preach in here, hopefully. So [LAUGHS] without further ado, I will tell you about the process and certification.

Just to start with, I have no relevant financial disclosures. I am currently serving as the past president of the AACC Point-of-Care Professional Certification Board for which I do not receive any income or pay for that.

I'm not going to spend much time on this slide. I think this group is well aware that the point-of-care market continues to expand and grow. These are just some numbers I've pulled from a markets report back in February 2021, indicating that the market is predicted to increase to $50.6 billion by 2025. Demand continues for small portable devices that can provide fast results with small specimen volumes. And the outcomes desired I think by all that are engaged in point of care, we want to see improved health outcomes. We want to see increased provider and patient satisfaction, and if possible, reduced cost.

With respect to point-of-care operators, we touched on this just a little bit in the former presentation. But typically in the US, as you're aware, most of our point-of-care operators are not specifically trained in the clinical laboratory scientist. We rely heavily on other health care providers or professionals such as medical assistants, nurses, respiratory therapists, radiology technicians, and increasingly, community pharmacists.

And I highlight that specifically because there is a movement within community pharmacy to really call out point-of-care testing as a potential revenue stream. And this is a quote that I took from the National Community Pharmacists Association where they said, "point-of-care testing provides an excellent opportunity for community pharmacies to enhance revenue by expanding patient care services while improving health at the patient and population levels." And I certainly think there's some truth to that as we also just heard in the urgent care settings, right? That it's an incredible role for them in expanding access to health care. I think there may be also a role for that in community pharmacies.

So why community pharmacies? This is some of the thinking about why that might be advantageous. It can be seen as an alternative to emergency departments for minor issues. There are abundant locations and expanded hours, even sometimes expanded beyond what our colleagues in urgent care centers can provide. And there are certainly examples of existing point-of-care utilization in community pharmacies such as influenza testing, strep, lipid testing, A1C, PT/INR, and we're all aware of the COVID-19 testing that has been performed in those sites. The additional thing that can occur in pharmacy is through these collaborative practice agreements where you have a pharmacist being allowed to dispense certain medications or drugs per some sort of written provider protocols. You have typically a sponsoring physician who's on the other end of this. So you can see in this scenario, you might have someone come in, get tested for strep, and then under this collaborative practice agreement, be able to walk out the door with an antibiotic in hand.

Additionally, when we think about training in point-of-care, training is certainly variable. Some places do a really great job. Some places do nothing. And I would argue there's no standardized curriculum in clinical lab science schools. There's zero to little formal training in nursing programs. I think there's a huge opportunity here to really form strong partnerships with our schools of nursing to put point-of-care on the table, and then also use that as the entryway to maybe discuss in a more broader sense the principles of laboratory medicine, because we know our nursing colleagues are at the front. They're engaged. They're doing laboratory testing. They're looking and ordering results. So I will point out, a standardized curriculum has been proposed as part of training in public health officials by Dr. Kost. So there is some literature emerging on this that's very specific to schools of public health. It's very specific to utilization of point-of-care testing, particularly within the setting of disaster response and recovery. But it is something that we could look at and say, could we also develop a nationalized or standardized curriculum and recommendations for various schools? The takeaway really is that there are educational gaps that continue to persist in the US with respect to training and point-of-care testing.

And recognizing that, I think back in 2008, the critical and point-of-care testing division of the AACC launched a Point-of-Care Specialist Certificate Program. It was an online course that consisted of the following eight modules where participants would learn about relevant point-of-care regulations, quality management, policies and procedures, on and on. Even some administration, communication, and leadership was covered in that certificate program.

And following the completion of those eight online modules, there would be an assessment. So they took a test that would assess their learning, and then that provided them a certificate of successful completion. And that was really something that they could put on their walls, something they could provide to their boss to say, look. I completed this professional development course. I've used it as a way to introduce medical technologists who are wanting to get into point-of-care as sort of a point-of-care 101, so to speak. Back when I prepared this presentation in the fall of last year, there were approximately 1,700 individuals that had completed this professional development certificate course. And it continues to be fairly well subscribed to.

It does need, I think, to be updated. And what is being discussed now is to try to maybe incorporate some international regulatory standards such as ISO 15189 or the ISO 22870. And I think by doing that, we could create an online certificate program that might have a little broader appeal internationally.

I want to take a moment on this slide, because this is a very important slide to help really call out the difference between a certificate program and a certification program. And these words sometimes get used interchangeably, but I think there's actually very defined sort of definitions for this. And that's what I've tried to do for you here. So when we think about a certificate course, it typically focuses on education and training, as did the AACC certificate course developed in 2008. It allows-- it demonstrates successful attendance and completion of an assessment. It's generally open to anyone. If you pay the fee, you get to take the course. It's not administered by a board, and there's typically-- it's not time-limited, meaning you get your completion of certificate. Nobody's going to take that away from you. Professional certification, on the other hand, is different. Individuals are evaluated against predetermined standards for knowledge, skills or competencies. It requires successful passing of a board-style exam. And a board-style exam is very different than a sort of general exam to test your ability to essentially recall what you just heard, which is a lot of times what certificate programs will-- that's how they will design their assessment. There are also requirements to sit for the exam. So you must meet certain educational requirements, experience requirements, or maybe even completing some sort of training program. It's administered by a board of recognized professionals, and it generally requires maintenance of certification, some demonstration that you are continuing and always learning in this particular field. And this is actually something that we are looking at now, recognizing that professional certification point-of-care testing also requires some level of maintenance of certification. And we hope to be rolling that out within this year.

So thinking about that and all that background and that sort of difference between certificate programs and certification programs, AACC made, as one of its strategic priorities, to establish a professional certification in point-of-care testing. A task force was established to develop the initial certification exam, which meant, of course, writing lots of exam questions. I'll get to that in a moment. And the task force partnered with psychometricians to really ensure that what was being developed, the questions, the way they were being written, were really meeting the standards, the standards of assessment, and particularly for a board-level type of exam. And that guidance was really critical for the success of this, I think.

So this started back in 2017. It's hard to believe it was that long ago already, but we all know the last couple of years have been a blur. I was selected to chair this. It was an honor to do that. And you can see the task force consisted of the other individuals. Some of the names you probably recognize as they are certainly leaders in point-of-care. You can see that we had representation from academic medical centers. We had also colleagues from IBD as well to sort of give their insight on this.

We were able to recruit 39 item writers. When I say item, item is synonymous with a question. So question writers, if you want to think about it that way. We put out a call. We had a really good response, which was amazing. And we had, again, good representation from really all of the various sectors of laboratory medicine. And a complete list of this can be found in an article that I wrote along with others that was recently published in the electronic Journal of IFCC. And it really was describing the evolution of this, what our process was who was engaged and involved with it. So if you want a complete history of this, I would refer you to that article.

We also went on after all of the item writing, all of the vetting of those questions, all of the trial runs of an initial exam, we went on to establish a board. And so the board was established to really oversee all aspects of this certification process, from application to the examination, the administration of the exam itself, the scoring, and of course, the maintenance of the exam item bank. Myself, along with another member of the task force were selected to serve on the inaugural board. And again, we used that as an opportunity to recruit additional expertise in this area to the board. The goal over time, of course, is that this Point-of-Care Professional Certification Board will eventually be populated by the very people that it certified. And this is very synonymous with what you see with other professional boards. I think about the American Board of Clinical Chemistry, for example. All of those individuals working on that, ensuring that the exam is high quality, ensuring that the standards are high are also ABCC board-certified individuals. And I'm happy to report that we're already well on our way of doing that here with this.

This was the inaugural board. This also gives you a sense of how we organized the board. So we have a president position, and then we have a secretary position. And then we have chairs of important committees that essentially execute the function of the board. And these chairs are considered officers of the board. So we have an Examination Committee that was originally chaired by Dr. Luzzi. We had a Credentials Committee chaired by Dr. Karon at the Mayo Clinic. And then we had a Nominating Committee that was chaired by Lou Ann Wyer another well-known name in the point-of-care field. And then within those-- I'm showing you also some of those initial committee members that helped really move this forward and help us maintain the momentum with launching this professional certification program.

This is the current board makeup. I have transitioned into the past president role. And we have a president-elect, president, past president model so that we can ensure that continuity of leadership. And I want to point out with the bolded there credentials that we have began the process of populating this board with certified point-of-care testing professionals with that designation CPP, which I'll come back to in just a moment.

So let me talk a little bit about the exam itself. So the eligibility to sit for the board exam is really modeled after the CLIA standards. We wanted to anchor this down to something official, so we thought CLIA was a good place to start, of course. And then we also wanted to use this because we recognized that many of the people that we think would want to sit for this exam are our clinical laboratory scientists, are our people who are working actively in the field of point-of-care testing. So we ask that you have a four-year degree in a biological, chemical, or physical or medical laboratory science, or in nursing, at least two years of direct work experience in point-of-care testing, a two-year degree, or a two-year degree in medical laboratory science and four years of direct work experience. So we bumped up the experience requirement if you only had a two-year degree in medical lab science. And the applications to sit for the board exam are then reviewed by that Professional Certification Credentials Committee. And what they're reviewing is they're reviewing transcripts to really confirm that all of the degree requirements were met, that enough of the sciences were there. They're reviewing letters of essentially attestation from these individuals' supervisors, attesting to their experience and providing the Credentials Committee some insight into what those experiences are. They do look at all of that material, and then they make a determination as to whether or not that person qualifies to sit for the exam.

So this slide is showing you the areas that are examined in the exam. Some of this is very similar to what you saw in the certificate program in terms of content areas. I will say that it is USA regulations and compliance-focused. We do have international test takers, people who apply for this, but we do upfront tell them that this is a USA-centric exam at this point. We cover quality management, education training, instrument selection, which would include validation, verification processes, connectivity, leadership, specimen types, policies and procedures, clinical applications, and technology and methodology. Now I do want to say, and I don't think I said earlier, the other difference here is the content may be same, but the style of questions is different. This exam is really testing one's competency. Not just their knowledge, not their ability to sort of say, this is what it is. There is some of that with recall-style questions. But this exam also has questions that require a synthesis. It requires analysis and things like that, because what we're really looking for is, can you apply this? Show us that you are competent in these different areas that we think are important to a high-quality point-of-care testing program. And that, again, is where the psychometricians were really, really helpful in helping us understand, how do you write a question that interrogates one ability to synthesize multiple pieces of information or to analyze multiple pieces of information? So this is not an easy exam. [LAUGHS] But it is one that we think is of high standards and sufficient for professional certification.

Since November 2018-- or I should say-- sorry, November 2018 is when we launched the first exam that was administered by the board. Since that time, it has been administered both in the spring and in the fall. It's offered two times a year.

And at the close of 2021, we had 69 individuals that successfully sat for and passed the board exam, and so were then able to designate after their name, if they so choose, and we encourage them to, to share with others that they have become certified, professionally certified in this area as CPP, which is short for Certified Point-of-care testing Professional. And you can see an example of that designation there with Peggy Mann. I'm using her as an example.

So we are happy about that. The real burning question probably is, why? Why certification? What were we hoping to get out of it? And I think-- and I'll come back to this in just a minute. You can see some of these are CPPs when asked, what did it do for you? What value did you get out of it? But what we hope to see with this certification program is greater leadership opportunities. Maybe this opening the door for individuals to serve in leadership positions. Greater job security, higher pay. Just recognition. I think this is really important. We all agree that point-of-care testing is very important, that it is, when done right, can be a very, very useful tool to improve health care outcomes. We have a lot of people who work very hard in this area who don't necessarily get the proper recognition-- proper professional recognition that I think they deserve. And so I think this has been a real nice way to say to them, we recognize you. This board recognizes you. And hopefully, eventually, society will recognize you in this role. But I do want to call out some of these sort of testimonials here. So you can see Gayle here says that "As an AACC certified point-of-care testing professional, I'm honored to belong to an elite group. This certification will solidify the importance of point-of-care testing among laboratory medicine professionals." And that sort of speaks to what I just said. And then Leh here says, "This is one of the most significant events in my career and serves as validation of my years of experience and knowledge in the point-of-care testing field." And Cathy indicates that "Within the AACC point-of-care testing professional certification, I plan to do consulting. Physician offices, urgent care facilities, and hospitals need sound, accurate advice to improve patient care." And I think these are really some great examples of how for these individuals personally it has helped them in their career.

For me and the board, if I said, well, how do we measure the success of this program, what are those metrics, for me a success looks like an increased number of certified point-of-care testing professionals who are providing technical and quality direction for point-of-care testing programs, whether that be in the hospital, whether that be in a pharmacy, whether that be in a nursing home or anywhere point-of-care testing is being done. Writing practice guidelines, serving on those national, international committees that are helping to guide best practice in point-of-care testing, and also perhaps are advancing the field through various research efforts. And then I guess ultimately, and certainly for this group to chew on would be success may look like federal recognition of this professional certification, just as it recognizes various other

professional boards, which then allow for certain abilities within the lab, certain responsibilities to hold within the laboratory. And I'd love to hear back from this group if you debate this and think about this. The board would certainly appreciate any feedback that you have on this.

So the next exam is coming up in November 14 through 18. It's administered over a few days, and that's because we do this all electronically. And actually, on that I do want to say we've set this up to really be user-friendly. So people do not have to go to testing sites. They can actually do this exam from their home. It is proctored. There is someone watching you as you take the exam. There are rules about how long your eyes can be away from the screen and things like that before someone might prompt you to ask, what are you doing? So it is proctored, but I think that has allowed us to really increase access so that people don't have to travel to a particular place. And then I put in this presentation-- hopefully, you'll all get a copy of it-- a link to the Point-of-Care Professional Certification Candidate handbook. And there's lots of really great information in there that will expand upon what I have presented today.

And then lastly, I'll just leave you with my email address. Please feel free to reach out to me if you've got any questions, if you are interested in this, if you're interested in serving on the board, if you're interested in helping to write new exam questions. We will take all of that effort if you're so willing to give it. And with that, I'll stop, Dr. Ng.

Committee Discussion

CLIAC CHAIR: Thank you very much, Dr. Isbell. Dr. Isbell's and Mr. Kossman's lectures are now both open for discussion. And the lineup so far is [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], and then [CLIAC MEMBER]. [CLIAC MEMBER], the floor is yours.

CLIAC MEMBER: Great. Thank you very much. And thank you for those excellent presentations. And Dr. Isbell, I have so many questions on yours. I'll try to restrain myself to just a few. So you mentioned your assessment-based certificate as well as the professional certification. And I'm curious how you see those two positioning if the assess-- and I'm looking at the criteria you've got for the assessment-based certificate. Are there any educational requirements for who can take that certificate? And is that a bridge for people when they first start doing waived testing? Because as we know, and as you pointed out, they're not all laboratorians. And some of our passion has been around, how do we get education to those folks without a laboratory background doing point-of-care testing? So my first question is, is the assessment-based certificate program-- your thought about how that entry-level would be promoted. I'm going to make an editorial comment that federal recognition would be wonderful. I don't believe that medical technologists have that federal recognition, so perhaps you could get us included in that as well. And then my other questions have to do with the pharmacy group that you discussed, because I think that sounds really exciting. And I was wondering what the feedback loop from the point-of-care testing in pharmacies is back to the provider, if there's any way of getting that back to physicians so that they also have that as part of the care plan. And then just sort of a plug, if you will, that anemia is seen in patient blood management as being a public health issue. That's far under-recognized. And whoever established this common menu in the pharmacy, community pharmacy menu lineup, anemia testing would be appreciated in there as well. So I gave you a whole bunch of questions, and thank you so much in advance of your answers.

DR. SCOTT ISBELL: You're welcome. Thank you. All very good questions. I'll start with the last one. I agree. Anemia testing, preoperative management of that anemia, I think there's a huge amount of value there, and it's just sort of screaming for some attention. So certainly, with those individuals that I'm aware who are sort of advocating and advancing the role of community pharmacy in point-of-care testing, I'll certainly make sure that's on their radar. Certainly back to the beginning, you asked about the certificate program, which is the online eight-course module thing. There's no educational requirements to take that. As I said, anyone essentially can register, sign up, take the course. Now that course I think-- I was part of that a long time ago. I would say that that course is-- the best audience for that course is probably somebody with some medical, laboratory science background. Now that being said, what I'm hearing in this discussion is there's no reason that that course couldn't be taken, and aspects of it taken and developed so that we are targeting more of an audience that would be engaged with just waived testing, right? So maybe what we have is we have that educational gap, and we need a very specific course for those individuals that are going to be performing waived testing in non-hospital, non-clinic sites where maybe you don't have that sort of support from your core laboratory or from a team. I think that's an interesting idea to think about, and it could fill a need. Now we kind of keep a wall up between the certificate program and the certification program. So the certification actually falls under a separate entity from AACC. They developed an AACC Board of Certification, which is sort of a high-level board. That said, you know, anyone who wants an entree into point-of-care, I would probably point them to that. They'll learn a lot. But it may not be enough for them to be successful on the certification exam. And that's because, as I indicated in the presentation, the certification exam is really testing one's competency, not just their knowledge. Can you apply this information? And some of that comes with not just a certificate

program or training. It comes with experience, right? It comes with working, going through that day-to-day, troubleshooting those results, figuring out how to validate things like that. So does that answer the question?
CLIAC MEMBER: Yes, to a large extent. Thank you. And then just kind of a thought, but in addition to federal recognition, would one way of leveraging this program be to also work with the payers? There's a program called FACT in cellular therapy that got established by becoming the Centers of Excellence, and they get-- and certain payers, if you don't have FACT, won't reimburse you. Obviously, this is a whole different level. But that might be-- it's also got volume, however, so there is some money associated with it. So one thought might be to hook onto payer recognition as well.

DR. SCOTT ISBELL: Hmm. That's a very good recommendation. Thank you for that.

CLIAC MEMBER: Oh, you're welcome. Thank you.

CLIAC CHAIR: Next is [CLIAC MEMBER]?

CLIAC MEMBER: I had a question about how much it costs to take either one of these certifications.

DR. SCOTT ISBELL: Oh, I didn't have that off the top of my head. I'll look it up real quick. Can I come back to you?

CLIAC MEMBER: Yeah, yeah, yeah. Just because I think it's one of those things, if it was worthwhile-- and I love [CLIAC MEMBER] idea about getting payer recognition for having quality people, especially in a POL setting and waived. I think there is a gap just for waived testing as well. But yeah, I'm just curious that it might get supported to get the certification if it wasn't that much.

DR. SCOTT ISBELL: Yeah, no, I agree with you. And even with our own point-of-care coordinator here, I mean, I said, look, if the hospital won't pay it, I'll pay it. I want you to be trained. I want-- [LAUGHS] obviously, if I have developed it, I've got a practice—

CLIAC MEMBER: Right, right. You've got to eat your own food there.

DR. SCOTT ISBELL: That's right. But I'll pull it up for you in just a minute and let you know.

CLIAC MEMBER: Thanks.

CLIAC CHAIR: And if you can pull it up and listen, maybe [CLIAC MEMBER] can ask her question.

DR. SCOTT ISBELL: Yeah. Go for it.

CLIAC MEMBER: Yes. And some of my questions I think were already answered as we are discussing this. But I just wanted to clarify, when we had concerns about qualifications of personnel in these non-traditional sites for the time being, we're going to call them, it's really from my perspective concerns about personnel who really have no medical training or completely laboratory-irrelevant training. It sounds to me like both the certificate program and the professional certification you're offering is really meant for individuals with credentials, education that would qualify them to work in the traditional laboratory and more directed towards point-of-care testing. Do you feel that's the correct characterization?

DR. SCOTT ISBELL: Yeah. And well, if I can kind of think about it as, who's applying to sit for the exam, right? I don't know the demographics in terms of the certificate program off the top of my head. But for the certification program, the vast majority of applicants are med techs, people who are coming in with some experience. We do have-- when we were designing this certification exam, we were not designing it specifically for medical laboratory technologists. We did want to make it applicable to nursing, to other technologists, technicians. The requirement really is pretty broad. We are asking that people come in with, at minimum, some education in the sciences, right? Sort of modeled after CLIA again. So we are looking for people who have bachelor's degrees in biology, chemistry, pharmacy, something, or they can come in through that sort of experience pathway. And that one really is limited really just to sort of medical technicians instead of medical technologists, people with an associate's degree with experience.

CLIAC MEMBER: The reason why I'm bringing this up is the concern that we can hardly afford to lose any more laboratory personnel [LAUGHS] going into and specializing in point-of-care testing. So what I would ideally like to see is more training opportunities directed towards individuals who do not have that science background that would really direct them towards laboratory work, and be more accessible perhaps and easier to complete than lengthy studying for a board certification. Not that it's without value, but because it's so inaccessible to many others who do not have that background. And that's where I think the greater need is at this time, to really make something available for those who do not have these basics. But on the flip side, I think I would like to ask one more question, and we'll leave you with that. Do you feel that individuals who are qualified to work in the laboratory and will receive training in the laboratory are not inherently

qualified to work in point-of-care settings? Or what are they missing from their background and training in a laboratory that they need to work on?

DR. SCOTT ISBELL: Yeah, I think when we look at our medical technologists, I think there are things that certainly transfer very easy, right? Concepts of quality control, quality assurance, method evaluations. Things like that I think translate very easily. I do think there are point-of-care-specific things that are not being taught in schools. They're not coming out of programs with a lot of knowledge about point-of-care technology and the limitations of those technologies. And I think we do need something that kind of bridges that. I mean, for example, my experience has always been we've got the point-of-care coordinator [LAUGHS] who then recruits somebody else in the lab, kind of brings them under their wing, and shows them the ropes, so to speak. And it's a lot of on-the-job sort of training. And then hopefully, that person likes it and they want to keep doing that. But that's not a very sustainable model sometimes, I think. So maybe being more intentional. I think you raised a good point. I think professional certification fills a particular need, right? It's intended to elevate the overall quality, recognize people who are really playing these sort of key managerial, administrative, leadership roles over point-of-care testing programs. But also, it doesn't satisfy some of our other needs, which I think collectively as a group we need to be working on, whether that be AACC or ASCP or some consortium of individuals saying, what educational things do we need to address? I think what we've all been concerned about is a staffing shortage, right? Pulling those individuals in who may not have the exact four-year degree that we would be looking for in biology or chemistry or something like that, but are interested in coming in and working and assisting with point-of-care testing. What sort of training do they need before they walk in the door? Maybe something that we can give them online, right? I think that's a good point. And I think the certificate program is a good starting point, right? Looking at that content and then saying, OK. How do we pull from this content the real just basic fundamentals that anybody walking in the door that we're going to then say, you're going to perform waived testing, or s going to have some oversight of this testing. What do they need to know? Is that kind of what you're getting at?

CLIAC MEMBER: Yes. Yes. Absolutely. I think it's the biggest need right now. Thank you.

DR. SCOTT ISBELL: Thank you, Dr. Ng.

CLIAC CHAIR: OK. I want to remind the members, please do not use chat to ask questions. Get your hand up so we can ask that out in public. Doctor Isbell did respond in the chat that the cost of this is $199 for AACC members and $274 for non AACC members. OK. [CLIAC MEMBER]is next on line, and then I'm going to put [CLIAC MEMBER] on the list. [CLIAC MEMBER]?

CLIAC MEMBER: Oh, you know, I've got most of my questions answered. I wanted to know what the cost was and then I wanted to know when the next classes were. So thank you so much for this. I think it's an outstanding program. And the discussion that you just finished up, there are unique programs that now go out into schools that provide these kinds of trainings to inspire kids in schools to get into health care. And they could include this kind of a position starting as early as junior high, before their school path has been decided on. So I'd love to work with you to find out if there's a way that we can get this career on a list, and if there's some way you can create the curriculum so that we can help grow this position and make sure we've got what we need for the future.

DR. SCOTT ISBELL: No, I love it. My note I wrote is pipelines in point-of-care, right? We need pipelines. And I would even say, you know, how about we create a whole new job combining some of these pre-analytical and point-of-care jobs, right? So instead of phlebotomist and point-of-care people, why can't we just have these bedside lab technicians, right? They go out. They might draw blood. They might perform point-of-care tests. They're assisting. They're bridging that gap between the lab and the patient beyond just a phlebotomist. I know they do this. For example, I talked to Dr. Karon at Mayo. They call them vascular access techs. Vascular access techs. They do phlebotomy. They do some point-of-care. They do a lot of other things. And I really like that idea, because then it's not just us going to these junior high kids and being like, hey, do you want to be a phlebotomist? Hey, do you want to be, like, this really cool, important job, right?

CLIAC MEMBER: Make it super cool.

DR. SCOTT ISBELL: Make it cool, right? And then you know what? Take some of that off nursing. Wouldn't that be cool? Let's take that point-of-care off nursing so that nursing can do all the other 100 things that they've got to do at the bedside, right? Because we know part of the quality issues is that they're distracted. They're doing 60 things at one time. And what if we kind of took that off and we're there to assess? I love these ideas, and I would be very happy to work with you to think about these pipelines, think about how AACC can support, think about how these certificate and certification programs might be integrated into some of that. Awesome.

CLIAC MEMBER: Right. And even integrated into the funding through government that is focused on those who need help, the underserved. I know there's a big program in Pennsylvania called Scrubs that I can fill you in on. And they are working with the state. And this might be a good kickoff to start out with. So I look forward to talking to you further.

DR. SCOTT ISBELL: Perfect. Thank you so much.

CLIAC CHAIR: We have nine minutes left. We have [CLIAC MEMBER]. Ren would like to make the final comments, so I'll have [CLIAC MEMBER], [CLIAC MEMBER], and then Ren in nine minutes. [CLIAC MEMBER].

CLIAC MEMBER: Thank you. My question was just, how many contact hours for each of the programs. For the certificate and for the certification, how many contact hours? Thank you.

DR. SCOTT ISBELL: Oh, yes. I don't know off the top of my head. It's a lot. Now the certification program, there's no contact hours in the sense that there's no modules that they're going through. They're just sitting for the exam, so it would just be time spent applying and then actually sitting for it. I will look back and see if I can get contact hours for you for the certificate program. Sorry I don't have that off the top of my head.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: Yes, I want to thank Dr. Isbell for that excellent information. And I listened carefully regarding the role of the nurses, potentially registered nurses, maybe even LPNs. I don't know. Were you also including LPNs as well as RNs? And they would be more suited for the certification one rather than the nurse aide ones that would be just technical training. And so this is something that I think we can take back to our various areas as you develop this more and share-- help get the word out. So this is, in my opinion, a very viable avenue and would contribute to the delivery of health care services. Thank you.

DR. SCOTT ISBELL: That's great. Thanks. I think we'd have to look at together, are our eligibility requirements that are currently set by the board, does that allow for an LPN who's interested in this to sit, right? Would they meet those qualifications? And if they don't, do we need to reassess the eligibility requirement if we think that there's a significant amount of-- a pool, right? Is there a big enough pool of LPNs that say, wow, I mean, we've got a lot of interest here. We've got people willing to learn and apply themselves in this area. Is that something we need to sort of be speaking to more?

CLIAC MEMBER: I think so, because LPNs are not used basically in acute care setting or hospital or general hospital settings. And so they mostly are relegated now to nursing homes or other type of settings outside of the acute care setting. And so often-- so they are interested, in my opinion, for other career options. And I don't know if you want to look at a third tier where it would address the LPNs as well. But certainly, this is good.

DR. SCOTT ISBELL: Well, that's great feedback. I will bring that back to the board. And of course, all of this discussion I'm going to bring back to the board. These are great directions, things for us to think about, things that we can maybe link this to. I've heard about reimbursement. I've heard about other pipeline programs, things like that. So this has all been really great. Thank you.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [CLIAC DFO] tends to be a man of very conciseness and clarity, so I'm going to sneak in a commentary from [CLIAC MEMBER] first.

CLIAC MEMBER: Thank you, [CLIAC CHAIR]. I just wanted to comment that this certification's really important, and I really am pleased to see it. And your comment about phlebotomy and taking that off the nurses' table really is linked to something that [CDC EX OFFICIO] mentioned early on this morning at the first presentation, because we see a lot of blood culture contamination. And I used to monitor this very closely in hospitals. And at the root were busy nurses who didn't have the time to do a good job with the collection as a phlebotomist does. So I think these two issues are very important, and I appreciate what you're doing to bring certification.

DR. SCOTT ISBELL: Certainly. Thank you for that.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC DFO], the floor is yours.

CLIAC DFO: OK. Thank you very much, [CLIAC CHAIR]. So my comments are not about the most recent presentations, but I do want to say that I thought it was a great discussion today. Really outstanding presentations, and much appreciate everyone participating for the full day. So I have a couple of administrative comments to fulfill my role as the designated federal official. And I probably should have been-- I should add this into my spiel at the beginning of this meeting every single time. But just a strong reminder to everyone that CLIAC is a federal advisory committee. And a federal-- all

interactions of a federal advisory committee must be public. And so our discussions, our questions, our comments all need to be made publicly and accessible to the public. So I know it's difficult, because the chat function is something that we now all use all the time in our regular meetings to help conduct the meetings. But for CLIAC, please do not only use the chat function to indicate to Valerie that you would like to get in the queue to make a comment or make a question. We really are not allowed to use the chat function for CLIAC discussions of any kind. My second comment is, again, something you've probably heard me say before in the past. And it's a real plea. These discussions are great, and hopefully you've found them valuable. But for the agencies themselves and ourselves, we need CLIAC to give us very clear recommendations, which need to be written. Those are our metrics, and those are actions that we have to be responsive to. If CLIAC has a really interesting meeting with really interesting discussion but no recommendations, the agencies are really not expected to take any specific action based on the discussions of CLIAC. And so if there is something based on today's discussions or tomorrow's discussions that you feel very strongly about that the agencies need to do to advance or improve clinical laboratory practice or medicine, I strongly encourage and ask you, and actually plead with you to work on some draft recommendations overnight. Because it's much easier if some of you or many of you come in to tomorrow's meetings with some drafted recommendations that we can share with the committee than to try to put something together during the meeting tomorrow. Tomorrow-- the second day always goes much faster than everyone expects. And so I would ask if you're willing or if you have passion around some of the topics that were discussed tomorrow or maybe-- were discussed today or maybe discussed tomorrow to spend a few minutes tonight or this afternoon if you're on the West Coast drafting up something for the committee to consider tomorrow. So thank you.

CLIAC CHAIR: Thank you, [CLIAC DFO]. So I just want to make some comments before we adjourn. I'm echoing [CLIAC DFO] comments around recommendations. Most of you will spend time tonight reflecting on what we talked about today and say, gee, I wish this would happen. I would like you to come forward with a draft recommendation for us to react to. The two most seemingly-- I'm going to use the word irritable. May not be correct, but the ones who really need to have it set tend to be [CLIAC MEMBER] and [CLIAC MEMBER]. So I'm looking to you two at least have some recommendation. [CLIAC MEMBER] has asked whether or not we should respond to the three questions that were posed to us at the beginning of today, and if those questions could be posted somewhere to refresh our memories. I'm going to ask each of you to look at the letters, the public comments that have been posted. There are 11 or 12 of them. Reflect on those and think about how that might relate to the recommendations you're going to make. And then finally, I want to remind you all that we already have some workgroups, one on personnel regulations, one on PPMP, Provider Perform Microscopic Procedures, and one to be formed on next generation sequencing. In addition, [CLIAC MEMBER] and [CLIAC MEMBER] are chairing the Committee on CLIA Regulation Updates. So whatever your recommendations are, if they can fit in within those frameworks, that would be greatly appreciated. So I'm going to thank each and every one of you for joining Day 1 of the Clinical Laboratory Improvement Advisory Committee meeting. We will begin at 11 o'clock Eastern Daylight Time tomorrow. Enjoy your night. Looking forward to seeing you all tomorrow. Thank you.

April 14, 2022

Call to Order/Roll Call/Meeting Announcements

CLIAC DFO: Good morning, everyone. Welcome back to day two of the Spring 2022 Clinical Laboratory Improvement Advisory Committee meeting. Thank you for joining us today. My name is Ren Salerno. I'm the designated federal official for CLIAC. 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 improving clinical laboratory quality and the practice of laboratory medicine. In addition, the committee provides advice and guidance on specific questions related to the possible revision of CLIAC's standards. Because this is a federal advisory committee, the proceedings are entirely public. However, Zoom chat and Q&A functions have been disabled for audience members. And only CLIAC members and presenters may participate in the discussions. If you are experiencing Zoom difficulties, please contact cliac@cdc.gov. Members of CLIAC are reminded of the importance of remaining in attendance on both days or today for the full meeting to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned. We also would ask members to be on video during committee discussions. Also, members please only use the member chat function to indicate to the CLIAC chair that you would like to make a comment or ask a question. Today, we have an extended public comment session. And during this period of-- following the public comments, there will be community discussion. And participation will be limited to CLIAC members only. The extended public comment session today is on the future of laboratory medicine in nontraditional testing sites. Public comment periods are scheduled for five minutes each. Those who did not previously send a request for a public comment but would like to participate, we ask that you email cliac@cdc.gov immediately, or at least within the next 15 minutes, to be added to this session. All written public comments received are available on the CLIAC meeting website. We currently have 11 comments on that web page.

CLIAC CHAIR: In terms of schedule and logistics, copies of all PowerPoint presentations and other meeting materials are posted on the CLIAC website 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 via Zoom webinar. Links for accessing the webinar provided on the CLIAC website. If you're 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. And then to reinforce Ren's comment, a reminder that all the CLIAC discussions and deliberations must be available to the public. The chat box is not available to the public for viewing. CLIAC members should not engage in topic discussions offline through the chat box. Please use the chat box only to notify me of your desire to comment during the discussions or ask the question of the speaker.

CLIAC DFO: Thank you, [CLIAC CHAIR]. Sorry, I forgot to do my one important role, which is to ensure that everyone is here today. So a quick call to order and I will call your name and if you could please just indicate that you are here or present. So we know that [Dr. Valerie Ng] and [Dr. Ren Salerno] are here. Dr. Birthale Archie?

DR. BIRTHALE ARCHIE: Here.

CLIAC DFO: Mr. Michael Black?

MS. HEATHER STANG: He is going to be arriving 30 minutes late today due to a previous commitment

CLIAC DFO: Thank you, Heather. Dr. Kimberle Chapin?

CLIAC CHAIR: She, too, will be late due to some conflicts.

CLIAC DFO: Ms. Heather Duncan? Oh, I'm sorry. Dr. James Crawford? I did that yesterday too.

DR. JAMES CRAWFORD: Here.

CLIAC DFO: Thanks, Jim. Ms. Heather Duncan?

MS. HEATHER DUNCAN: I'm here.

CLIAC DFO: Dr. Mary Edgerton?

DR. MARY EDGERTON: Present.

CLIAC DFO: Dr. Susan Gross?

DR. SUSAN GROSS: Present.

CLIAC DFO: Dr. Lee Hilborne?

DR. LEE HILBORNE: Present.

CLIAC DFO: Dr. Ewa King?

DR. EWA KING: Here.

CLIAC DFO: Dr. David Koch? I believe he's not participating. Is that correct, Heather?

MS. HEATHER STANG: That is correct.

CLIAC DFO: Dr. Lavinia Middleton?

DR. LAVINIA MIDDLETON: Present.

CLIAC DFO: Ms. Carole Moss?

MS. CAROLE MOSS: Present.

CLIAC DFO: Dr. Nirali Patel?

DR. NIRALI PATEL: Present.

CLIAC DFO: Dr. Michael Pentella?

DR. MICHAEL PENTELLA: Here.

CLIAC DFO: Ms. Jennifer Rhamy?

MS. JENNIFER RHAMY: Present.

CLIAC DFO: Dr. Gregory Sossaman?

DR. GREGORY SOSSAMAN: Here.

CLIAC DFO: Dr. Mark Tuthill?

DR. MARK TUTHILL: Present.

CLIAC DFO: Dr. Chip Watkins?

DR. CHIP WATKINS: Present.

CLIAC DFO: Dr. Donna Wolk?

DR. DONNA WOLK: Here.

CLIAC DFO: Mr. Andy Quintenz? Andy, are you with us today?

MS. HEATHER STANG: He has not joined yet. But we'll be on the lookout for him.

CLIAC DFO: Dr. Collette Fitzgerald?

DR. COLLETTE FITZGERALD: Present.

CLIAC DFO: Ms. Sarah Bennett?

MS. SARAH BENNETT: Here.

CLIAC DFO: Dr. Tim Stenzel?

DR. TIM STENZEL: Present.

CLIAC DFO: And Mrs. Nancy Anderson?

MS. NANCY ANDERSON: Here.

CLIAC DFO: Great. So I believe-- Heather, correct me if I'm wrong. But we now want to recognize our outgoing CLIAC members, right?

MS. HEATHER STANG: Yes.

Recognition of Outgoing CLIAC Members

CLIAC DFO: So I'm bringing up my notes. They're a little bit different than the slides. Sorry. I am ready for you, yes. This is always sort of a bittersweet time for us at CLIAC. We unfortunately have to say goodbye to six of our current members, all of whom have made tremendous contributions to CLIAC. And we're just incredibly grateful for their participation and their engagement and their contributions to CLIAC. So I will go through each one of them one by one. So next slide, please.

Dr. Susan Gross is a clinical professor of obstetrics and gynecology pediatrics and genetics and chief medical officer of cradle genomics. Dr. Gross provided a medical genetics perspective on a variety of committee discussions. She was

instrumental in drafting recommendations on many topics, including reducing diagnostic errors, considering laboratory workforce shortages, improving laboratory data exchange during COVID-19 and addressing laboratory-developed tests. We very much thank Dr. Gross for her service to the committee. Next slide, please.

Dr. Lee Hilborne, as senior medical director of Quest Diagnostics, a professor of pathology and laboratory medicine at the David Geffen School of Medicine at UCLA, and a previous CLIAC member, Dr. Hilborne provided valuable comments on many issues considered by CLIAC. Dr. Hilborne served as chair of CLIA personnel regulations workgroup, whose report resulted in 12 CLIAC recommendations. Dr. Hilborne led the development of recommendations for the laboratory workforce, laboratory data exchange and harmonization, and the clinical laboratory's role in identifying health inequities. He consistently pushed CLIAC to address how the laboratory should better address social determinants of health. He currently serves on the CLIA regulations assessment work group, and we very much appreciate Dr. Hilborne for his substantive contributions to CLIAC.

Dr. Lavinia Middleton, Dr. Middleton's role as a deputy chief medical officer and medical affairs, deputy division head of quality in the division of pathology and laboratory medicine at Anderson Cancer Center allowed her to provide extensive knowledge of surgical pathology, quality, and process improvements to the CLIAC discussions. Dr. Middleton provided contributions to the discussions and recommendations on the laboratory workforce, the role of a laboratory in improving diagnoses, integrating laboratory informatics systems with electronic health records, and advancing laboratory data exchange and harmonization. We much appreciate and thank Dr. Middleton for her valuable contributions to CLIAC.

Dr. Gregory Sossaman, as a system chairman of the Ochsner Health System department of pathology and laboratory medicine as well as the medical director of three Ochsner laboratories, Dr. Sossaman contributed a diverse perspective to many CLIAC discussions. His clinical pathology, cytopathology, and informatics expertise led to CLIAC recommendations on many topics, including the role of the laboratory in improving diagnoses and laboratory data exchange and harmonization. He's currently serving as the co-chair of the CLIA regulations assessment work group. We very much appreciate and thank Dr. Sossaman and his commitment to CLIAC.

Dr. Donna Wolk, as the system director for clinical and molecular microbiology in the Geisinger Health System, Dr. Wolk provided a microbiologist perspective to a variety of CLIAC discussions. She was instrumental in drafting recommendations on many topics including antibiotic resistance, next-generation sequencing, laboratory personnel, laboratory-developed tests, and the curation of standard codes for laboratory test orders and results. Dr. Wolk is also appointed as the CLIAC liaison to the CDC's Office of Infectious Diseases Board of Scientific Counselors, and we much appreciate and thank Dr. Wolk for her service to the committee.

The last person I need to thank-- and I saved her for last because we owe an incredible debt of gratitude to Dr. Valerie Ng, who has served as our client chair and has provided exemplary leadership to CLIAC and hopefully all of the members and everyone associated with CLIAC can understand my appreciation for Dr. Ng. Throughout her career, frankly, she has shown her dedication to CLIAC and the importance of CLIAC's mission, serving on CLIAC from 2000 to 2007. And she's been a member of CLIAC for the last five years as well. I'm not sure who keeps track of what CLIAC members we have had who have had the most years in office or on the committee. But Valerie definitely is among the leaders, I assume. She's responsible and oversaw 14 formal recommendations in one letter to HHS by CLIAC. She chaired the CLIAC nontraditional testing workflow model group. And this is not insignificant either is that she was the chair of CLIAC while we had to scramble and transition from an all in-person meeting to a totally virtual meeting of a committee. I'm not going to read through all of this, but I will just leave it up here for a minute. These slides are obviously part of the permanent record and are available on the website.

But as you can see here and in the next slide, Dr. Ng has overseen and supported CLIAC recommendations in an extremely wide variety of topics from laboratory workforce issues to guidelines for addressing health disparities to laboratory data exchange, really strengthening-- the need to strengthen the partnership between clinical laboratories and public health, and really pushing the CDC in particular but the government in general on the need to develop more and better training and educational materials for SARS-CoV-2 self-testing, point-of-care testing, follow-up care, test interpretation. We really can't say enough about all that Valerie has contributed to CLIAC.

And here, again, I won't read through this slide. But we wanted to make sure that it was part of the permanent record that during the time that Dr. Ng was chair of CLIAC, she and CLIAC achieved all of these specific outcomes. At one point in time, we had three active workgroups underway, which was the first time in history that we had more than one work group actively engaging on an issue at one time. And managing three separate workgroups simultaneously is no small task. And across the three agencies, I think it's fair to say that we've had some of the most productive years of our existence including responding to the COVID-19 pandemic. And obviously, not everything went smoothly or perfectly. But what we did achieve is in no part related to and significantly influenced by the work of CLIAC and the leadership of Dr. Ng.
So for those of you who don't know, the chair of the CLIAC unlike the members must attend a large number of meetings with CDC staff and as well as with FDA and CMS staff to determine agenda and lots of details. And the reason these

meetings go as smoothly as they do is largely also as a result of Dr. Ng's dedication to the committee. Her just wonderful personality who makes working with her extremely easy and pleasant. And so thank you to Dr. Ng.

But also, thank you to all of the CLIAC members who are in their last meeting for now. And I just want to again express how grateful I am to all of you for your participation and your commitment and your recognition of the value and the importance of this activity. So thank you. Let's see. Yes, OK, lots of claps. [CLAPPING]

So the other thing I need to say-- sorry, I need to get back to my other notes-- is for everyone, please visit the CLIAC meeting website to review presentation 12, which has a detailed list of all of the contributions of these particular members who we thank for their service. So now I get to turn it back over to [CLIAC CHAIR].

CLIAC CHAIR: Thank you, [CLIAC DFO]. That was so very kind. Obviously, CLIAC cannot accomplish anything without the unfailing, constant support of you, and Collette, and Heather, and Nancy. So we thank you. I personally have been very grateful and honored to be on CLIAC. I think my tenure is matched by that of Lee Hilborne and probably Pat Charache prior. And we stand on the shoulders of giants. I'm just going to name some, yell out some names-- Rhonda Whalen, Tom Hearn, Bob Thomas, Joe Boone, Toby Merlin, Lou Turner, Dev Howerton, Judy Yost, Steve Gutman. Just think of all those giants-- many, many more that I can't access in my remote memory. So thank you all. I'm counting on you all to carry on the good dialogue. Moving on, we are moving to our morning session, which is the expanded public comment session. We have written public comments available on our CLIAC meeting web page, and we have four presenters lined up for public comment today. In order, they will be Dr. Joseph Saad representing the College of American Pathologists, Dr. Sarah South representing the American College of Medical Genetics and Genomics, Mr. Mark Wade representing the Association of Public Health Laboratories, and Dr. Toby Cornish representing the Association for Pathology Informatics. After they've given their presentations, we will then use the remaining time to share summaries from the written public comments. We will start with Dr. Saad from the College of American Pathologists. Dr. Saad?

Expanded Public Comment Session on “The Future of Laboratory Medicine in Non-traditional Testing Sites”

Public Comments

DR. JOSEPH SAAD: Thank you, and good morning. My name is Joe Saad, and I'm a practicing pathologist in Dallas, Texas where I served as chief of pathology for the Methodist Health System I am here today representing the College of American Pathologists to speak to the Clinical Laboratory Improvement Advisory Committee on the topic of CLIAC nontraditional testing sites. Thank you for this opportunity to speak today, and we appreciate all the work that you have done during this public health crisis. As the world's leading-- the largest organization of board certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Since the inception of CLIA, nontraditional testing sites have exploded across a range of CLIA specialties and subspecialties. CLIA specialties and subspecialties should not be expanded since each application within a specialty and subspecialty would have notable differences that require additional specificity, which is not feasible in a regulatory process. Instead, the focus should be on adding personnel requirements for point-of-care testing, recognizing bioinformatics including standalone facilities as subject to CLIA, adding personnel requirements for bioinformaticists, revamping proficiency testing requirements to test the total testing process, and considerations for remote work. Qualified and trained personnel are vital to clinical laboratories providing reliable and accurate test results. CLIA specifies the level of training and education in laboratory science necessary to fulfill this mandate. The CAP believes the current CLIA requirements should be maintained to ensure the public's confidence in laboratory testing. However, with the advancement and explosion of technology leading to faster patient treatments, a new category of testing personnel should be considered for individuals that use point-of-care testing devices as a support function to their primary roles and have no formal laboratory training. For the separate qualifying degree, we recommend that the CMS create testing personnel criteria that leverage point-of-care testing in settings of a hospital or health care facility where specialized or intensive treatment-- for example, ICU-- is provided. This category would allow testing personnel in nontraditional site locations to fulfill their roles within the health care delivery team while ensuring the reliability and accuracy of laboratory testing. We also recommend that the CMS develop criteria for the technical consultant and general supervisor under the separate qualifying degree. That would allow experienced and trained testing personnel in these locations to fulfill the role of technical consultant and general supervisor while remaining under the supervision of a pathologist. All aspects of clinical laboratory testing performed in a distributive testing model should be regulated under CLIA, including bioinformatics and cloud-based software computing. Moreover, laboratories should observe good laboratory practices throughout the total testing process regardless of where any of the test components are performed. In addition, an important quality metric in determining clinical laboratory testing accuracy and reliability is to perform PT. Laboratory should perform PT by observing the same good laboratory practices they do for patient samples including moving samples among multiple sites to complete all aspects of testing. Doing so should not constitute intent to commit PT referral. In addition, bioinformatics expertise related to next-generation

sequencing technology has minimal overlap with the expertise of a pathologist, laboratorian, or geneticist. Therefore, roles should be added to CLIA for personnel performing bioinformatics or pathology laboratory informatics activity aligning with the existing categories in CLIA. Many pathology and laboratory practices in the United States have the infrastructure for remote sign-out. The CAP strongly advocated for the CMS to add the regulatory flexibility to allow remote sign-out because of benefits during the COVID-19 pandemic far outweigh the risks. While the CAP sees the benefits of continuing to allow remote work for clinical laboratory personnel, we're currently exploring, since the waiver has been in effect for a full-survey cycle, the risk and impact on clinical laboratory operations and patient care. The CAP looks forward to presenting these findings and recommendations to the CLIAC at a future meeting. In conclusion, the CAP supports the CLIAC efforts to examine the CLIA regulations to determine modifications to ensure the regulations accommodate advances in clinical laboratory practice. However, any modification should assure patient access to quality testing by affording the least burdensome approach to oversight. CLIA is a very important tool that can ensure the integrity of clinical laboratory testing and safety of patients. As clinical laboratory testing continues to evolve, the CMS and interested stakeholders such as the CAP will need to work closely to ensure smarter regulations and policies. And thank you for your time and attention.

CLIAC DFO: Thank you, Dr. Saad. Our next speaker will be Dr. Sarah South from the American College of Medical Genetics and Genomics Dr. South?

DR. SARAH SOUTH: Thank you. I'm here on behalf of the American College of Medical Genetics and Genomics to highlight aspects of CLIA regulations that require clarification as they relate to working remotely. Specifically, we ask this committee to push forward its previous recommendation that when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they should be deemed as performing those services at the primary site that houses the CLIA certificate. The advent of COVID-19 has challenged the American workforce to rethink the traditional employment paradigm by shifting into distance working. Across many disciplines, individuals have adapted to the use of secure portals such as VPNs to ensure secure and accurate data review while maintaining the same level of quality, safety, timeliness, accessibility, and productivity. Even as COVID-19 restrictions are relaxed, many institutions have and will continue to maintain a hybrid working model in which work can be performed on site or remotely as long as comparable level of quality, accuracy and security is reached. This has become the new normal working forward. Currently, much of the data generated from genetic testing laboratories are stored and accessed digitally within medical laboratory information systems that are designed to be accessed from any securely networked computer. In contrast to telemedicine where physical examinations may be less complete, secure remote work is as complete as that done on site. This is true for quantitative results, gene sequencing tests, digital images of Southern blots, PCR fragment length profiles, digitized images of metaphase spreads, fluorescent in situ hybridization signals within a cell, computer-generated or digitized images of chromatographs, and many other types of data. Recognition of this equivalency occurred even prior to the COVID-19 pandemic. In its November 2019 meeting, this CLIAC committee recommended that when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they should be deemed as performing those services at the primary site that houses the CLIA certificate. However, this recommendation has not been specifically reflected in the current regulations or supporting guidance documents. There are current regulations that have restricted some forms of digital pathology testing, such as cytology slides needing to be evaluated on the premise of the laboratory. This has on occasion been presumed to apply to other types of digital image review. Moreover, there have been instances in which remote work has been viewed as distributive testing or referral testing, both of which imply that at least some part of the testing is performed in another laboratory with a different CLIA license number. Confusion on the appropriate application of the existing regulatory wording has led to significant concern about the continuation of secure remote data review to meet the workforce requirements. The ACMG appreciates the rapid response from CMS at the beginning of the COVID-19 pandemic to state survey agency directors allowing for the remote review of pathology slides with certain defined conditions to ensure quality and security. We support the permanent continuation of this practice beyond the pandemic given the demonstration of its successful application over the past two years. And we request clarification within the regulatory language on the applicability of remote work to genetic testing whereby laboratory data and images are reviewed in a secure but alternative environment. Further, we contend that remote analysis and case sign-out of genetic and genomic data produced in a CLIA-certified laboratory and accessed through secure data portals such as VPN does not qualify as distributive testing or referral testing, but should instead be considered as a virtual extension of the primary CLIA-certified site which is a rational update consistent with modern technology and now proven practice equivalency. Thank you.

CLIAC CHAIR: Thank you very much, Dr. South. Our next speaker will be Mr. Mark Wade representing the Association of Public Health Laboratories. Mr. Wade?

Mr. MARK WADE: Good morning. My name is Mark Wade, and I'm the laboratory services director for the San Antonio Metropolitan Health District, which is the public health entity for the City of San Antonio and Bexar County. The Department serves a population of about 2 million, and my laboratory also serves a 29-county region in South Central Texas. The purpose of my speaking to you today is to describe what my agency and the city experienced recently with

pop-up COVID-19 testing labs. We loosely defined pop-up labs as non-governmental sanctioned testing sites that suddenly appeared in various locations around our jurisdiction in tents or other temporary, nontraditional mobile operations. I'd like to describe the details of a very specific case that I personally investigated and then shared the strategy we ultimately adopted to respond countywide to citizens' complaints. On January 4, I was contacted by the San Antonio Police Department financial crimes director. They were responding to a complaint to the police department about a fake lab operation and wanted me to accompany them to the location as a subject matter expert to help determine what was actually going on. They made a site visit earlier and captured some pictures of the lab location, which provided me some information on the test methods that they were using. We made a site visit to that Easy Lab Services working site of a vape shop building connected to a convenience store. They offered a free five-minute COVID-19 test. We found three folding tables set up outside the side of the building adjacent to the garbage dumpsters operating as a laboratory. A man identified himself as a lead supervisor for the group conducting the testing and was able to produce a photo of the lab's CLIA certificate of waiver, which was from Illinois. The lab was using a lateral flow rapid antigen test from PHASE Scientific. The lab manufacturer's window to read the test results is between 20 and 25 minutes. Obviously, they were not observed to be following the EUA in this case. The supervisor indicated readings were taken as soon as any color could be observed and was not aware of the actual time requirements. The packages are indicated external, positive, and negative controls as materials required but not provided. No such external controls were observed or documented. The intended use clause of the EUA indicates individuals to be tested within the first five days of symptom onset or if asymptomatic be tested serially over two or three days with at least 24 hours between tests to be valid. The site supervisor was unaware of this requirement in symptomology was not being captured. The EUA further state samples should be collected by a health care provider or self-collected under supervision of a health care provider. No health care provider was on site. The test is indicated to be run by trained clinical laboratory personnel and medical or health care personnel. None were observed on site. The EUA indicates disposal of used test contents as biohazardous waste. No biohazardous waste containers where observed. They were using cardboard boxes as trash receptacles, and there was waste observed under the table, on the ground, and at their feet. The site supervisor was identified by the financial crimes unit as the owner of the vape shop and the adjacent convenience store. A photo was captured by a client of the Easy Lab Services and sent as part of their complaint. Each client is told to take a picture of their test cartridge and test report as proof of testing. This cartridge and associated test report indicate that an RT-PCR test was ordered and performed, but a negative antigen test result was selected at the bottom of the report. However, the test cartridge showed no reaction at all. It was blank, which is an invalid result recording according to the package insert. This person was given a negative result on a test that was invalid. In this case, no criminal code violations were noted by the San Antonio Police Department and no local health code violations were noted by the public health authority. I did formally submit my findings on this case through our regional CLIA office in detail. This lab continued to test for another month or so and then stopped testing as the demand waned. Citizen complaints about pop-up labs were pouring into the police department through 311 and 911, directly to the health department, and to the city council offices. Initially, I was being tasked by city leadership to investigate each complaint on top of my duties operating the public health lab and quickly became overwhelmed with this situation. I was then able to develop a checklist of questions from our public health sanitariums responsible for restaurant and food establishment inspections all over our district. They would make site visits and provide their findings to me. If they did not operate under a CLIA waiver, then we were able to order them closed. Beyond that, we didn't have any authority to stop their operation unless they were in overt violation of city code or some criminal law. This lasted until early March. Most pop-ups were from out of state and brought their own people to operate the sites. Some were connected to legitimate commercial laboratories. Some were associated with physician groups. Some were completely nefarious or even unknown. The people utilizing these sites gave up their personal health information to less than legitimate organizations and in my findings were being defrauded with bogus test results, no test results, or otherwise their insurance was being defrauded not to consider that they were giving up their identity information and issues around identity theft. It's not clear to me how this can be addressed by CLIA. But it is clear a lot of fraud has taken place under the auspices of being a CLIA-waived to laboratory that gives a semblance of legitimacy to these pop-up lab operations. Thank you.

CLIAC CHAIR: Thank you very much, Mr. Wade. Our final speaker will be Dr. Toby Cornish representing the Association for Pathology Informatics. Dr. Cornish?

DR. TOBY CORNISH: Thank you. My name is Toby Cornish. I am a pathologist and clinical informaticist at the University of Colorado, and I am president of the Association of Pathology Informatics. Briefly, the API is the only national organization dedicated exclusively to pathology and laboratory informatics. Founded in the year 2000, the API has grown to include over 1,000 active members including many world leaders in informatics. We endeavor to play an active role in legal, ethical, social, and regulatory issues in the laboratory. The topic under discussion today, testing in nontraditional sites, is of great interest to the membership of the API as it is to many practicing pathologists. While the topic of testing in nontraditional sites touches on a range of laboratory practices, I will be focusing my comments today specifically on remote review and reporting of digital pathology slides. Current CLIA regulations mandate that all laboratory testing be performed on the premises of a CLIA-certified laboratory. Pathologists who wish to review and sign up cases remotely therefore need a separate CLIA certificate for each additional permanent site. Alternatively, a temporary site exception indicated on form 116 might be used for non-permanent, off-site testing. While such practices have been rare given the

physical nature of glass slides, recent advances in remote digital pathology have bolstered interest in them. The COVID-19 public health emergency brought new urgency to this issue. In March 2020, the CMS opted to quote "exercise enforcement discreption-- discretion to ensure pathologists may review pathology slides remotely," unquote at temporary testing sites, including, specifically, a pathologist's home. In April 2020, the FDA issued its own enforcement discretion policy related to digital pathology devices. Together, these actions significantly lowered barriers to adopting remote review of slides. As early as October, a College of American Pathologists survey found at least 6% of pathologists had experience using digital pathology devices for remote diagnosis. Since then, many more pathologists have adopted remote review. The last two years have demonstrated the remote review of digital pathology slides can be safe, secure, and effective. To date, we are not aware of any negative consequences from the decision by CMS and FDA to enact these enforcement discretions. At some point, though, this public health emergency will come to an end. Many labs faced with a return to full enforcement of laboratory site regulations will abandon the remote digital pathology programs. In doing so, they will lose the time and effort they have invested in establishing and validating these practices. A return to full enforcement represents a lost opportunity to build on what these labs have accomplished during the pandemic and to move forward into the future. The time has come to acknowledge that digital technologies are transforming laboratory practice and to remove the increasingly outdated requirement that a pathologist's interpretation must occur within the physical confines of a lab. Provided that communications are secured and all endpoints are validated and configured similarly, the risk profile of on-premises and remote digital pathology remain nearly identical. We strongly support permanent laboratory site exceptions for the remote digital review and reporting of pathology slides. Importantly, these site exceptions would not exempt a laboratory from the remainder of CLIA regulation or good laboratory practice. We recommend that a clinical laboratory site, which increasingly includes both co-located physical spaces and distributed digital components, should be considered as a single entity-- in other words, including both on-site and digital remote locations. This will ensure consistent quality and safety across all areas of the laboratory. To this end with the exception of site, remote review of pathology slides can be treated like other functions of the primary lab with requirements remaining for validation, standard operating procedures, training, competency assessments, and documentation. In closing, the API requests the CLIAC consider extending the current enforcement discretion beyond the end of the COVID-19 public health emergency so that a primary clinical laboratory site need not obtain separate CLIA certificates or submit multiple CMS 116 forms for all of its affiliated remote sites where pathology slides have reviewed. The API recommends that enforcement discretion should continue until a permanent exemption for remote review of pathology slides via digital pathology can be obtained. Similar exemptions should also be considered for other digital interpretive workflows in the lab such as in molecular diagnostics and certain sections of the clinical laboratory. The Association of Pathology Informatics appreciates your consideration of these comments, and we look forward to opportunities to work with CLIAC in our shared pursuit the highest possible health care and laboratory standards. Thank you.

CLIAC CHAIR: Thank you very much, Dr. Cornish. A reminder to all that these four presentations are also present on the website should you want to go revisit them. Moving forward, we are going to use the remaining time to share summaries from the written public comments which are not being presented orally. It's just to assure we all have the same basic understanding before we go into our community discussion.

I will read to you the summary of public comment number one from the American Clinical Laboratory Association. The ACLA urges CLIAC to advise HHS to extend the current enforcement discretion for remote review of digital pathology slides from a site other than the pathology from the primary laboratory without having to obtain a separate CLIA certificate for the remote site given fully validated systems that have been in place for many years now, the information available, examination, interpretation, and reporting remotely can be indistinguishable from at the primary laboratory but for the physical location. ACLA, therefore, comments that CLIAC recommends continuation of enforcement discretion beyond the end of the public health emergency until CMS can review CLIA regulations to formalize the policy.

CLIAC DFO: I will read the summary that was provided by the American Proficiency Institute. And just to reemphasize what [CLIAC CHAIR] said, these summaries were provided by the groups that provided the public comment. These are not CLIAC summaries. These are summaries that the public commenter provided, and we are reading them word for word.

The American Proficiency Institute, or API, provided a full written statement for could be accurate discussion on the future of laboratory medicine in nontraditional sites. Here is a summary of the major points made by API for CLIAC consideration. Number one, despite the resilience of proficiency testing, the inability to adopt technical rule changes more promptly ultimately hinders clinical laboratory performance and the testing accuracy. CLIAC should consider recommending mechanisms for adding and deleting regulated analytes under CLIA in a more timely manner. Number two, accommodate changes in instrumentation and the availability of sample materials, proficiency testing providers need to offer new modules. CLIA must offer flexibility to proficiency testing providers so that programs with fewer than 10 participants may still utilize the proficiency test, its source of samples, and comparison data. Instead of withdrawing a program for an initial dearth of participants, qualitative challenges should be graded based on reference values with fewer than 10 participants. CLIAC should actually consider making this recommendation so the proficiency programs are available for newer areas of testing. Number three, CLIAC should offer support to the Department of Health and Human

Services for efforts to standardize methods for new technologies. As next-generation sequencing testing becomes more widespread, we need quality assessment tools to confirm accuracy, standardization, or system proficiency testing community in addressing why testing variations moving forward. Number four, noting that some non-laboratory health care professionals assume clinical testing roles, CLIAC might deliberate on how to encourage proficiency testing for each individual performing moderate- and high-complexity testing. While proficiency testing assesses overall laboratory performance, it is also used to identify errors in the analysis and interpretation of an assay. Individual proficiency testing may help address errors with these nontraditional testing environments. Finally, API also asks that CLIAC recommend-- sorry, this is number five. API also asks that CLIAC recommend the public sharing of aggregate data on laboratory testing performance. This will allow us to continue to be innovators in this evolving clinical laboratory landscape.

CLIAC CHAIR: Public comment number three summary provided by Dr. Joseph Sirintrapun. CLIAC should recommend the US Department of Health and Human Services extend current enforcement discretion beyond the end of the COVID-19 public health emergency for remote pathology review and results reporting. The enforcement discretion assures no need to obtain separate CLIA certificates or submit multiple CMS 116 forms for all of a primary clinical laboratories accountable remote sites, which became impractical during the public health emergency. During the pandemic, the enforcement, discretion, and relaxations on FDA clearance of digital pathology technologies allowed laboratories to show sufficient experiential evidence that remote review and reporting are safe, secure, and effective with digital pathology technologies. CMS can assure the appropriate guardrails for public trust to its respective accreditation bodies. That is the College of American Pathologists Joint Commission in New York State. These guardrails include verification, validation, and evaluation of digital pathology processes and standard operating procedures to ensure that remote review and sign-out continue as a safe, secure, and effective endeavor moving forward. My letter details several possible avenues to pursue in formalizing guardrail policies to justify and sustain continued enforcement discretion.

CLIAC DFO: Public comment number four-- sorry. Alejandra Johns, the CEO of Virtual Scientific Inc provided this comment summary. Until recently, it was a universally accepted understanding that if a laboratory wanted to hire a remote cytogenetic technologist, a CLIA certificate for the technologist's home address would have to be issued by the appropriate state CLIA agency. However, in the past five years, due to the shortages of personnel and increased case volume, many laboratories began to hire remote cytogenetic technologists without applying for a CLIA certificate. It was being done quietly without the knowledge of many state CLIA agencies and/or accrediting organizations such as CAP. Since inspectors don't usually verify the location of personnel, laboratories did not have to disclose some of their staff members were remote. With time, this practice was soon discovered and complaints were filed, which were soon followed by an investigation by the appropriate state agency or accreditation organization. However, the practice of hiring remote technologists without a CLIA certificate is still happening. Many large companies are erroneously citing February 28, 2022 CMS memo entitled "Clinical Laboratory Improvement Amendments Guidance for Temporary Testing Sites" under the multiple site exception as proof that a CLIA certificate is not required for permanent remote technologists. Due to the wide range of interpretations of this memo from state CLIA agencies, there is much misunderstanding and misinformation regarding the subject. As a result, large companies are not being held accountable for having permanent remote technologists without a certificate, while smaller companies are being held firm to the practice. It is our opinion that there must be a definitive response to the current question and quick action to address the current misunderstanding within the cytogenetics laboratory community. And perhaps most importantly of all, there must be uniformity in the interpretation of the regulations across all state agencies.

CLIAC CHAIR: Public comment number seven from the American Society for Clinical Pathology, the American Society for Clinical Pathology has submitted comments on several issues. In brief, ASCP's comments urge CLIAC to do the following-- support continuing the ability of pathologists and other laboratory professionals to perform remote pathology and laboratory services as allowed under the existing enforcement discretion; outline recommendations to increase the level of federal oversight over nontraditional testing sites, specifically those laboratories that perform only waived tests; and urge CMS to update CLIA's personnel rules in line with CLIAC's 2019 recommendations. On the latter issue, the ASCP board of certification joined ASCP in submitting these comments.

[CLIAC DFO] had to step out, and I will continue reading on his behalf. Ms. Jeanette Williams-Smith provided this public comment PC8. In reference to the Florida State Senate Bill 1374, the following registered nurses will be exempted from clinical laboratory personnel licensure requirements. Registered nurses licensed under Chapter 464 who are determined by the clinical laboratory director of a hospital or hospital-based, off-campus emergency department licensed under Chapter 395 to be qualified under 42 CFR S 493.1423 to perform only moderate-level or waiver-level clinical laboratory testing in accordance with S395.0091 within the hospital or hospital-based, off-campus emergency department with a separate federal Clinical Laboratory Improvement Amendments, CLIA, program clinical laboratory certification under 42 CFR, Part 24-493. How does CLIA and other regulatory bodies plan to address HCA health-care sponsored bill 1374? That allows RNs and others with a high school diploma to perform moderate complex testing in Florida, a state that requires state licensure to perform moderate complexity. Do technologists no longer need to be licensed? Do the bodies understand the concern and outrage amongst the Florida technologist community?

Next public comment is PC11 from Chris-- I apologize if I'm not pronouncing her name correctly-- Balchunas, school nurse, Sebago Elementary School. In 2020, the State of Maine arranged for the point-of-care Binax COVID-19 testing in a public school setting. Would the committee look into other rapid tests in a school nurse setting such as strep or mono? These past two years, I did many tests to rule out COVID-19 at school. Then I would process to looking into a child's throat that looks like strep and smelled like strep. I wonder why the school nurse could not test. The school nurse is already gowned and gloved in PPE. Our school is in a rural area of Maine, and health care is hard to access. The point-of-care testing by a school nurse would have many positive impacts. Number one, decrease pain, discomfort and recovery time for the student. Number two, the student has a comfortable rapport with the school nurse from past visits and daily presence in the school. Three, shorten the student's time out of school-- therefore, increase their education learning time. Four, increase the parent's time at work. Five, decrease transportation costs to visit a primary care provider such as gas. In some cases, students have a hard time accessing any public transportation to medical appointments. In our area of Maine, the ED is about 40 minutes away by car. The student's primary care physician could be up to an hour or more away. I know parents of students that must drive one hour back to school to pick up the student and then another hour to drive the student to the primary care practitioner's office. It's not beyond a nurse's license to swab a throat. The obstacles are, one, getting a PCP order. Would the school physician order, or does each student's PCP need to order the test? In the past, it takes me about four hours to the next day for a PCP to call me back. Two, obtaining a parent's permission, can the school nurse obtain the parent's permission by phone call to give a Tylenol? Three, billing insurance for the testing versus adding the cost to the town's school budget for testing. Four, the package of test kits in amounts that would be used before the kit expires for the school nurse. Five, running controls and proficiency testing for small point-of-care testing, so half or more of the kit is not used on just doing quality testing. Six, CLIA should have documentation that is easy to access so that a school nurse can do this testing. I've heard it is not allowed by CLIA, period, end of discussion.

And then our final comment PC12 from Dr. Andrea Pitkus. Dr. Pitkus, a laboratory informaticist has provided written public comments on the topics of consumer-performed testing considerations, supportive digital pathology, laboratory interoperability needs, needs with FHIR, "fire," laboratory data implementations, and support of CLIA regulatory assessment workgroup recommendations. As CLIAC deliberates the scope of CLIA across the testing continuum, the examples and questions posed help illustrate some of the current widespread uses of laboratory data and impacts of implementation quality. That concludes the summary of our public comments.

Committee Discussion

CLIAC CHAIR: I want to thank all of the submitters as well as the public commenters. We will now continue our committee discussions until our 2:00 PM EDT break. That is about two hours. And I know a number of you reflected on the discussion yesterday probably with value added from the comments from today. And I know a number of you have submitted recommendations. So I'm going to open the floor with suggestions on how we move forward. Options include just putting up all the recommendations-- number two, having a discussion of what we just heard, how it reflects to the previous day. And on that note, I want to give you my assessment of what I heard. I heard multiple concurrent voices supporting the continued enforcement discretion for remote viewing of digital pathology and other digital information. There seemed to be no argument around that. I heard and as we discussed yesterday a need for attention to certificate of waiver laboratory sites, balancing the issues around quality and trust as Dr. Palm said yesterday around point-of-care testing, balancing that with fraud and abuse so cogently provided by Mr. Wade today. And along those lines, personnel requirements-- we heard yesterday from AACC about their certified point-of-care program, personnel program. But what I'm hearing and what I've learned from the pandemic is we need a new population of trainers. We cannot continue to divert our clinical laboratory scientists into these new vastly expanded testing arenas. And if that is true, what are the processes we need around the quality of our point-of-care tests so that we can trust the results? What do we need around personnel so that we can trust they're doing the test correctly and anything else related? So the floor is open-- chat or hands. Go for it, [CLIAC MEMBER].

CLIAC MEMBER: Well, actually, I jotted down some thoughts. And my sense was when you asked the question, what do we need to do? I think we need to put it in some groups and then deal with it because the recommendations fall that way. And I think you summarized it, frankly, better than I could. So I would recommend that our going forward discussion focus on those. I was certainly moved by the comments of fraud and abuse. And it made me reflect back to why we have CLIA in the first place, that there was people taking advantage of patients, really, in terms of laboratory testing. And so I think as we have this deliberation, we should as we talk about basically encouraging continuation of enforcement discretion related to remote pathology, which is appropriate, we need to make sure that even that has safeguards on it. So the kinds of things that we heard that other laboratories are doing does not happen in that space. And so it is clearly, for all of these, a balance between being more permissive in terms of the right things while at the same time making sure that we go back to the roots of CLIA, why it exists, and to make sure that we don't violate that going forward. I don't know. I was so moved by the discussion this morning. I just felt passionate to say that.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I think the challenge is to take all this very rich information and drop it to recommendations. And [CLIAC CHAIR], I think you've parsed out the three areas very succinctly, personnel, quality, and trust, and the role of remote activities. To me, the challenge as I was preparing some written draft material is, what is a direct recommendation to CLIA? And what is referred to a CLIAC working group? And certainly in my own draft submission, which was a riff on what [CLIAC MEMBER] submitted, is there are direct in essence statements made to CLIA. But the referral to the working group I think has an upside and a downside. The upside is that the detail required to have cogent recommendations that are well thought out is very important. My concern is the turnaround time for doing so. And this particularly applies to the availability of laboratory personnel. It was stated in our local environment. We're running out of runway, and we can't be using up time to establish procedure when we actually need to be actively in the field expanding our laboratory workforce both in the clinical-licensed laboratories, but also in support of these remote sites. So I invite discussion today on, what is referred to a CLIAC working group versus what is direct recommendation to CLIA?

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]? [CLIAC MEMBER], you're on mute.

CLIAC MEMBER: Thank you. I personally experienced similar conditions as Mr. Wade discussed from Texas in some of our larger, even-- I mean, he's talking about small pop-up mobile sites. In Pennsylvania, we had pop-up-- we call them predatory pop-up labs in our own jargon overseen by either MDs, PhDs, Bachelors of Science people that never did clinical laboratory testing before and rose to the occasion of for-profit opportunists in my personal perspective. And although some were good and filled a gap, it's almost impossible in the middle of a pandemic to assess the quality of these pop-up laboratories whether they're large or small. And I would say that if you follow the national press, there were many multistate laboratories shut down for imperfect practices that harmed patients. And frankly, it was sickening, the money grab that happened during the pandemic in certain circumstances. So one of the proposals that I put into maybe somewhat less than perfect form is that we as a group proactively recommend expansion of the medical laboratory science pipeline to address future pandemic needs beginning at the junior high, high school, university, and post-graduate level, creating a roadmap of sorts for non-- CLIA only addresses sort of MLT level and above. And with all the point of care, infrastructure, and investment by venture capital into the point of care space, we're going to have to figure out a way that we can engage high school students through vocational training. Perhaps they can have a certificate. Maybe we don't need to change CLIA law, but provide an option for quality vocational training at the high school level that would be something akin to an MLA, a Medical Laboratory Assistant, that could then come out of high school to fill some of these point-of-care gaps that are being created. And we will continue to see whether there's a pandemic or not. So I would propose discussion of some type of option that would allow us not only to fill that need but also provide an entryway for high school students and junior high to become interested in laboratory sciences that then could go on to MLT, MLS, master's, and doctoral-level laboratory scientists and communicate that with our schools and our communities so that there is an option. And then finally, I'd like to state that all point of care is not created equal. And I've been in charge of the point-of-care infectious disease activity for 23 urgent cares in our rural population in Pennsylvania. And I believe there has to be special attention given to the new wave of molecular-waived testing in terms of template control, biohazard issues in pandemics, cleaning, adherence to quality that may not happen with a glucose point of care. There are quality standards there. But this new trend of infectious disease testing in the point of care and at home is something that we need to address as well as the vendors who are-- some are quite responsible and have 24-hour hotlines to help with at-home testing. Others are just piling up on the pharmacy shelves with, frankly, product inserts that are not home-friendly, don't describe how a general person in multiple languages and levels of English and diversity settings would be able to perform that. So I feel that if there are at-home tests, whether that's from a for-profit, venture-capital-funded laboratory or a venture capital industry member who's making a ton of profit from these initiatives, that there has to be support and perhaps linkage to these training programs that can allow us to meet the challenges of the point of care in the future. There's a lot more on the way. Thank you.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER], [CLIAC MEMBER], then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you I appreciate the information that we have received as well in reference to point of care, particularly as it relates to the nontraditional testing sites. And I would reference WellStreet's report on urgent care. And so as I engaged a bit in my homework last evening, I was reflecting on that. And one part of that report that-- several parts stood out. But I think it was Dr. Isbell maybe talked about hiring staff and challenges that they have and the fact that there has been a lot of difficulty there. And I thought maybe one strategy might be to explore-- well, first of all, I'm in academia. And I understand about writing articulation agreements and cooperating or engaging in collaborative interdisciplinary relationships with other colleges and universities. So extrapolating from that, I wondered if there could be-- if we were to recommend something along the line of having recommended to what the powers to be that we would establish an articulation agreement between nursing programs and NP programs-- that is nurse practitioner programs-- with academic colleges and universities that would serve as a feeder into these urgent care settings because I think there were 80. And they were very understaffed. So anyway, I was just looking at, is there an opportunity for a feeder? If you established an articulation agreement or relationship with, let's say, Bowie State University, where we have nurse practitioners and we have students graduating with BSN, would there be an opportunity to impact staffing? And how would we go about that

and to stay within the guidelines that we have in our role as CLIA? So is there an avenue? It just bears discussion because I've used this strategy in terms of even providing clinical placement for our students. And so that is one of the points that I would like to put on the table in terms of how we may impact point of care, the personal challenges in nontraditional testing site, and the fact that there is a staffing shortage.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. Those were very good comments, [CLIAC MEMBER]. And I'm sure we'll be reflecting more on this later. I would like to ask go back to something that [CLIAC MEMBER] said, and that's that not all point of care is created equal. And we know that tests aren't categorized as point-of-care tests. They're categorized as waived, moderate, or high complexity. And some very interesting tests are used near patient sites or close to patients. And in some cases, I've seen some large analyzers that were put in a room next to an ICU and a laboratory technician stationed there to run it. And it was considered point of care for that institution. So I'm wondering, [CLIAC MEMBER], what your thoughts are about those, creating that pipeline of individuals for point-of-care testing when point-of-care testing isn't just waived testing? It also includes even some small moderate-complexity tests. And then second, I'm wondering what the members' thought is about asking one of the agencies to formalize a definition of point-of-care testing as there isn't one today.

CLIAC MEMBER: [CLIAC MEMBER], it's a good point. I'm a strong advocate for keeping laboratory testing under the umbrella of the laboratory. I understand there are times when that needs not to occur. However, with community partnership to clinics and nurses, I just think there's more important things for nurses and pharmacists to be doing that laboratorians are not-- were not licensed to do. And so it doesn't make any sense to me not to encourage more laboratory oversight and collaboration at the local, community, academic level, whatever level. Obviously, if people are using point-of-care testing in the ICU, that has to be under the director of the laboratory in my perspective. So yes, I believe that point of care-- the CLIA complexity is really the main thing we're dealing at. But with the onslaught of all these community-based, point-of-care, and at-home testing, I really think that your idea about definitions being applied would be useful. But also, I personally think that the laboratory community has a sacred responsibility to expand and support health care in the community and in our health care organizations that are focusing on community needs, outbreaks, emerging pathogens, you name it, and not just passing the ball to other people who are already in the building. I think there's plenty phlebotomy, point-of-care, waived testing, opportunities, and other things that could be accomplished by partnership with the laboratory. And I guess I'm just a strong advocate for laboratory outreach rather than internalizing and giving away laboratory expertise to other people who have a ton of health care responsibilities to do anyway.

CLIAC MEMBER: I totally get it. I appreciate your comments. So I think from what I'm hearing from you in that comment is support of your previous comment's support of high school graduate pipeline to point of care is probably more around the waived testing as opposed to moderate-complexity testing being performed in an near-patient setting.

CLIAC MEMBER: Oh, absolutely.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: Thank you, both. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. I have a couple of points I'd like to make, so please bear with me. First, it sounds like for the remote interpretation of digital pathology, we could write a recommendation now. It sounds like that's non-controversial. I did want to just mention that there might-- I don't know if we're going to be as specific to mention the modalities that can be performed remotely as cytogenetics, NGS, whatnot. But I'd like to remind you about flow cytometry. Particularly in HLA, generally that's being performed by a remote doctoral-level individual. And anyway, if we do get that specific, I'd like to remind you about HLA and flow cytometry. I think we've heard a lot of wonderful mechanisms for training the trainers for-- [CLIAC MEMBER]’s brought up a lot of good points about how we can train individuals. I hate to be a cynic, but I don't know if anybody is going to really do it unless CLIA makes them. And so I think at the end of the day, we've got a lot of wonderful opportunities for personnel development in the area of point of care, in the area of waived testing, particularly off site. But there has to be teeth in it. And so I think it does come back to a recommendation that CLIA establish personnel requirements as commented on. That might be a little bit of a time-consuming process. Perhaps that could be done in concert with the workgroup that's developing what those requirements look like concurrently with the regulatory process for developing a requirement from CLIA. 60,000 waived licenses is a pretty daunting task for CLIA to manage. And I'd like to just comment that there are accrediting agencies, and I hope they're brought to the table about some of these issues because I think CAP, Joint Commission, and COLA can help with the oversight. They are already going into organizations that may have certificates of waiver. Not all accrediting organizations review all-- make it a requirement that all CLIA certificates be reviewed. But that would be something. That's a discussion that might move this forward, so that asking CLIA to have more oversight doesn't all of a sudden mean that CLIA's got to inspect 60,000 certificates of waiver. I think they've got some partners that can help them in that endeavor. And, again, hopefully we bring those people to the table as we move forward. I think the suggestion about proficiency testing is an

excellent one. And I've been a bit of a broken record about result interpretation and counseling. And that could easily be worked into an educational challenge associated with proficiency testing. That might help with some of that issue as well. And so I hope that we might think about putting a recommendation together about proficiency testing to help that. And then last, I feel that we may be ignoring the elephant in the room when we talk about training of the point of care and waived. There's not enough laboratorians, and we've skirted around that. We've mentioned that several times, but it's real. Our VA hospital here in Grand Junction had to shut down acute care because they don't have enough laboratory staff for evenings and nights and weekends to remain open. They've literally had to shut their doors. And so I think discussions about training should be in large to talk about the laboratorian shortages. And perhaps that would be food for thought for the next CLIA meeting. So thank you for letting me go down my little list.

CLIAC CHAIR: [CLIAC MEMBER], [CLIAC MEMBER]? [CLIAC MEMBER], you're on mute.

CLIAC MEMBER: Good morning, everyone. Thank you. Thanks so much for all of the contributions from the comments. And last night, we've really done-- I went through all of these letters. And you could definitely see a repeating theme. And so I do think that it's probably a good time to pick out one topic that is critical that perhaps we can get resolved in a motion pretty quickly. I'd like to make a recommendation to make a motion as it relates to the development of a new type of testing personnel to support the rapid growth of point of care, a certification training program that would be required ongoing to fill the positions of a testing leader, a point-of-care testing leader. And this person would not be required to have the necessary degrees. But I'd like to start out with a proposed motion if I may be so inclined.

CLIAC CHAIR: The motion is--

CLIAC MEMBER: Would that be OK?

CLIAC CHAIR: Yes. Is there a second?

CLIAC MEMBER: [CLIAC CHAIR], this is [CLIAC MEMBER]. I can second.

CLIAC CHAIR: Great, then all six of you who are waiting to talk we have an open motion on the floor, and we will address the motion now.

CLIAC MEMBER: So here is my first stab at it. CLIAC recommends that HHS approve funding to develop a program to train and certified a new category of testing personnel to support the advancement of rapid growth point-of-care testing. The POC testing leader would not be required to have had a formal laboratory training. And certification and training programs will be required ongoing. The need to fill these positions is urgent, so we request the rollout to begin in June of 2022.

CLIAC CHAIR: If I could ask those of you with your hands up before this motion was approved, could you put your hands down so we can see who wants to respond to the motion? OK, [CMS EX OFFICIO]?

CMS EX OFFICIO: Thank you. I just wanted to provide a little bit of a point of clarification about personnel requirements in CLIA as you're moving forward with your deliberations. In certificate of waiver laboratories, there are no personnel requirements. So any individual who has the appropriate training can perform waived tests whether they're at point of care or in a laboratory. The other point of clarification I wanted to let you all know so you are aware as you deliberate is moderate-complexity testing personnel are allowed to qualify with a high school diploma and appropriate training, so just a little bit of background information on CLIA requirements that I don't know if it's going to affect your deliberations or whatever. But I thought you guys should know that going into your deliberations. Thank you.

CLIAC MEMBER: That's great news. Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. I actually had raised my hand, but it dovetails very nicely with the motion that's on the table. If you looked at draft recommendation number six, this is getting at the same issue. And there's only one draft recommendation under discussion. But in dissecting out the relationship between the certification program that was presented and discussed yesterday, the question I ask is, what constitutes sufficient and necessary training and proficiency assessment for someone who performs tests as compared to what is in the motion, which is a point-of-care testing leader who provides both supervision of the point-of-care testing and very importantly oversight of the quality of the test output? And I think that then begs the question of, what is the overall directorship of a physician, to use the example but it's not limited to it, physician office laboratory? You need to have a medical director of a physician office laboratory who can be a non-laboratory trained physician. How does this proposed position relate to other personnel who are

supposed to be directors? And I think in order to understand the implications of this motion, we have to sort out the layers of supervision and the responsibilities and jurisdiction of each layer.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Hello, did you call me?

CLIAC CHAIR: Yes

CLIAC MEMBER: Oh, OK. It didn't sound like it. I would like to speak to parts of the recommendation. That first part, I agree with. But that second part where it says, the point-of-care testing leaders would not be required to have any formal laboratory training, I would like more discussion from the maker of the recommendation on, what is their thinking? Because I'm not necessarily in agreement with that. I'm more in line with what Dr. Saad said, talked about that we would create criteria for testing personnel for nontraditional site testing because we are really determined to have accuracy in carrying out the test as well as increasing validity and reliability. One of my big issues is that more needs to be done to ensure that the rapid test, the point-of-care test, has a higher level of validity and reliability because of what I see in practice that people have a rapid test. And it's negative. And then later on, they're found to be positive. And it's beyond the treatment period where we could have done some things. And so it limits us, and so therein lies my concern. I'm more along the line of Dr. Saad.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you.

CLIAC MEMBER: Yes, hello. I appreciate the spirit of the motion, but I'm a little concerned of its scope. It seems very narrow to me. Well, we've heard these personnel challenges over the last couple of days. It's not just point of care. It's the entire laboratory pipeline whether we're talking about typical medical technologists, whether we're talking about cytogeneticists, or folks working in molecular. And as we heard from [CMS EX OFFICIO] there really are no barriers to people coming into the lab pipeline whether they're high school graduates, so forth, and so on. I don't know what we accomplish by creating and asking for a new position type that is specifically dedicated to point of care in and of itself. I'll just stop there.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Well, I think [CLIAC MEMBER] just touched on what I was going to say. I mean, the root cause here is really that we have failed to acknowledge and adequately fund and promote laboratory medicine as a whole. The reason we need to find this level of testing personnel is because we haven't funded the other one. So it may very well be that we need to identify specific competencies, education, training, and competencies associated with this, what might be a simpler level of testing. But I think that this needs to come, given what we've heard, in a context of a much broader approach, an urgent call to make sure that there are adequate laboratory personnel at all levels. So I'm agreeing with [CLIAC MEMBER]. That's what I was going to say anyway.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: To make a recommendation, I think we can all agree that the group has a lot of concerns about the qualifications and level of training for personnel in the testing sites mostly performing waived tests. I think we have several approaches to how to address this. And I'm wondering if it would be more useful to have them all side by side and pick and choose from these different recommendations then discuss every single one separately. I personally think that-- and I think that seconds what [CLIAC MEMBER] was saying is that unless there are specific requirements for particular levels of training or qualifications spelled out in CLIA requirements, there will be really no mechanism for enforcement as much as we might promote certain levels of training. So I do feel that that's where we possibly need to start.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. Good morning. I like parts of the recommendation. I think there's value to it, but I'm also taking a broader look. And I think there's two problems here. First-- and that was exemplified by the nurse from Maine's statement-- that rural areas have really a hard time accessing laboratory testing. And we really have to consider that. And we also, as [CLIAC MEMBER] pointed out very well, that we have the problem of the pipeline has dried up. And because the pipeline is dry particularly in rural areas, they look to other professionals in the hospital, for example, to take on this testing. So we need to have a way to increase that pipeline, and we need to have people easily getting into the pipeline in an emergency. And I think that's what the recommendation number one looks at. There should be a minimal amount of certification and training before someone can just start testing. And that should be quickly achieved, even achieved online,

and demonstrated so that they can do the testing they're needed to do. And we also need to think about the director in these cases because it should be the responsibility of the person who is the CLIA director to make sure that the people working there have the training that they need to do the work properly. So those are my thoughts. And I think we can look at these as a group and pick and choose what's most appropriate to achieve the goals as we discuss what the goals should be.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I agree with [CLIAC MEMBER]. And that is the sense that I was trying to portray in that CLIA already allows waived testing to be performed by high school people. But there is no-- they're being trained sometimes by people who range from nefarious to ill-informed to very good. So I think that the focus should be not just on CMS, but synergizing with CDC who are-- have expert skills and can put online programs together and perhaps could work with schools, and community college, et cetera to be able to create some kind of a training network that would establish quality standards for people in high school or at the community college level. So that's what I really think is most important is that we start feeding that pipeline from junior high to post-graduate and that there's a pathway. Other organizations-- nursing has shortages. Pharmacy has shortages. Everybody comes to the table and defends their profession. And laboratories need to do the same, in my humble opinion, and focus on training, pipeline, the journey through laboratory sciences, and partnering with our other health care colleagues in ways that the standards of laboratory medicine can be met and they're not easy to override by people who are just trying to profit from untoward issues like the pandemic.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: I agree with [CLIAC MEMBER] and several of the other commenters on that. I do strongly feel that laboratory professionals should be providing oversight and technical support for this testing. I've had a good deal of personal experience with providing support for rolling out a number of this testing through COVID. And I have seen the struggle. We have several workgroups in process that are looking at personnel requirements and also potential expanded oversight for certificate of waiver. So perhaps we could just direct the recommendation towards providing educational resource as we don't really have the teeth right now to really support any other requirements. And that maybe would support any further action that may come out of the workgroups.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: So I would make a suggestion on an edit to this recommendation and to clarify just a little bit further. As we are addressing remote and nontraditional locations for testing, maybe we change this from leader to point-of-care tester and make sure that everyone is clear on where and how this kind of resource would be used and how important it is, that we need a lot of these people right now. And it could be an entry point for many people to get into this. And as you see within the recommendation or the motion, that certification and training programs will be required ongoing. So naturally, they will have certification, and they would need to be renewed for licensing just like other professionals within health care. So this wouldn't be somebody that wouldn't know a thing about what they're going to be doing. They would definitely need certification and training. But this is just to develop a new category of remote tester that we can work with schools and give them an entryway and a possibility without having degrees. And quite frankly, it's going to take a lot of people and a lot of time to spin up qualified pathologists to fill the needs of what we need now. We really need to get moving and get some of these people that are eager to have new careers and direct them to this line of work.

CLIAC CHAIR: Thank you. [CMS EX OFFICIO]?

CMS EX OFFICIO: Sorry, real quick too, other points of clarification as you move forward with your deliberations-- the first is with the number of COW laboratories that I believe [CLIAC MEMBER] was talking about. Since March of 2020, we've seen an increase in approximately 60,000 CLIA certificates. Of those 60,000, about 57,000 were certificate of waiver laboratories. However our entire universe of certificate of waiver laboratories is around 246,000. That 57,000 was just what it's gone up during the pandemic. So I just want that as a point of clarification. I know that makes the scope even larger, [CLIAC MEMBER]. And then the other point of clarification I wanted to make for your all's awareness is that, as I said during my presentation, we do not have personnel requirements, either education or training, for certificate of waiver laboratories. That actually is a statutory requirement. So moving forward if that is something, it would require a statutory change-- not just a regulatory change, a statutory change. And I do know we talked a little bit about the COW PPM workgroup. As [CLIAC MEMBER] said, that may be something you want those types of suggestions related to COW, education, and training, and that type of thing that may be something that workgroup could take a look at and address as well. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. To kind of build—[CMS EX OFFICIO], thank you for expanding that number. The 60,000 was just the new. But, again, it's still overwhelming numbers for CLIA to try to oversee through any kind of oversight process. And I still think the accrediting organizations are important. I wanted to also build on one of [CMS EX OFFICIO] comments, just pointing out there are no personnel requirements for the director of a certificate of waiver lab. And I've heard several comments that I wholeheartedly agree with, that the director should be overseeing much of this quality. But even in an inpatient facility, there's no requirement that the certificate holder be under the laboratory. It could be an ED doc. It could be a hematologist. It could be a number of different people. So I think we need some attention, as pointed out, but also maybe some specific attention on who is directing these laboratories and, of course, the off-site laboratories. There are no director requirements for who these individuals are. And so we've spoken a lot about the testing personnel, but we really haven't talked a lot about who should the director be. And that's something I would like us to think about in these recommendations. And then my other comment about recommendation number one, I really struggle. And I appreciate [CLIAC MEMBER]'s recommendation too. That fits better for me of that we need funding throughout the laboratory continuum. I'm hard-pressed to put those rare dollars only towards training point-of-care personnel when we have hospitals literally having to shut down some services because there aren't enough lab techs. I think we need to look at the whole continuum. So I would be more supportive of recommendation number two. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: [CLIAC MEMBER] made a lot of the comments that I was about to make. I think the idea behind a draft recommendation one is that we need to increase recruitment of people into lab medicine. And as everyone else has pointed out, it is not the training that is the blocker currently. It is the ability to recruit people in. And so I would then move to-- I don't know if it's table draft recommendation one, which I think led to a lot of really great conversation to inform. I think potentially moving to draft recommendation two, which would be really money to increase recruitment rather than focus on a training program because we do have a lot of people who are high school educated and would be eligible to be point-of-care testers. We're just having difficulty recruiting people into the laboratory workforce.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: No, I concur with certainly the statements that in my opinion certainly support draft recommendation number two. We're seeing the same thing here in the Midwest. And I think it is crucial that-- not to say the other ones focus on a certain area. But I think all the way from eighth grade on up or maybe even younger than that. I know we hit elementaries. But I don't necessarily see the support. Or maybe there needs to be-- maybe a better word is increased support of just the laboratory field in general and not a specific area. So I know that's been repeated throughout. But certainly from an operations standpoint, you definitely see that over and over again.

CLIAC CHAIR: Thank you. So hearing all this conversation, we started with-- we still have an open motion on [CLIAC MEMBER] proposal, which provided a wonderful platform to gather all this additional input. From what I'm hearing, the tensions that come out is that we need a rapidly growing population, not our existing lab population, to address surge testing. We need to assure quality of that testing, however that's provided through training, certification, licensure, whatever. And how do we accommodate that so it happens rapidly? As we heard from [CMS EX OFFICIO], if we want to create a new category that requires some sort of oversight, I think [CLIAC MEMBER] maybe alluded to that. But that's like 260,000 laboratories. That's almost undoable. And this excitement around the expanded testing for waived testing is predicated on tests that are trustworthy and perform well. What I see is an FDA function. So with that, I'm going to suggest we withdraw the motion and talk about instead in a more larger global fashion how we find some semblance of agreement between number one and five and move forward with some conglomeration of that as a motion. But I'd like to hear from [CMS EX OFFICIO] first.

CMS EX OFFICIO: Thank you. I wanted to provide some more clarification for you based on what [CLIAC MEMBER] said about oversight. The other area that the statute exempts certificate of waiver laboratories from is inspections. They do not get regular inspections. The only time we actually go in and perform an inspection on a certificate of waiver laboratory is if we receive a complaint. Thanks.

CLIAC CHAIR: Thank you. So [CLIAC MEMBER], are you in agreement with my recommendation we withdraw that open motion and then focus on a much larger motion?

CLIAC MEMBER: So did you say by combining recommendation one and five?

CLIAC CHAIR: Not necessarily combining, but coming up with some synthesis of, what are the key concepts? And we can pick and choose.

CLIAC MEMBER: Yeah, absolutely. That absolutely makes sense. Thank you.

CLIAC CHAIR: Thank you. Robert's Rules, sorry. So we're going to close the motion on number one. But now it's time for the committee to talk about all those concepts we heard and, what do we want to move forward with? We have five of them in front of us. I happen to-- all right, so there's more, six, seven. Yeah, I happen to-- [CLIAC MEMBER]'s recommendation struck a chord with me in that holding the laboratory director as responsible. So whoever signs up for that certificate of waiver would be responsible for not only having completed some very basic education around waived point-of-care testing, but also would be imbued with the responsibility for the quality of that testing. And also, as we think about this, I want to separate out, so we don't confuse it. Home testing is not governed by CLIA at all. So while many of the tests, we saw coming out for COVID during the EUA were approved for waived as well as home testing in the home testing environment. That's not our purview. So we're looking at waived testing where someone's doing a testing on someone else. And I would argue that people who successfully test at home should be able to move easily into test personnel for these point-of-care sites that do waived test. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. Just one or two comments about waived testing. As [CMS EX OFFICO] said, I think waived testing is statutory statutorily defined. So there's not a lot we can do to change that. But I wonder if some of the things that-- again, we keep talking about waived testing and point-of-care testing sometimes interchangeably and sometimes not which, [CLIAC CHAIR], as you just said, is not necessarily the case. And I wonder if some of our conversations and worry about the use of point-of-care testing, if it's possible, if we could expand or further subdivide what we've lumped in as moderate-complexity testing. Now, I'm not sure that some things that truly get defined as waived testing should really be waived as a waived test. I think it's defined very broadly as being almost-- not foolproof. That's not quite the right language, but very simple, almost very limited capability for creating an error. And I wonder if some of the tests that we've really ended up in waived categorizations are probably better put into another category. We just don't have that category now. We've got moderate, which is most of the laboratory testing that we do in a hospital or outpatient lab. And that's a pretty broad category. So I wonder if there's a place for a further subcategorization under moderate that would cover a lot of the point-of-care testing that is done in hospitals now and then further characterize some of the personnel qualifications under a new grouping under moderate. I'm not sure if that gets us further along or more complicates it, more complicates the scenario. But I'm just trying to balance what we can do around that, what's in the law versus what we can make and modify right now. I'm not sure if that's helpful or not.

CLIAC CHAIR: [CLIAC MEMBER] and [CLIAC MEMBER], you still have your hands up.

CLIAC MEMBER: Well, I didn't want to say anything, but now after [CLIAC MEMBER] spoke I sort of do. And then I'll take my hand down. So I apologize. But I think that that's really it. We're talking about the regulations and what you can do with waived testing. But when waived testing occurred, there were eight tests and they were defined as being so simple a monkey could do it. And even if you got it wrong, it didn't matter anyway. Now we've got many, many tests. And we've talked about this at CLIAC ever since my first CLIAC round is that those definitions are different. So it may be that the personnel or the regulations workgroup needs to look at that intermediate, moderate complexity light or something. I don't want to belabor it here. But I think we need to discuss that because this has been-- one of the concerns is that waived testing and the personnel rate requirements and what now is in waived testing are pretty discordant.

CLIAC CHAIR: Thank you. I want to comment around the workforce. And while we have a lot of energy around increasing the pipeline and recruitment, I do want to raise we don't have enough people in the lab to train them. That's been the classic roadblock probably for the last decade or two at least in my local area. The schools are overpacked with folks applying. The ratio of application to acceptance is something like 10 or 20 to 1. And then once they get through, finding the clinical site for that practical training is near impossible because we are understaffed. And we don't have time to train someone. I know the CDC has done a fantastic job in bringing up virtual-type training. And I would like to throw out, is that something we want to make a recommendation for licensure, training that would be accepted for licensure? [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: I'm a little confused by why we're so focused on the licensure and qualifications when really what we've been talking about and as you're alluding to, [CLIAC CHAIR], is the pipeline. And thus I really think that some of the language in recommendation number two from [CLIAC MEMBER] is critical because this is the only way you're going to put people into that pipeline. And I can give a specific example. We just reopened our med tech school after having had it closed for 20 years. And to get that done, we had zero funding. There were no grants available. It was really challenging for us to do as an organization. And then connecting this back to some of the conversation we heard yesterday and I'm too new to actually have it framed. But I know that there's a working group on the staffing crisis that we're facing right now when people were talking about a lab AmeriCorps. Well, if you want to do a lab AmeriCorps, you're never going to pull that off if you don't have the funding. And if you think about something like that-- and I realize that's kind of sensational language. But I mean the idea fits almost everything that people have been talking about. It speaks to some of the things that [CLIAC MEMBER] has been doing. It speaks to some of the issues that have been brought up by the lack of personnel in the laboratory to do training or the ability to support point of care. So I really think that funding and emphasizing the critical need of financing these programs is essential to anything that we recommend at this point in time.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, I just want to support your comments about looking for how we do virtual training, how we get that clinical training performed. And the example here in Colorado, our schools are closing. As you were describing your situation, I had a moment of envy going, well, at least you've got schools because we don't. And they're very few and far between. And a large piece of that is because you can't find the clinical training. And our university here in Grand Junction sends out hundreds of biology majors every year who have no career pathway with just that BS in biology. And wouldn't it be fabulous? And I know [CLIAC MEMBER] mentioned before some of the unique things they've done at Ochsner. But that does involve having staff in the lab to do those clinical trainings. And that's always been the obstacle to converting that to a med tech program. And I think at previous CLIAC, I've asked, how can CDC help us with developing those clinical training programs for those folks graduating with a BS in biology that don't know what they want to do next and would be fabulous med techs if we just could figure out how to get them the training? So [CLIAC CHAIR], I absolutely support your suggestion.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: This CLIAC that conversation exactly reflects conversations we've been having regional at the New York state level. And just to summarize conversations from earlier this week at the New York level, the shortest runway is doing precisely what [CLIAC MEMBER] identified which is baccalaureate persons who have not yet found their career. And the plus one is basically to give them the clinical training opportunity. Very nascent is the concept of linking that to loan forgiveness programs and other financial instruments whereby not only does a career immediately come into view, but there's financial incentive for doing it. So that's the first part of our regional conversation. The second is the fact that there are actually three pinch points. The first is attracting young people to this profession. And I think that's a separate discussion that doesn't drop to a motion per se. But the second is the practical training within NACCL's accredited programs. And I've really been thinking, [CLIAC CHAIR], about how virtual might vastly lower that barrier is to give the formal classroom training, virtual practicum so that then the third and most critical pinch point being the clinical laboratory experience comes into view. And our local discussions are, can we modify that so that the hurdle for pulling an active laboratory technologist off the bench to teach can be lowered and to rebalance the observational and, in essence, collateral educational including virtual so that a trainee can be in the laboratory but not reduce the productivity of the person they're observing? All of that is pipeline. But I think in the discussion we've had so far, we really are mingling two separate topics. And the opening motion was addressing the first and not. The second is pipeline. The first is the trust and quality of the product. And I recommend that CLIAC keep both of these in view in bringing recommendations forward so that we are addressing the product of nontraditional remote-- sorry, nontraditional waived testing by whatever mechanism, and we address pipeline on two separate recommendations, not drop one in favor of the other.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I see no more hands up. Time check, we have one hour and four minutes left for our deliberation and to submit recommendations. I want to call the committee back to the roots of how this conversation started. It started with the lessons learned from the pandemic and the need for a rapid surge of testing personnel for waived tests in point-of-care sites to accommodate that testing. And because of the shortage, that's what all this conversation is about that has morphed into test complexity, morphed into clinical lab versus point-of-care, et cetera. So I would like to bring the group back do we have a recommendation for any of the agencies around point-of-care waived testing and how to rapidly expand test personnel? [CLIAC MEMBER], you still have your hand on.

CLIAC MEMBER: It's intentional. So your final clause, drawing these together again as opposed to keeping them separate-- and so my question back to you is, are you asking the committee to meld the expansion of the pipeline with the ability to do waived testing? Or do we keep them separate, recognizing the broader crisis in all of our laboratory settings, not just waived? I recommend the latter.

CLIAC CHAIR: In my brain, I keep them separate because surge testing has to happen. And the pipeline cannot be big enough to accommodate a surge.

CLIAC MEMBER: And then the third, I'm putting completely separate remote practice. That's another motion. It's another discussion.

CLIAC CHAIR: Oh, yeah, yeah. I would like to park remote practice because I think we can cap that off pretty quickly since it's not controversial. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. I just want to echo [CLIAC MEMBER] comments. And while I appreciate that surge capacity is an issue, you can't surge fast enough if you don't have a robust platform to start with. And I think that's what some of us are talking about and saying, let's make sure we have a healthy laboratory industry and that we've got the right pieces in place for the status quo. That's going to help us a lot for surge because you're going to have even more trouble trying-- I hope this makes sense-- trying to surge off of an already weak platform. And from that standpoint, I'd like

to suggest that having making sure that we got people in place when the surge occurs is part of surge preparation. Thank you.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: Yeah, I just wanted to say not even as a doctor or a laboratory director but as a dad, having put several kids through college to have a kid go through college and then take a job that doesn't require a college degree seems like that would be painful. And I think if we approach this more perhaps along kind of a trade school type of ramp up-- I'm not saying that somebody with a BS in biology couldn't do it. It just seems like that's a lot of school and a lot of money to put then into a career path that doesn't require that BA or BS. So that's just a thought, if we could kind of-- if we're going to be talking about, where do we get this workforce? It feels like college or maybe making it some sort of a trade school type of thing.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Did you say [CLIAC MEMBER]?

CLIAC CHAIR: We said [CLIAC MEMBER], and we hear [CLIAC MEMBER].

CLIAC MEMBER: Yeah, OK. So I've just been trying to look at all of these recommendations and categorize them into some buckets because there's a lot. I actually think the topics that we should look to be combining are the overall laboratory workforce pipeline, the directorship, the reclassification of what is really waived tests, which I think is a critical point to this in that what was intended to be waived-- if you look at some of the waived tests, they seem to apply. And then other waived tests categorization, our nurses and high school people would have a little bit of a hard time with.
So that's the third one and then promoting funding for partnerships with the laboratory sciences and other allied health care to meet the needs of the rural communities so that there could be in areas that are underserved. It's perhaps a collaboration of laboratories and public health that would serve as reference people. We're not in the world of we have to train people on sites anymore. And I think that regional collaboration with laboratories and public health is important as well as the ability to recruit on a categorical basis, which has really saved us and we haven't talked about today.
But a bachelor of science in biochemistry or microbiology can take 15 credits in some of the categorical and mean come a microbiologist and certify for the MASCP. And I think that we have to get away from the all-or-none thinking of you're completely out of your realm if it is not a full med tech is what we're going to have to try to look towards. And those are the big five buckets that I see. And I think we could make those five recommendations out of what people have written if we focus on one of those five buckets at a time.

CLIAC CHAIR: [CLIAC MEMBER], [CLIAC MEMBER]?

CLIAC MEMBER: I guess I'm just a little confused because there is a statute in place. So we're talking a lot about point of care, which happens to take place quite a bit in a surge situation in either the home or a CLIA-waived paradigm. And if by statute the personnel are not required to have any training, then what can we recommend to HHS? That they pursue a new statute? So I'm confused there now. And then in terms of the lack of personnel, if they don't require training is it that they are not informed that these jobs are available? Or is it the Great Resignation hitting the laboratories at this point? Is there a cultural phenomenon that is ongoing that's affecting us? And I'm not sure that our recommendations are addressing either the statute or the cultural sense of resignation.

CLIAC CHAIR: Thank you. I'm hearing enough mulling around all the different aspects of what we've been trying to tackle without full agreement. So I would like to go sideways at this point, which is something I think we might reach quick agreement on. I believe there's a recommendation around the remote access. And it's an encouragement that HHS authorize permanent remote access without requiring another CLIA license. And I believe it references our 2019 CLIAC act recommendation. I believe it was-- so it's a combination of 14 and 13 and 12 and 11, those four, 11, 12, 13, 14. I would like to open the floor for discussion. [CLIAC MEMBER] first, then [CLIAC MEMBER], then [CLIAC MEMBER]. [CLIAC MEMBER] took her hand down. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, sorry that was old.

CLIAC MEMBER: Just some clarification in number 13 and an attempt to address the broader scope of digital practice to include cytogenetics and laboratory medicine, I said digital pathology and digital laboratory medicine services. Hopefully, that's sufficiently encompassing. If there's better terminology, I welcome it, number one. Number two, drawing from one of the public comment letters, I inserted the wording "remote analysis sites" rather than just remote locations so that it's clear that this is the practice of medicine through digital analysis. I completely left aside anything regarding bioinformatics, which was another public comment. And then in being bland with this terminology, I'm hoping to be sufficiently encompassing.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, hello. I think that for the most part I've represented my thoughts in number 14. But I think that these comments are really all quite synergistic. And I agree with [CLIAC MEMBER] to the extent that while many people were speaking specifically about remote surgical pathology diagnosis on slides, that is really no different than any sort of objective interpretation of data or information outside of the formal laboratory walls.

CLIAC MEMBER: And there was tremendous public support for this. I think we've seen a real-world example that this is actually safe and effective through the pandemic and how people have been using this technology. And it certainly is constraining people. We've also seen people comment that they feel like they're being treated unfairly in some of the public comments because there's sort of an AC/DC approach to whether this is truly being enforced for large versus small corporations. So leveling the playing field was something I hadn't really thought about. But, again, I think that this is an activity whose time has come. We've shown that we can do this effectively, safely, and at high quality. And so I think the question becomes, how do we get this to become permanent? People have seemed to ask for an extension of the relaxation of enforcement. But they followed that up with a further request to make this become permanent. And I would support that.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: I totally agree, especially looking at all of these, I really do like draft recommendation 13 and would move that that be moved forward for the wordsmithing that I think would be pretty quick. And my only recommendation would be change the wording of the "until such time" in order to say maybe it would be, CMS and HHS work actively towards updating CLIA regulations to provide a permanent provision for the performance of such remote sites. So we have the immediate waiver as well as a call to action for someone to pursue that solution instead of continuing to kick the can down the road.

CLIAC MEMBER: I speak in favor-- oh, I have to put my hand up.

CLIAC CHAIR: You got to put your hand up. [CLIAC MEMBER]?

CLIAC MEMBER: I agree with all previous comments, but I would like to add the word "molecular pathology."

CLIAC CHAIR: And I would like to interject. I'm looking at number 12 because I like that opening statement. And I like the comment, "performing data analysis or interpretation." And I would insert "of digital information." And digital information is all encompassing. And then I would wordsmith further, "when working remotely, when working remotely and under the home laboratory's physical CLIA license." Delete everything at the bottom. I saved you three lives. [CLIAC MEMBER], you can react to that and if no reaction, then [CLIAC MEMBER].

CLIAC MEMBER: I think my reaction is that since we've called out digital pathology, perhaps cytopathology is recommended and lab medicine. I think it would be remiss of us not to add molecular pathology.

CLIAC CHAIR: So then after data analysis if we could put, parentheses "e.g. digital pathology comma molecular pathology comma et cetera" because there's chromatograms. There's electropherograms. There's other stuff. Are you OK with that? Can we, [CLIAC MEMBER]? OK, [CLIAC MEMBER]?

CLIAC MEMBER: And actually, this wordsmithing, the goal is to be as encompassing as possible whether explicitly or by remaining silent. I do want to call out one additional item in the draft recommendation 11, which is what Valerie already referenced which is linkage to a primary site because whether it's draft recommendation 12 or 13 absent mention of a primary site, that is a recommendation that leaves hanging where the quality oversight is going to come from. And reading through the public comments from multiple sources, my sense was that the recommendation was to have the quality oversight linked to the primary site. And so my invitation to this discussion is how we make sure-- number one, do we agree with the premise that the recommendation should be linking the remote practice to a primary site or whether we want to remain silent on it? My sense is that we want to make reference to this being linked to quality oversight from a primary site however we choose the language.

CLIAC CHAIR: So I agree with you completely, and I'll take the prerogative. So if we can take all these recommendations and at the point "and/or interpretation of digital information." So right after information we're going to snap in [CLIAC MEMBER]'s, "under the quality oversight of the primary site." And then we can wordsmith that.

CLIAC MEMBER: The follow-on is that it makes the actual recommendation 11 moot, which is we're not referring it to the regulatory assessment workgroup. We're simply making a statement to CMS. Do it.

CLIAC CHAIR: Correct. [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Yeah, and actually, I think you've covered much of what I was getting ready to say. But I'm very supportive of 13. I'm supportive of 12. I think the word "analysis" and "interpretation" are important because we would hate for people to start doing wet work at home. And I'm not saying anybody would, but I think it's important that we make that distinction.

CLIAC CHAIR: Thank you. [CLIAC EXECUTIVE SECRETARY]?

CLIAC EXECUTIVE SECRETARY: Yeah, I wanted to remind you that in 2019 there was a similar recommendation made. And I think it's great to have another recommendation now because things have changed since 2019. But there may be some phrases from this previous recommendation that you want to think about as you come up with the new one. So I will just read it to you. This came about after the workgroups in 2019. It said, "CLIAC recommends that the CLIA program consider that when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment that they shall be deemed as performing those services at the primary site that houses the CLIA certificate." So I think that last phrase ties in to the points that Jim was just making.

CLIAC CHAIR: Thank you, [CLIAC EXECUTIVE SECRETARY]. [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: I just wonder if we need to add a statement about security so that as we say under the quality oversight to include security of information so that it's not just the quality, but also to make sure that people are appropriately transmitting information through a secure line.

CLIAC CHAIR: So in the 2019 in red, "secure" is at the end of the second line. And maybe all of our conversation should just be distilled down to encouraging the CLIA program to move forward on the 2019 recommendation.

CLIAC MEMBER: I think that's true.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, my apologies if I'm already asking something that's already been stated. I did get here a little late. I guess maybe to [CLIAC MEMBER] or others, can you-- or is it somewhere else? Can you explain the term digital "laboratory medicine"? Because from an operation side, I could see that. I mean, is that blood bank? Is that micro? Is that just an all-encompassing term? Or is that just a generic term on purpose?

CLIAC MEMBER: May I respond?

CLIAC CHAIR: Yes.

CLIAC MEMBER: I was trying on what I read in the public comment contributions, which was referring to pulling up digital information from laboratory practice, whether it's SPEPs, or cytogenetics, or molecular pathology. And analyzing and interpreting, that's what I was trying to capture. We could say, well, is this digital? Or is there a better word? I think somewhere, but just by saying digital information it provides an encompassing approach to it.

CLIAC MEMBER: The only reason I bring that up is because we've really struggled. I think Northwell is certainly the leading edge. But take microbiology, for instance. I mean, we have digital microbiology right now. That's the reason why I ask that question.

CLIAC CHAIR: It would be included, [CLIAC MEMBER]. So look at the colony. Does it match the gram Stain does it match the biochemicals? That's all the synthesis and the interpretation of those data into an analysis.

CLIAC MEMBER: In essence, if you can pull information up through a secure link, this is what we're trying to capture.

CLIAC MEMBER: Very good, thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I just wanted to make sure that we're able to really codify what we want. And given the, I think, thoroughness and well thought out nature of the 2019 CLIAC recommendation and pulling from I think some of the previous information given by our committee representatives, how do we make it be actionable? How do we make it a true

action or a call for HHS or CMS to actually permanently make the 2019 CLIAC recommendation or our either draft recommendation 12 or 13? How do we get that action term done? I guess that's more of a procedural thing because I think we all do agree that the current enforcement discretion should be continued until we are able to permanently enshrine what sounds like that 2019 clear-cut recommendation legislatively. But this is when I look to our committee folks for the gentle nudge as to who. And I know previously, it was a legislative fix. But I don't know if there's a workaround for that.

CLIAC CHAIR: [CLIAC MEMBER], I'm going to have [CLIAC MEMBER] talk. But then I'm going to ask [CLIAC EXECUTIVE SECRETARY], Heather, and [CLIAC DFO] how we emphasize, can we just do it for 2019 recommendations? What are the barriers? OK, [CLIAC MEMBER]?

CLIAC MEMBER: I was just going to comment that that's what I really liked about [CLIAC MEMBER]'s proposal because you're very specifically asking CMS and HHS to act on our proposal. So maybe that's what we need to do is to say, would you please act on our 2019 proposal that we already gave to you? But I'll stand back and listen to how we actually affect these changes because that's always the hard part.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, and I like [CLIAC MEMBER]'s proposal as well because it reflects what's happened since 2019 and is contemporary and saying, OK, you've already done this. You've had a exemption. Now move on that exemption. So I like the contemporary nature of number 12.

CLIAC CHAIR: So [CLIAC EXECUTIVE SECRETARY], Heather, and [CLIAC DFO], do you have a suggestion how we do this one? It could be we submit draft recommendation 12 with the final sentence, "This enhances the 2019 CLIAC recommendation, period, we are looking for action and relief," or something that is not so inflammatory.

CLIAC DFO: Yeah, this is [CLIAC DFO]. I mean, I would suggest maybe even starting the recommendation with reference to the CLIAC 2019 recommendation that has not yet been acted upon and something like, it becomes-- the last two years raises what makes this more important or something. And then I hope I don't get in trouble for this. But maybe I could ask Sarah from CMS to comment on this issue.

CMS EX OFFICIO: Well, thank you, [CLIAC DFO]. And you are in trouble. Yes, I think whatever you want to put forward as your recommendation, we certainly are more than welcome to consider. This 2019 recommendation that came out of CLIAC in 2019 came right before the pandemic hit. So as you all know, certain things have-- priorities have shifted based on the pandemic. So I think if you want to restress this recommendation and another recommendation, that certainly sounds reasonable to us at CMS.

CLIAC CHAIR: So I'm going to wordsmith this. And I'm going to take out that first phrase "in reference." Yeah, to the common, take that out. But don't lose it. Laboratory practices, capital L, for the last two years have demonstrated-- have demonstrated, not illustrated, have demonstrated the success of remote analysis and interpretation of digital data. Yeah, [CLIAC MEMBER], yeah. CLIAC augments its 2019 recommendation to CMS and the US Department of Health, blah, blah, blah. I think the "its" doesn't have a apostrophe. What do you all think? Oh, [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Yes, and I don't want to be a nag about it, but somewhere remote, by accessing data remotely in a secure environment. Somewhere I would-- demonstrated the success of remote analysis in a secure environment, remote analysis and interpretation of digital data in a secure environment.

CLIAC CHAIR: How about remote analysis and interpretation of digital data securely?

CLIAC MEMBER: Sure.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I'll second that because that's precisely what I was going to point out is "remote" needs to be in there. "Secure" needs to be in there. And then my final thing is "laboratory practice," singular. So it has-- you could say laboratory practices, or laboratory practice has.

CLIAC CHAIR: Yeah. I'm going to give you the virtual red pen. The king of the red pen is [CLIAC DFO] right now. OK, [ADVAMED LIAISON]?

ADVAMED LIAISON: Yeah, just quickly, I looked up the 2019 recommendation on the CLIAC table. And the response was this recommendation we put on the agenda for the new CLIA regulations assessment workgroup to consider. I would hope that this maybe-- I don't know if there's a word that needs to be added in here. But I would hope that we don't continue to wait for them to finish their work to come back with this because I think, as you've said here, we demonstrated its success.

CLIAC CHAIR: Thank you, [ADVAMED LIAISON]. I agree. Going to a work group seems going backwards.

CLIAC MEMBER: Yes.

CLIAC CHAIR: This is--

CLIAC MEMBER: Absolutely.

CLIAC CHAIR: --CLIA straight up. So why are we going internal? OK, thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. This may come up later, may be more appropriate for later. But the regulatory assessment workgroup pointed out some things that I want to make sure the language in here covers around interpretation of off-site bioinformatic data, that the group felt that was definitely-- when that was a separate entity, a separate company, separate group, that was definitely a separate activity from the primary laboratory and that entity should have its own CLIA license. And that interpretation was taking place separate from the primary laboratory. I just want to make sure we all agree that the language here-- I think we all know what we're talking about here, but make sure that the language covers that piece specifically. Then also mention that we may want to look at the word "employees of the laboratory." Some people in looking at this data may not be strictly employed by the laboratory if it's an outside pathology group. And then one last quick comment, I believe at the assessment workgroup Dr. Carter mentioned that some of the current HIPAA standards require some security encryption, things like that, that that would be encompassed with some of those standards now. And so that may give some comfort to those who are concerned about the security piece with this language.

CLIAC CHAIR: So [CLIAC MEMBER], do you have recommendations for wordsmithing the current recommendation? You want to think well we have [CLIAC MEMBER] talk?

CLIAC MEMBER: Yeah, let me think. [CLIAC MEMBER] may handle this for me. Thank you.

CLIAC MEMBER: I'm not going to lie. I pulled some of this verbiage directly from one of you guys' slides, which is why it may look familiar. But I do think as far as the bioinformatics pipelines and referral out, CAP guidelines do state you should have reference procedures. There's the business associate agreements. I personally think, especially if you're thinking one of these outside bioinformatics analysis groups, I actually think we would be covered by the current specifying that employees of the laboratory doing the digital component are covered by that home CLIA license because if it's a third-party vendor, then they would still be obligated if-- regulatorily required to have their own CLIA license. So then that would shift to that distributive referral testing model. I do share your concern that we need to make sure that everyone feeding into the process is vetted. But I believe we are avoiding any huge gaps in the limitation of coverage for this. So if I had a variance scientist from a contract company that is not affiliated with my lab doing this, we would need to set up that business associate agreement with that third-party vendor in order to allow them to feed in, I believe. But Alexis can probably correct me.

CLIAC CHAIR: I think bioinformatics is an arena unto itself that we're struggling with. And I think our recommendation is written broadly enough that could either encompass it under the home laboratory CLIA license, or the regulations workgroup could set up the criteria around bioinformatics operating under a separate CLIA license. And we would not need to go into that detail in this recommendation. I want to say there's an elephant in the room that nobody has addressed, but we've heard about it, which is cytology and the statute-- not the regulation, the statute-- that the cytology is a geographic location. And the statute, as I heard-- I'm not an expert on this-- may prohibit remote analysis. And if I'm interpreting that correctly, I'd like to know from anyone on this meeting how that could be incorporated in this without violating the statute. All my CLIA experts, don't make me call you out. I'm going to you, [CMS EX OFFICIO].

CMS EX OFFICIO: I know. I'm turning to my statute, so I can tell you exactly what the language says because I don't want to misspeak. Yeah, I'm going to go right where it is. It's just going to take me a second to find it.

CLIAC CHAIR: Let me go get my book. You guys keep talking. [CLIAC MEMBER], you talk.

CLIAC MEMBER: Oh, in general--

CMS EX OFFICIO: OK. I'm sorry, go ahead. I have it, but go ahead.

CLIAC MEMBER: OK, I was just going to say that when we are working remotely using digital images, we are generally viewing something that is sitting on a file server in the workplace. So there is some sense of the fact that data is sitting in the workplace where we access it usually through a VPN network. And so I'm not sure it's really-- we're sitting outside the workplace, but that image is in the workplace. I mean, I don't have a huge server here and I download everything to my server and work on it here. Radiologists do that. But digital images and pathology are much too large. And so we usually only bring over pieces of it as needed to view it.

CLIAC CHAIR: I agree. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, comment and two comments, actually. The first is cloud storage, I think, makes that statement potentially inaccurate as to where the data is stored. But actually, the reason I raised my hand was my suggestion is that the statutory requirements for quality oversight of cytology interpretation I would hope cover the primary site's quality oversight of remote. In other words, if there is reason to state in the recommendation to include cytology adherence to requirements for quality control, which is kind of at the heart of the statute, that might bring cytology into this recommendation without requiring statutory correction.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER] and then Sarah.

CLIAC MEMBER: I was just going to speak to [CLIAC MEMBER]'s point about the location of the data. This has really been adjudicated in telemedicine for a long time. It really doesn't matter where the data is. It matters where you are. So for example, if I'm doing a consult in New York, I can't say, well, I'm in Michigan. I don't need a New York license. New York has said, no, you need a New York license and you need a Michigan license. So we really don't have to go down that line too far to say, oh, it's all in my server, so I'm actually in Michigan even though I'm in an airplane.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CMS EX OFFICIO]?

CMS EX OFFICIO: OK, so the statutory language says all cytological screening be done on the premises of a laboratory that is certified under this section. And the regulatory language is at 1274(a). It's called "Cytology Slide Examination Site." "All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology."

CLIAC CHAIR: Thank you, [CMS EX OFFICIO]. Is there any wiggle room, virtual world, that a remote access to the location where the data is stored, much as what [CLIAC MEMBER] has suggested, be considered by the regulators as occurring on the premises? You don't have to answer right now. I'll just throw it out and let you think about it.

CMS EX OFFICIO: Thank you for not making me answer right now because what I would say is we'd have to look into that. But that has not been the interpretation under which we've been operating. But certainly, it's something for us to take a look at if the recommendation moves forward to HHS.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So I will say in our 2019 CLIAC recommendation we do say, "They shall be deemed as performing those services at the primary site that houses a CLIA certificate." So haven't we already encompassed-- not explicitly encompassed that, but sort of folded that into our potential directive? And I know that may not hold weight yet. But I feel like if we're redefining what a site is or we're recommending that that be slightly redefined, do we think we have maybe enough there?

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: To draw on contractual language, should we choose to put our arms around cytology? I would also recommend saying, ruling regarding cytology should in no way invalidate the remainder of this recommendation because I would hate for the recommendation to go down in its whole because of a specific clause.

CLIAC CHAIR: OK, so I'm going to suggest-- I brought up cytology, which was the elephant in the room. But prior to that, I believe we were in agreement with draft number 12. And I want to take cytology off the table and have a consideration around that as a separate recommendation so that we don't jeopardize this one. So I'm going to make the motion that we approve draft recommendation number 12? Is there a second?

CLIAC MEMBER: Move so moved.

CLIAC MEMBER: Yep, I'll second.

CLIAC CHAIR: Is there a discussion? Do you have your hand up? [CLIAC MEMBER] first, I'm sorry.

CLIAC MEMBER: Oh, I was just going to make a second, so you're good.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I was going to second it. But I'm not sure that cytology is not implicitly included in this recommendation anyway so that maybe we just need a separate, after we deal with this, to say that consideration should be given to ensure that cytology is included or something.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I agree with you and I agree with [CLIAC MEMBER] that we thought the original recommendation would incorporate cytology. But hearing the public comments today, it remains still a point of contention. So given that, I'm thinking we should break it out separately. Is there further discussion? Oh, [CLIAC DFO]?

CLIAC DFO: Yeah, this is [CLIAC DFO], just kind of reminding the committee that something like this would require a regulatory change, which would have to go through a public comment process. And so I guess what I'm saying is I wouldn't worry too much about for absolutely precise wording of these recommendations and ensuring that they're clear enough that the government understands CLIAC's intent. And then the details will get addressed through the regulatory revision process, over.

CLIAC CHAIR: Thank you, [CLIAC DFO]. So then what do you all think? When we have the parenthesis e.g. digital pathology, molecular pathology, why don't we just insert cytology before the et cetera just to make sure it's captured in that recommendation? [CLIAC DFO], and then [CLIAC MEMBER]? Trying to take your hand down?

CLIAC DFO: Yeah, I'm trying to take my hand down.

CLIAC CHAIR: That's OK. [CLIAC MEMBER] and [CLIAC MEMBER].

CLIAC MEMBER: So just from dealing with a lot of legal documents, sometimes more is problematic. So especially et ceteras. My worry is if we-- so let's say we add psychology, et cetera. What would happen? It's so inclusive. What would happen if we just didn't have the parentheses at all? So what-- do we lose something? Is that your worry, that without saying specifically "cytology--" Is this really going to tank if we took that out all together and--

CLIAC CHAIR: I'm sorry. I interrupted. I'm thinking instead because the other closet red pen person, [CLIAC MEMBER] popped up and said if we have 'eg," for example. We don't need the "et cetera."

CLIAC MEMBER: Right. So one of them has to go, but—

CLIAC MEMBER: So the "et cetera" should go.

CLIAC MEMBER: So something has to go, but just my question is, if we take it out altogether, then it potentially will cover everything. Or are you afraid that if we don't put in-- what does it add to have that there? Is it-- what is the benefit? Because once you put in "for example" or "et cetera," it actually becomes very muddy. If you take it out, it really incorporates all aspects, which is what we're kind to try to get to here. And again not wanting to be too Talmudic, but you put molecular pathology. Well, does that mean if it's not molecular pathology. I'm just putting that out there.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: I agree with [CLIAC MEMBER], in that a lot of the sequencing and digital informatics is going on outside of the realm of Molecular Pathology and microbiology, and performed by, many times, PhDs that are then rubber stamped by M.D. pathologists. So by calling out pathology all the time, instead of something broader like laboratory medicine or laboratory sciences, I think that gets a little bit muddier by just calling out the ones that are obvious. So I think it stands alone without those as well, but it does beg the question of then people interpreting what those analyses are.
I think it would be better not to call out the subspecialties, but to perhaps give examples of the functions, like the dry pipeline or image analysis, that could happen in really every laboratory subspecialty that there is. As someone pointed out, there's image analysis now going on in microbiology. And in Europe, their microbiologists are sitting at home reading agar plates, So I think we have to focus it down to the core sciences, rather than the subspecialties of the laboratory.

CLIAC CHAIR: Yeah. [CLIAC MEMBER].

CLIAC MEMBER: Yes, thank you. I agree with both [CLIAC MEMBER] and [CLIAC MEMBER], and I always liked the way that [CLIAC MEMBER] originally stated it-- digital laboratory medicine services. And I think that makes it broader than just pathology, and I think that's all inclusive. Thanks.

CLIAC CHAIR: I'm hearing we should eliminate the parenthesis section, and I would ask we are discussing different terminologies for digital information, bucketing it under laboratory medicine, bucketing it under other options. My preference is to leave it alone, so that we don't get trapped again into buckets. This is rather broad. And if unless there is dissent-- [CLIAC MEMBER], you still have your hand up. [CLIAC MEMBER]?

CLIAC MEMBER: I think the anchor is the CLIA license and the CLIA license is encompassing.

CLIAC CHAIR: Is there further discussion? Eight seconds. OK. [CLIAC EXECUTIVE SECRETARY]?

CLIAC EXECUTIVE SECRETARY: Yeah, I just want to clarify that CLIA does not license laboratories, they certify them. So you may want to change "license" to "certificate."

CLIAC CHAIR: Thank you. Excellent point. Last word, Heather. CLIA certificate. Seeing no hands. I'm going to call the vote. Any opposed? Hearing no opposition, any abstained? Seeing no abstention, this recommendation is approved. Thank you. It is 10:43, 17 minutes between you and your lunch. We spent an hour this morning talking about all that other stuff-- point-of-care, waived, personnel, et cetera. Does anybody have the stomach to go back and do a concise recommendation or direction where this committee should go with this? Of all of this universal conversation, the one that seems simplest to tackle is the semantic one, which was [CLIAC MEMBER]'s very last suggestion about using different terms for "traditional" and "non-traditional." I think if there's interest in this, we can crank this out in 16 minutes. Is there interest in this? Is there a motion to have this discussed?

CLIAC MEMBER: So move-- I'll put my hand up.

CLIAC CHAIR: [CLIAC MEMBER] has his hand up. [CLIAC MEMBER] are you motioning? Are you seconding? Or you have a comment? [INAUDIBLE] and [CLIAC MEMBER], are you seconding?

CLIAC MEMBER: I second it.

CLIAC MEMBER: Well-- but I think having learned from the previous one, instead of "licensed," do we have to say "certified clinical laboratory?"

CLIAC CHAIR: Correct. Correct. But I think he's just talking about a central lab in the remote lab, So what do we want to call them.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: And then—

CLIAC MEMBER: What about certified home laboratory?

CLIAC CHAIR: [? Still ?] [? up. ?] We want to hear from you. [FDA EX OFFICIO], if you're talking, you're on mute. We can't hear you.

FDA EX OFFICIO: I started talking because I hadn't been recognized. What I'm trying to do is get away from the concept of non-traditional. I think the last two years have long since demonstrated that near patient testing is a way of life, and to call it "non-traditional" I think is just the wrong optics. So that in our recommendations previously, we're still using the terminology that we entered the meeting with, but what I'm giving you is a set of vocabulary words to say, what do we want to call this? Is it "near patient?" is it "decentralized?" Is it "distributed?" I'm sure everybody has their own opinions, but my primary recommendation was that we don't use "nontraditional." it's just setting the wrong tone. So drawing from the vast materials that we had in front of us, I picked out vocabulary words. "Centralized," I actually don't like because a certified clinical laboratory, to some, might be a remote or a satellite or something like that, so I think "centralized" goes in the wrong direction. "Certified clinical laboratory--" I think the key word is "clinical" to distinguish from a physician office laboratory, a school nurse's little mini lab over on the side, whatever distinguishes what we, as laboratorians, think of a certified clinical laboratory versus everything else. So the first option is what do we want to call the home of a laboratory professional? And then the entire other world, not-- but leaving out home testing. Other world other than home testing. Is it "distributed" or is it "decentralized?" Is it "near- patient?" I invite your preferences. Sooner or later, we have to decide whether we say anything to change-- to get rid of the term "nontraditional."

CLIAC CHAIR: Yes. [CLIAC MEMBER].

CLIAC MEMBER: Not to muddy the waters, but technically, aren't the distributed settings also certified because they have a certificate of waiver?

CLIAC CHAIR: Yes.

CLIAC MEMBER: So I'm not sure that wording works.

FDA EX OFFICIO: And that's why the word "clinical laboratory--" again, we get tangled in our own tongues here. Is a clinical laboratory different than a certified laboratory somewhere else? Beats me.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I just wanted to speak to [CLIAC MEMBER]'s point in support. I agree, the term "nontraditional testing" really doesn't reflect what we're talking about. I have to say I do like the terms "distributed" or "decentralized" and have come up with them on my own, and then saw them used in other public commentary. One of the things I think we should be thinking about is what this looks like in the future. So what about continuous monitoring? What about testing that comes to us from different methodologies that are really distributed or decentralized? So I think those are good terms, [CLIAC MEMBER]. I'm not sure which one I prefer, but I'm with him.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. Speaking in support of using a different vocabulary, although I would bring up here that I'm not entirely sure who we are making this recommendation to-- if this is really to CLIAC, ourselves, that we want to be using, or whether this is to be used by CMS. I'm partial to the distributed perhaps setting, and would like to point out that the "near-patient" is not necessarily the case in many of these situations. Much like the "point-of-care" vocabulary, we're using is not necessarily near any actual patient care provided other than that testing. During the pandemic especially, I think we have divorce testing from the health care system. Sufficiently, though, that that's not always the case.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: My view is a little bit different there. Since what we're doing here is focusing on ways to improve point of care testing, it's obviously for patients, and I like what [CLIAC MEMBER] has outlined here as "certified near-patient settings."

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I guess I would be in contrast to using the distributed settings because many clinical laboratories have distributed settings as well, so I think there needs to be something certified clinical laboratory or I mean we can't say non-certified because they are certified, but we can say "nonclinical laboratory settings." And maybe it's not about certification, it's about oversight. So laboratories with clinical testing services, with clinical certified clinical laboratory oversight versus something else-- than certified, near patient settings, or whatever you want to call it. Since both types of laboratories are certified, I don't know I don't know what the public will think of that if we don't talk about oversight in the process.

CLIAC CHAIR: [CMS EX OFFICIO]?

CMS EX OFFICIO: Sorry. I saw all the other hands up. I do want to give you some more information for your deliberation. We have a definition in the CLIA regs for distributive testing and it means it's a laboratory testing that's performed on the same specimen or an aliquot of it that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation-- boy, this is a lot of words-- necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing. And I wanted to provide one more clarification for [CLIAC MEMBER] is all laboratories that are CLIA certified-- there is an oversight component to all of them. We have oversight of all of those laboratories. While we may not necessarily go on site on a regular basis, we do have the authority for oversight of all of the CLIA-certified laboratories.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: Who thought this was going to be so hard? (LAUGHS)

CLIAC CHAIR: It's not. It's not. And [CLIAC MEMBER]'s sending snarky comments in the chat saying, so much for my 16-minute estimate.

CLIAC MEMBER: OK. Well, let me throw out a suggestion. I mean, at the end of the day, aren't we talked about laboratory and non-laboratory settings?

CLIAC CHAIR: Yes. So maybe non-laboratory?

CLIAC CHAIR: I am going to interrupt this conversation, that I thought it would be simple, but clearly there's a lot of opinion, and that the term "distributed" does not encompasses something broader that than what is currently in the regulation that Sarah alerted us to. So I'm going to suggest we send this discussion to the CLIA regulations assessment worker-- to [CLIAC MEMBER] and [CLIAC MEMBER]-- for them to debate and come with a recommendation.

CLIAC CHAIR: Is there a disagreement around that? I see three hands up [CLIAC MEMBER], [CLIAC MEMBER], and [CMS EX OFFICIO]. If there is no disagreement-- OK we tabled that. And then I just want to, before you break for lunch, I want you guys to think about if we can scroll back up to the top, all of this conversation around testing personnel that became apparent during the surge for point of care, waived testing. We have an hour to think about that and to think about all of these ideas, and whether or not you can craft a recommendation that you think we can work through in 30 minutes at the end of this meeting. And perhaps-- are we allowed to at least email this or post this to the website so that we can have it in front of us while we're eating lunch?

MS. HEATHER STANG: I can email it to everyone and then-- yeah.

CLIAC CHAIR: And then--

MS. HEATHER STANG: And then--

CLIAC CHAIR: Thank you.

MS. HEATHER STANG: I can just-- send me. I'll try to combine the edits before the next discussion period of everyone, so yes. I'll email it out.

CLIAC CHAIR: OK. So for you all to think, we're running down to the end of this meeting. We have another big topic in front of us, the CLIA regulations assessment work group report. So think about what we are all so passionate about, but we could not arrive at a recommendation and whether or not you're able to do so. With that, I'm going to adjourn this morning session. We're now going to have a 1 hour break, one hour and six minute break. CLIAC members, please ensure you are on mute with your video during the break and please return promptly at 3:00 Eastern Daylight Time to begin the next session. Thank you very much. See you soon.

CLIA Regulations Assessment Workgroup

CLIAC CHAIR: My atomic clock just struck 1:00. So I would like to call this meeting back to order. Welcome back, everyone. We will close out the day with an update on the CLIA Regulations Assessment work group with a brief introductory presentation from Miss Heather Stang, and a report from the work group chairs, originally Dr. Kim Chapin and Dr. Greg Sossaman. If Dr. Kim Chapin is not here, I believe Dr. Greg Sossaman will carry the baton. Heather. Back to you.

Introduction
Heather L. Stang, MS, MT

MS. HEATHER STANG: Thank you, Dr. Ng. Good afternoon, everyone. I'm Heather Stang. I'm the Deputy of the Quality and Safety Systems Branch in the Division of Laboratory Systems, but I'm also serving as the designated federal official for the CLIA Regulations Assessment workgroup. Many of you may remember back at our November 2021 CLIAC meeting, Nancy Anderson provided an update on this work group. But as a refresher, CDC in collaboration with FDA and CMS, convened three workgroups related to personnel regulations, nontraditional workflow models, and next generation sequencing.

These work groups reported to CLIAC at the April 2019 meeting, which led to a record-tying 23 recommendations. Two of those recommendations led to the formation of this work group. The first recommendation was basically that HHS should update the CLIA regulations to address new technologies and changes in laboratory practices. And the second was that this new work group be formed to provide input to CLIAC on the topic so that recommendations could potentially be made by CLIAC to HHS.

So now after COVID and after recruitment of the subject matter expert members, we finally have kicked off the CLIA Regulations Assessment workgroup. And as you can see here, this work group is charged to provide input to CLIAC for deliberation on how CLIA specifically be updated, especially thinking about the reports and the recommendations and suggestions from the previous workgroups.

CDC, CMS, and FDA met to identify and organize the topics that this workgroup will address. The first topic is a review of the total testing process, looking at the whole workflow that's involved with testing, and discussing where CLIA should start and where CLIA coverage of the testing process should end. Again, we're focusing on these newer technologies and how they impact the total testing process. The next topic will be data as a specimen. Should this be something that's considered under CLIA, and how should the CLIA definitions be updated to incorporate data? The workgroup is then going to move on to address questions and issues related to histopathology, to anatomic pathology testing processes, and personnel who are involved in histopathology section of the laboratory. Whether moving into analytical testing specifications, looking at new technology and thinking about how to establish performance specifications or verify performance specifications for commercial methods, We're also going to open up workgroup discussions for advice on other parts of Subpart K, as far as what other changes may be needed to this section, which covers the analytic part of the testing process. And the last topic, as discussed in Dr. Kaplan's presentation yesterday, and in fact, a lot today during your recommendation discussions, is that digital pathology and pathology that utilizes images or digital images in the laboratory.

So we have a simple 32 subject matter experts, including two client members serving as co-chairs, Dr. Kimberle Chapin and Dr. Gregory Sossaman. We also have the previous work group chairs, Dr. Ng, Dr. Hillborne, and Dr. Laser involved in this work group. And rounding it out, we have our CMS and CDC ex-officios and numerous agency staff that are serving kind of behind the scenes as subject matter experts.

So to set the stage for our first work group meeting, this updated diagram of the total testing process was presented. This diagram describes the workflow that's associated with a clinical laboratory test and this representation emphasizes a broad integration of laboratory practice into health care delivery, while also integrating the concepts that are described in multiple publications since this diagram was first described in 1981. So in looking at this new diagram, we're going to look from the inner to the outer full circle, and if you look at those rings of the diagram, you're going to see four main elements. Resources-- this represents the physical, administrative, financial, staffing, and organizational requirements for clinical laboratory testing services. Then we move out to a competent workforce. This highlights the need for a competent workforce in carrying out clinical laboratory functions that meet acceptable quality standards. Moving on to quality practices, this represents all activities required to offer accurate, timely, and actionable clinical laboratory testing services that are consistent with best practices, standards and regulatory requirements. The outer ring of the total testing process diagram represents the phases of the total testing process. In this new diagram, you can see that there are 11 activities that comprise the total testing process. I want to call your attention now to some new elements of this diagram, and because of rapid growth of medical knowledge, an increasing number of test options and interpretive complexity supported the need for a closer collaboration between clinical and laboratory professionals. In this updated diagram, we illustrate that need by including the outer circle of activities that are called laboratory interpretation and reporting, and include clinical interpretation and follow-up and test selection. These activities represent important opportunities for engagement to ensure that knowledge of the uses and limitations of the test are incorporated into clinical decision making. Another important feature that we added is patient engagement. This element acknowledges the importance of patients in making informed decisions. We are also going to note the inclusion of data and informatics the two half circles and box cover the collection, analysis, and use of data to support appropriate test utilization for a given patient, which can also inform broader policy and practices directed to assure the quality of medical care.

So we're happy to report that our first work group meeting was just a couple of weeks ago on April 1st. We're going to continue with regular meetings scheduled for the first Friday of the month until all topics have been addressed, and it seems like we now have a new topic to address, as closed out before lunch, so expect this workgroup to report again during the November 2022 CLIAC meeting.

So this slide here shows the topics that we discussed during our first meeting on April 1st, which was the total testing process. At what point in the process should CLIA regulations apply, and where do CLIA coverage end? We also moved into a workgroup discussion of definitions. And if you go to the CLIAC site, attached as a PDF to this presentation is also the workgroup summary report, and I invite you to look at that and read through it. And I'm going to stop sharing my slides and turn it over to Dr. Gregory Sossaman. Thank you.

Report from the CLIA Regulations Assessment Workgroup Meeting
Gregory N. Sossaman, MD

DR. GREGORY SOSSAMAN: Thank you, Heather. And I would like to thank Heather and the rest of the CMS, FDA, and CDC members on the workgroup, as well as many of the other members who are present today as part of CLIAC. It's a very diverse group of experts, and so we appreciate everybody's input. It was a tremendous dialogue and great start. And Dr. Chapin would be here, but had some other pressing issues, and so I'm going to try to do this justice as far as report the gist of the conversation. So the next slide, Heather, please.

So as Heather set us up very well as to how the work group was pulled together and how we decided to proceed, the discussion really centered around the diversity of the topics-- digital pathology, personnel regulations, the non-traditional workflow. How should we start to pull all these topics together? And as a group, we decided that really we need to look at the total testing process. Does CLIA now encompass the totality of that testing process? And I'm sure-- there were several people looking at that diagram from 1981 that Heather mentioned. That was George Lundberg's diagram that he put out there. I'm sure Dr. Ng knows that or remembers that. And it's a fantastic diagram, but as we looked at that as a group, we had to acknowledge that there are just pieces of that have changed tremendously over the intervening time. Particularly during the public health emergency with the emergence of patient at home testing, that diagram is-- not that it's not incomplete, but it needs to be updated as we looked at it. And so some of the conversation around the total testing process-- some of the thoughts were-- next slide, please.

Some of the thoughts and some of the comments were, as we've said, their landscape has changed. Laboratories are now-- many of us are involved in stewardship and trying to intervene further down in the process to help very busy clinicians who are overwhelmed by the number of tests out there pick the right test, instead of just relying on a panel of tests that's in the EMR. And now there's emergence of facilitated test selection with artificial intelligence that will play a role in the future. Several of our members felt that the regulation should begin at the time of the request of the order, with that kind of guidance with test selection, and others really felt that clear regulations really had to start when the lab received the specimen because that was really the lab's ownership of the process. But the conversation around stewardship was very robust, and we looked at ways that we could-- that the quality aspect of the laboratory process could extend through that stewardship piece around specimen ordering patterns with the test menu reflecting the specimen types that were validated by the laboratory or in a specimen collection manual that was very specific for what should and shouldn't be collected and sent to the laboratory. We felt that if the laboratory owned its own specimen collection stations that they should be covered as part of the laboratories CLIA certificate. And then again, some opportunity for expansion of CLIA around the pre-analytic assessment specimens conditions and acceptability should be part of that. We did have some conversation around home collection and those type of things, and what the effect on laboratory testing would be. Next slide, please.

So where should CLIA end was a little bit harder discussion, and it was felt it would be difficult for CLIA regulations to cover clinical interpretation and follow up past the reporting piece, so to speak. The ability for remote telepathology and how data is handled once it leaves the lab makes it difficult to determine where CLIA regulations should end. And though although the it was felt that the testing process should include data interpretation, even if it was performed remotely and that CLIA should regulate the interpretation of bioinformatic data and variant calling. I think some of this conversation is very similar to what we've had in this group before, and what we've had earlier, a little bit earlier today, with the discussion about this distributive testing model. Next slide, please.

And as part of this, I think is this group, a few minutes ago, wandered into this discussion on semantics and was slowed down. We decided that, as part of this conversation, as part of our work group, we should really look at all these definitions in the CLIA regulations to decide we do we need to modify anything or do we need to add anything. Next slide.

And just to cover this a little bit, we started with the definition of the test system and you can read that this statement that the instructions that all the instrumentation equipment, re-agent supplies needed to perform assay or examination generate test results. We felt that needed to be modified to include an algorithm or software algorithm that would be used to modify a test result, and that the definition may need to include these components that have an impact on what the physician is going to use to make that clinical decision. And again, when the data leaves the laboratory in a distributed model where analysis or interpretation may happen at another site that's not part of that CLIA lab with its own CLIA certificate, that process should be considered part of the test system, and then that downstream process where that happens, that should be considered a laboratory and they should also have their CLIA certificate, as I mentioned. We also then considered adding the term "materials" to the definition of the test system and then and include a definition of materials in the CLIA regulations. Next slide.

As the term "materials" is included in several sections of the requirements but a definition is not provided.
And we did revisit this recommendation that HHS from the 2019 nontraditional testing workflow model that the word "materials" be updated to include images, genetic and protein sequences, omics data, and other data so that's already been a recommendation that came from CLIAC. Then we discussed expanding the definition of materials to encompass, again, many other things. Again, the data that might be handled by an outside entity like a software company that would a bioinformatics company that would handle and analyze that data. Next slide, please.

And interestingly we talked about the definition of distributed testing earlier and made mention of a handling of a specimen it's interesting that in the CLIA standard specimen it's not really identified-- or not defined. Excuse me. And we discussed that the data analysis and sequencing and image analysis are all really integral pieces, and we may need to actually define "specimen" in CLIA so as not to impede any workflows or efficiencies that are currently in place. Next slide.

So the definition of the "clinical laboratory" or "laboratory," we discuss this quite a bit just a little bit ago before lunch, and the definition in the law includes the statement that materials derive from the human body, and the term "derived" can be used to apply images and data that are derivations from materials of the human body, and it's used in this definition of clinical-- the term "clinical laboratory," as you see in CLIA. And so this may-- obviously, it would be-- it's harder to change what's in the, again, in statute, and this is the definition or the working definition we have at this point. Next slide.

So those were the definitional discussions that we had. As you can see again, referencing our prior discussion today, that words matter. That not just semantics, but all of these terms that we use, we really wanted to go back and ensure that we had a broad enough interpretation, but were also specific enough as we tried to look at changes that we need to suggest to CLIAC. So as far as other discussion points-- next slide, please.

We talked about remote analysis. And again, not to belabor that, but we came much of the discussion centered around the same things that have already been discussed today. If someone is working through as part of a laboratory employee, and they have to be working at home through a VPN and looking at data produced by that laboratory that they should be covered under that home laboratory's CLIA certificate, as distinct from a distributed model where laboratory A would do the wet work and another entity, or entity which should be considered laboratory B, does the interpretation, that that second site or those two sites are separate, and then would have a distinct need for each of them for their own CLIA certificates. Next slide, please.

We discussed some at-home specimen collection issues as these have become prominent during the public health emergency. And some of the discussion centered really around requirements for stability from the FDA approval standpoint for vendors, and then how would the lab confirm some of those viability? Or as they may struggle with some of the viability issues-- how were the specimens collected? How were they handled? Were the temperatures monitored in transport those kind of things? And again, that goes back to what should the lab be responsible for. Some of those questions are relatively difficult to address, and that there was a suggestion around specimen collection devices in ensuring internal controls to make sure the specimen collection was sufficient and the integrity of specimen was maintained. Next slide, please.

We talked a little bit about VPN and encryption standards, and that there was a need for current standards to be defined in regulatory language and that HIPAA already requires any public health information or protected health information-- excuse me-- including genetic information, to adhere to requirements under their security rule. Next slide.

And this was, again, around a little bit of the next generation sequencing data and the bioinformatics pipeline, so to speak, where data is sent to an outside entity for manipulation analysis and returned to the clinical laboratory. And the discussion really centered around that this is interpretation of the data is manipulated, and that that entity is acting as a laboratory and that they need to be governed under CLIA, also. Next slide.

And again, goes back to the same piece that the outside companies need to-- again, if they're handling bioinformatics or other data, they're part of the total testing process, many of the current laboratory directors who review some of this information may not have sufficient, up-to-date knowledge on this. And in this distributive model, these sites need to be regulated. There may also be a need for personnel or professional certification for these individuals who operate in these type of environments and that may be in a new class of personnel. Next slide.

Oh, that was it. That doesn't probably do justice to the totality of the conversation and the expertise in the group, but know this conversation will continue and I expect-- we expect a lot of great work from this group and keep adding. Hopefully, you'll keep adding to this mission, as you did today, and will take on those topics also. So that's it. Thank you.

Public Comments

CLIAC CHAIR: Heather, is there public comment on this?

MS. HEATHER STANG: There is no public comment on the topic.

Committee Discussion

CLIAC CHAIR: Thank you. That means we can move to committee discussion. Who would like to comment on this report? Raise your hand. There's this postprandial, like, can't think. OK. [CLIAC MEMBER] and then [CLIAC MEMBER].

[CLIAC MEMBER]: Well, I found the report extremely interesting, and I'm really glad you guys are working on these topics. One of the things that struck me, though, was where does biosafety practices fit into this? Because we spend a lot of time in the laboratory taking the right precautions and things, but where do we account for that, and is that something your group considered?

DR. GREGORY SOSSAMAN: We did not get there yet. I think the first step was in ascertaining that, perhaps, a entity that's acting as a software company, if they're taking data in, they need to be considered as a laboratory. And so then I think we need to decide which of the applicable standards would then be enforceable for an entity like that. again if it's a software company. And again, there's no biomaterial that ends up there, so we just got into that and I think maybe we'll have to have further discussions on that piece.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [ADVAMED LIAISON].

ADVAMED LIAISON: Sure so first and foremost, I want to say thank you to-- thank you, Greg and to the entire workgroup because this is really good work just from the outset of tackling many thorny issues. And certainly in reading some of this beforehand as it was available helped form some of the discussion, I think, this morning and yesterday. So I have two questions. One is, can you give kind of a viewpoint of next steps with the workgroup and next areas of tackling? And then, one specific question was, on the last slide about non-CLIA labs, I wondered if you could elaborate a little bit more on new class of personnel for drug screening toxicology?

DR. GREGORY SOSSAMAN: Sure. Yeah and thanks, [ADVAMED LIAISON]. I appreciate your comments. And again, it's a very robust group, so we had lots of really good conversation and I didn't probably convey all of it. But as Heather said, the next topics-- we've set up a series of conversations. The next topic we'll be looking at is data as a specimen. So we wanted to start with a total testing process to kind of define that piece and then the definitional issues, and to make sure we're all saying the same thing, hopefully. Then we're going to be tackling data as a specimen and work our way down through the other topics as we were given as priorities as the work group, again, which will include histopathology and digital pathology.

[INTERPOSING VOICES]

CLIAC MEMBER: OK. So. Can I just ask-- I may have misunderstood. So then this is the end of the total testing process, then you're going to the next topic?

DR. GREGORY SOSSAMAN: Well, we'll see where we go. This has to be, I think, incorporated into all the other discussions, but this was the first place to start. For instance, when we get to digital pathology, I think some of these other considerations, again, for the total testing process come into play. So we definitely have not left the total testing process discussion, we just needed to have that first. I may not have said that well. And then, I'm sorry. Repeat your second question for me, please.
ADVAMED LIAISON: Yeah, I was just asking for a little bit more elaboration on the need for a new class of personnel for the drug screen toxicology, especially referring to the post-analytical side it looks like.

DR. GREGORY SOSSAMAN: I think that wasn't-- it was more a comment on just new testing personnel, all classification regarding anyone who may-- say if, for instance, someone, again, who works in a software company who handles data, and I think we'll talk about this more as data as a specimen. Than once we get to that piece, then we'll start to begin to look into do we need personnel classifications or new personnel classifications for those individuals who work in those type of new entities that we're thinking about.

ADVAMED LIAISON: OK. Thanks. I just misunderstood the original comment, so I appreciate the clarification.

DR. GREGORY SOSSAMAN: Thank you.

CLIAC CHAIR: Are there other comments? And I would ask, [ADVAMED LIAISON], is there something specific you want to ask around toxicology and drug testing?

ADVAMED LIAISON: No, no. This is simply a misunderstanding. I wasn't thinking about in terms of drug-- or post-testing analysis of those results in a data format. It was-- my mind had gone somewhere else as they were talking about and I-- yeah. I just misunderstood what you were saying.

CLIAC CHAIR: OK. Thank you. [ADVAMED LIAISON].

CLIAC MEMBER: This seems a reasonable place to ask a question that's been nagging me is trying to understand where to insert a program, such as the AACC certification program, because we had extensive prior discussion of laboratory personnel in waived settings for which there-- for whom there is not a clear requirement for training, and we have yesterday's presentation of what appears to be a stunning program. And between the CLIA lab director and their statements in our draft recommendations about what should be appropriate language there and whatever entry level is there for expanding the workforce that does waived testing, I haven't been able to figure out where to slot a program such as the AACC certificate program. And in your work group's deliberations, where you're talking about a new class of personnel, do you have a sense of how to link and crosswalk to a program such as what the AACC did. In draft language I provided, I said "deemed," if there's some "deemed" program that creates directorship or oversight. I just don't know where to put it.

DR. GREGORY SOSSAMAN: So [CLIAC MEMBER], I don't know either. That wasn't the focus of the initial conversation. It may happen as we begin to have other conversations around personnel. We didn't handle much, in the way of conversations around personnel requirements, really at all. I think it may come up. I think it needs to come up, but your specific question around the point of care and AACC certificate or certification process, I really don't have a good answer for that.

CLIAC CHAIR: As we go forward, we have to be mindful that all of these terms we're using have great overlap. So for example, "waived testing." We think about that as point of care, but point of care can include any layer of complexity testing. Meanwhile, in the clinical laboratory, we typically think of as moderate or high complexity, but we do a lot of waived testing in the clinical laboratory. So I think we have to be mindful of how this overlap occurs then, when we move forward with for recommendations. This group is very quiet around Greg's report. [CLIAC MEMBER].

CLIAC MEMBER: I just didn't want you to be so lonely. That's all. But no. First of all, I think the work group has really done a good job, and I think just to sort of answer that question of how does the AACC program fit in, or other programs, because the personnel group talked about that as well-- certification, board certification, certification from the ASCP BOC, for example, is that those are probably issues of minimum criteria that would be discussed, and proof of that to show education training and competency that the director would then be able to use for that purpose. So I think I think where it fits in is there. Exactly how it fits in and the extent to which it is a "deemed" status for some process is probably something that we need to discuss further. That came up at the personnel workgroup and is continued now in this group.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER].

CLIAC MEMBER: Yes. Thank you. I think the circle showing the total testing process is excellent. I really think that captures what we're doing. I think to-- I had the same question [CLIAC MEMBER], I guess, is in where do we fit some of the other issues because it seems, if I understand correctly, and this is a question for you, you're focusing really, mainly, on bioinformatics, some of the newer technologies and some of the newer personnel classifications and roles, rather than going back and looking at some of the current roles that are occurring. We talked about the certification, perhaps, for point-of-care and how we see some of those roles. And my question would have been also, when do we go back and look at the current roles for moderate and high complexity level personnel? What is it about the laboratory profession that we're having so much trouble recruiting people to come into the profession? And so, I was wondering when the time would be for those conversations as well. And [CLIAC CHAIR], perhaps that's something that we talk about in future topics a little bit later.

CLIAC CHAIR: Thank you. I'm not going to be here for the future, right? Except as the audience, not allowed to talk. But I do endorse that, and I will let you know, as a snapshot, if there are no other suggestions for Greg, we have lined up four recommendations for this group to entertain. Two of which, at a minimum, relate to the pipeline and recruiting into the profession. So I'm going to give it one more call for questions for Greg. Greg has his hand up, so Greg--

DR. GREGORY SOSSAMAN: Just to make one quick point, that I think that the workgroup that [CLIAC MEMBER] chaired a couple of years ago was empowered to look at a number of things. And there were a lot of recommendations that came out of that that are in process now that at some point we may want to review. But [CLIAC MEMBER], to your point, our group was focused on a couple of issues. More specifically, again, around-- as you said-- the next generation sequencing

as a technology, but maybe in a broader sense, and then digital pathology, some other things. So we weren't going back to specifically look at all categories of personnel. Thank you.

CLIAC CHAIR: And I want to tee up for future discussion-- in either a workgroup or this committee-- the discussion around waived testing and how we started with eight very simple things, and it's morphed into 140 different types with different clinical implications. So line that up for the future. Is there further discussion on the CLIA regulations assessment workgroup? Hearing done. We have one hour. We have 55 minutes to consider the remainder of what we've been talking about for the last day and a half. And we've assembled what I am calling four buckets of recommendations. [CLIAC EXECUTIVE SECRETARY] has her hand up. I'm sorry.

CLIAC EXECUTIVE SECRETARY: Yeah, I was just going to remind everyone that while the workgroup is doing wonderful work and providing great input, there are no official recommendations that can come from the workgroup. So if CLIAC thinks that anything that Greg has presented today is worthy of a formal recommendation, it needs to come from you all. And if you don't feel ready to do it now, maybe the next meeting, you will. But just a reminder that the workgroup is convened to provide input for any decisions you would like to make and recommendations.

CLIAC CHAIR: Thank you, [CLIAC EXECUTIVE SECRETARY]. Greg, were there any concrete recommendations from the workgroup to CLIAC?

DR. GREGORY SOSSAMAN: No, not as yet. Just the thoughts and the takeaways that we presented here. But again, as [CLIAC EXECUTIVE SECRETARY] said, it's up to CLIAC to do as it will with the information we present. So, I think we'll have some more concrete outcomes. And then that will come to the group in the future.

CLIAC CHAIR: [CLIAC EXECUTIVE SECRETARY]? Oh, [CLIAC MEMBER]?

CLIAC MEMBER: So, having just heard what Greg Sossaman said, maybe we need to wait until they're completed. But in a very general sense, I think that we could advise CMS to develop a glossary of terms and definitions so that when we make recommendations we are making them about specific things that we agree upon. And that they include pathologists. There are not very many pathologists up there in that Washington office. That they include pathologists in defining the terms.

CLIAC CHAIR: Do we have a glossary in CLIA? Yes, we do.

CMS EX OFFICIO: Well, for CLIA purposes, we go by the definitions that are in the regulations.

CLIAC CHAIR: Thank you.

CMS EX OFFICIO: There may be some other areas that have terms, but for us, we go by the regulatory definitions.

CLIAC CHAIR: So, [CLIAC MEMBER], it sounds like we would go through the workgroup and add to that glossary with the definitions that would be recommended up to CLIAC to move forward.

CLIAC MEMBER: And I just want to say, in separate work in looking at some of the things coming out of the ONC-- I don't know if y'all saw some of the USCDI definitions but "pathology report" was defined as a narrative as interpreted by another specialist. Which dates back to the days when we all had paper, and you looked at the pathology report, and you kind of assessed it in your note as the general doc. And is completely out of date. And so I think there might need to be a workgroup or that workgroup actually look at the regulations and pull out the definitions and refine them. I hate to say that because that's a lot of work.

CLIAC CHAIR: [CLIAC MEMBER], were you referring to CLIA, or are you referring to another organization?

CLIAC MEMBER: Well, I was referring to another government organization. But the regulations and interpretations coming from the Office of the National Coordinator of medical terms. So true enough, not CLIA itself, but it suggests to me that there's not a good set of robust definitions.

CLIAC CHAIR: Greg, you have your hand up.

DR. GREGORY SOSSAMAN: Yes, thank you. So be happy to look at those terms, [CLIAC MEMBER]. But as far as the pathology report, something like that would go, Dr. Chip and I talked about this. We would view those things as an interpretive report by a physician as the practice of medicine. And that was definitely outside of the scope of what we were going to be talking about. So that was not something that we would be talking about in this workgroup.

CLIAC MEMBER: Indeed. I just threw that out as an example of how other people view pathology terminology. How important it would be to have domain experts, pathologists, determine the definition. So I didn't mean for that to be one, to include it. But just as an example of how we're viewed.

DR. GREGORY SOSSAMAN: I think we'd be happy to gather any terminology.

CLIAC CHAIR: We've had conversations in the past around the ONC and other parts of the government where their work effort would impinge on what we do and how to harmonize that. So I'd have to go back and look at previous minutes. I do know we had an impassioned presentation from an FDA informaticist, when we talked about mapping and linking, of where lab data leaving one system ends up in a second system, and what the recommendations were that were not always followed by the software vendors. So we have touched on those areas before. We will be mindful of that going forward. Is there further discussion? It sounds like we have no recommendation moving forward from the assessment workgroup, and of course I want to get back to these four buckets. Now we have 48 minutes, and with your indulgence, I was hoping Heather could-- or someone could display the four recommendations that crystallized out of this morning's conversation. And they centered around the pipeline. There were two coming forward on funding, which kind of gets to what [CLIAC MEMBER] was suggesting. There's one focused on-- two on the directorship. And then one on waived testing. I would say the waived testing is too diffuse to have a conversation around in our last few minutes, but I do think the funding is something that we could tackle. I think the work-- and in conjunction with the workforce pipeline. So I'm going to ask [CLIAC MEMBER] to introduce these, and she put them together with commentary by me.

CLIAC MEMBER: All I did was take the original. I don't lay claim to creating these so, transparency and disclosure. What I tried to do over lunch was take all the comments that were delivered by various people and put them into certain buckets as described. So the first one is a combination of mine and [CLIAC MEMBER]'s and multiple other people. And then this recommendation to the personnel workgroup, I didn't know if that comes through CLIAC, but it was listed. So for [CLIAC MEMBER] and [CLIAC MEMBER], and then I just took some other ones and whittled it down to simple sentences that maybe we could agree on. So I don't know where you want to start, [CLIAC CHAIR]. But—

CLIAC CHAIR: I'm going to start with [CLIAC MEMBER] and [CLIAC MEMBER] because they have their hands up.

CLIAC MEMBER: Yeah. Thank you, [CLIAC MEMBER], for putting this together. It's very well written. But I think-- in the third paragraph-- we don't have enough people doing high complexity. I think the pipeline is a wonderful idea, but there needs to be a pipeline to something. And the something, I think [CLIAC MEMBER] stated it very well-- why get a bachelor's degree if you just need a high school degree to do testing? And we don't have enough people to do the high complexity testing either. So I would amend the third paragraph. We're very focused on the waive to moderate complexity point of care testing quality right now. But the personnel shortage is all the way through the laboratory continuum of laboratory professionals. And so I would just say the growth of and recognition of laboratory professionals because it's—

CLIAC MEMBER: And I tried to include all the complexity levels that people had talked about in that first paragraph, but I did leave those two standalone comments in case pieces of those had to be incorporated. And then I wasn't sure if CLIAC recommends to the workgroup or if we recommend to somebody else. So I left that there too. But basically, the third and fourth are comments that were maybe partly described in the first paragraph. And maybe it's too long and wordy and we need to limit it, but I just wanted it-- I don't want to lose them in case somebody wants them to be incorporated.

CLIAC MEMBER: Well, thank you for the explanation, and that helps. I guess maybe what we add-- perhaps we could add another bullet to the personnel workgroup that also looks at the role of laboratorians. Because a lot of what we're suggesting here are things that we've-- that the industry's looked at for many years now. And why don't people want to go into the laboratory profession? Are we utilizing our professionals appropriately, or do we need to look at their scope of practice? Do we need to look at the recognition? But how do we? I think the personnel workgroup perhaps could do us a great service by also looking at how we utilize laboratorians so that it's a profession people want to go into.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: The top paragraph, I think, is its own recommendation. And it's not a referral to the personnel group. It's a direct request to HHS and CDC. And I think it should stand alone. And we can wordsmith it as we see, but I believe that this is a direct recommendation from CLIAC to funding agencies. The second is, to me, the procedural question that I asked earlier. Which is when should we refer to a workgroup which can only come back through a subsequent meeting of CLIAC? And when do we just make a direct straight shot to action entities? And so, since the pipeline is a current crisis, I think we need to have a direct recommendation that's folded into the top paragraph. And having then saying, OK, what is the personnel workgroup going to do, hopefully between now and six months from now and a year from now-- because this all takes time-- to continue to shape the profession that we hope to be recruiting to? And I think the two can run in parallel.

CLIAC CHAIR: I would ask-- the proposal on the screen right now is broad and encompasses many aspects of the pipeline. Since it's predicated on funding, I would ask can we scroll down to the very crisp statements around funding. And is that something that we would want to put forward as the recommendation?

CLIAC MEMBER: If I still have the floor, when we co-mingle certificate of waivers and the target part of the workforce with funding, I think we're making a mistake. I think funding should be an explicit statement without subcategorizing.

CLIAC CHAIR: Would you agree [CLIAC MEMBER]'s is appropriately restricted?

CLIAC MEMBER: I think there's a little magic. I mean, his is more concise. I think there's some magic in what [CLIAC MEMBER] has up top, and just make sure that we don't-- if there's magic to bring down into [CLIAC MEMBER]'s, I think that's worth taking a look at. I will yield the floor.

CLIAC CHAIR: OK, thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Can you hear me?

CLIAC CHAIR: Yes.

CLIAC MEMBER: Oh, I'm sorry. I am fighting a massive windstorm here. I finally gave up with the computer and just-- I'm on my cell phone, so I apologize you can't see my face. But I just wanted to support [CLIAC MEMBER]'s comment about teasing out the funding specifically. I think that the actual nuances between the three different paragraphs-- I'd have to sit there and just try to chop them together-- but I think asking for funding for the pipeline, asking for funding from the right government agencies, and trying to tie this to either currently existing programs or developing a new program is something that is really clearly lacking. And it's something that I've been after our specialty societies to take on as well. And there just seems to be no desire to really push this along. It's very near and dear to my heart as the husband of a med tech, the father of a med tech. I see how these folks really are still trying to find their value in the hospital. I think they've been increasingly devalued. So finding a way to bring people into this subspecialty, as we've talked about all day long here, I think is absolutely critical to this pipeline process.

CLIAC CHAIR: Thank you. I'm hearing there's coalescence around liking this first paragraph of [CLIAC MEMBER]'s laboratory workforce pipeline. So I'm going to make a motion that we--

CLIAC MEMBER: And I don't want to take credit for this because this is coming from a bunch of different people, but-- and to [CLIAC MEMBER]'s point about [CLIAC MEMBER]'s comment, it is the most succinct one that we have about funding. And maybe needs to be the predicate to the laboratory pipeline conversation. Because the urgency of the funding is the most critical thing, and he does a really nice job of just summarizing that very succinctly. And if I remember previous CLIAC meetings, either we take the other pieces and make them subcategories of the recommendation or we make them separate recommendations. And I think that could easily be done if we start with that one as the predicate.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yes. And I like [CLIAC MEMBER]'s statement because it doesn't call out specific roles. I had a bit of an issue in the first paragraph with medical lab assistants-- which there actually aren't a whole lot of those in most laboratories-- to doctoral and kind of skips the actual medical lab technicians and technologists. And then what about phlebotomists? And you can't call out everybody. So I struggled a little bit with calling out folks that actually don't work in the lab very much. They'll do a lot of waived testing, and doctors, not mentioning other people, can you mention everybody. Anyway, so I'm sorry I'm being wordy. But I think the way that he's got it kind of broadly-- "competent laboratory personnel--" I like that.

CLIAC MEMBER: Yeah, I think we could fix the other one by saying, high school, associate, bachelor, master's, and doctoral level. Without calling out names of the profession, we could probably-- is the whole point of that is that it's a journey. It's a process, it's a pipeline that we need to start early and often and then progress to. Because there is a pathologist shortage as well. So I think calling it out maybe by academic level would be better. But still agree, starting with [CLIAC MEMBER]'s.

CLIAC MEMBER: Yeah, trained and competent lab personnel, I think that's lovely, actually.

CLIAC CHAIR: So can we cut [CLIAC MEMBER]'s sentence and paste it into the first paragraph to replace-- in front of "CLIAC recommends." Let's see if that's duplicative. Just paste it there. And then make it all one paragraph, and see how you all react to that.

CLIAC MEMBER: There's an extra "that" in line four. "CLIAC recommends that" has to come out.

CLIAC CHAIR: Right. So in that first line, it's "CLIAC is recommending HRSA funding," whereas the next sentence recommends HHS and CDC funding. Comments? [CLIAC MEMBER] first, and then [CLIAC MEMBER].

CLIAC MEMBER: This will be brief. I would just-- I do also support the beginning with [CLIAC MEMBER]'s statement. But instead of saying "impending crisis," I would say "current crisis." Because I would say the crisis is upon us, and not impending anymore.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I was just wondering, because I know the headlines are funding, and I guess my question-- I know it says funding education. And I don't know where the other piece is. So funding education, training, and certification of personnel nationwide, the biggest thing that I hear from MLSes and MLTs is number one, pay me more, and number two, forgive my loans. That's really what I hear continually. And I guess my question is, so who are you going to train, and who are you going to educate. I mean, we have to get their attention. The only way you get their attention is, in my opinion, by increasing the salaries and loan forgiveness. That's what, in my opinion at least, that's what brings people to these universities in the first place. I mean, you go to any of these high schoolers, and the first thing-- one of the first questions they ask is how much do you make. So that one area. And then the other piece that always gets people involved and really perks the ears up is loan forgiveness programs. Then the last piece that-- I know this is probably not the place to talk about this-- but we are on the back end. We are unseen. Whereas nursing and pharmacy, they are patient-facing. And that's one of the things that probably we can't fix. But certainly education, to me that would be a big education piece about what we do. I think COVID-19 has certainly helped with that. Bringing the laboratory scientists to the forefront. But my opinion, somewhere, at some point, you have to look at the pay. How do we increase that across the nation? As well as, potentially, loan forgiveness. And I think you will see-- and maybe I'm just naive-- but I think he would see an influx of laboratorians at least showing more interest. We just-- we don't pay a whole lot. And there's a lot of other programs out there for other medical fields that do offer loan forgiveness. So I guess that's my statement about that.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I think [CLIAC MEMBER] hit the nail on the head. And I think some of that comes back to scope of practice and looking at the personnel requirements. But with that said, my original comment was we've got "CLIAC recommends urgent HHS funding" and then the next sentence says recommends "HHS and CDC funding." I'm wondering if that's redundant, if we can kind of merge that. And then again, I still have a little bit of a problem with the sentence that says, "the program would focus on broadly representing and addressing-- from medical lab assistants to doctors." If we could reword that a little bit.

CLIAC CHAIR: So first of all, I agree with you. The gray sentence is duplicative and I would recommend we delete it. And in terms of the pathologists, which is five lines up, "addressing the needs of a full continuum of laboratory practices." You are recommending we strike "pathologists" from that sentence?

CLIAC MEMBER: No, no, no. I'm recommending that we say "for the continuum of laboratory professionals" or something along those lines, as opposed to calling out specific roles. Because there's a lot of roles like medical technologists or phlebotomists we're not including. I'm wondering if we're being too specific and not specific enough at the same time. If we can change that wording to be a little more general.

CLIAC MEMBER: I think she wants a period after "laboratory practices" and scrap the rest.

CLIAC CHAIR: I think she wants "laboratory professionals." She wants "practices" replaced with "professionals" and then period.

CLIAC MEMBER: Yes. Thank you. That's exactly what I was asking. Thank you for reading my mind, Valerie.

CLIAC CHAIR: Oh, all you red pen people. OK, [CLIAC MEMBER].

CLIAC MEMBER: I'll come back to [CLIAC MEMBER]’s comments in a moment. Just reading through on the fly. I think we should remove "additional" because even strengthening additional as a current program. So we should be subtracting words at every opportunity to be as broad as possible. And if we go to the bottom, for example, "medical laboratory sciences" is the term that I've heard rather than "clinical and bioinformatics." In other words, what is a medical laboratory scientist? It's a broad term, and that would be career options in the medical laboratory sciences, and just leave it at that. The issue of basically mending our own house. Salary, loan forgiveness, career ladder is the other. And my editorial observation is that laboratory services are held to cost per test in a way that compares very unfavorably to the other

health professions that are more attractive. I don't yet know how to put "pay more" into this particular paragraph. Because this paragraph really focuses on training and recruitment, not on actually paying existing personnel more. And my inclination is that needs to be a separate recommendation. We should not co-mingle "pay us more" with this recommendation as it stands, however worded.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I would like to just quickly draw everyone's attention to the first bullets that we have under "CLIAC recommends that the personnel workgroup." I believe it's a little-- it could, maybe the clarity could be improved, of that particular recommendation. I think it reads that we're looking to expand eligibility, which I think is the intent here. I think if we were to strike "sufficiently trained personnel" that intent would be actually clear. Because it's a bit contradictory to have someone already sufficiently trained but we expanding eligibility to enter the laboratory. Presumably they get trained after they are recruited.

CLIAC CHAIR: Thank you. I just want to note that the pipeline recommendation appears to be relatively distinct from the personnel workgroup recommendations. And so, from my mind, those would be two separate types of recommendations. And then it would be back to [CLIAC MEMBER]'s question. And [CLIAC MEMBER], actually [CLIAC MEMBER], how do we make a recommendation that the workgroup consider versus going straight up the ladder. I'm going to move on to [CLIAC MEMBER].

CLIAC MEMBER: And this may be too simplistic of a understanding. But in terms of how to pay folks more, I would like to have the powers that be look into public-private partnerships with hospitals. It seems to me, that if-- particularly hospitals and urgent care and those types of folks-- that they could kind of put up some money along with the government funding, that might be an option. The other thing, obviously I'd love to see, would be-- and there was some talk a year and a half ago about free community college. And I mentioned this being kind of a trade school entree, but having it go through community college and have that be free, would be probably the ultimate thing. I'd love to see the two year degrees for nurses come back. [CLIAC MEMBER] may smack me, but you know, I don't know. Just because it's so hard to find nurses too, and now they've all got BSNs, and you have to pay them a whole lot more. Anyway, so that's on the wish list. But developing private-public partnerships to fund this is the idea.

CLIAC CHAIR: Well, OK, so we would say-- I would ask you to think about the wordsmithing, [CLIAC MEMBER]. And where you would put that in. So, a place could be, end of the second line-- "CLIAC recommends urgent sufficient HHS funding and/or public private 'partnerships."

CLIAC MEMBER: Perfect.

CLIAC CHAIR: Find out somebody else will want to red pen it. That's a placeholder.

CLIAC MEMBER: And you know, it probably doesn't do any good to talk about free community college, but, man, that seems to me to be a no-brainer.

CLIAC CHAIR: It's beyond our scope.
CLIAC MEMBER: I guess so.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. OK, [CLIAC MEMBER]?

CLIAC MEMBER: Just a minor point. On the fifth line from the bottom, when we say, "exposure to," I'd like to change that "interest" to "interest in laboratory careers." Because some articles I've read have indicated that having exposure in the laboratory actually causes people to leave the profession.

CLIAC CHAIR: Oh, I was actually thinking the biosafety thing there, [CLIAC MEMBER].

CLIAC MEMBER: Yeah, that's where I'm coming from. Thanks.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: This may be beyond the purview of this committee, but I do think the salary issue is a big one. And the fact that when cost-cutting comes to reimbursements, it's pathology just gets squeezed more and more and more. And I don't think-- I don't know that this committee can do something about it. But I don't think people understand how important laboratory testing is, with the exception of maybe [CLIAC MEMBER]. But to get the general public to realize that these tests are important, and they're expensive, and they require expensive equipment, and they require trained people. And at the very least, people who are very careful in maintaining chain of custody and identity preservation and so on. And I just--

when I look at reimbursement for pathology testing, I'm just like, hey, if my kids ask me, I tell them go into interventional radiology. It's a nice lifestyle, and you're going to get paid for the procedures. But I don't think people recognize their surgeon took their tumor out, but the surgeon had to come to the pathologists to find out if they got enough out. And then the medical oncologist has to come to the pathologist to find out how to treat the patient, and we're just not seen, and we're not reimbursed.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I think the pay, the loan forgiveness, the recognition-- it needs to come from AMA or somewhere else, not this group. And I think all of us on this call recognize laboratories and pathology are like gas, water, and electricity for health care system. They're fundamental, and you must have them. Now, how do we get others to recognize? [CLIAC MEMBER], [CLIAC MEMBER], and then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Two comments and then a suggestion. First of all, I really do believe it's time for this career and these professionals need to have a makeover to be superheroes. And that's not hard to do. I mean, there is a way that we can advertise the power and importance of your role and to make a recommendation into this motion. I do believe this is a critical place to put-- where it says, "funding would create incentives to recruit and retain" and then "and oversee programs" because the bottom line is absolutely right. We do programs with Niles Project going into schools, and we show them how much you can make as a nurse, as an infection preventionist, because that's what they need to see in low income places with children that are in high risk areas. They need to see how much you can make. So they are looking at incomes. And it is critical that everyone is getting paid fairly. So we know how much all these tests are costing. It's obscene. And I really do think this would fit. Incentives and recruit, to recruit and retain is key. Because if you're not getting paid enough, you're not going to drive these new students to your career. It's just not going to happen.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. So on the third line from the bottom, "the programs would focus on recruitment comma incentives and retention."

CLIAC MEMBER: That's good.

CLIAC CHAIR: I like the makeover. CDC did make us superheroes. A couple of times, I have my cape.

CLIAC MEMBER: Yeah, I mean, seriously this is not hard to do. And I think we should. That could be another recommendation is a full campaign, a marketing campaign for all of you. It's just really important.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. I'm listening to this discussion, and it seems to me that the first paragraph is the key recommendation. And then we're talking about a bunch of hows. And it would seem to me that those could be bullets under there. The issue about improving the recognition of the profession and within the scope of medicine-- it's like, what is the funding get used for. To improve training, we talked about loan forgiveness-- which is beyond what we would do-- but to ease the entry into the profession, to promote retention, et cetera. It seemed to me that the things that follow under it are actually bullet points for the first sentence, which is the ask.

CLIAC CHAIR: So they do want on the side, create the bullets, and then send it to Heather to upload, while we hear from CLIAC MEMBER], [CLIAC DFO], and then [CLIAC MEMBER] and [CLIAC MEMBER].

CLIAC MEMBER: Yeah, OK. But Heather, I guess you have to email it to me because this is just a screen.

CLIAC CHAIR: Let you guys work the magic. OK, [CLIAC MEMBER]?

CLIAC MEMBER: Open mouth, insert foot.

CLIAC MEMBER: So, based on the discussion and looking at the history of nursing and pharmacy and how they made their comebacks, I think one, I agree with [CLIAC MEMBER]'s statement to take the nationwide period and then subset. But I think at the end of that first section, we need to consider advocacy. Like the laboratory sciences are very split. We all have our own specialties, it's so broad. And the same exists in nursing and pharmacy. We have an infectious disease. But at the end of the day, they have very strong advocacy programs to Congress to-- and not that we can recommend that, but I think advocacy, education, training, and certification of personnel nationwide, or some combination there. We don't have one voice. We don't-- we're subsequent, and many of us are-- laboratory scientists at the bachelor's level are the handmaidens of the CAP. That's a pathology organization, and really, the laboratory scientists career is very different than the pathology career. And yet that's what most people belong to. And I'm not saying the CAP is a bad thing. I'm just saying we need advocacy for the profession at all levels.

CLIAC CHAIR: [CLIAC MEMBER]. [ADVAMED LIAISON]?

ADVAMED LIAISON: Yeah. So I think it's a really good discussion, and I fully support these ideas of what could be done to improve the pipeline of laboratory professionals in all categories. However, I'm struck with conversations we've had at previous CLIACs where we recognize that funding and things that are outside the purview of CMS, CDC, and FDA simply go to the HHS, which then acknowledges receipt of the letter and thanks us for it. And these aren't really things that the agencies who are tasked with CLIA can actually deliver on. So I'm wondering-- so I'm kind of thinking we might be overly spending time trying to clean up a recommendation to HHS that the Secretary may, in high likelihood, may just file for future reference. And I know that's a controversial statement. And again, I believe in all of this that's happening, but I don't think it's anything that the agencies are going to be able to act on.

CLIAC CHAIR: Thank you, [ADVAMED LIAISON]. [CLIAC MEMBER]?

CLIAC MEMBER: OK, I was looking at the laboratory workforce pipeline, and I had made a comment. And I was reading this big paragraph to see if my thoughts were reflected here that probably relates to "the funding would create and oversee programs for Clinical Laboratory sciences, sciences training programs, and partnership with the laboratory science community to increase interest in laboratory careers, creating a roadmap beginning with middle, high school, vocational school and extending to University and fellowship setting. " I don't think that-- I like that. I like really everything that's there. But what I had proposed, which I said often works for nursing and other areas that we look at, not just create an interest in partnerships in that regard, but-- and maybe partnerships could address it-- but truly establishing an articulation agreement. Which means that we would select those institutions of higher learning, or even other institutions, where there are graduates coming out of the various settings. And we would have a written agreement, and I don't know if that could be arranged. But I said some strategic interaction where we would have an articulation agreement that the students who were graduating from there, that that University at the top administrative level would say we have a partnership with Well Street Urgent Care, wherever. And so it would provide an opportunity for persons who are looking to add to the workforce could come and speak and encourage persons to consider their facility or facilities. Do you see any relevance in that? I know it works in nursing when we want to obtain clinical sites for our students to be able to practice. And I don't think-- when I was reading this, I don't think it really indicates to work toward the feasibility of a possibility of establishing an articulation agreement.

CLIAC MEMBER: Public, private, and academic partnerships? Would that help?

CLIAC MEMBER: Either on site or virtually.

CLIAC MEMBER: Yeah, even though as partnerships, it doesn't say that it's an articulation agreement. And I don't know if you can be that clear. And maybe it is here, if you think it is. But that is a very viable, quantitatively tool, strategy to use. Because you have people who have already bought into, we want to support this industry because there's a need. And we don't know how many more-- we hope that we don't have any more outbreaks, epidemic nor pandemics. But it's kind of like preparing ahead of time to serve as a feeder into this industry.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. We're more mulling that over, whether or not to be that specific.
CLIAC MEMBER: I would invite your critique, your critical thinking in that regard.

CLIAC CHAIR: I am pulled back to [CLIAC MEMBER]'s comment that, can any of the three agencies on this meeting achieve any of that. Can they achieve HHS funding? Because if they cannot, then we're wasting our time.
So with kind of a downer, I'm going to have [CLIAC MEMBER], and then I think [CLIAC MEMBER] had her hand up. But it went down. So it'll be [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Thank you, [CLIAC CHAIR]. Looking at the range of recruitment opportunities, and one of the things that nursing offers is a career ladder. And I don't know how the group feels about this, let me throw it out there. As we look at the role of laboratorians in the second section, is it time for us to look at a career ladder, and what is the role of master's prepared laboratorians? For example there are master's level programs in blood banking. Is there an opportunity for a mid-level that would help cushion some of the gaps throughout the continuum of laboratorians? So again, my-- so what I'm saying is when we look at the role of laboratorians, including master's prepared mid-level roles to provide a career ladder-- that might be a way of getting people into the profession.

CLIAC CHAIR: Thank you. I would also think this would be a subject for very robust discussion in the CLIA regulations assessment workgroup. [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER]. [CLIAC MEMBER].

CLIAC MEMBER: OK, so in response to [CLIAC MEMBER]’s comments and your follow up, [CLIAC CHAIR]. This is a moment for everyone to speak up and to make a very clear and concise recommendation based on what we've been through and what is happening today. So if we don't reach out and make these specific requests, then you can just put us in the category of well, how long did they know this and what did they do. So if we don't ask, we won't get. And I think

what we need to do is make this recommendation as we described with the first paragraph and then bullet points, and then finish it. Because our time is coming to the end, we know what needs to happen. And I think the very first paragraph is perfect and all the other things bullet pointed I think we need to get it done before this meeting is over, because a lot of people that have worked on this will be gone. And I think this will be a good success for everyone to feel good about and it's urgently needed.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Going right from that, if you remove that line, remove the statement "CLIAC recommends that the personnel workgroup" and simply say-- just remove both of those. Now, don't remove the bullets. Remove that and say, at the end of the opening paragraph, "This shall include" and then you have three bullets.
And you go straight to capital E for expand eligibility, and you can get the syntax right. But basically say expand eligibility and there's duplication. We can wordsmith. But I think what [CLIAC MEMBER] said is critically important, to examine the career of laboratorians including-- wordsmithing. Yeah, we can do that-- including remuneration and career opportunities. The career ladder is a message that has come through loud and clear from deans of health sciences, health professions here in the New York area. Which is that potential students, they look at the pay, and they look at the absence of any information on a career ladder, and the sense is you get parked at a bench for 50 years. Why would you want to go into that profession? And I think we've done a very poor job of making clear that there's tremendous opportunity for career ladder in the medical sciences, medical laboratory sciences. So however we choose the words for these three bullets, I think we've already got them. And to follow on what [CLIAC MEMBER] says is we're kicking this right up saying, we've got to do this. And yes the personnel workgroup or the regulations workgroup can work in parallel, but I don't think it should be in series. Going back to my earlier comment, we've run out of runway.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. We're going to see some magic transformation. [CLIAC MEMBER] has done some editing, and Heather will put it up. But let's hear from [CLIAC MEMBER] and then [CLIAC DFO]. And [CLIAC MEMBER], I'm assuming-- [CLIAC MEMBER] and [CLIAC MEMBER] you still have your hands up. OK, thank you. So [CLIAC MEMBER]?

CLIAC MEMBER: I was just going to just make a comment. That's it. I know that there are probably some other committees that are dealing with DCLS, but I do think that is an avenue as far as the role of MLSes, or just clinical lab in general, that's not highly talked about. It's my understanding there are only three universities in the US right now that's offering that program. And I actually do not think that DCLS is actually-- I could be wrong on this, but I don't think it's actually recognized at the CLIA level. So it's more of a statement, and maybe some other workgroup is working on that, but I wanted to point that out.

CLIAC CHAIR: Thank you. [CLIAC DFO]?

CLIAC DFO: OK, so I may be a little bit of a downer here, and I apologize. But I think it's really important that we pause for a second and remind ourselves what CLIAC is and what CLIAC can do and what CLIAC really can't do. You know CLIAC is a Federal Advisory committee for the CLIA program. The CLIA program is jointly run by the three agencies that are represented here at this meeting. The three agencies that provide you with an update at the beginning of every CLIA meeting to clarify for you what the agencies do and can do within the CLIA program I think it's really also important for you all to understand that the CLIA program has no funding from-- no congressionally appropriated funding. All the CLIA funding that goes to our three programs at FDA, CMS, and CDC comes from the CLIA fees that the laboratories and the CLIA certificate facilities pay, which is not insignificant, but really not an extraordinary amount of money. As important as this issue is, this-- as far as I'm concerned-- this is something that you all should be doing with your professional organizations. And you should be lobbying Congress directly. And I have to say that there's nothing-- speaking on behalf of my colleagues at CMS and CDC and FDA, we can't-- as much as we care about this, and as much as we agree with you on these issues, we're not going to be able to effect change from where we sit on this. And I really would like to ask CLIAC members to focus their recommendations on the CLIA program itself, and what we in our three agencies can do right now in the next six months before the next meeting to help improve the CLIA program. So I'll stop there. Thank you.

CLIAC CHAIR: Thank you, [CLIAC DFO]. [CLIAC MEMBER]?

CLIAC MEMBER: I just wanted to ask clarity on that one entry that says, "look at the role of laboratorians." From what perspective? I'm trying to see if that could be more measurable. Will it have been achieved if they just look at it or is there an interest in what?

CLIAC CHAIR: Which line are you referring to?

CLIAC MEMBER: Those three that are added to-- let me go back to where I was here. OK, could you go back to those three that were included and that was the third one. It says expand.

CLIAC CHAIR: [CLIAC MEMBER], with all due respect, we're not even-- we don't have time to even talk about the pipeline bullets. We are looking at this preamble that as I understand is not within the authority of the agencies in this meeting. And therefore, we should just stop. So unless [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], or [CLIAC MEMBER] have any comments to make. We are all passionate about this, but this is-- OK, [CLIAC MEMBER].

CLIAC MEMBER: So and I've got a comment to the career ladder recommendation that I made down below. Looking at the role of master's prepared-- that would require a clear regulation change. And I believe some of the certification discussions we've had from [CLIAC MEMBER] group, talk about bioinformatic roles, as well as the discussions we've had about training requirements for those holding a certificate of waived testing-- both for the director and personnel-- those are all CLIA regulation changes that we're asking for. So I think those pieces got smushed in a little bit to the funding but that I would think would be within our purview and we are asking for attention from CLIA.

CLIAC CHAIR: Thank you. [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: So I just have a question for [CLIAC DFO], if that is the case, that funding and these types of programs or program support is not covered or a purview of this committee, why didn't you say anything sooner? We have just wasted hours on this topic. So I don't understand why you didn't inform us earlier so we could have spent time on other things.

CLIAC DFO: Thank you for your comment, [CLIAC MEMBER].

CLIAC CHAIR: And I take responsibility, too. I should have focused the group better. [CLIAC MEMBER]?

CLIAC MEMBER: Two comments. Well, three. Very brief. Number one, thank you for the correction. Very, very important. Number two, please be assured that there is advocacy precisely as you described. We are really making a noise. And so hopefully, my third comment, which is operate in parallel. I think whether we refer it to a CLIAC working committee or work directly with CLIA to say, how do we work in parallel with the advocacy that we should be doing as citizens, I don't think our discussion has been in vain. I think there is opportunity either through working group and/or through direct recommendation to CLIA to say, how can we intrain and smooth these pathways so that we have the regulatory environment converging on having a better pipeline, and quite honestly better retention.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: I think there's opportunity here.

CLIAC CHAIR: I would put [CLIAC MEMBER] on alert that these items which engendered this conversation need to be discussed at the CLIA regulations assessment workgroup. So on your list of things. Well I'm hearing career ladder, I'm hearing DCLS, I'm hearing recruitment, retention, how to get the pipeline going, if there's anything the regulations can do to assist. There is a comment in the chat box from [CLIAC MEMBER]. "Is there anything of the subtopics bullets that could be redirected to CMS or CDC?" My comment is right now, to use [CLIAC MEMBER]'s words from a few meetings ago, this is half-baked. It is not baked and ready to go, and it is 4:30. This meeting ends at-- I'm sorry. So, whoa, is this true? We have another hour and a half? So then I will go back to [CLIAC MEMBER] saying is there anything we can pull out of this discussion that we think CMS or CDC or FDA can address? And from that we can make a very specific recommendation. [CLIAC MEMBER], you put the question in so I'm assuming you have a suggestion.

CLIAC MEMBER: Well, I mean, CDC's role is education, biosafety, and many other things. But the DLS focuses on their training initiatives. And so I think there are certain things that maybe could be incorporated if we would whittle them down. They've done great work with their existing online programs, but perhaps they could work on an educational program that would highlight laboratory sciences, not only for clinical but for public health. Which they may be able to incorporate that into their venue. And then in terms of CMS, I think the-- or sorry I'll go back to FDA. I think there's some suggestions from the larger group about looking at the waived testing category. And I tried to summarize those from multiple sources that we could ask the FDA. And in terms of CMS, I think they're really already working on a lot of things with Dr. Sossaman's and Kim Chapin's group. So I guess that's where I would focus the discussion then. Are there specific things we can ask for that we've discussed as subcategories of this that doesn't require funding but would require some type of an agency effort? And I'd be looking to the clinical partners to see if anything-- I don't know if they're not allowed to suggest. But within their roles, is there something that resonates with them that is accomplishable without the urge for funding. Because that's been the focus of our entire day is how to get-- the government issued Recovery Act, the money, to public health. They did not include clinical laboratories nor issue funding for Clinical Laboratory support, which truly handled, also, a bulk of the outbreak. And so the question is, how do we-- if that's at the professional level, and lobby level, then yes, that's what we need to continue to do. But is there some way that some of the funding can be piggybacked or jointly

aligned so that public health laboratories and clinical laboratories could be described as distinct entities in their training or something to that nature. I don't know the answers to those questions.

CLIAC CHAIR: [CLIAC MEMBER]. I'm going to jump the line and ask [CLIAC MEMBER], who I cut off too shortly previously, if she would like to continue the point she was making.

CLIAC MEMBER: Thank you, Madam Chair. I merely just wanted information on the one entry related to-- I don't have that section brought up. I mean, we're past that section now, on where it was written in red that says, "look at the role of laboratorians." I was thinking that was incomplete. From what perspective? I'm usually a measurable quantitative thinker, and what would be gained if you only looked at it, if you weren't thinking. I think it's good. I know it was put on the table. I was merely asking for clarity.

CLIAC MEMBER: I was one that put it on the table.

CLIAC MEMBER: Could that be improved upon?

CLIAC MEMBER: Yeah I was the one that put it on the table, and I was looking mainly at scope of practice in CLIA regulations.

CLIAC MEMBER: OK. And I think it would be improved upon if you were to indicate that.

CLIAC MEMBER: I agree .

CLIAC MEMBER: Thank you.

CLIAC MEMBER: I think it was a placeholder.

CLIAC CHAIR: [CLIAC MEMBER], then [CLIAC MEMBER], [CLIAC DFO], and [CLIAC MEMBER]. [CLIAC MEMBER]. She took her hand down, so--

CLIAC MEMBER: Oh, yeah, that was up there from the last time. Thanks, [CLIAC CHAIR].

CLIAC CHAIR: Thank you. OK, [CLIAC MEMBER]?

CLIAC MEMBER: Yes. I think to the point that [CLIAC MEMBER] was making about, are there pieces from our partners that lend itself to the training-- I remember, I think from my first CLIAC meeting, a wonderful presentation from CDC about their virtual laboratory training program. And I was wondering if there's been-- what, if anything, has happened with that program. And to me that fits into what [CLIAC CHAIR] brought up a little bit ago. We know that we've got these college graduates who don't have a career path. How do we get them in? We could do that through-- we struggle with finding clinical sites. Would that virtual program from CDC be what we're requesting to help augment and to provide an avenue to train bachelor's degree science graduates into laboratorians? And, so I guess my question is to [CLIAC DFO], where is that program and could our ask perhaps be to expand that program?

CLIAC CHAIR: Thank you. [CLIAC DFO]?

CLIAC DFO: Yeah, exactly. That's what I was going to say. I mean, I think if-- the first two bullets, for instance, could be, if you wanted to, directed to CDC. CDC through its Outreach Communication training, guidance-- whatever language you want to use-- should work to raise the recognition of laboratory professionals in health care. Partnerships. The CDC should promote a core training program to reduce the burden on individual training programs. Those would be extremely appropriate recommendations that CDC could and should be-- in fact, I think we already are, but I mean, I think you could emphasize it if you think there's something that we're not doing or need to do more of.

CLIAC CHAIR: Thank you, [CLIAC DFO]. [CLIAC MEMBER]?

CLIAC MEMBER: Could we recommend an updated survey of current laboratory professionals to guide and permit promotion of retention of laboratory professionals and also guide entry of professionals into the career? I know we've mentioned some things but I think there's more. And I think it may also be regional. So is that something that we could also recommend within the bullet points here? That's something that's achievable within our scope?

CLIAC CHAIR: Certainly is. Would you want to propose the bullet?

CLIAC MEMBER: Let me work on the wordsmithing, yes.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I am just wondering if the group would like to pull out the piece of recommendation for CMS to establish some kind of mandatory training for waived sites, or sites performing waived testing, their laboratory directors. This was included at some point here, not very explicitly, but if we want to be directing it to a specific agency. And [CLIAC MEMBER] and I were thinking that could be still pulled out and be fairly specific.

CLIAC CHAIR: Right. And to jump on [CLIAC MEMBER]'s comment, if we scroll down this document, we can see the lab director show up. It's in one of these. The directorship from [CLIAC MEMBER].
And the suggestion is to direct this to CMS. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I would support what it just said. And I'd also like to point out that one of the items that [CLIAC MEMBER] [INAUDIBLE] brought to us in his discussion and description of what occurred during the pandemic-- and I know we experienced this nationally-- we don't know the impact. And I think we really have an obligation, and it's within our purview because it impacted quality, to address that. And I think working with the directors is the right way to go.

CLIAC CHAIR: [CMS EX OFFICIO]?

CMS EX OFFICIO: Oh I saw other people ahead of me. I just want to speak to what [CLIAC MEMBER] said. I want you guys to remember when you're making these recommendations with regards to waived testing, that this would require a statutory change.

CLIAC CHAIR: So noted. Thank you. [CLIAC EXECUTIVE SECRETARY]?

CLIAC EXECUTIVE SECRETARY: Yeah. My comments were pretty much the same as what [CMS EX OFFICIO] just said, but I left my hand up. And I think it bears repeating that without a change in the CLIA law, there can be no standards applied to waived testing. And there are no inspections. So just bear in mind that if there are other recommendations related to improving the quality in these testing sites that would not require this, but that might be something CMS or CDC or FDA could do, those would be welcomed.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I just wanted to mention that I think that some of the comments that people have made around-- I'm going to call it broadening the funnel for those who may want to come into the laboratory in the workforce-- I think we can look at as part of the task force. Although we're focused on- or the work group-- we're focused on a few items around non-traditional workflow and NGS and other things. I think some of these can be incorporated as to how we look at some other aspects of personnel and some of those standards. So I'm hopeful that we could include some of this. Not to create new personnel categories perhaps, but maybe something close to that. Not creating personnel ladders, those kind of things, but looking at how we can maybe make some suggestions to be more inclusive rather than sometimes exclusive as CLIA is currently enacted. So I think that, with the permission of this group, that we can take that into the current workgroup. It's not necessarily within the purview, but if our CDC and FDA colleagues agree, CMS colleagues agree, that I think I'm hearing that should be part of-- or try to be part of-- what we look at in the workgroup. If I'm mistaken in that, please correct me. But I think we could try to incorporate some of that where applicable in what we're looking at.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: I just think on this directorship language there probably needs to be some kind of qualifier, maybe. You start out with a bold statement like, the world has changed. What started out with eight laboratory tests is now 240. And given the growth and complexity of waived testing, changes need to be made. Some sort of qualifying statement.
CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Hearing what the impact would be to change in CLIA law. And that seems like a can of worms nobody wants to open at the moment. Is there a way that perhaps these directorship requirements could be funneled under the EUA categorization for pandemic? Because that's where all the craziness comes out, right? That's where the pop-ups start going. Is there a way that you could keep CMS the same, and the waiver, the certificate of waiver could be issued with some requirement under the FDA EUA categorization that people directing and performing EUA tests would have to take some kind of online training that would give them at least minimum information and highlight their legal obligation to quality practices? And in conjunction with CDC training? I don't know. I'm sort of grasping at straws here, but I wonder-- because the biggest impact was seen, is seen, when challenges create opportunities for making money. Whether it's pop-

up laboratories or whatever. Maybe that we could bridge the issue and not amend CLIA but roll it under FDA to require this with EUA testing, and CDC to work with them for training for laboratories-- people who are doing this kind of testing. And maybe that's a weird idea, but I just throw it out there.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [FDA EX OFFICIO] came right up, so let's hear from him.

FDA EX OFFICIO: Yeah. No, I mean, you've got some real expertise in the ex officios. And in [CLIAC DFO], who are here to assist CLIAC members in your wishes. And you're welcome to always pick our brains. And with your desired ends, how do we accomplish those things. So I haven't been invited to opine on any of these things. And I haven't wanted to necessarily stick my nose in here, because this is your committee. This is your work. So just know that we're always here to help and wanting to do so. And I'll just give you some perspective on the CLIA waiver authorizations, both EUAs and full authorizations. And what we look for in tests that meet the CLIA waiver requirements, which they have to be extremely simple to perform. Think of a rapid strep test in a physician's office. It's really hard to get a cheap test that's more simple than a rapid strep test. And so that's kind of what we look for. There is a formal process that we go through to assign whether it can be CLIA waived, whether it's moderate complexity or high complexity. And then when we write instructions, and we work with the sponsors to write instructions, we aim for the seventh grade level of understanding. So it's all designed to make this as easy as possible. Now we've received during the pandemic some really great feedback recently. As we have moved forward with these massive deliveries of home COVID tests and people have begun using them in high volumes, then they have been reporting back through various organizations about what works and what hasn't worked. And so we've been having very long listening sessions during this. And this is an ongoing and important function that's going on, and the administration has given NIH tens of millions of dollars to work on this particular issue. So it is one that federal authorities are well aware of and seek to assist with. But the other thing to consider is when we either do an OTC, over-the-counter, test for home use or we make a point of care CLIA waive designation, we're really saying that the personnel that work in those offices, in those physician offices-- and during the pandemic, it's really any place that gets a CLIA certificate-- we're saying that any personnel in those settings should be able to run this test. So anyways I just wanted to give you the reasoning, what we use to make our decisions. But also what we're trying to do. But we are trying to make things as simple as possible. I think we've learned-- I've heard it today, I've also heard it from all these long listening sessions-- that we can do some more. It will involve changing the test, making the test simpler. It will also involve improving the instructions for use so that even more people can do this in the professional setting, at school settings if they have a CLIA certificate, or at home if they have an over-the-counter test. Things like, even increasing the font size. We are looking at, we-- NIH and FDA recently completed a study on self-collection of nasal swabs, from kids down to the age of five. Publication came out, a pre-print came out, and they do amazingly well with a little bit of training and some visuals. And so we are looking at leveraging that study and that data to provide specific instructions that go specifically to kids to do this. So we're excited about that opportunity. We're excited about the study showing that kids can do such a great job given minimal training. They basically watch a video of other kids self-collecting their nasal sample. So there are ways to do this, and there are ways to advance the science here and the regulations and the work of a-- really in the tri agencies. And you're all help. So we're here to help. And hopefully my comments here give some perspective on this, about what we're aiming for. And totally support more workforce, totally support more funding for it-- although FDA doesn't have a budget for that-- and additional training to improve testing for patients themselves and in point of care settings. Thanks.

CLIAC CHAIR: Thank you, [FDA EX OFFICIO]. [CLIAC MEMBER]?

CLIAC MEMBER: Yes. Thank you. I think we've had a lot of discussion about where we think CLIA regulations might need some changes at the entry level, the mid-level, and at the doctoral level, the director level. And those, as [CLIAC MEMBER] pointed out, are lengthy changes. And we've been stymied, if you will, on how to make those happen.
I wonder if, perhaps, one way of solving this, which would be outside the purview of this committee-- but maybe there's a way that we can get support and get the word out-- is to look at state licensure. And when you think about other medical professions, many of those have their criteria for practice defined at the state level. And I know New York's done a nice job of defining medical or laboratory practice and having higher level requirements than what's required by CLIA. There's nothing that would stop a state, as I understand it, and I look to our agency partners to confirm that. There was nothing that would stop a state-- or an accrediting agency, although state would have more teeth in it-- from requiring that waived laboratory sites have a qualified director, have personnel that have been trained, and that they perform PT, and doing some of the things that we think are important. So would one way of getting to the quality metric that we're concerned about with the way of testing those folks holding a certificate of waived testing be to encourage states to start implementing their own regulations? So just to mix things up, I'll throw that out there for comment in the group.

CLIAC CHAIR: We did have a public comment that indicated Florida was going the opposite direction. Lessening the requirements to perform moderate and high complexity testing. So, [CLIAC MEMBER], you still have your hand up, and [CLIAC DFO] hand is up. So I think, [CLIAC DFO], the floor is yours.

CLIAC DFO: Yeah. So, thanks for that comment, [CLIAC MEMBER]. As difficult as it is to change the statute, I don't think that we should be afraid of asking our members of Congress to consider that. But I guess, so in other words, if CLIAC thinks that that's a recommendation that is a letter to Secretary of HHS, then I would encourage you to do that. So, I guess that's my first point. In terms of recommending that states take other actions, this is a Federal Advisory committee. And so, your only audience really is the federal government. And hopefully we've done a good enough job of explaining to you what we do and how the federal CLIA program works and what levers we can pull. But where we work is with the regulations. And we have a process where we can update and revise the regulations through public comment. And we've done that successfully with many issues that CLIAC has brought up to us. We're not in a position to ask for the law to be rewritten, but no one says that CLIAC can't ask for that. But I also think you should be aware that this is an advisory committee for the executive branch of the government. Over.

CLIAC CHAIR: Thank you, [CLIAC DFO]. [FDA EX OFFICIO]?

FDA EX OFFICIO: Yeah. I just want to augment what [CLIAC DFO] shared. So HHS does have a process by which they can propose legislation. It's complicated, it's complex, but it can happen. And the other thing, with any state-- you can ask HHS, if you so wish, to look into whether a state or states are abiding by federal law. And federal law may supersede state law in some cases, and then there is a process. We have an office I go through here at the FDA called the inter-government affairs person. And we can reach out to states and have conversations. So I've done that so many times during COVID, I can't even remember. So there's a process to dialogue with states and what they're doing. So this committee can certainly make a recommendation that be pursued if that's what they wish.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So along those lines of what [CLIAC DFO] just said, I'm curious and wondering. Since our request was for funding to HHS and only representative of the people on CLIAC, why couldn't we move forward with the request for funding to HHS? We're not asking for CLIAC or for CMS or for CDC to provide the funding. But HHS does have access to funding to support the improvement in increased resources of this career that we desperately need. Isn't there a way that we can include that funding request because of all the experts on this committee? Or do we need to do it separately offline and do a private letter and send that to HHS? That's my question. Could we do CLIAC submitting it or do we all need to get together on another call, on a separate topic, on a private discussion?

CLIAC DFO: Now, I'm not sure who you are asking the question to, but I'll take a stab at an answer. Those of us who are employed by the federal government are ex-officios, and I'm just the designated federal official. As [FDA EX OFFICO] said, this is your committee, and you may do what whatever you choose. I think what I was trying to say, I think what [ADVAMED LIAISON] was trying to say, is that CLIAC has a very long history of writing letters to the Secretary of HHS that get a response from the secretary's office that says, thank you very much. And so, in my own opinion-- and I'm giving you an opinion that you don't have to agree with or acknowledge. But funding, large-scale funding for large scale, long-term initiatives are-- there's not a whole lot of discretionary funding in the government. And when it exists, it's highly sought after. And my impression is that when you're asking for a long-term initiative that requires a lot of money, that's really more in the realm of congressional appropriations and not something that we in the executive can sort of easily move funds around to do. But again, I think that you will have-- if that's your goal, you'll have much more success using professional organizations and organizations that have highly developed lobbying professionals in Washington who understand how to make those kinds of things happen. That's not what, in my opinion, CLIAC is designed to do.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I'm really interested in how we can have some safeguards against fraud and lack of quality in the future. So I want to ask [CMS EX OFFICIO]. I know that from what I heard in Iowa that labs were closed as a result of bad practices that were detected by the CLIA inspectors on their visits to some of these laboratories. Is there any fines or anything that would take away the incentive to do this in the future? And could we suggest that fines be mandated without having to reopen the law? Because I understand the risk of reopening the law. It could go the wrong way, and I don't want to risk that. But is there anything we could do that would be a disincentive for this to happen in the future?

CMS EX OFFICIO: So we do have in our enforcement arsenal the ability to levy civil money penalties, but there's a process that we have to go through before we can actually impose those types of monetary sanction. We don't really have any other avenue for anything other than CMPs. And those are-- there's due processes required before we can-- we have to propose them, then they have to be imposed, and then they have to have the ability to request a hearing. So there's a whole enforcement process and due process that we have to go through to be able to do that.

CLIAC MEMBER: Does that occur very often, [CMS EX OFFICIO]? Or is that something that because the length of the process it's not feasible?

CMS EX OFFICIO: Oh it's feasible. And we look at it on a case-by-case basis, because we don't always impose sanctions that we propose because the lab is able to come back into compliance before we get to that point. So while we may use them as tools to get the laboratory to come into compliance, they are not always imposed. If the laboratory is able to come into compliance. Yeah, I hope that helped, [CLIAC MEMBER]. I did want to-- I did have my hand up. It it OK, [CLIAC CHAIR], if I speak to what the user fee funded? I just wanted to kind of tag on to what [CLIAC DFO] said earlier about the user fee funded program that the CLIA program operates under. When we say, "user fee funded," that means that the laboratories who are certified fund our entire program. We do not have any avenues for additional funding like you all are talking here, for giving to HHS. That would not get to the CLIA program in any way, shape, or form probably. Nor, as [CLIAC DFO] said, do we get any appropriations from Congress. So we are required to operate within the funds that we collect through the user fee funded program. Thanks.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: This may be a stretch, but back to [CLIAC MEMBER] top comment there, with the multiple bullets at the top of the document. If we can't-- what if we focus, what if we remove the HHS funding. Would one of the agencies, perhaps CDC, be able to launch an investigation into public, private, and academic partnership, including NAACLS, that would seek to inform the rest of those issues that we've disclosed? And have they ever engaged in public-private partnerships for some type of profession before, say nursing or pharmacy shortages? Is there any way that this group could recommend investigation into that as a vehicle for moving forward with all the things we talked about today?

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: If you could get to the full paragraph to view. I think the edit, the top paragraph. Oh, OK, maybe that's it. I've lost track of which. Anyway, not the bullets, but the preamble. OK, [CLIAC MEMBER] is a master of taking long paragraphs and making them short. In essence, what it's changing is "CLIAC recommends." And what I hear [CLIAC MEMBER] saying is "that CDC examine the following issues" and then we list the issues that this committee wants to develop further insight into. For the purpose of this smoothing of the way. "Recommends that CDC--" and again I welcome wordsmithing here because the question is quite simply what can we ask CDC to do. And we've already articulated in some of these bullets some ideas there. "Examines the following issues." What I don't know is whether that constitutes surveys, development of educational programs. It's, in essence, a working relationship between CLIAC and the CDC to come back to CLIA. If I understand all of this discussion, to come back to CLIA and say, OK, this is what might work under our current statutory architecture. And to make that a six month goal, so that as we reconvene in November, we have a sense, quite honestly, of what's possible in our current statutory environment. All the while, advocacy with our organizations and work with educational institutions, yada yada yada.

CLIAC CHAIR: So, I'm going to make two comments. The first two bullets were crafted upon suggestions of what CDC was able to do. There's a third bullet from [CLIAC MEMBER] in the chat. And it is "CLIAC recommends that CDC conduct a workplace survey of laboratory professionals in order to support and guide critical recruitment and retention activities." That should be the third bullet.

CLIAC MEMBER: I think it's a superb third bullet. And the fourth one might be, again, "CDC--" again, I am unschooled in what we can ask the CDC to do. But if I understand the relationship, CDC is where we obtain content and CLIA is where content might be applied. And so the fourth bullet, which is roadmap. We translate bullet three, that's actually for CLIAC to do, is to take the information from the CDC and help craft the roadmap. I actually think that's a CLIAC activity more than it is CDC, but again, however the working relationship between CDC as a government entity and CLIAC is parsed out. I think bullets four and five are the parsing into career-- including retention and career ladders. I would collapse the bullets four, five, six. And then the question is, is that a CLIAC activity? Which I would refer to the appropriate working group over to wrestle with over the next six months. That's my attempt to, in essence, lean this up, have a working relationship with CDC, have CLIAC have a productive November meeting with the information that comes back to the committee.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. So if I'm hearing this correct, we would stop the recommendation after the third bullet. And four or five bullets-- four, five, and six go to [CLIAC MEMBER] for consideration.

CLIAC MEMBER: And are collapsed.

CLIAC CHAIR: Yes. For consideration and then recommendations to come back to CLIAC on those topics. The career ladder, the entry, et cetera.

CLIAC MEMBER: Right. And retention. And that's my proposal.

CLIAC CHAIR: Now, in reading the chat, [CLIAC MEMBER] has a couple of wordsmithing comments. [CLIAC MEMBER] and [CLIAC MEMBER]. And I just want to touch base with them to make sure if they want to revise what is on the screen. So the current recommendation is that top.

CLIAC MEMBER: Oh, not for me. Thanks, [CLIAC CHAIR].

CLIAC MEMBER: It's OK. Yeah. ,

CLIAC CHAIR: So, the recommendation has morphed into something we are asking CDC to do.

CLIAC MEMBER: The top three.

CLIAC CHAIR: Yes, the top. Above the line.

CLIAC MEMBER: And we are assigning to ourselves, through the workgroup, the lower bullets.

CLIAC CHAIR: Now, [CLIAC MEMBER], you have your hand up.

CLIAC MEMBER: Yeah. Hi. This has really been a great. And I really appreciate both [CLIAC DFO] and [CLIAC MEMBER] both sobering us and redirecting us, even though it cast a bit of a pall on us for a bit. We've regrouped, and we've now started to do what we can do, which is to ask the appropriate government agencies to do things that they can do. Because if you ask for people to do things that they can't, they do exactly what [CLIAC DFO] said. They say, thank you very much, and they put it in the drawer. And so I think we're now coming on to something practical. Although I have to say, I always get concerned when we ask people to study things, because they can go away interminably. So I think [CLIAC MEMBER]'s point about putting some sort of a time limit or a goal on this is very important. That way there is a response that happens in real time. But I still think that what I've heard throughout the whole discussion is we all believe that the pipeline is absolutely critical. And this may be a little bit of a non sequitur, but when we were talking about salaries and improving salaries and retention, we don't have any way to do that. In fact, as a capitalist society, none of us have a way to do that. We have to follow market forces. In fact, if we think about it, the thing that has most recently helped medical technologists in their recognition, in their salaries, has been the shortage. And if there were a dearth-- when there's a dearth of them, they get well-recognized, they get bonuses, and they get paid. So on the flip side of this, you have to be careful that a lot of recruitment and retention doesn't dilute the value of the individual. So we're dealing with a very difficult issue. How do you create energy in an environment, in a culture? And then what can we get the government agencies that we've been tasked to work with to do? And recommend to them that they can actually carry out? And I think we can probably think through this, again, for both the FDA as well as CMS. But I think the key focus right now is, appropriately, on what we can ask the CDC to do for us. Thank you.

CLIAC CHAIR: Thank you. So there's no hands up, and we've had a lot of discussion of this. Spoke too soon. [CLIAC MEMBER] has her hand up. Because I'm getting ready to ask is this baked and ready to move forward. [CLIAC MEMBER] took her hand down. [CLIAC MEMBER], your hand's--

CLIAC MEMBER: One thing I think that needs a little bit of information is that NAACLS already oversees clinical laboratory science training programs. So maybe that "promote a core training program" might be work with NAACLS to expand core training programs or something of that nature, because you're not starting from scratch. There is an organization that-- I don't know if they collaborate with CDC, but if they don't, then that is really the way to pull in academia, as [CLIAC MEMBER] talked about. And maybe somebody could weigh in on that. I know it's been discussed before at CLIAC, some kind of affiliation with NAACLS but I don't think we ever actually did it.

CLIAC CHAIR: [CLIAC MEMBER]? OK. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. When I had oversight of a NAACLS accredited program-- and just speaking from that background, so don't want to speak for NAACLS-- but they provided the regulations and the standards for what the program would look like. However, they did not provide any assistance with actually conducting or providing materials for those programs. So I think work with partners is a good update to that bullet because I don't know that NAACLS would necessarily help us produce the content for the clinical laboratory sciences section of what is missing right now in lab training. Just my thoughts from having worked with NAACLS before.

CLIAC CHAIR: So maybe the sentence needs to be "work with partners to augment core training programs."

CLIAC MEMBER: We really want to produce one. I mean, there is not a virtual-- to my knowledge, besides what the CDC has started on-- a virtual training program that could be used in place of know some of the hands on training that's so difficult to come by.

CLIAC CHAIR: So would it be "to create and thereby expand access to a core training program?"

CLIAC MEMBER: Yes.

CLIAC CHAIR: To reduce the burden.

CLIAC MEMBER: Well stated.

CLIAC CHAIR: And then, [CLIAC MEMBER]. [CLIAC MEMBER].

CLIAC MEMBER: I'm glad to see the second bullet taking more shape. I actually-- be just a little more broad-- "create and expand access to a core training program." And I think there's-- "and look for other opportunities to reduce the burden on individual training programs." I spent an hour this morning-- an example of a partner, excuse me, is the hour I spent this morning with leadership of the New York City Pandemic Response Group, which has formed a workforce task force and laboratory is the top of the list. So there are partners in the field, present and future.

CLIAC CHAIR: And I would just take out the words "look for." "And other opportunities."

CLIAC MEMBER: "To expand access to core training program."

CLIAC CHAIR: [INAUDIBLE] it would be identified. OK, [CLIAC MEMBER] and then [CLIAC EXECUTIVE SECRETARY].

CLIAC MEMBER: So, again, this is kind of following up on "other," but as I'm sitting here racking my brain saying, how do we fund these things, the NIH came into my mind. They have done educational development grants, so forth and so on. So I don't know if there's a way that we can ask the CDC to ask the NIH to study this. Or is there a way we can engage the NIH. Who funds biomedical training programs that need to have stimulus? That's what came to my mind, was the NIH. And I don't know how we would make that ask. OK well I stunned you into silence on that one, I guess.

CLIAC CHAIR: I think no one has a ready answer.

CLIAC MEMBER: You're welcome to ask any of the agencies to work with other organizations, including government agencies to do things. So happy to pursue that path.

CLIAC MEMBER: Maybe that comes under the "work with partners."

CLIAC CHAIR: [CLIAC EXECUTIVE SECRETARY].

CLIAC EXECUTIVE SECRETARY: Maybe it's only me, because no one else has the question, but it's not clear to me when you say a "core training program" what kind of a core training program you're referring to. Other than for someone who works in the laboratory, but there are different levels of individuals, and there are different specialties, and there's the clinical side versus…

CLIAC CHAIR: [CLIAC MEMBER], can you go on mute? Thank you. Go ahead, [CLIAC EXECUTIVE SECRETARY].

CLIAC EXECUTIVE SECRETARY: No, I was just asking if it's possible to clarify what kind of core training program you're talking about there. And whether it's something that would be done independently or done in conjunction with an academic program. So if you're asking us to do something, I'm not clear what you're asking.

CLIAC CHAIR: I'll just state the introductory statement seems to be focused on clinical laboratories. And the bullets, for me, reflected back to clinical laboratory science. But maybe I'm just too narrow in my perspective. [CLIAC MEMBER]?

CLIAC MEMBER: I think you're seeing a little late afternoon fatigue setting in, in terms of our trying to articulate what would be useful. If we take, for example, the virtual lab training program that you presented six months ago, work with partners to create and expand access to. And then there's je ne sais quoi. What are we looking for that can help individual programs expand their pinch points? And my understanding is a key pinch point is the practicum, and your virtual training program helps address the practicum. But anything that can lower the speed bumps for present, and yes, the additional training programs that we hope to come into place. This is what we need to insert here. "Create and expands access to core--" materials has been used before in a different context. "Core--" and I'm just too tired to insert the word-- that will

enable individual training programs to expand their pipelines. There's educational materials, there's virtual practicums. I look for expansion of this creative space, and I just don't have the words in mind right now.

CLIAC CHAIR: So, [CLIAC EXECUTIVE SECRETARY], are you asking whether or not this was intended to define the basic core curriculum of a laboratory science training and to make accessible other materials, as in the virtual CDC programs?

CLIAC MEMBER: Educational content and resources.

CLIAC EXECUTIVE SECRETARY: I think that's helpful. That leaves it more open. A core training program, to me, sounds like something very specific. And even with laboratory scientists, there are the clinical laboratory scientists, which is a degree level. And then there are technicians, which is probably an associate degree, so I wasn't sure. I think what you've got now is better.

CLIAC CHAIR: [CLIAC MEMBER], your hand's still up. But I want to move to [CLIAC MEMBER]. [CLIAC MEMBER].

CLIAC MEMBER: Having CDC's success with the virtual training content? Does it make sense to focus on web based or virtual educational content to supplement? It's not going to replace the core training, but does it make sense to focus on their-- or to synergize with their expertise and/or mention the primary focus might be pandemic skills for way of testing. But include all levels, something like that, because of what we faced? Is there a way of prioritizing what that is? Might help. Or focusing on their synergies.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yes and I thank you, [CLIAC MEMBER], for providing the word practicum. I think that's the late afternoon fatigue, we were all struggling with that word. But I would say that not only is it the practicum, but also the didactic lectures on clinical laboratory science that individual programs have a difficulty pulling together, going through the whole NAACLS process. There's a lot of structure involved with NAACLs approval. So I think it's practicum and didactic training and clinical laboratory sciences.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I think [CLIAC MEMBER] just said what I had intended to say, which was, kind of look at CDC university sort of. And if I'm a training program, there may be plenty of stuff that my team wants to do, but we already heard that we're already short staffed. So if I don't have a good microbiology editor, and there is a module for microbiology that's been developed, that can fill that role of at least the didactic portion. And so if there's a spectrum for all levels of laboratory training, I think that would go a long way to fill in the gaps. Because we ask for a lot of diversity in laboratory training, and having such a set either could be used whole cloth or more likely to be used to supplement where there are not the strengths in any individual programs.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. I think that's important. I just think we have to be careful of not competing with the existing online medical laboratory science programs that are out there and expanding and are available for the taking. I don't know that we need to recreate every wheel. But if we can somehow wordsmith that to focus on filling the gaps in the curriculum, perhaps which isn't routinely taught by the NAACLs programs at the moment. And that would maybe encompass point of care, molecular expertise, which CDC has plenty of. And so there's a lot of NAACLs accredited programs online, and I just don't want to recreate that wheel.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you, and I agree with what [CLIAC MEMBER] said. But I'd like to also point out that many organizations-- and again [CLIAC MEMBER] mentioned this a couple of CLIACs ago, how his organization was approaching this. That rather than having NAACLs program-trained individuals, that they're having to train on the ground because there's not enough programs, there's not enough people that can get the programs, particularly in rural areas. So I think in addition to what [CLIAC MEMBER] mentioned, I think we also have to look at the homegrown training that people are doing to try to get laboratorians into their laboratory. And both with the hands-on training, as well as the didactic. So really kind of plug and play programs, both for NAACLs programs, but also for folks that are training in their own laboratories.

CLIAC CHAIR: You think this second bullet is general enough to cover that?

CLIAC MEMBER: I think it's general enough. I think the point that [CLIAC EXECUTIVE SECRETARY] was making, is it specific enough? And I would defer to [CLIAC EXECUTIVE SECRETARY]. Have we given you enough yet to work with?

CLIAC EXECUTIVE SECRETARY: Yeah, I think so. This is clearer to me than what was there before.

CLIAC CHAIR: OK, it is 4:29. Your hands have stopped going up, and I am going to call this to a vote. The motion on the table is this recommendation from us to the CDC. Is there a second?

CLIAC MEMBER: So move. [CLIAC MEMBER].

CLIAC MEMBER: Second.

CLIAC CHAIR: Is there any further discussion? OK. 8 seconds of silence. Hearing no discussion, is there any-- I'm calling the vote. Is there any opposition? Hearing no opposition, are there any abstentions? Hearing no abstentions, the motion is approved. Thank you, all. It is 5:30. It is 5:30, and on our agenda, is a time to solicit from you all future CLIAC topic discussions. So who wants to hear about what in the future? Just start raising your hand. [CLIAC MEMBER]?

Future CLIAC Topic Discussion

CLIAC MEMBER: Just looking back at my notes from the same discussion six months ago, we've done a lovely job of addressing a substantial slug of what was expressed in October of 2021. The three things that were hanging out there are data activities and bioinformatics, number one. Number two, career pathways as a specific topic in medical laboratory sciences. Number three, consolidation of laboratories. My own personal feeling is that we should have a second redux of what we've been dealing with. I think that we should be bringing back, at least for a substantive portion of the meeting, this discussion with whatever's happened in the last six months. And I would invite comment from the field of what has happened in the last six months at the professional society level and at individual institutional levels. And a comment there, is that the Association of Pathology chairs is literally doing a gathering in over the next three months of what member institutions are doing in their part. But I think we should definitely cast a broader net for, in essence, the entire laboratory community on what they are doing now both for training, for publicizing, and yes, working with educational institutions, so that CLIAC is well-equipped to know what the environment is. And then how we can do our part to address the current crisis. So I recommend continuation of the current topic.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: I want to get back to something we never got to because of COVID. But we had some discussion three years ago about productivity consultants and their negative impact on laboratory scientists. Part of the recruitment and retention issue is burnout. And I put up the argument then that we have medical device companies that are regulated and transparent and need to provide certain quality for medical IVDs. We have good laboratory practices, we have good manufacturing processes, we have those quality initiatives, and yet there is no good consulting practices that is being overseen by anybody. I don't know who the right entity would be. FDA maybe, because they oversee the good manufacturing practices and things of that nature. But if they continue to scrunch down the laboratory budget from $0.03 on the health care dollar, now down to $0.02 on the health care dollar, and there is no transparency in the productivity recommendations, to gut the laboratory and say, well, we gutted the last laboratory, so now you need to gut your laboratory-- if we can't get a handle on this as a laboratory profession, it it will kill laboratory sciences even further. And I do think-- I don't know where the right place is. But it is something that is not transparent, there's no standardization or regulation or metrics around it. And I do think that some kind of benchmarking at the national level supported by CLIAC is appropriate. You try to get more staff or more pathologists, there's no national benchmarks for that. There's nurse ratios, there's all these other things, and we have none that are not forced by people who make money on slashing laboratory positions. And I think it's an unfortunate event that just needs to be fixed.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you, Madam Chair. I would like to see more dialogue on ensuring that educational literature and AV information on utilizing and accessing health information be prepared in a variety of languages. Especially languages that would allow us to appropriately educate the Hispanic, the Mexican community. There was some comment in terms of that being a problem with population health.

CLIAC CHAIR: Thank you. That fits so well with our desire for equity, diversity, and inclusion. Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. Hi. I wanted to bring up some things I'm seeing around the Cures Act. I think everyone is aware of the Cures Act and its mandate for interoperability and lack of data blocking. Interestingly, what we're starting to see, is

this is being turned around at us and being used as an excuse to interface with our competitors because we have to, to be compliant with the Cures Act, which I think is a little bit of an overread. If you took this to its logical conclusion, that would mean you'd need to have an electronic data feed to bit players in your organization. I don't think that I've seen any rational discussion of how the Cures Act actually plays into interoperability and what information blocking means when we come to speaking about large reference labs that may be competing with hospital-based testing. So forth and so on. So I don't know how we create a conversation about that or even whether anyone else thinks it's relevant or anyone else is seeing that problem. But we've recently been asked to interface now to our two largest national competitors for our hospital-based laboratory which will have a very negative impact on, not only our bottom line, but it will also disintegrate our electronic medical record.

CLIAC CHAIR: More? [CLIAC MEMBER]?

CLIAC MEMBER: So, aside from saying thank you for an amazing experience and honor of being on this committee, it came up yesterday-- and again, my area really is more the clinical realm. Although, I've definitely been involved with lab medicine intensively, as well, in my career. This disconnect between what happened with point of care testing, but especially the at-home testing for COVID, has been really difficult time for the clinical community. Having lost that connection between lab reports, missing out on the discussion of talking to patients about what to do. That example that we heard yesterday, where somebody was still quite sick but, hey, their COVID test was negative, so we're good to go. All those things that really make the patient-physician relationship sacrosanct and drives good care went away. And that's aside from the issue, also, of how we connect these tests now back to the public health system. So that's my public health hat coming on. I don't know-- again, the discussion's been very eye-opening about what we can and cannot do. And I won't be here for that discussion next time around. But if our issue is public health, to me, if there's some way to address that, it would be really something extremely meaningful for my community. It has been just the most difficult time. And for so many reasons. But that's one aspect. Again, we're supportive. But if there's something, some way to think about how we can actually link things back up again that might be of interest.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: You support what [CLIAC MEMBER] has just said. Because as you know, early part of our meeting, I mentioned about my serious concern about the validity and reliability of the rapid test. I'm in practice, and I see that sometimes people have done just what she said. They have taken the rapid test. The test results was negative, but by the time they get to us, it's devastating. Because some of the early treatment that could have been implemented, we're beyond those number of days. And so I really would like to see, at least some dialogue on, what is our role of, what could be our role, in facilitating either additional research or providing funding or engaging in collaborations to ensure a greater percentage of validity and reliability in terms of the findings of that particular test or tests. Thank you.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: I'm interested and very focused on finding ways to use what we've learned on COVID for remote access in doctor's offices. I'd like to see if we can expand that to fentanyl, to other types of infectious diseases, especially in this area of opioid addiction. We need to help the people out there right now, give them some tools at least to help and prevent deaths. So if we can expand into remote locations for testing with very simple, fast tests for these people that are drug users and have habits that really need help right now.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Actually, thank you, [CLIAC MEMBER], for bringing that up. I echo the need to look into testing to assist with curbing the drug epidemic. I want to shift gears a little bit and talk about the area of biomarkers. There are laboratories and reference laboratories and so on that look at biomarkers for different kinds of diseases. And some of them are what we call predictive, because they indicate whether or not you'll respond to therapy. I've seen people who have in situ carcinoma, which doesn't require treatment, sending things out to laboratories that must be operating under a waiver-- or actually I think this one was actually in Germany-- to find out what their tumor would respond to when actually it's not even invasive. So they've wasted this money. And I think that-- I'm not going to go down that road of reimbursement, but I think biomarkers are going to be a key part of laboratories assistance in clinical care. And that's an area we should look at and address in terms of interoperability, because many of these will go to reference laboratories. How will we address interoperability and being able to compare values between laboratories? So if patients move around, how will one maintain a record of what your biomarkers are?

CLIAC CHAIR: I just want to add on to [CLIAC MEMBER] tapping into the fentanyl and opioid epidemic that what we saw with the COVID pandemic and the rapid surge and population effect I sense is coming with fentanyl. And I would like that the lessons learned from the COVID pandemic include what we learned about waived testing, pop-up testing sites,

sourced tests that are not FDA approved. What can we learn from that to apply to this next epidemic that is barreling down the tracks at us now? [CLIAC MEMBER].

CLIAC MEMBER: Yes, and to add to that, [CLIAC CHAIR], what can we do with remote-- I guess, because we're not using nontraditional anymore-- remote access to laboratory tests in rural areas. Such as the pharmacy example that we saw. I'd like to hear a lot more about that. And how can we give feedback to them of what tests we'd like to see them offering, for tests to treat as well as pre-op. It's a wonderful opportunity for improving pre-op testing.
And that whole concept of these waive sites being able to amplify in an easy way tests that people need access to as well as the fentanyl. But I think there's some other assays that would inform people about their health.

CLIAC CHAIR: I agree. The school nurse example just sticks in my mind. You know what can we do to empower the school nurse, especially the school nurse in a rural area. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. With regard to some of the comments, public comments, there were a number of them around proficiency testing. And I think it would be a good topic to ask the agencies to-- in light of those comments, what is their perspective on the state of the US proficiency testing programs. And how are labs doing with those, and are there changes that they would like to make or questions that they have for CLIAC with regards to that.

CLIAC CHAIR: I see no more hands. Are we tapped out? [CLIAC MEMBER].

CLIAC MEMBER: I just want to get the opportunity to say thank you, [CLIAC CHAIR], at the end. That's all. I'm just honored to be a part of this group, and I learned so much from everyone. So I don't want to cut into the discussion of new topics, but I am eternally grateful to all of you.

CLIAC CHAIR: I echo that, too. It was a great professional development for all of us.

CLIAC MEMBER: And, also, just personally, watching how to chair a committee. I've never seen anything like this in my entire life. I have sat on a gazillion committees, and my career isn't over, but kind of coming to an end, and nobody really touches what I saw you pull off. So, thank you, just as a mentor. Very much appreciate.

CLIAC CHAIR: She's just amazed, because I sort of know how to use Robert's Rules. Sort of. OK, [CLIAC MEMBER].

CLIAC MEMBER: Well, and while we're thanking everybody, for those of us that are outgoing, I think a big shout out to CDC, CMS, and FDA staff for doing an incredible job of keeping us together. And--

CLIAC MEMBER: Absolutely.

CLIAC MEMBER: I'm on the workgroup, I'm not going anywhere, but they worked so hard. And we need to appreciate our federal officials.

CLIAC CHAIR: And I really appreciate how they remind us of the guardrails in such a gentle way. And if we could figure out how to do this, how to do a wave soon. But that's just too difficult. So if we are silent, I would suggest we adjourn 14 minutes early, unless there's any disagreement around that.

CLIAC DFO: [CLIAC CHAIR], could I jump in?

CLIAC CHAIR: Sure.

CLIAC DFO: Yeah. So a couple of things I want to mention. It's been suggested to me that I need to clarify one thing I said earlier in case it was misunderstood. I think all of you who are members of CLIAC know that you are special government employees of CDC. And so therefore, you cannot register as a lobbyist. And so I did not mean to suggest that you as individuals should lobby on behalf of a clinical laboratory funding. What I meant to say, I thought I said, but just to be clear, that is a function that many professional organizations have and do. And so, you're all welcome to work through your respective professional organizations. But if you intend to lobby directly as an individual, then we would need to ask you to resign your position on CLIAC. The second thing I wanted to mention was we're really working hard to reconvene CLIAC in person in the fall. And if the pandemic goes our way, we intend to do that. Just, I think, today, CDC loosened its rules for meetings of more than 50 people on campus. Assuming that rule remains in effect in November, that will make it much, much easier for us to host CLIAC in person than it has been during the pandemic. And I think-- my own opinion is that some of these discussions could be a little bit easier if we were all in person. So I would-- if we're able to do that in November-- I think inevitably, we will have to, probably forever, have to do this meeting in a hybrid fashion. But I'd like to encourage all of you if you're able, if we are able, to attend in person. And then the last thing is, just a huge thank you to all of you for your participation. I know these sorts of meetings are challenging. They're very different than most of the

meetings that most of us participate in on a daily basis. We have lots of arcane rules and guardrails that are not always clear to all of us all the time. And so I appreciate your patience with working within this Federal Advisory system. And really, really appreciate your expertise and your patience and your willingness to work through and provide us with feedback and guidance and, honestly, with direction on where we need to spend the majority of our time moving forward. Thank you so much to all of you who are outgoing members. Really, really appreciate your efforts. And again, just reinforcing what's been said, thank you to Valerie for her incredible efforts. This is a difficult committee to chair, as most Federal Advisory committees are. And so thank you again to [CLIAC CHAIR].

CLIAC CHAIR: Thank you. [CLIAC MEMBER], you have your hand up.

CLIAC MEMBER: Are you ready for a motion to adjourn?

CLIAC CHAIR: I am so ready, but I don't think we need a motion.

CLIAC MEMBER]: Oh OK.

CLIAC CHAIR: If you agree. I think-- [CLIAC MEMBER] still has her hand up. I didn't know it [CLIAC MEMBER] had another comment. Well, she took it down. So with that being said, thank you, [CLIAC MEMBER], for offering the motion, but we are adjourned. Be well, everyone.

CLIAC MEMBER: Thank you, everyone.